# Draft Assessment Report

## Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**
as it applies in Great Britain

# Pydiflumetofen

## Volume 3 – B.8 (AS)

### Environmental Fate & Behaviour

Great Britain

June 2023

# Version History

| When | What |
|---|---|
| October 2022 | Initial GB DAR |
| June 2023 | Post Expert Committee on Pesticides (ECP)<br>Independent Scientific Advice (ISA) |
| | |
| | |

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# B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

This document summarises all the environmental fate and behaviour data which are relevant for the approval of pydiflumetofen and the proposed representative uses under retained Regulation (EC) No 1107/2009 in accordance with the requirements of Regulation No 283/2013.

As background to this evaluation, pydiflumetofen has been reviewed in the EU peer-review procedure for pesticide active substances and an EFSA Conclusion[1] is available for this substance. In performing an independent GB evaluation of the available data, HSE has taken into consideration decisions made in the EU peer review procedure as the EU procedure is based on the same legislation and guidance documents currently used for GB assessments.

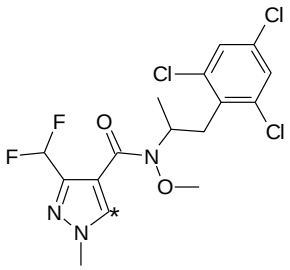
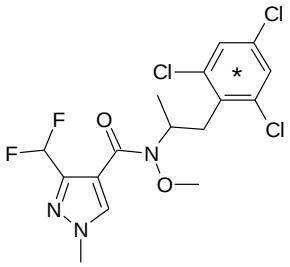
**Introduction**

Pydiflumetofen (applicant code SYN545974, also known by the applicant as Adepidyn) is a new broad-spectrum fungicide of the chemical group of N-methoxy-(phenyl-ethyl)-pyrazole-carboxamide. The mode of action of the active substance is respiration inhibition at complex II (Succinate-DeHydrogenase) in mitochondria of phytopathogenic fungi, thus pydiflumetofen belongs to the SDHI fungicide group.

The proposed use of pydiflumetofen associated with this submission for approval is on cereals and oilseed rape crops with a single dose per year of up to 200 g a.s./ha.

The environmental fate and behaviour studies were performed with pydiflumetofen labelled on the phenyl or pyrazole rings.

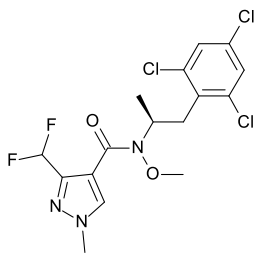
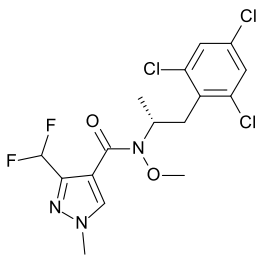
**Table B.8. 1 Structure of pydiflumetofen and positions of $^{14}$C-labels as used within environmental studies**

| Structure and applicant's code name | IUPAC Chemical name | Comments |
|---|---|---|
| SYN545974<br>  <br><br>  <br> | N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide | *- denotes the position of 14C in the pyrazole ring [14C]-pyrazole label<br><br>* - denotes the position of 14C (uniform phenyl ring label)<br>[14C]-phenyl label |

Pydiflumetofen contains two enantiomers, both of which are biologically active. The two enantiomers are separately numbered SYN546968 and SYN546969. Specification for technical pydiflumetofen covers an enantiomer ratio of 1 (in all cases expressed as SYN546968/SYN546969, *i.e.*, an enantiomer fraction ratio for SYN546968:SYN546969 of 50:50).

[1] Peer review of the pesticide risk assessment of the active substance pydiflumetofen (wiley.com)

**Table B.8. 2 Structure of pydiflumetofen enantiomers**

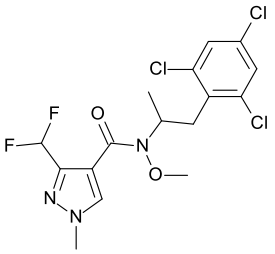
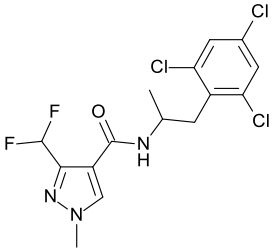
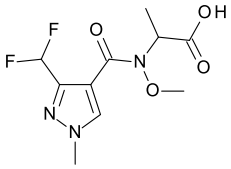
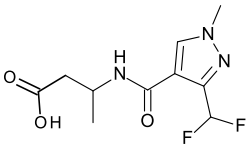
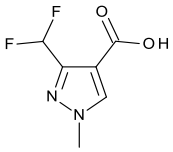
| | |
|---|---|
| ABSOLUTE  | ABSOLUTE  |
| SYN546968<br>(S)-3-Difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid methoxy-[1-methyl-2-(2,4,6-trichloro-phenyl)-ethyl]-amide | SYN546969<br>(R)-3-Difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid methoxy-[1-methyl-2-(2,4,6-trichloro-phenyl)-ethyl]-amide |

Enantiomers are non-superimposable mirror images which have identical physicochemical properties and can be resolved chromatographically only in a suitable chiral environment. In polarized light enantiomers show (+)- or (-)- optical rotation. Interconversion reactions may be of a simple chemical nature or involve enzyme (racemase) catalysis. The majority of racemases exert their effect on a carbon centre adjacent to a carbonyl functionality and reversibly cleave a C-H bond.

The ratio of the pydiflumetofen enantiomers has been examined in selected samples from the laboratory aerobic and anaerobic soil studies, the soil photolysis study, the field soil studies, the aqueous photolysis studies and the water sediment study. HSE assessed the data relating to the enantiomers in these studies and the consideration of this is given below in the overall summary of fate and behaviour in the environment.

A summary of the metabolites identified in the environmental fate studies and their structures, codes and maximum levels is provided in the table below.

**Table B.8. 3 Structures, codes and synonyms for pydiflumetofen and metabolites identified in environmental fate studies**

| Code Number (Synonyms) | Description | Structure |
|---|---|---|
| SYN545974<br>CSCD678790 | N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide<br><br>1H-Pyrazole-4-carboxamide, 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]- |  |
| SYN545547<br>CSCD550897 | 3-(difluoromethyl)-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]pyrazole-4-carboxamide |  |
| SYN548261<br>AP3 | 3-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]-methoxy-amino]butanoic acid |  |
| SYN548262<br>AP2 | 3-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]amino]butanoic acid |  |
| NOA449410<br>CSAA798670<br>R648993 | 3-(difluoromethyl)-1-methyl-pyrazole-4-carboxylic acid |  |

**Overall summary of fate and behaviour in the environment**

Pydiflumetofen is composed of two enantiomers. The studies were conducted prior to the adoption in GB of the EFSA Stereoisomers guidance but HSE have used the guidance for useful indicators and principles for evaluation that help in this assessment. It is noted that as well as the standard regulatory studies int eh data package, a single published reference was available on enantiomeric behaviour. The amount of information on the degradation and/or dissipation behaviour of the enantiomers in each study was very limited, both in terms of the number of samples analysed to allow any trend in change in ratio to be detected, and in terms of the limited amount of parent degradation that occurred. Both of these aspects make it challenging to conclude definitively on the degradation behaviour of individual enantiomers. In some studies, specifically the aerobic soil degradation, soil photolysis and aerobic mineralisation in surface water studies, the change in enantiomer excess was either greater than the threshold of 10% change or by extrapolation might have exceeded the 10% threshold had the study been allowed to continue to 50% degradation of pydiflumetofen. However in many cases the degree of extrapolation was high due to limited degradation, and the limited number of samples analysed made it more difficult to determine a clear pattern in changing isomer ratios. In the anaerobic soil study, the change in enantiomer excess was smaller and uncertain whether the 10% change threshold would have been exceeded had the study continued to 50% degradation of pydiflumetofen. In the water/sediment study and field dissipation studies where enantiomer ratio was measured, the change in enantiomer excess extrapolated to a point of 50%

dissipation was estimated to be less than 10%; again, it should be noted that in most cases the degree of extrapolation to 50% decline was high. The published study had greater measurement of enantiomer concentrations but experimental details were poorly reported and the degradation behaviour was markedly different to that in the standard regulatory studies. HSE considers that the field dissipation studies represent a more realistic environment with respect to degradation and dissipation processes compared to laboratory conditions. The results of the aqueous photolysis study could also be taken into consideration. Whilst this study does not pose what the EFSA Stereoisomer guidance terms an 'asymmetric environment', i.e. an environment that could induce a change in enantiomer excess via microbial activity, some change in enantiomer excess was seen. The change was likely to be less than the threshold 10% change in enantiomer excess when the results were extrapolated out to 50% degradation. However this suggests that changes in enantiomer excess seen in other studies with active microbial communities might not have been as a result of the influence of an asymmetric environment but may have been due to experimental variability. HSE considers that there is some uncertainty over the change in enantiomer excess. However, based on the weight of evidence, i.e. the results in the more realistic field dissipation studies and that apparent changes in enantiomer excess could be seen in non-asymmetric environments, no further investigation of stereoisomer issues is required with respect to environmental fate and behaviour. HSE considers that the change in enantiomer ratio is unlikely to be significant in the overall environmental behaviour of pydiflumetofen and does not need to be taken into consideration in the environmental exposure assessment.

In laboratory soil studies pydiflumetofen was slowly degraded with 'trigger' DT50 values in aerobic soils ranging from 398 to 2380 days, and $DT_{90}$ values ranging from 1320 to 7640 days. Slow degradation was also seen in anaerobic soils and in the soil photolysis studies with DT50 and DT90 values in all laboratory soil studies extrapolated beyond study duration. Levels of metabolite formation were low; HSE consider on the basis of the results that no metabolites formed in soil formally trigger inclusion in risk assessment. However HSE notes that at the end of the aerobic soil study there was still 50-84% AR remaining as unchanged pydiflumetofen.

Field dissipation studies confirmed that pydiflumetofen degrades slowly in soil. Field studies where pydiflumetofen was applied to bare soil which subsequently had grass growth develop suggest that other processes, such as soil surface photolysis or plant uptake might increase the rate of dissipation. However dissipation was still slow.

In both laboratory and field studies there is some uncertainty associated with calculated kinetic parameters because the DT50s in nearly all cases and the DT90s in all cases are extrapolated significantly beyond study duration.

Pydiflumetofen was relatively strongly adsorbed to soil with Kfoc values ranging from 1165 to 2206 mL/g.

In water studies, pydiflumetofen was stable to hydrolysis but showed faster degradation in an aqueous photolysis study, particularly in a sterile natural water (half-life values of 35 and 93 days in natural water and sterile pH7 buffer solution). Pydiflumetofen is classified as 'not readily biodegradable'. Only small amounts of degradation were seen in an aerobic mineralisation in surface water test.

Two metabolites formed in the aqueous photolysis study, SYN548261 and NOA449410, were considered by HSE to trigger inclusion in surface water exposure assessment.

In an aerobic water/sediment study, pydiflumetofen was found to dissipate relatively rapidly from water. The predominant route of dissipation from water was partitioning into sediment where subsequent decline was not clearly defined. One metabolite, SYN545547, was formed at sufficiently high levels to trigger inclusion in sediment exposure assessment.

The evidence from soil and water studies is that pydiflumetofen would be classified as P or vP in relation to POP, PBT and vPvB classification.

## B.8.1. FATE AND BEHAVIOUR IN SOIL

### B.8.1.1. Route and rate of degradation in soil

### B.8.1.1.1. Route of degradation in soil

#### B.8.1.1.1.1. Aerobic degradation

| | |
|---|---|
| **Report:** | K-CA 7.1.1.1/01. [redacted] (2016), SYN545974 - Aerobic Soil Metabolism of $^{14}$C-SYN545974, Report Number 3200099. Smithers Viscient (ESG) Ltd. Otley Road, Harrogate, North Yorkshire HG3 1PY, UK<br>(Syngenta File No. SYN545974_50164 including amendment 2, September 2016). |

**Guideline(s):** OECD 307 (2002), EPA Guideline Series OPPTS 835.4100 (2008), SETAC 1995
**GLP/GEP:** Yes
**Deviation(s):** No major deviation identified
**Acceptability** Yes

**Material and Methods**
The rate and route of aerobic degradation of $^{14}$C-labelled pydiflumetofen was investigated in five different soils: Gartenacker (loam) with both $^{14}$C-phenyl ring labelled SYN545974 and $^{14}$C-pyrazole ring labelled pydiflumetofen and 18 Acres (sandy clay loam), Sarpy (silt loam), East Anglia (sandy loam) and Capay (clay loam) with $^{14}$C-phenyl ring labelled pydiflumetofen only.

| **Test Material:** | **[Pyrazole-5-$^{14}$C]-SYN545974** | **[Phenyl-U-$^{14}$C]-SYN545974** |
|---|---|---|
| Lot/Batch #: | 5271GAR001-4 | RDR-XV-94 |
| Specific activity: | 5.06 MBq/mg | 5.791 MBq/mg |
| Purity: | 95.4% (chemical)<br>99.2% (radiochemical) | 97.6% (chemical)<br>99.1% (radiochemical) |
| Application vehicle: | Acetonitrile | Acetonitrile |

The soils had not received any pesticides for the last 5-10 years (except for East Anglia for which no information was available). The absence of previous pesticide history for the East Anglia soil is a study guideline deviation. The principle behind this guideline requirement is to avoid situations where the microbial community could have become adapted to similar chemistry and lead to enhanced degradation. Scrutiny of the best fit kinetic parameters presented later in the assessment (section B.8.1.1.2.1.1.) indicated that the DT50 and DT90 in the East Anglia soil were the second longest values from the five soils in the study. Thus whilst the absence of previous pesticide treatment history is a significant deviation, in this case HSE can accept the deviation as it appears unlikely that it significantly impacts on regulatory decision-making.

The soils were stored in the dark at 4±2°C in loosely tied plastic bags. All soils were sieved using a 2 mm mesh sieve prior to analysis and acclimation. They were acclimated and incubated as close to pF2 as practicable under darkness at 20±2°C. Soils characteristics are reported below.

**Table B.8. 4 Soils characteristics**

| **Name** | | **Gartenacker** | | **18 Acres** | | **Sarpy** | | **East Anglia** | | **Capay** | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Sampling location | | Gartenacker, Les Barges, Switzerland | | Jealott's Hill Farm Bracknell, UK | | Louisville, NE Sarpy County, USA | | Stody Estate Norfolk, UK | | Woodland, CA, USA | |
| Sampling depth (cm) | | 5-20 cm | | 5-20 cm | | 0-15.24 cm[1] | | 5-30 cm | | 0-15.24 cm[1] | |
| Duration of storage (days) | | 76 | | 83 | | 80 | | 59 | | 72 | |
| Particle size (% w/w): | Clay (<2 µm) | 12 | | 25 | | 27 | | 11 | | 37 | |
| | Silt (50-2 µm) | 43 | | 24 | | 55 | | 28 | | 36 | |
| | Sand (2000-50 µm) | 45 | | 51 | | 18 | | 61 | | 27 | |
| Texture (USDA) | | Loam | | Sandy clay loam | | Silty clay loam | | Sandy loam | | Clay loam | |
| pH (water) | | 7.4 | | 6.5 | | 6.8 | | 7.8 | | 8.4 | |
| pH (0.01M $CaCl_2$) | | 6.9 | | 5.5 | | 6.2 | | 7.1 | | 7.6 | |
| Organic matter (%) | | 3.3 | | 4.8 | | 3.4 | | 4.1 | | 1.6 | |
| Organic carbon (OC) (%) | | 1.9 | | 2.8 | | 2.0 | | 2.4 | | 0.9 | |
| CEC (meq/100 g soil) | | 10.8 | | 18.9 | | 34.3 | | 18.7 | | 27.0 | |
| Moisture at pF0 (w/w %) | | 70.2 | | 60.1 | | 63.6 | | 51.0 | | 41.5 | |
| Moisture at pF2 (w/w %) | | 39.0 | | 29.8 | | 36.7 | | 26.9 | | 28.5 | |
| Biomass | | µg C/g | % of OC | µg C/g | % of OC | µg C/g | % of OC | µg C/g | % of OC | µg C/g | % of OC |
| Bulk (prior to study start) | | 571.4 | 3.0 | 685.8 | 2.4 | 346.8 | 1.7 | 643.2 | 2.7 | 132.0 | 1.5 |
| Initial (start of study) | | 488.1 | 2.6 | 654.1 | 2.3 | 359.4 | 1.8 | 611.2 | 2.5 | 90.3 | 1.0 |
| Interim (120 DAT) | | 408.1 | 2.1 | 493.2 | 1.8 | 246.0 | 1.2 | 399.1 | 1.7 | 66.3 | 0.7 |
| Final (end of study) | | 327.8 | 1.7 | 364.8 | 1.3 | 186.9 | 0.9 | 453.2 | 1.9 | 75.1 | 0.8 |

[1] Soils from USA, sampled from 0-6 inch depth, i.e. 0 – 15.24 cm

$^{14}$C-Labelled pydiflumetofen was applied at a dose rate of 0.33 mg/kg dry weight soil, equivalent to a single field application rate of 250 g ai/ha (assuming an incorporation depth of 5 cm and a bulk density of 1.5 g/cm$^3$). The test conditions consisted of test vessels containing treated soil connected to flow through apparatus. Treated soils were incubated aerobically, for up to 365 days, in the dark at a nominal temperature of 20±2°C, by passing a stream of moist air through each vessel. The moisture content of the soil samples was maintained at pF2 throughout the incubation period. Any volatile radiolabelled products in the effluent air were trapped in either sodium hydroxide ($^{14}CO_2$) or ethanediol (organic volatiles).

It should be noted that the study duration normally recommended by the OECD 307 study guideline is 120 days. This is because after such time the microbial activity of the soil would be expected to decline under artificial laboratory system conditions. However, the guideline states the following:

*"Where necessary to characterise the decline of the test substance and the formation and decline of major transformation products, studies can be continued for longer periods (e.g. 6 or 12 months) (8). Longer incubation periods should be justified in the test report and accompanied by biomass measurements during and at the end of these periods."*

The results of the incubations of the five soils indicate that pydiflumetofen is very persistent and there was 63.1 – 89.8% AR remaining as pydiflumetofen at 120 days. Therefore it seems justified to continue the study to 365 days to investigate degradation over a longer period of time. In addition, microbial biomass measurements were taken at 120 days and at study end. Thus HSE considers that the longer study duration is within the scope of the OECD 307 guideline requirements.

It was noted that the microbial biomass fell below 1% of organic carbon by the end of the study in the Capay and Sarpy soils. In the case of the Sarpy soil the microbial biomass fell below 1% after 120 days although the microbial biomass was only 1.2% at 120 days. In the case of the Capay soil the microbial biomass was already less than 1% at 120 days. The OECD 307 guideline for conduct of aerobic laboratory studies indicates that soils should have microbial biomass at least 1% of organic carbon. However the pattern of degradation in these soils

was similar to that in the other soils. If the decline in microbial biomass played such a significant role it would be expected that the rate of degradation of pydiflumetofen would have been even slower beyond 120 days, but this did not occur. HSE accepts that the results from these soils can be used for regulatory purposes.

For each soil, duplicate samples were taken for analysis at 0, 7, 14, 29, 60, 90, 120, 239 and 365 days after treatment (DAT). The soil was extracted once with acetonitrile : 0.1 M ammonium acetate (80:20 v/v) and twice with acetonitrile : water (80:20 v/v, water acidified to ca pH 3). This was termed 'non-harsh extraction'. The amount of radioactivity recovered was determined by LSC quantification prior to HPLC analysis. Unextracted residues were determined by combustion. A mass balance for each sample was determined by summation of the radioactivity recovered in the soil extracts, the total $^{14}CO_2$ evolved and the unextracted residues.

At some sampling times, the aliquots of extracted soil which were subject to combustion showed > 10% AR present as non-extracted radioactivity. Soil aliquots from these samples were subject to additional reflux extraction (8h) using acetonitrile : water (80:20 v/v, water acidified to ca pH 3). This additional extraction was termed 'harsh extraction'. Some samples (Gartenacker, Sarpy and Capay soils) still contained >10% AR (up to 14.9% AR) following reflux. Both replicates from the final sampling interval (365 DAT) were selected for organic matter fractionation.

Structural assignment of extracted substances was initially made by co-chromatography (by HPLC) with authenticated reference standards. Confirmation of the presence of parent and its metabolite (SYN545547) was made by TLC analysis of selected samples. Pydiflumetofen was confirmed in a selected sample per radiolabel by LC-MS.

Chiral HPLC was performed on one unit treated with [phenyl-U-$^{14}$C]-pydiflumetofen and on one unit treated with [pyrazole-5-$^{14}$C]-pydiflumetofen, both of which had been incubated for 365 days after treatment. The purpose of this analysis was to check whether there was any change to the enantiomer ratio of pydiflumetofen during the course of the study.

**Findings: Mass Balance**

Gartenacker, 18 Acres and East Anglia soils demonstrated microbial biomass as a % of organic carbon (% OC) to be in excess of 1% throughout the study. Biomass in Sarpy and Capay soils gradually decreased such that biomass as % of OC at 120 DAT was 1.3 and 0.7% respectively, and by the end (365 DAT) it was 0.9 (Sarpy) and 0.8 % OC (Capay). Although the biomass in terms of % of OC suggest that Sarpy and Capay soils may have been no longer viable, comparison of degradation to that in the viable Gartenacker, 18 Acres and East Anglia soils shows a similar profile.

The total recoveries and distribution of radioactivity from each soil are shown in detail in the tables below. The mean mass balance from all soils was 97.9% AR, with a range of 90.9 – 101.4 % AR. Mineralisation to $^{14}CO_2$ was highest in Gartenacker soil, reaching a maximum 15 - 17 % of AR by the end of soil incubations, but low in all other soils, reaching a maximum of 0.2 - 5.2% AR.

Unextracted residues (bound residues) increased slowly throughout the study, reaching a maximum of 12% - 46% of AR by the end of their incubations, prior to harsh reflux conditions. Harsh extraction methods released a further 4 - 31% AR, leaving 3 - 15% AR as non-extractable residue. Organic matter fractionation (OMF) of the bound residues in selected 365 DAT samples demonstrated that $^{14}$C was associated predominantly with the humin fraction (up to 9 % AR) and to a lesser extent with the humic acid (≤ 3% AR) and fulvic acid fractions (≤ 3% AR).

**Table B.8. 5 Mass balance and distribution of radioactivity in extracts of Gartenacker – individual replicates (values as % of applied) - [Phenyl-$^{14}$C]-pydiflumetofen**

| [Phenyl-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Extract 1 (non-harsh) | A | 77.0 | 76.6 | 75.8 | 58.9 | 62.1 | 66.1 | 62.4 | 53.1 | 43.5 |
| | B | 77.2 | 75.3 | 73.5 | 60.5 | 64.5 | 63.8 | 59.8 | 51.3 | 47.4 |
| | **Mean** | **77.1** | **76.0** | **74.7** | **59.7** | **63.3** | **65.0** | **61.1** | **52.2** | **45.5** |
| Extract 2 (non-harsh) | A | 17.0 | 18.4 | 16.4 | 28.2 | 15.3 | 17.4 | 16.6 | 14.9 | 11.5 |
| | B | 16.9 | 18.7 | 19.0 | 26.5 | 15.4 | 18.0 | 17.0 | 14.5 | 12.8 |
| | **Mean** | **17.0** | **18.6** | **17.7** | **27.4** | **15.4** | **17.7** | **17.7** | **14.7** | **12.2** |
| Extract 3 (non-harsh) | A | 3.5 | 4.3 | 3.9 | 6.2 | 9.9 | 4.2 | 4.5 | 3.3 | 3.5 |
| | B | 3.2 | 4.4 | 4.1 | 5.6 | 10.3 | 4.7 | 4.6 | 3.7 | 3.6 |
| | **Mean** | **3.4** | **4.4** | **4.0** | **5.9** | **10.1** | **4.5** | **4.6** | **3.5** | **3.6** |
| **Total Extractables** (non-harsh) | **Mean** | **97.4** | **98.9** | **96.4** | **93.0** | **88.8** | **87.1** | **82.5** | **70.4** | **61.2** |
| Non-Extractables* | A | 0.9 | 2.2 | 2.5 | 4.4 | 9.7 | 7.9 | 10.5 | 15.6 | 19.9 |
| | B | 0.9 | 1.9 | 2.4 | 4.8 | 9.3 | 8.4 | 11.8 | 16.4 | 18.1 |
| | **Mean** | **0.9** | **2.1** | **2.5** | **4.6** | **9.5** | **8.2** | **11.2** | **16.0** | **19.0** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | 0.1 | 0.2 | 0.5 | 1.9 | 2.7 | 4.8 | 12.0 | 17.7 |
| | B | NA | 0.1 | 0.2 | 0.6 | 1.8 | 3.1 | 5.7 | 11.3 | 15.3 |
| | **Mean** | **NA** | **0.1** | **0.2** | **0.6** | **1.9** | **2.9** | **5.3** | **11.7** | **16.5** |
| Other Volatiles | A | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | B | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | **Mean** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 98.4 | 101.6 | 98.8 | 98.2 | 98.9 | 98.3 | 98.8 | 98.9 | 96.1 |
| | B | 98.2 | 100.4 | 99.2 | 98.0 | 101.3 | 98.0 | 98.9 | 97.2 | 97.2 |
| | **Mean** | **98.3** | **101.0** | **99.0** | **98.1** | **100.1** | **98.2** | **98.9** | **98.1** | **96.7** |
| **Overall Mean ± SD** | | **98.3 ± 0.5** | | | | | | | | |

* Prior to harsh extraction..

NA = Not applicable. ND = Not detected or <0.1% AR

Note: %AR values reported above for extracts are prior to concentrating samples for chromatographic analyses. Procedural recoveries were ≥ 93 % of their initial sample radioactivity.

**Table B.8. 6 Mass balance and distribution of radioactivity in extracts of Gartenacker – individual replicates (values as % of applied) - [Pyrazole-$^{14}$C]-pydiflumetofen**

| [Pyrazole-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Extract 1 (non-harsh) | A | 76.5 | 77.2 | 72.5 | 62.7 | 65.9 | 67.3 | 67.2 | 58.7 | 48.3 |
| | B | 77.6 | 74.8 | 75.6 | 67.6 | 64.0 | 66.7 | 67.6 | 51.3 | 49.7 |
| | **Mean** | **77.1** | **76.0** | **74.1** | **65.2** | **65.0** | **67.2** | **67.4** | **55.0** | **49.0** |
| Extract 2 (non-harsh) | A | 18.4 | 17.5 | 21.9 | 26.1 | 21.7 | 19.7 | 17.6 | 16.7 | 13.7 |
| | B | 17.6 | 18.1 | 18.3 | 20.4 | 20.5 | 19.7 | 18.2 | 14.6 | 14.4 |
| | **Mean** | **18.0** | **17.8** | **20.1** | **23.3** | **21.1** | **19.7** | **17.9** | **15.7** | **14.1** |
| Extract 3 (non-harsh) | A | 3.3 | 4.3 | 4.5 | 7.0 | 5.4 | 4.7 | 4.6 | 3.8 | 4.1 |
| | B | 3.8 | 4.0 | 3.9 | 6.4 | 8.5 | 4.9 | 4.7 | 3.7 | 4.0 |
| | **Mean** | **3.6** | **4.2** | **4.2** | **6.7** | **7.0** | **4.8** | **4.7** | **3.8** | **4.1** |
| **Total Extractables** (non-harsh) | **Mean** | **98.6** | **98.0** | **98.4** | **95.1** | **93.0** | **91.5** | **90.0** | **74.4** | **67.1** |
| Non-Extractables* | A | 1.0 | 2.0 | 2.6 | 4.3 | 6.7 | 7.0 | 8.3 | 13.8 | 17.9 |
| | B | 0.7 | 2.4 | 2.8 | 4.4 | 7.1 | 6.9 | 7.9 | 12.1 | 16.6 |
| | **Mean** | **0.9** | **2.2** | **2.7** | **4.4** | **6.9** | **7.0** | **8.1** | **13.0** | **17.3** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | ND | 0.1 | 0.2 | 1.7 | 2.5 | 3.3 | 8.7 | 15.6 |
| | B | NA | ND | 0.1 | 0.2 | 1.3 | 1.8 | 3.1 | 8.0 | 13.3 |
| | **Mean** | **NA** | **ND** | **0.1** | **0.2** | **1.5** | **2.2** | **3.2** | **8.4** | **14.5** |
| Other Volatiles | A | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | B | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | **Mean** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 99.2 | 101.0 | 101.6 | 100.3 | 101.4 | 101.2 | 101.0 | 101.7 | 99.6 |
| | B | 99.7 | 99.3 | 100.7 | 99.0 | 101.4 | 100.0 | 101.5 | 89.7 | 98.0 |
| | **Mean** | **99.5** | **100.2** | **101.2** | **99.7** | **101.4** | **100.6** | **101.3** | **95.7** | **98.8** |
| **Overall Mean ± SD** | | **99.8 ± 2.7%** | | | | | | | | |

* Prior to harsh extraction.

NA = Not applicable. ND = Not detected or <0.1% AR

Note: %AR values reported above for extracts are prior to concentrating samples for chromatographic analyses. Procedural recoveries were ≥ 96 % of their initial sample radioactivity.

**Table B.8. 7 Mass balance and distribution of radioactivity in extracts of 18 Acres – individual replicates (values as % of applied) - [Phenyl-$^{14}$C]-pydiflumetofen**

| [Phenyl-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Extract 1 (non-harsh) | A | 83.7 | 79.3 | 81.5 | 71.1 | 75.7 | 72.5 | 70.8 | 69.9 | 70.3 |
| | B | 81.2 | 78.6 | 79.8 | 76.7 | 75.9 | 73.4 | 74.0 | 71.0 | 69.2 |
| | **Mean** | **82.5** | **79.0** | **80.7** | **73.9** | **75.8** | **73.0** | **72.4** | **70.5** | **69.8** |
| Extract 2 (non-harsh) | A | 14.4 | 15.7 | 15.2 | 19.0 | 13.8 | 17.2 | 15.7 | 15.7 | 13.8 |
| | B | 13.8 | 16.7 | 15.6 | 15.8 | 14.1 | 16.8 | 15.4 | 15.7 | 14.2 |
| | **Mean** | **14.1** | **15.9** | **15.4** | **17.4** | **14.0** | **17.0** | **15.6** | **15.7** | **14.0** |
| Extract 3 (non-harsh) | A | 2.4 | 2.9 | 2.7 | 5.2 | 3.4 | 3.2 | 3.8 | 3.5 | 3.1 |
| | B | 2.4 | 3.0 | 2.9 | 4.2 | 3.3 | 3.2 | 4.0 | 3.5 | 3.0 |
| | **Mean** | **2.4** | **3.0** | **2.8** | **4.7** | **3.4** | **3.2** | **3.9** | **3.5** | **3.1** |
| **Total Extractables** (non-harsh) | **Mean** | **99.0** | **97.8** | **98.9** | **96.0** | **93.1** | **93.2** | **91.9** | **89.7** | **86.8** |
| Non-Extractables* | A | 0.5 | 1.9 | 2.6 | 4.4 | 7.1 | 6.9 | 7.3 | 9.8 | 12.7 |
| | B | 0.4 | 1.8 | 2.1 | 4.4 | 6.5 | 6.2 | 7.4 | 9.8 | 11.9 |
| | **Mean** | **0.5** | **1.9** | **2.4** | **4.4** | **6.8** | **6.6** | **7.4** | **9.8** | **12.3** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | 0.1 | 0.1 | 0.1 | 0.3 | 0.3 | 0.3 | 0.3 | 0.4 |
| | B | NA | 0.1 | 0.2 | 0.1 | 0.2 | 0.3 | 0.3 | 0.3 | 0.4 |
| | **Mean** | **NA** | **0.1** | **0.2** | **0.1** | **0.3** | **0.3** | **0.3** | **0.3** | **0.4** |
| Other Volatiles | A | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | B | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | **Mean** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 101.0 | 99.9 | 102.1 | 99.8 | 100.3 | 100.1 | 97.9 | 99.2 | 100.3 |
| | B | 97.8 | 99.6 | 100.6 | 101.2 | 100.0 | 99.9 | 101.1 | 100.3 | 98.7 |
| | **Mean** | **99.4** | **99.8** | **101.4** | **100.5** | **100.2** | **100.0** | **99.5** | **99.8** | **99.5** |
| **Overall Mean ± SD** | | **100 ± 1.1%** | | | | | | | | |

* Prior to harsh extraction.

NA = Not applicable. ND = Not detected or <0.1% AR

Note: %AR values reported above for extracts are prior to concentrating samples for chromatographic analyses. Procedural recoveries were ≥ 95 % of their initial sample radioactivity.

**Table B.8. 8 Mass balance and distribution of radioactivity in extracts of Sarpy – individual replicates (values as % of applied) - [Phenyl-$^{14}$C]-pydiflumetofen**

| [Phenyl-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Extract 1 (non-harsh) | A | 82.2 | 72.6 | 69.2 | 62.8 | 52.6 | 52.8 | 55.3 | 46.9 | 42.5 |
| | B | 80.5 | 70.6 | 68.2 | 61.3 | 47.8 | 52.1 | 52.4 | 46.1 | 42.5 |
| | **Mean** | **81.4** | **71.6** | **68.7** | **62.1** | **50.2** | **52.5** | **53.9** | **46.5** | **42.5** |
| Extract 2 (non-harsh) | A | 14.6 | 14.1 | 14.9 | 13.8 | 11.7 | 15.4 | 12.9 | 14.2 | 11.9 |
| | B | 15.4 | 12.5 | 15.1 | 16.8 | 11.8 | 15.5 | 12.8 | 14.1 | 11.3 |
| | **Mean** | **15.0** | **13.3** | **15.0** | **15.3** | **11.8** | **15.5** | **12.9** | **14.2** | **11.5** |
| Extract 3 (non-harsh) | A | 2.4 | 3.7 | 3.7 | 5.8 | 4.3 | 3.8 | 4.6 | 3.9 | 4.5 |
| | B | 2.6 | 4.2 | 4.2 | 5.9 | 5.6 | 3.9 | 5.0 | 3.9 | 4.2 |
| | **Mean** | **2.5** | **4.0** | **4.0** | **5.9** | **5.0** | **3.9** | **4.8** | **3.9** | **4.4** |
| **Total Extractables** (non-harsh) | **Mean** | **98.9** | **88.9** | **87.7** | **83.2** | **66.9** | **71.8** | **71.5** | **64.6** | **58.5** |
| Non-Extractables* | A | 0.6 | 6.1 | 7.8 | 9.0 | 21.2 | 17.3 | 17.0 | 22.7 | 27.3 |
| | B | 0.6 | 6.1 | 6.6 | 9.0 | 24.8 | 17.1 | 19.7 | 22.7 | 27.1 |
| | **Mean** | **0.6** | **6.1** | **7.2** | **9.0** | **23.0** | **17.2** | **18.4** | **22.7** | **27.2** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | 0.1 | 0.3 | 0.6 | 1.8 | 2.1 | 2.0 | 4.4 | 4.3 |
| | B | NA | 0.1 | 0.2 | 0.6 | 0.8 | 2.4 | 3.0 | 3.7 | 6.1 |
| | **Mean** | **NA** | **0.1** | **0.3** | **0.6** | **1.3** | **2.3** | **2.5** | **4.1** | **5.2** |
| Other Volatiles | A | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | B | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | **Mean** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 99.8 | 96.6 | 95.9 | 92.0 | 91.6 | 91.4 | 91.8 | 92.1 | 90.5 |
| | B | 99.1 | 93.5 | 94.3 | 93.6 | 90.8 | 91.0 | 92.9 | 90.5 | 91.2 |
| | **Mean** | **99.5** | **95.1** | **95.1** | **92.8** | **91.2** | **91.2** | **92.4** | **91.3** | **90.9** |
| **Overall Mean ± SD** | | **93.3 ± 2.9%** | | | | | | | | |

* Prior to harsh extraction.

NA = Not applicable. ND = Not detected or <0.1% AR

Note: % AR values reported above for extracts are prior to concentrating samples for chromatographic analyses. Procedural recoveries were ≥ 96 % of their initial sample radioactivity.

**Table B.8. 9 Mass balance and distribution of radioactivity in extracts of East Anglia – individual replicates (values as % of applied) - [Phenyl-$^{14}$C]-pydiflumetofen**

| [Phenyl-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Extract 1 (non-harsh) | A | 82.0 | 75.4 | 73.2 | 71.5 | 64.2 | 67.4 | 68.5 | 65.6 | 63.1 |
| | B | 84.1 | 77.3 | 75.7 | 71.8 | 39.0 | 68.3 | 68.9 | 64.1 | 61.9 |
| | **Mean** | **83.1** | **76.4** | **74.5** | **71.7** | **51.6** | **67.9** | **68.7** | **64.9** | **62.5** |
| Extract 2 (non-harsh) | A | 14.4 | 14.7 | 16.4 | 16.6 | 19.6 | 17.0 | 14.3 | 15.6 | 13.8 |
| | B | 14.0 | 14.4 | 15.4 | 17.0 | 40.5 | 17.0 | 14.3 | 15.9 | 13.7 |
| | **Mean** | **14.2** | **14.6** | **15.9** | **16.8** | **30.1** | **17.0** | **14.3** | **15.8** | **13.8** |
| Extract 3 (non-harsh) | A | 2.4 | 2.9 | 3.6 | 3.9 | 4.6 | 3.4 | 4.0 | 3.3 | 3.5 |
| | B | 2.3 | 3.1 | 3.6 | 4.1 | 8.8 | 3.1 | 3.8 | 3.4 | 3.6 |
| | **Mean** | **2.4** | **3.0** | **3.6** | **4.0** | **6.7** | **3.3** | **3.9** | **3.4** | **3.6** |
| **Total Extractables** (non-harsh) | **Mean** | **99.6** | **93.9** | **94.0** | **92.5** | **88.4** | **88.1** | **86.9** | **84.0** | **79.8** |
| Non-Extractables* | A | 0.4 | 2.4 | 2.8 | 4.7 | 8.1 | 7.9 | 9.0 | 10.8 | 15.0 |
| | B | 0.3 | 2.1 | 2.7 | 4.9 | 8.6 | 7.9 | 8.1 | 11.9 | 14.8 |
| | **Mean** | **0.4** | **2.3** | **2.8** | **4.8** | **8.4** | **7.9** | **8.6** | **11.4** | **14.9** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | 0.1 | 0.1 | 0.2 | 0.4 | 0.7 | 0.9 | 1.6 | 2.1 |
| | B | NA | 0.1 | 0.1 | 0.2 | 0.4 | 0.7 | 0.7 | 1.7 | 2.9 |
| | **Mean** | **NA** | **0.1** | **0.1** | **0.2** | **0.4** | **0.7** | **0.8** | **1.7** | **2.5** |
| Other Volatiles | A | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | B | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | **Mean** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 99.2 | 95.5 | 96.1 | 96.9 | 96.9 | 96.4 | 96.7 | 96.9 | 97.5 |
| | B | 100.7 | 97.0 | 97.5 | 98.0 | 97.3 | 97.0 | 95.8 | 97.0 | 96.9 |
| | **Mean** | **100.0** | **96.3** | **96.8** | **97.5** | **97.1** | **96.7** | **96.3** | **97.0** | **97.2** |
| **Overall Mean ± SD** | | **97.2 ± 1.2%** | | | | | | | | |

* Prior to harsh extraction.

NA = Not applicable. ND = Not detected or <0.1% AR

Note: % AR values reported above for extracts are prior to concentrating samples for chromatographic analyses. Procedural recoveries were ≥ 95 % of their initial sample radioactivity.

**Table B.8. 10 Mass balance and distribution of radioactivity in extracts of Capay – individual replicates (values as % of applied) - [Phenyl-$^{14}$C]-pydiflumetofen**

| [Phenyl-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Extract 1 (non-harsh) | A | 84.8 | 61.7 | 52.8 | 58.1 | 44.1 | 16.2 | 44.8 | 40.2 | 37.5 |
| | B | 84.9 | 69.6 | 67.3 | 54.7 | 45.3 | 16.8 | 48.8 | 40.4 | 37.3 |
| | **Mean** | **84.9** | **65.7** | **60.1** | **56.4** | **44.7** | **16.5** | **46.8** | **40.3** | **37.4** |
| Extract 2 (non-harsh) | A | 12.2 | 15.4 | 20.0 | 13.0 | 12.4 | 3.6 | 10.2 | 13.9 | 9.9 |
| | B | 12.2 | 12.9 | 16.2 | 14.0 | 10.7 | 3.1 | 10.2 | 14.4 | 9.9 |
| | **Mean** | **12.2** | **14.2** | **18.1** | **13.5** | **11.6** | **3.4** | **10.2** | **14.2** | **9.9** |
| Extract 3 (non-harsh) | A | 2.1 | 8.8 | 9.0 | 5.4 | 5.0 | 2.0 | 7.2 | 5.3 | 4.5 |
| | B | 2.1 | 9.1 | 4.5 | 6.5 | 7.1 | 2.0 | 6.4 | 5.2 | 5.0 |
| | **Mean** | **2.1** | **9.0** | **6.8** | **6.0** | **6.1** | **2.0** | **6.8** | **5.3** | **4.8** |
| Extract 5 (non-harsh) | A | NA | NA | NA | NA | NA | 41.3 | NA | NA | NA |
| | B | NA | NA | NA | NA | NA | 44.4 | NA | NA | NA |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **42.9** | **NA** | **NA** | **NA** |
| **Total Extractables** (non-harsh) | **Mean** | **99.2** | **88.8** | **84.9** | **75.9** | **62.3** | **64.7** | **63.8** | **59.7** | **52.1** |
| Non-Extractables** | A | 0.6 | 12.1 | 15.8 | 20.8 | 37.2 | 34.2 | 34.6 | 39.2 | 46.5 |
| | B | 0.6 | 10.7 | 11.5 | 21.9 | 36.2 | 30.8 | 32.1 | 38.2 | 45.8 |
| | **Mean** | **0.6** | **11.4** | **13.7** | **21.4** | **36.7** | **32.5** | **33.4** | **38.7** | **46.2** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | ND | ND | ND | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 |
| | B | NA | ND | ND | ND | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 |
| | **Mean** | **NA** | **ND** | **ND** | **ND** | **0.1** | **0.1** | **0.2** | **0.2** | **0.2** |
| Other Volatiles | A | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | B | NA | ND | ND | ND | ND | ND | ND | ND | ND |
| | **Mean** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 99.7 | 98.0 | 97.6 | 97.3 | 98.8 | 97.4 | 97.0 | 98.8 | 98.6 |
| | B | 99.8 | 102.3 | 99.5 | 97.1 | 99.4 | 97.2 | 97.7 | 98.4 | 98.2 |
| | **Mean** | **99.8** | **100.2** | **98.6** | **97.2** | **99.1** | **97.3** | **97.4** | **98.6** | **98.4** |
| **Overall Mean ± SD** | | **98.5 ± 1.3%** | | | | | | | | |

*For this sampling interval only, an additional extraction was performed as the incorrect extraction solvent had been used in error on Extract 1.

** Prior to harsh extraction.

NA = Not applicable. ND = Not detected or <0.1% AR

Note: % AR values reported above for extracts are prior to concentrating samples for chromatographic analyses. Procedural recoveries were ≥ 94 % of their initial sample radioactivity.

**Table B.8. 11 Unextracted residue characterisation of soil samples (individual replicates): Gartenacker**

| **Characterisation of Gartenacker Bound Residues from [Phenyl-$^{14}$C]-pydiflumetofen Treated Soil** | | | | | |
|---|---|---|---|---|---|
| **Unit code** | **Sampling interval** | **% AR Recovered in combusted residue** | **% AR recovered in reflux extraction** | **Amount extracted from residue as % of AR in combusted sample** | **Estimated% AR left in soil** |
| A11 | 90 DAT | 7.9 | 3.4 | 43.0 | 4.5 |
| A12 | | 8.4 | 3.6 | 42.9 | 4.8 |
| **Mean** | | **8.2** | **3.5** | **42.9** | **4.7** |
| A13 | 120 DAT | 10.5 | 4.2 | 40.0 | 6.3 |
| A14 | | 11.8 | 4.5 | 38.1 | 7.3 |
| **Mean** | | **11.2** | **4.4** | **39.1** | **6.8** |
| A15 | 239 DAT | 15.6 | 4.9 | 31.4 | 10.7 |
| A16 | | 16.4 | 5.1 | 31.1 | 11.3 |
| **Mean** | | **16.0** | **5.0** | **31.3** | **11.0** |
| A17 | 365 DAT | 19.9 | 6.0 | 30.2 | 13.9 |
| A18 | | 18.1 | 5.3 | 29.3 | 12.8 |
| **Mean** | | **19.0** | **5.7** | **29.7** | **13.4** |

| **Characterisation of Gartenacker Bound Residues from [Pyrazole-$^{14}$C]-pydiflumetofen Treated Soil** | | | | | |
|---|---|---|---|---|---|
| **Unit code** | **Sampling interval** | **% AR Recovered in combusted residue** | **% AR recovered in reflux extraction** | **% AR extracted from residue** | **Estimated % AR left in soil** |
| B11 | 90 DAT | 7.0 | 3.8 | 54.3 | 3.2 |
| B12 | | 6.9 | 3.6 | 52.2 | 3.3 |
| **Mean** | | **7.0** | **3.7** | **53.2** | **3.3** |
| B13 | 120 DAT | 8.3 | 4.0 | 48.2 | 4.3 |
| B14 | | 7.9 | 3.9 | 49.4 | 4.0 |
| **Mean** | | **8.1** | **4.0** | **48.8** | **4.2** |
| B15 | 239 DAT | 13.8 | 4.9 | 35.5 | 8.9 |
| B16 | | 12.1 | 4.6 | 38.0 | 7.5 |
| **Mean** | | **13.0** | **4.8** | **36.8** | **8.2** |
| B17 | 365 DAT | 17.9 | 5.9 | 33.0 | 12.0 |
| B18 | | 16.6 | 5.5 | 33.1 | 11.1 |
| **Mean** | | **17.3** | **5.7** | **33.0** | **11.6** |

**Table B.8. 12 Unextracted residue characterisation of soil samples (individual replicates): 18 Acres**

| Characterisation of 18 Acres Bound Residues from [Phenyl-$^{14}$C]-pydiflumetofen Treated Soil | | | | | |
|---|---|---|---|---|---|
| **Unit code** | **Sampling interval** | **% AR Recovered in combusted residue** | **% AR recovered in reflux extraction** | **% AR extracted from residue** | **Estimated % AR left in soil** |
| C11 | 90 DAT | 6.9 | 4.0 | 58.0 | 2.9 |
| C12 | | 6.2 | 4.1 | 66.1 | 2.1 |
| **Mean** | | **6.6** | **4.1** | **62.1** | **2.5** |
| C13 | 120 DAT | 7.3 | 4.2 | 57.5 | 3.1 |
| C14 | | 7.4 | 4.9 | 66.2 | 2.5 |
| **Mean** | | **7.4** | **4.6** | **61.9** | **2.8** |
| C15 | 239 DAT | 9.8 | 4.7 | 48.0 | 5.1 |
| C16 | | 9.8 | 6.1 | 62.2 | 3.7 |
| **Mean** | | **9.8** | **5.4** | **55.1** | **4.4** |
| C17 | 365 DAT | 12.7 | 7.0 | 55.1 | 5.7 |
| C18 | | 11.9 | 7.2 | 60.5 | 4.7 |
| **Mean** | | **12.3** | **7.1** | **57.8** | **5.2** |

**Table B.8. 13 Unextracted residue characterisation of soil samples (individual replicates): Sarpy**

| Characterisation of Sarpy Bound Residues from [Phenyl-$^{14}$C]-pydiflumetofen Treated Soil | | | | | |
|---|---|---|---|---|---|
| **Unit code** | **Sampling interval** | **% AR Recovered in combusted residue** | **% AR recovered in reflux extraction** | **% AR extracted from residue** | **Estimated % AR left in soil** |
| D9 | 60 DAT | 21.2 | 13.8 | 65.1 | 7.4 |
| D10 | | 24.8 | 18.6 | 75.0 | 6.2 |
| **Mean** | | **23.0** | **16.2** | **70.0** | **6.8** |
| D11 | 90 DAT | 17.3 | 11.7 | 67.6 | 5.6 |
| D12 | | 17.1 | 11.0 | 64.3 | 6.1 |
| **Mean** | | **17.2** | **11.4** | **66.0** | **5.9** |
| D13 | 120 DAT | 17.0 | 10.7 | 62.9 | 6.3 |
| D14 | | 19.7 | 12.2 | 61.9 | 7.5 |
| **Mean** | | **18.4** | **11.5** | **62.4** | **6.9** |
| D15 | 239 DAT | 22.7 | 12.0 | 52.9 | 10.7 |
| D16 | | 22.7 | 13.0 | 57.3 | 9.7 |
| **Mean** | | **22.7** | **12.5** | **55.1** | **10.2** |
| D17 | 365 DAT | 27.3 | 17.9 | 65.6 | 9.4 |
| D18 | | 27.1 | 16.5 | 60.9 | 10.6 |
| **Mean** | | **27.2** | **17.2** | **63.2** | **10.0** |

**Table B.8. 14 Unextracted residue characterisation of soil samples (individual replicates): East Anglia**

| Characterisation of East Anglia Bound Residues from [Phenyl-$^{14}$C]-pydiflumetofen Treated Soil | | | | | |
|---|---|---|---|---|---|
| **Unit code** | **Sampling interval** | **% AR Recovered in combusted residue** | **% AR recovered in reflux extraction** | **% AR extracted from residue** | **Estimated % AR left in soil** |
| E11 | 90 DAT | 7.9 | 4.8 | 60.8 | 3.1 |
| E12 | | 7.9 | 4.5 | 57.0 | 3.4 |
| **Mean** | | **7.9** | **4.7** | **58.9** | **3.3** |
| E13 | 120 DAT | 9.0 | 5.1 | 56.7 | 3.9 |
| E14 | | 8.1 | 4.5 | 55.6 | 3.6 |
| **Mean** | | **8.6** | **4.8** | **56.1** | **3.8** |
| E15 | 239 DAT | 10.8 | 5.8 | 53.7 | 5.0 |
| E16 | | 11.9 | 6.7 | 56.3 | 5.2 |
| **Mean** | | **11.4** | **6.3** | **55.0** | **5.1** |
| E17 | 365 DAT | 15.0 | 8.2 | 54.7 | 6.8 |
| E18 | | 14.8 | 8.3 | 56.1 | 6.5 |
| **Mean** | | **14.9** | **8.3** | **55.4** | **6.7** |

**Table B.8. 15 Unextracted residue characterisation of soil samples (individual replicates): Capay**

| Characterisation of Capay Bound Residues from [Phenyl-$^{14}$C]-pydiflumetofen Treated Soil | | | | | |
|---|---|---|---|---|---|
| **Unit code** | **Sampling interval** | **% AR Recovered in combusted residue** | **% AR recovered in reflux extraction** | **% AR extracted from residue** | **Estimated % AR left in soil** |
| F3 | 7 DAT | 12.1 | 8.9 | 73.6 | 3.2 |
| F4 | | 10.7 | 7.3 | 68.2 | 3.4 |
| **Mean** | | **11.4** | **8.1** | **70.9** | **3.3** |
| F5 | 14 DAT | 15.8 | 11.4 | 72.2 | 4.4 |
| F6 | | 11.5 | 8.0 | 69.6 | 3.5 |
| **Mean** | | **13.7** | **9.7** | **70.9** | **4.0** |
| F7 | 30 DAT | 20.8 | 15.5 | 74.5 | 5.3 |
| F8 | | 21.9 | 16.2 | 74.0 | 5.7 |
| **Mean** | | **21.4** | **15.9** | **74.2** | **5.5** |
| F9 | 60 DAT | 37.2 | 25.7 | 69.1 | 11.5 |
| F10 | | 36.2 | 25.0 | 69.1 | 11.2 |
| **Mean** | | **36.7** | **25.4** | **69.1** | **11.4** |
| F11 | 90 DAT | 34.2 | 22.4 | 65.5 | 11.8 |
| F12 | | 30.8 | 21.2 | 68.8 | 9.6 |
| **Mean** | | **32.5** | **21.8** | **67.2** | **10.7** |
| F13 | 120 DAT | 34.6 | 21.7 | 62.7 | 12.9 |
| F14 | | 32.1 | 21.2 | 66.0 | 10.9 |
| **Mean** | | **33.4** | **21.5** | **64.4** | **11.9** |
| F15 | 239 DAT | 39.2 | 26.5 | 67.6 | 12.7 |
| F16 | | 38.2 | 26.4 | 69.1 | 11.8 |
| **Mean** | | **38.7** | **26.5** | **68.4** | **12.3** |
| F17 | 365 DAT | 46.5 | 31.3 | 67.3 | 15.2 |
| F18 | | 45.8 | 31.3 | 68.3 | 14.5 |
| **Mean** | | **46.2** | **31.3** | **67.8** | **14.9** |

**Findings: Characterisation of Radioactivity**

Characterisation of radioactive residues in soil extracts (prior to harsh extraction) is presented in the tables below. No degradation products of pydiflumetofen were formed at ≥ 5% AR. SYN545547 was observed at levels of 0.2 - 1.8% AR on average (maximum individual level 2.3% AR), however SYN545547 was also observed at up to 0.8% AR in both the $^{14}$C-pyrazole and $^{14}$C-phenyl label application solutions and so was not considered by the applicant to be to be a significant degradation product. In addition, a number of discreet unknown metabolites were also characterised, each individually not exceeding 3% AR. Levels of these minor metabolites were comparable throughout the duration of the study.

HSE notes that SYN545547 was observed to form at up to 1.8% AR ('non-harsh' extraction, 2.1% AR under 'harsh extraction) at study end (365 days) and had not apparently reached its maximum. EU approaches and guidance in place at the time of the UK exiting the EU indicate that identified metabolites formed at less than 5% AR should be considered for inclusion in risk assessment. During the admissibility check for the GB submission of pydiflumetofen, the applicant was requested by HSE to address why it should not be considered in exposure assessment.

The applicant replied that "*levels of SYN545547 detected in the study are extremely low. In all cases the levels of SYN545547 are significantly less than 5% AR and in most cases at later time points levels are around 0.5 – 1.5% AR. At these very low levels there will be inherent variability in the data due to the very low peak areas measured in the HPLC radio-chromatograms. In addition, as noted in the aerobic soil metabolism report, application solutions (for both [pyrazole-5-14C]-SYN545974 and [phenyl-U-14C]-SYN545974) contained low levels of SYN545547 of up to 0.6% AR. Therefore, degradation to SYN545547 was not considered to be significant and was not interpreted as rising at the end of the study. For these reasons SYN545547 was not included in groundwater assessments.*"

HSE checked the study report and confirmed from the chromatograms of the application solution that SYN545547 was present in the application solution at 0.5 – 0.6% AR. In three of the soil incubations SYN545547 was found at detectable levels of 0.2 – 0.6% AR at the day 0 sample time; in the other three soil incubations it was not detected at 0 DAT. No additional SYN545547 was extracted with the 'harsh' extraction methodology at 0 DAT. As noted by the applicant, the levels seen through the incubations are at low levels and seem to be subject to variability. The information suggests that SYN545547 is likely to be formed at low levels, although it is observed that pydiflumetofen underwent relatively limited degradation with 49.6 – 84.3% AR remaining as the a.s. after 'non-harsh' extractions. On balance, HSE considers that SYN545547 is unlikely to reach significant levels and therefore can be excluded from risk assessment. As background information, it is noted that the EU assessment came to a comparable conclusion.

**Table B.8. 16 Characterisation of radioactive residues in non-harsh soil extracts (individual replicates): Gartenacker – Phenyl label**

| **$^{14}$C-Residues Soil: Gartenacker Radiolabel: Phenyl** | **Replicate** | **% of Applied by DAT** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 96.8 | 97.1 | 94.7 | 90.6 | 83.4 | 82.9 | 78.3 | 63.9 | 50.3 |
| | B | 97.0 | 97.1 | 94.7 | 90.2 | 88.3 | 82.9 | 76.2 | 62.0 | 56.4 |
| | **Mean** | **96.9** | **97.1** | **94.7** | **90.4** | **85.8** | **82.9** | **77.2** | **63.0** | **53.4** |
| SYN545547 | A | ND | 0.4 | ND | 0.8 | 0.8 | 1.2 | 1.2 | 1.3 | 1.3 |
| | B | ND | ND | ND | 0.9 | 0.8 | 0.9 | 1.4 | 1.1 | 2.3 |
| | **Mean** | **ND** | **0.2** | **ND** | **0.9** | **0.8** | **1.1** | **1.3** | **1.2** | **1.8** |
| Unknown metabolites | A | ND | ND | ND | 1.0 | 1.9 | 3.0 | 3.3 | 6.1 | 6.7 |
| | B | ND | ND | ND | 0.8 | 0.4 | 2.6 | 3.4 | 6.3 | 4.6 |
| | **Mean** | **ND** | **ND** | **ND** | **0.9** | **1.1** | **2.8** | **3.4** | **6.2** | **5.7** |
| Largest single unknown metabolite | A | NA | NA | NA | 1.0 | 1.2 | 1.9 | 1.7 | 2.0 | 2.5 |
| | B | NA | NA | NA | 0.8 | 0.4 | 1.7 | 1.9 | 2.1 | 2.0 |
| Non-discrete Extractables | A | 0.7 | 1.8 | 1.4 | 0.9 | 1.2 | 0.7 | 0.8 | 0.1 | 0.1 |
| | B | 0.3 | 1.3 | 1.9 | 0.7 | 0.8 | ND | 0.4 | 0.1 | 0.4 |
| | **Mean** | **0.5** | **1.6** | **1.6** | **0.8** | **1.0** | **0.3** | **0.6** | **0.1** | **0.3** |
| Total Extractables | A | 97.5 | 99.3 | 96.1 | 93.3 | 87.3 | 87.7 | 83.5 | 71.3 | 58.5 |
| | B | 97.3 | 98.4 | 96.6 | 92.6 | 90.2 | 86.5 | 81.4 | 69.5 | 63.8 |
| | **Mean** | **97.4** | **98.9** | **96.4** | **93.0** | **88.8** | **87.1** | **82.4** | **70.4** | **61.1** |

NA: Not applicable. ND: Not detected or <0.1% AR

**Table B.8. 17 Characterisation of radioactive residues in non-harsh soil extracts (individual replicates): Gartenacker – Pyrazole label**

| **$^{14}$C-Residues Soil: Gartenacker Radiolabel: Pyrazole** | **Replicate** | **% of Applied by DAT** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 97.1 | 96.7 | 96.8 | 93.7 | 89.1 | 87.3 | 83.5 | 64.3 | 47.6 |
| | B | 96.8 | 95.6 | 96.9 | 91.4 | 89.2 | 87.6 | 85.7 | 56.3 | 57.7 |
| | **Mean** | **96.9** | **96.2** | **96.8** | **92.6** | **89.2** | **87.4** | **84.6** | **60.3** | **52.6** |
| SYN545547 | A | ND | ND | 0.3 | 0.8 | 1.2 | 0.9 | 1.6 | 1.2 | 1.6 |
| | B | 0.3 | ND | ND | 0.6 | 1.1 | 0.6 | 1.3 | 1.4 | 1.4 |
| | **Mean** | **0.2** | **ND** | **0.2** | **0.7** | **1.2** | **0.7** | **1.4** | **1.3** | **1.5** |
| Unknown metabolites | A | ND | 0.5 | 1.1 | 1.1 | 2.4 | 2.8 | 3.5 | 13.2 | 16.0 |
| | B | 1.0 | 0.4 | 0.6 | 1.2 | 2.1 | 1.8 | 2.9 | 11.2 | 8.7 |
| | **Mean** | **0.5** | **0.5** | **0.8** | **1.2** | **2.2** | **2.3** | **3.2** | **12.2** | **12.3** |
| Largest single unknown metabolite | A | NA | 0.5 | 1.1 | 1.1 | 1.6 | 1.8 | 2.2 | 2.0 | 2.8 |
| | B | 0.7 | 0.4 | 0.6 | 1.2 | 1.7 | 1.2 | 1.8 | 2.1 | 2.7 |
| Non-discrete Extractables | A | 1.1 | 1.8 | 0.7 | 0.2 | 0.3 | 0.7 | 0.8 | 0.5 | 0.9 |
| | B | 0.9 | 0.9 | 0.4 | 1.2 | 0.6 | 1.3 | 0.6 | 0.7 | 0.3 |
| | **Mean** | **1.0** | **1.3** | **0.5** | **0.7** | **0.5** | **1.0** | **0.7** | **0.6** | **0.6** |
| Total Extractables | A | 98.2 | 99.0 | 98.9 | 95.8 | 93.0 | 91.7 | 89.4 | 79.2 | 66.1 |
| | B | 99.0 | 96.9 | 97.8 | 94.4 | 93.0 | 91.3 | 90.5 | 69.6 | 68.1 |
| | **Mean** | **98.6** | **98.0** | **98.4** | **95.1** | **93.0** | **91.5** | **90.0** | **74.4** | **67.1** |

NA: Not applicable. ND: Not detected or <0.1% AR

**Table B.8. 18 Characterisation of radioactive residues in non-harsh soil extracts (individual replicates): 18 Acres – Phenyl label**

| **$^{14}$C-Residues Soil: 18 Acres Radiolabel: Phenyl** | **Replicate** | **% of Applied by DAT** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 99.1 | 96.8 | 97.6 | 93.0 | 90.8 | 91.2 | 88.3 | 86.6 | 84.3 |
| | B | 95.8 | 96.9 | 95.5 | 95.3 | 91.6 | 91.8 | 91.3 | 87.1 | 84.3 |
| | **Mean** | **97.4** | **96.8** | **96.5** | **94.1** | **91.2** | **91.5** | **89.8** | **86.8** | **84.3** |
| SYN545547 | A | ND | ND | 0.7 | 0.6 | 0.9 | 0.6 | 0.8 | 0.5 | 1.0 |
| | B | ND | 0.3 | 1.3 | 0.8 | 0.6 | 0.8 | 0.5 | 0.7 | 1.2 |
| | **Mean** | **ND** | **0.1** | **1.0** | **0.7** | **0.7** | **0.7** | **0.7** | **0.6** | **1.1** |
| Unknown metabolites | A | ND | ND | ND | 0.5 | 0.4 | 0.4 | 0.5 | 0.7 | 1.2 |
| | B | ND | ND | ND | 0.5 | 0.2 | 0.2 | 0.4 | 2.0 | 0.5 |
| | **Mean** | **ND** | **ND** | **ND** | **0.5** | **0.3** | **0.3** | **0.5** | **1.4** | **0.8** |
| Largest single unknown metabolite | A | NA | NA | NA | 0.5 | 0.4 | 0.4 | 0.5 | 0.4 | 1.2 |
| | B | NA | NA | NA | 0.5 | 0.2 | 0.2 | 0.4 | 0.8 | 0.5 |
| Non-discrete Extractables | A | 1.5 | 1.1 | 1.2 | 1.2 | 0.9 | 0.7 | 0.7 | 1.3 | 0.7 |
| | B | 1.6 | 0.6 | 1.5 | 0.1 | 0.9 | 0.6 | 1.1 | 0.4 | 0.5 |
| | **Mean** | **1.5** | **0.9** | **1.4** | **0.7** | **0.9** | **0.7** | **0.9** | **0.8** | **0.6** |
| Total Extractables | A | 100.5 | 97.9 | 99.4 | 95.3 | 92.9 | 92.9 | 90.3 | 89.1 | 87.2 |
| | B | 97.4 | 97.7 | 98.3 | 96.7 | 93.3 | 93.4 | 93.4 | 90.2 | 86.4 |
| | **Mean** | **99.0** | **97.8** | **98.9** | **96.0** | **93.1** | **93.2** | **91.9** | **89.6** | **86.8** |

NA: Not applicable. ND: Not detected or <0.1% AR

**Table B.8. 19 Characterisation of radioactive residues in non-harsh soil extracts (individual replicates): Sarpy – Phenyl label**

| **$^{14}$C-Residues Soil: Sarpy Radiolabel: Phenyl** | **Replicate** | **% of Applied by DAT** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 97.1 | 89.0 | 86.6 | 80.2 | 66.5 | 69.0 | 70.4 | 61.4 | 56.9 |
| | B | 96.8 | 86.8 | 86.2 | 81.5 | 63.3 | 69.1 | 66.9 | 61.3 | 54.0 |
| | **Mean** | **97.0** | **87.9** | **86.4** | **80.8** | **64.9** | **69.1** | **68.6** | **61.4** | **55.4** |
| SYN545547 | A | 0.5 | 0.6 | 0.4 | 0.7 | 0.6 | 0.8 | 0.7 | 0.3 | 0.9 |
| | B | 0.3 | 0.4 | 0.4 | 0.9 | 0.6 | 0.6 | 1.1 | 0.7 | 1.2 |
| | **Mean** | **0.4** | **0.5** | **0.4** | **0.8** | **0.6** | **0.7** | **0.9** | **0.5** | **1.1** |
| Unknown metabolites | A | ND | ND | ND | ND | 0.3 | 1.4 | 1.1 | 2.6 | 1.1 |
| | B | ND | ND | ND | ND | 0.3 | 1.0 | 1.3 | 1.4 | 2.0 |
| | **Mean** | **ND** | **ND** | **ND** | **ND** | **0.3** | **1.2** | **1.2** | **2.0** | **1.5** |
| Largest single unknown metabolite | A | NA | NA | NA | NA | 0.3 | 0.5 | 0.4 | 1.2 | 0.7 |
| | B | NA | NA | NA | NA | 0.3 | 0.4 | 0.5 | 0.9 | 0.8 |
| Non-discrete Extractables | A | 1.6 | 0.8 | 0.8 | 1.6 | 1.3 | 0.8 | 0.7 | 0.7 | ND |
| | B | 1.5 | 0.1 | 1.0 | 1.6 | 1.0 | 0.8 | 1.0 | 0.6 | 0.9 |
| | **Mean** | **1.5** | **0.4** | **0.9** | **1.6** | **1.1** | **0.8** | **0.8** | **0.7** | **0.4** |
| Total Extractables | A | 99.2 | 90.4 | 87.8 | 82.4 | 68.6 | 72.0 | 72.8 | 65.0 | 58.9 |
| | B | 98.5 | 87.3 | 87.5 | 84.0 | 65.2 | 71.5 | 70.2 | 64.1 | 58.0 |
| | **Mean** | **98.9** | **88.9** | **87.7** | **83.2** | **66.9** | **71.8** | **71.5** | **64.5** | **58.5** |

NA: Not applicable. ND: Not detected or <0.1% AR

**Table B.8. 20 Characterisation of radioactive residues in non-harsh soil extracts (individual replicates): East Anglia – Phenyl label**

| **$^{14}$C-Residues Soil: East Anglia Radiolabel: Phenyl** | **Replicate** | **% of Applied by DAT** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 98.2 | 91.7 | 92.0 | 89.9 | 86.5 | 84.1 | 84.2 | 80.1 | 77.5 |
| | B | 97.9 | 93.8 | 91.2 | 91.4 | 86.4 | 85.5 | 84.2 | 78.6 | 75.1 |
| | **Mean** | **98.1** | **92.8** | **91.6** | **90.7** | **86.4** | **84.8** | **84.2** | **79.4** | **76.3** |
| SYN545547 | A | 0.3 | 1.1 | ND | 0.8 | 0.9 | 1.2 | 0.9 | 0.9 | 1.3 |
| | B | 1.0 | ND | 1.3 | 0.5 | 0.8 | 1.3 | 1.0 | 0.7 | 1.5 |
| | **Mean** | **0.6** | **0.5** | **0.7** | **0.6** | **0.8** | **1.3** | **1.0** | **0.8** | **1.4** |
| Unknown metabolites | A | ND | ND | ND | 0.6 | 0.9 | 1.4 | 1.3 | 2.9 | 1.4 |
| | B | 1.1 | 0.3 | ND | 0.4 | 0.6 | 0.9 | 0.8 | 3.8 | 2.4 |
| | **Mean** | **0.6** | **0.2** | **ND** | **0.5** | **0.7** | **1.1** | **1.0** | **3.4** | **1.9** |
| Largest single unknown metabolite | A | NA | NA | NA | 0.6 | 0.9 | 1.0 | 0.8 | 1.4 | 0.7 |
| | B | 0.8 | 0.3 | NA | 0.4 | 0.6 | 0.6 | 0.8 | 1.9 | 1.1 |
| Non-discrete Extractables | A | 0.4 | 0.2 | 1.2 | 0.7 | 0.2 | 1.1 | 0.4 | 0.6 | 0.2 |
| | B | 0.3 | 0.7 | 2.1 | 0.6 | 0.5 | 0.7 | 1.0 | 0.2 | 0.2 |
| | **Mean** | **0.4** | **0.4** | **1.7** | **0.7** | **0.3** | **0.9** | **0.7** | **0.4** | **0.2** |
| Total Extractables | A | 98.8 | 93.0 | 93.2 | 92.0 | 88.4 | 87.8 | 86.8 | 84.5 | 80.4 |
| | B | 100.4 | 94.8 | 94.7 | 92.9 | 88.3 | 88.4 | 87.0 | 83.4 | 79.2 |
| | **Mean** | **99.6** | **93.9** | **94.0** | **92.5** | **88.4** | **88.1** | **86.9** | **84.0** | **79.8** |

NA: Not applicable. ND: Not detected or <0.1% AR

**Table B.8. 21 Characterisation of radioactive residues in non-harsh soil extracts (individual replicates): Capay – Phenyl label**

| **$^{14}$C-Residues Soil: Capay Radiolabel: Phenyl** | **Replicate** | **% of Applied by DAT** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 97.7 | 84.3 | 80.1 | 75.6 | 60.9 | 62.3 | 61.3 | 58.3 | 47.9 |
| | B | 97.7 | 91.2 | 86.8 | 74.2 | 62.0 | 66.3 | 64.9 | 58.3 | 51.2 |
| | **Mean** | **97.7** | **87.8** | **83.4** | **74.9** | **61.4** | **64.3** | **63.1** | **58.3** | **49.6** |
| SYN545547 | A | ND | ND | 0.6 | ND | ND | ND | 0.4 | 0.1 | ND |
| | B | ND | ND | ND | ND | ND | ND | 0.3 | 0.1 | 0.4 |
| | **Mean** | **ND** | **ND** | **0.3** | **ND** | **ND** | **ND** | **0.4** | **0.1** | **0.2** |
| Unknown metabolites | A | ND | ND | ND | ND | ND | ND | 0.3 | 0.8 | 3.3 |
| | B | ND | ND | ND | ND | ND | ND | 0.2 | 1.0 | 0.4 |
| | **Mean** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **0.2** | **0.9** | **1.9** |
| Largest single unknown metabolite | A | NA | NA | NA | NA | NA | NA | 0.3 | 0.8 | 1.9 |
| | B | NA | NA | NA | NA | NA | NA | 0.2 | 1.0 | 0.4 |
| Non-discrete Extractables | A | 1.4 | 1.6 | 1.0 | 0.9 | 0.6 | 0.8 | 0.2 | 0.1 | 0.6 |
| | B | 1.5 | 0.4 | 1.3 | 1.0 | 1.1 | ND | ND | 0.6 | 0.2 |
| | **Mean** | **1.5** | **1.0** | **1.1** | **0.9** | **0.9** | **0.4** | **0.1** | **0.4** | **0.4** |
| Total Extractables | A | 99.1 | 85.9 | 81.8 | 76.5 | 61.5 | 63.1 | 62.2 | 59.4 | 51.9 |
| | B | 99.2 | 91.6 | 88.0 | 75.2 | 63.1 | 66.3 | 65.4 | 60.0 | 52.2 |
| | **Mean** | **99.2** | **88.8** | **84.9** | **75.9** | **62.3** | **64.7** | **63.8** | **59.7** | **52.1** |

NA: Not applicable. ND: Not detected or <0.1% AR

**Findings: Characterisation of Radioactivity – additional extraction**

Characterisation of radioactive residues in soil extracts (non-harsh plus harsh extracts) is presented in the tables below. SYN545547 was observed at maximum levels of 0.6-2.1% AR (maximum individual level: 2.5% AR). Unknown metabolites did not individually exceed 3% AR.

**Table B.8. 22 Characterisation of radioactive residues in non-harsh plus harsh soil extracts (individual replicates): Gartenacker – Phenyl label**

| **$^{14}$C-Residues Soil: Gartenacker Radiolabel: Phenyl** | **Replicate** | **% of Applied by DAT** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 97.1 | 96.7 | 96.8 | 93.7 | 89.1 | 90.7 | 87.0 | 68.0 | 52.6 |
| | B | 96.8 | 95.6 | 96.9 | 91.4 | 89.2 | 90.8 | 89.2 | 59.5 | 62.5 |
| | **Mean** | **96.9** | **96.2** | **96.8** | **92.6** | **89.2** | **90.8** | **88.1** | **63.7** | **57.5** |
| SYN545547 | A | ND | ND | 0.3 | 0.8 | 1.2 | 1.0 | 1.6 | 1.3 | 1.8 |
| | B | 0.3 | ND | ND | 0.6 | 1.1 | 0.6 | 1.4 | 1.6 | 1.6 |
| | **Mean** | **0.2** | **ND** | **0.2** | **0.7** | **1.2** | **0.8** | **1.5** | **1.5** | **1.7** |
| Unknown metabolites | A | ND | 0.5 | 1.1 | 1.1 | 2.4 | 3.1 | 3.9 | 14.1 | 16.7 |
| | B | 1.0 | 0.4 | 0.6 | 1.2 | 2.1 | 2.0 | 3.2 | 12.3 | 9.2 |
| | **Mean** | **0.5** | **0.5** | **0.8** | **1.2** | **2.2** | **2.6** | **3.6** | **13.2** | **13** |
| Largest single unknown metabolite | A | NA | 0.5 | 1.1 | 1.1 | 1.6 | 1.8 | 2.2 | 2.0 | 2.8 |
| | B | 0.7 | 0.4 | 0.6 | 1.2 | 1.7 | 1.2 | 1.8 | 2.1 | 2.7 |
| Non-discrete Extractables | A | 1.1 | 1.8 | 0.7 | 0.2 | 0.3 | 0.7 | 0.9 | 0.6 | 1.0 |
| | B | 0.9 | 0.9 | 0.4 | 1.2 | 0.6 | 1.4 | 0.6 | 0.7 | 0.3 |
| | **Mean** | **1.0** | **1.3** | **0.5** | **0.7** | **0.5** | **1.0** | **0.7** | **0.7** | **0.6** |
| Total Extractables | A | 98.2 | 99 | 98.9 | 95.8 | 93.0 | 95.5 | 93.4 | 84.0 | 72.0 |
| | B | 99.0 | 96.9 | 97.8 | 94.4 | 93.0 | 94.9 | 94.4 | 74.1 | 73.6 |
| | **Mean** | **98.6** | **98.0** | **98.4** | **95.1** | **93.0** | **95.2** | **93.9** | **79.1** | **72.8** |

**Table B.8. 23 Characterisation of radioactive residues in non-harsh plus harsh soil extracts (individual replicates): Gartenacker – Pyrazole label**

| $^{14}$C-Residues **Soil: Gartenacker Radiolabel: Pyrazole** | Replicate | % of Applied by DAT | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 96.8 | 97.1 | 94.7 | 90.6 | 83.4 | 85.9 | 82.0 | 67.8 | 55.3 |
| | B | 97.0 | 97.1 | 94.7 | 90.2 | 88.3 | 86.1 | 80.0 | 65.9 | 61.0 |
| | **Mean** | **96.9** | **97.1** | **94.7** | **90.4** | **85.8** | **86.0** | **81.0** | **66.8** | **58.2** |
| SYN545547 | A | ND | 0.4 | ND | 0.8 | 0.8 | 1.3 | 1.2 | 1.7 | 1.6 |
| | B | ND | ND | ND | 0.9 | 0.8 | 1.0 | 1.4 | 1.2 | 2.5 |
| | **Mean** | **ND** | **0.2** | **ND** | **0.9** | **0.8** | **1.2** | **1.3** | **1.4** | **2.1** |
| Unknown metabolites | A | ND | ND | ND | 1.0 | 1.9 | 3.3 | 3.7 | 6.4 | 7.4 |
| | B | ND | ND | ND | 0.8 | 0.4 | 2.9 | 4.0 | 7.1 | 5.2 |
| | **Mean** | **ND** | **ND** | **ND** | **0.9** | **1.1** | **3.1** | **3.8** | **6.8** | **6.3** |
| Largest single unknown metabolite | A | NA | NA | NA | 1 | 1.2 | 1.9 | 1.7 | 2.0 | 2.5 |
| | B | NA | NA | NA | 0.8 | 0.4 | 1.7 | 1.9 | 2.1 | 2.0 |
| Non-discrete Extractables | A | 0.7 | 1.8 | 1.4 | 0.9 | 1.2 | 0.7 | 0.8 | 0.2 | 0.2 |
| | B | 0.3 | 1.3 | 1.9 | 0.7 | 0.8 | 0.1 | 0.5 | 0.1 | 0.4 |
| | **Mean** | **0.5** | **1.6** | **1.6** | **0.8** | **1.0** | **0.4** | **0.6** | **0.1** | **0.3** |
| Total Extractables | A | 97.5 | 99.3 | 96.1 | 93.3 | 87.3 | 91.1 | 87.7 | 76 | 64.5 |
| | B | 97.3 | 98.4 | 96.6 | 92.6 | 90.2 | 90.1 | 85.9 | 74.3 | 69.1 |
| | **Mean** | **97.4** | **98.9** | **96.4** | **93.0** | **88.8** | **90.6** | **86.8** | **75.2** | **66.8** |

**Table B.8. 24 Characterisation of radioactive residues in non-harsh plus harsh soil extracts (individual replicates): 18 Acres – Phenyl label**

| $^{14}$C-Residues **Soil: 18 Acres Radiolabel: Phenyl** | Replicate | % of Applied by DAT | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 99.1 | 96.8 | 97.6 | 93.0 | 90.8 | 95.1 | 92.4 | 91.2 | 91.2 |
| | B | 95.8 | 96.9 | 95.5 | 95.3 | 91.6 | 95.7 | 96.0 | 93.0 | 91.3 |
| | **Mean** | **97.4** | **96.8** | **96.5** | **94.1** | **91.2** | **95.4** | **94.2** | **92.1** | **91.2** |
| SYN545547 | A | ND | ND | 0.7 | 0.6 | 0.9 | 0.6 | 0.8 | 0.6 | 1.1 |
| | B | ND | 0.3 | 1.3 | 0.8 | 0.6 | 0.9 | 0.6 | 0.9 | 1.4 |
| | **Mean** | **ND** | **0.1** | **1.0** | **0.7** | **0.7** | **0.7** | **0.7** | **0.7** | **1.3** |
| Unknown metabolites | A | ND | ND | ND | 0.5 | 0.4 | 0.5 | 0.6 | 0.7 | 1.2 |
| | B | ND | ND | ND | 0.5 | 0.2 | 0.3 | 0.5 | 2.0 | 0.5 |
| | **Mean** | **ND** | **ND** | **ND** | **0.5** | **0.3** | **0.4** | **0.5** | **1.4** | **0.8** |
| Largest single unknown metabolite | A | NA | NA | NA | 0.5 | 0.4 | 0.4 | 0.5 | 0.4 | 1.2 |
| | B | NA | NA | NA | 0.5 | 0.2 | 0.2 | 0.4 | 0.8 | 0.5 |
| Non-discrete Extractables | A | 1.5 | 1.1 | 1.2 | 1.2 | 0.9 | 0.8 | 0.7 | 1.3 | 0.7 |
| | B | 1.6 | 0.6 | 1.5 | 0.1 | 0.9 | 0.7 | 1.2 | 0.4 | 0.5 |
| | **Mean** | **1.5** | **0.9** | **1.4** | **0.7** | **0.9** | **0.7** | **1.0** | **0.9** | **0.6** |
| Total Extractables | A | 100.5 | 97.9 | 99.4 | 95.3 | 92.9 | 96.9 | 94.5 | 93.8 | 94.2 |
| | B | 97.4 | 97.7 | 98.3 | 96.7 | 93.3 | 97.5 | 98.3 | 96.3 | 93.6 |
| | **Mean** | **99.0** | **97.8** | **98.9** | **96.0** | **93.1** | **97.2** | **96.4** | **95.0** | **93.9** |

**Table B.8. 25 Characterisation of radioactive residues in non-harsh plus harsh soil extracts (individual replicates): Sarpy – Phenyl label**

| **$^{14}$C-Residues Soil: Sarpy Radiolabel: Phenyl** | **Replicate** | **% of Applied by DAT** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 97.1 | 89 | 86.6 | 80.2 | 79.8 | 80.5 | 80.6 | 73.0 | 74.6 |
| | B | 96.8 | 86.8 | 86.2 | 81.5 | 81.2 | 79.7 | 78.6 | 73.8 | 70.2 |
| | **Mean** | **97.0** | **87.9** | **86.4** | **80.8** | **80.5** | **80.1** | **79.6** | **73.4** | **72.4** |
| SYN545547 | A | 0.5 | 0.6 | 0.4 | 0.7 | 0.8 | 1.0 | 0.8 | 0.5 | 1.1 |
| | B | 0.3 | 0.4 | 0.4 | 0.9 | 0.9 | 0.6 | 1.2 | 0.9 | 1.5 |
| | **Mean** | **0.4** | **0.5** | **0.4** | **0.8** | **0.8** | **0.8** | **1.0** | **0.7** | **1.3** |
| Unknown metabolites | A | ND | ND | ND | ND | 0.5 | 1.5 | 1.2 | 2.8 | 1.1 |
| | B | ND | ND | ND | ND | 0.6 | 1.3 | 1.5 | 1.5 | 2.0 |
| | **Mean** | **ND** | **ND** | **ND** | **ND** | **0.5** | **1.4** | **1.4** | **2.2** | **1.5** |
| Largest single unknown metabolite | A | NA | NA | NA | NA | 0.3 | 0.5 | 0.4 | 0.6 | 0.7 |
| | B | NA | NA | NA | NA | 0.3 | 0.4 | 0.5 | 0.9 | 0.8 |
| Non-discrete Extractables | A | 1.6 | 0.8 | 0.8 | 1.6 | 1.4 | 0.8 | 0.8 | 0.8 | ND |
| | B | 1.5 | 0.1 | 1.0 | 1.6 | 1.2 | 0.9 | 1.1 | 0.8 | 0.9 |
| | **Mean** | **1.5** | **0.4** | **0.9** | **1.6** | **1.3** | **0.8** | **1.0** | **0.8** | **0.5** |
| Total Extractables | A | 99.2 | 90.4 | 87.8 | 82.4 | 82.4 | 83.7 | 83.5 | 77.0 | 76.8 |
| | B | 98.5 | 87.3 | 87.5 | 84.0 | 83.8 | 82.5 | 82.4 | 77.1 | 74.5 |
| | **Mean** | **98.9** | **88.9** | **87.7** | **83.2** | **83.1** | **83.1** | **83.0** | **77.0** | **75.7** |

**Table B.8. 26 Characterisation of radioactive residues in non-harsh plus harsh soil extracts (individual replicates): East Anglia – Phenyl label**

| **$^{14}$C-Residues Soil: East Anglia Radiolabel: Phenyl** | **Replicate** | **% of Applied by DAT** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 98.2 | 91.7 | 92.0 | 89.9 | 86.5 | 88.6 | 89 | 85.7 | 85.4 |
| | B | 97.9 | 93.8 | 91.2 | 91.4 | 86.4 | 89.7 | 88.5 | 85.0 | 83.0 |
| | **Mean** | **98.1** | **92.8** | **91.6** | **90.7** | **86.4** | **89.1** | **88.8** | **85.3** | **84.2** |
| SYN545547 | A | 0.3 | 1.1 | ND | 0.8 | 0.9 | 1.3 | 1.0 | 1.0 | 1.5 |
| | B | 1.0 | ND | 1.3 | 0.5 | 0.8 | 1.4 | 1.1 | 0.9 | 1.6 |
| | **Mean** | **0.6** | **0.5** | **0.7** | **0.6** | **0.8** | **1.3** | **1.0** | **0.9** | **1.6** |
| Unknown metabolites | A | ND | ND | ND | 0.6 | 0.9 | 1.6 | 1.5 | 3.1 | 1.6 |
| | B | 1.1 | 0.3 | ND | 0.4 | 0.6 | 1.0 | 0.9 | 3.9 | 2.7 |
| | **Mean** | **0.6** | **0.2** | **ND** | **0.5** | **0.7** | **1.3** | **1.2** | **3.5** | **2.1** |
| Largest single unknown metabolite | A | NA | NA | NA | 0.6 | 0.9 | 1.0 | 0.8 | 1.4 | 0.7 |
| | B | 0.8 | 0.3 | NA | 0.4 | 0.6 | 0.6 | 0.8 | 1.9 | 1.1 |
| Non-discrete Extractables | A | 0.4 | 0.2 | 1.2 | 0.7 | 0.2 | 1.2 | 0.5 | 0.6 | 0.2 |
| | B | 0.3 | 0.7 | 2.1 | 0.6 | 0.5 | 0.8 | 1.0 | 0.3 | 0.2 |
| | **Mean** | **0.4** | **0.4** | **1.7** | **0.7** | **0.3** | **1.0** | **0.7** | **0.4** | **0.2** |
| Total Extractables | A | 98.8 | 93.0 | 93.2 | 92.0 | 88.4 | 92.6 | 91.9 | 90.3 | 88.6 |
| | B | 100.4 | 94.8 | 94.7 | 92.9 | 88.3 | 92.9 | 91.5 | 90.1 | 87.5 |
| | **Mean** | **99.6** | **93.9** | **94.0** | **92.5** | **88.4** | **92.8** | **91.7** | **90.2** | **88.1** |

**Table B.8. 27 Characterisation of radioactive residues in non-harsh plus harsh soil extracts (individual replicates): Capay – Phenyl label**

| $^{14}$C-Residues<br>Soil: Capay<br>Radiolabel: Phenyl | Replicate | % of Applied by DAT | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **7** | **14** | **29** | **60** | **90** | **120** | **239** | **365** |
| Parent (pydiflumetofen) | A | 97.7 | 92.9 | 91.3 | 90.9 | 86.2 | 84.3 | 82.7 | 84.3 | 78.7 |
| | B | 97.7 | 98.2 | 94.7 | 90.3 | 86.1 | 87.2 | 85.8 | 84.3 | 81.8 |
| | **Mean** | **97.7** | **95.6** | **93.0** | **90.6** | **86.1** | **85.7** | **84.2** | **84.3** | **80.3** |
| SYN545547 | A | ND | 0.1 | 0.7 | 0.2 | 0.2 | 0.1 | 0.5 | 0.3 | 0.3 |
| | B | ND | 0.1 | 0.1 | ND | 0.4 | 0.1 | 0.5 | 0.3 | 0.8 |
| | **Mean** | **ND** | **0.1** | **0.4** | **0.1** | **0.3** | **0.1** | **0.5** | **0.3** | **0.6** |
| Unknown metabolites | A | ND | 0.2 | 0.1 | ND | 0.1 | 0.1 | 0.3 | 0.8 | 3.5 |
| | B | ND | 0.1 | ND | 0.1 | 0.1 | 0.1 | 0.3 | 1.0 | 0.6 |
| | **Mean** | **ND** | **0.2** | **ND** | **0.1** | **0.1** | **0.1** | **0.3** | **0.9** | **2.1** |
| Largest single unknown metabolite | A | NA | 0.1 | 0.6 | NA | 0.1 | 0.1 | 0.3 | 0.8 | 1.9 |
| | B | NA | 0.1 | ND | ND | 0.1 | 0.1 | 0.2 | 1.0 | 0.4 |
| Non-discrete Extractables | A | 1.4 | 1.6 | 1.1 | 0.9 | 0.7 | 0.9 | 0.3 | 0.5 | 0.7 |
| | B | 1.5 | 0.5 | 1.3 | 1.0 | 1.5 | 0.1 | 0.1 | 0.9 | 0.3 |
| | **Mean** | **1.5** | **1.1** | **1.2** | **1.0** | **1.1** | **0.5** | **0.2** | **0.7** | **0.5** |
| Total Extractables | A | 99.1 | 94.8 | 93.2 | 92 | 87.2 | 85.5 | 83.9 | 85.9 | 83.2 |
| | B | 99.2 | 98.9 | 96.1 | 91.4 | 88.1 | 87.5 | 86.6 | 86.4 | 83.5 |
| | **Mean** | **99.2** | **96.9** | **94.6** | **91.7** | **87.7** | **86.5** | **85.2** | **86.2** | **83.4** |

**Findings: Enantiomeric composition**

Pydiflumetofen contains two enantiomers. In GB there is currently no agreed guidance on the assessment of active substances that have stereoisomers as components. However the EU has introduced guidance on this subject ("Guidance of EFSA on risk assessments for active substances of plant protection products that have stereoisomers as components or impurities and for transformation products of active substances that may have stereoisomers", henceforward referred to as the "EFSA Stereoisomers guidance"). Whilst not currently adopted in GB, the EFSA Stereoisomers guidance contains some useful indicators and principles for evaluation that help in this assessment. Therefore the guidance has been taken into consideration for this and the other evaluated studies where analysis of stereoisomer content was undertaken.

For studies that present an 'asymmetric environment', i.e. those that have metabolic processes such as presented by an active microbial community, the guidance indicates that a 10% or greater change in the enantiomeric excess would be considered significant by the end of a route of degradation study. This threshold is applied in the case where at least 50% of the bulk substance had degraded by the end of the study, or by extrapolation if 50% of the substance had not degraded by the end of the study.

The enantiomeric composition of pydiflumetofen in soil was considered by the applicant to not change significantly during the course of the study. The pydiflumetofen enantiomer ratio was 0.96 in the application solutions and 1.19 to 1.31 in the Gartenacker soil sample extracts taken at 365 DAT. HSE has added an assessment of the change in enantiomer excess. The change in enantiomer excess is calculated as the difference between the enantiomer excess in the stock solution and in the soil samples at the end of the study.

**Table B.8. 28 Pydiflumetofen enantiomer ratios in application solutions and aerobic soil at 365 DAT**

| | | % Sample activity as | | | | |
|---|---|---|---|---|---|---|
| **Sample Type** | **Label** | **1st eluting enantiomer** | **2nd eluting enantiomer** | **Enantiomer Ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| **Stock solution 3 (SS3)** | **Phenyl** | **44.36** | **46.39** | 0.96 | -2.24 | |
| **A17-ext 5(Gartenacker 365 DAT)** | | **46.88** | **35.80** | 1.31 | 13.40 | 15.64 |
| **Application solution 2 (AS2)** | **Pyrazole** | **47.43** | **49.19** | 0.96 | -1.82 | |
| **B18-ext 5(Gartenacker 365 DAT)** | | **41.19** | **34.47** | 1.19 | 8.88 | 10.70 |

HSE noted that there was an apparent change in the enantiomer ratio of the a.s. during this study in the single soil analysed for enantiomer ratio; this was based on the change in enantiomer excess between the dosing solution and the samples at the end of the study. The change in enantiomer excess was of the magnitude of approximately 11 – 16%. Given that assessment of the relative amounts of each enantiomer are only available at the beginning and end of the incubation and only in a single soil, it is not known whether this is a consistent trend for soils under aerobic laboratory conditions. Ideally the enantiomer excess should have been measured in the soil at day 0 as it is conceivable that the enantiomer excess in the soil could have been different to that in the dosing solution. It is also noted that in this single soil where the enantiomers were measured, greater than 50% of applied radioactivity remained as unchanged pydiflumetofen at the end of the study. Thus if the change in enantiomer excess between the dosing solution and in the soil at study end was real and was consistent, the change in enantiomer excess may have been greater than 11-16% had the study been allowed to run until at least 50% of the a.s. had degraded.

**Conclusions**

The study is considered by HSE to be acceptable and the results can be accepted for risk assessment.

Pydiflumetofen degraded very slowly with little formation of identified metabolites. No aerobic soil metabolites are considered to trigger risk assessment. Mineralisation was in the range of 0.2 – 5.3% AR at 120 days with both radiolabelling positions. Unextracted residues were in the range of 7.4 - 33.4% at 120 days with both radiolabelling positions.

The kinetic assessment of this study is in section B.8.1.1.2.1.1.

Pydiflumetofen contains two enantiomers. In the absence of current GB guidance in this area, HSE used the "EFSA Stereoisomers guidance" for useful indicators and principles for evaluation that help in this assessment. Therefore the guidance has been taken into consideration for this and the other evaluated studies where analysis of stereoisomer content was undertaken.

It was noted that there was an apparent change in the enantiomer excess of the a.s. during this study in the single soil of approximately 11 – 16%. If the change in enantiomer excess between the dosing solution and in the soil at study end was real and was consistent, the change in enantiomer excess may have been greater than 11-16% had the study been allowed to run until at least 50% of the a.s. had degraded.

It is noted that the study was performed prior to the introduction of the EU guidance and the stereoisomers guidance is not currently adopted in GB. The overall summary of the fate and behaviour of pydiflumetofen at the beginning of this B.8 section describes the considerations of stereoisomerism across the range of the submitted environmental fate studies and the weight of evidence approach that has been taken.

It is noted that the applicant considers that the data from the 'harsh' extraction methodology, i.e. acetonitrile:water at pH3 with reflux for eight hours, should not be used for risk assessment purposes. To contextualise the discussion, there is no globally accepted guidance on what constitutes an appropriate strength

of extraction solvents for use in regulatory soil route and rate of degradation experiments. The OECD 307 test method merely states that the overall recovery of radioactivity should be within 90 – 110% for radiolabelled substances. Overall recovery with 'non-harsh' extraction was within this range for each soil. In addition, the extractable and unextracted residues in each soil were neither remarkably low or high and appeared to be within the range typically seen in aerobic soil incubations. Certainly the unextracted residues were not close to the 70% AR unextracted residue that, coupled with low mineralisation of <5% AR, would trigger concerns relating to accumulation of unextracted residues (as specified in the 'Uniform Principles' of Regulation 546 of 2011). The 'non-harsh' extraction was able to remove the bulk of the radioactive residue from each of the soils. HSE considers that the 'harsh' extraction would be likely to over-estimate the amount of pydiflumetofen that would be available for leaching. The conditions employed in the harsh extraction procedure are unlikely to represent 'extraction' processes in the natural environment because such extractions are not biological or natural abiotic processes in the environment. Nonetheless it is not clear whether the material extracted using the 'harsh' extraction would be bioavailable. It is noted that use of the data from the 'non-harsh' extractions leads to consistency with the extraction methodology used in the field dissipation studies in section B.8.1.1.2.2. Considering that the issues relating to strength of extraction are not easily addressed, HSE notes that in this case the use of the 'non-harsh' extraction data is consistent with decision-making over many years of the EU peer review procedure that the UK participated in when an EU MS. Overall HSE can accept this approach for the submission for approval in GB.

### B.8.1.1.1.2. Anaerobic degradation

| | |
|---|---|
| **Report:** | K-CA 7.1.1.2/01. [redacted] (2015a), SYN545974 - Anaerobic Soil Metabolism of $^{14}$C-SYN545974, Report Number 3200130. Smithers Viscient (ESG) Ltd. Otley Road, Harrogate, North Yorkshire HG3 1PY, UK and 108 Woodfield Drive, Harrogate, North Yorkshire, HG1 4LS, UK<br>(Syngenta File No. SYN545974_50166) |

| | |
|---|---|
| **Guideline(s):** | OECD 307 (2002), EPA Guideline Series OPPTS 835.4200 (2008) |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**

The rate and route of anaerobic degradation of $^{14}$C-labelled pydiflumetofen was investigated in four different soils: Gartenacker (loam) with both $^{14}$C-phenyl ring labelled pydiflumetofen and $^{14}$C-pyrazole ring labelled pydiflumetofen, and 18 Acres (sandy clay loam), Sarpy (silt loam) and Capay (clay loam) with $^{14}$C-phenyl ring labelled pydiflumetofen.

| **Test Material:** | **[Pyrazole-5-$^{14}$C]-SYN545974** | **[Phenyl-U-$^{14}$C]-SYN545974** |
|---|---|---|
| Lot/Batch #: | 5271GAR001-4 | RDR-XV-94 |
| Specific activity: | 5.06 MBq/mg | 5.791 MBq/mg |
| Purity: | 95.4% (chemical)<br>99.2% (radiochemical) | 97.6% (chemical)<br>>99% (radiochemical) |
| Application vehicle: | Acetonitrile | Acetonitrile |

The soils had not received any pesticides for the last 5 years. Each soil was passed through a 2 mm mesh sieve with the minimum of air drying prior to storage in the dark at 4°C ± 2°C. Gartenacker, 18 Acres and Sarpy soils were acclimated and incubated at pF2 at 20±2°C. Capay soil was acclimated and incubated at pF2-2.5 at 20±2°C. Soils characteristics are reported below.

**Table B.8. 29 Soils characteristics**

| **Name** | **Gartenacker** | | **18 Acres** | | **Sarpy** | | **Capay** | |
|---|---|---|---|---|---|---|---|---|
| Sampling location | Gartenacker, Switzerland | | Bracknell, UK | | Sarpy, NE, USA | | Yolo County, CA, USA | |
| Sampling depth | 5-20 cm | | 5-20 cm | | 0-15.24 cm (0-6 inches) | | 0-15 24 cm (0-6 inches) | |
| Duration of storage | 69 | | 64 | | 81 | | 83 | |
| USDA Particle size (% w/w): | | | | | | | | |
| Clay (<2 µm) | 12 | | 25 | | 24 | | 35 | |
| Silt (50-2 µm) | 43 | | 24 | | 56 | | 33 | |
| Sand (2000-50 µm) | 45 | | 51 | | 20 | | 32 | |
| Texture (USDA) | Loam | | Sandy clay loam | | Silt loam | | Clay loam | |
| pH (water) | 8.2 | | 7.0 | | 7.5 | | 7.6 | |
| pH (0.01M $CaCl_2$) | 7.5 | | 6.1 | | 6.7 | | 6.7 | |
| Organic matter (%) | 2.4 | | 4.7 | | 2.8 | | 1.4 | |
| Organic carbon (%) | 1.4 | | 2.7 | | 1.6 | | 0.8 | |
| CEC (meq/100 g soil) | 10.8 | | 18.9 | | 25.4 | | 24.6 | |
| Moisture at pF2.0 (0.1bar, w/w %) | 39.0 | | 29.8 | | 33.5 | | 29.1 | |
| Moisture at pF2.5 (0.33 bar, w/w %) | 28.8 | | 23.6 | | 27.3 | | 22.1 | |
| Biomass | µg C/g | % of OC | µg C/g | % of OC | µg C/g | % of OC | µg C/g | % of OC |
| Bulk (prior to study start) | 302.4 | 2.2 | 531.8 | 2.0 | 289.2 | 1.8 | 78.5 | 1.0 |
| Initial (start of study) | 209.3 | 1.5 | 402.8 | 1.5 | 213.3 | 1.3 | 64.4 | 0.8 |
| Final (end of study) | 224.3 | 1.6 | 376.8 | 1.4 | 210.6 | 1.3 | 55.3 | 0.7 |

It was noted that the microbial biomass of the Capay soil was below 1% of organic carbon at the start of the study. The OECD 307 guideline for conduct of anaerobic laboratory studies indicates that soils should have microbial biomass at least 1% of organic carbon. However the pattern of degradation in these soils was similar to that in the other soils. HSE accepts that the results from this soil can be used for regulatory purposes.

$^{14}$C-Labelled pydiflumetofen was applied at a dose rate of 0.33 mg/kg dry weight soil, equivalent to a single field application rate of 250 g ai/ha (assuming an incorporation depth of 5 cm and a bulk density of 1.5 g/cm$^3$). Initially, the treated soils were incubated for 0-30 days under aerobic conditions at 20°C ± 2°C (in darkness) at a soil moisture of pF 2 (pF 2 to 2.5 in Capay soil) and sampled in duplicate at 0 DAT (days after treatment, *i.e.* immediately after treatment) and at 30 DAT (just prior to the addition of water to the remaining units). Thereafter, the test systems were flooded with reverse osmosis (RO) water sparged with nitrogen (3 cm above soil surface) and purged continuously with nitrogen gas for up to 90 additional days. For each treated flooded soil, duplicate samples were taken for analysis at 37, 44, 61, 76, 90 and 120 DAT (or 7, 14, 31, 46, 60 and 90 days after induced anaerobicity [DAIA], respectively).

At each sampling time, each treated sample (in its entirety) was extracted once with 80% acetonitrile in 0.1 M ammonium acetate, followed by twice with 80% acetonitrile in water which had been acidified to pH 3. All extracts were pooled. The amount of radioactivity recovered was determined by LSC quantification. Extractable $^{14}$C-residues were characterised by HPLC and quantitation confirmed by TLC of selected samples. Unextracted residues were determined by combustion. Harsh extraction methods (80% acetonitrile in water acidified to pH 3 and refluxed for *ca* 8 hours) were used on samples which showed ≥ 10% AR present in the soil residue. Two samples still contained ≥ 10% AR following harsh reflux extraction and were subjected to organic matter fractionation. Any volatile radioactivity was continuously flushed from the vessels, collected in traps (2M NaOH) and analysed. A catalytic converter was attached to the 120 DAT samples to collect methane. A mass balance was determined for each sample.

Separate microbial biomass and anaerobicity surrogate samples were similarly incubated and analysed appropriately. Dissolved oxygen (DO) concentration, pH and redox potentials (Eh) were measured after flooding the soil and throughout the remainder of the study to measure anaerobicity of the test systems.

Chiral HPLC was performed on one unit treated with [phenyl-U-$^{14}$C]-pydiflumetofen and on one unit treated with [pyrazole-5-$^{14}$C]-pydiflumetofen, both of which had been incubated for 120 days after treatment. The purpose of this analysis was to check whether there was any change to the enantiomer ratio of pydiflumetofen during the course of the study.

**Findings: Redox potential and Mass Balance**
Gartenacker, 18 Acres and Sarpy soils demonstrated microbial biomass as a % of organic carbon (% OC) to be in excess of 1% throughout the study. Biomass in Capay soil gradually decreased such that biomass was 0.7% of OC at 120 DAT. Although the biomass in terms of % OC suggest that Capay soil is no longer viable, comparison of degradation to the viable Gartenacker, 18 Acres and Sarpy soils shows a similar profile.

The evolution with time of redox potential in both water and sediment and of dissolved oxygen in water is presented below.

**Table B.8. 30 Redox potential in pydiflumetofen anaerobic soil study**

| Day (DAIA) | Soil | Water Anaerobicity Parameters | | | Soil Anaerobicity Parameters | |
|---|---|---|---|---|---|---|
| | | Dissolved Oxygen (mg/L) | pH | Redox (mV) | pH | Redox[1] (mV) |
| 7 | Gartenacker | 1.3 | 7.9 | 448 | 7.8 | 442 |
| 14 | | 0.4 | 7.8 | 249 | 7.7 | 413 |
| 31 | | 0.3 | 8.8 | 228 | 8.4 | 366 |
| 46 | | 0.2 | 8.6 | 373 | 8.3 | 351 |
| 60 | | 0.3 | 8.9 | 377 | 8.3 | 314 |
| 90 | | 0.4 | 9.0 | 321 | 8.5 | 82 |
| 7 | 18 Acres | 1.6 | 6.9 | 360 | 6.1 | 401 |
| 14 | | 0.5 | 7.1 | 339 | 6.3 | 339 |
| 31 | | 0.2 | 7.4 | 365 | 6.3 | 92 |
| 46 | | 0.2 | 7.4 | 275 | 6.8 | -167 |
| 60 | | 0.4 | 8.1 | 176 | 7.3 | -230 |
| 90 | | 0.1 | 8.1 | -98 | 7.6 | -237 |
| 7 | Sarpy | 1.6 | 6.8 | 417 | 6.7 | 477 |
| 14 | | 0.5 | 7.0 | 380 | 6.8 | 442 |
| 31 | | 0.2 | 7.7 | 399 | 6.9 | 338 |
| 46 | | 0.2 | 8.0 | 379 | 7.4 | 148 |
| 60 | | 0.2 | 8.3 | 270 | 7.1 | 32 |
| 90 | | 0.2 | 8.0 | 252 | 7.2 | -185 |
| 7 | Capay | 1.1 | 7.3 | 446 | 6.9 | 538 |
| 14 | | 0.3 | 7.2 | 385 | 6.9 | 472 |
| 31 | | 0.2 | 7.6 | 361 | 7.0 | 362 |
| 46 | | 0.3 | 7.8 | 383 | 7.1 | 277 |
| 60 | | 0.2 | 7.9 | 324 | 7.2 | 311 |
| 90 | | 0.2 | 8.0 | 294 | 7.4 | 259 |

The total recoveries and distribution of radioactivity from each soil are shown in detail in the tables below. During the course of the study (aerobic and anaerobic phase), the mass balance ranged from 94.7 to 102.3% AR.

Negligible amounts (≤ 0.7%) of $^{14}CO_2$ and organic volatiles were generated throughout the course of the study in all soils. The total extractability (non-harsh) at 0 DAT was high, ranging from 98.4 to 100.9% AR and generally declined in all soils over the course of the experiment, reaching levels of 80.0 to 97.1% AR at the end of the aerobic phase (30 DAT/0 DAIA) and 64.3 to 92.6% AR by the end of the experiment (120 DAT/90 DAIA). The amount of AR extracted was generally higher in 18 Acres and Gartenacker soils than in Sarpy and Capay soils.

Unextracted residues at 0 DAT were low (0.7 to 1.4%) and generally increased in all soils throughout the duration of the study, reaching levels of 4.4 to 22.2% at the end of the aerobic phase (30 DAT/0DAIA) and 7.8 to 32.6% by the end of the experiment (120 DAT/90 DAIA). Harsh extractions released a further 6.4-22.7% AR of bound radioactivity which was then analysed by HPLC separately to the non-harsh extracts.

Organic matter fractionation (OMF) of the bound residues was performed in samples of Capay soil which contained ≥10% AR in individual replicates after non-harsh extractions, followed by harsh reflux. Results demonstrated 14C associated predominantly with the humin fraction (up to 8.4% AR) and to a lesser extent with the fulvic acid (up to 4.1% AR) and humic acid (up to 0.4% AR) fractions.

**Table B.8. 31 Mass balance and distribution of radioactivity in extracts of Gartenacker – individual replicates (values as % of applied) - [Pyrazole-5-$^{14}$C]-pydiflumetofen**

| **[Pyrazole-5-$^{14}$C]-pydiflumetofen** | **Rep** | **Percent of Applied Radioactivity by Incubation time (days)** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Extract 1 (non-harsh) | A | 89.8 | 76.2 | 77.8 | 79.4 | 75.5 | 77.9 | 75.1 | 72.5 |
| | B | 88.0 | 75.5 | 77.4 | 92.9 | 76.4 | 75.8 | 74.9 | 75.3 |
| | **Mean** | **88.9** | **75.9** | **77.6** | **86.2** | **76.0** | **76.9** | **75.0** | **73.9** |
| Extract 2 (non-harsh) | A | 9.4 | 16.9 | 14.9 | 17.8 | 13.8 | 14.5 | 14.9 | 14.2 |
| | B | 10.2 | 17.2 | 15.3 | 16.2 | 14.4 | 14.5 | 15.2 | 14.0 |
| | **Mean** | **9.8** | **17.1** | **15.1** | **17.0** | **14.1** | **14.5** | **15.1** | **14.1** |
| Extract 3 (non-harsh) | A | 2.1 | 4.1 | 3.6 | 3.8 | 3.6 | 3.0 | 3.7 | 4.6 |
| | B | 2.3 | 4.2 | 3.5 | 3.7 | 3.5 | 3.1 | 3.7 | 4.5 |
| | **Mean** | **2.2** | **4.2** | **3.6** | **3.8** | **3.6** | **3.1** | **3.7** | **4.6** |
| **Total Extractables** (non-harsh) | **Mean** | **100.9** | **97.1** | **96.3** | **106.9*** | **93.6** | **94.4** | **93.8** | **92.6** |
| Non-Extractables | A | 0.6 | 4.3 | 4.4 | 5.2 | 6.0 | 6.8 | 6.9 | 8.9 |
| | B | 0.7 | 4.4 | 4.6 | 5.3 | 5.7 | 6.8 | 7.2 | 7.6 |
| | **Mean** | **0.7** | **4.4** | **4.5** | **5.3** | **5.9** | **6.8** | **7.1** | **8.3** |
| Total Volatiles | A | NA | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| | B | NA | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | ND |
| | **Mean** | **NA** | **0.1** | **0.1** | **0.1** | **0.1** | **0.1** | **0.1** | **0.1** |
| Total % recovery | A | 101.9 | 101.6 | 100.8 | 98.4 | 99.0 | 102.3 | 100.7 | 100.3 |
| | B | 101.2 | 101.4 | 100.9 | 98.9 | 100.1 | 100.3 | 101.1 | 101.4 |
| | **Mean** | **101.6** | **101.5** | **100.9** | **98.7** | **99.6** | **101.3** | **100.9** | **100.9** |
| **Overall Mean ± SD** | | **100.6 ± 1.105** | | | | | | | |

ND: Not detected, or <0.1% AR. NA: Not applicable

*The extracts (1-3) assayed at 44 DAT gave anomalous results, with higher than expected levels of recovered radioactivity. The extracts were combined (Extract 4) and the amount of radioactivity determined in Extract 4 was more in line to expected results (based on previous sampling intervals). As such, the %AR measured in Extract 4 (93.3% AR) was used as a TRR value for HPLC and TLC analyses.

**Table B.8. 32 Mass balance and distribution of radioactivity in extracts of Gartenacker – individual replicates (values as % of applied) - [Phenyl-U-$^{14}$C]-pydiflumetofen**

| [Phenyl-U-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Extract 1 (non-harsh) | A | 87.0 | 74.3 | 76.8 | 79.6 | 75.7 | 74.4 | 74.1 | 71.3 |
| | B | 88.5 | 76.1 | 76.3 | 83.4 | 75.3 | 75.5 | 73.3 | 73.8 |
| | **Mean** | **87.8** | **75.2** | **76.6** | **81.5** | **75.5** | **75.0** | **73.7** | **72.6** |
| Extract 2 (non-harsh) | A | 10.2 | 17.0 | 15.4 | 15.6 | 13.5 | 14.6 | 15.9 | 13.6 |
| | B | 9.4 | 16.5 | 15.4 | 16.8 | 13.7 | 14.4 | 15.0 | 13.7 |
| | **Mean** | **9.8** | **16.8** | **15.4** | **16.2** | **13.6** | **14.5** | **15.5** | **13.7** |
| Extract 3 (non-harsh) | A | 2.2 | 4.1 | 3.5 | 3.4 | 3.2 | 3.1 | 4.1 | 4.4 |
| | B | 2.0 | 3.9 | 3.6 | 3.7 | 3.3 | 3.1 | 3.8 | 4.3 |
| | **Mean** | **2.1** | **4.0** | **3.6** | **3.6** | **3.3** | **3.1** | **4.0** | **4.4** |
| **Total Extractables** (non-harsh) | **Mean** | **99.7** | **96.0** | **95.5** | **101.3*** | **92.4** | **92.6** | **93.1** | **90.6** |
| Non-Extractables | A | 0.9 | 4.8 | 5.0 | 5.7 | 6.3 | 6.9 | 7.2 | 8.3 |
| | B | 0.8 | 4.7 | 4.6 | 5.6 | 6.3 | 6.6 | 7.3 | 7.2 |
| | **Mean** | **0.9** | **4.8** | **4.8** | **5.7** | **6.3** | **6.8** | **7.3** | **7.8** |
| Total Volatiles | A | NA | 0.7 | 0.5 | 0.5 | 0.4 | 0.6 | 0.4 | 0.5 |
| | B | NA | 0.6 | 0.3 | 0.5 | 0.7 | 0.4 | 0.6 | 0.2 |
| | **Mean** | **NA** | **0.7** | **0.4** | **0.5** | **0.6** | **0.5** | **0.5** | **0.4** |
| Total % recovery | A | 100.3 | 100.9 | 101.2 | 96.7 | 99.1 | 99.6 | 101.7 | 98.1 |
| | B | 100.7 | 101.8 | 100.2 | 97.4 | 99.3 | 100.0 | 100.0 | 99.2 |
| | **Mean** | **100.5** | **101.4** | **100.7** | **97.1** | **99.2** | **99.8** | **100.9** | **98.7** |
| **Overall Mean ± SD** | | **99.8 ± 1.448** | | | | | | | |

ND: Not detected, or <0.1% AR. NA: Not applicable

*The extracts (1-3) assayed at 44 DAT gave anomalous results, with higher than expected levels of recovered radioactivity. The extracts were combined (Extract 4) and the amount of radioactivity determined in Extract 4 was more in line to expected results (based on previous sampling intervals). As such, the %AR measured in Extract 4 (90.9% AR) was used as a TRR value for HPLC and TLC analyses.

**Table B.8. 33 Mass balance and distribution of radioactivity in extracts of 18 Acres – individual replicates (values as % of applied) - [Phenyl-U-$^{14}$C]-pydiflumetofen**

| [Phenyl-U-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Extract 1 (non-harsh) | A | 91.6 | 78.3 | 79.2 | 78.0 | 77.4 | 74.1 | 43.3 | 67.2 |
| | B | 87.7 | 77.9 | 78.5 | 92.3 | 76.7 | 73.9 | 59.1 | 73.0 |
| | **Mean** | **89.7** | **78.1** | **78.9** | **85.2** | **77.1** | **74.0** | **51.2** | **70.1** |
| Extract 2 (non-harsh) | A | 8.5 | 13.6 | 12.8 | 13.4 | 12.3 | 13.9 | 29.4 | 14.3 |
| | B | 10.0 | 13.1 | 13.3 | 13.9 | 11.9 | 13.4 | 19.7 | 13.8 |
| | **Mean** | **9.3** | **13.4** | **13.1** | **13.7** | **12.1** | **13.7** | **24.6** | **14.1** |
| Extract 3 (non-harsh) | A | 1.4 | 2.6 | 3.2 | 2.9 | 2.9 | 2.9 | 11.4 | 3.7 |
| | B | 1.7 | 2.7 | 3.1 | 2.9 | 2.8 | 3.1 | 7.5 | 3.6 |
| | **Mean** | **1.6** | **2.7** | **3.2** | **2.9** | **2.9** | **3.0** | **9.5** | **3.7** |
| Extract 3a (non-harsh) | A | NA | NA | NA | NA | NA | NA | 6.6 | NA |
| | B | NA | NA | NA | NA | NA | NA | 4.9 | NA |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **5.8** | **NA** |
| **Total Extractables** (non-harsh) | **Mean** | **100.5** | **94.1** | **95.1** | **101.7*** | **92.0** | **90.7** | **91.0** | **87.8** |
| Non-Extractables** | A | 0.7 | 4.0 | 4.6 | 5.7 | 6.1 | 7.4 | 8.2 | 13.4 |
| | B | 0.7 | 4.5 | 4.4 | 5.4 | 6.7 | 8.2 | 7.7 | 8.9 |
| | **Mean** | **0.7** | **4.3** | **4.5** | **5.6** | **6.4** | **7.8** | **8.0** | **11.2** |
| Total Volatiles | A | NA | 0.5 | 0.1 | 0.4 | 0.3 | 0.3 | 0.3 | 0.3 |
| | B | NA | 0.3 | 0.4 | 0.2 | 0.6 | 0.2 | 0.3 | 0.2 |
| | **Mean** | **NA** | **0.4** | **0.3** | **0.3** | **0.5** | **0.3** | **0.3** | **0.3** |
| Total % recovery | A | 102.2 | 99.0 | 99.9 | 98.0 | 99.0 | 98.6 | 99.2 | 98.9 |
| | B | 100.1 | 98.5 | 99.7 | 96.5 | 98.7 | 98.8 | 99.2 | 99.5 |
| | **Mean** | **101.2** | **98.8** | **99.8** | **97.3** | **98.9** | **98.7** | **99.2** | **99.2** |
| **Overall Mean ± SD** | | **99.1±1.174** | | | | | | | |

NA: Not applicable.

*The extracts (1-3) assayed at 44 DAT gave anomalous results, with higher than expected levels of recovered radioactivity. The extracts were combined (Extract 4) and the amount of radioactivity determined in Extract 4 was more in line to expected results (based on previous sampling intervals). As such, the %AR measured in Extract 4 (91.4% AR) was used as a TRR value for HPLC and TLC analyses.

** Harsh extraction methods were performed on samples with >10% AR unextractable radioactivity, following combustion of soil residues.

**Table B.8. 34 Mass balance and distribution of radioactivity in extracts of Sarpy – individual replicates (values as % of applied) - [Phenyl-U-$^{14}$C]-pydiflumetofen**

| [Phenyl-U-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Extract 1 (non-harsh) | A | 85.3 | 65.7 | 62.0 | 69.5 | 61.4 | 59.3 | 48.8 | 56.0 |
| | B | 86.8 | 67.2 | 62.5 | 67.6 | 59.1 | 61.0 | 51.0 | 39.0 |
| | **Mean** | **86.1** | **66.5** | **62.3** | **68.6** | **60.3** | **60.2** | **49.9** | **47.5** |
| Extract 2 (non-harsh) | A | 10.8 | 13.0 | 16.3 | 21.1 | 14.3 | 13.3 | 14.2 | 13.4 |
| | B | 11.0 | 8.7 | 16.3 | 17.6 | 15.0 | 12.6 | 13.4 | 20.9 |
| | **Mean** | **10.9** | **10.9** | **16.3** | **19.4** | **14.7** | **13.0** | **13.8** | **17.2** |
| Extract 3 (non-harsh) | A | 1.9 | 4.4 | 5.4 | 5.2 | 4.6 | 5.3 | 6.8 | 6.1 |
| | B | 2.0 | 3.7 | 5.6 | 4.9 | 4.9 | 4.8 | 5.5 | 10.6 |
| | **Mean** | **2.0** | **4.1** | **5.5** | **5.1** | **4.8** | **5.1** | **6.2** | **8.4** |
| Extract 3a[#] (non-harsh) | A | NA | NA | NA | NA | NA | NA | NA | 5.1 |
| | B | NA | NA | NA | NA | NA | NA | NA | 8.8 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **7.0** |
| **Total Extractables** (non-harsh) | **Mean** | **98.9** | **81.4** | **84.1** | **93.0*** | **79.7** | **78.2** | **69.9** | **80.0** |
| Non-Extractables** | A | 1.0 | 13.4 | 11.3 | 14.5 | 16.3 | 18.0 | 25.6 | 16.2 |
| | B | 1.0 | 13.0 | 12.1 | 15.0 | 15.0 | 17.7 | 24.7 | 16.6 |
| | **Mean** | **1.0** | **13.2** | **11.7** | **14.8** | **15.7** | **17.9** | **25.2** | **16.4** |
| Total Volatiles | A | NA | 0.5 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.1 |
| | B | NA | 0.2 | 0.3 | 0.2 | 0.1 | 0.1 | 0.2 | 0.2 |
| | **Mean** | **NA** | **0.4** | **0.3** | **0.3** | **0.2** | **0.2** | **0.3** | **0.2** |
| Total % recovery | A | 99.0 | 97.0 | 95.3 | 94.6 | 96.9 | 96.2 | 95.7 | 96.9 |
| | B | 100.8 | 92.8 | 96.8 | 94.7 | 94.1 | 96.2 | 94.8 | 96.1 |
| | **Mean** | **99.9** | **94.9** | **96.1** | **94.7** | **95.5** | **96.2** | **95.3** | **96.5** |
| **Overall Mean ± SD** | | **96.1±1.909** | | | | | | | |

NA: Not applicable

*The extracts (1-3) assayed at 44 DAT gave anomalous results, with higher than expected levels of recovered radioactivity. The extracts were combined (Extract 4) and the amount of radioactivity determined in Extract 4 was more in line to expected results (based on previous sampling intervals). As such, the %AR measured in Extract 4 (79.7% AR) was used as a TRR value for HPLC and TLC analyses.

** Harsh extraction methods were performed on samples with >10% AR unextractable radioactivity, following combustion of soil residues.

#An additional extraction was performed, thereby artificially increasing the extractability. At 90 DAT, 69.9% AR was recovered in the initial extracts.

**Table B.8. 35 Mass balance and distribution of radioactivity in extracts of Capay – individual replicates (values as % of applied) - [Phenyl-U-$^{14}$C]-pydiflumetofen**

| [Phenyl-U-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Extract 1 (non-harsh) | A | 86.3 | 64.2 | 59.5 | 56.1 | 51.2 | 48.6 | 43.8 | 43.5 |
| | B | 88.8 | 63.9 | 59.6 | 63.4 | 50.9 | 48.9 | 47.4 | 44.4 |
| | **Mean** | **87.6** | **64.1** | **59.6** | **59.8** | **51.1** | **48.8** | **45.6** | **44.0** |
| Extract 2 (non-harsh) | A | 8.6 | 10.4 | 15.0 | 13.4 | 14.9 | 12.2 | 18.2 | 12.8 |
| | B | 9.2 | 13.7 | 14.9 | 12.3 | 14.4 | 12.8 | 16.4 | 12.2 |
| | **Mean** | **8.9** | **12.1** | **15.0** | **12.9** | **14.7** | **12.5** | **17.3** | **12.5** |
| Extract 3 (non-harsh) | A | 1.9 | 3.5 | 4.7 | 5.7 | 4.8 | 7.0 | 6.7 | 8.2 |
| | B | 2.0 | 4.2 | 4.6 | 4.4 | 4.8 | 6.5 | 5.9 | 7.4 |
| | **Mean** | **2.0** | **3.9** | **4.7** | **5.1** | **4.8** | **6.8** | **6.3** | **7.8** |
| **Total Extractables** (non-harsh) | **Mean** | **98.4** | **80.0** | **79.2** | **77.7*** | **70.5** | **68.0** | **69.2** | **64.3** |
| Non-Extractables** | A | 1.2 | 21.7 | 19.3 | 23.5 | 26.2 | 30.1 | 29.4 | 32.7 |
| | B | 1.5 | 22.7 | 18.6 | 21.9 | 26.5 | 29.3 | 27.8 | 32.5 |
| | **Mean** | **1.4** | **22.2** | **19.0** | **22.7** | **26.4** | **29.7** | **28.6** | **32.6** |
| Total Volatiles | A | NA | 0.1 | 0.1 | 0.2 | 0.2 | 0.0 | 0.1 | 0.1 |
| | B | NA | 0.1 | 0.2 | 0.1 | 0.2 | 0.1 | 0.1 | 0.1 |
| | **Mean** | **NA** | **0.1** | **0.2** | **0.2** | **0.2** | **0.1** | **0.1** | **0.1** |
| Total % recovery | A | 98.0 | 99.9 | 98.6 | 95.5 | 97.3 | 97.9 | 98.2 | 97.3 |
| | B | 101.5 | 104.6 | 97.9 | 94.2 | 96.8 | 97.6 | 97.6 | 96.6 |
| | **Mean** | **99.8** | **102.3** | **98.3** | **94.9** | **97.1** | **97.8** | **97.9** | **97.0** |
| **Overall Mean ± SD** | | **98.1±2.382** | | | | | | | |

NA: Not applicable.

*The extracts (1-3) assayed at 44 DAT gave anomalous results, with higher than expected levels of recovered radioactivity. The extracts were combined (Extract 4) and the amount of radioactivity determined in Extract 4 was more in line to expected results (based on previous sampling intervals). As such, the %AR measured in Extract 4 (72.0% AR) was used as a TRR value for HPLC and TLC analyses.

** Harsh extraction methods were performed on samples with >10% AR unextractable radioactivity, following combustion of soil residues.

**Table B.8. 36 Recovery of radioactivity following harsh extraction (individual replicates) – 18 Acres**

| [Phenyl-U-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Unextractable (prior to harsh extraction) | A | NA | NA | NA | NA | NA | NA | NA | 13.4 |
| | B | NA | NA | NA | NA | NA | NA | NA | 8.9 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **11.2** |
| Extractable (harsh extraction) | A | NA | NA | NA | NA | NA | NA | NA | 6.8 |
| | B | NA | NA | NA | NA | NA | NA | NA | 6 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **6.4** |
| Unextractable (after harsh extraction) | A | NA | NA | NA | NA | NA | NA | NA | 6.6 |
| | B | NA | NA | NA | NA | NA | NA | NA | 2.9 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **4.8** |

**Table B.8. 37 Recovery of radioactivity following harsh extraction (individual replicates) – Sarpy**

| [Phenyl-U-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Unextractable (prior to harsh extraction) | A | NA | 13.4 | 11.3 | 14.5 | 16.3 | 18 | 25.6 | 16.2 |
| | B | NA | 13 | 12.1 | 15 | 15 | 17.7 | 24.7 | 16.6 |
| | **Mean** | **NA** | **13.2** | **11.7** | **14.8** | **15.7** | **17.9** | **25.2** | **16.4** |
| Extractable (harsh extraction) | A | NA | 10.2 | 9.3 | 9.8 | 13.7 | 14.1 | 21 | 9.9 |
| | B | NA | 9.6 | 9.8 | 10.1 | 11.6 | 13.1 | 20.2 | 11.7 |
| | **Mean** | **NA** | **9.9** | **9.6** | **10** | **12.7** | **13.6** | **20.6** | **10.8** |
| Unextractable (after harsh extraction) | A | NA | 3.2 | 2 | 4.7 | 2.6 | 3.9 | 4.6 | 6.3 |
| | B | NA | 3.4 | 2.3 | 4.9 | 3.4 | 4.6 | 4.5 | 4.9 |
| | **Mean** | **NA** | **3.3** | **2.2** | **4.8** | **3.0** | **4.3** | **4.6** | **5.6** |

**Table B.8. 38 Recovery of radioactivity following harsh extraction (individual replicates) – Capay**

| [Phenyl-U-$^{14}$C]-pydiflumetofen | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Unextractable (prior to harsh extraction) | A | NA | 21.7 | 19.3 | 23.5 | 26.2 | 30.1 | 29.4 | 32.7 |
| | B | NA | 22.7 | 18.6 | 21.9 | 26.5 | 29.3 | 27.8 | 32.5 |
| | **Mean** | **NA** | **22.2** | **19** | **22.7** | **26.4** | **29.7** | **28.6** | **32.6** |
| Extractable (harsh extraction) | A | NA | 14.3 | 11.5 | 18.2 | 17.8 | 21 | 20.8 | 21.2 |
| | B | NA | 14.4 | 12.4 | 14.5 | 16.5 | 21.9 | 20.9 | 24.1 |
| | **Mean** | **NA** | **14.4** | **12** | **16.4** | **17.2** | **21.5** | **20.9** | **22.7** |
| Unextractable (after harsh extraction) | A | NA | 7.4 | 7.8 | 5.3 | 8.4 | 9.1 | 8.6 | 11.5 |
| | B | NA | 8.3 | 6.2 | 7.4 | 10 | 7.4 | 6.9 | 8.4 |
| | **Mean** | **NA** | **7.9** | **7** | **6.4** | **9.2** | **8.3** | **7.8** | **10** |

**Findings: Characterisation of Radioactivity**

Characterisation of radioactive residues in soil extracts (prior to harsh extraction and after harsh extraction) is presented in the tables below. Minimal degradation of the parent pydiflumetofen occurred throughout the study in Gartenacker and 18 Acres soils, with levels declining to 88.6, 88.1 and 84.7% AR by the end of the incubation period (120 DAT/90 DAIA) in the pyrazole-labelled Gartenacker, phenyl-labelled Gartenacker and 18 Acres soils, respectively. Levels of pydiflumetofen decreased from 95.5 and 94.5% AR at 0 DAT to 77.7 and 77.6% AR at the end of the aerobic phase (30 DAT/0 DAIA) to 78.2 and 62.6% AR by the end of the anaerobic phase (120 DAT/90 DAIA) in Sarpy and Capay soils respectively.

No major metabolites were detected in any of the soils studied. One identified metabolite, SYN545547, was observed to form at up to 1.6% AR ('non-harsh' extraction, 1.8% AR with 'harsh extraction) at study end in the 18 Acres soil and had not apparently reached its maximum. However, SYN545547 was also observed at similar levels in the application solutions and as a result, this was not thought by the applicant to be a true soil degradation product. As with the aerobic laboratory soil study HSE consider that this metabolite is formed at very low levels and does not require assessment as an anaerobic metabolite.

A number of discrete unknown minor metabolites were also observed, the sum of which did not exceed 2.6% AR (aerobic phase) or 3.1% AR (anaerobic phase). No single unknown degradate exceeded 1.5% AR in either the aerobic or anaerobic phase.

**Table B.8. 39 Characterisation of radioactive residues in soil extracts (pyrazole label, individual replicates): Gartenacker**

| **$^{14}$C-Residues Soil: Gartenacker Radiolabel: Pyrazole** | **Rep** | **% of Applied by DAT** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90[#]** | **120** |
| Parent (pydiflumetofen) | A | 96.1 | 93.1 | 91.5 | 87.8 | 88.2 | 92.3 | 17.9 | 86.5 |
| | B | 96.2 | 91.8 | 90.2 | 89.8 | 91.6 | 90.1 | 18.4 | 90.8 |
| | **Mean** | **96.1** | **92.4** | **90.9** | **88.8** | **89.9** | **91.2** | **18.2** | **88.6** |
| SYN545547 | A | 1.6 | 1.7 | 0.8 | 1.1 | 1.5 | 1.4 | 0.3 | 1.0 |
| | B | 0.9 | 0.8 | 1.5 | 0.9 | 1.3 | 1.6 | 0.2 | 1.4 |
| | **Mean** | **1.3** | **1.3** | **1.2** | **1.0** | **1.4** | **1.5** | **0.3** | **1.2** |
| Unknown metabolites | A | 2.3 | 1.5 | 2.9 | 3.3 | 1.5 | 1.5 | 0.3 | 3.1 |
| | B | 2.7 | 3.2 | 3.3 | 2.2 | 1.3 | 1.4 | 0.2 | 1.5 |
| | **Mean** | **2.5** | **2.3** | **3.1** | **2.7** | **1.4** | **1.4** | **0.2** | **2.3** |
| Largest single unknown metabolite | A | 1.3 | 1.5 | 1.1 | 1.4 | 0.2 | 1.5 | 0.3 | 1.5 |
| | B | 1.4 | 0.9 | 1.5 | 1.5 | 0.6 | 1.2 | 0.2 | 0.6 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** |
| Non-discrete extractables | A | 1.3 | 0.9 | 1.1 | 0.9 | 1.7 | 0.2 | 0.1 | 0.6 |
| | B | 0.7 | 1.2 | 1.1 | 0.6 | 0.1 | 0.4 | 0.1 | 0.1 |
| | **Mean** | **1.0** | **1.0** | **1.1** | **0.8** | **0.9** | **0.3** | **0.1** | **0.4** |
| Total extractables | A | 101.3 | 97.2 | 96.3 | 93.1 | 92.9 | 95.4 | 18.6 | 91.3 |
| | B | 100.5 | 96.9 | 96.2 | 93.5 | 94.3 | 93.4 | 18.9 | 93.8 |
| | **Mean** | **100.9** | **97.1** | **96.3** | **93.3** | **93.6** | **94.4** | **18.8** | **92.6** |

# Extract 1 was combined with extract 1 for units A13, A14 and B13 in error. Extracts 2 and 3 were combined per unit and it is this combined extract which was analysed chromatographically, hence the lower than anticipated recovery of radioactivity. These data were discounted from use in kinetic evaluations.
NA: Not Applicable
ND: Not Detected or <0.1% AR
Only non-harsh extractions performed as sufficient radioactivity was recovered.

**Table B.8. 40 Characterisation of radioactive residues in soil extracts (phenyl label, individual replicates): Gartenacker**

| **$^{14}$C-Residues Soil: Gartenacker Radiolabel: Phenyl** | **Rep** | **% of Applied by DAT** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Parent (pydiflumetofen) | A | 97.0 | 92.6 | 93.2 | 87.6 | 89.5 | 89.6 | 19.3# | 86.6 |
| | B | 95.0 | 92.4 | 92.2 | 87.5 | 89.5 | 90.0 | 89.7 | 89.6 |
| | **Mean** | **96.0** | **92.5** | **92.7** | **87.5** | **89.5** | **89.8** | **NA** | **88.1** |
| SYN545547 | A | 0.4 | 1.0 | 0.8 | 0.9 | 1.1 | 1.1 | 0.3# | 1.2 |
| | B | 0.9 | 1.6 | 1.2 | 1.4 | 1.2 | 1.2 | 1.3 | 0.8 |
| | **Mean** | **0.6** | **1.3** | **1.0** | **1.2** | **1.2** | **1.1** | **NA** | **1.0** |
| Unidentified regions | A | 1.9 | 1.2 | 1.6 | 1.6 | 1.0 | 1.1 | 0.2# | 0.8 |
| | B | 2.9 | 1.8 | 0.8 | 2.0 | 1.0 | 0.6 | 0.8 | 0.5 |
| | **Mean** | **2.4** | **1.5** | **1.2** | **1.8** | **1.0** | **0.8** | **NA** | **0.7** |
| Largest single unknown metabolite | A | 0.6 | 0.8 | 0.8 | 0.6 | 0.9 | 0.6 | 0.1 | 0.7 |
| | B | 0.8 | 1.1 | 0.8 | 0.9 | 0.5 | 0.6 | 0.8 | 0.4 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** |
| Non-discrete extractables | A | 0.1 | 0.6 | 0.2 | 0.4 | 0.8 | 0.4 | 0.2 | 0.8 |
| | B | 1.1 | 0.8 | 1.1 | 0.4 | 0.6 | 1.3 | 0.4 | 0.8 |
| | **Mean** | **0.6** | **0.7** | **0.6** | **0.4** | **0.7** | **0.8** | **NA** | **0.8** |
| Total extractables | A | 99.4 | 95.4 | 95.7 | 90.5 | 92.4 | 92.1 | 20.0# | 89.3 |
| | B | 99.9 | 96.5 | 95.3 | 91.3 | 92.3 | 93.0 | 92.1 | 91.8 |
| | **Mean** | **99.7** | **96.0** | **95.5** | **90.9** | **92.3** | **92.6** | **NA** | **90.6** |

# Extract 1 was combined with extract 1 for units A13, A14 and B13 in error. Extracts 2 and 3 were combined per unit and it is this combined extract which was analysed chromatographically, hence the lower than anticipated recovery of radioactivity. These data were discounted from use in kinetic evaluations.
NA: Not Applicable.
Only non-harsh extractions performed as sufficient radioactivity was recovered.

**Table B.8. 41 Characterisation of radioactive residues in soil extracts[#] (individual replicates): 18 Acres**

| **$^{14}$C-Residues Soil: 18 Acres Radiolabel: Phenyl** | **Rep** | **% of Applied by DAT** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Parent (pydiflumetofen) | A | 97.7 | 89.4 | 93.1 | 89.5 | 89.7 | 88.0 | 88.3 | 81.6 (88.1) |
| | B | 96.2 | 89.6 | 92.7 | 88.5 | 87.9 | 87.9 | 87.9 | 87.7 (93.5) |
| | **Mean** | **96.9** | **89.5** | **92.9** | **89.0** | **88.8** | **87.9** | **88.1** | **84.7 (90.8)** |
| SYN545547 | A | 1.3 | 1.3 | 1.0 | 1.4 | 1.4 | 1.4 | 1.4 | 2.2 (2.5) |
| | B | 1.2 | 1.4 | 1.3 | 1.1 | 1.7 | 1.3 | 1.8 | 1.1 (1.2) |
| | **Mean** | **1.3** | **1.3** | **1.1** | **1.2** | **1.5** | **1.3** | **1.6** | **1.6 (1.8)** |
| Unidentified regions | A | 1.4 | 3.0 | 1.1 | 0.7 | 0.7 | 0.7 | 0.3 | 0.7 (0.7) |
| | B | 1.0 | 2.3 | 0.7 | 1.0 | 0.8 | 0.5 | 0.6 | 0.6 (0.7) |
| | **Mean** | **1.2** | **2.6** | **0.9** | **0.8** | **0.8** | **0.6** | **0.4** | **0.6 (0.7)** |
| Largest single unknown metabolite | A | 0.6 | 0.9 | 0.7 | 0.4 | 0.5 | 0.5 | 0.3 | 0.4 |
| | B | 0.5 | 1.1 | 0.3 | 0.4 | 0.6 | 0.2 | 0.5 | 0.2 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** |
| Non-discrete extractables | A | 1.2 | 0.9 | ND | 0.4 | 0.8 | 0.9 | 0.8 | 0.7 (0.8) |
| | B | 1.0 | 0.5 | 0.3 | 0.3 | 1.0 | 0.8 | 1.0 | 1.0 (1.0) |
| | **Mean** | **1.1** | **0.7** | **0.1** | **0.4** | **0.9** | **0.8** | **0.9** | **0.8 (0.9)** |
| Total extractables | A | 101.5 | 94.5 | 95.2 | 91.9 | 92.6 | 90.9 | 90.7 | 85.2 (92.0) |
| | B | 99.4 | 93.7 | 94.9 | 90.9 | 91.4 | 90.4 | 91.3 | 90.4 (96.4) |
| | **Mean** | **100.5** | **94.1** | **95.1** | **91.4** | **92.0** | **90.7** | **91.0** | **87.8 (94.2)** |

[#]: Based on non-harsh extractions. Values reported in brackets include harsh extraction.
NA: Not applicable.

**Table B.8. 42 Characterisation of radioactive residues in soil extracts[#] (individual replicates): Sarpy**

| **$^{14}$C-Residues Soil: Sarpy Radiolabel: Phenyl** | **Rep** | **% of Applied by DAT** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Parent (pydiflumetofen) | A | 95.1 | 80.3 (90.0) | 81.2 (90.2) | 77.2 (86.7) | 77.9 (91.2) | 76.1 (89.8) | 68.3 (88.6) | 78.3 (87.9) |
| | B | 95.9 | 75.2 (84.3) | 81.6 (91.0) | 76.9 (86.7) | 76.7 (87.9) | 76.9 (89.5) | 68.3 (87.8) | 78.2 (89.5) |
| | **Mean** | **95.5** | **77.7 (87.3)** | **81.4 (90.6)** | **77.1 (86.7)** | **77.3 (89.5)** | **76.5 (89.6)** | **68.3 (88.2)** | **78.2 (88.7)** |
| SYN545547 | A | 1.1 | 0.5 (0.7) | 1.2 (1.4) | 1.1 (1.4) | 0.5 (0.8) | 0.8 (1.0) | 1.0 (1.4) | 1.0 (1.2) |
| | B | 1.4 | 1.0 (1.2) | 1.3 (1.5) | 0.9 (1.1) | 1.1 (1.3) | 0.7 (1.0) | 0.8 (1.1) | 0.7 (1.0) |
| | **Mean** | **1.2** | **0.7 (0.9)** | **1.3 (1.5)** | **1.0 (1.2)** | **0.8 (1.1)** | **0.8 (1.0)** | **0.9 (1.3)** | **0.9 (1.1)** |
| Unidentified regions | A | 0.9 | 1.5 (1.6) | 0.9 (0.9) | 1.1 (1.1) | 0.8 (0.9) | 0.9 (1.1) | 0.5 (0.6) | 0.6 (0.7) |
| | B | 1.7 | 2.1 (2.2) | 0.3 (0.5) | 1.2 (1.2) | 0.6 (0.7) | 0.3 (0.5) | 0.4 (0.5) | 0.4 (0.4) |
| | **Mean** | **1.3** | **1.8 (1.9)** | **0.6 (0.7)** | **1.1 (1.2)** | **0.7 (0.8)** | **0.6 (0.8)** | **0.4 (0.6)** | **0.5 (0.5)** |
| Largest single unknown metabolite | A | 0.3 | 0.6 | 0.5 | 0.5 | 0.4 | 0.6 | 0.5 | 0.3 |
| | B | 0.8 | 1.3 | 0.2 | 0.6 | 0.5 | 0.3 | 0.4 | 0.3 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** |
| Non-discrete extractables | A | 0.9 | 0.9 (1.0) | 0.5 (0.5) | 0.4 (0.4) | 1.1 (1.1) | 0.1 (0.1) | 0.1 (0.3) | 0.7 (0.8) |
| | B | 0.8 | 1.3 (1.3) | 1.2 (1.2) | 0.5 (0.6) | 0.5 (0.7) | 0.5 (0.5) | 0.4 (0.6) | ND (0.1) |
| | **Mean** | **0.9** | **1.1 (1.2)** | **0.8 (0.9)** | **0.4 (0.5)** | **0.8 (0.9)** | **0.3 (0.3)** | **0.3 (0.5)** | **0.4 (0.4)** |
| Total extractables | A | 98.0 | 83.1 (93.3) | 83.7 (93.0) | 79.8 (89.6) | 80.3 (94.0) | 77.9 (92.0) | 69.8 (90.8) | 80.6 (90.5) |
| | B | 99.8 | 79.6 (88.6) | 84.4 (94.2) | 79.5 (89.6) | 79.0 (90.6) | 78.4 (91.5) | 69.9 (90.1) | 79.3 (91.0) |
| | **Mean** | **98.9** | **81.4 (90.9)** | **84.1 (93.6)** | **79.7 (89.6)** | **79.6 (92.3)** | **78.1 (91.8)** | **69.9 (90.5)** | **79.9 (90.7)** |

[#]: Based on non-harsh extractions. Values reported in brackets include harsh extraction.
NA: Not applicable.

**Table B.8. 43 Characterisation of radioactive residues in soil extracts[#] (individual replicates): Capay**

| $^{14}$C-Residues **Soil: Capay Radiolabel: Phenyl** | **Rep** | **% of Applied by DAT** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **30** | **37** | **44** | **61** | **76** | **90** | **120** |
| Parent (pydiflumetofen) | A | 92.7 | 76.3(90.1) | 74.6 (85.8) | 69.8 (87.4) | 69.4 (86.8) | 66.0 (86.4) | 67.0 (87.1) | 62.7 (83.4) |
| | B | 96.4 | 78.8 (93.0) | 77.1 (89.1) | 70.0 (84.0) | 68.9 (84.8) | 66.0 (87.5) | 68.1 (88.5) | 62.5 (85.9) |
| | **Mean** | **94.5** | **77.6 (91.5)** | **75.8 (87.4)** | **69.9 (85.7)** | **69.1 (85.8)** | **66.0 (86.9)** | **67.6 (87.8)** | **62.6 (84.6)** |
| SYN545547 | A | 0.9 | 0.7 (1.0) | 0.9 (1.1) | 0.7 (1.0) | 0.8 (1.0) | 0.5 (0.7) | 0.8 (1.2) | 0.6 (0.9) |
| | B | 1.2 | 1.1 (1.3) | 1.1 (1.3) | 0.8 (1.1) | 0.7 (1.0) | 1.0 (1.2) | 0.8 (1.2) | 0.5 (1.0) |
| | **Mean** | **1.0** | **0.9 (1.1)** | **1.0 (1.2)** | **0.8 (1.1)** | **0.7 (1.0)** | **0.7 (1.0)** | **0.8 (1.2)** | **0.5 (0.9)** |
| Unidentified regions | A | 2.3 | 1.0 (1.1) | 3.0 (3.1) | 0.7 (0.8) | 0.4 (0.5) | 1.1 (1.3) | 0.5 (0.6) | 0.7 (0.9) |
| | B | 2.0 | 0.8 (0.9) | 0.9 (1.0) | 1.4 (1.4) | 0.3 (0.5) | 0.7 (0.8) | 0.4 (0.6) | 0.8 (0.9) |
| | **Mean** | **2.1** | **0.9 (1.0)** | **2.0 (2.1)** | **1.0 (1.1)** | **0.4 (0.5)** | **0.9 (1.1)** | **0.5 (0.6)** | **0.7 (0.9)** |
| Largest single unknown metabolite | A | 0.6 | 0.4 | 0.9 | 0.2 | 0.4 | 0.5 | 0.2 | 0.2 |
| | B | 1.3 | 0.3 | 0.6 | 0.9 | 0.2 | 0.5 | 0.2 | 0.4 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** | **NA** |
| Non-discrete extractables | A | 1.0 | 0.1 (0.2) | 0.7 (0.8) | 0.6 (0.8) | 0.4 (0.5) | 0.2 (0.4) | 0.4 (0.6) | 0.5 (0.5) |
| | B | 0.4 | 1.0 (1.1) | 0.0 (0.1) | 0.1 (0.2) | 0.2 (0.3) | 0.5 (0.6) | 0.3 (0.4) | 0.2 (0.4) |
| | **Mean** | **0.7** | **0.5 (0.6)** | **0.4 (0.4)** | **0.3 (0.5)** | **0.3 (0.4)** | **0.4 (0.5)** | **0.3 (0.5)** | **0.4 (0.4)** |
| Total extractables | A | 96.8 | 78.1 (92.4) | 79.2 (90.7) | 71.8 (90.0) | 70.9 (88.7) | 67.8 (88.8) | 68.7 (89.5) | 64.5 (85.7) |
| | B | 100.0 | 81.8 (96.2) | 79.1 (91.5) | 72.2 (86.7) | 70.1 (86.6) | 68.2 (90.1) | 69.7 (90.6) | 64.0 (88.1) |
| | **Mean** | **98.4** | **80.0 (94.3)** | **79.2 (91.1)** | **72.0 (88.3)** | **70.5 (87.7)** | **68.0 (89.5)** | **69.2 (90.0)** | **64.3 (86.9)** |

[#]: Based on non-harsh extractions. Values reported in brackets include harsh extraction.
NA: Not applicable

**Findings: Enantiomeric Composition**

The applicant considered that the enantiomeric composition of pydiflumetofen did not change significantly during the course of the study. The pydiflumetofen enantiomer ratio was 1.0 in the application solutions and 0.9 in the soil sample extracts taken at 120 DAT. HSE has added an assessment of the change in enantiomeric excess as described for the aerobic laboratory soil assessment.

**Table B.8. 44 Pydiflumetofen enantiomer ratios in stock solutions and anaerobic soil at 120 DAT**

| | | % Sample activity as | | | | |
|---|---|---|---|---|---|---|
| **Sample Type** | **Label** | **1st eluting enantiomer** | **2nd eluting enantiomer** | **Enantiomer Ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| Stock solution (SS2) | Pyrazole | 47.40 | 47.34 | 1.0 | 0.06 | |
| Gartenacker (120 DAT) | | 39.44 | 44.57 | 0.9 | -6.11 | 6.17 |
| Stock solution (SS1) | Phenyl | 47.01 | 48.50 | 1.0 | -1.56 | |
| Gartenacker (120 DAT) | | 43.24 | 46.95 | 0.9 | -4.11 | 2.55 |

HSE notes that there was less than 10% change in enantiomeric excess in this study but there was less than 50% degradation of the a.s. before study end.

**Conclusion**

The study is considered by HSE to be acceptable and the results can be accepted for risk assessment.

Pydiflumetofen (SYN545974) degraded very slowly with little formation of identified metabolites. No anaerobic soil metabolites are considered by HSE to trigger inclusion in risk assessment. Mineralisation was low, ranging from 0.1 – 0.4% AR after 120 days with both radiolabelled positions. Unextracted residues ranged from 7.8 – 32.6% AR after 120 days with both radiolabelled positions.

The kinetic assessment of this study is presented in section B.8.1.1.2.1.3.

As with the aerobic laboratory soil study, there are similar issues relating to strength of extraction methodology. Taking into account the use of data from studies using similar extraction methodology in other regulatory submissions, it was considered appropriate to only use the data from the 'non-harsh' extractions to derive degradation endpoints. This is consistent with the approach taken in the aerobic soil laboratory degradation study in section B.8.1.1.1.1. It is noted that this also leads to consistency with the extraction methodology used in the field dissipation studies in section B.8.1.1.2.2. HSE can accept this approach for the submission for approval in GB.

It was also noted that the enantiomeric ratio did not appear to change in this study. This seems confirmed by an assessment of change in enantiomeric excess, which ranged from approximately 2.5 – 6% between the beginning of the study and 120 DAT. However there was very little degradation in the soil that was analysed for the two enantiomers, with approximately 88% of applied radioactivity remaining as unchanged pydiflumetofen at the end of the study. As noted in the evaluation of the aerobic soil laboratory study in section B.8.1.1.1.1, the EFSA Stereoisomers guidance indicates that a 10% or greater change in the enantiomeric excess would be considered significant by the end of a route of degradation study. This threshold is applied in the case where at least 50% of the bulk substance had degraded by the end of the study, or by extrapolation if 50% of the substance had not degraded by the end of the study. If the rate of change in enantiomer excess was consistent and extrapolated out to a point where 50% of the active substance had degraded, the change in enantiomer excess would be in the approximate range of 5 – 15%. It is noted that the study was performed prior to the introduction of the EFSA Stereoisomers guidance and the guidance is not currently adopted in GB. The overall summary of the fate and behaviour of pydiflumetofen at the beginning of this B.8 section describes the considerations of stereoisomerism across the range of the submitted environmental fate studies and the weight of evidence approach that has been taken.

**B.8.1.1.1.3. Soil photolysis**

| | |
|---|---|
| **Report:** | K-CA 7.1.1.3/01. [redacted] [redacted] (2014), SYN545974 - Soil Photolysis of $^{14}$C-SYN545974, Report Number 3200128. Smithers Viscient (ESG) Ltd., Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK<br>(Syngenta File No. SYN545974_50182). |

**Guideline(s):** SETAC 1995, EPA Guideline Series, OPPTS 835.2410 (2008),
**GLP/GEP:** Yes
**Deviation(s):** No major deviation identified
**Acceptability** Yes

**Material and Methods**
The soil photolysis of $^{14}$C-phenyl ring labelled and $^{14}$C-pyrazole ring labelled pydiflumetofen was investigated on a sandy clay loam soil, both on dry and moist surfaces.

| **Test Material:** | **[Pyrazole-5-$^{14}$C]-SYN545974** | **[Phenyl-U-$^{14}$C]-SYN545974** |
|---|---|---|
| Lot/Batch #: | 5271GAR001-4 | RDR-XV-94 |
| Specific activity: | 5.06 MBq/mg | 5.791 MBq/mg |
| Purity: | 95.4% (chemical)<br>99.2% (radiochemical) | 97.6% (chemical)<br>97.8% (radiochemical) |
| Application vehicle: | Acetonitrile | Acetonitrile |

The soil was passed through a 2 mm mesh sieve with the minimum of air drying prior to storage in the dark at 4°C ± 2°C in loosely tied plastic bags. Soil characteristics are reported below.

**Table B.8. 45 Soils characteristics**

| **Name** | **18 Acres** |
|---|---|
| Sampling location | Jealott's Hill Farm, Bracknell, UK |
| Sampling depth (cm) | 5 – 20 cm |
| Duration of storage | Moist 80 days (from arrival to dispensing of the final units)<br>Dry 193 days (from arrival to dispensing of the final units) |
| Particle size (% w/w): | |
| Clay (<2 µm) | 25 |
| Silt (50-2 µm) | 24 |
| Sand (2000-50 µm) | 51 |
| Texture (USDA) | Sandy clay loam |
| pH (water) | 6.8 |
| pH (0.01M $CaCl_2$) | 6.1 |
| Organic matter (%) | 4.0 |
| Organic carbon (%) | 2.3 |
| CEC (meq/100 g soil) | 18.9 |
| Moisture at pF2 (w/w %) | 29.8 |
| Moisture at pF2.5 (w/w %) | 23.6 |

Pydiflumetofen was applied, at rates equivalent to *ca* 250 g ai/ha, to thin layers (*ca* 1 mm for dry soil, *ca* 3 mm for moist soil) of 18 Acres soil (sandy clay loam, UK) in individual photolysis vessels. The treated soils were continuously irradiated using light from a xenon arc lamp. The emitted light was filtered to give a spectral distribution (290 – 800 nm) close to that of natural sunlight at a light intensity in the range of 46 - 52 W/m$^2$. The samples were maintained at 20°C ± 2°C and were irradiated for periods up to the equivalent of *ca* 30 days summer sunlight at latitudes 30 - 50°N. At day 0, moist soil was adjusted to pF2 moisture tension; dry soil tests used air dried soil. During the experiment, dry soils received no moisture maintenance, whereas moist soils were checked and moisture adjusted to pF2 if required.

In each test, duplicate samples were taken for analysis at up to six intervals during irradiation. 'Dark control' samples were also prepared and maintained at *ca* 20°C. Dark control samples were taken for analysis at intervals equivalent to or exceeding that of the irradiation test. Any volatile radioactivity was continuously flushed from the vessels and collected in liquid traps (2M NaOH).

At each sampling time, each treated sample was extracted once with acetonitrile : 0.1 M ammonium acetate (80:20 v/v), followed by twice with acetonitrile : water (80:20 v/v, water acidified to pH 3). All extracts were pooled. The amount of radioactivity recovered was determined by LSC quantification. Extractable $^{14}$C-residues were characterised by HPLC and quantitation confirmed by TLC of selected samples. Unextracted residues

were determined by combustion. A mass balance for each sample was determined by summation of the radioactivity recovered in the soil extracts, the total $^{14}CO_2$ evolved and the unextracted residues.

LC-MS-MS was also used to provide qualitative confirmation of the identification of $^{14}$C-phenyl ring labelled and $^{14}$C-pyrazole ring labelled pydiflumetofen by matching LC-MS retention times of cold reference standard pydiflumetofen, pyrazole labelled reference standard, phenyl labelled reference standard, radio-chromatogram retention times and product fragmentation spectra.

Chiral HPLC was performed on one irradiated moist soil sample, incubated for 15 days after treatment with the pyrazole labelled pydiflumetofen and one irradiated dry soil sample, also incubated for 15 days after treatment with the phenyl labelled pydiflumetofen. The purpose of this analysis was to check whether there was any change to the enantiomer ratio of pydiflumetofen during light irradiation.

The rate of degradation of pydiflumetofen was estimated using single first order kinetics using CAKE software (version 2). True replicates were included individually in the optimisations. Radioactivity at day 0 was left to the measured value of pydiflumetofen. All data points were unweighted. For optimal goodness of fit, the initial value was also allowed to be estimated by the model. The fit of SFO model was assessed on the basis of a visual assessment of the goodness of fit (diagrams of measured and calculated values versus time, diagrams of residuals versus time) and on the basis of the $\chi^2$ scaled-error criterion.

**Findings: Light Intensity and Mass Balance**
Overall mean light intensity integrated between 300 and 400 nm ranged from 45.7 to 52.3 W/m$^2$.

The mass balance (mean of two replicate values from each sample time) from the irradiated samples was in the range of 91.0 – 99.4% applied radioactivity (% AR) and from the dark controls was 87.0 – 100.6% AR, mean of duplicate samples quoted. There were some instances where the overall recovery was lower than 90%, i.e. the normal lower limit of acceptability This was typically because one replicate had dropped below 90%. HSE did not consider there to be a pattern of increasing loss over the course of the incubations. HSE noted that the dark control incubation of the dry soil treated with [pyrazole-$^{14}$C]-pydiflumetofen showed a number of instances of losses of radioactivity in replicate B but the reason for this is not apparent, there being instances of lower radioactivity in extract 1 in this incubation. Overall HSE accepts the validity of the study in this case in spite of these losses of radioactivity. The losses of radioactivity do not alter the conclusions in relation to the slow degradation of the active substance or of low metabolite formation in the study. Carbon dioxide and unextractable radioactivity remained negligible (<5% AR).

**Table B.8. 46 Mass balance and distribution of radioactivity: [Pyrazole-$^{14}$C]-pydiflumetofen, irradiated, dry soil– individual replicates (values as % of applied)**

| **[Pyrazole-$^{14}$C]-pydiflumetofen** | | **Rep** | **Actual experimental days after treatment#** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3 (5.2)** | **5 (9.9)** | **8 (14.5)** | **10 (20.4)** | **12 (25.1)** | **16 (29.0)** |
| Extract 1 | irradiated | A | 90.2 | 93.4 | 96.8 | 94.7 | 93.5 | 91.1 | 88.4 |
| | | B | 97.8 | 92.8 | 95.0 | 94.7 | 91.0 | 94.1 | 84.9 |
| | | **Mean** | **94.0** | **93.1** | **95.9** | **94.7** | **92.3** | **92.6** | **86.7** |
| Extract 2 | irradiated | A | 3.0 | 2.3 | 2.6 | 2.6 | 2.2 | 1.9 | 2.4 |
| | | B | 3.0 | 2.2 | 2.4 | 2.6 | 2.1 | 2.0 | 2.7 |
| | | **Mean** | **3.0** | **2.3** | **2.5** | **2.6** | **2.2** | **2.0** | **2.6** |
| Extract 3 | irradiated | A | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 | 0.3 | 0.2 |
| | | B | 0.1 | 0.1 | 0.2 | 0.2 | 0.1 | 0.2 | 0.3 |
| | | **Mean** | **0.1** | **0.1** | **0.2** | **0.2** | **0.2** | **0.3** | **0.3** |
| **Total Extractables** | **irradiated** | **Mean** | **97.1** | **95.5** | **98.6** | **97.5** | **94.6** | **94.8** | **89.5** |
| Non-Extractables | irradiated | A | ND | 0.5 | 0.7 | 1.2 | 1.0 | 1.3 | 1.2 |
| | | B | ND | 0.5 | 0.7 | 0.9 | 1.0 | 1.3 | 1.5 |
| | | **Mean** | **ND** | **0.5** | **0.7** | **1.1** | **1.0** | **1.3** | **1.4** |
| $^{14}CO_2$* | irradiated | A | NA | 0.1 | ND | 0.2 | 0.7 | 0.6 | 0.1 |
| | | B | NA | 0.1 | 0.1 | 0.4 | 0.6 | 0.3 | 0.3 |
| | | **Mean** | **NA** | **0.1** | **0.1** | **0.3** | **0.7** | **0.5** | **0.2** |
| Total % recovery | irradiated | A | 93.3 | 96.4 | 100.3 | 98.9 | 97.6 | 95.2 | 92.3 |
| | | B | 100.9 | 95.7 | 98.4 | 98.8 | 94.8 | 97.9 | 89.7 |
| | | **Mean** | **97.1** | **96.1** | **99.4** | **98.9** | **96.2** | **96.6** | **91.0** |
| **Overall Mean ± SD** | | | **96.5 ± 2.7** | | | | | | |

*The nature of the volatiles was assumed to be $CO_2$ but was not determined due to low levels of mineralisation
# Values in brackets correspond to equivalent UK/US days (assuming summer natural midday sunlight intensity at UK/US between 300-400 nm is 67 W/m$^2$ (OECD 2002))
ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 47 Mass balance and distribution of radioactivity: [Phenyl-$^{14}$C]-pydiflumetofen, irradiated, dry soil– individual replicates (values as % of applied)**

| **[Phenyl-$^{14}$C]-pydiflumetofen** | | **Rep** | **Actual experimental days after treatment[#]** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3 (6.0)** | **5 (10.8)** | **8 (16.0)** | **10 (19.8)** | **12 (25.6)** | **14 (31.1)** |
| Extract 1 | irradiated | A | 95.4 | 94.9 | 93.9 | 81.9 | 86.3 | 89.4 | 85.0 |
| | | B | 92.2 | 92.2 | 94.3 | 93.4 | 88.9 | 95.7 | 89.5 |
| | | **Mean** | **93.8** | **93.6** | **94.1** | **87.7** | **87.6** | **92.6** | **87.3** |
| Extract 2 | irradiated | A | 3.3 | 2.4 | 2.6 | 2.6 | 2.0 | 1.7 | 2.7 |
| | | B | 3.0 | 2.6 | 2.4 | 2.4 | 2.1 | 2.0 | 2.2 |
| | | **Mean** | **3.2** | **2.5** | **2.5** | **2.5** | **2.1** | **1.9** | **2.5** |
| Extract 3 | irradiated | A | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 | 0.2 | 0.4 |
| | | B | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| | | **Mean** | **0.1** | **0.1** | **0.2** | **0.2** | **0.2** | **0.2** | **0.3** |
| **Total Extractables** | **irradiated** | **Mean** | **97.1** | **96.2** | **96.8** | **90.4** | **89.9** | **94.6** | **90.0** |
| Non-Extractables | irradiated | A | 0.2 | 0.8 | 1.0 | 1.4 | 1.6 | 1.6 | 2.0 |
| | | B | 0.2 | 0.8 | 0.8 | 1.2 | 1.5 | 1.1 | 1.3 |
| | | **Mean** | **0.2** | **0.8** | **0.9** | **1.3** | **1.6** | **1.4** | **1.7** |
| $^{14}CO_2$* | irradiated | A | NA | 0.3 | 0.7 | 3.0 | 5.4 | 3.8 | 1.8 |
| | | B | NA | 0.3 | 0.4 | 1.5 | 2.9 | 0.5 | 1.1 |
| | | **Mean** | **NA** | **0.3** | **0.6** | **2.3** | **4.2** | **2.2** | **1.5** |
| Total % recovery | irradiated | A | 99.0 | 98.5 | 98.4 | 89.1 | 95.5 | 96.7 | 91.9 |
| | | B | 95.5 | 96.0 | 98.1 | 98.7 | 95.6 | 99.5 | 94.3 |
| | | **Mean** | **97.3** | **97.3** | **98.3** | **93.9** | **95.6** | **98.1** | **93.1** |
| **Overall Mean ± SD** | | | **96.2 ± 2.1** | | | | | | |

*The nature of the volatiles was assumed to be $CO_2$ but was not determined due to low levels of mineralisation.
[#] Values in brackets correspond to equivalent UK/US days (assuming summer natural midday sunlight intensity at UK/US between 300-400 nm is 67 W/m$^2$ (OECD 2002))
NA: Not applicable

**Table B.8. 48 Mass balance and distribution of radioactivity: [Pyrazole-$^{14}$C]-pydiflumetofen, dark control, dry soil– individual replicates (values as % of applied)**

| **[Pyrazole-$^{14}$C]-pydiflumetofen** | | **Rep** | **Actual experimental days after treatment** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3** | **5** | **8** | **10** | **12** | **16** |
| Extract 1 | dark | A | 90.2 | 93.5 | 92.7 | 92.8 | 94.1 | 91.5 | 92.1 |
| | | B | 97.8 | 92.6 | 81.0 | 87.3 | 94.2 | 80.4 | 86.0 |
| | | **Mean** | **94.0** | **93.1** | **86.9** | **90.1** | **94.2** | **86.0** | **89.1** |
| Extract 2 | dark | A | 3.0 | 2.1 | 2.2 | 2.4 | 2.3 | 1.8 | 2.7 |
| | | B | 3.0 | 2.0 | 2.2 | 2.3 | 2.2 | 1.6 | 2.5 |
| | | **Mean** | **3.0** | **2.1** | **2.2** | **2.4** | **2.3** | **1.7** | **2.6** |
| Extract 3 | dark | A | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| | | B | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 |
| | | **Mean** | **0.1** | **0.1** | **0.1** | **0.1** | **0.1** | **0.1** | **0.2** |
| **Total Extractables** | **dark** | **Mean** | **97.1** | **95.2** | **89.2** | **92.5** | **96.5** | **87.8** | **91.8** |
| Non-Extractables | dark | A | ND | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.3 |
| | | B | ND | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.4 |
| | | **Mean** | **ND** | **0.2** | **0.2** | **0.2** | **0.2** | **0.2** | **0.4** |
| $^{14}CO_2$* | dark | A | NA | ND | ND | ND | ND | ND | ND |
| | | B | NA | ND | ND | ND | ND | ND | ND |
| | | **Mean** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | dark | A | 93.3 | 95.9 | 95.2 | 95.5 | 96.7 | 93.6 | 95.2 |
| | | B | 100.9 | 94.9 | 83.5 | 89.9 | 96.7 | 82.3 | 89.1 |
| | | **Mean** | **97.1** | **95.4** | **89.4** | **92.7** | **96.7** | **88.0** | **92.2** |
| **Overall Mean ± SD** | | | **93.1 ± 3.5** | | | | | | |

*The nature of the volatiles was assumed to be $CO_2$ but was not determined due to low levels of mineralisation.
ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 49 Mass balance and distribution of radioactivity: [Phenyl-$^{14}$C]-pydiflumetofen, dark control, dry soil– individual replicates (values as % of applied)**

| **[Phenyl-$^{14}$C]-pydiflumetofen** | | **Rep** | **Actual experimental days after treatment** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3** | **5** | **8** | **10** | **12** | **14** |
| Extract 1 | dark | A | 95.4 | 91.3 | 78.4 | 88.9 | 95.1 | 96.5 | 98.1 |
| | | B | 92.2 | 77.4 | 90.1 | 84.2 | 95.5 | 96.3 | 95.5 |
| | | **Mean** | **93.8** | **84.4** | **84.3** | **86.6** | **95.3** | **96.4** | **96.8** |
| Extract 2 | dark | A | 3.3 | 2.4 | 2.1 | 2.1 | 2.5 | 1.8 | 2.7 |
| | | B | 3.0 | 1.9 | 3.1 | 2.6 | 2.2 | 1.8 | 3.3 |
| | | **Mean** | **3.2** | **2.2** | **2.6** | **2.4** | **2.4** | **1.8** | **3.0** |
| Extract 3 | dark | A | 0.1 | 0.1 | 0.2 | 0.1 | 0.1 | 0.1 | 0.2 |
| | | B | 0.1 | 0.1 | 0.2 | 0.1 | 0.1 | 0.1 | 0.3 |
| | | **Mean** | **0.1** | **0.1** | **0.2** | **0.1** | **0.1** | **0.1** | **0.3** |
| **Total Extractables** | **dark** | **Mean** | **97.1** | **86.6** | **87.1** | **89.0** | **97.8** | **98.3** | **100.1** |
| Non-Extractables | dark | A | 0.2 | 0.4 | 0.7 | 0.5 | 0.5 | 0.5 | 0.5 |
| | | B | 0.2 | 0.4 | 0.4 | 0.4 | 0.5 | 0.5 | 0.6 |
| | | **Mean** | **0.2** | **0.4** | **0.6** | **0.5** | **0.5** | **0.5** | **0.6** |
| $^{14}CO_2$* | dark | A | NA | ND | ND | ND | ND | ND | ND |
| | | B | NA | ND | ND | ND | ND | ND | ND |
| | | **Mean** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | dark | A | 99.0 | 94.2 | 81.4 | 91.6 | 98.2 | 98.9 | 101.5 |
| | | B | 95.5 | 79.8 | 93.8 | 87.3 | 98.3 | 98.7 | 99.7 |
| | | **Mean** | **97.3** | **87.0** | **87.6** | **89.5** | **98.3** | **98.8** | **100.6** |
| **Overall Mean ± SD** | | | **94.1 ± 5.9** | | | | | | |

*The nature of the volatiles was assumed to be $CO_2$ but was not determined due to low levels of mineralisation.
ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 50 Mass balance and distribution of radioactivity: [Pyrazole-$^{14}$C]-pydiflumetofen, irradiated, moist soil– individual replicates (values as % of applied)**

| **[Pyrazole-$^{14}$C]-pydiflumetofen** | | **Rep** | **Actual experimental days after treatment[#]** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3 (5.0)** | **6 (10.9)** | **8 (15.9)** | **11 (19.9)** | **14 (24.9)** | **15 (30.3)** |
| Extract 1 | irradiated | A | 91.8 | 87.4 | 89.2 | 86.1 | 87.8 | 89.8 | 86.7 |
| | | B | 90.4 | 85.5 | 88.4 | 83.7 | 85.5 | 86.7 | 84.0 |
| | | **Mean** | **91.1** | **86.5** | **88.8** | **84.9** | **86.7** | **88.3** | **85.4** |
| Extract 2 | irradiated | A | 6.8 | 7.5 | 7.2 | 7.3 | 7.3 | 6.6 | 6.3 |
| | | B | 6.3 | 8.4 | 6.0 | 10.3 | 9.0 | 7.1 | 6.7 |
| | | **Mean** | **6.6** | **8.0** | **6.6** | **8.8** | **8.2** | **6.9** | **6.5** |
| Extract 3 | irradiated | A | 0.5 | 0.7 | 0.6 | 0.7 | 0.9 | 0.8 | 0.6 |
| | | B | 0.5 | 0.9 | 0.5 | 1.4 | 1.1 | 0.9 | 0.7 |
| | | **Mean** | **0.5** | **0.8** | **0.6** | **1.1** | **1.0** | **0.9** | **0.7** |
| **Total Extractables** | **irradiated** | **Mean** | **98.2** | **95.2** | **96.0** | **94.8** | **95.8** | **96.0** | **92.5** |
| Non-Extractables | irradiated | A | 0.1 | 1.3 | 1.8 | 1.6 | 2.4 | 2.1 | 2.4 |
| | | B | 0.1 | 1.5 | 1.6 | 1.9 | 2.5 | 2.3 | 2.8 |
| | | **Mean** | **0.1** | **1.4** | **1.7** | **1.8** | **2.5** | **2.2** | **2.6** |
| $^{14}CO_2$* | irradiated | A | NA | ND | 0.1 | ND | 0.2 | 0.2 | 0.2 |
| | | B | NA | ND | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 |
| | | **Mean** | **NA** | **ND** | **0.1** | **0.1** | **0.2** | **0.2** | **0.2** |
| Total % recovery | irradiated | A | 99.2 | 96.9 | 98.9 | 95.7 | 98.6 | 99.5 | 96.0 |
| | | B | 97.3 | 96.3 | 96.6 | 97.4 | 98.2 | 97.1 | 94.2 |
| | | **Mean** | **98.3** | **96.6** | **97.8** | **96.6** | **98.4** | **98.3** | **95.1** |
| **Overall Mean ± SD** | | | **97.3 ± 1.2** | | | | | | |

*The nature of the volatiles was assumed to be $CO_2$ but was not determined due to low levels of mineralisation.
[#] Values in brackets correspond to equivalent UK/US days (assuming summer natural midday sunlight intensity at UK/US between 300-400 nm is 67 W/m$^2$ (OECD 2002))
ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 51 Mass balance and distribution of radioactivity: [Phenyl-$^{14}$C]-pydiflumetofen, irradiated, moist soil– individual replicates (values as % of applied)**

| **[Phenyl-$^{14}$C]-pydiflumetofen** | | **Rep** | **Actual experimental days after treatment[#]** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3 (5.4)** | **6 (11.1)** | **8 (16.1)** | **12 (19.3)** | **14 (24.2)** | **15 (28.9)** |
| Extract 1 | irradiated | A | 91.0 | 89.4 | 84.6 | 89.1 | 85.5 | 80.6 | 82.8 |
| | | B | 90.5 | 86.4 | 84.1 | 84.4 | 88.3 | 82.7 | 84.3 |
| | | **Mean** | **90.8** | **87.9** | **84.4** | **86.8** | **86.9** | **81.7** | **83.6** |
| Extract 2 | irradiated | A | 6.3 | 7.7 | 9.9 | 8.3 | 6.3 | 7.4 | 9.5 |
| | | B | 7.1 | 9.9 | 8.7 | 6.6 | 6.9 | 6.5 | 7.6 |
| | | **Mean** | **6.7** | **8.8** | **9.3** | **7.5** | **6.6** | **7.0** | **8.6** |
| Extract 3 | irradiated | A | 0.5 | 0.8 | 0.9 | 0.8 | 0.9 | 0.9 | 1.0 |
| | | B | 0.5 | 1.0 | 0.8 | 0.7 | 0.9 | 1.0 | 0.8 |
| | | **Mean** | **0.5** | **0.9** | **0.9** | **0.8** | **0.9** | **1.0** | **0.9** |
| **Total Extractables** | **irradiated** | **Mean** | **98.0** | **97.6** | **94.5** | **95.0** | **94.4** | **89.6** | **93.0** |
| Non-Extractables | irradiated | A | 0.2 | 1.5 | 1.9 | 2.2 | 1.0 | 3.0 | 3.2 |
| | | B | 0.2 | 1.6 | 1.8 | 2.3 | 1.3 | 3.0 | 3.2 |
| | | **Mean** | **0.2** | **1.6** | **1.9** | **2.3** | **1.3** | **3.0** | **3.2** |
| $^{14}CO_2$* | irradiated | A | NA | 0.2 | 0.2 | 0.3 | 0.4 | 0.4 | 0.4 |
| | | B | NA | 0.2 | 0.2 | 0.4 | 0.3 | 0.4 | 0.4 |
| | | **Mean** | **NA** | **0.2** | **0.2** | **0.4** | **0.4** | **0.4** | **0.4** |
| Total % recovery | irradiated | A | 98.0 | 99.6 | 97.5 | 100.7 | 94.1 | 92.3 | 96.9 |
| | | B | 98.3 | 99.1 | 95.6 | 94.4 | 98.0 | 93.5 | 96.2 |
| | | **Mean** | **98.2** | **99.4** | **96.6** | **97.6** | **96.1** | **92.9** | **96.6** |
| **Overall Mean ± SD** | | | **96.8 ± 2.0** | | | | | | |

*The nature of the volatiles was assumed to be $CO_2$ but was not determined due to low levels of mineralisation.
[#] Values in brackets correspond to equivalent UK/US days (assuming summer natural midday sunlight intensity at UK/US between 300-400 nm is 67 W/m$^2$ (OECD 2002))
NA: Not applicable

**Table B.8. 52 Mass balance and distribution of radioactivity: [Pyrazole-$^{14}$C]-pydiflumetofen, dark control, moist soil– individual replicates (values as % of applied)**

| **[Pyrazole-$^{14}$C]-pydiflumetofen** | | **Rep** | **Actual experimental days after treatment** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3** | **6** | **8** | **11[1]** | **14** | **15** |
| Extract 1 | dark | A | 91.8 | 84.6 | 90.5 | 89.2 | 87.1 | 84.8 | 86.8 |
| | | B | 90.4 | 87.3 | 87.7 | 90.4 | 30.4 | 86.5 | 86.6 |
| | | **Mean** | **91.1** | **86.0** | **89.1** | **89.8** | **87.1** | **85.7** | **86.7** |
| Extract 2 | dark | A | 6.8 | 6.1 | 6.2 | 6.9 | 6.7 | 6.9 | 7.8 |
| | | B | 6.3 | 7.0 | 6.2 | 5.6 | 7.4 | 6.7 | 6.9 |
| | | **Mean** | **6.6** | **6.6** | **6.2** | **6.3** | **6.7** | **6.8** | **7.4** |
| Extract 3 | dark | A | 0.5 | 0.6 | 0.5 | 0.6 | 0.5 | 0.9 | 0.8 |
| | | B | 0.5 | 0.7 | 0.5 | 0.6 | 0.8 | 0.9 | 0.7 |
| | | **Mean** | **0.5** | **0.7** | **0.5** | **0.6** | **0.5** | **0.9** | **0.8** |
| **Total Extractables** | **dark** | **Mean** | **98.2** | **93.2** | **95.8** | **96.7** | **94.3** | **93.4** | **94.8** |
| Non-Extractables | dark | A | 0.1 | 1.1 | 1.4 | 1.8 | 1.8 | 1.8 | 2.0 |
| | | B | 0.1 | 1.2 | 1.4 | 1.7 | 1.9 | 2.0 | 2.0 |
| | | **Mean** | **0.1** | **1.2** | **1.4** | **1.8** | **1.8** | **1.9** | **2.0** |
| $^{14}CO_2$* | dark | A | NA | ND | ND | ND | ND | ND | ND |
| | | B | NA | ND | ND | ND | ND | ND | ND |
| | | **Mean** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | dark | A | 99.2 | 92.4 | 98.6 | 98.5 | 96.1 | 94.4 | 97.4 |
| | | B | 97.3 | 96.2 | 95.8 | 98.3 | 40.5 | 96.1 | 96.2 |
| | | **Mean** | **98.3** | **94.3** | **97.2** | **98.4** | **96.1** | **95.3** | **96.8** |
| **Overall Mean ± SD** | | | **96.6 ± 1.5** | | | | | | |

[1] Replicate B was excluded from subsequent calculations as it was anomalous. It is assumed that a small portion of the soil had become dislodged from the unit and with it lost a significant amount of applied radioactivity.
*The nature of the volatiles was assumed to be $CO_2$ but was not determined due to low levels of mineralisation.
ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 53 Mass balance and distribution of radioactivity: [Phenyl-$^{14}$C]-pydiflumetofen, dark control, moist soil– individual replicates (values as % of applied)**

| **[Phenyl-$^{14}$C]-SY N545974** | | **Rep** | **Actual experimental days after treatment** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3** | **6** | **8** | **12** | **14** | **15** |
| Extract 1 | dark | A | 91.0 | 86.9 | 93.2 | 82.7 | 85.0 | 87.0 | 88.9 |
| | | B | 90.5 | 88.8 | 87.1 | 85.1 | 88.2 | 86.0 | 83.3 |
| | | **Mean** | **90.8** | **87.9** | **90.2** | **83.9** | **86.6** | **86.5** | **86.1** |
| Extract 2 | dark | A | 6.3 | 9.0 | 6.3 | 7.1 | 6.7 | 6.8 | 7.0 |
| | | B | 7.1 | 6.5 | 6.9 | 5.9 | 6.7 | 6.9 | 6.5 |
| | | **Mean** | **6.7** | **7.8** | **6.6** | **6.5** | **6.7** | **6.9** | **6.8** |
| Extract 3 | dark | A | 0.5 | 0.9 | 0.6 | 0.7 | 0.9 | 0.9 | 0.7 |
| | | B | 0.5 | 0.6 | 0.6 | 0.6 | 0.8 | 0.9 | 0.6 |
| | | Mean | 0.5 | 0.8 | 0.6 | 0.7 | 0.9 | 0.9 | 0.7 |
| **Total Extractables** | **dark** | **Mean** | **98.0** | **96.4** | **97.4** | **91.1** | **94.2** | **94.3** | **93.5** |
| Non-Extractables | dark | A | 0.2 | 1.6 | 1.7 | 2.0 | 1.6 | 2.2 | 2.0 |
| | | B | 0.2 | 1.3 | 1.7 | 1.9 | 1.9 | 2.0 | 2.1 |
| | | **Mean** | **0.2** | **1.5** | **1.7** | **2.0** | **1.8** | **2.1** | **2.1** |
| $^{14}CO_2$* | dark | A | NA | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 |
| | | B | NA | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 |
| | | **Mean** | **NA** | **0.1** | **0.1** | **0.1** | **0.2** | **0.2** | **0.2** |
| Total % recovery | dark | A | 98.0 | 98.5 | 101.9 | 92.6 | 94.4 | 97.1 | 98.8 |
| | | B | 98.3 | 97.3 | 96.4 | 93.6 | 97.8 | 96.0 | 92.7 |
| | | **Mean** | **98.2** | **97.9** | **99.2** | **93.1** | **96.1** | **96.6** | **95.8** |
| **Overall Mean ± SD** | | | **96.7 ± 2.0** | | | | | | |

*The nature of the volatiles was assumed to be $CO_2$ but was not determined due to low levels of mineralisation.
NA: Not applicable

**Findings: Characterisation of radioactivity**

Distribution of extractable radioactivity is presented below. Degradation of pydiflumetofen in all the dark controls under both dry and moist conditions was negligible. Degradation of pydiflumetofen was relatively slow in irradiated samples treated with [pyrazole-5-$^{14}$C]-pydiflumetofen or [phenyl-U-$^{14}$C]-pydiflumetofen, regardless of experimental conditions.

No single metabolite was observed at > 3.5% AR. SYN545547 was observed at levels of up to 2.7% AR (in a single replicate) in irradiated samples. Levels in irradiated soil appeared to be slightly elevated compared to those in the dark controls. As SYN545547 was also found in the application solutions at levels of 1.2 – 1.3% AR, SYN545547 was not regarded by the applicant as a true photo-degradation product. There was little or no evidence that this metabolite was increasing at the end of the study. Levels of formation under illumination were marginally higher than in the dark controls. This may be related to the greater degradation of the parent under illuminated conditions. However the HSE evaluation concludes that degradation was slow and no metabolites reached levels that triggered further assessment.

**Table B.8. 54 Phototransformation of [Pyrazole-$^{14}$C]-pydiflumetofen in irradiated dry soil, expressed as percentage of the applied radioactivity (individual replicates)**

| [Pyrazole-$^{14}$C]-pydiflumetofen | | Rep | Actual experimental days after treatment[#] | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3 (5.2)** | **5 (9.9)** | **8 (14.5)** | **10 (20.4)** | **12 (25.1)** | **16 (29.0)** |
| Parent compound | irradiated | A | 89.7 | 90.6 | 95.2 | 92.1 | 88.9 | 84.3 | 87.7 |
| | | B | 97.8 | 90.7 | 93.4 | 90.8 | 86.3 | 87.9 | 77.4 |
| | | **Mean** | **93.8** | **90.7** | **94.3** | **91.5** | **87.6** | **86.1** | **82.6** |
| SYN545547 | irradiated | A | 1.5 | 1.7 | 2.2 | 2.1 | 1.2 | 1.9 | 1.8 |
| | | B | 1.4 | 1.2 | 1.6 | 1.7 | 1.9 | 2.7 | 1.4 |
| | | **Mean** | **1.4** | **1.5** | **1.9** | **1.9** | **1.5** | **2.3** | **1.6** |
| Unidentified regions | irradiated | A | 1.1 | 2.4 | 1.2 | 2.2 | 4.7 | 6.7 | 1.4 |
| | | B | 1.1 | 2.1 | 1.6 | 3.2 | 3.5 | 5.7 | 7.3 |
| | | **Mean** | **1.1** | **2.2** | **1.4** | **2.7** | **4.1** | **6.2** | **4.3** |
| Largest single unidentified region[1] | irradiated | A | 1.1 | 1.5 | 1.2 | 1.3 | 1.6 | 2.4 | 0.8 |
| | | B | 1.1 | 1.8 | 1.6 | 1.9 | 1.4 | 2.1 | 3.0 |
| Unresolved background | irradiated | A | 1.1 | 1.1 | 0.9 | 1.1 | 1.1 | 0.4 | 0.2 |
| | | B | 0.6 | 1.0 | 0.9 | 1.8 | 1.5 | ND | 1.7 |
| | | **Mean** | **0.8** | **1.1** | **0.9** | **1.5** | **1.3** | **0.2** | **0.9** |

[1] Included in unidentified regions total

[#] Values in brackets correspond to equivalent UK/US days (assuming summer natural midday sunlight intensity at UK/US between 300-400 nm is 67 W/m$^2$ (OECD 2002))

ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 55 Phototransformation of [Phenyl-$^{14}$C]-pydiflumetofen in irradiated dry soil, expressed as percentage of the applied radioactivity (individual replicates)**

| [Phenyl-$^{14}$C]-pydiflumetofen | | Rep | Actual experimental days after treatment[#] | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3 (6.0)** | **5 (10.8)** | **8 (16.0)** | **10 (19.8)** | **12 (25.6)** | **14 (31.1)** |
| Parent compound | irradiated | A | 95.6 | 94.0 | 92.3 | 78.1 | 79.1 | 84.1 | 73.5 |
| | | B | 92.3 | 92.4 | 93.6 | 91.1 | 84.9 | 93.4 | 87.2 |
| | | **Mean** | **94.0** | **93.2** | **93.0** | **84.6** | **82.0** | **88.8** | **80.3** |
| SYN545547 | irradiated | A | 1.4 | 1.4 | 1.2 | 1.4 | 1.5 | 2.0 | 0.8 |
| | | B | 1.6 | 1.3 | 0.9 | 1.4 | 1.9 | 1.9 | 1.7 |
| | | **Mean** | **1.5** | **1.3** | **1.0** | **1.4** | **1.7** | **1.9** | **1.3** |
| Unidentified regions | irradiated | A | 0.4 | 1.3 | 2.1 | 4.0 | 6.3 | 4.0 | 12.2 |
| | | B | 0.6 | 0.7 | 1.0 | 2.3 | 3.0 | 2.0 | 2.7 |
| | | **Mean** | **0.5** | **1.0** | **1.6** | **3.1** | **4.7** | **3.0** | **7.4** |
| Largest single unidentified region[1] | irradiated | A | 0.4 | 0.6 | 1.3 | 1.0 | 2.0 | 2.0 | 3.5 |
| | | B | 0.6 | 0.7 | 0.4 | 0.9 | 1.2 | 1.0 | 1.4 |
| Unresolved background | irradiated | A | 1.4 | 0.7 | 1.1 | 1.3 | 1.6 | 1.2 | 1.6 |
| | | B | 0.8 | 0.5 | 1.4 | 1.3 | 1.4 | 0.6 | 0.4 |
| | | **Mean** | **1.1** | **0.6** | **1.3** | **1.3** | **1.5** | **0.9** | **1.0** |

[1] Included in unidentified regions total

[#] Values in brackets correspond to equivalent UK/US days (assuming summer natural midday sunlight intensity at UK/US between 300-400 nm is 67 W/m$^2$ (OECD 2002))

NA: Not applicable

**Table B.8. 56 Phototransformation of [Pyrazole-$^{14}$C]-pydiflumetofen in dark control dry soil, expressed as percentage of the applied radioactivity (individual replicates)**

| [Pyrazole-$^{14}$C]-pydiflumetofen | | Rep | Actual experimental days after treatment | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3** | **5** | **8** | **10** | **12** | **16** |
| Parent compound | dark | A | 89.7 | 92.4 | 91.6 | 91.7 | 92.7 | 91.4 | 93.2 |
| | | B | 97.8 | 91.4 | 80.2 | 87.0 | 93.4 | 78.6 | 85.4 |
| | | **Mean** | **93.8** | **91.9** | **85.9** | **89.3** | **93.1** | **85.0** | **89.3** |
| SYN545547 | dark | A | 1.5 | 1.5 | 1.4 | 1.5 | 1.1 | 0.6 | 0.4 |
| | | B | 1.4 | 0.9 | 1.1 | 1.1 | 1.2 | 1.5 | 0.8 |
| | | **Mean** | **1.4** | **1.2** | **1.2** | **1.3** | **1.1** | **1.0** | **0.6** |
| Unidentified regions | dark | A | 1.1 | 1.3 | 0.7 | 1.1 | 1.9 | 1.3 | 1.2 |
| | | B | 1.1 | 1.1 | 1.2 | 1.4 | 1.2 | 1.5 | 0.9 |
| | | **Mean** | **1.1** | **1.2** | **0.9** | **1.2** | **1.5** | **1.4** | **1.1** |
| Largest single unidentified region[1] | dark | A | 1.1 | 1.1 | 0.7 | 1.1 | 0.6 | 1.3 | 0.8 |
| | | B | 1.1 | 1.1 | 1.2 | 1.4 | 1.2 | 1.5 | 0.6 |
| Unresolved background | dark | A | 1.1 | 0.5 | 1.3 | 1.1 | 0.8 | 0.2 | 0.1 |
| | | B | 0.6 | 1.3 | 0.8 | 0.2 | 0.7 | 0.5 | 1.5 |
| | | **Mean** | **0.8** | **0.9** | **1.1** | **0.7** | **0.8** | **0.4** | **0.8** |

[1] Included in unidentified regions total
ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 57 Phototransformation of [Phenyl-$^{14}$C]-pydiflumetofen in dark control dry soil, expressed as percentage of the applied radioactivity (individual replicates)**

| [Phenyl-$^{14}$C]-pydiflumetofen | | Rep | Actual experimental days after treatment | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3** | **5** | **8** | **10** | **12** | **14** |
| Parent compound | dark | A | 95.6 | 91.8 | 79.5 | 89.3 | 95.9 | 96.3 | 98.4 |
| | | B | 92.3 | 77.3 | 90.4 | 84.4 | 95.3 | 95.0 | 97.5 |
| | | **Mean** | **94.0** | **84.6** | **84.9** | **86.9** | **95.6** | **95.6** | **97.9** |
| SYN545547 | dark | A | 1.4 | 0.7 | 1.1 | 0.7 | 1.2 | 0.8 | 1.0 |
| | | B | 1.6 | 0.8 | 0.9 | 0.4 | 0.9 | 1.1 | 0.9 |
| | | **Mean** | **1.5** | **0.8** | **1.0** | **0.5** | **1.1** | **1.0** | **0.9** |
| Unidentified regions | dark | A | 0.4 | 0.9 | ND | 0.8 | ND | 1.2 | 0.9 |
| | | B | 0.6 | 0.4 | 0.8 | 1.4 | 0.3 | 1.2 | ND |
| | | **Mean** | **0.5** | **0.7** | **0.4** | **1.1** | **0.2** | **1.2** | **0.4** |
| Largest single unidentified region[1] | dark | A | 0.4 | 0.5 | NA | 0.3 | NA | 0.6 | 0.5 |
| | | B | 0.6 | 0.4 | 0.4 | 0.6 | 0.3 | 0.7 | NA |
| Unresolved background | dark | A | 1.4 | 0.4 | ND | 0.2 | 0.6 | 0.2 | 0.8 |
| | | B | 0.8 | 0.9 | 1.4 | 0.7 | 1.3 | 0.9 | 0.8 |
| | | **Mean** | **1.1** | **0.6** | **0.7** | **0.5** | **0.9** | **0.5** | **0.8** |

[1] Included in unidentified regions total
ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 58 Phototransformation of [Pyrazole-$^{14}$C]-pydiflumetofen in irradiated moist soil, expressed as percentage of the applied radioactivity (individual replicates)**

| **[Pyrazole-$^{14}$C]-pydiflumetofen** | | **Rep** | **Actual experimental days after treatment[#]** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3 (5.0)** | **6 (10.9)** | **8 (15.9)** | **11 (19.9)** | **14 (24.9)** | **15 (30.3)** |
| Parent compound | irradiated | A | 95.9 | 91.5 | 94.3 | 91.4 | 92.4 | 94.5 | 90.9 |
| | | B | 92.6 | 92.9 | 92.3 | 92.8 | 91.0 | 93.1 | 87.7 |
| | | **Mean** | **94.2** | **92.2** | **93.3** | **92.1** | **91.7** | **93.8** | **89.3** |
| SYN545547 | irradiated | A | 0.6 | 1.8 | 1.6 | 1.1 | 1.9 | 1.8 | 0.7 |
| | | B | 1.3 | 1.5 | 1.5 | 0.5 | 1.4 | 1.0 | 1.7 |
| | | **Mean** | **0.9** | **1.7** | **1.5** | **0.8** | **1.7** | **1.4** | **1.2** |
| Unidentified regions | irradiated | A | 1.6 | 1.9 | ND | 0.4 | 1.1 | 0.8 | 1.8 |
| | | B | 1.8 | ND | 0.8 | 0.9 | 2.0 | 0.6 | 0.9 |
| | | **Mean** | **1.7** | **0.9** | **0.4** | **0.6** | **1.6** | **0.7** | **1.3** |
| Largest single unidentified region[1] | irradiated | A | 0.8 | 1.3 | NA | 0.4 | 0.9 | 0.8 | 0.9 |
| | | B | 1.2 | NA | 0.8 | 0.9 | 2.0 | 0.6 | 0.9 |
| Unresolved background | irradiated | A | 1.0 | 0.4 | 1.1 | 1.2 | 0.6 | 0.1 | 0.3 |
| | | B | 1.6 | 0.4 | 0.4 | 1.3 | 1.1 | ND | 1.1 |
| | | **Mean** | **1.3** | **0.4** | **0.8** | **1.3** | **0.9** | **0.1** | **0.7** |

[1] Included in unidentified regions total

[#] Values in brackets correspond to equivalent UK/US days (assuming summer natural midday sunlight intensity at UK/US between 300-400 nm is 67 W/m$^2$ (OECD 2002))

ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 59 Phototransformation of [Phenyl-$^{14}$C]-pydiflumetofen in irradiated moist soil, expressed as percentage of the applied radioactivity (individual replicates)**

| **[Phenyl-$^{14}$C]-pydiflumetofen** | | **Rep** | **Actual experimental days after treatment[#]** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3 (5.4)** | **6 (11.1)** | **8 (16.1)** | **12 (19.3)** | **14 (24.2)** | **15 (28.9)** |
| Parent compound | irradiated | A | 95.4 | 95.0 | 91.5 | 94.1 | 89.4 | 85.0 | 90.5 |
| | | B | 96.1 | 96.1 | 92.4 | 89.9 | 94.1 | 88.6 | 89.9 |
| | | **Mean** | **95.7** | **95.5** | **91.9** | **92.0** | **91.7** | **86.8** | **90.2** |
| SYN545547 | irradiated | A | 1.1 | 1.5 | 1.6 | 2.2 | 1.2 | 1.6 | 1.4 |
| | | B | 1.4 | 0.9 | 0.5 | 0.9 | 1.2 | 0.7 | 1.1 |
| | | **Mean** | **1.3** | **1.2** | **1.1** | **1.6** | **1.2** | **1.2** | **1.3** |
| Unidentified regions | irradiated | A | 0.4 | ND | 1.0 | 1.1 | 0.9 | 0.8 | 1.0 |
| | | B | 0.3 | ND | ND | ND | ND | 0.8 | 0.7 |
| | | **Mean** | **0.4** | **ND** | **0.5** | **0.5** | **0.4** | **0.8** | **0.9** |
| Largest single unidentified region[1] | irradiated | A | 0.4 | NA | 1.0 | 1.1 | 0.9 | 0.8 | 1.0 |
| | | B | 0.3 | NA | NA | NA | NA | 0.8 | 0.7 |
| Unresolved background | irradiated | A | 0.9 | 1.5 | 1.3 | 0.8 | 1.2 | 1.6 | 0.4 |
| | | B | 0.3 | 0.4 | 0.7 | 0.9 | 0.8 | ND | 0.9 |
| | | **Mean** | **0.6** | **0.9** | **1.0** | **0.8** | **1.0** | **0.8** | **0.6** |

[1] Included in unidentified regions total

[#] Values in brackets correspond to equivalent UK/US days (assuming summer natural midday sunlight intensity at UK/US between 300-400 nm is 67 W/m$^2$ (OECD 2002))

ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 60 Phototransformation of [Pyrazole-$^{14}$C]-pydiflumetofen in dark control moist soil, expressed as percentage of the applied radioactivity (individual replicates)**

| [Pyrazole-$^{14}$C]-pydiflumetofen | | Rep | Actual experimental days after treatment | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3** | **6** | **8** | **11** | **14** | **15** |
| Parent compound | dark | A | 95.9 | 87.5 | 94.9 | 92.4 | 91.4 | 89.6 | 92.7 |
| | | B | 92.6 | 92.5 | 92.0 | 93.1 | 38.2[#] | 92.4 | 91.9 |
| | | **Mean** | **94.2** | **90.0** | **93.4** | **92.7** | **91.4** | **91.0** | **92.3** |
| SYN545547 | dark | A | 0.6 | 1.0 | 1.3 | 1.5 | 1.0 | 0.8 | 1.3 |
| | | B | 1.3 | 1.1 | 0.9 | ND | 0.3[#] | ND | 0.9 |
| | | **Mean** | **0.9** | **1.0** | **1.1** | **0.8** | **1.0** | **0.4** | **1.1** |
| Unidentified regions | dark | A | 1.6 | 1.9 | 1.0 | 1.4 | 0.9 | 1.2 | ND |
| | | B | 1.8 | 0.6 | 1.4 | 3.2 | ND[#] | 1.0 | 1.1 |
| | | **Mean** | **1.7** | **1.3** | **1.2** | **2.3** | **0.9** | **1.1** | **0.5** |
| Largest single unidentified region[1] | dark | A | 0.8 | 1.4 | 1.0 | 1.4 | 0.9 | 1.2 | NA |
| | | B | 1.2 | 0.4 | 0.9 | 1.9 | NA | 0.6 | 0.7 |
| Unresolved background | dark | A | 1.0 | 1.0 | 0.1 | 1.4 | 1.1 | 1.0 | 1.4 |
| | | B | 1.6 | 0.8 | 0.2 | 0.3 | 0.1[#] | 0.7 | 0.3 |
| | | **Mean** | **1.3** | **0.9** | **0.2** | **0.9** | **1.1** | **0.9** | **0.9** |

[1] Included in unidentified regions total
ND: Not detected, or <0.1% AR, NA: Not applicable

**Table B.8. 61 Phototransformation of [Phenyl-$^{14}$C]-pydiflumetofen in dark control moist soil, expressed as percentage of the applied radioactivity (individual replicates)**

| [Phenyl-$^{14}$C]-pydiflumetofen | | Rep | Actual experimental days after treatment | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **0** | **3** | **6** | **8** | **12** | **14** | **15** |
| Parent compound | dark | A | 95.4 | 95.9 | 96.7 | 88.9 | 89.8 | 93.5 | 94.9 |
| | | B | 96.1 | 95.2 | 91.8 | 90.4 | 94.4 | 92.2 | 88.6 |
| | | **Mean** | **95.7** | **95.5** | **94.3** | **89.7** | **92.1** | **92.9** | **91.8** |
| SYN545547 | dark | A | 1.1 | 0.6 | 2.0 | 1.4 | 1.6 | 0.4 | 0.5 |
| | | B | 1.4 | 0.7 | 1.7 | 0.9 | 1.2 | 1.0 | 0.4 |
| | | **Mean** | **1.3** | **0.7** | **1.8** | **1.1** | **1.4** | **0.7** | **0.4** |
| Unidentified regions | dark | A | 0.4 | ND | ND | ND | ND | 0.6 | 0.4 |
| | | B | 0.3 | ND | ND | ND | ND | 0.4 | 0.4 |
| | | **Mean** | **0.4** | **ND** | **ND** | **ND** | **ND** | **0.5** | **0.4** |
| Largest single unidentified region[1] | dark | A | 0.4 | NA | NA | NA | NA | 0.6 | 0.4 |
| | | B | 0.3 | NA | NA | NA | NA | 0.4 | 0.4 |
| Unresolved background | dark | A | 0.9 | 0.3 | 1.4 | 0.2 | 1.2 | 0.1 | 0.8 |
| | | B | 0.3 | 0.1 | 1.2 | 0.3 | 0.1 | 0.3 | 1.0 |
| | | **Mean** | **0.6** | **0.2** | **1.3** | **0.3** | **0.7** | **0.2** | **0.9** |

[1] Included in unidentified regions total
ND: Not detected, or <0.1% AR, NA: Not applicable

**Findings: Enantiomeric Composition**

The applicant considered that the enantiomeric composition of pydiflumetofen did not change significantly in either the dry or moist irradiated soil during the course of the study. The pydiflumetofen enantiomer ratio was 0.90 to 1.01 in the stock solutions used to prepare the application solutions and 1.00 to 1.10 in the soil sample extracts at the end of the irradiation period. HSE has added calculations of the change in enantiomeric excess.

**Table B.8. 62 Pydiflumetofen enantiomer ratios in stock solutions and moist and dry soil irradiated for 15 days under the Xenon lamp**

| | | % Sample activity as | | | | |
|---|---|---|---|---|---|---|
| **Sample Type** | **Label** | **1st eluting enantiomer** | **2nd eluting enantiomer** | **Enantiomer Ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| Stock solution (SS2) | Pyrazole | 44.35 | 43.70 | 1.01 | 0.74 | |
| Moist soil (16 DAT) | | 44.31 | 40.46 | 1.10 | 4.54 | 3.80 |
| Stock solution (SS1) | Phenyl | 41.19 | 45.58 | 0.90 | -5.06 | |
| Dry soil (16 DAT) | | 48.91 | 48.95 | 1.00 | -0.04 | 5.02 |

Examination of the results indicated that there was a 3.8% change in enantiomer excess from the stock solution in the moist soil by the end of the study and a 5.02% change in enantiomer excess in the dry soil. However it was also noted by HSE that there was less than 50% degradation of pydiflumetofen in the study.

**Kinetic Assessment**

The $DegT_{50}$ and $DegT_{90}$ values were calculated from the data for the $^{14}C$-phenyl ring labelled, $^{14}C$-pyrazole ring labelled pydiflumetofen and for the combined labels from irradiated samples using non-linear regression and first-order kinetics (SFO). Degradation was extrapolated well beyond the 16 day study period (equivalent to 30 summer days), with $DegT_{50}$ reached in approximately one third of the time in irradiated dry soil than in irradiated moist soil. Results are summarised below. Statistical data and visual and residual fitting are only presented from the combined results of the two radiolabels as these are effectively replicates of each other.

**Table B.8. 63 SFO $DegT_{50}$ and $DegT_{90}$ values for [Pyrazole-$^{14}C$]-pydiflumetofen and [Phenyl-$^{14}C$]-pydiflumetofen combined in irradiated and dark control soil**

| **Test System** | **[Dry Soil]** | | | | **[Moist Soil]** | | | |
|---|---|---|---|---|---|---|---|---|
| | **$DegT_{50}$ [days]** | **$DegT_{90}$ [days]** | **$\chi^2$%** | **Prob > t** | **$DegT_{50}$ [days]** | **$DegT_{90}$ [days]** | **$\chi^2$%** | **Prob > t** |
| Irradiated (experimental result) | 77 | 254 | 1.745 | 5.1E-5 | 197 | 654 | 1.005 | 9.8E-5 |
| Dark control (experimental result)* | >1000 | >1000 | 3.384 | 0.5 | 369 | 1227 | 1.005 | 0.026 |
| **Corrected $DT_{50}$ for different latitudes** | | | | | | | | |
| Summer Sunlight 30-50ºN (OECD) | 154 | 507 | - | - | 361 | 1198 | - | - |

All values were extrapolated beyond the test period.

*data to be treated with caution as values were unable to be calculated accurately due to negative confidence intervals as a result of fluctuations in recovery of applied radioactivity.

**Figure B.8. 1 Visual and residual fitting of pydiflumetofen in dry, irradiated soil (two radiolabels combined)**

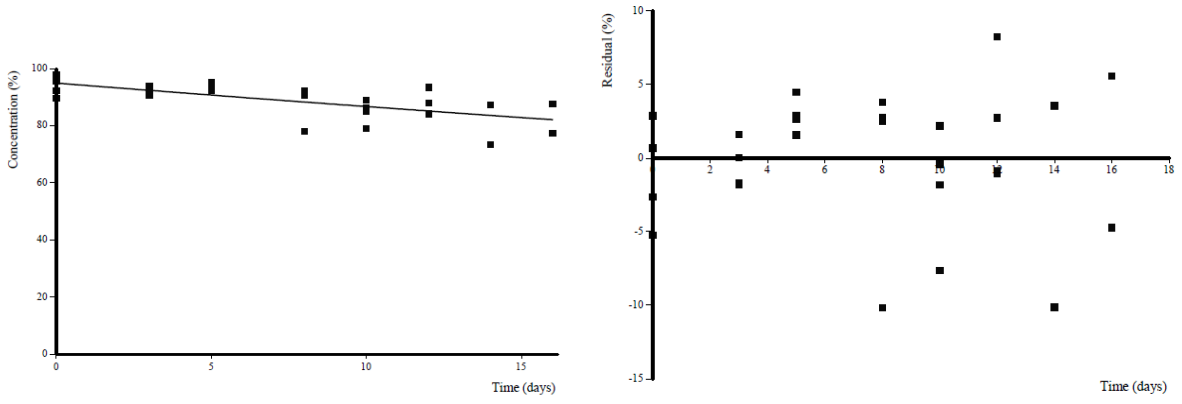


**Figure B.8. 2 Visual and residual fitting of pydiflumetofen in dry, dark control soil (two radiolabels combined)**

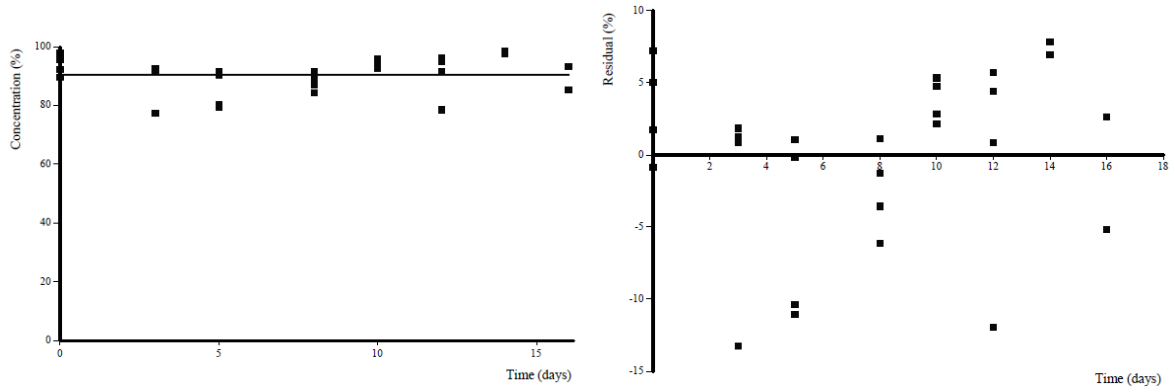



**Figure B.8. 3 Visual and residual fitting of pydiflumetofen in moist, irradiated soil (two radiolabels combined)**

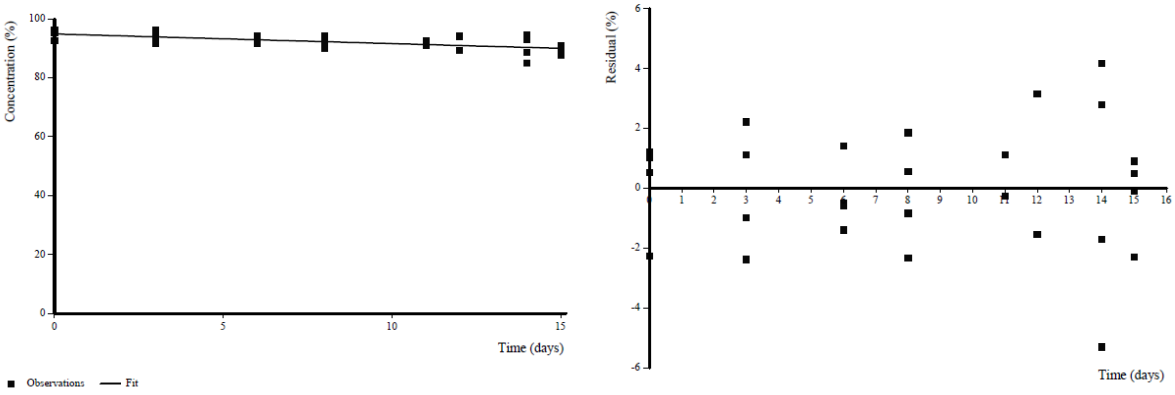
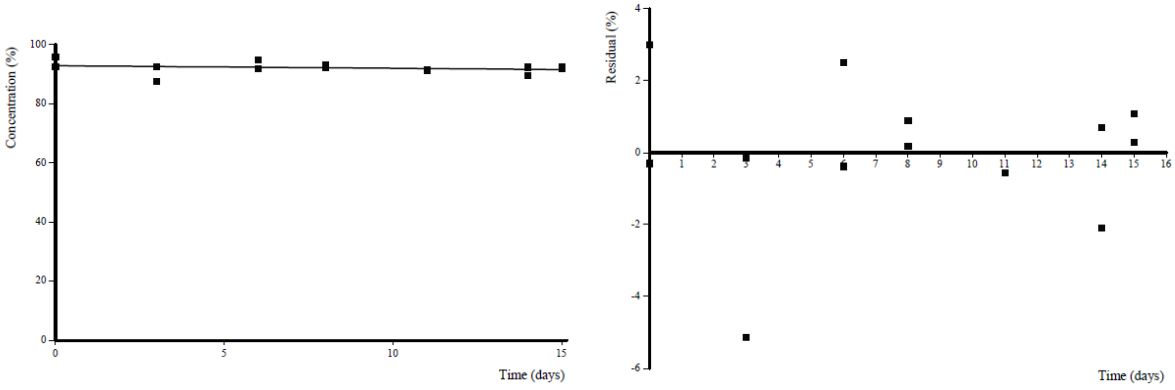



**Figure B.8. 4 Visual and residual fitting of pydiflumetofen in moist, dark control soil (two radiolabels combined)**




HSE accepts the kinetic assessment conducted by the study author. The kinetic assessment of the dark controls gave lower confidence intervals for the rate constant that included zero, i.e. the confidence intervals were negative. This may be partly the result of poor mass balances in some replicates, probably from apparent loss of radioactivity in the first extract. However, in general, there was little degradation seen over the course of the 15 day incubation and the confidence intervals and relatively high t-test results most likely reflect the very low decline seen.

**Conclusion**

The study is considered by HSE to be acceptable and the results can be accepted for risk assessment.

Pydiflumetofen degraded very slowly under both illuminated and dark conditions with little formation of identified metabolites; no soil photolysis metabolites are considered by HSE to trigger risk assessment. However there was evidence that degradation was greater under illuminated conditions in dry and moist soils than in the dark controls. However degradation was still very slow and the calculated DT50 values were extrapolated well beyond study end. The half-life in dry irradiated soils was calculated at 77 experimental days or 154 equivalent summer sunlight days (30-50$^{o}$N), with a longer half-life calculated in moist irradiated soils of 197 experimental days or 361 equivalent summer sunlight days (30-50$^{o}$N). Degradation in the dark controls was negligible over the study period.

The kinetic assessment performed for the a.s. as part of the study is considered by HSE as acceptable.

It was also noted that the enantiomeric ratio did not appear to change significantly in this study. Examination of the results indicated that there was a 3.8% change in enantiomer excess from the stock solution in the moist soil by the end of the study and a 5.02% change in enantiomer excess in the dry soil. As there was less than 50% degradation of pydiflumetofen in the study, the enantiomer excess results have been extrapolated forwards to a point where 50% degradation would be expected assuming a linear relationship for change in enantiomer excess. For the moist soil, the change in enantiomer excess might be >80%. For dry soil, the change in enantiomer excess might be >40%. However it should be noted that this is based on a study duration of 15 days and with an extrapolation so far beyond the study end the predicted change in enantiomer excess is very uncertain.

As indicated, the rate of degradation in in the soil photolysis study is very slow. The extrapolated change in enantiomer excess makes the assumption that the substance remains on the soil surface. In practice this would not be expected to occur. The intended uses in GB are for use as a foliar fungicide on arable field crops. Use on emerged crops would be likely to reduce the intensity of effect of solar irradiation on a soil surface residue due to crop shading. In addition, it is unlikely that a residue would remain entirely on the soil surface, the action of rainfall being likely to transfer most below the immediate surface. Thus it is anticipated that the extent of change in enantiomer excess would be unlikely to be observed in practice. The overall summary of the fate and behaviour of pydiflumetofen at the beginning of this B.8 section describes the considerations of stereoisomerism across the range of the submitted environmental fate studies and the weight of evidence approach that has been taken.

**B.8.1.1.1.4. Enantiomeric composition in soil**

| | |
|---|---|
| **Report:** | Xiuming Wu, Fengshou Dong, Jun Xu, Xingang Liu, Xiaohu Wu, and Yongquan Zheng (2020), Enantioselective separation and dissipation of pydiflumetofen enantiomers in grape and soil by supercritical fluid chromatography–tandem mass spectrometry. Journal of Separation Science, Vol.43, pp. 2217-2227 |

| | |
|---|---|
| **Guideline(s):** | Not known |
| **GLP/GEP:** | Not known |
| **Deviation(s):** | Not applicable |
| **Acceptability** | Yes, but with reservations over the poorly reported experimental method and apparent lack of consistency in behaviour compared to standard regulatory studies |

This published study was identified by the Applicant literature search as being relevant to the environmental fate and behaviour assessment of pydiflumetofen.

The enantiomeric composition of grapes and soil samples was analysed using chiral analysis; only results for soil are reported here. The study reported the method of analysis, the optimization of analytical approaches for successful chiral separation of the enantiomers and supporting method validation data in relative detail. In addition the study reported results of an experiment in which soil residues of pydiflumetofen were measured. Details of the experimental methodology of application to soil, soil sampling methodology and the study conditions were sparse. The soil was described as being a silty loam with a pH of 8.3 (method of pH

determination was unstated) and organic matter content of 13.7 g/kg (1.37% OM, equivalent to approximately 0.8% OC). Application rates were not described. It was not clear whether the study was conducted in a laboratory, glasshouse of field situation. Application was stated to have been to the foliage of grapes. No details of temperature and soil moisture conditions were given. Soil sampling was on five occasions between 0 and approximately 22 days (results only presented graphically thus sample times were estimated from the graphs). It was unclear whether replicate samples or single samples were taken at each sample point. Soil samples were stated to have been extracted with water with the addition of NaCl and $MgSO_4$. There was an additional sample clean-up step. With the chosen clean-up step, average recovery of the enantiomers at a fortification level of 0.10 mg/kg was 94% for the '+' enantiomer and 90% for the '-' enantiomer. The LOQ was stated to be 0.005 mg/kg.

Evaluation of the results was by considering degradation rates and enantiomeric fraction given by the following equations.

The degradation kinetics of the two enantiomers in grape and soil samples were estimated using first-order kinetics.

The enantiomeric fraction (EF), which was used to investigate the enantioselective dissipation of pydiflumetofen enantiomers in grape and soil samples, was described using the following equation:

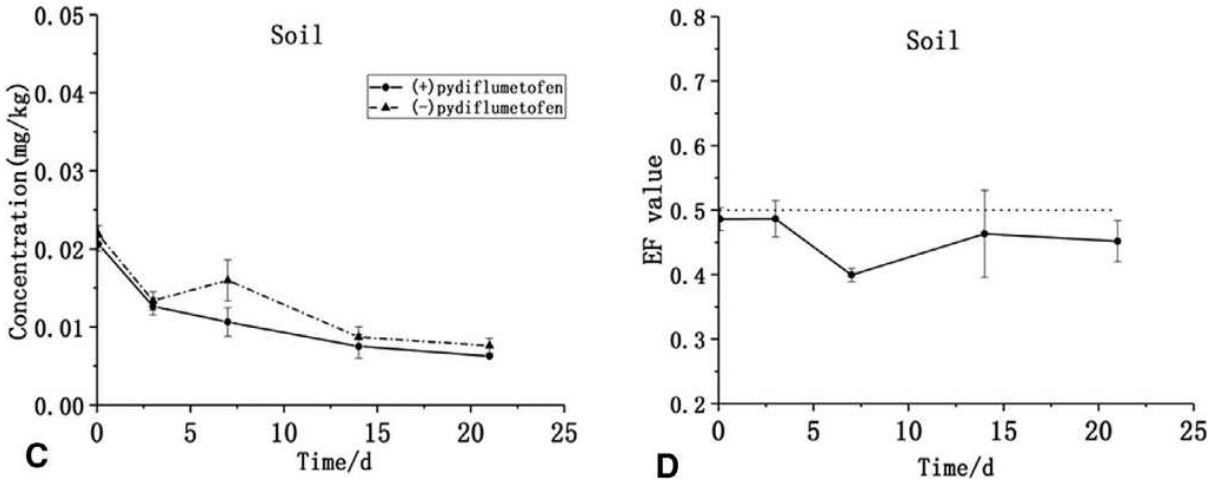
$$EF = \frac{(+)A}{(+)A + (-)A}$$

where (+)A and (−)A represent the concentrations of the two enantiomers. Thus EF = 0.5 represents a racemic mixture, and values for EF range from 0 to 1.

The residue concentrations of both pydiflumetofen enantiomers in soil samples decreased gradually with time after foliar application. The half-lives were estimated as follows.

Soil: (+)-pydiflumetofen: estimated half-life of 13.33 days
Soil: (-)-pydiflumetofen: estimated half-life of 14.75 days

The concentrations determined over time and the associated EF values are in the following graphs:




The study authors considered that (+)-pydiflumetofen was degraded more rapidly than (-)-pydiflumetofen. This was stated to be significantly different using a students paired t-test , $P<0.05$, leading to an enrichment of (+)-pydiflumetofen residues (R-enantiomer of pydiflumetofen). The authors stated that in soil, (+)-pydiflumetofen was preferentially degraded, leading to an enrichment of (-)-pydiflumetofen residues.

HSE notes that the applicant has used the standard (R)/(S) nomenclature in the naming of the enantiomers of pydiflumetofen. It should be noted that this system cannot be transposed directly onto the (+)/(-) nomenclature which refers to the direction of optical rotation of plane-polarised light by an enantiomer. HSE have not

determined the attribution of (R)/(S) for the (+) and (-) enantiomers described in the study. HSE considers that it is the overall behaviour of the different enantiomers that is more important to regulatory decision-making in the first instance.

HSE consider that the results of the study are of interest but have concerns over the lack of detail in the reporting. The calculated half-lives in soil are markedly different to those reported for the racemic mixture. For example, in the 'standard' OECD 307 laboratory aerobic soil route and rate of degradation study, the fastest DT50 was reported to be 398 days over a one year study duration as opposed to 13-15 days in this study. It is possible that this is attributable to a relatively simple extraction methodology using only water with NaCl and MgSO4, whereas the OECD 307 study used mixtures of acetonitrile + ammonium acetate and acetonitrile + water. If the extractability of the residue using water + salts diminished rapidly with time, this could explain the relatively rapid DT50 values in this published study.

Whilst there was an apparent reduction in the EF value over time, HSE note the relatively large deviation in the concentration of the (-)-enantiomer at approximately 6 DAT. This could mean that the apparent change in EF is within experimental error rather than being a definitive change. HSE consider that the apparent difference in EF is similar to that seen in other environmental fate and behaviour studies in the data package.

Overall, HSE considers that the information provided in this study does not contribute significantly to the overall knowledge on the enantiomeric behaviour.

**B.8.1.1.1.5. Summary on route of degradation**

The route of degradation in soil studies and their results are accepted by HSE and can be used for risk assessment.

The fate and behaviour of pydiflumetofen in soils was investigated using both [$^{14}$C]-phenyl labelled and [$^{14}$C]-pyrazole labelled test substance. Data reported below are based on results not including harsh extractions and correspond to mean replicate values. The decision to use data from 'non-harsh' extractions is in line with regulatory precedent.

The degradation of pydiflumetofen under dark, aerobic laboratory soil was investigated in five soils. Degradation was slow and no metabolites were observed at levels ≥5% of applied radioactivity. Consequently, after consideration of the slow degradation of the parent and the profile of metabolite formation, no metabolites in this study were considered by HSE to trigger inclusion in groundwater assessment. Levels of evolved carbon dioxide ($^{14}CO_2$) reached 0.2% to 16.5% AR by the end of the aerobic soil incubations at 365 DAT and unextracted residues increased slowly to between 5.2 12.3% AR and 46.2% AR at 365 DAT.

The degradation of pydiflumetofen under anaerobic laboratory soil conditions was also very slow. The study was conducted with four soils, with a preliminary aerobic incubation of 30 days before flooding the test soil samples. No novel metabolites were identified or formed at ≥5% AR during the anaerobic incubation; consequently no anaerobic soil metabolites were considered to trigger inclusion in groundwater assessment. Mineralisation to carbon dioxide ($^{14}CO_2$) was negligible in all soils, reaching a maximum of <1% AR by the end of soil incubations (120 days). Unextracted residues increased slowly to between 4.8 7.8% AR and 32.6% AR at 120 DAT.

In a laboratory soil photolysis study pydiflumetofen degraded relatively slowly in both dry and moist soil. Whilst the rate of degradation was faster under illuminated conditions than in the dark control incubations, the SFO DT50s were still extrapolated well beyond the 15 day study duration. No novel metabolites were identified or formed at ≥5% AR and did not appear to be increasing at study end. Consequently no soil photolysis metabolites were considered to trigger inclusion in groundwater assessment.

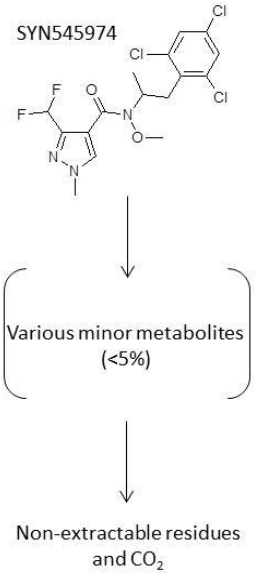
A common metabolite, SYN 545547, was seen in the aerobic, anaerobic and soil photolysis studies. As noted above, it was always observed at low levels (<5% AR) and never observed in quantities which HSE consider would trigger inclusion in risk assessment.

The enantiomeric composition of pydiflumetofen in soils was determined at the end of the aerobic and anaerobic incubations and at the end of the irradiation period in the soil photolysis study compared to the ratio in the

pydiflumetofen application solutions. The pydiflumetofen enantiomer ratio did not change significantly over the course of these degradation studies. However applying the principles of the EFSA Stereoisomers guidance suggests that the change in enantiomer excess, either within the study duration or extrapolated to a point where 50% degradation would be anticipated, would be greater than the 10% threshold considered to be significant. Other environmental fate studies described later in this evaluation also included measurements of the enantiomers. The overall summary of the fate and behaviour of pydiflumetofen at the beginning of this B.8 section describes the considerations of stereoisomerism across the range of the submitted environmental fate studies and the weight of evidence approach that has been taken.

The proposed metabolic pathway in soil is shown in the following figure. In consideration of current guidance applying in GB, no soil metabolites are considered to trigger inclusion in risk assessment.

**Figure B.8. 5 Proposed metabolic pathway of pydiflumetofen in soil**




## B.8.1.1.2. Rate of degradation

### B.8.1.1.2.1. Laboratory studies

#### B.8.1.1.2.1.1. Aerobic degradation rates of the active substance

The aerobic degradation of pydiflumetofen has been determined from the data from the laboratory aerobic degradation study reported by ([redacted], 2015). The kinetics assessment has been performed based on the residues of pydiflumetofen from non-harsh extraction ([redacted], 2015a), which are discussed in the route of degradation section as being the environmentally relevant residues.

| | |
|---|---|
| **Report:** | K-CA 7.1.2.1.1/01. [redacted] (2015a), SYN545974 – Laboratory Degradation Kinetics for Trigger and Modelling Endpoints for Parent, Report Number SYN/48/01-KIN01. JSC International Limited, Harrogate, North Yorkshire, UK<br>(Syngenta File No. SYN545974_10373). |

| | |
|---|---|
| **Report:** | K-CA 7.1.2.1.1/02. [redacted] (2016a), SYN545974 – Laboratory Degradation Kinetics for Trigger and Modelling Endpoints for Parent - Including Harsh Extraction, Report Number SYN/48/01-KIN02. JSC International Limited, Harrogate, North Yorkshire, UK<br>(Syngenta File No. SYN545974_10461. |

| | |
|---|---|
| **Guideline(s):** | FOCUS (2006)[2], FOCUS (2011)[3] |
| **GLP/GEP:** | Not applicable |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**

The rate of degradation of pydiflumetofen under dark aerobic conditions has been studied in the laboratory in five soils by [redacted], 2015 (see B.8.1.1.1.1). The original data from this study were used in the present reports to calculate the rate of degradation of pydiflumetofen in soil, following the guidance in FOCUS Kinetics (2006, 2011) and using the analysis software CAKE v3.1 (2015). These reports present the calculations of $DegT_{50}$ and $DegT_{90}$ values for pydiflumetofen for both trigger and modelling endpoints according to the flowcharts defined in the guidance in FOCUS Kinetics (2006, 2011).

Data were generated according to the data handling recommendations made in the FOCUS guidance for degradation kinetics (FOCUS 2006, 2011). For each soil, kinetic models were fitted to the levels of readily extractable pydiflumetofen (based on non-harsh extracts, [redacted] 2015a).

True replicates were included individually in the optimisations. Both $^{14}$C-phenyl ring labelled pydiflumetofen and $^{14}$C-pyrazole ring labelled pydiflumetofen were investigated in Gartenacker soil with two replicate systems for each label (total of four replicates) per sampling occasion; for kinetic analysis all four of these replicates were fitted in a single optimisation. Levels of pydiflumetofen remained above the limit of detection (LOD) throughout the study in all soils. Correction of values below the LOD was, therefore, not required for these data. Initial pydiflumetofen levels in the model input data were set to the total extractable radioactivity measured in the time zero samples.

All data points were unweighted. For optimal goodness of fit, the initial value was also allowed to be estimated by the model.

Confidence in the resulting parameters has been assessed visually and from the confidence intervals for the α and β parameters of the first order multi compartment (FOMC) model or probability values for a t-test of the rate parameters for the single first order (SFO), dual first order in parallel (DFOP) and hockey stick (HS) models. Where the parameters for a particular model are not significantly different from zero at the 95$^{th}$ or 90$^{th}$ percentile significance level, the study author concluded that the model was not appropriate to represent the degradation behaviour of pydiflumetofen in that soil. The $\chi^2$ error % parameter has been used to determine goodness of fit and where two models are an appropriate fit to the data, the choice of best fit has been based on the lowest value of this parameter. In considering these acceptability criteria, HSE has placed more weight on the visual and residual fits and the $\chi^2$ error. Confidence intervals and t-test results have been given less weight in overall decision-making as experience indicates that their use can lead to rejection of otherwise good fits, particularly where degradation is slow and/or there is variability in the dataset.

The degradation study was conducted at 20°C and at a soil moisture content equal to pF2. Normalisation of endpoints was, therefore, not required.

**Findings**

Results from the kinetic fitting are presented in the following tables; the choice of kinetics chosen for each soil given in the tables are those of the study author and HSE is not necessarily in agreement with these. With respect to modelling endpoints, it is noted that SFO kinetics are generally preferred given the that the majority of environmental exposure models have been developed to SFO parameters. FOCUS Degradation Kinetics guidance allows for greater latitude in accepting SFO kinetics than is recommended for the calculation of persistence ('trigger') endpoints. Therefore the fitting of each of the soils deemed to require DFOP kinetics for modelling has been considered in more detail.

[2] FOCUS (2006). Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005, version 2.0, 434 pp.
[3] FOCUS (2011). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Version 1.0, 436 pp.

**Table B.8. 64 Summary of kinetic parameters and statistics of the fittings for pydiflumetofen – Based on non-harsh residues**

| Soil | Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / Confidence interval (95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|---|
| Gartenacker | SFO | k=0.001744 | Good/Good | 1.34 | k: <0.05 | 398 | 1320 |
| | FOMC | α=15.26 β=8600 | Good/Good | 1.41 | α and β CI contain 0 | 400 | 1400 |
| | **Trigger endpoint: FOMC not better than SFO, SFO selected Modelling endpoint: SFO selected** | | | | | | |
| 18 Acres | SFO | k=0.000411 | Good/Acceptable | 1.42 | k: <0.05 | 1690 | 5600 |
| | FOMC | α=0.05363 β=22.86 | Good/Good | 0.49 | β CI contains 0* | >10000 | >10000 |
| | DFOP | $k_1$=0.03734 $k_2$= 0.000264 g=0.06232 | Good/Good | 0.41 | $k_1$: <0.05 $k_2$: <0.05 | 2380 | 7640 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected Modelling endpoint: SFO selected** | | | | | | |
| Sarpy | SFO | k=0.001527 | Poor/Poor | 7.55 | k: <0.05 | 454 | 1510 |
| | FOMC | α=0.1378 β=6.618 | Good/Good | 3.22 | β CI contains 0* | 1000 | >10000 |
| | DFOP | $k_1$=0.04405 $k_2$= 0.000669 g=0.2693 | Good/Good | 3.15 | $k_1$: <0.05 $k_2$: <0.05 | 567 | 2970 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected Modelling endpoint: SFO not acceptable, 10% of initial level not reached → fit DFOP; DFOP selected** | | | | | | |
| East Anglia | SFO | k=0.000636 | Acceptable/Poor | 2.62 | k: <0.05 | 1090 | 3620 |
| | FOMC | α=0.06078 β=7.123 | Good/Good | 1.06 | α and β CI do not contain 0 | >10000 | >10000 |
| | DFOP | $k_1$=0.09243 $k_2$= 0.000452 g=0.1005 | Good/Good | 0.96 | $k_1$: <0.05 $k_2$: <0.05 | 1300 | 4870 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected Modelling endpoint: SFO not acceptable, 10% of initial level not reached → fit DFOP; DFOP selected** | | | | | | |
| Capay | SFO | k=0.00183 | Poor/Poor | 9.11 | k: <0.05 | 379 | 1260 |
| | FOMC | α= 0.1557 β=5.436 | Good/Good | 3.07 | α and β CI do not contain 0 | 461 | >10000 |
| | DFOP | $k_1$=0.05022 $k_2$= 0.000756 g=0.3183 | Good/Good | 2.54 | $k_1$: <0.05 $k_2$: <0.05 | 410 | 2540 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected Modelling endpoint: SFO not acceptable, 10% of initial level not reached → fit DFOP; DFOP selected** | | | | | | |

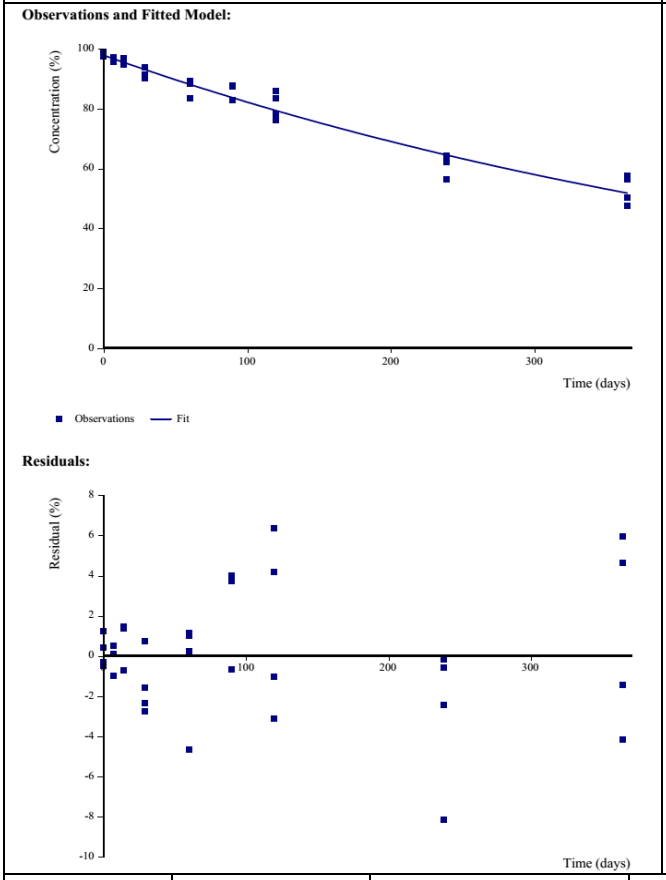
* 95th percentile CI does contain 0 but 90th percentile CI does not contain 0

Visual fits and residual plots are reported below.

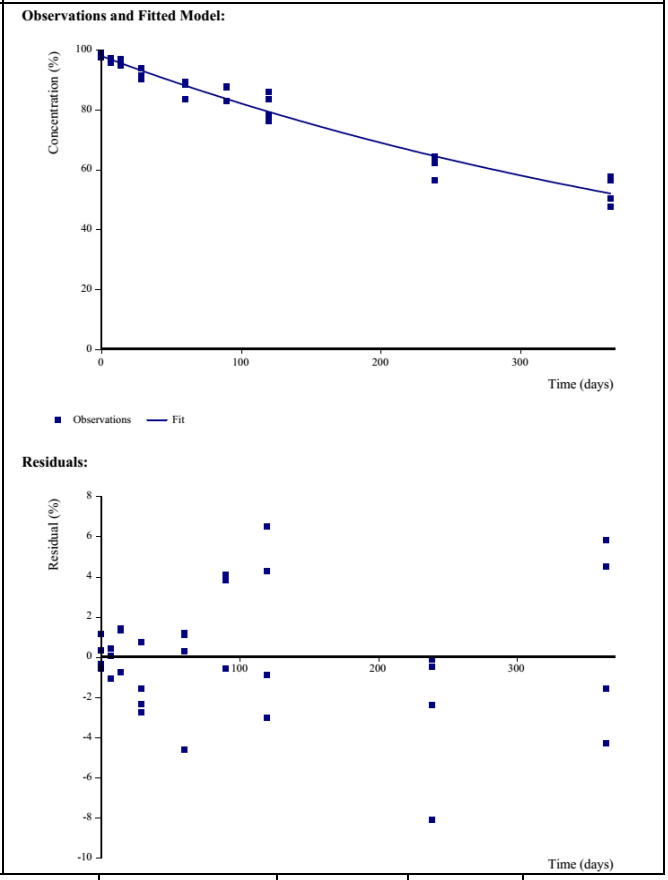
**Figure B.8. 6 Visual fits and residual plots – Based on non-harsh residues**

**Gartenacker (Based on non-harsh residues)**

SFO



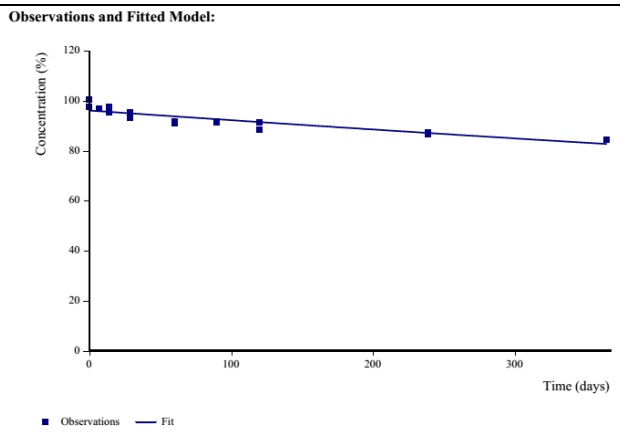

FOMC

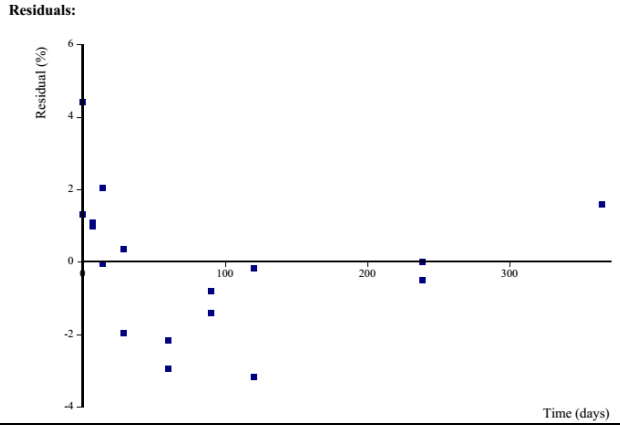



| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.001744 | Good/Good | 1.34 | k: <0.05 | 398 | 1320 |
| FOMC | α=15.26<br>β=8600 | Good/Good | 1.41 | α and β CI contain 0 | 400 | 1400 |
| **Trigger endpoint: FOMC not better than SFO, SFO selected**<br>**Modelling endpoint: SFO selected** | | | | | | |

**18 Acres (Based on non-harsh residues)**

SFO

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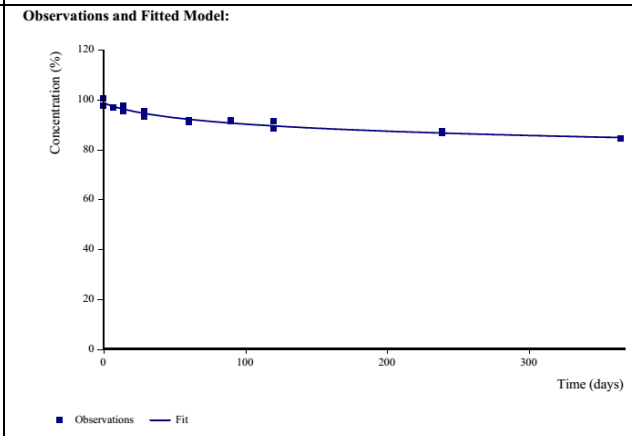
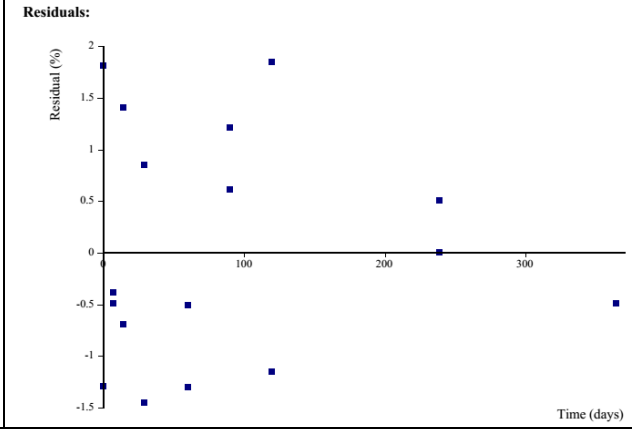
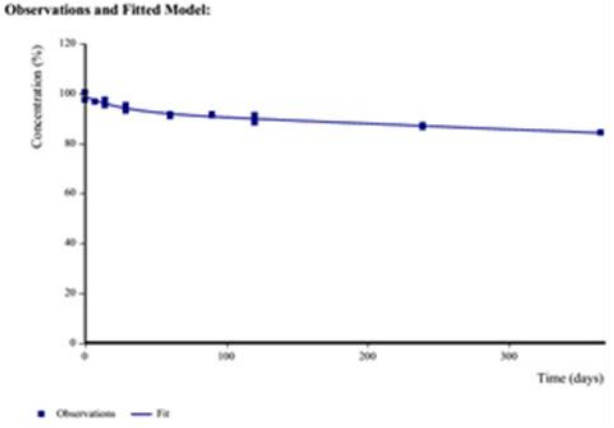
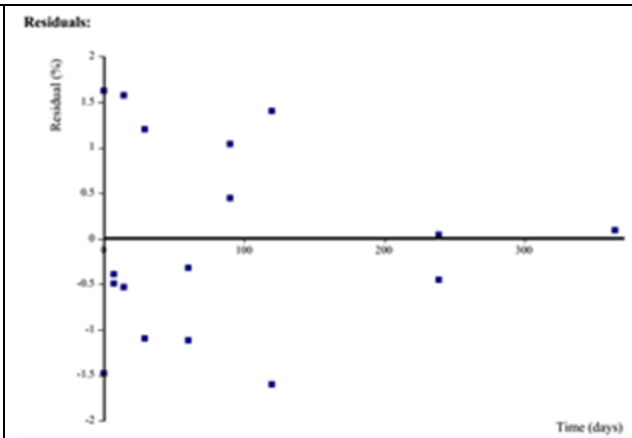



DFOP

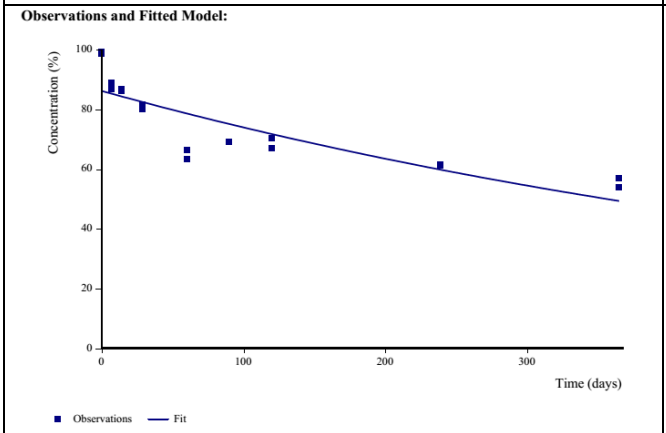


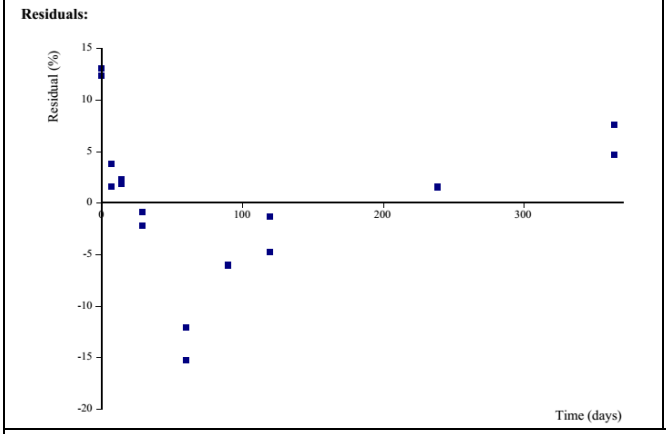




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.000411 | Good/Acceptable | 1.42 | k: <0.05 | 1690 | 5600 |
| FOMC | α=0.05363<br>β=22.86 | Good/Good | 0.49 | β CI contains 0* | >10000 | >10000 |
| DFOP | $k_1$=0.03734<br>$k_2$= 0.000264<br>g=0.06232 | Good/Good | 0.41 | $k_1$: <0.05<br>$k_2$: <0.05 | 2380 | 7640 |
| **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected**<br>**Modelling endpoint: SFO selected** | | | | | | |

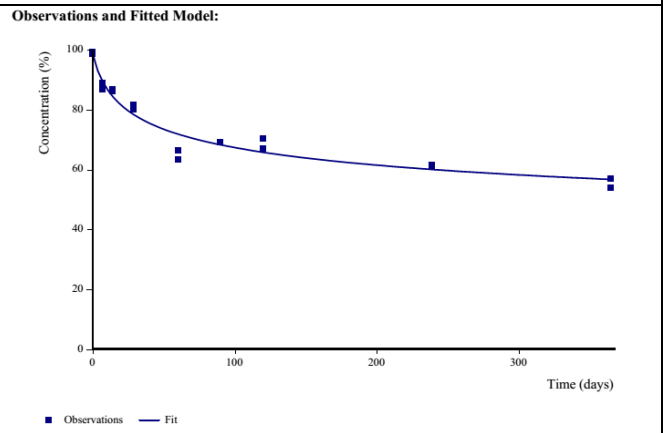
**Sarpy (Based on non-harsh residues)**

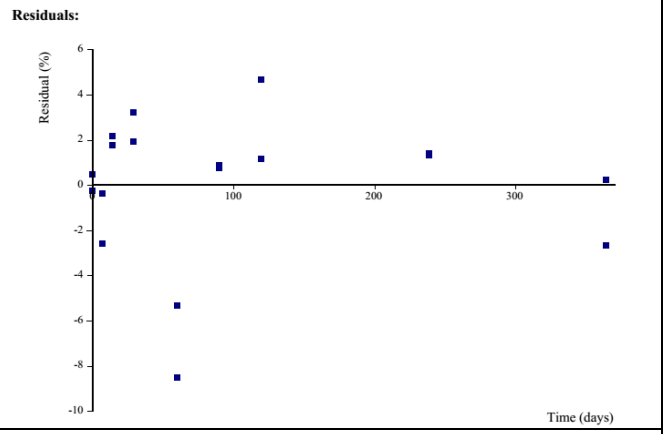
SFO



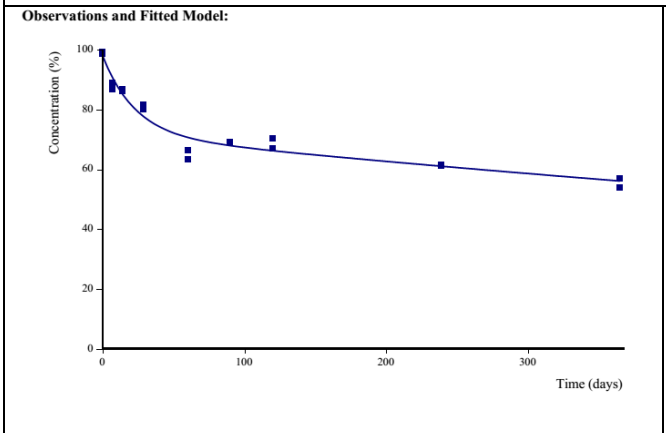



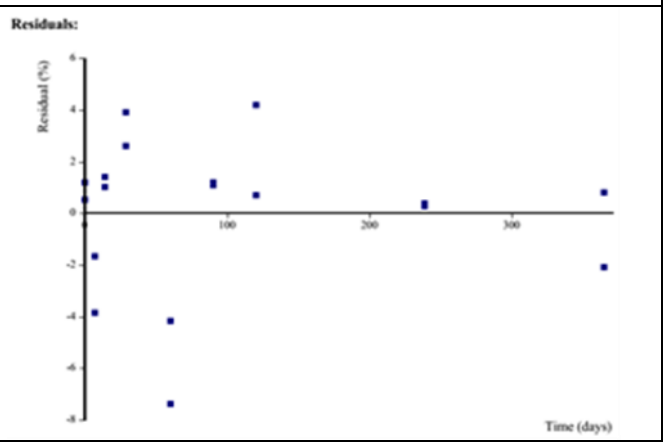

FOMC




DFOP

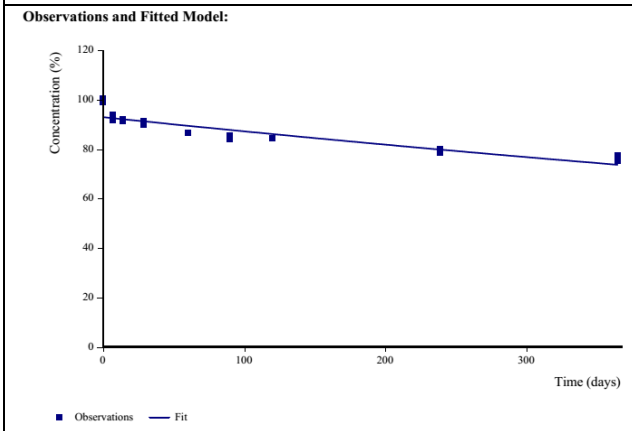


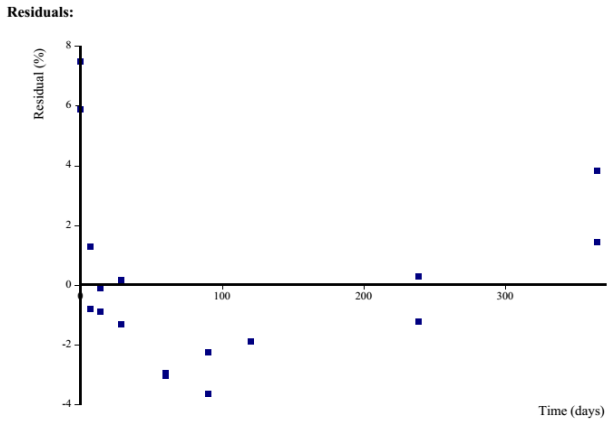




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.001527 | Poor/Poor | 7.55 | k: <0.05 | 454 | 1510 |
| FOMC | α=0.1378<br>β=6.618 | Good/Good | 3.22 | β CI contains 0* | 1000 | >10000 |
| DFOP | $k_1$=0.04405<br>$k_2$= 0.000669<br>g=0.2693 | Good/Good | 3.15 | $k_1$: <0.05<br>$k_2$: <0.05 | 567 | 2970 |
| **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected**<br>**Modelling endpoint: SFO not acceptable, 10% of initial level not reached → fit DFOP; DFOP selected** | | | | | | |

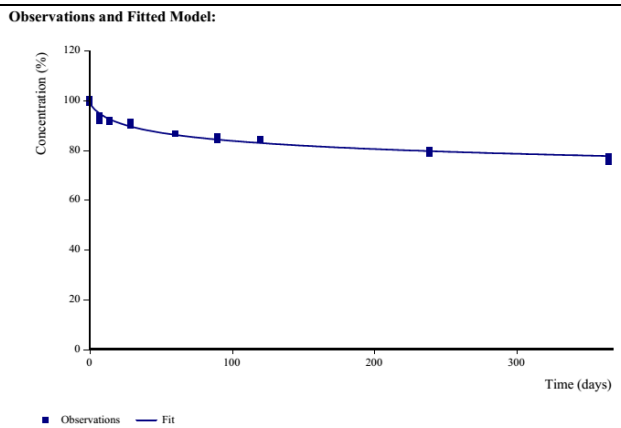
**East Anglia (Based on non-harsh residues)**

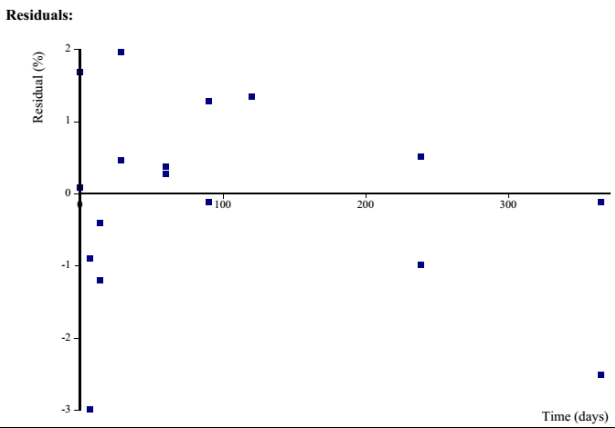
SFO



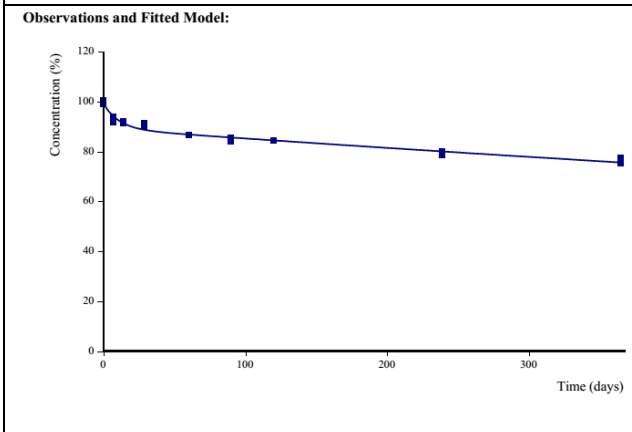



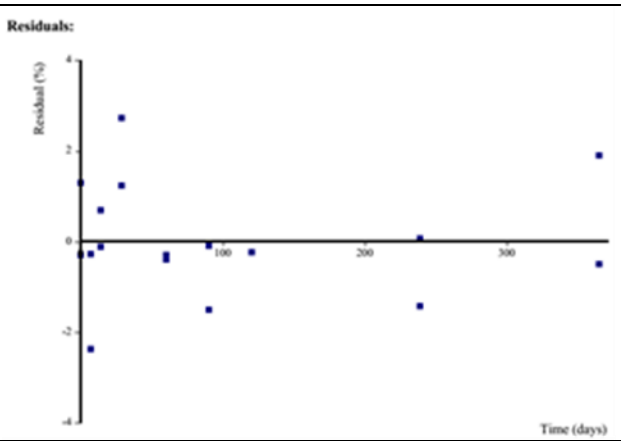

FOMC




DFOP



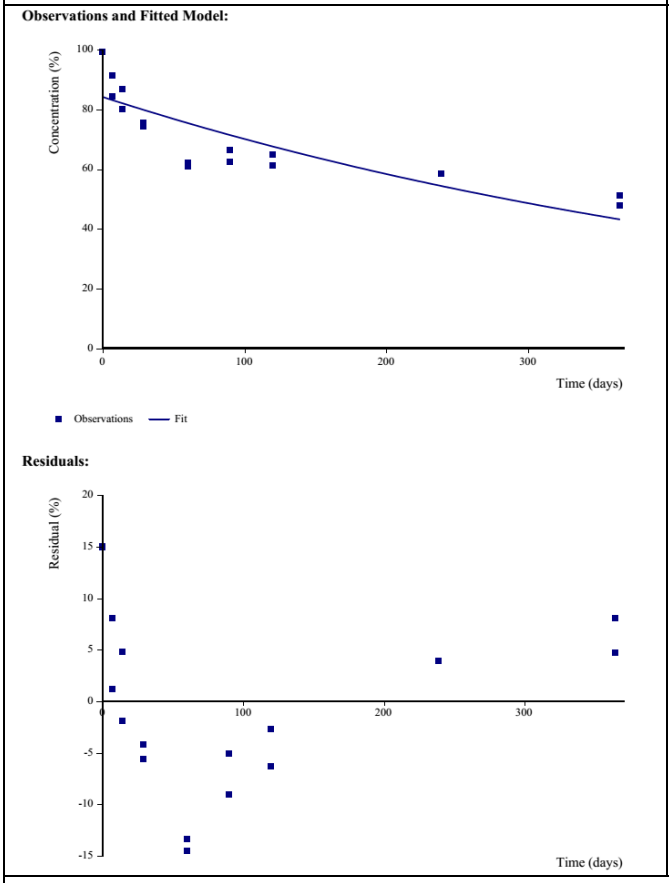




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.000636 | Acceptable/Poor | 2.62 | k: <0.05 | 1090 | 3620 |
| FOMC | α=0.06078<br>β=7.123 | Good/Good | 1.06 | α and β CI do not contain 0 | >10000 | >10000 |
| DFOP | $k_1$=0.09243<br>$k_2$= 0.000452<br>g=0.1005 | Good/Good | 0.96 | $k_1$: <0.05<br>$k_2$: <0.05 | 1300 | 4870 |
| **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected**<br>**Modelling endpoint: SFO not acceptable, 10% of initial level not reached → fit DFOP; DFOP selected*** | | | | | | |

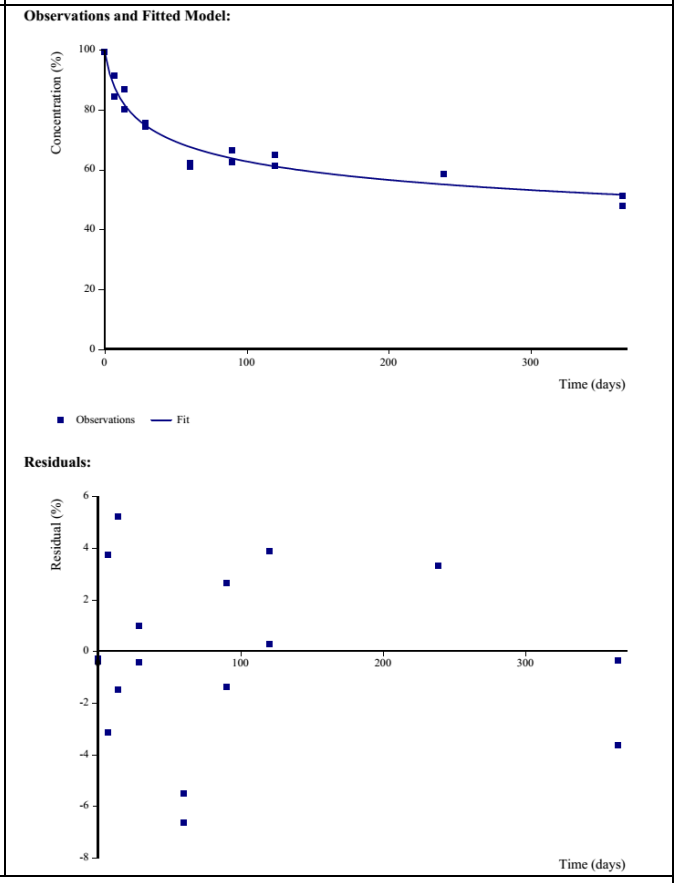
*Note comments in following conclusion regarding accepting SFO for modelling endpoint for this soil.

**Capay (Based on non-harsh residues)**

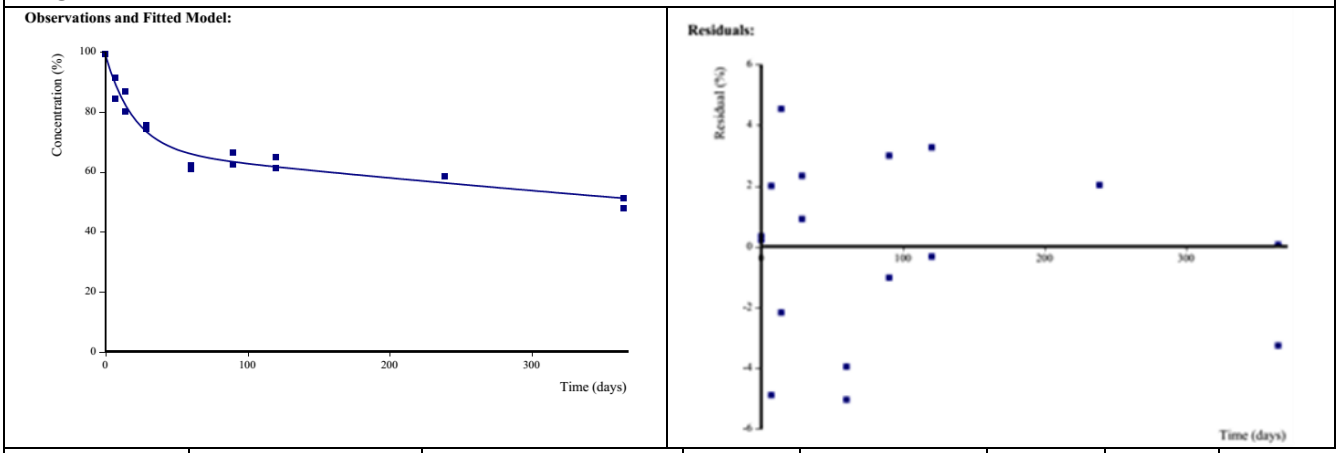
SFO




FOMC




DFOP




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| **SFO** | **k=0.00183** | **Poor/Poor** | **9.11** | **k: <0.05** | **379** | **1260** |
| **FOMC** | **α= 0.1557 β=5.436** | **Good/Good** | **3.07** | **α and β CI do not contain 0** | **461** | **>10000** |
| **DFOP** | **$k_1$=0.05022 $k_2$= 0.000756 g=0.3183** | **Good/Good** | **2.54** | **$k_1$: <0.05 $k_2$: <0.05** | **410** | **2540** |
| **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected Modelling endpoint: SFO not acceptable, 10% of initial level not reached → fit DFOP; DFOP selected** | | | | | | |

The selected trigger and modelling endpoints are reported below.

**Conclusion**
Modelling and persistence endpoints representing the degradation rate of pydiflumetofen in laboratory soils have been calculated in accordance with FOCUS Degradation Kinetics guidance and the methodology was considered by HSE to be acceptable.

Based on the residues of pydiflumetofen from non-harsh extraction, which HSE consider to be the appropriate residues to use for kinetic assessment, trigger $DegT_{50}$ values for pydiflumetofen ranged from 398 to 2380 days, with $DegT_{90}$ values ranging from 1320 to 7640 days. Modelling $DegT_{50}$ values selected by the applicant for pydiflumetofen ranged from 398 to 1690 days, with a geometric mean of 940 days.

The trigger endpoints calculated confirm that pydiflumetofen triggers the conduct of field dissipation studies. Each of the four soils had DT50 values at 20°C & pF2 >60 days and DT90 values >90 days.

With respect to modelling endpoints, it is noted that SFO kinetics are generally preferred given the that the majority of environmental exposure models have been developed to SFO parameters. FOCUS Degradation Kinetics guidance allows for greater latitude in accepting SFO kinetics than is recommended for the calculation of persistence ('trigger') endpoints. Therefore the fitting of each of the soils deemed to require DFOP kinetics for modelling has been considered in more detail by HSE.

For Sarpy soil, the distribution of the residues appears to be slightly biphasic and there was a marked improvement in visual and residual fitting and $\chi^2$ parameter with both FOMC and DFOP. Thus overall the choice of DFOP kinetics (and DT50 corresponding to the slow phase of DFOP) can be accepted.

The Capay soil shows a similar if not greater improvement in visual and residual fitting and $\chi^2$ parameter using biphasic kinetics than the Sarpy soil. Therefore, as with the Sarpy soil, the choice of DFOP kinetics (and DT50 corresponding to the slow phase of DFOP can be accepted.

For the East Anglia soil, the position is less clear. The improvement in fitting with biphasic kinetics, whilst demonstrable, is much less marked than with the Sarpy and Capay soils. The residual fit for SFO is described as 'poor', there being a systematic over prediction of residues before and just after 100 DAT. Whilst there is some over prediction of residues at three consecutive time points, the extent of this is small. Given the relatively small improvement from biphasic kinetics in this case it is considered that SFO kinetics could be accepted for the East Anglia soil although DFOP does result in more conservative DT50 and DT90.

The trigger and modelling endpoints from this fitting from the 'non-harsh' extractions in the aerobic soil incubations can be accepted for use in risk assessment. However, from a practical regulatory point of view, the results of the kinetic fitting from the laboratory studies are only used with respect to whether field dissipation studies are triggered. The modelling endpoints from the laboratory study are not used in exposure assessment. This is because, according to the EU EFSA 'DegT50' guidance retained for use in GB post-EU Exit, where laboratory DegT50 values are >240 days and acceptable modelling parameter results from field dissipation studies are available, the field DegT50 results are used in preference to the laboratory DegT50 results. This is the case for pydiflumetofen where all the laboratory DegT50 values are >240 days. Section B.8.1.1.1.2.3 describes the calculation of DegT50 studies from appropriate field dissipation studies. In addition, non-normalised DisT50 from field dissipation studies at ambient environmental temperatures are typically considered to be more representative of behaviour in the field than results from laboratory studies at 20°C for PECsoil calculations.

A summary of the trigger and modelling endpoints from this study are presented below.

**Table B.8. 65 Detailed trigger $DT_{50}$ and $DT_{90}$ values for pydiflumetofen**

| Soil name | Soil texture (USDA) | Soil pH ($H_2O$) | Results based on non-harsh residues ([redacted], 2015) | | |
|---|---|---|---|---|---|
| | | | Study Endpoints (days) | | Kinetic Model |
| | | | $DT_{50}$ | $DT_{90}$ | |
| Gartenacker | Loam | 7.4 | 398 | 1320 | SFO |
| 18 Acres | Sandy clay loam | 6.5 | 2380 | 7640 | DFOP |
| Sarpy | Silty clay loam | 6.8 | 567 | 2970 | DFOP |
| East Anglia | Sandy loam | 7.8 | 1300 | 4870 | DFOP |
| Capay | Clay loam | 8.4 | 410 | 2540 | DFOP |
| **Maximum** | | | **2380** | 7640 | |

**Table B.8. 66 Detailed modelling $DegT_{50}$ values for pydiflumetofen**

| Soil name | Soil texture (USDA) | Soil pH ($H_2O$) | Results based on non-harsh residues ([redacted], 2015) | |
|---|---|---|---|---|
| | | | Measured $DegT_{50}$ at 20°C & pF2 (days) | Kinetic model |
| Gartenacker | Loam | 7.4 | 398 | SFO |
| 18 Acres | Sandy clay loam | 6.5 | 1690 | SFO |
| Sarpy | Silty clay loam | 6.8 | 1036 [a] | DFOP |
| East Anglia | Sandy loam | 7.8 | 1090 | SFO |
| Capay | Clay loam | 8.4 | 917 [a] | DFOP |
| **Geometric mean** | | | **930** | |

[a] $DegT_{50}$ calculated from slow phase rate constant ($ln(2)/k_2$)

#### B.8.1.1.2.1.2. Aerobic degradation rates of degradation products

HSE consider that no soil metabolites were formed in amounts triggering an environmental risk assessment. Consequently there is no kinetic assessment for any soil metabolites.

### B.8.1.1.2.1.3. Anaerobic degradation rates of the active substance

The anaerobic degradation of pydiflumetofen has been determined from the data from the laboratory anaerobic degradation study reported by [redacted], 2015a (see B.8.1.1.1.2). The kinetics assessment has been performed based on the environmentally relevant residues of pydiflumetofen from non-harsh extraction.

| | |
|---|---|
| **Report:** | K-CA 7.1.1.2/01. [redacted] (2015a), SYN545974 - Anaerobic Soil Metabolism of $^{14}$C-SYN545974, Report Number 3200130. Smithers Viscient (ESG) Ltd. Otley Road, Harrogate, North Yorkshire HG3 1PY, UK and 108 Woodfield Drive, Harrogate, North Yorkshire, HG1 4LS, UK<br>(Syngenta File No. SYN545974_50166) |

**Guideline(s):** OECD 307 (2002), EPA Guideline Series OPPTS 835.4200 (2008)
**GLP/GEP:** Yes
**Deviation(s):** No major deviation identified
**Acceptability** Yes

**Material and Methods**
The design of the study is presented under B.8.1.1.1.2.

The rate of degradation in the four soils was estimated using single first order kinetics using CAKE software (version 2). For each soil except Gartenacker soil, kinetic models were fitted to the levels of readily extractable pydiflumetofen (based on non-harsh extracts, [redacted] 2015a).

Data points from 30 DAT (equivalent to 0 DAIA) were used in the fitting. True replicates were included individually in the optimisations. All data points were unweighted. For optimal goodness of fit, the initial value was also allowed to be estimated by the model.

The fit of SFO model was assessed on the basis of a visual assessment of the goodness of fit (diagrams of measured and calculated values versus time, diagrams of residuals versus time) and on the basis of the chi$^2$ scaled-error criterion and t-test.

**Findings**
Results from the kinetic fitting are presented in the following tables and figures. HSE consider that the fitting is appropriate and acceptable although SFO kinetics only were used. Given that kinetic parameters from anaerobic soil studies are typically not used in risk assessment, fitting using SFO kinetics is accepted by HSE.

**Table B.8. 67 Kinetic parameters and statistics of the fittings for pydiflumetofen – Based on non-harsh residues**

| Soil | Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|---|
| Gartenacker | SFO | k=3.51e-4 | Good/Good | 1.05 | k: <0.05 | 1970 | 6550 |
| 18 Acres | SFO | k=9.87e-4 | Good/Good | 1.63 | k: <0.05 | 702 | 2330 |
| Sarpy | SFO | k=6.58e-4 | Good/Good | 3.54 | k: <0.10 | 1050 | 3500 |
| Capay | SFO | k=0.002218 | Good/Good | 2.21 | k: <0.05 | 313 | 1040 |

**Figure B.8. 7 Visual and residual fits for pydiflumetofen (combined radiolabels) in anaerobic Gartenacker soil**

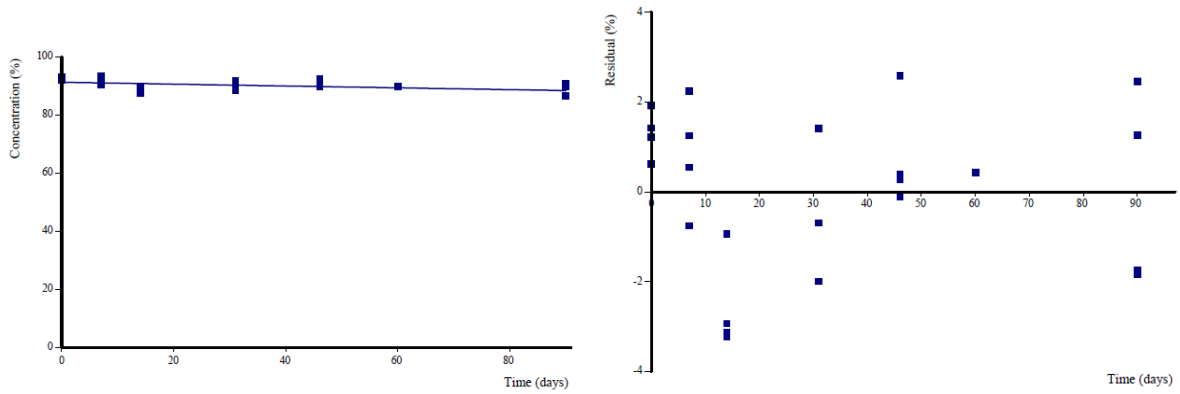



**Figure B.8. 8 Visual and residual fits for pydiflumetofen in anaerobic 18 Acres soil**

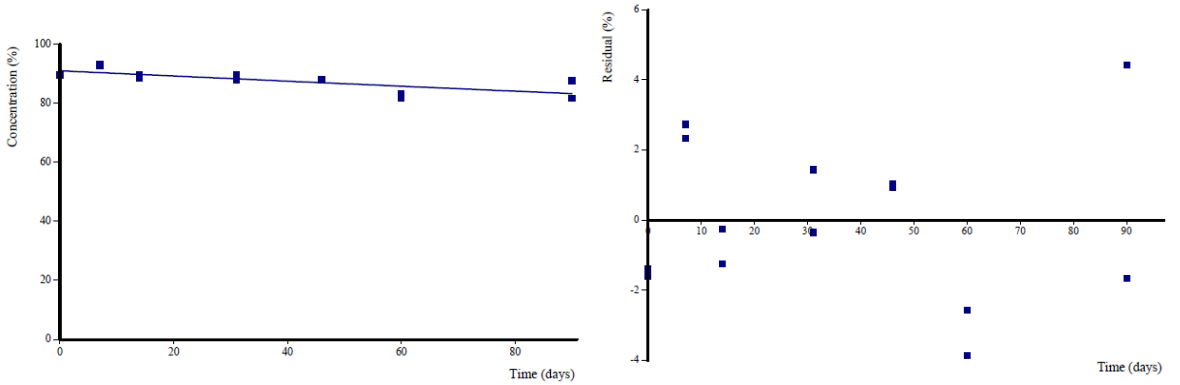



**Figure B.8. 9 Visual and residual fits for pydiflumetofen in anaerobic Sarpy soil**

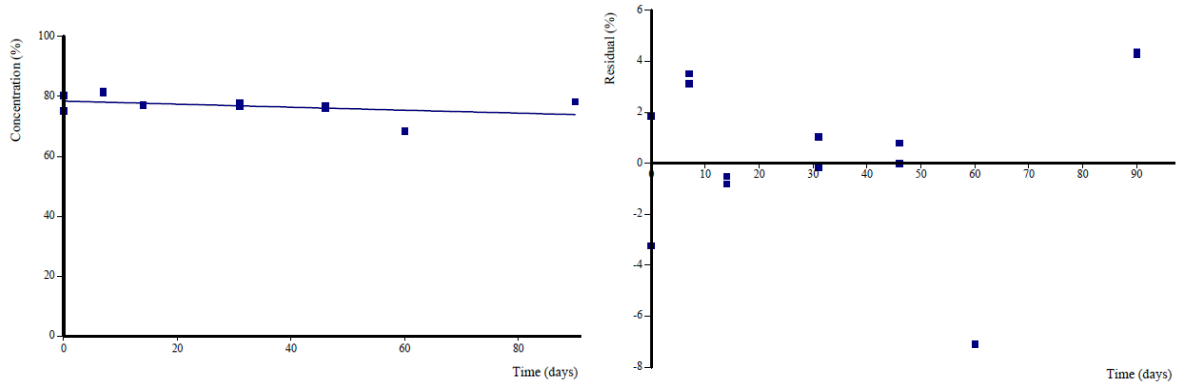
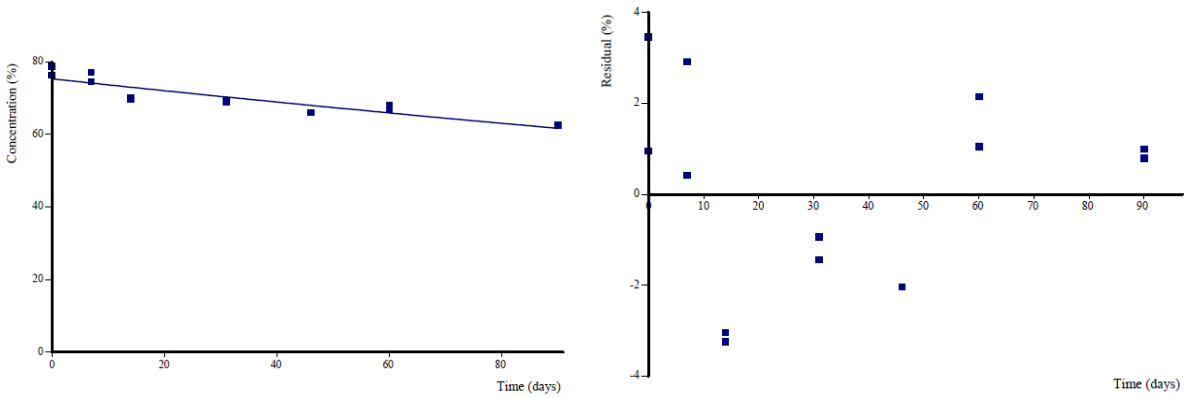


**Figure B.8. 10 Visual and residual fits for pydiflumetofen in anaerobic Capay soil**




The calculated degradation half-life (DegT50) values obtained from the anaerobic phase were all extrapolated beyond the 120 day (90 day anaerobicity) study period. A summary of the degradation kinetics is shown below.

**Table B.8. 68 Summary of $DegT_{50}$ and $DegT_{90}$ values for pydiflumetofen under anaerobic conditions**

| **Soil** | **Results based on non-harsh residues ([redacted] 2015a)** | |
|---|---|---|
| | **$DegT_{50}$ [days]** | **$DegT_{90}$ [days]** |
| Gartenacker – labels combined | 1970 | 6550 |
| 18 Acres | 702 | 2330 |
| Sarpy | 1050 | 3500 |
| Capay | 313 | 1040 |

**Conclusion**
The SFO (non-linear) half-life range for pydiflumetofen of 313 days to >1000 days was extrapolated beyond the study duration. This is confirmation of the negligible degradation of pydiflumetofen observed over the duration of the anaerobic soil degradation study.

### B.8.1.1.2.2. Field studies

It is noted that the results of the laboratory aerobic soil studies for pydiflumetofen clearly triggered the conduct of field dissipation studies to investigate dissipation under more realistic field conditions. Therefore the submission of field dissipation studies to address persistence under more realistic usage conditions is appropriate.

The rate of degradation of pydiflumetofen applied to bare soil has been studied in the field in studies located across Europe. The design of the initial six studies included covering the treated field plots after application with >3mm of fine sand, in accordance with EFSA (2014) guidance for designing field dissipation studies to derive soil matrix $DegT_{50}$ values. As noted previously in the assessment, pydiflumetofen clearly triggered the conduct of field dissipation studies because of the magnitude of the DT50 and DT90 values in the laboratory aerobic rate of degradation study. The use of the EFSA DegT50 study design is not standard to address the field dissipation study data requirement in Regulation 283/2013. The application of a sand layer immediately after application is designed to minimise surface loss processes such as photolysis and volatilisation and facilitate the generation of kinetic modelling endpoints for environmental exposure modelling. The use of such a design is entirely the choice of the applicant, there being no strict legislative requirement to generate DegT50 values for environmental exposure modelling from field dissipation studies. The legislative requirement via the data requirements is to investigate the dissipation of substances under more realistic field conditions. Historically the legislative requirement has been addressed using bare soil field dissipation studies without any covering of sand or any other procedure to minimise substance losses from the soil surface following application. The consequence is that whilst the initial six studies with the so-called 'EFSA DegT50' design can be accepted to

address the data requirement, they may under-estimate dissipation compared to a more typical study designed to assess total dissipation in field situations.

Subsequently the applicant provided a further set of four European field dissipation studies (each of which has an associated study report on preparation of the field site) which they described as being 'higher tier'. The studies utilised a design whereby a single application was made to bare soil, but grass, the seed of which had been sown prior to application, was allowed to grow following the application. In the view of HSE these four studies represent a design which is closer to those historically submitted to address the data requirement for field dissipation studies with the possible exception that the sites were allowed to develop a grass covering following application of pydiflumetofen. The standard field dissipation study design is for application to bare soil plots which are subsequently maintained virtually vegetation free (the US EPA study guideline currently specified in the data requirements expects weed control to be conducted 'according with good agricultural practice'). Whilst allowing such grass coverage to develop is not a standard feature of more typical field dissipation studies, it is not without precedent and is arguably closer to the situation in which pydiflumetofen would be used, i.e. applied in a cropped situation. HSE considers that the study design is reasonable and of sufficient merit for the results to be taken into consideration.

The applicant also submitted a study reporting additional sampling of five of the European field dissipation sites. Three of these were the former sites of field DegT50 studies and two were bare soil sites where grass had been allowed to grow after application. The sites had been 'decommissioned' following the completion of the original studies and the plot layouts were no longer evident. New samples were taken from the estimated positions of previously treated plots with an interval between the new samples and the final samples in the studies of between 3.1 and 5.2 years. The intention of the applicant appears to be to demonstrate that pydiflumetofen shows faster dissipation over the extended time period than the original DegT50 studies indicated. Whilst the conduct over such an extended time is unusual, OECD guidance on field dissipation studies indicates that field dissipation studies should not be terminated until 90% dissipation has been achieved. In this particular case, HSE has concerns over the potential for dilution of the residues from the original applications due to decommissioning of the trials sites and return to normal use. Consequently, whilst of interest, HSE considers that the results cannot be used in regulatory risk assessment.

To support registration of pydiflumetofen outside Europe, the applicant had conducted field dissipation studies in North America (four in the USA and two in Canada) and in Asia (four in China, two in South Korea and two in Japan). These were submitted to support registration in GB as further evidence that dissipation occurs faster than the European DegT50 studies indicated. According to European guidance[4] retained by Great Britain, the results of field dissipation studies conducted at non-European sites can be accepted for use in European assessments provided that the conditions during the study are representative of European conditions. This was the position in GB prior to exit from the European Union. In the absence of GB-specific guidance on the appropriateness of non-GB field dissipation studies to support GB risk assessments, HSE has continued to follow existing EU guidance in this area. This means that field dissipation studies conducted in Europe are considered acceptable to support GB risk assessments, and in addition non-European field studies that are determined to be comparable to European conditions are also considered acceptable to support GB assessments. HSE has not considered the relevance of non-European studies specifically to GB conditions, however this is an area where further guidance could be developed in the future.

As an initial step, the representativeness of each site to European soil and weather conditions needs to be demonstrated before inclusion in the GB assessment. To this end the applicant also submitted a study using the OECD ENASGIPS model (with an adapted approach to consider the Asian studies – ENASGIPS is only supplied with North American and European data) to consider the similarity of the ecoregions in which the studies were conducted to European ecoregions. Some of the studies were conducted on cropped plots and involved multiple applications to reflect the GAPs in other countries. Such practice can complicate the interpretation of fate and behaviour. HSE consider that the sites were not comparable to European conditions and thus the results from these sites are not used in regulatory risk assessment.

In summary, the following endpoints are proposed for use in risk assessment from the field dissipation studies.

[4] EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp.

**Table B.8. 69 Field Dissipation DT50 and DT90 – pydiflumetofen – Trigger endpoints**

| Parent | Aerobic conditions – **Trigger endpoints** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Soil type. | Location (country or USA state). | pH[a)] | Depth (cm) | Overall $DT_{50}$ (d) actual | Overall $DT_{90}$(d) actual | St. ($\chi^2$) | Kinetic parameters | Method of calculation |
| Sandy loam[b] | Germany | 5.68 | 0-20 | 8540[d] | >10000[d] | 6.5 | $k_1$=0.05381 $k_2$= 0.000043 g=0.2484 | DFOP |
| Clay loam[b] | Italy | 7.40 | 0-100 | 1110[d] | 3680[d] | 11.6 | - | SFO |
| Silty clay loam[b] | Northern France | 7.52 | 0-100 | 4030[d] | >10000[d] | 9.7 | - | SFO |
| Sandy loam[b] | Southern France | 7.48 | 0-50 | 29 | 1820[d] | 13.3 | $k_1$=0.08239 $k_2$= 0.000842 g=0.5381 | DFOP |
| Sandy loam[b] | Spain | 7.27 | 0.-30 | No reliable fit could be obtained | | | | |
| Loam[b] | UK | 6.84 | 0-30 | 2810[d] | 9350[d] | 11.2 | - | SFO |
| Loamy sand[c] | Germany | 6.23 | 0-30 | 1310[d] | 4360[d] | 8.7 | - | SFO |
| Silty clay[c] | Northern France | 6.13 | 0-20 | 639[d] | 2120[d] | 13.2 | - | SFO |
| Silt loam[c] | Southern France | 7.68 | 0-30 | 23.4 | 2130[d] | 9.1 | k1: 0.07406 k2: 0.000584 g: 0.6006 | DFOP |
| Loamy sand[c] | Portugal | 6.23 | 0-50 | 227 | 755[d] | 14.5 | - | SFO |
| **Maximum for Tier 1 PECsoil calculation** | | | | **8540** | **>10000** | | | **DFOP** |
| **Value for Tier 2 PECsoil calculation** | | | | **1310** | **4360** | | | **SFO** |

[a)] Measured in calcium chloride solution
[b)] application to bare soil, DegT50 design
[c)] application to bare soil, grass cover subsequently developed
[d)] DT50 or DT90 extrapolated beyond study duration

**Table B.8. 70 Field DegT50matrix – pydiflumetofen – Modelling endpoints**

| Parent | Aerobic conditions – **Modelling endpoints** | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | pH[a)] | Depth (cm) | $DT_{50}$ (d) Norm[b)]. | Kinetic parameters | St. ($\chi^2$) | Method of calculation |
| Sandy loam (bare soil) | Germany | 5.68 | 0-20 | 997 | - | 8.8 | SFO |
| Clay loam (bare soil) | Italy | 7.40 | 0-100 | 1110 | - | 11.4 | SFO |
| Silty clay loam (bare soil) | Northern France | 7.52 | 0-100 | 3210 | - | 9.8 | SFO |
| Sandy loam (bare soil) | Southern France | 7.48 | 0-50 | 654[c)] | $k_1$=0.04618 $k_2$= 0.00106 g=0.502 | 12.5 | DFOP |
| Sandy loam (bare soil) | Spain | 7.27 | 0.-30 | No reliable fit could be obtained | | | |
| Loam (bare soil) | UK | 6.84 | 0-30 | 1820 | | 11.3 | SFO |
| **Geometric mean** (if not pH dependent) | | | | **1334** | | | |
| pH dependence | | | | No | | | |

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
[c)] Calculated from DFOP k2 parameter (ln(2)/k2)

### B.8.1.1.2.2.1. Field dissipation studies

#### B.8.1.1.2.2.1.1 European DegT50 studies

| | |
|---|---|
| **Report: (1 of 6)** | K-CA 7.1.2.2.1/01. [redacted] (2015), SYN545974 – Bare Soil Plot Soil Dissipation Study in Germany in 2013-2015. Report Number S13-02237-FINAL, Eurofins Agroscience Services GmbH, Carl-Goerdeler-Weg 5, D21684 Stade, Germany (Syngenta File No. A19649B_10166) |

| | |
|---|---|
| **Report: (2 of 6)** | K-CA 7.1.2.2.1/02. [redacted] (2015a), SYN545974 – Bare Soil Plot Soil Dissipation Study in Italy in 2013-2015. Report Number S13-02241-FINAL, Eurofins Agroscience Services GmbH, Carl-Goerdeler-Weg 5, D21684 Stade, Germany<br>(Syngenta File No. A19649B_10167) |

| | |
|---|---|
| **Report: (3 of 6)** | K-CA 7.1.2.2.1/03. [redacted] (2015b), SYN545974 – Bare Soil Plot Soil Dissipation Study in Northern France in 2013-2015. Report Number S13-02238-FINAL, Eurofins Agroscience Services GmbH, Carl-Goerdeler-Weg 5, D21684 Stade, Germany<br>(Syngenta File No. A19649B_10168) |

| | |
|---|---|
| **Report: (4 of 6)** | K-CA 7.1.2.2.1/04. [redacted] (2015c), SYN545974 – Bare Soil Plot Soil Dissipation Study in Southern France in 2013-2015. Report Number S13-02239-FINAL, Eurofins Agroscience Services GmbH, Carl-Goerdeler-Weg 5, D21684 Stade, Germany<br>(Syngenta File No. A19649B_10170) |

| | |
|---|---|
| **Report: (5 of 6)** | K-CA 7.1.2.2.1/05. [redacted] (2015d), SYN545974 – Bare Soil Plot Soil Dissipation Study in Spain in 2013-2015. Report Number S13-02240-FINAL, Eurofins Agroscience Services GmbH, Carl-Goerdeler-Weg 5, D21684 Stade, Germany<br>(Syngenta File No. A19649B_10171) |

| | |
|---|---|
| **Report: (6 of 6)** | K-CA 7.1.2.2.1/06. [redacted] (2015e), SYN545974 – Bare Soil Plot Soil Dissipation Study in UK in 2013-2015. Report Number S13-02236-FINAL, Eurofins Agroscience Services GmbH, Carl-Goerdeler-Weg 5, D21684 Stade, Germany<br>(Syngenta File No. A19649B_10172) |

| | |
|---|---|
| **Guideline(s):** | EPA Guideline Series OPPTS 835.6100 (2008), SETAC 1995 |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | Due to the applicants own requirement (NOT the regulatory authorities requirement) that these studies should also generate data for use in EU modelling, the study design was adapted resulting in deviations from the EPA guidelines (a single application was applied to a bare soil plot that was immediately covered with sand). HSE considers this to be acceptable as the practice is in line with EFSA guidance on generation of DegT50 values from field dissipation studies. However the consequence is that dissipation may be under-estimated. |
| **Acceptability** | Yes |

**Material and Methods**

Field studies were performed using pydiflumetofen, as formulated product A19649B (200 g/L SC formulation), at six European locations (Germany, Italy, Southern France, Northern France, Spain and the United Kingdom).

**Description of the trial sites**

A summary of the history of each site is provided below. Main soil characteristics at each trial site are also reported below. The plots were located in areas not prone to flooding or erosion on level ground (2% slope for Southern France trial, no slope for other trials).

**Table B.8. 71 History of test sites**

| Country / Location | Application date | Monitoring period | Crops grown / plot history | Pesticides used |
|---|---|---|---|---|
| Ohrensen, Lower Saxony, Germany (location: 21698) | 27/05/2013 | 715 days | Rye (2010 to 2013) | Azoxystrobin, chlormequat, cyproconazole, deltamethrin, diflufenican, epoxiconazole, ethephon, fenpropimorph, flufenacet, flupyrsulfuron, flurtamone, isoproturon, lambda-cyhalothrin, mepiquat, metrafenone, pendimethalin, prohexadione, tebuconazole, tribenuron, triadimenol, triadimenol, trinexapac |
| Stiatico, Emilia Romagna, Italy (location: 40016) | 27/05/2013 | 716 days | Wheat (2010) maize (2011) bare soil (2012 to 2013) | Fluroxypyr and tribenuron-methyl (wheat) Fluroxypyr and bromoxynil (maize) Glyphosate (bare soil) |
| Sand, Bas-Rhin, Northern France (location: 67230) | 30/05/2013 | 721 days | Maize (2010, 2011 and 2013) winter wheat (2012) | Florasulam, fluroxypyr, glyphosate, nicosulfuron, sulcotrione and tefluthrin (maize only, no pesticides applied for winter wheat) |
| Meauzac, Midi-Pyrénées, Southern France (location: 82290) | 01/07/2013 | 721 days | Maize (2010 to 2012) fallow (2013) | Bentazone, dicamba, foramsulfuron, mesotrione and nicosulfuron (maize) glyphosate (fallow) |
| Canals, Valencia, Spain (location: 46690) | 24/05/2013 | 714 days | Fallow (2008 to 2013) | None |
| Wilson, Derbyshire, United Kingdom (location: DE73-8AG) | 23/05/2013 | 718 days | Fallow (2010 to 2013) | Glyphosate |

HSE understands that the active substances used are not related to pydiflumetofen and thus are not a concern with respect to potential to affect the degradation of pydiflumetofen.

**Table B.8. 72 Soil characteristics at field dissipation trial sites (0-10 cm soil layer)**

| Location | pH | | CEC (meq/100 g) | O.C. (%) | WHC # | | Sand (%) | Silt (%) | Clay (%) | USDA Class |
|---|---|---|---|---|---|---|---|---|---|---|
| | ($H_2O$) | ($CaCl_2$) | | | pF 2.0 | pF 4.2 | | | | |
| Ohrensen, Lower Saxony, Germany | 6.22 | 5.68 | 5.0 | 1.4 | 13.7 | 2.9 | 77.8 | 14.4 | 7.9 | Sandy loam |
| Stiatico, Emilia Romagna, Italy | 7.22 | 7.40 | 18.4 | 1.8 | 23.8 | 15.0 | 36.0 | 28.6 | 35.5 | Clay loam |
| Sand, Bas-Rhin, France | 6.87 | 7.52 | 15.3 | 1.2 | 23.3 | 11.0 | 8.4 | 63.9 | 27.8 | Silty clay loam |
| Meauzac, Midi-Pyrénées, France | 6.23 | 7.48 | 6.1 | 0.47 | 16.6 | 4.9 | 65.9 | 22.1 | 12.0 | Sandy loam |
| Canals, Valencia, Spain | 6.27 | 7.27 | 11.4 | 2.1 | 17.4 | 6.8 | 73.5 | 9.9 | 16.6 | Sandy loam |
| Wilson, Derbyshire, UK | 6.52 | 6.84 | 10.4 | 1.7 | 23.9 | 10.0 | 44.7 | 35.4 | 20.0 | Loam |

# = water holding capacity (%)

Daily weather data (air temperature, air humidity, precipitation, soil temperature, soil moisture, wind speed and solar radiation) were recorded using on-site weather stations (for Southern France and UK trial, in a few instances missing weather data were taken from a weather station located approximately 7 km and 0.5 km from the trial areas, respectively). Data recorded during the experiments from the on-site weather stations were compared to long-term precipitation and temperature data from official weather stations located close to the trials sites (see following table). Collection of on-site weather data is expected for modern studies. Comparison to historical weather data from official weather stations is considered by HSE to be acceptable and appropriate. The historical data sets used for Germany are relatively old compared to the dates of study conduct. However the historical data are simply for context setting and play no other part in the assessment.

**Table B.8. 73 Origin of long-term weather data**

| Trial site | Distance of the official weather station from the site | Long-term data used for monthly mean air temperature | Long-term data used for monthly precipitation |
|---|---|---|---|
| Germany | 16.7 km | 1961-1990 | 1961-1990 |
| Italy | 6.0 km | 2007-2014 | 1999-2011 |
| Northern France | 15.0 km | 1971-2000 | 1971-2000 |
| Southern France | 15.0 km | 1990-2000 | 1990-2000 |
| Spain | 6.1 km | 2002-2012 | 2002-2012 |
| UK | 9.0 km | 1971-2000 | 1971-2000 |

***Experimental treatment***

At each site single un-replicated plots were treated. Plot sizes ranged from 36 m long by 3 m wide to 63 m long by 3 m wide, with treatment plot areas ranging from 108 to 261 $m^2$. Each plot was subdivided into three subplots, which ranged from 12 m long by 3 m wide to 29 m long by 3 m wide.

At each site, pydiflumetofen was applied at a rate of 1000 mL product/ha (equivalent to 204 g a.s./ha based on analysed content; note that this close to the requested dose for the representative GAPs in this submission for approval) to bare soil, as a broadcast soil spray using a 6 nozzle Schachtner boom sprayer producing a flat fan spray pattern. Nozzles used were Lechler IDK 120-02 (Germany), LD03-F110 (Italy, Southern France and Spain), DG 110 03 VS (Northern France) and reduced drift fan Hypro 110 015 (United Kingdom). Immediately following application, the treated plots were covered with up to 5-10 mm of sand to minimise the potential impact of any surface processes.

**Table B.8. 74 Environmental data at application**

| Site | Air temperature (°C) | Humidity (%) | Wind speed (m/s) | Rainfall within 24 hours of application (mm) | Rainfall within 72 hours of application (mm) | Onset of rainfall after application (hours) | Cloud cover (%) |
|---|---|---|---|---|---|---|---|
| Germany | 19.8 | 66.7 | 0.5 | 5.6[a] | 9.4 | 7 | 30 |
| Italy | 27.1 | 60.5 | 1.0-1.5 | 0 | 0 | 174 | 0 |
| Northern France | 16.0 | 69 | 1.0-1.5 | 0 | 0 | 112 | 0 |
| Southern France | 23.4-25.0 | 68-68 | 0.2-0.6 | 0 | 6.6 | 35-36 | 0 |
| Spain | 23.4 | 28 | ≤1.5 | 0 | 3.1 | 40.5 | 25 |
| UK | 16.3-18.9 | 34.2-57.2 | 1.3-1.7 | 0 | 0 | 196.5-197.5 | 5-10 |

[a] 0.6 mm of precipitation starting 7 hours after application, 5 mm of precipitation starting 20 hours after application, 0.4 mm of precipitation 24:40 hours:min after application

Prior to application, deposition trays were placed in the plots for verification of the application rate.

***Sampling***

Samples were taken from the treated subplots for analysis 1 to 21 days before the application (DBA) and immediately after application (up to a depth of 10 cm). Soil samples were taken at 3 and 7 days after application (DAA) (up to a depth of 30 cm) and at various pre-determined intervals between 14 and 721 DAA (up to a depth of 100 cm). At each sampling point, 5 soil cores were taken from each subplot, using hydraulic corers, which ranged in size from 3.9 to 8.0 cm (inner diameter).

All samples were placed in a deep freeze within 5 hours of sampling and were generally maintained at ≤ -18 °C during storage.

At all sites, the 30 cm soil cores were cut into three 10 cm profiles, representing the soil layers: 0-10, 10–20 and 20–30 cm. Each layer was removed from the liners and the corresponding layers were bulked to give composite samples for each subplot.

For the 0 to 100 cm soil cores, division of the soil cores varied from site to site. Overall, the soil cores were cut into four profiles, representing the soil layers: 0–10, 10–20, 20–30 cm and remaining 30-100 cm. For 0–10, 10–20, 20–30 cm the soil from each layer was removed from the liners and the corresponding layers were bulked to give composite samples for each subplot.

For the Spanish site, the soil cores from 178 DAA onwards were divided into six profiles, representing the soil layers: 0–10, 10–20, 20–30, 30-50, 50-70 and 70–100 cm.

For the Northern France site, the 546 and 721 DAA samples the 0-100 cm soil cores were cut into six profiles, representing the soil layers: 0–10, 10–20, 20–30, 30-50, 50-70 and 70–100 cm.

For the Southern France site, the 121, 366 and 533 DAA samples the 0-100 cm soil cores were cut before shipment into two profiles, representing the actual soil layers: 0–50 and 50–100 cm. The 0-50 cm segments were then cut into four profiles representing the soil layers: 0–10, 10–20, 20–30 cm and 30–50 cm. Again, the soil from each layer was removed from the liners and the corresponding layers were bulked to give composite samples for each subplot.

For the United Kingdom site, the 0-100 cm soil cores for 15 DAA up to 118 DAA were cut into three profiles, representing the soil layers: 0–10, 10–20 cm and remaining 20–100 cm. The 0-100 cm soil cores for 182 DAA onwards except for the 539 DAA interval were cut into four profiles, representing the soil layers: 0–10, 10–20, 20–30 cm and remaining 30–100 cm. The 0-100 cm soil cores for 539 DAA were cut into six profiles, representing the soil layers: 0–10, 10–20, 20–30, 30-50, 50-70 and 70–100 cm. For 0–10, 10–20, 20–30 cm the soil from each layer was removed from the liners and the corresponding layers were bulked to give composite samples for each subplot. For the 539 DAA interval all six layers were removed from the liners and the corresponding layers were bulked to give composite samples for each subplot.

After determination of the corresponding mass, the combined segments were homogenised by milling in the presence of dry ice.

***Analytical procedure***
Residues of pydiflumetofen were analysed using modified Syngenta Global Residue Method GRM061.04A (see Vol.3 B.5). In summary, 10 g of soil were extracted with 80/20 (v/v) acetonitrile/0.1 M ammonium acetate aqueous solution by shaking. After centrifugation, the extract was decanted into a plastic flask and the soil was extracted a second time with 80/20 (v/v) acetonitrile/0.1% acetic acid in demineralized water. After centrifugation, the supernatant was decanted and collected with the first extract in the centrifuge bottle. This extraction step with 80/20 (v/v) acetonitrile/0.1% acetic acid in ultra-pure water was repeated. The collected extracts were mixed well and filtered through 'piggy backed' filter papers (HSE assumes this means that double filter papers were used) into a clean bottle.

Approximately 1 mL was transferred into a HPLC vial and analysed by high performance liquid chromatography with triple quadruple mass spectroscopy determination (LC-MS/MS). For expected residues greater than 5 µg/kg, samples were diluted further and mixed thoroughly.

In the United Kingdom field trial, aliquots (10 mL) of the filtered extracts were evaporated to <0.5 mL to remove the acetonitrile and mixed with 1 mL of 0.1% acetic acid in ultra-pure water. The samples were then loaded onto preconditioned SPE cartridges and rinsed with 2.0 mL of 60/40 (v/v) methanol/0.1% acetic acid in demineralized water. pydiflumetofen was eluted from the SPE cartridge with 2 mL of 60/40 (v/v) methanol/0.1% acetic acid in ultra-pure water followed by 3 mL of methanol and evaporated again to <0.5 mL. The samples were finally mixed with 1.5 mL of methanol and diluted to 5 mL with 0.1% acetic acid. Aliquots were then transferred to HPLC vials for final residue determination by high performance liquid chromatography with triple quadrupole mass spectroscopy determination (LC-MS/MS). For expected residues greater than 5 µg/kg, samples were diluted further and mixed thoroughly.

The limit of quantification (LOQ) of the method was 0.5 µg/kg wet soil for pydiflumetofen.

HSE notes that the LOQ of the analytical method was reported to be 0.5 µg/kg wet weight of soil. LOD was reported to be 0.15 µg/kg wet weight of soil. Normally residues are reported in relation to dry weight of soil to ensure consistency of reporting of residues across the study duration; with respect to kinetic fitting it also aids in a consistent approach to how residues <LOQ are treated.

It was noted that whilst the LOD and LOQ were reported, residues <LOQ were simply reported as '<LOQ' with no measured value attributed.

HSE notes that where the residue was <LOQ in wet weight samples, the corresponding g/ha value was set to 0. In relation to the use of soil residues data for the calculation of DT50 and DT90 values, this is not in accordance with FOCUS Degradation Kinetics guidance. The guidance indicates that where measured residues between LOD and LOQ are reported, these should be used directly in the kinetic analysis; if the actual value has not been reported a value of 0.5 x (LOQ + LOD) should be used. Value < LOD should be set to a value of 0.5 x LOD, although subsequent values <LOD after the first non-detection should not be included in kinetic assessment if no further positive detections >LOQ are recorded.

Reporting of the residues in the applicant summary was only on the basis of g/ha rather than µg/kg dry weight of soil. This was also the primary way of reporting the residues in the study reports. The results in the primary tables also only give the mean results, whereas triplicate values were reported in appendices in the study reports . Analytical results are normally reported in µg/kg or mg/kg dry weight with the replicate values rather than means. Reporting of residues in this manner is recommended in EPA and OECD guidance. It is also noted that reporting the replicate values facilitates kinetic assessment which requires fitting to replicate values rather than means; this is detailed in FOCUS Degradation Kinetics guidance. Ideally the analytical results in µg/kg or mg/kg should also be reported as these will not be subject to artefacts inherent in the conversion of the concentrations to a g/ha equivalent. There are minor criticisms of the study author and applicants reporting of the results but are not of large importance because the appropriate replicate results in µg/kg were able to be retrieved from the study reports

Sample extracts of the 0 DAA and 533 to 546 DAA (0-10 cm depth) samples were diluted with methanol/water + 0.1 % acetic acid (30/70, v/v) to achieve baseline separation for determination of pydiflumetofen enantiomers SYN546968 and SYN546969. The enantiomer ratio was then calculated as SYN546968 peak area/SYN546969 peak area.

The applicant provided some argumentation in relation to the analytical method used in these field dissipation studies and in comparison with that used in the laboratory aerobic soil study as follows. This was because during the EU assessment of pydiflumetofen questions had been raised regarding the extraction procedures. HSE also notes that unless the extraction procedure in laboratory and field studies are comparable then it is not possible to compare any kinetic parameters from laboratory and field studies on a 'like-for-like' basis.

*"The same soil extraction method has been used in both the laboratory and field studies. In both cases all the soil samples were extracted with three extraction steps, each involving shaking at room temperature for 20 minutes with acetonitrile : 0.1 M ammonium acetate (80:20 v/v). This method has been demonstrated to be highly effective and robust. Data from the laboratory study with $^{14}$C-SYN545974 show that for all five soils investigated virtually all of the applied radioactivity was extracted from the all the samples taken on the day of application (in total 98.4% to 100.9%). Most of this radioactivity was recovered in the first extraction step (86.1% to 89.7%), a further 8.9% to 10.9% was released in the second step and the remaining 1.6% to 2.2% in the third step.*

*As the data from the laboratory soil degradation study (K-CA 7.1.1.1/01. [redacted], 2015) demonstrated that the extraction efficiency of the soil analytical method used in both laboratory study and in the field dissipation studies significantly exceeds the relevant guideline requirements, i.e. from OECD (2002)[5]: Recoveries should range from 90% to 110% for labelled chemicals, additional harsh extraction steps were not warranted. Additionally, as noted by the EU RMS in the Pydiflumetofen EU Commenting Table in response to comments on soil extraction techniques, the geometric mean $DT_{50}$ based on residues including harsh extraction in the laboratory rate of degradation study (laboratory soil modelling $DT_{50}$ 1440 days, Pydiflumetofen DAR List of Endpoints) is similar to the geometric mean $DT_{50}$ based on normalised field soil data $DT_{50}$ (field soil modelling $DT_{50}$ 1334 days, Pydiflumetofen DAR List of Endpoints). This finding substantiates the adequacy of the extraction efficiency of the soil analytical method used in the field studies.*

*The primary purpose of field soil studies with SYN545974 was to provide estimates of the time required for dissipation of 50 % and 90 % (DisT50 field and DisT90 field) and, if possible, of the time required for degradation of 50 % and 90 % (DegT50 field and DegT90 field), under European field conditions (COMMISSION REGULATION (EU) No 283/2013). Therefore the harsh extraction techniques such as that employed in the SYN545974 aerobic laboratory soil study (8 hour reflux in 80:20 acetonitrile/water adjusted to pH3, i.e. soil sample in contact with boiling solvent mixture for 8 hours at >76°C, based on azeotrope boiling point at ambient pressure at 83.7 % acetonitrile), would not have been appropriate for this purpose. The assumptions inherent within the regulatory exposure models should be considered when deriving the appropriate DegT50 input values. Using a half-life value including the harsh extraction residues in the FOCUS models is very conservative, as this assumes that the total residue extracted is available in soil to be degraded or to leach. This is likely to lead to an over estimation of the soil transport and leaching potential of SYN545974. The three-step soil extraction method used in the field soil dissipation studies is considered to provide the required level of extraction efficiency and to generate residue data that are suitable for determining the dissipation and degradation rate information required in accordance with in accordance with Regulation (EC) No 1107/2009."*

Based on the study reports, the extraction methods used in laboratory and field are the same for the 1st extraction step but are not exactly the same for the 2nd and 3rd extraction steps, as shown in the following table.

[5] OECD (Organisation for Economic Co-operation and Development), 2002. OECD guideline for the testing of chemicals. Aerobic and anaerobic transformation in soil. OECD Guideline 307, OECD, Paris.

**Table B.8. 75 Comparison of the extraction methods used in laboratory and field experiments**

| | **Laboratory** | **Field** |
|---|---|---|
| **1st extraction step** | acetonitrile : 0.1 M ammonium acetate (80:20 v/v) | |
| **2nd and 3rd extraction steps** | acetonitrile : water (80:20 v/v, water acidified to ca pH 3) | acetonitrile/0.1% acetic acid in demineralized water (80:20 v/v) |

HSE considers that the methods used for the 2nd and 3rd extraction steps are likely to be similar. It is agreed that data from the laboratory study show that for all five soils investigated virtually all of the applied radioactivity was extracted from the all the samples taken on the day of application. The similar method used in the field study can therefore be considered appropriate and kinetic assessments of residue decline in laboratory and field studies can be compared on a 'like-for-like' basis.

**Findings**

***Weather data***

Weather conditions during the study are compared to long-term average data for context setting. This does not affect acceptability of the studies.

*Germany*
The average air temperature during the field phase of the study was slightly warmer than the 30 year long term average. July and August 2013 were 1.9 °C and 1.5 °C, respectively, warmer than the long term average air temperature. In addition, December 2013 and February through to April 2014 were 3-4 °C warmer (3.2, 4.3, 3.4 and 3.5 °C, respectively), July 2014, September to November 2014, January 2015 and March 2015 were 2-3.5°C warmer (3.4, 2.9, 3.5, 2.0, 2.5 and 2.0 °C respectively. Rainfall was more erratic. From May 2013 to May 2015 monthly rainfall was significantly lower (>20% difference) than the long term average for 11 out of 25 months and significantly higher (>20% difference) than the long term average for 7 out of 25 months. The total rainfall from the date of application until the last sampling (28 May 2013 – 13 May 2015) was 1267.6 mm, which is slightly lower than the long term average of 1424.9 mm over the same time period. The trial plot was irrigated on those months of lower rainfall to compensate for these drier months. A total of 514.6 mm irrigation was applied to account for the monthly deficits.

*Italy*
The average air temperature during the field phase of the study was slightly warmer than the average for 2007-2014. December 2013 and January to March 2014 and October through to December 2014 were 1.3 to 3.6 °C warmer (1.3, 2.7, 3.6, 1.5, 1.7, 2.8 and 2.9 °C, respectively). Rainfall was more erratic. From June 2013 to June 2015 monthly rainfall was significantly lower (>20% difference) than the long term average for 7 out of 25 months and significantly higher (>20% difference) than the long term average for 12 out of 25 months. Precipitation >100 mm per month was observed in October 2013 (129 mm), November 2013 (105.4 mm), January 2014 (113.8 mm), February 2014 (101 mm), July 2014 (103.2 mm), February 2015 (180.2 mm), March 2015 (100.8 mm) and April 2015 (117.2 mm). The total rainfall from the date of the application until the last sampling (17 June 2013 – 03 June 2015) was 1809.6 mm, which is much higher than the long term average of 1312.6 mm over the same time period. The trial plot was generally irrigated, on months of lower rainfall, to compensate for these drier months. A total of 450.5 mm irrigation was applied to account for the monthly deficits. However, not all deficits were compensated as required.

*Northern France*
The average air temperature during the field phase of the study was generally comparable to the 30 year long term average. It was slightly warmer January to April 2014 (2.5, 2.1, 1.5 and 1.7 °C, respectively), in October and November 2014 (1.7 and 1.8 °C, respectively) and in January 2015 (1.1 °C). It was slightly colder in July and August 2014 (-1.0 and -3.2 °C, respectively) and in February 2015 (-2.0 °C). Rainfall was more erratic. From June 2013 to May 2015 monthly rainfall was significantly lower (>20% difference) than the long term average for 7 out of 24 months and significantly higher (>20% difference) than the long term average for 13 out of 24 months. Very high precipitation (>100 mm per month) was observed in October 2013 (119.4 mm), July 2014 (242.8 mm), September 2014 (118.8 mm) and November 2014 (144.2 mm). Very low precipitation (<20 mm per month) was observed in July 2013 (18.2 mm), March 2014 (13.2 mm), June 2014 (19.4 mm) and March 2015 (16.4 mm). The total rainfall from the date of the application until the last sampling (05 June 2013 – 27

May 2015) was 1701.8 mm, which is much higher than the long term average of 1215.9 mm over the same time period. The trial plot was irrigated on those months of lower rainfall to compensate for these drier months. A total of 267.4 mm irrigation was applied to account for the monthly deficits.

*Southern France*
The average air temperature during the field phase of the study generally followed the 10 year long term average. September, November, December 2013, May, July and August 2014 and February 2015 were slightly colder than the long term average. All other months between July 2013 and June 2015 were on average approximately 1.5 °C warmer than the 10 year long term average. Rainfall was more erratic. Rainfall was significantly lower (>20% difference) than the long term average for 14 out of 24 months and significantly higher (>20% difference) than the long term average for 4 out of 24 months. Very low rainfall (< 20 mm) was observed in March 2014 (1.8 mm), June 2014 (14.0 mm) and October 2014 (11.2 mm). Very high rainfall (> 80 mm) was in November 2013 (94.2 mm) and January 2014 (92.4 mm). The total rainfall during the field phase from date of the application until the last sampling (22 June 2015), was 1073.4 mm which is lower than the long term average of 1439.6 mm over the same time period. The trial plot was generally irrigated, on months of lower rainfall, to compensate for these drier months. A total of 877 mm irrigation was applied to account for the monthly deficits.

*Spain*
The average air temperature during the field phase of the study was in a range of -1.9 °C to +2.4 °C in comparison to the long term average. 12 of the 25 months were slightly colder (-0.1 to -2.0 °C) and 12 of the 25 months were slightly warmer (+0.2 to 2.4 °C). One month was exactly the same as the long term average. Rainfall was more erratic. Rainfall was significantly lower (>20% difference) than the long term average for 17 out of 25 months and significantly higher (>20% difference) than the long term average for 2 out of 25 months. The total rainfall, during the field phase (from date of application on 28 May 2013 to last sampling on 12 May 2015), was 626.0 mm which was much lower than the long term average of 1278.4 mm over the same time period. The trial plot was irrigated, on months of lower rainfall, to compensate for the drier months. A total of 2104.9 mm irrigation was applied to account for the monthly deficits.

*United Kingdom*
The average air temperature during the field phase of the study was much warmer than the 30 year long term average. Average on-site air temperatures were higher than long term average from October 2013 through to April 2014 (3.1, 1.2, 4.7, 5.3, 5.4, 3.7 and 2.8 °C, respectively) and from October 2014 through to April 2015 (3.1, 3.0, 3.3, 4.4, 3.1, 2.6 and 1.7 °C, respectively). Rainfall was more erratic. From June 2013 to June 2014 monthly rainfall was significantly lower (>20% difference) than the long term average for 10 out of 24 months and significantly higher (>20% difference) than the long term average for 7 out of 24 months. Very high monthly on-site precipitation was observed in October 2013 (109 mm), January 2014 (107.6 mm), May 2014 (90.8 mm) and November 2014 (98.8 mm).Very low monthly on-site precipitation was observed in September 2013 (8.0 mm), September 2014 (0.4 mm) and April 2015 (19.8 mm). The total rainfall from the date of the application until the last sampling (04 June 2013 – 23 May 2015) was 1241.8 mm which is slightly higher than the long term average of 1193.4 mm over the same time period. The trial plot was irrigated on months of lower rainfall, to compensate for drier months. No irrigation was applied to compensate for September 2013 since the pump was broken in October 2013. No irrigation was applied in November and December 2013, March 2014, December 2014, January 2015 and February 2015 because the soil was already very wet. The moisture requirements were further not met in August, September, October 2014, March 2015 as well as April 2015. A total of 268.2 mm irrigation was applied to account for the monthly deficits.

***Application Verification***
The following table provides for each site the application rate determined based on the application solution remaining in the spray tanks, the application rate determined from the deposition trays, and the application rate determined from the cores taken immediately after application. As can be seen, there was some variability in application rate calculated from residues seen in deposition trays and from soil sampling compared to that planned. However experience suggests that variability of soil residues in the first few weeks of field dissipation studies is a common occurrence and not easily explained. The variability is not of undue concern to HSE, noting that decline rates are calculated from measured soil residues.

**Table B.8. 76 Verification of application rate**

| Field trial | Application rate (g/ha)* based on | | |
|---|---|---|---|
| | Application solution remaining in the spray tanks | Deposition trays | Soil sample at 0 DAA |
| Germany | 199 | 169 | 145 |
| Italy | 204 | 181 | 153 |
| Northern France | 206 | 164 | 116 |
| Southern France | 208 | 149 | 217 |
| Spain | 214 | 185 | 189 |
| United Kingdom | 188 | 117 | 125 |

* Mean of triplicates

***Residue Analysis***

Procedural recoveries ranged from 68% to 118% for pydiflumetofen, with the limit of quantification (LOQ) of the method at 0.5 µg/kg wet soil across all sites. It is noted that the lower value of the range would be considered to be outside the normally acceptable range; the normal range is 70 – 120% recovery. Low recovery was found in the study at the UK site and was for soil samples fortified at 0.5 µg/kg and 2000 µg/kg. Recovery at an intermediate concentration of 5.0 µg/kg was 83 – 94% and the overall recovery across three concentrations spanning 0.5 – 2000 µg/kg was 80%. It was noted that the highest measured concentration at the UK study was 127 µg/kg, i.e. more than an order of magnitude below the highest fortification concentration. Concentrations in the 10-20 cm horizon at the UK site were as low as 0.6 µg/kg but these accounted for a very small proportion of the residues as the majority of the residue remained in the 0-10cm layer during the study. The evaluation of the analytical method in Volume 3, section CA B.5.1.2 notes that the mean recoveries in the studies are within the acceptable range and with acceptable repeatability. Overall, whilst the occurrence of low recoveries are not ideal, HSE consider that in practice these instances of low procedural recovery are unlikely to impact significantly on the results of the UK study.

The results for all field trials are summarised in the tables below for all individual soil layers. In addition, the residues expressed in g/ha for each replicate plot and depth are presented in Appendix I. The g/ha residues data used in kinetic analysis are presented in Appendix II.

The soil samples were analysed for residues of pydiflumetofen at each sampling point. pydiflumetofen was found to remain mostly in the top soil layer (0 to 10 cm) with initial concentrations in the range of 116 to 189 g a.s./ha, gradually declining to a range of 46 to 118 g a.s./ha at the end of the study period. At lower layers, levels of parent were in the range of 17 g a.s./ha to not detected at 10 – 20 cm, dropping to 13 g a.s./ha to not detected at 20 – 30 cm. At one site (Germany) no parent was detected below 10 cm depth.

**Table B.8. 77 Residues of pydiflumetofen (mean of triplicates) in the individual soil layers for Germany**

| Sampling Date | DAA | Pydiflumetofen [g a.s./ha] | | | |
|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | Total* |
| 27 May 2013 | -1# | ND | ND | ND | ND |
| 28 May 2013 | 0 | 145 | NA | NA | 145 |
| 31 May 2013 | 3 | 157 | ND | NA | 157 |
| 04 Jun 2013 | 7 | 131 | <LOQ | NA | 131 |
| 11 Jun 2013 | 14 | 142 | <LOQ | NA | 142 |
| 26 Jun 2013 | 29 | 117 | ND | NA | 117 |
| 25 Jul 2013 | 58 | 105 | ND | NA | 105 |
| 24 Sep 2013 | 119 | 109 | <LOQ | NA | 109 |
| 22 Nov 2013 | 178 | 131 | ND | NA | 131 |
| 21 May 2014 | 358 | 111 | <LOQ | NA | 111 |
| 12 Nov 2014 | 533 | 144 | <LOQ | NA | 144 |
| 13 May 2015 | 715 | 112 | <LOQ | NA | 112 |

DAA - days after application (-1#: 1 day before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).
* The total residue is summed from the individual soil layer unrounded residue values.

**Figure B.8. 11 Pydiflumetofen residues with time - Germany**

**Germany**

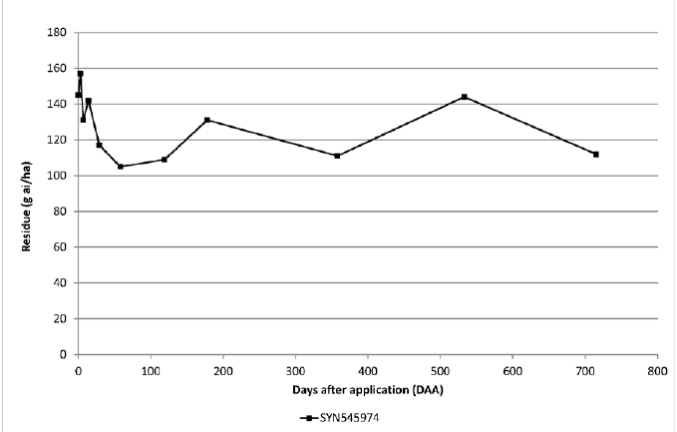


**Table B.8. 78 Residues of pydiflumetofen (triplicate values) in the individual soil layers for Germany**

| Timing | Pydiflumetofen (µg/kg) dry weight Horizon | | | |
|---|---|---|---|---|
| | 0-10 cm | 10-20 cm | 20-30 cm | 30-50 cm |
| 1 DBA | ND | ND | NA | NA |
| 1 DBA | ND | ND | NA | NA |
| 1 DBA | ND | ND | NA | NA |
| 1 DBA | ND | ND | NA | NA |
| 0 DAA | 93.8 | - | NA | NA |
| 0 DAA | 101.7 | - | NA | NA |
| 0 DAA | 97.3 | - | NA | NA |
| 3 DAA | 123.9 | ND | NA | NA |
| 3 DAA | 107.6 | ND | NA | NA |
| 3 DAA | 88.8 | ND | NA | NA |
| 7 DAA | 89.0 | ND | NA | NA |
| 7 DAA | 89.9 | <LOQ | NA | NA |
| 7 DAA | 92.5 | ND | NA | NA |
| 14 DAA | 78.7 | <LOQ | NA | NA |
| 14 DAA | 106.8 | ND | NA | NA |
| 14 DAA | 83.7 | ND | NA | NA |
| 29 DAA | 71.1 | ND | NA | NA |
| 29 DAA | 79.7 | ND | NA | NA |
| 29 DAA | 76.0 | ND | NA | NA |
| 58 DAA | 55.8 | ND | NA | NA |
| 58 DAA | 71.9 | ND | NA | NA |
| 58 DAA | 72.6 | ND | NA | NA |
| 119 DAA | 69.4 | <LOQ | NA | NA |
| 119 DAA | 78.4 | ND | NA | NA |
| 119 DAA | 71.5 | ND | NA | NA |
| 178 DAA | 88.9 | ND | NA | NA |
| 178 DAA | 73.7 | ND | NA | NA |
| 178 DAA | 83.6 | ND | NA | NA |
| 358 DAA | 69.9 | ND | NA | NA |
| 358 DAA | 70.1 | ND | NA | NA |
| 358 DAA | 66.5 | <LOQ | NA | NA |
| 533 DAA | 74.1 | ND | NA | NA |
| 533 DAA | 128.0 | ND | NA | NA |
| 533 DAA | 49.4 | <LOQ | NA | NA |
| 715 DAA | 60.7 | ND | NA | NA |
| 715 DAA | 58.0 | ND | NA | NA |
| 715 DAA | 67.4 | <LOQ | NA | NA |

DBA - days before application DAA – days after application

<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)

ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)

NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)

**Table B.8. 79 Residues of pydiflumetofen (mean of triplicates) in the individual soil layers for Italy**

| Sampling Date | DAA | Pydiflumetofen [g a.s./ha] | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | 30-50 cm | 50-70 cm | 70-100 cm | Total* |
| 27 May 2013 | -21# | ND | ND | NA | NA | NA | NA | ND |
| 17 Jun 2013 | 0 | 153 | NA | NA | NA | NA | NA | 153 |
| 20 Jun 2013 | 3 | 106 | 4 | 2 | NA | NA | NA | 112 |
| 24 Jun 2013 | 7 | 148 | 3 | 2 | NA | NA | NA | 153 |
| 01 Jul 2013 | 14 | 155 | 4 | 2 | 2 | 0 | NA | 163 |
| 15 Jul 2013 | 28 | 126 | 2 | 1 | 2 | 1 | 2 | 134 |
| 14 Aug 2013 | 58 | 132 | 3 | 2 | 2 | 0 | NA | 139 |
| 16 Oct 2013 | 121 | 93 | 0 | NA | NA | NA | NA | 93 |
| 16 Dec 2013 | 182 | 119 | 0 | 0 | NA | NA | NA | 119 |
| 18 Jun 2014 | 366 | 112 | 2 | 2 | NA | NA | NA | 116 |
| 11 Dec 2014 | 542 | 116 | 3 | 1 | 0 | NA | NA | 120 |
| 03 Jun 2015 | 716 | 69 | 4 | 2 | 2 | 0 | NA | 77 |

DAA - days after application (-21#: 21 days before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).
* The total residue is summed from the individual soil layer unrounded residue values

**Figure B.8. 12 Pydiflumetofen residues with time - Italy**

**Italy**

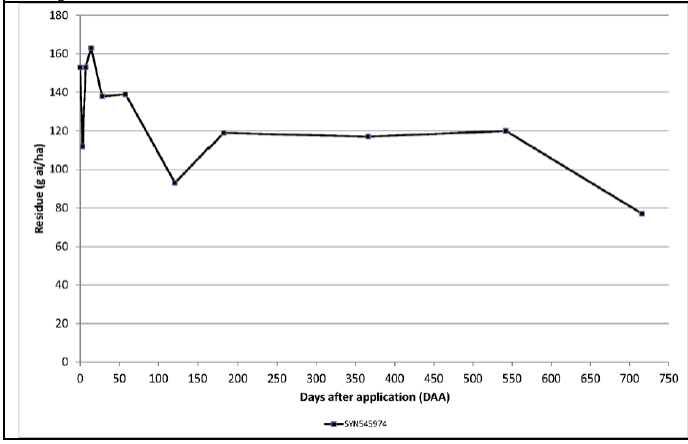


**Table B.8. 80 Residues of pydiflumetofen (triplicate values) in the individual soil layers for Italy**

| DAA | Pydiflumetofen (µg/kg) dry weight<br>Horizon | | | | | |
|---|---|---|---|---|---|---|
| | **0–10 cm** | **10–20 cm** | **20–30 cm** | **30-50 cm** | **50-70 cm** | **70-100 cm** |
| -21# | ND | ND | NA | NA | NA | NA |
| | ND | ND | NA | NA | NA | NA |
| | ND | ND | NA | NA | NA | NA |
| 0 | 122 | NA | NA | NA | NA | NA |
| 0 | 135 | NA | NA | NA | NA | NA |
| 0 | 78.9 | NA | NA | NA | NA | NA |
| 3 | 95.0 | 4.3 | 2.4 | NA | NA | NA |
| 3 | 97.2 | 2.5 | 0.8 | NA | NA | NA |
| 3 | 57.0 | 2.0 | 0.9 | NA | NA | NA |
| 7 | 98.7 | 2.7 | 2.4 | NA | NA | NA |
| 7 | 134 | 2.0 | 1.4 | NA | NA | NA |
| 7 | 66.3 | 1.7 | 0.7 | NA | NA | NA |
| 14 | 113 | 1.8 | 1.8 | 0.7 | ND | NA |
| 14 | 117 | 3.9 | 1.1 | 0.7 | ND | NA |
| 14 | 101 | 1.5 | 1.3 | 0.7 | <LOQ | NA |
| 28 | 93.1 | 1.4 | 1.1 | 0.7 | <LOQ | NA |
| 28 | 88.0 | 1.9 | 0.8 | <LOQ | NA | NA |
| 28 | 92.5 | 1.8 | 1.5 | 1.3 | 0.9 | 1.0 |
| 58 | 89.1 | 2.7 | 1.6 | 0.9 | <LOQ | NA |
| 58 | 67.1 | 2.1 | 1.4 | <LOQ | NA | NA |
| 58 | 138 | 2.6 | 2.0 | 1.1 | <LOQ | NA |
| 121 | 55.5 | ND | NA | NA | NA | NA |
| 121 | 54.5 | <LOQ | NA | NA | NA | NA |
| 121 | 80.9 | ND | NA | NA | NA | NA |
| 182 | 99.0 | <LOQ | NA | NA | NA | NA |
| 182 | 80.5 | <LOQ | NA | NA | NA | NA |
| 182 | 97.1 | 0.9 | ND | NA | NA | NA |
| 366 | 75.5 | 0.7 | ND | NA | NA | NA |
| 366 | 74.2 | <LOQ | NA | NA | NA | NA |
| 366 | 84.9 | 3.0 | 2.6 | <LOQ | NA | NA |
| 542 | 66.9 | 1.1 | <LOQ | NA | NA | NA |
| 542 | 59.3 | <LOQ | NA | NA | NA | NA |
| 542 | 95.7 | 4.7 | 2.1 | <LOQ | NA | NA |
| 716 | 58.1 | 1.3 | <LOQ | NA | NA | NA |
| 716 | 44.5 | 1.3 | 1.2 | <LOQ | NA | NA |
| 716 | 50.5 | 5.1 | 2.2 | 1.7 | ND | NA |

DAA - days after application (-21#: 21 days before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)

**Table B.8. 81 Residues of pydiflumetofen (mean of triplicates) in the individual soil layers for Northern France**

| Sampling Date | DAA | Pydiflumetofen [g a.s./ha] | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | 30–50 cm | 50–70 cm | 70–100 cm | Total* |
| 30 May 2013 | -6# | ND | ND | ND | ND | ND | ND | ND |
| 05 Jun 2013 | 0 | 116 | NA | NA | NA | NA | NA | 116 |
| 08 Jun 2013 | 3 | 120 | <LOQ | NA | NA | NA | NA | 120 |
| 12 Jun 2013 | 7 | 157 | <LOQ | NA | NA | NA | NA | 157 |
| 18 Jun 2013 | 13 | 133 | 3 | 3 | 2 | 1 | <LOQ | 142 |
| 02 Jul 2013 | 27 | 123 | 2 | 1 | <LOQ | NA | NA | 126 |
| 06 Aug 2013 | 62 | 132 | 7 | 4 | 2 | <LOQ | NA | 145 |
| 02 Oct 2013 | 119 | 137 | 3 | <LOQ | NA | NA | NA | 140 |
| 29 Nov 2013 | 177 | 144 | 4 | 1 | <LOQ | NA | NA | 149 |
| 10 Jun 2014 | 370 | 142 | 4 | 1 | <LOQ | NA | NA | 147 |
| 03 Dec 2014 | 546 | 91 | 5 | 1 | ND | NA | NA | 97 |
| 27 May 2015 | 721 | 118 | 8 | 1 | <LOQ | NA | NA | 127 |

DAA - days after application (-6#: 6 days before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).
* The total residue is summed from the individual soil layer unrounded residue values.

**Figure B.8. 13 Pydiflumetofen residues with time – Northern France**

**Northern France**

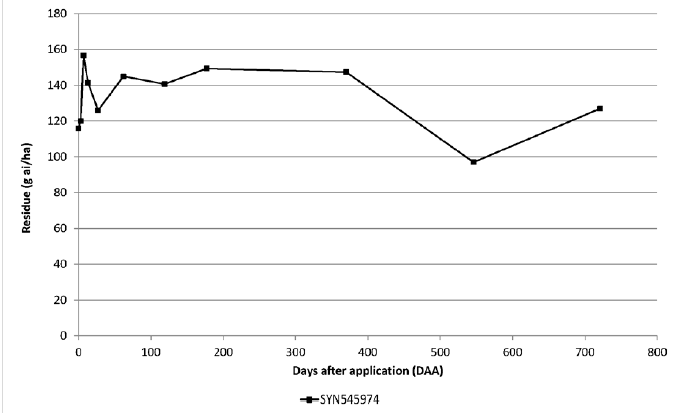


**Table B.8. 82 Residues of pydiflumetofen (triplicate values) in the individual soil layers for Northern France**

| DAA | Pydiflumetofen (µg/kg) dry weight<br>Horizon | | | | | |
|---|---|---|---|---|---|---|
| | **0–10 cm** | **10–20 cm** | **20–30 cm** | **30–50 cm** | **50–70 cm** | **70–100 cm** |
| -6# | ND | ND | NA | NA | NA | NA |
| -6# | ND | ND | NA | NA | NA | NA |
| -6# | ND | ND | NA | NA | NA | NA |
| 0 | 81.3 | NA | NA | NA | NA | NA |
| 0 | 91.5 | NA | NA | NA | NA | NA |
| 0 | 81.2 | NA | NA | NA | NA | NA |
| 3 | 92.8 | <LOQ | NA | NA | NA | NA |
| 3 | 92.1 | <LOQ | NA | NA | NA | NA |
| 3 | 94.4 | <LOQ | NA | NA | NA | NA |
| 7 | 130 | <LOQ | NA | NA | NA | NA |
| 7 | 124 | <LOQ | NA | NA | NA | NA |
| 7 | 105 | <LOQ | NA | NA | NA | NA |
| 13 | 92.8 | 2.3 | 2.3 | 1.1 | 0.7 | <LOQ |
| 13 | 72.1 | 1.4 | 1.3 | 1.0 | <LOQ | NA |
| 13 | 60.2 | 1.7 | 0.6 | <LOQ | NA | NA |
| 27 | 58.6 | 1.3 | <LOQ | NA | NA | NA |
| 27 | 67.0 | 2.0 | 1.1 | <LOQ | NA | NA |
| 27 | 76.5 | 0.8 | <LOQ | NA | NA | NA |
| 62 | 88.5 | 2.6 | 1.6 | <LOQ | NA | NA |
| 62 | 159 | 5.1 | 2.3 | 0.7 | <LOQ | NA |
| 62 | 61.7 | 5.3 | 2.7 | 1.1 | <LOQ | NA |
| 119 | 84.0 | 6.1 | <LOQ | NA | NA | NA |
| 119 | 76.2 | <LOQ | NA | NA | NA | NA |
| 119 | 74.8 | <LOQ | NA | NA | NA | NA |
| 177 | 96.1 | 2.1 | <LOQ | NA | NA | NA |
| 177 | 78.2 | 3.1 | 0.9 | ND | NA | NA |
| 177 | 73.9 | 1.4 | 0.7 | <LOQ | NA | NA |
| 370 | 75.4 | 1.6 | 0.6 | <LOQ | NA | NA |
| 370 | 111 | 3.0 | 0.6 | <LOQ | NA | NA |
| 370 | 75.8 | 3.0 | <LOQ | NA | NA | NA |
| 546 | 70.1 | 2.8 | <LOQ | NA | NA | NA |
| 546 | 59.3 | 2.2 | 1.1 | <LOQ | NA | NA |
| 546 | 49.9 | 2.7 | <LOQ | NA | NA | NA |
| 721 | 87.1 | 2.1 | 1.1 | <LOQ | NA | NA |
| 721 | 55.2 | 6.9 | <LOQ | NA | NA | NA |
| 721 | 57.3 | 2.8 | 1.2 | <LOQ | NA | NA |

DAA - days after application (-6#: 6 days before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)

**Table B.8. 83 Residues of pydiflumetofen (mean of triplicates) in the individual soil layers for Southern France**

| Sampling Date | DAA | Pydiflumetofen [g a.s./ha] | | | | |
|---|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | 30–50 cm | Total* |
| 01 Jul 2013 | -0# | ND | ND | ND | NA | ND |
| 01 Jul 2013 | 0 | 217 | NA | NA | NA | 217 |
| 04 Jul 2013 | 3 | 179 | 2 | 0 | NA | 181 |
| 08 Jul 2013 | 7 | 182 | 17 | 13 | NA | 212 |
| 16 Jul 2013 | 15 | 93 | 5 | 2 | 2 | 102 |
| 30 Jul 2013 | 29 | 111 | 2 | ND | NA | 113 |
| 29 Aug 2013 | 59 | 95 | ND | NA | NA | 95 |
| 30 Oct 2013 | 121 | 100 | <LOQ | NA | NA | 100 |
| 20 Dec 2013 | 172 | 85 | <LOQ | NA | NA | 85 |
| 02 Jul 2014 | 366 | 84 | 1 | <LOQ | NA | 85 |
| 16 Dec 2014 | 533 | 63 | 1 | <LOQ | NA | 64 |
| 22 Jun 2015 | 721 | 46 | 1 | 1 | ND | 48 |

DAA - days after application (-0#: 0 days before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).
* The total residue is summed from the individual soil layer unrounded residue values.

**Figure B.8. 14 Pydiflumetofen residues with time – Southern France**

**Southern France**

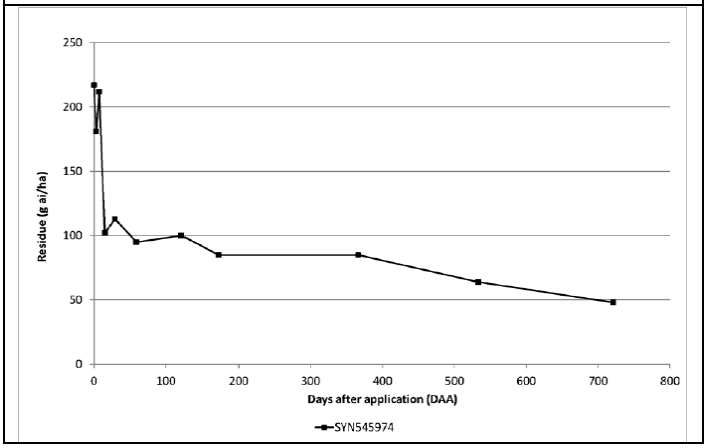


**Table B.8. 84 Residues of pydiflumetofen (triplicate values) in the individual soil layers for Southern France**

| DAA | Pydiflumetofen (µg/kg) dry weight<br>Horizon | | | | |
|---|---|---|---|---|---|
| | **0–10 cm** | **10–20 cm** | **20–30 cm** | **30–50 cm** | **50-70 cm** |
| -0# | ND | ND | NA | NA | NA |
| -0# | ND | ND | NA | NA | NA |
| -0# | ND | ND | NA | NA | NA |
| 0 | 176 | NA | NA | NA | NA |
| 0 | 140 | NA | NA | NA | NA |
| 0 | 134 | NA | NA | NA | NA |
| 3 | 104 | 0.6 | <LOQ | NA | NA |
| 3 | 154 | 1.5 | 1.0 | NA | NA |
| 3 | 187 | 1.6 | <LOQ | NA | NA |
| 7 | 173 | 9.0 | 6.7 | NA | NA |
| 7 | 192 | 20.1 | 10.8 | NA | NA |
| 7 | 114 | 9.7 | 15.3 | NA | NA |
| 15 | 102 | 5.8 | 2.7 | 0.6 | ND |
| 15 | 59.9 | 2.4 | 2.1 | 1.1 | ND |
| 15 | 58.6 | 2.2 | 1.5 | 0.6 | ND |
| 29 | 83.2 | 4.3 | ND | NA | NA |
| 29 | 70.7 | ND | NA | NA | NA |
| 29 | 80.5 | ND | NA | NA | NA |
| 59 | 61.8 | ND | NA | NA | NA |
| 59 | 84.5 | <LOQ | NA | NA | NA |
| 59 | 56.8 | ND | NA | NA | NA |
| 121 | 90.8 | <LOQ | NA | NA | NA |
| 121 | 74.5 | ND | NA | NA | NA |
| 121 | 53.3 | ND | NA | NA | NA |
| 172 | 74.0 | <LOQ | NA | NA | NA |
| 172 | 45.8 | <LOQ | NA | NA | NA |
| 172 | 67.6 | <LOQ | NA | NA | NA |
| 366 | 55.4 | 0.6 | <LOQ | NA | NA |
| 366 | 62.3 | 0.9 | <LOQ | NA | NA |
| 366 | 74.3 | 1.0 | <LOQ | NA | NA |
| 533 | 48.6 | 0.7 | <LOQ | NA | NA |
| 533 | 70.3 | <LOQ | NA | NA | NA |
| 533 | 40.8 | 0.9 | <LOQ | NA | NA |
| 721 | 46.2 | 1.0 | 1.9 | ND | NA |
| 721 | 29.2 | 1.5 | <LOQ | NA | NA |
| 721 | 28.2 | <LOQ | NA | NA | NA |

DAA - days after application (-0#: 0 days before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)

**Table B.8. 85 Residues of pydiflumetofen (mean of triplicates) in the individual soil layers for Spain**

| Sampling Date | DAA | Pydiflumetofen [g a.s./ha] | | | |
|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | Total* |
| 24 May 2013 | -4# | ND | ND | ND | ND |
| 28 May 2013 | 0 | 189 | NA | NA | 189 |
| 31 May 2013 | 3 | 231 | 1 | ND | 232 |
| 04 Jun 2013 | 7 | 210 | 1 | <LOQ | 211 |
| 11 Jun 2013 | 14 | 65 | <LOQ | NA | 65 |
| 26 Jun 2013 | 29 | 81 | 1 | ND | 82 |
| 29 Jul 2013 | 62 | 110 | 2 | <LOQ | 112 |
| 24 Sep 2013 | 119 | 106 | 11 | ND | 117 |
| 22 Nov 2013 | 178 | 146 | <LOQ | NA | 146 |
| 21 May 2014 | 358 | 144 | 2 | ND | 146 |
| 17 Nov 2014 | 538 | 80 | 3 | <LOQ | 83 |
| 12 May 2015 | 714 | 91 | 5 | <LOQ | 96 |

DAA - days after application (-4#: 4 days before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).
* The total residue is summed from the individual soil layer unrounded residue values.

**Figure B.8. 15 Pydiflumetofen residues with time – Spain**

**Spain**

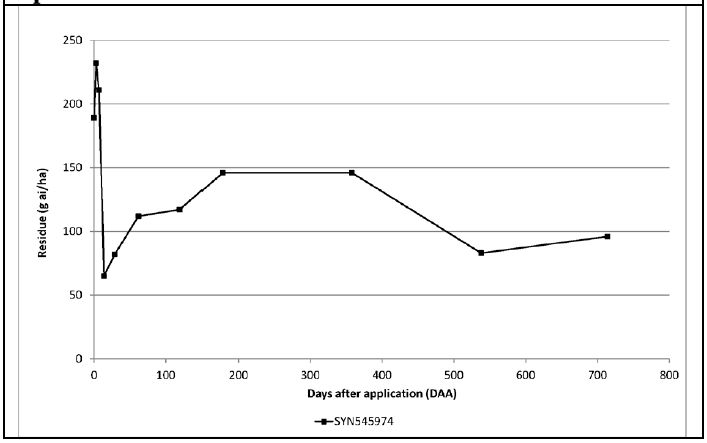


**Table B.8. 86 Residues of pydiflumetofen (triplicate values) in the individual soil layers for Spain**

| DAA | Pydiflumetofen(µg/kg) dry weight<br>Horizon | | | |
|---|---|---|---|---|
| | **0–10 cm** | **10–20 cm** | **20–30 cm** | **30-50 cm** |
| -4# | ND | ND | NA | NA |
| -4# | ND | ND | NA | NA |
| -4# | ND | ND | NA | NA |
| 0 | 144 | NA | NA | NA |
| 0 | 141 | NA | NA | NA |
| 0 | 158 | NA | NA | NA |
| 3 | 187 | <LOQ | NA | NA |
| 3 | 167 | 2.3 | ND | NA |
| 3 | 159 | <LOQ | NA | NA |
| 7 | 182 | <LOQ | NA | NA |
| 7 | 127 | 2.0 | <LOQ | NA |
| 7 | 161 | 0.7 | <LOQ | NA |
| 14 | 29.7 | ND | NA | NA |
| 14 | 25.0 | ND | NA | NA |
| 14 | 81.4 | <LOQ | NA | NA |
| 29 | 95.3 | <LOQ | NA | NA |
| 29 | 35.7 | <LOQ | NA | NA |
| 29 | 45.5 | 2.1 | ND | NA |
| 62 | 65.4 | 2.0 | <LOQ | NA |
| 62 | 80.4 | 0.8 | ND | NA |
| 62 | 92.9 | 0.7 | <LOQ | NA |
| 119 | 68.4 | 1.5 | ND | NA |
| 119 | 68.4 | 19.3 | ND | NA |
| 119 | 71.5 | ND | NA | NA |
| 178 | 77.6 | <LOQ | NA | NA |
| 178 | 99.6 | <LOQ | NA | NA |
| 178 | 131 | <LOQ | NA | NA |
| 358 | 79.3 | <LOQ | NA | NA |
| 358 | 123 | 2.2 | ND | NA |
| 358 | 106 | 0.8 | ND | NA |
| 538 | 45.1 | <LOQ | NA | NA |
| 538 | 61.8 | 3.5 | <LOQ | NA |
| 538 | 50.3 | 1.3 | ND | NA |
| 714 | 48.1 | 5.4 | <LOQ | NA |
| 714 | 81.1 | 5.2 | 0.8 | ND |
| 714 | 76.0 | 4.7 | <LOQ | NA |

DAA - days after application (-4#: 4 days before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)

**Table B.8. 87 Residues of pydiflumetofen (mean of triplicates) in the individual soil layers for the United Kingdom**

| Sampling Date | DAA | Pydiflumetofen [g a.s./ha] | | | |
|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | Total* |
| 03 Jun 2013 | -1# | ND | ND | ND | ND |
| 04 Jun 2013 | 0 | 125 | NA | NA | 125 |
| 07 Jun 2013 | 3 | 132 | ND | NA | 132 |
| 11 Jun 2013 | 7 | 148 | <LOQ | NA | 148 |
| 19 Jun 2013 | 15 | 111 | 1 | <LOQ | 112 |
| 01 Jul 2013 | 27 | 105 | 1 | ND | 106 |
| 02 Aug 2013 | 59 | 132 | 1 | ND | 133 |
| 30 Sep 2013 | 118 | 108 | <LOQ | NA | 108 |
| 03 Dec 2013 | 182 | 154 | 1 | <LOQ | 155 |
| 11 Jun 2014 | 372 | 132 | <LOQ | <LOQ | 132 |
| 25 Nov 2014 | 539 | 119 | 1 | <LOQ | 120 |
| 23 May 2015 | 718 | 85 | 2 | <LOQ | 87 |

DAA - days after application (-1#: 1 day before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).
* The total residue is summed from the individual soil layer unrounded residue values.

**Figure B.8. 16 Pydiflumetofen residues with time – UK**

**UK**

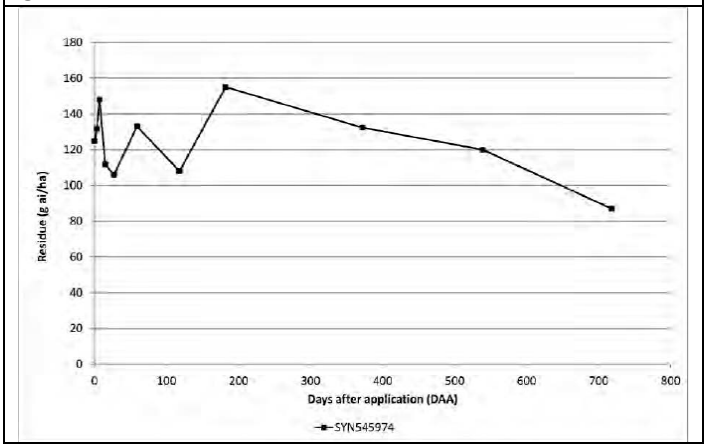


**Table B.8. 88 Residues of pydiflumetofen (triplicate values) in the individual soil layers for the United Kingdom**

| DAA | Pydiflumetofen(µg/kg) dry weight<br>Horizon | | |
|---|---|---|---|
| | **0–10 cm** | **10–20 cm** | **20–30 cm** |
| -1# | ND | ND | NA |
| -1# | ND | ND | NA |
| -1# | ND | ND | NA |
| 0 | 87.0 | NA | NA |
| 0 | 87.6 | NA | NA |
| 0 | 76.5 | NA | NA |
| 3 | 99.1 | ND | NA |
| 3 | 116 | ND | NA |
| 3 | 94.2 | ND | NA |
| 7 | 109 | ND | NA |
| 7 | 127 | ND | NA |
| 7 | 110 | <LOQ | NA |
| 15 | 98.3 | <LOQ | NA |
| 15 | 101 | <LOQ | NA |
| 15 | 77.2 | 1.3 | <LOQ |
| 27 | 97.9 | 0.6 | ND |
| 27 | 87.6 | 0.6 | ND |
| 27 | 86.3 | 0.8 | ND |
| 59 | 113 | 0.9 | ND |
| 59 | 86.6 | <LOQ | NA |
| 59 | 129 | 0.8 | ND |
| 118 | 105 | <LOQ | NA |
| 118 | 78.8 | <LOQ | NA |
| 118 | 85.6 | <LOQ | NA |
| 182 | 118 | <LOQ | NA |
| 182 | 112 | ND | NA |
| 182 | 110 | 1.2 | <LOQ |
| 372 | 96.6 | <LOQ | NA |
| 372 | 112 | <LOQ | NA |
| 372 | 101 | 0.7 | <LOQ |
| 539 | 116 | 1.4 | <LOQ |
| 539 | 141 | 5.6 | <LOQ |
| 539 | 83.8 | 1.3 | ND |
| 718 | 103 | 2.9 | <LOQ |
| 718 | 55.1 | 1.0 | <LOQ |
| 718 | 46.2 | <LOQ | NA |

DAA - days after application (-1#: 1 day before application);
<LOQ - Residues are below the limit of quantification (0.5 µg/kg wet weight soil)
ND - Residues are below the limit of detection (0.15 µg/kg wet weight soil)
NA - Not analysed (only 0-10 cm cores taken at 0 DAA and 20-30 depths not analysed as the 10-20 cm soil layer had residues below the LOQ of the method, 0.5 µg/kg wet soil weight)

**Chiral analysis**

Chiral analysis of the 0 DAA and 533 to 546 DAA samples for the pydiflumetofen enantiomers SYN546968 and SYN546969 was done on the 0-10 cm depth soil segments as the majority of the pydiflumetofen residue was found in this soil layer. The results of the chiral analysis are shown below. The enantiomer elution order was confirmed to be SYN546968 before SYN546969. No significant change in the enantiomer ratio between the two time points was observed for all sites, with initial ratios in the range of 0.95 to 1.03 and final ratios in the range

of 0.97 to 1.08. HSE has also added calculations of the enantiomer excess for each site and the % change seen. The values are calculated on the means of the three subplots.

Due to the lack of downward movement with only low residues found at lower depths and it was considered by the applicant to be not technically feasible to conduct an enantiomer analysis at various depths in the samples from any of the six studies. The LOQ for the analytical methods used for the determination of total soil residues is 0.5 µg/kg. A separate chiral analytical method is required to analyse for individual enantiomers levels, the LOD at which reliable enantiomers residues can be determined is 15 µg/kg. The maximum residue level of pydiflumetofen at lower depths in the 18 months sample is 4.7 µg/kg which is well below the level at which reliable results can be obtained (15µg/kg).

**Table B.8. 89 Enantiomer Ratio of 0 DAA and 533 DAA (0-10 cm depth) Soil Samples in Germany (average of 3 sub plots)**

| | % Sample activity as | | | | |
|---|---|---|---|---|---|
| **Sample Interval** | **SYN546968 Area** | **SYN546969 Area** | **Enantiomer ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| 0 DAA | 3316.00 | 3351.67 | 0.99 | -0.53 | |
| 533 DAA | 3222.67 | 3272.00 | 0.99 | -0.76 | 0.22 |

**Table B.8. 90 Enantiomer Ratio of 0 DAA and 542 DAA (0-10 cm depth) Soil Samples in Italy (average of 3 sub plots)**

| | % Sample activity as | | | | |
|---|---|---|---|---|---|
| **Sample Interval** | **SYN546968 Area** | **SYN546969 Area** | **Enantiomer ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| 0 DAA | 5976.33 | 6002.00 | 0.99 | -0.21 | |
| 542 DAA | 6582.67 | 6636.00 | 0.99 | -0.40 | 0.19 |

**Table B.8. 91 Enantiomer Ratio of 0 DAA and 546 DAA (0-10 cm depth) Soil Samples in Northern France (average of 3 sub plots)**

| | % Sample activity as | | | | |
|---|---|---|---|---|---|
| **Sample Interval** | **SYN546968 Area** | **SYN546969 Area** | **Enantiomer ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| 0 DAA | 7148.67 | 7297.00 | 0.98 | -1.03 | |
| 546 DAA | 5068.67 | 5157.67 | 0.99 | -0.87 | 0.16 |

**Table B.8. 92 Enantiomer Ration of 0 DAA and 533 DAA (0-10 cm depth) Soil Samples in Southern France (average of 3 sub plots)**

| | % Sample activity as | | | | |
|---|---|---|---|---|---|
| **Sample Interval** | **SYN546968 Area** | **SYN546969 Area** | **Enantiomer ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| 0 DAA | 4327.67 | 4315.33 | 1.00 | 0.14 | |
| 533 DAA | 3128.67 | 2957.33 | 1.05 | 2.82 | 2.67 |

**Table B.8. 93 Enantiomer Ratio of 0 DAA and 538 DAA (0-10 cm depth) Soil Samples in Spain (average of 3 sub plots)**

| | % Sample activity as | | | | |
|---|---|---|---|---|---|
| **Sample Interval** | **SYN546968 Area** | **SYN546969 Area** | **Enantiomer ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| 0 DAA | 6588.67 | 6768.33 | 0.97 | -1.35 | |
| 538 DAA | 4406.33 | 4189.67 | 1.05 | 2.52 | 3.87 |

**Table B.8. 94 Enantiomer Ratio of 0 DAA and 539 DAA (0-10 cm depth) Soil Samples in the United Kingdom (average of 3 sub plots)**

| | % Sample activity as | | | | |
|---|---|---|---|---|---|
| **Sample Interval** | **SYN546968 Area** | **SYN546969 Area** | **Enantiomer ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| 0 DAA | 7502.00 | 7536.00 | 1.00 | -0.23 | |
| 539 DAA | 8811.67 | 8785.67 | 1.00 | 0.15 | 0.37 |

HSE notes that the change seen in enantiomer excess was relatively small, i.e. 0.16 – 3.87%. However the measurement was taken well before the calculated DT50 for five out of the six study sites.

**Conclusions**

The six field dissipation studies reported here are considered by HSE to be acceptable. EU guidance retained by GB post-EU Exit indicates that European studies can be accepted for use in regulatory assessments.

At all sites, pydiflumetofen was found to remain mostly in the top soil layer (0 to 10 cm). At one site (Germany) no pydiflumetofen was detected below 10 cm depth. At the end of the sampling period, after approximately two years total soil residues of pydiflumetofen at the six trial locations had dissipated by 38% to 76%, based on the nominal application rate. HSE notes that historically, field dissipation studies have tended to be run for up to two years duration although the typical guidance followed, e.g. SETAC guidance, does not give a specific duration. The EPA guidance mentions the historical two year duration but states that the duration "*should be sufficient to determine the DT75 of the parent compound*". As noted, pydiflumetofen declined to 38 – 76% of the highest measured residue in these studies. Only one site would have declined to 25% if the amount applied as measured by the application solution remaining in the spray tank was taken into consideration. Whilst a longer study duration would have been preferable, the EPA guideline could be interpreted that the duration should be sufficient to determine the DT75 by extrapolation of the residue decline, rather than continuing until the residue had declined to 75% of the highest measured residue. Thus whilst the study duration is shorter than would have been desirable for this substance, HSE cannot reject the studies as being unacceptable on these grounds alone.

The change in enantiomer ratio was measured once for each site. The change in enantiomer excess seen was relatively small, i.e. 0.16 – 3.87%. However the measurement was taken well before the calculated DT50 for five out of the six study sites. Assuming a linear relationship for the change, the extrapolated change in enantiomer excess was anticipated to be less than 10% by the time of 50% dissipation. As with other studies, the availability of only a single data point after the day 0 sample leaves some uncertainty. However the change in enantiomer excess appears to be lower than that seen in the aerobic laboratory soil incubation or other laboratory soil studies. This might suggest that under more realistic field conditions the change in enantiomer excess is not as significant as suggested by laboratory study results.

The study design used at each field site is optimised to allow the calculation of normalised degradation rates in the bulk soil matrix (DegT50) as the soil surface was covered in sand immediately after application. This is to minimise surface losses from processes such as volatilisation and soil surface photolysis. As such this study design may under-estimate dissipation under field conditions. This is recognised in the EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil (EFSA Journal 2014;12(5):3662) which presents a study design for DegT50 derivation; this guidance is retained for use in GB post EU Exit. It was noted in the laboratory soil photolysis study reported in section B.8.1.1.1.3 that there was

evidence that pydiflumetofen declined more quickly under illuminated conditions than under dark conditions. Whilst the rate of decline under illuminated conditions was slow, for a persistent substance such as pydiflumetofen, soil surface photolysis may play a role in the decline of residues on the soil surface. The covering of the soil surface with sand immediately after application in the field dissipation studies prevented photolysis occurring. Consequently the decline of pydiflumetofen seen in these field studies may not be fully representative of what may be seen in the field situation when applied to a crop where the residue reaching the soil surface may be exposed to surface processes. Use of non-normalised DisT50 and DisT90 values from these studies may give a conservative assessment of the extent of accumulation in soil over time.

The g/ha residue at each sample time was calculated from the wet weight concentration. The wet weight concentration was multiplied by the total wet sample weight from five cores to give the residue in the total sample. The total surface area ($cm^2$) of the five core samples was calculated from the individual core diameter. The residue per total sample core area was then converted to a g/ha residue (1 hectare = 1 x $10^8$ $cm^2$). This is acceptable as the effect of variability of sample moisture content on concentration is removed. In addition, as this procedure was performed for each soil layer sampled, the total residue over the sampled soil depth is calculated by adding the g/ha residue in each soil layer. Any inconsistencies in concentration caused by different sampling depths are also removed making it easier to calculate the total residue over the analysed soil depths at each sample time. Therefore, apart for the issue of reporting of values <LOQ, the reporting of g/ha values is acceptable.

The kinetic assessment of these studies is in sections B.8.1.1.1.2.2 (persistence endpoints) and B.8.1.1.1.2.3 (modelling endpoints).

#### B.8.1.1.2.2.1.2 European bare soil field dissipation studies, grass cover allowed to develop

| | |
|---|---|
| **Report: (1 of 8)** | K-CA 7.1.2.2.1/07. [redacted] and [redacted] (2019a), SYN545974 - Preparation of Field Plot in Germany in 2016-2017. Report Number S16-02736, Eurofins Agroscience Services GmbH |

| | |
|---|---|
| **Report: (2 of 8)** | K-CA 7.1.2.2.1/08. [redacted] and [redacted] (2019b), SYN545974 – Soil Dissipation Study in Germany in 2016-2017. Report Number S16-01816, Eurofins Agroscience Services GmbH |

| | |
|---|---|
| **Report: (3 of 8)** | K-CA 7.1.2.2.1/09. [redacted] (2020a), SYN545974 - Preparation of Field Plot in Northern France in 2016-2017. Report Number S16-02739, Eurofins Agroscience Services GmbH |

| | |
|---|---|
| **Report: (4 of 8)** | K-CA 7.1.2.2.1/10. [redacted] (2020b), SYN545974 – Soil Dissipation Study in Northern France in 2016-2017, Final Report Amendment 1. Report Number S16-02708, Eurofins Agroscience Services GmbH |

| | |
|---|---|
| **Report: (5 of 8)** | K-CA 7.1.2.2.1/11. [redacted] (2020c), SYN545974 - Preparation of Field Plot in Southern France in 2016-2017. Report Number S16-02740, Eurofins Agroscience Services GmbH |

| | |
|---|---|
| **Report: (6 of 8)** | K-CA 7.1.2.2.1/12. [redacted] (2020d), SYN545974 – Soil Dissipation Study in Southern France in 2016-2017, Final Report Amendment 1. Report Number S16-02711, Eurofins Agroscience Services GmbH |

| | |
|---|---|
| **Report: (7 of 8)** | K-CA 7.1.2.2.1/13. [redacted] (2020e), SYN545974 - Preparation of Field Plot in Portugal in 2016-2017. Report Number S16-02741, Eurofins Agroscience Services GmbH |

| | |
|---|---|
| **Report:** **(8 of 8)** | K-CA 7.1.2.2.1/14. [redacted] (2020f), SYN545974 – Soil Dissipation Study in Portugal in 2016-2017, Final Report Amendment 1. Report Number S16-02712, Eurofins Agroscience Services GmbH |

| | |
|---|---|
| **Guideline(s):** | EPA Guideline Series OPPTS 835.6100 (2008), SETAC 1995, EFSA (2014), OECD ENV/JM/MONO(2016)6 |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | Due to the applicant requirement that these studies should also generate data for use in EU modelling, the study design was adapted resulting in deviations from the EPA guidelines. The main deviation was that a single application was applied to a bare soil plot. HSE considers that this is acceptable as the historic context for European field dissipation studies is for treatment of bare soil.<br>HSE considers it unlikely that the studies are fully compliant with the DegT50 study design in EFSA (2014). This is because no specific actions were taken to minimise surface losses. In addition, whilst applications were made to bare soil, the sites were sown with grass which was allowed to grow over the duration of the studies. The DegT50 study design specifies an essentially bare soil where there would be no possibility for plant uptake to contribute to residue decline. Nevertheless, this does not detract from the studies being acceptable field dissipation studies to investigate persistence of the a.s. under field conditions. |
| **Acceptability** | Yes |

The applicant submitted reports of field dissipation studies on an additional four European sites. The sites were in Northern Germany, Northern France, Southern France and Portugal. Each site had two reports, one detailing the preparations made to the site prior to application of the test substance and a further report detailing the field dissipation study. Each study used the same design and methodology and differed only in details such as site history and dates of key operations such as application, sampling and irrigation.

**Materials**

| | |
|---|---|
| **Test Material:** | A19649B |
| **Description:** | 200 SC formulation (liquid / white) |
| **Lot/Batch #:** | JHU002-037-001 |
| **Purity (actual concentration):** | 200 g a.s./L (18.3 % w/w) |
| **Stability of test compound:** | The formulation is stable when stored at <30ºC. (the test item was stored dark and dry at room temperature at 19.1 – 23.6°C) |

**Test system and trial layout**

The treated plots were located in area typical for cereal cultivation which were not prone to flooding or erosion on level ground (no slope). The sites were easily accessible, was not set up in the headland of the field or close to any trees. The soils were homogenous and not too stony, and the sites had not been cultivated with trees or vines in the previous 3 years prior to study start. A summary of the soil characteristics and taxonomy is presented below.

**Table B.8. 95 Soil Physicochemical Properties Northern Germany (Burweg)**

| **Soil Depth (cm)** | | **0-10** | **10-20** | **20-30** | **30-50** | **50-70** | **70-100** |
|---|---|---|---|---|---|---|---|
| Particle Size Distribution (USDA) (% w/w) | : Sand | 78.3 | 77.5 | 78.2 | 73.0 | 72.2 | 70.0 |
| | : Silt | 14.4 | 14.9 | 14.5 | 18.5 | 15.6 | 13.6 |
| | : Clay | 7.4 | 7.7 | 7.3 | 8.6 | 12.3 | 16.5 |
| Classification (USDA) | | Loamy sand | Sandy loam | Loamy sand | Sandy loam | Sandy loam | Sandy loam |
| Total Carbon (% w/w) | | 3.9 | 3.9 | 2.6 | 1.3 | 0.42 | <0.3 |
| Total Organic Carbon (% w/w) | | 2.9 | 2.9 | 2.5 | 1.1 | 0.42 | <0.3 |
| $C_{org}$ (TOC * 1.724) | | 5.0 | 5.0 | 4.3 | 1.9 | 0.72 | <0.5 |
| pH (water) | | 4.96 | 5.12 | 5.03 | 4.74 | 4.53 | 4.66 |
| pH (0.01M $CaCl_2$) | | 6.23 | 6.33 | 6.06 | 5.42 | 4.36 | 4.00 |
| Cation Exchange Capacity (meq/100g) | | 11.0 | 11.0 | 10.1 | 5.4 | 3.8 | 5.3 |
| Soil Bulk Density (g/L) | | 1480 | 1520 | 1540 | 1760 | 1930 | 1970 |
| **Soil Depth (cm)** | | **0-4 (nominal)** | | | | | |
| Moisture Retention Capacity (g/100 g dry matter) pF 2.0 | | 22.8 | | | | | |
| Moisture Retention Capacity (g/100 g dry matter) pF 4.2 | | 8.4 | | | | | |
| Biomass (mg C/100 g soil dry mass, 0-100cm) | | 60.2 | | | | | |

**Table B.8. 96 Soil Physicochemical Properties Northern France (Stotzheim)**

| **Soil Depth (cm)** | | **0-10** | **10-20** | **20-30** | **30-50** | **50-70** | **70-100** |
|---|---|---|---|---|---|---|---|
| Particle Size Distribution (USDA) (% w/w) | : Sand | 7.6 | 7.6 | 4.8 | 3.4 | 3.1 | 4.8 |
| | : Silt | 51.5 | 52.0 | 53.3 | 49.0 | 51.6 | 68.8 |
| | : Clay | 41.0 | 40.5 | 42.0 | 47.7 | 45.4 | 26.5 |
| Classification (USDA) | | silty clay | silty clay | silty clay | silty clay | silty clay | silt loam |
| Total Carbon (% w/w) | | 2.3 | 2.1 | 1.6 | 0.69 | < 0.3 | 1.6 |
| Total Organic Carbon (% w/w) | | 2.3 | 2.1 | 1.4 | 0.68 | < 0.3 | < 0.3 |
| $C_{org}$ (TOC * 1.724) | | 4.0 | 3.6 | 2.4 | 1.2 | < 0.5 | < 0.5 |
| pH (water) | | 5.45 | 5.20 | 4.96 | 4.78 | 6.72 | 7.33 |
| pH (0.01M $CaCl_2$) | | 6.13 | 5.65 | 5.71 | 6.01 | 6.64 | 7.58 |
| Cation Exchange Capacity (meq/100g) | | 19.4 | 19.5 | 18.2 | 20.0 | 21.8 | 16.3 |
| Soil Bulk Density (g/L) | | 1080 | 1190 | 1220 | 1310 | 1370 | 1450 |
| **Soil Depth (cm)** | | **4-8 (nominal)** | | | | | |
| Moisture Retention Capacity (g/100 g dry matter) pF 2.0 | | 32.6 | | | | | |
| Moisture Retention Capacity (g/100 g dry matter) pF 4.2 | | 26.5 | | | | | |
| Biomass (mg C/100 g soil dry mass, 0-100cm) | | 74.5 | | | | | |

**Table B.8. 97 Soil Physicochemical Properties Southern France (Barry d'Islemade)**

| **Soil Depth (cm)** | | **0-10** | **10-20** | **20-30** | **30-50** | **50-70** | **70-100** |
|---|---|---|---|---|---|---|---|
| Particle Size Distribution (USDA) (% w/w) | : Sand | 22.0 | 22.3 | 22.0 | 23.0 | 25.2 | 20.2 |
| | : Silt | 54.7 | 54.0 | 54.8 | 53.9 | 51.6 | 52.9 |
| | : Clay | 23.4 | 23.8 | 23.3 | 23.2 | 23.3 | 26.9 |
| Classification (USDA) | | Silt loam | Silt loam | Silt loam | Silt loam | Silt loam | Silt loam |
| Total Carbon (% w/w) | | 2.0 | 2.0 | 2.1 | 2.0 | 2.2 | 1.6 |
| Total Organic Carbon (% w/w) | | 0.84 | 0.93 | 0.72 | 0.50 | 0.41 | 0.67 |
| $C_{org}$ (TOC * 1.724) | | 1.4 | 1.6 | 1.2 | 0.86 | 0.71 | 1.2 |
| pH (water) | | 7.35 | 7.22 | 7.14 | 7.46 | 7.47 | 7.56 |
| pH (0.01M $CaCl_2$) | | 7.68 | 7.73 | 7.74 | 7.78 | 7.78 | 7.79 |
| Cation Exchange Capacity (meq/100g) | | 10.3 | 10.3 | 10.3 | 10.9 | 11.8 | 13.5 |
| Soil Bulk Density (g/L) | | 1520 | 1520 | 1570 | 1620 | 1460 | 1480 |
| **Soil Depth (cm)** | | **0-4 (nominal)** | | | | | |
| Moisture Retention Capacity (g/100 g dry matter) pF 2.0 | | 23.7 | | | | | |
| Moisture Retention Capacity (g/100 g dry matter) pF 4.2 | | 18.6 | | | | | |
| Biomass (mg C/100 g soil dry mass, 0-100cm) | | 52.9 | | | | | |

**Table B.8. 98 Soil Physicochemical Properties Portugal (Valença De Minho)**

| **Soil Depth (cm)** | | **0-10** | **10-20** | **20-30** | **30-50** | **50-70** | **70-100** |
|---|---|---|---|---|---|---|---|
| Particle Size Distribution (USDA) (% w/w) | : Sand | 77.3 | 76.2 | 76.4 | 77.9 | 80.4 | 79.3 |
| | : Silt | 16.7 | 17.8 | 18.3 | 16.5 | 14.4 | 15.1 |
| | : Clay | 6.1 | 6.0 | 5.4 | 5.7 | 5.3 | 5.7 |
| Classification (USDA) | | Loamy sand | Loamy sand | Loamy sand | Loamy sand | Loamy sand | Loamy sand |
| Total Carbon (% w/w) | | 3.9 | 1.1 | 0.98 | 1.4 | 0.86 | 1.5 |
| Total Organic Carbon (% w/w) | | 2.9 | 1.0 | 0.89 | 1.0 | 0.82 | 1.1 |
| $C_{org}$ (TOC * 1.724) | | 5.0 | 1.7 | 1.5 | 1.7 | 1.4 | 1.9 |
| pH (water) | | 4.96 | 4.16 | 4.09 | 4.13 | 4.18 | 4.17 |
| pH (0.01M $CaCl_2$) | | 6.23 | 4.08 | 3.99 | 4.00 | 4.29 | 4.23 |
| Cation Exchange Capacity (meq/100g) | | 11.0 | 2.7 | 2.9 | 3.1 | 2.7 | 2.6 |
| Soil Bulk Density (g/L) | | 1480 | 1440 | 1420 | 1390 | 1480 | 1460 |
| **Soil Depth (cm)** | | **0-4 (nominal)** | | | | | |
| Moisture Retention Capacity (g/100 g dry matter) pF 2.0 | | 18.4 | | | | | |
| Moisture Retention Capacity (g/100 g dry matter) pF 4.2 | | 5.4 | | | | | |
| Biomass (mg C/100 g soil dry mass, 0-100cm) | | 14.3 | | | | | |

The test item had not been used at the trial sites in the previous 3 years. Details of the active substances applied at the sites in the three years before the field dissipation studies are given below.

**Table B.8. 99 Site history**

| Year | Crop | Active substance applied |
|---|---|---|
| **Northern Germany (Burweg)** | | |
| 2015* | Potato | Terbuthylazine, pethoxamid, mesotrione, nicosulfuron, cyananamide, tolclofos-methyl, amino acids, metribuzin, prosulfocarb, rimsulfuron, mancozeb, cyazofamid, deltamethrin, cymoxanil, mandipropamide, metalaxyl-M, diquat |
| 2014 | Maize | Terbuthylazine, pethoxamid, dimethenamid-P, topramezone, mesotrione, bromoxynil, iodosulfuron, foramsulfuron |
| 2013 | | Terbuthylazine, pethoxamid, dimethenamid-P, topramezone, mesotrione, bromoxynil, iodosulfuron, foramsulfuron |
| 2012 | | Iodosulfuron, foramsulfuron, bromoxynil, prosulfuron, sulcotrione |
| **Northern France (Stotzheim)** | | |
| 2015* | Bare soil | Glyphosate |
| 2014 | Bare soil | Glyphosate, ryanodine receptor agonist |
| 2013 | Maize | Mesotrione, nicosulfuron |
| **Southern France (Barry d'Islemade)** | | |
| 2015 | Maize | Acetochlor, mesotrione+nicosulfuron, dicamba |
| 2014 | Maize | Foramsulfuron + isoxadifen-ethyl, bentazone + dicamba |
| 2013 | Maize | Foramsulfuron + isoxadifen-ethyl, bentazone + dicamba |
| **Portugal (Valença De Minho)** | | |
| 2015* | Oats | 2.4 D + MCPA |
| 2014 | Oats | 2.4 D + MCPA |
| 2013 | Oats | 2.4 D + MCPA |

*until start of trial

HSE understands that the active substances used are not related to pydiflumetofen and thus are not a concern with respect to potential to affect the degradation of pydiflumetofen.

A single plot for treatment was marked out at each site, with different dimensions depending on the site. Dimensions ranged from 288 – 373.5 $m^2$. The untreated plot was divided into three sub-plots with a separation of 2 – 4 m between each subplot. Each subplot was further divided into a number of 'sub-subplots'. Each sub-subplot was used for soil sampling for a specific sample time. Therefore each field site had three replicates at each sampling time for the a.s. treatment. An untreated plot was also allocated at each site with a separation from the treated area at least 10m.

Preparation of the treated area was started in the spring of the year in which the study commenced. The area was cultivated and rolled. Following this, an application of the herbicide mesotrione was made and the area covered with a fibre mat. The plots were usually irrigated on a weekly basis to keep the soil moist. Irrigation occurred up to two days before application with the exception of the Portuguese site where irrigation occurred on the day of application. The applicant was able to confirm from evidence supplied by the study contractor that the irrigation was applied prior to application of the test item. The intention of the regime was to mimic the soil conditions under a cereal crop. Either two days before application or on the day of, but before application, the fibre mat was removed and grass seed was sown on the plot. On the sites sown two days before application the fibre mat was returned to the plot. The fibre mat was removed permanently from each site before application.

Following application the grass was cut regularly to keep the grass below a maximum height of 20cm. Maximum height varied between sites. Irrigation was also carried out in some months at each site in an attempt to keep the precipitation near to the long term average.

**Experimental treatment**
A single application of pydiflumetofen SC (200) (A19649B), a suspension concentrate (SC) formulation, was applied to a trial at a nominal rate of 200 g a.s./ha as a broadcast spray application to the bare soil surface. Application dates were:

Germany - 17 June 2016.

Northern France – 8 July 2016

Southern France 21 June 2016

Portugal – 24 June 2016

The application method was a broadcast spray application using a 3 m width nozzle boom sprayer with a boom fitted with nozzles producing a flat fan spray pattern. Each individually mixed spray solution was prepared by diluting the required quantity of A19649B with water. No adjuvant was used.

As an aid to verification of the application dose, petri dishes filled with soil were placed in the treated plots, ten per sub-plot.

**Sampling**
Samples for soil characterisation, bulk density, soil taxonomy and water holding capacity were taken between 0-4 days before application from the four corners of the treated plot boundaries at the sites. Cores were taken to a depth of 100 cm.

Untreated control soil residue samples (0-100 cm) were taken from each subplot of the control plot for residue analysis 0-14 days before application.

For verification of the application rate, ten petri dishes (10.8 cm diameter), filled with sieved soil, were placed on the soil surface of each treated subplot prior to application and then sampled immediately after application (10 dishes per subplot which were bulked to form one sample per subplot). The target application was 200 g a.s./ha. The mean pydiflumetofen residue in the application verification petri dish samples was 112 - 272 g/ha. This corresponded to an application rate of 56 - 136%, based on the target application rate of 200 g a.s./ha. As can be seen, there was some variability in application rate calculated from residues seen in deposition trays compared to that planned. However experience suggests that variability of soil residues in the first few weeks of field dissipation studies is a common occurrence and not easily explained. The variability is not of undue concern to HSE, noting that decline rates are calculated from measured soil residues.

Treated soil residue samples were taken from each subplot following application. An S-shaped pattern was followed in determining the location of each soil core. Ten cores were taken using a zero contamination manual corer to a depth of 10 cm (7.9 cm inner diameter of liner) from each subplot immediately after application (0 DAA). Samples were then taken at 3-4 and 7 DAA using a manual corer to a depth of 30 cm and at six additional sample times at regular intervals until approximately one year after application using a hydraulic corer to a depth of 100 cm. The sampling schedule for each site is shown below.

The untreated and treated residue samples were stored deep frozen at the test site facility before being transferred deep frozen to the analytical test site where, upon sample receipt, the samples were stored deep frozen (typically ≤ - 18°C). The soil characterisation, taxonomy, biomass and bulk density samples were kept at ambient temperature.

**Table B.8. 100 Sampling summary**

| Sampling Interval (DAA) | Control (C) Treatment (T) | Sampling Date |
|---|---|---|
| **Northern Germany (Burweg)** | | |
| 3 DBA | C | 14 June 2016 |
| 0 | T | 17 June 2016 |
| 3 | T | 20 June 2016 |
| 7 | T | 24 June 2016 |
| 13 | T | 30 June 2016 |
| 26 | T | 13 July 2016 |
| 59 | T | 15 August 2016 |
| 122 | T | 17 October 2016 |
| 173 | T | 07 December 2016 |
| 367 | T | 19 June 2017 |
| **Northern France (Stotzheim)** | | |
| 3 DBA | C | 24 June 2016 |
| 0 | T | 08 July 2016 |
| 4 | T | 12 July 2016 |
| 7 | T | 15 July 2016 |
| 13 | T | 21 July 2016 |
| 26 | T | 03 August 2016 |
| 61 | T | 07 September 2016 |
| 118 | T | 03 November 2016 |
| 192 | T | 16 January 2017 |
| 360 | T | 03 July 2017 |
| **Southern France (Barry d'Islemade)** | | |
| 0 DBA | C | 21 June 2016 |
| 0 | T | 21 June 2016 |
| 3 | T | 24 June 2016 |
| 7 | T | 28 June 2016 |
| 14 | T | 05 July 2016 |
| 27 | T | 18 July 2016 |
| 58 | T | 18 August 2016 |
| 121 | T | 20 October 2016 |
| 177 | T | 15 December 2016 |
| 366 | T | 22 June 2017 |
| **Portugal (Valença De Minho)** | | |
| 1 DBA | C | 23 June 2016 |
| 0 | T | 24 June 2016 |
| 3 | T | 27 June 2016 |
| 7 | T | 01 July 2016 |
| 13/14 | T | 07/08 July 2016 |
| 27 | T | 21 July 2016 |
| 60 | T | 23 August 2016 |
| 118 | T | 20 October 2016 |
| 174 | T | 15 December 2016 |
| 363 | T | 22 June 2017 |

DAA – Days after application; DBA – days before application; NA – Not applicable

The deep frozen soil cores were cut into depths of 0-10, 10-20, 20-30, 30-50, 50-70 and 70-100 cm. The soil cores taken at 0 DAA (0-10 cm cores) required no cutting. For the 0-10 and 10-20 cm soil layers, all 10 cores of each sample were cut, the soil from each layer was removed from the liners and the corresponding layers from each core were bulked to give composite samples. The samples were homogenised by milling and sieving (4 mm mesh size) in the presence of dry ice. The 20-30, 30-50, 50-70 and 70-100 cm horizons were generally stored non-milled but in some cases deeper horizons of 20-30 and 30-50 cm were milled since residues >LOQ were

detected in the corresponding horizons. One aliquot of at least 400 g frozen homogenised soil was taken for analysis and stored deep frozen until analysis. Petri dish soil samples were homogenised by agitation.

The soil characterisation sample cores were cut into depths of 0-10, 10-20, 20-30, 30-50, 50-70 and 70-100 cm before being homogenised.

**Description of analytical procedure**
Soil samples up to and including the 367 DAA sampling event were analysed for pydiflumetofen residues according to procedures outlined in modified residue analytical method GRM061.04A. This is the same method of analysis used in the initial six European field dissipation studies reported in section B.8.1.1.2.2.1.1.

In summary, 10 g of soil was extracted with 80/20 (v/v) acetonitrile/0.1 M ammonium acetate aqueous solution by shaking. After centrifugation, the extract was decanted into a plastic flask and the soil was extracted a second time with 80/20 (v/v) acetonitrile/0.1% acetic acid in demineralized water. After centrifugation, the supernatant was decanted and combined with the first extract in the centrifuge bottle. This extraction step with 80/20 (v/v) acetonitrile/0.1% acetic acid in demineralized water was repeated. The collected extracts were mixed well and filtered through piggy backed filter papers into a clean bottle. Approximately 1 mL was transferred into a HPLC vial and analysed by high performance liquid chromatography with triple quadruple mass spectroscopy determination (LC-MS/MS). For expected residues greater than 5 µg/kg, samples were diluted further and mixed thoroughly. The limit of quantification (LOQ) was 0.5 µg/kg; The limit of detection (LOD) was 0.15 µg/kg. No enantiomer-specific analysis was undertaken.

Matrix effects were tested by comparing the response of a standard solution without matrix to a control soil sample fortified to the identical analyte concentration.

Control samples were analysed to demonstrate no interference at the retention times of the analyte.

Method performance was checked concurrently to the analysis of treated samples by fortifying control samples at various fortification levels.

Procedural recovery of the a.s. was assessed for each soil. Recovery at the LOQ of 0.5 µg/kg (a single procedural recovery sample for each soil) was 99-108%. At 10 x LOQ (five samples per soil) the recovery was 75-105%. At 10000 x LOQ (two samples per soil) the recovery was 94 – 99%. Procedural recoveries were acceptable over this range.

**Results and Discussion**
The residue values (µg/kg) determined from the analytical methods were converted to g/ha values using the weight of wet soil sampled and the surface area of the sampling cores.

**Trial Residue Analysis**
The study authors presented the results of the field dissipation studies primarily in g a.s./ha format rather than in µg/kg. Whilst the presentation of results as g/ha is acceptable, it is not transparent in terms of relating residues to the analytical LOQ. This can be particularly important in understanding whether significant residues have leached to the lowest analysed soil layer and therefore whether there could have been further dissipation of the residues via leaching beyond the lowest analysed layer. In the study reports the g/ha residues were presented for each of the analysed soil layers and for each subplot. However the applicant's summaries of the residues only presented the g/ha values as means of the subplots and summed over the entire analysed depth. Thus the summarised results give no indication of movement down the soil profile or of the significance of the residues, particularly at lower soil layers, with respect to the analytical LOQ. However, the results in µg/kg in each replicate and at each depth were also presented in the study reports. Consequently these results are also reproduced below.

The LOQ for the analytical method is 0.5 µg/kg; it should be noted that this is based on wet weight concentrations, hence the measured dry weight values that are stated to be <LOQ are sometimes >0.5 µg/kg. The analytical method must be able to quantify down to at least 10% of the highest residue in order to be able to identify when 90% decline has occurred. In practice it is helpful if the LOQ is much lower than 10% of the highest residue as it allows better understanding of the reduction in residues, particularly as residues decline in magnitude further down the soil profile. The LOQ expressed as the % of the highest residue in each study is

shown below. As is often the case in field dissipation studies, the highest residues were not always recorded on the day of application.

**Table B.8. 101 Highest residue in each field study and the LOQ in relation to it.**

| Site | Highest residue (µg/kg)1 | Day on which highest residue occurred | LOQ as % of highest residue |
|---|---|---|---|
| Germany | 126.4 | 7 DAT | 0.40% |
| Northern France | 121.6 | 4 DAT | 0.41% |
| Southern France | 163.3 | 0 DAT | 0.31% |
| Portugal | 110.6 | 13 DAT | 0.45% |

1 Total summed residue from analysed soil layers; average residue over three subplots calculated from total summed residue in each subplot

Results were given as µg/kg wet weight and µg/kg dry weight. As is customary for field dissipation study assessments, the residues in µg/kg dry weight have been presented. Residues as g/ha were also calculated taking account of the wet weight residues at each sample time, the wet weight of the soil cores and the area of the soil cores as follows:

(Wet weight residue (µg/kg) x wet sample weight (kg))/(Core area ($cm^2$) x $10^8$) / $10^6$
The factor of $10^8$ converts $cm^2$ to hectares. The factor of $10^6$ converts µg to g.

The calculation is appropriate. The applicant has based the subsequent kinetic assessments on the g/ha residues.

No residues equal to or greater than the LOQ were determined in any of the untreated control samples.

Results are presented below. Note that for sampling times of 0 DAT until study conclusion, results are presented from three replicates, hence three separate results are presented for each sampling date.

**Table B.8. 102 Residue Results (µg/kg dry weight) of pydiflumetofen, Northern Germany (Burweg)**

| Timing | Pydiflumetofen (µg/kg) dry weight Horizon | | | |
|---|---|---|---|---|
| | **0-10 cm** | **10-20 cm** | **20-30 cm** | **30-50 cm** |
| 3 DBA | n.c. | n.c. | - | - |
| 3 DBA | n.c. | n.c. | - | - |
| 3 DBA | n.c. | n.c. | - | - |
| 3 DBA | n.c. | n.c. | - | - |
| 0 DAA | 100 | - | - | - |
| 0 DAA | 122 | - | - | - |
| 0 DAA | 126 | - | - | - |
| 3 DAA | 110 | <LOQ (0.46) | - | - |
| 3 DAA | 101 | <LOQ (0.34) | - | - |
| 3 DAA | 99.2 | <LOQ (0.50) | - | - |
| 7 DAA | 139 | <LOQ (0.38) | - | - |
| 7 DAA | 114 | n.c. | - | - |
| 7 DAA | 125 | 0.75 | n.c. | - |
| 13 DAA | 88.9 | n.c. | - | - |
| 13 DAA | 82.6 | <LOQ (0.25) | - | - |
| 13 DAA | 91.9 | <LOQ (0.52) | - | - |
| 26 DAA | 104 | <LOQ (0.58) | - | - |
| 26 DAA | 70.3 | <LOQ (0.51) | - | - |
| 26 DAA | 83.9 | 2.24 | 0.81 | n.c. |
| 59 DAA | 75.2 | 0.63 | n.c. | - |
| 59 DAA | 111 | 2.35 | n.c. | - |
| 59 DAA | 88.3 | 1.09 | n.c. | - |
| 122 DAA | 82.2 | <LOQ (0.29) | - | - |
| 122 DAA | 112 | <LOQ (0.34) | - | - |
| 122 DAA | 71.3 | 1.28 | n.c. | - |
| 173 DAA | 88.0 | n.c. | - | - |
| 173 DAA | 118 | 0.76 | n.c. | - |
| 173 DAA | 93.3 | <LOQ (0.32) | - | - |
| 367 DAA | 55.6 | n.c. | - | - |
| 367 DAA | 97.6 | 1.25 | n.c. | - |
| 367 DAA | 108 | <LOQ (0.18) | - | - |

DAA: Days after application; DBA: Days before application.
<LOQ: less than limit of quantification (<0.5 µg/kg), however, greater than the limit of detection;
n.c. = not calculated on basis that <LOD (<0.15 µg/kg) in wet weight samples; -: not analysed

**Table B.8. 103 Summary Residue Results (g/ha) of pydiflumetofen, Northern Germany (Burweg)**

| Sampling Interval | Sample type | Core Depth (cm)[c] | Pydiflumetofen (g/ha)[a] |
|---|---|---|---|
| 3 DBA | Untreated | 0-20 | 0 |
| 0 DAA | Treated (Petri dish)[b] | N/A | 172 |
| 0 DAA | Treated | 0-10 | 161 |
| 3 DAA | Treated | 0-20 | 129 |
| 7 DAA | Treated | 0-30 | 172 |
| 13 DAA | Treated | 0-20 | 136 |
| 26 DAA | Treated | 0-50 | 120 |
| 59 DAA | Treated | 0-30 | 127 |
| 122 DAA | Treated | 0-30 | 134 |
| 173 DAA | Treated | 0-30 | 135 |
| 367 DAA | Treated | 0-30 | 120 |

[a] Mean result from the three subplots
[b] Application verification sample
DBA -Days before application; DAA - Days after application; NA - not applicable
The limit of quantification was 0.5 µg/kg wet soil.
Where the wet weight residue was <LOQ or n.d., the calculated g a.s./ha residue was set to zero.
[c] Not all soil depths were analysed at all dates. Analysis of lower depths (e.g. 20-30 cm) was only carried out if a residue at or above the LOQ was measured in the corresponding depth above (e.g. 10-20 cm)

**Table B.8. 104 Residue Results (µg/kg dry weight) of pydiflumetofen, Northern France (Stotzheim)**

| Timing | Pydiflumetofen (µg/kg) dry weight Horizon | | |
|---|---|---|---|
| | **0-10 cm** | **10-20 cm** | **20-30 cm** |
| 4 DBA | n.c. | n.c. | - |
| 4 DBA | n.c. | n.c. | - |
| 4 DBA | n.c. | n.c. | - |
| 4 DBA | n.c. | n.c. | - |
| 0 DAA | 62.4 | - | - |
| 0 DAA | 75.8 | - | - |
| 0 DAA | 46.8 | - | - |
| 4 DAA | 125 | <LOQ (0.44) | - |
| 4 DAA | 116 | <LOQ (0.46) | - |
| 4 DAA | 122 | 0.82 | <LOQ (0.21) |
| 7 DAA | 119 | 0.79 | <LOQ (0.23) |
| 7 DAA | 121 | <LOQ (0.44) | - |
| 7 DAA | 120 | 0.89 | n.c. |
| 13 DAA | 98.6 | 2.29 | <LOQ (0.25) |
| 13 DAA | 122 | 1.10 | n.c. |
| 13 DAA | 94.5 | <LOQ (0.42) | - |
| 26 DAA | 93.5 | 1.46 | <LOQ (0.32) |
| 26 DAA | 112 | 1.34 | <LOQ (0.22) |
| 26 DAA | 110 | <LOQ (0.49) | - |
| 61 DAA | 91.6 | 1.41 | n.c. |
| 61 DAA | 91.0 | 1.33 | n.c. |
| 61 DAA | 98.5 | 1.34 | n.c. |
| 118 DAA | 95.2 | 9.71 | n.c. |
| 118 DAA | 69.1 | 5.30 | n.c. |
| 118 DAA | 65.1 | 3.61 | n.c. |
| 195 DAA | 99.3 | 5.25 | <LOQ (0.51) |
| 195 DAA | 66.9 | 3.81 | n.c. |
| 195 DAA | 84.4 | 7.21 | n.c. |
| 360 DAA | 45.6 | 4.43 | n.c. |
| 360 DAA | 57.9 | 6.51 | n.c. |
| 360 DAA | 56.1 | 5.67 | n.c. |

DAA: Days after application; DBA: Days before application.
<LOQ: less than limit of quantification (<0.5 µg/kg), however, greater than the limit of detection;
n.c. = not calculated on basis that <LOD (<0.15 µg/kg) in wet weight samples; -: not analysed

**Table B.8. 105 Summary Residue Results (g/ha) of pydiflumetofen, Northern France (Stotzheim)**

| Sampling Interval | Sample type | Core Depth (cm)[c] | Pydiflumetofen (g/ha)[a] |
|---|---|---|---|
| 14 DBA | Untreated | 0-20 | 0 |
| 0 DAA | Treated (Petri dish)[b] | N/A | 172 |
| 0 DAA | Treated | 0-10 | 80 |
| 4 DAA | Treated | 0-30 | 139 |
| 7 DAA | Treated | 0-30 | 132 |
| 13 DAA | Treated | 0-30 | 137 |
| 26 DAA | Treated | 0-30 | 145 |
| 61 DAA | Treated | 0-30 | 118 |
| 118 DAA | Treated | 0-30 | 104 |
| 192 DAA | Treated | 0-30 | 116 |
| 360 DAA | Treated | 0-30 | 79 |

[a] Mean result from the three subplots
[b] Application verification sample
DBA -Days before application; DAA - Days after application; NA - not applicable
The limit of quantification was 0.5 µg/kg wet soil.
Where the wet weight residue was <LOQ or n.d., the calculated g a.s./ha residue was set to zero.
[c] Not all soil depths were analysed at all dates. Analysis of lower depths (e.g. 20-30 cm) was only carried out if a residue at or above the LOQ was measured in the corresponding depth above (e.g. 10-20 cm)

**Table B.8. 106 Residue Results (µg/kg dry weight) of pydiflumetofen, Southern France (Barry d'Islemade)**

| Timing | Pydiflumetofen (µg/kg) dry weight Horizon | | | |
|---|---|---|---|---|
| | **0-10 cm** | **10-20 cm** | **20-30 cm** | **30-50 cm** |
| 0 DBA | n.c. | n.c. | - | - |
| 0 DBA | n.c. | n.c. | - | - |
| 0 DBA | n.c. | n.c. | - | - |
| 0 DBA | n.c. | n.c. | - | - |
| 0 DAA | 199 | - | - | - |
| 0 DAA | 163 | - | - | - |
| 0 DAA | 128 | - | - | - |
| 3 DAA | 127 | <LOQ (0.21) | - | - |
| 3 DAA | 109 | n.c. | - | - |
| 3 DAA | 124 | n.c. | - | - |
| 7 DAA | 113 | <LOQ (0.31) | - | - |
| 7 DAA | 173 | <LOQ (0.44) | - | - |
| 7 DAA | 96.0 | 0.65 | n.c. | - |
| 14 DAA | 93.7 | <LOQ (0.26) | - | - |
| 14 DAA | 85.9 | <LOQ (0.22) | - | - |
| 14 DAA | 43.3 | <LOQ (0.17) | - | - |
| 27 DAA | 43.0 | n.c. | - | - |
| 27 DAA | 89.0 | <LOQ (0.18) | - | - |
| 27 DAA | 29.3 | 0.69 | 0.88 | n.c. |
| 58 DAA | 31.6 | <LOQ (0.58) | - | - |
| 58 DAA | 73.6 | 0.63 | n.c. | - |
| 58 DAA | 24.3 | 0.61 | n.c. | - |
| 121 DAA | 44.9 | <LOQ (0.31) | - | - |
| 121 DAA | 30.9 | n.c. | - | - |
| 121 DAA | 49.1 | n.c. | - | - |
| 177 DAA | 51.2 | 3.82 | n.c. | - |
| 177 DAA | 75.6 | <LOQ (0.48) | - | - |
| 177 DAA | 43.2 | <LOQ (0.28) | - | - |
| 366 DAA | 39.8 | 1.45 | n.c. | - |
| 366 DAA | 46.9 | n.c. | - | - |
| 366 DAA | 24.1 | n.c. | - | - |

DAA: Days after application; DBA: Days before application.
<LOQ: less than limit of quantification (<0.5 µg/kg), however, greater than the limit of detection;
n.c. = not calculated on basis that <LOD (<0.15 µg/kg) in wet weight samples; -: not analysed

**Table B.8. 107 Summary Residue Results (g/ha) of pydiflumetofen, Southern France (Barry d'Islemade)**

| Sampling Interval | Sample type | Core Depth (cm)[c] | Pydiflumetofen (g/ha)[a] |
|---|---|---|---|
| 0 DBA | Untreated | 0-20 | 0 |
| 0 DAA | Treated (Petri dish)[b] | N/A | 112 |
| 0 DAA | Treated | 0-10 | 171 |
| 3 DAA | Treated | 0-20 | 145 |
| 7 DAA | Treated | 0-30 | 148 |
| 14 DAA | Treated | 0-20 | 105 |
| 27 DAA | Treated | 0-50 | 76 |
| 58 DAA | Treated | 0-30 | 64 |
| 121 DAA | Treated | 0-20 | 61 |
| 177 DAA | Treated | 0-30 | 86 |
| 366 DAA | Treated | 0-30 | 48 |

[a] Mean result from the three subplots
[b] Application verification sample
DBA -Days before application; DAA - Days after application; NA - not applicable
The limit of quantification was 0.5 µg/kg wet soil.
Where the wet weight residue was <LOQ or n.d., the calculated g a.s./ha residue was set to zero.
[c] Not all soil depths were analysed at all dates. Analysis of lower depths (e.g. 20-30 cm) was only carried out if a residue at or above the LOQ was measured in the corresponding depth above (e.g. 10-20 cm)

**Table B.8. 108 Residue Results (µg/kg dry weight) of pydiflumetofen, Portugal (Valença De Minho)**

| Timing | Pydiflumetofen (µg/kg) dry weight Horizon | | | |
|---|---|---|---|---|
| | **0-10 cm** | **10-20 cm** | **20-30 cm** | **30-50 cm** |
| 1 DBA | n.c. | n.c. | - | - |
| 1 DBA | n.c. | n.c. | - | - |
| 1 DBA | n.c. | n.c. | - | - |
| 1 DBA | n.c. | n.c. | - | - |
| 0 DAA | 94.3 | - | - | - |
| 0 DAA | 102 | - | - | - |
| 0 DAA | 85.0 | - | - | - |
| 3 DAA | 67.4 | 0.78 | - | - |
| 3 DAA | 82.8 | <LOQ (0.38) | - | - |
| 3 DAA | 93.1 | <LOQ (0.43) | - | - |
| 7 DAA | 104 | <LOQ (0.17) | - | - |
| 7 DAA | 91.6 | <LOQ (0.18) | - | - |
| 7 DAA | 81.7 | n.c. | - | - |
| 13 DAA | 77.8 | 2.51 | 2.00 | <LOQ (0.20) |
| 13 DAA | 97.5 | 3.49 | 3.62 | <LOQ (0.28) |
| 14 DAA | 144 | <LOQ (0.45) | - | - |
| 27 DAA | 62.9 | 4.95 | 6.15 | <LOQ (0.23) |
| 27 DAA | 67.9 | 4.21 | 0.98 | n.c. |
| 27 DAA | 80.6 | 0.73 | <LOQ (0.21) | - |
| 60 DAA | 54.2 | 3.43 | n.c. | - |
| 60 DAA | 35.5 | 0.93 | n.c. | - |
| 60 DAA | 72.5 | 1.10 | n.c. | - |
| 118 DAA | 60.1 | <LOQ (0.30) | - | - |
| 118 DAA | 38.3 | <LOQ (0.41) | - | - |
| 118 DAA | 52.6 | <LOQ (0.38) | - | - |
| 174 DAA | 66.4 | 1.26 | n.c. | - |
| 174 DAA | 96.2 | 0.64 | n.c. | - |
| 174 DAA | 70.2 | <LOQ (0.30) | - | - |
| 363 DAA | 28.1 | n.c. | - | - |
| 363 DAA | 28.4 | 1.27 | n.c. | - |
| 363 DAA | 33.3 | 2.33 | n.c. | - |

DAA: Days after application; DBA: Days before application.
<LOQ: less than limit of quantification (<0.5 µg/kg), however, greater than the limit of detection;
n.c. = not calculated on basis that <LOD (<0.15 µg/kg) in wet weight samples; -: not analysed

**Table B.8. 109 Summary Residue Results (g/ha) of pydiflumetofen, Portugal (Valença De Minho)**

| Sampling Interval | Sample type | Core Depth (cm)[c] | Pydiflumetofen (g/ha)[a] |
|---|---|---|---|
| 1 DBA | Untreated | 0-20 | 0 |
| 0 DAA | Treated (Petri dish)[b] | N/A | 272 |
| 0 DAA | Treated | 0-10 | 129 |
| 3 DAA | Treated | 0-20 | 106 |
| 7 DAA | Treated | 0-20 | 119 |
| 13/14 DAA | Treated | 0-50 | 130 |
| 27 DAA | Treated | 0-50 | 93 |
| 60 DAA | Treated | 0-30 | 67 |
| 118 DAA | Treated | 0-20 | 66 |
| 174 DAA | Treated | 0-30 | 92 |
| 363 DAA | Treated | 0-30 | 36 |

[a] Mean result from the three subplots
[b] Application verification sample
DBA -Days before application; DAA - Days after application; NA - not applicable
The limit of quantification was 0.5 µg/kg wet soil.
Where the wet weight residue was <LOQ or n.d., the calculated g a.s./ha residue was set to zero.
[c] Not all soil depths were analysed at all dates. Analysis of lower depths (e.g. 20-30 cm) was only carried out if a residue at or above the LOQ was measured in the corresponding depth above (e.g. 10-20 cm)

**Conclusions**
Residue levels of pydiflumetofen were determined in soil after one application of A19649B, a 200 g/L SC formulation, to bare soil over a time period of 367 days. Decline appeared to be relatively slow as there was 22.9 – 69.2% of the a.s. remaining at the end of the study at the four sites. The percentage of the highest residue remaining at the study end is shown below.

**Table B.8. 110 Percentage of highest residue remaining at each study site at study end**

| Site | Highest residue (µg/kg) | Residue at final sample time (µg/kg) | Residue at final sample time as % of highest residue |
|---|---|---|---|
| Germany | 126.4 | 87.5 | 69.2% |
| Northern France | 121.6 | 58.7 | 48.3% |
| Southern France | 163.3 | 37.4 | 22.9% |
| Portugal | 110.6 | 31.1 | 28.1% |

Note: Residues are averages of three replicates and summed over soil layers where resides were >LOD

The majority of the residue appeared to be confined to the top 20cm depth although quantifiable residues were seen down to 30cm, particularly in the Portuguese site; residues <LOQ were sometimes seen in the 30-50cm horizon. The analysis was conducted to appropriate depths; analysis at individual sampling times was not conducted on deeper horizons where the residue in the lowest analysed soil layer had been either <LOD or <LOQ. Given that the LOQ represented less than 0.5% of the average highest residues at each site, it is likely that losses due to leaching below the analysed soil horizons would have been minimal. Analysis of only the 0-10 cm layer at 0 DAT is considered appropriate as it is unlikely that any residues would have leached to greater than 10 cm depth on the day of application.

The applicant provided separate kinetic calculations based on the wet weight µg/kg residues converted to g/ha. The use of g/ha residue data is acceptable. The kinetic calculations were for:

i) comparison to 'trigger' values and were based on non-normalised time sequence data and
ii) generation of DegT50 values for modelling based on time-step normalisation of the study duration.

The kinetic calculations are discussed in sections B.8.1.1.2.2.2 (persistence/dissipation endpoints) and B.8.1.1.2.2.3 (modelling endpoints).

No analysis of the enantiomers of pydiflumetofen was conducted in these studies. Thus no additional

information on potential for change in enantiomer excess can be obtained from these studies.

Overall, it is considered that these studies can be used to address the primary data requirement of assessing dissipation under field conditions.

### B.8.1.1.2.2.1.3 Re-sampling of European field dissipation studies

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1/07. [redacted] (2020g), SYN545974 - Additional Soil Sampling and Analysis at Five Historical Field Dissipation Sites in Northern Germany, Northern France and UK in 2020. Report Number S20-06491, Eurofins Agroscience Services GmbH |

This study was a follow-up study to those described in sections B.8.1.1.2.2.1.1 and B.8.1.1.2.2.1.2; five out of the ten European field dissipation study sites were revisited. As such the study locations and site preparations are previously described above.

In this study the site locations at Burweg and Ohrensen in Germany, Stotzheim and Sand in Northern France and Wilson in the UK were revisited and new samples taken down to 100cm depth. The study appears to be an attempt to demonstrate that pydiflumetofen is not as persistent as the original field dissipation studies appeared to show. Brief details of the sites are given below.

**Table B.8. 111 Summary of study sites**

| Location | Plot conditions | Previous sample (DAA) | New sample (DAA) | Interval between samples (days) |
|---|---|---|---|---|
| Burweg, Germany | Bare plot, sown with grass 2 days before application | 367 | 1525 | 1158 |
| Ohrensen, Germany | Bare plot | 715 | 2642 | 1927 |
| Stotzheim, France | Bare plot, sown with grass 2 days before application | 360 | 1497 | 1137 |
| Sand, France | Bare plot | 721 | 2626 | 1905 |
| Wilson, UK | Bare plot | 718 | 2628 | 1910 |

In some cases the sites had returned to agricultural use and the location of the treated plots had to be identified from archived details of the studies. Details of the subsequent land use are given below.

**Table B.8. 112 Land use pesticides applied at former field dissipation study sites between end of former study and re-sampling**

| Site location | Year | Crop | Active ingredient |
|---|---|---|---|
| Burweg, Germany | 2016 -2018 | Grass | None (SYN545794 in 2016) |
| | 2019 | Spring Oilseed Rape | Metazachlor, lambda-Cyhalothrin, Clethodim |
| | 2020* | Maize | Not available (herbicide for maize) |
| Ohrensen, Germany | 2016 | Bare Soil | Glyphosate |
| | 2017 | Winter wheat (until BBCH 22) | Glyphosate, Sedaxane |
| | 2018 | Bare Soil | Glyphosate |
| | 2019 | Onion | Glyphosate, Fludioxonil, Fluoxypyr |
| | 2020* | Barley | None |
| Stotzheim, N France | 2016-2017 | Grass | None (SYN545794 in 2016) |
| | 2018 | Grass | Glyphosate |
| | 2019 | Winter Wheat | Prothioconazole, Trifloxystrobin |
| | 2020 | Winter Oilseed rape | Fluazifop-P-butyl |
| Sand, N France | 2015 | Maize | Dicamba, Mesotrione, Nicosulfuron |
| | 2016 | Maize | Dicamba, Mesotrione, Nicosulfuron |
| | 2017 | Maize | Dicamba, Mesotrione, Nicosulfuron |
| | 2018 | Maize | Dicamba, Mesotrione, Nicosulfuron |
| | 2019 | Maize | Dicamba, Mesotrione, Nicosulfuron |
| | 2020* | Maize | Dicamba, Mesotrione, Nicosulfuron |
| Wilson, UK | 2015 | Fallow | Glyphosate |
| | 2016 | Fallow | Glyphosate |
| | 2017 | Winter Oats | Glyphosate |
| | 2018 | Winter Wheat | Glyphosate, Pendimethalin, Flufenacet, Diflufenacet** |
| | 2019 | Winter Wheat | Chlormequat, Prothioconazole |
| | 2020* | Fallow | Glyphosate |

* until start of sampling

** the identity of this a.s. is unknown to HSE but is probably a typographical error in the study report; the correct identity is probably diflufenican

Most of a.s. applied appear to not be related to pydiflumetofen (pydiflumetofen currently classified by the Fungicide Resistance Action Committee as being the only member of the N-methoxy-(phenyl-ethyl)-pyrazole-carboxamide group) and thus comply with guideline requirements that related substances should not have been applied in the three years before treatment. One a.s., sedaxane, used at the Ohrensen site, has the same mode of action as pydiflumetofen and it is unsure whether this could have influenced the subsequent dissipation of pydiflumetofen. Overall, with the exception of sedaxane, HSE considers it unlikely that treatment with these substances would have interfered directly with dissipation of pydiflumetofen. The impact of the use of sedaxane is not known.

Cultivation details for each site are provided below.

**Table B.8. 113 Cultivation details at former field dissipation study sites between end of former study and re-sampling**

| Site location | Date | Activity |
|---|---|---|
| Burweg, Germany | 2018 | No cultivation |
| | May 2019 | Disced (20 cm depth) and harrowing (15 cm depth) |
| | Sep 2019 | Disced (20 cm depth) |
| Ohrensen, Germany | 2016 | No cultivation |
| | Oct 2017 | Harrowed (15 cm depth) |
| | 2018 | Harrowed (15 cm depth) |
| | May 2019 | Milling* (20 cm depth) |
| | Jun 2019 | Harrowed (15 cm depth) |
| | Sep 2019 | Disced (20 cm depth) |
| | Oct 2019 | Harrowed (15 cm depth) |
| | Aug 2020 | Disced (20 cm depth) |
| Stotzheim, N France | 15 Oct 2018 | Power harrowed (15 cm depth) |
| | 15 Oct 2018 | Ploughed (25 cm depth) |
| | 25 Aug 2019 | Power harrowed (15 cm depth) |
| | 25 Aug 2019 | Ploughed (25 cm depth) |
| | 17 Jul 2020 | Decompactor (15 cm depth) |
| Sand, N France | 01 Dec 2015 | Ploughed (25 cm depth) |
| | 01 Mar 2016 | Harrowed (15 cm depth) |
| | 01 Apr 2016 | Harrowed (10 cm depth) |
| | 01 Oct 2016 | Ploughed (25 cm depth) |
| | 01 Mar 2017 | Harrowed (15 cm depth) |
| | 01 Apr 2017 | Harrowed (10 cm depth) |
| | 01 Oct 2017 | Ploughed (25 cm depth) |
| | 01 Mar 2018 | Harrowed (10 cm depth) |
| | 01 Apr 2018 | Harrowed (15 cm depth) |
| | 01 Nov 2018 | Ploughed (25 cm depth) |
| | 01 Mar 2019 | Harrowed (15 cm depth) |
| | 01 Apr 2019 | Harrowed (10 cm depth) |
| | 01 Oct 2019 | Ploughed (25 cm depth) |
| | 01 Mar 2020 | Harrowed (15 cm depth) |
| | 01 Apr 2020 | Harrowed (10 cm depth), rolled |
| | 01 Jun 2020 | Harrowed (5 cm depth) |
| Wilson, UK | 10 Oct 2017 | Disced (10 cm depth) |
| | 06 Nov 2018 | Ploughed (25 cm depth) |
| | 07 Nov 2018 | Power harrowed (10 cm depth) |

* The meaning of this term in respect to cultivation is unknown to HSE

As can be seen, each site was cultivated to at least 20 or 25 cm depth following the end of the former field dissipation study and the commencement of the additional sampling. This would have led to some redistribution of residues within the treated areas and potentially moving untreated soil into the treated area and/or treated soil out of the treated area. It is also noted that during the former field dissipation studies, after sampling the holes left following removal of soil cores were backfilled with untreated soil. This is a recommended practice for field dissipation studies. Whilst cultivation is likely to reduce the impact of new soil core sampling coinciding wholly with an area of untreated soil added to a previously sampled area, it is possible that the backfilling practice could affect the concentration of residues in the new soil core samples.

Given that the sites of the former studies had to be re-established by scrutiny of the archived study details, it is possible that the precise location of the plots may not have been truly reproduced. Sketches of the areas for resampling showed that the new samples were taken from the middle part of the subplots that the study operatives had relocated. This may help with concerns that the relocated areas may not truly match the original

plot areas but some uncertainly may still exist whether all samples will have only contained previously treated soil.

The methodology for taking the soil samples, their subsequent handling and storage prior to analysis and the extraction and analysis were the same as those in the previously described field dissipation studies. The analytical method had an LOQ of 0.5 µg/kg and an LOD of 0.1 µg/kg. No enantiomer-specific analysis was undertaken.

As in the previous field dissipation studies, the results were presented primarily in g/ha although results in µg/kg dry weight were available in the study appendices. Results are presented below. It is noted that the applicant set values <LOQ and <LOD to zero. The results expressed in µg/kg in the appendices to the study report do not give measured values where these were <LOQ. For kinetic calculations, these should be reported as ½ (LOQ + LOD). In this case this would be 0.3 µg/kg. Values <LOD would be set to ½ LOD, i.e. 0.05 µg/kg.

Results in g/ha were calculated from the wet weight residue using the following approach,

(Wet weight residue (µg/kg) x wet sample weight (kg))/(Core area ($cm^2$) x $10^8$) / $10^6$

The factor of $10^8$ converts $cm^2$ to hectares. The factor of $10^6$ converts µg to g.

The calculation is appropriate.

**Table B.8. 114 Residues of pydiflumetofen (µg/kg dry weight)– Burweg, Germany at 1525 DAT**

| Sub-plot | Pydiflumetofen (µg/kg) dry weight Horizon | | | |
|---|---|---|---|---|
| | **0-10 cm** | **10-20 cm** | **20-30 cm** | **30-50 cm** |
| SP1 | 8.9 | 9.2 | < LOD | < LOD |
| SP2 | 6.2 | 14 | 1.8 | < LOD |
| SP3 | 5.6 | 8.5 | 1.6 | < LOD |

<LOQ: less than limit of quantification (<0.5 µg/kg), however, greater than the limit of detection;
<LOD (<0.10 µg/kg)

**Table B.8. 115 Residues of pydiflumetofen and calculated g/ha residues at 1525 DAT– Burweg, Germany**

| Sampling Interval | Core Depth (cm) | Plot No. / Sub-plot No. | Pydiflumetofen Residue (wet weight µg/kg) | Sample Weight (kg) | Pydiflumetofen Residue (µg) | Individual Core Diameter (cm)* | Total Core Area ($cm^2$) ** | Pydiflumetofen Residue (g a.s./ha) | Mean pydiflumetofen Residue (g a.s./ha) |
|---|---|---|---|---|---|---|---|---|---|
| 1525 DAA | 0-10 | 2/1 | 8.2 | 2.650 | 21.730 | 4.6 | 166.2 | 13.1 | 9.6 |
| | 0-10 | 2/2 | 5.8 | 2.310 | 13.398 | 4.6 | 166.2 | 8.1 | |
| | 0-10 | 2/3 | 5.2 | 2.440 | 12.688 | 4.6 | 166.2 | 7.6 | |
| | 10-20 | 2/1 | 8.6 | 2.080 | 17.888 | 4.6 | 166.2 | 10.8 | 12.8 |
| | 10-20 | 2/2 | 13.0 | 2.210 | 28.730 | 4.6 | 166.2 | 17.3 | |
| | 10-20 | 2/3 | 8.0 | 2.140 | 17.120 | 4.6 | 166.2 | 10.3 | |
| | 20-30 | 2/1 | <LOD | 2.610 | 0 | 4.6 | 166.2 | 0 | 1.6 |
| | 20-30 | 2/2 | 1.7 | 2.600 | 4.420 | 4.6 | 166.2 | 2.7 | |
| | 20-30 | 2/3 | 1.5 | 2.430 | 3.645 | 4.6 | 166.2 | 2.2 | |
| | 30-50 | 2/1 | <LOD | 4.860 | 0 | 4.6 | 166.2 | 0 | 0 |
| | 30-50 | 2/2 | <LOD | 5.720 | 0 | 4.6 | 166.2 | 0 | |
| | 30-50 | 2/3 | <LOD | 5.570 | 0 | 4.6 | 166.2 | 0 | |

*inner diameter of corer tip

**Total core area is based on 10 cores with each individual core area calculated using $\pi r^2$ with $\pi$ rounded to 3.142.

DAA: Days after application.

<LOD: Residues are below the limit of detection (LOD), 0.1 µg/kg wet soil).

<LOQ: Residues are below the LOQ (0.5 µg/kg wet soil) but above the LOD (0.1 µg/kg wet soil). Where the wet weight residue was either <LOQ or n.d., the calculated g a.s./ha residue was set to zero.

Residues were calculated by using unrounded values, therefore results cannot be calculated accurately from the values presented in the table.

**Table B.8. 116 Residues of pydiflumetofen (µg/kg dry weight)– Ohrensen, Germany at 2642 DAT**

| Sub-plot | Pydiflumetofen (µg/kg) dry weight Horizon | | | |
|---|---|---|---|---|
| | **0-10 cm** | **10-20 cm** | **20-30 cm** | **30-50 cm** |
| SP1 | 4.1 | 13 | 20 | < LOQ |
| SP2 | 6.1 | 13 | 14 | < LOD |
| SP3 | 4.7 | 14 | 9.2 | < LOD |

<LOQ: less than limit of quantification (<0.5 µg/kg), however, greater than the limit of detection; <LOD (<0.10 µg/kg)

**Table B.8. 117 Residues of pydiflumetofen and calculated g/ha residues at 2642 DAT – Ohrensen, Germany**

| Sampling Interval | Core Depth (cm) | Plot No. / Sub-plot No. | Pydiflumetofen Residue (wet weight µg/kg) | Sample Weight (kg) | Pydiflumetofen Residue (µg) | Individual Core Diameter (cm)* | Total Core Area ($cm^2$) ** | Pydiflumetofen Residue (g a.s./ha) | Mean pydiflumetofen Residue (g a.s./ha) |
|---|---|---|---|---|---|---|---|---|---|
| 2642 DAA | 0-10 | 2/1 | 3.9 | 2.950 | 11.505 | 4.6 | 166.2 | 6.9 | 8.7 |
| | 0-10 | 2/2 | 5.7 | 3.240 | 18.468 | 4.6 | 166.2 | 11.1 | |
| | 0-10 | 2/3 | 4.4 | 3.050 | 13.420 | 4.6 | 166.2 | 8.1 | |
| | 10-20 | 2/1 | 12.0 | 3.000 | 36.000 | 4.6 | 166.2 | 21.7 | 21.9 |
| | 10-20 | 2/2 | 12.0 | 2.930 | 35.160 | 4.6 | 166.2 | 21.2 | |
| | 10-20 | 2/3 | 13.0 | 2.910 | 37.830 | 4.6 | 166.2 | 22.8 | |
| | 20-30 | 2/1 | 19.0 | 3.090 | 58.710 | 4.6 | 166.2 | 35.3 | 25.3 |
| | 20-30 | 2/2 | 13.0 | 3.170 | 41.210 | 4.6 | 166.2 | 24.8 | |
| | 20-30 | 2/3 | 8.5 | 3.080 | 26.180 | 4.6 | 166.2 | 15.8 | |
| | 30-50 | 2/1 | <LOQ | 6.390 | 0 | 4.6 | 166.2 | 0 | 0 |
| | 30-50 | 2/2 | <LOD | 6.250 | 0 | 4.6 | 166.2 | 0 | |
| | 30-50 | 2/3 | <LOD | 6.080 | 0 | 4.6 | 166.2 | 0 | |

*inner diameter of corer tip

**Total core area is based on 10 cores with each individual core area calculated using $\pi r^2$ with $\pi$ rounded to 3.142.

DAA: Days after application.

<LOD: Residues are below the limit of detection (LOD), 0.1 µg/kg wet soil).

<LOQ: Residues are below the LOQ (0.5 µg/kg wet soil) but above the LOD (0.1 µg/kg wet soil). Where the wet weight residue was either <LOQ or n.d., the calculated g a.s./ha residue was set to zero.

Residues were calculated by using unrounded values, therefore results cannot be calculated accurately from the values presented in the table.

**Table B.8. 118 Residues of pydiflumetofen (µg/kg dry weight)– Stotzheim, Northern France at 1497 DAT**

| Sub-plot | Pydiflumetofen (µg/kg) dry weight Horizon | | | |
|---|---|---|---|---|
| | **0-10 cm** | **10-20 cm** | **20-30 cm** | **30-50 cm** |
| SP1 | 5.8 | 4.1 | < LOQ | < LOQ |
| SP2 | 4.1 | 5.6 | 1.4 | < LOD |
| SP3 | 9.3 | 7.8 | < LOQ | < LOQ |

<LOQ: less than limit of quantification (<0.5 µg/kg), however, greater than the limit of detection; <LOD (<0.10 µg/kg)

**Table B.8. 119 Residues of pydiflumetofen and calculated g/ha residues at 1497 DAT – Stotzheim, Northern France**

| Samp-ling Interval | Core Depth (cm) | Plot No. / Sub-plot No. | Pydiflumetofen Residue (wet weight µg/kg) | Sample Weight (kg) | Pydiflumetofen Residue (µg) | Individual Core Diameter (cm)* | Total Core Area ($cm^2$) ** | Pydiflumetofen Residue (g a.s./ha) | Mean pydiflumetofen Residue (g a.s./ha) |
|---|---|---|---|---|---|---|---|---|---|
| 1497 DAA | 0-10 | 2/1 | 5.2 | 1.900 | 9.880 | 4.6 | 166.2 | 5.9 | 7.0 |
| | 0-10 | 2/2 | 3.6 | 2.120 | 7.632 | 4.6 | 166.2 | 4.6 | |
| | 0-10 | 2/3 | 8.3 | 2.080 | 17.264 | 4.6 | 166.2 | 10.4 | |
| | 10-20 | 2/1 | 3.5 | 2.540 | 8.890 | 4.6 | 166.2 | 5.3 | 7.3 |
| | 10-20 | 2/2 | 4.7 | 2.340 | 10.998 | 4.6 | 166.2 | 6.6 | |
| | 10-20 | 2/3 | 6.6 | 2.550 | 16.830 | 4.6 | 166.2 | 10.1 | |
| | 20-30 | 2/1 | <LOQ | 2.760 | 0 | 4.6 | 166.2 | 0 | 0.7 |
| | 20-30 | 2/2 | 1.2 | 2.710 | 3.252 | 4.6 | 166.2 | 2.0 | |
| | 20-30 | 2/3 | <LOQ | 2.780 | 0 | 4.6 | 166.2 | 0 | |
| | 30-50 | 2/1 | <LOD | 5.920 | 0 | 4.6 | 166.2 | 0 | 0 |
| | 30-50 | 2/2 | <LOD | 6.000 | 0 | 4.6 | 166.2 | 0 | |
| | 30-50 | 2/3 | <LOD | 5.830 | 0 | 4.6 | 166.2 | 0 | |

*inner diameter of corer tip
**Total core area is based on 10 cores with each individual core area calculated using $\pi r^2$ with $\pi$ rounded to 3.142.
DAA: Days after application.
<LOD: Residues are below the limit of detection (LOD), 0.1 µg/kg wet soil).
<LOQ: Residues are below the LOQ (0.5 µg/kg wet soil) but above the LOD (0.1 µg/kg wet soil). Where the wet weight residue was either <LOQ or n.d., the calculated g a.s./ha residue was set to zero.
Residues were calculated by using unrounded values, therefore results cannot be calculated accurately from the values presented in the table.

**Table B.8. 120 Residues of pydiflumetofen (µg/kg dry weight)– Sand, Northern France at 2626 DAT**

| Sub-plot | Pydiflumetofen (µg/kg) dry weight Horizon | | | |
|---|---|---|---|---|
| | 0-10 cm | 10-20 cm | 20-30 cm | 30-50 cm |
| SP1 | < LOQ | < LOQ | < LOQ | < LOQ |
| SP2 | < LOQ | < LOQ | < LOQ | < LOQ |
| SP3 | < LOQ | < LOQ | < LOQ | < LOQ |

<LOQ: less than limit of quantification (<0.5 µg/kg), however, greater than the limit of detection; <LOD (<0.10 µg/kg)

**Table B.8. 121 Residues of pydiflumetofen and calculated g/ha residues at 2626 DAT – Sand, Northern France**

| Actual Sampling Interval | Core Depth (cm) | Plot No. / Sub-plot No. | Pydiflumetofen Residue (wet weight µg/kg) | Sample Weight (kg) | Pydiflumetofen Residue (µg) | Individual Core Diameter (cm)* | Total Core Area ($cm^2$) ** | Pydiflumetofen Residue (g a.s./ha) | Mean pydiflumetofen Residue (g a.s./ha) |
|---|---|---|---|---|---|---|---|---|---|
| 2626 DAA | 0-10 | 2/1 | <LOQ | 2.950 | 0 | 4.6 | 166.2 | 0 | 0 |
| | 0-10 | 2/2 | <LOQ | 2.880 | 0 | 4.6 | 166.2 | 0 | |
| | 0-10 | 2/3 | <LOQ | 3.060 | 0 | 4.6 | 166.2 | 0 | |
| | 10-20 | 2/1 | <LOQ | 2.930 | 0 | 4.6 | 166.2 | 0 | |
| | 10-20 | 2/2 | <LOQ | 2.610 | 0 | 4.6 | 166.2 | 0 | 0 |
| | 10-20 | 2/3 | <LOD | 2.880 | 0 | 4.6 | 166.2 | 0 | |
| | 20-30 | 2/1 | <LOD | 2.940 | 0 | 4.6 | 166.2 | 0 | |
| | 20-30 | 2/2 | <LOD | 2.890 | 0 | 4.6 | 166.2 | 0 | |
| | 20-30 | 2/3 | <LOD | 2.870 | 0 | 4.6 | 166.2 | 0 | 0 |
| | 30-50 | 2/1 | <LOD | 5.650 | 0 | 4.6 | 166.2 | 0 | |
| | 30-50 | 2/2 | <LOD | 5.210 | 0 | 4.6 | 166.2 | 0 | |
| | 30-50 | 2/3 | <LOD | 5.300 | 0 | 4.6 | 166.2 | 0 | |

*inner diameter of corer tip
**Total core area is based on 10 cores with each individual core area calculated using $\pi r^2$ with $\pi$ rounded to 3.142.
DAA: Days after application.
<LOD: Residues are below the limit of detection (LOD), 0.1 µg/kg wet soil).
<LOQ: Residues are below the LOQ (0.5 µg/kg wet soil) but above the LOD (0.1 µg/kg wet soil). Where the wet weight residue was either <LOQ or n.d., the calculated g a.s./ha residue was set to zero.
Residues were calculated by using unrounded values, therefore results cannot be calculated accurately from the values presented in the table.

**Table B.8. 122 Residues of pydiflumetofen (µg/kg dry weight)– Wilson, UK at 2628 DAT**

| Sub-plot | Pydiflumetofen (µg/kg) dry weight Horizon | | | | | |
|---|---|---|---|---|---|---|
| | 0-10 cm | 10-20 cm | 20-30 cm | 30-50 cm | 50-70 cm | 70-100 cm |
| SP1 | 8.4 | 8.4 | 5.6 | 1.9 | <LOQ | <LOQ |
| SP2 | 11.0 | 6.6 | 4.8 | 0.7 | < LOD | < LOD |
| SP3 | 5.1 | 4.0 | 2.4 | < LOD | - | - |

<LOQ: less than limit of quantification (<0.5 µg/kg), however, greater than the limit of detection; <LOD (<0.10 µg/kg)

**Table B.8. 123 Residues of pydiflumetofen and calculated g/ha residues at 2628 DAT – Wilson, UK**

| Actual Sampling Interval | Core Depth (cm) | Plot No. / Sub-plot No. | Pydiflumetofen Residue (wet weight µg/kg) | Sample Weight (kg) | Pydiflumetofen Residue (µg) | Individual Core Diameter (cm)* | Total Core Area ($cm^2$) ** | Pydiflumetofen Residue (g a.s./ha) | Mean pydiflumetofen Residue (g a.s./ha) |
|---|---|---|---|---|---|---|---|---|---|
| 2628 DAA | 0-10 | 2/1 | 7.6 | 2.270 | 17.252 | 4.8 | 181.0 | 9.5 | 9.0 |
| | 0-10 | 2/2 | 9.8 | 2.190 | 21.462 | 4.8 | 181.0 | 11.9 | |
| | 0-10 | 2/3 | 4.6 | 2.260 | 10.396 | 4.8 | 181.0 | 5.7 | |
| | 10-20 | 2/1 | 7.3 | 3.150 | 22.995 | 4.8 | 181.0 | 12.7 | 9.2 |
| | 10-20 | 2/2 | 5.7 | 2.970 | 16.929 | 4.8 | 181.0 | 9.4 | |
| | 10-20 | 2/3 | 3.4 | 2.860 | 9.724 | 4.8 | 181.0 | 5.4 | |
| | 20-30 | 2/1 | 4.8 | 3.160 | 15.168 | 4.8 | 181.0 | 8.4 | 6.3 |
| | 20-30 | 2/2 | 4.1 | 3.080 | 12.628 | 4.8 | 181.0 | 7.0 | |
| | 20-30 | 2/3 | 2.1 | 3.050 | 6.405 | 4.8 | 181.0 | 3.5 | |
| | 30-50 | 2/1 | 1.6 | 6.420 | 10.272 | 4.8 | 181.0 | 5.7 | 2.5 |
| | 30-50 | 2/2 | 0.6 | 5.760 | 3.456 | 4.8 | 181.0 | 1.9 | |
| | 30-50 | 2/3 | <LOD | 5.780 | 0 | 4.8 | 181.0 | 0 | |
| | 50-70 | 2/1 | <LOQ | 6.530 | 0 | 4.8 | 181.0 | 0 | 0 |
| | 50-70 | 2/2 | <LOD | 6.210 | 0 | 4.8 | 181.0 | 0 | |
| | 70-100 | 2/1 | <LOD | 6.810 | 0 | 4.8 | 181.0 | 0 | 0 |
| | 70-100 | 2/2 | <LOD | 6.670 | 0 | 4.8 | 181.0 | 0 | |

*inner diameter of corer tip
**Total core area is based on 10 cores with each individual core area calculated using $\pi r^2$ with $\pi$ rounded to 3.142.
DAA: Days after application.
<LOD: Residues are below the limit of detection (LOD), 0.1 µg/kg wet soil).
<LOQ: Residues are below the LOQ (0.5 µg/kg wet soil) but above the LOD (0.1 µg/kg wet soil). Where the wet weight residue was either <LOQ or n.d., the calculated g a.s./ha residue was set to zero.
Residues were calculated by using unrounded values, therefore results cannot be calculated accurately from the values presented in the table.

Revised kinetic assessments for each of these sites were presented in a separate modelling study report of [redacted] 2020a for 'trigger' endpoints. A separate study of [redacted] 2020b was submitted which calculated kinetic modelling endpoints from these sites. These are discussed in sections B.8.1.1.2.2.2 (persistence/dissipation endpoints) and B.8.1.1.2.2.3 (modelling endpoints).

**Conclusion**

Given the concerns identified earlier over the additional sampling of these former field dissipation sites (i.e. the potential for residues in formerly treated soil to be diluted with untreated soil), HSE considers that the revised kinetic values for these sites cannot be used as a refinement of the original kinetic parameters. In addition, with respect to the calculation of modelling endpoints, the fact that the sites had been cropped after the completion of the original studies and prior to resampling means that there is the possibility that plant uptake could also have contributed to apparent dissipation.

### B.8.1.1.2.2.1.4 Non-European field dissipation studies

In order to widen the database on the soil dissipation of pydiflumetofen under field conditions, the applicant submitted the results from a number of studies conducted outside of Europe. Results were available from studies at:

four sites in the USA;
two sites in Canada;
four sites in China;

two sites in South Korea;
two sites in Japan.

According to European guidance retained by Great Britain, the results of field dissipation studies conducted at non-European sites can be accepted for use in European assessments provided that the conditions during the study are representative of European conditions. Therefore as a first step, the applicant performed an assessment to determine comparability of conditions at the sites to European conditions. The assessment was performed using the OECD ENASGIPS tool which uses an 'ecoregion' approach to compare soil and climatic conditions. The tool was developed to consider North American and EU conditions, and the applicant has used this to compare the North American sites to European situations. As ENASGIPS does not extend to other global areas, an approach akin to ENASGIPS was taken using the same ecoregion and soils databases that ENASGIPS draws upon but utilising a different meteorological database.

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1/01. [redacted] (2020), Pydiflumetofen - Similarity Assessment of Terrestrial Field Dissipation Study Sites in North America and Asia to European Conditions: An Ecoregion Crosswalk Analysis. Report Number TK0572654<br>(Syngenta Document No. VV-867687). |

**Guideline(s):** OECD (ENV/JM/MOM(2012)11), ENASGIPS 3.0
**GLP/GEP:** Not applicable to a modelling exercise
**Deviation(s):** No major deviation identified
**Acceptability** Yes

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1/02. [redacted] and [redacted] (2022), Pydiflumetofen - Comparison of Monthly Temperature and Precipitation of Terrestrial Field Dissipation Study Sites in North America and Asia to European Crop Growing Areas. Supplementary and Supporting Information. Report Number TK0661858 |

| | |
|---|---|
| **Guideline(s):** | OECD (ENV/JM/MOM(2012)11), ENASGIPS 3.0 |
| **GLP/GEP:** | Not applicable to a modelling exercise |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Methods**
The ecoregion similarity assessment for the North American TFD study sites in the study of [redacted] (2020) was conducted using the Organisation for Economic Co-operation and Development (OECD) Europe – North America Soil Geographic Information for Pesticide Studies (ENASGIPS) v3.0 application (http://www.enasgips3.org/home.html). The ENASGIPS tool was developed to compare soil and climatic conditions of ecoregions in which terrestrial field dissipation (TFD) study sites in North America and Europe are located. In order to conduct ecoregion similarity assessment between TFD study sites in Asia and European ecoregions, an approach that involved similar datasets and methodology used in the ENASGIPS tool was applied. Specifically, the approach involved utilisation of the existing soil and climatic data from ENASGIPS tool for Europe ecoregions and developing appropriate data for the Asian ecoregions. The World Wildlife Fund Terrestrial Ecoregions data and Harmonised World Soil Database (ENASGIPS uses v.1.1 whereas the applicant used the updated v 1.2) were used because these are common to both Europe and Asia. However, similar meteorological datasets for Asia had to be acquired. In this case, because the MARS FOODSEC ERA-Interim Meteodata for 1978 – 2011 used in ENASGIPS was unavailable, the applicant approach was to use the WorldClim dataset. This presents monthly average temperature and precipitation data for the years 1970 – 2000. Average data were derived from this to be consistent with the ENASGIPS approach. The spatial resolution of the MARS dataset was 0.25 decimal degrees (equivalent to 0 degrees 15 minutes) whereas WorldClim data at a finer spatial resolution of 30 seconds was used. Whilst there is a difference of approximately 10 years between the MARS and WorldClim datasets, it is considered by HSE that at the broad scale of annual average data, this difference would not be sufficiently large to invalidate any comparisons. In addition, ecoregion similarity scores between the TFD study sites in Asia and Europe were calculated following the ecoregion similarity calculation approach prescribed in the ENASGIPS tool.

ENASGIPS is a component of an OECD project titled "Harmonized International Guidance for Pesticide Terrestrial Field Dissipation Studies and Crosswalk of North American and European Eco-regions". Its goal

was to maximize the use of pesticide field dissipation studies by developing harmonized international guidance for conducting the studies and identifying comparable North American and European ecoregions. The underlying premise of ENASGIPS tool is that the field dissipation behaviour of a pesticide in a region depends primarily on environmental factors, such as soils and climate. The concept behind the tool is that if these environmental factors are similar between regions, then field dissipation of a pesticide is expected to be similar in those regions.

ENASGIPS compares ecoregions based on five soil and climatic parameters/variables: mean annual air temperature, mean annual precipitation, mean soil pH, mean soil organic carbon, and soil texture. Depending on the properties of the pesticide of interest, not all parameters may be important for determining field dissipation and a subset of these five parameters may be used to refine the ecoregion comparison. When all five parameters are used the comparison is termed "holistic". Ecoregions are considered similar when their weighted similarity scores are 80% or higher.

It should be noted that a more detailed approach than the ENASGIPS approach has usually been required in European assessments prior to the UK exiting the EU. The ecoregion similarity scoring system can be useful in demonstrating broad similarities between areas. However the use within ENASGIPS of mean annual temperature and precipitation data, as well as mean soil pH and soil organic carbon, gives too broad a comparison between gross areas. In practice, the interpretation of European guidance which pre-dated the OECD Ecoregions approach is that the actual conditions at each study site should be comparable to European conditions. ENASGIPS cannot provide this detailed comparison and as such has not been used as the sole determinant as to whether conditions in a non-European field dissipation study can be considered comparable to European conditions and thus whether the study can used for European or GB risk assessments.

**Results**
Below is a summary of the 'root' ecoregions in which the fourteen TFD study sites evaluated in this report are located.

**Table B.8. 124 Summary of the ecoregions overlapping TFD study sites**

| Ecoregion name | Ecoregion code | TFD study site |
|---|---|---|
| *North America TFD sites* | | |
| California Central Valley grasslands | NA0801 | Madera-CA, California, USA |
| Central tall grasslands | NA0805 | Jefferson-IA, Iowa, USA |
| Snake-Columbia shrub steppe | NA1309 | Grant-WA, Washington, USA |
| Southeastern conifer and broadleaf forests | NA0529 | Tift-GA, Georgia, USA |
| Northern Prairies | NA0811 | Taber-AB, Alberta, Canada |
| Gulf of St. Lawrence lowland forests | NA0408 | New Glasgow-PE, Prince Edward Island, Canada |
| *Asia TFD sites* | | |
| Huang He Plain mixed forests | PA0424 | Dezhou, China |
| Huang He Plain mixed forests | PA0424 | Yangling, China |
| Changjiang Plain evergreen forests | PA0415 | Nanjing, China |
| South China-Vietnam subtropical evergreen forests | IM0149 | Nanning, China |
| Central Korean deciduous forests | PA0413 | Suwon-si, South Korea |
| Central Korean deciduous forests | PA0413 | Buyeo-gun, South Korea |
| Taiheiyo evergreen forests | PA0440 | Kochi, Japan |
| Taiheiyo evergreen forests | PA0440 | Ibaraki, Japan |

The following table summarizes the number of matching European ecoregions and similarity scores to each TFD study site 'root' ecoregion. Results indicated in the below table include 80% or higher similarity scores.

**Table B.8. 125 Summary of similarity scores**

| TFD study Site | TFD Ecoregion name | Similar European Ecoregions | | |
|---|---|---|---|---|
| | | Number | Minimum Similarity | Maximum Similarity |
| **Madera-CA, California, USA** | California Central Valley grasslands (NA0801) | **8** | **83%** | **97%** |
| **Jefferson-IA, Iowa, USA** | Central tall grasslands (NA0805) | **4** | **86%** | **98%** |
| **Grant-WA, Washington, USA** | Snake-Columbia shrub steppe (NA1309) | **7** | **80%** | **87%** |
| Tift-GA, Georgia, USA | Southeastern conifer and broadleaf forests (NA0529) | 0 | - | - |
| **Taber-AB, Alberta, Canada** | Northern Prairies (NA0811) | **2** | **81%** | **86%** |
| New Glasgow-PE, Prince Edward Island, Canada | Gulf of St. Lawrence lowland forests (NA0408) | 0 | - | - |
| **Dezhou, China** | Huang He Plain mixed forests (PA0424) | **14** | **80%** | **100%** |
| **Yangling, China** | | | | |
| **Nanjing, China** | Changjiang Plain evergreen forests (PA0415) | **7** | **80%** | **87%** |
| Nanning, China | South China-Vietnam subtropical evergreen forests (IM0149) | 0 | - | - |
| **Suwon-si, South Korea** | Central Korean deciduous forests (PA0413) | **1** | **86%** | - |
| **Buyeo-gun, South Korea** | | | | |
| **Kochi, Japan** | Taiheiyo evergreen forests (PA0440) | **9** | **81%** | **86%** |
| **Ibaraki, Japan** | | | | |

**Note: TFD sites considered by the applicant to be relevant to EU are indicated by bold font.**

**Conclusions**

The ENASGIPS analysis of the similarity of the North American pydiflumetofen TFD study sites with European ecoregions found that the 'root' ecoregions of three USA TFD study sites in California, Iowa, and Washington have numerous matching ecoregions in the European continent. The matching European ecoregions associated with these three TFD sites also showed significant overlap with crop areas proposed for pydiflumetofen uses. On the other hand, the ENASGIPS analysis of the ecoregion similarity of the site in Georgia found that there were no similar European ecoregions that met the 80% similarly threshold. For the Canadian TFD sites, there were two small ecoregions in Europe covering a limited geographical area found to have similarity with the 'root' ecoregion encompassing the Alberta site. There were no European ecoregions that met the 80% similarly threshold with the 'root' ecoregion of the Prince Edward Island site.

Using a similar approach to the ENASGIPS tool, similarity analysis of the 'root' ecoregions of the Asian TFD study sites found numerous matching ecoregions in Europe for Dezhou-China, Yangling-China, Nanjing-China, Ibaraki-Japan, and Kochi-Japan TFD sites. The similar European ecoregions associated with the Chinese and Japanese TFD study sites also showed significant overlap with crop growing areas proposed for pydiflumetofen uses in Europe. However, there were no similar European ecoregions that met the 80% similarly threshold with the Nanning, China, TFD site ecoregion. For the South Korean TFD sites, there was only one ecoregion in Europe covering a limited geographical area found to have similarity with the 'root' ecoregion of the sites.

**Table B.8. 126 Summary of TFD sites and associated 'root' ecoregions considered by the applicant to be suitable for EU assessment.**

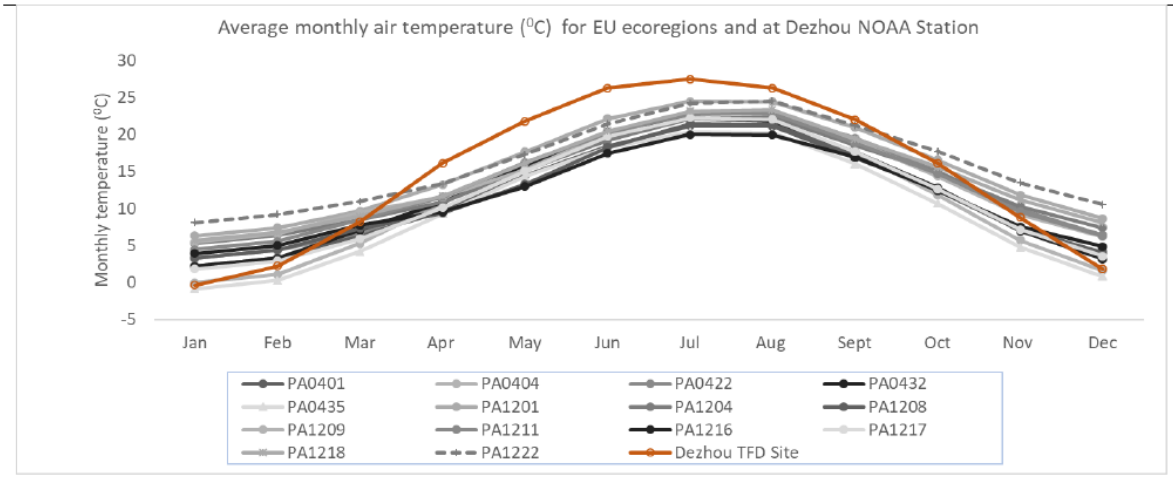
| TFD study Site | TFD Ecoregion name |
|---|---|
| Madera-CA, California, USA | California Central Valley grasslands (NA0801) |
| Jefferson-IA, Iowa, USA | Central tall grasslands (NA0805) |
| Grant-WA, Washington, USA | Snake-Columbia shrub steppe (NA1309) |
| Taber-AB, Alberta, Canada[a] | Northern Prairies (NA0811) |
| Dezhou, China | Huang He Plain mixed forests (PA0424) |
| Yangling, China | |
| Nanjing, China | Changjiang Plain evergreen forests (PA0415) |
| Suwon-si, South Korea[a] | Central Korean deciduous forests (PA0413) |
| Buyeo-gun, South Korea[a] | |
| Kochi, Japan | Taiheiyo evergreen forests (PA0440) |
| Ibaraki, Japan | |

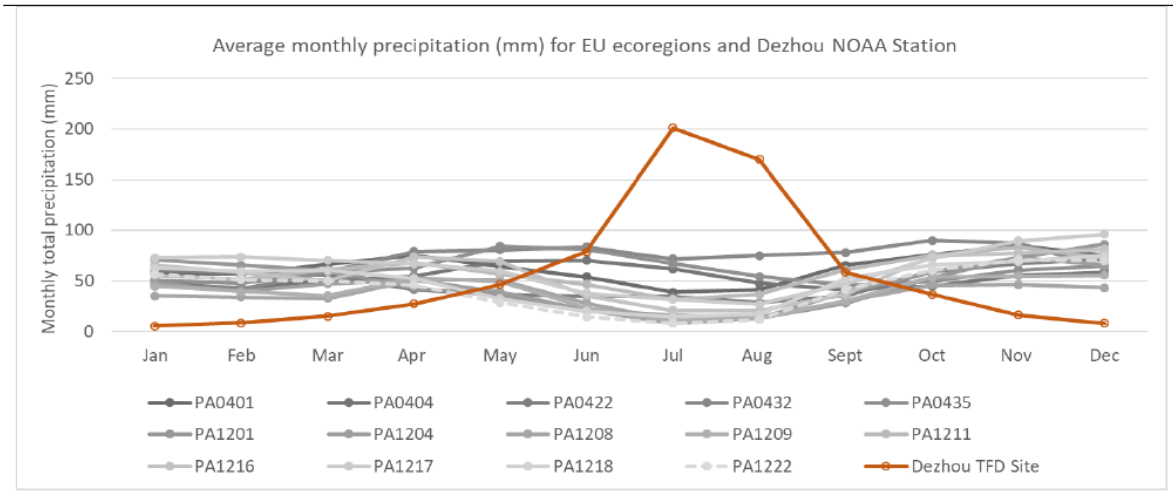
[a] exceeded the similarity threshold in one or two small geographic areas.

As mentioned above, the determinations of EU ecoregion climatic similarity were based on mean annual climate variables (precipitation and air temperature). Conversely, comparisons of monthly climate data (mainly precipitation) of TFD sites in China and Japan against the matching European ecoregions showed differences in the amount and the timing of precipitation. This is due to the prevalence of Monsoon climate in the areas where some Chinese and Japanese TFD sites were located, with hot, rainy summers and mild, dry winters. The Mediterranean climate in the similar European ecoregions typically has mild winters but the vast majority of the rainfall occurs in winter and has mild - hot and very dry summers.

The applicant considered that to capture the impact of inter-season variability of climate (mainly precipitation) and to best represent field dissipation behaviour of pydiflumetofen in Europe, normalisation of the Chinese and Japanese TFD pesticide residue data to the local climate may be necessary. Whilst it is correct that normalisation of field dissipation data to standard temperature and moisture can compensate for much of the effect of differences in these parameters between locations, European guidance states that the sites must be representative of European conditions before they can be used. The applicant presented graphs for average monthly temperature and precipitation at the Dezhou, China, Nanjing, China and the two Japanese sites. These were compared to the monthly averages for the European ecoregions for which the root ecosystems of the trials sites had an overall similarity score of at least 80%. These are shown below. As can be seen, much higher amounts of precipitation are seen during the summer in these Chinese and Japanese sites than the apparently similar European ecoregions; the Dezhou site also shows drier winter conditions. This may be a reason for considering that these particular Asian sites are not representative of European conditions and thus not suitable for use in this assessment.

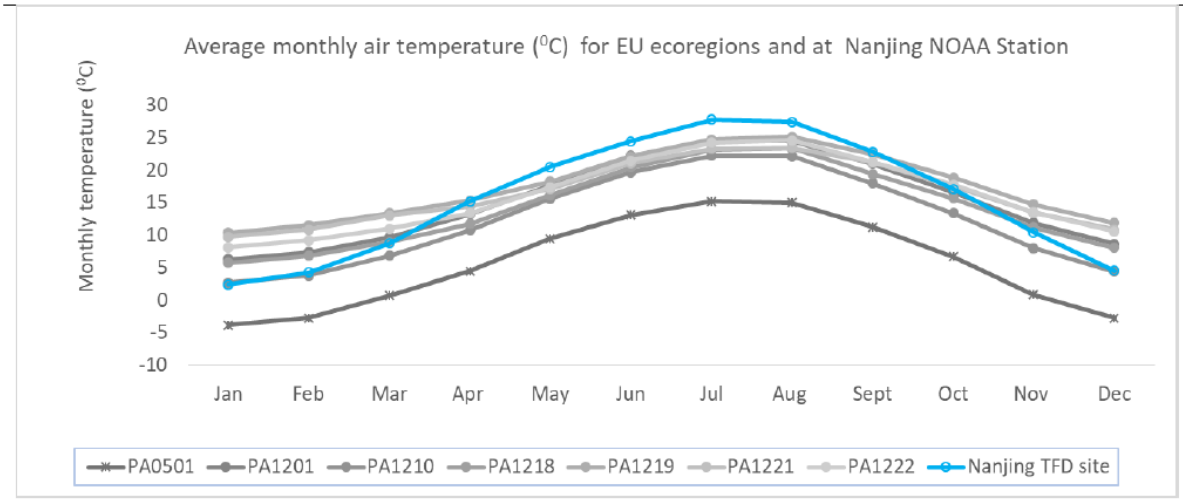
**Figure B.8. 17 Summary of the monthly temperature and precipitation of the Europe ecoregions matching Dezhou TFD Site, Shandong Province, China**

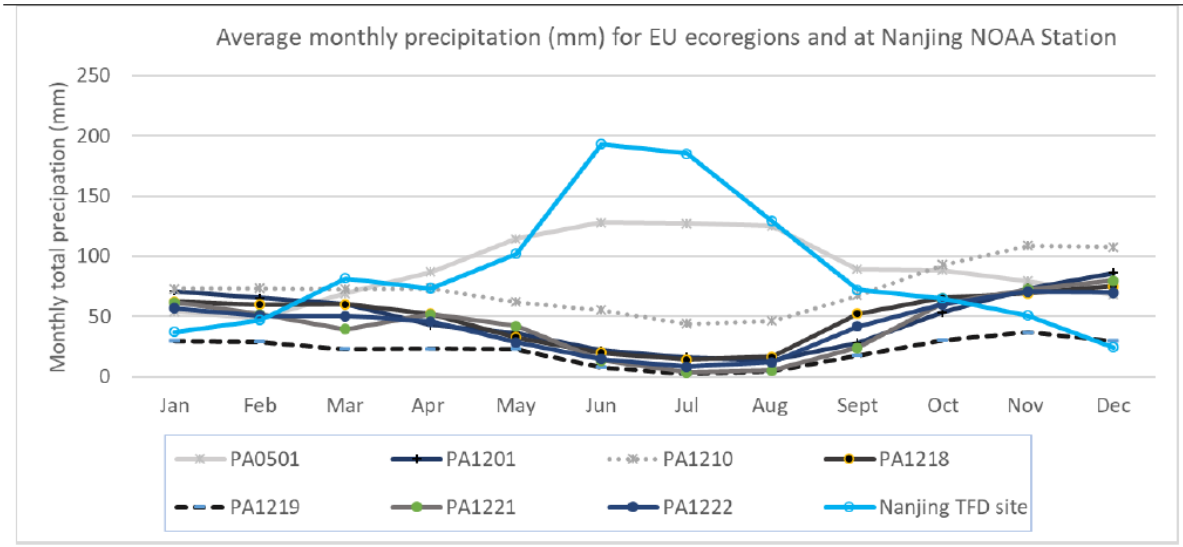



Note: long-term monthly air temperature and precipation data for the matching EU ecoregions were obtained from ENASGIPS database. For Dezhou TFD a 40-year average weather data at Dezhou, China station obtained from National Oceanic and Atomospheric Administration (NOAA) National Centers for Envirometnal Information <https://www.ncdc.noaa.gov/cdo-web/search>

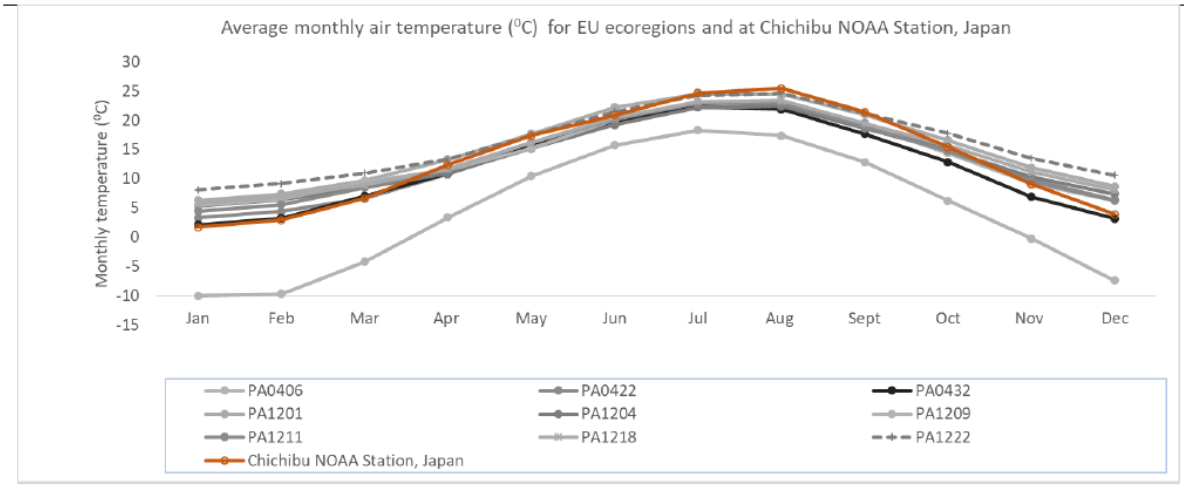
**Figure B.8. 18 Summary of the monthly temperature and precipitation of the Europe ecoregions matching Nanjing TFD site, Jiangsu Province, China**

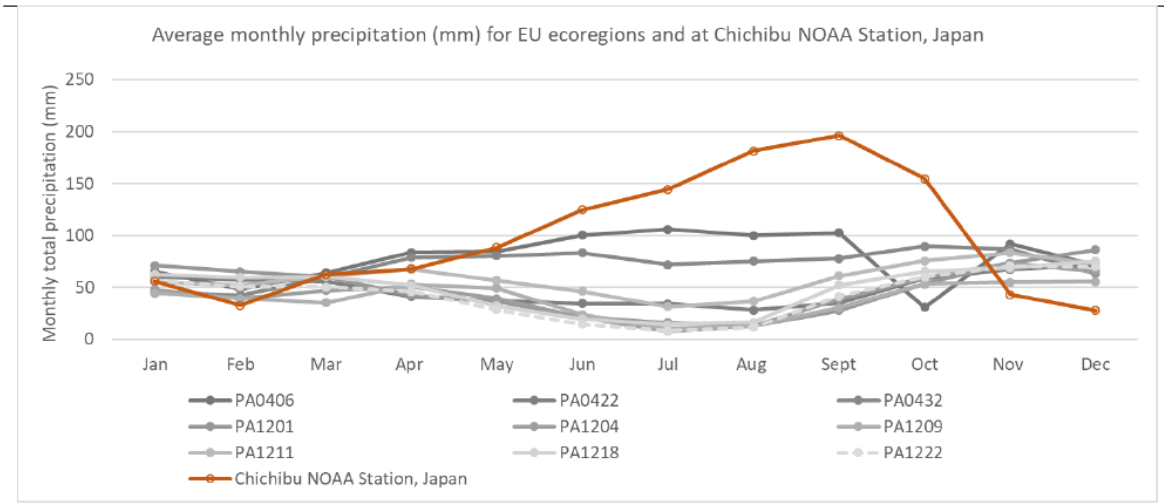



Note: long-term monthly temperature and precipation data for the matching EU ecoregions were obtained from ENASGIPS database. For Nanjing TFD site, 40-Year-average weather data obtained from a Nanjing, China, station obtained from National Oceanic and Atomospheric Administration (NOAA) National Centers for Envirometnal Information <https://www.ncdc.noaa.gov/cdo-web/search>

**Figure B.8. 19 Summary of the monthly temperature and precipitation of the Europe ecoregions matching Japan TFD sites, Japan**




Note: long-term monthly temperature and precipation data for the matching EU ecoregions were obtained from ENASGIPS database. For Chichibu NOAA station in Japan, 40-Year-average weather data obtained from a Chichibu NOAA station, Japan, obtained from National Oceanic and Atomospheric Administration (NOAA) National Centers for Envirometnal Information <https://www.ncdc.noaa.gov/cdo-web/search>

Notwithstanding the comment relating to the influence of monsoon climates on the conditions in some Asian TFD studies, HSE considers that the similarity score approach of ENASGIPS (and the similar approach taken for the Asian studies) is insufficient by itself to justify the relevance of the sites to European conditions. The approach to consideration of similarity of field dissipation sites should also take into account the actual soil and weather conditions during the study and not just the averages of the ecoregions in which they are located. This is stipulated by existing European guidance retained for GB assessments.

The applicant was asked to provide further information on climatic conditions, comparing the monthly average temperature and precipitation data at the sites with long-term average data for cropping-relevant areas of Europe. In response the applicant submitted a new study ([redacted] and [redacted], 2022) which detailed the comparison. Long-term monthly average temperature and total precipitation from the NetCDF Lat-Lon regular 25x25km grid meteorological data were obtained from the European Commission Joint Research Centre

European Commission. The period covered was 1986 – 2015. This dataset appears to be similar to the MARS long-term weather dataset held by the EU and which is the basis of much of the weather data used in FOCUS exposure models. The data were filtered to take into account relevant land use. In the wider European context of the crops that are sought for registration of pydiflumetofen, the weather data were filtered to take into account land used for grapes, pome fruits, cucurbits, tomatoes, potatoes, brassicas, berries and small fruit, cereals, oilseed rape, root vegetables and tuber. The current GB submission for is for use on cereal crops and oilseed rape. The basis of the land use data was the CORINE land cover database for 2018. Using the range of crops above, six land cover classes were identified within CORINE;

- non-irrigated arable land
- permanently irrigated land
- vineyards
- fruit trees and berry plantations
- annual crops associated with permanent crops
- land principally occupied by agriculture, with significant areas of natural vegetation.

For the selected crop growing areas in Europe, monthly temperature and total precipitation were extracted from the gridded meteorological data and averaged for the period of 1986 to 2015; the median, mean, quartiles and 5$^{th}$ and 95$^{th}$ percentiles were calculated for each month. The monthly average data from the individual sites were then plotted against the European monthly data for comparison. The comparison was only performed for those sites which had 'passed' the ENASGIPS (or equivalent for the Asian sites) assessment. Thus the comparison was not performed for the Georgia, USA, Prince Edward Island, Canada and Nanning, China sites. The comparison of weather conditions is presented below for each site together with the consideration of the individual soils.

Consideration of the soil characteristics indicates that the sites can be allocated into USDA textural classes (ENASGIPS uses the USDA textural classification system). However this does not mean that the soils at each site necessarily correspond with soils in Europe.

It is noted that the soil at the Ibaraki site in the Japanese field dissipation study is a volcanic soil. As such the Ibaraki results cannot be used because European guidance indicates that volcanic soils are excluded from consideration. This is because their chemical and physical properties differ substantially from those of temperate mineral soils (e.g. their colloids are variably charged, having a positive charge at low pH and a negative charge at high pH and they have a lower bulk density and a higher hydraulic conductivity than most mineral soils). Given that the soil is not considered to be representative of Europe, no further consideration has been made of the soil properties or weather for this site.

In addition, European guidance indicates that soils from temperate regions outside the EU are also considered acceptable provided their pH, organic matter and clay contents are within the range of values to be expected for top soils in the EU. Soils formed under tropical or sub-tropical conditions can be very different in terms of the physical and chemical properties compared to those formed under temperate conditions even if their mineral and organic carbon properties appear to be similar. This is because of their formation under hotter and wetter conditions compared to temperate soils. The soil at the Georgia, USA site is classified as being in the order Ultisols which are often associated with tropical or sub-tropical conditions. This may limit the ability to use the results from this site due to European guidance indicating that non-European *temperate* soils may be used in assessment provided that they meet criteria showing they are of relevance to European conditions. It is noted that the 'root' ecoregion in which the Georgia, USA site is located has no ecoregion matches in Europe, has a high annual average temperature of 20.5° and has a relatively high total precipitation of 1265 mm/year. This would suggest a possible sub-tropical or tropical climate.

As the assessment only considered comparability at the ecoregion level, HSE also considered the actual soil properties at the trial sites to the soils data in ENASGIPS. ENASGIPS considers the top 30 cm of soils and allocates a numerical value of 1 – 13 to the different USDA textural classes as follows.

**Table B.8. 127 ENASGIPS handling of USDA soil textural classifications**

| CODE * | VALUE | TextureRank | TextureGroup |
|---|---|---|---|
| 1 | clay(heavy) | 1 | FINE |
| 2 | silty clay | 2 | FINE |
| 3 | clay (light) | 3 | FINE |
| 4 | silty clay loam | 4 | FINE |
| 5 | clay loam | 5 | FINE |
| 8 | sandy clay | 6 | FINE |
| 6 | silt | 7 | MEDIUM |
| 7 | silt loam | 8 | MEDIUM |
| 9 | loam | 9 | MEDIUM |
| 10 | sandy clay loam | 10 | MEDIUM |
| 11 | sandy loam | 11 | COARSE |
| 12 | loamy sand | 12 | COARSE |
| 13 | sand | 13 | COARSE |

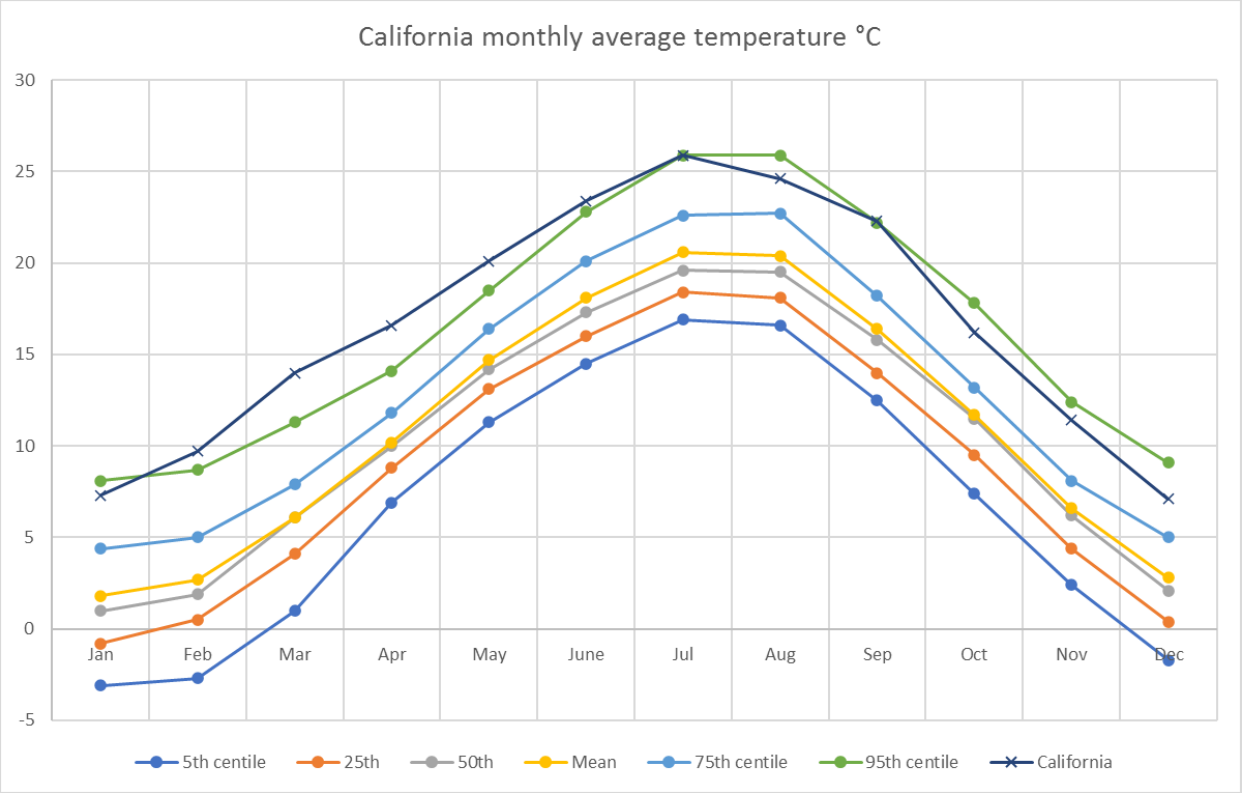
Each ecoregion is then assigned an overall rank (and standard deviation) based on the numerical values of the textual classes within the ecoregion according to the Harmonised World Soil Database (HWSD). ENASGIPS then compares the overall rank of the root ecoregion where the field dissipation study was located with the rankings of potential comparable ecoregions. However this does not take into account the textural classification or proportions of sand, silt and clay at the actual site of the study. In some cases the textural class at the site was very different to the ranking for the root ecoregion. It is possible to compare the textural class of individual trials sites with information for other ecoregions within ENASGIPS. However the accuracy of the comparison is limited because the soil textural search in ENASGIPS is limited to three broad categories of 'Fine', 'Medium' and 'Coarse' textures as the soil mapping is at a scale of 1:5 million (although the underlying data are at a resolution of approximately 1 km). These broad classifications are based on collections of USDA textural classifications rather than being able to input actual proportions of sand, silt and clay or the specific USDA classification for the soil. HSE used the broad textural classifications of the individual sites together with organic carbon and pH information to determine in a broad sense whether each soil was likely to have equivalent soils in Europe. The search was conducted by first filtering by Organic Carbon content (T_OC) and Texture. If the search did not result in many matching grids on the map (results are presented graphically, displaying grid squares on a map), then the search was repeated based on filtering for T_OC only. If T_OC + Texture resulted in a reasonable number of hits, the search was additionally filtered by pH.

The results of the searches are shown below.

**California, USA**

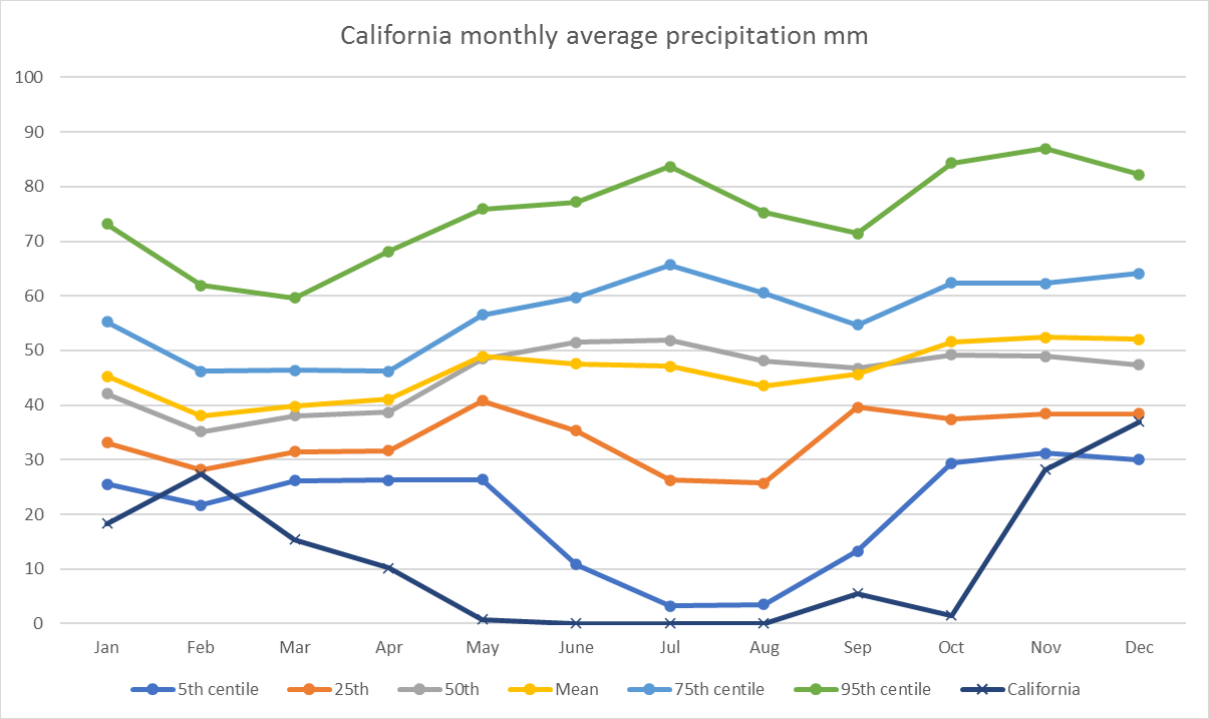
The consideration of the weather conditions for the California site is shown below. It is noted that the field dissipation study at the California site was conducted for approximately two years. However the comparison was only performed for January to December and it is assumed that the data for 'duplicate' months in the study were averaged rather than presenting the monthly averages for two years.

**Figure B.8. 20 Comparison of monthly average temperature data for the California field dissipation site with European long-term monthly average temperature data**



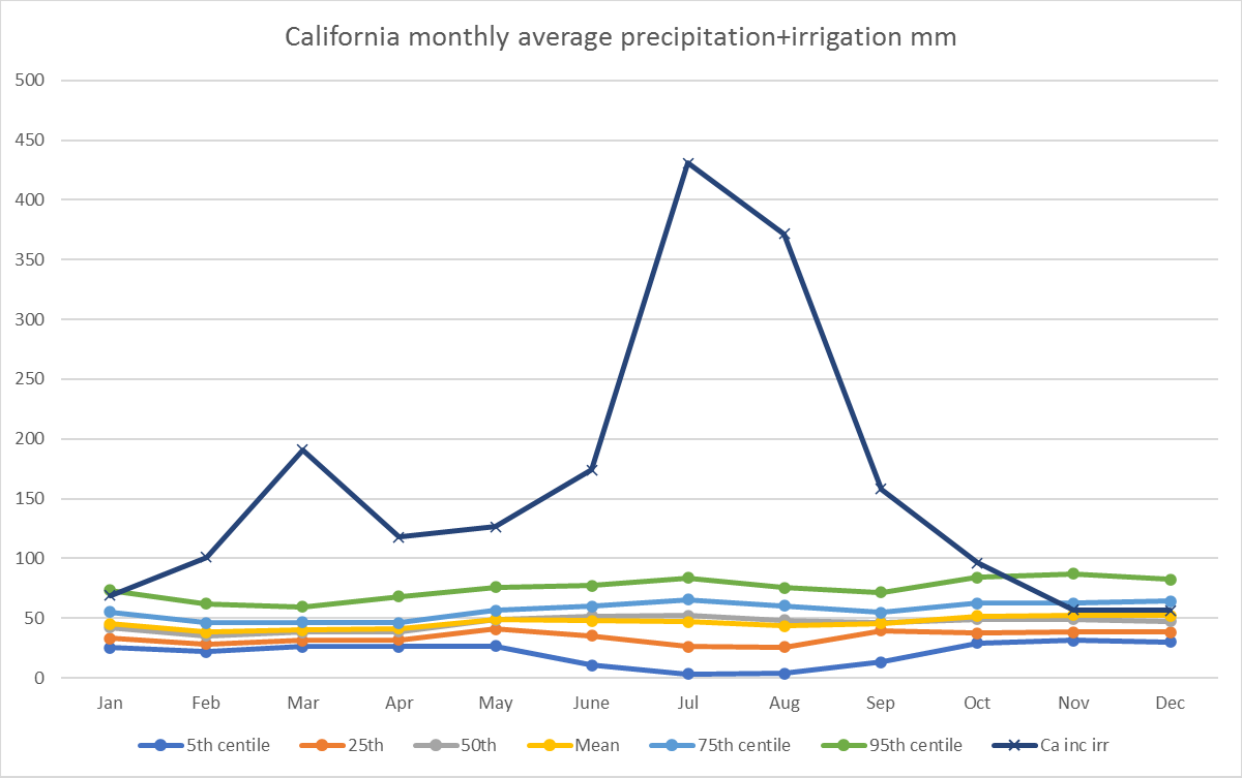

The data indicate that the California site experienced average monthly temperatures above the 95$^{th}$ percentile for Europe in six out of the 12 months comparison. A further month, July, had the same average temperature as the 95$^{th}$ percentile for Europe.

**Figure B.8. 21 Comparison of monthly average precipitation data for the California field dissipation site with European long-term monthly average precipitation data**




The precipitation data indicate that the California site had lower monthly precipitation than the 5$^{th}$ percentile in Europe. However natural precipitation was supplemented with irrigation which is not shown on the graph. Taking into account natural precipitation and irrigation the following comparison is achieved.

**Figure B.8. 22 Comparison of monthly average precipitation + irrigation data for the California field dissipation site with European long-term monthly average precipitation data**




Combined irrigation and rainfall at the site exceed the European 95$^{th}$ percentile monthly average for nine out of 12 months. Overall, it is considered that the climatic conditions at the California site are tending towards the extremes of European climates and it is considered that they are not representative of European conditions.

The California soil has the following soil characteristics in the top 30cm.

**Table B.8. 128 Soil characteristics at California, USA**

| Plot | Soil Depth (inches) | pH* | CEC (meq/ 100 g) | O.C. (%) | Bulk density (g/cc) | WHC (%) | | Sand (%) | Silt (%) | Clay (%) | USDA Class COARSE |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated bare soil | 0-3 | 7.5 | 6.6 | 0.45 | 1.33 | 6.1 | 3.7 | 82 | 12 | 6 | Loamy sand |
| | 3-6 | 7.4 | 6.2 | 0.34 | 1.32 | 5.9 | 3.4 | 82 | 12 | 6 | Loamy sand |
| | 6-12 | 7.5 | 6.0 | 0.21 | 1.31 | 6.1 | 3.6 | 80 | 12 | 8 | Loamy sand |

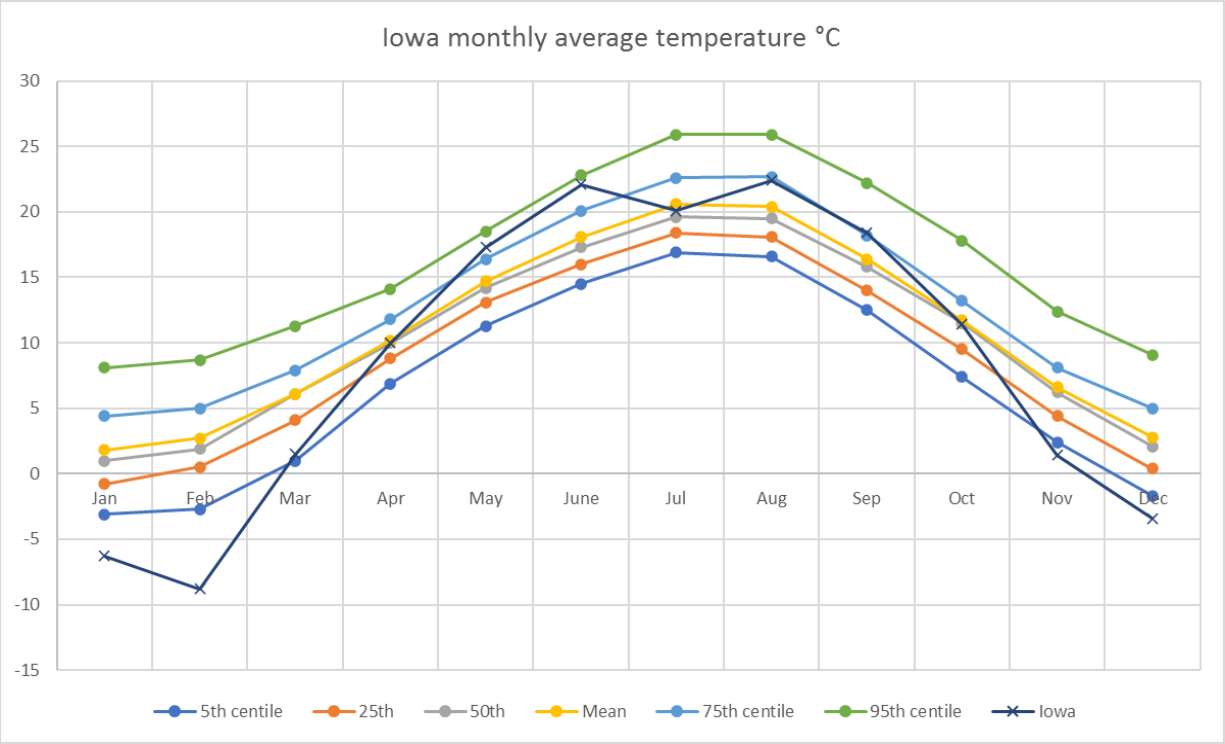
The initial search using Coarse texture and OC of 0.2 – 0.5% found very few matches, these being mainly limited to a few grid squares in the Iberian peninsula. Including a search term for pH of 7.0 – 8.0 eliminated nearly all matching grid squares with the exception of what appear to be two grid squares, one being in the Iberian peninsula and the other in Greece. Thus it appears that the soil will be likely to have an extremely limited representation in Europe and as such it is considered inappropriate to use it in the assessment.

Taking account of both weather and soils data, HSE consider that the California site is not representative of European conditions and cannot be used for risk assessment.

**Iowa, USA**

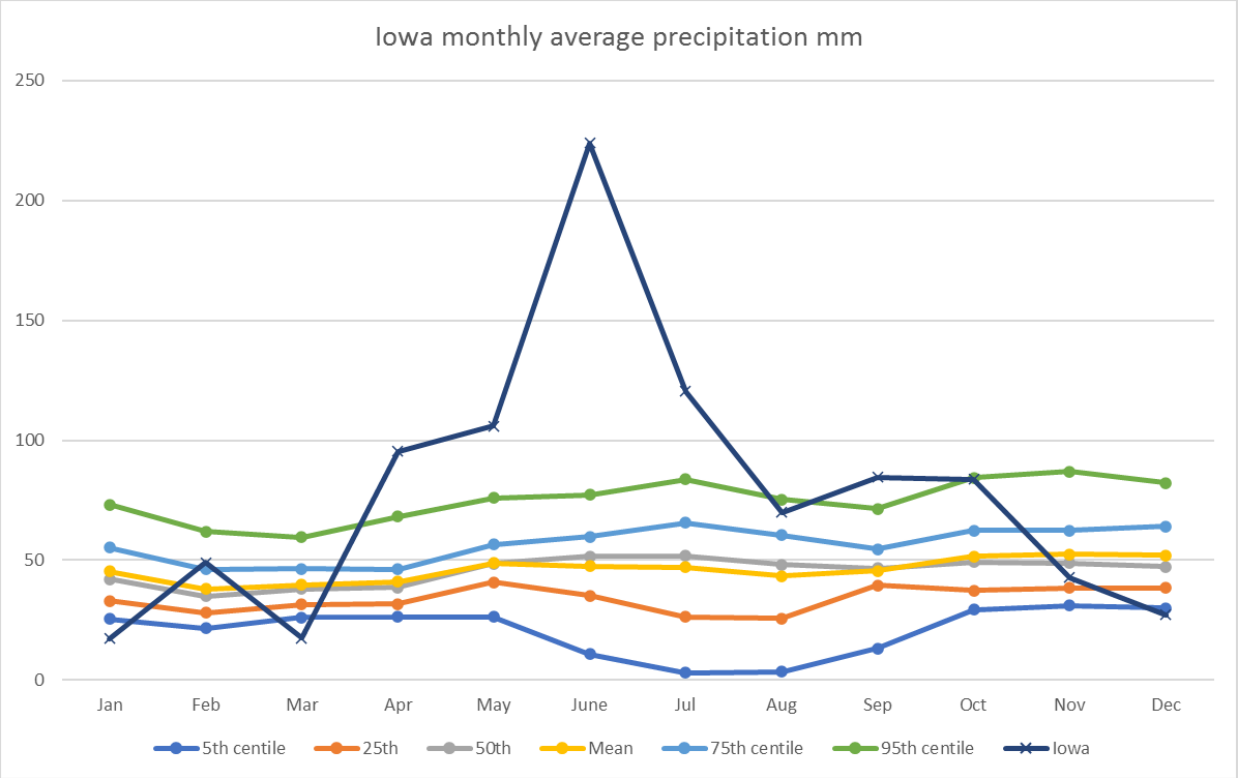
The consideration of the weather conditions for the Iowa site is shown below. It is noted that the field dissipation study at the Iowa site was conducted for approximately one year and eight months. However the comparison was only performed for January to December and it is assumed that the data for 'duplicate' months in the study were averaged rather than presenting the monthly averages for the whole study period.

**Figure B.8. 23 Comparison of monthly average temperature data for the Iowa field dissipation site with European long-term monthly average temperature data**




It is noted that the Iowa site had a pronounced amplitude in the temperature data with low winter temperature in five out of the twelve months either less than or very close to the 5$^{th}$ percentile of the European data. However, temperature in May – September were usually at or above the 75$^{th}$ percentile. Whilst the temperatures are within the 5 – 95$^{th}$ percentile range for March – October period, the amplitude of the temperature profile is of concern. Previous assessment has indicated that such pronounced amplitude in the monthly temperature data are not typical in Europe. This suggests that the Iowa climate is unlikely to be representative of European conditions.

**Figure B.8. 24 Comparison of monthly average precipitation data for the Iowa field dissipation site with European long-term monthly average precipitation data**




The monthly precipitation data for Iowa shows some marked amplitude with rainfall lower than the 5$^{th}$ percentile in three months and higher than the 95$^{th}$ percentile in five months. Rainfall was within the 5 – 95$^{th}$ percentile range in only four of the 12 months. Given the already high natural rainfall, the data on added irrigation has not been considered for this site.

The Iowa soil has the following soil characteristics in the top 30cm.

**Table B.8. 129 Soil characteristics at Iowa, USA**

| Plot | Soil Depth (inches) | pH* | CEC (meq/ 100 g) | O.C. (%) | Bulk density (g/cc) | WHC | | Sand (%) | Silt (%) | Clay (%) | USDA Class FINE |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated bare soil | 0-3 | 6.8 | 19.2 | 1.74 | 1.08 | 28.3 | 15.0 | 16 | 53 | 31 | Silty Clay Loam |
| | 3-6 | 6.7 | 19.7 | 1.74 | 1.11 | 29.0 | 14.2 | 20 | 49 | 31 | Clay Loam |
| | 6-12 | 6.3 | 19.7 | 1.51 | 1.12 | 31.0 | 16.7 | 12 | 53 | 35 | Silty Clay Loam |

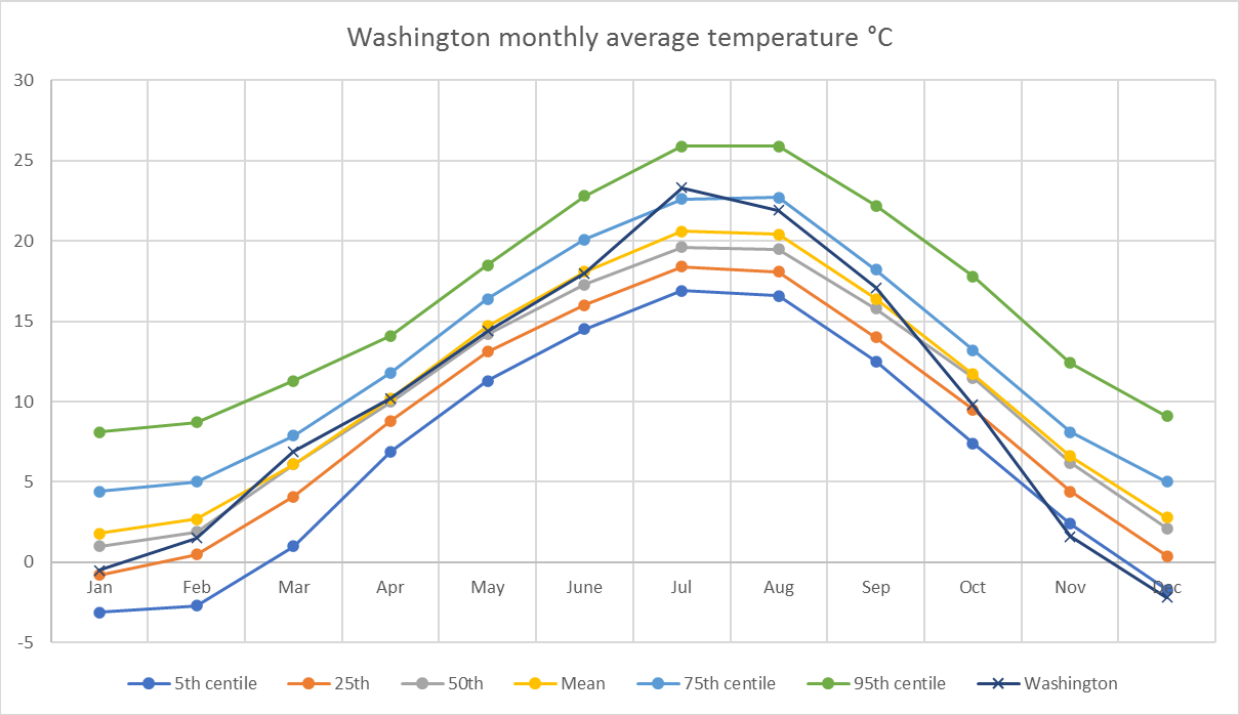
The initial search using Fine texture and OC of 1.5 – 1.8% found some a relatively limited number of matches, these being predominantly in the East (Bulgaria, Romania, Hungary, Poland). Including a search term for pH of 6.0 – 7.1 reduced the number of matching grid squares but not by a large amount. Whilst the representation of this soil in Europe appears to be limited, it is considered that it can be used in risk assessment.

Overall, it is considered that the weather data are not representative of European conditions. Whilst the soil appears to be representative of European soils, HSE consider that this site cannot be used for risk assessment purposes.

**Washington, USA**

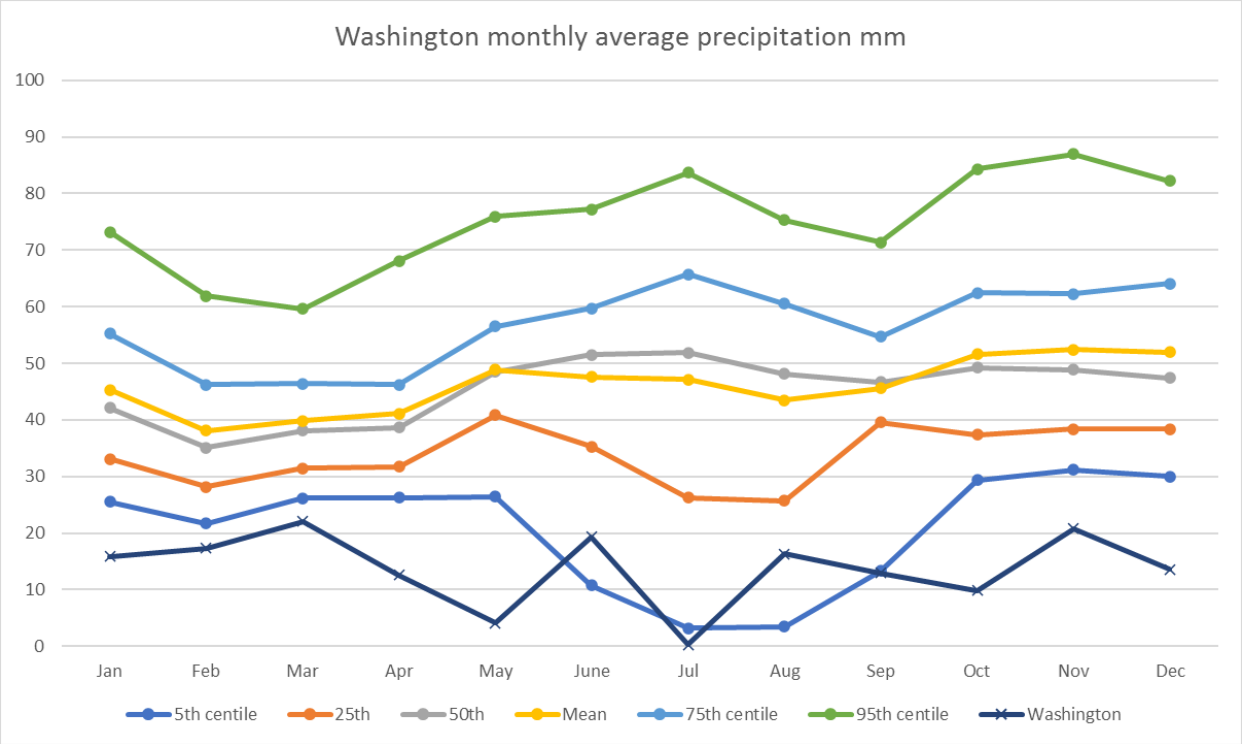
The consideration of the weather conditions for the Washington site is shown below. It is noted that the field dissipation study at the Washington site was conducted for approximately one year and eight months. However the comparison was only performed for January to December and it is assumed that the data for 'duplicate' months in the study were averaged rather than presenting the monthly averages for the whole study period.

**Figure B.8. 25 Comparison of monthly average temperature data for the Washington field dissipation site with European long-term monthly average temperature data**



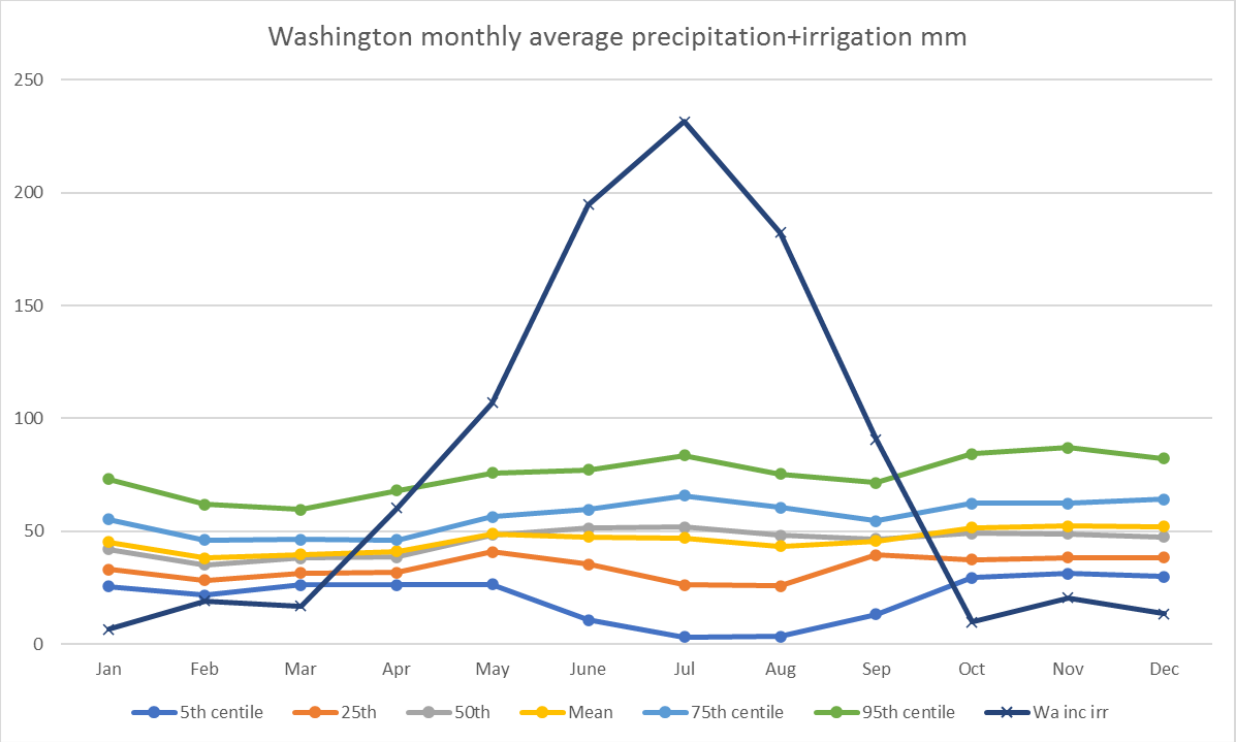

The monthly average temperatures for the Washington site appear to be mainly within the 25$^{th}$ – 75$^{th}$ percentiles but with November and December falling below the 5$^{th}$ percentile. Overall the temperatures appear to be reasonably representative of European conditions.

**Figure B.8. 26 Comparison of monthly average precipitation data for the Washington field dissipation site with European long-term monthly average precipitation data**




Precipitation for the Washington site appeared to be low, with month averages falling below the European 5$^{th}$ percentile for nine out of 12 months. Reasonable quantities of irrigation were applied during the course of the study. These have been displayed below.

**Figure B.8. 27 Comparison of monthly average precipitation + irrigation data for the Washington field dissipation site with European long-term monthly average precipitation data**




As can be seen, the addition of irrigation leads to a large amplitude in total precipitation, six months being below the European 5th percentile and five months being above the European 95th percentile. Overall the precipitation for the site is not considered to be representative of European conditions.

The Washington soil has the following soil characteristics in the top 30cm.

**Table B.8. 130 Soil characteristics at Washington, USA**

| Plot | Soil Depth (inches) | pH* | CEC (meq/ 100 g) | O.C. (%) | Bulk density (g/cc) | WHC | | Sand (%) | Silt (%) | Clay (%) | USDA Class COARSE |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated | 0-3 | 7.9 | 8.4 | 0.27 | 1.38 | 8.1 | 3.8 | 90 | 10 | 0 | Sand |
| | 3-6 | 8.1 | 8.5 | 0.27 | 1.39 | 7.2 | 3.8 | 90 | 10 | 0 | Sand |
| | 6-12 | 8.3 | 8.7 | 0.13 | 1.40 | 6.8 | 4.0 | 90 | 10 | 0 | Sand |

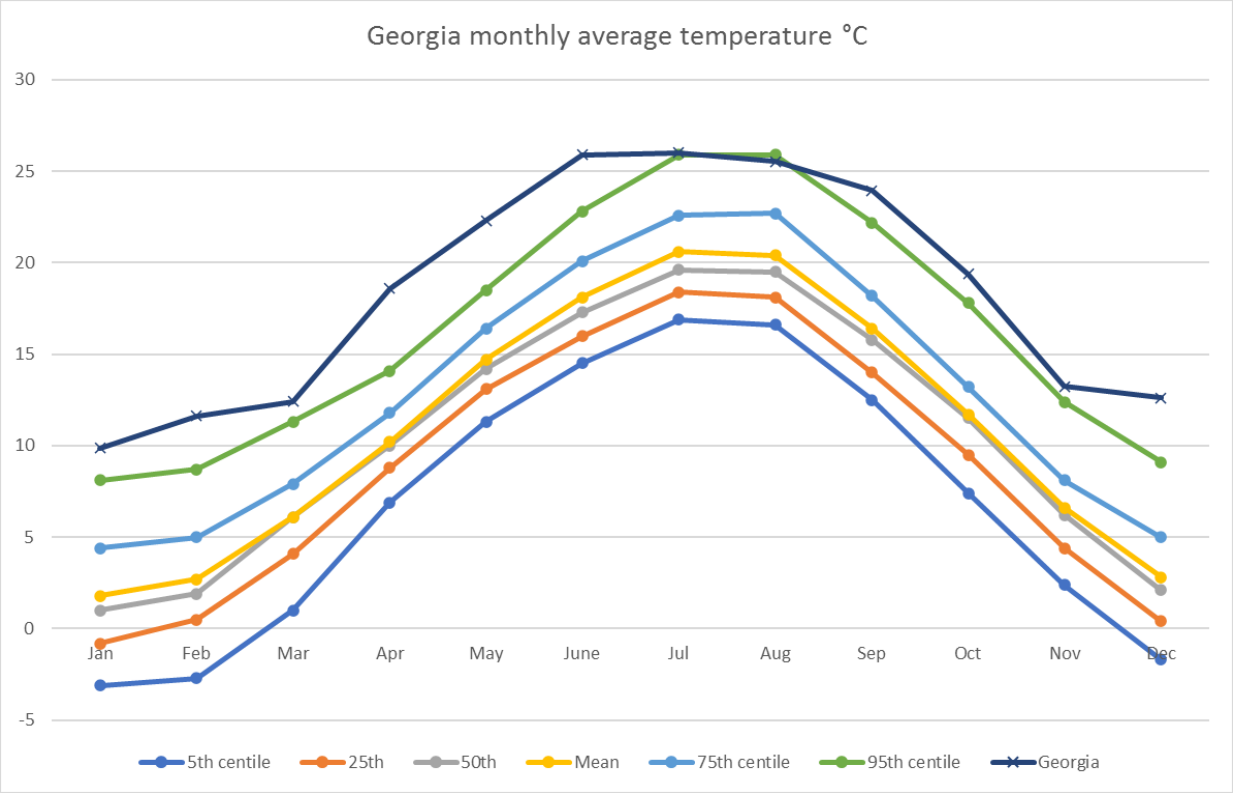
The initial search using Coarse texture and OC of 0.1 – 0.3% found no matching grid squares. Removing the textural class from the search also failed to find any matches. Whilst the search is limited by the 1:5 million scale of the map, the extremely high sand content and absence of clay suggests that this soil would at best have an extremely limited representation in Europe and as such it is considered inappropriate to use it in risk assessment.

Overall, it is considered that neither the weather (due to precipitation) and soil at the Washington site are representative of European conditions.

**Georgia, USA**

As no matching ecoregions were found by the ENASGIPS assessment for the Georgia site, the applicant did not perform a detailed assessment of the weather conditions. HSE performed a check on the temperature data in a similar way to the applicant. 'Duplicate' months in the data set were averaged to cover 12 months.

**Figure B.8. 28 Comparison of monthly average temperature data for the Georgia field dissipation site with European long-term monthly average temperature data**




As can be seen, the average monthly temperature is above the European 95$^{th}$ percentile for ten out of 12 months and the same as or only just below the European 95$^{th}$ percentile for the other two months. This confirms that the climate is unlikely to be representative of European conditions even without a consideration of precipitation.

The Georgia soil has the following soil characteristics in the top 30cm.

**Table B.8. 131 Soil characteristics at Georgia, USA**

| Plot | Soil Depth (inches) | pH* | CEC (meq/ 100 g) | O.C. (%) | Bulk density (g/cc) | WHC (%) | | Sand (%) | Silt (%) | Clay (%) | USDA Class COARSE |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated | 0-3 | 7.2 | 4.0 | 0.48 | 1.44 | 4.6 | 2.1 | 90 | 7 | 3 | Sand |
| | 3-6 | 6.8 | 3.6 | 0.40 | 1.43 | 4.9 | 2.1 | 89 | 8 | 3 | Sand |
| | 6-12 | 6.2 | 3.5 | 0.25 | 1.49 | 5.1 | 2.2 | 89 | 8 | 3 | Sand |

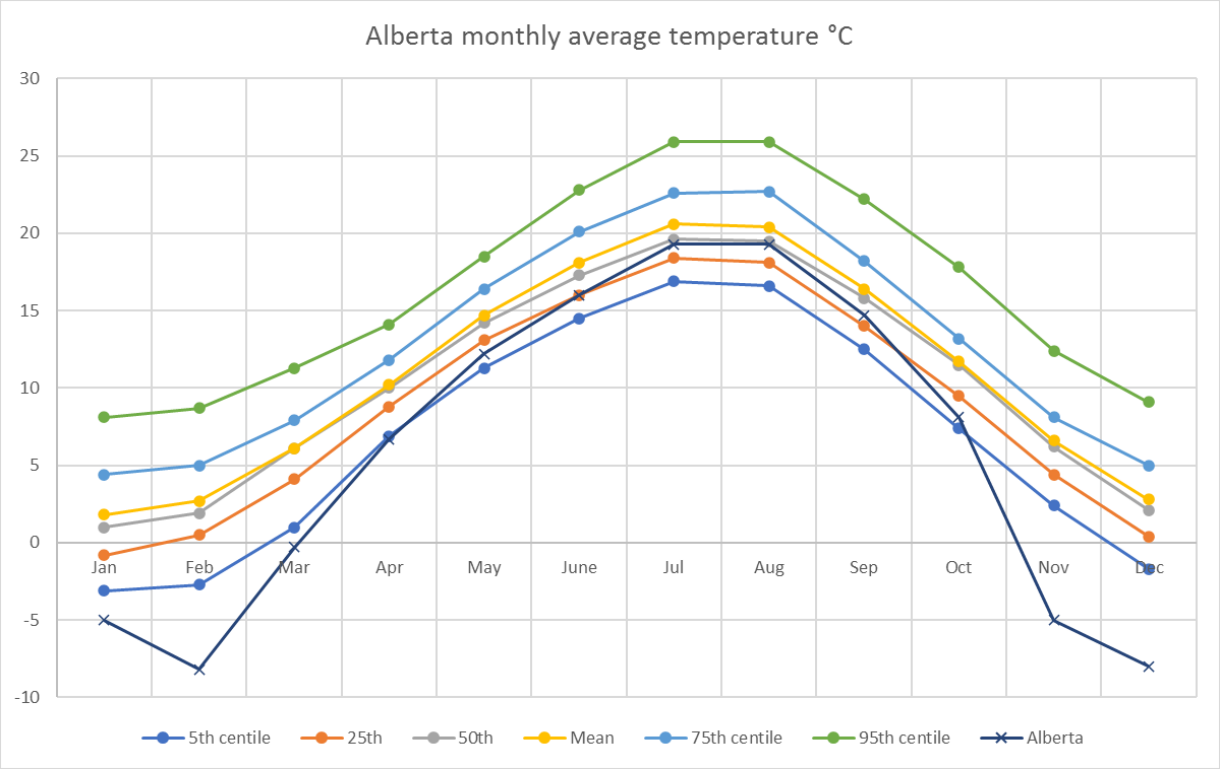
The initial search using Coarse texture and OC of 0.2 – 0.5% found very few matches, these being limited to a few grid squares in the Iberian peninsula. The search did not include the pH as the number of grid squares was so limited. It is also noted that this soil may be more representative of a tropical or sub-tropical soil. The combination of the soil properties and its taxonomic classification make it unlikely that this soil is representative of any in Europe. It is excluded from use in risk assessment.

Overall, both the climate and soil of the Georgia site are considered to be not representative of European conditions.

**Alberta, Canada**

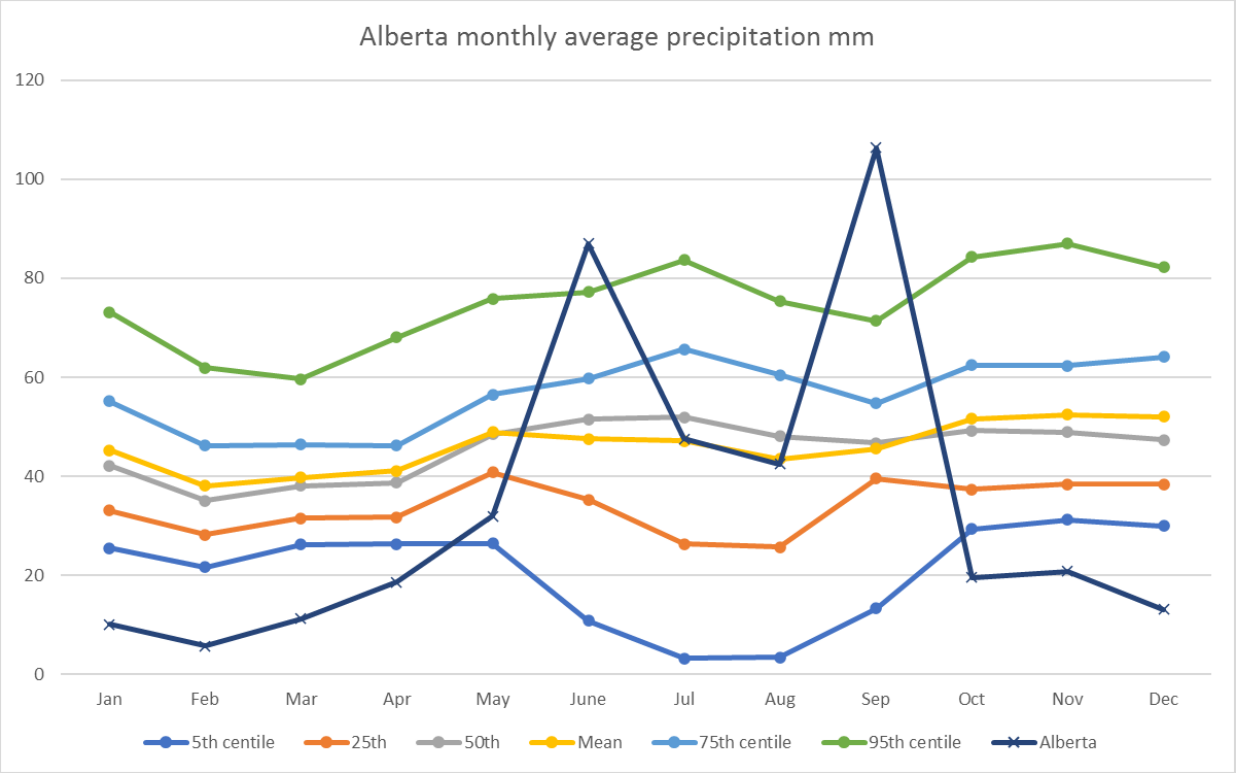
The consideration of the weather conditions for the Alberta site is shown below. It is noted that the field dissipation study at the Alberta site was conducted for approximately one year and 11 months. However the comparison was only performed for January to December and it is assumed that the data for 'duplicate' months in the study were averaged rather than presenting the monthly averages for the whole study period.

**Figure B.8. 29 Comparison of monthly average temperature data for the Alberta field dissipation site with European long-term monthly average temperature data**



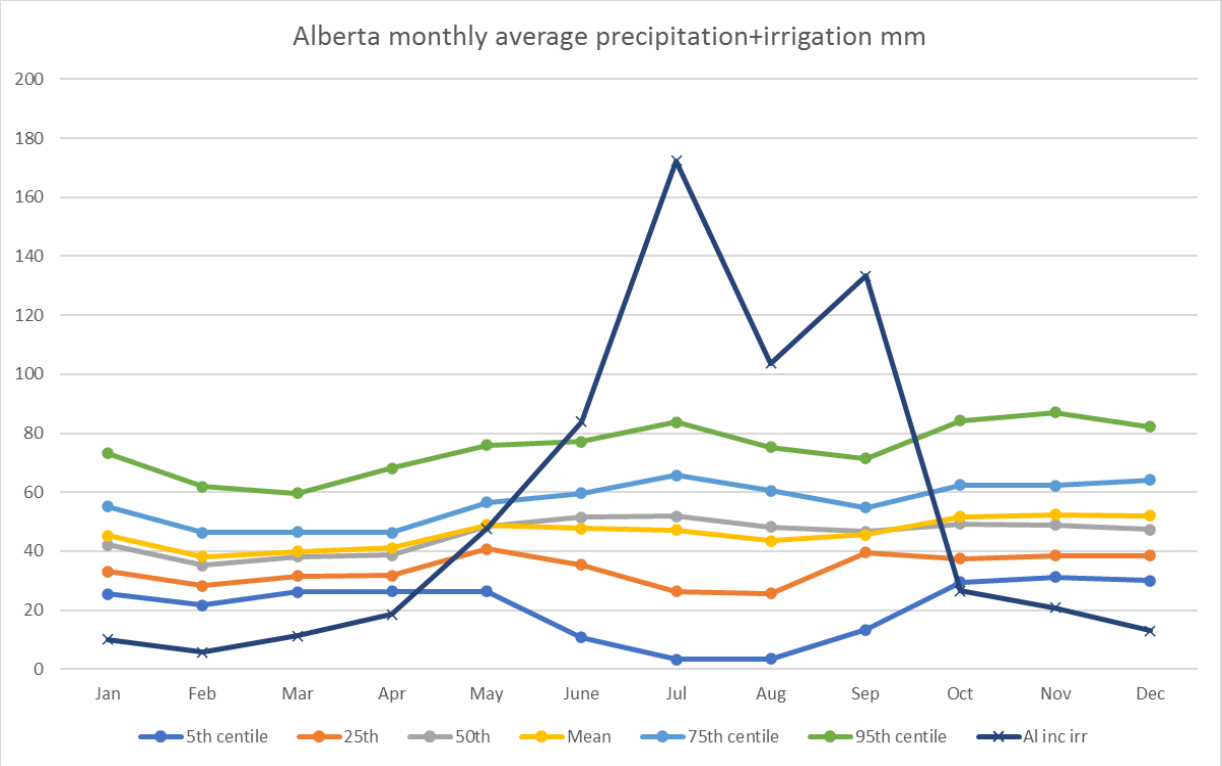

The average monthly temperature for the Alberta site is lower than the European 5$^{th}$ percentile for six out of 12 months and only just higher than the 5$^{th}$ percentile for a further two months which suggests that temperature at the site was not representative of European conditions.

**Figure B.8. 30 Comparison of monthly average precipitation data for the Alberta field dissipation site with European long-term monthly average precipitation data**




The precipitation data indicate the Alberta site has seven out of 12 months with lower amounts than the European 5$^{th}$ percentile and two months higher than the European 95$^{th}$ percentile. The effect of taking additional irrigation into account is shown below.

**Figure B.8. 31 Comparison of monthly average precipitation + irrigation data for the Alberta field dissipation site with European long-term monthly average precipitation data**




The additional irrigation further accentuates the differences to European conditions.

The Alberta soil has the following soil characteristics in the top 40cm.

**Table B.8. 132 Soil characteristics at Alberta Canada**

| Parameter | Depth range (cm) | | |
|---|---|---|---|
| | **0-10** | **10-25** | **25-40** |
| Sand (%) | 47.4 | 40.2 | 35.9 |
| Silt (%) | 29.7 | 33.5 | 37.4 |
| Clay (%) | 22.9 | 26.2 | 26.6 |
| Texture **MEDIUM** | Loam | Loam | Loam |
| Organic Carbon (%) | 1.50 | 1.10 | 0.70 |
| Cation Exchange Capacity (meq/100g) | 18.0 | 15.0 | 14.1 |
| pH* | 8.03 | 8.25 | 8.35 |
| Available Moisture (%, at bar)<br>1/3<br>15 | <br>14.7<br>10.9 | <br>15.8<br>12.4 | <br>15.7<br>12.0 |
| Bulk Density ($g/cm^3$) (undisturbed individual samples) | 1.32 ± 0.06 | ND | ND |
| Porosity (%) (undisturbed individual samples) | 50.0 ± 2.4 | ND | ND |

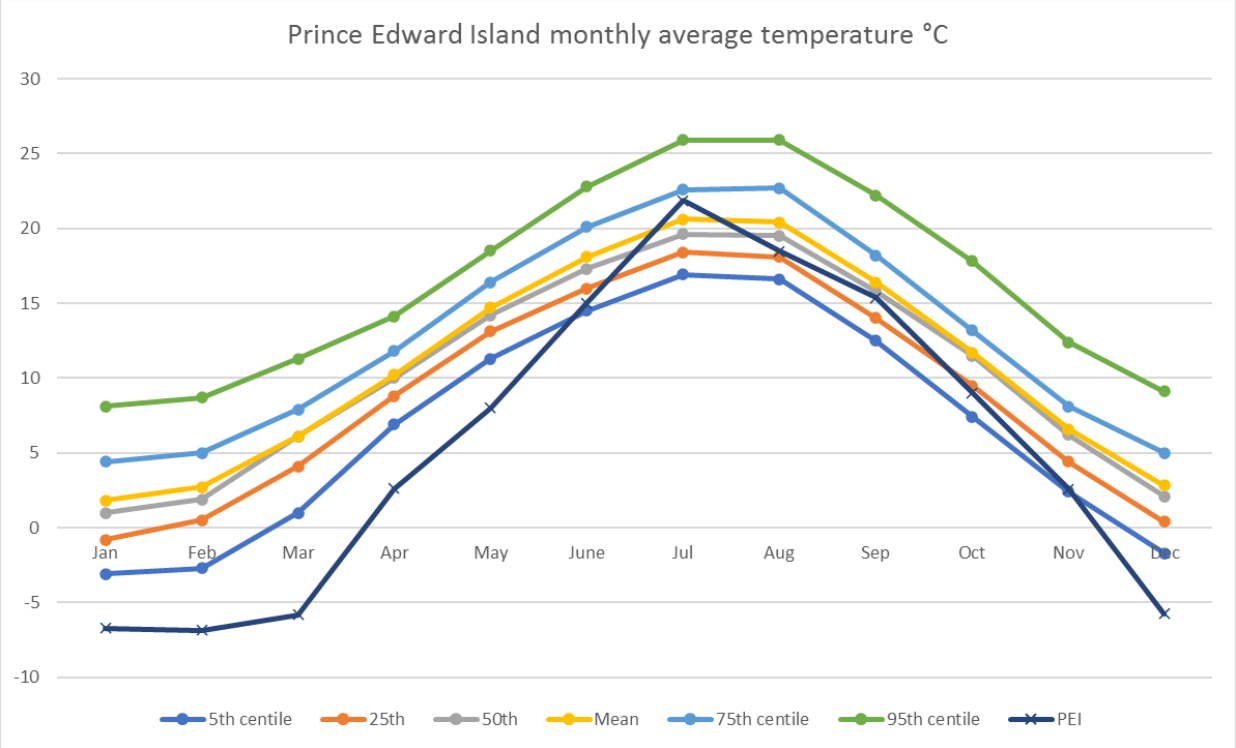
The initial search using Medium texture and OC of 0.6 – 1.6% found numerous matches distributed across the UK and the EU. Including a search term for pH >8.0 significantly reduced the number of matches to a small number mainly confined to the Baltic area, the Iberian peninsula and a single grid square in Romania. Whilst the textural and OC content seem to show widespread distribution throughout Europe the high pH seems to be a limiting factor in the prevalence of this soil. It is considered that the soil can be used in risk assessment.

Overall, whilst the soil appears to be representative of some European situations, the weather data suggest that the site is not representative of European conditions. The site cannot be used for risk assessment purposes.

**Prince Edward Island, Canada**

As no matching ecoregions were found by the ENASGIPS assessment for the Prince Edward Island site, the applicant did not perform a detailed assessment of the weather conditions. HSE performed a check on the temperature data in a similar way to the applicant. 'Duplicate' months in the data set were averaged to cover 12 months.

**Figure B.8. 32 Comparison of monthly average temperature data for the Prince Edward Island field dissipation site with European long-term monthly average temperature data**




The average monthly temperature is lower than the European 5th percentile for six months out of 12 and only just above the 5th percentile for another two months. It is considered by HSE that this indicates that the site is not representative of European conditions. Precipitation data were not checked.

The Alberta soil has the following soil characteristics in the top 30cm.

**Table B.8. 133 Soil characteristics at Prince Edward Island, Canada**

| Plot | Soil Depth (cm) | pH (1:1 $H_2O$) | CEC (meq/ 100 g) | O.C. (%) | Bulk density (g/cm$^3$) | WHC | | Sand (%) | Silt (%) | Clay (%) | USDA Class COARSE |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated bare soil | 0-7.5 | 6.4 | 8.0 | 1.91 | 1.02 | 22.8 | 9.0 | 62 | 26 | 12 | Sandy Loam |
| | 7.5-15 | 6.3 | 7.8 | 1.74 | 1.04 | 23.5 | 9.1 | 60 | 28 | 12 | Sandy Loam |
| | 15-30 | 5.4 | 6.5 | 1.22 | 1.05 | 19.2 | 9.1 | 63 | 23 | 14 | Sandy Loam |

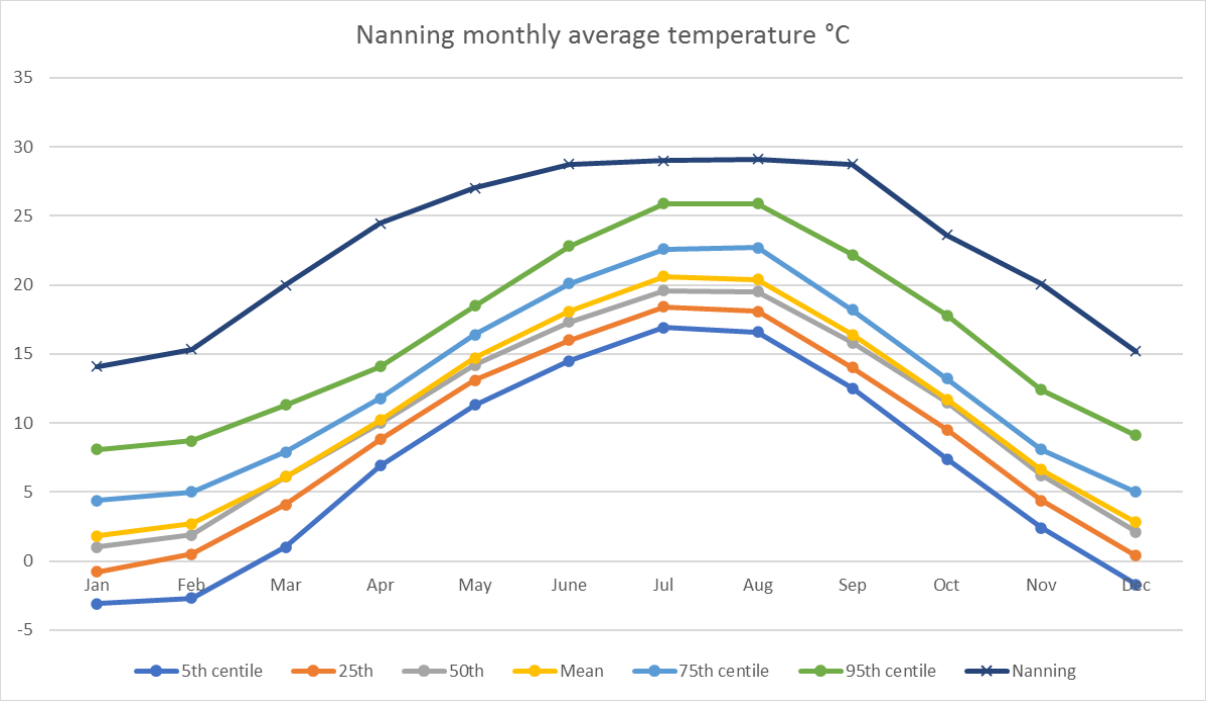
The initial search using Coarse texture and OC of 1.2 – 2.0% found numerous matches distributed across the UK and the EU. Including a search term for pH 5.2 – 6.6 reduced the number of matches but there was still a reasonable representation across Europe. It is considered that the soil can be used in risk assessment.

Overall, whilst the soil is likely to be representative of some European situations, the climate data and the ecoregion assessment suggest that the site is overall not representative of European conditions.

**Nanning, China**

As no matching ecoregions were found by the ENASGIPS assessment for the Nanning site, the applicant did not perform a detailed assessment of the weather conditions. HSE performed a check on the temperature data in a similar way to the applicant. 'Duplicate' months in the data set were averaged to cover 12 months.

**Figure B.8. 33 Comparison of monthly average temperature data for the Nanning field dissipation site with European long-term monthly average temperature data**




The data show that the average monthly temperature at the site was always above the European 95$^{th}$ percentile.

The Nanning soil has the following soil characteristics in the top 30cm.

**Table B.8. 134 Soil characteristics at Nanning, China**

| Parameter | Depth range (cm) | | |
|---|---|---|---|
| | **0-10** | **10-20** | **20-30** |
| Sand (%) | 13.2 | 12.8 | 10.8 |
| Silt (%) | 13.4 | 16.6 | 19.0 |
| Clay (%) | 73.4 | 70.6 | 70.2 |
| Texture (USDA) **FINE** | Clay | Clay | Clay |
| Organic Carbon (%) | 1.63 | 1.50 | 1.21 |
| Cation Exchange Capacity (meq/100g) | 9.90 | 9.13 | 8.12 |
| pH (in water) | 4.60 | 4.35 | 4.65 |
| Moisture Retention Capacity (% w/w) pF 2 (0-4 cm) | 44.1 | | |

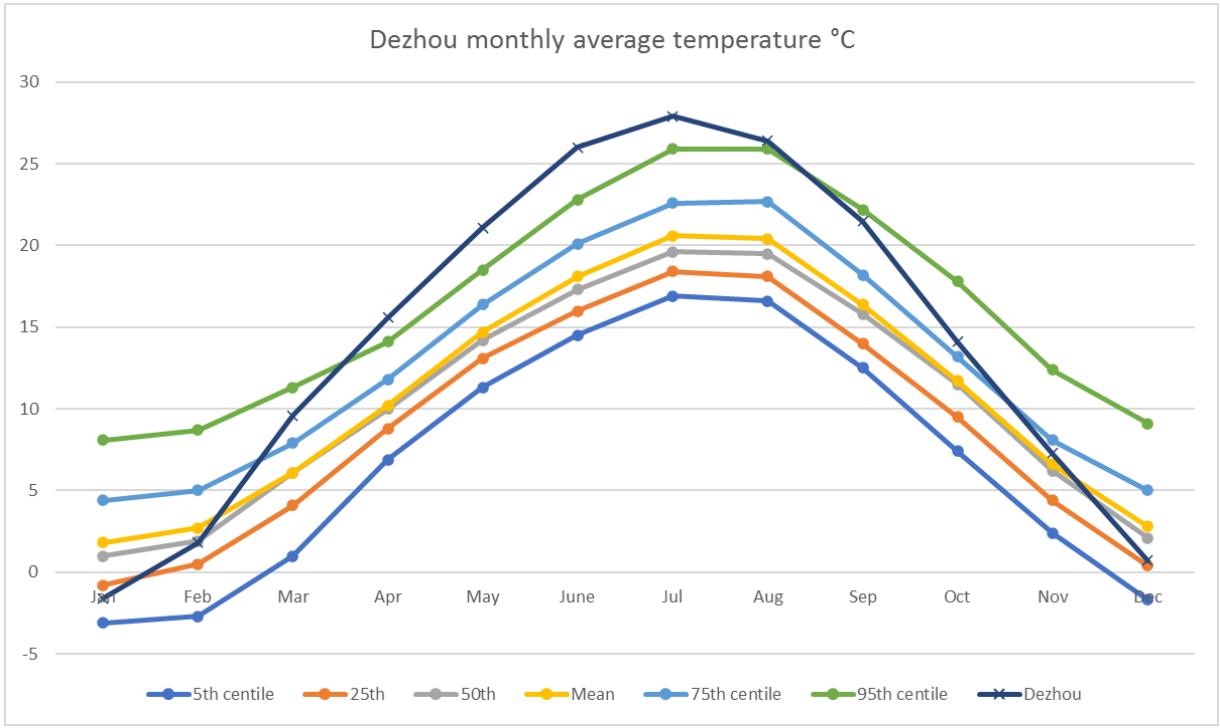
The initial search using Fine texture and OC of 1.1 – 1.8% found numerous matches distributed across the UK and the EU. Including a search term for pH <4.8 eliminated any matches. The low pH of the soil appears to be a major constraint on the potential distribution of a such a soil in Europe. It is considered that the soil cannot be used in risk assessment.

Both the temperature and soil at the Nanning site are considered to be not representative of European conditions.

**Dezhou, China**

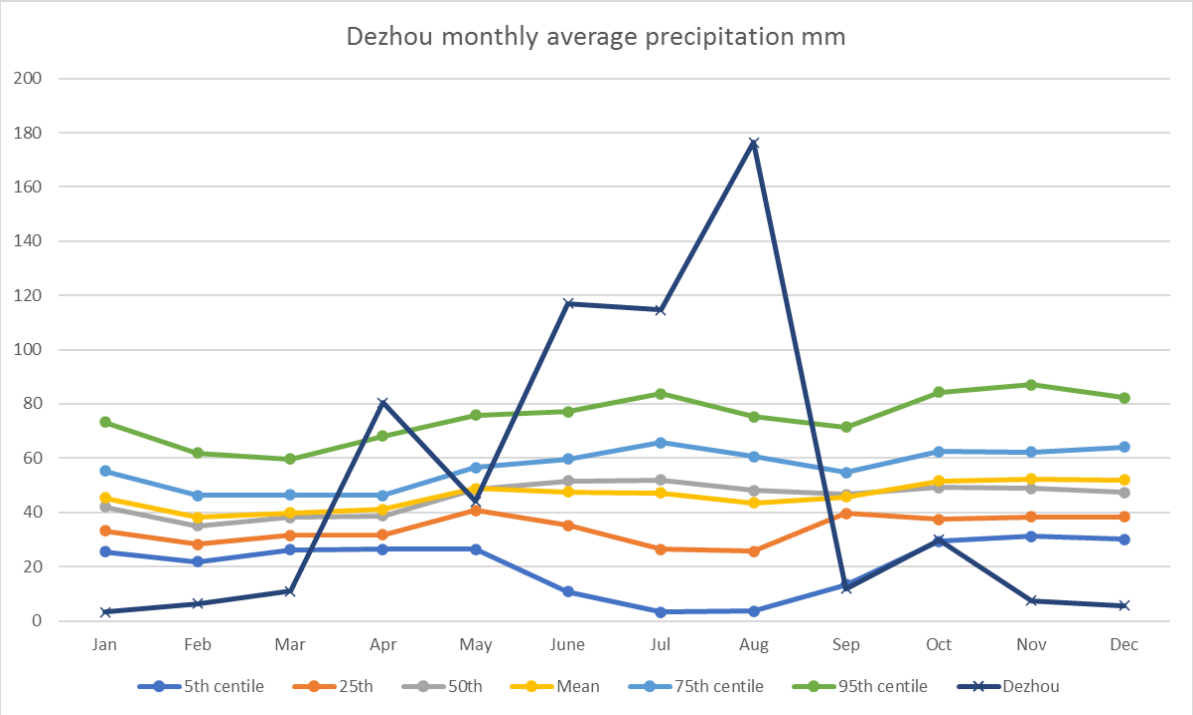
The consideration of the weather conditions for the Dezhou site is shown below. It is noted that the field dissipation study at the Dezhou site was conducted for approximately two years. However the comparison was only performed for January to December and it is assumed that the data for 'duplicate' months in the study were averaged rather than presenting the monthly averages for the whole study period.

**Figure B.8. 34 Comparison of monthly average temperature data for the Dezhou field dissipation site with European long-term monthly average temperature data**



The average monthly temperature data for the Dezhou site shows that it lies above the European 95th percentile for five out of 12 months. However the temperature in January and December lie close to the European 25th percentile suggesting a relatively large amplitude in temperature over the course of a year which may make the conditions unrepresentative of Europe.

**Figure B.8. 35 Comparison of monthly average precipitation data for the Dezhou field dissipation site with European long-term monthly average precipitation data**




The precipitation data show that the Dezhou site had amounts lower than the European 5th percentile in six out of 12 months and higher than the European 95th percentile in four out of 12 months. Irrigation was applied at this site on one occasion in June soon after application. This would raise the total for June further above the European 95th percentile.

The Dezhou soil has the following soil characteristics in the top 30cm.

**Table B.8. 135 Soil characteristics at Dezhou, China**

| Parameter | Depth range (cm) | | |
|---|---|---|---|
| | **0-10** | **10-20** | **20-30** |
| Sand (%) | 30.4 | 22.4 | 23.8 |
| Silt (%) | 53.0 | 60.2 | 58.6 |
| Clay (%) | 16.6 | 17.4 | 17.6 |
| Texture (USDA) **MEDIUM** | Silt loam | Silt loam | Silt loam |
| Organic Carbon (%) | 1.07 | 0.48 | 0.20 |
| Cation Exchange Capacity (meq/100g) | 8.13 | 7.49 | 5.98 |
| pH (water) | 7.50 | 7.55 | 8.05 |
| Moisture Retention Capacity (% w/w) pF 2 (0-4 cm) | 42 | | |

The initial search using Medium texture and OC of 0.1 – 1.2% found numerous matches distributed across the UK and the EU. Including a search term for pH 7.3 – 8.2 reduced the number of matches but there were still

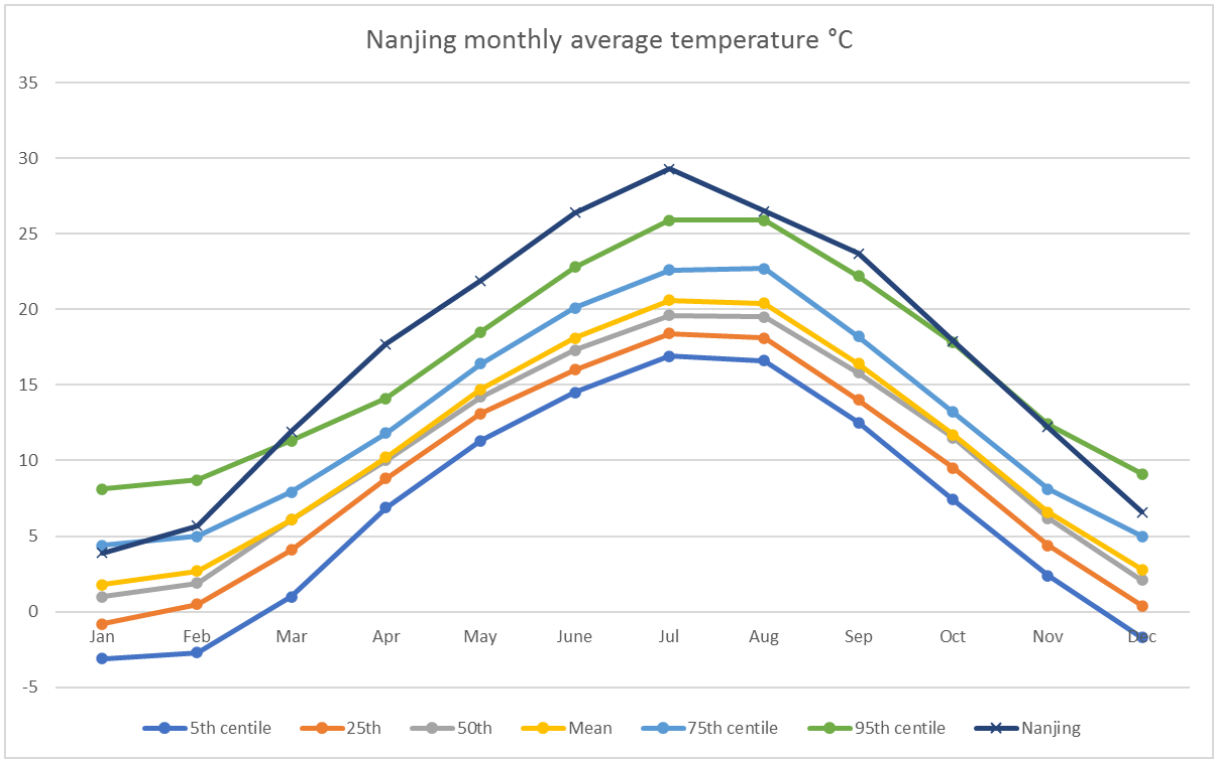
numerous matches across Europe, particularly in the Iberian peninsula and Greece. Other less frequent matches were found throughout the EU. It is considered that the soil can be used in risk assessment.

Overall, whilst the soil appears to be representative of European conditions, the weather data are considered to be not representative of European conditions. Therefore the site is not considered to be representative of European conditions.

**Nanjing, China**

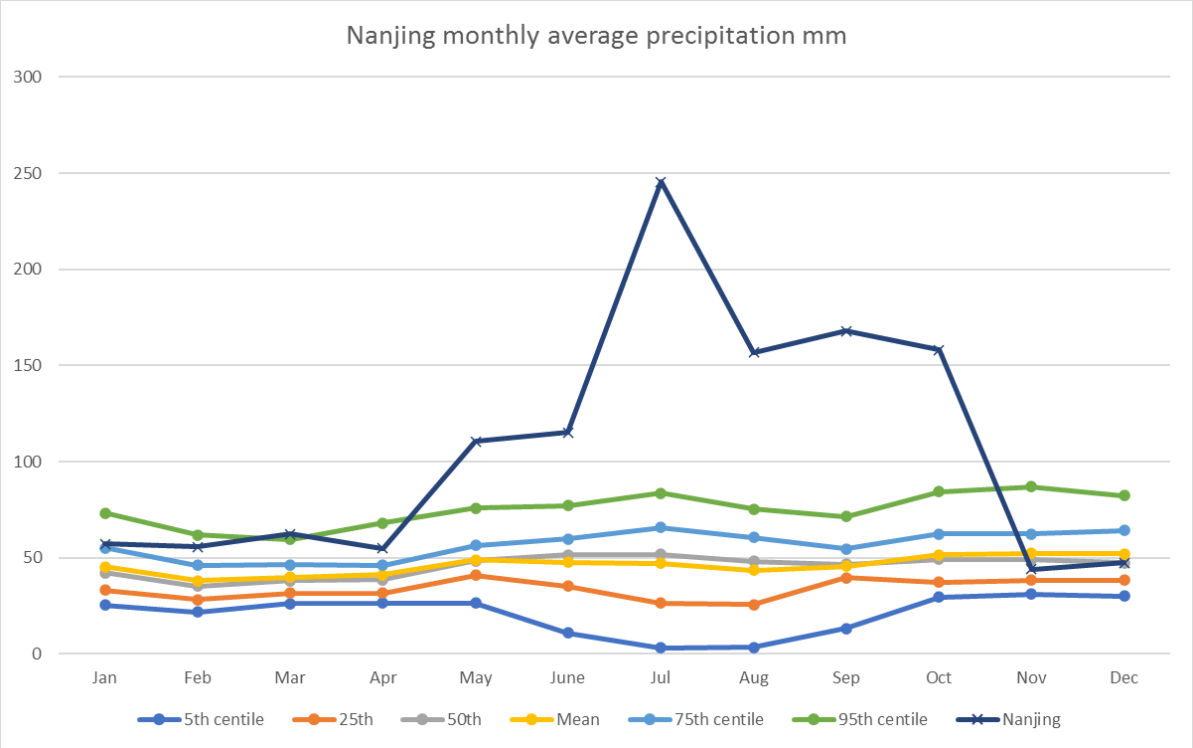
The consideration of the weather conditions for the Nanjing site is shown below. It is noted that the field dissipation study at the Nanjing site was conducted for approximately 2 years. However the comparison was only performed for January to December and it is assumed that the data for 'duplicate' months in the study were averaged rather than presenting the monthly averages for the whole study period.

**Figure B.8. 36 Comparison of monthly average temperature data for the Nanjing field dissipation site with European long-term monthly average temperature data**




The monthly average temperature at the Nanjing site was greater than the European 95$^{th}$ percentile in eight out of 12 months.

**Figure B.8. 37 Comparison of monthly average precipitation data for the Nanjing field dissipation site with European long-term monthly average precipitation data**




The monthly rainfall at the Nanjing site was above the European 95$^{th}$ percentile in seven months out of 12. No irrigation was applied at this site.

The Nanjing soil has the following soil characteristics in the top 30cm.

**Table B.8. 136 Soil characteristics at Nanjing, China**

| **Parameter** | **Depth range (cm)** | | |
|---|---|---|---|
| | **0-10** | **10-20** | **20-30** |
| Sand (%) | 8.4 | 9.6 | 10.0 |
| Silt (%) | 63.8 | 65.2 | 64.6 |
| Clay (%) | 27.8 | 25.2 | 25.4 |
| Texture (USDA) **MEDIUM** | Silty loam | Silty loam | Silty loam |
| Organic Carbon (%) | 1.07 | 0.84 | 0.71 |
| Cation Exchange Capacity (meq/100g) | 11.95 | 10.29 | 9.18 |
| pH (in water) | 6.85 | 6.85 | 6.55 |
| Moisture Retention Capacity (% w/w) pF 2 (0-4 cm) | 0.418 | | |

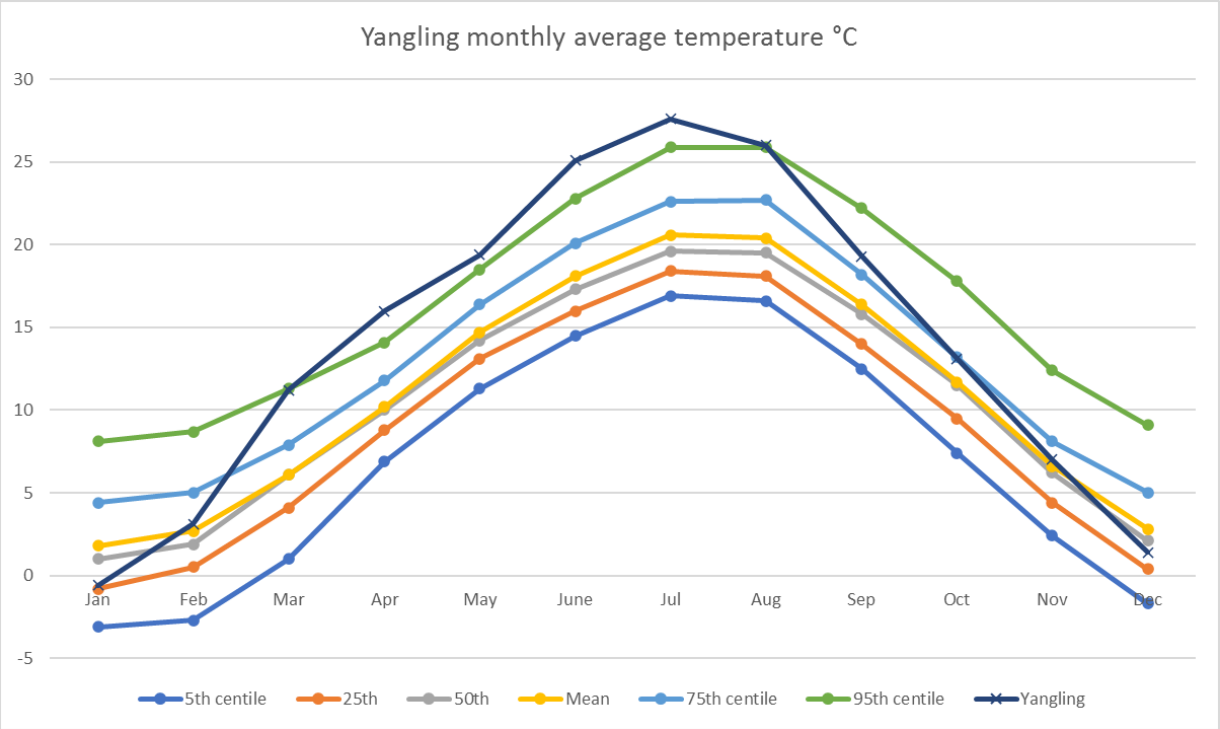
The initial search using Medium texture and OC of 0.6 – 1.2% found numerous matches distributed across the UK and the EU. Including a search term for pH 6.3 – 7.0 reduced the number of matches but there were still numerous matches across Europe, particularly in Italy. It is considered that the soil can be used in risk assessment.

Overall, whilst the soil appears to be representative of European conditions, the weather data are considered to not be representative of European conditions. Therefore the site is not considered to be representative of European conditions.

**Yangling, China**

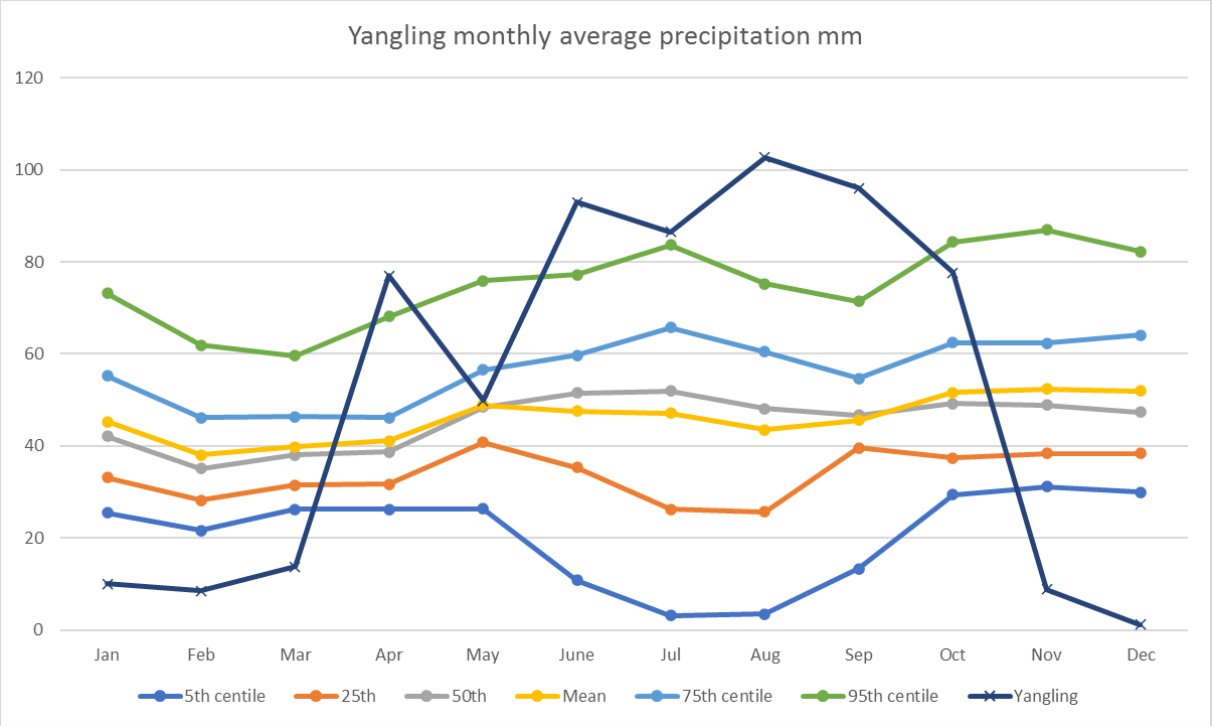
The consideration of the weather conditions for the Yangling site is shown below. It is noted that the field dissipation study at the Yangling site was conducted for approximately 2 years. However the comparison was only performed for January to December and it is assumed that the data for 'duplicate' months in the study were averaged rather than presenting the monthly averages for the whole study period.

**Figure B.8. 38 Comparison of monthly average temperature data for the Yangling field dissipation site with European long-term monthly average temperature data**




The average monthly temperature at the Yangling site was above the European 95$^{th}$ percentile for five months out of twelve. For the remainder of the time it was between the mean and the 95$^{th}$ percentile with the exception of January which was close to the 25$^{th}$ percentile.

**Figure B.8. 39 Comparison of monthly average precipitation data for the Yangling field dissipation site with European long-term monthly average precipitation data**




The monthly precipitation for the Yangling site showed a wide amplitude compared to the European long-term average data. Monthly rainfall at the site was less than the 5$^{th}$ percentile in five out of 12 months and greater than the 95$^{th}$ percentile in five out of 12 months. There were three instances of irrigation, all in July, which would have raised the total precipitation in that month further above the European 95$^{th}$ percentile.

The weather data suggest that the precipitation is not representative of European conditions and the temperatures are erring towards an extreme for much of the year..

The Yangling soil has the following soil characteristics in the top 30cm.

**Table B.8. 137 Soil characteristics at Yangling, China**

| Parameter | Depth range (cm) | | |
|---|---|---|---|
| | **0-10** | **10-20** | **20-30** |
| Sand (%) | 21.1 | 17.1 | 5.1 |
| Silt (%) | 60.0 | 56.0 | 64.0 |
| Clay (%) | 18.9 | 26.9 | 30.9 |
| Texture **MEDIUM/FINE*** | Silty loam | Silty loam | Silty clay loam |
| Organic Carbon (%) | 0.59 | | |
| Cation Exchange Capacity (cmol/kg(+)) | 14.6 | | |
| pH ($H_2O$) | 8.19 | | |
| Water holding capacity (%w/w)<br>pF 2<br>pF 2.5<br>pF 4.0 | <br>43.0<br>39.3<br>33.9 | <br>37.6<br>36.2<br>29.5 | <br>35.6<br>31.5<br>27.2 |
| Bulk Density (g/L) | 1102 | | |

* Within the ENASGIPS tool it is stated that the 'Fine' category is for soils with >35% clay, so the search was conducted on only the 'Medium' texture

The initial search using Medium texture and OC of 0.4 – 0.8% found a reasonable number of matches distributed across the EU, mainly in the Iberian peninsula. Including a search term for pH 7.9 – 8.3 reduced the number of matches but there were still numerous matches, mainly restricted to the Iberian peninsula. It is considered that the soil can be used in risk assessment.

Overall, it is considered that the weather conditions at the Yangling site, particularly the precipitation (but also noting high temperatures in a number of months), are not representative of European conditions.

**Suwon, S Korea**

It was noted that the study at the Suwon site was not conducted according to GLP and therefore the results from this site should not normally be used for regulatory purposes.

The applicant assessment indicated that the Suwon site had monthly temperatures within the range of European temperatures. Precipitation was quite variable and within the European 5 – 95$^{th}$ percentile in eight out of 12 months.

The Suwon soil has the following soil characteristics; the soil depth that these refer to was not stated in the report.

**Table B.8. 138 Soil characteristics at Suwon, S Korean**

| Soil | pH (1:5)* | CEC (meq/100 g) | O.C. (%) | Sand (%) | Silt (%) | Clay (%) | Soil texture |
|---|---|---|---|---|---|---|---|
| Suwon | 4.3 | 8.9 | 6.32 | 57.1 | 36.1 | 6.8 | Sandy loam **COARSE** |

The initial search using Coarse texture and OC of 0.4 – 0.8% found a limited number of matches distributed across the UK and EU. Including a search term for pH 4.0 – 5.0 resulted in no matches. This suggests that the actual soil is likely to be limited or potentially absent in its distribution in Europe. It is considered that the soil cannot be used in risk assessment.

Overall the site cannot be used because the study was not conducted in compliance with GLP and because the soil was of limited relevant to EU conditions.

**Bu Yeo, S Korea**

It was noted that the study at the Bu Yeo site was not conducted according to GLP and therefore the results from this site should not normally be used for regulatory purposes.

The applicant assessment indicated that the Bu Yeo site had monthly temperatures within the range of European temperatures. Precipitation was quite variable and within the European 5 – 95$^{th}$ percentile for six out of 12 months.

The Bu Yeo soil has the following soil characteristics; the soil depth that these refer to was not stated in the report.

**Table B.8. 139 Soil characteristics at Bu Yeo, S Korea**

| Soil | pH (1:5)* | CEC (meq/100 g) | O.C. (%) | Sand (%) | Silt (%) | Clay (%) | Soil texture |
|---|---|---|---|---|---|---|---|
| Bu Yeo | 7.7 | 25.4 | 23.20 | 73.6 | 17.0 | 9.4 | Sandy loam **COARSE** |

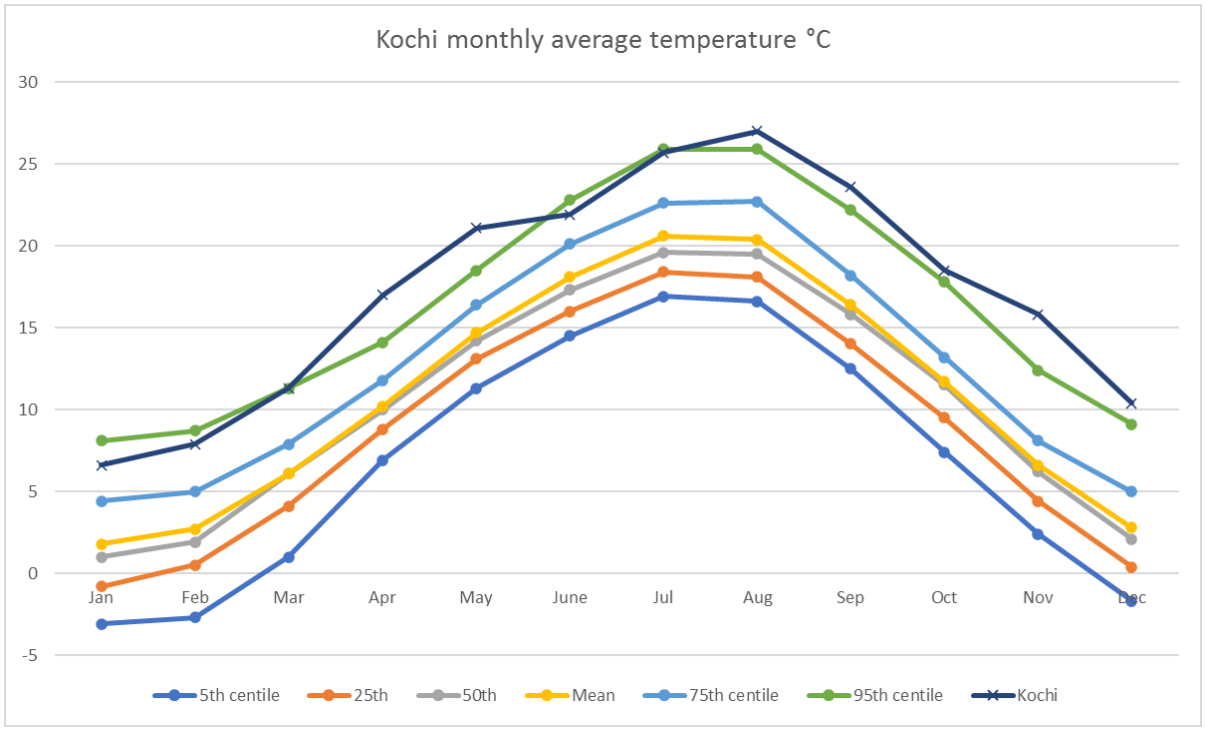
The initial search using Coarse texture and OC of 20 – 26% found no matches across the UK and EU. Restricting the search term to only OC of 20 – 26% resulted in some matches in Scandinavia, the Baltic and Scotland. The search results suggest that the actual soil is likely to be very limited or absent in its distribution in Europe. It is considered that the soil cannot be used in risk assessment.

Overall the site cannot be used because the study was not conducted in compliance with GLP and because the soil was of limited relevant to EU conditions.

**Kochi, Japan**

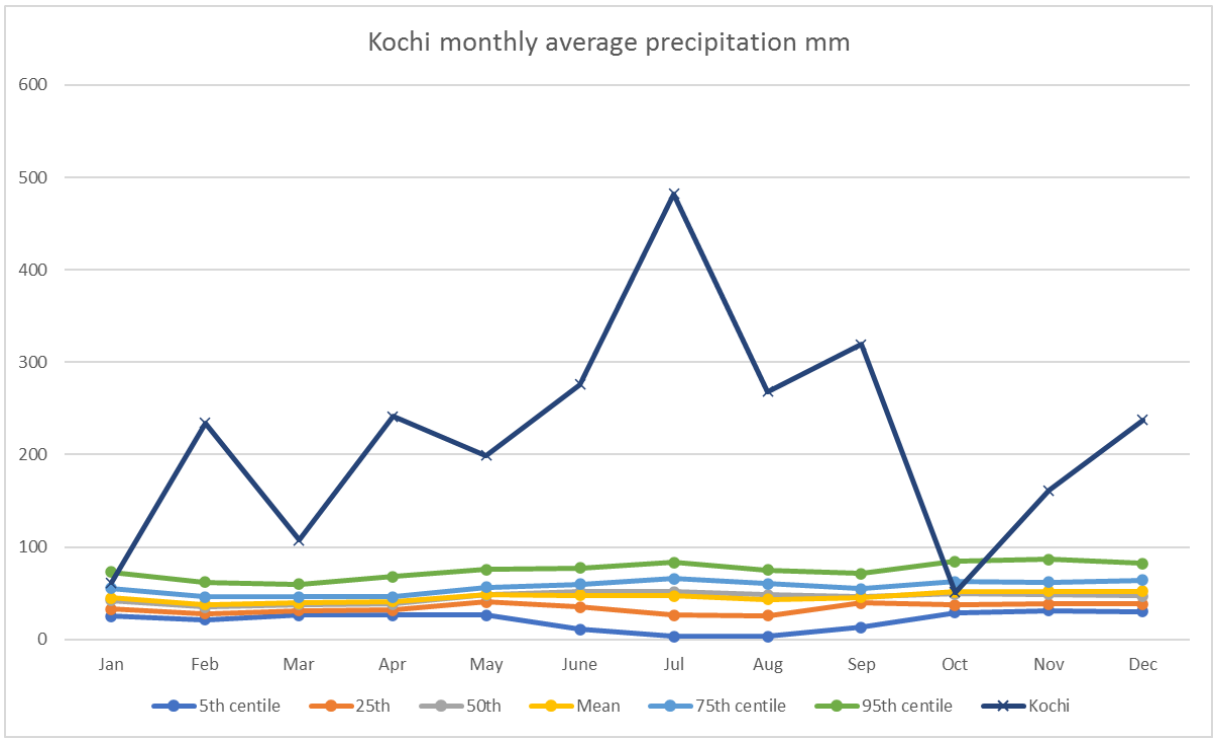
The consideration of the weather conditions for the Kochi site is shown below.

**Figure B.8. 40 Comparison of monthly average temperature data for the Kochi field dissipation site with European long-term monthly average temperature data**




The monthly average temperatures at the Kochi site were greater than the European 95$^{th}$ percentile for seven of the 12 months and the same as the 95$^{th}$ percentile for a further month. This suggests that the temperatures are not representative of European conditions.

**Figure B.8. 41 Comparison of monthly average precipitation data for the Kochi field dissipation site with European long-term monthly average precipitation data**



The monthly precipitation data for the Kochi site are greater than the European 95th percentile data for ten out of 12 months. This suggests that the precipitation at the site is not representative of European conditions.

The Kochi soil has the following soil characteristics; the soil depth that these refer to was not stated in the report.

**Table B.8. 140 Soil characteristics at Kochi, Japan**

| Soil | pH | CEC (meq/100 g) | OC (%) | Sand (%) | Silt (%) | Clay (%) | Maximum Water Holding Capacity (g/kg) | Soil origin | Soil texture (USDA) |
|---|---|---|---|---|---|---|---|---|---|
| Kochi | 6.2 | 15.0 | 16.9 | 40.9 | 40.3 | 18..8 | 525 | Alluvial Soil | Loam **MEDIUM** |

The initial search using Medium texture and OC of 14 - 20% resulted in some matches in Scandinavia, the Baltic states, Germany, Poland, Hungary and Scotland. Including a search term for pH 5.5 – 7.0 further restricted the matches to some in the Baltic states Germany, Poland and Hungary. The search results suggest that the actual soil is likely to be quite limited in its distribution in Europe but is probably present. It is considered that the soil can be used in risk assessment.

Overall, given that the weather data indicate that the site is not representative of European conditions, the results for the Kochi site cannot be used for risk assessment.

**Conclusions on considerations of representativeness of non-European studies to Europe**

The following table concludes on the representativeness of the soil and weather conditions in the studies to European conditions.

**Table B.8. 141 Summary of the representativeness of non-European field dissipation studies to European conditions**

| | GLP study? | Soil representative? | Weather representative? | Overall conclusion |
|---|---|---|---|---|
| California, USA | Yes | No | No | Not used |
| Iowa, USA | Yes | Yes | No | Not used |
| Washington, USA | Yes | No | No | Not used |
| Georgia, USA | Yes | No | No | Not used |
| Alberta, Canada | Yes | Yes | No | Not used |
| Prince Edward Island, Canada | Yes | Yes | No | Not used |
| Nanning, China | No[1] | No | No | Not used |
| Dezhou, China | No[1] | Yes | No | Not used |
| Nanjing, China | No[1] | Yes | No | Not used |
| Yangling, China | No[1] | Yes | No | Not used |
| Suwon, S Korea | No | No | No detailed consideration | Not used[2] |
| Bu Yeo, S Korea | No | No | No detailed consideration | Not used[2] |
| Ibaraki, Japan | Not stated | No | No detailed consideration | Not used |
| Kochi, Japan | Not stated | Yes | No | Not used |

[1] Studies stated to comply with Chinese GLP regulations. However China is not a member of OECD GLP MAD arrangements. Study facilities do not have accreditation from an OED GLP authority for the period of the study.

2 Site not used primarily because the study was stated to be not conducted in compliance with GLP.

Given issues either with GLP compliance of studies or lack of representativeness of the soil and/or weather conditions at the sites, none of the non-European studies are considered by HSE to be suitable for use in risk

assessment. This is in contrast to the applicant's ecoregion crosswalk analysis which concluded that only three of the 14 sites should be excluded.

**Given that the non-European field dissipation studies are not used in the environmental exposure and risk assessment, the applicant summaries of the studies have been presented only for information and not for risk assessment purposes.** The DT50 and DT90 values calculated in the report of [redacted] 2020 have been quoted with no detailed consideration of the kinetic assessment for each site.

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted], [redacted], [redacted], [redacted] and [redacted] (2015). SYN545974 SC (A19649B) - Dissipation of SYN545974 in Soil Applied at a Typical Fungicide Application Timing for Fresh Market Tomatoes in the Central Valley of California, Syngenta Crop Protection, LLC, Greensboro, North Carolina, USA; Syngenta Report No. 796.69. (Syngenta File No. VV-414740) |

**THE STUDY IS NOT CONSIDERED TO BE REPRESENTATIVE OF EUROPEAN CONDITIONS AND IS NOT USED FOR RISK ASSESSMENT PURPOSES. THE STUDY IS PRESENTED FOR INFORMATION ONLY.**

**Guidelines**

US EPA Fate, Transport and Transformation Test Guideline; OPPTS 835.6100 Terrestrial Field Dissipation. EPA 712-C-08-020.

**GLP**: Yes

**Materials and methods**

**Formulation:** SYN545974 SC (200)
**Product code:** A19649B
**Lot/Batch #:** 658672
**Formulation type: S**uspension concentrate
**Purity:** 197 g/L, 18.2% w/w

**Test Sites**

A field dissipation study was carried out at a site near Madera, California, USA. The site is located within the Sacramento and San Joaquin Valleys Major Land Resource Area and the 11.1 Mediterranean California (Level II) Ecological Region. Details of the test site are shown below. The taxonomic class of the Atwater Series is - coarse-loamy, mixed, active, thermic Typic Haploxeralfs (Order – Alfisols, Suborder – Xeralfs).

**Table B.8. 142 California, USA Site history**

| Country / Location | Co-ordinates | Slope | Crops grown / plot history | Pesticides use history (2008-2013) |
|---|---|---|---|---|
| USA / Madera, California | N 36 59.889, W 120 11.571 | 0-1% | 2007-2012: Fallow | 2007-2012: None |

**Table B.8. 143 Soil characteristics at California, USA trial site**

| Plot | Soil Depth (inches) | pH* | CEC (meq/ 100 g) | O.M. (%) | Bulk density (g/cc) | WHC (%) | | Sand (%) | Silt (%) | Clay (%) | USDA Class |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated bare soil | 0-3 | 7.5 | 6.6 | 0.77 | 1.33 | 6.1 | 3.7 | 82 | 12 | 6 | Loamy sand |
| | 3-6 | 7.4 | 6.2 | 0.59 | 1.32 | 5.9 | 3.4 | 82 | 12 | 6 | Loamy sand |
| | 6-12 | 7.5 | 6.0 | 0.36 | 1.31 | 6.1 | 3.6 | 80 | 12 | 8 | Loamy sand |
| | 12-18 | 6.8 | 6.1 | 0.23 | 1.31 | 6.0 | 3.7 | 78 | 13 | 9 | Sandy loam |
| | 18-24 | 7.6 | 7.3 | 0.18 | 1.32 | 6.2 | 4.1 | 80 | 10 | 10 | Loamy sand |
| | 24-30 | 7.3 | 8.6 | 0.23 | 1.31 | 7.3 | 5.0 | 78 | 10 | 12 | Sandy loam |
| | 30-36 | 7.5 | 11.6 | 0.14 | 1.27 | 10.8 | 7.4 | 74 | 10 | 16 | Sandy loam |
| Control bare soil | 0-3 | 7.6 | 6.0 | 0.94 | 1.34 | 5.9 | 3.1 | 88 | 10 | 2 | Sand |
| | 3-6 | 7.2 | 5.4 | 1.03 | 1.31 | 6.4 | 3.2 | 88 | 10 | 2 | Sand |
| | 6-12 | 7.7 | 5.0 | 0.49 | 1.37 | 5.6 | 2.6 | 88 | 10 | 2 | Sand |
| | 12-18 | 8.0 | 4.8 | 0.13 | 1.38 | 5.0 | 2.6 | 87 | 9 | 4 | Loamy sand |
| | 18-24 | 7.9 | 5.6 | 0.13 | 1.37 | 5.3 | 3.2 | 86 | 8 | 6 | Loamy sand |
| | 24-30 | 8.0 | 5.9 | 0.04 | 1.34 | 5.9 | 3.5 | 86 | 8 | 6 | Loamy sand |
| | 30-36 | 8.1 | 5.9 | 0.04 | 1.34 | 7.9 | 3.6 | 82 | 10 | 8 | Loamy sand |

*Medium not reported

**Study Design and Methods**

**Experimental Treatment**

The test site consisted of a treated bare soil plot and a control (untreated) bare soil plot, separated by a buffer of approximately 129 m. The treated bare soil plot measured approximately 12.2 x 19.8 m and was divided into three replicate areas (A, B and C), which were further subdivided into 26 subplots, each measuring 0.8 x 3.0 m. The control plot measured 3.0 x 11.4 m and was further divided into 15 subplots, each measuring 0.8 x 3.0 m.

Two applications of SYN545974 SC (200) were applied to bare soil at a rate of 220 g a.s./ha using a calibrated tractor mounted boom sprayer. Applications were made on 25 September and 9 October 2012, and were timed to approximate typical fungicide use on fresh market tomatoes at the test site location. Irrigation was applied to the plots to achieve a monthly target moisture input of either 160% of the estimated monthly crop water requirement (for tomatoes or a typical rotational crop such as cotton and wheat) or 110% of the average monthly precipitation based on the 30-year monthly average precipitation (1971-2000) obtained from NOAA Station No. 045233 (Madera, CA, approximately 13 miles from the test site), whichever was greater. Bare soil was maintained on the test plots by the application of glyphosate.

Daily weather data (air temperature, solar radiation, humidity, average wind speed, evapotranspiration, soil moisture and soil temperature) were obtained from an on-site weather station and from soil moisture/temperature probes placed within the treated bare soil plot at 5, 15, 30.5 and 61 cm depths. Precipitation data were obtained either on-site or from California Irrigation Management Information System (CIMIS) Station 145 (approx. 4 miles from the test site) or CIMIS Station 188 (approx. 6 miles from the test site).

**Sampling**

Actual application rates were verified using three metal pans (area 754.84 $cm^2$), each containing a pre-weighed soil sample, placed in each replicate of the treated bare soil plot. Application verification samples were collected immediately after application.

The treated plot was sampled prior to the first application (PA, -4 days), 0 DA1A (immediately after the first application), 3, 7 and 13 days after the first application (DA1A), 0 DA2A (immediately after the second application) and at fourteen different sampling intervals between 1 and 721 days after the second application (DA2A). Control plots were sampled prior to application (PA, -4 days), 7 days after the first application (DA1A), and at nine sampling intervals between 7 and 721 days after the second application (DA2A).

Soil cores were collected to a depth of 0 - 7.6 cm (11.4 cm internal diameter) and 7.6 - 91.4 cm (3.81 cm internal diameter). At each sampling interval, 5 cores were taken from one randomly selected subplot in each replicate of the treated plots (A, B and C), and 5 cores were taken from one randomly selected subplot in the control plots. The 7.6 - 91.4 cm cores were cut into 7.6- or 15.2 cm segments down to 91.4 cm. Soils from corresponding depths were combined, resulting in 3 replicate composite samples (A, B and C) for each depth for the treated plots, and one composite sample for each depth for the control plots.

Soil samples were stored in insulated containers with ice packs whilst in the field and during transport to the laboratory for analysis. Following arrival at the laboratory, the samples were stored frozen until analysis. Soil samples were extracted within 533 days of collection.

**Description of analytical procedure**
Soil extraction and analysis was conducted by two analytical facilities: MPI Research Inc. and North Coast Laboratories Ltd (NCL). MPI received all samples up to 270 DA2A, 360 DA2A (0-3, 3-6, 6-12, 12-18 and 18-24 inches), and 480 and 600 DA2A (0-3, 3-6, 6-12, 12-18 inches). NCL received samples from 360 DA2A (18-24 and 24-30 inch), 480 DA2A (18-24, 24-30 and 30-36 inch), 600 DA2A (18-24 and 24-30 inches), 720 DA2A (all depths), and the application monitoring soil pans.

At both facilities, residues of pydiflumetofen in soil were analysed using Syngenta Method GRM061.04A.

Soil sub-samples (10 g) were extracted with acetonitrile/0.1M ammonia acetate aqueous solution (80:20 v/v, 1 x 40 mL), then acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). Extracts were combined, filtered and an aliquot (10 mL) evaporated to remove acetonitrile. One mL of 0.1% acetic acid was added and the sample loaded onto a preconditioned Bond Elute-C18 SPE cartridge (100 mg, 3 mL). The cartridge was rinsed with methanol/0.1% acetic acid (60:40 v/v, 1 x 2.5 mL), then eluted with methanol/0.1% acetic acid (60:40 v/v, 1 x 2 mL) and methanol (1 x 3 mL). Eluates were combined, and evaporated to remove methanol. The sample was mixed with 1.5 mL methanol and diluted to 5 mL with 0.1% acetic acid for analysis by LC-MS/MS. The limit of quantification (LOQ) for pydiflumetofen in soil was 0.5 ppb (µg/kg). The study authors assumed that the LOD in the study was 0.5 x LOQ, i.e. 0.25 (µg/kg).

**Results and Discussion**

**Analytical Method Performance**
Mean procedural recoveries and relative standard deviation (RSD) for the recovery of pydiflumetofen from soil samples at the LOQ of 0.5 µg/kg were 86 ± 11% (n = 21) and 93 ± 4.2% (n = 14), for samples analysed at MPI and NCL, respectively. Recovery up to 500 µg/kg or 5000 µg/kg was tested and was acceptable.

**Application Rate Verification**
The application verification samples showed 93 ± 6.7% and 89 ± 18% of target rate was achieved in the treated plot for the first (0 DA1A) and second (0 DA2A) applications, respectively. Analysis of the application day soil cores (0 DA1A and 0 DA2A) from the treated bare soil plot, showed application rates of 200 g a.s./ha and 195 g a.s./ha (minus 13 DA1A residues) were achieved, respectively, equivalent to 91% and 89% of the target rate (220 g a.s./ha).

**Residue Analysis**
Residues of pydiflumetofen in treated plots (mean of 3 replicates unless otherwise stated) are summarised in the table below. Residues lower than the LOQ were presented as '<0.5'. No residues of pydiflumetofen were detected in control samples at or above the limit of detection (LOD, defined as ½ LOQ), with the exception of 360 DA2A and 480 DA2A, 0-3"/ 0-7.6 cm samples in which apparent residues of 0.21 and 0.37 µg/kg (mean of duplicate analysis) were observed, respectively.

Results of mean and replicate dry weight concentrations are shown below. It was noted that the study report contained some mistakes in that in some places the code for pydiflumetofen, SYN545974, was incorrectly given as SYN545192.

**Table B.8. 144 Residues of pydiflumetofen in California, USA soil with depth – Treated bare soil plot (mean values)**

| Scheduled Sampling Event (Actual Sampling Date) | Actual DAPA[2] | Actual DA1A[2] | Pydiflumetofen Mean Residues (µg/kg dry weight) Found[1] | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | 0-7.6 cm | 7.6-15.2 cm | 15.2-30.5 cm | 30.5-45.7 cm | 45.7-61 cm | 61-76.2 cm | 76.2-91.4 cm |
| PA[3] (9/20/12) | -4 | -4 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | -- | -- |
| 0 DA1A[3] (9/25/12) | 0 | 0 | 180 | <0.5 | <0.5 | -- | -- | -- | -- |
| 3 DA1A (9/28/12) | 3 | 3 | 156 | <0.5 | <0.5 | -- | -- | -- | -- |
| 7 DA1A (10/02/12) | 7 | 7 | 143 | 0.51[a] | <0.5 | <0.5 | <0.5 | -- | -- |
| 13 DA1A (10/08/12) | 13 | 13 | 136 | <0.5 | 0.61[a] | <0.5 | <0.5 | -- | -- |
| 0 DA2A[3] (10/09/12) | 0 | 14 | 305 | <0.5 | <0.5 | -- | -- | -- | -- |
| 1 DA2A (10/10/12) | 1 | 15 | 271 | <0.5 | <0.5 | -- | -- | -- | -- |
| 3 DA2A (10/12/12) | 3 | 17 | 282 | <0.5 | <0.5 | -- | -- | -- | -- |
| 7 DA2A (10/16/12) | 7 | 21 | 244 | <0.5 | <0.5 | -- | -- | -- | -- |
| 14 DA2A (10/23/12) | 14 | 28 | 296 | <0.5 | <0.5 | -- | -- | -- | -- |
| 30 DA2A (11/08/12) | 30 | 44 | 272 | <0.5 | <0.5 | -- | -- | -- | -- |
| 60 DA2A (12/07/12) | 59 | 73 | 260 | 1.1[b] | 0.52[a] | <0.5 | <0.5 | -- | -- |
| 90 DA2A (1/07/13) | 90 | 104 | 196 | <0.5 | <0.5 | <0.5 | <0.5 | -- | -- |
| 120 DA2A (2/06/13) | 120 | 134 | 199 | 1.1[a] | 0.57[a] | <0.5 | <0.5 | -- | -- |
| 180 DA2A (4/09/13) | 182 | 196 | 218 | 14 | 1.6[b] | <0.5 | <0.5 | -- | -- |
| 270 DA2A (7/11/13) | 275 | 289 | 196 | 42 | 1.1[b] | <0.5 | <0.5 | -- | -- |
| 360 DA2A (10/02/13) | 358 | 372 | 99 | 53 | 3.6 | 1.0[b] | 0.50[a] | <0.5 | -- |
| 480 DA2A (1/29/14) | 477 | 491 | 81 | 26 | 2.1[b] | 0.53[a] | 0.84[b] | 0.97[a] | <0.5 |
| 600 DA2A (5/30/14) | 598 | 612 | 95 | 57 | 4.6 | 0.86[b] | <0.5 | <0.5 | -- |
| 720 DA2A (9/30/14) | 721 | 735 | 48 | 41 | 9.8 | 4.7 | 1.3[a] | <0.5 | -- |

[1] Residues are presented on a dry weight basis. Mean of residues from replicate treated plots - A, B and C; however, in some instances means are based on more than three data points, i.e., repeat analysis of individual replicate samples.

[2] DAPA = days after previous application; DA1A = days after first application.

[3] PA = Pre-application, 0 DA1A and 0 DA2A were application days; *NS = not sampled, -- = not analysed.

[a] Only one of the replicates had residues detected > LOQ.

[b] Only two of the replicates had residues detected > LOQ.

**Conclusions**

The use of two applications in field dissipation studies can lead to issues in interpretation of fate and behaviour. However in this case as the a.s. is relatively persistent, no metabolites are analysed for and movement out of the top layers of soil appear to take some time, the consequences of two applications in the study do not create particular issues.

Taking the soil depths where there were detections above the LOD, pydiflumetofen dissipated by approximately 60% over approximately 24 months following the second application; the substance did not reach 90%

dissipation by the end of the study. The highest residue was not recorded until 14 days after the second application. There was a period between 90 and 275 days after the second application where there appeared to be little dissipation of the residues. pydiflumetofen residues remained predominately in the top 15.2 cm of soil for the study duration. Consistent detections at relatively low concentrations were found in the 15.2-30.5 cm soil depth from around 6 months after the second application. Low-level residues were also found from approximately 12 and 15 months after the second application in the 30.5-45.7 cm and 48.7-61.0 cm soil horizons. Only one quantifiable (i.e., ≥ LOQ) residue of pydiflumetofen was found below 61.0 cm soil depth, this being at 477 DA2A, Rep A, 61.0-76.2 cm depth, 0.97 µg/kg. Residues in the layer below this were <LOQ.

The calculated DT50 was 674 days and DT90 2340 days (SFO).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted], [redacted], [redacted] (2015). SYN545974 (A19649B) - Dissipation of SYN545974 (SC 200) in Soil Applied at a Typical Fungicide Application Timing for Soybeans in the Midwestern United States. Syngenta Crop Protection, LLC, Greensboro, North Carolina, USA; Syngenta Report No. TK0103779. (Syngenta File No. VV-414469) |

**THE STUDY IS NOT CONSIDERED TO BE REPRESENTATIVE OF EUROPEAN CONDITIONS AND IS NOT USED FOR RISK ASSESSMENT PURPOSES. THE STUDY IS PRESENTED FOR INFORMATION ONLY.**

**Guidelines**

US EPA Fate, Transport and Transformation Test Guideline; OPPTS 835.6100 Terrestrial Field Dissipation. EPA 712-C-08-020.

**GLP**: Yes

**Materials and methods**

**Formulation:** SYN545974 SC (200)
**Product code:** A19649B
**Lot/Batch #:** 681692
**Formulation type:** Suspension concentrate
**Purity:** 18.6% a.s. w/w (204 g a.s./L)

**Test Sites**

A field dissipation study was carried out at a site located in Jefferson County, Iowa, USA. The study design and conduct were very similar to that described above for the site at Madera, California, USA. Details of the test site are shown below. The series and soil type at the test site was identified as a Taintor silty clay loam (fine, smectitic, mesic Vertic Argiaquolls) (Order – Mollisols, Suborder – Aquolls) (USDA).

**Table B.8. 145 Iowa, USA site history**

| Country / Location | Co-ordinates | Slope | Crops grown / Plot history | Pesticides use history |
|---|---|---|---|---|
| USA / Jefferson County, Iowa | 41.14799 -92.00887 | 1% | 2008: Soybean<br>2009: Corn<br>2010: Soybean<br>2012: Soybean<br>2013*: Fallow | 2008: glyphosate<br>2009: s-metolachlor, atrazine, glyphosate<br>2010: glyphosate<br>2011: glyphosate<br>2012: pendimethalin, flumioxazin, chlorimuron ethyl, clethodim, glyphosate<br>2013*: glyphosate, s-metolachlor, flumioxazin, metribuzin |

*Prior to test substance application

None of the pesticides used appear to be in the same chemical group as pydiflumetofen.

**Table B.8. 146 Soil characteristics at Iowa, USA trial site**

| Plot | Soil Depth (inches) | pH* | CEC (meq/ 100 g) | O.M. (%) | Bulk density (g/cc) | WHC | | Sand (%) | Silt (%) | Clay (%) | USDA Class |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated bare soil | 0-3 | 6.8 | 19.2 | 3.0 | 1.08 | 28.3 | 15.0 | 16 | 53 | 31 | Silty Clay Loam |
| | 3-6 | 6.7 | 19.7 | 3.0 | 1.11 | 29.0 | 14.2 | 20 | 49 | 31 | Clay Loam |
| | 6-12 | 6.3 | 19.7 | 2.6 | 1.12 | 31.0 | 16.7 | 12 | 53 | 35 | Silty Clay Loam |
| | 12-18 | 5.8 | 21.4 | 1.3 | 1.07 | 33.7 | 22.9 | 30 | 37 | 33 | Clay Loam |
| | 18-24 | 6.1 | 26.9 | 0.35 | 1.12 | 38.5 | 24.5 | 30 | 35 | 35 | Clay Loam |
| | 24-30 | 5.7 | 29.2 | 0.72 | 1.13 | 39.5 | 26.2 | 34 | 29 | 37 | Clay Loam |
| | 30-36 | 5.9 | 29.2 | 0.43 | 1.14 | 38.7 | 26.1 | 44 | 25 | 31 | Clay Loam |
| Control | 0-3 | 6.5 | 16.8 | 3.1 | 1.06 | 26.7 | 13.2 | 16 | 57 | 27 | Silt Loam |
| | 3-6 | 6.1 | 18.2 | 3.0 | 1.13 | 28.1 | 14.3 | 14 | 55 | 31 | Silty Clay Loam |
| | 6-12 | 5.5 | 18.0 | 2.5 | 1.11 | 30.0 | 19.0 | 16 | 49 | 35 | Silty Clay Loam |
| | 12-18 | 5.6 | 20.4 | 1.7 | 1.12 | 31.7 | 20.4 | 14 | 51 | 35 | Silty Clay Loam |
| | 18-24 | 5.7 | 25.2 | 0.97 | 1.14 | 36.3 | 22.1 | 32 | 33 | 35 | Clay Loam |
| | 24-30 | 6.0 | 26.5 | 0.31 | 1.13 | 37.8 | 22.6 | 22 | 41 | 37 | Clay Loam |
| | 30-36 | 5.8 | 26.2 | 0.56 | 1.12 | 38.3 | 24.8 | 34 | 31 | 35 | Clay Loam |

*Medium not reported

**Study Design and Methods**

**Experimental Treatment**

The test site consisted of a treated bare soil plot and a control (untreated) bare soil plot, separated by a buffer zone of approximately 30.5 m. The treated bare soil plot measured approximately 22.9 x 38.1 m, divided into three replicate areas (A, B and C), each of which were further subdivided into 25 subplots measuring 1.5 x 4.6m. The control plot measured 4.6 x 18.3 m, divided into 12 subplots measuring 1.5 x 4.6m.

SYN545974 SC (200) was applied to the treated plots on 23 and 29 July 2013, at a rate of 220 g a.s./ha, using a calibrated, tractor-mounted boom sprayer. The first application was timed to approximate the start of typical fungicide use for soybean at the test site. Bare soil plots were maintained by the application of glyphosate. Irrigation was applied to the site to achieve a monthly target moisture input of 120% of the average monthly precipitation, assessed based on a 30 year (1971-2000) data set for Fairfield, Iowa (NOAA Station No. 132789), located approximately 12 miles from the test site.

Daily air and soil temperature, precipitation, relative humidity, wind speed, solar radiation and evapotranspiration measurements were obtained from an on-site weather station throughout the trial period.

**Sampling**

Actual application rates were verified using fifteen 15 cm diameter filter papers, placed in glass petri-dishes on the soil surface, and three metal pans (23.50 x 33.66 cm), each containing a pre-weighed soil sample, placed in each replicate of the treated bare soil plot. Application verification samples were collected immediately after application.

Treated plots were sampled prior to the first application (PA, -1 day), 0 DA1A (immediately after the first application), 3 and 6 days after the first application (DA1A), 0 DA2A (immediately after the second application)

and at eleven different sampling intervals between 3 and 595 days after the second application (DA2A). Control plots were sampled prior to the first application (PA, -1 day), 6 days after the first application (DA1A), and at seven sampling intervals between 7 and 595 days after the second application (DA2A).

Soil cores were collected to a depth of 0-7.6 cm (15.24 cm internal diameter) and 7.6-91.4 cm (4.24 cm internal diameter). At each sampling interval, 5 cores were taken from one randomly selected subplot in each replicate of the treated plots (A, B and C), and 5 cores were taken from one randomly selected subplot in the control plots. The 7.6-91.4 cm cores were cut into 7.6- or 15.2 cm segments down to 91.4 cm. Soils from corresponding depths were combined, resulting in 3 replicate composite samples (A, B and C) for each depth for the treated plots, and one composite sample for each depth for the control plots.

Samples were stored frozen until analysis. Soil samples were extracted within 577 days of collection.

**Description of analytical procedure**
Residues of pydiflumetofen in soil were analysed using Syngenta Method GRM061.04A.

Soil sub-samples (10 g) were extracted with acetonitrile/0.1M ammonia acetate aqueous solution (80:20 v/v, 1 x 40 mL), then acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). Extracts were combined and centrifuged to remove solids. An aliquot (50 µg/L) was diluted to 1 mL with methanol/0.1% acetic acid (30:70 v/v) for analysis by LC-MS/MS. The limit of quantification (LOQ) for pydiflumetofen in soil was 0.5 ppb (µg/kg). The limit of detection (LOD) was defined as ½ LOQ, i.e. 0.25 µg/kg.

Application monitoring filter papers were extracted with acetonitrile (1 x 200 mL) at ambient temperature, then sonicated for 5 minutes. An aliquot (20 µg/L) was diluted to 2 mL with methanol/water (50:50 v/v). An aliquot (20 µg/L) of the resulting solution was diluted to 2 mL with methanol/0.1% acetic acid (30:70 v/v) for analysis by LC-MS/MS. The LOQ for pydiflumetofen on filter papers was 0.01 mg/filter.

**Results and Discussion**

**Analytical Method Performance**
Mean procedural recoveries and relative standard deviation (RSD) for soil samples fortified at the LOQ were 100 ± 13.4% (n = 47). Recoveries at fortification at various concentrations up to 1000 µg/kg were acceptable.

**Application Rate Verification**

The application verification filter paper samples showed 91 ± 12.4% (n = 15) and 104 ± 12.2% (n = 15) of target rate was achieved for the first (0 DA1A) and second (0 DA2A) applications, respectively. The percent of theoretical application rate found in the soil pan samples were 75 ± 8.53% and 87 ± 9.71% for the first (0 DA1A) and second (0 DA2A) applications, respectively. Analysis of application day soil cores (0 DA1A and 0 DA2A) from the treated bare soil plot, showed application rates of 249 g/ha and 230 g/ha (minus 6 DA1A residues) were achieved, respectively, equivalent to 113 and 105% of the target rate (220 g a.s./ha).

**Residue Analysis**
Residues of pydiflumetofen in the treated bare soil plot (mean of 3 replicates unless otherwise stated) are summarised in the table below. Residues lower than the LOQ were presented as '<0.5'. No residues of pydiflumetofen were detected in any controls at or above the limit of detection (LOD, defined as ½ LOQ).

Results of mean and replicate dry weight concentrations are shown below.

**Table B.8. 147 Residues of pydiflumetofen in Iowa, USA soil with depth – Treated bare soil plot (mean values)**

| Scheduled Sampling Event (Actual Sampling Date) | Actual DAPA[2] | Actual DA1A[2] | Pydiflumetofen Mean Residues (µg/kg dry weight) Found[1] | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | 0-7.6 cm | 7.6-15.2 cm | 15.2-30.5 cm | 30.5-45.7 cm | 45.7-61 cm | 61-76.2 cm | 76.2-91.4 cm |
| PA[3] (7/22/13) | -1 | -1 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | -- | -- |
| 0 DA1A[3] (7/23/13) | 0 | 0 | 334 | NS | NS | NS | NS | NS | NS |
| 3 DA1A (7/26/13) | 3 | 3 | 338 | 0.56[a] | <0.5 | <0.5 | -- | -- | -- |
| 6 DA1A (7/29/13) | 6 | 6 | 274 | 3.5 | <0.5 | <0.5 | -- | -- | -- |
| 0 DA2A[3] (7/29/13) | 0 | 6 | 557 | 11 | <0.5 | <0.5 | -- | -- | -- |
| 3 DA2A (8/1/13) | 3 | 9 | 593 | 0.51[a] | <0.5 | <0.5 | -- | -- | -- |
| 7 DA2A (8/5/13) | 7 | 13 | 549 | 7.2 | <0.5 | <0.5 | -- | -- | -- |
| 14 DA2A (8/12/13) | 14 | 20 | 451 | 3.1 | <0.5 | <0.5 | -- | -- | -- |
| 28 DA2A (8/26/13) | 28 | 34 | 388 | 4.9 | <0.5 | <0.5 | -- | -- | -- |
| 60 DA2A (9/26/13) | 59 | 65 | 258 | 5.0 | <0.5 | <0.5 | -- | -- | -- |
| 90 DA2A (10/28/13) | 91 | 97 | 240 | 3.9 | <0.5 | <0.5 | -- | -- | -- |
| 120 DA2A (11/25/13) | 119 | 125 | 283 | 8.8 | <0.5 | <0.5 | -- | -- | -- |
| 270 DA2A (4/22/14) | 267 | 273 | 131 | 1.1[a] | <0.5 | <0.5 | -- | -- | -- |
| 360 DA2A (7/23/14) | 359 | 365 | 18 | <0.5 | <0.5 | <0.5 | -- | -- | -- |
| 450 DA2A (10/22/14) | 450 | 456 | 65 | 2.3[a] | <0.5 | -- | -- | -- | -- |
| 540 DA2A (3/16/15) | 595 | 601 | 29 | 0.80[a] | <0.5 | <0.5 | -- | -- | -- |

[1] Residues are presented on a dry weight basis. Mean of residues from replicate treated plots - A, B and C; however, in some instances means are based on more than three data points, i.e., repeat analysis of individual replicate samples.
[2] DAPA = days after previous application; DA1A = days after first application.
[3] PA = Pre-application, 0 DA1A and 0 DA2A were application days; *NS = not sampled, - - = not analysed.
[a] Only one of the replicates had residues detected > LOQ.

**Conclusions**

Taking the soil depths where there were detections above the LOD, pydiflumetofen dissipated by approximately 95% over 595 days from the highest residue following the second application. There was a period between 59 and 119 days after the second application where there was little if any dissipation of the residue. pydiflumetofen remained in the top 15.2 cm for the study duration. No quantifiable (*i.e.* ≥ LOQ) residues of pydiflumetofen were found below this depth.

The calculated DT50 was 14.3 days and DT90 406 days (DFOP).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted], [redacted], [redacted] (2015). pydiflumetofen SC (A19649B): Dissipation of pydiflumetofen in Soil Under Winter Wheat Crop Conditions in the Northwestern United States, Syngenta Crop Protection, LLC, Greensboro, North Carolina, USA; Syngenta Report No. TK0121180. (Syngenta File No. VV-414580) |

**THE STUDY IS NOT CONSIDERED TO BE REPRESENTATIVE OF EUROPEAN CONDITIONS AND IS NOT USED FOR RISK ASSESSMENT PURPOSES. THE STUDY IS PRESENTED FOR INFORMATION ONLY.**

**Guidelines**

US EPA Fate, Transport and Transformation Test Guideline; OPPTS 835.6100 Terrestrial Field Dissipation. EPA 712-C-08-020.

**GLP**: Yes

**Materials and methods**

**Formulation:** SYN545974 SC (200)
**Product code:** A19649B
**Lot/Batch #:** 681692
**Formulation type:** Suspension concentrate
**Purity:** 204 g ai/L, 18.6% w/w (measured)

**Test Sites**
A field dissipation study was carried out at a site located near Ephrata, Grant County, Washington, USA. The study design and conduct were very similar to that described above for the site at Madera, California, USA. Details of the test site are shown in the table below. The soil type at the test site was classified as a Quincy loamy fine sand – a very deep, excessively drained soil formed in sands on dunes and terraces. The USDA taxonomic class of the Quincy Series is – Mixed, mesic Zeric Torripsamments (Order – Entisols, Suborder – Psamments).

It should be noted that the site also included a treated plot of the same study design that was cropped with winter wheat. Field dissipation studies for use in European regulatory assessments are typically expected to be bare soil experiments as the presence of crops/plants in the treated areas can make interpretation of results difficult. Hence the results from the cropped plots are not considered here in detail.

**Table B.8. 148 Washington, USA site history**

| Country / Location | Co-ordinates | Slope | Crops grown / Plot history | Pesticides use history (2008-2013) |
|---|---|---|---|---|
| USA / Ephrata, Grant County, Washington | 47.1333464 N 119.554425 W | 0-1% | 2008: Fallow/bare soil<br>2009: Fallow/bare soil<br>2010: Spring wheat/fallow<br>2011: Fallow/spring wheat<br>2012: Fallow<br>2013: Winter wheat | Glyphosate<br>Aminocyclopyrachlor<br>Fenazaquin<br>Paraquat<br>2,4-D<br>Diquat<br>Thifensulfuron-methyl + tribenuron-methyl |

None of the pesticides used appear to be in the same chemical group as pydiflumetofen.

**Table B.8. 149 Soil characteristics at Washington, USA trial site**

| Plot | Soil Depth (inches) | pH* | CEC (meq/ 100 g) | O.M. (%) | Bulk density (g/cc) | WHC | | Sand (%) | Silt (%) | Clay (%) | USDA Class |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated | 0-3 | 7.9 | 8.4 | 0.47 | 1.38 | 8.1 | 3.8 | 90 | 10 | 0 | Sand |
| | 3-6 | 8.1 | 8.5 | 0.47 | 1.39 | 7.2 | 3.8 | 90 | 10 | 0 | Sand |
| | 6-12 | 8.3 | 8.7 | 0.23 | 1.40 | 6.8 | 4.0 | 90 | 10 | 0 | Sand |
| | 12-18 | 8.4 | 9.0 | 0.15 | 1.43 | 7.3 | 3.9 | 90 | 10 | 0 | Sand |
| | 18-24 | 8.3 | 9.5 | 0.19 | 1.44 | 8.1 | 4.0 | 86 | 14 | 0 | Sand |
| | 24-30 | 8.5 | 8.8 | 0.19 | 1.26 | 11.0 | 3.9 | 78 | 20 | 2 | Loamy Sand |
| | 30-36 | 8.6 | 11.0 | 0.10 | 1.33 | 14.3 | 4.0 | 68 | 30 | 2 | Sandy Loam |
| Control | 0-3 | 7.9 | 8.3 | 0.80 | 1.32 | 16.9 | 3.4 | 90 | 10 | 0 | Sand |
| | 3-6 | 8.2 | 8.2 | 0.39 | 1.36 | 17.4 | 3.5 | 90 | 10 | 0 | Sand |
| | 6-12 | 8.1 | 8.0 | 0.19 | 1.42 | 15.1 | 3.3 | 90 | 10 | 0 | Sand |
| | 12-18 | 8.2 | 8.4 | 0.31 | 1.45 | 15.5 | 3.4 | 90 | 10 | 0 | Sand |
| | 18-24 | 8.2 | 8.4 | 0.23 | 1.38 | 16.5 | 3.6 | 90 | 10 | 0 | Sand |
| | 24-30 | 8.2 | 8.8 | 0.15 | 1.43 | 18.3 | 3.5 | 87 | 13 | 0 | Sand |
| | 30-36 | 8.3 | 8.7 | 0.10 | 1.43 | 19.0 | 3.2 | 86 | 14 | 0 | Sand |

*Medium not reported

**Study Design and Methods**

**Experimental Treatment**

The test site consisted of two test plots: a treated bare soil plot and a control bare soil plot. Control and treated plots were separated by an 24.4 m buffer zone. The treated plot measured 16.8 x 27.4 m, and was further sub-divided into 3 replicate areas (A, B and C), each consisting of 24 sub-plots measuring 1.5 x 3.0 m. The control plot measured 16.8 x 4.6 m, and was sub-divided into 12 sub-plots measuring 1.5 x 3.0 m.

SYN545974 SC (200) formulation was applied to the treated plot on 14 May and 21 May 2013, at a rate of 220 g a.s./ha, using a calibrated, tractor-mounted boom sprayer. Both applications included a non-ionic surfactant at a rate of 0.125% v/v. The first application was timed to occur at BBCH 37-41 of a winter wheat crop.

Irrigation was applied to the test plots to achieve a monthly target moisture input of 120% of either the estimated monthly crop water requirement (for either wheat or a simulated typical rotational crop i.e. potatoes) or the average monthly precipitation, whichever was greater. Normal monthly precipitation was assessed based on a 30 year (1971-2000) average monthly precipitation data set for Ephrata, Washington (NOAA Station No. 452614), located approximately 11.5 miles north of the test site. Bare soil plots were kept free of weeds by the application of herbicides (paraquat and glyphosate).

Daily measurements of air temperature, soil temperature and moisture, precipitation, solar radiation, humidity, wind speed and evapotranspiration were recorded on-site.

**Sampling**

Actual application rates were verified using three metal pans each containing approximately 800 g soil, placed in each replicate of the treated bare soil plot. Application verification samples were collected immediately after application.

The treated plot was sampled prior to the first application (PA, -4 day), 0 DA1A (immediately after the first application), 3 and 6 days after the first application (DA1A), 0 DA2A (immediately after the second application) and at thirteen different sampling intervals between 3 and 720 days after the second application (DA2A). The control plot was sampled prior to the first application (PA, -4 day), 6 days after the first application (DA1A), and at ten sampling intervals between 7 and 720 days after the second application (DA2A).

Soil cores were collected to a depth of 0-7.6 cm (8.9 cm internal diameter) and 7.6-91.4 cm (4.4 cm internal diameter), except for the treated plot on 0 DA1A when only 0-7.6 cm cores were collected. At each sampling interval, 5 cores were taken from one randomly selected subplot in each replicate of the treated plot (A, B and C), and 5 cores were taken from one randomly selected subplot in the control plot. The 7.6-91.4 cm cores were cut into 7.6- or 15.2 cm segments down to 91.4 cm. Soils from corresponding depths were combined, resulting in 3 replicate composite samples (A, B and C) for each depth for the treated plot, and one composite sample for each depth for the control plot.

Samples were stored frozen until analysis. Soil samples were extracted within 457 days of collection.

**Description of analytical procedure**

Soil samples were analysed for the parent substance, pydiflumetofen, only, using Syngenta Method GRM061.04A.

Soil sub-samples (10 g) were extracted with acetonitrile/0.1M ammonia acetate aqueous solution (80:20 v/v, 1 x 40 mL), then acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). Extracts were combined, filtered and an aliquot (10 mL) evaporated to remove acetonitrile. One mL of 0.1% acetic acid was added and the sample loaded onto a preconditioned Bond Elute-C18 SPE cartridge (100 mg, 3 mL). The cartridge was rinsed with methanol/0.1% acetic acid (60:40 v/v, 1 x 2.5 mL), then eluted with methanol/0.1% acetic acid (60:40 v/v, 1 x 2 mL) and methanol (1 x 3 mL). Rinsate and eluate were combined, and evaporated to remove methanol. The sample was mixed with 1.5 mL methanol and diluted to 5 mL with 0.1% acetic acid for analysis by LC-MS/MS. The limit of quantitation (LOQ) for pydiflumetofen in soil was 0.5 µg/kg. The limit of detection (LOD) was considered to be ½ LOQ, i.e. 0.25 µg/kg.

**Results and Discussion**

**Analytical Method Performance**

Mean procedural recoveries and relative standard deviation (RSD) for soil samples from bare soil were 90 ± 17.2% (n = 16). Acceptable recoveries were achieved for fortification levels up to 50 µg/kg.

**Application Rate Verification**

The application verification samples showed 108 ± 8.36% and 93 ± 8.92% of target rate was achieved in the bare soil plot for the first (0 DA1A) and second (0 DA2A) applications, respectively.

Analysis of application day soil cores (0 DA1A and 0 DA2A) from the treated bare soil plot, showed application rates of 234.81 g/ha and 197.97 g/ha (minus 6 DA1A residues) were achieved, respectively, equivalent to 107 and 90% of the target rate (220 g a.s./ha).

**Residue Analysis**

Residues of pydiflumetofen in the treated bare soil plot (mean of 3 replicates unless otherwise stated) are summarised in the table below. Due to time constraints, the 720 DA2A soil samples were not analysed. No residues of pydiflumetofen were detected in any controls at or above the limit of detection (LOD, defined as ½ LOQ).

Results of mean and replicate dry weight concentrations are shown below. It was noted that the study report contained some mistakes in that in some places the code for pydiflumetofen, SYN545974, was incorrectly given as SYN545192. Whilst analysis of the 45.7-61.0 cm horizon was conducted at various times, these results are not shown in the tabulated results for replicate concentration values as all the residues in the horizon immediately above were <LOQ.

**Table B.8. 150 Residues of pydiflumetofen in Washington, USA soil with depth – Treated bare soil plot (mean values)**

| Scheduled Sampling Event (Actual Sampling Date) | Actual DAPA[2] | Actual DA1A[2] | Pydiflumetofen Mean Residues (µg/kg dry weight) Found[1] | | | | |
|---|---|---|---|---|---|---|---|
| | | | 0-7.6 cm | 7.6-15.2 cm | 15.2-30.5 cm | 30.5-45.7 cm | 45.7-61 cm |
| PA[3] (5/10/13) | PA | -4 | <0.50 | <0.50 | <0.50 | <0.50 | <0.50 |
| 0 DA1A[3] (5/14/13) | 0 | 0 | 200 | NS | NS | NS | NS |
| 3 DA1A (5/17/13) | 3 | 3 | 186 | 0.98[B] | <0.50 | <0.50 | -- |
| 6 DA1A (5/20/13) | 6 | 6 | 164 | <0.50 | <0.50 | <0.50 | -- |
| 0 DA2A[3] (5/21/13) | 0 | 7 | 337 | 0.86[B] | <0.50 | <0.50 | -- |
| 3 DA2A (5/24/13) | 3 | 10 | 311 | 0.63[B] | 0.51[A] | <0.50 | <0.50 |
| 7 DA2A (5/28/13) | 7 | 14 | 339 | 0.77[B] | <0.50 | <0.50 | -- |
| 14 DA2A (6/4/13) | 14 | 21 | 317 | <0.50 | <0.50 | <0.50 | -- |
| 30 DA2A (6/20/13) | 30 | 37 | 293 | 0.69[A] | <0.50 | <0.50 | -- |
| 60 DA2A (7/19/13) | 59 | 66 | 201 | 35 | <0.50 | <0.50 | -- |
| 90 DA2A (8/19/13) | 90 | 97 | 225 | 18[A] | <0.50 | <0.50 | -- |
| 120 DA2A (9/18/13) | 120 | 127 | 212 | 21[B] | <0.50 | <0.50 | -- |
| 180 DA2A (11/18/13) | 181 | 188 | 171 | 34[A] | <0.50 | <0.50 | <0.50 |
| 270 DA2A (2/17/14) | 272 | 279 | 195 | 4.0[B] | 0.61[A] | <0.50 | <0.50 |
| 360 DA2A (5/16/14) | 360 | 367 | 174 | 1.3[A] | <0.50 | <0.50 | -- |
| 480 DA2A (9/12/14) | 479 | 486 | 143 | 60 | 0.64[A] | <0.50 | <0.50 |
| 600 DA2A (1/14/15) | 603 | 610 | 103 | 52 | 3.8[A] | <0.50 | <0.50 |

[1] Residues are presented on a dry weight basis. Mean of residues from replicate treated plots - A, B and C; however, in some instances means are based on more than three data points, *i.e.*, repeat analysis of individual replicate samples.

[2] DAPA = days after previous application; DA1A = days after first application.

[3] PA = Pre-application, 0 DA1A and 0 DA2A were application days.

NS = not sampled

-- = Sample not analysed

[A] One replicate sample was ≥ LOQ.

[B] Two replicate samples were ≥ LOQ.

As noted previously, the study also included a plot cropped with wheat. Summary soil concentration results from the cropped plot are also presented below.

**Table B.8. 151 Residues of pydiflumetofen in Washington, USA soil with depth – Treated cropped soil plot (mean values)**

| Scheduled Sampling Event (Actual Sampling Date) | **Actual DAPA[2]** | **Actual DA1A[2]** | **Pydiflumetofen Mean Residues Found[1]** | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **0-7.6 cm** | **7.6-15.2 cm** | **15.2-30.5 cm** | **30.5-45.7 cm** | **45.7-61 cm** | **61-91.4 cm** |
| PA[3] (5/10/13) | PA | -4 | <0.50 | <0.50 | <0.50 | <0.50 | <0.50 | -- |
| 0 DA1A[3] (5/14/13) | 0 | 0 | **93** | NS | NS | NS | NS | NS |
| 3 DA1A (5/17/13) | 3 | 3 | **126** | **1.0[A]** | <0.50 | <0.50 | -- | -- |
| 6 DA1A (5/20/13) | 6 | 6 | **129** | **1.7** | <0.50 | <0.50 | -- | -- |
| 0 DA2A[3] (5/21/13) | 0 | 7 | **228** | <0.50 | <0.50 | <0.50 | -- | -- |
| 3 DA2A (5/24/13) | 3 | 10 | **237** | <0.50 | <0.50 | <0.50 | -- | -- |
| 7 DA2A (5/28/13) | 7 | 14 | **203** | **0.67[A]** | <0.50 | <0.50 | -- | -- |
| 14 DA2A (6/4/13) | 14 | 21 | **215** | <0.50 | <0.50 | <0.50 | -- | -- |
| 30 DA2A (6/20/13) | 30 | 37 | **233** | **0.57[A]** | <0.50 | <0.50 | -- | -- |
| 60 DA2A (7/19/13) | 59 | 66 | **163** | **0.81[A]** | <0.50 | <0.50 | -- | -- |
| 90 DA2A (8/19/13) | 90 | 97 | **174** | **1.7** | <0.50 | <0.50 | -- | -- |
| 120 DA2A (9/18/13) | 120 | 127 | **151** | **16[A]** | **4.9[A]** | **0.50[B]** | <0.50 | <0.50 |
| 180 DA2A (11/18/13) | 181 | 188 | **141** | **5.3** | <0.50 | <0.50 | -- | -- |
| 270 DA2A (2/17/14) | 272 | 279 | **133** | <0.50 | <0.50 | <0.50 | -- | -- |
| 360 DA2A (5/16/14) | 360 | 367 | **133** | **5.1** | **0.56** | **0.63[A]** | <0.50 | <0.50 |
| 480 DA2A (9/12/14) | 479 | 486 | **126** | **38** | **1.1[A]** | <0.50 | <0.50 | -- |
| 600 DA2A (1/14/15) | 603 | 610 | **137** | **46** | <0.50 | <0.50 | <0.50 | -- |

[1] Residues are presented on a dry weight basis. Mean of residues from replicate treated plots - A, B and C; however, in some instances means are based on more than three data points, *i.e.*, repeat analysis of individual replicate samples.

[2] DAPA = days after previous application; DA1A = days after first application.

[3] PA = Pre-application, 0 DA1A and 0 DA2A were application days.

NS = not sampled -- = Sample not analysed

[A] One replicate sample was > LOQ.

[B] Two replicate samples were > LOQ.

**Conclusions**

Pydiflumetofen dissipated from treated bare soil by 53% over the approximately 20 month period following the second application (the highest residues following the second application occurring at 7 days after the second application). Between 59 and 360 days after the second application the residues seemed to be particularly variable. Pydiflumetofen remained predominantly in the top 15.2 cm of soil throughout the study duration. Only occasional detections above the LOQ were seen in lower soil layers, the highest of these being a finding of 10 µg/kg in one replicate in the 15.2 – 30.5 cm layer at 603 DAT2. There were no residues greater than the LOQ in the soil layer below 30.5 cm.

Whilst results from cropped plots have historically been of less utility in European assessments, the results here are of interest. Taking into account the results in the top 15 cm, the residues at the final sample point had declined to 77% of the highest residues after the second treatment (highest residue recorded at 3 days after second treatment). As with the bare plots, the residues appeared to be quite variable during the course of the study.

The calculated DT50 was 634 days and DT90 3820 days (DFOP).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted], [redacted], [redacted], [redacted] (2015). SYN545974: Dissipation of SYN545974 in Soil Under Bare Soil and Peanut Crop Conditions in the Southeastern United States, Syngenta Crop Protection, LLC, Greensboro, North Carolina, USA; Syngenta Report No. 796.68. (Syngenta File No. VV-414445) |

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**Guidelines**

US EPA Fate, Transport and Transformation Test Guideline; OPPTS 835.6100 Terrestrial Field Dissipation. EPA 712-C-08-020.

**GLP**: Yes

**Materials and methods**
**Test Material**
**Formulation:** SYN545974 SC (200)
**Product code:** A19649B
**Lot/Batch #:** 658672
**Formulation type: S**uspension concentrate
**Purity:** 197 g pydiflumetofen/L

**Test Sites**
A field dissipation study was carried out at a site located in Chula in Tift County, Georgia, USA. The study design and conduct were very similar to that described above for the site at Madera, California, USA. Details of the test site are shown in the table below. The soil type at the test site was classified as a Tifton loamy sand – a very deep, well drained, moderately slowly permeable soil that formed in loamy marine sediments. The USDA taxonomic class of the Tifton Series is – Fine-loamy, kaolinitic, thermic Plinthic Kandiudults (Order – Ultisols, Suborder – Udults). It is noted that the order Ultisols are often associated with tropical or sub-tropical conditions. This may limit the ability to use the results from this site due to European guidance indicating that non-European *temperate* soils may be used in assessment provided that they meet criteria showing they are of relevance to European conditions.

It should be noted that the site also included a treated plot of the same study design that was cropped with peanut. Field dissipation studies for use in European regulatory assessments are typically expected to be bare soil experiments as the presence of crops/plants in the treated areas can make interpretation of results difficult. Hence the results from the cropped plots are not considered here in detail.

**Table B.8. 152 History of Georgia, USA test site**

| Country / Location | Co-ordinates | Slope | Crops grown / Plot history | Pesticides use history (2007-2012) |
|---|---|---|---|---|
| USA / Tift County, Georgia | 31 34 40.52 N 83 35 5.11 W | ~1% | Control plots: 2007 – fallow, 2008-2009 – cotton, 2010-2012 – fallow<br><br>Treated plots: 2007-2009 – cotton, 2010-2011 – soybean / bare soil, 2012 - fallow | Control plots: aldicarb, glyphosate, flumeturon, pendimethalin, glufosinate-ammonium, fomesafen, MSMA, S-metolachlor, mepiquat chloride, spinosad, indoxacarb, zeta-cypermethrin, dicrotophos, thiadiazuron/diuron, ethephon, cyclanilide<br><br>Treated plots: aldicarb, glyphosate, fluometuron, pendimethalin, glufosinate, fomesafen, MSMA, S-metolachlor, mepiquat chloride, spinosad, indoxacarb, zeta-cypermethrin, dicrotophos, thiadiazuron/diuron, ethephon, cyclanilide, ethephon, fluazifop-P-butyl |

**Table B.8. 153 Soil characteristics at Georgia, USA trial site**

| Plot | Soil Depth (inches) | pH* | CEC (meq/ 100 g) | O.M. (%) | Bulk density (g/cc) | WHC (%) | | Sand (%) | Silt (%) | Clay (%) | USDA Class |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated | 0-3 | 7.2 | 4.0 | 0.82 | 1.44 | 4.6 | 2.1 | 90 | 7 | 3 | Sand |
| | 3-6 | 6.8 | 3.6 | 0.69 | 1.43 | 4.9 | 2.1 | 89 | 8 | 3 | Sand |
| | 6-12 | 6.2 | 3.5 | 0.43 | 1.49 | 5.1 | 2.2 | 89 | 8 | 3 | Sand |
| | 12-18 | 6.1 | 4.5 | 0.26 | 1.38 | 8.3 | 4.9 | 77 | 10 | 13 | Sandy Loam |
| | 18-24 | 5.7 | 5.4 | 0.30 | 1.29 | 13.0 | 8.6 | 71 | 8 | 21 | Sandy Clay Loam |
| | 24-30 | 5.3 | 6.2 | 0.30 | 1.21 | 15.8 | 10.5 | 63 | 10 | 27 | Sandy Clay Loam |
| | 30-36 | 5.3 | 6.0 | 0.22 | 1.20 | 17.5 | 12.7 | 63 | 8 | 29 | Sandy Clay Loam |
| Control | 0-3 | 7.1 | 4.2 | 0.90 | 1.46 | 5.5 | 2.3 | 89 | 8 | 3 | Sand |
| | 3-6 | 6.8 | 3.6 | 0.56 | 1.51 | 5.2 | 2.2 | 89 | 8 | 3 | Sand |
| | 6-12 | 6.2 | 3.6 | 0.52 | 1.46 | 5.7 | 2.5 | 87 | 8 | 5 | Loamy Sand |
| | 12-18 | 6.2 | 4.8 | 0.43 | 1.36 | 11.5 | 5.8 | 77 | 8 | 15 | Sandy Loam |
| | 18-24 | 6.1 | 5.3 | 0.30 | 1.28 | 17.2 | 9.0 | 70 | 7 | 23 | Sandy Clay Loam |
| | 24-30 | 5.5 | 5.6 | 0.22 | 1.23 | 18.2 | 10.1 | 67 | 8 | 25 | Sandy Clay Loam |
| | 30-36 | 5.3 | 5.6 | 0.09 | 1.21 | 19.7 | 11.1 | 65 | 8 | 27 | Sandy Clay Loam |

*Medium not reported

**Study Design and Methods**

**Experimental Treatment**

The test site consisted of two test plots: a treated bare soil plot and a control bare soil plot, separated by a buffer of approximately 41.1 m. The treated bare soil plot measured 18.3 x 22.9 m and was divided into three replicate areas (A, B and C), each subdivided into 30 subplots measuring 0.8 x 3.7 m. The control plot measured 3.7 x 22.9 m which was divided into 15 subplots measuring 1.5 x 3.7 m.

Four applications of SYN545974 SC (200) were made to the treated plots at a rate of 110 g a.s./ha per application using a calibrated tractor-mounted boom sprayer. Applications were made on July 31 and August 7, 14 and 21, 2012, and were timed to approximate the typical start of fungicide applications in peanuts in the Southeastern US.

Irrigation was applied to the site to achieve a monthly target moisture input of 110% of the typical peanut crop requirement or the 30-year (1971-2000) average monthly precipitation assessed based on data from NOAA Station No. 098703 (Chula, Georgia, approximately 7 miles from the test site), whichever was greater. Bare soil plots were maintained by the application of herbicides (glyphosate, fluazifop-P-butyl, s-metolachlor, glufosinate-ammonium).

Daily weather data (air temperature, solar radiation, humidity, average wind speed, soil temperature and moisture) were recorded on-site. Rainfall measurements were obtained from a rain gauge located approximately 0.5 miles from the test site.

**Sampling**

Application monitoring samples (tank-mix samples, tank-mix water samples and application verification filter papers placed on the soil surface) were collected for each application, but were not analysed.

Soil cores were collected from the treated bare soil and control plots prior to the first application (PA, -1 day), immediately after each application (0 DA1A, 0 DA2A, 0 DA3A, 0 DA4A), 3 and 6 days after the first, second and third applications (DA1A, DA2A and DA3A) and at 15 different sampling intervals between 1 and 723 days after the fourth application (DA4A). At each interval, soil cores were collected in two stages: to a depth of 0-3 inches/0-7.6 cm (6 inch/15.2 cm diameter) and 3-36 inches/7.6-91.4 cm (1.75 inch/4.4 cm diameter), except 0 DA1A when only 0-3 inch/0-7.6 cm cores were collected. At each interval, 5 cores were taken from each replicate (A, B and C) of the treated plot and the control plot. Cores were sectioned into 3- to 6 inch/7.6- to 15.2 cm segments and corresponding soil depth layers combined for each replicate.

Samples were stored frozen until analysis. Soil samples were extracted within 743 days of collection.

**Description of analytical procedure**

Soil extraction and analysis was conducted by two analytical facilities: ALS Environmental and ADPEN Laboratories Inc. ALS analysed all soil samples to 360 DA4A to a depth of 30.5 cm. ADPEN analysed all soil samples below 30.5 cm depth and all soil samples from 480 DA4A onwards.

At both facilities, soil samples were analysed for the parent substance, pydiflumetofen, only, using Syngenta Method GRM061.04A.

Soil sub-samples (10 g) were extracted with acetonitrile/0.1M ammonia acetate aqueous solution (80:20 v/v, 1 x 40 mL), then acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). Extracts were combined and an aliquot (10 mL) evaporated to remove acetonitrile. One mL of 0.1% acetic acid was added and the sample loaded onto a preconditioned Bond Elute-C18 or Strata $C_{18}$ SPE cartridge. The cartridge was rinsed with methanol/0.1% acetic acid (60:40 v/v, 1 x 2.5 or 4.5 mL), then eluted with methanol/0.1% acetic acid (60:40 v/v, 1 x 2 mL) and/or methanol (1 x 3 mL). Eluates were combined and evaporated to remove methanol. For samples analysed by ADPEN, rinsates were combined with the eluates before evaporation. The sample was mixed with 1.5 mL methanol and diluted to 5 mL with 0.1% acetic acid for analysis by LC-MS/MS. The limit of quantitation (LOQ) for pydiflumetofen in soil was 0.5 µg/kg. The calculated limit of detection (LOD) was 0.21 µg/kg.

**Results and Discussion**

**Analytical Method Performance**
Mean procedural recoveries and relative standard deviation (RSD) for the recovery from bare soil samples at the LOQ were 98 ± 13% (n = 21) and 101 ± 13% (n = 8) for the samples sets analysed at ALS and ADPEN, respectively. Procedural recovery was tested at various concentrations at up to 300-500 µg/kg with acceptable results.

**Application Rate Verification**
The total residues of pydiflumetofen found immediately after each application (0 DA1A, 0 DA2A, 0 DA3A and 0 DA4A) and subsequent events within 3 days of application if the total increased (3 DA3A) are presented below. Actual application rates achieved were 79%, 99%, 90% and 105% of the target rate (110 g a.s./ha) after the first, second, third (measured at 3 DA3A) and fourth applications, respectively. The total residues found in soil samples were considered adequate to demonstrate the actual application rates were at the intended rate, therefore the application day monitoring samples (tank-mix, tank-mix water and filter papers) were not analysed.

**Table B.8. 154 Total residues of pydiflumetofen in Georgia, USA soil after each application – Treated bare soil plot (mean values)**

| Sampling Event | Pydiflumetofen Mean Residues | | Percent of target rate[2] |
|---|---|---|---|
| | Total (g/ha) | Adjusted[1] (g/ha) | |
| 0 DA1A | 87 | 87 | 79 |
| 0 DA2A | 169 | 109 | 99 |
| 0 DA3A | 192 | 65 | 59 |
| 3 DA3A | 226 | 99 | 90 |
| 0 DA4A | 300 | 116 | 105 |

[1] Adjusted g/ha = Total g a.s./ha - Day before application residues (*i.e.* 6 DA1A, 6 DA2A and 6 DA3A). Applicable to 0 DA2A, 0 DA3A and 0 DA4A applications.
[2] Target application rate (110 g a.s./ha)

**Residue Analysis**
Residues of pydiflumetofen in treated plots are summarised in the table below. It was noted that the study report contained some mistakes in that in some places the code for pydiflumetofen, SYN545974, was incorrectly given as SYN545192. No residues of pydiflumetofen were detected in controls samples at or above the limit of detection (LOD, calculated as 0.21 µg/kg for ALS samples, and defined as ½ LOQ for ADPEN samples), with the exception of the 7 DA4A, 7.6-15.2 cm in which residues of 17.3 µg/kg (mean of duplicate analysis) was observed and attributed to laboratory contamination.

Pydiflumetofen dissipated gradually in the treated bare soil plot over approximately 24 months. Residues of pydiflumetofen were at approximately 31% of the levels observed after the fourth application. Pydiflumetofen residues remained predominantly in the surface 3 inches/7.6 cm of soil for the study duration. Residues in the 3-6 inch/7.6-15.2 cm depth typically ranged from <1 to 4% of the residue levels found in the 0-3 inch/0-7.6 cm depth over the 744 day trial. Pydiflumetofen was detected at quantifiable levels (*i.e.* ≥ LOQ) at only one sampling interval in the 6-12 inch/15.2-30.5 cm depth soil layer: 3 DA4A at a mean concentration of 0.73 µg/kg. No quantifiable residues of pydiflumetofen were observed below the 6-12 inch/15.2-30.5 cm depth.

**Table B.8. 155 Residues of pydiflumetofen in Georgia, USA soil with depth – Treated bare soil plot (mean values)**

| Scheduled Sampling Event (Actual Sampling Date) | Actual DAPA[2] | Actual DA1A[2] | Pydiflumetofen Mean Residues (µg/kg dry weight) Found[1] | | | | |
|---|---|---|---|---|---|---|---|
| | | | 0-7.6 cm | 7.6-15.2 cm | 15.2-30.5 cm | 30.5-45.7 cm | 45.7-61 cm |
| PA[3] (7/30/12) | -1 | -1 | <0.5 | <0.50 | <0.50 | <0.50 | <0.50 |
| 0 DA1A[3] (7/31/12) | 0 | 0 | 72 | <0.50 | <0.50 | -- | -- |
| 3 DA1A (8/03/12) | 3 | 3 | 65 | <0.50 | <0.50 | -- | -- |
| 6 DA1A (8/06/12) | 6 | 6 | 49 | 0.51 | <0.50 | -- | -- |
| 0 DA2A[3] (8/7/12) | 0 | 7 | 137 | <0.50 | <0.50 | -- | -- |
| 3 DA2A (8/10/12) | 3 | 10 | 95 | <0.50 | <0.50 | -- | -- |
| 6 DA2A (8/13/12) | 6 | 13 | 104 | <0.50 | <0.50 | -- | -- |
| 0 DA3A[3] (8/14/12) | 0 | 14 | 162 | <0.50 | <0.50 | -- | -- |
| 3 DA3A (8/17/12) | 3 | 17 | 170 | <0.50 | <0.50 | -- | -- |
| 6 DA3A (8/20/12) | 6 | 20 | 143 | 0.52 | <0.50 | <0.50 | -- |
| 0 DA4A (8/21/12) | 0 | 21 | 240 | <0.50 | <0.50 | <0.50 | -- |
| 1 DA4A (8/22/12) | 1 | 22 | 224 | 0.62 | <0.50 | <0.50 | -- |
| 3 DA4A (8/24/12) | 3 | 24 | 189 | <0.50 | 0.73 | <0.50 | <0.50 |
| 7 DA4A (8/28/12) | 7 | 28 | 230 | <0.50 | <0.50 | <0.50 | <0.50 |
| 14 DA4A (9/4/2012) | 14 | 35 | 224 | <0.50 | <0.50 | -- | -- |
| 30 DA4A (9/20/12) | 30 | 51 | 192 | <0.50 | <0.50 | -- | -- |
| 60 DA4A (10/18/12) | 58 | 79 | 179 | <0.50 | <0.50 | -- | -- |
| 90 DA4A (11/15/12) | 86 | 107 | 171 | <0.50 | <0.50 | -- | -- |
| 120 DA4A (12/19/12) | 120 | 141 | 161 | <0.50 | <0.50 | -- | -- |
| 180 DA4A (2/18/13) | 181 | 202 | 167 | 0.66 | <0.50 | <0.50 | -- |
| 270 DA4A (5/16/13) | 268 | 289 | 120 | <0.50 | <0.50 | <0.50 | -- |
| 360 DA4A (8/19/13) | 363 | 384 | 73 | 1.2 | <0.50 | <0.50 | -- |
| 480 DA4A (12/13/13) | 479 | 500 | 76 | 1.4 | <0.50 | <0.50 | -- |
| 600 DA4A (4/11/14) | 598 | 619 | 69 | 0.87 | <0.50 | <0.50 | -- |
| 720 DA4A (8/14/14) | 723 | 744 | 79 | 2.6 | <0.50 | <0.50 | -- |

[1] Residues are presented on a dry weight basis. Mean of residues from replicate treated plots - A, B and C; however, in some instances means are based on more than three data points, *i.e.*, repeat analysis of individual replicate samples.

[2] DAPA = days after previous application; DA1A = days after first application.
[3] PA = Pre-application, 0 DA1A, 0 DA2A, 0 DA3A and 0 DA4A were application days, -- = not analysed.

**Conclusions**
Pydiflumetofen dissipated from treated bare soil by 66% over the approximately 24 month period following the fourth application (the highest residues occurring at 0 days after the fourth application). Pydiflumetofen remained predominantly in the surface 7.6 cm of soil for the study duration. Low concentrations were found in the 7.6-15.2 cm layer. Pydiflumetofen was detected in the 15.2-30.5 cm depth soil layer at 3 DA4A slightly above the LOQ. This was the only time there was a quantifiable residue at this depth. No quantifiable residues of pydiflumetofen were observed below 30.5 cm depth.

The calculated DT50 was 263 days and DT90 2750 days (FOMC).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted] (2015). SYN545974 SC (A19649B) – Soil Dissipation Trial to Determine Persistence and Leaching Movement of SYN545974 after Application of SYN545974 200SC Fungicide. Syngenta Canada Inc., Guelph, ON, Canada; Syngenta Report No. TK0121181 (Syngenta File No. VV-511235) |

**THE STUDY IS NOT CONSIDERED TO BE REPRESENTATIVE OF EUROPEAN CONDITIONS AND IS NOT USED FOR RISK ASSESSMENT PURPOSES. THE STUDY IS PRESENTED FOR INFORMATION ONLY.**

**Guidelines**

US EPA Fate, Transport and Transformation Test Guideline; OPPTS 835.6100 Terrestrial Field Dissipation. EPA 712-C-08-020.

**GLP**: Yes

**Materials and methods**
**Test Material**
**Formulation:** SYN545974 SC (200)
**Product code:** A19649B
**Lot/Batch #:** SMU2JP001 / 681692
**Formulation type:** 200 g/L SC formulation
**Purity:** 204 g pydiflumetofen/L
**Stability:** Stable at ambient temperature

**Test Sites**

A field trial site (T600) was selected in the West-Central Semi-Arid Prairies Ecoregion (9.3) of the Ecological Regions of North America Level I-II map near Taber, Alberta, Canada.

**Table B.8. 156 History of test site**

| Site/ Location/ Country | Co-ordinates | Slope | Crops grown / Plot history | Pesticides use |
|---|---|---|---|---|
| T600 / Taber, Alberta / Canada | 49.775315, -112.024747 | <2% | 2010: Barley, tilled spring+fall<br>2011: Canola, tilled spring+fall<br>2012: Wheat, tilled spring+fall<br>2013: No crop, tilled spring+ summer<br>2014: No crop, no tillage<br>2015: No crop, no tillage | 2010: bromoxynil, ethalfluralin<br>2011: thiamethoxam, difenoconazole, fludioxanil, glyphosate, quizalofop-P-ethyl, ethametsulfuron-methyl, boscalid, lambda-cyhalothrin<br>2012: bromoxynil, MCPA<br>2013: glyphosate, 2,4-D<br>2014: glyphosate<br>2015: glyphosate, 2,4-D |

**Table B.8. 157 Soil characteristics at Alberta, Canada trial site**

| Parameter | Depth range (cm) | | | | | |
|---|---|---|---|---|---|---|
| | 0-10 | 10-25 | 25-40 | 40-55 | 55-70 | 70-100 |
| Sand (%) | 47.4 | 40.2 | 35.9 | 31.7 | 30.9 | 39.9 |
| Silt (%) | 29.7 | 33.5 | 37.4 | 41.7 | 37.2 | 31.2 |
| Clay (%) | 22.9 | 26.2 | 26.6 | 26.6 | 31.9 | 28.8 |
| Texture | Loam | Loam | Loam | Loam | Clay loam | Clay loam |
| Organic Carbon (%) | 1.50 | 1.10 | 0.70 | 0.50 | 0.50 | 0.40 |
| Organic Matter (%)[1] | 2.65 | 1.86 | 1.13 | 0.86 | 0.84 | <0.70 |
| Cation Exchange Capacity (meq/100g) | 18.0 | 15.0 | 14.1 | 13.0 | 15.0 | 13.1 |
| pH* | 8.03 | 8.25 | 8.35 | 8.51 | 8.70 | 8.46 |
| Available Moisture (%, at bar)<br>1/3<br>15 | <br>14.7<br>10.9 | <br>15.8<br>12.4 | <br>15.7<br>12.0 | <br>15.6<br>9.7 | <br>15.9<br>11.7 | <br>14.1<br>10.3 |
| Bulk Density ($g/cm^3$) (undisturbed individual samples) | 1.32 ± 0.06 | ND | ND | ND | ND | ND |
| Porosity (%) (undisturbed individual samples) | 50.0 ± 2.4 | ND | ND | ND | ND | ND |

*Medium not reported
ND = not determined
[1] Organic matter (%) = Organic Carbon (%) x 1.7

**Study Design and Methods**
**Experimental Treatment**
The test site consisted of one treated and one untreated control plot. The treated plot (40 x 4 m) was divided into 3 replicates (12.5 x 4 m) which were further divided into 5 sub-plots (2.5 x 4 m). A single sub-plot located at the eastern end of replicate 3 remained unused over the study duration. The untreated control plot (15 x 4 m) was divided into 6 equal sub-plots (2.5 x 4 m), one of which remained unused over the duration of the study.

Two broadcast spray applications of SYN545974 SC (200) were made to bare soil on July 2 and 9, 2013, at a target rate of 220 g a.s./ha per application, using a calibrated tractor-mounted boom sprayer equipped with windscreens appropriate to the wind speed and direction on the day of application. The first application timing approximately coincided with a typical Prairie fungicide timing.

Bare soil was maintained during the course of the study with glyphosate and 2,4-D applications. Irrigation was applied to trial plots to achieve 110% of the approximate requirements for a canola crop in Southern Alberta or 120% of the 30 year average for Taber, whichever was higher. No single irrigation event exceeded 25 mm or caused visible run-off from the treated plot.

Daily weather data (air temperature, solar radiation, humidity, average wind speed and direction, soil temperature and soil moisture) were obtained daily from weather readings measured on site during the growing season (May-September) and from Vauxhall weather station (Environment Canada weather station ID 3036682), located approximately 30 km from the test site, over the winter months (October – April).

**Sampling**
Application rates were verified by the collection of samples deposited onto application monitoring devices (AMD, thick cellulose filter paper with an aluminium foil backing) placed onto the soil surface prior to application.

Soil cores were obtained prior to the first test item application (-15 DA1A), then on 16 subsequent days between 0 and 703 DA1A. At each sampling interval, cores (2 on 0 DA1A, 1 at all other intervals) were taken to depths of 0-10 cm (5.7 cm diameter) and 10-100 cm (4.2 cm diameter) from each sub-plot within each replicate. The 10-100 cm cores were divided into 5 horizons: 10-25 cm, 25-40 cm, 40-55 cm, 55-70 cm and 70-100 cm. Samples from corresponding soil depths were combined for each replicate plot.

Soil samples were stored frozen until analysis.

**Description of analytical procedure**
Residues of pydiflumetofen in soil were determined according to Syngenta method GRM061.04A.

Following homogenisation under dry ice, representative samples (10 g) were extracted with acetonitrile/0.1M ammonium acetate (80:20 v/v, 1 x 30 mL) and acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). Extracts were combined and adjusted to 100 mL. An aliquot (5 mL) was evaporated to remove acetonitrile, and mixed with 1 mL 0.1% acetic acid. Sample extracts were cleaned using SPE (Bond Elut-C18), eluted with methanol/0.1% acetic acid (60:40 v/v, 1 x 1 mL) and methanol (1 x 3 mL). The eluates were evaporated to remove methanol and the residue reconstituted in methanol/0.1% acetic acid (30:70 v/v). Samples were analysed using LC-MS/MS. The limit of quantitation (LOQ) was 0.5 ppb (µg/kg).

AMD samples had the aluminium foil backing removed. The filter paper and foil were cut into smaller pieces and extracted with acetonitrile/0.1% acetic acid (80:20 v/v, 1 x 300 mL). An aliquot of the extract was removed and diluted to a known volume with methanol/0.1% acetic acid (30:70 v/v) prior to analysis by LC-MS/MS (LOQ not determined).

**Results and Discussion**

**Analytical Method Performance**
Procedural recoveries (mean ± standard deviation) for analysis of pydiflumetofen in the AMD and soil samples were 100.3 ± 2.4% (n=6) and 86.3 ± 7.0% (n=49), respectively.

**Application Rate Verification**
The mean calculated application rates of pydiflumetofen derived from the AMD samples were 206 ± 34 g a.s./ha and 232 ± 24 g a.s./ha for the first and second applications, respectively.

**Residue Analysis**
Residues of pydiflumetofen in the treated plot (mean of treated replicates A, B and C) at each soil depth are summarised below. No residues of pydiflumetofen were detected in any control samples at or above the LOQ.

Dissipation of pydiflumetofen residues occurred steadily over the course of the study, declining in the surface layer (0-10 cm) from 162 µg/kg (mean) immediately after the second application (7 DA1A) to 52 µg/kg (mean) on 696 DA1A. Pydiflumetofen residues were primarily found in the 0-10 cm soil layer. Residues in the 10-25 cm depths were detected consistently over the study period, typically being 1-2 µg/kg, with a maximum concentration of 8.8 µg/kg. Pydiflumetofen residues in the 10-25 cm soil horizon were highest in one plot

replicate sample obtained 3 days after the second application (10 DA1A), likely due to the moist soil conditions during the second application resulting directly in preferential flow, or indirectly by physical disturbance of the moist soil during application. There were three detections of pydiflumetofen above LOQ in the 25-40 cm soil layer, all were <1 µg/kg, and no residue was observed below this depth over the course of the trial (696 days).

**Table B.8. 158 Residues of pydiflumetofen in Alberta, Canada treated soil with depth (values are mean of treated plot replicates expressed on a dry weight basis)**

| Sample Date (D-M-Y) | Days After First Application (DA1A) | Mean Residues Found (µg/kg, dry weight)[1] | | | | | |
|---|---|---|---|---|---|---|---|
| | | 0-10 cm | 10-25 cm | 25-40 cm | 40-55 cm | 55-70 cm | 70-100 cm |
| 17-Jun-13 | -15 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| 02-Jul-13 | 0 | 130 | NS | NS | NS | NS | NS |
| 05-Jul-13 | 3 | 115 | 0.93 | <0.5 | <0.5 | <0.5 | <0.5 |
| 08-Jul-13 | 6 | 63 | 0.52 | <0.5 | <0.5 | <0.5 | <0.5 |
| 09-Jul-13[2] | 7 | 162 | NS | NS | NS | NS | NS |
| 12-Jul-13 | 10 | 173 | 8.8 | <0.5 | <0.5 | <0.5 | <0.5 |
| 16-Jul-13 | 14 | 178 | 2.7 | <0.5 | <0.5 | <0.5 | <0.5 |
| 23-Jul-13 | 21 | 155 | 1.7 | <0.5 | <0.5 | <0.5 | <0.5 |
| 09-Aug-13 | 38 | 130 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| 05-Sep-13 | 65 | 129 | 2.0 | 0.54 | <0.5 | <0.5 | <0.5 |
| 23-Oct-13 | 113 | 152 | 1.5 | 0.53 | <0.5 | <0.5 | <0.5 |
| 08-May-14 | 310 | 71 | 2.1 | <0.5 | <0.5 | <0.5 | <0.5 |
| 25-Jun-14 | 358 | 60 | 2.3 | 0.59 | <0.5 | <0.5 | <0.5 |
| 18-Aug-14 | 412 | 93.7 | 1.2 | <0.5 | <0.5 | <0.5 | <0.5 |
| 30-Oct-14 | 485 | 39 | 1.0 | <0.5 | <0.5 | <0.5 | <0.5 |
| 30-Apr-15 | 667 | 73 | 1.8 | <0.5 | <0.5 | <0.5 | <0.5 |
| 05-Jun-15 | 696 | 52 | 1.3 | <0.5 | <0.5 | <0.5 | <0.5 |

NS = not sampled
<0.5 = residue below the limit of quantitation (LOQ = 0.5 µg/kg)
[1]Mean of residues from treated plot replicates A, B and C. In some instances, means are based on more than three data points, i.e., repeat analysis of individual replicate samples. Mean residue were calculated in the 10-25 and 25-40 cm depths by treating any values equal or below LOQ values as equal to 0.5 µg/kg.
[2]Date of second application

**Conclusions**
Dissipation of pydiflumetofen residues occurred over the course of the study, declining in the surface layer (0-10 cm) from 178 µg/kg (mean) 7 days after the second application (14 DA1A) to 52 µg/kg (mean) on 696 DA1A. This represents approximately 70% dissipation 1 year and 11 months. Residues in the treated bare soil plot were found primarily in the uppermost soil layer (0-10 cm), while minor but detectable amounts were consistently observed in the 10-25 cm depth horizon. There were three detections of pydiflumetofen in the 25-40 cm depth horizon, all were <1 µg/kg, and no residue was observed below this depth over the course of the trial period.

The calculated DT50 was 284 days and DT90 4300 days (FOMC).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted], [redacted], [redacted], [redacted], [redacted] (2015). SYN545974 (A19649B) - Field Dissipation of SYN545974 in Soil Under Turf and Bare Soil Conditions in Prince Edward Island, Canada; Syngenta Crop Protection, LLC, Greensboro, North Carolina, USA; Syngenta Report No. TK0174758 (Syngenta File No. VV-414581) |

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**Guidelines**

US EPA Fate, Transport and Transformation Test Guideline; OPPTS 835.6100 Terrestrial Field Dissipation. EPA 712-C-08-020.

**GLP**: Yes

**Materials and methods**
**Test Material**
**Formulation:** SYN545974 SC (200)
**Product code:** A19649B
**Lot/Batch #:** SMU2JP001 (Solo batch ID 681692)
**Formulation type:** Suspension concentrate
**Purity:** 204 g pydiflumetofen/L

**Test Sites**
Field trials were carried out at a site approximately 2.2 km from New Glasgow, Queens County, Prince Edward Island, Canada. Details of the test site are shown in the table below. The test site was located within North American (Level II) Ecological Region 8.1, Eastern Temperate Forests - Mixed Wood Plains. The soil series at the test site was identified as an Alberry moderately coarse sandy loam (Orthic Humo Ferric Podzol).

**Table B.8. 159 History of test site**

| **Country / Location** | **Co-ordinates** | **Slope** | **Crops grown / Plot history** | **Pesticides use history** |
|---|---|---|---|---|
| Canada / New Glasgow, Queens County, Prince Edward Island | N 46°24.3<br>W 63°19.3 | ~1.5% | 2008: Potato<br>2009: Fallow<br>2010: Soybeans<br>2011: Brassica Caranata<br>2012: Fallow | 2008: chlorothalonil, thiamethoxam, fludioxonil, difenoconazole, fluazifop-P-butyl<br>2009: diquat, glyphosate<br>2010: glyphosate<br>2011:ethametsulfuron-methyl, prothioconazole, diquat<br>2012: diquat, glyphosate |

**Table B.8. 160 Soil characteristics at Prince Edward Island, Canada trial site**

| Plot | Soil Depth (cm) | pH (1:1 $H_2O$) | CEC (meq/ 100 g) | O.M. (%) | Bulk density (g/cm$^3$) | WHC | | Sand (%) | Silt (%) | Clay (%) | USDA Class |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1/3 Bar | 15 Bar | | | | |
| Treated bare soil | 0-7.5 | 6.4 | 8.0 | 3.3 | 1.02 | 22.8 | 9.0 | 62 | 26 | 12 | Sandy Loam |
| | 7.5-15 | 6.3 | 7.8 | 3.0 | 1.04 | 23.5 | 9.1 | 60 | 28 | 12 | Sandy Loam |
| | 15-30 | 5.4 | 6.5 | 2.1 | 1.05 | 19.2 | 9.1 | 63 | 23 | 14 | Sandy Loam |
| | 30-45 | 5.2 | 5.9 | 0.88 | 1.12 | 16.4 | 8.2 | 65 | 21 | 14 | Sandy Loam |
| | 45-60 | 5.2 | 4.9 | 0.43 | 1.23 | 11.3 | 6.1 | 69 | 19 | 12 | Sandy Loam |
| | 60-75 | 5.2 | 5.2 | 0.07 | 1.21 | 14.1 | 6.6 | 59 | 25 | 16 | Sandy Loam |
| | 75-90 | 5.0 | 4.9 | 0.02 | 1.22 | 16.6 | 6.3 | 56 | 30 | 14 | Sandy Loam |
| Control | 0-7.5 | 6.6 | 8.3 | 3.6 | 1.01 | 23.2 | 8.9 | 60 | 28 | 12 | Sandy Loam |
| | 7.5-15 | 6.1 | 8.0 | 3.2 | 1.01 | 22.6 | 9.5 | 58 | 29 | 13 | Sandy Loam |
| | 15-30 | 5.4 | 7.3 | 2.5 | 1.03 | 25.8 | 9.6 | 60 | 26 | 14 | Sandy Loam |
| | 30-45 | 5.1 | 6.2 | 0.61 | 1.10 | 21.0 | 8.3 | 54 | 28 | 18 | Sandy Loam |
| | 45-60 | 5.0 | 5.3 | 0.20 | 1.17 | 16.9 | 7.3 | 56 | 26 | 18 | Sandy Loam |
| | 60-75 | 4.9 | 5.4 | 0.16 | 1.20 | 17.6 | 7.0 | 56 | 26 | 18 | Sandy Loam |
| | 75-90 | 4.8 | 5.0 | 0.16 | 1.21 | 16.1 | 6.6 | 60 | 24 | 16 | Sandy Loam |

**Study Design and Methods**

**Experimental Treatment**

The test site consisted of a treated bare soil plot and an untreated control bare soil plot, separated by a buffer zone of approximately 32 m (105 ft). The treated plots were divided into three sampling replicates (A, B and C) measuring 6 x 22.5 m (20 x 74 ft), each containing 120 subplots measuring 0.75 x 1.5 m (2.5 x 5 ft). The control plot measured 6 x 9 m (20 x 30 ft), containing 48 subplots measuring 0.75 x 1.5 m (2.5 x 5 ft).

Two applications of SYN545974 SC (200) were made to bare soil at a rate of 220 g a.s./ha (0.20 lb a.s./A) using a calibrated tractor-mounted boom sprayer. Applications were made on July 9 and 16, 2013, at a typical timing for summer disease control in cold season turf grass species. Irrigation was applied to the sites to achieve a monthly target moisture of 120% of the 30-year (1971-2000) average monthly rainfall for Charlottetown, Queens County, Prince Edward Island. Trial plots were periodically treated with herbicide (glyphosate, diquat) to control weed growth.

Daily air and soil temperature, soil moisture, relative humidity, wind speed and solar radiation were recorded at a weather station located approximately 27 m (90 ft) from the treated plot, throughout the trial period.

**Sampling**

Actual application rates were verified using fifteen 15 cm diameter filter papers, placed in glass petri-dishes on the soil surface. Application verification samples were collected immediately after application.

Soil cores were collected from the treated plot prior to the initial application (PA, -2 day), 0 DA1A (immediately after the first application), 3 and 6 days after the first application (DA1A), 0 DA2A (immediately after the second application) and at ten different sampling intervals between 3 and 456 days after the second application (DA2A). Soils were collected from the control plot prior to application (PA, -2 day), 3 days after the first application (DA1A) and 3, 91 and 371 days after the second application (DA2A).

Cores were collected to a depth of 90 cm (36 in.) in two stages: 0-15 cm (0-6 in.) and 15-90 cm (6-36 in.) and section into 7.5- to 15 cm (3- to 6 in.) depth intervals. Five cores were collected from each replicate of the treated pot, and five from the control plot. Soils from corresponding depths were combined, resulting in 3 replicate composite samples (A, B and C) for each depth for the treated plots, and one composite sample for each depth for the control plots.

Samples were stored frozen until analysis. Soil samples were extracted within 576 days of collection.

**Description of analytical procedure**
Sample extractions and analysis was conducted by two analytical facilities: ALS Environmental Inc. and Golden Pacific Laboratories (GPL), LLC. ALS analysed samples up to 90 DA2A at 0-7.5 cm (0-3 in.) and 7.5-15 cm (3-6 in.) depths. Samples up to 90 DA2A at depths >15 cm (> 6 in.), all samples from 120 DA2A onwards and the application monitoring filter papers were analysed by GPL.

At both testing facilities, soil samples were analysed for the parent substance, pydiflumetofen, only, using Syngenta Method GRM061.04A.

Soil sub-samples (10 g) were extracted with acetonitrile/0.1M ammonia acetate aqueous solution (80:20 v/v, 1 x 40 mL), then acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). Extracts were centrifuged to remove solids and combined. An aliquot (50 µg/L) was diluted to 1 mL with methanol/0.1% acetic acid (30:70, v/v) for analysis by LC-MS/MS. The limit of quantitation (LOQ) for pydiflumetofen in soil was 0.5 ppb (µg/kg).

Application monitoring filter papers were cut into strips and extracted with acetonitrile/water (80:20 v/v, 1 x 200 mL) at ambient temperature, then sonicated for 5 minutes. An aliquot of the sample was filtered through a 25 mm, 0.45-µm PTFE filter and serially diluted in methanol/water (50:50 v/v) then methanol/0.1% acetic acid (30:70, v/v) to a final level suitable for analysis by LC-MS/MS.

**Results and Discussion**

**Analytical Method Performance**
Mean procedural recoveries and relative standard deviation (RSD) for the overall recovery of pydiflumetofen from soil samples were 97 ± 11% (n = 16) and 91.8 ± 12.4% (n = 28), for samples analysed at ALS and GPL, respectively.

**Application Rate Verification**
The application verification samples showed that 87.5 ± 28.7% (n = 15) and 84.8 ± 11.9% (n = 15) of target rate was achieved in the bare soil plot for the first (0 DA1A) and second (0 DA2A) applications, respectively. Analysis of the application day soil cores (0 DA1A and 0 DA2A) from the treated bare soil plot, showed application rates of 156 g a.s./ha and 157 g a.s./ha (minus 6 DA1A residues) were achieved, respectively, equivalent to 70.9% and 71.4% of the target rate (220 g a.s./ha).

**Residue Analysis**
Residues of pydiflumetofen in treated plots (mean of three replicates unless otherwise stated) are summarised in the table below. No residues of pydiflumetofen were detected in any controls at or above the limit of detection (LOD, calculated as 0.21 µg/kg for samples analysed by ALS and 0.182 µg/kg for samples analysed by GPL).

In the treated bare soil plot, pydiflumetofen dissipated steadily over the trial period. Maximum mean pydiflumetofen residues were 424 µg/kg in the 0-7.5 cm soil depth at 15 DA2A, which dissipated to 198 µg/kg by the end of the trial (456 DA2A). Quantifiable residues of pydiflumetofen were confined to the 0-30 cm soil depth with minor exceptions; at 270 DA2A when the mean residue in the 30-45 cm layer was slightly above the LOQ (0.602 µg/kg), and on 122 DA2A and 456 DA2A when mean residues of 1.01 and 4.62 µg/kg, respectively, were observed at the 60-75 cm soil depth.

**Table B.8. 161 Residues of pydiflumetofen in Prince Edward Island, Canada soil with depth – Treated bare soil plot (mean values)**

| Scheduled Sampling Event (Actual Sampling Date) | Actual DA1A | Actual DA2A | Pydiflumetofen Mean Residues Found[1, 2] | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | 0-7.5 cm (µg/kg) | 7.5-15 cm (µg/kg) | 15-30 cm (µg/kg) | 30-45 cm (µg/kg) | 45-60 cm (µg/kg) | 60-75 cm (µg/kg) | 75-90 cm (µg/kg) |
| -1 DA1A (07/07/13) | -2 | -9 | -- | -- | <0.5 | <0.5 | NS | NS | NS |
| 0 DA1A (07/09/13) | 0 | -7 | 150 | 7.2 | NS | NS | NS | NS | NS |
| 3 DA1A (07/12/13) | 3 | -4 | 151 | 12.7 | 0.843 | <0.5 | <0.5 | -- | -- |
| 6 DA1A (07/15/13) | 6 | -1 | 179 | 12.1 | 0.569 | <0.5 | <0.5 | -- | -- |
| 0 DA2A (07/16/13) | 7 | 0 | 335 | 36.3 | 0.813 | <0.5 | <0.5 | -- | -- |
| 3 DA2A (07/09/13) | 10 | 3 | 355 | 8.0 | <0.5 | <0.5 | -- | -- | -- |
| 7 DA2A (07/23/13) | 14 | 7 | 382 | 6.87 | 0.648 | <0.5 | <0.5 | -- | -- |
| 14 DA2A (07/31/13) | 22 | 15 | 424 | 4.0 | 0.529 | <0.5 | -- | -- | -- |
| 28 DA2A (08/14/13) | 36 | 29 | 412 | 1.69 | <0.5 | <0.5 | -- | -- | -- |
| 60 DA2A (19/18/13) | 71 | 64 | 404 | 3.78 | <0.5 | <0.5 | -- | -- | -- |
| 90 DA2A (10/15/13) | 98 | 91 | 311 | 2.43 | 0.646 | <0.5 | <0.5 | -- | -- |
| 120 DA2A (11/15/13) | 129 | 122 | 225 | 3.44 | 0.783 | <0.5 | <0.5 | 1.01 | -- |
| 270 DA2A (05/24/14) | 319 | 312 | 254 | 8.72 | 0.935 | 0.602 | <0.5 | <0.5 | -- |
| 360 DA2A (07/22/14) | 378 | 371 | 236 | 4.24 | 3.02 | <0.5 | <0.5 | <0.5 | -- |
| 450 DA2A (10/15/14) | 463 | 456 | 198 | 3.07 | <0.5 | <0.5 | <0.5 | 4.62 | -- |

[1] Mean result of all individual replicate analyses for a given sampling event presented. Residue results reported as dry weight. To calculate the mean pydiflumetofen detected for a given sampling event any individual replicate results that were <0.5 µg/kg (<LOQ) were reported as 0.5 µg/kg if at least one replicate was > LOQ.

[2] Following significant amounts of snow followed by heavy rainfall a number of erosion channels were observed within the bare soil treated plot on May 6, 2014. The last soil sampling event for which data were generated for Replicate C is at 120 days after second application (DA2A) sampling event.

-- = sample not analysed
cm = centimetre(s)
DA1A = days after first application
DA2A = days after second application
LOQ = limit of quantitation (0.5 µg/kg)
ND = not detected
NS = not sampled

**Conclusions**

In the treated bare soil plot, pydiflumetofen dissipated relatively slowly over the trial period (463 days). Maximum mean pydiflumetofen residues were 424 µg/kg in the 0-7.5 cm soil layer at 15 DA2A, which dissipated to 198 µg/kg by the end of the trial (456 DA2A). This represents approximately 53% dissipation over approximately one year and three months. Quantifiable residues of pydiflumetofen were mainly confined to the 0-30 cm soil depth with only minor levels observed sporadically at lower depths.

The calculated DT50 was 356 days and DT90 <10000 days (FOMC).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted] (2019a). SYN545974 - Dissipation of SYN545974 under Field Soil Conditions in Guangxi Nanning, China in 2017/2019 – Final Report; Nanjing Institute of Environmental Sciences (NIES), Ministry of Environmental Protection (MEP) Nanjing 210042, China. Report Number: R2017TFD01-1-FIN. (Syngenta File No. VV-618876) |

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**Guidelines**

The study was designed to comply with the Chinese Regulation Terrestrial Field Dissipation/ Degradation, NY/T 3149-2017. The study was conducted according to the method described in OPPTS 835.6100(2008) and in compliance with the Chinese Pesticide registration test quality management specification (2017).

**GLP**: The study is stated to comply with Chinese GLP regulations. However China is not a member of OECD GLP MAD arrangements. Study facilities do not have accreditation from an OECD GLP authority for the period of the study. HSE have usually not accepted such studies for use in regulatory assessments where compliance with OECD GLP is a requirement. Therefore the study should not be used explicitly for regulatory decision-making.

**Materials and methods**

**Test Material**

**Formulation:** SYN545974 SC (200)
**Product code:** A19649B
**Lot/Batch #:** JHU002-037-001
**Formulation type:** 200 g/L SC formulation

**Test Sites**

The trial was carried out in Nanning, China between 17 May 2017 (first application) and 17 May 2019 (dispatch of last specimens). Details of the test site and soil characteristics of treated and control plots are summarised in the tables below.

**Table B.8. 162 History of test site**

| Site/ Location/ Country | Co-ordinates | Crops grown / Plot history | Pesticides use |
|---|---|---|---|
| Nanning, Test Site of Guangxi university, Qvli, Fusui, China | N:22°34′25.284″ E:107°48′0.172″ | 2014: Corn<br>2015: Banana<br>2016: Banana<br>2017: Fallow | 2014: imidacloprid; acetamiprid<br>2015: chlorothalonil; prochloraz<br>2016: chlorothalonil; prochloraz<br>2017: None |

**Table B.8. 163 Soil characteristics at Nanning, China trial site**

| Parameter | Depth range (cm) | | |
|---|---|---|---|
| | **0-10** | **10-20** | **20-30** |
| Sand (%) | 13.2 | 12.8 | 10.8 |
| Silt (%) | 13.4 | 16.6 | 19.0 |
| Clay (%) | 73.4 | 70.6 | 70.2 |
| Texture (USDA) | Clay | Clay | Clay |
| Organic Carbon (%) | 1.63 | 1.50 | 1.21 |
| Organic Matter (%)[1] | 2.80 | 2.58 | 2.09 |
| Cation Exchange Capacity (meq/100g) | 9.90 | 9.13 | 8.12 |
| pH (in water) | 4.60 | 4.35 | 4.65 |
| Moisture Retention Capacity (% w/w) pF 2 (0-4 cm) | 44.1 | | |

[1] Organic matter (%) = Organic Carbon (%) x 1.7

**Study Design and Methods**

**Experimental Treatment**

The test site consisted of three replicated sub-plots (21.0 x 3.0 m) to give a 63.0 $m^2$ treatment per sub-plot and total 189 $m^2$ treated plot area treatment.

A single spray application of SYN545974 SC (200) was made to bare soil on 17 May 2017, at a target rate of 2.025 L product/ha (equivalent to 405 g a.s./ha) in water at 400 L/ha using a 6 nozzle knapsack sprayer with a boom fitted with Teejet AIXR110025 nozzles producing a flat fan spray pattern.

Bare soil was maintained during the course of the study with applications of glyphosate. The trial plot was irrigated, on months of lower rainfall, to compensate for these drier months. A total of 10 mm irrigation was applied to account for the monthly deficits.

Daily weather data (air temperature, solar radiation, humidity, average wind speed and direction, soil temperature and soil moisture) were recorded daily using a weather station located 5 km from the treated plot.

**Sampling**

Application rates were verified by the collection of samples deposited onto spray deposition collectors (Petri-dishes lined with filter paper, 15 cm diameter) placed onto the soil surface prior to application. After allowing the spray deposit to dry, the Petri-dishes were retrieved from the plot and the filter papers collected for analysis.

Soil samples were obtained from the treated plot for residue analysis on the day of but prior to application. Ten cores were taken immediately after application to a depth of 10 cm from each subplot. Samples were then taken at 7 days, 14 days, 28 days, 56 days, 120 days, 180 days, 273 days, and 365 days after the application. At each sampling intervals ten cores were taken from each subplot to a depth of 0-10 cm (5 cm diameter) and then ten cores were taken from the10-30 cm depth (2.5 cm diameter) using a manual corer.

All samples were placed in a freezer within 3 hours after sampling. Soils samples were frozen (<-18°C) until analysis.

**Description of analytical procedure**

Residues of pydiflumetofen in soil were determined according to Syngenta method GRM061.04A.

Following homogenisation, representative samples (10 g) were extracted with acetonitrile/0.1M ammonium acetate (80:20 v/v, 1 x 40 mL) and acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). The extracts were combined and filtered through filter papers. An aliquot (10 mL) was evaporated to remove acetonitrile and mixed with 1.5 mL of MeOH and diluted with 5 mL 0.1% acetic acid. Samples were analysed using LC-MS/MS. The limit of quantitation (LOQ) was 0.5 µg/kg (µg/kg) and the limit of detection (LOD) was 0.1 µg/kg (µg/kg).

**Results and Discussion**

**Application Verification**

Procedural recoveries (mean ± relative standard deviation) for analysis of pydiflumetofen in soil samples were calculated as 81.9 ± 3.4%.

The day zero recovery in the 0-10 cm soil horizon was 114.1 %. Petri dish filter paper sample analysis showed a mean recovery of 112.1 % of the expected pydiflumetofen residue after treatment. These results verify that the correct rate of formulated pydiflumetofen was applied.

**Application Rate Verification**

The mean calculated application rates of pydiflumetofen derived from the Petri dish filter paper samples was determined as 457.6 ± 22.0 g a.s./ha.

**Residue Analysis**

Residues of pydiflumetofen in the treated plot (mean of treated replicates A, B and C) at each soil depth are summarised in the table below. No residues of pydiflumetofen were detected in any control samples at or above the LOQ.

Dissipation of pydiflumetofen residues occurred steadily over the course of the study, declining in the surface layer (0-10 cm) from 347 µg/kg (mean of three replicates) to 117 µg/kg (mean of three replicates) on Day 727 (maximum 123 µg/kg on Day 548). Pydiflumetofen residues were primarily found in the 0-10 cm soil layer. Residues in the 10-20 cm depths were detected consistently over the study period, typically being 1-2 µg/kg, with a maximum concentration of 12.8 µg/kg (mean of three replicates) recorded on Day 56. Pydiflumetofen residues in the 20-30 cm soil horizon were highest in samples obtained 365 days after the application resulting in 1.5 µg/kg (mean of three replicates).

**Table B.8. 164 Residues of pydiflumetofen in Nanning, China treated soil with depth (values are mean of treated plot replicates expressed on a dry weight basis)**

| Days After First Application | Sample Type | Mean Residues Found (µg/kg, dry weight)[1] | | |
|---|---|---|---|---|
| | | 0-10 cm | 10-20 cm | 20-30 cm |
| 0 | Control | <0.5 | <0.5 | <0.5 |
| 0 | Treated | 347 | NS | NS |
| 7 | Treated | 233 | <0.5 | <0.5 |
| 14 | Treated | 183 | 0.6 | 0.8 |
| 28 | Treated | 193 | 2.1 | 0.7 |
| 56 | Treated | 213 | 12.8 | <0.5 |
| 120 | Treated | 190 | <0.5 | <0.5 |
| 180 | Treated | 130 | <0.5 | <0.5 |
| 273 | Treated | 90 | <0.5 | <0.5 |
| 365 | Treated | 107 | 2.3 | 1.5 |
| 727 | Treated | 117 | 2.5 | 0.5 |

NS = not sampled

<0.5 = residue below the limit of quantitation (LOQ = 0.5 µg/kg)

[1]Mean value of residues from treated plot replicates A, B and C. In some instances, mean values are based on more than three data points, i.e., repeat analysis of individual replicate samples. Mean residue values were calculated in the 0-10, 10-20 and 20-30 cm depths by treating any values equal or below LOQ values as equal to 0.5 µg/kg.

**Conclusions**

Dissipation of pydiflumetofen residues occurred over the course of the study, declining in the surface layer (0-10 cm) from 347 µg/kg (mean of three replicates) to 117 µg/kg (mean of three replicates) on Day 727. This represents approximately 66% dissipation over approximately two years. Pydiflumetofen residues were

primarily found in the 0-10 cm soil layer. Residues in the 10-20 cm depths were detected consistently over the study period, typically being 1-2 µg/kg, with a maximum concentration of 12.8 µg/kg (mean of three replicates) recorded on Day 56. Pydiflumetofen residues in the 20-30 cm soil horizon were highest in samples obtained 365 days after the application resulting in 1.5 µg/kg (mean of three replicates).

The calculated DT50 was 54.4 days and DT90 >10000 days (FOMC).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted] (2019b). SYN545974 - Dissipation of SYN545974 under Field Soil Conditions in Shandong Dezhou, China in 2017/2019; Nanjing Institute of Environmental Sciences (NIES), Ministry of Environmental Protection (MEP) Nanjing 210042, China. Report Number: R2017TFD01-2-FIN. (Syngenta File No. VV-618874) |

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**Guidelines**
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**GLP**: The study is stated to comply with Chinese GLP regulations. However China is not a member of OECD GLP MAD arrangements. Study facilities do not have accreditation from an OECD GLP authority for the period of the study. HSE have usually not accepted such studies for use in regulatory assessments where compliance with OECD GLP is a requirement. Therefore the study should not be used explicitly for regulatory decision-making.

**Materials and methods**
**Test Material**
**Formulation:** SYN545974 SC (200)
**Product code:** A19649B
**Lot/Batch #:** JHU002-037-001
**Formulation type:** 200 g/L SC formulation

**Test Sites**
The trial was carried out in Dezhou, Shandong Province, China between 08 June 2017 (first application) and 11 June 2019 (dispatch of last specimens in 2019). Details of the test site are shown in the table below.

**Table B.8. 165 History of test site**

| Site/ Location/ Country | Co-ordinates | Crops grown / Plot history | Pesticides use |
|---|---|---|---|
| Quanjing family farm, Biaobaosi town, Qihe County, Dezhou City, China | N:36°52′46.51″ W:116°55′11.77″ | 2014: Wheat/Corn<br>2015: Wheat/Corn<br>2016: Wheat/Corn<br>2017: Wheat | 2014: imidacloprid; acetamiprid<br>2015: 2,4-D; tribenuron-methyl; acetamiprid; imidacloprid<br>2016: avermectin; imidacloprid<br>2017: 2,4-D; tribenuron-methyl; acetamiprid |

**Table B.8. 166 Soil characteristics at Dezhou, China trial site**

| Parameter | Depth range (cm) | | |
|---|---|---|---|
| | **0-10** | **10-20** | **20-30** |
| Sand (%) | 30.4 | 22.4 | 23.8 |
| Silt (%) | 53.0 | 60.2 | 58.6 |
| Clay (%) | 16.6 | 17.4 | 17.6 |
| Texture (USDA) | Silt loam | Silt loam | Silt loam |
| Organic Carbon (%) | 1.07 | 0.48 | 0.20 |
| Organic Matter (%)[1] | 1.85 | 0.82 | 0.34 |
| Cation Exchange Capacity (meq/100g) | 8.13 | 7.49 | 5.98 |
| pH (water) | 7.50 | 7.55 | 8.05 |
| Moisture Retention Capacity (% w/w) pF 2 (0-4 cm) | 42 | | |

[1] Organic matter (%) = Organic Carbon (%) x 1.7

**Study Design and Methods**

**Experimental Treatment**

The test site consisted of three replicated sub-plots (21.0 x 3.0 m) to give a 63.0 $m^2$ treatment per sub-plot and total 189 $m^2$ treated plot area treatment.

A single spray application of SYN545974 SC (200) was made to bare soil on 08 June 2017, at a target rate of 2.025 L product/ha (equivalent to 405 g a.s./ha) in water at 400 L/ha using a 6 nozzle knapsack sprayer with a boom fitted with Teejet AIXR110025 nozzles producing a flat fan spray pattern.

Bare soil was maintained during the course of the study with applications of glyphosate. The trial plot was irrigated, on months of lower rainfall, to compensate for these drier months. A total 10 mm irrigation was applied to account for the monthly deficits.

Daily weather data (air temperature, solar radiation, humidity, average wind speed and direction, soil temperature and soil moisture) were recorded daily using a weather station located 5 km from the treated plot.

**Sampling**

Application rates were verified by the collection of samples deposited onto spray deposition collectors (Petri-dishes lined with filter paper, 15 cm diameter) placed onto the soil surface prior to application. After allowing the spray deposit to dry, the Petri-dishes were retrieved from the plot and the filter papers collected for analysis.

Soil samples were obtained from the treated plot for residue analysis on the day of, but prior to, application. Ten cores were taken immediately after application to a depth of 10 cm from each subplot. Samples were then taken at 7 days, 14 days, 28 days, 60 days, 126 days, 179 days, 277 days, 370 days, 558 days and 733 days after the application. At each sampling intervals ten cores were taken from each subplot to a depth of 0-10 cm (5 cm diameter) and then ten cores were taken from the 10-30 cm depth (2.5 cm diameter) using a manual corer.

All samples were placed in a freezer within 3 hours after sampling. Soils samples were frozen (<-18°C) until analysis.

**Description of analytical procedure**

Residues of pydiflumetofen in soil were determined according to Syngenta method GRM061.04A.

Following homogenisation, representative samples (10 g) were extracted with acetonitrile/0.1M ammonium acetate (80:20 v/v, 1 x 40 mL) and acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). The extracts were combined and filtered through filter papers. An aliquot (10 mL) was evaporated to remove acetonitrile and mixed with 1.5 mL of MeOH and diluted with 5 mL 0.1% acetic acid. Samples were analysed using LC-MS/MS. The limit of quantitation (LOQ) was 0.5 ppb (µg/kg) and the limit of detection (LOD) was 0.1 ppb (µg/kg).

**Results and Discussion**

**Analytical Method Performance**

Procedural recoveries (mean ± relative standard deviation) for analysis of pydiflumetofen in soil samples were calculated as 81.9 ± 3.4%.

The day zero recovery in the 0-10 cm soil horizon was 92.0 %. Petri dish filter paper sample analysis showed a mean recovery of 95.7 % of the expected pydiflumetofen residue after treatment. These results verify that the correct rate of formulated pydiflumetofen was applied.

**Application Rate Verification**

The mean calculated application rates of pydiflumetofen derived from the Petri dish filter paper samples was determined as 377.5 ± 34.8 g a.s./ha.

**Residue Analysis**

Residues of pydiflumetofen in the treated plot (mean of treated replicates A, B and C) at each soil depth are summarised in the table below. No residues of pydiflumetofen were detected in any control samples at or above the LOQ.

Dissipation of pydiflumetofen residues occurred steadily over the course of the study, declining in the surface layer (0-10 cm) from 253 µg/kg (mean) to 46.3 µg/kg (mean) on Day 733. Pydiflumetofen residues were primarily found in the 0-10 cm soil layer. Pydiflumetofen residues in the 10-20 cm soil horizon were highest in samples obtained 126 days after the application resulting in 11.1 µg/kg (mean of three replicates). No residues above the limit of quantification (LOQ) was observed in the 20-30 cm soil horizon over the course of the trial (733 days).

**Table B.8. 167 Residues of pydiflumetofen in Dezhou, China treated soil with depth (values are mean of treated plot replicates expressed on a dry weight basis)**

| Days After First Application | Sample Type | Mean Residues Found (µg/kg, dry weight)[1] | | |
|---|---|---|---|---|
| | | 0-10 cm | 10-20 cm | 20-30 cm |
| 0 | Control | <0.5 | <0.5 | <0.5 |
| 0 | Treated | 253 | NS | NS |
| 7 | Treated | 220 | 7.7 | <0.5 |
| 14 | Treated | 200 | 2.7 | <0.5 |
| 28 | Treated | 160 | <0.5 | <0.5 |
| 60 | Treated | 137 | <0.5 | <0.5 |
| 126 | Treated | 113 | 10.3 | <0.5 |
| 179 | Treated | 103 | <0.5 | <0.5 |
| 277 | Treated | 107 | 6.0 | <0.5 |
| 370 | Treated | 120 | 1.0 | <0.5 |
| 558 | Treated | 82 | 0.8 | <0.5 |
| 733 | Treated | 46.3 | 1.8 | <0.5 |

NS = not sampled

<0.5 = residue below the limit of quantitation (LOQ = 0.5 µg/kg)

[1]Mean value of residues from treated plot replicates A, B and C. In some instances, mean values are based on more than three data points, i.e., repeat analysis of individual replicate samples. Mean residue values were calculated in the 0-10, 10-20 and 20-30 cm depths by treating any values equal or below LOQ values as equal to 0.5 µg/kg.

**Conclusions**

Dissipation of pydiflumetofen residues occurred over the course of the study, declining in the surface layer (0-10 cm) from 253 µg/kg (mean) to 46.3 µg/kg (mean) on Day 733. This represent approximately 82% dissipation in the top most layer in the approximate two year duration of the study. Pydiflumetofen residues were primarily found in the 0-10 cm soil layer. Pydiflumetofen residues in the 10-20 cm soil horizon were highest in samples obtained 126 days after the application resulting in 10.3 µg/kg (mean of three replicates). No residues above the limit of quantification (LOQ) was observed in the 20-30 cm soil horizon over the course of the study.

The calculated DT50 was 64.6 days and DT90 2680 days (DFOP).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted] (2019c). SYN545974 - Dissipation of SYN545974 under Field Soil Conditions in Jiangsu Nanjing, China in 2017/2019 – Final Report; Nanjing Institute of Environmental Sciences (NIES), Ministry of Environmental Protection (MEP) Nanjing 210042, China. Report Number: R2017TFD01-3-FIN. (Syngenta File No. VV-618875) |

**THE STUDY IS NOT CONSIDERED TO BE REPRESENTATIVE OF EUROPEAN CONDITIONS AND IS NOT USED FOR RISK ASSESSMENT PURPOSES. THE STUDY IS PRESENTED FOR INFORMATION ONLY.**

**Guidelines**
The study was designed to comply with the Chinese Regulation Terrestrial Field Dissipation/ Degradation, NY/T 3149-2017 and was conducted according to the method described in OPPTS 835.6100(2008) and in compliance with the Chinese Pesticide registration test quality management specification (2017).

**GLP:** The study is stated to comply with Chinese GLP regulations. However China is not a member of OECD GLP MAD arrangements. Study facilities do not have accreditation from an OECD GLP authority for the period of the study. HSE have usually not accepted such studies for use in regulatory assessments where compliance with OECD GLP is a requirement. Therefore the study should not be used explicitly for regulatory decision-making.

**Materials and methods**
**Test Material**
**Formulation:** SYN545974 SC (200)
**Product code:** A19649B
**Lot/Batch #:** JHU002-037-001
**Formulation type:** 200 g/L SC formulation

**Test Sites**
The trial was carried out in Nanjing, Jiangsu Province, China between 04 August 2017 (first application) and 25 July 2019 (dispatch of last specimens in 2019). Details of the test site are shown in the table below.

**Table B.8. 168 History of Nanjing, China test site**

| Site/ Location/ Country | Co-ordinates | Crops grown / Plot history | Pesticides use |
|---|---|---|---|
| Nanjing Institute of Vegetable Science / Jiangsu Province, Hengxi / China | N:118°46′15.58″ E:31°43′14.20″ | 2013: Fallow<br>2014: Rice<br>2015: Rice<br>2016: Fallow<br>2017: Fallow | 2013: None<br>2014: chlorpyrifos; avermectin; imidacloprid; indoxacarb<br>2015: chlorpyrifos; avermectin; imidacloprid; indoxacarb<br>2016: None<br>2017: None |

**Table B.8. 169 Soil characteristics at Nanjing, China trial site**

| Parameter | Depth range (cm) | | |
|---|---|---|---|
| | 0-10 | 10-20 | 20-30 |
| Sand (%) | 8.4 | 9.6 | 10.0 |
| Silt (%) | 63.8 | 65.2 | 64.6 |
| Clay (%) | 27.8 | 25.2 | 25.4 |
| Texture (USDA) | Silty loam | Silty loam | Silty loam |

| | | | |
|---|---|---|---|
| Organic Carbon (%) | 1.07 | 0.84 | 0.71 |
| Organic Matter (%)[1] | 1.84 | 1.45 | 1.23 |
| Cation Exchange Capacity (meq/100g) | 11.95 | 10.29 | 9.18 |
| pH (in water) | 6.85 | 6.85 | 6.55 |
| Moisture Retention Capacity (% w/w) pF 2 (0-4 cm) | 0.418 | | |

[1] Organic matter (%) = Organic Carbon (%) x 1.7

**Study Design and Methods**

**Experimental Treatment**

The test site consisted of three replicated sub-plots (21.0 x 3.0 m) to give a 63.0 $m^2$ treatment per sub-plot and total 189 $m^2$ treated plot area treatment.

A single spray application of SYN545974 SC (200) was made to bare soil on 17 May 2017, at a target rate of 2.025 L product/ha (equivalent to 405 g a.s./ha) in water at 400 L/ha using a 6 nozzle knapsack sprayer with a boom fitted with Teejet AIXR110025 nozzles producing a flat fan spray pattern.

Bare soil was maintained during the course of the study with applications of glyphosate.

Daily weather data (air temperature, solar radiation, humidity, average wind speed and direction, soil temperature and soil moisture) were recorded daily using a weather station located 5 km from the treated plot.

**Sampling**

Application rates were verified by the collection of samples deposited onto spray deposition collectors (Petri-dishes lined with filter paper, 15 cm diameter) placed onto the soil surface prior to application. After allowing the spray deposit to dry, the Petri-dishes were retrieved from the plot and the filter papers collected for analysis.

Soil samples were obtained from the treated plot for residue analysis on the day of, but prior to, application. Ten cores were taken immediately after application to a depth of 10 cm from each subplot. Samples were then taken at 7 days, 14 days, 27 days, 64 days, 119 days, 183 days, 273 days, 371 days, 557 days and 720 days after application. At each sampling intervals ten cores were taken from each subplot to a depth of 0-10 cm (5 cm diameter) and then ten cores were taken from the10-30 cm depth (2.5 cm diameter) using a manual corer.

All samples were placed in a freezer within 3 hours after sampling. Soils samples were frozen (<-18°C) until analysis.

**Description of analytical procedure**

Residues of pydiflumetofen in soil were determined according to Syngenta method GRM061.04A. Following homogenisation, representative samples (10 g) were extracted with acetonitrile/0.1M ammonium acetate (80:20 v/v, 1 x 40 mL) and acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). The extracts were combined and filtered through filter papers. An aliquot (10 mL) was evaporated to remove acetonitrile and mixed with 1.5 mL of MeOH and diluted with 5 mL 0.1% acetic acid. Samples were analysed using LC-MS/MS. The limit of quantitation (LOQ) was 0.5 ppb (µg/kg) and the limit of detection (LOD) was 0.1 ppb (µg/kg).

**Results and Discussion**

**Analytical Method Performance**

Procedural recoveries (mean ± relative standard deviation) for analysis of pydiflumetofen in soil samples were calculated as 81.9 ± 3.4%.

The day zero recovery in the 0-10 cm soil horizon was 113.3%. Petri dish filter paper sample analysis showed a mean recovery of 115.3% of the expected pydiflumetofen residue after treatment. These results verify that the correct rate of formulated pydiflumetofen was applied.

**Application Rate Verification**

The mean calculated application rates of pydiflumetofen derived from the Petri dish filter paper samples was determined as 466.9 ± 19.3 g a.s./ha.

**Residue Analysis**

Residues of pydiflumetofen in the treated plot (mean of treated replicates A, B and C) at each soil depth are summarised in the table below. No residues of pydiflumetofen were detected in any control samples at or above the LOQ.

Dissipation of pydiflumetofen residues occurred steadily over the course of the study, declining in the surface layer (0-10 cm) from 343 µg/kg (mean) to 60 µg/kg (mean) on Day 720. Pydiflumetofen residues were primarily found in the 0-10 cm soil layer. Pydiflumetofen residues in the 10-20 cm soil horizon were highest in samples obtained 7 days after the application resulting in 40 µg/kg (mean of three replicates). The maximum concentration of pydiflumetofen residues in the 20-30 cm depth were obtained 273 days after application resulting in 1 µg/kg (mean of three replicates).

**Table B.8. 170 Residues of pydiflumetofen in Nanjing, China treated soil with depth (values are mean of treated plot replicates expressed on a dry weight basis)**

| Days After First Application | Sample Type | Mean Residues Found (µg/kg, dry weight)[1] | | |
|---|---|---|---|---|
| | | 0-10 cm | 10-20 cm | 20-30 cm |
| 0 | Control | <0.5 | <0.5 | <0.5 |
| 0 | Treated | 343 | NS | NS |
| 7 | Treated | 303 | 40 | <0.5 |
| 14 | Treated | 227 | <0.5 | <0.5 |
| 27 | Treated | 223 | <0.5 | <0.5 |
| 64 | Treated | 130 | <0.5 | <0.5 |
| 119 | Treated | 93 | <0.5 | <0.5 |
| 183 | Treated | 80 | <0.5 | <0.5 |
| 273 | Treated | 100 | 4.0 | 1.0 |
| 371 | Treated | 97 | 1.8 | <0.5 |
| 557 | Treated | 93 | 2.2 | <0.5 |
| 720 | Treated | 60 | 2.7 | <0.5 |

NS = not sampled
<0.5 = residue below the limit of quantitation (LOQ = 0.5 µg/kg)
[1]Mean value of residues from treated plot replicates A, B and C. In some instances, mean values are based on more than three data points, i.e., repeat analysis of individual replicate samples. Mean residue values were calculated in the 0-10, 10-20 and 20-30 cm depths by treating any values equal or below LOQ values as equal to 0.5 µg/kg.

**Conclusions**

Dissipation of pydiflumetofen residues occurred over the course of the study, declining in the surface layer (0-10 cm) from 343 µg/kg (mean) to 60 µg/kg (mean) on Day 720. This represents approximately 82% dissipation over the two year period of the study. Pydiflumetofen residues were primarily found in the 0-10 cm soil layer. Pydiflumetofen residues in the 10-20 cm soil horizon were highest in samples obtained 7 days after the application resulting in 40 µg/kg (mean of three replicates). The maximum concentration of pydiflumetofen residues in the 20-30 cm depth were obtained 273 days after application resulting in 1 µg/kg (mean of three replicates).

The calculated DT50 was 37.7 days and DT90 3150 days (DFOP).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted] (2019). SYN545974 – Dissipation of SYN545974 under Field Soil Conditions in Shanxi Yangling, China in 2017/2019 – Final report. Institute of plant protection, Chinese Academy of Agricultural Sciences (IPPC) Beijing 100193, China. Report Number IPPC-EA-17-A-034-9. (Syngenta File No. VV-618873) |

**THE STUDY IS NOT CONSIDERED TO BE REPRESENTATIVE OF EUROPEAN CONDITIONS AND IS NOT USED FOR RISK ASSESSMENT PURPOSES. THE STUDY IS PRESENTED FOR INFORMATION ONLY.**

**Guidelines**

Chinese Chemical Pesticide Guideline for Terrestrial Field Dissipation/Degradation. NY/T3149-2017.

**GLP**: The study is stated to comply with Chinese GLP regulations. However China is not a member of OECD GLP MAD arrangements. Study facilities do not have accreditation from an OECD GLP authority for the period of the study. HSE have usually not accepted such studies for use in regulatory assessments where compliance with OECD GLP is a requirement. Therefore the study should not be used explicitly for regulatory decision-making.

**Materials and methods**
**Test Material**

**Test item:** SYN545974 SC (200)
**Description:** 200 g/L SC formulation
**Formulation No:** A19649B
**Lot/Batch #:** JHU002-037-001
**Purity:** 18.3 % w/w

**Test Sites**
A field trial site was selected in Yangling, Shanxi Province, China. Details of the test site are shown in the table below.

**Table B.8. 171 History of Yangling, China test site**

| Site/ Location/ Country | Co-ordinates | Crops grown / Plot history (2014-2017) | Pesticides use (2014-2017) |
|---|---|---|---|
| Yangling / Xian Yang / China | N:34°29′77.10″ W:108°07′65.82″ | Wheat, cabbage | Chlorfenapyr, imidacloprid, lambda-cyhalotrhin, avermectins, emamectin, clodinafop-propargyl, pymetrozine |

**Table B.8. 172 Soil characteristics at Yangling, China trial site**

| Parameter | Depth range (cm) | | |
|---|---|---|---|
| | **0-10** | **10-20** | **20-30** |
| Sand (%) | 21.1 | 17.1 | 5.1 |
| Silt (%) | 60.0 | 56.0 | 64.0 |
| Clay (%) | 18.9 | 26.9 | 30.9 |
| Texture | Silty loam | Silty loam | Silty clay loam |
| Organic Carbon (%) | 0.59 | | |
| Organic Matter (%) | 1.01 | | |
| Cation Exchange Capacity (cmol/kg(+)) | 14.6 | | |
| pH ($H_2O$) | 8.19 | | |
| Water holding capacity (%w/w)<br>pF 2<br>pF 2.5<br>pF 4.0 | <br>43.0<br>39.3<br>33.9 | <br>37.6<br>36.2<br>29.5 | <br>35.6<br>31.5<br>27.2 |
| Bulk Density (g/L) | 1102 | | |

**Study Design and Methods**
**Experimental Treatment**
The test site consisted of one treated plot (202.5 $m^2$) which was divided into 3 sub-plots (22.5 x 3 m). Pydiflumetofen was applied as A19649B, a 200 g/L SC formulation, to bare soil on 18 June 2016, at a target rate of 405 g a.s./ha, using a 6 nozzle knapsack sprayer. Bare soil was maintained during the course of the study with glyphosate. Irrigation was applied to the test site on 3 occasions (2, 8 and 16 July 2017) with 4.44 mm applied at each event.

Daily weather data (air temperature, humidity, precipitation and wind speed) were recorded using a weather station located 10 m from the treated plot. Daily soil temperatures and moistures were recorded using duplicate soil probes installed at a 10 cm depth in the control plots.

**Sampling**
Application rates were verified by the collection of samples deposited on five filter papers (within a petri-dish, 15 cm diameter) placed onto the soil surface in each subplot prior to application.

Soil cores were obtained prior to the test item application, immediately after application and then on eleven subsequent days up to 730 days after application (DAA). At each sampling interval, ten cores were taken from each sub-plot to a depth of 0-10 cm (5 cm diameter) and 10-30 cm (2.5 cm diameter). Soil cores were divided into 10 cm profiles and samples from corresponding soil depths were combined for each sub-plot.

Soil samples were freeze dried (72 h at ≤ -40 °C and <20 Pa) and stored frozen for up to 432 days prior to analysis.

**Description of analytical procedure**
Residues of pydiflumetofen in soil were determined according to Syngenta method GRM061.04A.

Following homogenisation, representative samples (10 g) were extracted with acetonitrile/0.1M ammonium acetate (80:20 v/v, 1 x 40 mL) and acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 30 mL). Extracts were combined and filtered. An aliquot (10 mL) was evaporated to remove acetonitrile, and mixed with 1 mL 0.1% acetic acid. Sample extracts were cleaned using SPE (Cleanert S C18), rinsed with methanol/0.1% acetic acid (60:40 v/v, 1 x 2.5 mL) and eluted with methanol/0.1% acetic acid (60:40 v/v, 1 x 2 mL) and methanol (1 x 3 mL). The eluates were evaporated to remove methanol and the residue reconstituted with 1.5 mL methanol and diluted to 5 mL with 0.1% acetic acid. Samples were analysed using LC-MS/MS. The limit of quantification (LOQ) was 0.005 mg/kg and the limit of detection (LOD) was 0.0000263 mg/kg.

**Results and Discussion**

**Analytical Method Performance**

Overall, procedural recoveries (mean ± standard deviation) for the analysis of pydiflumetofen in the soil samples were 97.4 ± 7.0%.

**Application Rate Verification**

The mean calculated application rate of pydiflumetofen derived from the filter paper samples was 96.7% of the target rate (range 94.1-98.3%).

**Residue Analysis**

Residues of pydiflumetofen in the treated plot at each soil depth are summarised in the table below. No residues of pydiflumetofen above the LOQ were determined in any of the soil sub-samples taken at 0 days before application (0 DBA), which were regarded as untreated (control) specimens. Pydiflumetofen dissipated from soil over the course of the study. Mean residues of pydiflumetofen in the 0-10 cm soil core depths were 241.3 µg/kg at 0 DAA, declining to 24.4 µg/kg at 730 DAA. Pydiflumetofen residues were confined to the 0-10 cm soil layer. Pydiflumetofen residues were below the LOQ in all 10-20 cm and 20-30 cm soil samples at all sampling intervals.

**Table B.8. 173 Residues of pydiflumetofen in Yangling, China treated soil with depth**

| Sampling interval | Sample type | Sub-plot | Pydiflumetofen Residues (mg/kg, dry weight) | | |
|---|---|---|---|---|---|
| | | | 0-10 cm | 10-20 cm | 20-30 cm |
| 0 DBA | Control | A | <0.005 | <0.005 | <0.005 |
| | | B | <0.005 | <0.005 | <0.005 |
| | | C | <0.005 | <0.005 | <0.005 |
| | | Mean | <0.005 | <0.005 | <0.005 |
| 0 DAA | Treated | A | 0.230 | n.a | n.a |
| | | B | 0.264 | n.a | n.a |
| | | C | 0.230 | n.a | n.a |
| | | Mean | 0.241 | n.a | n.a |
| 7 DAA | Treated | A | 0.308 | <0.005 | <0.005 |
| | | B | 0.305 | <0.005 | <0.005 |
| | | C | 0.316 | <0.005 | <0.005 |
| | | Mean | 0.310 | <0.005 | <0.005 |
| 14 DAA | Treated | A | 0.167 | <0.005 | <0.005 |
| | | B | 0.166 | <0.005 | <0.005 |
| | | C | 0.232 | <0.005 | <0.005 |
| | | Mean | 0.188 | <0.005 | <0.005 |
| 28 DAA | Treated | A | 0.180 | <0.005 | <0.005 |
| | | B | 0.101 | <0.005 | <0.005 |
| | | C | 0.125 | <0.005 | <0.005 |
| | | Mean | 0.135 | <0.005 | <0.005 |
| 61 DAA | Treated | A | 0.158 | <0.005 | <0.005 |
| | | B | 0.113 | <0.005 | <0.005 |
| | | C | 0.0981 | <0.005 | <0.005 |
| | | Mean | 0.123 | <0.005 | <0.005 |
| 123 DAA | Treated | A | 0.161 | <0.005 | <0.005 |
| | | B | 0.107 | <0.005 | <0.005 |
| | | C | 0.0858 | <0.005 | <0.005 |
| | | Mean | 0.118 | <0.005 | <0.005 |
| 183 DAA | Treated | A | 0.140 | <0.005 | <0.005 |
| | | B | 0.0964 | <0.005 | <0.005 |
| | | C | 0.0739 | <0.005 | <0.005 |
| | | Mean | 0.103 | <0.005 | <0.005 |
| 271 DAA | Treated | A | 0.113 | <0.005 | <0.005 |
| | | B | 0.0822 | <0.005 | <0.005 |
| | | C | 0.0617 | <0.005 | <0.005 |
| | | Mean | 0.0856 | <0.005 | <0.005 |
| 367 DAA | Treated | A | 0.0559 | <0.005 | <0.005 |
| | | B | 0.0474 | <0.005 | <0.005 |
| | | C | 0.0448 | <0.005 | <0.005 |
| | | Mean | 0.0494 | <0.005 | <0.005 |
| 499 DAA | Treated | A | 0.0361 | <0.005 | <0.005 |
| | | B | 0.0361 | <0.005 | <0.005 |
| | | C | 0.0371 | <0.005 | <0.005 |
| | | Mean | 0.0364 | <0.005 | <0.005 |
| 676 DAA | Treated | A | 0.0268 | <0.005 | <0.005 |
| | | B | 0.0295 | <0.005 | <0.005 |
| | | C | 0.0287 | <0.005 | <0.005 |
| | | Mean | 0.0283 | <0.005 | <0.005 |
| 730 DAA | Treated | A | 0.0287 | <0.005 | <0.005 |
| | | B | 0.0224 | <0.005 | <0.005 |
| | | C | 0.0222 | <0.005 | <0.005 |
| | | Mean | 0.0244 | <0.005 | <0.005 |

DBA = days before application
DAA = days after application
n.a = not analysed
<0.005 = residue below the limit of quantitation (LOQ)

**Conclusions**
pydiflumetofen dissipated from soil over the course of the study. Mean residues of pydiflumetofen in the 0-10 cm soil core depths were 241.3 µg/kg at 0 DAA, declining to 24.4 µg/kg at 730 DAA. This represents approximately 90% dissipation over the approximately 2 year study duration. Pydiflumetofen residues were confined to the 0-10 cm soil layer. Pydiflumetofen residues were below the LOQ in all 10-20 cm and 20-30 cm soil samples at all sampling intervals.

The calculated DT50 was 68.8 days and DT90 3070 days (DFOP).

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted] (2017). Pydiflumetofen residue study in upland soil in South Korea in 2016-2017, Shinseong NB Research Centre, South Korea. Report No. SE-R16-098. (Syngenta File No. VV-471035) |

**THE STUDY IS NOT CONSIDERED TO BE REPRESENTATIVE OF EUROPEAN CONDITIONS AND IS NOT USED FOR RISK ASSESSMENT PURPOSES. THE STUDY IS PRESENTED FOR INFORMATION ONLY.**

**Guidelines**:
Not reported.

**GLP**: No. The analytical laboratory has South Korean government accreditation. As no GLP compliance is claimed the study should not be used explicitly for regulatory decision-making.

**Materials and methods**
**Test Material**
**Formulation:** Pydiflumetofen 18.35% SC
**Lot/Batch #:** Not reported.
**Formulation type:** soluble concentrate
**Purity:** 18.35% w/w (nominal)

**Test Sites**
Field dissipation trials were carried out at two upland sites in South Korea: Suwon (Suwon), Kyeonggi-do and BuYeo (Bu Yeo), Chungcheongham-do. Soil characteristics at the sites are summarised in the table below.

**Table B.8. 174 Soil characteristics at the trial site**

| Soil | pH (1:5)* | CEC (meq/100 g) | O.M. (%) | Sand (%) | Silt (%) | Clay (%) | Soil texture |
|---|---|---|---|---|---|---|---|
| Suwon | 4.3 | 8.9 | 10.9 | 57.1 | 36.1 | 6.8 | Sandy loam |
| Bu Yeo | 7.7 | 25.4 | 40.0 | 73.6 | 17.0 | 9.4 | Sandy loam |

**Study Design and Methods**
At both sites, Pydiflumetofen 18.35% SC was applied to bare soil at two application rates: 0.2 kg a.s./ha (application X1) and 0.4 kg a.s./ha (application X2). Single applications at each rate were applied to separate plots on 11 July 2016. Soils samples (three replicates) were taken at 0, 14, 30, 70, 119, 274 and 367 days after treatment. Soils were analysed for the active substance, pydiflumetofen, using LC-MS/MSD at Shinseong NB Research Center. The limit of quantification (LOQ) was 0.005 mg/kg.

**Results and Discussion**

Residues of pydiflumetofen in soils 1 and 2 are summarised in the tables below. No residues of pydiflumetofen were detected in untreated control samples at either site, at or above the LOQ.

At both sites, and at both application rates, pydiflumetofen dissipated steadily over the study period. In Suwon (Suwon), pydiflumetofen residues declined to 31% and 23% (mean values) of the initial concentrations (0 days after treatment) by the final sampling interval (day 367), for the X1 and X2 applications, respectively. In Bu Yeo (BuYeo), pydiflumetofen residues declined to 26% and 38% (mean values) of the initial concentrations (0 days after treatment) by the final sampling interval (day 367), for the X1 and X2 applications, respectively.

**Table B.8. 175 Residues of pydiflumetofen in Suwon (Suwon) following a single application of Pydiflumetofen 18.35% SC**

| Sampling interval (days after last treatment) | Residue (mg/kg) | | | |
|---|---|---|---|---|
| | Replicate 1 | Replicate 2 | Replicate 3 | Mean |
| **X1 application** | | | | |
| 0 | 0.138 | 0.165 | 0.184 | 0.162 |
| 14 | 0.134 | 0.102 | 0.132 | 0.123 |
| 30 | 0.100 | 0.111 | 0.113 | 0.108 |
| 70 | 0.109 | 0.079 | 0.110 | 0.099 |
| 119 | 0.108 | 0.074 | 0.074 | 0.085 |
| 274 | 0.063 | 0.071 | 0.050 | 0.061 |
| 367 | 0.051 | 0.038 | 0.060 | 0.050 |
| **X2 application** | | | | |
| 0 | 0.411 | 0.317 | 0.232 | 0.320 |
| 14 | 0.245 | 0.240 | 0.202 | 0.229 |
| 30 | 0.172 | 0.206 | 0.232 | 0.203 |
| 70 | 0.212 | 0.198 | 0.186 | 0.199 |
| 119 | 0.186 | 0.170 | 0.143 | 0.166 |
| 274 | 0.112 | 0.143 | 0.126 | 0.127 |
| 367 | 0.069 | 0.072 | 0.074 | 0.072 |

**Table B.8. 176 Residues of pydiflumetofen in Bu Yeo (BuYeo) following a single application of Pydiflumetofen 18.35% SC**

| Sampling interval (days after last treatment) | Residue (mg/kg) | | | |
|---|---|---|---|---|
| | Replicate 1 | Replicate 2 | Replicate 3 | Mean |
| **X1 application** | | | | |
| 0 | 0.171 | 0.171 | 0.234 | 0.192 |
| 14 | 0.131 | 0.226 | 0.118 | 0.158 |
| 30 | 0.126 | 0.140 | 0.100 | 0.122 |
| 70 | 0.107 | 0.100 | 0.087 | 0.098 |
| 119 | 0.099 | 0.100 | 0.056 | 0.085 |
| 274 | 0.081 | 0.049 | 0.083 | 0.071 |
| 367 | 0.034 | 0.046 | 0.068 | 0.049 |
| **X2 application** | | | | |
| 0 | 0.375 | 0.327 | 0.319 | 0.340 |
| 14 | 0.264 | 0.301 | 0.311 | 0.292 |
| 30 | 0.237 | 0.245 | 0.258 | 0.247 |
| 70 | 0.210 | 0.206 | 0.229 | 0.215 |
| 119 | 0.214 | 0.192 | 0.208 | 0.205 |
| 274 | 0.126 | 0.155 | 0.186 | 0.156 |
| 367 | 0.149 | 0.140 | 0.101 | 0.130 |

**Conclusions**

Pydiflumetofen dissipated steadily over 367 days at two upland bare soil field sites in South Korea. Separate kinetic calculations were performed for the individual dosing rates at each site. The following DT50s and DT90s were calculated.

**Table B.8. 177 DT50 and DT90 values for the Suwon and BuYeo S. Korean field dissipation sites**

| Site | Application dose | DT50 | DT90 | Kinetics |
|---|---|---|---|---|
| Suwon | x1 | 150 | 856 | DFOP |
| Suwon | x2 | 137 | 749 | DFOP |
| Bu Yeo | x1 | 73.5 | 948 | DFOP |
| Bu Yeo | x2 | 211 | 1190 | DFOP |

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1. [redacted] (2016). Dissipation study of pydiflumetofen in soils [Field Study under the upland Field condition]. Syngenta Japan K, Tokyo, Japan. Report No. Soil28P-2-05. (Syngenta File No. VV-471034) |

**THE STUDY IS NOT CONSIDERED TO BE REPRESENTATIVE OF EUROPEAN CONDITIONS AND IS NOT USED FOR RISK ASSESSMENT PURPOSES. THE STUDY IS PRESENTED FOR INFORMATION ONLY.**

**Guidelines**:
Not reported.

**GLP**: Not reported. The applicant stated that the study is not compliant with GLP as the Japanese regulatory authority has no requirement for field dissipation studies to be GLP compliant. Therefore the study should not be used explicitly for regulatory decision-making.

**Materials and methods**
**Test Material**
**Formulation:** Pydiflumetofen 20.0%
**Product code:** SYN545974 (SYJ-264) SC
**Lot/Batch #:** CWA002-078-001
**Formulation type:** Wettable powder (flowable)
**Purity:** 20.0% w/v

**Test Sites**
Field trials were carried out at Ibaraki Research Institute, Japan Plant Protection Association and Noichi-cho, Konan-shi, Kochi, Japan Field of Kochi Experiment Station, Japan Plant Protection Association. Soil characteristics at the sites are summarised in the table below.

**Table B.8. 178 Soil characteristics at the trial sites**

| Soil | pH | CEC (meq/100 g) | OC (%) | Sand (%) | Silt (%) | Clay (%) | Maximum Water Holding Capacity (g/kg) | Soil origin | Soil texture (USDA) |
|---|---|---|---|---|---|---|---|---|---|
| Ibaraki | 6.6 ($H_2O$), 5.6 (KCl) | 29.2 | 38.7 | 37.0 | 33.7 | 22.9 | 1140 | Volcanic ash soil | Loam |
| Kochi | 6.2 ($H_2O$), 4.8 (KCl) | 15.0 | 16.9 | 40.9 | 40.3 | 18..8 | 525 | Alluvial Soil | Loam |

It is noted that the Ibaraki soil is a volcanic soil. As such the results from this soil/site cannot be used. European guidance retained for GB assessments indicates that volcanic soils are excluded because their chemical and physical properties differ substantially from those of temperate mineral soils (e.g. their colloids are variably charged, having a positive charge at low pH and a negative charge at high pH and they have a lower bulk density and a higher hydraulic conductivity than most mineral soils).

**Study Design and Methods**
**Experimental Treatment**

For both Ibaraki and Kochi fields, a 1500 fold dilution of the pydiflumetofen flowable formulation was applied twice to bare soil at the application rate of 150 L/10 a (200 g pydiflumetofen/ha). The target volume of the test substance solution was uniformly sprayed using a knapsack power sprayer and hand boom nozzles. For Ibaraki fields application of the test substance was performed during May 12 and 19, 2015. While Kochi fields received application of the test substance on May 26 and June 2, 2015. Soils samples were taken immediately before and after application and at 3, 7, 14, 30, 62, 120, 180, 240 and 359 days after final application for the Ibaraki site. While for the Kochi site samples were collected immediately before and after application, 3, 7, 14, 30, 62, 120, 181, 240 and 359 days after final application. Soils were analysed for the active substance, pydiflumetofen, using LC-MS/MSD. The limit of quantification (LOQ) was 0.01 mg/kg (spiked experiment).

Daily weather data were recorded at each site. Rainfall measurements were obtained from a rain gauge located approximately within 2 km from both test sites.

**Sampling**
At both facilities, each test plot was divided into 8 areas. One columnar soil sample was collected from one arbitrary point in each area by inserting a borer to the depth of 10 cm. The columnar soils from each area were combined and mixed to make one sample.

Immediately after arrival, the coarse organic matters and gravels were removed from the soil sample. The soil was then passed through a 5-mm mesh. After measuring the water content, the sieved sample was stored in a freezer at -20°C until analysis, a maximum of 14 days later.

Samples from both sites were tested for frozen storage stability over a period of 14 days and showed a mean recovery percentage of 100% and 98%; for Ibaraki and Kochi respectively.

**Description of analytical procedure**

At both facilities, soil samples were analysed for the parent substance, pydiflumetofen, using Syngenta method GRM061.04A.

Soil sub-samples (20 g) were extracted with acetonitrile/0.1M ammonia acetate aqueous solution (80:20 v/v, 1 x 80 mL) before being filtrated through Celite. The precipitate was further extracted with acetonitrile/0.1% acetic acid (80:20 v/v, 2 x 60 mL). Both extracts were combined and diluted (ca. 200 mL) before being further purified using an Oasis HLB cartridge column. The column was preconditioned with 10 mL of water/acetonitrile (6:4, v/v) and then pydiflumetofen was eluted with 10 mL of acetonitrile which achieved good recoveries. The eluate is concentrated by rotary-evaporation (in a water bath at below 40°C) and then evaporated to dryness under the stream of nitrogen gas. Samples were reconstituted in water/acetonitrile (1:1, v/v) before being analysed by LC/MS/MS.

**Table B.8. 179 Operating conditions of high performance liquid chromatograph mass spectrometer for Japanese field dissipation studies**

| | |
|---|---|
| Column | Kinetex (2.6 µm) Phenyl-Hexyl, 2.1 mm x 100 mm |
| Mobile Phase | (A) 0.2% Acetic acid (B) Acetonitrile (A) 40 (B) 60 → 6 min. 0.2 mL/min |
| MS detector | Ionization method, ESI (Turbo ion-spray) |
| Retention Time | About 3.7 min |

**Results and Discussion**

**Analytical Method Performance**
Mean procedural recoveries and relative standard deviation (RSD) for the overall recovery of pydiflumetofen from soil samples were 93 (RSD 4.8%, n = 3) and 90 (RSD 7.7%, n = 3), for samples analysed from Ibaraki and Kochi soils, respectively. As the recoveries and their RSD were acceptable at the spiked concentration of 0.01 mg/kg, the limit of quantification was set to be 0.01 mg/kg.

A control sample was spiked with standard solutions at concentration of 10 times and 100 times of the limit of quantification and the spiked samples were analysed to determine the recoveries. As shown in the table below, the recoveries and their RSD were acceptable.

**Table B.8. 180 Recovery data at the trial sites**

| Sample | Analyte | Spiked level (ppm) | Recovery (%) | Mean (%) | RSD (%) |
|---|---|---|---|---|---|
| Ibaraki | Pydiflumetofen | 0.1 | 92, 90, 82 | 88 | 6.0 |
| | | 1 | 106, 105, 95, | 102 | 6.0 |
| Kochi | Pydiflumetofen | 0.1 | 92, 88, 83 | 88 | 5.1 |
| | | 1 | 104, 98, 94 | 99 | 5.1 |

**Summary of field study**

Residues of pydiflumetofen in Ibaraki and Kochi are summarised in Tables 2 and 3. At both sites, and at both application rates, pydiflumetofen dissipated steadily over the study period. The theoretical concentration of pydiflumetofen (initial concentration in soil) in Ibaraki sample (volcanic ash soil) was 0.66 mg/kg. From the field sample, pydiflumetofen was detected at the maximum residue level of 0.69 mg/kg at immediately after application and then the residue declined gradually. The residue level at 359 days after final application was 0.27 mg/kg.

The theoretical concentration of pydiflumetofen (initial concentration in soil) in Kochi sample (alluvial soil) was 0.33 mg/kg. From the field sample, pydiflumetofen was detected at the maximum residue level of 0.46 mg/kg at immediately after application and then the residue declined gradually. The residue level at 359 days after final application was 0.18 mg/kg.

**Table B.8. 181 Residues (mg/kg) of pydiflumetofen in Ibaraki soil following a single application of Pydiflumetofen 20.0% SC**

| Sampling interval (days after last treatment) | Replicate 1 | Replicate 2 | Mean |
|---|---|---|---|
| 0 | 0.74 | 0.64 | 0.69 |
| 3 | 0.63 | 0.47 | 0.55 |
| 7 | 0.59 | 0.49 | 0.54 |
| 14 | 0.54 | 0.50 | 0.52 |
| 30 | 0.59 | 0.57 | 0.58 |
| 62 | 0.39 | 0.36 | 0.38 |
| 120 | 0.29 | 0.29 | 0.29 |
| 180 | 0.30 | 0.30 | 0.30 |
| 240 | 0.27 | 0.25 | 0.26 |
| 359 | 0.28 | 0.25 | 0.27 |

**Table B.8. 182 Residues (mg/kg) of pydiflumetofen in Kochi soil following a single application of Pydiflumetofen 20.0% SC**

| Sampling interval (days after last treatment) | Replicate 1 | Replicate 2 | Mean |
|---|---|---|---|
| 0 | 0.48 | 0.44 | 0.46 |
| 3 | 0.47 | 0.44 | 0.46 |
| 7 | 0.37 | 0.30 | 0.34 |
| 14 | 0.37 | 0.35 | 0.36 |
| 30 | 0.33 | 0.31 | 0.32 |
| 62 | 0.24 | 0.23 | 0.24 |
| 120 | 0.14 | 0.13 | 0.14 |
| 180 | 0.06 | 0.05 | 0.06 |
| 240 | 0.12 | 0.12 | 0.12 |
| 359 | 0.18 | 0.17 | 0.18 |

**Conclusions**
In the treated of volcanic ash soil plot (Ibaraki), pydiflumetofen dissipated steadily over the trial period (359 days). Maximum mean pydiflumetofen residues were 0.69 mg/kg, which dissipated to 0.27 mg/kg by the end of the trial. This represents approximately 61% decline in approximately one year. The calculated DT50 was 148 days and the DT90 >10000 days (FOMC).

In the treated of alluvial soil plot (Kochi), pydiflumetofen dissipated steadily over the trial period (359 days). Maximum mean pydiflumetofen residues were 0.46 mg/kg, which dissipated to 0.18 mg/kg by the end of the trial. This represents approximately 61% decline in approximately one year. The calculated DT50 was 57.7 days and the DT90 >10000 days (DFOP.) It is of interest that the lowest residues were seen at 180 DAT but these increased from the lowest level of 0.06 mg/kg at 180 DAT to 0.18 mg/kg at 359 DAT.

### B.8.1.1.2.2.2. Kinetic evaluation of the field dissipation studies – Persistence endpoints

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2/01. [redacted] (2016a), SYN545974 – Kinetic Assessment of Field Dissipation Data for Persistence Endpoints, Report Number SYN/48/01-KIN06. JSC International Limited, Harrogate, North Yorkshire, UK<br>(Syngenta File No. SYN545974_10445). |

| | |
|---|---|
| **Guideline(s):** | FOCUS 2006 |
| **GLP/GEP:** | Not applicable |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**
The data from the six EU DegT50 study design field dissipation studies described under B.8.1.1.2.2.1 were used to calculate trigger endpoints $DT_{50}$ and $DT_{90}$ values for pydiflumetofen in soil, following the guidance FOCUS Kinetics (2006). Kinetic modelling was conducted using CAKE v3.2 (2016).

Input data were generated according to the data handling recommendations made in the FOCUS Kinetics guidance. The LOD and LOQ for all six studies/sites were reported to be 0.15 and 0.5 µg/kg wet soil respectively. As residues were reported and fitted in the units g a.s./ha, the surrogate values for samples <LOD or <LOQ were calculated for each replicate based on the sample wet weight and total sampled core area for that replicate. With respect to kinetic assessment, HSE noted that the author of the field dissipation studies reported values <LOQ incorrectly by ascribing them values of 0 g/ha. However the author of the modelling report appropriately calculated correct g/ha values for values reported as being <LOQ for use in kinetic assessment. The method described in the study report was checked in relation to the method in the FOCUS Degradation Kinetics guidance and found to be acceptable. Where values were reported as being <LOQ wet soil weight, the residue was assumed to be 0.5 x (LOQ + LOD), i.e. 0.5 x (0.5 µg/kg + 0.15 µg/kg) = 0.325 µg/kg. Values reported as <LOD were set to 0.5 x LOD, i.e. 0.075 µg/kg. The residues in g/ha were then calculated as described in the HSE comments for the field dissipation studies. Overall, the values described as being <LOQ were calculated to have assumed residues of 0.5 – 1.5 g/ha. These values typically add approximately 1% to the residue used in the kinetic assessment at individual timepoints and are expected to have a very limited effect on the dissipation rates calculated.

No guidance is provided in FOCUS Kinetics guidance for handling of values <LOQ or <LOD with respect to the sampling depth/horizon in which they are measured. In the six studies fitted, residues in lower soil horizons were only reported where residues >LOQ were recorded in the horizon immediately above. All values reported as <LOD or <LOQ have, therefore, been handled using the methodology described in FOCUS Kinetics guidance.

Three true replicates were reported for each site/sampling occasion; these replicates were included individually in the model input data in accordance with FOCUS Kinetics guidance. For Germany site, the pydiflumetofen residue measured in the B replicate 0-10 cm sample at 533 days after treatment (223.3 g a.s./ha) was double the residue observed in the A and C replicates, and was higher than the level of pydiflumetofen observed in any other sample over the entire duration of the study. This replicate sample was, therefore, omitted from the data for kinetic fitting as an outlier.

The data were directly fitted un-weighted with the complete data set and unconstrained initial concentration (M0) for parent. The flowchart described in the FOCUS Kinetics guidance for persistence endpoints was followed.

The quality of the resulting fits has been assessed visually and statistically by the $\chi^2$ error. Confidence in parameter estimates has been derived from probability values for a t-test of the rate parameters for the SFO, DFOP and HS models. Degradation rates estimates with a significance level greater than 95% are acceptable and, if greater than 90%, may be accepted where the visual fit is acceptable or good. Where significance levels are less than 90%, the estimates are not considered reliable. FOMC fits have been assessed by checking whether the α and β parameters are significantly different from zero. Parameters were considered reliable if both estimates have a 95% confidence interval which does not contain zero or a 90% confidence interval which does not contain zero if the visual fit was acceptable or good.

For fits that are visually acceptable or good, but for which a robust degradation rate cannot be established, *i.e.* a t-test of <90% probability, the visual plot of the fit has been given further consideration. Where the optimised model provides a good fit to the observed decline of pydiflumetofen and the endpoints ($DT_{50}$ and $DT_{90}$) provide a conservative estimate of the persistent nature of pydiflumetofen then the $DT_{50}$ and $DT_{90}$ have been deemed acceptable.

**Findings**
Results from the kinetic fitting are presented in the following table.

**Table B.8. 183 Kinetic parameters and statistics of the fittings for pydiflumetofen, persistence endpoints**

| Site | Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / Confidence interval (90/95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|---|
| Germany | SFO | k=0.000363 | Acceptable/Acceptable | 9.21 | k: <0.05 | 1910 | 6350 |
| | FOMC | α=0.05809 β=1.928 | Good/Acceptable | 7.14 | β CI contains 0 | >10000 | >10000 |
| | DFOP | $k_1$=0.05381 $k_2$= 0.000043 g=0.2484 | Good/Acceptable | 6.51 | $k_1$: <0.10 $k_2$: >0.10 | 8540 | >10000 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected** The poor statistical confidence in the k2 parameter estimate could be attributed to the rate of degradation being very slow and, therefore, not significantly different from zero. The endpoints calculated were considered to be long enough to be indicative of the slow rate of degradation of pydiflumetofen under field conditions. | | | | | | |
| Italy | SFO | k=0.000625 | Acceptable/Acceptable | 11.6 | k: <0.05 | 1110 | 3680 |
| | FOMC | α=0.1618 β=61.53 | Acceptable/Acceptable | 11.8 | α and β CI contain 0 | 4410 | >10000 |
| | **Trigger endpoint: SFO better than FOMC → SFO selected** | | | | | | |
| Northern France | SFO | k=0.000172 | Acceptable/Acceptable | 9.7 | k: >0.1 | 4030 | >10000 |
| | FOMC | α=6E-09 β=0.02086 | Acceptable/Acceptable | 10.7 | Could not be calculated | >10000 | >10000 |
| | **Trigger endpoint: SFO better than FOMC → SFO selected** The poor statistical confidence in the k parameter estimate could be attributed to the rate of degradation being very slow and, therefore, not significantly different from zero. The endpoints calculated were considered to be long enough to be indicative of the slow rate of degradation of pydiflumetofen under field conditions. | | | | | | |
| Southern France | SFO | k=0.002284 | Poor/Poor | 24.8 | k: <0.05 | 304 | 1010 |
| | FOMC | α=0.2415 β=2.938 | Good/good | 14.7 | β CI contains 0 | 48.9 | >10000 |
| | DFOP | $k_1$=0.08239 $k_2$= 0.000842 g=0.5381 | Good/good | 13.3 | $k_1$: <0.05 $k_2$: <0.05 | 29 | 1820 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected** | | | | | | |
| Spain | SFO | k=0.00087 | Poor/Poor | 29.6 | k: <0.10 | 797 | 2650 |
| | FOMC | α=0.1202 β=1.244 | Poor/Poor | 27.1 | α and β CI contain 0[a] | 397 | >10000 |
| | DFOP | $k_1$=0.1116 $k_2$= 1.12E-06 g=0.5041 | Poor/Poor | 24.5 | $k_1$: <0.10 $k_2$: >0.10 | 43.1 | >10000 |
| | **No kinetic models provided an acceptable fit. Data display a large degree of scatter and residues increase between 14 DAT and 358 DAT. Data from this site is considered unsuitable for deriving trigger endpoints** | | | | | | |
| UK | SFO | k=0.000246 | Acceptable/Acceptable | 11.2 | k: <0.10 | 2810 | 9350 |
| | FOMC | α=0.3926 β=936.8 | Acceptable/Acceptable | 11.7 | α and β CI contain 0 | 4540 | >10000 |
| | **Trigger endpoint: SFO better than FOMC → SFO selected** | | | | | | |

[a] For α, 95th percentile CI contains 0 but 90th percentile CI does not contain 0

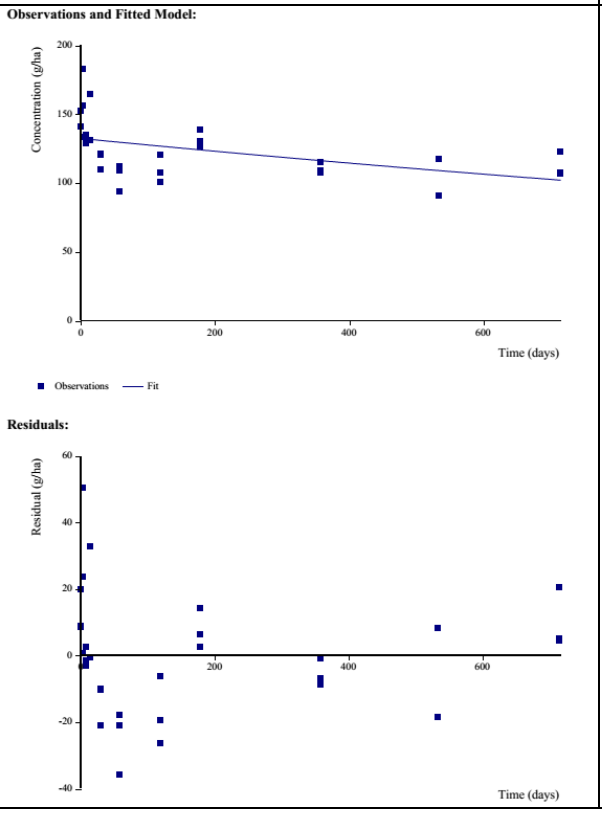
It is noted that the DT50 was within the duration of the study at only the Southern France site and in all cases the DT90s are extrapolated well beyond the study end.

Visual fits and residual plots are reported below.

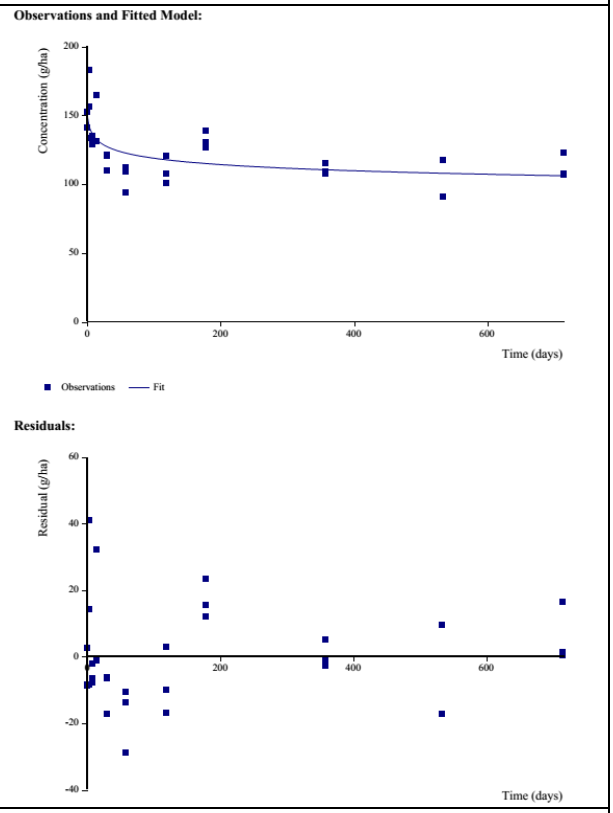
**Figure B.8. 42 Visual fits and residual plots, non-normalised field dissipation data**

**Germany**

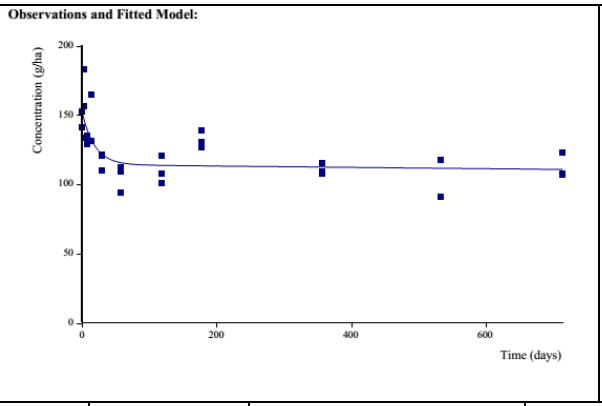
SFO

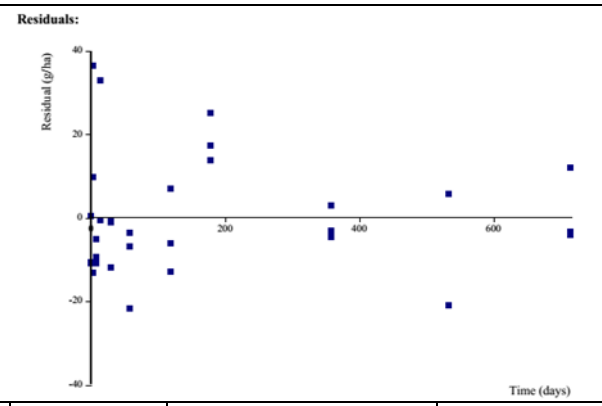



FOMC




DFOP



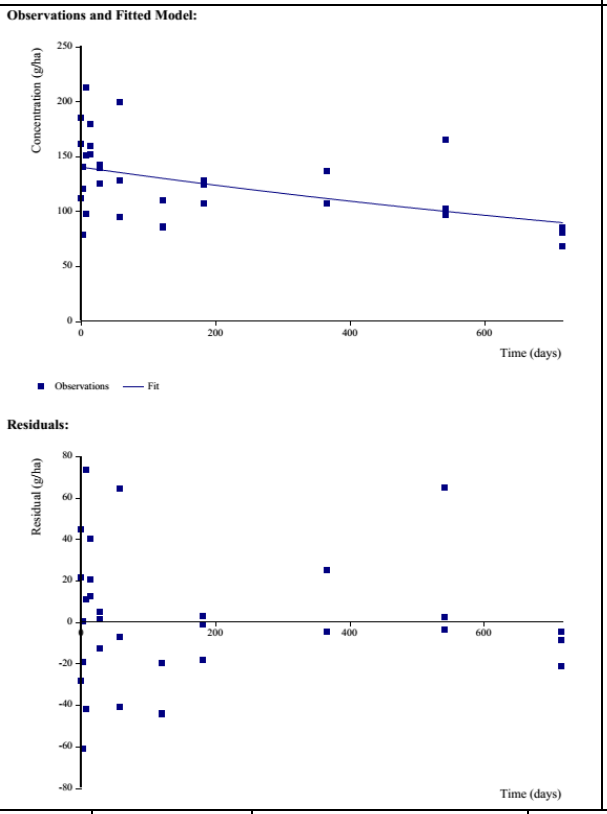

| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (90/95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.000363 | Acceptable/Acceptable | 9.21 | k: <0.05 | 1910 | 6350 |
| FOMC | α=0.05809<br>β=1.928 | Good/Acceptable | 7.14 | β CI contains 0 | >10000 | >10000 |
| DFOP | $k_1$=0.05381<br>$k_2$= 0.000043<br>g=0.2484 | Good/Acceptable | 6.51 | $k_1$: <0.10<br>$k_2$: >0.10 | 8540 | >10000 |

**Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected**

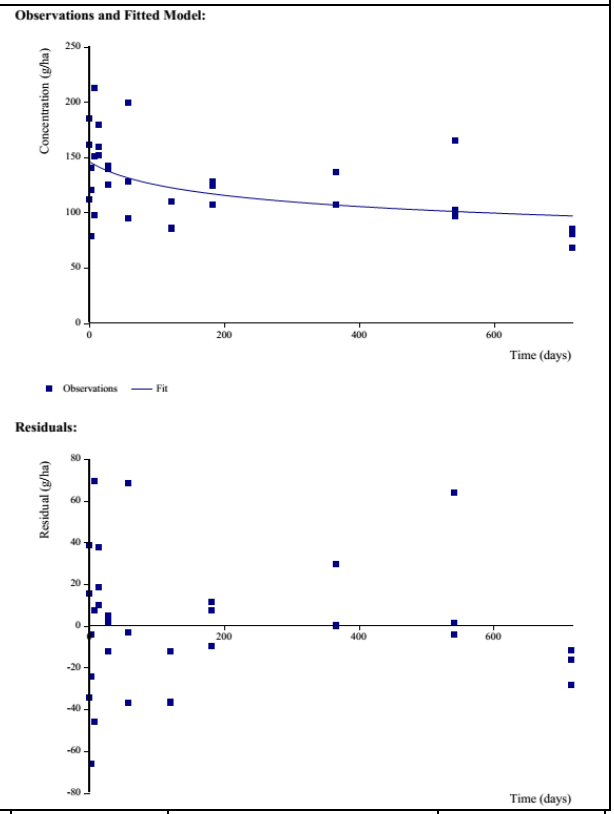
The poor statistical confidence in the k2 parameter estimate could be attributed to the rate of degradation being very slow and, therefore, not significantly different from zero. The endpoints calculated were considered to be long enough to be indicative of the slow rate of degradation of pydiflumetofen under field conditions.

**Italy**

SFO



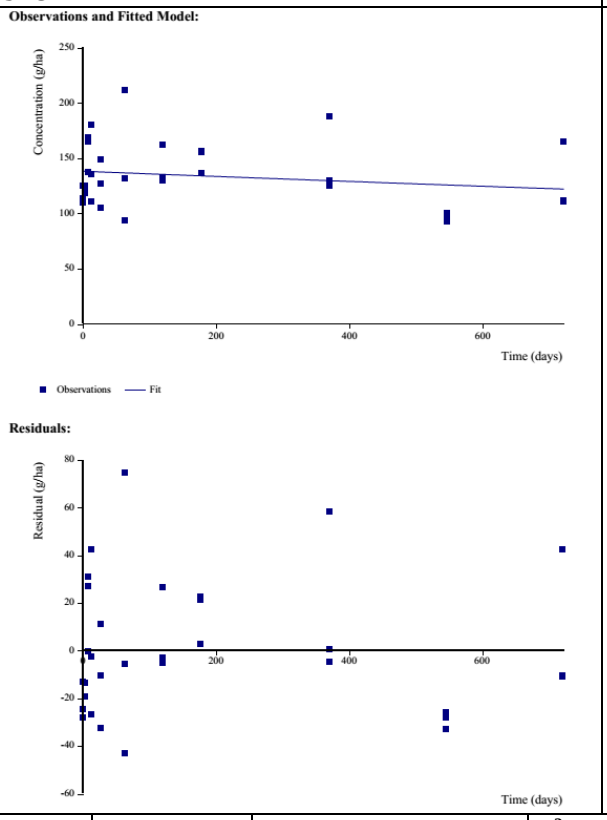

FOMC



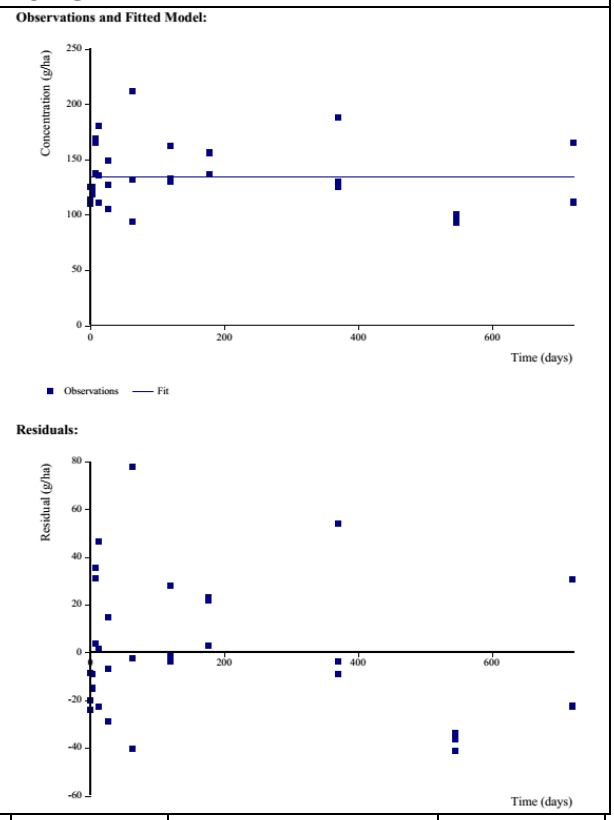

| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (90/95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.000625 | Acceptable/Acceptable | 11.6 | k: <0.05 | 1110 | 3680 |
| FOMC | α=0.1618 β=61.53 | Acceptable/Acceptable | 11.8 | α and β CI contain 0 | 4410 | >10000 |
| **Trigger endpoint: SFO better than FOMC → SFO selected** | | | | | | |

**Northern France**

SFO




FOMC



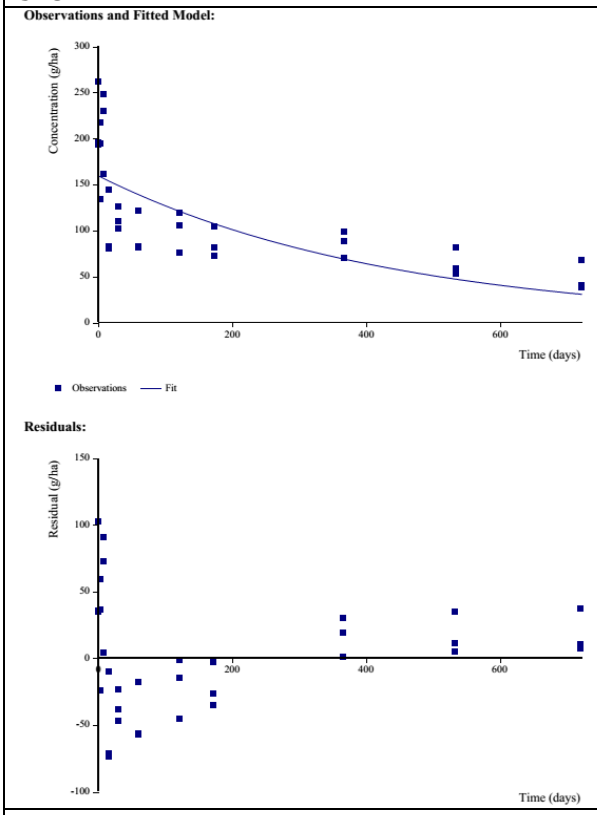

| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (90/95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.000172 | Acceptable/Acceptable | 9.7 | k: >0.1 | 4030 | >10000 |
| FOMC | α=6E-09<br>β=0.02086 | Acceptable/Acceptable | 10.7 | Could not be calculated | >10000 | >10000 |

**Trigger endpoint: SFO better than FOMC → SFO selected**

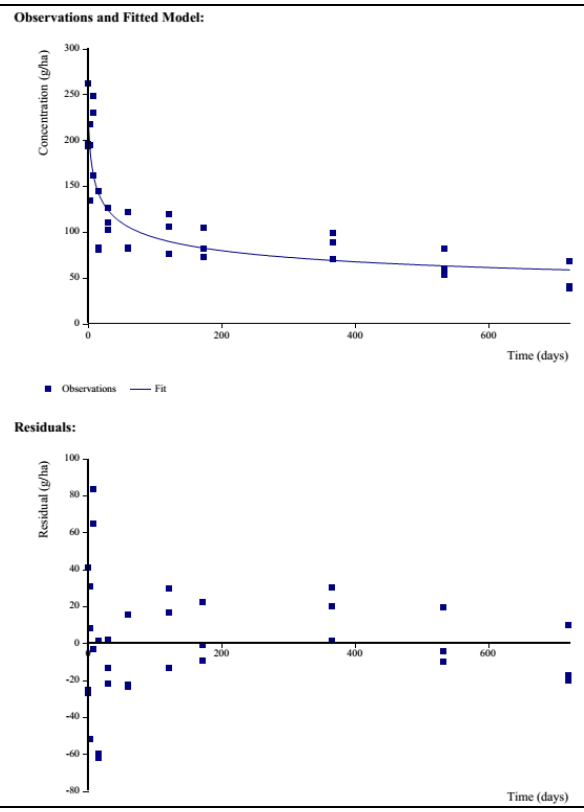
The poor statistical confidence in the k parameter estimate could be attributed to the rate of degradation being very slow and, therefore, not significantly different from zero. The endpoints calculated were considered to be long enough to be indicative of the slow rate of degradation of pydiflumetofen under field conditions.

**Southern France**

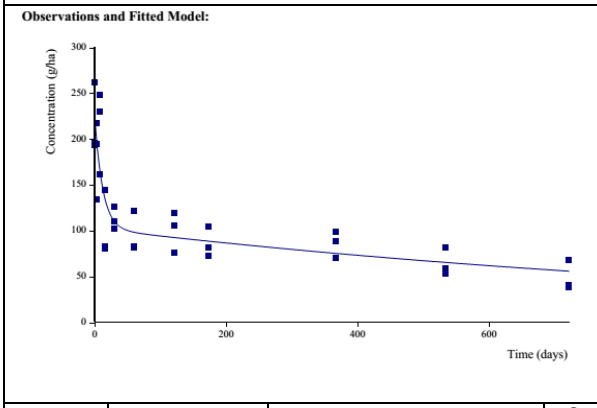
SFO

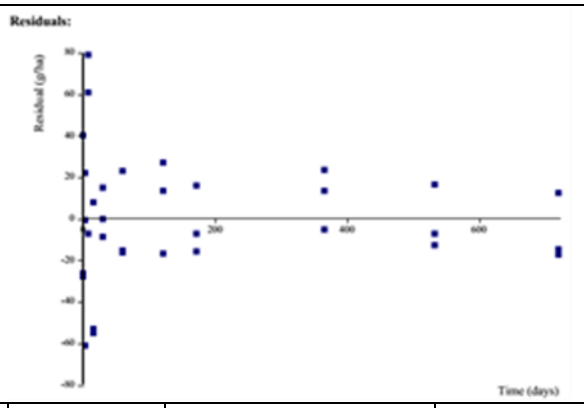



FOMC




DFOP

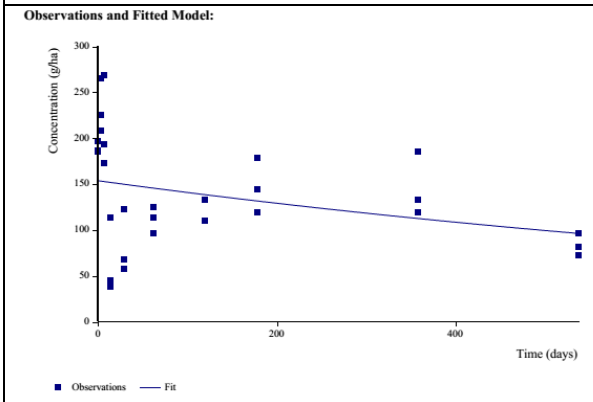


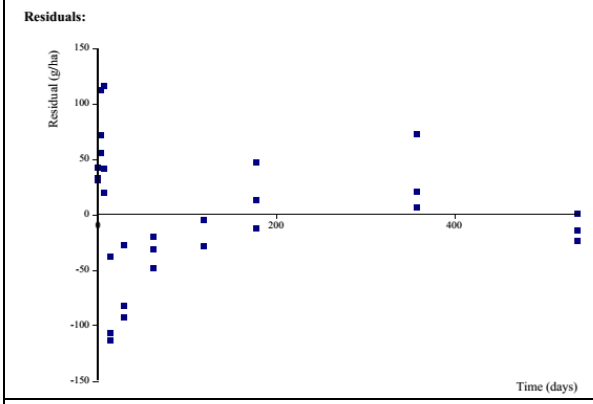




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (90/95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.002284 | Poor/Poor | 24.8 | k: <0.05 | 304 | 1010 |
| FOMC | α=0.2415 β=2.938 | Good/good | 14.7 | β CI contains 0 | 48.9 | >10000 |
| DFOP | $k_1$=0.08239 $k_2$= 0.000842 g=0.5381 | Good/good | 13.3 | $k_1$: <0.05 $k_2$: <0.05 | 29 | 1820 |
| **Trigger endpoint: FOMC better than SFO → fit DFOP; DFOP better than FOMC, DFOP selected** | | | | | | |

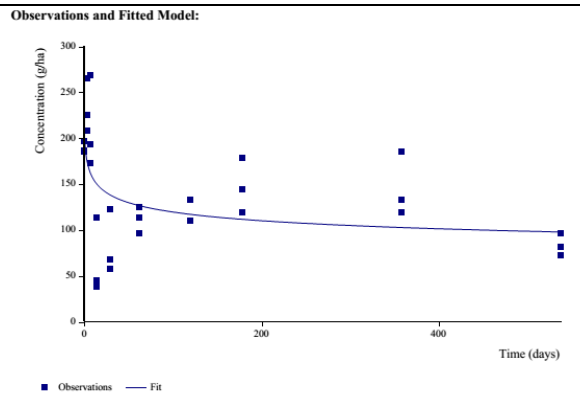
**Spain**

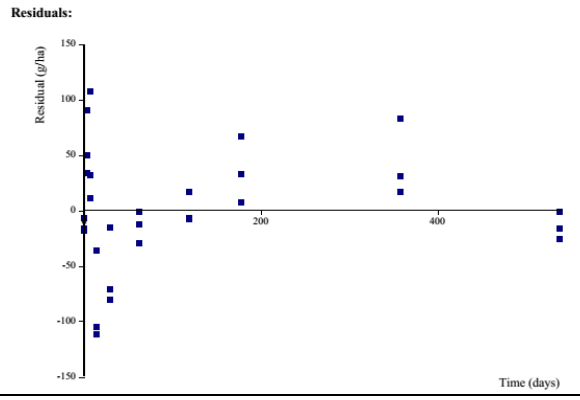
SFO



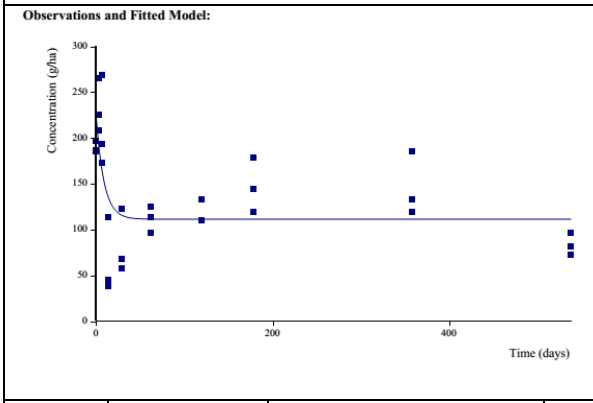



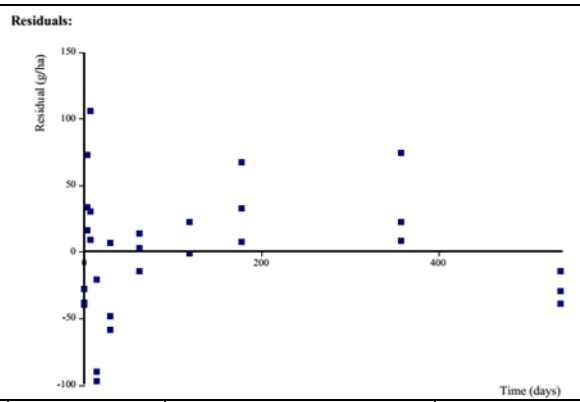

FOMC




DFOP



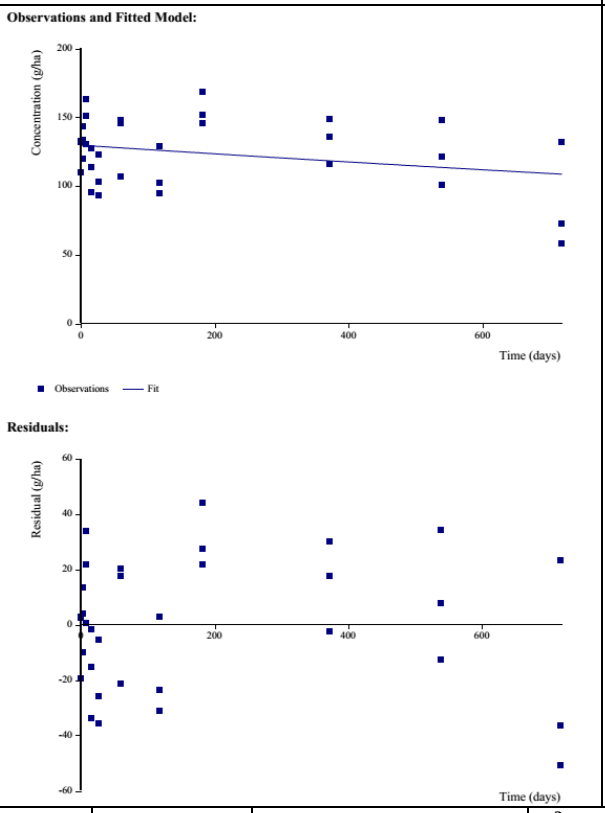




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (90/95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.00087 | Poor/Poor | 29.6 | k: <0.10 | 797 | 2650 |
| FOMC | α=0.1202<br>β=1.244 | Poor/Poor | 27.1 | α and β CI contain 0[a] | 397 | >10000 |
| DFOP | $k_1$=0.1116<br>$k_2$= 1.12E-06<br>g=0.5041 | Poor/Poor | 24.5 | $k_1$: <0.10<br>$k_2$: >0.10 | 43.1 | >10000 |

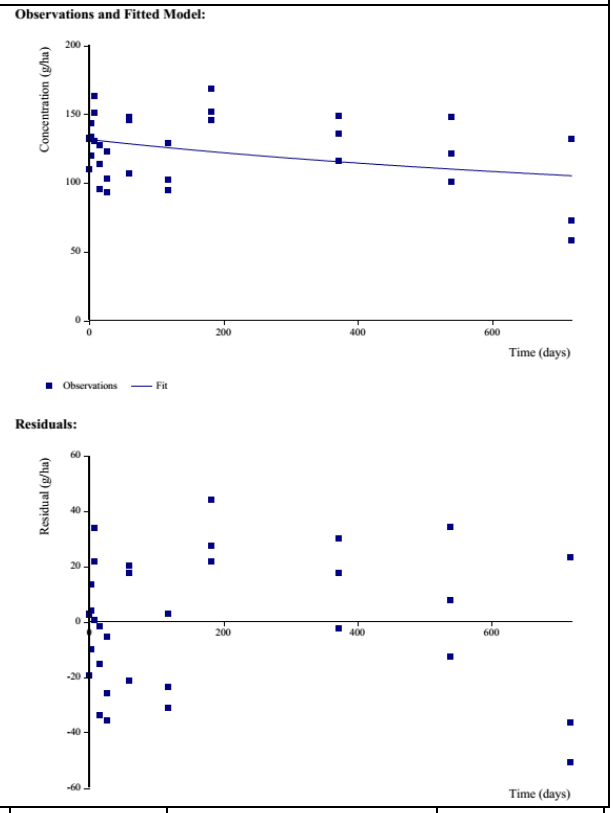
**No kinetic models provided an acceptable fit. Data display a large degree of scatter and residues increase between 14 DAT and 358 DAT. Data from this site is considered unsuitable for deriving trigger endpoints**

**UK**

SFO




FOMC




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (90/95%) | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.000246 | Acceptable/Acceptable | 11.2 | k: <0.10 | 2810 | 9350 |
| FOMC | α=0.3926 β=936.8 | Acceptable/Acceptable | 11.7 | α and β CI contain 0 | 4540 | >10000 |
| **Trigger endpoint: SFO better than FOMC → SFO selected** | | | | | | |

A summary of the selected $DT_{50}$ and $DT_{90}$ values is presented below.

**Table B.8. 184 Summary of trigger endpoint DT50 and DT90 values for pydiflumetofen**

| Trial location | Soil texture | Soil pH ($CaCl_2$) | $\chi^2$ error % | $DT_{50}$ / $DT_{90}$ (days) | Kinetic |
|---|---|---|---|---|---|
| Germany | Sandy loam | 5.68 | 6.51 | 8540 / > 10000 | DFOP |
| Italy | Clay Loam | 7.40 | 11.6 | 1110 / 3680 | SFO |
| Northern France | Silty clay loam | 7.52 | 9.7 | 4030 / > 10000 | SFO |
| Southern France | Sandy loam | 7.48 | 13.3 | 29 / 1820 | DFOP |
| Spain | Sandy loam | 7.27 | N/A[a] | N/A[a] | None[a] |
| UK | Loam | 6.84 | 11.2 | 2810 / 9350 | SFO |
| **Maximum** | | | | **8540 / > 10000** | **DFOP** |

[a] Data displayed a large degree of scatter and residues increased between 14 DAT and 358 DAT. Data from this site were considered unsuitable for deriving modelling endpoints.

**Conclusion**

HSE agrees with the outcome of the kinetic assessment. In general it is noted that the data were often scattered between sample time times and between replicates at individual sample times. The scattering often led to relatively high chi$^2$ values. In addition, because the residue decline appeared to be very slow, the calculated

parameters may be relatively uncertain as even a small deviation in the slope/curvature of the fitted curve would lead to relatively large differences in the magnitude of DT50 and DT90 calculated. In the case of the Spanish site where the fitted parameters were rejected, the residues pattern was unlikely to be able to be fitted well by any kinetic assessment software given the apparent rapid fall in residues followed by an increase and then a decrease. The reasons for this unusual behaviour are not known but the results support the overall picture that pydiflumetofen is a persistent substance.

'Trigger' dissipation $DT_{50}$ values for pydiflumetofen in these six European field soil dissipation studies ranged from 29 to 8540 days, with $DT_{90}$ values ranging from 1820 to >10000 days. It is noted that the DT50 was within the duration of the study at only one site and in all cases the DT90s are extrapolated well beyond the study end.

It is noted in the case of the German and Northern France sites that the best fit DT90s were expressed as >10000 days; this is the default presentation for the CAKE model. Given the relative uncertainty associated with the calculations due to the slow decline and data scatter, DT90s calculated by HSE from the kinetic parameters are uncertain but have been presented to give some idea of the relative magnitude:
Germany – DT50 8540 days, DT90 ~47,000 days
N France – DT50 4030 days, DT90 13,387 days

As noted previously, the calculated persistence endpoints from these field dissipation sites may well be conservative due to the use of a sand covering applied immediately after application. This is likely to have minimised surface processes which may be feasible mechanisms for dissipation of pydiflumetofen in real world situations.

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2/02. [redacted] (2020a), Pydiflumetofen - Non-standard surface applied FOCUS EU TFD Kinetics Trigger Endpoints, Report Number RAJ01352B. Syngenta, Jealott's Hill, UK (Syngenta Document No. VV-864726). |

**Guideline(s):** FOCUS 2006; FOCUS 2014; EFSA 2014
**GLP/GEP:** Not applicable
**Deviation(s):** No major deviation identified
**Acceptability** Yes

**Methods**
**Data source**
EU field dissipation studies considered in the kinetics evaluation are summarised below:

**Table B.8. 185 Details of field dissipation studies for pydiflumetofen used to calculate trigger endpoints**

| Location | Application Rate (g a.s./ha) | Plot description | Soil texture (topsoil) | Soil pH ($CaCl_2$, topsoil) | Study duration (days) | Reference |
|---|---|---|---|---|---|---|
| Burweg (Germany) | 1 x 200 (bare soil) | Grassed (germination after application) | Loamy Sand | 6.23 | 367 | [redacted] and [redacted], 2019 |
| Stotzheim (N. France) | 1 x 200 (bare soil) | Grassed (germination after application) | Silty Clay | 6.13 | 360 | [redacted], 2020a |
| Barry d'Islemade (S. France) | 1 x 200 (bare soil) | Grassed (germination after application) | Silt Loam | 7.68 | 366 | [redacted], 2020b |
| Valenca De Minho (Portugal) | 1 x 200 (bare soil) | Grassed (germination after application) | Loamy Sand | 6.23 | 353 | [redacted], 2020c |

**Kinetic fitting**
The data from the studies indicated in Table 7.1.2.2-7 were used to calculate $DT_{50}$ values for pydiflumetofen in soil suitable for derivation of a trigger endpoint, following the principles of FOCUS Kinetics (2006), and where appropriate the EFSA guidance (2014) which excludes surface processes, using the analysis software CAKE v3.3 (2018). Data handling was appropriate and in accordance with the FOCUS Kinetics guidance.

The quality of the resulting fits has been assessed visually and statistically by the $\chi^2$ error% measure of goodness of fit. Confidence in parameter estimates has been derived from probability values for a t-test of the rate parameters for the single first order (SFO) and dual first order in parallel (DFOP) models, the 90$^{th}$ percentile confidence intervals were taken into account for the α and β parameters for first order multicompartmental (FOMC). Parameter estimates with a significance level greater than 95% are acceptable and, if greater than 90%, may be accepted where the visual fit is acceptable or good. Where significance levels are less than 90%, the estimates are not considered reliable. For $DT_{50}$ (SFO) fits the assessment was based on the t-test probability value of the estimate of the degradation rates (k).

For fits that are visually acceptable or good, but for which a robust degradation rate cannot be established, i.e. a t-test of <90% probability, the visual plot of the fit has been given further consideration. Where the optimised model provides a good fit to the observed decline of pydiflumetofen and the endpoints ($DT_{50}$ and $DT_{90}$) provide a conservative estimate of the persistent nature of pydiflumetofen then the $DT_{50}$ and $DT_{90}$ have been deemed acceptable.

Due to significant residues of pydiflumetofen (75 times > limit of quantification (LOQ) for all timepoints in the 0-10 cm soil depth) being observed throughout the study only residues greater than the LOQ (0.5 µg/kg wet soil)

were included in the kinetic analysis. The study author considered this would have a negligible impact on the calculated $DT_{50}$ values. Such an approach is not in line with the specific recommendations of FOCUS Degradation Kinetics guidance which states that values <LOQ should be set either to the measured value of to ½ (LOQ + LOD). However, this approach would be most likely to have a significant impact where there was significant dissipation of the substance and overall residues across analysed soil layers were nearing LOQ. In the case of this group of four field dissipation studies, measured values <LOQ were available. HSE checked the significance of this approach by calculating what % of the 0-10 layer residue at the same time point the <LOQ value represented. It should be noted that the vast majority of the residues remained in the 0-10 cm layer at all four sites. As there was relatively slow dissipation of pydiflumetofen in all studies, the values which were <LOQ represented a maximum of 1.8% of the associated 0-10cm layer concentration. There was one other instance where the <LOQ value was >1% and all other instances were <0.75%. Thus whilst HSE does not generally advocate such practice, as a pragmatic approach it can be accepted on this occasion.

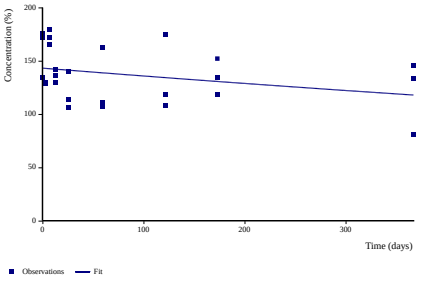
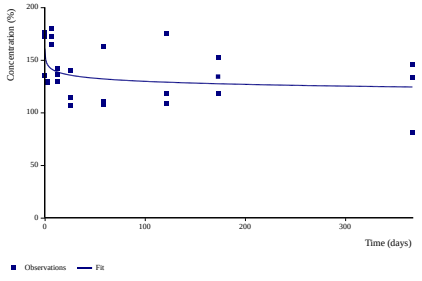
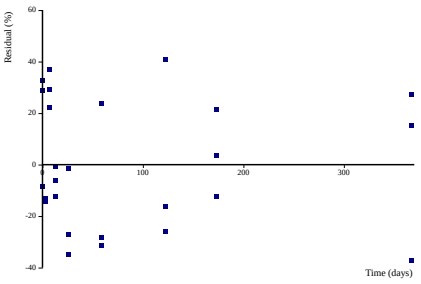
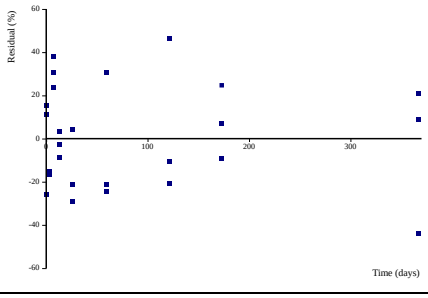
Three true replicates were reported for each site/sampling occasion; these replicates were included individually in the model input data in accordance with FOCUS (2006) guidance.

Each study has been considered following the steps in the flowcharts in FOCUS (2006) or where appropriate, EFSA (2014).

**Results**

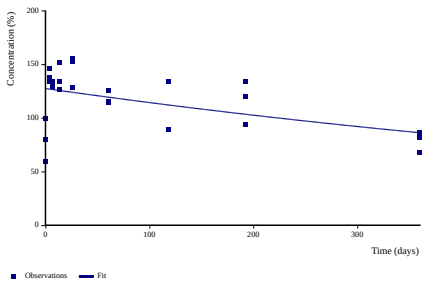
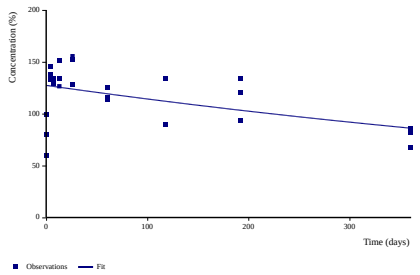
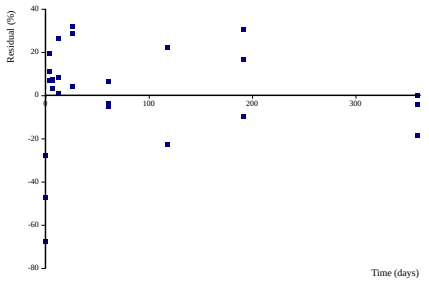
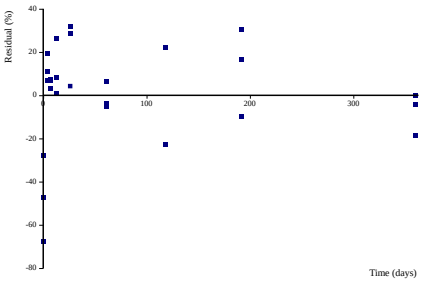
Table 7.1.2.2-6 provides a summary of the $DT_{50}$ values for all studies analysed, following the FOCUS (2006) and EFSA (2014) flowcharts. Summary statistics, visual fit analysis and decisions made are provided for each kinetic fit in Table 7.1.2.2-8. Brief summaries, including plots of residuals and kinetic fits are shown in Table 7.1.2.2-9. HSE checked a sample of the calculations using the µg/kg dry weight data and obtained similar outcomes. Whilst results of the applicant modelling could not be reproduced, this is considered to be unsurprising as both the g/ha and µg/kg dry weight data points have been produced by calculation from the wet weight residue data. This can result in some relative differences in the positions of some data points which can result in slightly different fitting and resulting kinetic parameters. The method of calculating the g/ha from the residues results is acceptable.

**Table B.8. 186 Summary of plots of kinetic fits for pydiflumetofen, Burweg, Germany**

| **Soil (code) (ref)** | **[redacted] and [redacted], 2019 - Burweg (Germany)** | |
|---|---|---|
| **Kinetic Model** | SFO | FOMC |
| **Visual Fit** | Acceptable | Acceptable |
| **Residuals (visual)** | Acceptable | Acceptable |
| **χ2 error (%)** | 8.73 | 8.14 |
| **Rate Parameters** | kP: 0.000528 | α: 0.03249 |
| | | β: 0.1338 |
| **Rate Parameters: probability** | p = 0.06312 | α: 90th %ile CI contains 0<br>β: 90th %ile CI contains 0 |
| **$DT_{50}$ (days)** | 1310 | >10,000 |
| **$DT_{90}$ (days)** | 4360 | >10,000 |
| **Trigger $DT_{50}$ (days)** | 1310 | |
| **FOCUS decision step** | SFO better than FOMC. SFO selected as best fit model for trigger endpoints | |
| **Modelled vs. observed** |  |  |
| **Residual** |  |  |

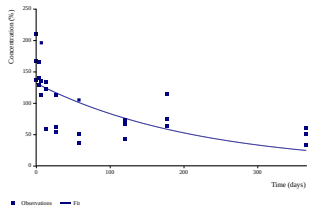
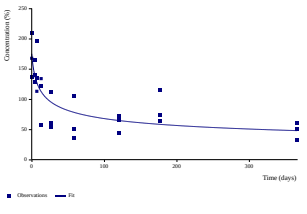
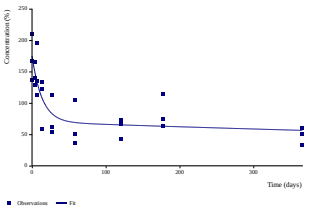
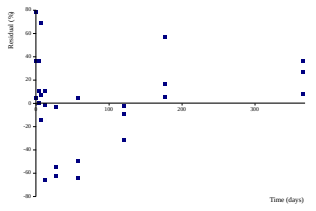
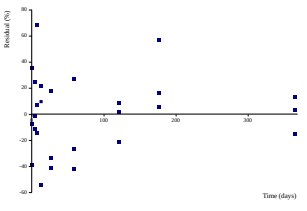
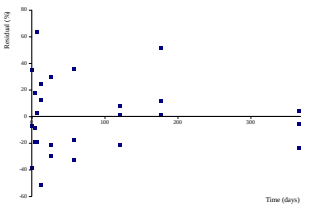
Overall it is noted that there is relatively little dissipation during the course of the study and that the replicate data are quite scattered. Whilst FOMC give a slightly better fit than SFO in terms of the $\chi^2$ error and a slightly narrower spread of residuals, the FOMC fitting has some uncertainty given that the lower 90$^{th}$ percentile confidence intervals for both α and β parameters contain 0. Given the limited amount of dissipation seen and the somewhat scattered replicate data, this is unsurprising. In addition it is noted that with such low residue decline, FOMC can be particularly sensitive to small changes in the fitted curve which can lead to very large effects on predicted DT50 and D90 values. It is noted however that the SFO rate constant has a p value of 0.063, slightly higher than the optimum upper value of 0.05; again this is likely to reflect the low amount of dissipation and the rather scattered nature of the replicate data. Overall HSE can accept the choice of SFO for the Burweg, Germany site as it is unlikely to impact the overall regulatory outcome.

**Table B.8. 187 Summary of plots of kinetic fits for pydiflumetofen, Stotzheim, N. France**

| **Soil (code) (ref)** | **[redacted], 2020 – Stotzheim (N. France)** | |
|---|---|---|
| **Kinetic Model** | SFO | FOMC |
| **Visual Fit** | Acceptable | Acceptable |
| **Residuals (visual)** | Acceptable | Acceptable |
| **χ2 error (%)** | 13.2 | 13.9 |
| **Rate Parameter** | kP: 0.001086 | α: 261.2 |
| | | β: 241000 |
| **Rate Parameters: probability** | p = <0.01 | α: 90th %ile CI contains 0<br>β: 90th %ile CI contains 0 |
| **$DT_{50}$ (days)** | 639 | 639 |
| **$DT_{90}$ (days)** | 2120 | 2130 |
| **Trigger $DT_{50}$ (days)** | 639 | |
| **FOCUS decision step** | SFO better than FOMC. SFO selected as best fit model for trigger endpoints | |
| **Modelled vs. observed** |  |  |
| **Residual** |  |  |

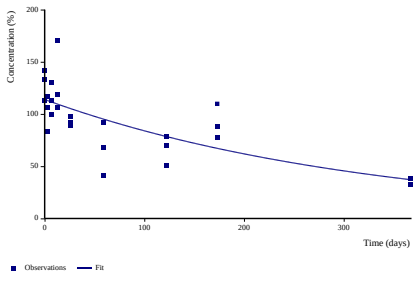
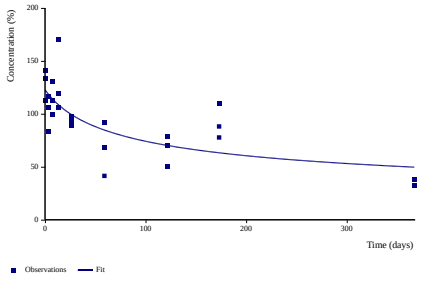
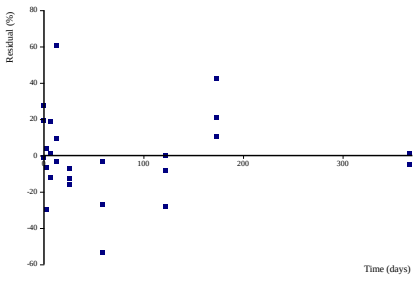
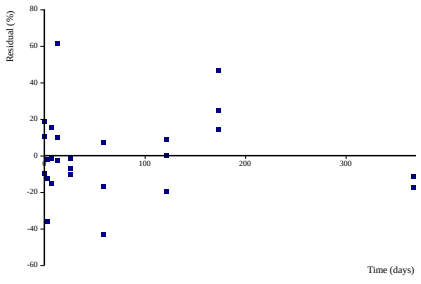
The SFO and FOMC fits are almost identical with SFO giving a slightly better $\chi^2$ error. It is noted that the DT50s are identical and the DT90s very similar. HSE can accept the choice of SFO for the Stotzheim, France site.

**Table B.8. 188 Summary of plots of kinetic fits for pydiflumetofen, Barry d'Islemade, S. France**

| **Soil (code) (ref)** | **[redacted], 2020 - Barry d'Islemade (S. France)** | | |
|---|---|---|---|
| **Kinetic Model** | SFO | FOMC | DFOP |
| **Visual Fit** | Poor | Acceptable | Good |
| **Residuals (visual)** | Poor | Acceptable | Good |
| **$\chi$2 error (%)** | 22.3 | 11.8 | 9.1 |
| **Rate parameter** | kP: 0.004594 | $\alpha$: 0.2724 | k1: 0.07406 |
| | | $\beta$: 3.183 | k2: 0.000585 |
| | | | g: 0.6006 |
| **Rate Parameters: probability** | p = <0.01 | $\alpha$: 95th %ile CI does not contain 0<br>$\beta$: 90th %ile CI contains 0 | k1: p = 0.02<br>k2: p = 0.323 |
| **$DT_{50}$ (days)** | 151 | 37.4 | 23.4 |
| **$DT_{90}$ (days)** | 501 | >10000 | 2130 |
| **Trigger $DT_{50}$ (days)** | | | 23.4 |
| **FOCUS decision step** | FOMC better visually and statistically than SFO, therefore DFOP run | | DFOP better visually and statistically than FOMC, therefore DFOP chosen |
| **Modelled vs. observed** |  |  |  |
| **Residual** |  |  |  |

It is noted that there is a reasonable amount of scatter in the replicate data and variability between sample times. In particular the data at day 177 appear to show elevated residues compared to the sample times either side. Given the variability it is unsurprising that the fitting is relatively poor. SFO is clearly a relatively poor fit with a high $\chi^2$ error and a wider spread of residuals than the other kinetic models. Biphasic fitting gives clear improvement as evidenced by the lower $\chi^2$ error values and improved spread of residuals. Both FOMC and DFOP have statistical issues (FOMC $\beta$ value 90th %ile confidence interval contains 0; DFOP k2 value has a high p value). These are most likely associated with the very slow dissipation predicted by the slow phase of decline. However it is considered that the much improved visual and residual fitting outweigh the issues and the DFOP parameters can be accepted.

**Table B.8. 189 Summary of plots of kinetic fits for pydiflumetofen, Valenca De Minho, Portugal**

| **Soil (code) (ref)** | **[redacted], 2020– Valenca De Minho (Portugal)** | |
|---|---|---|
| **Kinetic Model** | SFO | FOMC |
| **Visual Fit** | Acceptable | Acceptable |
| **Residuals (visual)** | Acceptable | Acceptable |
| **χ2 error (%)** | 14.5 | 14.4 |
| | kP: 0.003052 | α: 0.3635 |
| | | β: 33.35 |
| **Rate Parameters: probability** | p = <0.01 | α: 90th %ile CI contains 0<br>β: 90th %ile CI contains 0 |
| **$DT_{50}$ (days)** | 227 | 191 |
| **$DT_{90}$ (days)** | 755 | >10000 |
| **Trigger $DT_{50}$ (days)** | 227 | |
| **FOCUS decision step** | SFO better than FOMC. SFO selected as best fit model for trigger endpoints | |
| **Modelled vs. observed** |  |  |
| **Residual** |  |  |

As with the other field dissipation sites the replicate data are quite scattered and there is some variability between sample times. In particular the data at day 174 appear to show elevated residues compared to the sample times either side. Both SFO and FOMC show relatively high $\chi^2$ error and FOMC is only marginally better. There is little discernible improvement in the overall visual and residual fitting from FOMC compared to SFO. In addition both FOMC α and β parameter 90th %ile confidence intervals contain 0 which is probably reflective of the relatively slow dissipation. Overall it is considered that whilst FOMC gives marginally improved fitting, the SFO fitting can be accepted.

**Conclusion**

HSE consider that the kinetic assessment of these additional four European field dissipation studies was conducted appropriately and in accordance with FOCUS Degradation kinetics.

The dissipation of pydiflumetofen in four additional EU field trial soils has been calculated. $DT_{50}$ values for pydiflumetofen ranged from 23.4 to 1310 days and DT90s from 755 to 4360 days. The DT90s were all extrapolated well beyond the study duration. A summary of the kinetic values are presented below.

**Table B.8. 190 Summary of trigger DT50 values for pydiflumetofen from field sites with grassed plots**

| Trial location | Soil texture | Soil pH ($H_2O$) | $\chi^2$ error % | Overall $DT_{50}$ (days) | Overall $DT_{90}$ (days) | Kinetic parameters | Method of calculation | Reference |
|---|---|---|---|---|---|---|---|---|
| Burweg (Germany) | Loamy Sand | 4.96 | 8.7 | 1310 | 4360 | - | SFO | [redacted] and [redacted], 2019 |
| Stotzheim (N. France) | Silty Clay | 5.45 | 13.2 | 639 | 2120 | - | SFO | [redacted], 2020 |
| Barry d'Islemade (S. France) | Silt Loam | 7.35 | 9.1 | 23.4 | 2130 | k1: 0.07406 k2: 0.000584 g: 0.6006 | DFOP | [redacted], 2020 |
| Valenca De Minho (Portugal) | Loamy Sand | 4.16 | 14.5 | 227 | 755 | - | SFO | [redacted], 2020 |
| **Maximum** | | | | **1310** | **4360** | | **SFO** | |

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2/03. [redacted] (2020a), SYN545974 - Kinetic Modelling Evaluation of Data from EU Terrestrial Field Dissipation Studies for Calculation of Trigger Endpoints for Parent, Report Number NC/20/034A. Battelle UK Ltd, UK (Syngenta Document No. VV- 876962). |

| | |
|---|---|
| **Guideline(s):** | FOCUS 2006; FOCUS 2014; EFSA 2014 |
| **GLP/GEP:** | Not applicable |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes for calculation methods, but note comments below. |

This study reports kinetic calculations as a result of additional sampling conducted 3.1 – 5.3 years after termination of the original studies at five European field dissipation sites. As noted in section B.8.1.1.1.2.1.3, HSE has significant concerns over the validity of the study findings as there is considerable uncertainty over the influence of aspects such as cultivation and other dilution effects to have influenced the soil residues in the additional samples. As such, a detailed assessment of the kinetic calculations has not been conducted. HSE do not consider that this assessment can be used to modify the DT50 and DT90 values derived from the data from the original studies. Nevertheless, a comparison of the new DT50 and DT90 values (not validated by HSE) taking account of the additional samples compared to the original DT50 and DT90 values is presented below in order to form the basis of discussion.

**Table B.8. 191 Original dissipation DT50 and DT90 values from five European field dissipation sites compared to values after additional sampling 3.1 – 5.3 years after termination of original studies; new DT50/DT90 values not validated by HSE**

| Trial location | Study design<br>Interval between study end and new sampling time | Original DT50 | Original DT90 | Kinetic | New $DT_{50}$ | New $DT_{90}$ | Kinetic |
|---|---|---|---|---|---|---|---|
| Ohrensen (DE) | DegT50, sand cover<br>1927 days | 8540 | >10000 | DFOP | 1850 | 8240 | DFOP |
| Bas Rhin (FR) | DegT50, sand cover<br>1905 days | 4030 | >10000 | SFO | 1300 | 4330 | SFO |
| Burweg (DE) | Bare soil, grass cover developed<br>1158 days | 1310 | 4360 | SFO | 753 | 2500 | SFO |
| Stotzheim (FR) | Bare soil, grass cover developed<br>1137 days | 639 | 2120 | SFO | 566 | 1880 | SFO |
| Wilson (UK) | DegT50, sand cover<br>1910 | 2810 | 9350 | SFO | 1590 | 5270 | SFO |

As can be seen, in all cases the dissipation times taking into account the additional soil sampling are shorter than the dissipation times from the original study results. The decrease in dissipation times is considerable in the case of the Ohrensen (Germany) and Bas Rhin (France) sites. These were both sites which used the EFSA DegT50 study design, being bare soil and having been covered in sand immediately after application; in addition, these sites were maintained as bare soil plots. It is possible that the decrease in apparent dissipation times may be attributable to:

- dilution effects such as cultivation practice after the original study terminated,
- potentially not being to align the positions of the study plots properly, or
- sample cores coinciding partly or wholly with untreated backfill from previous coring.

Additionally as the sites were all cropped after the original study termination, some dissipation may be attributable to uptake of soil residues by crops. The smallest decreases in dissipation times were at the two sites which had a design allowing grass growth after application. Thus it is possible that the smaller difference in dissipation times may be due to surface processes soon after application but also to the presence of vegetative cover with associated plant uptake occurring during the original study and in the intervening time between the end of the study and the new samples being collected, i.e. crop uptake was a common process both during the study and afterwards. Being a common process during and after the study at these two sites may be a reason why there was less difference in the dissipation times than at those sites where there was no vegetative growth in original study period.

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2/03. [redacted] (2020a), SYN545974 - Kinetic Assessment of Non-EU Field Dissipation Data for Persistence Endpoints, Modelling Assessment. Report Number 0485665-Kin05. ERM, UK<br>(Syngenta Document No. VV- 875692). |

**Guideline(s):** FOCUS 2006; FOCUS 2014; EFSA 2014
**GLP/GEP:** Not applicable
**Deviation(s):** No major deviation identified
**Acceptability** Yes for calculation methods, but note comments below.

This kinetic modelling report was submitted to calculate dissipation DT50 and DT90 values for the non-European field studies described in section B.8.1.1.2.2.1.4. As described, none of the field dissipation studies are considered to be relevant to European conditions and therefore are not used in risk assessment. Consequently the kinetic calculations in this study have not been assessed in detail. The best fit DT50 and DT90 values for each site have been quoted in the description of each non-European study site above to give an indication of the rate of dissipation at each site.

### B.8.1.1.2.2.3. Kinetic evaluation of the field dissipation studies – Modelling endpoints

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2/02. [redacted] (2016b), SYN545974 – Kinetic Assessment of Field Dissipation Data for Modelling Endpoints, Report Number SYN/48/01-KIN05. JSC International Limited, Harrogate, North Yorkshire, UK<br>(Syngenta File No. SYN545974_10444. |

| | |
|---|---|
| **Guideline(s):** | FOCUS 2006, EFSA 2014 |
| **GLP/GEP:** | Not applicable |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**

The rate of degradation of pydiflumetofen applied to bare soil has been studied in the field in six studies located across Europe. These studies are summarised under B.8.1.1.2.2.1. The design of all six studies included coverage of the treated field plots after application with >3mm of fine sand, in accordance with EFSA (2014) guidance for designing field dissipation studies to derive soil matrix $DegT_{50}$ values. As such it was applicable to follow the FOCUS Kinetics (2006) flow chart for deriving modelling endpoints for all six sites. Kinetic modelling was conducted using CAKE v3.2 (2016).

Input data were generated according to the data handling recommendations made in the FOCUS Kinetics guidance. The LOD and LOQ for all six studies/sites were reported to be 0.15 and 0.5 µg/kg wet soil respectively. As residues were reported and fitted in the units g a.s./ha, the surrogate values for samples <LOD or <LOQ were calculated for each replicate based on the sample wet weight and total sampled core area for that replicate.

No guidance is provided in FOCUS Kinetics guidance for handling of values <LOQ or <LOD with respect to the sampling depth/horizon in which they are measured. In the six studies fitted, residues in lower soil horizons were only reported where residues >LOQ were recorded in the horizon immediately above. All values reported as <LOD or <LOQ have, therefore, been handled using the methodology described in FOCUS Kinetics guidance.

Three true replicates were reported for each site/sampling occasion; these replicates were included individually in the model input data in accordance with FOCUS Kinetics guidance.

A timestep normalisation of the data was performed in accordance with FOCUS Kinetics guidance to allow for calculation of DegT50 values corrected to the standard conditions of 20ºC and moisture at 10 kPa (pF2), in order to produce values suitable for use in environmental models. Timestep normalisation of the input data was performed using daily soil moisture and temperature recorded on site at each of the study locations. For Italy, Northern France and Southern France, soil moisture and temperature recorded on-site were missing for some days. In these cases, missing values in the soil data were filled by either averaging the daily values either side of a single missing value, or by simulating soil temperature from daily on site weather data using the PERSIST model for longer periods of missing data. As soil moisture was generally maintained above pF2 through irrigation it was assumed that moisture was above pF2 during periods of missing data. The temperatures calculated by PERSIST were deemed suitable for use in normalisation as they followed the general trend of the measured data. HSE notes that the more common approach to simulation of soil temperature and soil moisture data is the use of the PEARL model but this is normally within a context of a simulation of soil temperature and moisture for the entire duration of the study. The use of PERSIST is not very common but not without precedent; indeed, PERSIST is mentioned in FOCUS Kinetics guidance as a model which has had the routines for calculating soil temperature and moisture validated. As such its use can be accepted. In the view of HSE, the absence of measured data for relatively short periods in relation to the approximately 2 year duration of the studies is unlikely to have a significant impact on the calculated kinetic parameters.

**Table B.8. 192 Estimation of missing soil temperature and moisture values**

| Site | Missing values | Method used |
|---|---|---|
| Italy | 18 & 19/01/2015 (soil temp. & moisture)<br>03/03/2015 (soil temp. & moisture) | Soil temp. & moisture entered as average of 17 & 20/01/2015<br>average of 02 & 04/03/2015 |
| Northern France | 29/01/2015 to 25/02/2015 (soil temp. & moisture) | Soil temp. estimated with PERSIST, soil moisture assumed to be ≥ pF2 |
| Southern France | 21/04 to 25/02/2015 (soil temp. & moisture)<br>14/10 to 28/10/2015 (soil temp. & moisture) | Soil temp. estimated with PERSIST, soil moisture assumed to be ≥ pF2 |
| | 27/02/2015 (soil temp. & moisture) | Soil temp. & moisture entered as average of 26 & 28/02/2015 |
| | 14/10 to 28/10/2014 (soil moisture) | Soil moisture assumed to be ≥ pF2 |
| | 13/04/2015 (soil temp. & moisture)<br>19/04/2015(soil temp. & moisture) | Soil temp. & moisture entered as Average of 12 & 14/04/2015<br>Average of 18 & 20/04/2015 |

Note: error in dates, 21/4/2014 – 05/5/2014; in addition 29/03/2015 – 01/04/2015 (soil temp. & moisture) missing

The resulting timestep normalised times are presented below.

**Table B.8. 193 Comparison of reported time and timestep normalised time**

| Germany | | Italy | | Northern France | |
|---|---|---|---|---|---|
| **Reported time (days)** | **Timestep normalised time (days)** | **Reported time (days)** | **Timestep normalised time (days)** | **Reported time (days)** | **Timestep normalised time (days)** |
| 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 3 | 2.0 | 3 | 3.9 | 3 | 3.0 |
| 7 | 4.8 | 7 | 11.6 | 7 | 7.9 |
| 14 | 10.9 | 14 | 21.7 | 13 | 16.1 |
| 29 | 24.5 | 28 | 49.2 | 27 | 34.8 |
| 58 | 57.8 | 58 | 123.9 | 62 | 101.2 |
| 119 | 117.0 | 121 | 215.8 | 119 | 161.3 |
| 178 | 140.3 | 182 | 248.1 | 177 | 186.5 |
| 358 | 196.3 | 366 | 403.4 | 370 | 273.6 |
| 533 | 350.2 | 542 | 619.9 | 546 | 413.4 |
| 715 | 399.9 | 716 | 708.0 | 721 | 474.3 |

| Southern France | | Spain | | UK | |
|---|---|---|---|---|---|
| **Reported time (days)** | **Timestep normalised time (days)** | **Reported time (days)** | **Timestep normalised time (days)** | **Reported time (days)** | **Timestep normalised time (days)** |
| 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 3 | 4.8 | 3 | 3.6 | 3 | 2.3 |
| 7 | 11.8 | 7 | 8.4 | 7 | 5.5 |
| 15 | 30.7 | 14 | 17.9 | 15 | 11.5 |
| 29 | 63.2 | 29 | 43.0 | 27 | 21.2 |
| 59 | 115.1 | 62 | 111.1 | 59 | 64.2 |
| 121 | 175.7 | 119 | 223.0 | 118 | 115.4 |
| 172 | 193.6 | 178 | 282.8 | 182 | 141.4 |
| 366 | 338.3 | 358 | 411.7 | 372 | 217.7 |
| 533 | 503.4 | 538 | 774.7 | 539 | 354.9 |
| 721 | 622.8 | - | - | 718 | 415.4 |

The data were then directly fitted un-weighted with the complete data set and unconstrained initial concentration (M0) for parent. The flowchart described in the FOCUS Kinetics guidance for modelling endpoints was followed.

The quality of the resulting fits has been assessed visually and statistically by the $\chi^2$ error. Confidence in the resulting parameters has been assessed from probability values for a t-test of the rate parameters for the SFO and DFOP models. Where the parameters for a particular model are not significantly different from zero at the 95% or 90% significance level, it has been concluded that the model may not be appropriate to represent the degradation behaviour in that soil.

For fits that are visually acceptable or good, but for which a robust degradation rate cannot be established, *i.e.* a t-test of <90% probability, then the suitability of the selected endpoints or defaults has been justified through comparison with other datasets and set into context considering data quality and the conservative nature of the estimates.

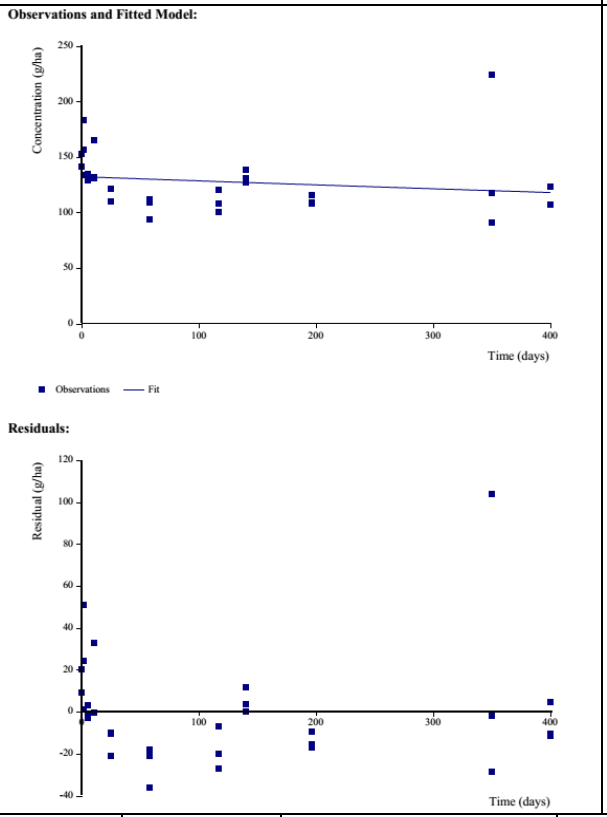
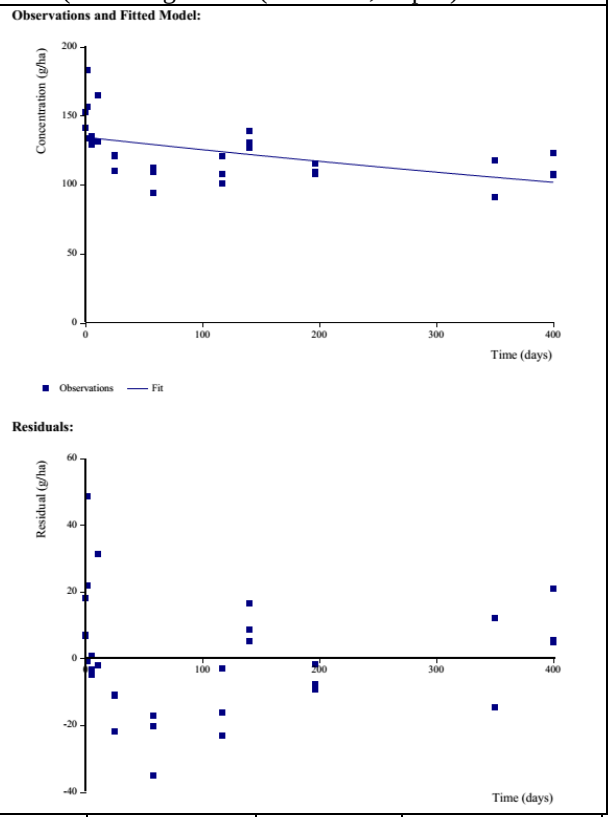
**Findings**
Results from the kinetic fitting are presented in the following table.

**Table B.8. 194 Kinetic parameters and statistics of the fittings for pydiflumetofen, normalised field dissipation data**

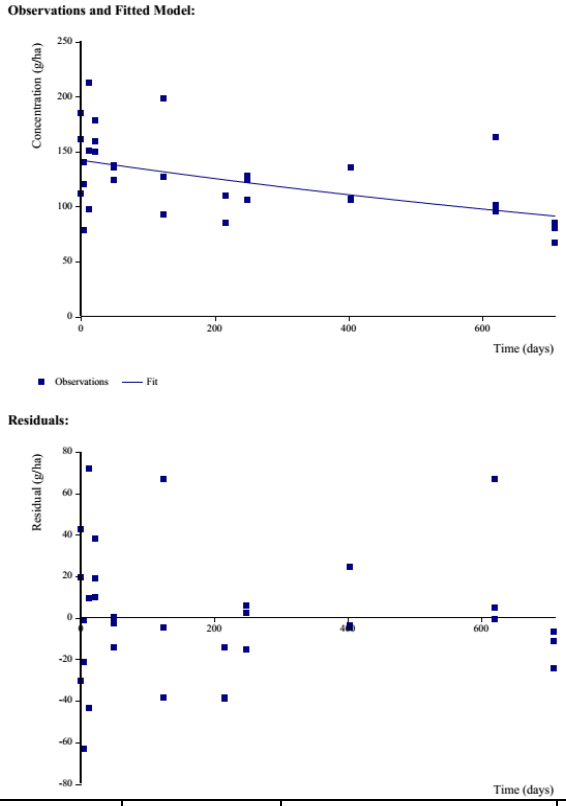
| Site | Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / Confidence interval (90/95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|---|
| Germany | SFO | k=0.000284 | Poor/Poor | 10.3 | k: >0.1 | 2440 | 8100 |
| | SFO (outlier excluded) | k=0.000695 | Acceptable/Acceptable | 8.75 | k: <0.05 | 997 | 3310 |
| | **Modelling endpoint: SFO not acceptable.**<br>**Exclusion of potential outlier (533 DAT; Rep B) → SFO selected** | | | | | | |
| Italy | SFO | k=0.000625 | Good/Good | 11.4 | k: <0.05 | 1110 | 3690 |
| | **Modelling endpoint: SFO selected** | | | | | | |
| Northern France | SFO | k=0.000216 | Acceptable/Acceptable | 9.83 | k: >0.1 | 3210 | >10000 |
| | **Modelling endpoint: SFO selected**<br>Poor statistical confidence in rate parameter estimate (p = 0.18) can be attributed to the rate of degradation being very slow and, therefore, not statistically different from zero. The endpoint $DegT_{50}$ was considered suitable for modelling. | | | | | | |
| Southern France | SFO | k=0.00286 | Poor/Poor | 21.1 | k: <0.05 | 242 | 805 |
| | DFOP | $k_1$=0.04618<br>$k_2$= 0.00106<br>g=0.502 | Good/Good | 12.5 | $k_1$: <0.05<br>$k_2$: <0.05 | 59.4 | 1520 |
| | **Modelling endpoint: SFO not acceptable.**<br>**10% initial concentration not reached → fit DFOP; DFOP selected** | | | | | | |
| Spain | SFO | k=0.000703 | Poor/Poor | 29.2 | k: <0.05 | 986 | 3270 |
| | DFOP | $k_1$=0.08778<br>$k_2$= 6.72E-08<br>g=0.5057 | Poor/Poor | 24.0 | $k_1$: <0.10<br>$k_2$: >0.10 | 51.1 | >10000 |
| | **Modelling endpoint: SFO not acceptable.**<br>**10% initial concentration not reached → fit DFOP; DFOP not acceptable.**<br>Data display a large degree of scatter and residues increase between 14 DAT and 358 DAT. Data from this site is considered unsuitable for deriving modelling endpoints | | | | | | |
| UK | SFO | k=0.000382 | Good/Good | 11.3 | k: <0.10 | 1820 | 6030 |
| | **Modelling endpoint: SFO selected** | | | | | | |

Visual fits and residual plots are reported below.

**Figure B.8. 43 Visual fits and residual plots, normalised field dissipation data**

| **Germany** | |
|---|---|
| SFO | SFO (excluding outlier (533 DAT, Rep B) |
|  |  |

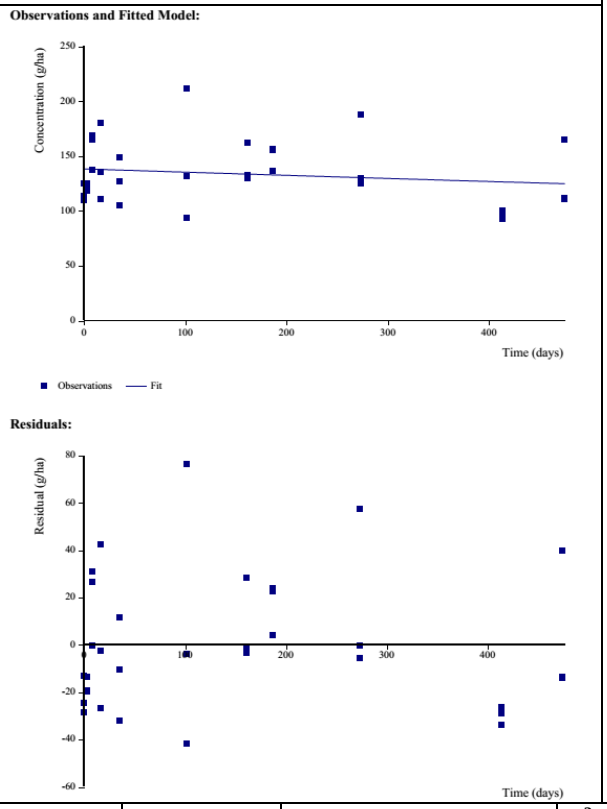
| **Model** | **Kinetic parameters** | **Visual fit/residuals** | **$\chi^2$ error %** | **T-test / CI (90/95%)** | **$DT_{50}$ (days)** | **$DT_{90}$ (days)** |
|---|---|---|---|---|---|---|
| SFO | k=0.000284 | Poor/Poor | 10.3 | k: >0.1 | 2440 | 8100 |
| SFO (outlier excluded) | k=0.000695 | Acceptable/Acceptable | 8.75 | k: <0.05 | 997 | 3310 |
| **Modelling endpoint: SFO not acceptable.**<br>**Exclusion of potential outlier (533 DAT; Rep B) → SFO selected** | | | | | | |

| **Italy** | |
|---|---|
| SFO | |
|  | |

| **Model** | **Kinetic parameters** | **Visual fit/residuals** | **$\chi^2$ error %** | **T-test / CI (90/95%)** | **$DT_{50}$ (days)** | **$DT_{90}$ (days)** |
|---|---|---|---|---|---|---|
| SFO | k=0.000625 | Good/Good | 11.4 | k: <0.05 | 1110 | 3690 |
| **Modelling endpoint: SFO selected** | | | | | | |

**Northern France**

SFO

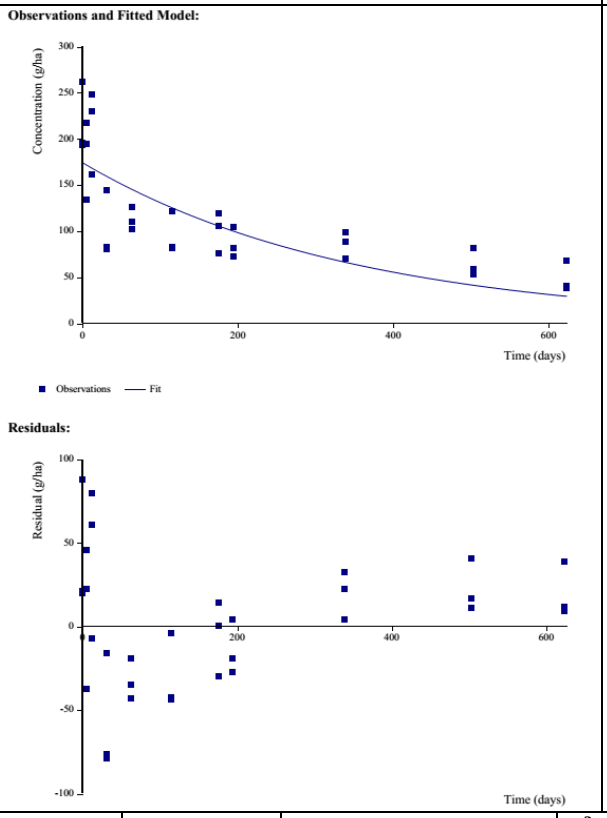
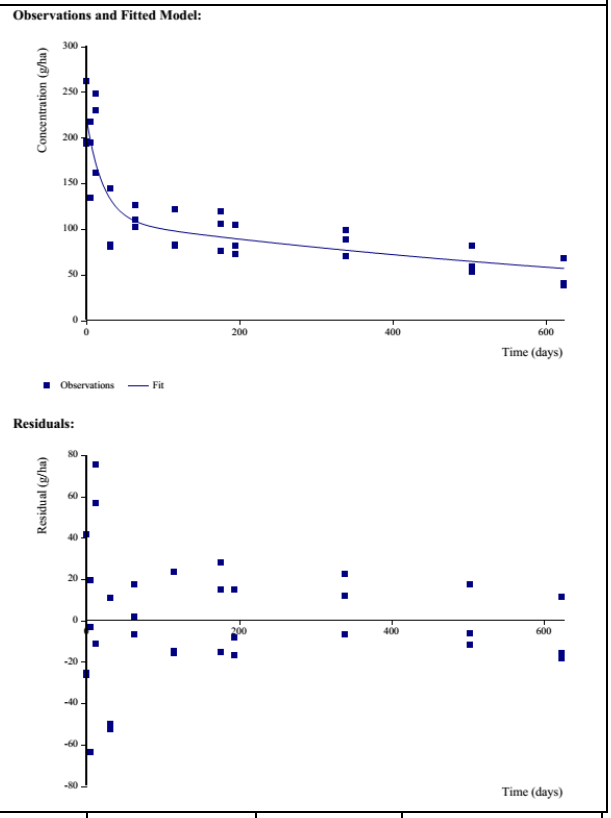



| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (90/95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.000216 | Acceptable/Acceptable | 9.83 | k: >0.1 | 3210 | >10000 |

**Modelling endpoint: SFO selected**

Poor statistical confidence in rate parameter estimate (p = 0.18) can be attributed to the rate of degradation being very slow and, therefore, not statistically different from zero. The endpoint $DegT_{50}$ was considered suitable for modelling.

**Southern France**

| SFO | DFOP |
|---|---|
|  |  |

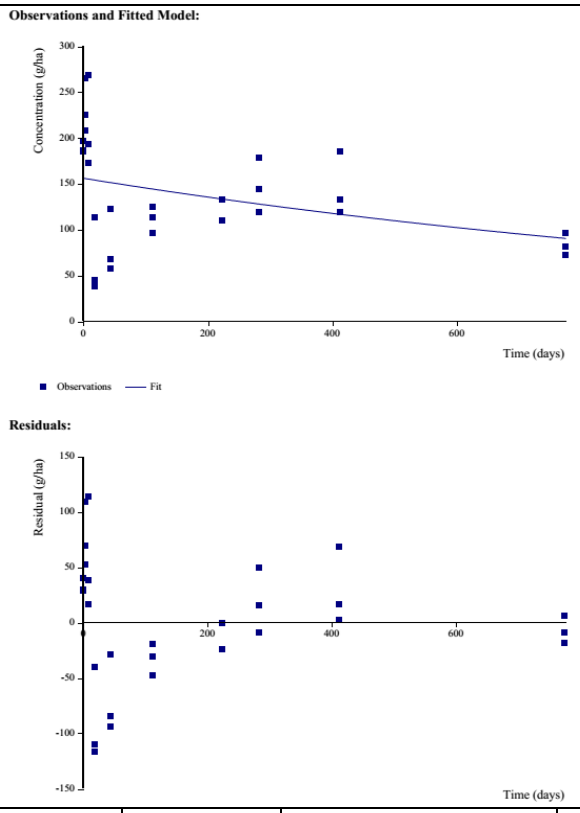


| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (90/95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.00286 | Poor/Poor | 21.1 | k: <0.05 | 242 | 805 |
| DFOP | $k_1$=0.04618<br>$k_2$= 0.00106<br>g=0.502 | Good/Good | 12.5 | $k_1$: <0.05<br>$k_2$: <0.05 | 59.4 | 1520 |

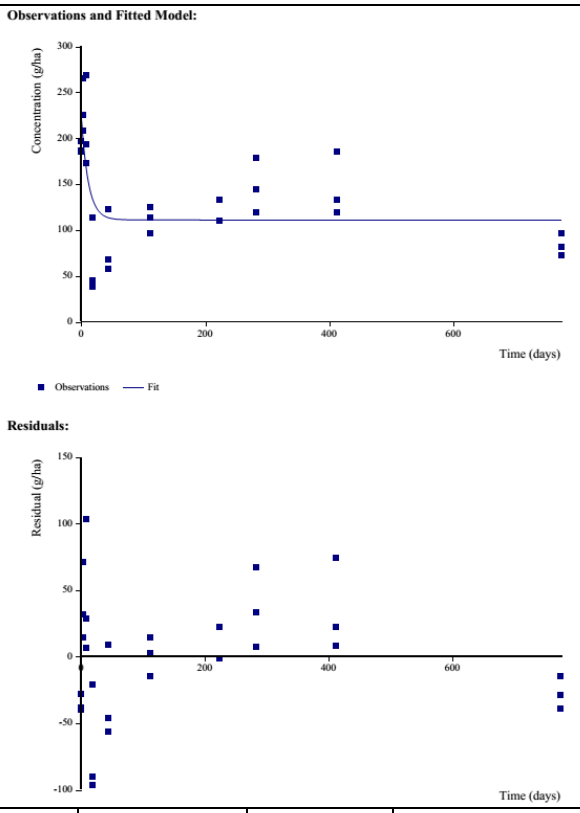
**Modelling endpoint: SFO not acceptable.**
**10% initial concentration not reached → fit DFOP; DFOP selected**

**Spain**

SFO

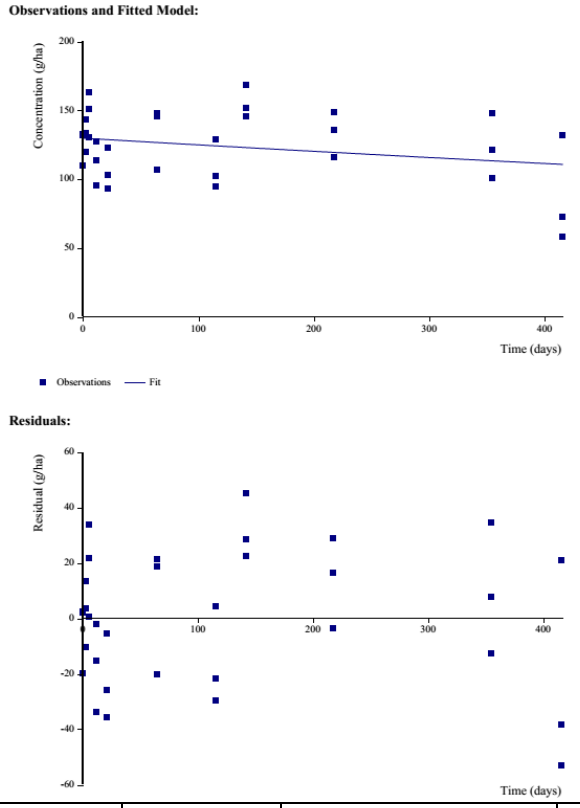



DFOP




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (90/95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.000703 | Poor/Poor | 29.2 | k: <0.05 | 986 | 3270 |
| DFOP | $k_1$=0.08778<br>$k_2$= 6.72E-08<br>g=0.5057 | Poor/Poor | 24.0 | $k_1$: <0.10<br>$k_2$: >0.10 | 51.1 | >10000 |

**Modelling endpoint: SFO not acceptable.**
**10% initial concentration not reached → fit DFOP; DFOP not acceptable.**
Data display a large degree of scatter and residues increase between 14 DAT and 358 DAT. Data from this site is considered unsuitable for deriving modelling endpoints

| **UK** | |
|---|---|
| SFO | |
|  | |

| **Model** | **Kinetic parameters** | **Visual fit/residuals** | **$\chi^2$ error %** | **T-test / CI (90/95%)** | **$DT_{50}$ (days)** | **$DT_{90}$ (days)** |
|---|---|---|---|---|---|---|
| SFO | k=0.000382 | Good/Good | 11.3 | k: <0.10 | 1820 | 6030 |
| **Modelling endpoint: SFO selected** | | | | | | |

A summary of the $DegT_{50matrix}$ values corrected to the standard conditions of 20ºC and moisture at 10 kPa (pF2) is presented in the following table. These endpoints are suitable for use in environmental models.

**Table B.8. 195 Summary of modelling DegT50 matrix values for pydiflumetofen**

| **Trial location** | **Soil texture** | **Soil pH ($H_2O$)** | **$\chi^2$ error %** | **$DegT_{50}$ matrix (days)** | **Kinetic** |
|---|---|---|---|---|---|
| Germany | Sandy loam | 5.68 | 8.75 | 997 | SFO |
| Italy | Clay Loam | 7.40 | 11.4 | 1110 | SFO |
| Northern France | Silty clay loam | 7.52 | 9.83 | 3210 | SFO |
| Southern France | Sandy loam | 7.48 | 12.5 | 654[a] | DFOP |
| Spain | Sandy loam | 7.27 | N/A[b] | N/A[b] | None[b] |
| UK | Loam | 6.84 | 11.3 | 1820 | SFO |
| **Geometric mean** | | | | **1334** | **SFO** |

[a] Modelling $DegT_{50}$ calculated from DFOP k2 parameter (ln(2)/k2).
[b] Data displayed a large degree of scatter and residues increased between 14 DAT and 358 DAT. Data from this site were considered unsuitable for deriving modelling endpoints.

**Conclusion**

The results of the kinetic modelling are accepted by HSE. The decision-making seems appropriate. The results, in comparison with those from the aerobic laboratory soil incubations, confirm the slow degradation of pydiflumetofen when degraded in the bulk soil matrix.

The field soil DegT50matrix values for pydiflumetofen corrected to the standard conditions of 20ºC and moisture at 10 kPa (pF2) ranged from 654 to 1820 days, with a geometric mean of 1334 days. The results of the kinetic assessment are considered by HSE to be suitable for use in environmental exposure assessment.

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2/03. [redacted] (2020b), Pydiflumetofen - Non-standard surface applied FOCUS EU TFD Kinetics Modelling Endpoints, Report Number RAJ01353B. Syngenta, Jealott's Hill, UK<br>(Syngenta Document No. VV-864729). |

| | |
|---|---|
| **Guideline(s):** | FOCUS 2006; FOCUS 2014; EFSA 2014 |
| **GLP/GEP:** | Not applicable |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes for calculation methods, but note comments below. |

As was noted in section B.8.1.1.2.2.1.2, the four field dissipation studies addressed by these kinetic calculations were specifically designed to allow grass to develop on the treated plots after application had been made. Whilst this study design is considered by HSE to allow a more realistic representation of dissipation under field conditions, it is potentially problematic from the point of view of generating modelling endpoints from these studies. In order to derive modelling endpoints, the decline of the substance in the study has to be virtually exclusively due to degradation in the soil bulk matrix and discounting other routes of dissipation such as soil surface photolysis, leaching and plant uptake. Whilst the kinetic assessment has excluded data from before the occurrence of 10mm rainfall/irrigation to discount the influence of soil surface photolysis at the beginning of the study, the assessment does not consider the potential influence that plant uptake may have had on the soil residues.

The EFSA DegT50 guidance which is used to guide the assessment of field dissipation studies indicates that it is expected that the treated plots will be bare soil with no vegetative growth. This is to prevent the potential for uptake of the soil residue by plants and to impact the decline of the soil residue. In the case of these studies, the presence of an establishing grass crop could have resulted in the take up of soil-borne residues into the grass. If this were the case, the use of the residues data for calculation of modelling endpoints would be doubtful.

The use of grassed plots in the context of obtaining modelling endpoints from field dissipation studies is discussed in Appendix A, section B of the EFSA DegT50 guidance. This appendix details the design of the field study intended to generate DegT50 data. Section B of Appendix A indicates that the use of grassed plots is an option for applicants where there are robust data in the registration dossier confirming that plant uptake is not a significant route of dissipation from soil and that the presence of plant roots may enhance microbially mediated degradation. In such a case, the guidance says that an option is to conduct a study using parallel grassed and bare soil plots. The results of both plots would be interpreted using a suitably parameterised soil root zone model to provide an interpretation of the contribution that plant uptake may have had to any difference in DT50 values in the grassed and bare soil plots. However, in this case the field dissipation studies did not include parallel bare soil plots in addition to the grassed plots.

The uptake of substances from soil is simulated in the suite of exposure models using the transpiration stream concentration factor (TSCF). The TSCF can be predicted from the log Kow using the Briggs equation as given in the FOCUSgw generic guidance. Pydiflumetofen has a log Kow of 3.8 (see section B.2.7). The Briggs equation predicts a TSCF of 0.147. A TSCF of 0 would result in exposure models simulating no plant uptake. Whilst being much lower than the maximum of 0.8, a TSCF of 0.147 still suggests that plant uptake could contribute to dissipation of the soil residue.

The applicant has also submitted data from confined rotational crop metabolism studies (Volume 3, section B.7.6.1., Chapleo and Johnson (2015)). These showed that soil-borne residues of pydiflumetofen can be taken up into plants. The applicant considers that the residues in commodities such as wheat straw are relatively low and that uptake into plants would contribute little to dissipation of pydiflumetofen from soil. Assessment of the rotational crops studies indicates that a relatively low proportion of the applied dose appears to have been taken into aerial parts of plants but this does not take into account the amount that could have been taken up into the root system of plants such as cereals.

It is also noted at section B.8.1.1.1.2.1.3 that a study was submitted where the sites of previous field dissipation studies using pydiflumetofen were resampled between 3.1 and 5.3 years after the original studies had terminated. One of the concerns about the use of the additional sampling data to generate new modelling endpoints from these sites was that the sites had been cropped in the intervening time. As a consequence, plant uptake may have contributed to the additional decline in residues.

Whilst not implying that cropping of the field plots from these studies leads to a very significant dissipation of soil residues from plant uptake, this route of dissipation has to be excluded in order to be able to calculate DegT50 values for modelling purposes. Due to the presence of other information such as the rotational crops studies and the predicted TSCF from the log Kow value, plant uptake in these studies cannot be excluded.

Overall, whilst it is considered that these studies can be used to address the primary data requirement of assessing dissipation under field conditions, it is questionable whether the studies can be used to generate DegT50 values for modelling purposes. Therefore the kinetic assessment for determination of modelling endpoints from these four field dissipation studies has not been evaluated.

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2/04. [redacted] (2020b), SYN545974 - Kinetic Modelling Evaluation of Data from EU Terrestrial Field Dissipation Studies for Calculation of Modelling Endpoints for Parent, Modelling Assessment. Report Number NC/20/034B. Battelle UK Ltd, UK<br>(Syngenta Document No. VV- 877011). |

| | |
|---|---|
| **Guideline(s):** | FOCUS 2006; FOCUS 2014; EFSA 2014 |
| **GLP/GEP:** | Not applicable |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes for calculation methods, but note comments below. |

This study reports kinetic calculations as a result of additional sampling conducted 3.1 – 5.3 years after termination of the original studies at five European field dissipation sites. As noted in section B.8.1.1.2.2.1.3, HSE has significant concerns over the validity of the study findings as the there is considerable uncertainty over the influence of aspects such as cultivation and other dilution effects to have influenced the soil residues in the additional samples. In addition, as two of the study sites had grass growth following application and all sites were cropped after the termination of the original study period, it is possible that plant uptake could have contributed to the dissipation of residues. As such, a detailed assessment of the kinetic calculations has not been conducted and the modelling endpoints from this report are considered to be not suitable for use in risk assessment.

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2/03. [redacted] (2020b), SYN545974 - Kinetic Assessment of Non-EU Field Dissipation Data for Modelling Endpoints, Modelling Assessment. Report Number 0485665-Kin04. ERM, UK<br>(Syngenta Document No. VV-875689). |

| | |
|---|---|
| **Guideline(s):** | FOCUS 2006; FOCUS 2014; EFSA 2014 |
| **GLP/GEP:** | Not applicable |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes for calculation methods, but note comments below. |

This kinetic modelling report was submitted to calculate modelling kinetic parameters for the non-European field dissipation studies described in section B.8.1.1.2.2.1.4. As described, none of the field dissipation studies are considered to be relevant to European conditions and therefore are not used in risk assessment. Consequently the kinetic calculations in this study have not been assessed.

### B.8.1.1.2.2.4. Storage stability

| | |
|---|---|
| **Report:** | K-CA 7.1.2.2.1/07. [redacted], [redacted] and [redacted] 2015. Stability of SYN545974 in Representative Turfgrass Clippings, Turf Thatch-Sod Layer and Soil Matrices Under Freezer Storage Conditions, Syngenta Crop Protection, LLC, Greensboro, North Carolina, USA. (Syngenta Report No. TK0228507) (Syngenta File No. SYN545974_50216) |

| | |
|---|---|
| **Guideline(s):** | U.S. EPA OPPTS 835.6100 |
| **GLP:** | Yes |
| **Deviation(s):** | None |
| **Acceptability** | Yes |

The stability of pydiflumetofen was investigated for approximately 1 year at -20 ºC in the following soil/field matrices: turfgrass clippings, turf thatch-sod layer and soil.

**Test System**

The test conditions of the storage stability study on pydiflumetofen were as follows:

Test substance: pydiflumetofen
Plant matrices: turfgrass clippings and turf thatch-sod layer
Soil matrices: soil
Storage temperature: approx. -20 ºC
Storage intervals (nominal, months): 0, 3, 6, 9, 12

**Test commodities**

Samples were sourced from terrestrial field dissipation (TFD) studies, conducted in support of pydiflumetofen. Three soil samples, from three separate North American TFDs were tested – these studies are: TK0174758 (Prince Edward Island, Canada); TK0103779 (Iowa, USA); and TK0121177 (California, USA). The turfgrass clippings and thatch-sod were obtained from trial TK0174758 (Prince Edward Island, Canada).

**Test methods**

Untreated soil samples (10 g) from the three test sites and untreated thatch-sod samples (10 g) from the Canadian test site were fortified to achieve an analyte concentration of 0.01 mg/kg for SYN545974. Untreated turfgrass clipping samples (10 g) from the test site were homogenised and fortified to achieve an analyte concentration of 0.5 mg/kg for SYN545974. All matrices after fortification were placed in freezer storage at approximately −20 °C, the same conditions under which actual field dissipation samples were stored prior to their analysis.

Triplicate replicate samples of the zero-time samples were extracted for analysis after fortification. Triplicate stored samples were extracted for analysis at 3, 6, 9 and 12 months. A control sample and two freshly spiked samples (procedural recovery) were analysed in parallel with each stored sample. Several sets also included a method blank to monitor potential sample contamination.

Residues in soil and thatch-sod were analysed using LC-MS/MS method ‘GRM061.04A’; residues in turfgrass clippings were determined using LC-MS/MS method ‘GRM061.03A’. The LOQ of ‘GRM061.04A’ is 0.0005 mg/kg for soil and thatch-sod. The LOQ of ‘GRM061.03A’ is 0.01 mg/kg for turfgrass clippings. The mean recovery for each commodity was within the acceptable range of 70 – 110 %; the RSD for each commodity was < 20 %, n=10 for each commodity; except for thatch-sod samples, where n=8.

Matrix effects were investigated for each commodity. Matrix matched standards were not used.

The fresh samples being assessed for procedural recovery, were analysed within 13 day of extraction. The stored samples were extracted at the same time as the procedural recovery values; no details were given on the date of analysis for stored samples – however, it is likely this was performed at the same time as the analysis of procedural recovery samples. No details were provided on the storage conditions of the extracts. The stability of sample extracts has not been specifically investigated; however, the procedural recovery for each matrix at each

time point is within 70 – 110 %, this is sufficient. Given these acceptable procedural recovery results, extract stability can be considered sufficiently addressed, for all samples analysed in the study.

**Results**

Several control samples contained pydiflumetofen residues >LOQ – the samples affected are detailed in the table below. The contamination was not significant, less than 5 % of the fortification level in all cases (max 3.2 %), with the vast majority less than 1 %. As the contamination of the control samples is not significant, it would be preferable to present storage stability analysis without correcting for residues in the control. However, uncorrected results were not provided in the study report. Given that contamination is low, ≤3.2 %, the corrected values are unlikely to differ significantly from the uncorrected results. Therefore, in the absence of uncorrected results, the corrected results will be relied upon.

**Table B.8. 196 Summary of residues in control samples**

| Sample | Time of analysis (months – nominal) | Residue (ppb/ppm) † | Control contamination as a % of nominal fortification level |
|---|---|---|---|
| **Soil (Iowa – silt loam)** | 0 | 0.06 | 0.6 |
| | 3 | 0.077 | 0.77 |
| | 6 | 0.036 | 0.36 |
| | 9 | 0 | 0 |
| | 12 | 0.064 | 0.64 |
| **Soil (California – sand)** | 0 | 0.023 | 0.23 |
| | 3 | 0.226 | 2.26 |
| | 6 | 0.094 | 0.94 |
| | 9 | 0 | 0 |
| | 12 | 0 | 0 |
| **Soil (Canada – sandy loam)** | 0 | 0.024 | 0.24 |
| | 3 | 0.049 | 0.49 |
| | 6 | 0.020 | 0.20 |
| | 9 | 0.211 | 2.11 |
| | 12 | 0.010 | 0.1 |
| **Thatch-sod (Canada)** | 0 | 0.046 | 0.46 |
| | 3 | 0.131 | 1.31 |
| | 6 | 0.263 | 2.63 |
| | 9 | 0.320 | 3.2 |
| | 12 | 0.320 | 3.2 |
| **Turfgrass clippings (Canada)** | 0 | 0 | 0 |
| | 3 | 0.002 | 0.4 |
| | 6 | 0 | 0 |
| | 9 | 0.001 | 0.2 |
| | 12 | 0 | 0 |

† Ppb for soil and thatch-sod samples, ppm for turfgrass clippings.

The results of the freezer storage stability of pydiflumetofen are summarised in table xx; the results were not corrected for the procedural recovery. The mean procedural recovery of the freshly spiked sample is also reported to demonstrate the effectiveness of the method at the time of analysis.

**Table B.8. 197 Summary of storage stability data for pydiflumetofen in TFD studies**

| Commodity | Storage period (days) | Residue level in stored sample (ppb/ppm) [1] | | Mean recovery stored sample – uncorrected (% of fortification level) [2] | Procedural recovery for freshly spiked sample (%) | |
|---|---|---|---|---|---|---|
| | | Individual | Mean | | Individual values | Mean |
| **Soil (Iowa – silt loam)** | 0 | 7.1, 7.9, 8.1 | 7.7 | 77 | 82, 86 | 84 |
| | 96 | 7.6, 7.7, 7.9 | 7.7 | 77 | 82, 86 | 84 |
| | 188 | 8.7, 8.9, 9.3 | 9.0 | 90 | 90, 93 | 92 |
| | 271 | 8.9, 11.5, 11.8 | 10.8 | 108 | 87, 104 | 96 |
| | 365 [3] | 7.7, 7.7, 7.8 | 7.7 | 77 | 101, 103 | 102 |
| | | *8.2, 8.3, 11.5* | *9.3* | *93* | *104, 105* | *105* |
| | 384 [4] | 11.1, 11.3, 11.3 | 11.2 | 112 | 111, 114 | 113 |
| **Soil (California – sand)** | 0 | 8.2, 8.5, 8.7 | 8.5 | 85 | 82, 84 | 83 |
| | 96 | 6.9, 8.3, 9.3 | 8.2 | 82 | 91, 98 | 95 |
| | 203 | 9.0, 9.1, 9.1 | 9.1 | 91 | 93, 95 | 94 |
| | 287 | 9.7, 9.8, 10.1 | 9.9 | 99 | 101, 101 | 101 |
| | 365 | 8.2, 8.4, 8.5 | 8.4 | 84 | 82, 86 | 84 |
| **Soil (Canada – sandy loam)** | 0 | 9.7, 9.8, 9.9 | 9.8 | 98 | 98, 98 | 98 |
| | 96 | 7.6, 8.0, 8.0 | 7.8 | 78 | 81, 89 | 85 |
| | 188 | 8.3, 8.8, 8.9 | 8.6 | 86 | 89, 98 | 94 |
| | 271 | 8.6, 8.6, 9.2 | 8.8 | 88 | 89, 100 | 94 |
| | 365 | 8.4, 9.6, 9.6 | 9.2 | 92 | 95, 95 | 95 |
| **Thatch-sod (Canada)** | 0 | 10.0, 10.1, 10.2 | 10.1 | 101 | 99, 100 | 99 |
| | 96 | 7.6, 7.8, 7.9 | 7.8 | 78 | 52, 78 | 78 |
| | 203 | 89, 91, 94 | 9.1 | 91 | 60, 86 | 86 |
| | 271 | 9.0, 9.5, 10.1 | 9.6 | 96 | 99, 102 | 100 |
| | 365 | 9.4, 9.6, 10.3 | 9.8 | 98 | 110, 112 | 111 |
| **Turfgrass clippings (Canada)** | 0 | 0.447, 0.479, 0.497 | 0.474 | 95 | 95, 95 | 95 |
| | 97 | 0.470, 0.475, 0.484 | 0.476 | 95 | 99, 102 | 101 |
| | 187 | 0.514, 0.516, 0.518 | 0.516 | 103 | 108, 109 | 108 |
| | 271 | 0.461, 0.469, 0.478 | 0.469 | 94 | 90, 92 | 91 |
| | 365 | 0.413, 0.416, 0.449 | 0.426 | 85 | 93, 99 | 96 |

1. Ppb for soil and thatch-sod samples, ppm for turfgrass clippings.
2. Value is uncorrected with respect to procedural recovery value. Mean recovery has been corrected for contamination in control, see above for details.
3. Initial 365-Day results. Set was diluted (values in italics are diluted values) and reanalysed for possible matrix suppression; however, reanalysis results confirmed initial results. A contingency set was analysed to confirm.
4. Contingency set analysed to confirm initial 365-Day results.

**Conclusion**

Residues of pydiflumetofen are considered stable in soil (sandy loam, sand and silt loam), thatch-sod and turfgrass clippings for 1 year under frozen conditions (≤ -20 ºC).

**B.8.1.1.2.3. Summary of rates of degradation**

The rate of degradation of pydiflumetofen in standard dark aerobic laboratory studies has been determined in five different soil types at 20°C and pF2. DT50 values were calculated based on residues from non-harsh extractions.

Pydiflumetofen does not degrade significantly, and trigger DT50 values (based on non-harsh residues) range from 398 to 2380 days, with $DT_{90}$ values ranging from 1320 to 7640 days. Modelling $DegT_{50}$ values range from 398 to 1690 days, with a geometric mean of 930 days. Slow degradation was also seen in the anaerobic soil.

In the soil photolysis study, pydiflumetofen was observed to degrade more quickly when exposed to light conditions than in the dark with SFO DT50 of 77 – 197 days compared to 369 ->1000 days in the dark controls. When corrected for latitude (30-50°N), the SFO DT50s under light conditions were 154 days in dry soil and 361 days in moist soil. It should be noted that the actual study duration was 14 – 16 days in length and therefore the DT50s are extrapolated well beyond the study duration which in itself leads to some uncertainty over the kinetic parameters.

HSE noted generally for all the laboratory soil studies the DT50 and DT90 values were extrapolated well beyond study duration and therefore there is significant uncertainty associated with the values.

Field soil dissipation studies were performed at ten locations across Northern and Southern Europe. Pydiflumetofen was applied to bare soil. At six of the sites, the treated plots were covered with a thin layer of sand immediately after application to minimise the potential impact of surface processes on dissipation and were also kept vegetation free throughout the trial period; this is in accordance with the DegT50 study design in the EFSA (2014) guidance. At a further four sites the treated plots had been previously sown with grass. Consequently, whilst application was made to bare soil, the plots were subsequently allowed to develop grass growth. Such a design, whilst not in accordance with the EFSA DegT50 study design, is perhaps more in keeping with addressing the regulatory data requirement to address dissipation under field conditions. Information from studies following this type of design may be considered appropriate for use in long term soil exposure assessments. It should be noted that there is no specific regulatory requirement to conduct a study to obtain DegT50 values using the DegT50 study design. However studies performed in accordance with the EFSA degT50 design can more easily be interpreted with regards deriving a long term bulk soil matrix DT50 appropriate for FOCUS groundwater modelling. Soil core samples were taken to a depth of up to 100 cm and analysed for residues of pydiflumetofen. At the end of the sampling period (approximately two years) in the six DegT50 study design sites, total soil residues of pydiflumetofen had dissipated by 38% to 76%, based on the nominal application rate. At the other four sites which were approximately one year duration, 23-69% dissipation had occurred. The enantiomeric composition of pydiflumetofen was only measured at six of the sites and did not change significantly during the field soil dissipation studies. The results are not considered to represent a significant change in enantiomeric excess as defined in European guidance on stereoisomers.

A further study resampling five of the ten European field dissipation studies was submitted. Resampling occurred between 3 to 5 years after termination of the original studies. The calculation of persistence and degradation end points from this study is not accepted by HSE due to concerns over the potential for dilution effects, including from cultivation and plant uptake, to have affected the decline in residues.

Study reports from an additional 14 field dissipation sites in North America and Asia were submitted. Current guidance indicates that non-European sites must be shown to be representative of European conditions in terms of both soil and meteorological conditions before they can be used in GB risk assessments. Following such an assessment, none of the sites are considered by HSE to be of representative of European conditions. Consequently the results have not been used in risk assessment.

**Consideration of kinetic parameters for use in PECsoil calculations**

Non-normalised field dissipation $DT_{50}$ values for pydiflumetofen at European sites ranged from 23 to 8540 days, with dissipation $DT_{90}$ values ranging from 755 to >10000 days. Consideration of the kinetic analysis suggest that dissipation was slower at sites that were designed according to the DegT50 guidance of EFSA (2014). At these sites losses *via* surface processes such as photolysis and volatilisation were minimised and plots were maintained vegetation free; the residue decline seen was representative of degradation in the bulk soil matrix only. The sites where grass was allowed to grow appear to show faster dissipation. This may be because the sites would have been subject to surface processes immediately after application but also potentially because plant uptake could have contributed to dissipation of the residue. Microbial biomass may also have been higher in the grassed plots compared to under the bare soil conditions maintained in the plots designed to follow the EFSA DegT50 guidance. In practice, the intended GAPs for pydiflumetofen are for application to emerged arable crops. In light of this, it is likely that the crops where grass was allowed to develop following application may be a better representation of dissipation under more realistic conditions. However, it is uncertain whether the grassed plots are wholly representative of proposed use, i.e. application to established crops as opposed to germinating and establishing grass, and whether grass is representative of cereals or oilseed rape. It is also acknowledged that dissipation or degradation rates were highly variable across all sites, irrespective of plot design. It is proposed that the longest non-normalised dissipation DT50 and DT90 from all field sites (DFOP

DT50 8540 days, DT90 >10000 days) is used in first tier PECsoil calculations, including calculation of accumulation. Following presentation to the Expert Committee on Pesticides (ECP) in the process of seeking Independent Scientific Advice (ISA), the ECP advice was that as a higher tier the longest non-normalised dissipation DT50 and DT90 from the four grassed sites (SFO DT50 1310 days) could be used in the PECsoil calculations. This was due to the grassed sites having a closer reflection of the intended use to environmental conditions in the field. The additional PECsoil calculations using different DT50/DT90 from all sites allows for the examination of the impact of the choice of DT50/90 on the terrestrial risk assessment.

**Consideration of kinetic parameters for use in FOCUS groundwater modelling**

The applicant performed calculations to derive field soil DegT50matrix values for pydiflumetofen corrected to the standard conditions of 20ºC and moisture at 10 kPa (pF2) for all ten sites. HSE consider that only the six sites which used the DegT50 study design are suitable for calculation of DegT50 and thus for FOCUS groundwater modelling. This is because the other four sites allowed grass growth to develop and therefore plant uptake could have contributed to the observed decline in residues, potentially invalidating the use of endpoints in FOCUS modelling. Field DegT50 values range from 654 to 3210 days, with a geometric mean of 1334 days.

According to the flow chart in Figure 3 of EFSA DegT50 guidance (2014)[6], since geomean laboratory DT50 is longer than 240 days and since at least 4 field $DegT_{50matrix}$ are available, the geomean of field $DegT_{50matrix}$ values should be used for environmental exposure modelling.

**Table B.8. 198 Degradation rates in soil under dark aerobic laboratory conditions – pydiflumetofen – Trigger endpoints – NOTE all DT50 values extrapolated beyond study duration**

| Parent | Dark aerobic conditions – **Trigger endpoints** | | | | | |
|---|---|---|---|---|---|---|
| Soil type | pH[a)] | t. ºC / % MWHC | Overall $DT_{50}$ /$DT_{90}$ (d) | Kinetic parameters | St. ($\chi^2$) | Method of calculation |
| Gartenacker (loam) | 6.9 | 20°C / pF2 | 398/1320 | - | 1.34 | SFO |
| 18 Acres (sandy clay loam) | 5.5 | 20°C / pF2 | 2380/7640 | $k_1$=0.03734 $k_2$= 0.000264 g=0.06232 | 0.41 | DFOP |
| Sarpy (silt loam) | 6.2 | 20°C / pF2 | 567/2970 | $k_1$=0.04405 $k_2$= 0.000669 g=0.2693 | 3.15 | DFOP |
| East Anglia (sandy loam) | 7.1 | 20°C / pF2 | 1300/4870 | $k_1$=0.09243 $k_2$= 0.000452 g=0.1005 | 0.96 | DFOP |
| Capay (clay loam) | 7.6 | 20°C / pF2 | 410/2540 | $k_1$=0.05022 $k_2$= 0.000756 g=0.3183 | 2.54 | DFOP |
| **Maximum** | | | **2380 / 7640** | | | **DFOP** |

[a)] Measured in calcium chloride solution

[6] European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662

**Table B.8. 199 Degradation rates in soil under dark aerobic laboratory conditions – pydiflumetofen – Modelling endpoints – NOTE all DT50 values extrapolated beyond study duration**

| Parent | Dark aerobic conditions – **Modelling endpoints** | | | | | |
|---|---|---|---|---|---|---|
| Soil type | pH[a)] | t. °C / % MWHC | $DT_{50}$ /$DT_{90}$ (d) | $DT_{50}$ (d) 20 °C pF2/10kPa[b)] | St. ($\chi^2$) | Method of calculation |
| Gartenacker (loam) | 6.9 | 20°C / pF2 | 398/1320 | 398 | 1.34 | SFO |
| 18 Acres (sandy clay loam) | 5.5 | 20°C / pF2 | 1690/5600 | 1690 | 1.42 | SFO |
| Sarpy (silt loam) | 6.2 | 20°C / pF2 | 567/2970 | 1036[c)] | 3.15 | DFOP |
| East Anglia (sandy loam) | 7.1 | 20°C / pF2 | 1090/3620 | 1090 | 2.62 | SFO |
| Capay (clay loam) | 7.6 | 20°C / pF2 | 410/2540 | 917[c)] | 2.54 | DFOP |
| **Geometric mean** (if not pH dependent) | | | | **930** | | **SFO** |
| pH dependence | | | | No | | |

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] Calculated from DFOP k2 parameter (ln(2)/k2)

**Table B.8. 200 Field Dissipation DT50 and DT90 – pydiflumetofen – Trigger endpoints**

| Parent | Aerobic conditions – **Trigger endpoints** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Soil type. | Location (country or USA state). | pH[a)] | Depth (cm) | Overall $DT_{50}$ (d) actual | Overall $DT_{90}$(d) actual | St. ($\chi^2$) | Kinetic parameters | Method of calculation |
| Sandy loam[b] | Germany | 5.68 | 0-20 | 8540[d] | >10000[d] | 6.5 | $k_1$=0.05381 $k_2$= 0.000043 g=0.2484 | DFOP |
| Clay loam[b] | Italy | 7.40 | 0-100 | 1110[d] | 3680[d] | 11.6 | - | SFO |
| Silty clay loam[b] | Northern France | 7.52 | 0-100 | 4030[d] | >10000[d] | 9.7 | - | SFO |
| Sandy loam[b] | Southern France | 7.48 | 0-50 | 29 | 1820[d] | 13.3 | $k_1$=0.08239 $k_2$= 0.000842 g=0.5381 | DFOP |
| Sandy loam[b] | Spain | 7.27 | 0.-30 | No reliable fit could be obtained | | | | |
| Loam[b] | UK | 6.84 | 0-30 | 2810[d] | 9350[d] | 11.2 | - | SFO |
| Loamy sand[c] | Germany | 6.23 | 0-30 | 1310[d] | 4360[d] | 8.7 | - | SFO |
| Silty clay[c] | Northern France | 6.13 | 0-20 | 639[d] | 2120[d] | 13.2 | - | SFO |
| Silt loam[c] | Southern France | 7.68 | 0-30 | 23.4 | 2130[d] | 9.1 | k1: 0.07406 k2: 0.000584 g: 0.6006 | DFOP |
| Loamy sand[c] | Portugal | 6.23 | 0-50 | 227 | 755[d] | 14.5 | - | SFO |
| **Maximum for Tier 1 PECsoil calculation** | | | | **8540** | **>10000** | | | **DFOP** |
| **Value for Tier 2 PECsoil calculation** | | | | **1310** | **4360** | | | **SFO** |

[a)] Measured in calcium chloride solution
[b)] application to bare soil, DegT50 design
[c)] application to bare soil, grass cover subsequently developed
[d)] DT50 or DT90 extrapolated beyond study duration

**Table B.8. 201 Field DegT50matrix – pydiflumetofen – Modelling endpoints**

| Parent | Aerobic conditions – **Modelling endpoints** | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | pH[a)] | Depth (cm) | $DT_{50}$ (d) Norm[b)]. | Kinetic parameters | St. ($\chi^2$) | Method of calculation |
| Sandy loam (bare soil) | Germany | 5.68 | 0-20 | 997 | - | 8.8 | SFO |
| Clay loam (bare soil) | Italy | 7.40 | 0-100 | 1110 | - | 11.4 | SFO |
| Silty clay loam (bare soil) | Northern France | 7.52 | 0-100 | 3210 | - | 9.8 | SFO |
| Sandy loam (bare soil) | Southern France | 7.48 | 0-50 | 654[c)] | $k_1$=0.04618 $k_2$= 0.00106 g=0.502 | 12.5 | DFOP |
| Sandy loam (bare soil) | Spain | 7.27 | 0.-30 | No reliable fit could be obtained | | | |
| Loam (bare soil) | UK | 6.84 | 0-30 | 1820 | | 11.3 | SFO |
| **Geometric mean** (if not pH dependent) | | | | **1334** | | | |
| pH dependence | | | | No | | | |

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
[c)] Calculated from DFOP k2 parameter (ln(2)/k2)

The data on DT50 and DT90 above can also be used for the purposes of comparison against persistence criteria for PBT/vPvB/POPs classification. According to Regulation 1107/2009, a substance meets the POP criteria in soil if the DT50 is greater than 6 months; for PBT, the substance meets the persistence criteria in soil if the half-life is greater than 120 days; for vPvB the substance meets the persistence criteria in soil if the half-life is greater than 180 days. From both laboratory and field studies (particularly the six sites which used the DegT50 study design) there is clear evidence that pydiflumetofen would be classified as 'persistent' or 'very persistent' according to each of these criteria. It should be noted that meeting the persistence criteria alone is insufficient for a substance to be classified as PBT, vPvB or POP.

## B.8.1.2. Adsorption and desorption in soil

### B.8.1.2.1. Adsorption and desorption of the active substance

| | |
|---|---|
| **Report:** | K-CA 7.1.3.1.1/01. [redacted], [redacted] (2013), SYN545974 - Adsorption and Desorption of $^{14}$C-SYN545974, Report Number 8252103. Smithers Viscient (ESG) Limited, Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK (Syngenta File No. SYN545974_10060) |

| | |
|---|---|
| **Guideline(s):** | OECD 106 (2000), EPA Guideline Series OPPTS 835-1230 (2008), SETAC (1995) |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**
The adsorption/desorption characteristics of $^{14}$C-pydiflumetofen were studied in six different soils using a standard batch equilibrium method.

| **Test Material:** | **[Pyrazole-5-$^{14}$C]-SYN545974** |
|---|---|
| Lot/Batch #: | 5222MFO001-1 |
| Specific activity: | 5.07 MBq/mg |
| Radiochemical Purity: | 97.8% |
| Application vehicle: | Acetonitrile (< 0.1% volume) |

Prior to use, the soils were air-dried and stored in the dark at room temperature in loosely tied plastic bags. The soils characteristics are presented below.

**Table B.8. 202 Soils characteristics**

| | 18 Acres | Gartenacker | Sarpy | Capay | Seven Springs | Marysville |
|---|---|---|---|---|---|---|
| Sampling location | Jealott's Hill Farm, Bracknell, UK | CH-1896 Vouvry, Les Barges, Switzerland | Cornish Road, Springfield NE, USA | Woodland, Yolo CA, USA | Seven Springs, Wayne Co, NC, USA | McClain Farm, Marysville OH, USA |
| Sampling depth | 5 - 20cm | 5 - 20cm | 0 - 15 cm | 0 - 15 cm | 0 – 15 cm | 0 - 15 cm |
| Particle size (% w/w): | | | | | | |
| Clay (< 2 µm) | 25 | 12 | 23 | 36 | 6 | 37 |
| Silt (2 – 50 µm) | 24 | 43 | 54 | 35 | 10 | 42 |
| Sand (50-2000 µm) | 51 | 45 | 23 | 29 | 84 | 21 |
| Texture (USDA) | Sandy clay loam | Loam | Silt loam | Clay loam | Loamy sand | Clay loam |
| pH (water) | 6.9 | 8.4 | ND | ND | ND | ND |
| pH (0.01M $CaCl_2$) | 6.0 | 7.2 | 6.5 | 6.7 | 5.2 | 7.6 |
| Organic matter (%) | 3.8 | 3.1 | 3.0 | 1.7 | 1.0 | 2.8 |
| Organic carbon (%) | 2.2 | 1.8 | 1.7 | 1.0 | 0.6 | 1.6 |
| CEC (meq/100 g soil) | 18.9 | 10.8 | 18.1 | 21.3 | 5.4 | 16.6 |
| Moisture at pF0 (w/w %) | 57.3 | 69.4 | ND | ND | ND | ND |
| Moisture at pF2.0 (w/w %) | 29.8 | 39.0 | 42.2 | 26.5 | 8.8 | 31.0 |

ND – Not determined

**Preliminary tests:**
Preliminary tests were conducted on all six soils to determine the conditions to be used in the definitive study.

Solubility: Duplicate application solutions, at a concentration of 0.5 µg/mL, were prepared to assess the solubility of pydiflumetofen in 0.01M calcium chloride solution. Recovery of applied radioactivity in solution (nominal 0.5 µg/mL) was 63-70% in plastic containers, 69-79% in Teflon® containers and 92-96% in glass containers. The containers affected the apparent solubility because the test item partially adsorbed to them. This was confirmed in the adsorption to containers test.

Adsorption to Containers test: A test was performed to determine whether pydiflumetofen adsorbed to plastic, Teflon® and glass vessels from a 0.005 µg/mL application solution. The recovery of applied radioactivity was *ca* 15% in plastic containers, 88% in Teflon® containers and 92% in glass containers after 24 h mixing. Glass tubes were used for the definitive test.

Ratio of soil to aqueous test at 0.5 µg/mL test item concentration: The determination of the optimum soil:aqueous ratio for use in the definitive test was conducted using all six soils at a test item concentration of 0.5 µg/mL and soil:solution ratios of 1:5, 1:10 and 1:20. A soil:solution ratio of 1:20 w/v was chosen for the definitive test with 18 Acres, Gartenacker, Sarpy and Marysville soils and a ratio of 1:10 w/v with Capay and Seven Springs soils.

Time to adsorption equilibrium: The adsorption equilibrium times for all six soils were determined over a 72 hour period using a test item concentration equivalent to 0.05 µg/mL and a soil:solution ratio of 1:10 (Capay and Seven Springs) or 1:20 (18 Acres, Gartenacker, Sarpy and Marysville). An adsorption equilibrium time of 48 hours was selected for use in the definitive test.

Time to desorption equilibrium: The desorption equilibrium times for all six soils were determined over a 48 hour period using a test item concentration equivalent to 0.05 µg/mL and a soil:solution ratio of 1:10 (Capay and Seven Springs) or 1:20 (18 Acres, Gartenacker, Sarpy and Marysville). A desorption equilibrium time of 48 hours was selected for use in the definitive test.

Stability during equilibrium time determination: Stability of the test item during the adsorption time determination was assessed at the 72-hour time point. Recovery of applied radioactivity as 14C-pydiflumetofen was ≥ 96%.

**Definitive test:**
Adsorption and desorption isotherms were determined on all six soils at a soil:solution ratio of a 1:10 (Capay and Seven Springs) or 1:20 (18 Acres, Gartenacker, Sarpy and Marysville) over five test item concentrations (nominally 0.5, 0.2, 0.05, 0.02 and 0.005 µg/mL), with a 48 hour adsorption followed by a 48 hour desorption step, in the dark at 20°C.

All samples were shaken in 0.01 M $CaCl_2$ solution for 48 hours (the adsorption equilibrium time) then centrifuged for 67 minutes at 3000 rpm. Weighed aliquots were taken for liquid scintillation counting (LSC) analysis before removing as much of the adsorption supernatant as possible from each unit into a pre-weighed vessel. The pH value of each adsorption supernatant was determined.

The weight of adsorption supernatant removed was replaced by an equal weight of fresh 0.01M $CaCl_2$ solution. Each test vessel was shaken vigorously to break up the soil packed at the bottom of the vessel and to re-mix it with the solution. The samples were shaken for 48 hours (the desorption equilibrium time), centrifuged for 67 minutes at 3000 rpm and radioactivity in the desorption supernatants was determined by LSC.

Stability of pydiflumetofen during the definitive test was checked in one replicate from each concentration from Sarpy soil, and in one replicate at the highest concentration only for the 5 other soils. For stability testing, radioactivity in supernatants was extracted from selected samples by solid phase extraction (SPE) and was analysed for pydiflumetofen by HPLC. Soil was extracted with acetonitrile:water (80:20 w/v), adjusted to pH 3 with formic acid. Extracts were concentrated under nitrogen and were analysed for pydiflumetofen by HPLC. Extracted soils were combusted to determine the radioactivity remaining in the soil.

Partition adsorption coefficients ($K_D$) and Freundlich adsorption coefficient ($K_F$) were calculated according to OECD 106. Isotherms were established based on log transformed data for individual replicates.

**Findings**
For all soils the recovery of radioactivity was quantitative. The mean mass balance was 101.5% (range 100.0 - 103.9%).

Extracts of soil and supernatant were analysed by HPLC and the recovery of applied radioactivity as $^{14}C$-pydiflumetofen was 95.0 to 103.0%, except in Sarpy soil at the lowest concentration of 0.005 µg/mL where recovery was 85%. However at this low concentration this could have been a chromatography issue rather than genuine degradation. Pydiflumetofen can be considered stable throughout the incubation period.

Concentrations of pydiflumetofen in the adsorption supernatants and adsorbed to the soil are presented below.

**Table B.8. 203 Concentration of $^{14}$C-pydiflumetofen in the supernatant and soil at the end of adsorption and desorption equilibration period in 18 Acres Soil**

| Nominal dose level (µg/mL) | Replicate | Adsorption | | | Desorption | | |
|---|---|---|---|---|---|---|---|
| | | $C_e$ (µg/mL) | X/m (µg/g) | % adsorbed* | $C_1$ (µg/mL) | $X_1$/m (µg/g) | % desorbed as % of the adsorbed |
| 0.5 | 1 | 0.1546 | 6.9734 | 69.4 | 0.0937 | 5.2556 | 24.6 |
| | 2 | 0.1649 | 6.7560 | 67.1 | 0.0964 | 4.9686 | 26.5 |
| | **Mean** | **0.1598** | **6.8647** | **68.2** | **0.0950** | **5.1121** | **25.5** |
| 0.2 | 1 | 0.0564 | 2.9937 | 72.8 | 0.0361 | 2.3287 | 22.2 |
| | 2 | 0.0551 | 3.0241 | 73.4 | 0.0349 | 2.3846 | 21.1 |
| | **Mean** | **0.0557** | **3.0089** | **73.1** | **0.0355** | **2.3566** | **21.7** |
| 0.05 | 1 | 0.0122 | 0.7821 | 76.5 | 0.0071 | 0.6518 | 16.7 |
| | 2 | 0.0129 | 0.7735 | 75.2 | 0.0079 | 0.6285 | 18.7 |
| | **Mean** | **0.0125** | **0.7778** | **75.8** | **0.0075** | **0.6401** | **17.7** |
| 0.02 | 1 | 0.0046 | 0.3103 | 77.2 | 0.0028 | 0.2586 | 16.6 |
| | 2 | 0.0045 | 0.3130 | 78.0 | 0.0029 | 0.2608 | 16.7 |
| | **Mean** | **0.0045** | **0.3117** | **77.6** | **0.0029** | **0.2597** | **16.7** |
| 0.005 | 1 | 0.0011 | 0.0918 | 80.4 | 0.0008 | 0.0777 | 15.3 |
| | 2 | 0.0011 | 0.0919 | 80.1 | 0.0008 | 0.0777 | 15.5 |
| | **Mean** | **0.0011** | **0.0919** | **80.2** | **0.0008** | **0.0777** | **15.4** |

*: % adsorbed as the % of the applied

**Table B.8. 204 Concentration of $^{14}$C-pydiflumetofen in the supernatant and soil at the end of adsorption and desorption equilibration period in Gartenacker Soil**

| Nominal dose level (µg/mL) | Replicate | Adsorption | | | Desorption | | |
|---|---|---|---|---|---|---|---|
| | | $C_e$ (µg/mL) | X/m (µg/g) | % adsorbed* | $C_1$ (µg/mL) | $X_1$/m (µg/g) | % desorbed as % of the adsorbed |
| 0.5 | 1 | 0.2278 | 5.5270 | 54.8 | 0.1113 | 3.5331 | 36.1 |
| | 2 | 0.2292 | 5.4650 | 54.6 | 0.1123 | 3.4580 | 36.7 |
| | **Mean** | **0.2285** | **5.4960** | **54.7** | **0.1118** | **3.4955** | **36.4** |
| 0.2 | 1 | 0.0772 | 2.5867 | 62.7 | 0.0439 | 1.7887 | 30.8 |
| | 2 | 0.0844 | 2.4401 | 59.3 | 0.0447 | 1.6299 | 33.2 |
| | **Mean** | **0.0808** | **2.5134** | **61.0** | **0.0443** | **1.7093** | **32.0** |
| 0.05 | 1 | 0.0195 | 0.6463 | 62.4 | 0.0096 | 0.4720 | 27.0 |
| | 2 | 0.0190 | 0.6550 | 63.4 | 0.0094 | 0.4842 | 26.1 |
| | **Mean** | **0.0193** | **0.6507** | **62.9** | **0.0095** | **0.4781** | **26.5** |
| 0.02 | 1 | 0.0067 | 0.2689 | 67.0 | 0.0037 | 0.2015 | 25.1 |
| | 2 | 0.0068 | 0.2677 | 66.6 | 0.0037 | 0.2008 | 25.0 |
| | **Mean** | **0.0067** | **0.2683** | **66.8** | **0.0037** | **0.2012** | **25.0** |
| 0.005 | 1 | 0.0017 | 0.0799 | 69.9 | 0.0010 | 0.0623 | 22.0 |
| | 2 | 0.0017 | 0.0802 | 70.2 | 0.0010 | 0.0618 | 22.9 |
| | **Mean** | **0.0017** | **0.0801** | **70.0** | **0.0010** | **0.0621** | **22.5** |

*: % adsorbed as the % of the applied

**Table B.8. 205 Concentration of $^{14}$C-pydiflumetofen in the supernatant and soil at the end of adsorption and desorption equilibration period in Sarpy Soil**

| Nominal dose level (µg/mL) | Replicate | Adsorption | | | Desorption | | |
|---|---|---|---|---|---|---|---|
| | | $C_e$ (µg/mL) | X/m (µg/g) | % adsorbed* | $C_1$ (µg/mL) | $X_1$/m (µg/g) | % desorbed as % of the adsorbed |
| 0.5 | 1 | 0.1691 | 6.6160 | 66.2 | 0.0925 | 4.9248 | 25.6 |
| | 2 | 0.1703 | 6.6332 | 66.3 | 0.0942 | 4.9278 | 25.7 |
| | **Mean** | **0.1697** | **6.6246** | **66.3** | **0.0933** | **4.9263** | **25.6** |
| 0.2 | 1 | 0.0586 | 2.9583 | 71.8 | 0.0338 | 2.3419 | 20.8 |
| | 2 | 0.0584 | 2.9583 | 71.8 | 0.0344 | 2.3312 | 21.2 |
| | **Mean** | **0.0585** | **2.9583** | **71.8** | **0.0341** | **2.3365** | **21.0** |
| 0.05 | 1 | 0.0126 | 0.7760 | 75.6 | 0.0073 | 0.6431 | 17.1 |
| | 2 | 0.0124 | 0.7873 | 76.1 | 0.0073 | 0.6537 | 17.0 |
| | **Mean** | **0.0125** | **0.7817** | **75.8** | **0.0073** | **0.6484** | **17.1** |
| 0.02 | 1 | 0.0043 | 0.3157 | 78.6 | 0.0027 | 0.2672 | 15.4 |
| | 2 | 0.0042 | 0.3189 | 79.3 | 0.0027 | 0.2699 | 15.4 |
| | **Mean** | **0.0042** | **0.3173** | **78.9** | **0.0027** | **0.2686** | **15.4** |
| 0.005 | 1 | 0.0010 | 0.0941 | 81.9 | 0.0007 | 0.0819 | 12.9 |
| | 2 | ** | ** | ** | ** | ** | ** |
| | **Mean** | **0.0010** | **0.0941** | **81.9** | **0.0007** | **0.0819** | **12.9** |

*: % adsorbed as the % of the applied
** Tube broke in centrifuge

**Table B.8. 206 Concentration of $^{14}$C-pydiflumetofen in the supernatant and soil at the end of adsorption and desorption equilibration period in Capay Soil**

| Nominal dose level (µg/mL) | Replicate | Adsorption | | | Desorption | | |
|---|---|---|---|---|---|---|---|
| | | $C_e$ (µg/mL) | X/m (µg/g) | % adsorbed* | $C_1$ (µg/mL) | $X_1$/m (µg/g) | % desorbed as % of the adsorbed |
| 0.5 | 1 | 0.1799 | 3.2360 | 64.2 | 0.0974 | 2.3904 | 26.1 |
| | 2 | 0.1738 | 3.3025 | 65.5 | 0.1011 | 2.4205 | 26.7 |
| | **Mean** | **0.1769** | **3.2692** | **64.9** | **0.0992** | **2.4054** | **26.4** |
| 0.2 | 1 | 0.0612 | 1.4540 | 70.6 | 0.0352 | 1.1502 | 20.9 |
| | 2 | 0.0613 | 1.4492 | 70.3 | 0.0338 | 1.1574 | 20.1 |
| | **Mean** | **0.0612** | **1.4516** | **70.5** | **0.0345** | **1.1538** | **20.5** |
| 0.05 | 1 | 0.0144 | 0.3715 | 72.2 | 0.0082 | 0.2999 | 19.3 |
| | 2 | 0.0144 | 0.3722 | 72.1 | 0.0081 | 0.3015 | 19.0 |
| | **Mean** | **0.0144** | **0.3718** | **72.2** | **0.0082** | **0.3007** | **19.1** |
| 0.02 | 1 | 0.0049 | 0.1525 | 75.9 | 0.0029 | 0.1275 | 16.3 |
| | 2 | 0.0050 | 0.1512 | 75.2 | 0.0031 | 0.1248 | 17.5 |
| | **Mean** | **0.0049** | **0.1518** | **75.6** | **0.0030** | **0.1262** | **16.9** |
| 0.005 | 1 | 0.0014 | 0.0430 | 75.2 | 0.0008 | 0.0358 | 16.7 |
| | 2 | 0.0014 | 0.0431 | 75.3 | 0.0008 | 0.0361 | 16.2 |
| | **Mean** | **0.0014** | **0.0431** | **75.3** | **0.0008** | **0.0360** | **16.5** |

*: % adsorbed as the % of the applied

**Table B.8. 207 Concentration of $^{14}$C-pydiflumetofen in the supernatant and soil at the end of adsorption and desorption equilibration period in Seven Springs Soil**

| Nominal dose level (µg/mL) | Replicate | Adsorption | | | Desorption | | |
|---|---|---|---|---|---|---|---|
| | | $C_e$ (µg/mL) | X/m (µg/g) | % adsorbed* | $C_1$ (µg/mL) | $X_1$/m (µg/g) | % desorbed as % of the adsorbed |
| 0.5 | 1 | 0.2236 | 2.8071 | 55.8 | 0.1064 | 1.8693 | 33.4 |
| | 2 | ** | ** | ** | ** | ** | ** |
| | **Mean** | **0.2236** | **2.8071** | **55.8** | **0.1064** | **1.8693** | **33.4** |
| 0.2 | 1 | 0.0761 | 1.3130 | 63.7 | 0.0364 | 0.9698 | 26.1 |
| | 2 | 0.0747 | 1.3187 | 64.0 | 0.0380 | 0.9795 | 25.7 |
| | **Mean** | **0.0754** | **1.3158** | **63.9** | **0.0372** | **0.9746** | **25.9** |
| 0.05 | 1 | 0.0187 | 0.3310 | 64.1 | 0.0084 | 0.2565 | 22.5 |
| | 2 | 0.0212 | 0.3049 | 59.1 | 0.0091 | 0.2241 | 26.5 |
| | **Mean** | **0.0199** | **0.3179** | **61.6** | **0.0088** | **0.2403** | **24.5** |
| 0.02 | 1 | 0.0054 | 0.1472 | 73.3 | 0.0033 | 0.1171 | 20.4 |
| | 2 | 0.0062 | 0.1398 | 69.6 | 0.0032 | 0.1114 | 20.3 |
| | **Mean** | **0.0058** | **0.1435** | **71.4** | **0.0033** | **0.1143** | **20.4** |
| 0.005 | 1 | 0.0017 | 0.0403 | 70.4 | 0.0008 | 0.0330 | 18.0 |
| | 2 | 0.0019 | 0.0382 | 67.7 | 0.0009 | 0.0301 | 21.1 |
| | **Mean** | **0.0018** | **0.0393** | **69.0** | **0.0009** | **0.0316** | **19.6** |

*: % adsorbed as the % of the applied
** Tube broke in centrifuge

**Table B.8. 208 Concentration of $^{14}$C-pydiflumetofen in the supernatant and soil at the end of adsorption and desorption equilibration period in Marysville Soil**

| Nominal dose level (µg/mL) | Replicate | Adsorption | | | Desorption | | |
|---|---|---|---|---|---|---|---|
| | | $C_e$ (µg/mL) | X/m (µg/g) | % adsorbed* | $C_1$ (µg/mL) | $X_1$/m (µg/g) | % desorbed as % of the adsorbed |
| 0.5 | 1 | 0.1756 | 6.5401 | 65.1 | 0.0900 | 4.9226 | 24.7 |
| | 2 | 0.1716 | 6.6247 | 65.8 | 0.0853 | 5.0902 | 23.2 |
| | **Mean** | **0.1736** | **6.5824** | **65.5** | **0.0877** | **5.0064** | **23.9** |
| 0.2 | 1 | 0.0576 | 2.9754 | 72.2 | 0.0315 | 2.4081 | 19.1 |
| | 2 | 0.0576 | 2.9744 | 72.2 | 0.0312 | 2.4051 | 19.1 |
| | **Mean** | **0.0576** | **2.9749** | **72.2** | **0.0313** | **2.4066** | **19.1** |
| 0.05 | 1 | 0.0122 | 0.7857 | 76.4 | 0.0063 | 0.6716 | 14.5 |
| | 2 | 0.0092 | 0.8440 | 82.2 | 0.0045 | 0.7641 | 9.5 |
| | **Mean** | **0.0107** | **0.8148** | **79.3** | **0.0054** | **0.7178** | **12.0** |
| 0.02 | 1 | 0.0044 | 0.3141 | 78.4 | 0.0024 | 0.2717 | 13.5 |
| | 2 | 0.0042 | 0.3136 | 78.3 | 0.0023 | 0.2691 | 14.2 |
| | **Mean** | **0.0043** | **0.3138** | **78.3** | **0.0023** | **0.2704** | **13.8** |
| 0.005 | 1 | 0.0018 | 0.0782 | 68.5 | 0.0007 | 0.0666 | 14.8 |
| | 2 | 0.0011 | 0.0929 | 80.8 | 0.0006 | 0.0813 | 12.5 |
| | **Mean** | **0.0015** | **0.0855** | **74.7** | **0.0007** | **0.0740** | **13.6** |

*: % adsorbed as the % of the applied

Adsorption and desorption parameters are presented below. Freundlich adsorption and desorption isotherms are also presented below. Averaged values for partition coefficients ($K_d$) per soil were in the range 18.60 to 63.37 mL/g and corresponding ($K_{OC}$) values were in the range 1949 to 3808 mL/g. The Freundlich equations showed a good fit to the data with $K_F$ values from 11.76 to 36.10 mL/g. $K_{FOC}$ values ranged from 1165 to 2206 mL/g. The corresponding 1/n values ranged from 0.8367 to 0.8983.

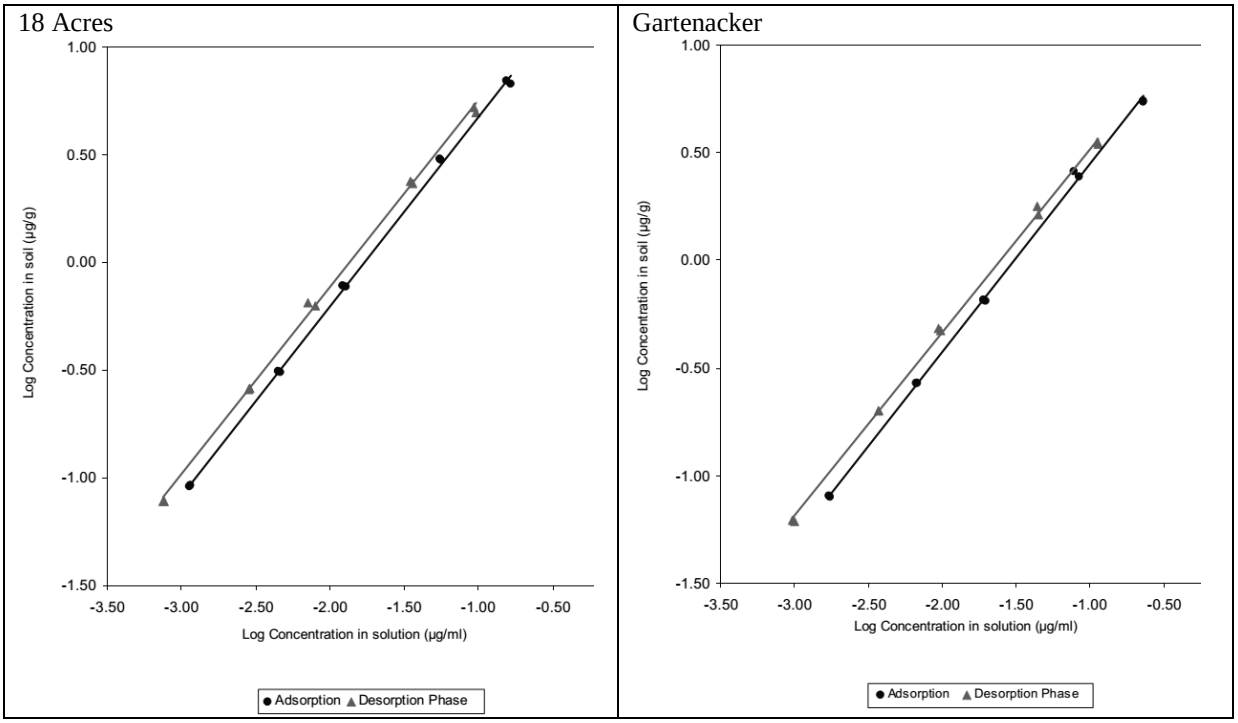
The $K_d$, $K_{OC}$, $K_F$ and $K_{FOC}$ values after the desorption step were all higher than those after the adsorption step for all soils. These data suggest that adsorption of $^{14}$C-pydiflumetofen is not fully reversible. Averaged values for desorption coefficients ($K_d$) per soil were in the range 28.59 to 100.30 mL/g and $K_{OC}$ values were in the range 2636 to 6269 mL/g. The Freundlich equations showed a good fit to the data with $K_F$ values from 15.36 to 45.05 mL/g. The corresponding 1/n values ranged from 0.8290 to 0.8813.

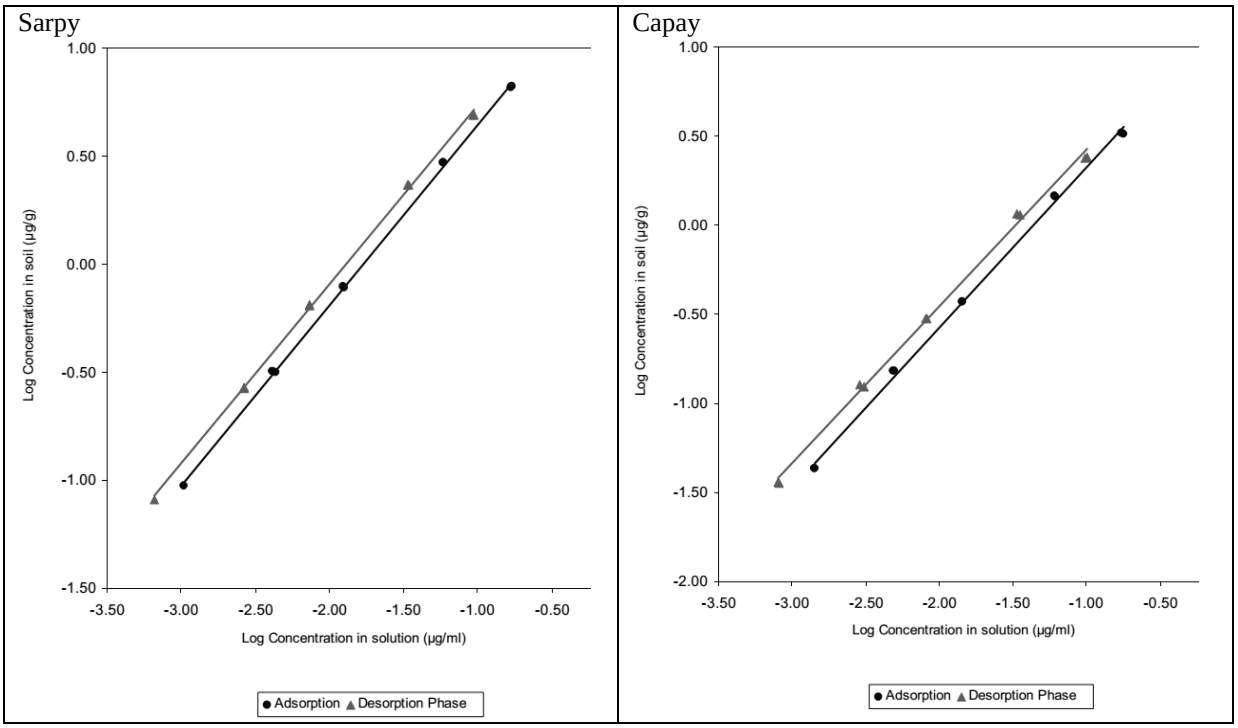
**Table B.8. 209 Adsorption and desorption parameters of pydiflumetofen**

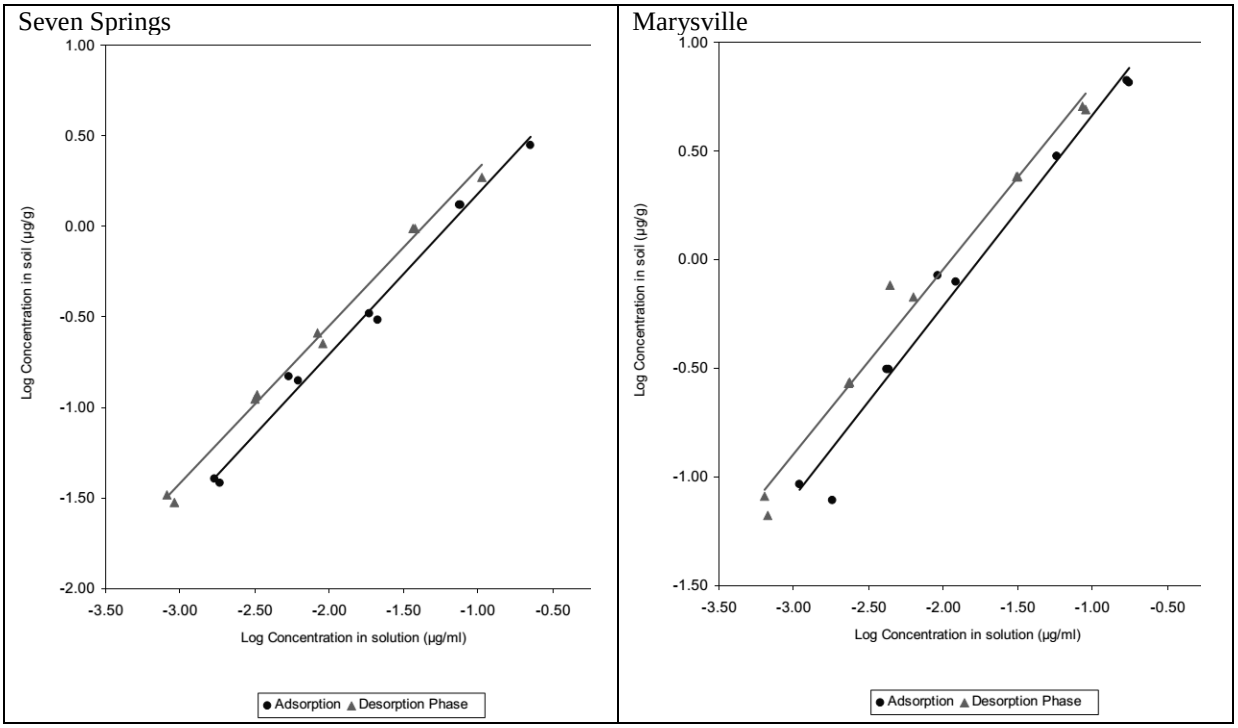
| **Parameter**[1] | **18 Acres (UK)** | **Gartenacker (Switzerland)** | **Sarpy (USA)** | **Capay (USA)** | **Seven Springs USA** | **Marysville USA** |
|---|---|---|---|---|---|---|
| Texture | Sandy clay loam | Loam | Silt loam | Clay loam | Loamy sand | Clay loam |
| pH (0.01M $CaCl_2$) | 6.0 | 7.2 | 6.5 | 6.7 | 5.2 | 7.6 |
| %OC | 2.2 | 1.8 | 1.7 | 1.0 | 0.6 | 1.6 |
| **Adsorption** | | | | | | |
| $K_F$ | 36.10 | 20.97 | 30.40 | 16.68 | 11.76 | 35.30 |
| $K_{FOC}$ | 1641 | 1165 | 1788 | 1668 | 1960 | 2206 |
| 1/n | 0.8794 | 0.8733 | 0.8367 | 0.8983 | 0.8876 | 0.8820 |
| $r^2$ | 0.9993 | 0.9988 | 0.9995 | 0.9983 | 0.9902 | 0.9783 |
| $K_d$ (averaged) | 61.69 | 35.07 | 63.37 | 25.81 | 18.60 | 60.92 |
| $K_{OC}$ (averaged) | 2804 | 1949 | 3728 | 2581 | 3101 | 3808 |
| **Desorption** | | | | | | |
| $K_F$ | 41.77 | 23.86 | 36.90 | 20.35 | 15.36 | 45.05 |
| $K_{FOC}$ | 1899 | 1325 | 2171 | 2035 | 2561 | 2816 |
| 1/n | 0.8688 | 0.8539 | 0.8290 | 0.8813 | 0.8693 | 0.8482 |
| $r^2$ | 0.9983 | 0.9988 | 0.9992 | 0.9975 | 0.9938 | 0.9814 |
| $K_d$ (averaged) | 79.70 | 47.45 | 86.97 | 36.27 | 28.59 | 100.30 |
| $K_{OC}$ (averaged) | 3622 | 2636 | 5116 | 3627 | 4765 | 6269 |

[1]. $K_F$, $K_{FOC}$, $K_d$ and $K_{OC}$ all have the units mL/g

**Figure B.8. 44 Freundlich adsorption and desorption isotherms for pydiflumetofen**






Using the McCall Classification scale to assess a chemical's potential mobility in soil (based on its $K_{FOC}$ from the adsorption step), pydiflumetofen can be classified as having a 'low' potential mobility in all but Marysville soil where it can be classified as having 'slight' potential mobility.

**Conclusion**

The applicant assessment of the pydiflumetofen soil adsorption study appeared to have been conducted before the guidance on the evaluation of OECD 106 soil adsorption studies (the OECD 106 evaluators checklist) was adopted or available. Consequently HSE has used the checklist to validate the acceptability of the study.

The study description gives little detail of the analytical methods used in the study. Liquid scintillation counting appears to have been the primary method of quantifying radioactivity in the definitive test. However, LSC is not substance specific and it's use relies on an assumption that the test substance is stable and the vast majority of radioactivity in supernatants and soil extracts is comprised of the test substance. Information on the amount of pydiflumetofen in the aqueous supernatants and in soil extracts comes from the stability tests during the preliminary test phase. Each of the six tested soils was used in the stability test with a 72 hour equilibration period; the dosing concentration in the aqueous phase was 0.05 µg/mL with a soil:solution ratio of 1:10 (two soils) or 1:20 (four soils), the soil:solution ratios having been previously determined. At the end of the equilibration period, the aqueous supernatants were removed and soils extracts were extracted with acetonitrile:water (80:20 v/v) adjusted to pH 3, this being similar to the extraction used in soil route and rate of degradation studies. The aqueous supernatants were then subject to solid phase extraction. Analysis of the extracts was by HPLC; a secondary TLC method was used to confirm identity. During the preliminary study stability checks the following results were seen:

**Table B.8. 210 Results of stability checks in preliminary tests of pydiflumetofen soil adsorption study**

| Soil | | % of Applied Radioactivity | | |
|---|---|---|---|---|
| | **Adsorption Supernatant** | **Soil Extract** | **Unextracted from soil** | **Total** |
| 18 Acres | 22.5 | 79.5 | 0.4 | 102.4 |
| Gartenacker | 32.1 | 66.9 | 0.8 | 99.8 |
| Sarpy | 22.4 | 74.8 | 1.5 | 98.7 |
| Capay | 23.2 | 74.5 | 2.7 | 100.4 |
| Seven Springs | 31.3 | 67.2 | 1.0 | 99.5 |
| Marysville | 20.4 | 78.7 | 0.6 | 99.7 |

Analysis of the extracts using HPLC gave the following results:

**Table B.8. 211 Results of preliminary test analysis of adsorption supernatant and soil extracts**

| | % Applied Radioactivity as pydiflumetofen | | |
|---|---|---|---|
| **Soil** | **Adsorption Supernatant** | **Soil Extract** | **Total** |
| 18 Acres | 22.5 | 79.3 | 101.8 |
| Gartenacker | 30.9 | 66.8 | 97.7 |
| Sarpy | 22.3 | 73.7 | 95.9 |
| Capay | 23.0 | 73.0 | 96.0 |
| Seven Springs | 30.7 | 66.2 | 96.9 |
| Marysville | 20.2 | 77.7 | 97.9 |

The results confirm that pydiflumetofen was sufficiently stable with extractable mass balances of 95.9 – 101.8% at 72 hours. As noted, a 48 hour equilibrium time was chosen for the definitive test. Therefore stability during the definitive test would not be expected to be worse over the shorter time period.

In addition, stability of pydiflumetofen was checked during the definitive test. In this phase of the study, one replicate was taken from each concentration from the Sarpy soil; Sarpy was chosen has it gave the highest Kd values. In addition one replicate was taken from the highest test concentration for each of the other five soils. The results from this testing are presented below.

**Table B.8. 212 Results of stability checks in the definitive test of pydiflumetofen soil adsorption study**

| | | % of chromatogram formed by pydiflumetofen | | |
|---|---|---|---|---|
| **Soil** | **Concentration (µg/mL)** | **% pydiflumetofen in adsorption supernatant** | **% pydiflumetofen in desorption supernatant** | **% pydiflumetofen in soil extract** |
| Sarpy | 0.5 | 99.9 | 99.2 | 98.2 |
| Sarpy | 0.2 | 98.4 | 99.5 | 97.3 |
| Sarpy | 0.05 | 99.9 | 99.7 | 99.3 |
| Sarpy | 0.02 | 98.5 | 94.2 | 97.5 |
| Sarpy | 0.005 | 83.0* | 95.2 | 85.4* |
| 18 Acres | 0.5 | 99.8 | 99.7 | 98.0 |
| Gartenacker | 0.5 | 99.9 | 99.7 | 99.9 |
| Capay | 0.5 | 99.8 | 99.6 | 98.3 |
| Seven Springs | 0.5 | 99.9 | 99.8 | 99.1 |
| Marysville | 0.5 | 99.1 | 99.5 | 99.9 |

*The study author considered at this low concentration that the low values could have been the result of a chromatography issue rather than genuine degradation. Given the persistence of pydiflumetofen in soil, HSE agrees that this is unlikely to be degradation.

**Table B.8. 213 Results of stability checks in the definitive test of pydiflumetofen soil adsorption study**

| | | Total extracted as pydiflumetofen | | | |
|---|---|---|---|---|---|
| **Soil** | **Concent-ration (µg/mL)** | **% in adsorption supernatant** | **% in desorption supernatant** | **% in soil extract** | **% total pydiflumetofen** |
| Sarpy | 0.5 | 32.2 | 17.6 | 51.0 | 100.7 |
| Sarpy | 0.2 | 26.4 | 15.6 | 54.4 | 96.4 |
| Sarpy | 0.05 | 23.2 | 13.5 | 61.5 | 98.1 |
| Sarpy | 0.02 | 19.4 | 11.8 | 63.9 | 95.0 |
| Sarpy | 0.005 | 14.4 | 10.4 | 60.3 | 85.0 |
| 18 Acres | 0.5 | 29.1 | 17.6 | 53.7 | 100.4 |
| Gartenacker | 0.5 | 42.8 | 21.0 | 38.0 | 101.8 |
| Capay | 0.5 | 33.0 | 17.9 | 48.7 | 99.6 |
| Seven Springs | 0.5 | 41.6 | 20.0 | 37.8 | 99.4 |
| Marysville | 0.5 | 32.8 | 16.9 | 53.3 | 103.0 |

Apart from the apparent low recovery of pydiflumetofen in the Sarpy soil at the lowest tested concentration, the stability of pydiflumetofen was confirmed. It also appears to be the reason why the LSC counting was relied upon as a surrogate for directly measured pydiflumetofen quantified by HPLC. In view of the general stability of pydiflumetofen seen in the soil studies, the high proportion of pydiflumetofen in extracts and the low level of unextracted residues seen in the preliminary test, it is considered by HSE that this was an acceptable approach to take.

The OECD 106 checklist indicates that the limit of quantification of the analytical method should be at least two orders of magnitude below the lowest nominal concentration tested. The LOQ or LOD were not clearly stated in terms of the concentration, only in terms of the % AR. This was only given for one example for adsorption supernatants at 0.5 µg/mL, i.e. the top dose for a soil using a 1:20 soil solution ratio. The LOD for the LSC method was stated to be 0.1% AR based on the LOD being set to 1.5x the background radioactivity. The applicant clarified that the theoretical LOQ was equivalent to 0.00006 µg/mL. Given that the lowest nominal concentration tested was 0.005 µg/mL the LOQ is approximately two orders of magnitude below the lowest nominal concentration. It is considered that the analytical method was sufficient in this study.

Whilst not stated directly it appears that the test mainly used the indirect method of determining the Freundlich isotherms, i.e. concentrations in soil were calculated by subtraction of the amount in the aqueous supernatant concentration from the initial dose. As noted above with respect to stability checks, soil extractions were only carried out on one replicate per dose for a single soil and for only a single replicate across all doses in the other five soils. Given the stability and high adsorption demonstrated, HSE consider that the indirect approach was reasonable in this case.

The soil:solution ratios appear to have been chosen appropriately although ideally a single ratio would have been chosen. Adsorption at the 1:5 ratio was probably judged too high for all soils (70 – 90% adsorption). Adsorption at the 1:10 ratio was probably judged too high in the 18 Acres, Gartenacker, Sarpy and Marysville soils to leave a reasonable mass remaining in the supernatant for analysis. At 1:20 the amount adsorbed was reduced to 50-70% in those soils, but had reduced to 30-40% for Capay and Seven Springs soils. Thus the 1:20 ratio was judged to be not appropriate for Capay and Seven Springs soils. Given that there may have been some issues with the LOQ of the method, the choice of soil:solution ratio appears to have given an appropriate balance between sufficient adsorption but still retaining sufficient substance in the supernatant to enable analysis at the lowest tested concentration.

The check of systematic errors (KfE/Kf ratio) indicated that the ratios were all less than the 1.2 suggested as a 'rule-of-thumb' in the OECD 106 evaluators checklist. Overall the losses seen in the study were relatively small with low unextracted residues and the vast majority of extractable radioactivity attributable to the test substance.

Fitting of the Freundlich isotherms was undertaken in the HSE check by calculating the amount adsorbed to soil from the amount applied and the concentration in the supernatant. Small differences in the calculated parameters (Kf,ads and 1/n) compared to the those in the study were seen but these are not considered to be significant. The $r^2$ values of the fits were ≥0.990 with the exception of the Marysville soil with an $r^2$ of 0.978. The OECD 106 evaluators checklist suggests that $r^2$ should be typically greater than 0.975. For Marysville soil, there were some relatively large deviations from the zero line in the residual plot for the fit for two replicate values. The lower and upper 95$^{th}$ percentile confidence intervals for Kf and 1/n are also relatively wide. However, given the relatively low result for the check of systematic errors and the overall reasonable fit of the isotherm this is not considered to be indicative of a poorly fitted isotherm. In addition, it is noted that the calculated values of Kf and 1/n for Marysville soil were reasonably consistent with the remaining database.

A summary of the fitted parameters with 95$^{th}$ percentile confidence intervals for Kf and 1/n values are presented below.

**Table B.8. 214 Results of HSE fitting of Freundlich isotherm to pydiflumetofen soil adsorption study data**

| Soil | $K_F$,ads | Lower 95 CI | Upper 95 CI | $K_{Foc}$, ads | 1/n | Lower 95 CI | Upper 95 CI | r2 |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| 18 Acres | 35.512 | 31.791 | 39.669 | 1614 | 0.872 | 0.848 | 0.896 | 0.999 |
| Gartenacker | 20.803 | 18.358 | 23.573 | 1156 | 0.869 | 0.839 | 0.898 | 0.998 |
| Sarpy | 30.266 | 27.739 | 33.025 | 1780 | 0.833 | 0.812 | 0.853 | 0.999 |
| Capay | 16.522 | 14.420 | 18.932 | 1652 | 0.894 | 0.863 | 0.924 | 0.998 |
| Seven Springs | 11.812 | 8.307 | 16.796 | 1969 | 0.887 | 0.812 | 0.853 | 0.990 |
| Marysville | 35.295 | 21.656 | 57.524 | 2206 | 0.880 | 0.773 | 0.986 | 0.978 |

Overall the results of the soil adsorption study on pydiflumetofen and the applicants calculated parameters from it can be accepted by HSE.

### B.8.1.2.2. Adsorption and desorption of degradation products

Adsorption parameters were determined for metabolites SYN545547 and NOA449410 which are formed at significant levels in water studies. It should be noted that the soil adsorption endpoints for these metabolites are not required for risk assessment purposes in GB/NI.

### B.8.1.2.2.1. Adsorption and desorption of SYN545547

| | |
|---|---|
| **Report:** | K-CA 7.1.3.1.2/01. [redacted], [redacted], [redacted] (2015) SYN545547 - Adsorption and Desorption of [$^{14}$C]-SYN545547 in Five Soils. Report Number SR20150709A Symbiotic Research, LLC, 350 Clark Drive, Mount Olive, NJ 07828 (Syngenta File No. SYN545547_50000) |

| | |
|---|---|
| **Guideline(s):** | OECD 106 (2000), US EPA Pesticide Assessment Guidelines OPPTS 835-1230 (2008), SETAC (1995) |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**

The adsorption/desorption characteristics of $^{14}$C-SYN545547 was studied in five different soils using a standard batch equilibrium method.

| **Test Material:** | **[pyrazole-5-14C]-SYN545547** |
|---|---|
| Lot/Batch #: | 5357MFO001-1 |
| Specific activity: | 134.4 µCi/mg (298,368 dpm/µg; 4.97 MBq/mg) |
| Radiochemical Purity: | 98.7% |
| Application vehicle: | Acetonitrile |

Prior to use, the soils were sieved using a 2 mm mesh and stored air-dried in the dark at ambient temperature in loosely tied plastic bags. The soils characteristics are presented below.

**Table B.8. 215 Soils characteristics**

| | **Seven Springs** | **18 Acres** | **Sarpy** | **Gartenacker** | **Marysville** |
|---|---|---|---|---|---|
| Sampling location | Seven Springs, Wayne Co., NC, USA | Jealott's Hill Farm, Bracknell, UK | Cornish Road, Springfield, NE, USA | CH-1896 Les Barges, Vouvry, Switzerland | McClain Farm, Marysville, OH, USA |
| Sampling depth | 0-15 | 5-20 | 0-15 | 5-20 | 0-15 |
| Particle size (% w/w) | | | | | |
| Clay (< 2 µm) | 2 | 25 | 23 | 12 | 41 |
| Silt (2 – 50 µm) | 9 | 16 | 54 | 43 | 34 |
| Sand (50-2000 µm) | 89 | 59 | 23 | 45 | 25 |
| Texture (USDA) | Sand | Sandy clay loam | Silt loam | Loam | Clay |
| Bulk Density (gm/cc) | 1.21 | 1.13 | 1.14 | 0.93 | 1.11 |
| pH (water) | 6.0 | 6.2 | 6.9 | 7.2 | 7.8 |
| pH (0.01M $CaCl_2$) | 5.3 | 5.8 | 6.5 | 7.0 | 7.5 |
| Organic matter (%) | 1.3 | 3.7 | 3.0 | 4.7 | 3.1 |
| Organic carbon (%) | 0.75 | 2.15 | 1.74 | 2.73 | 1.80 |
| CEC (meq/100 g soil) | 4.1 | 15.8 | 18.1 | 10.8 | 17.0 |
| Moisture at pF2.0 (w/w %) | 11.0 | 29.78 | 42.2 | 38.95 | 36.9 |
| Moisture at 0.33 bar (w/w %) | 6.7 | 19.3 | 27.8 | 28.8 | 26.3 |
| Moisture at 15 bar (w/w %) | NA | 12.7 | NA | NA | NA |

**Preliminary tests**

Preliminary tests were conducted on all five soils to determine the conditions to be used in the definitive study.

Solubility: Duplicate application solutions, at a concentration of 10 µg/mL, were prepared to assess the solubility of SYN545547 in 0.01M calcium chloride solution. Since results were not satisfactory (recovery < 90%), further tests were done using 0.98% co-solvent (acetonitrile). The mean recovery for each of the two replicates at 10 µg SYN545547/mL 0.01M CaCl2 containing 0.98% ACN co-solvent was 97.2% and 98.3%.

Adsorption to Containers test: A test was performed to determine whether SYN545547 adsorbed to plastic, Teflon® and glass vessels from a 0.01 µg/mL application solution. The recovery of applied radioactivity in 50-mL glass tubes, 30-mL glass tubes and 50-mL polypropylene tubes was 94.7-102.2%, 91.6-92.4% and 62.3-62.8%, respectively. Solutions in glass tubes were mixed for 24 hours and solutions in polypropylene tubes were mixed for 17 hours. The polypropylene tubes were unacceptable based on recovery. The 50-mL glass tubes were found to break during centrifugation in the ratio test so therefore the 30-mL glass tubes were selected for all further work including the definitive test.

Ratio of soil to aqueous test at 0.1 µg/mL test item concentration: The determination of the optimum soil:aqueous ratio for use in the definitive test was conducted using all five soils at a test item concentration of 0.1 µg/mL and soil:solution ratios of 1:5, 1:10 and 1:25. A ratio of 1:10 w/v was selected for use with all soils in the definitive test.

Time to adsorption equilibrium: The adsorption equilibrium time for all five soils were determined over a 72 hour period using a test item concentration equivalent to 0.1 µg/mL and a soil:solution ratio of 1:10. An adsorption equilibrium time of 48 hours was selected for use in the definitive test.

Time to desorption equilibrium: The desorption equilibrium time for all six soils were determined over a 96 hour period using a test item concentration equivalent to 0.1 µg/mL and a soil:solution ratio of 1:10. A desorption equilibrium time of 6 hours was selected for use in the definitive test.

Stability during equilibrium time determination: Stability of the test item during the adsorption time determination was assessed. Recovery of applied radioactivity as $^{14}$C-SYN545547 was ≥97% in the 72 hour adsorption equilibrium time samples and >98% in the 1 µg/mL SYN545547 in 0.01M $CaCl_2$ samples incubated for 144 hours.

**Definitive test**
Adsorption and desorption isotherms were determined on all five soils at a soil:solution ratio of a 1:10 over five test item concentrations (nominally 0.01, 0.05, 0.1, 0.5 and 1.0 µg/mL), with a 48 hour adsorption followed by a 6 hour desorption step, in the dark at 20°C. In addition to the treated samples, blank (untreated soil samples with just 0.01M $CaCl_2$; one per soil type) and control (treated 0.01M $CaCl_2$ without soil; duplicate per test item concentration) samples were also incubated.

All samples were shaken in 0.01 M $CaCl_2$ solution for 48 hours (the adsorption equilibrium time) then centrifuged for 15 minutes at 5000 rpm. Weighed aliquots were taken for liquid scintillation counting (LSC) analysis before removing as much of the adsorption supernatant as possible from each unit into a pre-weighed vessel. The pH value of each adsorption supernatant was determined.

The weight of adsorption supernatant removed was replaced by an equal weight of fresh 0.01 M $CaCl_2$ solution. Each test vessel was shaken vigorously to break up the soil packed at the bottom of the vessel and to re-mix it with the solution. The samples were shaken for 48 hours (the desorption equilibrium time), centrifuged for 15 minutes at 5000 rpm and radioactivity in the desorption supernatants was determined by LSC.

Stability of SYN545547 during the definitive test was checked in one replicate from each concentration from Sarpy soil, and in one replicate at the highest concentration only for the 4 other soils. For stability testing, radioactivity in supernatants was concentrated by lyophilization and reconstitution in 1:1 acetonitrile: water containing 0.1% formic acid or were diluted 1:1 with acetonitrile before filtration and analysis of SYN545547 by HPLC with radio-detection. Soil was extracted with acetonitrile:water (80:20 w/v), adjusted to pH 3 with formic acid. Extracts were concentrated under nitrogen and were analysed for SYN545547 by HPLC. Extracted soils were combusted to determine the radioactivity remaining in the soil.

Partition adsorption coefficients ($K_D$) and Freundlich adsorption coefficient ($K_F$) were calculated according to OECD 106. Isotherms were established based on log transformed data for individual replicates.

**Findings**
For all soils the recovery of radioactivity was quantitative. The mean mass balance from all soils was 98.9% (range 97.5 – 100.7%). The test item was stable throughout the incubation period.

Concentrations of SYN545547 in the adsorption supernatants and adsorbed to the soil are presented below.

**Table B.8. 216 Concentration of $^{14}$C-SYN545547 in the supernatant and soil at the end of adsorption and desorption equilibration period in Seven Springs Soil**

| Nominal dose (µg/mL) | level | Replicate | Adsorption | | | Desorption | | |
|---|---|---|---|---|---|---|---|---|
| | | | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) | % adsorbed* | $Caq_{des}$ (µg/mL) | $Cs_{des}$ (µg/g) | % desorbed as % of the adsorbed |
| 0.01 | | 1 | 0.0044 | 0.0561 | 56.3 | 0.0019 | 0.0405 | 27.9 |
| | | 2 | 0.0043 | 0.0579 | 57.5 | 0.0023 | 0.0381 | 34.1 |
| | | **Mean** | **0.0043** | **0.0570** | **56.9** | **0.0021** | **0.0393** | **31.0** |
| 0.05 | | 1 | 0.0234 | 0.2454 | 50.9 | 0.0095 | 0.1691 | 31.1 |
| | | 2 | 0.0231 | 0.2440 | 51.6 | 0.0096 | 0.1668 | 31.6 |
| | | **Mean** | **0.0232** | **0.2447** | **51.2** | **0.0095** | **0.1680** | **31.4** |
| 0.1 | | 1 | 0.0495 | 0.4614 | 48.1 | 0.0191 | 0.3030 | 34.3 |
| | | 2 | 0.0473 | 0.4795 | 50.3 | 0.0188 | 0.3185 | 33.6 |
| | | **Mean** | **0.0484** | **0.4705** | **49.2** | **0.0190** | **0.3107** | **34.0** |
| 0.5 | | 1 | 0.2952 | 1.9932 | 40.3 | 0.0974 | 1.2268 | 38.5 |
| | | 2 | 0.2884 | 2.0712 | 42.1 | 0.0972 | 1.2804 | 38.2 |
| | | **Mean** | **0.2918** | **2.0322** | **41.2** | **0.0973** | **1.2536** | **38.3** |
| 1.0 | | 1 | 0.6182 | 3.8032 | 38.3 | 0.1872 | 2.2790 | 40.1 |
| | | 2 | 0.6263 | 3.6743 | 37.3 | 0.1905 | 2.1693 | 41.0 |
| | | **Mean** | **0.6222** | **3.7387** | **37.8** | **0.1888** | **2.2241** | **40.5** |

*: % adsorbed as the % of the applied.

**Table B.8. 217 Concentration of $^{14}$C-SYN545547 in the supernatant and soil at the end of adsorption and desorption equilibration period in 18 Acres Soil**

| Nominal dose (µg/mL) | level | Replicate | Adsorption | | | Desorption | | |
|---|---|---|---|---|---|---|---|---|
| | | | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) | % adsorbed* | $Caq_{des}$ (µg/mL) | $Cs_{des}$ (µg/g) | % desorbed as % of the adsorbed |
| 0.01 | | 1 | 0.0027 | 0.0734 | 73.4 | 0.0018 | 0.0576 | 21.5 |
| | | 2 | 0.0026 | 0.0744 | 74.3 | 0.0017 | 0.0593 | 20.3 |
| | | **Mean** | **0.0026** | **0.0739** | **73.8** | **0.0018** | **0.0585** | **20.9** |
| 0.05 | | 1 | 0.0137 | 0.3399 | 71.2 | 0.0088 | 0.2634 | 22.5 |
| | | 2 | 0.0142 | 0.3325 | 70.1 | 0.0090 | 0.2547 | 23.4 |
| | | **Mean** | **0.0139** | **0.3362** | **70.7** | **0.0089** | **0.2591** | **23.0** |
| 0.1 | | 1 | 0.0301 | 0.6601 | 68.4 | 0.0188 | 0.4946 | 25.1 |
| | | 2 | 0.0290 | 0.6612 | 69.5 | 0.0185 | 0.4998 | 24.4 |
| | | **Mean** | **0.0295** | **0.6607** | **68.9** | **0.0187** | **0.4972** | **24.7** |
| 0.5 | | 1 | 0.1694 | 3.3052 | 65.9 | 0.1010 | 2.4315 | 26.4 |
| | | 2 | 0.1736 | 3.2561 | 65.1 | 0.1026 | 2.3660 | 27.3 |
| | | **Mean** | **0.1715** | **3.2806** | **65.5** | **0.1018** | **2.3987** | **26.9** |
| 1.0 | | 1 | 0.3753 | 6.1359 | 62.4 | 0.2100 | 4.3547 | 29.0 |
| | | 2 | 0.3739 | 6.1611 | 62.5 | 0.2114 | 4.3612 | 29.2 |
| | | **Mean** | **0.3746** | **6.1485** | **62.5** | **0.2107** | **4.3580** | **29.1** |

*: % adsorbed as the % of the applied.

**Table B.8. 218 Concentration of $^{14}$C-SYN545547 in the supernatant and soil at the end of adsorption and desorption equilibration period in Sarpy Soil**

| Nominal dose (µg/mL) | level | Replicate | Adsorption | | Desorption | | | |
|---|---|---|---|---|---|---|---|---|
| | | | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) |
| 0.01 | | 1 | 0.0024 | 0.0764 | 76.0 | 0.0016 | 0.0627 | 17.9 |
| | | 2 | 0.0024 | 0.0773 | 76.4 | 0.0015 | 0.0640 | 17.2 |
| | | **Mean** | **0.0024** | **0.0769** | **76.2** | **0.0015** | **0.0633** | **17.6** |
| 0.05 | | 1 | 0.0133 | 0.3456 | 72.0 | 0.0082 | 0.2729 | 21.0 |
| | | 2 | 0.0130 | 0.3439 | 72.7 | 0.0082 | 0.2731 | 20.6 |
| | | **Mean** | **0.0131** | **0.3447** | **72.3** | **0.0082** | **0.2730** | **20.8** |
| 0.1 | | 1 | 0.0292 | 0.6624 | 69.3 | 0.0173 | 0.5119 | 22.7 |
| | | 2 | 0.0283 | 0.6660 | 70.3 | 0.0073 | 0.5177 | 22.3 |
| | | **Mean** | **0.0287** | **0.6642** | **69.8** | **0.0173** | **0.5148** | **22.5** |
| 0.5 | | 1 | 0.1842 | 3.1353 | 62.8 | 0.0990 | 2.2800 | 27.3 |
| | | 2 | 0.1832 | 3.1027 | 62.9 | 0.0988 | 2.2905 | 26.2 |
| | | **Mean** | **0.1837** | **3.1190** | **62.9** | **0.0989** | **2.2853** | **26.7** |
| 1.0 | | 1 | 0.4145 | 5.8403 | 58.4 | 0.2046 | 4.0742 | 30.2 |
| | | 2 | 0.3985 | 5.9612 | 60.0 | 0.2036 | 4.2081 | 29.4 |
| | | **Mean** | **0.4065** | **5.9008** | **59.2** | **0.2041** | **4.1412** | **29.8** |

*: % adsorbed as the % of the applied.

**Table B.8. 219 Concentration of $^{14}$C-SYN545547 in the supernatant and soil at the end of adsorption and desorption equilibration period in Gartenacker Soil**

| Nominal dose (µg/mL) | level | Replicate | Adsorption | | Desorption | | | |
|---|---|---|---|---|---|---|---|---|
| | | | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) |
| 0.01 | | 1 | 0.0035 | 0.0652 | 64.6 | 0.0021 | 0.04702 | 27.9 |
| | | 2 | 0.0035 | 0.0649 | 65.0 | 0.0021 | 0.04644 | 28.4 |
| | | **Mean** | **0.0035** | **0.0651** | **64.8** | **0.0021** | **0.0467** | **28.2** |
| 0.05 | | 1 | 0.0191 | 0.2845 | 59.6 | 0.0108 | 0.19287 | 32.2 |
| | | 2 | 0.0194 | 0.2835 | 58.9 | 0.0110 | 0.18852 | 33.5 |
| | | **Mean** | **0.0193** | **0.2840** | **59.3** | **0.0109** | **0.1907** | **32.9** |
| 0.1 | | 1 | 0.0414 | 0.5344 | 56.3 | 0.0224 | 0.34482 | 35.5 |
| | | 2 | 0.0401 | 0.5461 | 57.6 | 0.0222 | 0.35817 | 34.4 |
| | | **Mean** | **0.0408** | **0.5402** | **56.9** | **0.0223** | **0.3515** | **34.9** |
| 0.5 | | 1 | 0.2375 | 2.5456 | 51.7 | 0.1150 | 1.59376 | 37.4 |
| | | 2 | 0.2394 | 2.5724 | 51.6 | 0.1158 | 1.60488 | 37.6 |
| | | **Mean** | **0.2384** | **2.5590** | **51.7** | **0.1154** | **1.5993** | **37.5** |
| 1.0 | | 1 | 0.5067 | 4.8491 | 48.6 | 0.2258 | 3.15618 | 34.9 |
| | | 2 | 0.5042 | 4.8373 | 49.0 | 0.2298 | 2.93291 | 39.4 |
| | | **Mean** | **0.5054** | **4.8432** | **48.8** | **0.2278** | **3.0445** | **37.1** |

*: % adsorbed as the % of the applied.

**Table B.8. 220 Concentration of $^{14}$C-SYN545547 in the supernatant and soil at the end of adsorption and desorption equilibration period in Marysville Soil**

| Nominal dose level (µg/mL) | Replicate | Adsorption | | | Desorption | | |
|---|---|---|---|---|---|---|---|
| | | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) | $Caq_{ads}$ (µg/mL) | $Cs_{ads}$ (µg/g) |
| 0.01 | 1 | 0.0030 | 0.0703 | 70.2 | 0.0018 | 0.0546 | 22.3 |
| | 2 | 0.0029 | 0.0712 | 71.4 | 0.0017 | 0.0563 | 21.0 |
| | **Mean** | **0.0029** | **0.0707** | **70.8** | **0.0018** | **0.0554** | **21.6** |
| 0.05 | 1 | 0.0139 | 0.3360 | 70.8 | 0.0080 | 0.2662 | 20.8 |
| | 2 | 0.0154 | 0.3235 | 67.7 | 0.0086 | 0.2486 | 23.1 |
| | **Mean** | **0.0146** | **0.3298** | **69.2** | **0.0083** | **0.2574** | **22.0** |
| 0.1 | 1 | 0.0353 | 0.6071 | 63.0 | 0.0189 | 0.4420 | 27.2 |
| | 2 | 0.0325 | 0.6239 | 66.0 | 0.0182 | 0.4682 | 24.9 |
| | **Mean** | **0.0339** | **0.6155** | **64.5** | **0.0186** | **0.4551** | **26.1** |
| 0.5 | 1 | 0.2055 | 2.9030 | 58.7 | 0.0988 | 2.0716 | 28.6 |
| | 2 | 0.1991 | 2.9608 | 59.9 | 0.0972 | 2.1382 | 27.8 |
| | **Mean** | **0.2023** | **2.9319** | **59.3** | **0.0980** | **2.1049** | **28.2** |
| 1.0 | 1 | 0.4296 | 5.6068 | 57.0 | 0.1995 | 3.9275 | 30.0 |
| | 2 | 0.4597 | 5.3764 | 53.9 | 0.2055 | 3.7568 | 30.1 |
| | **Mean** | **0.4446** | **5.4916** | **55.4** | **0.2025** | **3.8422** | **30.0** |

*: % adsorbed as the % of the applied.

Adsorption and desorption parameters and Freundlich adsorption isotherms are presented below.

Average values for adsorption partition coefficients ($K_d$) ranged from 9.273 to 22.62 mL/g with the corresponding average $K_{OC}$ values of 490.7 to 1300 mL/g. The Freundlich equations showed a good fit to the data with $K_F$ values from 5.727 to15.35 mL/g. $K_{FOC}$ values ranged from 322.5 to 759.4 mL/g. The corresponding 1/n values ranged from 0.8413 to 0.8955.

The Kd, $K_{OC}$, $K_F$ and $K_{FOC}$ values after the desorption step were all higher than those after the adsorption step for all soils. These data suggest that adsorption of $^{14}$C- SYN545547 is not fully reversible.

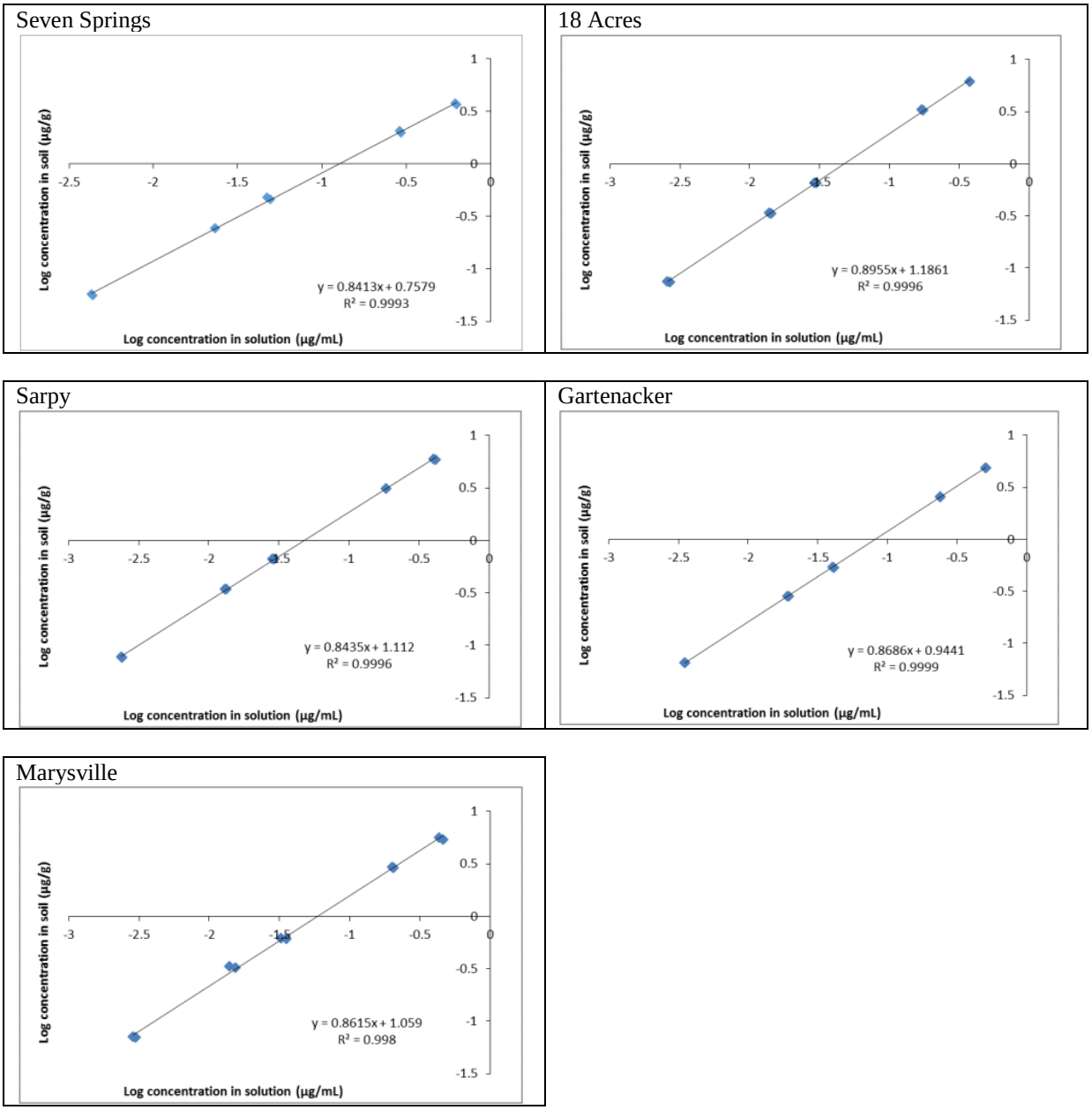
Average values for desorption coefficients (Kd) per soil were in the range 15.49 to 29.55 mL/g and $K_{OC}$ values were in the range 605 to 2054 mL/g. The Freundlich equations showed a good fit to the data with $K_F$ values from 10.11 to 18.34 mL/g mL/g. The corresponding 1/n values ranged from 0.8553 to 0.9045.

**Table B.8. 221 Adsorption and desorption parameters of SYN545547**

| **Parameter**[1] | **Seven Springs (USA)** | **18 Acres (UK)** | **Sarpy (USA)** | **Gartenacker (Switzerland)** | **Marysville (USA)** |
|---|---|---|---|---|---|
| Texture | Sand | Sandy clay Loam | Silt loam | Loam | Clay |
| pH (0.01M $CaCl_2$) | 5.3 | 5.8 | 6.5 | 7.0 | 7.5 |
| %OC | 0.75 | 2.15 | 1.74 | 2.73 | 1.80 |
| **Adsorption** | | | | | |
| $K_F$ | 5.727 | 15.35 | 12.94 | 8.792 | 11.45 |
| $K_{FOC}$ | 759.4 | 715.3 | 743.8 | 322.5 | 637.0 |
| 1/n | 0.8413 | 0.8955 | 0.8435 | 0.8686 | 0.8615 |
| $r^2$ | 0.9993 | 0.9996 | 0.9996 | 0.9999 | 0.9980 |
| $K_d$ (averaged) | 9.273 | 22.05 | 22.62 | 13.38 | 18.36 |
| $K_{OC}$ (averaged) | 1230 | 1027 | 1300 | 490.7 | 1021 |
| **Desorption** | | | | | |
| $K_F$ | 10.11 | 18.34 | 16.39 | 11.06 | 16.31 |
| $K_{FOC}$ | 1340 | 854.6 | 942.0 | 405.7 | 906.9 |
| 1/n | 0.8909 | 0.9045 | 0.8553 | 0.8944 | 0.8883 |
| $r^2$ | 0.9979 | 0.9996 | 0.9998 | 0.9993 | 0.9978 |
| $K_d$ (averaged) | 15.49 | 26.67 29 | 29.55 | 16.49 | 25.46 |
| $K_{OC}$ (averaged) | 2054 | 1243 | 1698 | 605 | 1416 |

[1]. $K_F$, $K_{FOC}$, $K_d$ and $K_{OC}$ all have the units mL/g

**Figure B.8. 45 Freundlich adsorption isotherms for SYN545547**




The adsorption/desorption properties of $^{14}C$- SYN545547 were studied in five soils. Freundlich adsorption coefficients were in the range 5.727 to 15.35 mL/g. and $K_{FOC}$ values ranged from 322.5 to 759.4 mL/g.

Freundlich desorption coefficients were in the range 10.11 to 18.34 mL/g and the corresponding $K_{FOC}$ values ranged from 405.7 to 1340 mL/g. Adsorption was not fully reversible.

Using the McCall Classification scale to assess a chemical's potential mobility in soil (based on its $K_{FOC}$ from the adsorption step), SYN545547 can be classified as having a 'low or medium mobility. There is no indication of a relationship between soil adsorption of SYN545547 and soil pH.

**Conclusion**

The applicant assessment of the SYN545547 soil adsorption study appeared to have been conducted before the guidance on the evaluation of OECD 106 soil adsorption studies (the OECD 106 evaluators checklist) was adopted or available. Consequently HSE has used the checklist to validate the acceptability of the study.

The study description gives little detail of the analytical methods used in the study. Liquid scintillation counting appears to have been the primary method of quantifying radioactivity in the definitive test. However, LSC is not substance specific and it's use relies on an assumption that the test substance is stable and the vast majority of radioactivity in supernatants and soil extracts is comprised of the test substance. Information on the amount of SYN545547 in the aqueous supernatants and in soil extracts comes from the stability tests during the preliminary test phase. Each of the six tested soils was used in the stability test with a 72 hour equilibration period; the dosing concentration in the aqueous phase was 0.1 µg/mL with a soil:solution ratio of 1:10, the soil:solution ratio having been previously determined. At the end of the equilibration period, the aqueous supernatants were removed and soils extracts were extracted with acetonitrile:water (80:20 v/v) adjusted to pH 3, this being similar to the extraction used in soil route and rate of degradation studies. The aqueous supernatants were lyophilised (freeze-dried) and reconstituted in acetonitrile:water containing 0.1% formic acid (1:1). Analysis of the extracts was by HPLC; a secondary TLC method was used to confirm identity. During the preliminary study stability checks the following results were seen:

**Table B.8. 222 Results of preliminary test stability checks in preliminary test of SYN545547 soil adsorption study**

| Soil | | % of Applied Radioactivity | | |
|---|---|---|---|---|
| | **Adsorption Supernatant** | **Soil Extract** | **Unextracted from soil** | **Total** |
| Seven Springs | 46.53 | 51.83 | 1.08 | 99.45 |
| 18 Acres | 29.17 | 68.77 | 0.82 | 98.76 |
| Sarpy | 28.42 | 67.47 | 2.10 | 97.99 |
| Gartenacker | 40.23 | 57.50 | 1.27 | 99.00 |
| Marysville | 31.17 | 68.15 | 1.05 | 100.37 |

Analysis of the extracts using HPLC gave the following results:

**Table B.8. 223 Results of preliminary test analysis of adsorption supernatant and soil extracts**

| | % Applied Radioactivity as SYN545547 | | |
|---|---|---|---|
| **Soil** | **Adsorption Supernatant** | **Soil Extract** | **Total** |
| Seven Springs | 45.7 | 51.1 | 96.7 |
| 18 Acres | 28.6 | 67.6 | 96.2 |
| Sarpy | 27.7 | 65.7 | 93.4 |
| Gartenacker | 39.4 | 56.3 | 95.7 |
| Marysville | 30.2 | 66.4 | 96.5 |

The results confirm that SYN545547 was sufficiently stable with extractable mass balances of 93.4 – 96.7% at 72 hours. As noted, a 48 hour equilibrium time was chosen for the definitive test. Therefore stability during the definitive test would not be expected to be worse over the shorter time period.

Stability of SYN545547 was also checked during the definitive test. In this phase of the study, one replicate was taken from each concentration from the Sarpy soil. In addition one replicate was taken from the highest test concentration for each of the other four soils. The results from this testing are presented below.

**Table B.8. 224 Results of stability checks in the definitive test of SYN545547soil adsorption study**

| | | % of chromatogram formed by SYN545547 | | |
|---|---|---|---|---|
| **Soil** | **Concentration (µg/mL)** | **% SYN545547 in adsorption supernatant** | **% SYN545547 in desorption supernatant** | **% SYN545547 in soil extract** |
| Seven Springs | 1.0 | 98.3 | 100.0 | 98.2 |
| 18 Acres | 1.0 | 98.0 | 99.0 | 98.6 |
| Gartenacker | 1.0 | 98.0 | 99.2 | 98.2 |
| Marysville | 1.0 | 97.8 | 98.8 | 97.9 |
| Sarpy | 1.0 | 98.3 | 98.6 | 98.0 |
| Sarpy | 0.5 | 98.4 | 98.4 | 100.0 |
| Sarpy | 0.1 | 97.0 | 98.5 | 98.3 |
| Sarpy | 0.05 | 95.7 | 98.2 | 98.4 |
| Sarpy | 0.01 | 100.0 | 100.0 | 99.1 |

**Table B.8. 225 Results of stability checks in the definitive test of SYN545547 soil adsorption study**

| | | Total extracted as SYN545547 | | | |
|---|---|---|---|---|---|
| **Soil** | **Concent-ration (µg/mL)** | **% in adsorption supernatant** | **% in desorption supernatant** | **% in soil extract** | **% total SYN545547** |
| Seven Springs | 1.0 | 57.5 | 17.4 | 19.5 | 94.4 |
| 18 Acres | 1.0 | 34.2 | 19.0 | 41.8 | 95.0 |
| Gartenacker | 1.0 | 46.3 | 21.0 | 27.1 | 94.4 |
| Marysville | 1.0 | 39.3 | 18.3 | 36.2 | 93.8 |
| Sarpy | 1.0 | 38.1 | 18.6 | 36.7 | 93.4 |
| Sarpy | 0.5 | 34.0 | 18.0 | 41.9 | 93.9 |
| Sarpy | 0.1 | 27.8 | 16.3 | 49.7 | 93.7 |
| Sarpy | 0.05 | 25.1 | 15.5 | 51.5 | 92.0 |
| Sarpy | 0.01 | 22.2 | 14.1 | 57.4 | 93.7 |

The stability of SYN545547 was confirmed. It also appears to be the reason why the LSC counting was relied upon as a surrogate for directly measured SYN545547 quantified by HPLC. In view of the general stability of SYN545547 seen in the soil studies, the high proportion of SYN545547 in extracts and the low level of unextracted residues seen in the preliminary test, it is considered by HSE that this was an acceptable approach to take.

The OECD 106 checklist indicates that the limit of quantification of the analytical method should be at least two orders of magnitude below the lowest nominal concentration tested. The LOQ of the LSC method was stated to be maximum of 0.3% AR based on the dosing of the lowest concentration used in the test. The applicant clarified that the theoretical LOQ was equivalent to 0.0004 µg/mL. Given that the lowest nominal concentration tested was 0.01 µg/mL the LOQ is approximately two orders of magnitude below the lowest nominal concentration. It is considered that the analytical method was sufficient in this study.

Whilst not stated directly it appears that the test mainly used the indirect method of determining the Freundlich isotherms, i.e. concentrations in soil were calculated by subtraction of the amount in the aqueous supernatant concentration from the initial dose. As noted above with respect to stability checks, soil extractions were only carried out on one replicate per dose for a single soil and for only a single replicate across all doses in the other five soils. HSE accepts the use of the indirect method in this study based on the results in relation to the OECD 106 checklist.

The soil:solution ratios appear to have been chosen appropriately. Adsorption at the 1:5 ratio was probably judged too high for all soils (65 – 83% adsorption). Adsorption at the 1:10 ratio was probably judged as appropriate with 50 – 70% adsorption. At 1:20 the amount adsorbed was reduced to 27 – 50%.

The check of systematic errors (KfE/Kf ratio) indicated that the ratios were all less than the 1.2 suggested as a 'rule-of-thumb' in the OECD 106 evaluators checklist. Overall the losses seen in the study were relatively small with low unextracted residues and the vast majority of extractable radioactivity attributable to the test substance.

Fitting of the Freundlich isotherms was undertaken in the HSE check by calculating the amount adsorbed to soil from the amount applied and the concentration in the supernatant. Small differences in the calculated parameters (Kf,ads and 1/n) compared to the those in the study were seen but these are not considered to be significant. The $r^2$ values of the fits were ≥0.990. The OECD 106 evaluators checklist suggests that $r^2$ should be typically greater than 0.975. Fitting was good with residual plots showing generally small differences from the zero line.

A summary of the fitted parameters with 95$^{th}$ percentile confidence intervals for Kf and 1/n vales are presented below.

**Table B.8. 226 Results of HSE fitting of Freundlich isotherm to SYN545547 soil adsorption study data**

| Soil | KF,ads | Lower 95 | Upper 95 | Kfoc ,ads | 1/n | Lower 95 | Upper 95 | r2 |
|---|---|---|---|---|---|---|---|---|
| Seven Springs | 5.838 | 5.235 | 6.510 | 778 | 0.841 | 0.808 | 0.874 | 0.998 |
| 18 Acres | 15.601 | 14.438 | 16.858 | 726 | 0.897 | 0.876 | 0.917 | 0.999 |
| Sarpy | 13.151 | 11.989 | 14.424 | 756 | 0.844 | 0.820 | 0.869 | 0.999 |
| Gartenacker | 9.023 | 8.555 | 9.518 | 331 | 0.869 | 0.853 | 0.884 | 1.000 |
| Marysville | 11.644 | 10.182 | 13.317 | 647 | 0.862 | 0.825 | 0.898 | 0.997 |

Overall the results of the soil adsorption study on SYN545547 and the applicants calculated parameters from it can be accepted by HSE.

### B.8.1.2.2.2. Adsorption and desorption of NOA449410 (alternative code: CSAA798670)

Preliminary note: this metabolite is common to several active substances, among which sedaxane and benzovindiflupyr. The following adsorption study [redacted] 2009 was summarised and accepted in the DAR of these substances.

| | |
|---|---|
| **Report:** | K-CA 7.1.3.1.2/02. [redacted], (2009), CSAA798670: Adsorption Properties in Five Soils, Report Number 115 01 014. Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, CH-4108 Witterswil/Switzerland. Syngenta file No. SYN524464_11135 |

| | |
|---|---|
| **Guideline(s):** | OECD 106 (2000), US EPA, Subdivision N, §163-1 |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | Percentage adsorbed < 20% in all soils |
| **Acceptability** | Yes |

**Material and Methods**

The adsorption characteristics of $^{14}$C-NOA449410 (radiochemical purity: 99%, re-determined by IES before use to be 100%; specific activity: 12.36 MBq/mg) were investigated in five different soils using a standard batch equilibrium method.

| **Test Material:** | **14C-NOA449410** |
|---|---|
| Lot/Batch #: | 5046GAR005-2 |
| Specific activity: | 12.36 MBq mg$^{-1}$ |
| Radiochemical purity: | 99.0%; re-determined by IES before use to be 100.0% |
| Application vehicle: | 0.01M $CaCl_2$ |

The soils characteristics are reported in the table below.

**Table B.8. 227 Soil characteristics**

| Name | Soil 1 | Soil 2 | Soil 3 | Soil 4 | Soil 5 |
|---|---|---|---|---|---|
| Sampling location | Gartenacker Switzerland | 18 Acres United Kingdom | Marsillargues France | North Dakota United States of America | California United States of America |
| Sampling depth (cm) | 20 cm | 20 cm | 15 cm | 15 cm | 20 cm |
| Storage conditions | Room temperature | Room temperature | Room temperature | Room temperature | Room temperature |
| Particle size (% w/w): Clay (<2 µm) | 12.0 | 25.0 | 39.0 | 14.0 | 4.0 |
| Silt (50-2 µm) | 43.0 | 24.0 | 56.0 | 30.0 | 11.0 |
| Sand (2000-50 µm) | 45.0 | 51.0 | 6.0 | 56.0 | 85.0 |
| Texture (USDA) | Loam | Sandy clay loam | Silty clay | Sandy loam | Loamy sand |
| pH (0.01M $CaCl_2$) | 6.1 | 7.2 | 7.6 | 6.8 | 6.8 |
| Organic matter (%) | 3.65 | 4.34 | 1.13 | 6.70 | 0.60 |
| Organic carbon (%) | 2.12 | 2.52 | 0.66 | 3.89 | 0.35 |
| CEC (meq/100 g soil) | 17.3 | 19.4 | 27.2 | 19.7 | 3.3 |

**Preliminary tests**
The optimal soil to solution ratio was 1/1. At this ratio, 2.5 to 16.3% of the test item were adsorbed onto soils after 72 hours shaking. The results of the adsorption kinetics show that adsorption equilibrium was almost reached after 24 hours of shaking and a slight increase was observed for longer intervals. No significant degradation was observed in the aqueous phases of the samples. Therefore, the test item was stable throughout the 72 hours adsorption interval.

The resulting Kd values were << 0.1 mL/g to 0.2 mL/g for all soils. Since Kd values were below 0.3, a desorption step was not performed because the accuracy of the results could not be guaranteed (as outlined in OECD guideline 106).

The amounts recovered in the supernatants of the control samples (containing no soil) ranged from 95.2% to 99.0% confirming only insignificant adsorption to walls of the Teflon tubes. No radioactivity was observed in the blank samples (containing only soil and 0.01 M $CaCl_2$ solution). Recoveries of radioactivity after 72 hours of adsorption ranged from 93.6% to 104.2% of the applied dose for all soils.

**Definitive test**
In order to determine the Freundlich adsorption isotherm, the definitive test was performed for all soils at five initial test item concentrations (0.1, 0.04, 0.01, 0.004 and 0.001 mg/L). Based on the results of the preliminary test, a soil-to-solution ratio of 1/1 and an adsorption time of 72 hours were selected for the definitive test. All experiments were performed at a constant temperature of 20 ± 2 °C.

After shaking, duplicate samples were taken and centrifuged for 10 minutes at 3200 rpm followed by a high speed centrifugation step at 12000 rpm (centrifugation force was capable of removing particles larger than 0.2 µm from the solution). Thereafter, subsamples of the supernatant were taken and subjected to LSC measurement for their radioactivity content (for determination of the test item concentration) and HPLC analysis to confirm stability of the test item (highest concentration for all soils, only). Due to low adsorption, only soil II (applied at the highest test item concentration) was extracted. The corresponding extracts were concentrated by a factor of 2.5 under a gentle stream of nitrogen and subjected to HPLC analysis.

The equilibrium concentration of the test item (Ce) and its total amount in the aqueous phase were calculated based on the results of the radio-assays. The amount of test item adsorbed onto soil particles (x/m; x: amount of test item adsorbed, m: mass of dry soil) was obtained from the difference between the initial and final amount of the test item in the aqueous phase, i.e. the indirect method was used. HSE generally considers that for substances with low adsorption it is generally preferable to use the direct method. As the study was accepted for other approved a.s., it is considered acceptable at this time for use within the pydiflumetofen assessment.

**Findings**
Recovered radioactivity in the control samples ranged between 96.1 to 99.7%. HPLC analysis showed that the test item was stable throughout the 72-h agitation period. The percentages of applied [$^{14}$C]-NOA449410 adsorbed during the isotherm adsorption definitive experiments are reported in the following table.

**Table B.8. 228 Percentage of [14C]-NOA449410 adsorbed (mean of replicates)**

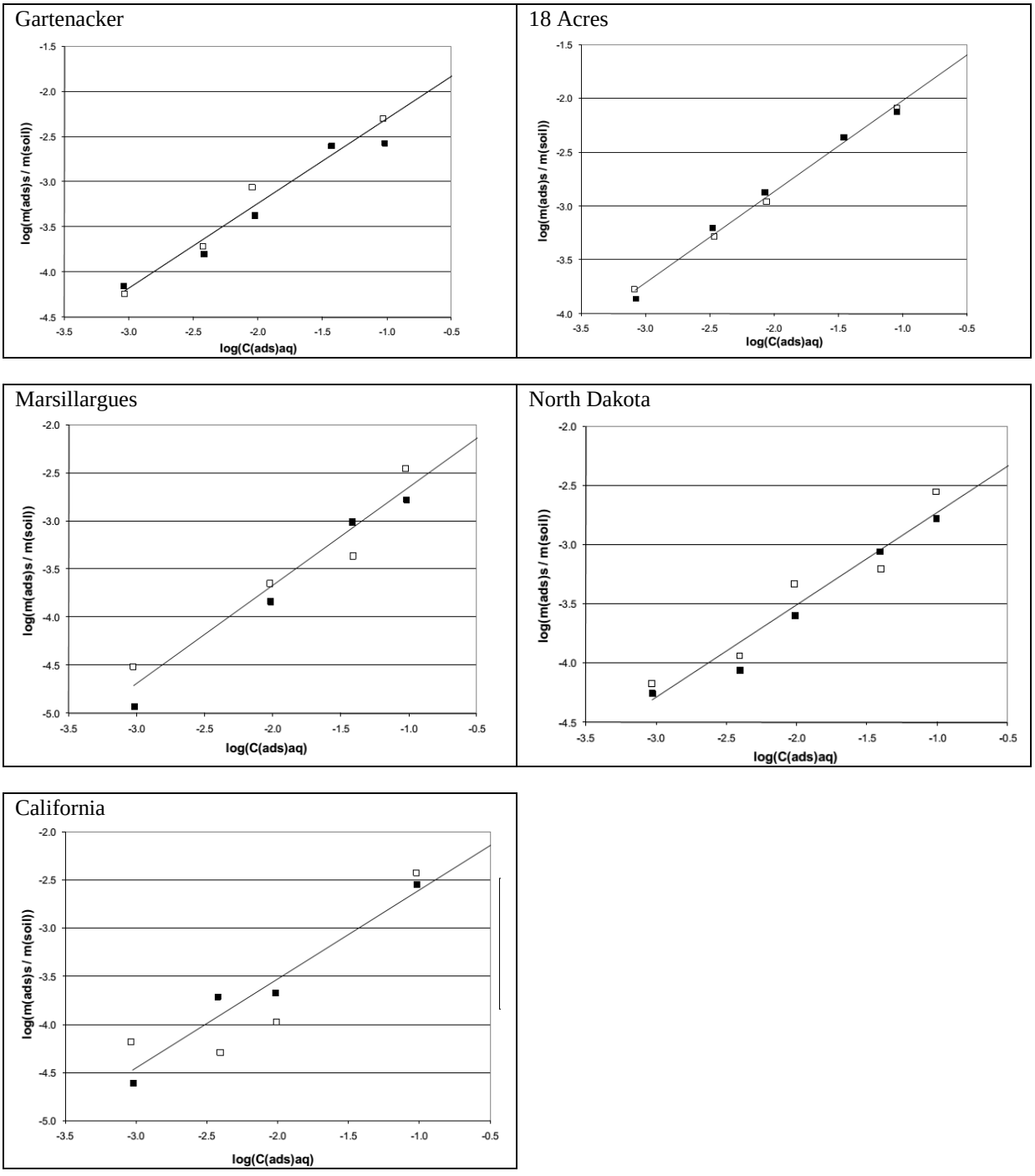
| Concentration (mg/L) | Gartenacker | 18 Acres | Marsillargues | North Dakota | California |
|---|---|---|---|---|---|
| 0.1 | 3.8 | 7.7 | 2.6 | 2.2 | 3.3 |
| 0.04 | 6.2 | 10.6 | 1.7 | 1.9 | -0.2 |
| 0.01 | 6.4 | 11.9 | 1.8 | 3.6 | 1.6 |
| 0.004 | 4.3 | 14.0 | -2.5 | 2.5 | 3.0 |
| 0.001 | 6.3 | 15.0 | 2.1 | 6.2 | 4.5 |

NOA449410 was weakly adsorbed to all soils with a mean $K_{FOC}$ value of 3.0 mL/g and mean slope (1/n) of 0.90. A summary of the key values is shown in the following table.

**Table B.8. 229 Soil adsorption constants for NOA449410 in 5 Soils**

| Parameter | Soil 1 Gartenacker Loam | Soil 2 18 Acres Sandy clay loam | Soil 3 Marsillargues Silty clay | Soil 4 North Dakota Sandy loam | Soil 5 California Loamy sand |
|---|---|---|---|---|---|
| pH (0.01M $CaCl_2$) | 6.1 | 7.2 | 7.6 | 6.8 | 6.8 |
| %OC | 2.1 | 2.5 | 0.7 | 3.9 | 0.4 |
| $K_F$ | 0.04 | 0.07 | 0.02 | 0.01 | 0.02 |
| $K_{FOC}$ | 2.1 | 2.7 | 3.6 | 0.3 | 6.1 |
| 1/n | 0.94 | 0.85 | 1.02 | 0.78 | 0.93 |
| $r^2$ | 0.982 | 0.997 | 0.993 | 0.965 | 0.945 |

**Figure B.8. 46 Freundlich adsorption isotherms for NOA449410**




**Conclusion**

NOA449410 was weakly adsorbed to all five soils with a mean $K_{FOC}$ of 3 mL/g. Due to low adsorption no desorption was performed.

The percentage of metabolite adsorbed is below 20% at all concentrations for all soils (according to OECD 106, the percentage adsorbed should be above 20%, and preferably > 50%). However, this reflects the high mobility of NOA449410. It is not expected to impact the validity of the results. In addition, with a substance exhibiting such low adsorption, HSE would have preferred for the study to have been performed using the direct method. Nevertheless, HSE consider the study is acceptable.

It is noted that this study was submitted for the approved substances sedaxane and benzovindiflupyr. The agreed endpoints from this study were adopted whilst the UK was part of the EU and would be used for GB assessments for authorisation of PPPs containing these a.s. Therefore the study has not been assessed using the OECD 106 evaluators checklist.

It is noted that this metabolite is found in the aqueous photolysis study at >5% and not in soil studies. Thus it is unlikely that the results of this soil adsorption study will be used directly in GB environmental exposure assessment.

### B.8.1.2.3. Column leaching studies

Column leaching studies were not conducted since reliable adsorption coefficient values could be obtained from the adsorption/desorption studies reported above. No studies are required.

### B.8.1.2.4. Aged residue column leaching

Aged residue column leaching studies were not conducted since reliable adsorption coefficient values could be obtained from the adsorption/desorption studies reported above. No studies are required.

### B.8.1.2.5. Lysimeter studies

Lysimeter studies are not considered necessary since reliable adsorption coefficient values could be obtained from the adsorption/desorption studies reported above. No studies are required.

### B.8.1.2.6. Summary on the mobility in soil of pydiflumetofen and its metabolites

The soil adsorption studies submitted are considered by HSE to be acceptable.

Adsorption coefficients for pydiflumetofen were determined in 6 soils using the batch equilibrium method. $K_{FOC}$ values ranged from 1165 to 2206 mL/g (geomean: 1706 mL/g) and 1/n ranged from 0.84 to 0.90 (arithmetic mean: 0.88). There is no indication of a relationship between soil adsorption of pydiflumetofen and soil pH. Using the McCall Classification scale, pydiflumetofen can be classified as having a low to slight potential mobility in soil.

Adsorption coefficients were also determined for the 2 water metabolites SYN545547 and NOA449410 in 5 soils, using the batch equilibrium method.

For SYN545547, $K_{FOC}$ values ranged from 323 to 759 mL/g (geomean: 608 mL/g) and 1/n ranged from 0.84 to 0.90 (arithmetic mean: 0.86). There is no indication of a relationship between soil adsorption of SYN545547 and soil pH. Using the McCall Classification scale, SYN545547 can be classified as having a low to medium potential mobility in soil.

For NOA449410, $K_{FOC}$ values ranged from 0.3 to 6.1 mL/g (geomean: 2.1 mL/g) and 1/n ranged from 0.78 to 1.02 (arithmetic mean: 0.90). There is no indication of a relationship between soil adsorption of NOA449410 and soil pH. Using the McCall Classification scale, NOA449410 can be classified as having a very high potential mobility in soil.

**Table B.8. 230 Soil adsorption parameters for pydiflumetofen**

| Parent | | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil Type | OC % | Soil pH[a)] | $K_d$ (mL/g) | $K_{doc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | 1/n |
| Sandy clay loam | 2.2 | 6.0 | - | - | 36.10 | 1641 | 0.8794 |
| Loam | 1.8 | 7.2 | - | - | 20.97 | 1165 | 0.8733 |
| Silt loam | 1.7 | 6.5 | - | - | 30.40 | 1788 | 0.8367 |
| Clay loam | 1.0 | 6.7 | - | - | 16.68 | 1668 | 0.8983 |
| Loamy sand | 0.6 | 5.2 | - | - | 11.76 | 1960 | 0.8876 |
| Clay loam | 1.6 | 7.6 | - | - | 35.30 | 2206 | 0.8820 |
| Geometric mean (if not pH dependent) | | | | | 23.3 | 1706 | |
| Arithmetic mean (if not pH dependent) | | | | | | | 0.876 |
| pH dependence | | | No | | | | |

[a)] Measured in calcium chloride solution

**Table B.8. 231 Soil adsorption parameters for SYN545547**

| SYN545547 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil Type | OC % | Soil pH[a)] | $K_d$ (mL/g) | $K_{doc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | 1/n |
| Sand | 0.8 | 5.3 | - | - | 5.727 | 759.4 | 0.8413 |
| Sandy clay loam | 2.2 | 5.8 | - | - | 15.35 | 715.3 | 0.8955 |
| Silt loam | 1.7 | 6.5 | - | - | 12.94 | 743.8 | 0.8435 |
| Loam | 2.7 | 7.0 | - | - | 8.792 | 322.5 | 0.8686 |
| Clay | 1.8 | 7.5 | - | - | 11.45 | 637 | 0.8615 |
| Geometric mean (if not pH dependent) | | | | | 10.3 | 607.9 | |
| Arithmetic mean (if not pH dependent) | | | | | | | 0.862 |
| pH dependence | | | No | | | | |

[a)] Measured in calcium chloride solution

**Table B.8. 232 Soil adsorption parameters for NOA449410**

| NOA449410 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil Type | OC % | Soil pH[a)] | $K_d$ (mL/g) | $K_{doc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | 1/n |
| Loam | 2.1 | 6.1 | - | - | 0.04 | 2.1 | 0.94 |
| Sandy clay loam | 2.5 | 7.2 | - | - | 0.07 | 2.7 | 0.85 |
| Silty clay | 0.7 | 7.6 | - | - | 0.02 | 3.6 | 1.02 |
| Sandy loam | 3.9 | 6.8 | - | - | 0.01 | 0.3 | 0.78 |
| Loamy sand | 0.4 | 6.8 | - | - | 0.02 | 6.1 | 0.93 |
| Geometric mean (if not pH dependent) | | | | | 0.03 | 2.1 | |
| Arithmetic mean (if not pH dependent) | | | | | | | 0.90 |
| pH dependence | | | No | | | | |

[a)] Measured in calcium chloride solution

Column leaching studies, aged residue column leaching studies and lysimeter studies were not conducted since reliable adsorption coefficient values could be obtained from the adsorption/desorption studies reported. No studies are required.

## B.8.2. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

### B.8.2.1. Route and rate of degradation in aquatic systems (chemical and photochemical degradation)

#### B.8.2.1.1. Hydrolysis

| | |
|---|---|
| **Report:** | K-CA 7.2.1.1/01. [redacted], [redacted], (2015), SYN545974 - $^{14}$C-SYN545974: Hydrolysis in Sterile Buffer at pH 4, 7 and 9, Report Number 3200053. Smithers Viscient (ESG) Ltd / Otley Road, Harrogate, North Yorkshire HG3 1PY, UK<br>(Syngenta File No. SYN545974_50052) |

| | |
|---|---|
| **Guideline(s):** | OECD 111 (2004), EPA Guideline Series OPPTS 835.2120 (2008) |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**

The hydrolysis of $^{14}$C-pydiflumetofen at 0.6 µg/mL was studied in the dark in sterile aqueous buffered solutions containing acetonitrile (0.3%) at pH 4, pH 7 and pH 9 at 50°C for 5 days.

| **Test Material:** | **[Pyrazole-5-$^{14}$C]-SYN545974** |
|---|---|
| Lot/Batch #: | 5222MFO001-1 |
| Specific activity: | 5.07 MBq/mg |
| Purity: | 97.8% (radiochemical purity) |
| Application vehicle: | Acetonitrile |

Duplicate samples from each pH were analysed at zero time and after 3 and 5 days incubation at 50°C. Acetonitrile (300 µL) was added to the aqueous solutions prior to analysis by liquid scintillation counting (LSC) and high performance liquid chromatography (HPLC) with radio-detection. Selected samples were analysed by thin layer chromatography (TLC) to confirm identity and quantification of components.

**Findings**

The temperatures remained constant throughout the incubation periods (50 ± 0.5 °C) and there was no significant variation in the pH values of the buffered solutions. The samples also remained sterile throughout the study.

The total recoveries and distribution of radioactivity in each test set are shown below. The mean radioactivity balance was 98.7% (range 95.4 to 100.3%), indicating that no losses from the test system had taken place.

Pydiflumetofen was found to be hydrolytically stable at pH 4, 7 and 9 for up to five days at 50ºC. Pydiflumetofen accounted for ≥ 92% of applied radioactivity in every sample analysed. Only minor transformation products (≤ 4%) were observed in the HPLC analysis of any of the samples.

The hydrolytic half-life at 25°C was therefore estimated to be over a year at all three pH values.

**Table B.8. 233 Mass balance and distribution of radioactivity in pH 4 buffer at 50ºC – individual replicates (values as % of applied)**

| Fractions | Rep. | Incubation time (days) | | |
|---|---|---|---|---|
| | | **0** | **3** | **5** |
| Pydiflumetofen | A | 96.3 | 94.9 | 96.9 |
| | B | 95.1 | 97.8 | 94.8 |
| | **Mean** | **95.7** | **96.3** | **95.9** |
| Others* | A | 2.9 | 4.4 | 2.5 |
| | B | 4.2 | 2.5 | 3.1 |
| | **Mean** | **3.6** | **3.5** | **2.8** |
| Total (mass balance) | A | 99.2 | 99.3 | 99.4 |
| | B | 99.3 | 100.3 | 97.9 |
| | **Mean** | **99.3** | **99.8** | **98.7** |
| Mean ± SD | | 99.2 ± 0.5 | | |

* Includes small unknown components on chromatograms and any unresolved background. No single component exceeded 1.60%.

**Table B.8. 234 Mass balance and distribution of radioactivity in pH 7 buffer at 50ºC – individual replicates (values as % of applied)**

| Fractions | Rep. | Incubation time (days) | | |
|---|---|---|---|---|
| | | **0** | **3** | **5** |
| Pydiflumetofen | A | 96.2 | 97.4 | 93.6 |
| | B | 96.5 | 96.3 | 95.6 |
| | **Mean** | **96.4** | **96.9** | **94.6** |
| Others* | A | 3.4 | 2.7 | 4.1 |
| | B | 2.2 | 2.2 | 2.8 |
| | **Mean** | **2.8** | **2.5** | **3.5** |
| Total (mass balance) | A | 99.6 | 100.1 | 97.7 |
| | B | 98.7 | 98.5 | 98.4 |
| | **Mean** | **99.2** | **99.3** | **98.1** |
| Mean ± SD | | 98.8 ± 0.6 | | |

* Includes small unknown components on chromatograms and any unresolved background. No single component exceeded 1.71%.

**Table B.8. 235 Mass balance and distribution of radioactivity in pH 9 buffer at 50ºC – individual replicates (values as % of applied)**

| Fractions | Rep. | Incubation time (days) | | |
|---|---|---|---|---|
| | | **0** | **3** | **5** |
| Pydiflumetofen | A | 92.0 | 94.4 | 95.8 |
| | B | 94.9 | 96.8 | 96.0 |
| | **Mean** | **93.5** | **95.6** | **95.9** |
| Others* | A | 3.4 | 4.0 | 3.5 |
| | B | 2.7 | 2.8 | 2.2 |
| | **Mean** | **3.0** | **3.4** | **2.9** |
| Total (mass balance) | A | 95.4 | 98.4 | 99.3 |
| | B | 97.6 | 99.6 | 98.2 |
| | **Mean** | **96.5** | **99.0** | **98.8** |
| Mean ± SD | | 98.1 ± 1.1 | | |

* Includes small unknown components on chromatograms and any unresolved background. No single component exceeded 1.65%.

**Conclusion**
The study is considered by HSE to be acceptable . The results can be accepted for risk assessment.

Pydiflumetofen was found to be hydrolytically stable at pH 4, 7 and 9 for up to five days at 50ºC and showed no degradation.

In the study, pydiflumetofen was applied to the test system with acetonitrile as a co-solvent; the concentration of acetonitrile was approximately 0.3%. The addition of acetonitrile had the effect of improving the recoverable radioactivity from 90 – 97% to 96 – 100%. OECD 111 indicates that a co-solvent can be applied with the test substance with the co-solvent having a concentration normally not exceeding 1% v/v. In addition the co-solvent should not hydrolyse the test substance. As acetonitrile did not hydrolyse pydiflumetofen and was at a lower concentration than the normally accepted maximum its use is acceptable.

The short test duration of 5 days at 50° is acceptable and in line with OECD 111 recommendations given the apparent absence of degradation. Pydiflumetofen can be considered to be stable to hydrolysis given that there was no discernible degradation over the 5 day study duration at 50°C. Given the hydrolytic stability the use of only a single radiolabelling position is acceptable.

### B.8.2.1.2. Aqueous Photolysis

| | |
|---|---|
| **Report:** | K-CA 7.2.1.2/01. [redacted], (2015), SYN545974 – Aqueous photolysis of [$^{14}$C] SYN545974, Report Number 3200127. Smithers Viscient (ESG) Ltd, Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK and 108 Woodfield Drive, Harrogate, North Yorkshire, HG1 4LG, UK<br>(Syngenta File No. SYN545974_50168). |

| | |
|---|---|
| **Guideline(s):** | OECD 316 (2008), EPA Guideline Series OPPTS 835-2240 (2008) |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**
The photolysis of pydiflumetofen was investigated in sterile, pH 7 buffer solution (direct photolysis) and sterilised natural water (indirect photolysis).

| **Test Material:** | **[Pyrazole-5-$^{14}$C]-SYN545974** | **[Phenyl-U-$^{14}$C]-SYN545974** |
|---|---|---|
| Lot/Batch #: | 5271GAR001-4 | RDR-XV-94 |
| Specific activity: | 5.06 MBq/mg | 5.791 MBq/mg |
| Radiochemical purity: | 99.2% | 97.8% |
| Application vehicle: | Acetonitrile | Acetonitrile |

Pydiflumetofen (phenyl-U and pyrazole-5 labels) was applied, at a concentration of 1 µg/mL, to the buffer solution or natural water in individual photolysis vessels. Natural water was taken from Middle Row Pond in UK. It was stored in an environmental chamber routinely maintained at 4 ± 2°C, with free access to air. Water was sieved (0.2 mm) prior to use and characterization. It was sterilized by gamma irradiation. Properties of natural water used are reported below.

**Table B.8. 236 Properties of natural water**

| Parameter | Description |
|---|---|
| **Geographic location** | Middle Row Pond, Hardwick Hall, Derbyshire. Grid reference 45687 63915 |
| **pH** | 8.1 |
| **Conductivity (µS/cm)** | 347 |
| **Dissolved oxygen (mg/L)** | 8.6 |
| **Material left after evaporation (mg/L)** | 272 |
| **Suspended solids (mg/L)** | 6.6 |
| **Nitrate (mg/L $NO_3$-N)** | 3.2 |

The treated solutions were irradiated using light from a xenon arc lamp, which emitted light that was filtered to give a spectral distribution close to that of natural sunlight. The mean intensity values were 25.5 to 27.1 W/m$^2$. The samples were maintained at 25 ± 2°C and were continuously irradiated for periods up to the equivalent of *ca* 30 days summer sunlight. Treated samples were also incubated under the same conditions, but in the dark, as controls.

A flow-through system was used with polyurethane foam bung and two 2 M sodium hydroxide traps to trap non-polar volatiles and carbon dioxide, respectively. Maximum incubation time was 30 days after treatment (DAT). In each test, duplicate samples were taken for analysis up to six intervals during irradiation. Duplicate dark control samples were taken for analysis at the start of the incubation and up to three intervals equivalent to or exceeding that of the irradiation test.

Samples were analysed directly by reverse phase high performance liquid chromatography (HPLC). Selected samples (at 30 DAT, for both buffer solution and natural water, with pyrazole label) were analysed by chiral HPLC to check for any enantiomer change during incubation and selected samples were analysed by thin layer chromatography (TLC) to confirm metabolites identified by HPLC. Three metabolites that did not initially have reference standards were identified by LC-MS/MS, of which two were confirmed afterwards with reference standards. The sodium hydroxide trapping solutions were also removed for quantification when associated samples were removed for analysis.

Chemical actinometers were used for the calculation of quantum yield and were incubated with the pyrazole label direct photolysis samples. The actinometer solutions consisted of pyridine (0.005 M) and PNAP (1 x 10-5 M) dissolved in water.

The degradation rate ($DegT_{50}$) of the parent was determined using non-linear regression and a single first order kinetic model (SFO, CAKE, version 1.4). Data from both labels were combined for each test system. Where possible, individual replicates were used. Data from replicates where recovery was < 90% AR was not used for kinetics. Data used for 0 DAT were the mass balance values. All datapoints were unweighted. For optimal goodness of fit, the initial value was also allowed to be estimated by the model.

**Findings**
The total recoveries and distribution of radioactivity are shown in the tables below.

In direct photolysis experiments, the mean mass balance from the phenyl label irradiated samples was 97.6% (range 95.6 - 99.3%) and from the dark controls was 96.9% (range 96.0 - 98.1%). The mean mass balance from the pyrazole label irradiated samples was 99.3% (range 98.3 -100.2%) and from the dark controls was 98.2% (range 96.9 – 99.0%). Carbon dioxide accounted for 4.3 and 0.3% AR for phenyl and pyrazole labels, respectively.

In natural water photolysis experiments, the mean mass balance from the phenyl label irradiated samples was 95.9% (range 95.4 – 96.8%[7]) and from the dark controls was 95.7% (range 93.3 - 98.6%). The mean mass balance from the pyrazole label irradiated samples was 99.2% (range 97.0 – 100.7%) and from the dark controls

[7] Mean of two replicates except for 21 and 30 DAT, where only one of the two replicates were > 90% and the lower values were not used for kinetics.

was 99.5% (range 98.2 – 101.2%). Carbon dioxide accounted for 12.6 and 1.0% AR for phenyl and pyrazole labels, respectively.

**Table B.8. 237 Mass balance and distribution of radioactivity in irradiated pH 7 buffer – individual replicates (values as % of applied) - [Phenyl-$^{14}$C]-pydiflumetofen**

| **[Phenyl-$^{14}$C]-pydiflumetofen** | | **Rep** | **Sampling times (DAT)** | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **2** | **4** | **7** | **14** | **21** | **30** |
| Treated solution | irradiated | A | 97.5 | 98.8 | 98.6 | 93.7 | 94.8 | 91.6 |
| | | B | 96.6 | 98.9 | 97.3 | 95.5 | 95.5 | 89.2 |
| | | **Mean** | **97.1** | **98.9** | **98.0** | **94.6** | **95.2** | **90.4** |
| NaOH Traps | irradiated | A | 0.1 | 0.2 | 0.3 | 1.3 | 1.8 | 3.3 |
| | | B | 0.1 | 0.2 | 0.4 | 1.3 | 1.4 | 5.3 |
| | | **Mean** | **0.1** | **0.2** | **0.4** | **1.3** | **1.6** | **4.3** |
| Foam bung | irradiated | A | 0.1 | 0.2 | 0.3 | 2.1 | 0.8 | 1.3 |
| | | B | 0.1 | 0.2 | 0.4 | 0.7 | 0.8 | 0.5 |
| | | **Mean** | **0.1** | **0.2** | **0.4** | **1.4** | **0.8** | **0.9** |
| Total volatiles | irradiated | A | 0.2 | 0.4 | 0.6 | 3.4 | 2.6 | 4.6 |
| | | B | 0.2 | 0.4 | 0.8 | 2.0 | 2.2 | 5.8 |
| | | **Mean** | **0.2** | **0.4** | **0.7** | **2.7** | **2.4** | **5.2** |
| Total % recovery | irradiated | A | 97.7 | 99.2 | 99.2 | 97.1 | 97.4 | 96.2 |
| | | B | 96.8 | 99.3 | 98.1 | 97.5 | 97.7 | 95.0 |
| | | **Mean** | **97.3** | **99.3** | **98.7** | **97.3** | **97.6** | **95.6** |
| **Overall Mean ± SD** | | | **97.6 ± 1.3** | | | | | |

**Table B.8. 238 Mass balance and distribution of radioactivity in irradiated pH 7 buffer – individual replicates (values as % of applied) - [Pyrazole-$^{14}$C]-pydiflumetofen**

| **[Pyrazole-$^{14}$C]-pydiflumetofen** | | **Rep** | **Sampling times (DAT)** | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **2** | **4** | **7** | **14** | **21** | **30** |
| Treated solution | irradiated | A | 98.7 | 98.2 | 99.8 | 99.1 | 99.9 | 99.1 |
| | | B | 99.0 | 98.4 | 100.2 | 99.6 | 100.2 | 98.5 |
| | | **Mean** | **98.9** | **98.3** | **100.0** | **99.4** | **100.1** | **98.8** |
| NaOH Traps | irradiated | A | ND | ND | ND | ND | 0.1 | 0.3 |
| | | B | ND | ND | 0.1 | ND | 0.1 | 0.2 |
| | | **Mean** | **ND** | **ND** | **0.1** | **ND** | **0.1** | **0.3** |
| Foam bung | irradiated | A | 0.1 | ND | ND | ND | ND | 0.2 |
| | | B | ND | ND | ND | ND | ND | ND |
| | | **Mean** | **0.1** | **ND** | **ND** | **ND** | **ND** | **0.1** |
| Total volatiles | irradiated | A | 0.1 | ND | ND | ND | 0.1 | 0.5 |
| | | B | ND | ND | 0.1 | ND | 0.1 | 0.2 |
| | | **Mean** | **0.1** | **ND** | **0.1** | **ND** | **0.1** | **0.4** |
| Total % recovery | irradiated | A | 98.8 | 98.2 | 99.8 | 99.1 | 100.0 | 99.6 |
| | | B | 99.0 | 98.4 | 100.3 | 99.6 | 100.3 | 98.7 |
| | | **Mean** | **98.9** | **98.3** | **100.1** | **99.4** | **100.2** | **99.2** |
| **Overall Mean ± SD** | | | **99.3 ± 0.7** | | | | | |

ND = Not detected or < 0.1%

**Table B.8. 239 Mass balance and distribution of radioactivity in pH 7 buffer dark controls – individual replicates (values as % of applied) - [Phenyl-$^{14}$C]-pydiflumetofen**

| **[Phenyl-$^{14}$C]-pydiflumetofen** | | **Rep** | **Sampling times (DAT)** | | | |
|---|---|---|---|---|---|---|
| | | | **0** | **7** | **14** | **30** |
| Treated solution | dark | A | 95.8 | 95.1 | 97.5 | 99.0 |
| | | B | 97.7 | 98.4 | 94.5 | 97.1 |
| | | **Mean** | **96.8** | **96.8** | **96.0** | **98.1** |
| Total % recovery | dark | A | 95.8 | 95.1 | 97.5 | 99.0 |
| | | B | 97.7 | 98.4 | 94.5 | 97.1 |
| | | **Mean** | **96.8** | **96.8** | **96.0** | **98.1** |
| **Overall Mean ± SD** | | | **96.9 ± 0.9** | | | |

**Table B.8. 240 Mass balance and distribution of radioactivity in pH 7 buffer dark controls – individual replicates (values as % of applied) (continued) - [Pyrazole-$^{14}$C]-pydiflumetofen**

| **[Pyrazole-$^{14}$C]-pydiflumetofen** | | **Rep** | **Sampling times (DAT)** | | | |
|---|---|---|---|---|---|---|
| | | | **0** | **7** | **14** | **30** |
| Treated solution | dark | A | 96.1 | 97.6 | 99.1 | 98.3 |
| | | B | 97.7 | 98.0 | 98.7 | 99.7 |
| | | **Mean** | **96.9** | **97.8** | **98.9** | **99.0** |
| Total % recovery | dark | A | 96.1 | 97.6 | 99.1 | 98.3 |
| | | B | 97.7 | 98.0 | 98.7 | 99.7 |
| | | **Mean** | **96.9** | **97.8** | **98.9** | **99.0** |
| **Overall Mean ± SD** | | | **98.2 ± 1.0** | | | |

**Table B.8. 241 Mass balance and distribution of radioactivity in irradiated natural water – individual replicates (values as % of applied) - [Phenyl-$^{14}$C]-pydiflumetofen**

| **[Phenyl-$^{14}$C]-pydiflumetofen** | | **Rep** | **Sampling times (DAT)** | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **2** | **4** | **7** | **14** | **21*** | **30*** |
| Treated solution | irradiated | A | 96.1 | 94.9 | 95.5 | 88.8 | *75.8* | 82.4 |
| | | B | 97.0 | 95.1 | 92.0 | 91.0 | 84.6 | *64.7* |
| | | **Mean** | **96.6** | **95.0** | **93.8** | **89.9** | **NA** | **NA** |
| NaOH Traps | irradiated | A | 0.1 | 0.2 | 1.5 | 5.5 | *6.5* | 12.6 |
| | | B | 0.1 | 0.2 | 1.7 | 4.3 | 10.1 | *8.1* |
| | | **Mean** | **0.1** | **0.2** | **1.6** | **4.9** | **NA** | **NA** |
| Foam bung | irradiated | A | 0.1 | 0.2 | 0.5 | 0.9 | *1.6* | 1.0 |
| | | B | 0.1 | 0.2 | 0.5 | 0.8 | 1.1 | *0.7* |
| | | **Mean** | **0.1** | **0.2** | **0.5** | **0.9** | **NA** | **NA** |
| Total volatiles | irradiated | A | 0.2 | 0.4 | 2.0 | 6.4 | *8.1* | 13.6 |
| | | B | 0.2 | 0.4 | 2.2 | 5.1 | 11.2 | *8.8* |
| | | **Mean** | **0.2** | **0.4** | **2.1** | **5.8** | **NA** | **NA** |
| Total % recovery | irradiated | A | 96.3 | 95.3 | 97.5 | 95.2 | *83.9* | 96.0 |
| | | B | 97.2 | 95.5 | 94.2 | 96.1 | 95.8 | *73.5* |
| | | **Mean** | **96.8** | **95.4** | **95.9** | **95.7** | **NA** | **NA** |
| **Overall Mean ± SD** | | | **95.9 ± 0.5*** | | | | | |

*Values in italics were not used due to low mass balance and therefore mean values are not applicable (NA). Overall mean uses just one value from 21 and 30 DAT samples.

**Table B.8. 242 Mass balance and distribution of radioactivity in irradiated natural water – individual replicates (values as % of applied) - [Pyrazole-$^{14}$C]-pydiflumetofen**

| **[Pyrazole-$^{14}$C]-pydiflumetofen** | | **Rep** | **Sampling times (DAT)** | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **2** | **4** | **7** | **14** | **21** | **30** |
| Treated solution | irradiated | A | 101.0 | 95.7 | 99.3 | 99.2 | 99.0 | 100.8 |
| | | B | 97.8 | 95.4 | 98.2 | 99.2 | 98.2 | 98.7 |
| | | **Mean** | **99.4** | **95.6** | **98.8** | **99.2** | **98.6** | **99.8** |
| NaOH Traps | irradiated | A | ND | ND | 0.2 | 0.2 | 1.0 | 0.5 |
| | | B | ND | ND | 0.1 | 0.5 | 0.9 | 1.4 |
| | | **Mean** | **ND** | **ND** | **0.2** | **0.4** | **1.0** | **1.0** |
| Foam bung | irradiated | A | 0.4 | 2.8 | ND | ND | ND | ND |
| | | B | 0.2 | ND | 0.2 | ND | ND | ND |
| | | **Mean** | **0.3** | **1.4** | **0.1** | **ND** | **ND** | **ND** |
| Total volatiles | irradiated | A | 0.4 | 2.8 | 0.2 | 0.2 | 1.0 | 0.5 |
| | | B | 0.2 | ND | 0.3 | 0.5 | 0.9 | 1.4 |
| | | **Mean** | **0.3** | **1.4** | **0.3** | **0.4** | **1.0** | **1.0** |
| Total % recovery | irradiated | A | 101.4 | 98.5 | 99.5 | 99.4 | 100.0 | 101.3 |
| | | B | 98.0 | 95.4 | 98.5 | 99.7 | 99.1 | 100.1 |
| | | **Mean** | **99.7** | **97.0** | **99.0** | **99.6** | **99.6** | **100.7** |
| **Overall Mean ± SD** | | | **99.2 ± 1.3** | | | | | |

ND = Not detected or < 0.1%

**Table B.8. 243 Mass balance and distribution of radioactivity in natural water dark controls – individual replicates (values as % of applied) - [Phenyl-$^{14}$C]-pydiflumetofen**

| **[Phenyl-$^{14}$C]-pydiflumetofen** | | **Rep** | **Sampling times (DAT)** | | | |
|---|---|---|---|---|---|---|
| | | | **0** | **7** | **14** | **30** |
| Treated solution | dark | A | 99.1 | 91.5 | 95.7 | 92.8 |
| | | B | 98.0 | 95.0 | 95.7 | 98.0 |
| | | **Mean** | **98.6** | **93.3** | **95.7** | **95.4** |
| Total % recovery | dark | A | 99.1 | 91.5 | 95.7 | 92.8 |
| | | B | 98.0 | 95.0 | 95.7 | 98.0 |
| | | **Mean** | **98.6** | **93.3** | **95.7** | **95.4** |
| **Overall Mean ± SD** | | | **95.7 ± 2.2** | | | |

**Table B.8. 244 Mass balance and distribution of radioactivity in natural water dark controls – individual replicates (values as % of applied) - [Pyrazole-$^{14}$C]-pydiflumetofen**

| **[Pyrazole-$^{14}$C]-pydiflumetofen** | | **Rep** | **Sampling times (DAT)** | | | |
|---|---|---|---|---|---|---|
| | | | **0** | **7** | **14** | **30** |
| Treated solution | dark | A | 99.4 | 98.5 | 98.9 | 100.5 |
| | | B | 99.5 | 97.9 | 99.2 | 101.9 |
| | | **Mean** | **99.5** | **98.2** | **99.1** | **101.2** |
| Total % recovery | dark | A | 99.4 | 98.5 | 98.9 | 100.5 |
| | | B | 99.5 | 97.9 | 99.2 | 101.9 |
| | | **Mean** | **99.5** | **98.2** | **99.1** | **101.2** |
| **Overall Mean ± SD** | | | **99.5 ± 1.3** | | | |

Characterization of radioactivity into parent and photolysis products is reported below.

In sterile buffer, pydiflumetofen degraded slowly with 72.5% and 78.8% of the applied radioactivity (AR) remaining as pydiflumetofen at 30 DAT (phenyl and pyrazole labels, respectively). There were no major degradation products (> 10% AR, or two consecutive times > 5% AR) present. SYN548261 and NOA449410, both of which were pyrazole label metabolites identified within the study, reached maximum individual values

of 2.0% and 2.6% AR, respectively at 30 DAT. A de-chlorinated metabolite, referred to as Unk AP2, reached maximum individual values of 6.2% AR at 21 DAT (phenyl label) and 3.2% AR at 30 DAT (pyrazole label).

In natural water, pydiflumetofen degraded more quickly with 52.3% and 61.2% AR remaining at 30 DAT (phenyl and pyrazole labels, respectively). No degradation products were present at > 10% AR. SYN548261 was present at > 5% AR between 7 and 30 DAT (maximum individual value 8.6% AR) and Unk AP2 and NOA449410 were present at maximum values of 2.5% AR and 5.8% AR, respectively, at 30 DAT. SYN548262 was identified in irradiated natural water but was a minor metabolite present at 1.7% AR at 30 DAT.

SYN545547 was detected in the application solutions but may also have been a minor metabolite (maximum 2.9% in sterile buffer, 1.3% in natural water). Several other degradation products were observed at low levels, all less than 5% of applied.

No notable degradation was apparent in any of the 'dark controls' indicating that the degradation in irradiated samples was due to photodegradation only.

**Table B.8. 245 Phototransformation of pydiflumetofen in pH 7 buffer, expressed as percentage of the applied radioactivity – Phenyl**

| **[Phenyl-$^{14}$C]-pydiflumetofen** | | **Rep** | **Sampling times (DAT)** | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **2** | **4** | **7** | **14** | **21** | **30** |
| Parent compound | irradiated | A | 93.6 | 92.5 | 89.3 | 81.3 | 76.6 | 75.6 |
| | | B | 90.6 | 95.0 | 90.8 | 81.2 | 79.1 | 69.4 |
| | | **Mean** | **92.1** | **93.8** | **90.0** | **81.2** | **77.8** | **72.5** |
| SYN545547 | irradiated | A | 1.6 | 0.9 | 2.5 | 1.2 | 2.5 | 2.3 |
| | | B | 2.2 | 1.4 | 1.4 | 1.9 | 2.4 | 2.9 |
| | | **Mean** | **1.9** | **1.2** | **1.9** | **1.6** | **2.4** | **2.6** |
| Unknown AP2 (SYN548262) | irradiated | A | 0.9 | 1.5 | 2.5 | 2.8 | 6.2 | 3.4 |
| | | B | 1.1 | 1.3 | 1.3 | 4.1 | 5.1 | 1.1 |
| | | **Mean** | **1.0** | **1.4** | **1.9** | **3.5** | **5.6** | **2.2** |
| Unretained | irradiated | A | ND | ND | 0.5 | 1.6 | 2.0 | 2.1 |
| | | B | ND | ND | 0.4 | 1.4 | 1.7 | 5.3 |
| | | **Mean** | **ND** | **ND** | **0.5** | **1.5** | **1.8** | **3.7** |
| Other unidentified products | irradiated | A | 0.7 | 1.5 | 1.4 | 2.3 | 4.7 | 4.3 |
| | | B | 1.9 | 1.1 | 1.0 | 2.7 | 4.0 | 7.7 |
| | | **Mean** | **1.3** | **1.3** | **1.2** | **2.5** | **4.4** | **6.0**[a] |

ND = Not detected or < 0.1%

[a] Up to 13 other unknowns were present at 30 DAT. The maximum level of any single unknown was 1.3% AR at 2 DAT.

**Table B.8. 246 Phototransformation of pydiflumetofen in pH 7 buffer, expressed as percentage of the applied radioactivity – Pyrazole**

| [Pyrazole-$^{14}$C]-pydiflumetofen | | Rep | Sampling times (DAT) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **2** | **4** | **7** | **14** | **21** | **30** |
| Parent compound | irradiated | A | 95.8 | 93.9 | 93.8 | 91.8 | 87.8 | 78.5 |
| | | B | 96.6 | 93.1 | 95.5 | 92.4 | 88.9 | 79.1 |
| | | **Mean** | **96.2** | **93.5** | **94.6** | **92.1** | **88.4** | **78.8** |
| SYN545547 | irradiated | A | 1.1 | 1.1 | 1.4 | 1.4 | 2.0 | 1.6 |
| | | B | 1.0 | 1.4 | 1.6 | 1.4 | 1.5 | 1.6 |
| | | **Mean** | **1.0** | **1.2** | **1.5** | **1.4** | **1.8** | **1.6** |
| NOA449410 (Unk AP4) | irradiated | A | ND | ND | ND | 0.9 | 1.5 | 2.6 |
| | | B | ND | ND | ND | 0.5 | 1.6 | 2.6 |
| | | **Mean** | **ND** | **ND** | **ND** | **0.7** | **1.6** | **2.6** |
| Unknown AP2 (SYN548262) | irradiated | A | ND | ND | 0.8 | 1.3 | 2.2 | 3.2 |
| | | B | ND | ND | ND | 1.2 | 2.3 | 3.2 |
| | | **Mean** | **ND** | **ND** | **0.4** | **1.2** | **2.3** | **3.2** |
| SYN548261 (Unk AP3) | irradiated | A | ND | ND | ND | ND | ND | 2.0 |
| | | B | ND | ND | ND | ND | ND | 1.8 |
| | | **Mean** | **ND** | **ND** | **ND** | **ND** | **ND** | **1.9** |
| Unretained | irradiated | A | ND | ND | ND | ND | ND | 0.2 |
| | | B | ND | ND | ND | ND | ND | 0.2 |
| | | **Mean** | **ND** | **ND** | **ND** | **ND** | **ND** | **0.2** |
| Other unidentified products | irradiated | A | 0.9 | 1.0 | 2.9 | 2.5 | 4.8 | 8.8 |
| | | B | 1.0 | 1.0 | 1.3 | 2.3 | 4.6 | 8.0 |
| | | **Mean** | **1.0** | **1.0** | **2.1** | **2.4** | **4.7** | **8.4**[a] |

ND = Not detected or < 0.1%

[a] The maximum number of other unknowns was 13 (in a 30 DAT sample) and the maximum amount of any single other unknown was 2.8% (in a 30 DAT sample)

**Table B.8. 247 Transformation of pydiflumetofen in pH 7 buffer dark controls, expressed as percentage of the applied radioactivity – Phenyl**

| [Phenyl-$^{14}$C]-pydiflumetofen | | Rep | Sampling times (DAT) | | | |
|---|---|---|---|---|---|---|
| | | | **0** | **7** | **14** | **30** |
| Parent compound | dark | A | 93.3 | 93.4 | 94.1 | 95.7 |
| | | B | 94.9 | 95.9 | 92.2 | 94.4 |
| | | **Mean** | **94.1** | **94.6** | **93.1** | **95.1** |
| SYN545547 | dark | A | 1.2 | 1.0 | 1.3 | 1.1 |
| | | B | 0.9 | 0.9 | 1.0 | 1.0 |
| | | **Mean** | **1.0** | **1.0** | **1.2** | **1.1** |
| Other unidentified products | dark | A | 0.4 | 0.6 | ND | 0.5 |
| | | B | 0.8 | 0.8 | 0.5 | 0.5 |
| | | **Mean** | **0.6** | **0.7** | **0.3** | **0.5** |

**Table B.8. 248 Transformation of pydiflumetofen in pH 7 buffer dark controls, expressed as percentage of the applied radioactivity – Pyrazole**

| [Pyrazole-$^{14}$C]-pydiflumetofen | | Rep | Sampling times (DAT) | | | |
|---|---|---|---|---|---|---|
| | | | **0** | **7** | **14** | **30** |
| Parent compound | dark | A | 93.3 | 94.3 | 94.8 | 94.8 |
| | | B | 94.4 | 95.6 | 95.2 | 94.9 |
| | | **Mean** | **93.8** | **95.0** | **95.0** | **94.8** |
| SYN545547 | dark | A | 1.1 | 1.0 | 1.2 | 1.2 |
| | | B | 1.4 | 1.0 | 1.0 | 1.2 |
| | | **Mean** | **1.2** | **1.0** | **1.1** | **1.2** |
| Other unidentified products | dark | A | 1.4 | 1.0 | 1.6 | 1.6 |
| | | B | 1.7 | 0.9 | 1.8 | 1.6 |
| | | **Mean** | **1.6** | **0.9** | **1.7** | **1.6** |

**Table B.8. 249 Phototransformation of test material in natural water, expressed as percentage of the applied radioactivity – Phenyl**

| [Phenyl-$^{14}$C]-pydiflumetofen | | Rep | Sampling times (DAT) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **2** | **4** | **7** | **14** | **21*** | **30*** |
| Parent compound | irradiated | A | 92.2 | 85.7 | 72.8 | 65.0 | *35.8* | 52.3 |
| | | B | 83.3 | 84.6 | 67.0 | 66.4 | 57.6 | *32.4* |
| | | **Mean** | **87.8** | **85.2** | **69.9** | **65.7** | **NA** | **NA** |
| SYN545547 | irradiated | A | 0.4 | 0.8 | 1.2 | 1.4 | *0.8* | 1.7 |
| | | B | 1.1 | 1.2 | 1.2 | 1.2 | 1.5 | *0.7* |
| | | **Mean** | **0.8** | **1.0** | **1.2** | **1.3** | **NA** | **NA** |
| Unknown AP2 (SYN548262) | irradiated | A | 0.4 | ND | 1.0 | 1.5 | *1.1* | 2.5 |
| | | B | 0.3 | 0.4 | 0.9 | 1.5 | 1.5 | *1.4* |
| | | **Mean** | **0.4** | **0.2** | **1.0** | **1.5** | **NA** | **NA** |
| Unretained | irradiated | A | ND | 1.5 | 3.8 | 4.9 | *12.6* | 9.3 |
| | | B | 1.7 | 1.5 | 3.9 | 4.9 | 6.9 | *13.7* |
| | | **Mean** | **0.9** | **1.5** | **3.8** | **4.9** | **NA** | **NA** |
| Other unidentified products[a] | irradiated | A | ND | 3.3 | 13.4 | 13.0 | *23.6* | 14.6 |
| | | B | 6.3 | 5.1 | 14.9 | 13.5 | 13.9 | *15.8* |
| | | **Mean** | **3.1** | **4.2** | **14.2** | **13.2** | **NA** | **NA** |

ND = Not detected or < 0.1%

*Values in italics were not used for kinetics due to low mass balance and therefore mean values are not applicable (NA)

[a] The maximum number of other unknowns was 20 (14 and 21 DAT samples, 30 DAT in italics excluded) and the maximum amount of any single other unknown was 3.4% (in a 7 DAT sample)

**Table B.8. 250 Phototransformation of test material in natural water, expressed as percentage of the applied radioactivity – Pyrazole**

| [Pyrazole-$^{14}$C]-pydiflumetofen | | Rep | Sampling times (DAT) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | **2** | **4** | **7** | **14** | **21** | **30** |
| Parent compound | irradiated | A | 83.6 | 75.9 | 53.4 | 66.2 | 54.7 | 70.8 |
| | | B | 83.4 | 78.8 | 59.2 | 55.4 | 55.3 | 51.6 |
| | | **Mean** | **83.5** | **77.4** | **56.3** | **60.8** | **55.0** | **61.2** |
| SYN545547 | irradiated | A | 1.2 | 1.2 | 1.0 | 1.1 | 0.9 | 1.4 |
| | | B | 1.1 | 1.2 | 1.2 | 0.8 | 1.0 | 0.7 |
| | | **Mean** | **1.1** | **1.2** | **1.1** | **0.9** | **1.0** | **1.0** |
| NOA449410 (Unk AP4) | irradiated | A | 1.0 | 1.2 | 3.2 | 2.6 | 4.5 | 5.8 |
| | | B | 1.0 | 1.1 | 5.7 | 3.5 | 3.8 | 5.1 |
| | | **Mean** | **1.0** | **1.1** | **4.5** | **3.1** | **4.1** | **5.4** |
| Unknown AP2 (SYN548262) | irradiated | A | 0.4 | 0.8 | 1.1 | 0.9 | 1.1 | 1.7 |
| | | B | 0.4 | 0.7 | 1.1 | 0.7 | 1.1 | 0.7 |
| | | **Mean** | **0.4** | **0.8** | **1.1** | **0.8** | **1.1** | **1.2** |
| SYN548261 (Unk AP3) | irradiated | A | 2.5 | 2.9 | 7.8 | 5.6 | 7.5 | 4.1 |
| | | B | 1.9 | 2.0 | 5.8 | 7.9 | 7.1 | 8.6 |
| | | **Mean** | **2.2** | **2.5** | **6.8** | **6.7** | **7.3** | **6.4** |
| Unretained | irradiated | A | ND | 0.2 | 0.7 | 0.4 | 0.9 | 0.4 |
| | | B | ND | 0.2 | 0.6 | 0.7 | 0.8 | 0.9 |
| | | **Mean** | **ND** | **0.2** | **0.6** | **0.6** | **0.8** | **0.7** |
| Other unidentified products[a] | irradiated | A | 9.7 | 10.6 | 31.1 | 20.7 | 26.1 | 14.1 |
| | | B | 8.4 | 9.4 | 22.1 | 26.9 | 26.6 | 27.5 |
| | | **Mean** | **9.1** | **10.0** | **26.6** | **23.8** | **26.4** | **20.8** |

ND = Not detected or < 0.1%
SYN548262 was characterised by retention time only in a 30 DAT sample and comprised 1.7% AR.
[a] The maximum number of other unknowns was 28 (in a 7 DAT sample) and the maximum amount of any single other unknown was 4.6% (in a 21 and a 30 DAT sample).

**Table B.8. 251 Transformation of pydiflumetofen in natural water dark controls, expressed as percentage of the applied radioactivity – Phenyl**

| [Phenyl-$^{14}$C]-pydiflumetofen | | Rep | Sampling times (DAT) | | | |
|---|---|---|---|---|---|---|
| | | | **0** | **7** | **14** | **30** |
| Parent compound | dark | A | 96.6 | 87.7 | 92.2 | 89.3 |
| | | B | 93.4 | 91.3 | 91.9 | 95.3 |
| | | **Mean** | **95.0** | **89.5** | **92.1** | **92.3** |
| SYN545547 | dark | A | 1.0 | 1.0 | 1.0 | 1.6 |
| | | B | 1.5 | 1.0 | 0.9 | 1.2 |
| | | **Mean** | **1.3** | **1.0** | **1.0** | **1.4** |
| Other unidentified products | dark | A | 0.8 | 0.9 | ND | 0.3 |
| | | B | 1.3 | 0.7 | ND | 0.8 |
| | | **Mean** | **1.0** | **0.8** | **ND** | **0.5** |

ND = Not detected or < 0.1%

**Table B.8. 252 Transformation of pydiflumetofen in natural water dark controls, expressed as percentage of the applied radioactivity – Pyrazole**

| [Pyrazole-$^{14}$C]-pydiflumetofen | | Rep | Sampling times (DAT) | | | |
|---|---|---|---|---|---|---|
| | | | **0** | **7** | **14** | **30** |
| Parent compound | dark | A | 95.0 | 94.0 | 93.9 | 96.3 |
| | | B | 95.4 | 93.0 | 93.6 | 98.2 |
| | | **Mean** | **95.2** | **93.5** | **93.7** | **97.3** |
| SYN545547 | dark | A | 1.2 | 1.2 | 1.1 | 1.1 |
| | | B | 1.2 | 1.1 | 1.2 | 1.5 |
| | | **Mean** | **1.2** | **1.2** | **1.1** | **1.3** |
| Other unidentified products | dark | A | 1.8 | 1.5 | 1.4 | 1.5 |
| | | B | 1.7 | 1.7 | 1.6 | 0.9 |
| | | **Mean** | **1.7** | **1.6** | **1.5** | **1.2** |

Chiral HPLC analysis suggested that light irradiation of pydiflumetofen in buffer or natural water did not change the enantiomer ratio. The pydiflumetofen enantiomer ratio in the $^{14}$C-pyrazole application solution was 0.97 and the enantiomer ratio in samples taken at the end of the irradiation period at 30 DAT was 0.98 to 1.01. Only the pyrazole label was used in the test because any change in isomer ratio would be detected whichever radiolabel was used. In line with the EFSA Stereoisomers guidance, HSE calculated the change in enantiomer excess.

**Table B.8. 253 Pydiflumetofen enantiomer ratios in $^{14}$C-pyrazole application solution and samples irradiated for 30 days under the Xenon lamp**

| | | % Sample activity as | | | | |
|---|---|---|---|---|---|---|
| **Sample Type** | **Sample** | **1st eluting enantiomer** | **2nd eluting enantiomer** | **Enantiomer Ratio** | **Enantiomer Excess (ee)** | **Change in ee**** |
| Application solution | **Mean** | **30.70** | **30.16** | **0.97** | **0.89** | |
| 30 DAT Irradiated buffer | **Mean** | **39.90** | **39.82** | **1.01** | **0.10** | **0.79** |
| 30 DAT Irradiated natural water | **Mean** | **26.56** | **27.38** | **0.98** | **-1.52** | **2.41** |

*Application solution 5 was analysed (pydiflumetofen appeared to have degraded during storage/preparation but the two isomers could clearly be detected) ** change in enantiomer excess relative to application solution

SFO kinetics described the degradation of pydiflumetofen well with $\chi^2$ values of 1.0 and 8.5 for buffer and natural water, respectively. There was no significant degradation in the dark so no compensation for dark controls was required. By comparison of the light intensity of the Xenon Arc lamp with that of natural sunlight, the half-life in hours of continuous irradiation was converted to the equivalent half-lives in days of summer sunlight (30-50°N) and Tokyo spring sunlight. The results are presented in the following table and figures.

**Table B.8. 254 SFO DegT$_{50}$ and DegT$_{90}$ values for pydiflumetofen under irradiated conditions – note all DT50 and DT90 values extrapolated beyond study duration**

| Test System | pH 7 buffer | | | | natural water | | | |
|---|---|---|---|---|---|---|---|---|
| | **DegT$_{50}$ [days]** | **DegT$_{90}$ [days]** | **$\chi^2$%** | **Prob>t** | **DegT$_{50}$ [days]** | **DegT$_{90}$ [days]** | **$\chi^2$%** | **Prob>t** |
| Irradiated (experimental result) | 89.1 | 295.8 | 1.01 | <0.05 | 33.3 | 110.5 | 8.49 | <0.05 |
| **Corrected DT$_{50}$ for different latitudes** | | | | | | | | |
| Summer Sunlight 30-50°N (OECD)[1] | 92.7 | 307.6 | - | - | 35.0 | 116.0 | - | - |
| Tokyo Spring Sunlight[2] | 298.5 | 990.9 | - | - | 112.6 | 373.5 | - | - |

[1] Assuming that the sum of the summer natural midday sunlight intensity at UK/US (between 300-400 nm) is 67 W/m$^2$ (OECD 2002 for soil photolysis). This value is then corrected by 0.75 (conversion factor to take into account variation over 12-hour) and by 0.5 (conversion factor for 12-h light per day to a 24-h day). Final summer sunlight intensity is 25.125 W/m$^2$.

[2] Assuming Tokyo spring sunlight intensity is 7.77778 W/m$^2$.

**Figure B.8. 47 Visual and residual fits of pydiflumetofen(both radiolabels) aqueous photolysis in pH 7 buffer, SFO kinetics**

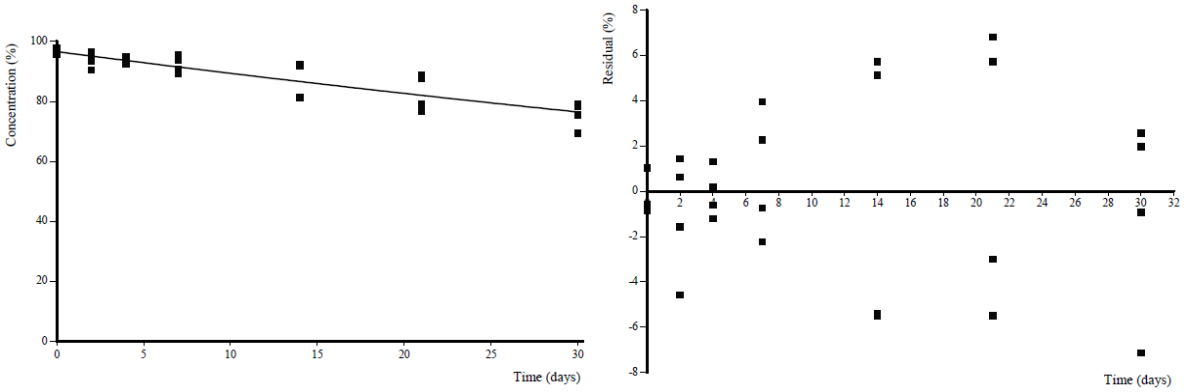
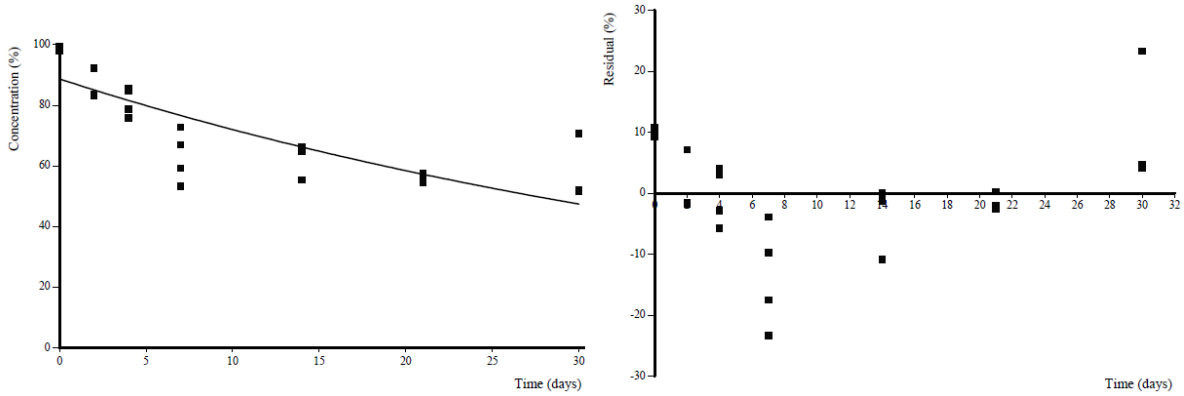



**Figure B.8. 48 Visual and residual fits of pydiflumetofen(both radiolabels) aqueous photolysis in sterile natural water, SFO kinetics**




The calculated quantum yield under direct photolysis for pydiflumetofen was 0.0105.

**Conclusion**

The study was considered by HSE to be acceptable. The results can be accepted for risk assessment.

Photolysis of pydiflumetofen was more rapid in natural water than in pH 7 buffer with half-life ($DegT_{50}$) values of 35 and 93 days, respectively (UK/US summer days equivalent). Degradation in the dark controls was insignificant.

Pydiflumetofen was primarily photodegraded by dechlorination and phenyl ring degradation to produce phenyl-hydroxylated metabolites, carboxylic acid metabolites and carbon dioxide. Photolysis in natural water led to the formation of SYN548261 at >5% AR at two consecutive sampling intervals (maximum level of 7.3% AR, mean of two replicates) and NOA449410 a maximum level of 5.4% AR (mean of two replicates) by the end of the experimental period. Metabolite SYN548262 in pH7 buffer occurred at up to 5.6% AR (mean of two replicates) at a single sample time of 21 days, but reduced to 2.2% AR at 30 days. Therefore this metabolite is not considered to trigger risk assessment.

In the study, pydiflumetofen was applied to the test system with acetonitrile as a co-solvent; the concentration of acetonitrile was stated to be less than 1%. The addition of acetonitrile was to increase the solubility of the test item. OECD 316 indicates that a co-solvent can be applied with the test substance with the co-solvent having a concentration normally not exceeding 1% v/v. In addition the co-solvent should not be a photosensitiser and acetonitrile is mentioned in OECD 316 as being a generally recommended co-solvent. Thus the use of acetonitrile within this study is acceptable.

There was little apparent change in the isomer ratio during the 30 day study duration which suggested no inherent tendency towards change in isomer ratio. As for other Environmental Fate and Behaviour studies, the EFSA Stereoisomers guidance has also been taken into consideration by HSE. The guidance indicates that changes might be expected where the substance containing enantiomers is exposed to an 'asymmetric environment'. According to the guidance, studies such as sterile hydrolysis and sterile aqueous photolysis studies do not present asymmetric environments. However the guidance also indicates that an enantiomer-specific method of analysis should still be used because some chemical reactions can induce racemisation of pure enantiomers. In this case, the aqueous photolysis study used sterile pure and sterile natural waters. Thus the study does not pose an asymmetric environment. Nevertheless, there did appear to be small changes in enantiomer excess in both buffer and natural water systems. Extrapolated out to the point where 50% degradation would have occurred, there would be expected to be less than 10% change in enantiomer excess. HSE does not consider that the small changes in enantiomer excess were likely to be caused by chemical reactions but were probably related to experimental variation.

The results indicated that light irradiation in sterile pure water at pH7 initiated some photodegradation although this was relatively slow with approximately 70-80% AR remaining as unchanged a.s. after 30 days continuous irradiation. There was no apparent degradation in the dark controls confirming the hydrolytic stability of pydiflumetofen. Metabolite formation in irradiated sterile pure water was low with only up to mean 2.6% formation of any individual metabolite.

Irradiation in sterile natural water indicated that there was enhanced photodegradation. This might be expected where the presence of other constituents or contaminants could act as photosensitisers. Such effects have been seen for other substances in regulatory studies. The incubation with phenyl-labelled pydiflumetofen experienced problems with poor recovery of radioactivity in some duplicate samples, but overall it appeared that decline after 30 days continuous irradiation was greater than in sterile water with approximately 50-60% AR remaining as unchanged a.s. Metabolite formation remained relatively low with metabolite SYN548261 reaching mean maximum of 7.3% AR after 21 days and NOA 449410 reaching mean maximum 5.4% AR at 30 days, i.e. study end.

It should be noted that the aqueous photolysis study was conducted with photolysis vessels of 28mm diameter, thus the light pathway was very short and will tend to lead to optimising potential for any photolytic effects. This will not necessarily be the case in natural water bodies in the environment. Whilst natural water was used, this was filtered prior to dosing which would have reduced the amount of suspended particles. In the natural environment, particularly that associated with agriculture, water bodies are often turbid and significant light penetration is often limited to a very shallow depth. The water sediment study described in section B.8.2.2.1 also indicates that there was significant partitioning from the water phase into sediment over a relatively short period of time. For many shallow water bodies associated with agriculture such partitioning will tend to further reduce the importance of aqueous photolysis as a route of degradation for pydiflumetofen. Thus it is likely that the effect of photolysis on pydiflumetofen in natural water bodies in the agricultural environment will be less than seen in this study.

## B.8.2.2. Route and rate of biological degradation in aquatic systems

### B.8.2.2.1. Ready biodegradability

| | |
|---|---|
| **Report:** | K-CA 7.2.2.1/01. [redacted], (2015) SYN545974 - Ready Biodegradability in a Manometric Respirometry Test. Report Number SYN-029/5-09. Fraunhofer Institute for Molecular Biology and Applied Ecology (IME). Auf dem Aberg 157392 Schmallenberg, Germany. (Syngenta File No. SYN545974_10145) |

| | |
|---|---|
| **Guideline(s):** | OECD 301F (1992); EPA Guideline Series OPPTS 835.3110 (1998) |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**

The ready biodegradability of pydiflumetofen was determined by observing the BOD (biochemical oxygen demand) using manometric methods over 28 days.

| | |
|---|---|
| **Test Material** | SYN545974 |
| **Lot/Batch #:** | AMS 1432/1 |
| **Purity** | 99.5 % |

Aerobic activated sludge from a waste water treatment plant treating predominantly domestic wastewater was used as the inoculum.

The test flasks were prepared as indicated in the following table. Due to the expected low water solubility of the test item, the required amount to ensure a final concentration of 44 mg/L (11 mg per 250 mL) was added directly on a weight basis via Teflon discs. Subsequently, the mineral medium was added to the vessels. The reference item sodium benzoate was added from a stock solution (positive control). Activated sludge was added to each flask and the flasks were made up to a volume of 250 mL with test water. The toxicity control contained both test material and the reference item sodium benzoate.

**Table B.8. 255 Preparation of the test solutions**

| **Identification** | **Replicate No** | **Amount of test item[1]** | | | **Amount of reference item[1]** | | |
|---|---|---|---|---|---|---|---|
| | | **mg/L** | **$ThOD_{NH3}$[2]** | **$ThOD_{NO3}$[3]** | **mg/L** | **$ThOD_{NH3}$[2]** | **$ThOD_{NO3}$[3]** |
| Test item | 1 | 44 | 53 | 73 | --- | na | na |
| Test item | 2 | 44 | 53 | 73 | --- | na | na |
| Inoculum control | 1 | --- | na | na | --- | na | na |
| Inoculum control | 2 | --- | na | na | --- | na | na |
| Procedure control | 1 | --- | na | na | 100 | 167 | 167 |
| Procedure control | 2 | --- | na | na | 100 | 167 | 167 |
| Toxicity control[4] | 1 | 44 | 53 | 73 | 100 | 167 | 167 |
| Toxicity control[4] | 2 | 44 | 53 | 73 | 100 | 167 | 167 |
| Abiotic control | 1 | 44 | 53 | 73 | --- | na | na |
| Abiotic control | 2 | 44 | 53 | 73 | --- | na | na |

[1] The tabulated values represent rounded values obtained by calculation using the exact raw data.
[2] Theoretical oxygen demand in mg $O_2$/L test solution ($NH_3$: without nitrification)
[3] Theoretical oxygen demand in mg $O_2$/L test solution ($NO_3$: with nitrification)
[4] The test item can be assumed to be inhibitory if in the toxicity control less than 25% degradation (based on total ThOD) occurs within 14 days.
na: not applicable

The test flasks were continuously stirred and incubated in a manometric respirometer at 22°C in the dark for 28 days. Oxygen consumption was recorded continuously on a computer. The biodegradation process consumes the dissolved oxygen in the liquid and generates $CO_2$. The $CO_2$ is adsorbed by soda lime and the total pressure decreases in the airtight test flasks. The pressure drop results in closing an electrical circuit. The consumed oxygen is replaced by electrolytically generated oxygen from a copper sulphate solution.

**Findings**
The percentage biodegradation of test material and of the reference item sodium benzoate was calculated based on their biochemical oxygen demand (BOD) and theoretical oxygen demand (ThOD). Since the test item contains nitrogen, the % biodegradation was calculated based on the $ThOD_{NH4}$ (considering that nitrification is absent) and $ThOD_{NO3}$ (considering that nitrification is complete). No significant biological oxygen demand was observed and consequently the effects of nitrification did not need to be considered.

*Biodegradation in sludge exposed to the test item*
The biochemical oxygen demand (BOD) of the test item pydiflumetofen in the test media was in the range of the inoculum controls throughout the study period of 28 days. Consequently, pydiflumetofen was not biodegradable under the test conditions within 28 days.

*Biodegradation of the reference item in the procedure controls*
In the procedural controls, the reference item was degraded by an average of 81% by Exposure Day 14, thus confirming suitability of the activated sludge. At the end of the test (Day 28), the reference item was degraded by an average of 84%.

*Biodegradation in the toxicity control*
In the toxicity control containing both the test item pydiflumetofen and the reference item the course of oxygen consumption over the 28 day exposure period was similar to the two procedure controls, containing only the reference item. Within 14 days of exposure, biodegradation amounted to 58% based on the $ThOD_{NO3}$ and to 64% based on the $ThOD_{NH3}$.

Thus, according to the test guidelines, the test item had no inhibitory effect on activated sludge microorganisms at the tested concentration of 44 mg/L because biodegradation in the toxicity control was >25% within 14 days.

**Table B.8. 256 Biodegradation of pydiflumetofen and the reference item in a manometric respirometry test over 28 days**

| **Time** days | **Percentage Biodegradation[1]** | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Test item based on** | | | | **Abiotic control based on** | | | | **Procedure control based on** | | | | **Toxicity control based on** | | | |
| | **$ThOD_{NH4}$** | | **$ThOD_{NO3}$** | | **$ThOD_{NH4}$** | | **$ThOD_{NO3}$** | | **$ThOD_{NH4}$** | | **$ThOD_{NO3}$** | | **$ThOD_{NH4}$** | | **$ThOD_{NO3}$** | |
| | **Flask No.** | | **Flask No.** | | **Flask No** | | **Flask No.** | | **Flask No.** | | **Flask No.** | | **Flask No.** | | **Flask No.** | |
| | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** |
| 0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0 | 0 | 0 | 0 |
| 1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 18.0 | 25.2 | 18.0 | 25.2 | 15.0 | 20.5 | 13.8 | 18.8 |
| 2 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 36.6 | 40.8 | 36.6 | 40.8 | 33.3 | 33.3 | 30.5 | 30.5 |
| 3 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 45.6 | 50.4 | 45.6 | 50.4 | 41.0 | 40.6 | 37.6 | 37.2 |
| 4 | 1.9 | 1.9 | 1.4 | 1.4 | 0.0 | 0.0 | 0.0 | 0.0 | 52.2 | 69.7 | 52.2 | 69.7 | 47.0 | 46.5 | 43.1 | 42.7 |
| 5 | 1.9 | 1.9 | 1.4 | 1.4 | 1.9 | 0.0 | 1.4 | 0.0 | 59.4 | 75.7 | 59.4 | 75.7 | 51.5 | 51.5 | 47.3 | 47.3 |
| 6 | 2.8 | 2.8 | 2.1 | 2.1 | 3.8 | 0.0 | 2.8 | 0.0 | 65.1 | 79.0 | 65.1 | 79.0 | 54.5 | 54.9 | 50.0 | 50.4 |
| 7 | 1.9 | 1.9 | 1.4 | 1.4 | 3.8 | 0.0 | 2.8 | 0.0 | 68.5 | 81.1 | 68.5 | 81.1 | 57.0 | 57.0 | 52.3 | 52.3 |
| 8 | 2.8 | 0.9 | 2.1 | 0.7 | 3.8 | 0.0 | 2.8 | 0.0 | 70.6 | 82.0 | 70.6 | 82.0 | 58.1 | 58.6 | 53.3 | 53.7 |
| 9 | 2.8 | 0.9 | 2.1 | 0.7 | 3.8 | 0.0 | 2.8 | 0.0 | 71.8 | 83.2 | 71.8 | 83.2 | 60.0 | 60.4 | 55.0 | 55.4 |
| 10 | 2.8 | 0.9 | 2.1 | 0.7 | 5.7 | 0.0 | 4.1 | 0.0 | 73.0 | 84.4 | 73.0 | 84.4 | 60.9 | 61.3 | 55.8 | 56.2 |
| 11 | 4.7 | 2.8 | 3.4 | 2.1 | 5.7 | 0.0 | 4.1 | 0.0 | 73.6 | 85.0 | 73.6 | 85.0 | 61.8 | 62.2 | 56.7 | 57.1 |
| 12 | 2.8 | 0.9 | 2.1 | 0.7 | 7.6 | 0.0 | 5.5 | 0.0 | 74.2 | 85.0 | 74.2 | 85.0 | 61.8 | 62.7 | 56.7 | 57.5 |
| 13 | 2.8 | 0.9 | 2.1 | 0.7 | 7.6 | 0.0 | 5.5 | 0.0 | 75.4 | 85.6 | 75.4 | 85.6 | 62.7 | 63.1 | 57.5 | 57.9 |
| 14 | 4.7 | 0.9 | 3.4 | 0.7 | 7.6 | 0.0 | 5.5 | 0.0 | 76.0 | 86.2 | 76.0 | 86.2 | 63.1 | 64.1 | 57.9 | 58.8 |
| 15 | 3.8 | 0.0 | 2.8 | 0.0 | 11.4 | 0.0 | 8.3 | 0.0 | 76.9 | 86.5 | 76.9 | 86.5 | 63.4 | 64.3 | 58.1 | 59.0 |
| 16 | 2.8 | 0.9 | 2.1 | 0.7 | 11.4 | 0.0 | 8.3 | 0.0 | 77.2 | 86.8 | 77.2 | 86.8 | 63.6 | 64.5 | 58.3 | 59.2 |
| 17 | 4.7 | 0.9 | 3.4 | 0.7 | 11. | 0.0 | 8.3 | 0.0 | 77. | 86. | 77. | 86. | 64. | 65. | 58. | 59.6 |

| **Time** days | **Percentage Biodegradation**[1] | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Test item based on** | | | | **Abiotic control based on** | | | | **Procedure control based on** | | | | **Toxicity control based on** | | | |
| | **$ThOD_{NH4}$** | | **$ThOD_{NO3}$** | | **$ThOD_{NH4}$** | | **$ThOD_{NO3}$** | | **$ThOD_{NH4}$** | | **$ThOD_{NO3}$** | | **$ThOD_{NH4}$** | | **$ThOD_{NO3}$** | |
| | **Flask No.** | | **Flask No.** | | **Flask No** | | **Flask No.** | | **Flask No.** | | **Flask No.** | | **Flask No.** | | **Flask No.** | |
| | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** | **1** | **2** |
| | | | | | 4 | | | | 2 | 8 | 2 | 8 | 1 | 0 | 8 | |
| 18 | 4.7 | 0.9 | 3.4 | 0.7 | 11.4 | 0.0 | 8.3 | 0.0 | 77.2 | 87.4 | 77.2 | 87.4 | 64.1 | 65.0 | 58.8 | 59.6 |
| 19 | 3.8 | 0.0 | 2.8 | 0.0 | 11.4 | 0.0 | 8.3 | 0.0 | 76.9 | 87.7 | 76.9 | 87.7 | 64.3 | 65.2 | 59.0 | 59.8 |
| 20 | 2.8 | -0.9 | 2.1 | -0.7 | 11.4 | 0.0 | 8.3 | 0.0 | 76.6 | 87.4 | 76.6 | 87.4 | 64.5 | 65.4 | 59.2 | 60.0 |
| 21 | 2.8 | -0.9 | 2.1 | -0.7 | 11.4 | 0.0 | 8.3 | 0.0 | 77.2 | 88.0 | 77.2 | 88.0 | 64.5 | 65.9 | 59.2 | 60.4 |
| 22 | 2.8 | -0.9 | 2.1 | -0.7 | 13.3 | 0.0 | 9.6 | 0.0 | 77.2 | 88.6 | 77.2 | 88.6 | 65.0 | 66.3 | 59.6 | 60.8 |
| 23 | 4.7 | -0.9 | 3.4 | -0.7 | 13.3 | 0.0 | 9.6 | 0.0 | 77.2 | 88.6 | 77.2 | 88.6 | 65.4 | 66.3 | 60.0 | 60.8 |
| 24 | 3.8 | -1.9 | 2.8 | -1.4 | 13.3 | 0.0 | 9.6 | 0.0 | 76.9 | 88.9 | 76.9 | 88.9 | 65.2 | 66.6 | 59.8 | 61.1 |
| 25 | 2.8 | -2.8 | 2.1 | -2.1 | 13.3 | 0.0 | 9.6 | 0.0 | 77.2 | 89.2 | 77.2 | 89.2 | 65.4 | 67.2 | 60.0 | 61.7 |
| 26 | 2.8 | -0.9 | 2.1 | -0.7 | 15.2 | 0.0 | 11.0 | 0.0 | 77.2 | 89.2 | 77.2 | 89.2 | 65.9 | 68.2 | 60.4 | 62.5 |
| 27 | 2.8 | -0.9 | 2.1 | -0.7 | 15.2 | 0.0 | 11.0 | 0.0 | 77.2 | 89.8 | 77.2 | 89.8 | 65.9 | 68.2 | 60.4 | 62.5 |
| 28 | 4.7 | -0.9 | 3.4 | -0.7 | 15.2 | 0.0 | 11.0 | 0.0 | 77.2 | 89.8 | 77.2 | 89.8 | 66.3 | 68.6 | 60.8 | 62.9 |

1 Single values of the parallel test vessels.

**Conclusion**
Pydiflumetofen was found not to be biodegradable under the conditions of the test within 28 days. Consequently pydiflumetofen is classified as 'not readily biodegradable'.

### B.8.2.2.2. Aerobic mineralisation in surface water

| | |
|---|---|
| **Report:** | K-CA 7.2.2.2/01. [redacted], (2015b), SYN545974 – Aerobic mineralisation of $^{14}$C-SYN545974 in surface water, Report Number 3200503. Smithers Viscient (ESG) 108 Woodfield Drive, Harrogate, North Yorkshire, HG1 4LG, UK (Syngenta File No. SYN545974_50210). |

| | |
|---|---|
| **Guideline(s):** | OECD 309 (2004) |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**
The extent of mineralisation and the rate and route of degradation of [$^{14}$C]-phenyl ring labelled pydiflumetofen and [$^{14}$C]-pyrazole ring labelled pydiflumetofen was investigated in natural water.

| **Test Material:** | **[Pyrazole-5-$^{14}$C]-SYN545974** | **[Phenyl-U-$^{14}$C]-SYN545974** |
|---|---|---|
| Lot/Batch #: | 5271GAR001-4 | RDR-XX-31 |
| Specific activity: | 5.06 MBq/mg | 6.072 MBq/mg |
| Application vehicle | Acetonitrile | Acetonitrile |
| Purity: | 95.4% (chemical)<br>99.2% (radiochemical) | 97.1% (chemical)<br>97.4% (radiochemical) |

The study was conducted using Fountains Abbey natural water and suspended sediment (0.02 g/L). The water and sediment were sampled at The Lake, Studley Royal, Fountains Abbey, Ripon, UK. The water was scooped from the lake into a clear plastic container. The sediment was collected using a net from the top 5 cm. After receipt, the water and sediment were stored together in plastic containers routinely maintained at 4 ± 2°C in the dark, with free access to air. Prior to use, the water was sieved using a 100 µm sieve and the sediment was sieved using a 2 mm sieve. The key characteristics of the water and sediment are summarized in the following table.

**Table B.8. 257 Sediment and water characteristics**

| | **Dark incubation*** | **Light/dark incubation*** |
|---|---|---|
| **Physical and chemical properties of sediment** | | |
| Particle size (% w/w): | | |
| Clay (<2 µm) | 11 | 15 |
| Silt (50-2 µm) | 27 | 36 |
| Sand (2000-50 µm) | 62 | 49 |
| Texture (USDA) | Sandy loam | Loam |
| pH | | |
| Deionised water | 7.7 | 7.2 |
| 0.01M $CaCl_2$ | 7.1 | 6.8 |
| Organic Matter (%) | 7.6 | 2.4 |
| Organic carbon (%) | 4.4 | 1.4 |
| **Physical and chemical properties of water** | | |
| Temperature at collection (°C) | 15.8 | 20.3°C |
| pH at collection | 7.9 | 8.54 |
| Oxygen concentration at collection (%) | 8.79 | 10.91 |
| pH | | |
| Start of study | 8.00 | 8.19 |
| End of study | 8.45 | 7.87 |
| Oxygen concentration (mg/L) | | |
| Start of study | 9.55 | 9.17 |
| End of study | 9.35 | 8.27 |
| Total organic carbon (ppm) | 9.95 | 9.33 |
| Suspended solids (mg/L) | 1.56 | 1.97 |
| Nitrogen (total, mg/L) | 0 | 0.0004 |
| Nitrate (mg/L) | 1.1 | 1.8 |
| Ammonium (mg/L) | 0.697 | 0.149 |
| Phosphorous (total, mg/L) | 0.19 | 1.46 |
| Dissolved Orthophosphate (total, mg/L) | 0.17 | 1.28 |

* water and sediment were collected on 03 June 2014 for use in the dark incubations and on 31 July 2014 for use in the light/dark incubations

For each radiolabel, [$^{14}$C-pydiflumetofen] was applied in acetonitrile to the water at nominal rates of 10 and 95 µg/L (low and high, respectively). The acetonitrile concentration was 0.014 - 0.145%. This is less than the OECD 309 maximum recommended concentration of 1% v/v and is therefore acceptable. The 95 µg/L rate was also applied to a single sterilised test system per radiolabel. The systems were incubated under aerobic conditions and maintained in dark conditions at 20 ± 2°C for up to 58 days. For each non-sterile test concentration, duplicate samples were taken for analysis at up to seven intervals. The sterile units were sampled at the final interval.

In addition to the units maintained under dark incubation conditions, [$^{14}$C-pydiflumetofen] (with both radiolabels) was also applied (same methods and concentrations as previously described) to vessels incubated

under diffuse light/dark conditions (16 hours light followed by 8 hours dark, mean range of intensity of 9.28 to 10.26 W/m$^2$, overall mean of 9.86 W/m$^2$) at 20 ± 2°C for up to 60 days.

At each sampling time (0, 7, 14, 30/32, 44/45, 58/60 days), acetonitrile (50 mL) was added to the incubation unit and the contents transferred to a separate vessel prior to analysis by liquid scintillation counting (LSC). The water and sediment were separated by centrifugation and the water analysed, by reverse phase high performance liquid chromatography (HPLC), with gradient elution. The suspended sediment did not require analysis. The test vessels and magnetic stirrer bar were rinsed with acetonitrile : water adjusted to pH 3 (80:20 v/v, *ca* 100 mL) and the quantity of radioactivity in the organic wash was determined by LSC. Any volatile radioactivity was continuously flushed from the vessels, collected in traps (2M NaOH) and quantified by LSC. A mass balance was determined for each sample. TLC and LC/MS were used on selected samples to confirm the presence of pydiflumetofen.

Separate reference samples (treated with $^{14}$C-sodium benzoate at 10 µg/L) of natural water were prepared to determine whether a viable microbial population was present in the test system under both incubation conditions (dark and light/dark). Separate blank control samples were similarly incubated to allow water quality measurements at each sampling interval.

Enantiomer ratios in dark and irradiated samples were assessed by comparison chromatography from application solutions (prepared with phenyl or pyrazole labelled pydiflumetofen) used to treat the samples with samples removed at 58 or 45 DAT.

The half-lives (DegT$_{50}$) of $^{14}$C-pydiflumetofen (from the HPLC analysis) were determined using CAKE software (version 2) by fitting single-first-order kinetics (SFO) to the data. True replicates were included individually in the optimisations. Initial pydiflumetofen levels in the model input data were set to the recovery measured in the surface water fraction in the time zero samples. For optimal goodness of fit, the initial value was also allowed to be estimated by the model.

**Findings**
The total recoveries from each system are shown below.

The mean overall mass balance values for the low and high test concentration dark incubation samples were 96.8 to 97.1% AR (low concentration) and 96.4 to 97.5% AR (high concentration). The mass balance values for the sterilised, dark incubation groups were 94.7% AR (phenyl label) and 98.9% AR (pyrazole label).

The mean mass balance values for the low and high test concentration light/dark incubation samples were 99.2 to 99.5% AR (low concentration) and 99.3 to 99.5% AR (high concentration). The mass balance values for the sterilised, light/dark incubation groups were 97.3% AR (phenyl label) and 100.3% AR (pyrazole label).

Reference samples treated with [$^{14}$C]-sodium benzoate achieved mean mineralisation of 93.5% applied radioactivity (AR) by 44 DAT (dark incubation) and 87.8% AR by 60 DAT (light/dark incubation), indicating that the test systems remained viable throughout the study.

**Table B.8. 258 Distribution and Recovery of Radioactivity: Natural Water Plus 0.02 g/L Suspended Sediment - [Phenyl-$^{14}$C]-pydiflumetofen – Dark Incubation**

| Fraction | Rep. | Incubation time (days) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Low dose (10 µg/L) | | | | | | High dose (95 µg/L) | | | | | |
| | | **0** | **7** | **14** | **30** | **44** | **58** | **0** | **7** | **14** | **30** | **44** | **58** |
| Surface water | A | 96.9 | 95.9 | 91.9 | 97.0 | 98.7 | 93.7 | 99.1 | 97.7 | 96.1 | 95.6 | 95.3 | 94.1 |
| | B | 98.2 | 96.7 | 92.3 | 77.3[a] | 97.6 | 96.7 | 100.3 | 96.3 | 97.5 | 94.4 | 96.0 | 79.9[a] |
| | Mean | **97.6** | **96.3** | **92.1** | **97.0** | **98.2** | **95.2** | **99.7** | **97.0** | **96.8** | **95.0** | **95.7** | **94.1** |
| Organic wash | A | ND | 0.5 | 1.0 | 2.2 | 1.6 | 1.3 | 0.1 | 0.8 | 1.0 | 2.0 | 1.2 | 1.1 |
| | B | ND | 0.5 | 0.7 | 2.5 | 1.1 | 1.2 | 0.1 | 0.7 | 1.1 | 2.1 | 1.0 | 0.6 |
| | Mean | **ND** | **0.5** | **0.9** | **2.2** | **1.4** | **1.3** | **0.1** | **0.8** | **1.1** | **2.1** | **1.1** | **1.1** |
| Total Volatiles | A | NA | ND | ND | ND | 0.1 | ND | NA | ND | 0.1 | 0.1 | 0.1 | 0.1 |
| | B | NA | ND | ND | ND | 0.3 | 0.2 | NA | ND | 0.1 | 0.1 | 0.1 | 0.1 |
| | Mean | **NA** | **ND** | **ND** | **ND** | **0.2** | **0.1** | **NA** | **ND** | **0.1** | **0.1** | **0.1** | **0.1** |
| **TOTAL** | **A** | 96.9 | 96.4 | 92.9 | 99.2 | 100.4 | 95.0 | 99.2 | 98.5 | 97.2 | 97.7 | 96.6 | 95.3 |
| | **B** | 98.2 | 97.2 | 93.0 | 79.8[a] | 99.0 | 98.1 | 100.4 | 97.0 | 98.7 | 96.6 | 97.1 | 80.6[a] |
| | **Mean** | **97.6** | **96.8** | **93.0** | **99.2[b]** | **99.7** | **96.6** | **99.8** | **97.8** | **98.0** | **97.2** | **96.9** | **95.3[b]** |
| **Mean ± SD** | | **97.1 ± 2.4%** | | | | | | **97.5 ± 1.5%** | | | | | |

[a] low mass balance was attributed to a mis-dose. The data was not used in subsequent calculations.
[b] Based on replicate A only.
NA: Not Applicable ND: not detected or <0.1% AR

**Table B.8. 259 Distribution and Recovery of Radioactivity: Natural Water Plus 0.02 g/L Suspended Sediment - [Pyrazole-$^{14}$C]-pydiflumetofen – Dark Incubation**

| Fraction | Rep. | Incubation time (days) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Low dose (10 µg/L) | | | | | | High dose (95 µg/L) | | | | | |
| | | **0** | **7** | **14** | **30** | **44** | **58** | **0** | **7** | **14** | **30** | **44** | **58** |
| Surface water | A | 99.5 | 91.8 | 98.0 | 98.6 | 94.9 | 91.8 | 99.0 | 94.4 | 91.9 | 95.3 | 93.9 | 94.5 |
| | B | 99.3 | 96.1 | 94.7 | 95.4 | 94.4 | 94.4 | 99.5 | 96.6 | 96.1 | 94.6 | 87.8 | 98.9 |
| | Mean | **99.4** | **94.0** | **96.4** | **97.0** | **94.7** | **93.1** | **99.3** | **95.5** | **94.0** | **95.0** | **90.9** | **96.7** |
| Organic wash | A | ND | 1.0 | 1.0 | 1.7 | 1.5 | 1.2 | 0.1 | 0.8 | 1.4 | 2.0 | 1.0 | 2.3 |
| | B | ND | 0.9 | 0.9 | 2.4 | 1.2 | 1.1 | ND | 0.8 | 1.2 | 2.2 | 0.9 | 1.1 |
| | Mean | **ND** | **1.0** | **1.0** | **2.1** | **1.4** | **1.2** | **0.1** | **0.8** | **1.3** | **2.1** | **1.0** | **1.7** |
| Total Volatiles | A | NA | ND | ND | ND | ND | ND | NA | ND | ND | ND | ND | ND |
| | B | NA | ND | ND | ND | ND | ND | NA | ND | ND | ND | ND | 0.1 |
| | Mean | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **NA** | **ND** | **ND** | **ND** | **ND** | **0.1** |
| **TOTAL** | **A** | 99.5 | 92.8 | 99.0 | 100.3 | 96.4 | 93.0 | 99.1 | 95.2 | 93.3 | 97.3 | 94.9 | 96.8 |
| | **B** | 99.3 | 97.0 | 95.6 | 97.8 | 95.6 | 95.5 | 99.5 | 97.4 | 97.3 | 96.8 | 88.7 | 100.1 |
| | **Mean** | **99.4** | **94.9** | **97.3** | **99.1** | **96.0** | **94.3** | **99.3** | **96.3** | **95.3** | **97.1** | **91.8** | **98.5** |
| **Mean ± SD** | | **96.8 ± 2.1%** | | | | | | **96.4 ± 2.7%** | | | | | |

NA: Not Applicable ND: not detected or <0.1% AR

**Table B.8. 260 Distribution and Recovery of Radioactivity: Natural Water Plus 0.02 g/L Suspended Sediment - [Phenyl-$^{14}$C]-pydiflumetofen – Light/Dark Incubation**

| Fraction | Rep. | Incubation time (days) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Low dose (10 µg/L) | | | | | | High dose (95 µg/L) | | | | | |
| | | **0** | **7** | **14** | **32** | **45** | **60** | **0** | **7** | **14** | **32** | **45** | **58** |
| Surface water | A | 101.0 | 92.1 | 102.1 | 100.5 | 96.0 | 96.8 | 99.7 | 99.1 | 99.2 | 97.6 | 98.0 | 98.1 |
| | B | 101.0 | 99.7 | 98.0 | 99.6 | 96.2 | 92.4 | 97.0 | 99.8 | 98.0 | 98.4 | 99.1 | 98.1 |
| | Mean | **101.0** | **95.9** | **100.1** | **100.1** | **96.1** | **94.6** | **98.4** | **99.5** | **98.6** | **98.0** | **98.6** | **98.1** |
| Organic wash | A | 0.7 | 0.9 | 0.8 | 0.9 | 0.7 | 1.5 | 0.6 | 0.8 | 0.7 | 1.0 | 0.7 | 0.8 |
| | B | 0.7 | 0.7 | 0.7 | 0.8 | 0.7 | 2.8 | 0.6 | 0.7 | 0.7 | 1.2 | 0.8 | 1.2 |
| | Mean | **0.7** | **0.8** | **0.8** | **0.9** | **0.7** | **2.2** | **0.6** | **0.8** | **0.7** | **1.1** | **0.8** | **1.0** |
| Total Volatiles | A | NA | ND | ND | 0.3 | 0.6 | 0.7 | NA | ND | 0.1 | 0.1 | 0.2 | 0.6 |
| | B | NA | ND | 0.3 | 0.3 | 0.4 | 0.8 | NA | ND | 0.1 | 0.1 | 0.3 | 0.4 |
| | Mean | **NA** | **ND** | **0.2** | **0.3** | **0.5** | **0.8** | **NA** | **ND** | **0.1** | **0.1** | **0.3** | **0.5** |
| **TOTAL** | **A** | 101.7 | 93.0 | 102.9 | 101.7 | 97.3 | 99.0 | 100.3 | 99.9 | 100.0 | 98.7 | 98.9 | 99.5 |
| | **B** | 101.7 | 100.4 | 99.0 | 100.7 | 97.3 | 96.0 | 97.6 | 100.5 | 98.8 | 99.7 | 100.2 | 99.7 |
| | **Mean** | **101.7** | **96.7** | **101.0** | **101.2** | **97.3** | **97.5** | **99.0** | **100.2** | **99.4** | **99.2** | **99.6** | **99.6** |
| **Mean ± SD** | | **99.2 ± 2.3%** | | | | | | **99.5 ± 0.4%** | | | | | |

NA: Not Applicable ND: not detected or <0.1% AR

**Table B.8. 261 Distribution and Recovery of Radioactivity: Natural Water Plus 0.02 g/L Suspended Sediment - [Pyrazole-$^{14}$C]-pydiflumetofen – Light/Dark Incubation**

| Fraction | Rep. | Incubation time (days) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Low dose (10 µg/L) | | | | | | High dose (95 µg/L) | | | | | |
| | | **0** | **7** | **14** | **32** | **45** | **60** | **0** | **7** | **14** | **32** | **45** | **58** |
| Surface water | A | 98.3 | 99.2 | 97.5 | 98.4 | 97.7 | 98.3 | 99.6 | 100.0 | 99.9 | 99.0 | 98.1 | 98.0 |
| | B | 103.1 | 98.0 | 95.8 | 96.9 | 100.6 | 98.2 | 99.5 | 100.0 | 95.2 | 97.4 | 97.0 | 96.2 |
| | Mean | **100.7** | **98.6** | **96.7** | **97.7** | **99.2** | **98.3** | **99.6** | **100.0** | **97.6** | **98.2** | **97.6** | **97.1** |
| Organic wash | A | 0.8 | 0.7 | 0.9 | 1.2 | 1.8 | 1.1 | 0.6 | 0.6 | 0.8 | 1.2 | 0.7 | 1.1 |
| | B | 0.6 | 0.8 | 0.8 | 1.1 | 1.2 | 1.2 | 0.6 | 0.8 | 1.2 | 1.1 | 0.8 | 1.2 |
| | Mean | **0.7** | **0.8** | **0.9** | **1.2** | **1.5** | **1.2** | **0.6** | **0.7** | **1.0** | **1.2** | **0.8** | **1.2** |
| Total Volatiles | A | NA | ND | ND | ND | ND | ND | NA | ND | ND | 0.1 | 0.1 | ND |
| | B | NA | ND | ND | 0.2 | 0.1 | ND | NA | ND | ND | 0.1 | ND | 0.1 |
| | Mean | **NA** | **ND** | **ND** | **0.1** | **0.1** | **ND** | **NA** | **ND** | **ND** | **0.1** | **0.1** | **0.1** |
| **TOTAL** | **A** | 99.1 | 99.9 | 98.4 | 99.6 | 99.5 | 99.4 | 100.2 | 100.6 | 100.7 | 100.3 | 98.9 | 99.1 |
| | **B** | 103.7 | 98.8 | 96.6 | 98.2 | 101.9 | 99.4 | 100.1 | 100.8 | 96.4 | 98.6 | 97.8 | 97.5 |
| | **Mean** | **101.4** | **99.4** | **97.5** | **98.9** | **100.7** | **99.4** | **100.2** | **100.7** | **98.6** | **99.5** | **98.4** | **98.3** |
| **Mean ± SD** | | **99.5 ± 1.4%** | | | | | | **99.3 ± 1.0%** | | | | | |

NA: Not Applicable ND: not detected or <0.1% AR

**Table B.8. 262 Distribution and Recovery of Radioactivity: Sterilised Natural Water Plus 0.02 g/L Suspended Sediment**

| Fraction | Rep. | Dark incubation, high dose (95 µg/L) – 58 days | | Light/Dark incubation, high dose (95 µg/L) 60 days | |
|---|---|---|---|---|---|
| | | **Phenyl** | **Pyrazole** | **Phenyl** | **Pyrazole** |
| Surface water | A | 93.5 | 97.7 | 98.3 | 98.3 |
| | B | 64.1[a] | 97.9 | 93.3 | 99.8 |
| | Mean | **93.5** | **97.8** | **95.8** | **99.1** |
| Organic wash | A | 1.2 | 1.1 | 1.1 | 1.3 |
| | B | 1.1 | 1.1 | 1.3 | 1.2 |
| | Mean | **1.2** | **1.1** | **1.2** | **1.3** |
| Total volatiles | A | ND | ND | 0.3 | ND |
| | B | ND | ND | 0.2 | ND |
| | Mean | **ND** | **ND** | **0.2** | **ND** |
| **TOTAL** | **A** | 94.7 | 98.8 | 99.7 | 99.6 |
| | **B** | 65.2[a] | 99.0 | 94.8 | 101.0 |
| | **Mean** | **94.7**[b] | **98.9** | **97.3** | **100.3** |

[a] low mass balance was attributed to a mis-dose. The data was not used in subsequent calculations.
[b] Based on replicate A only.
NA: Not Applicable ND: not detected or <0.1% AR

**Table B.8. 263 Distribution and Recovery of Radioactivity: Natural Water plus 0.02 g/L Suspended Sediment Sodium - $^{14}$C-Benzoate Treated (10 µg/L) Reference Samples**

| Fraction | Rep. | Dark incubation[a] | | | | | Light/Dark incubation | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Incubation time (days) | | | | | Incubation time (days) | | | | |
| | | **3** | **7** | **14** | **30** | **44** | **3** | **7** | **14** | **32** | **60** |
| $^{14}CO_2$ | A | 107.1 | 154.6 | 162.8 | 166.9 | 167.8 | 56.9 | 80.9 | 86.2 | 90.5 | 92.3 |
| | B | 8.5 | 11.3 | 15.7 | 17.9 | 18.6 | 29.1 | 67.4 | 75.3 | 79.5 | 83.2 |
| | **Mean** | **58.0** | **83.2** | **89.6** | **92.7** | **93.5** | **43.0** | **74.2** | **80.8** | **85.0** | **87.8** |

[a] Replicate A was assumed to have received a portion of application solution that ought to have been added to replicate B unit. The average of the 2 units gave data which was in keeping with expected values.

Characterization of radioactivity from each system is shown below.

***Dark incubations***
Mean levels of pydiflumetofen indicated some degradation had occurred during the incubation period, ranging from 94.8 to 97.8% AR at 0 DAT to 90.9 to 94.1% AR by 58 DAT. The known metabolite SYN545547 was observed, but this was seen at a mean level of < 3% AR. Unknown metabolites were observed but at levels of < 3% in total.

For the sterilised samples (high concentration), the mean level of parent compound was 92.7% AR (phenyl treated) and 96.2% AR (pyrazole treated) at 58 DAT.

***Light/dark cycle incubations***

Mean levels of pydiflumetofen indicated some degradation had occurred during the incubation period and to a greater extent than that observed in the dark incubations. Levels at 0 DAT were in the range of 97.2 to 100.7% AR, whilst at 60 DAT, these mean levels had declined to between 86.7 and 94.0% AR. The known metabolite SYN545547 was observed at levels of up to 7.3% AR, with the highest levels observed at 60 DAT. Unknown metabolites were observed but at levels of < 4% in total.

For the sterilised samples (high concentration), the mean level of parent compound was 94.8% AR (phenyl treated) and 98.8% AR (pyrazole treated) at 60 DAT.

**Table B.8. 264 Characterisation of Radioactive Residues in Natural Water plus 0.02 g/L Suspended Sediment - [Phenyl-$^{14}$C]-pydiflumetofen – Dark Incubation**

| [Phenyl-$^{14}$C]-pydiflumetofen | Rep | Sampling times (DAT) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Low dose (10 µg/L) | | | | | | High dose (95 µg/L) | | | | | |
| | | **0** | **7** | **14** | **30[a]** | **44** | **58** | **0** | **7** | **14** | **30** | **44** | **58[a]** |
| **Parent compound** | A | 96.0 | 95.6 | 91.3 | 96.2 | 97.6 | 92.4 | 97.2 | 95.3 | 93.2 | 93.3 | 92.3 | 91.7 |
| | B | 97.5 | 94.9 | 90.8 | 76.1 | 95.9 | 95.9 | 98.4 | 94.0 | 95.2 | 92.1 | 93.6 | 74.2 |
| | **Mean** | **96.8** | **95.3** | **91.0** | **96.2** | **96.7** | **94.1** | **97.8** | **94.6** | **94.2** | **92.7** | **92.9** | **91.7** |
| **SYN545547** | A | ND | ND | ND | ND | ND | ND | 0.9 | 0.9 | 1.3 | 1.1 | 1.2 | 1.3 |
| | B | ND | ND | ND | ND | 1.0 | ND | 0.8 | 1.1 | 1.4 | 1.1 | 1.0 | 2.9 |
| | **Mean** | **ND** | **ND** | **ND** | **ND** | **0.5** | **ND** | **0.8** | **1.0** | **1.4** | **1.1** | **1.1** | **1.3** |
| **Unknown 1** | A | ND | ND | ND | ND | ND | ND | 0.3 | 0.3 | 0.7 | 0.5 | 0.6 | ND |
| | B | ND | ND | ND | ND | ND | 0.8 | 0.4 | 0.7 | ND | 0.6 | 0.6 | 2.0 |
| | **Mean** | **ND** | **ND** | **ND** | **ND** | **ND** | **0.4** | **0.4** | **0.5** | **0.3** | **0.5** | **0.6** | **ND** |
| **Unidentified product(s)** | A | ND | ND | ND | ND | ND | ND | ND | 0.3 | ND | ND | ND | ND |
| | B | ND | ND | ND | ND | ND | ND | ND | 0.2 | 0.3 | ND | ND | ND |
| | **Mean** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **0.3** | **0.2** | **ND** | **ND** | **ND** |
| **Unresolved background** | A | 0.9 | 0.3 | 0.6 | 0.8 | 1.1 | 1.3 | 0.8 | 1.0 | 0.9 | 0.7 | 1.3 | 1.1 |
| | B | 0.7 | 1.8 | 1.5 | **1.2** | 0.7 | 0.0 | 0.8 | 0.3 | 0.6 | 0.7 | 0.9 | 0.8 |
| | **Mean** | **0.8** | **1.0** | **1.1** | **0.8** | **0.9** | **0.7** | **0.8** | **0.7** | **0.8** | **0.7** | **1.1** | **1.1** |

[a] Low mass balance was obtained for replicate B, therefore lower values generated by chromatography. Although the % chromatogram for each region was comparable to replicate A, the data were not used in subsequent calculations.

NA: Not applicable ND: not detected or < 0.1% AR

**Table B.8. 265 Characterisation of Radioactive Residues: Natural Water plus 0.02 g/L Suspended Sediment - [Pyrazole-$^{14}$C]-pydiflumetofen – Dark Incubation**

| [Pyrazole-$^{14}$C]-pydiflumetofen | Rep | Sampling times (DAT) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Low dose (10 µg/L) | | | | | | High dose (95 µg/L) | | | | | |
| | | **0** | **7** | **14** | **30** | **44** | **58** | **0** | **7** | **14** | **30** | **44** | **58** |
| **Parent compound** | A | 97.9 | 91.2 | 92.9 | 97.2 | 93.6 | 88.0 | 94.1 | 89.1 | 86.4 | 90.9 | 89.1 | 89.5 |
| | B | 95.8 | 88.3 | 93.7 | 93.0 | 93.6 | 93.8 | 95.6 | 91.9 | 90.3 | 90.1 | 83.9 | 95.5 |
| | **Mean** | **96.8** | **89.8** | **93.3** | **95.1** | **93.6** | **90.9** | **94.8** | **90.5** | **88.3** | **90.5** | **86.5** | **92.5** |
| **SYN545547** | A | 1.0 | ND | 4.7 | ND | ND | 3.1 | 1.8 | 2.4 | 2.2 | 2.2 | 2.2 | 2.4 |
| | B | 2.6 | 3.7 | ND | 2.3 | ND | ND | 2.3 | 2.7 | 2.0 | 1.9 | 2.1 | 1.8 |
| | **Mean** | **1.8** | **1.8** | **2.3** | **1.1** | **ND** | **1.6** | **2.0** | **2.5** | **2.1** | **2.1** | **2.2** | **2.1** |
| **Unknown 1** | A | ND | ND | ND | ND | ND | ND | 1.9 | 1.7 | 1.6 | 1.7 | 1.7 | 1.3 |
| | B | ND | 3.4 | ND | ND | ND | ND | 1.6 | 1.5 | 2.1 | 1.7 | 1.6 | 1.5 |
| | **Mean** | **ND** | **1.7** | **ND** | **ND** | **ND** | **ND** | **1.7** | **1.6** | **1.8** | **1.7** | **1.7** | **1.4** |
| **Unidentified product(s)** | A | ND | ND | ND | ND | ND | ND | ND | ND | 0.4 | ND | ND | ND |
| | B | ND | ND | ND | ND | ND | ND | ND | 0.5 | 0.4 | ND | ND | ND |
| | **Mean** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **0.2** | **0.4** | **ND** | **ND** | **ND** |
| **Unresolved background** | A | 0.7 | 0.6 | 0.4 | 1.4 | 1.3 | 0.7 | 1.2 | 1.2 | 1.3 | 0.5 | 0.9 | 1.3 |
| | B | 0.9 | 0.7 | 1.0 | 0.2 | 0.8 | 0.6 | 0.1 | 0.1 | 1.5 | 0.9 | 0.2 | 0.2 |
| | **Mean** | **0.8** | **0.7** | **0.7** | **0.8** | **1.0** | **0.7** | **0.6** | **0.6** | **1.4** | **0.7** | **0.5** | **0.7** |

NA: Not applicable ND: not detected or < 0.1% AR

**Table B.8. 266 Characterisation of Radioactive Residues: Natural Water plus 0.02 g/L Suspended Sediment - [Phenyl-$^{14}$C]-pydiflumetofen – Light/Dark Incubation**

| [Phenyl-$^{14}$C]-pydiflumetofen | Rep | Sampling times (DAT) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Low dose (10 µg/L) | | | | | | High dose (95 µg/L) | | | | | |
| | | **0** | **7** | **14** | **32** | **45** | **60** | **0** | **7** | **14** | **32** | **45** | **60** |
| **Parent compound** | A | 100.8 | 91.9 | 101.0 | 98.4 | 94.4 | 87.2 | 99.6 | 97.0 | 96.5 | 95.8 | 95.9 | 94.1 |
| | B | 100.5 | 97.6 | 97.5 | 98.8 | 94.8 | 86.3 | 96.8 | 97.5 | 95.9 | 96.2 | 94.9 | 93.8 |
| | **Mean** | **100.7** | **94.8** | **99.2** | **98.6** | **94.6** | **86.7** | **98.2** | **97.3** | **96.2** | **96.0** | **95.4** | **94.0** |
| **SYN545547** | A | ND | ND | ND | 1.7 | ND | 6.0 | ND | 1.1 | 1.2 | 0.9 | 1.5 | 2.7 |
| | B | ND | 1.8 | ND | ND | ND | 3.5 | ND | 1.2 | 1.3 | 1.0 | 2.2 | 2.0 |
| | **Mean** | **ND** | **0.9** | **ND** | **0.9** | **ND** | **4.8** | **ND** | **1.1** | **1.2** | **1.0** | **1.8** | **2.3** |
| **Unknown 1** | A | ND | ND | ND | ND | ND | 3.0 | ND | 0.6 | 0.5 | 0.3 | 0.5 | 0.8 |
| | B | ND | ND | ND | ND | ND | 1.9 | ND | 0.6 | 0.5 | 0.4 | 0.7 | 0.6 |
| | **Mean** | **ND** | **ND** | **ND** | **ND** | **ND** | **2.4** | **ND** | **0.6** | **0.5** | **0.4** | **0.6** | **0.7** |
| **Unidentified product(s)** | A | ND | ND | ND | ND | ND | ND | ND | ND | 0.9 | ND | 0.1 | ND |
| | B | ND | ND | ND | 0.8 | ND | ND | ND | 0.4 | ND | 0.2 | ND | ND |
| | **Mean** | **ND** | **ND** | **ND** | **0.4** | **ND** | **ND** | **ND** | **0.2** | **0.4** | **0.1** | **0.1** | **ND** |
| **Unresolved background** | A | 0.2 | 0.2 | 1.1 | 0.4 | 1.6 | 0.7 | 0.1 | 0.3 | 0.2 | 0.5 | 0.1 | 0.6 |
| | B | 0.5 | 0.4 | 0.5 | ND | 1.4 | 0.7 | 0.2 | 0.1 | 0.3 | 0.6 | 1.3 | 1.7 |
| | **Mean** | **0.4** | **0.3** | **0.8** | **0.2** | **1.5** | **0.7** | **0.1** | **0.2** | **0.3** | **0.6** | **0.7** | **1.1** |

NA: Not applicable ND: not detected or < 0.1% AR

**Table B.8. 267 Characterisation of Radioactive Residues: Natural Water plus 0.02 g/L Suspended Sediment [Pyrazole-$^{14}$C]-pydiflumetofen Treated (10 µg/L) – Light/Dark Incubation**

| [Pyrazole-$^{14}$C]-pydiflumetofen | Rep | Sampling times (DAT) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Low dose (10 µg/L) | | | | | | High dose (95 µg/L) | | | | | |
| | | **0** | **7** | **14** | **32** | **45** | **60** | **0** | **7** | **14** | **32** | **45** | **60** |
| **Parent compound** | A | 98.3 | 95.6 | 91.6 | 89.6 | 87.3 | 88.9 | 99.6 | 96.1 | 95.1 | 94.9 | 92.7 | 92.1 |
| | B | 102.9 | 91.0 | 90.9 | 87.4 | 93.5 | 88.2 | 94.7 | 95.7 | 89.8 | 91.6 | 91.7 | 85.8 |
| | **Mean** | **100.6** | **93.3** | **91.3** | **88.5** | **90.4** | **88.6** | **97.2** | **95.9** | **92.4** | **93.2** | **92.2** | **88.9** |
| **SYN545547** | A | ND | 2.6 | 4.3 | 4.8 | 4.4 | 7.6 | ND | 1.9 | 2.5 | 2.4 | 2.4 | 3.4 |
| | B | ND | 4.2 | 2.7 | 4.4 | 5.3 | 7.1 | 4.4 | 2.4 | 2.5 | 2.5 | 2.6 | 8.0 |
| | **Mean** | **ND** | **3.4** | **3.5** | **4.6** | **4.8** | **7.3** | **2.2** | **2.2** | **2.5** | **2.5** | **2.5** | **5.7** |
| **Unknown 1** | A | ND | ND | ND | 3.0 | 3.1 | ND | ND | 1.9 | 1.6 | 1.7 | 1.6 | 2.4 |
| | B | ND | 2.6 | 1.2 | 2.2 | ND | 2.3 | ND | 1.9 | 1.6 | 1.6 | 1.6 | 1.7 |
| | **Mean** | **ND** | **1.3** | **0.6** | **2.6** | **1.6** | **1.1** | **ND** | **1.9** | **1.6** | **1.6** | **1.6** | **2.0** |
| **Unidentified product(s)** | A | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |
| | B | ND | ND | ND | 1.5 | ND | ND | ND | ND | ND | ND | ND | ND |
| | **Mean** | **ND** | **ND** | **ND** | **0.7** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| **Unresolved background** | A | 0.0 | 1.0 | 1.6 | 1.0 | 2.9 | 1.8 | ND | 0.1 | 0.8 | ND | 1.3 | 0.2 |
| | B | 0.2 | 0.1 | 1.1 | 1.5 | 1.9 | 0.7 | 0.3 | ND | 1.3 | 1.7 | 1.2 | 0.7 |
| | **Mean** | **0.1** | **0.6** | **1.3** | **1.2** | **2.4** | **1.2** | **0.2** | **0.0** | **1.0** | **0.9** | **1.3** | **0.4** |

NA: Not applicable ND: not detected or < 0.1% AR

**Table B.8. 268 Characterisation of Radioactive Residues: Sterilised Natural Water plus 0.02 g/L Suspended Sediment**

| | Rep | Dark incubation, high dose (95 µg/L) – 58 days | | Light/Dark incubation, high dose (95 µg/L) 60 days | |
|---|---|---|---|---|---|
| | | **Phenyl[a]** | **Pyrazole** | **Phenyl** | **Pyrazole** |
| **Parent compound** | A | 92.7 | 96.0 | 96.9 | 97.9 |
| | B | 63.4 | 96.5 | 92.6 | 99.7 |
| | **Mean** | **92.7** | **96.2** | **94.8** | **98.8** |
| **SYN545547** | A | ND | ND | ND | ND |
| | B | ND | ND | ND | ND |
| | **Mean** | **ND** | **ND** | **ND** | **ND** |
| **Unknown 1** | A | ND | ND | ND | ND |
| | B | ND | ND | ND | ND |
| | **Mean** | **ND** | **ND** | **ND** | **ND** |
| **Unidentified product(s)** | A | ND | ND | ND | ND |
| | B | ND | ND | ND | ND |
| | **Mean** | **ND** | **ND** | **ND** | **ND** |
| **Unresolved background** | A | 0.8 | 1.7 | 1.4 | 0.4 |
| | B | 0.7 | 1.4 | 0.7 | 0.1 |
| | **Mean** | **0.8** | **1.6** | **1.1** | **0.2** |
| **Total volatiles** | A | ND | ND | 0.3 | ND |
| | B | ND | ND | 0.2 | ND |
| | **Mean** | **ND** | **ND** | **0.3** | **ND** |

[a] Low mass balance was obtained for replicate B, therefore lower values generated by chromatography. Although the % chromatogram for each region was comparable to replicate A, the data was not used in subsequent calculations.

ND: not detected or < 0.1% AR

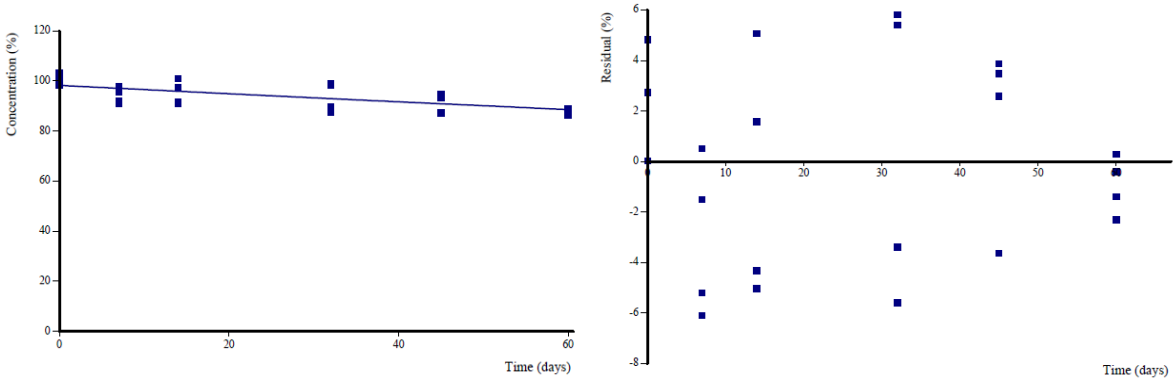
The $DegT_{50}$ values based on replicates for both labels are presented in the following table. They were extrapolated beyond the study duration in all incubation groups and ranged from 402 to >1000 days (both radiolabels combined).

**Table B.8. 269 DegT$_{50}$ values for pydiflumetofen – all DT50 values extrapolated beyond study duration**

| Test conditions | Test concentration (µg/L) | $DegT_{50}$ / $DegT_{90}$ (days) | k | $\chi^2$ | Prob > t | Model |
|---|---|---|---|---|---|---|
| Dark incubation | 10 | >1000 / >1000 | $3.62x10^{-4}$ | 1.81 | 0.14 | SFO |
| | 95 | 637 / >1000 | 0.0011 | 2.14 | <0.05 | SFO |
| Diffuse light/dark incubation | 10 | 402 / >1000 | 0.0017 | 1.55 | <0.05 | SFO |
| | 95 | 662 / >1000 | 0.001 | 1.01 | <0.05 | SFO |

As the kinetics are not used directly in the GB environmental exposure assessment, one example of visual and residual fit from the diffuse light/dark incubation with the system dosed at 10 µg/L is shown. All other incubations showed less decline.

**Figure B.8. 49 SFO visual and residual fitting for pydiflumetofen (both radiolabels) the aerobic mineralisation diffuse light/dark incubation, 10 µg/L dose.**




**Enantiomer composition**

The ratio of the two enantiomers of pydiflumetofen did not significantly change. HSE has added an assessment of the change in enantiomer excess.

**Table B.8. 270 Pydiflumetofen enantiomer ratios in application solutions and in natural water samples incubated under aerobic conditions**

| | % Sample activity as | | | | |
|---|---|---|---|---|---|
| **Sample Interval** | **1st eluting enantiomer** | **2nd eluting enantiomer** | **Enantiomer Ratio** | **Enantiomer Excess (ee)** | **Change in ee (%)** |
| Application solution 5 | 43.64 | 47.83 | 0.91 | -4.58 | |
| 45 DAT in light/dark, 10 µg/L | 40.67 | 45.93 | 0.89 | -6.07 | 1.49 |
| Application solution 4 | 43.87 | 47.73 | 0.92 | -4.21 | |
| 58 DAT in dark, 95 µg/L | 33.52 | 37.35 | 0.90 | -5.40 | 1.19 |

**Conclusions**

The study is considered to be acceptable by HSE. The results can be accepted for regulatory decision-making.

Over the duration of the study, pydiflumetofen showed only small amounts of degradation in the test system.

The enantiomer ratio of pydiflumetofen did not appear to alter significantly during the course of the study. Taking into consideration the EFSA Stereoisomers guidance, the aerobic mineralisation study presents an asymmetric environment. Small changes in the enantiomer excess were seen, however only a small amount of degradation was seen, the DT50 values in both incubations in the study being extrapolated well beyond the end of the study. Extrapolating out to the expected time when the DT50 would have occurred (402 days for the illuminated, low dose incubation; 637 days for the dark, high dose incubation), it would be expected that the change in enantiomer excess would have been >10% in both cases. Normally the aerobic mineralisation has a limited role in the regulatory assessment, typically being used in relation to comparison to the persistence criteria for POP/PBT/vPvB. With this in mind, it is considered that it is better to use the results of the water sediment study as a better representation of potential change in enantiomer excess in small water bodies with an active microbial population in the agricultural environment.

The light/dark cycle incubations were conducted using fluorescent lights. Neither the type of light source that may be used under 'diffuse light' conditions nor the purpose of the light are specified in OECD 309. It is possible that the inclusion of the use of diffuse light might be either to provide the possibility of photolytically induced degradation that might occur in deeper natural water bodies or to provide the possibility for microorganisms in the natural water to photosynthesise and thus present a more realistic microbial metabolic environment. The irradiance between 400-700 nm was given in an appendix to the study report. Compared to the measured natural sunlight or the xenon light source used in the aqueous photolysis study, the light spectrum from the fluorescent light source appeared to be quite different, being much 'peakier' at certain wavelengths. Irrespective of the differences in wavelength or the reasoning behind the inclusion of a light source in this type of study, there was marginally greater degradation in the light/dark cycle incubation compared to the dark incubation. However, degradation in both dark and light/dark cycle incubations was very slow with slightly less than 90% of pydiflumetofen remaining at study end at 60 days.

The normal use of the aerobic mineralisation study under Regulation 1107/2009 has been to generate data on persistence for the purposes of comparison against persistence criteria for PBT/vPvB/POPs classification. According to Regulation 1107/2009, a substance meets the POP criteria in water if the DegT50 is greater than 2 months; for PBT, the substance meets the persistence criteria in fresh water if the half-life is greater than 40 days; for vPvB the substance meets the persistence criteria in fresh water if the half-life is greater than 60 days. This aerobic mineralisation study suggests that pydiflumetofen would be classified as 'persistent' or 'very persistent' according to each of these criteria. It is noted that the findings of this study support the findings in the soil studies (section B.8.1.1) where the DT50 values indicate that pydiflumetofen would be classified as 'persistent' or 'very persistent'. It should be noted that meeting the persistence criteria alone is insufficient for a substance to be classified as PBT, vPvB or POP.

## B.8.2.2.3. Water/sediment studies

### B.8.2.2.3.1. Route of degradation in 2 water/sediment systems

| | |
|---|---|
| **Report:** | K-CA 7.2.2.3/01 [redacted] (2015), SYN545974 - Aerobic and Anaerobic Aquatic Sediment Metabolism of $^{14}$C- SYN545974, Report Number 3200129. Smithers Viscient (ESG) Ltd, 108 Woodfield Drive, Harrogate, HG1 4LS, UK<br>(Syngenta File No. SYN545974_50204) |

| | |
|---|---|
| **Guideline(s):** | OECD 308 (2002), EPA Guideline Series OPPTS 835.4300 & 835.4400 (2008), SETAC 1995 |
| **GLP/GEP:** | Yes |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**

The rate and route of degradation of [$^{14}$C]-pydiflumetofen, labelled in phenyl and pyrazole positions, was investigated under aerobic and anaerobic conditions in two different water-sediment systems.

| **Test Material:** | **[Pyrazole-5-$^{14}$C]-SYN545974** | **[Phenyl-U-$^{14}$C]-SYN545974** |
|---|---|---|
| Lot/Batch #: | 5271GAR001-4 | RDR-XV-94 |
| Specific activity: | 5.06 MBq/mg | 5.791 MBq/mg |
| Purity: | 99.2% (radiochemical) | 97.8% (radiochemical) |
| Application vehicle: | Acetonitrile | Acetonitrile |

The study was conducted using two water-sediment systems sampled at Calwich, Staffordshire, England and Chatsworth, Derbyshire, England, respectively. The aerobic water samples were scooped from the lake and passed through a sieve (212 µm) into containers with an air space. The anaerobic water samples were scooped from the lake and, unfiltered, placed into containers without an air space The aerobic sediment was scooped from the top 5 cm and sieved (2 mm) into containers. The anaerobic sediment was sampled from the top 10 cm and placed into containers.

After receipt, the anaerobic samples were sieved (sediment 2mm, water 212 µm) and the water-sediment systems were thoroughly mixed and stored, waterlogged (*ca* 6 - 10 cm water layer) and routinely maintained at 4 ± 2°C. The aerobic samples had free access to air but the anaerobic samples were tightly sealed. The key characteristics of the water-sediment systems are summarised below.

**Table B.8. 271 Characteristics of the water/sediment systems**

| **Name** | **Calwich Abbey** | | **Swiss Lake** | |
|---|---|---|---|---|
| **Physical and chemical properties of sediment** | | | | |
| Particle size (% w/w): | | | | |
| Clay (<2 µm) | 4 | | 2 | |
| Silt (50-2 µm) | 78 | | 9 | |
| Sand (2000-50 µm) | 18 | | 89 | |
| Texture (USDA) | Silt loam | | Sand | |
| pH | | | | |
| Water | 7.9 | | 5.5 | |
| 0.01M $CaCl_2$ | 7.6 | | 5.1 | |
| Redox potential (mV)* | Aerobic | Anaerobic | Aerobic | Anaerobic |
| Start of acclimation | -254 | -245 | -267 | -256 |
| Start of study | -261 | -263 | -220 | -225 |
| End of study | -244 | -211 | -201 | -198 |
| Organic Matter (%) | Aerobic | Anaerobic | Aerobic | Anaerobic |
| Start of study | 8.1 | 7.2 | 1.0 | 1.2 |
| End of study | 7.8 | 6.7 | 1.4 | 1.9 |
| Organic carbon (%) | Aerobic | Anaerobic | Aerobic | Anaerobic |
| Start of study | 4.7 | 4.2 | 0.6 | 0.7 |
| End of study | 4.5 | 3.9 | 0.8 | 1.1 |
| CEC (meq/100 g sediment) | 15.2 | | 2.6 | |
| Biomass (mg carbon/kg sediment): | Aerobic | Anaerobic | Aerobic | Anaerobic |
| Start of study | 872.2 | 484.4 | 195.8 | 148.1 |
| End of study | 1839.2 | 846.8 | 249.9 | 285.9 |
| Biomass % organic carbon: | | | | |
| Start of study | 1.9 | 1.2 | 3.3 | 2.1 |
| End of study | 4.1 | 2.2 | 3.1 | 2.6 |
| **Water** | **Calwich Abbey** | | **Swiss Lake** | |
| **Physical and chemical properties of water** | | | | |
| Temperature at collection | 16.8 | | 15.7 | |
| pH at collection | 8.1 | | 7.1 | |
| $O_2$ concentration at collection (%) | 194.1 | | 87.5 | |
| pH** | Aerobic | Anaerobic | Aerobic | Anaerobic |
| Start of acclimation | 8.3 | 7.5 | 7.5 | 7.4 |
| Start of study | 8.4 | 7.5 | 7.9 | 7.8 |
| End of study | 8.0 | 8.1 | 7.8 | 7.9 |
| Redox potential (mV)* | Aerobic | Anaerobic | Aerobic | Anaerobic |
| Start of acclimation | 373 | 378 | 390 | -236 |
| Start of study | 411 | -49 | 398 | -252 |
| End of study | 433 | 11 | 447 | -59 |
| Oxygen concentration (mg/L) | Aerobic | Anaerobic | Aerobic | Anaerobic |
| Start of acclimation | 7 | 1 | 7 | 1 |
| Start of study | 7 | 0 | 7 | 0 |
| End of study | 7 | 0 | 8 | 0 |
| Total organic carbon (ppm) | Aerobic | Anaerobic | Aerobic | Anaerobic |
| Start of acclimation | 2.1 | | 9.2 | |
| End of study | 9.1 | 7.5 | 5.2 | 16.1 |
| Suspended solid (mg/L) | 1.8 | | 3 | |
| Hardness (mg equiv $CaCO_3$/L) | 251 | | 18 | |

*Redox potential measurements were made using a silver chloride electrode. The reported values have been converted to those of the hydrogen scale.

** pH measurements made during the incubation period were made using either a silver chloride or a polymer-based electrode.

Aliquots of the appropriate sediment were dispensed into labelled glass incubation units (10 cm diameter) to a depth of 3 cm (equivalent to 147.7 and 287.6 g dry weight for Calwich Abbey and Swiss Lake sediments, respectively). With the minimum of disturbance, the associated surface water was added to a depth of 9 cm above the sediment surface. Ratios of approximately 1:3 (v/v, based upon sediment: water depth) were obtained for all samples of both systems.

[$^{14}$C]-pydiflumetofen was applied to the water at a nominal rate of 83 µg/L in the water phase (equivalent to direct overspray of 250 g ai./ha to a water body with a water depth of 30 cm). For each water-sediment and label type, one sample set was maintained under aerobic conditions and one under anaerobic conditions (8 incubation groups). The systems were incubated in the laboratory and maintained in dark conditions at 20°C for up to 100 days after treatment (DAT). Volatile radiolabelled products were trapped in 2M NaOH. Duplicate samples from each system and incubation condition were taken for analysis immediately after treatment and at six other intervals (7, 14, 30, 45/47, 59/61 and 100 days).

The surface waters were analysed by LSC and initially analysed directly by HPLC. Later samples were partitioned with dichloromethane and the organic phases concentrated and analysed by HPLC. Sediments were extracted three times with acetonitrile: 0.1M ammonium acetate (80:20 v/v, initial extract) and twice with acetonitrile: water acidified to pH3 (80:20 v/v, acidified extract). The radioactivity in all the extracts was quantified by LSC. Sediment extracts were combined and concentrated prior to HPLC. Confirmation of identity and quantification was carried out by TLC. LC-MS was used to provide qualitative confirmation of the identification of pydiflumetofen and the degradate SYN545547. Post-extraction sediments were combusted to obtain mass balance. Organic matter fractionation was performed on selected 100 DAT samples from each aerobic and one anaerobic incubation group. Chiral HPLC was used to determine the enantiomer ratio for pydiflumetofen in selected sample extracts.

The percentage of applied radioactivity present as parent pydiflumetofen in the water and in the total water-sediment system, determined using HPLC, was plotted against days of incubation and fitted to single first-order (SFO) kinetics using CAKE version 2 software. True replicates for both labels were included individually in the optimisations. For total system, initial pydiflumetofen levels in the model input data were set to the total recovery measured in the time zero samples. All data points were unweighted. For optimal goodness of fit, the initial value was also allowed to be estimated by the model.

**Findings**

For the aerobic experiment, the aerobic system Dissolved Oxygen (DO) concentrations were at least 7 mg/L throughout the study. The water redox values also remained high confirming that the water was aerobic. The sediment for the aerobic incubation groups was anaerobic throughout with redox potentials (Eh) below -100 mV.

The anaerobic sediment redox values were also < –100 mV. Mean water redox values converted to the hydrogen scale in the anaerobic systems were not always < –100 mV. However, DO values after test substance application were 0 mg/L demonstrating anaerobic conditions.

The total recoveries and distribution of radioactivity from each water/sediment system are shown below. The mean recoveries for all water/sediment systems was between the acceptable range 90-110% AR, with the exception of 2 values which were slightly below (86 and 89% AR at 45 DAT in Calwich Abbey system for phenyl and pyrazole labels respectively, portions of samples were lost).

Carbon dioxide was a minor product of metabolism in both aerobic and anaerobic systems reaching a maximum of <1% AR. Unextracted residues increased slowly throughout the incubation, reaching maxima of 10.1% to 16.2% AR under aerobic conditions and 6.9% to 9.5% under anaerobic conditions by the end of the incubation.

Radioactive residues analysed by organic matter fractionation consisted primarily of humin with lesser amounts of fulvic acid and humic acid.

**Table B.8. 272 Mass balance and distribution of radioactivity in Calwich Abbey, aerobic incubation (values as % of applied)**

| | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **45** | **59** | **100** | **0** | **7** | **14** | **30** | **45** | **59** | **100** |
| Surface water | A | 89.3 | 30.2 | 19.5 | 5.6 | 3.5 | 5.0 | 3.7 | 79.4 | 29.2 | 24.6 | 11.1 | 4.2 | 13.3 | 3.7 |
| | B | 84.5 | 35.7 | 20.3 | NS | 3.2 | 2.8 | 3.2 | 87.4 | 29.6 | 34.4 | NS | 4.5 | 6.6 | 4.1 |
| | **Mean** | **86.9** | **33.0** | **19.9** | **5.6** | **3.4** | **3.9** | **3.5** | **83.4** | **29.4** | **29.5** | **11.1** | **4.4** | **10.0** | **3.9** |
| Initial Sediment extract | A | 7.0 | 52.8 | 60.9 | 68.5 | 61.2 ** | 69.7 | 72.6 | 14.4 | 53.9 | 58.5 | 74.5 | 71.7 | 65.3 | 71.6 |
| | B | 9.9 | 48.3 | 62.0 | NS | 64.9 ** | 73.3 | 72.2 | 8.4 | 54.7 | 50.2 | NS | 55.0 ** | 70.5 | 72.2 |
| | **Mean** | **8.5** | **50.6** | **61.5** | **68.5** | **63.1** | **71.5** | **72.4** | **11.4** | **54.3** | **54.4** | **74.5** | **63.4** | **67.9** | **71.9** |
| Acidic Sediment extract | A | 1.0 | 10.0 | 9.7 | 14.3 | 12.9 | 13.9 | 11.4 | 2.7 | 10.6 | 9.8 | 8.9 | 12.9 | 12.2 | 12.9 |
| | B | 1.7 | 9.4 | 9.6 | NS | 10.4 | 13.0 | 11.8 | 1.4 | 9.6 | 8.4 | NS | 13.9 | 13.2 | 11.7 |
| | **Mean** | **1.4** | **9.7** | **9.7** | **14.3** | **11.7** | **13.5** | **11.6** | **2.1** | **10.1** | **9.1** | **8.9** | **13.4** | **12.7** | **12.3** |
| **Total Extract.*** | **Mean** | **96.7** | **93.2** | **91.0** | **88.4** | **78.1** | **88.9** | **87.5** | **96.9** | **93.8** | **93.0** | **94.5** | **81.1** | **90.6** | **88.1** |
| Non-Extractable Residues | A | 0.3 | 4.2 | 4.2 | 7.4 | 8.0 | 8.6 | 9.9 | 0.7 | 3.7 | 4.6 | 5.6 | 7.3 | 8.1 | 10.7 |
| | B | 0.5 | 3.6 | 3.8 | NS | 6.8 | 7.9 | 10.4 | 0.4 | 3.3 | 3.8 | NS | 8.5 | 8.1 | 9.5 |
| | **Mean** | **0.4** | **3.9** | **4.0** | **7.4** | **7.4** | **8.3** | **10.2** | **0.6** | **3.5** | **4.2** | **5.6** | **7.9** | **8.1** | **10.1** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | 0.1 | 0.3 | 0.4 | 0.5 | 0.5 | 0.8 | NA | ND | ND | ND | ND | ND | ND |
| | B | NA | 0.1 | 0.3 | NS | 0.5 | 0.5 | 0.7 | NA | ND | ND | NS | ND | ND | ND |
| | **Mean** | **NA** | **0.1** | **0.3** | **0.4** | **0.5** | **0.5** | **0.8** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 97.6 | 97.3 | 94.6 | 96.2 | 86.1 | 97.7 | 98.4 | 97.2 | 97.4 | 97.5 | 100.1 | 96.1 | 98.9 | 98.9 |
| | B | 96.6 | 97.1 | 96.0 | NS | 85.8 | 97.5 | 98.3 | 97.6 | 97.2 | 96.8 | NS | 81.9 ** | 98.4 | 97.5 |
| | **Mean** | **97.1** | **97.2** | **95.3** | **96.2** | **86.0** ** | **97.6** | **98.4** | **97.4** | **97.3** | **97.2** | **100.1** | **89.0** | **98.7** | **98.2** |
| **Overall Mean ± SD** | | **95.4 ± 4.3** | | | | | | | **96.8 ± 3.6** | | | | | | |

NA = Not applicable ND = Not detected (or < 0.1%) NS = No sample (lost due to an error in extraction).

* Includes surface water

** Portion of sample lost on freezing prior to quantification.

**Table B.8. 273 Mass balance and distribution of radioactivity in Swiss Lake, aerobic incubation (values as % of applied)**

| | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **45** | **59** | **100** | **0** | **7** | **14** | **30** | **45** | **59** | **100** |
| Surface water | A | 89.1 | 58.0 | 41.7 | 34.0 | 23.1 | 6.2 | 20.6 | 88.0 | 51.8 | 44.1 | 30.8 | 25.2 | 25.2 | 7.8 |
| | B | 90.8 | 52.1 | 44.7 | NS | 25.3 | 16.8 | 6.5 | 85.5 | 50.5 | 46.8 | NS | 36.4 | 9.9 | 14.2 |
| | **Mean** | **90.0** | **55.1** | **43.2** | **34.0** | **24.2** | **11.5** | **13.6** | **86.8** | **51.2** | **45.5** | **30.8** | **30.8** | **17.6** | **11.0** |
| Initial Sediment extract | A | 6.1 | 30.1 | 35.2 | 48.2 | 57.0 | 63.0 | 58.6 | 6.9 | 32.5 | 40.8 | 52.1 | 52.7 | 61.1 | 55.9 |
| | B | 4.6 | 34.8 | 41.2 | NS | 52.9 | 55.1 | 58.1 | 8.0 | 38.0 | 37.2 | NS | 46.4 | 51.3 | 65.1 |
| | **Mean** | **5.4** | **32.5** | **38.2** | **48.2** | **55.0** | **59.1** | **58.4** | **7.5** | **35.3** | **39.0** | **52.1** | **49.6** | **56.2** | **60.5** |
| Acidic Sediment extract | A | 1.1 | 4.1 | 6.2 | 7.4 | 6.2 | 11.5 | 7.6 | 1.0 | 5.6 | 5.6 | 6.1 | 8.7 | 9.2 | 10.5 |
| | B | 0.7 | 4.9 | 5.8 | NS | 8.9 | 11.1 | 10.6 | 1.0 | 4.2 | 5.3 | NS | 6.2 | 10.4 | 7.3 |
| | **Mean** | **0.9** | **4.5** | **6.0** | **7.4** | **7.6** | **11.3** | **9.1** | **1.0** | **4.9** | **5.5** | **6.1** | **7.5** | **9.8** | **8.9** |
| **Total Extract.*** | **Mean** | **96.2** | **92.0** | **87.4** | **89.6** | **86.7** | **81.9** | **81.0** | **95.2** | **91.3** | **89.9** | **89.0** | **87.8** | **83.6** | **80.4** |
| Non-Extractable Residues | A | 0.2 | 1.3 | 2.9 | 4.6 | 8.5 | 13.1 | 12.5 | 0.2 | 1.4 | 3.6 | 7.4 | 9.0 | 10.7 | 16.5 |
| | B | 0.1 | 1.4 | 2.3 | NS | 8.6 | 10.6 | 19.8 | 0.2 | 1.6 | 5.4 | NS | 7.8 | 18.9 | 12.9 |
| | **Mean** | **0.2** | **1.4** | **2.6** | **4.6** | **8.6** | **11.9** | **16.2** | **0.2** | **1.5** | **4.5** | **7.4** | **8.4** | **14.8** | **14.7** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | 0.2 | 0.3 | 0.5 | 0.6 | 0.7 | 0.9 | NA | ND | ND | ND | ND | ND | ND |
| | B | NA | 0.1 | 0.3 | NS | 0.7 | 0.8 | 0.8 | NA | ND | ND | NS | ND | ND | ND |
| | **Mean** | **NA** | **0.2** | **0.3** | **0.5** | **0.7** | **0.8** | **0.9** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 96.5 | 93.7 | 86.3 | 94.7 | 95.4 | 94.5 | 100.2 | 96.1 | 91.3 | 94.1 | 96.4 | 95.6 | 106.2 | 90.7 |
| | B | 96.2 | 93.3 | 94.3 | NS | 96.4 | 94.4 | 95.8 | 94.7 | 94.3 | 94.7 | NS | 96.8 | 90.5 | 99.5 |
| | **Mean** | **96.4** | **93.5** | **90.3** | **94.7** | **95.9** | **94.5** | **98.0** | **95.4** | **92.8** | **94.4** | **96.4** | **96.2** | **98.4** | **95.1** |
| **Overall Mean ± SD** | | **94.7 ± 2.4** | | | | | | | **95.5 ± 1.7** | | | | | | |

NA = Not applicable ND = Not detected (or < 0.1%) NS = No sample (lost due to an error in extraction).

* Includes surface water

**Table B.8. 274 Mass balance and distribution of radioactivity in Calwich Abbey, anaerobic incubation (values as % of applied)**

| | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **47** | **61** | **100** | **0** | **7** | **14** | **30** | **47** | **61** | **100** |
| Surface water | A | 92.8 | 85.6 | 70.4 | 29.2 | 31.0 | 18.8 | 15.7 | 91.8 | 83.3 | 61.2 | 44.6 | 35.9 | 22.5 | 18.0 |
| | B | 80.8 | 72.9 | 65.3 | 66.5 | 35.3 | 33.4 | 16.6 | 88.2 | 83.1 | 70.9 | 57.3 | 43.9 | 30.2 | 16.3 |
| | **Mean** | **86.8** | **79.3** | **67.9** | **47.9** | **33.2** | **26.1** | **16.2** | **90.0** | **83.2** | **66.1** | **51.0** | **39.9** | **26.4** | **17.2** |
| Initial Sediment extract | A | 3.9 | 7.2 | 16.6 | 54.1 | 52.4 | 62.9 | 64.3 | 4.3 | 9.5 | 28.2 | 41.2 | 48.3 | 62.4 | 62.9 |
| | B | 13.2 | 18.7 | 24.8 | 21.3 | 50.2 | 50.6 | 63.4 | 4.3 | 9.6 | 19.7 | 32.8 | 42.7 | 51.4 | 63.9 |
| | **Mean** | **8.6** | **13.0** | **20.7** | **37.7** | **51.3** | **56.8** | **63.9** | **4.3** | **9.6** | **24.0** | **37.0** | **45.5** | **56.9** | **63.4** |
| Acidic Sediment extract | A | 0.7 | 1.5 | 2.7 | 8.9 | 8.2 | 9.8 | 10.7 | 0.5 | 1.5 | 5.0 | 6.0 | 7.7 | 8.5 | 9.6 |
| | B | 2.3 | 3.4 | 4.4 | 4.0 | 8.7 | 8.3 | 10.7 | 0.6 | 1.4 | 3.2 | 2.8 | 5.5 | 10.1 | 9.8 |
| | **Mean** | **1.5** | **2.5** | **3.6** | **6.5** | **8.5** | **9.1** | **10.7** | **0.6** | **1.5** | **4.1** | **4.4** | **6.6** | **9.3** | **9.7** |
| **Total Extract.*** | **Mean** | **96.9** | **94.7** | **92.1** | **92.0** | **92.9** | **91.9** | **90.7** | **94.9** | **94.2** | **94.1** | **92.4** | **92.0** | **92.6** | **90.3** |
| Non-Extractable Residues | A | 0.2 | 0.5 | 1.0 | 4.9 | 4.0 | 6.1 | 7.5 | 0.2 | 0.3 | 1.8 | 2.9 | 4.0 | 4.9 | 6.5 |
| | B | 0.8 | 0.7 | 1.9 | 1.9 | 4.4 | 4.5 | 7.4 | 0.2 | 0.5 | 1.3 | 1.9 | 2.8 | 5.2 | 7.3 |
| | **Mean** | **0.5** | **0.6** | **1.5** | **3.4** | **4.2** | **5.3** | **7.5** | **0.2** | **0.4** | **1.6** | **2.4** | **3.4** | **5.1** | **6.9** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | 0.1 | 0.1 | 0.2 | 0.1 | 0.3 | 0.3 | NA | ND | ND | ND | ND | ND | ND |
| | B | NA | ND | 0.1 | 0.2 | 0.2 | 0.2 | 0.3 | NA | ND | ND | ND | ND | ND | ND |
| | **Mean** | **NA** | **0.1** | **0.1** | **0.2** | **0.2** | **0.3** | **0.3** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 97.6 | 94.9 | 90.8 | 97.3 | 95.7 | 97.9 | 98.5 | 96.8 | 94.6 | 96.2 | 94.7 | 95.9 | 98.3 | 97.0 |
| | B | 97.1 | 95.7 | 96.5 | 93.9 | 98.8 | 97.0 | 98.4 | 93.3 | 94.6 | 95.1 | 94.8 | 94.9 | 96.9 | 97.3 |
| | **Mean** | **97.4** | **95.3** | **93.7** | **95.6** | **97.3** | **97.5** | **98.5** | **95.1** | **94.6** | **95.7** | **94.8** | **95.4** | **97.6** | **97.2** |
| **Overall Mean ± SD** | | **96.4 ± 1.6** | | | | | | | **95.7 ± 1.2** | | | | | | |

NA = Not applicable ND = Not detected (or < 0.1%)

* Includes surface water

**Table B.8. 275 Mass balance and distribution of radioactivity in Swiss Lake, anaerobic incubation (values as % of applied)**

| | Rep | Percent of Applied Radioactivity by Incubation time (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **47** | **61** | **100** | **0** | **7** | **14** | **30** | **47** | **61** | **100** |
| Surface water | A | 86.8 | 79.4 | 69.8 | 47.2 | 36.8 | 37.0 | 26.8 | 90.6 | 79.3 | 71.9 | 56.8 | 46.0 | 32.8 | 33.0 |
| | B | 86.5 | 82.6 | 71.6 | 48.4 | 37.2 | 34.9 | 30.3 | 87.9 | 76.2 | 68.6 | 57.3 | 45.2 | 40.1 | 32.7 |
| | **Mean** | **86.7** | **81.0** | **70.7** | **47.8** | **37.0** | **36.0** | **28.6** | **89.3** | **77.8** | **70.3** | **57.1** | **45.6** | **36.5** | **32.9** |
| Initial Sediment extract | A | 7.4 | 13.9 | 16.4 | 36.5 | 44.8 | 44.9 | 51.9 | 5.3 | 11.9 | 20.0 | 31.7 | 36.2 | 48.4 | 47.9 |
| | B | 8.5 | 11.8 | 19.5 | 39.0 | 46.9 | 48.4 | 50.8 | 6.8 | 16.2 | 22.0 | 29.4 | 37.1 | 41.2 | 47.5 |
| | **Mean** | **8.0** | **12.9** | **18.0** | **37.8** | **45.9** | **46.7** | **51.4** | **6.1** | **14.1** | **21.0** | **30.6** | **36.7** | **44.8** | **47.7** |
| Acidic Sediment extract | A | 1.1 | 1.7 | 3.4 | 6.6 | 7.8 | 7.4 | 7.9 | 0.6 | 1.5 | 3.3 | 4.0 | 6.3 | 8.1 | 7.2 |
| | B | 1.1 | 1.4 | 3.4 | 4.5 | 6.8 | 7.3 | 7.9 | 0.9 | 2.0 | 3.7 | 3.3 | 9.0 | 7.8 | 7.7 |
| | **Mean** | **1.1** | **1.6** | **3.4** | **5.6** | **7.3** | **7.4** | **7.9** | 0.8 | 1.8 | 3.5 | 3.7 | 7.7 | 8.0 | 7.5 |
| **Total Extract.*** | **Mean** | **95.7** | **95.4** | **92.1** | **91.1** | **90.2** | **90.0** | **87.8** | **96.1** | **93.6** | **94.8** | **91.3** | **89.9** | **89.2** | **88.0** |
| Non-Extractable Residues | A | 0.6 | 0.3 | 1.5 | 5.0 | 5.9 | 6.3 | 7.9 | 0.2 | 0.3 | 1.8 | 2.8 | 5.2 | 6.6 | 9.5 |
| | B | 0.5 | 0.3 | 1.6 | 3.8 | 6.7 | 5.2 | 6.3 | 0.4 | 0.3 | 1.7 | 2.5 | 6.3 | 7.1 | 9.5 |
| | **Mean** | **0.6** | **0.3** | **1.6** | **4.4** | **6.3** | **5.8** | **7.1** | **0.3** | **0.3** | **1.8** | **2.7** | **5.8** | **6.9** | **9.5** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | ND | 0.1 | 0.2 | 0.2 | 0.3 | 0.3 | NA | ND | ND | ND | ND | ND | ND |
| | B | NA | 0.1 | 0.1 | 0.1 | 0.1 | 0.3 | 0.1 | NA | ND | ND | ND | ND | ND | ND |
| | **Mean** | **NA** | **0.1** | **0.1** | **0.2** | **0.2** | **0.3** | **0.2** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |
| Total % recovery | A | 95.9 | 95.3 | 91.2 | 95.5 | 95.5 | 95.9 | 94.8 | 96.7 | 93.0 | 97.0 | 95.3 | 93.7 | 95.9 | 97.6 |
| | B | 96.6 | 96.2 | 96.2 | 95.8 | 97.7 | 96.1 | 95.4 | 96.0 | 94.7 | 96.0 | 92.5 | 97.6 | 96.2 | 97.4 |
| | **Mean** | **96.3** | **95.8** | **93.7** | **95.7** | **96.6** | **96.0** | **95.1** | **96.4** | **93.9** | **96.5** | **93.9** | **95.7** | **96.1** | **97.5** |
| **Overall Mean ± SD** | | **95.6 ± 1.0** | | | | | | | **95.7 ± 1.4** | | | | | | |

NA = Not applicable ND = Not detected (or < 0.1%)

* Includes surface water

Characterisation of extractable radioactivity is presented in the tables below.

Under aerobic conditions, mean levels of parent compound in total system decreased from 91-94% AR at 0 DAT to 70-74% AR at 100 DAT. Mean levels of parent compound in the water phase decreased from 81-86% AR at 0 DAT to 2-12% AR at 100 DAT. Mean levels of parent compound in the sediment extracts increased to maximum values of 62% (100 DAT) to 79% AR (30 DAT).

Under anaerobic conditions, mean levels of parent compound in total system decreased from 91-93% AR at 0 DAT to 54-64% AR at 100 DAT. Mean levels of parent compound in the water phase decreased from 83-86% AR at 0 DAT to 10-21% AR at 100 DAT. Mean levels of parent compound in the sediment extracts increased to maximum values of 44% (60 DAT) to 52% AR (100 DAT).

The largest degradation product was SYN545547 for all incubation groups and was found primarily in sediment extracts. For aerobic incubation groups it accounted for up to 12.3% AR (sample average) in sediment extracts and 12.8% AR (sample average) in the total system. For anaerobic incubation groups it accounted for up to 26.5% AR (sample average) in sediment extracts and 32.4 % AR (sample average) in the total system. SYN545547 recoveries increased throughout the duration of the study. In addition, a number of discrete

unknown metabolites were also observed, each individually not exceeding 2.2% and 1.8% of applied activity under aerobic and anaerobic conditions, respectively.

**Table B.8. 276 Summary of product distribution in the total system of Calwich Abbey, aerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **45** | **59** | **100** | **0** | **7** | **14** | **30** | **45** | **59** | **100** |
| Parent | A | 94.8 | 89.6 | 86.9 | 70.4 | 70.1 | 77.3 | 72.0 | 92.9 | 89.9 | 89.1 | 88.3 | 79.7 | 78.6 | 71.3 |
| | B | 93.3 | 90.7 | 89.4 | NS | 71.5 | 77.4 | 72.3 | 94.7 | 90.2 | 89.3 | NS | 65.5 | 77.9 | 72.6 |
| | **Mean** | **94.0** | **90.2** | **88.1** | **70.4** | **70.8** | **77.4** | **72.2** | **93.8** | **90.1** | **89.2** | **88.3** | **72.6** | **78.2** | **71.9** |
| SYN545547 | A | 2.3 | 2.1 | 1.8 | 3.2 | 5.5 | 8.9 | 13.2 | 1.0 | 2.7 | 1.8 | 3.7 | 5.6 | 7.7 | 14.0 |
| | B | 1.5 | 2.1 | 1.8 | NS | 5.5 | 9.3 | 11.7 | ND | 1.6 | 1.9 | NS | 5.1 | 9.1 | 11.6 |
| | **Mean** | **1.9** | **2.1** | **1.8** | **3.2** | **5.5** | **9.1** | **12.4** | **0.5** | **2.2** | **1.9** | **3.7** | **5.4** | **8.4** | **12.8** |
| Unidentified product(s), if any | A | ND | 0.5 | 0.9 | 0.5 | 0.7 | 0.9 | 1.4 | 1.3 | 0.9 | 1.0 | 1.3 | 1.9 | 2.1 | 1.3 |
| | B | 0.9 | 0.4 | 0.7 | NS | 0.9 | 1.6 | 1.4 | 1.4 | 1.4 | 1.0 | NS | 1.2 | 1.9 | 1.6 |
| | **Mean** | **0.5** | **0.4** | **0.8** | **0.5** | **0.8** | **1.2** | **1.4** | **1.3** | **1.2** | **1.0** | **1.3** | **1.6** | **2.0** | **1.5** |
| Unresolved Background | A | 0.2 | 0.8 | 0.5 | 0.2 | 0.6 | 0.9 | 0.4 | 1.3 | 0.2 | 0.9 | 0.4 | 0.6 | 0.8 | 0.3 |
| | B | 0.4 | 0.2 | 0.1 | NS | ND | 0.1 | 1.1 | 1.2 | 0.6 | 0.8 | NS | 0.6 | 0.2 | 0.9 |
| | **Mean** | **0.3** | **0.5** | **0.3** | **0.2** | **0.3** | **0.5** | **0.7** | **1.2** | **0.4** | **0.9** | **0.4** | **0.6** | **0.5** | **0.6** |
| Aqueous phase of water partition[1] | A | NA | NA | NA | 0.6 | 0.6 | 0.7 | 0.7 | NA | NA | NA | 0.8 | 1.0 | 1.6 | 1.3 |
| | B | NA | NA | NA | NS | 0.6 | 0.6 | 0.7 | NA | NA | NA | NS | 1.0 | 1.3 | 1.3 |
| | **Mean** | **NA** | **NA** | **NA** | **0.6** | **0.6** | **0.7** | **0.7** | **NA** | **NA** | **NA** | **0.8** | **1.0** | **1.5** | **1.3** |

[1] After partition with dichloromethane

NA = Not applicable ND = Not detected (or < 0.1%) NS: No sample (lost due to an error in extraction)

**Table B.8. 277 Summary of product distribution in the water column of Calwich Abbey, aerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **45** | **59** | **100** | **0** | **7** | **14** | **30** | **45** | **59** | **100** |
| Parent | A | 86.9 | 29.1 | 19.3 | 4.7 | 2.5 | 3.8 | 2.2 | 76.0 | 27.9 | 24.3 | 9.3 | 2.7 | 10.1 | 1.8 |
| | B | 81.8 | 34.7 | 20.2 | NS | 2.1 | 1.7 | 1.9 | 84.9 | 28.9 | 34.2 | NS | 3.1 | 4.6 | 2.3 |
| | **Mean** | **84.3** | **31.9** | **19.7** | **4.7** | **2.3** | **2.7** | **2.0** | **80.5** | **28.4** | **29.2** | **9.3** | **2.9** | **7.4** | **2.0** |
| SYN545547 | A | 2.3 | 0.9 | ND | 0.2 | 0.3 | 0.4 | 0.7 | 1.0 | 1.2 | ND | 0.5 | 0.2 | 0.9 | 0.5 |
| | B | 1.5 | 1.0 | ND | NS | 0.3 | 0.5 | 0.6 | ND | ND | ND | NS | 0.3 | 0.5 | 0.4 |
| | **Mean** | **1.9** | **0.9** | **ND** | **0.2** | **0.3** | **0.5** | **0.7** | **0.5** | **0.6** | **ND** | **0.5** | **0.2** | **0.7** | **0.5** |
| Unidentified product(s), if any | A | ND | ND | ND | 0.1 | 0.1 | 0.1 | ND | 1.3 | ND | ND | 0.3 | 0.3 | 0.5 | 0.1 |
| | B | 0.9 | ND | ND | NS | 0.1 | ND | ND | 1.4 | 0.6 | ND | NS | ND | 0.2 | 0.1 |
| | **Mean** | **0.5** | **ND** | **ND** | **0.1** | **0.1** | **ND** | **ND** | **1.3** | **0.3** | **ND** | **0.3** | **0.2** | **0.3** | **0.1** |
| Unresolved Background | A | 0.1 | 0.2 | 0.3 | ND | ND | ND | ND | 1.1 | 0.2 | 0.3 | 0.2 | ND | 0.1 | ND |
| | B | 0.3 | ND | 0.1 | NS | ND | ND | ND | 1.1 | 0.1 | 0.3 | NS | 0.1 | ND | ND |
| | **Mean** | **0.2** | **0.1** | **0.2** | **ND** | **ND** | **ND** | **ND** | 1.1 | 0.1 | 0.3 | 0.2 | ND | 0.1 | ND |
| Aqueous phase of water partition[1] | A | NA | NA | NA | 0.6 | 0.6 | 0.7 | 0.7 | NA | NA | NA | 0.8 | 1.0 | 1.6 | 1.3 |
| | B | NA | NA | NA | NS | 0.6 | 0.6 | 0.7 | NA | NA | NA | NS | 1.0 | 1.3 | 1.3 |
| | **Mean** | **NA** | **NA** | **NA** | **0.6** | **0.6** | **0.7** | **0.7** | **NA** | **NA** | **NA** | **0.8** | **1.0** | **1.5** | **1.3** |

[1] After partition with dichloromethane

NA = Not applicable ND = Not detected (or < 0.1%) NS: No sample (lost due to an error in extraction)

**Table B.8. 278 Summary of product distribution in the sediment of Calwich Abbey, aerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **45** | **59** | **100** | **0** | **7** | **14** | **30** | **45** | **59** | **100** |
| Parent | A | 7.9 | 60.5 | 67.7 | 65.7 | 67.6 | 73.5 | 69.8 | 16.9 | 62.0 | 64.8 | 79.0 | 77.0 | 68.5 | 69.5 |
| | B | 11.5 | 56.0 | 69.1 | NS | 69.4 | 75.7 | 70.5 | 9.8 | 61.3 | 55.2 | NS | 62.3 | 73.3 | 70.3 |
| | **Mean** | **9.7** | **58.3** | **68.4** | **65.7** | **68.5** | **74.6** | **70.1** | **13.3** | **61.7** | **60.0** | **79.0** | **69.7** | **70.9** | **69.9** |
| SYN545547 | A | ND | 1.2 | 1.8 | 2.9 | 5.2 | 8.4 | 12.5 | ND | 1.6 | 1.8 | 3.2 | 5.4 | 6.8 | 13.5 |
| | B | ND | 1.2 | 1.8 | NS | 5.2 | 8.8 | 11.1 | ND | 1.6 | 1.9 | NS | 4.8 | 8.6 | 11.2 |
| | **Mean** | **ND** | **1.2** | **1.8** | **2.9** | **5.2** | **8.6** | **11.8** | **ND** | **1.6** | **1.9** | **3.2** | **5.1** | **7.7** | **12.3** |
| Unidentified product(s), if any | A | ND | 0.5 | 0.9 | 0.5 | 0.6 | 0.8 | 1.4 | ND | 0.9 | 1.0 | 1.0 | 1.6 | 1.6 | 1.3 |
| | B | ND | 0.4 | 0.7 | NS | 0.8 | 1.6 | 1.4 | ND | 0.9 | 1.0 | NS | 1.2 | 1.7 | 1.5 |
| | **Mean** | **ND** | **0.4** | **0.8** | **0.5** | **0.7** | **1.2** | **1.4** | **ND** | **0.9** | **1.0** | **1.0** | **1.4** | **1.6** | **1.4** |
| Unresolved Background | A | 0.1 | 0.6 | 0.3 | 0.2 | 0.5 | 0.8 | 0.4 | 0.2 | ND | 0.7 | 0.3 | 0.6 | 0.7 | 0.3 |
| | B | 0.1 | 0.1 | ND | NS | ND | 0.1 | 1.1 | 0.1 | 0.5 | 0.5 | NS | 0.5 | 0.2 | 0.9 |
| | **Mean** | **0.1** | **0.4** | **0.1** | **0.2** | **0.3** | **0.5** | **0.7** | **0.1** | **0.3** | **0.6** | **0.3** | **0.6** | **0.5** | **0.6** |
| Alkaline Traps (as $^{14}CO_2$) | A | NA | 0.1 | 0.3 | 0.4 | 0.5 | 0.5 | 0.8 | NA | ND | ND | ND | ND | ND | ND |
| | B | NA | 0.1 | 0.3 | NS | 0.5 | 0.5 | 0.7 | NA | ND | ND | NS | ND | ND | ND |
| | **Mean** | **NA** | **0.1** | **0.3** | **0.4** | **0.5** | **0.5** | **0.8** | **NA** | **ND** | **ND** | **ND** | **ND** | **ND** | **ND** |

NA = Not applicable ND = Not detected (or < 0.1%) NS: No sample (lost due to an error in extraction)

**Table B.8. 279 Summary of product distribution in the total system of Swiss Lake, aerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **45** | **59** | **100** | **0** | **7** | **14** | **30** | **45** | **59** | **100** |
| Parent | A | 92.3 | 89.1 | 86.7 | 85.4 | 80.5 | 77.2 | 79.1 | 92.3 | 87.9 | 84.5 | 81.5 | 77.5 | 86.7 | 64.9 |
| | B | 92.8 | 89.0 | 88.1 | NS | 81.8 | 78.5 | 68.3 | 90.5 | 89.3 | 83.2 | NS | 74.5 | 64.0 | 75.5 |
| | **Mean** | **92.6** | **89.1** | **87.4** | **85.4** | **81.2** | **77.8** | **73.7** | **91.4** | **88.6** | **83.8** | **81.5** | **76.0** | **75.4** | **70.2** |
| SYN545547 | A | 2.4 | 2.1 | 2.4 | 2.8 | 3.3 | 2.5 | 4.5 | 1.4 | 0.9 | 3.1 | 4.5 | 5.1 | 6.4 | 5.9 |
| | B | 1.5 | 1.4 | 2.2 | NS | 3.3 | 3.0 | 4.4 | 1.7 | 1.4 | 3.4 | NS | 10.6 | 4.2 | 7.5 |
| | **Mean** | **1.9** | **1.8** | **2.3** | **2.8** | **3.3** | **2.7** | **4.4** | **1.5** | **1.1** | **3.3** | **4.5** | **7.8** | **5.3** | **6.7** |
| Unidentified product(s), if any | A | 1.3 | 0.2 | 0.3 | 0.4 | 1.7 | 1.2 | 1.3 | 1.8 | 0.6 | 2.2 | 2.0 | 2.7 | 2.0 | 1.5 |
| | B | 0.9 | 0.4 | 0.4 | NS | 1.0 | 1.3 | 0.8 | 2.0 | 1.6 | 2.2 | NS | 3.1 | 1.7 | 1.6 |
| | **Mean** | **1.1** | **0.3** | **0.4** | **0.4** | **1.4** | **1.3** | **1.1** | **1.9** | **1.1** | **2.2** | **2.0** | **2.9** | **1.9** | **1.5** |
| Unresolved Background | A | 0.3 | 0.8 | 0.5 | 1.0 | 0.9 | 0.1 | 0.6 | 0.4 | 0.6 | 0.8 | 0.9 | 1.3 | 0.4 | 0.4 |
| | B | 0.9 | 0.9 | 1.0 | NS | 1.0 | 0.2 | 1.0 | 0.3 | 0.5 | 0.5 | NS | 0.8 | 0.5 | 0.2 |
| | **Mean** | **0.6** | **0.8** | **0.8** | **1.0** | **0.9** | **0.2** | **0.8** | **0.3** | **0.5** | **0.6** | **0.9** | **1.1** | **0.5** | **0.3** |
| Aqueous phase of water partition[1] | A | NA | NA | NA | NA | NA | 0.8 | 1.3 | NA | NA | NA | NA | NA | NA | 1.5 |
| | B | NA | NA | NA | NS | NA | NA | 0.7 | NA | NA | NA | NS | NA | 1.2 | 1.8 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **0.8** | **1.0** | **NA** | **NA** | **NA** | **NA** | **NA** | **1.2** | **1.7** |

[1] After partition with dichloromethane

NA = Not applicable ND = Not detected (or < 0.1%) NS: No sample (lost due to an error in extraction)

**Table B.8. 280 Summary of product distribution in the water column of Swiss Lake, aerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **45** | **59** | **100** | **0** | **7** | **14** | **30** | **45** | **59** | **100** |
| Parent | A | 85.2 | 56.4 | 40.3 | 32.9 | 21.4 | 6.0 | 18.0 | 84.5 | 51.6 | 41.1 | 28.5 | 21.9 | 23.1 | 5.3 |
| | B | 87.6 | 50.6 | 42.7 | NS | 23.9 | 15.8 | 5.2 | 81.6 | 49.6 | 43.5 | NS | 30.5 | 7.2 | 10.9 |
| | **Mean** | **86.4** | **53.5** | **41.5** | **32.9** | **22.6** | **10.9** | **11.6** | **83.0** | **50.6** | **42.3** | **28.5** | **26.2** | **15.1** | **8.1** |
| SYN545547 | A | 2.4 | 1.0 | 1.0 | 0.8 | 0.9 | 0.4 | 0.9 | 1.4 | ND | 1.5 | 1.0 | 1.3 | 1.2 | 0.7 |
| | B | 1.5 | 1.0 | 1.4 | NS | 0.9 | 0.7 | 0.5 | 1.7 | ND | 1.7 | NS | 3.4 | 0.9 | 1.1 |
| | **Mean** | **1.9** | **1.0** | **1.2** | **0.8** | **0.9** | **0.5** | **0.7** | **1.5** | **ND** | **1.6** | **1.0** | **2.3** | **1.0** | **0.9** |
| Unidentified product(s), if any | A | 1.3 | ND | ND | ND | 0.6 | ND | 0.3 | 1.8 | ND | 1.5 | 1.1 | 1.8 | 0.8 | 0.3 |
| | B | 0.9 | ND | ND | NS | 0.4 | 0.3 | 0.1 | 2.0 | 0.8 | 1.5 | NS | 2.1 | 0.6 | 0.3 |
| | **Mean** | **1.1** | **ND** | **ND** | **ND** | **0.5** | **0.1** | **0.2** | **1.9** | **0.4** | **1.5** | **1.1** | **2.0** | **0.7** | **0.3** |
| Unresolved Background | A | 0.3 | 0.5 | 0.5 | 0.3 | 0.2 | 0.1 | 0.2 | 0.3 | 0.3 | ND | 0.2 | 0.3 | 0.2 | 0.1 |
| | B | 0.8 | 0.5 | 0.6 | NS | 0.2 | 0.1 | ND | 0.2 | 0.1 | ND | NS | 0.4 | 0.1 | 0.1 |
| | **Mean** | **0.5** | **0.5** | **0.5** | **0.3** | **0.2** | **0.1** | **0.1** | **0.3** | **0.2** | **ND** | **0.2** | **0.4** | **0.1** | **0.1** |
| Aqueous phase of water partition[1] | A | NA | NA | NA | NA | NA | 0.8 | 1.3 | NA | NA | NA | NA | NA | NA | 1.5 |
| | B | NA | NA | NA | NS | NA | NA | 0.7 | NA | NA | NA | NS | NA | 1.2 | 1.8 |
| | **Mean** | **NA** | **NA** | **NA** | **NA** | **NA** | **0.8** | **1.0** | **NA** | **NA** | **NA** | **NA** | **NA** | **1.2** | **1.7** |

[1] After partition with dichloromethane

NA = Not applicable ND = Not detected (or < 0.1%) NS: No sample (lost due to an error in extraction)

**Table B.8. 281 Summary of product distribution in the sediment of Swiss Lake, aerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **45** | **59** | **100** | **0** | **7** | **14** | **30** | **45** | **59** | **100** |
| Parent | A | 7.2 | 32.7 | 46.4 | 52.5 | 59.1 | 71.2 | 61.1 | 7.8 | 36.4 | 43.4 | 53.0 | 55.6 | 63.6 | 59.6 |
| | B | 5.3 | 38.4 | 45.3 | NS | 58.0 | 62.8 | 63.2 | 8.9 | 39.7 | 39.6 | NS | 44.1 | 56.9 | 64.6 |
| | **Mean** | **6.2** | **35.6** | **45.9** | **52.5** | **58.5** | **67.0** | **62.1** | **8.4** | **38.0** | **41.5** | **53.0** | **49.8** | **60.2** | **62.1** |
| SYN545547 | A | ND | 1.1 | 1.5 | 2.0 | 2.4 | 2.1 | 3.6 | ND | 0.9 | 1.6 | 3.5 | 3.8 | 5.3 | 5.3 |
| | B | ND | 0.4 | 0.9 | NS | 2.4 | 2.3 | 3.9 | ND | 1.4 | 1.7 | NS | 7.2 | 3.3 | 6.4 |
| | **Mean** | **ND** | **0.8** | **1.2** | **2.0** | **2.4** | **2.2** | **3.7** | **ND** | **1.1** | **1.7** | **3.5** | **5.5** | **4.3** | **5.8** |
| Unidentified product(s), if any | A | ND | 0.2 | 0.3 | 0.4 | 1.1 | 1.2 | 1.1 | ND | 0.6 | 0.7 | 1.0 | 0.9 | 1.2 | 1.3 |
| | B | ND | 0.4 | 0.4 | NS | 0.6 | 1.0 | 0.7 | ND | 0.8 | 0.7 | NS | 1.0 | 1.1 | 1.3 |
| | **Mean** | **ND** | **0.3** | **0.4** | **0.4** | **0.9** | **1.1** | **0.9** | **ND** | **0.7** | **0.7** | **1.0** | **0.9** | **1.2** | **1.3** |
| Unresolved Background | A | ND | 0.2 | ND | 0.7 | 0.7 | ND | 0.5 | 0.1 | 0.3 | 0.8 | 0.7 | 1.1 | 0.2 | 0.3 |
| | B | ND | 0.4 | 0.4 | NS | 0.8 | 0.2 | 0.9 | 0.1 | 0.4 | 0.5 | NS | 0.4 | 0.5 | 0.1 |
| | **Mean** | **ND** | **0.3** | **0.2** | **0.7** | **0.7** | **0.1** | **0.7** | **0.1** | **0.4** | **0.6** | **0.7** | **0.7** | **0.3** | **0.2** |

NA = Not applicable ND = Not detected (or < 0.1%) NS: No sample (lost due to an error in extraction)

**Table B.8. 282 Summary of product distribution in the total system of Calwich Abbey, anaerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **47** | **61** | **100** | **0** | **7** | **14** | **30** | **47** | **61** | **100** |
| Parent | A | 93.7 | 91.3 | 88.8 | 82.2 | 80.6 | 63.8 | 63.0 | 92.7 | 90.7 | 89.6 | 84.6 | 81.0 | 70.3 | 56.9 |
| | B | 92.9 | 91.3 | 91.2 | 87.1 | 81.1 | 78.7 | 64.3 | 89.4 | 87.0 | 90.9 | 85.4 | 80.6 | 74.7 | 51.9 |
| | **Mean** | **93.3** | **91.3** | **90.0** | **84.6** | **80.9** | **71.2** | **63.7** | **91.0** | **88.8** | **90.3** | **85.0** | **80.8** | **72.5** | **54.4** |
| SYN545547 | A | 2.2 | 1.9 | 0.5 | 8.7 | 10.2 | 26.0 | 26.2 | 2.1 | 1.1 | 3.9 | 6.3 | 8.4 | 20.1 | 31.1 |
| | B | 1.7 | 1.8 | 2.3 | 3.0 | 12.1 | 12.0 | 24.2 | 1.3 | 2.3 | 1.7 | 5.1 | 8.5 | 13.5 | 33.7 |
| | **Mean** | **2.0** | **1.8** | **1.4** | **5.8** | **11.2** | **19.0** | **25.2** | **1.7** | **1.7** | **2.8** | **5.7** | **8.4** | **16.8** | **32.4** |
| Unidentified product(s), if any | A | 1.4 | 0.3 | ND | 0.9 | ND | 1.2 | 0.5 | 1.4 | 1.7 | 0.4 | 0.7 | 1.9 | 2.1 | 1.8 |
| | B | 0.9 | 1.0 | ND | 0.8 | ND | 1.0 | 1.6 | 1.7 | 3.5 | 0.4 | 1.5 | 2.4 | 3.1 | 3.5 |
| | **Mean** | **1.2** | **0.7** | **ND** | **0.8** | **ND** | **1.1** | **1.1** | **1.6** | **2.6** | **0.4** | **1.1** | **2.2** | **2.6** | **2.6** |
| Unresolved Background | A | 0.1 | 0.8 | 0.4 | 0.5 | 0.8 | 0.6 | 1.0 | 0.4 | 0.8 | 0.4 | 0.3 | 0.6 | 1.0 | 0.8 |
| | B | 0.8 | 0.8 | 1.0 | 1.0 | 1.0 | 0.6 | 0.6 | 0.7 | 1.3 | 0.7 | 0.9 | 0.5 | 0.4 | 0.9 |
| | **Mean** | **0.4** | **0.8** | **0.7** | **0.7** | **0.9** | **0.6** | **0.8** | **0.6** | **1.1** | **0.6** | **0.6** | **0.6** | **0.7** | **0.9** |

ND = Not detected (or < 0.1%)

**Table B.8. 283 Summary of product distribution in the water column of Calwich Abbey, anaerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **47** | **61** | **100** | **0** | **7** | **14** | **30** | **47** | **61** | **100** |
| Parent | A | 89.2 | 83.1 | 70.1 | 26.9 | 28.6 | 12.7 | 11.7 | 87.9 | 79.8 | 58.6 | 42.7 | 32.8 | 17.5 | 10.9 |
| | B | 77.6 | 70.5 | 63.5 | 63.9 | 33.0 | 30.9 | 12.2 | 84.5 | 76.7 | 69.8 | 54.3 | 39.7 | 26.1 | 8.4 |
| | **Mean** | **83.4** | **76.8** | **66.8** | **45.4** | **30.8** | **21.8** | **12.0** | **86.2** | **78.2** | **64.2** | **48.5** | **36.3** | **21.8** | **9.7** |
| SYN545547 | A | 2.2 | 1.9 | ND | 2.0 | 2.4 | 5.4 | 3.8 | 2.1 | 1.1 | 2.5 | 1.7 | 1.9 | 3.7 | 6.2 |
| | B | 1.7 | 0.9 | 1.1 | 1.3 | 2.2 | 2.1 | 3.4 | 1.3 | 2.0 | 0.6 | 1.5 | 1.8 | 2.1 | 5.6 |
| | **Mean** | **2.0** | **1.4** | **0.5** | **1.6** | **2.3** | **3.8** | **3.6** | **1.7** | **1.5** | **1.5** | **1.6** | **1.8** | **2.9** | **5.9** |
| Unidentified product(s), if any | A | 1.3 | ND | ND | ND | ND | 0.5 | ND | 1.4 | 1.7 | ND | ND | 1.1 | 1.1 | 0.8 |
| | B | 0.9 | 1.0 | ND | 0.7 | ND | 0.4 | 0.9 | 1.7 | 3.2 | ND | 1.0 | 1.9 | 1.8 | 2.2 |
| | **Mean** | **1.1** | **0.5** | **ND** | **0.3** | **ND** | **0.4** | **0.4** | **1.6** | **2.4** | **ND** | **0.5** | **1.5** | **1.4** | **1.5** |
| Unresolved Background | A | ND | 0.6 | 0.3 | 0.3 | ND | 0.2 | 0.2 | 0.4 | 0.7 | 0.1 | 0.2 | 0.1 | 0.2 | 0.1 |
| | B | 0.6 | 0.5 | 0.8 | 0.7 | 0.1 | ND | 0.2 | 0.7 | 1.3 | 0.6 | 0.6 | 0.4 | 0.3 | 0.1 |
| | **Mean** | **0.3** | **0.6** | **0.5** | **0.5** | **0.1** | **0.1** | **0.2** | **0.5** | **1.0** | **0.3** | **0.4** | **0.3** | **0.2** | **0.1** |

ND = Not detected (or < 0.1%)

**Table B.8. 284 Summary of product distribution in the sediment of Calwich Abbey, anaerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **47** | **61** | **100** | **0** | **7** | **14** | **30** | **47** | **61** | **100** |
| Parent | A | 4.5 | 8.2 | 18.6 | 55.2 | 52.0 | 51.1 | 51.3 | 4.8 | 10.9 | 31.0 | 41.9 | 48.2 | 52.8 | 46.0 |
| | B | 15.3 | 20.9 | 27.7 | 23.1 | 48.2 | 47.9 | 52.1 | 4.9 | 10.3 | 21.2 | 31.1 | 40.9 | 48.6 | 43.5 |
| | **Mean** | **9.9** | **14.6** | **23.2** | **39.2** | **50.1** | **49.5** | **51.7** | **4.8** | **10.6** | **26.1** | **36.5** | **44.5** | **50.7** | **44.7** |
| SYN545547 | A | ND | ND | 0.5 | 6.7 | 7.8 | 20.5 | 22.4 | ND | ND | 1.4 | 4.6 | 6.5 | 16.3 | 24.9 |
| | B | ND | 1.0 | 1.2 | 1.7 | 9.9 | 9.9 | 20.8 | ND | 0.3 | 1.2 | 3.6 | 6.7 | 11.4 | 28.0 |
| | **Mean** | **ND** | **0.5** | **0.9** | **4.2** | **8.8** | **15.2** | **21.6** | **ND** | **0.2** | **1.3** | **4.1** | **6.6** | **13.9** | **26.5** |
| Unidentified product(s), if any | A | 0.1 | 0.3 | ND | 0.9 | ND | 0.7 | 0.5 | ND | ND | 0.4 | 0.7 | 0.8 | 1.0 | 0.9 |
| | B | ND | ND | ND | 0.2 | ND | 0.6 | 0.7 | ND | 0.3 | 0.4 | 0.5 | 0.5 | 1.4 | 1.4 |
| | **Mean** | **ND** | **0.2** | **ND** | **0.5** | **ND** | **0.7** | **0.6** | **ND** | **0.2** | **0.4** | **0.6** | **0.7** | **1.2** | **1.1** |
| Unresolved Background | A | ND | 0.1 | 0.2 | 0.2 | 0.8 | 0.4 | 0.8 | ND | 0.1 | 0.3 | ND | 0.5 | 0.8 | 0.7 |
| | B | 0.2 | 0.3 | 0.3 | 0.3 | 0.9 | 0.6 | 0.5 | ND | 0.1 | 0.1 | 0.3 | 0.1 | 0.1 | 0.8 |
| | **Mean** | **0.1** | **0.2** | **0.2** | **0.3** | **0.8** | **0.5** | **0.6** | **ND** | **0.1** | **0.2** | **0.2** | **0.3** | **0.5** | **0.8** |

ND = Not detected (or < 0.1%)

**Table B.8. 285 Summary of product distribution in the total system of Swiss Lake, anaerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **47** | **61** | **100** | **0** | **7** | **14** | **30** | **47** | **61** | **100** |
| Parent | A | 92.2 | 93.1 | 86.0 | 82.4 | 77.8 | 74.7 | 61.4 | 93.0 | 88.5 | 89.3 | 86.7 | 78.6 | 75.5 | 61.2 |
| | B | 91.2 | 91.3 | 90.8 | 84.7 | 78.5 | 72.7 | 66.2 | 92.2 | 91.2 | 90.0 | 83.8 | 78.6 | 74.2 | 56.9 |
| | **Mean** | **91.7** | **92.2** | **88.4** | **83.5** | **78.1** | **73.7** | **63.8** | **92.6** | **89.8** | **89.6** | **85.2** | **78.6** | **74.9** | **59.1** |
| SYN545547 | A | 1.9 | 1.6 | 2.6 | 6.3 | 9.1 | 13.1 | 22.6 | 1.5 | 2.0 | 3.5 | 4.2 | 7.6 | 11.5 | 25.1 |
| | B | 1.5 | 2.7 | 2.9 | 5.9 | 9.9 | 13.1 | 21.0 | 2.0 | 1.6 | 2.8 | 3.8 | 8.8 | 10.3 | 24.8 |
| | **Mean** | **1.7** | **2.2** | **2.7** | **6.1** | **9.5** | **13.1** | **21.8** | **1.7** | **1.8** | **3.2** | **4.0** | **8.2** | **10.9** | **24.9** |
| Unidentified product(s), if any | A | 0.7 | ND | ND | 1.2 | 2.3 | 0.5 | 1.9 | 1.3 | 1.5 | 2.0 | 0.6 | 1.6 | 2.1 | 1.0 |
| | B | 1.9 | 1.1 | ND | 0.5 | 1.5 | 3.9 | 1.5 | 1.0 | 0.9 | 0.6 | 1.6 | 3.3 | 3.9 | 5.5 |
| | **Mean** | **1.3** | **0.5** | **ND** | **0.8** | **1.9** | **2.2** | **1.7** | **1.1** | **1.2** | **1.3** | **1.1** | **2.4** | **3.0** | **3.3** |
| Unresolved Background | A | 0.5 | 0.3 | 1.0 | 0.5 | 0.2 | 1.1 | 0.8 | 0.7 | 0.7 | 0.4 | 1.1 | 0.8 | 0.2 | 0.7 |
| | B | 1.6 | 0.8 | 0.8 | 0.9 | 1.0 | 0.9 | 0.4 | 0.4 | 0.8 | 0.9 | 0.9 | 0.6 | 0.7 | 0.7 |
| | **Mean** | **1.0** | **0.5** | **0.9** | **0.7** | **0.6** | **1.0** | **0.6** | **0.6** | **0.7** | **0.7** | **0.9** | **0.7** | **0.5** | **0.7** |

ND = Not detected (or < 0.1%)

**Table B.8. 286 Summary of product distribution in the water column of Swiss Lake, anaerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **47** | **61** | **100** | **0** | **7** | **14** | **30** | **47** | **61** | **100** |
| Parent | A | 83.8 | 77.7 | 67.2 | 44.0 | 31.9 | 31.7 | 19.8 | 87.2 | 75.8 | 67.7 | 54.5 | 42.1 | 28.4 | 22.1 |
| | B | 81.9 | 78.7 | 69.5 | 45.5 | 32.5 | 27.5 | 22.7 | 84.7 | 73.8 | 66.1 | 54.4 | 39.1 | 33.5 | 16.6 |
| | **Mean** | **82.9** | **78.2** | **68.4** | **44.7** | **32.2** | **29.6** | **21.3** | **85.9** | **74.8** | **66.9** | **54.5** | **40.6** | **31.0** | **19.3** |
| SYN545547 | A | 1.9 | 1.6 | 1.8 | 2.7 | 3.4 | 4.8 | 6.0 | 1.5 | 1.6 | 2.3 | 1.8 | 2.7 | 3.1 | 10.6 |
| | B | 1.5 | 2.4 | 1.6 | 2.6 | 3.6 | 4.2 | 6.7 | 1.8 | 1.2 | 1.6 | 1.3 | 3.0 | 3.1 | 11.1 |
| | **Mean** | **1.7** | **2.0** | **1.7** | **2.6** | **3.5** | **4.5** | **6.3** | **1.7** | **1.4** | **2.0** | **1.5** | **2.8** | **3.1** | **10.8** |
| Unidentified product(s), if any | A | 0.7 | ND | ND | 0.6 | 1.4 | ND | 0.8 | 1.3 | 1.4 | 1.6 | ND | 1.0 | 1.3 | ND |
| | B | 1.6 | 1.1 | ND | ND | 1.0 | 2.6 | 0.7 | 1.0 | 0.6 | ND | 1.1 | 2.6 | 2.8 | 4.8 |
| | **Mean** | **1.1** | **0.5** | **ND** | **0.3** | **1.2** | **1.3** | **0.8** | **1.1** | **1.0** | **0.8** | **0.6** | **1.8** | **2.1** | **2.4** |
| Unresolved Background | A | 0.4 | 0.1 | 0.8 | ND | 0.2 | 0.5 | 0.2 | 0.6 | 0.6 | 0.2 | 0.6 | 0.3 | ND | 0.3 |
| | B | 1.6 | 0.5 | 0.5 | 0.4 | 0.2 | 0.5 | 0.2 | 0.4 | 0.6 | 0.9 | 0.4 | 0.5 | 0.6 | 0.3 |
| | **Mean** | **1.0** | **0.3** | **0.7** | **0.2** | **0.2** | **0.5** | **0.2** | **0.5** | **0.6** | **0.5** | **0.5** | **0.4** | **0.3** | **0.3** |

ND = Not detected (or < 0.1%)

**Table B.8. 287 Summary of product distribution in the sediment of Swiss Lake, anaerobic incubation (values as % of applied)**

| | Rep | Sampling times (days) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | [Phenyl-$^{14}$C]-pydiflumetofen | | | | | | | [Pyrazole-5-$^{14}$C]-pydiflumetofen | | | | | | |
| | | **0** | **7** | **14** | **30** | **47** | **61** | **100** | **0** | **7** | **14** | **30** | **47** | **61** | **100** |
| Parent | A | 8.4 | 15.4 | 18.8 | 38.4 | 45.9 | 43.0 | 41.6 | 5.8 | 12.7 | 21.6 | 32.2 | 36.5 | 47.1 | 39.1 |
| | B | 9.3 | 12.6 | 21.3 | 39.2 | 46.1 | 45.1 | 43.4 | 7.5 | 17.4 | 23.9 | 29.4 | 39.5 | 40.7 | 40.3 |
| | **Mean** | **8.8** | **14.0** | **20.1** | **38.8** | **46.0** | **44.0** | **42.5** | **6.7** | **15.1** | **22.7** | **30.8** | **38.0** | **43.9** | **39.7** |
| SYN545547 | A | ND | ND | 0.8 | 3.6 | 5.7 | 8.3 | 16.6 | ND | 0.5 | 1.2 | 2.5 | 4.9 | 8.5 | 14.5 |
| | B | ND | 0.4 | 1.3 | 3.3 | 6.3 | 8.9 | 14.3 | 0.2 | 0.3 | 1.2 | 2.4 | 5.8 | 7.2 | 13.7 |
| | **Mean** | **ND** | **0.2** | **1.1** | **3.5** | **6.0** | **8.6** | **15.4** | **0.1** | **0.4** | **1.2** | **2.4** | **5.4** | **7.8** | **14.1** |
| Unidentified product(s), if any | A | ND | ND | ND | 0.6 | 0.9 | 0.5 | 1.1 | ND | 0.1 | 0.3 | 0.6 | 0.6 | 0.8 | 1.0 |
| | B | 0.3 | ND | ND | 0.5 | 0.5 | 1.3 | 0.8 | ND | 0.3 | 0.6 | 0.5 | 0.7 | 1.1 | 0.7 |
| | **Mean** | **0.2** | **ND** | **ND** | **0.5** | **0.7** | **0.9** | **1.0** | **ND** | **0.2** | **0.4** | **0.5** | **0.6** | **0.9** | **0.9** |
| Unresolved Background | A | 0.1 | 0.2 | 0.2 | 0.5 | 0.1 | 0.6 | 0.6 | 0.1 | 0.1 | 0.2 | 0.5 | 0.5 | 0.2 | 0.5 |
| | B | ND | 0.2 | 0.3 | 0.5 | 0.8 | 0.4 | 0.2 | ND | 0.2 | 0.1 | 0.4 | 0.2 | 0.1 | 0.4 |
| | **Mean** | **0.1** | **0.2** | **0.2** | **0.5** | **0.4** | **0.5** | **0.4** | **ND** | **0.1** | **0.2** | **0.5** | **0.3** | **0.1** | **0.4** |

ND = Not detected (or < 0.1%)

The pydiflumetofen enantiomer ratio was determined in selected sediment and water extracts from samples collected from both the aerobic and anaerobic systems at 100 DAT (47 DAT in the case of one sediment extract) and found to range from 0.92 to 1.04. The ratio was not significantly different to the SYN54597 enantiomer ratio determined in the application stick solution SS2. HSE has also added an assessment of the change in enantiomer excess seen in the study.

**Table B.8. 288 Pydiflumetofen enantiomer ratios in application stock solution and selected water and sediment samples**

| | % Sample activity as | | | | |
|---|---|---|---|---|---|
| **Sample Interval** | **1st eluting enantiomer** | **2nd eluting enantiomer** | **Enantiomer Ratio** | **Enantiomer Excess (ee)** | **Change in ee (%) relative to stock solution** |
| Stock solution (SS2) | 47.40 | 47.34 | 1.00 | 0.06 | |
| Sediment extract, Calwich Abbey, aerobic, 100 DAT | 35.39 | 34.89 | 1.01 | 0.71 | 0.65 |
| Sediment extract, Swiss Lake, aerobic, 45 DAT | 22.36 | 22.88 | 0.98 | -1.15 | 1.21 |
| Surface water, Calwich Abbey, anaerobic, 100 DAT | 5.04 | 5.45 | 0.92 | -3.91 | 3.97 |
| Sediment extract, Calwich Abbey, anaerobic, 100 DAT | 22.01 | 22.26 | 0.99 | -0.56 | 0.63 |
| Surface water, Swiss Lake, anaerobic, 100 DAT | 12.96 | 12.46 | 1.04 | 1.97 | 1.90 |
| Sediment extract, Swiss Lake, anaerobic, 100 DAT | 19.63 | 21.05 | 0.93 | -3.49 | 3.55 |

The enantiomer ratio of pydiflumetofen did not appear to alter significantly during the course of the study with the ratio varying from 0.92 – 1.04. There was no clear trend to consistent change in ratio over time. Taking into consideration the EFSA Stereoisomer guidance as has been done for other parts of the assessment, it was noted that there were relatively small changes in the enantiomer excess over the course of the study. The DT50 values for the whole systems were extrapolated well beyond study duration. Extrapolating the change in enantiomer excess to the point of 50% degradation in the whole system (Calwich Abbey aerobic DT50 244 days; Swiss lake aerobic 252 days) it would be expected that the change in enantiomer excess would be less than 10% in aerobic systems.

The dissipation and degradation rates were calculated using non-linear regression and first-order kinetics (SFO). However, a separate kinetic study ([redacted], 2015a) was submitted and thus the kinetics performed as part of the water/sediment study are not reported. The study of [redacted], 2015a is reported below.

**Conclusion**

The study is acceptable and the results can be agreed by HSE. As the anaerobic water/sediment systems are not generally considered to be particularly representative of natural water bodies associated with the agricultural environment, the results of the anaerobic incubations have not been checked and the results are not used in risk assessment. The results from the aerobic water/anaerobic sediment incubations can be accepted for risk assessment purposes. The comments below relate to the aerobic incubations.

Pydiflumetofen was applied to the test systems in water with acetonitrile as a co-solvent; the acetonitrile concentration was 0.01%. This is less than the OECD 308 maximum recommended concentration of 1% v/v.

Relatively little information on relative changes in enantiomer excess was available. The available information suggested that had the study continued to the point of 50% degradation of pydiflumetofen, the change in enantiomer excess in the aerobic incubations would have been less than 10%.

The route of degradation in water/sediment systems was similar for both aerobic and anaerobic incubation. Carbon dioxide was a minor product of metabolism reaching a maximum of <1% AR. Unextracted residues increased throughout the incubation, reaching maxima of 16.

Pydiflumetofen dissipated relatively rapidly from the water phase, but the main route of dissipation from water was partitioning to sediment. Consequently, whilst there was less than 10% AR as pydiflumetofen in the water phase of both systems by day 30, there was 65 – 80% AR as pydiflumetofen in sediment at the same sample time. Consequently there was slow decline of pydiflumetofen in the whole system with greater than 70% AR remaining as pydiflumetofen in the whole system at the study end (100 days). An additional study of [redacted] 2015a has been submitted with calculated kinetic endpoints from this water/sediment study and has been used in preference to the kinetic calculations performed as part of the water/sediment study. It should also be noted that it was difficult to discern a clear decline phase in sediment in either system, which suggests persistence in sediment. The lack of clear decline in sediment precludes the calculation of a robust dissipation time for sediment; it is noted that there is no attempt to calculate sediment dissipation times in [redacted] 2015a.

Metabolite occurrence in the water phase was low with levels not triggering risk assessment for surface water. However levels of metabolite SYN545547 in sediment were noted to increase over time. Levels were highest in the Calwich Abbey system where levels in sediment rose to a maximum of 13% AR at the study end. Consequently this metabolite needs to be included in risk assessment for sediment.

### B.8.2.2.3.2. Kinetic analysis of data from water/sediment systems

| | |
|---|---|
| **Report:** | K-CA 7.2.2.3/02. [redacted], (2015a), SYN545974 – Laboratory Water/Sediment Degradation Kinetics for Modelling and Persistence Endpoints for Parent at Level PI and Metabolite SYN545547 at Level MI, Report Number SYN/48/01-KIN03. JSC International Limited, Harrogate, North Yorkshire, UK<br>(Syngenta File No. SYN545974_10378). |

| | |
|---|---|
| **Guideline(s):** | FOCUS (2006)[8], FOCUS (2011)[9] |
| **GLP/GEP:** | Not applicable |
| **Deviation(s):** | No major deviation identified |
| **Acceptability** | Yes |

**Material and Methods**

The route and rate of degradation of pydiflumetofen in two aquatic systems has been studied in the laboratory by [redacted], 2015 (see B.8.2.2.3.1). The original data from this study were used in the present report to calculate the rate of degradation of pydiflumetofen and its metabolite SYN545547 in aquatic systems under aerobic conditions, following the flowcharts described in the guidance FOCUS Kinetics (2006, 2011) for persistence and modelling endpoints. The analysis software CAKE v3.1 (2015) was used.

Persistence endpoints were calculated for pydiflumetofen for the whole system (Level PI degradation) and water column (Level PI dissipation); there were too few sampling occasions following the maximum pydiflumetofen occurrence in sediment to derive sediment decline (peak down) kinetics in either system. For the metabolite SYN545547, level MI modelling endpoints were calculated for SYN545547 formed from pydiflumetofen.

Input data were generated according to the data handling recommendations made in the FOCUS guidance for degradation kinetics (FOCUS, 2006, 2011). True replicates were included individually in the optimisations. Aerobic metabolism of pydiflumetofen was investigated using two different 14C radiolabel positions (14C-phenyl and 14C-pyrazolyl) with two replicate systems for each label. As these different labels were incubated under identical conditions and the only major metabolite identified with either label was SYN545547, they were considered as true replicates and fitted simultaneously in the same kinetic model (i.e. four replicates per system for each sampling occasion).

[8] FOCUS (2006). Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005, version 2.0, 434 pp.
[9] FOCUS (2011). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Version 1.0, 436 pp.

Time zero pydiflumetofen concentrations for the water compartment and whole system data were entered in the input data as the total extractable radioactivity (% AR) in the system (water + sediment). Pydiflumetofen concentrations in sediment and metabolite concentrations at time zero were all entered as zero.

Samples below the limit of detection (LOD), just before the first, or just after the last, detectable amount were set to half of the LOD and previous or subsequent samples below the LOD were omitted. Samples below the LOD occurring between two samples above the LOD were also omitted to avoid adverse effects on the optimisation of the models and the goodness of fit assessments.

FOCUS (2006) guidance recommends that appreciable loss of mass balance in individual samples or a decrease in recovery with time should not occur. Recoveries reported in [redacted] (2015) were generally consistent and mean recoveries were ~ 95% with small standard deviation and no decrease of mass balance with time. A larger standard deviation was noted for the Calwich Abbey, phenyl labelled system (±5.1%) and could be attributed to poor recoveries (<90%) in a couple of replicates. As mass balance was very consistent throughout the study, samples with total recovery outside of the range 90% - 110% (replicates A and B for phenyl label and replicate B for pyrazole label at 45 DAT in Calwich Abbey system; replicate A for phenyl label at 14 DAT in Swiss Lake system) were considered as outliers and excluded from the data for kinetic analysis.

It was noted by HSE that the kinetic assessment used the sum of extracted residues from the water and sediment for day 0 input in the kinetic assessment. Normally the day 0 mass balance or radiochemical purity would be expected to be used to account for the true day 0 radioactivity at the point of dosing into the system. However as there was very little mineralisation in any of the incubations (no measurements were made at day 0) and there was only 0.2 – 0.6% AR recorded as unextracted radioactivity at 0 DAT it is considered in this case that there will be little impact on the kinetic assessments from taking this approach. It is appropriate that pydiflumetofen concentrations in sediment at 0 DAT and metabolite concentrations at 0 DAT were assumed to be zero. From scrutiny of the report, the data handling for kinetic fitting was appropriate and in conformity with guidance.

Confidence in the resulting parameters was assessed visually and from the confidence intervals for the $\alpha$ and $\beta$ parameters of the first order multi compartment (FOMC) model or probability values for a t-test of the rate parameters for the single first order (SFO) and dual first order in parallel (DFOP) and hockey-stick (HS) models. Where the parameters for a particular model were not significantly different from zero at the 95th or 90th significance level, it was concluded that the model is not appropriate to represent the degradation behaviour in that system unless the calculated endpoints are conservative and justifiable. The $\chi^2$ error% parameter was used to determine goodness of fit and where two models were an appropriate fit to the data, the choice of best fit was based on the lowest value of this parameter.

**Findings**

*Parent endpoints*

The following tables provide a summary of the model fit statistics and assessment decisions taken. Visual fits and residuals are also presented.

**Table B.8. 289 Level PI whole system trigger and modelling endpoints for pydiflumetofen**

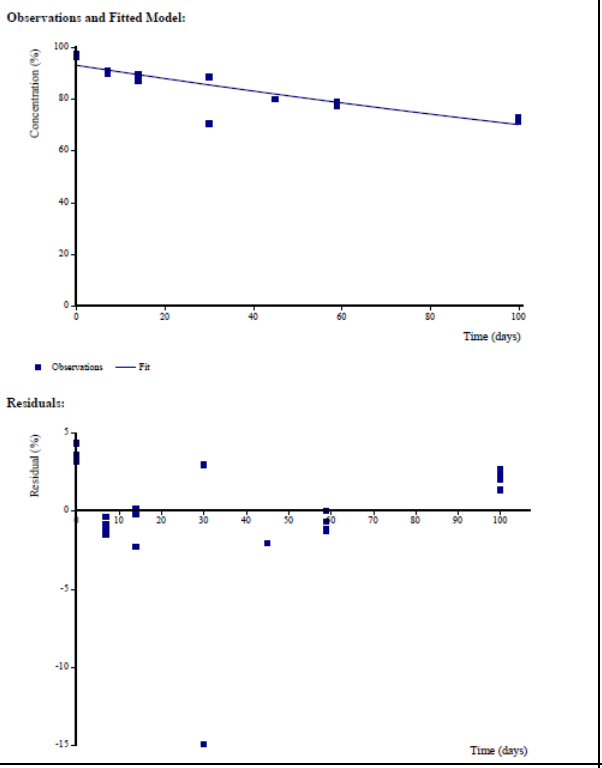
| System | Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / Confidence interval (95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|---|
| Calwich Abbey | SFO | k=0.002836 | Acceptable/Acceptable | 2.82 | k: <0.05 | 244 | 812 |
| | FOMC | α=0.1256<br>β=11.32 | Good/Good | 1.35 | β CI contains 0 | 2810 | >10000 |
| | DFOP | $k_1$=0.06806<br>$k_2$= 0.001521<br>g=0.1293 | Good/Good | 1.42 | $k_1$: <0.10<br>$k_2$: <0.05 | 365 | 1420 |
| | HS | $k_1$=0.01021<br>$k_2$= 0.00228<br>$t_b$=9.853 | Good/Good | 2.10 | $k_1$: <0.05<br>$k_2$: <0.05 | 270 | 976 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP and HS; HS selected<br>Modelling endpoint: SFO selected** | | | | | | |
| Swiss [redacted] | SFO | k=0.002747 | Good/Good | 2.28 | k: <0.05 | 252 | 838 |
| | FOMC | α=0.1073<br>β=8.572 | Good/Good | 1.02 | β CI contains 0 | 5470 | >10000 |
| | DFOP | $k_1$=0.1232<br>$k_2$= 0.001802<br>g=0.103 | Good/Good | 0.90 | $k_1$: >0.10<br>$k_2$: <0.05 | 324 | 1220 |
| | HS | $k_1$=0.01061<br>$k_2$= 0.002004<br>$t_b$=10.91 | Good/Good | 0.89 | $k_1$: <0.05<br>$k_2$: <0.05 | 299 | 1100 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP and HS; HS selected<br>Modelling endpoint: SFO selected** | | | | | | |

**Table B.8. 290 Level PI water column dissipation trigger and modelling endpoints for pydiflumetofen – Calwich Abbey**

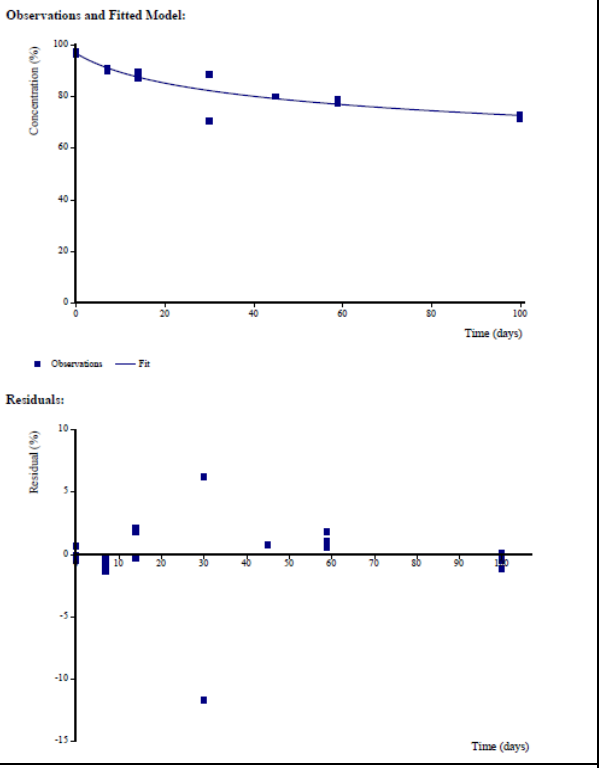
| System | Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / Confidence interval (95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|---|
| Calwich Abbey | SFO | k=0.1305 | Poor/Poor | 18.20 | k: <0.05 | 5.31 | 17.6 |
| | FOMC | α=1.028<br>β=3.725 | Good/Good | 10.40 | α & β CI do not contain 0 | 3.59 | 31.3 |
| | DFOP | $k_1$=2.665<br>$k_2$= 0.04446<br>g=0.5645 | Good/Good | 9.01 | $k_1$: <0.05<br>$k_2$: <0.05 | 0.74 | 33.1 |
| | HS | $k_1$=0.1324<br>$k_2$= 0.01536<br>$t_b$=18.71 | Acceptable/Acceptable | 18.80 | $k_1$: <0.05<br>$k_2$: >0.10 | 5.24 | 17.4 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP and HS; DFOP selected<br>Modelling endpoint: SFO not acceptable, 10% of initial concentration reached → fit FOMC, HS or DFOP; DFOP most appropriate → DT50 back calculated from $DT_{90}$** | | | | | | |
| Swiss Lake | SFO | k=0.03631 | Poor/Poor | 17.80 | k: <0.05 | 19.1 | 63.4 |
| | FOMC | α=0.7183<br>β=5.991 | Good/Good | 7.09 | α & β CI do not contain 0 | 9.73 | 142 |
| | DFOP | $k_1$=0.3451<br>$k_2$= 0.02023<br>g=0.4161 | Good/Good | 4.69 | $k_1$: <0.05<br>$k_2$: <0.05 | 9.33 | 87.2 |
| | HS | $k_1$=0.087<br>$k_2$= 0.0204<br>$t_b$=7.947 | Good/Good | 4.69 | $k_1$: <0.05<br>$k_2$: <0.05 | 8.03 | 86.9 |
| | **Trigger endpoint: FOMC better than SFO → fit DFOP and HS; HS selected<br>Modelling endpoint: SFO not acceptable, 10% of initial concentration reached → fit FOMC, HS or DFOP; HS most appropriate → DT50 back calculated from $DT_{90}$** | | | | | | |

**Figure B.8. 50 Visual fit and residuals for parent for Calwich Abbey – whole system**

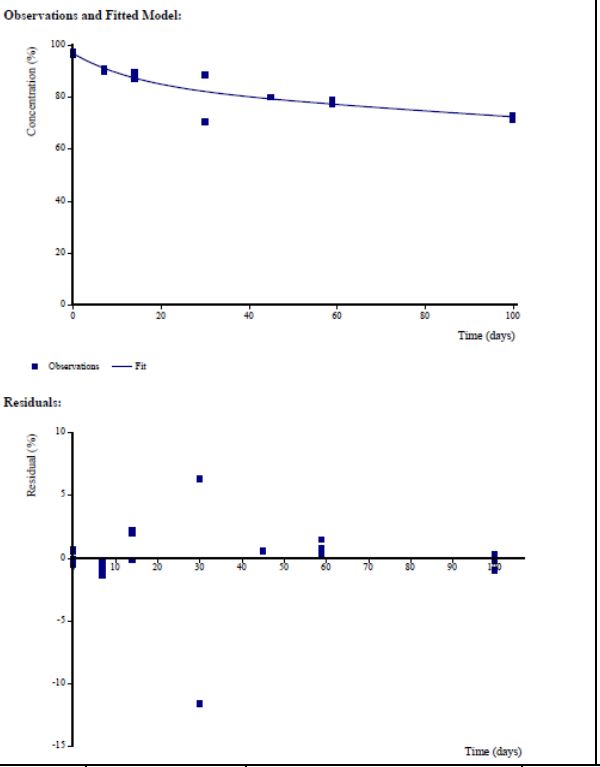
SFO



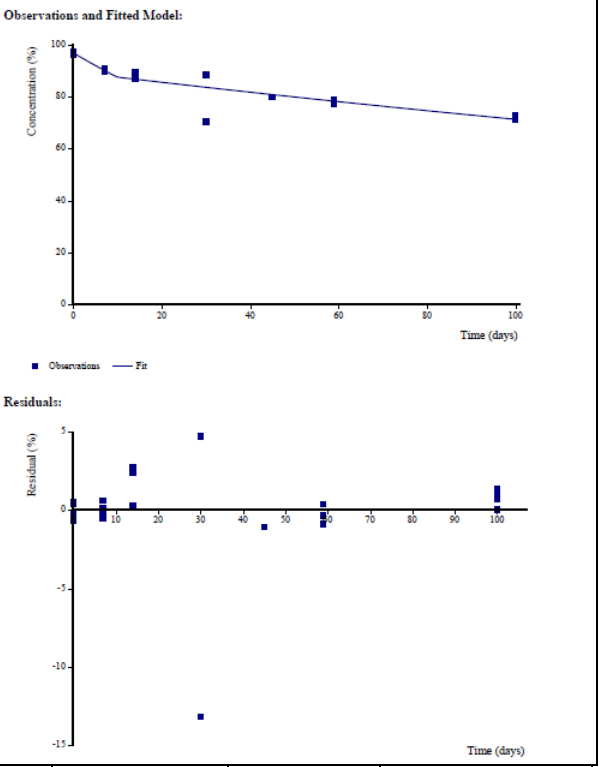

FOMC




DFOP



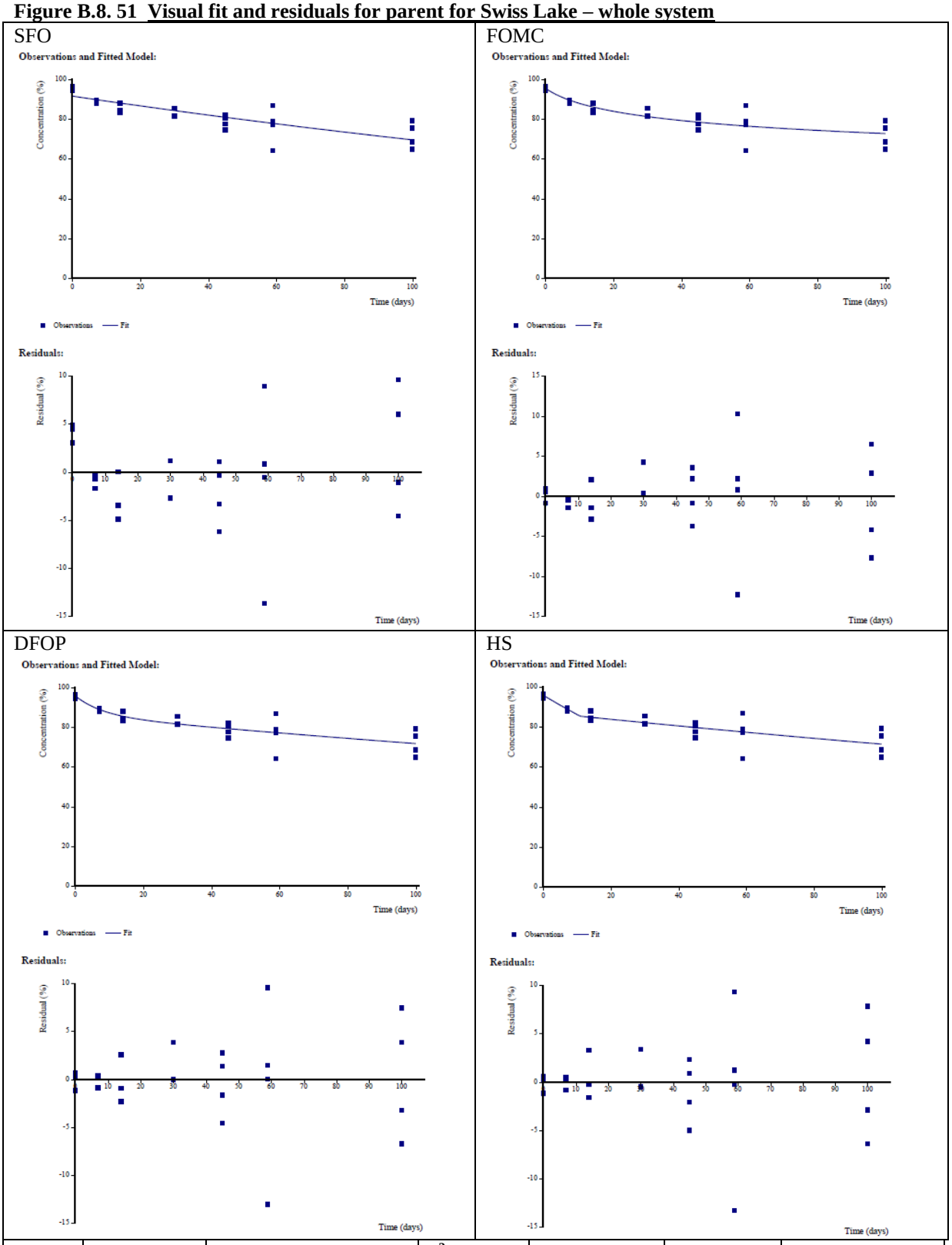

HS




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.002836 | Acceptable/Acceptable | 2.82 | k: <0.05 | 244 | 812 |
| FOMC | α=0.1256 β=11.32 | Good/Good | 1.35 | β CI contains 0 | 2810 | >10000 |
| DFOP | $k_1$=0.06806 | Good/Good | 1.42 | $k_1$: <0.10 | 365 | 1420 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | $k_2$= 0.001521 g=0.1293 | | | $k_2$: <0.05 | | |
| HS | $k_1$=0.01021 $k_2$= 0.00228 $t_b$=9.853 | Good/Good | 2.10 | $k_1$: <0.05 $k_2$: <0.05 | 270 | 976 |
| **Trigger endpoint: FOMC better than SFO → fit DFOP and HS; HS selected Modelling endpoint: SFO selected** | | | | | | |

**Figure B.8. 51 Visual fit and residuals for parent for Swiss Lake – whole system**

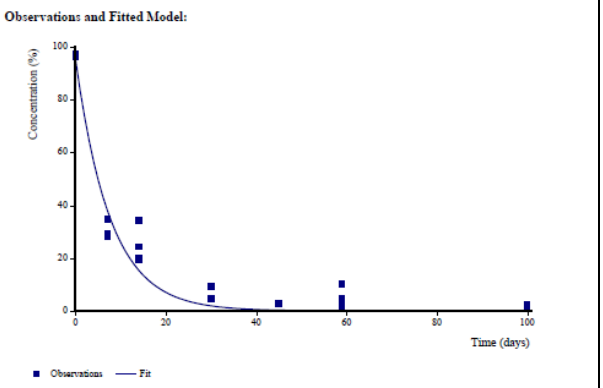


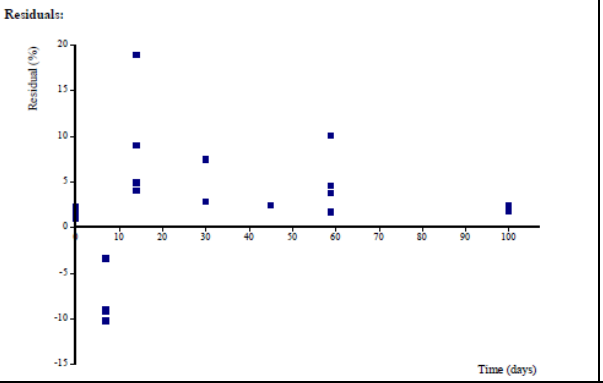

| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.002747 | Good/Good | 2.28 | k: <0.05 | 252 | 838 |
| FOMC | α=0.1073 β=8.572 | Good/Good | 1.02 | β CI contains 0 | 5470 | >10000 |
| DFOP | $k_1$=0.1232 | Good/Good | 0.90 | $k_1$: >0.10 | 324 | 1220 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | $k_2$= 0.001802 g=0.103 | | | $k_2$: <0.05 | | |
| HS | $k_1$=0.01061 $k_2$= 0.002004 $t_b$=10.91 | Good/Good | 0.89 | $k_1$: <0.05 $k_2$: <0.05 | 299 | 1100 |
| **Trigger endpoint: FOMC better than SFO → fit DFOP and HS; HS selected Modelling endpoint: SFO selected** | | | | | | |

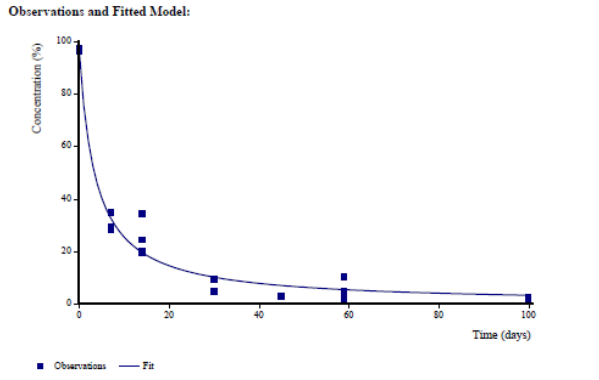
**Figure B.8. 52 Visual fit and residuals for parent for Calwich Abbey – water**

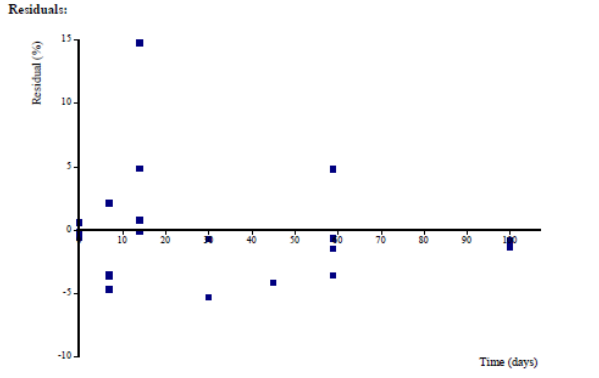
SFO



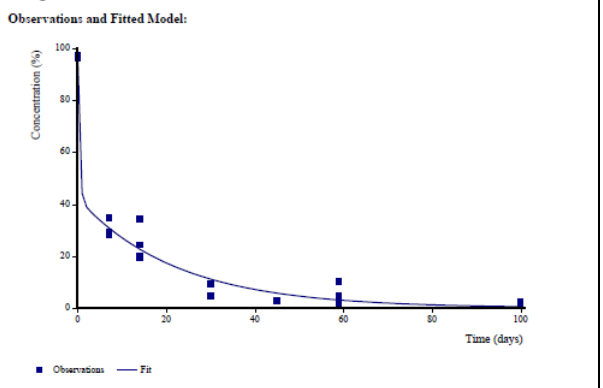



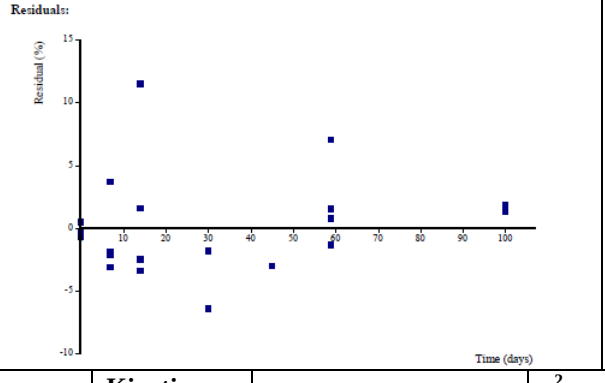

FOMC



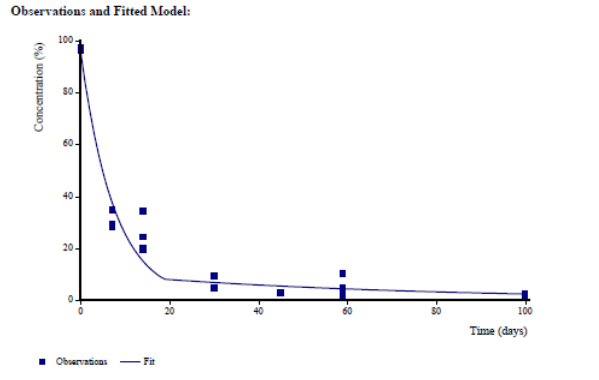



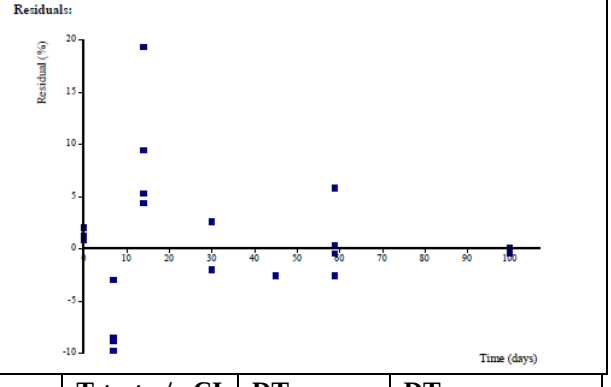

DFOP




HS



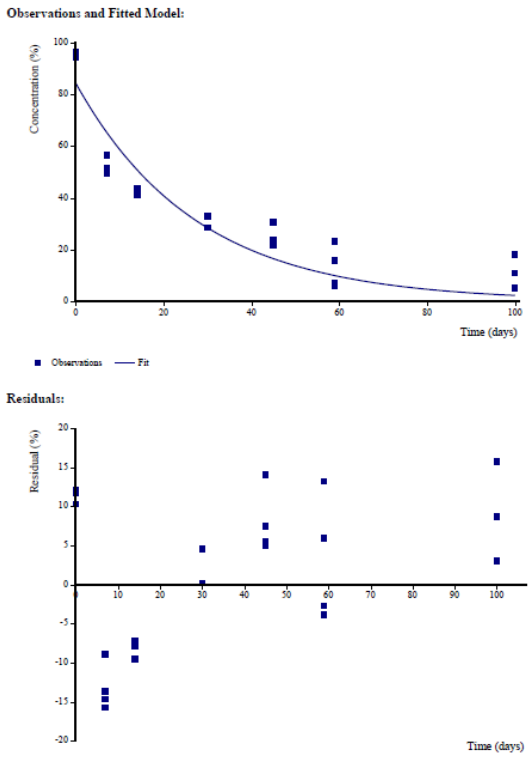




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.1305 | Poor/Poor | 18.20 | k: <0.05 | 5.31 | 17.6 |
| FOMC | α=1.028<br>β=3.725 | Good/Good | 10.40 | α & β CI do not contain 0 | 3.59 | 31.3 |
| DFOP | $k_1$=2.665 | Good/Good | 9.01 | $k_1$: <0.05 | 0.74 | 33.1 |

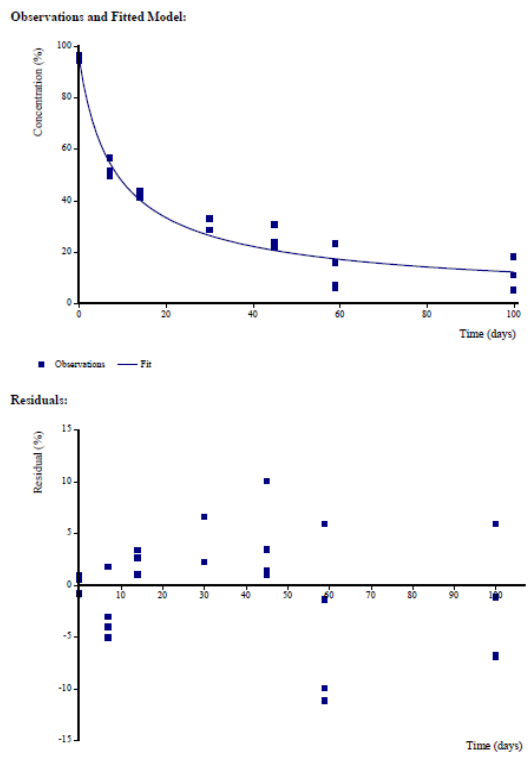
| | | | | | | |
|---|---|---|---|---|---|---|
| | $k_2$= 0.04446<br>g=0.5645 | | | $k_2$: <0.05 | | |
| HS | $k_1$=0.1324<br>$k_2$= 0.01536<br>$t_b$=18.71 | Acceptable/Acceptable | 18.80 | $k_1$: <0.05<br>$k_2$: >0.10 | 5.24 | 17.4 |
| **Trigger endpoint: FOMC better than SFO → fit DFOP and HS; DFOP selected**<br>**Modelling endpoint: SFO not acceptable, 10% of initial concentration reached → fit FOMC, HS or DFOP; DFOP most appropriate → DT50 back calculated from $DT_{90}$** | | | | | | |

**Figure B.8. 53 Visual fit and residuals for parent for Swiss Lake – water**

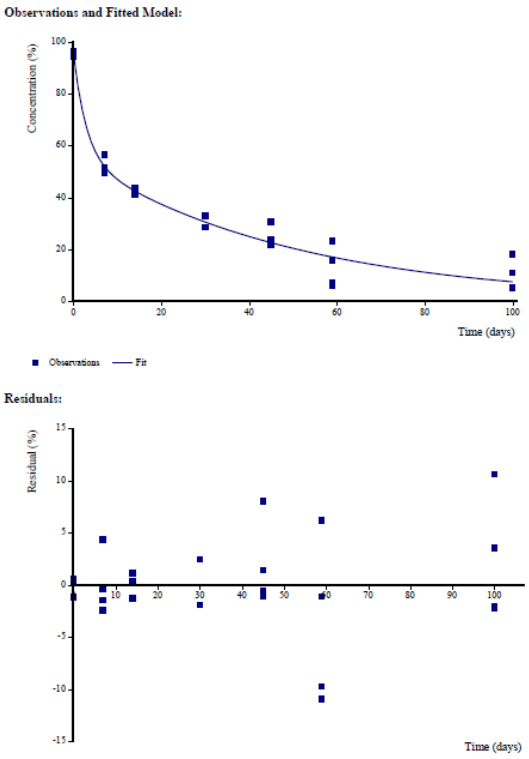
SFO



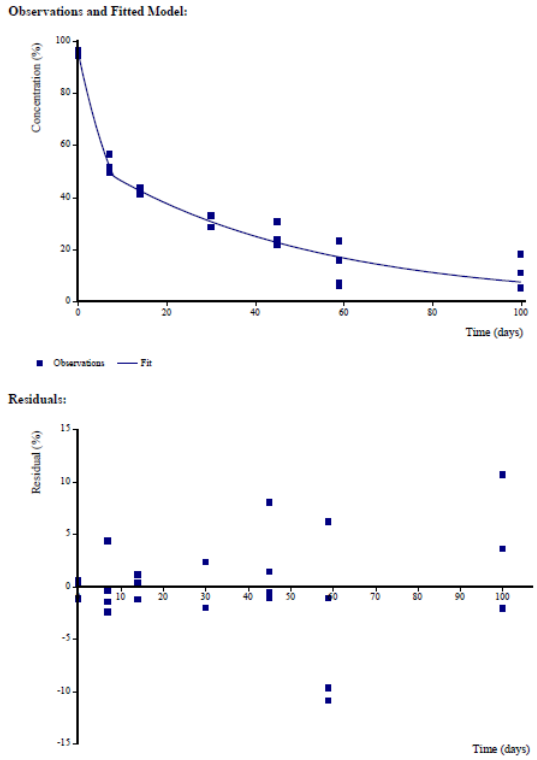

FOMC




DFOP




HS




| Model | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / CI (95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| SFO | k=0.03631 | Poor/Poor | 17.80 | k: <0.05 | 19.1 | 63.4 |
| FOMC | α=0.7183 β=5.991 | Good/Good | 7.09 | α & β CI do not contain 0 | 9.73 | 142 |
| DFOP | $k_1$=0.3451 | Good/Good | 4.69 | $k_1$: <0.05 | 9.33 | 87.2 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | $k_2$= 0.02023<br>g=0.4161 | | | $k_2$: <0.05 | | |
| HS | $k_1$=0.087<br>$k_2$= 0.0204<br>$t_b$=7.947 | Good/Good | 4.69 | $k_1$: <0.05<br>$k_2$: <0.05 | 8.03 | 86.9 |
| **Trigger endpoint: FOMC better than SFO → fit DFOP and HS; HS selected**<br>**Modelling endpoint: SFO not acceptable, 10% of initial concentration reached → fit FOMC, HS or DFOP; HS most appropriate → DT50 back calculated from $DT_{90}$** | | | | | | |

*Metabolite SYN 545547 endpoints*

The following table provides a summary of the model fit statistics and assessment decisions taken. Visual fits and residuals are also presented. SFO kinetics were selected to calculate modelling endpoints for pydiflumetofen at Level PI and provided an acceptable description of >90% of the observed parent degradation in both systems. SFO parent kinetics were, therefore, selected as the basis of the metabolite calculations in accordance with FOCUS (2006) guidance.

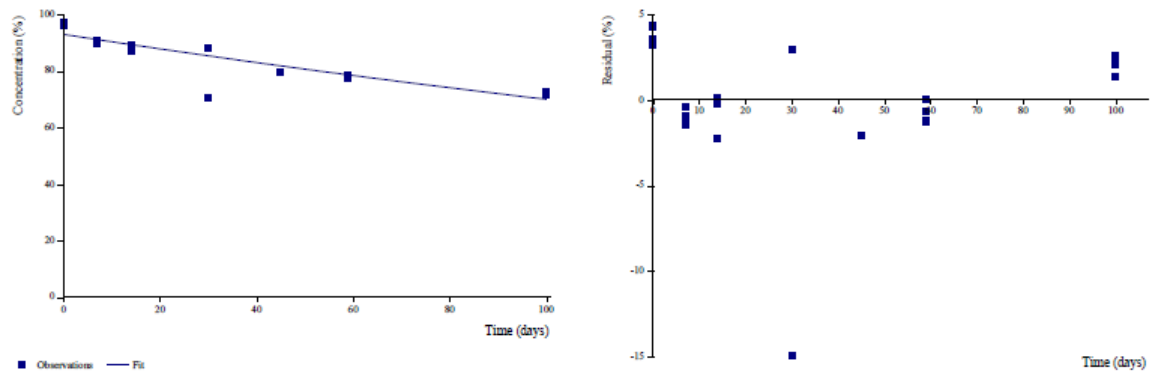
**Table B.8. 291 Level MI whole system modelling endpoints for SYN545547 (Parent SFO / Metabolite SFO)**

| System | Compound | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / Confidence interval (95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|---|
| Calwich Abbey | Parent | k=0.002835 | - | 2.82 | k: <0.05 | 245 | 812 |
| | Metabolite | k=0.001523<br>ffm=0.60 | Good/Good | 10.4 | k: >0.10 | 455 | 1510 |
| | **Trigger & modelling endpoint: SFO metabolite acceptable** | | | | | | |
| Swiss Lake | Parent | k=0.002737 | - | 2.28 | k: <0.05 | 253 | 841 |
| | Metabolite | k=0.03723<br>ffm=0.96 | Good/Good* | 12.8 | k: <0.05 | 18.6 | 61.9 |
| | **Trigger & modelling endpoint: SFO metabolite acceptable** | | | | | | |

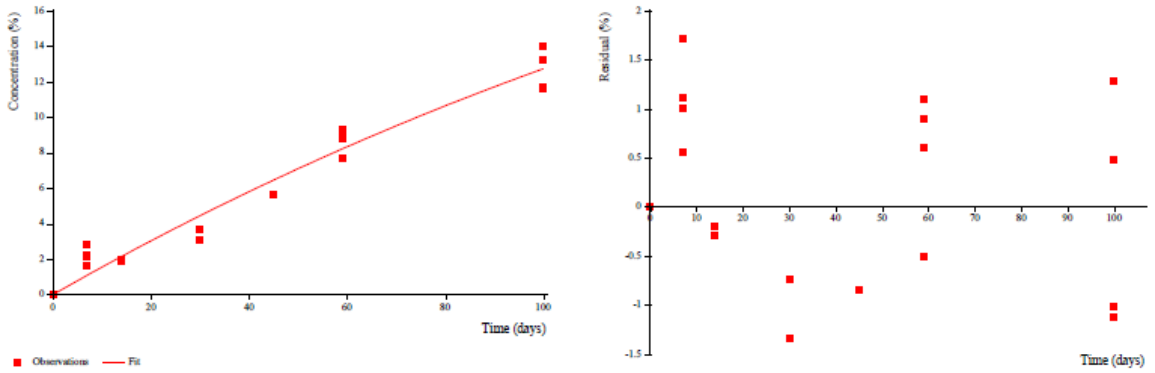
* study authors view of goodness of visual fit. HSE is not in full agreement as the data are quite scattered.

**Figure B.8. 54 Visual fit and residuals for parent / metabolite for Calwich Abbey – whole system**

Parent SFO



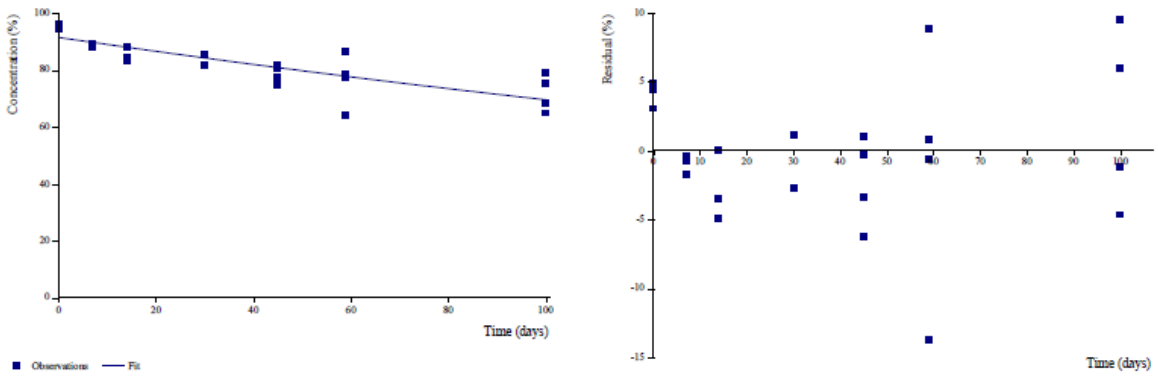

Metabolite SFO



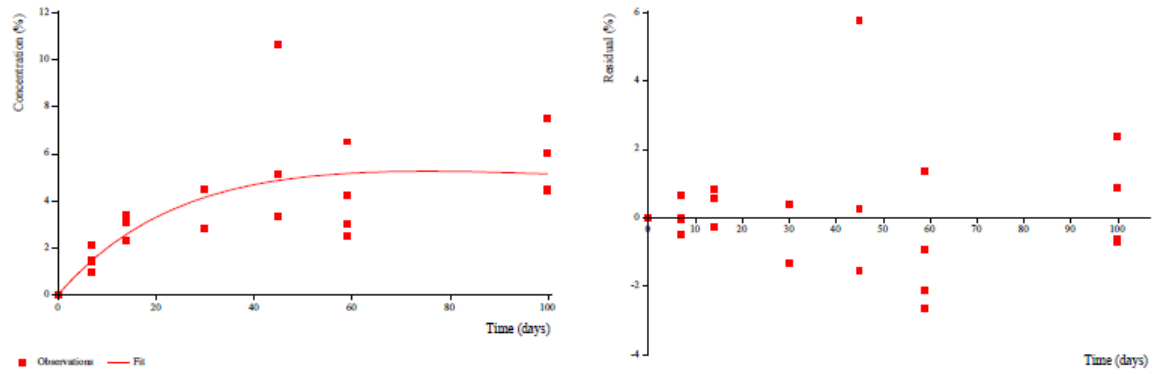

| Compound | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / Confidence interval (95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| Parent | k=0.002835 | - | 2.82 | k: <0.05 | 245 | 812 |
| Metabolite | k=0.001523 ffm=0.60 | Good/Good | 10.4 | k: >0.10 | 455 | 1510 |
| **Trigger & modelling endpoint: SFO metabolite acceptable** | | | | | | |

**Figure B.8. 55 Visual fit and residuals for parent / metabolite for Swiss Lake – whole system**

Parent SFO



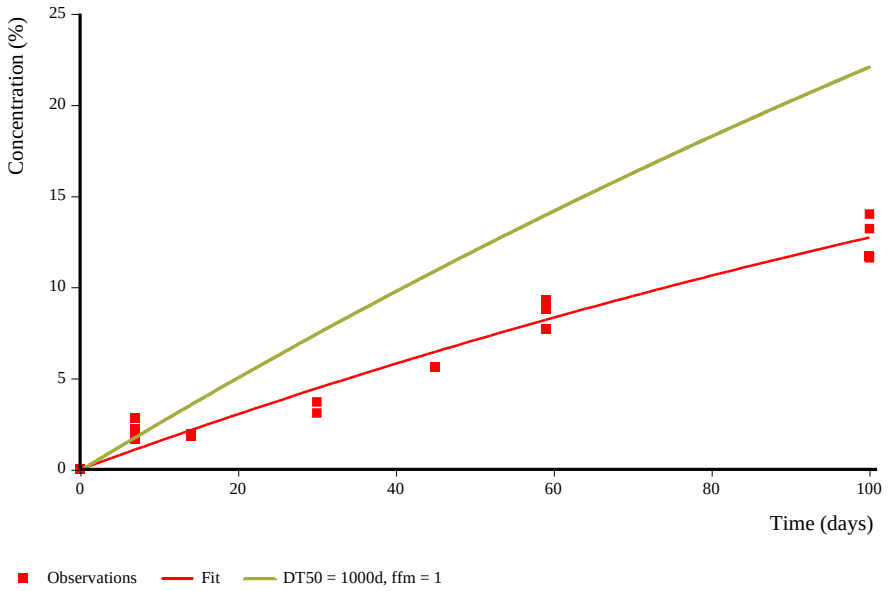

Metabolite SFO




| Compound | Kinetic parameters | Visual fit/residuals | $\chi^2$ error % | T-test / Confidence interval (95%) | $DT_{50}$ (days) | $DT_{90}$ (days) |
|---|---|---|---|---|---|---|
| Parent | k=0.002737 | - | 2.28 | k: <0.05 | 253 | 841 |
| Metabolite | k=0.03723 ffm=0.96 | Good/Good* | 12.8 | k: <0.05 | 18.6 | 61.9 |
| **Trigger & modelling endpoint: SFO metabolite acceptable** | | | | | | |

In Calwich Abbey system, the estimated degradation rate for metabolite SYN 545547 is very small and, therefore, not statistically different from zero. The study author considered that the $DT_{50}$ and formation fraction provided a suitable estimation of the rate of formation and should be considered more suitable than conservative default values ($DT_{50}$ = 1000 days, ffm = 1; see following figure). HSE considers that there is much uncertainty over the kinetic values for the metabolite given the lack of decline. In addition, the 1000 day value is the 'degradation' rate and not the overall decline rate. Thus HSE considers that a default sediment SFO dissipation DT50 of 1000 days is appropriate to use in the GB methodology for calculation of PECsed values.

**Figure B.8. 56 Whole system modelling for SYN545547- Comparison of fitted endpoints (DT50 = 455 days, ffm = 0.6) and worst case defaults ($DT_{50}$ = 1000 days, ffm = 1.0)**




*Summary of selected endpoints*

A summary of the selected endpoints is provided in the following tables.

**Table B.8. 292 Summary of Level PI whole system endpoints for pydiflumetofen**

| System Name | Trigger endpoints | | | Modelling[1] endpoint | |
|---|---|---|---|---|---|
| | Calculated $DegT_{50}$ (days) | Calculated $DegT_{90}$ (days) | Kinetic Model | Calculated $DegT_{50}$ (days) | Kinetic Model |
| Calwich Abbey | 270 | 976 | HS | 244 | SFO |
| Swiss Lake | 299 | 1100 | HS | 252 | SFO |

[1] Whole system modelling endpoint calculated principally for FOCUSsw modelling purposes in EU. A DT50 of 1000 days is proposed for assessment of exposure of sediment to pydiflumetofen.

**Table B.8. 293 Summary of Level PI water column dissipation endpoints for pydiflumetofen**

| System Name | Trigger endpoints | | | Modelling[1] endpoint | |
|---|---|---|---|---|---|
| | Calculated $DegT_{50}$ (days) | Calculated $DegT_{90}$ (days) | Kinetic Model | Calculated $DegT_{50}$ (days) | Kinetic Model |
| Calwich Abbey | 0.74 | 33.1 | DFOP | 10.0* | DFOP |
| Swiss Lake | 8.03 | 86.9 | HS | 26.2* | HS |

[1] Water phase modelling endpoint is applicable to GB/NI PECsw approach.

* $DT_{50}$ calculated from DT90 / 3.32

**Table B.8. 294 Summary of Level MI whole system modelling[1] endpoints for SYN545547**

| System Name | Calculated $DegT_{50}$ (days) | Formation fraction | Kinetic Model |
|---|---|---|---|
| Calwich Abbey | 455 | 0.60 | SFO |
| Swiss Lake | 18.6 | 0.96 | SFO |

[1] Modelling endpoint calculated principally for FOCUSsw modelling purposes in EU. Not applicable to GB/NI PECsw approach. A DT50 of 1000 days is proposed for assessment of sediment exposure to this metabolite.

**Conclusion**

Overall the kinetic modelling is considered by HSE to be acceptable . A summary of the validated endpoints is presented under B.8.2.5.

With respect to fitting and the choice of kinetic parameters, HSE has the following comments.

Pydiflumetofen Calwich Abbey whole system: study author chose HS for the 'trigger' endpoint. None of the fitting was poor. Whilst the $\chi^2$ parameter for HS is better than SFO, it is inferior to both FOMC and DFOP. However the study author choice appears to be driven by the fact that of the three biphasic models, HS had the more reliable statistical assessment, i.e. FOMC 95$^{th}$ percentile confidence interval for β included 0, DFOP k2 values has a relatively high p value, i.e.>0.05. Greater weight is typically placed on visual fitting rather than on the statistical parameters. However given that the outcome of the assessment is that pydiflumetofen is still very persistent with the DT50 extrapolated well beyond study end, it is considered that HS can be accepted as the kinetic for pydiflumetofen in the Calwich Abbey total system for comparison to persistence 'triggers'. The choice of SFO for the modelling whole system endpoint is appropriate.

Pydiflumetofen Calwich Abbey water phase: note that the endpoint for water phase dissipation is particularly pertinent to GB-specific assessment of concentration in surface water. The choice of DFOP for both 'trigger' and modelling endpoints is appropriate. SFO appeared to be inferior and not an appropriate choice as it over-estimated dissipation out of the water phase after the second sample time.

Pydiflumetofen Swiss Lake whole system: study author chose HS for the 'trigger' endpoint. As for Calwich Abbey, none of the fitting was poor. HS gave the lowest $\chi^2$ parameter of the four kinetic models and biphasic kinetics were better than SFO; the differences between fits were not large. HS also has the advantage that it had better statistical parameters than the other biphasic models. Therefore HS can be accepted as the 'trigger' endpoint for pydiflumetofen in the Swiss Lake whole system. The choice of SFO for the modelling whole system endpoint is appropriate.

Pydiflumetofen Swiss Lake water phase: SFO is clearly inferior to biphasic kinetics. Both HS and DFOP gave better fitting than FOMC and appeared to give almost identical results in terms of visual fit, residuals, statistics and optimised parameters. The choice of HS for both trigger and modelling endpoints is acceptable.

HSE can accept the whole system trigger values for pydiflumetofen derived at level PI. $DT_{50}$ were 270-299 days ($DT_{90}$ 976-1100 days) and water column dissipation trigger $DT_{50}$ values were 0.74-8.03 days ($DT_{90}$ 33.1-86.9 days).

Whole system modelling $DegT_{50}$ values for pydiflumetofen at level PI were 244-252 days. Water column dissipation modelling $DT_{50}$ values were 10 – 26.2 days.

For environmental exposure assessment in GB, the modelling endpoints for dissipation from the water column are important with respect to calculation of PECsw via spray drift; the DT50 of 26.2 days is appropriate for use in PECsw, spray drift calculations. The decline of pydiflumetofen in the water column was driven principally by partitioning into sediment rather than by degradation. Taking the results from both radiolabelled incubations for each of the water/sediment systems, it was difficult to discern a clear decline phase in sediment, possibly because residues of pydiflumetofen in the water phase continued to partition to sediment late into the study. No attempt was made to calculate a dissipation rate from sediment, and indeed this would not have been possible due to the lack of a clear decline phase. However whole system kinetic parameters were calculated. The residues in the whole system demonstrated clear, if slow decline. However this decline was not clearly seen in the sediment during the 100 day duration of the study. Given the lack of decline HSE considers it not appropriate to use the whole system DT50 to represent dissipation from the sediment. Therefore a default DT50 of 1000 days will be used to give a representation of potential accumulation in sediment.

The applicant fitting of metabolite SYN545547 used total system data. Given that pydiflumetofen dissipation from the water phase was predominantly via partitioning to sediment rather than by degradation, the majority of the formation of the metabolite was likely to be in the sediment. The relatively low concentrations of the metabolite in the water phase in both systems means that calculation of whole system degradation rates for the metabolite is reasonable.

It should also be noted that whole system kinetic parameters are typically not used in GB aquatic exposure assessments, thus the information is mainly of academic interest. However, it is clear that the metabolite did not demonstrate any clear decline and thus it is not possible to calculate kinetics relating to decline of this metabolite. From the residue profile it is possible that the metabolite could be persistent although it is difficult to interpret this because of the slow degradation of parent pydiflumetofen in the water/sediment systems. In light of this it is considered that a DT50 of 1000 days should be used in the calculation of accumulation in sediment using the current HSE method of PECsed calculation for the purposes of a conservative assessment.

Metabolite SYN545547 Calwich Abbey whole system: the fitting of SFO/SFO kinetics to parent and the metabolite data gave a reasonable fit. It is noted that the metabolite was still increasing at the study end and therefore there will be some uncertainty over the robustness of the optimised parameters.

Metabolite SYN545547 Swiss Lake whole system: the fitting of SFO/SFO kinetics to parent and the metabolite data gave a reasonable fit. The fitted curve for the metabolite does not appear to give a clear decline phase, rather that the concentration was plateauing. However the data from the final three sample times are relatively scattered and it is not clear from visual inspection whether concentration was still increasing or plateauing. Consequently there will be some uncertainty over the robustness of the optimised parameters.

The persistence of pydiflumetofen must also be considered in relation to the non-approval criteria within the POP, PBT and vPvB classifications specified in Regulation 1107/2009. Within each of the POP, PBT and vPvB classifications, separate criteria are available for water and sediment. Within the PBT and vPvB classifications, differentiation is made between freshwater, estuarine and marine systems. For pydiflumetofen, the appropriate system is freshwater as the water/sediment systems were sourced from freshwater environments.

EU guidance retained in GB on the interpretation of substance endpoints in relation to the POP, PBT and vPvB criteria indicate that that for data from water/sediment studies it must be established whether the water or the sediment is the degrading compartment. Once this is established, the whole system DT50 is compared to the appropriate water or sediment criterion. For pydiflumetofen, dissipation from the water column appears to be driven predominantly by partitioning to sediment. The results of the aerobic mineralisation study also suggest very slow degradation in non-sterile water. Thus it is likely that sediment is the dominant degrading compartment.

The relevant criteria for sediment in the classification schemes are:

PBT – half-life in freshwater sediment >120 days
vPvB - half-life in freshwater sediment >180 days
POP – DT50 in sediment >6 months (i.e. approximately 180 days)

The use of the term ‘half-life’ for the PBT and vPvB criteria for persistence suggest the use of SFO kinetics. For pydiflumetofen, the SFO DT50 (equivalent to half-life) values for the whole system were 244 – 252 days. Therefore pydiflumetofen meets the ‘P’ criterion in PBT classification and ‘vP’ criterion in vPvB classification.

For POP, the DT50 can be taken into account. This implies that biphasic kinetics could be used if this is the best expression of decline by degradation. The best fit kinetics for pydiflumetofen in the whole system was hockey-stick (HS). The DT50 values for the whole system using HS kinetics were 270 – 299 days. Therefore pydiflumetofen meets the ‘P’ criterion in POP classification.

#### B.8.2.2.4. Irradiated water/sediment studies

No data were provided. However sufficient information is available on the photo-chemical degradation of pydiflumetofen from the available photolysis study. The potential photolysis products identified in this study have been included in the risk assessment. An irradiated water-sediment dissipation study is therefore not required and further data are not provided.

### B.8.2.3. Degradation in the saturated zone

No data are available or are considered to be required.

### B.8.2.4. Impact of water treatment procedure

Information on the effect of water treatment processes on the nature of residues when water is abstracted for drinking water is needed according to Article 4(3) of Regulation (EC) No 1107/2009 which requires that '[the plant protection product] shall have no immediate or delayed harmful effects on human health, including that of vulnerable groups, or animal health,….through drinking water (taking into account substances resulting from water treatment)'.

The following statement was provided by the applicant.

"*No agreed guidance exists for assessing the effects of water treatment processes on residues that may occur in drinking water nor is there a data requirement in Regulations 283/2013 and 284/2013. The potential formation of harmful substances from water treatment processes such as chlorination, ozonation or UV radiation is applicable to any organic chemical in raw water and is not specific to pesticides. Ground and surface water FOCUS scenarios are set up to estimate the potential movement of a pesticide in very conservative conditions and, as such, the predicted concentrations are most likely significant over estimates of concentrations at the drinking water abstraction point. The surface water concentrations are modelled for a ditch at the edge of a field and any residues, if present, will be significantly diluted once they reach the main streams and rivers. Further dissipation and degradation will occur in the stream and river systems before reaching any potential abstraction point. Groundwater concentrations in the FOCUS models are predicted for 1 m soil depth and they will be further diluted should any reach a ground water aquifer used for drinking water.*

*Considering the proposed use of A19649B according to "Good Agricultural Practice", the maximum concentrations of SYN545974 and its metabolites, predicted from the FOCUS scenarios and assuming reasonable dilution factors, any hypothetical degradates that could be produced would enter water treatment at concentrations well below the appropriate threshold of toxicological concern[10,11] (45 µg/L for general toxicity, 0.075 µg/L if they have a genotoxicity alert, and 20% of each if they were also found in the diet[12]).*

*Input trace levels of SYN545974 and its metabolites in water abstracted for drinking are expected to be significantly reduced due to the initial aeration, flocculation and filtration processes. Subsequent oxidation/sterilisation procedures are expected to further reduce these concentrations. Any further degradates produced as a consequence will only occur at extremely low levels where exposure would not cause any concern, and these in turn will also be subject to further removal processes.*

*Considering the low predicted concentrations in ground and surface water following the proposed use of A19649B, potential treatment of SYN545974 and its metabolites in drinking water is not expected to produce degradates of toxicological hazard at levels that could cause unacceptable risk via this route.*"

It was noted that the statement provided by the applicant is based on a comparison between the concentrations of pydiflumetofen and its metabolites in water with the threshold of toxicological concern (TTC approach). It was noted that the TTC approach is only suitable for metabolites for which no toxicity reference value is defined (here SYN548261 and SYN545547). In addition, the statement from the applicant was general and no quantitative assessment based on the PECsw values was provided. As a consequence, this part of the requirement was considered as being not addressed.

It was also noted that the information provided did not specifically address the fate of pydiflumetofen and its metabolites once they are submitted to water treatment processes such as ozonation or chlorination. No information on the potential novel metabolites formed following these processes is available.

[10] EFSA Scientific Committee; Scientific Opinion on exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC). EFSA Journal 2012; 10(7):2750 [103 pp.] doi:10.2903/j.efsa.2012.2750

[11] Kroes R, Renwick A G, Cheeseman M A, Kleiner J, Mangelsdorf I, Piersma A, Schilter B, Schlatter J, van Schothorst F, Vos J G, Wurtzen G, 2004. Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet. Food and Chemical Toxicology 42: 65-83

[12] WHO 2011 Guidelines for Drinking-Water Quality, 4th Ed, 564 pp

Whilst GB is no longer part of the EU, a historical perspective of a.s. evaluations made before and after EU Exit indicates it has become increasingly common for applicants to address this Article of Regulation 1107/2009 by consideration of the following:

- An initial screening step based on examination of substance structure for potential formation of harmful degradates/metabolites/residues;
- If these harmful degradates/metabolites/residues are predicted, then risk mitigation-based approaches should be invoked.
- If risk mitigation leads to severe restrictions, then applicants should consider the generation of degradation data to disprove the prediction.
- If the prediction is confirmed, modelling or monitoring data showing levels of these harmful degradates are below 0.1 µg/l will have to be generated by the applicant(s) for the restrictions to be lifted.

The applicant was requested to address the impact on water treatment in a similar manner to that shown above. The applicant declined to do so, citing the lack of guidance. A data gap related to this issue will be identified. The time scale for submission of these data should be linked to adoption of advice in GB on this issue, for example within two years of adoption of guidance. At the time of writing the timescale for adoption of such guidance in GB is not known.

### B.8.2.5. Summary on route and rate of degradation in water

The fate and behaviour of pydiflumetofen in water was investigated using both [$^{14}$C]-phenyl labelled and [$^{14}$C]-pyrazole labelled test substance, except for hydrolysis which was studied with [$^{14}$C]-pyrazole labelled test substance only. Data reported below correspond to mean replicate values.

Pydiflumetofen was stable to hydrolysis under acidic, neutral and alkaline conditions at 50°C. It is therefore expected to be stable at 25°C.

Aqueous photolysis of pydiflumetofen was studied in pH7 buffer (direct photolysis) and in natural water (indirect photolysis). Pydiflumetofen was degraded, primarily by dechlorination and phenyl ring degradation to produce phenyl-hydroxylated metabolites, carboxylic acid metabolites and carbon dioxide. Estimated DT50 were 93 and 35 days (summer sunlight 30-50°N) in pH 7 buffer and natural water, respectively. No photo-degradates reached levels ≥ 5% AR via direct photolysis. Photolysis in natural water led to the formation of SYN548261 at ≥ 5% AR at two consecutive sampling intervals (maximum 7.3% AR after 21 days) and NOA449410 at a maximum level of 5.8% AR by the end of the experimental period (30 days). It is considered that these two metabolites trigger inclusion in the environmental exposure assessment for surface water.

Pydiflumetofen was not readily biodegradable under the conditions of the available test.

The aerobic mineralisation and degradation of pydiflumetofen in surface water was determined in the laboratory under dark conditions and light/dark conditions. No significant degradation of pydiflumetofen was observed throughout the study. Mineralization was low (< 1%) in all systems tested. DT50 were extrapolated beyond the study period in all incubation groups and ranged from 637 to >1000 days for dark incubation and from 402 to 662 days for light/dark incubation.

The rate and route of degradation of [$^{14}$C]-pydiflumetofen has been investigated in two water-sediment systems under laboratory aerobic and anaerobic conditions in the dark. The results from the aerobic incubation are used as it is generally considered in regulatory assessments that these are the better representation of surface water bodies associated with agricultural systems.

In the aerobic systems 70-74% of applied pydiflumetofen remained in the total systems after 100 days (end of study). Pydiflumetofen dissipated relatively rapidly from the water phase. The main route of dissipation from water was partitioning into sediment with up to 79% AR being observed at day 30. There was no clear decline phase of the residues in sediment. Only one metabolite was observed at levels above 5% AR and this was identified as SYN545547. It increased throughout the duration of the study and accounted for up to 12.3% AR in sediment extracts and 12.8% AR in the total system after 100 days; there was no clear evidence of decline of this metabolite in sediment. Therefore an environmental exposure assessment for this metabolite in sediment is required.

The enantiomeric composition of pydiflumetofen in water was determined at the end of the aerobic mineralisation study, at the end of the aerobic and anaerobic incubations in water/sediment studies, and at the end of the irradiation period in the water photolysis study compared to the ratio in the pydiflumetofen application solutions. The pydiflumetofen enantiomer ratio did not change significantly over the course of these degradation studies. The recommendations of the EFSA Stereoisomer guidance were also taken into consideration for the water studies. Sterile aqueous photolysis studies do not represent an asymmetric environment but other chemical processes could initiate racemisation. The change in enantiomer excess in the studies was unlikely to exceed 10% at 50% degradation. HSE considers that this might be evidence that apparent changes in enantiomer excess could be as a result of experimental variability rather than evidence of chemical reaction-induced racemisation. The aerobic mineralisation study does present an asymmetric environment but might not be as relevant to risk assessment as the aerobic water sediment study. Whilst the aerobic mineralisation study results suggested that the change in enantiomer excess could be >10% at 50% degradation, the aerobic water/sediment study results suggested that the change in enantiomer excess could be <10% at 50% degradation. For both studies, these changes were extrapolated well beyond study duration. Other environmental fate studies described in this evaluation also included measurements of the enantiomers. The overall summary of the fate and behaviour of pydiflumetofen at the beginning of this B.8 section describes the considerations of stereoisomerism across the range of the submitted environmental fate studies and the weight of evidence approach that has been taken.

Satisfactory information was not available to address the effect of water treatment processes on the nature of the residues that might be present in water when it is abstracted for drinking water. A data gap has been identified.

The following table provides a summary of the maximum occurrences of each metabolite in the water degradation studies relevant for risk assessment.

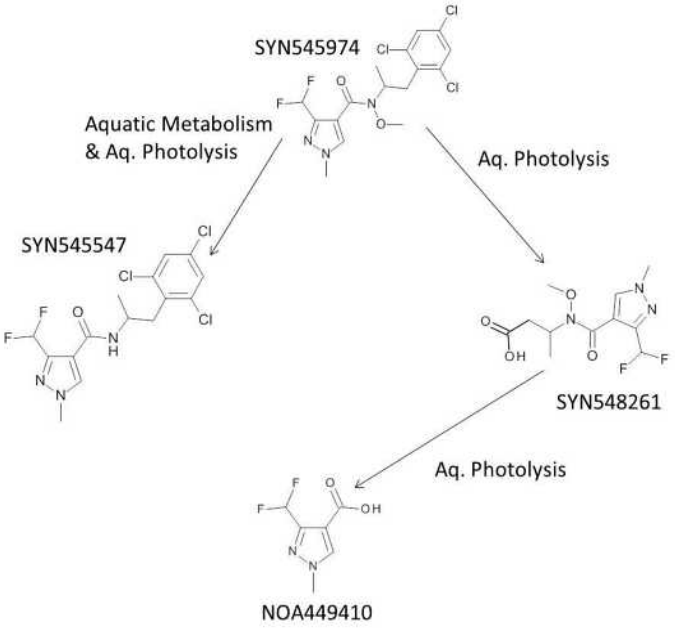
**Table B.8. 295 Summary of pydiflumetofen aquatic metabolites for risk assessment**

| **Study** | **Maximum level observed**[a] | | |
|---|---|---|---|
| | **SYN545547** | **SYN548261** | **NOA449410** |
| Hydrolysis | <5% | <5% | <5% |
| Aqueous Photolysis | <5% | 7.3% at 21 days[b] | 5.4% at 30 days[c] |
| Water Sediment (aerobic) | | | |
| Whole system | 12.8% at 100 days | <5% | <5% |
| Water | <5% | <5% | <5% |
| Sediment | 12.3% at 100 days | <5% | <5% |

[a] mean of replicates
[b] ≥5% at 2 consecutive sampling points
[c] ≥5% at the end of the study

The proposed metabolic pathway in aquatic systems is shown in the following figure.

**Figure B.8. 57 Proposed metabolic pathway of pydiflumetofen in aquatic systems**




The rate of degradation of pydiflumetofen and its metabolite SYN545547 in aquatic systems were assessed from the data from the water-sediment study according to FOCUS guidance on degradation kinetics (FOCUS 2006, 2011).

Data from the aerobic water/sediment study are presented below. The persistence endpoints for pydiflumetofen were $DegT_{50}$ 270-299 days ($DegT_{90}$ 976-1100 days) for degradation in the whole system and $DT_{50}$ 0.74-8.03 days ($DegT_{90}$ 33.1-86.9 days) for dissipation in the water column. The modelling endpoints for pydiflumetofen ranged from 244 to 252 days (geometric mean $DegT_{50}$ 248 days) for degradation in the whole system. The whole system DT50 is not used in the HSE assessment of PECsw of pydiflumetofen, the DissT50 in the water phase being most appropriate. For calculation of accumulation in sediment, a default DT50 of 1000 days is used due to the lack of evidence of clear decline of pydiflumetofen in sediment.

For the metabolite SYN545547, persistence endpoints were $DegT_{50}$ 18.6-455 days ($DegT_{90}$ 61.9-1510 days). The modelling whole system degradation endpoints ranged from 18.6 to 455 days (geometric mean $DegT_{50}$ 92.0 days). As with pydiflumetofen, the whole system DT50 is not used. Due to lack of a clear decline phase in sediment, a default DT50 of 1000 days is used for calculation of accumulation in sediment.

**Table B.8. 296 Degradation rates in dark aerobic water/sediment systems – pydiflumetofen**

| Trigger endpoints | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Water / sediment system | pH water phase | pH sed [a)] | t. °C | $DegT_{50}$ / $DegT_{90}$ whole sys. | St. ($\chi^2$) | Method of calculation | $DissT_{50}$ / $DissT_{90}$ water | St. ($\chi^2$) | Method of calculation |
| Calwich Abbey | 8.4 | 7.6 | 20 | 270/976[b] | 2.1 | HS<br>$k_1$: 0.01021<br>$k_2$: 0.00228<br>$t_b$: 9.853 | 0.74/33.1[b] | 9.0 | DFOP<br>$k_1$: 2.665<br>$k_2$: 0.04446<br>g: 0.5645 |
| Swiss Lake | 7.9 | 5.1 | 20 | 299/1100[b] | 0.9 | HS<br>$k_1$: 0.01061<br>$k_2$: 0.002004<br>$t_b$: 10.91 | 8.03/86.9[b] | 4.7 | HS<br>$k_1$: 0.087<br>$k_2$: 0.0204<br>$t_b$: 7.947 |

[a] Measured in calcium chloride solution
[b] Overall DT50 and DT90

| Modelling endpoints | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Water / sediment system | pH water phase | pH sed [a)] | t. °C | $DegT_{50}$ whole sys. | St. ($\chi^2$) | Method of calculation | $DissT_{50}$ water | St. ($\chi^2$) | Method of calculation |
| Calwich Abbey | 8.4 | 7.6 | 20 | 244[b] | 2.8 | SFO | 10[c)] | 9.0 | DFOP<br>$k_1$: 2.665<br>$k_2$: 0.04446<br>g: 0.5645 |
| Swiss Lake | 7.9 | 5.1 | 20 | 252[b] | 2.3 | SFO | 26.2[c)] | 4.7 | HS<br>$k_1$: 0.087<br>$k_2$: 0.0204<br>$t_b$: 7.947 |

[a] Measured in calcium chloride solution
[b] due to lack of clear decline in sediment, default DT50 of 1000 days is used for calculation of accumulation in sediment
[c)] Calculated from DT90 / 3.32

**Table B.8. 297 Degradation rates in dark aerobic water/sediment systems – SYN545547**

| Metabolite SYN545547 (trigger & modelling) | Distribution (max in water 2.3% after 45 d. Max. sed 12.3 % after 100 d). Max in total system 12.8 % after 100 days.<br>kinetic formation fraction ($k_f/k_{dp}$): from parent pydiflumetofen | | | | | | |
|---|---|---|---|---|---|---|---|
| Water / sediment system | pH water phase | pH sed [a)] | t. °C | $DT_{50}$ /$DT_{90}$ whole sys. | St. ($\chi^2$) | Formation fraction | Method of calculation |
| Calwich Abbey | 8.4 | 7.6 | 20 | 455/1510[b] | 10.4 | 0.60 | SFO |
| Swiss Lake | 7.9 | 5.1 | 20 | 18.6/61.9 | 12.8 | 0.96 | SFO |

[a)] Measured in calcium chloride solution
[b)] due to lack of clear decline in sediment, default DT50 of 1000 days is used for calculation of accumulation in sediment

## B.8.3. FATE AND BEHAVIOUR IN AIR

### B.8.3.1. Route and rate of degradation in air

Pydiflumetofen has a vapour pressure of 1.84 x $10^{-7}$ Pa at 20°C. According to FOCUS Air guidance criteria, pydiflumetofen does not need to be considered for short-range transport.

The reaction of pydiflumetofen in the atmosphere with hydroxyl radicals has been estimated using the method of Atkinson (1985[13], 1987[14] and 1988[15]) as developed in the Atmospheric Oxidation Program v1.91 (US EPA, 2009[16]), based on SMILES code O=C(c2c(nn(c2)C)C(F)F)N(OC)C(C)Cc1c(CL)cc(CL)cc1(CL) and molecular weight 426.68 g/mol. The Atmospheric Oxidation Program estimates the rate constant for the atmospheric, gas-phase reaction between photochemically produced hydroxyl radicals and organic chemicals. It also estimates the gas-phase reaction between ozone and olefinic/acetylinic compounds. The rate constants estimated by the program are used to calculate an atmospheric half-life for the organic compound based upon average atmospheric concentrations of hydroxyl radicals and ozone.

The estimated half-life (Atkinson method) of pydiflumetofen in the atmosphere (by hydroxyl radical oxidation) is 5.85 hours, based on OH (12h) concentration of 1.5 x $10^6$ radicals/$cm^3$ as recommended in FOCUS Air guidance document. Pydiflumetofen is therefore not expected to be persistent in air and does not meet the 'trigger' value of an atmospheric half-life of 2 days which would raise concerns relating to long range atmospheric transport.

### B.8.3.2. Transport via air

Based on the available information, pydiflumetofen is unlikely to undergo significant volatilisation and any residues reaching air will be rapidly degraded. Therefore the compound is not subject to significant concerns related to long range atmospheric transport and atmospheric accumulation.

### B.8.3.3. Local and global effects

Based on the available information, pydiflumetofen is unlikely to undergo significant volatilisation and any residues reaching air will be rapidly degraded. Therefore the compound is not subject to significant concerns related to local or global effects.

## B.8.4. MONITORING DATA CONCERNING FATE AND BEHAVIOUR OF THE ACTIVE SUBSTANCE, METABOLITES, DEGRADATION AND REACTION PRODUCTS

Pydiflumetofen is a new active substance and therefore monitoring data are not available. No monitoring data relative to metabolites was provided.

### B.8.4.1. Definition of the residue for risk assessment

A definition of the residue for risk assessment is provided below.

**Table B.8. 298 Residue definitions for relevant risk assessment for pydiflumetofen**

| Compartment | Residue definition for risk assessment |
|---|---|
| Soil | Pydiflumetofen |
| Groundwater | Pydiflumetofen |
| Surface water | Pydiflumetofen<br>NOA449410<br>SYN548261 |
| Sediment | Pydiflumetofen<br>SYN545547 |
| Air | Pydiflumetofen |

[13] Atkinson, R. 1985. Kinetics and mechanisms of the gas-phase reactions of the hydroxyl radical with organic compounds under atmospheric conditions. Chem. Rev. 85: 69-201

[14] Atkinson, R. 1987. A structure-activity relationship for the estimation of rate constants for the gas-phase reactions of OH radicals with organic compounds. Intern. J. Chem. Kinet. 19: 799-828

[15] Atkinson, R. 1988. Estimation of gas-phase hydroxyl radical rate constants for organic chemicals. Env. Toxic. Chem. 7: 435-442

[16] US EPA. 2009. Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.00. United States Environmental Protection Agency, Washington, DC, USA

### B.8.4.2. Definition of the residue for monitoring

The following is proposed as the definition of the residue for environmental monitoring of pydiflumetofen. TO BE COMPLETED ON FINALISATION OF THE RISK ASSESSMENT.

**Table B.8. 299 Residue definition for monitoring for pydiflumetofen**

| Compartment | Residue definition for risk assessment |
|---|---|
| Soil | Pydiflumetofen |
| Groundwater | Pydiflumetofen |
| Surface water | Pydiflumetofen |
| Sediment | Pydiflumetofen |
| Air | Pydiflumetofen |

## B.8.5. REFERENCES RELIED ON

The applicant submitted a literature review in support of pydiflumetofen and its metabolites in the area of environmental fate and behaviour. HSE considers that acceptable search criteria have been applied to this literature review when considering the residues and dietary exposure areas.

No studies were 'returned' by the original search, likely due to pydiflumetofen being a new active substance. The search was performed in November 2015, a few years before the submission to HSE (July 2020), so it possible that more recent studies could have been missed.

The updated literature review (dated 2022) yielded one paper of potential relevance in the area of environmental fate and behaviour. HSE consider that this paper is of potential interest for the environmental fate and behaviour assessment (on enantiomeric composition) and is summarised in section B.8.1.1.1.4.

**More detailed evaluation of literature review**

The applicant provided a review for pydiflumetofen (and its metabolites) in accordance with the EFSA 2011 Guidance (EFSA Journal 2011; 9(2):2092).

**Literature review report for** Pydiflumetofen: 5 September, 2022. Author "Syngenta - Jealott's Hill International Research Centre". The report was made available as document M-CA, Section 9 "Environmental Fate and Behaviour – Literature Data". The report was based on earlier versions (dated 2016, 2018 and 2021) that had been updated.

*Summary of methodology employed:*

1. A very broad search was conducted in 18 scientific source databases for Pydiflumetofen (SYN545974) and its metabolites.
2. Duplicates titles from between the databases were automatically removed from the output.
3. A rapid assessment of the titles was conducted to remove any additional duplicates and any obviously irrelevant titles (where enough information was available from the title alone).
4. A further rapid assessment was conducted using summary abstracts and any clearly irrelevant titles were removed.

*Timespan- scope of search.*

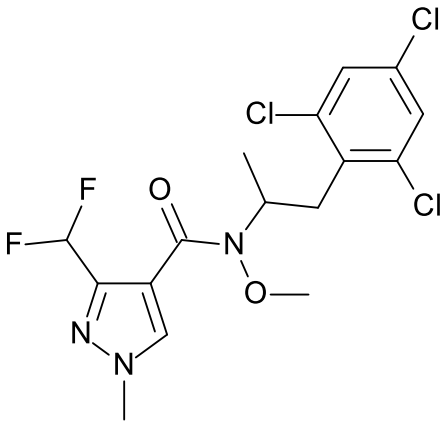
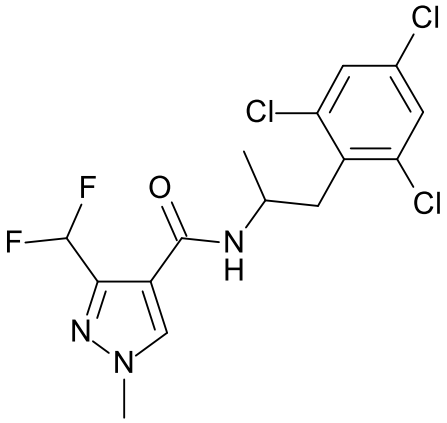
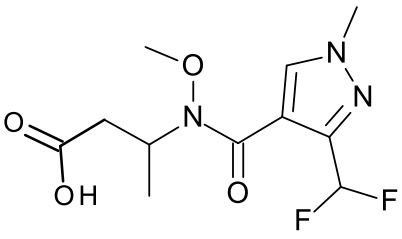
Whilst an initial search using pydiflumetofen was done in April 2015, this was updated in November 2015 and August 2022. A metabolite-specific search was also conducted in December 2021 The date span of the search covered a period 53 years.

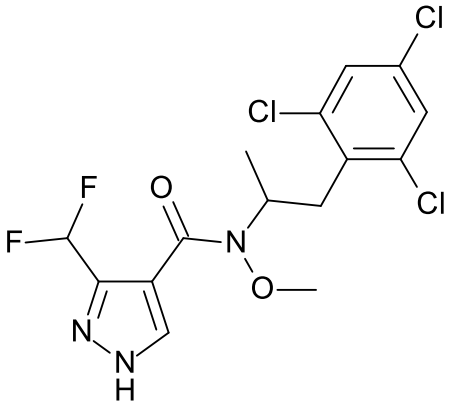
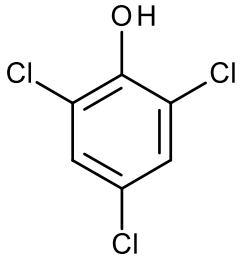
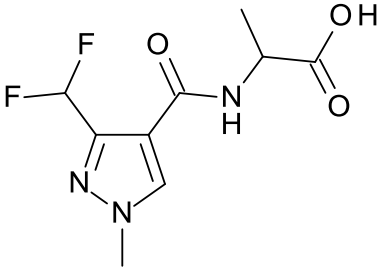
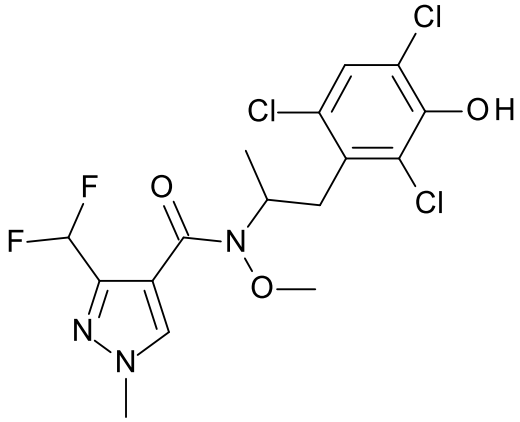
Regulation 1107/2009 states "*Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target*

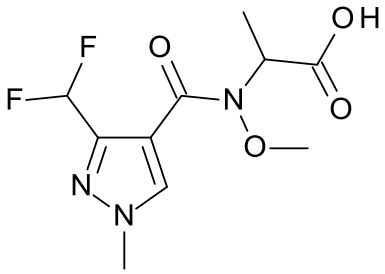
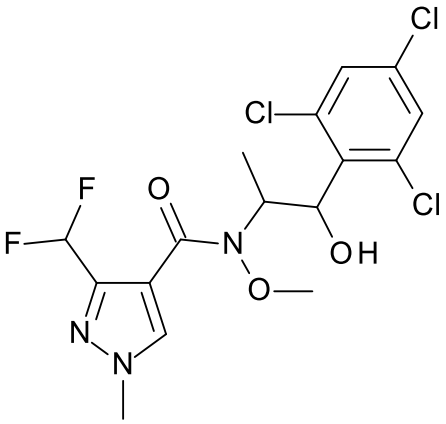
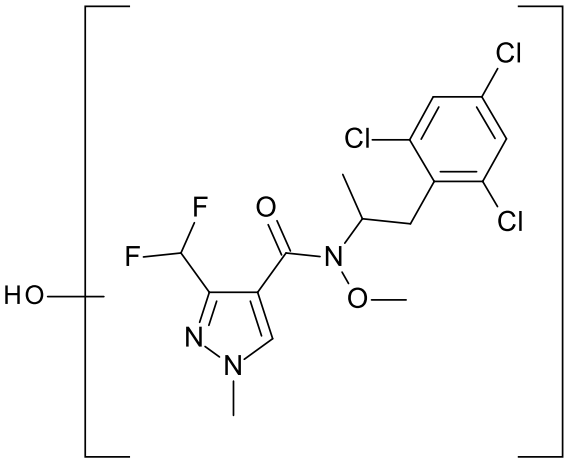
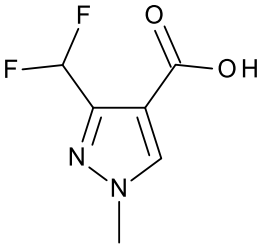
*species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.*"

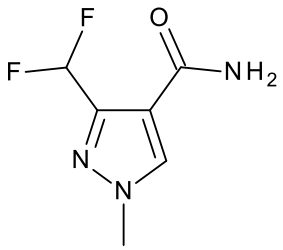
*Search terms:*

The search terms covered both the active substance pydiflumetofen and specific metabolites, including pydiflumetofen metabolites that are regarded as common SDHI metabolites; details of the substances included in the search are shown below. Search terms were provided and encompassed code names for active substance and the proposed names for the pesticide products as well as codes for the metabolites.

| **Code Number (Synonyms)** | **Description** | **Structure** |
|---|---|---|
| SYN545974<br>CSCD678790 | N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide<br><br>1H-Pyrazole-4-carboxamide, 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]- |  |
| SYN545547<br>CSCD550897 | 3-(difluoromethyl)-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]pyrazole-4-carboxamide |  |
| SYN548261 | 3-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]-methoxy-amino]butanoic acid |  |

| Code Number (Synonyms) | Description | Structure |
|---|---|---|
| SYN547891<br>CSCV764139 | 3-(difluoromethyl)-N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide |  |
| 2,4,6-Trichlorophenol<br>2,4,6-TCP | 2,4,6-trichlorophenol |  |
| SYN548264<br>CSCD548196<br>N-desmethoxy SYN548263 | 2-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]amino]propanoic acid |  |
| SYN547897<br>CSCV764146 | 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxy-phenyl)ethyl]pyrazole-4-carboxamide |  |

| **Code Number (Synonyms)** | **Description** | **Structure** |
|---|---|---|
| SYN548263<br>CSCZ159698 | 2-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]-methoxy-amino]propanoic acid |  |
| SYN547948<br>CSCY608054 | 3-(difluoromethyl)-N-[2-hydroxy-1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-N-methoxy-1-methyl-pyrazole-4-carboxamide |  |
| Hydroxylated SYN545974 | Hydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide |  |
| NOA449410<br>CSAA798670<br>R648993 | 3-(difluoromethyl)-1-methyl-pyrazole-4-carboxylic acid |  |

| Code Number (Synonyms) | Description | Structure |
|---|---|---|
| SYN508272<br>CSCC210616<br>R423363 | 3-(difluoromethyl)-1-methyl-pyrazole-4-carboxamide |  |

The search terms are listed below:

**Search Strategy**

Initial SYN545974 search :

L1 QUE (1228284-64-7 OR 1639015-49-8 OR 1639015-48-7)
L2 QUE (1485419-47-3 OR 1485419-44-0 OR (FUSHA(10A)FUNGICID?))
L3 QUE (SYN545974 OR (SYN(W)545974))
L4 QUE L1-3 FUSHA PLUS STEREOISOMERS
L5 QUE (1658468-84-8 OR 1561039-73-3 OR 1336797-48-8)
L6 QUE (1335518-65-4 OR 1245827-93-3 OR 1228286-43-8)
L7 QUE (1228284-63-6 OR 1204298-65-6 OR 1192017-82-5)
L8 QUE (1105713-22-1 OR 1004285-82-8 OR 960053-63-8)
L9 QUE (925689-10-7 OR 176969-34-9 OR 151734-02-0)
L10 QUE (SYN545547 OR SYN547894 OR SYN547892 OR SYN547893)
L11 QUE (NOA449410 OR SYN547895 OR SYN547890 OR SYN545720)
L12 QUE (SYN508272 OR SYN545357 OR SYN547896 OR SYN547897)
L13 QUE (SYN547891 OR SYN548263 OR SYN548264 OR SYN548265)
L14 QUE (SYN548279 OR (SYN(W)548279) OR (NOA(W)449410))
L15 QUE (SYN(W)(545547 OR 547894 OR 547892 OR 547893))
L16 QUE (SYN(W)(547895 OR 547890 OR 545720))
L17 QUE (SYN(W)(508272 OR 545357 OR 547896 OR 547897))
L18 QUE (SYN(W)(547891 OR 548263 OR 548264 OR 548265))

Top-up SYN545974 search :

L1 QUE SPE=ON ABB=ON PLU=ON (1639015-49-8 OR 1639015-48-7 OR 1485419-47-3 OR 1485419-44-0 OR
1228284-64-7)
L2 QUE SPE=ON ABB=ON PLU=ON (DIFLUOROMETHYL(1W)METHOXY(1W)METHYL(2W)METHYL(4W)
TRICHLOROPHENYL (W) ETHYL(1W)PYRAZOL?(1W)CARBOXAMID? OR DIFLUOROMETHYL (1W)

METHYL(1W)PYRAZOL?(1W)CARBOXYLIC(W)ACID(W)METHOXY(1W)METHYL(4W)TRICHLORO(W)
PHENYL(W)ETHYL(W)AMID?)
L3 QUE SPE=ON ABB=ON PLU=ON (ADEPIDYN OR FUSHA OR PYDIFLUMETOFEN# OR SYN545974 OR
SYN(W)545974)
L4 QUE SPE=ON ABB=ON PLU=ON (L1 OR L2 OR L3)
L5 QUE SPE=ON ABB=ON PLU=ON (1658468-84-8 OR 1561039-73-3 OR 1336797-48-8 OR 1335518-65-4 OR
1245827-93-3 OR 1228286-43-8 OR 1228284-63-6 OR 1204298-65-6 OR 1192017-82-5 OR 1105713-22-1 OR
1004285-82-8 OR 960053-63-8 OR 925689-10-7 OR 176969-34-9 OR 151734-02-0)
L6 QUE SPE=ON ABB=ON PLU=ON (SYN545547 OR SYN547894 OR SYN547892 OR

| **Search Strategy** |
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| SYN547893 OR<br>NOA449410 OR SYN547895 OR SYN547890 OR SYN545720 OR SYN508272 OR SYN545357 OR SYN547896<br>OR SYN547897 OR SYN547891 OR SYN548263 OR SYN548264 OR SYN548265)<br>L7 QUE SPE=ON ABB=ON PLU=ON (SYN548279 OR (SYN(W)548279) OR (NOA(W)449410) OR SYN(W)<br>(545547 OR 547894 OR 547892 OR 547893) OR SYN(W)(547895 OR 547890 OR 545720) OR SYN(W)(508272<br>OR 545357 OR 547896 OR 547897) OR SYN(W)(547891 OR 548263 OR 548264 OR 548265))<br>L8 QUE SPE=ON ABB=ON PLU=ON (DICHLOROPHENYL(1W)METHYLETHYL(1W)DIFLUOROMETHYL<br>(1W)METHOXY(1W)METHYL(1W)PYRAZOLE(1W)CARBOXAMIDE OR DIFLUOROMETHYL(1W)<br><br>HYDROXY(1W)METHYL(2W)METHYL(4W)TRICHLOROPHENYL(W)ETHYL(1W)PYRAZOLE (1W)<br>CARBOXAMIDE OR DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL#(1W)CARBOXAMID#)<br>L9 QUE SPE=ON ABB=ON PLU=ON (DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL#(1W)CARBOXYLIC<br>(W)ACID OR DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL#(1W)CARBOXYLIC(W)ACID(2W)<br>HYDROXY(1W)METHYLETHYL(W)AMIDE OR DIFLUOROMETHYL(1W) METHYL(1W)PYRAZOL #(1W)<br>L(W)CARBONYL(1W)ALANINE)<br>L10 QUE SPE=ON ABB=ON PLU=ON (DIFLUOROMETHYL(1W)METHYL(2W)METHYL(4W)<br>TRICHLOROPHENYL (W) ETHYL (1W) PYRAZOL#(1W)CARBOXAMIDE ORDIFLUOROMETHYL(1W)<br>METHYLPYRAZOL#(1W)CARBOXAMIDE OR DIFLUOROMETHYL(1W)METHYLPYRAZOL #(1W)<br>CARBOXYLIC(W)ACID)<br>L11 QUE SPE=ON ABB=ON PLU=ON (DIFLUOROMETHYL(1W)PYRAZOL#(1W)CARBOXYLIC(W)ACID OR<br><br>DIFLUOROMETHYL(2W)HYDROXY(1W)METHYLETHYL(1W)METHOXY(1W)METHYL(1W) PYRAZOL#<br>(1W)CARBOXAMIDE OR DIFLUOROMETHYL(3W)HYDROXYL(1W)METHYLETHYL(1W)METHYL (1W)<br>PYRAZOL#(1W)CARBOXAMID#)<br>L12 QUE SPE=ON ABB=ON PLU=ON(METHYL(1W)DIFLUOROMETHYL(W)PYRAZOL#(1W) CARBOXYLIC<br>(W)ACID OR TRICHLORO(1W)METHYL(1W)BENZENEETHANAMINE OR TRICHLORO(1W)METHYL(W)<br>BENZENE (W) ETHANAMIN#)<br><br>SYN545974 specific metabolites search :<br><br>L1 QUE SPE=ON ABB=ON PLU=ON (960053-63-8 OR DIFLUOROMETHYL(1W)METHYL(2W)METHYL(4W)<br>TRICHLOROPHENYL (W) ETHYL(2W)PYRAZOL?(1W)CARBOXAMID# OR SYN545547 OR SYN(W)545547)<br>L2 QUE SPE=ON ABB=ON PLU=ON (3784-03-0 OR 2591-21-1 OR 95-95-4 OR 88-06-2 OR 89465-86-1 OR<br>77001-45-7)<br>L3 QUE SPE=ON ABB=ON PLU=ON (TRICHLOROPHENOL OR TRICHLOROPHENATE OR<br>TRICHOROPHENOLATE OR TRICHLOROPHENOXIDE OR TRICHLORO(W)PHENOL OR<br>TRICHLOROPHENOXY OR TRICHLOROPHENIC(W)ACID OR TRICHLORO(1W)HYDROXYBENZENE)<br>L4 QUE SPE=ON ABB=ON PLU=ON (DOWICIDE OR NSC(W)2266 OR NSC2266 OR |

| **Search Strategy** |
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| PREVENTOL OR TCP OR<br>2(W)4(W)6(W)TCP OR BTS(W)45186 OR BTS45186 OR NSC(W)2165 OR NSC2165 OR OMAL OR<br>PHENACHLOR)<br>L5 QUE SPE=ON ABB=ON PLU=ON (FUNGI!ID? OR MOLDICID? OR PESTI!ID? OR MICROBIO!ID? OR<br>MICROBI!ID? OR BIO!ID? OR BI!ID? OR ANTIFUNG? OR ANTI(W)FUNG?)<br>L6 QUE SPE=ON ABB=ON PLU=ON L4(10A)L5<br>L7 QUE SPE=ON ABB=ON PLU=ON (1192017-82-5 OR SYN548264 OR SYN(W)548264)<br>L8 QUE SPE=ON ABB=ON PLU=ON (DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL#(1W)CARBONYL<br>(W) AMINO (W) PROPANOIC(W)ACID OR DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL#(1W)<br>CARBONYL (W) AMINO(W)PROPANOAT# OR DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL#(1W)<br>YL(W)CARBONYL(1W)ALANIN#)<br>L9 QUE SPE=ON ABB=ON PLU=ON (SYN547891 OR SYN(W)547891 OR DIFLUOROMETHYL(1W)<br>METHOXY (2W) METHYL(4W)TRICHLOROPHENYL(W)ETHYL(1W)PYRAZOL?(1W)CARBOXAMID?)<br>L10 QUE SPE=ON ABB=ON PLU=ON (SYN547897 OR SYN(W)547897 OR DIFLUOROMETHYL(1W) METHYL<br><br>(1W)PYRAZOL?(1W)CARBOXYLIC(W)ACID(W)METHOXY(1W)METHYL(4W)TRICHLORO(1W)<br>HYDROXYL (W)PHENYL(W)ETHYL(W)AMID?)<br>L11 QUE SPE=ON ABB=ON PLU=ON (SYN548263 OR SYN(W)548263 OR DIFLUOROMETHYL(1W)METHYL<br>(W) PYRAZOL?(1W)CARBONYL(W)METHOXY(W)AMINO(W)PROPANOIC(W)ACID OR<br>DIFLUOROMETHYL (1W) METHYL(W)PYRAZOL?(1W)CARBONYL(W)METHOXY(W) AMINO(W)<br>PROPANOAT? OR DIFLUOROMETHYL(1W)METHYL(W)PYRAZOL?(1W)CARBONYL(1W) METHOXY<br>(W)ALANIN#)<br>L12 QUE SPE=ON ABB=ON PLU=ON (SYN548261 OR SYN(W)548261 OR DIFLUOROMETHYL(1W)METHYL<br>(W)PYRAZOL?(1W) CARBONYL(W)METHOXY(W)AMINO(W)(BUTANOIC OR BUTYRIC OR<br>PROPANECARBOXYLIC)(W)ACID OR DIFLUOROMETHYL(1W)METHYL(W)PYRAZOL?(1W)CARBONYL<br>(W)METHOXY(W)AMINO(W)(BUTANOAT? OR BUTYRATE? OR PROPANECARBOXYLAT?))<br>L13 QUE SPE=ON ABB=ON PLU=ON (SYN547948 OR SYN(W)547948 OR DIFLUOROMETHYL(4W)<br>HYDROXY (1W) METHYL(4W)TRICHLOROPHENYL(W)ETHYL(1W)METHOXY(1W)METHYL(W)<br>PYRAZOL? (1W)CARBOXAMID?)<br>L14 QUE SPE=ON ABB=ON PLU=ON (1639015-49-8 OR 1639015-48-7 OR 1485419-47-3 OR 1485419-44-0 OR<br>1228284-64-7)<br>L15 QUE SPE=ON ABB=ON PLU=ON (DIFLUOROMETHYL(1W)METHOXY(1W)METHYL(2W)METHYL(4W)<br>TRICHLOROPHENYL (W)ETHYL(1W)PYRAZOL?(1W)CARBOXAMID? OR DIFLUOROMETHYL(1W)<br>METHYL (1W) PYRAZOL? (1W)CARBOXYLIC(W)ACID (W)METHOXY(1W)METHYL(4W) TRICHLORO<br>(W) PHENYL(W)ETHYL(W)AMID?)<br>L16 QUE SPE=ON ABB=ON PLU=ON (ADEPIDYN OR FUSHA OR PYDIFLUMETOFEN# OR SYN545974 OR |

**Search Strategy**

SYN(W)545974)
L17 QUE SPE=ON ABB=ON PLU=ON (HYDROXY OR OXY?)(3W)(L14 OR L15 OR L16)
L18 QUE SPE=ON ABB=ON PLU=ON ((L1 OR L2 OR L3) OR (L6 OR L7 OR L8 OR L9 OR L10 OR L11 OR L12
OR L13) OR L17)

SYN545974 metabolites that are common SDHI metabolites search :

L1 QUE SPE=ON ABB=ON PLU=ON (176969-34-9 OR 1334398-13-8 OR NOA (W)449410 OR NOA449410 OR
R(W)648993 OR R648993 OR DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL?(1W)CARBOXYLIC(W)
ACID OR (PYRAZOL?(1W)CARBOXYLIC(W)ACID)(1A)(DIFLUOROMETHYL(1W)METHYL))
L2 QUE SPE=ON ABB=ON PLU=ON (METHYL(1W)DIFLUOROMETHYL(1W)PYRAZOL?(1W)CARBOXYLIC
(W)ACID OR DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL? (1W)CARBOXYLAT? OR
DIFLUOROMETHYL (1W)METHYLPYRAZOL?(1W)CARBOXYLIC(W)ACID)
L3 QUE SPE=ON ABB=ON PLU=ON (925689-10-7 OR SYN(W)508272 OR SYN508272 OR R(W)423363 OR
R423363 OR DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL?(1W)CARBOXYLIC(W)ACID(W)AMID?
OR DIFLUOROMETHYL(1W)METHYL(1W)PYRAZOL?(1W)CARBOXAMID##)
L4 QUE SPE=ON ABB=ON PLU=ON ((PYRAZOL?(1W)CARBOXAMIDE)(1A)(DIFLUOROMETHYL (1W)
METHYL) OR DIFLUOROMETHYL(1W)METHYLPYRAZOL?(1W)CARBOXAMIDE##)
L5 QUE SPE=ON ABB=ON PLU=ON (L1 OR L2 OR L3 OR L4)

Plus
L1 QUE (FATE# OR DEGRAD? OR PERSIST? OR DECOMP? OR DECAY?)
L2 QUE (TRANSFORM? OR DETERIORAT? OR METAB? OR DEGENERAT?)
L3 QUE (BIODEGRAD? OR BIOTRANSFORM? OR BIODETERIORAT?)
L4 QUE (BIODEGENERAT? OR BREAKDOWN? OR BREAKSDOWN?)
L5 QUE (((BROKEN? OR BREAK?)(W)(UP OR DOWN)) OR HALFLIFE#)
L6 QUE (HALFLIVES OR HALF(W)(LIFE OR LIVES) OR DEGRDN# OR DECOMPN#)
L7 QUE (BIODEGRDN# OR DEGN# OR BIODEGN# OR DISSIP? OR RESIDUE?)
L8 QUE (LEACH? OR TRANSPORT? OR MOBIL? OR MOVEMENT? OR HYDROLY?)
L9 QUE (ADSORP? OR ADSORB? OR SORP? OR SORB? OR DESORP?)
L10 QUE (DESORB? OR RUNOFF OR (RUN#(W)OFF) OR DRAIN? OR PERCOLAT?)
L11 QUE (WASHOFF? OR WASHOUT? OR (WASH?(W)(OUT OR OFF)))
L12 QUE ((((OFF(W)TARGET) OR LATERAL OR HORIZONTAL)(3W)MOVE?))
L13 QUE (PHOTOLY? OR PHOTODEGRAD? OR PHOTODECOMP?)
L14 QUE (PHOTOTRANSFORM? OR PHOTOSTAB? OR PHOTODEGRDN# OR PHOTODEGN#)
L15 QUE ((PHOTO(W)(DECOMP? OR DEGRAD? OR TRANSFORM? OR STAB? OR CHEM?)))
L16 QUE (PHOTOCHEM? OR VOLATIL? OR VAPOUR? OR VAPOR? OR DT50 OR DT90)
L17 QUE ((DT(W)50) OR (DT(W)90) OR KDOC OR (K(W)DOC) OR KD OR KOC)
L18 QUE ((K(W)OC) OR (PARTITION?(3W)COEFF?) OR FREUNDLICH)
L19 QUE (SEDIMENT? OR SOIL OR SOILS OR PODZOL? OR CLAY? OR SAND?)
L20 QUE (SILT? OR CHERNOZEM? OR PODSOL? OR LOAM? OR PEAT?)
L21 QUE ((ORGANIC(2W)MATTER?) OR MONTMORIL? OR LATOSOL? OR HUMIC?)
L22 QUE (HUMUS? OR SUBSOIL? OR AIR OR WATER? OR ATMOSPHER?)
L23 QUE (RAIN### OR RAINWATER? OR RAINFALL? OR LEACH?)
L24 QUE (GROUNDWATER? OR ENVIRONMENT? OR PRECIPITAT? OR POND#)
L25 QUE (STREAM# OR RIVER# OR DELTA# OR ESTUAR? OR SEDIMENT?)
L26 QUE (AQUATIC? OR MARINE? OR TIDAL? OR BENTHIC? OR LAKE#)
L27 QUE (BENTHOS? OR LIMNO? OR FRESHWATER? OR SEAWATER?)
L28 QUE (SALTWATER? OR ((GROUND? OR FRESH OR SEA OR SALT)(W)WATER?))

| **Search Strategy** |
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| L29 QUE (LACUSTRINE? OR MIRE OR MIRES OR RESERVOIR# OR CANAL#)<br>L30 QUE (LOCH# OR SEA OR OCEAN OR OCEANS OR LAGOON? OR SEAS)<br>L31 QUE (SEABED OR SEAFLOOR OR INTERTIDAL? OR SHORE? OR COAST?)<br>L32 QUE (BRACKISH OR LITTORAL? OR SEASHORE? OR MEIOBENTH?)<br>L33 QUE (MICROBENTH? OR MACROBENTH? OR HARBOUR# OR FLUVIAL?)<br>L34 QUE (MARSH? OR BOG OR BOGS OR SWAMP? OR FEN OR FENS OR ALLUVI?)<br>L35 QUE (MUDFLAT? OR (MUD(W)FLAT?) OR BAY OR BAYS OR CREEK#)<br>L36 QUE (HYDROSOIL# OR (HYDRO(W)SOIL#) OR MESOCOSM? OR MICROCOSM?)<br>L37 QUE (WETLAND? OR FENLAND? OR ((WET OR FEN)(W)LAND?))<br>L38 QUE (WATERWAY? OR WATERSHED? OR (WATER(W)(WAY? OR SHED?)))<br>L39 QUE (CATCHMENT? OR DITCH? OR DRAIN# OR DRAINAG?)<br>L40 QUE (((FOLIAGE OR FOLIAR OR LEAF OR LEAVES)(5A)EVAPORAT?))<br>L41 QUE ((SPRAY? OR DUST?)(3A)DRIFT)<br>L42 QUE (L1 OR L2 OR L3 OR L4 OR L5 OR L6 OR L7 OR L8 OR L9 OR L10 OR L11 OR L12 OR L13 OR L14 OR L15 OR L16 OR L17 OR L18 OR L19 OR L20 OR L21 OR L22 OR L23 OR L24 OR L25 OR L26 OR L27 OR L28 OR L29 OR L30 OR L31 OR L32 OR L33 OR L34 OR L35 OR L36 OR L37 OR L38 OR L39 OR L40 OR L41)<br><br>Top-up search (August 2022)<br><br>Query – Pydiflumetofen parent and metabolites<br>L1 QUE “Pydiflumetofen”<br>L2 QUE “3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide” OR “3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-(2,4,6-trichlorophenyl)propan-2-yl]-4-pyrazolecarboxamide”<br>L3 QUE “3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[(2S)-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide” OR “3-(difluoromethyl)-N-methoxy-1-methyl-N-[(2S)-1-(2,4,6-trichlorophenyl)propan-2-yl]-4-pyrazolecarboxamide”<br>L4 QUE “3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[(2R)-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide” OR “3-(difluoromethyl)-N-methoxy-1-methyl-N-[(2R)-1-(2,4,6-trichlorophenyl)propan-2-yl]-4-pyrazolecarboxamide”<br>L5 QUE “FUSHA” OR “ADEPIDYN” OR “MIRAVIS”<br>L6 QUE (L1 OR L2 OR L3 OR L4 OR L5)<br>L7 QUE “(2R)-2-[[[3-(difluoromethyl)-1-methyl-4-pyrazolyl]-oxomethyl]amino]propanoic acid” OR “(2R)-2-[[3-[bis(fluoranyl)methyl]-1-methyl-pyrazol-4-yl]carbonylamino]propanoic acid”<br>L8 QUE “(2S)-2-[[[3-(difluoromethyl)-1-methyl-4-pyrazolyl]-oxomethyl]-methoxyamino]propanoic acid” OR “(2S)-2-[[3-[bis(fluoranyl)methyl]-1-methyl-pyrazol-4-yl]carbonyl-methoxy-amino]propanoic acid”<br>L9 QUE “(2R)-2-[[[3-(difluoromethyl)-1-methyl-4-pyrazolyl]-oxomethyl]-methoxyamino]propanoic acid” OR “(2R)-2-[[3-[bis(fluoranyl)methyl]-1-methyl-pyrazol-4-yl]carbonyl-methoxy-amino]propanoic acid”<br>L10 QUE “(3R)-3-[[[3-(difluoromethyl)-1-methyl-4-pyrazolyl]-oxomethyl]-methoxyamino]butanoic acid” OR “(3R)-3-[[3-[bis(fluoranyl)methyl]-1-methyl-pyrazol-4-yl]carbonyl-methoxy-amino]butanoic acid”<br>L11 QUE “(3S)-3-[[[3-(difluoromethyl)-1-methyl-4-pyrazolyl]-oxomethyl]-methoxyamino]butanoic acid” OR “(3S)-3-[[3-[bis(fluoranyl)methyl]-1-methyl-pyrazol-4-yl]carbonyl-methoxy-amino]butanoic acid”<br>L12 QUE “3-(difluoromethyl)-1-methyl-N-[(2S)-1-(2,4,6-trichlorophenyl)propan-2-yl]-4-pyrazolecarboxamide” OR “3-[bis(fluoranyl)methyl]-1-methyl-N-[(2S)-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide”<br>L13 QUE “3-(difluoromethyl)-1-methyl-N-[(2R)-1-(2,4,6-trichlorophenyl)propan-2-yl]-4-pyrazolecarboxamide” OR “3-[bis(fluoranyl)methyl]-1-methyl-N-[(2R)-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide”<br>L14 QUE “3-(difluoromethyl)-N-methoxy-N-[(2R)-1-(2,4,6-trichlorophenyl)propan-2-yl]-1H-pyrazole-4-carboxamide” OR “3-[bis(fluoranyl)methyl]-N-methoxy-N-[(2R)-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]-1H-pyrazole-4-carboxamide”<br>L15 QUE “3-(difluoromethyl)-N-methoxy-N-[(2S)-1-(2,4,6-trichlorophenyl)propan-2-yl]-1H-pyrazole-4-carboxamide” OR “3-[bis(fluoranyl)methyl]-N-methoxy-N-[(2S)-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]-1H-pyrazole-4-carboxamide”<br>L16 QUE “3-(difluoromethyl)-N-methoxy-1-methyl-N-[(2S)-1-(2,4,6-trichloro-3-hydroxyphenyl)propan-2-yl]-4-pyrazolecarboxamide” OR “3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[(2S)-1-[2,4,6- |

| **Search Strategy** |
|---|
| tris(chloranyl)-3-oxidanyl-phenyl]propan-2-yl]pyrazole-4-carboxamide" |
| L17 QUE "3-(difluoromethyl)-N-methoxy-1-methyl-N-[(2R)-1-(2,4,6-trichloro-3-hydroxyphenyl)propan-2-yl]-4-pyrazolecarboxamide" OR "3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[(2R)-1-[2,4,6-tris(chloranyl)-3-oxidanyl-phenyl]propan-2-yl]pyrazole-4-carboxamide" |
| L18 QUE "3-(difluoromethyl)-N-[(1R,2S)-1-hydroxy-1-(2,4,6-trichlorophenyl)propan-2-yl]-N-methoxy-1-methyl-4-pyrazolecarboxamide" OR "3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[(1R,2S)-1-oxidanyl-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide" |
| L19 QUE "3-(difluoromethyl)-N-[(1R,2R)-1-hydroxy-1-(2,4,6-trichlorophenyl)propan-2-yl]-N-methoxy-1-methyl-4-pyrazolecarboxamide" OR "3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[(1R,2R)-1-oxidanyl-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide" |
| L20 QUE "88-06-2" OR "2,4,6-trichlorophenol" OR "2,4,6-tris(chloranyl)phenol" |
| L21 QUE "3-(difluoromethyl)-1-methyl-N-[1-(2,4,6-trichlorophenyl)propan-2-yl]-4-pyrazolecarboxamide" OR "3-[bis(fluoranyl)methyl]-1-methyl-N-[1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide" |
| L22 QUE "3-(difluoromethyl)-N-methoxy-N-[1-(2,4,6-trichlorophenyl)propan-2-yl]-1H-pyrazole-4-carboxamide" OR "3-[bis(fluoranyl)methyl]-N-methoxy-N-[1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]-1H-pyrazole-4-carboxamide" |
| L23 QUE "3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-(2,4,6-trichloro-3-hydroxyphenyl)propan-2-yl]-4-pyrazolecarboxamide" OR "3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[1-[2,4,6-tris(chloranyl)-3-oxidanyl-phenyl]propan-2-yl]pyrazole-4-carboxamide" |
| L24 QUE "3-(difluoromethyl)-N-[1-hydroxy-1-(2,4,6-trichlorophenyl)propan-2-yl]-N-methoxy-1-methyl-4-pyrazolecarboxamide" OR "3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[1-oxidanyl-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide" |
| L25 QUE "3-(difluoromethyl)-N-methoxy-1-methyl-N-[rac-(1S,2S)-1-hydroxy-1-(2,4,6-trichlorophenyl)propan-2-yl]-4-pyrazolecarboxamide" OR "3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[rac-(1R,2R)-1-oxidanyl-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide" |
| L26 QUE "3-(difluoromethyl)-N-methoxy-1-methyl-N-[rac-(1S,2R)-1-hydroxy-1-(2,4,6-trichlorophenyl)propan-2-yl]-4-pyrazolecarboxamide" OR "3-[bis(fluoranyl)methyl]-N-methoxy-1-methyl-N-[rac-(1R,2S)-1-oxidanyl-1-[2,4,6-tris(chloranyl)phenyl]propan-2-yl]pyrazole-4-carboxamide" |
| L27 QUE "3-[[[3-(difluoromethyl)-1-methyl-4-pyrazolyl]-oxomethyl]-methoxyamino]butanoic acid" OR "3-[[3-[bis(fluoranyl)methyl]-1-methyl-pyrazol-4-yl]carbonyl-methoxy-amino]butanoic acid" |
| L28 QUE "2-[[[3-(difluoromethyl)-1-methyl-4-pyrazolyl]-oxomethyl]-methoxyamino]propanoic acid" OR "2-[[3-[bis(fluoranyl)methyl]-1-methyl-pyrazol-4-yl]carbonyl-methoxy-amino]propanoic acid" |
| L29 QUE "1192017-82-5" OR "2-[[[3-(difluoromethyl)-1-methyl-4-pyrazolyl]-oxomethyl]amino]propanoic acid" OR "2-[[3-[bis(fluoranyl)methyl]-1-methyl-pyrazol-4-yl]carbonylamino]propanoic acid" |
| L30 QUE "1192017-82-5" OR "(2S)-2-[[[3-(difluoromethyl)-1-methyl-4-pyrazolyl]-oxomethyl]amino]propanoic acid" OR "(2S)-2-[[3-[bis(fluoranyl)methyl]-1-methyl-pyrazol-4-yl]carbonylamino]propanoic acid" |
| L31 QUE (L6-30) |
| SAVE L31 PYDIPM/Q |
| |
| STN Query – environmental fate search filters |
| L1 QUE (FATE# OR DEGRAD? OR PERSIST? OR DECOMP? OR DECAY?) |
| L2 QUE (TRANSFORM? OR DETERIORAT? OR METAB? OR DEGENERAT?) |
| L3 QUE (BIODEGRAD? OR BIOTRANSFORM? OR BIODETERIORAT?) |
| L4 QUE (BIODEGENERAT? OR BREAKDOWN? OR BREAKSDOWN?) |
| L5 QUE (((BROKEN? OR BREAK?)(W)(UP OR DOWN)) OR HALFLIFE#) |
| L6 QUE (HALFLIVES OR HALF(W)(LIFE OR LIVES) OR DEGRDN# OR DECOMPN#) |
| L7 QUE (BIODEGRDN# OR DEGN# OR BIODEGN# OR DISSIP? OR RESIDUE?) |
| L8 QUE (LEACH? OR TRANSPORT? OR MOBIL? OR MOVEMENT? OR HYDROLY?) |
| L9 QUE (ADSORP? OR ADSORB? OR SORP? OR SORB? OR DESORP?) |
| L10 QUE (DESORB? OR RUNOFF OR (RUN#(W)OFF) OR DRAIN? OR PERCOLAT?) |
| L11 QUE (WASHOFF? OR WASHOUT? OR (WASH?(W)(OUT OR OFF))) |
| L12 QUE ((((OFF(W)TARGET) OR LATERAL OR HORIZONTAL)(3W)MOVE?)) |
| L13 QUE (PHOTOLY? OR PHOTODEGRAD? OR PHOTODECOMP?) |
| L14 QUE (PHOTOTRANSFORM? OR PHOTOSTAB? OR PHOTODEGRDN# OR PHOTODEGN#) |
| L15 QUE ((PHOTO(W)(DECOMP? OR DEGRAD? OR TRANSFORM? OR STAB? OR CHEM?))) |
| L16 QUE (PHOTOCHEM? OR VOLATIL? OR VAPOUR? OR VAPOR? OR DT50 OR DT90) |
| L17 QUE ((DT(W)50) OR (DT(W)90) OR KDOC OR (K(W)DOC) OR KD OR KOC) |

| **Search Strategy** |
|---|
| L18 QUE ((K(W)OC) OR (PARTITION?(3W)COEFF?) OR FREUNDLICH)<br>L19 QUE (SEDIMENT? OR SOIL OR SOILS OR PODZOL? OR CLAY? OR SAND?)<br>L20 QUE (SILT? OR CHERNOZEM? OR PODSOL? OR LOAM? OR PEAT?)<br>L21 QUE ((ORGANIC(2W)MATTER?) OR MONTMORIL? OR LATOSOL? OR HUMIC?)<br>L22 QUE (HUMUS? OR SUBSOIL? OR AIR OR WATER? OR ATMOSPHER?)<br>L23 QUE (RAIN### OR RAINWATER? OR RAINFALL? OR LEACH?)<br>L24 QUE (GROUNDWATER? OR ENVIRONMENT? OR PRECIPITAT? OR POND#)<br>L25 QUE (STREAM# OR RIVER# OR DELTA# OR ESTUAR? OR SEDIMENT?)<br>L26 QUE (AQUATIC? OR MARINE? OR TIDAL? OR BENTHIC? OR LAKE#)<br>L27 QUE (BENTHOS? OR LIMNO? OR FRESHWATER? OR SEAWATER?)<br>L28 QUE (SALTWATER? OR ((GROUND? OR FRESH OR SEA OR SALT)(W)WATER?))<br>L29 QUE (LACUSTRINE? OR MIRE OR MIRES OR RESERVOIR# OR CANAL#)<br>L30 QUE (LOCH# OR SEA OR OCEAN OR OCEANS OR LAGOON? OR SEAS)<br>L31 QUE (SEABED OR SEAFLOOR OR INTERTIDAL? OR SHORE? OR COAST?)<br>L32 QUE (BRACKISH OR LITTORAL? OR SEASHORE? OR MEIOBENTH?)<br>L33 QUE (MICROBENTH? OR MACROBENTH? OR HARBOUR# OR FLUVIAL?)<br>L34 QUE (MARSH? OR BOG OR BOGS OR SWAMP? OR FEN OR FENS OR ALLUVI?)<br>L35 QUE (MUDFLAT? OR (MUD(W)FLAT?) OR BAY OR BAYS OR CREEK#)<br>L36 QUE (HYDROSOIL# OR (HYDRO(W)SOIL#) OR MESOCOSM? OR MICROCOSM?)<br>L37 QUE (WETLAND? OR FENLAND? OR ((WET OR FEN)(W)LAND?))<br>L38 QUE (WATERWAY? OR WATERSHED? OR (WATER(W)(WAY? OR SHED?)))<br>L39 QUE (CATCHMENT? OR DITCH? OR DRAIN# OR DRAINAG?)<br>L40 QUE (((FOLIAGE OR FOLIAR OR LEAF OR LEAVES)(5A)EVAPORAT?))<br>L41 QUE ((SPRAY? OR DUST?)(3A)DRIFT)<br>L42 QUE (L1 OR L2 OR L3 OR L4 OR L5 OR L6 OR L7 OR L8 OR L9 OR L10 OR L11 OR L12 OR L13 OR L14 OR L15 OR L16 OR L17 OR L18 OR L19 OR L20 OR L21 OR L22 OR L23 OR L24 OR L25 OR L26 OR L27 OR L28 OR L29 OR L30 OR L31 OR L32 OR L33 OR L34 OR L35 OR L36 OR L37 OR L38 OR L39 OR L40 OR L41)<br>SAVE L42 EFATE/Q<br><br>STN Search (conducted 02 August 2022):<br>FILE MEDLINE EMBASE ESBIOBASE AGRICOLA BIOSIS CABA HCAPLUS FSTA GEOREF TOXCENTER PQSCITECH SCISEARCH ANABSTR<br>SET DUPORDER FILE<br>L1 s PYDIPM/Q AND EFATE/Q<br>L2 s L1 NOT PY<2015<br>L3 s L2 NOT ED<20151101<br>L4 s L3 NOT ED>20200731<br>L5 s L4 NOT PATENT/DT<br>L6 DUP REM L5<br>SAVE L6 PYDIPMFATE/A |

With respect to the common metabolites of SDHI substances, the following information was used:

| Substance name/organism/metabolite/product | PAC |
|---|---|
| IUPAC name | 3-(difluoromethyl)-1-methylpyrazole-4-carboxylic acid |
| Other names given to the substance/trade name | 3-(difluoromethyl)-1-methyl-4-pyrazolecarboxylic acid, CA4312, CSAA798670 |
| EC number | No official number assigned |
| CAS number | 176969-34-9 |

| Substance name/organism/metabolite/product | CSCC210616 |
|---|---|
| IUPAC name | 3-(difluoromethyl)-1-methylpyrazole-4-carboxamide |
| Other names given to the substance/trade name | SYN508272, 3-(difluoromethyl)-1-methyl-4-pyrazolecarboxamide |
| EC number | No official number assigned |
| CAS number | 925689-10-7 |

| | |
|---|---|
| Substance name/organism/metabolite/product | DMPAC |
| IUPAC name | 3-(difluoromethyl)-1(H)-pyrazole-4-carboxylic acid |
| Other names given to the substance/trade name | CSCD465008, SYN545720, R958945 |
| EC number | No official number assigned |
| CAS number | 151734-02-0 |

Query profiles were prepared containing all the search terms used to find relevant publications related to the common metabolites.

The SDHI common metabolites PAC, CSCC210616 and DMPAC were searched based on full details including CAS registry number.

The search strategy was conducted using bibliographic databases conducted using STN as host provider. STN provides electronic access to a large number of scientific and technical bibliographical databases. The applicant included a justification of each of the databases used. Taken together, these covered a comprehensive source for which to conduct an overall search covering environmental fate and behaviour assessment.

The following 18 (Host STN) databases were included:
MEDLINE, EMBASE, ESBIOBASE, AGRICOLA, BIOSIS, CABA, HCAPLUS, FSTA, FROSTI, GEOREF, TOXCENTER, PQSCITECH, PASCAL, SCISEARCH, ANABST, HCHEMLIST, CROPU, CROPB.

A subset of the individual databases (Pascal, Medline, and Agricola) are those that EFSA provided as a list of reliable databases (sent to EU MS by EFSA in March 2015). With the overall list of databases used by the applicant, the search covers a good range (e.g. including a global range). The STN database searches are efficient means of retrieval of papers from a large number of database searches. The STN approach described and used by the applicant for pydiflumetofen and metabolites is considered to be a comprehensive approach. It is used by a number of registrants in the undertaking of literature reviews.

The applicant considered that the bibliographic databases would provide a comprehensive search to retrieve quality peer reviewed literature, particularly as the search did not do further retrieval searches, such as web search (e.g. websites of conferences or organisations), search of journals' tables of contents, or search of reference lists of full-text journal articles (e.g. reviews).

*Relevancy criteria:*
The applicant set out a series of relevance criteria pertinent to the assessment of regulatory environmental fate and behaviour studies (as outlined below). These cover each of the respective data areas represented by the environmental fate and behaviour data requirements.

| **Data requirements(s) (indicated by the correspondent CA data point (s))** | **Criteria for relevance** |
|---|---|
| Route and rate of degradation in soil – Laboratory Studies – aerobic and anaerobic, parent and metabolites<br>CA 7.1.1<br>CA 7.1.1.1<br>CA 7.1.1.2 | 1. Well defined test material (including purity/content)<br>2. Soil(s) must be agricultural and relevant for the EU e.g. from temperate zone, no extreme characteristics (e.g. meets the criteria in OECD 307)<br>3. Soil collection, preparation and storage did not differ significantly from recommended protocols<br>4. Test soils had not previously been exposed to the test material or structural analogues.<br>5. Experimental conditions did not differ significantly from recommended protocols e.g. temperature and moisture<br>6. Application rate is within the range of the proposed use and can be verified from the data (time zero samples)<br>7. Sufficient number of samples taken to determine kinetics (minimum 5)<br>8. Extraction system was appropriate e.g. avoidance of excessive or inadequate methods<br>9. Analytical method well described, LOD/LOQ at appropriate level |

| | |
|---|---|
| | 10. Mass balance or recovery for radiolabelled and unlabelled studies respectively is adequate to support the conclusions, e.g. >90%.<br>11. Analytical method appears robust with suitable reproducibility and supports the conclusions made e.g. for unlabelled studies are suitable blank controls included<br>12. Identification of 'new' metabolites is robust with appropriate details of method used<br>13. Anaerobic conditions are verified by measurement |
| Route and rate of degradation in soil – Field Studies<br>CA 7.1.2.2 | 1. In addition to criteria under laboratory route and rate:<br>2. Field site(s) must be geoclimatically relevant for the EU<br>3. Adequate weather data available to verify relevance of study<br>4. Application technique relevant to proposed use (foliar, ST granule etc)<br>5. Sufficient sampling detail and description of sample handling prior to analysis<br>6. Initial and procedural recoveries are adequate to support the conclusions, e.g. 70-120%. |
| Soil photolysis<br>CA 7.1.1.3 | In addition to criteria under laboratory route and rate:<br>1. Light source was suitable with details of spectrum and intensity available<br>2. Dark control included and reported |
| Mobility studies<br>Adsorption, desorption – parent and metabolites<br>CA 7.1.3<br><br>Column or TLC leaching<br>CA 7.1.4.1.1, CA 7.1.4.1.2 | 1. Well defined test material (including purity/content)<br>2. Soil(s) must be agricultural and relevant for EU e.g. from temperate zone, no extreme characteristics (e.g. meets the criteria in OECD 106)<br>3. Soil collection, preparation and storage did not differ significantly from recommended protocols<br>4. Test soils had not previously been exposed to the test material or structural analogues.<br>5. Experimental conditions did not differ significantly from recommended protocols<br>6. Application rate is appropriate to the proposed use and can be verified from the data<br>7. Sufficient number of samples taken to determine isotherm (if done)<br>8. Stability of the test item in the system was demonstrated<br>9. Extraction system was appropriate e.g. avoidance of excessive or inadequate methods<br>10. Mass balance or recovery for radiolabelled and unlabelled studies respectively is adequate to support the conclusions, e.g. >90%<br>11. Analytical method well described, LOD/LOQ at appropriate level<br>12. Analytical method appears robust with suitable reproducibility and supports the conclusions made e.g. for unlabelled studies are suitable blank controls included |
| Lysimeter studies<br>CA 7.1.4.2 | In addition to criteria under laboratory route and rate:<br>1. Field site(s) must be geoclimatically relevant for the EU<br>2. Adequate weather data available to verify relevance of study. Combined rainfall/irrigation sufficient to meet guideline requirements<br>3. Minimum 1 m depth soil monolith<br>4. Study continued for sufficient years to support the conclusions |

| | |
|---|---|
| Field leaching<br>CA 7.1.4.3. | In addition to criteria under laboratory route and rate:<br>1. Field site(s) must be geoclimatically relevant for the EU<br>2. Adequate weather data and groundwater data (depth, direction) available to verify the validity of study<br>3. Installation and operation of lysimeters and/or wells and samplers follows recommended protocols<br>4. Study continued for sufficient years to support the conclusions |
| Hydrolysis<br>CA 7.2.1 | 1. Well defined test material (including purity/content)<br>2. Experimental conditions should not differ significantly from recommended protocols<br>3. Application rate is within an acceptable the range (e.g. consider solubility) and can be verified from the data (time zero samples)<br>4. Sufficient number of samples taken to determine kinetics (minimum 5)<br>5. Analytical method well described, LOD/LOQ at appropriate level<br>6. Mass balance or recovery for radiolabelled and unlabelled studies respectively is adequate to support the conclusions, e.g. >90%.<br>7. Analytical method appears robust with suitable reproducibility and supports the conclusions made e.g. for unlabelled studies are suitable blank controls included<br>8. Identification of 'new' metabolites is robust with appropriate details of method used |
| Aqueous photolysis<br>CA 7.2.1.2 | In addition to criteria under hydrolysis:<br>1. Light source was suitable with details of spectrum and intensity available<br>2. Dark control included and reported |
| Degradation in aquatic systems<br>CA 7.2.2 | 1. Well defined test material (including purity/content)<br>2. Water(s) and sediment(s) must be from an agricultural area and relevant for the EU e.g. from temperate zone, no extreme characteristics (e.g. meets the criteria in OECD 308)<br>3. Water/sediment collection, preparation and storage do not differ significantly from recommended protocols<br>4. Experimental conditions do not differ significantly from recommended protocols e.g. temperature and aeration<br>5. Application rate is within the range of the proposed use and can be verified from the data (time zero samples)<br>6. Sufficient number of samples taken to determine kinetics (minimum 5)<br>7. Extraction system was appropriate e.g. avoidance of excessive or inadequate methods<br>8. Analytical method well described, LOD/LOQ at appropriate level<br>9. Analytical method appears robust with suitable reproducibility and supports the conclusions made e.g. for unlabelled studies are suitable blank controls included<br>10. Mass balance or recovery for radiolabelled and unlabelled studies respectively is adequate to support the conclusions, e.g. >90%<br>11. Identification of 'new' metabolites is robust with appropriate details of method used<br>12. Anaerobic conditions are verified by measurement |

| | |
|---|---|
| Degradation in the saturated zone<br>CA 7.2.3 | 1. For laboratory studies refer to criteria under laboratory route and rate<br>2. Field site(s) must be geoclimatically relevant for the EU<br>3. Adequate site characterisation data available e.g. soils, geology, hydrology<br>4. Installation of samplers e.g. wells, lysimeters follows recommended protocols<br>5. Analytical method well described, LOD/LOQ at appropriate level<br>6. Analytical method appears robust with suitable reproducibility and supports the conclusions made e.g. for unlabelled studies are suitable blank controls included |
| Route and rate of degradation in air<br>CA 7.3.1 | 1. Experimental conditions or calculations differ significantly from recommended protocols<br>2. Analytical method well described, LOD/LOQ at appropriate level<br>3. Analytical method appears robust with suitable reproducibility and supports the conclusions made e.g. for unlabelled studies are suitable blank controls included |
| Monitoring<br>CA 7.5 | 1. Site(s) or areas must be geoclimatically relevant for the EU<br>2. Adequate site characterisation data available e.g. soils, geology, hydrology<br>3. Installation of samplers e.g. wells, lysimeters follows recommended protocols OR adequate description of wells is available (depth of well, length of screen, depth of screen opening, depth of groundwater)<br>4. Appropriate sampling methodology.<br>5. Analytical method well described, LOD/LOQ at appropriate level<br>6. Analytical method appears robust with suitable reproducibility and supports the conclusions made e.g. suitable blank controls included<br>7. For surface water: description of sampling methodology and handling of detects (peaks, interpolated time-step?), linked to rainfall intensity and volume). Discharge volumes, catchment drained area. |

* Recommended protocols under each data point include but are not limited to those listed in the Commission Communications 2013/C 95/01 and 2013/C 95/02

Excluding duplicate entries, the original and top-up literature searches retrieved a total of 10916 records (excluding duplicate records from different databases). The applicant supplied slightly different data on the outcome of the searches, providing a more detailed breakdown of categories that literature records fell within for the searches conducted between 2016 and 2018; the results of the 2016 and 2018 ‘top-up’ are presented below:

| Data requirement(s) captured in the search | Number SYN545974 Initial Search | Number SYN545974 Top-Up Search | Number SYN545974 Specific Metabolites Search | Number Common SDHI Metabolites Search | Total |
|---|---|---|---|---|---|
| Total number of *summary records* retrieved after *all** searches of peer-reviewed literature (excluding duplicates) | 3 | 125 | 9796 | 7 | 9931 |
| Number of *summary records* excluded from the search results after rapid assessment for relevance** | 3 | 125 | 9796 | 7 | 9931 |
| Total number of *full-text* documents assessed in detail* | 0 | 0 | 0 | 0 | 0 |
| Number of *studies* excluded from further consideration after detailed assessment for relevance | 0 | 0 | 0 | 0 | 0 |
| Number of *studies* not excluded for relevance after detailed assessment (i.e. relevant studies and studies of unclear relevance) | 0 | 0 | 0 | 0 | 0 |

*both from bibliographic databases and other sources of peer-reviewed literature
** aligned with EFSA Journal 2011; 9(2) 2092: rapid assessment means exclusion of "obviously irrelevant records" based on titles.

All of the references were excluded from the rapid assessment, as no external research had been published on the parent molecule pydiflumetofen, the pydiflumetofen-specific environmental metabolites (SYN545547 and SYN548261) and the common SDHI environmental metabolite, NOA449410. The pydiflumetofen-specific metabolite search, which returned many thousands of returns, did not contain any of the pydiflumetofen metabolites found in the environment, but rather many hits for common classes for chemistry e.g. trichlorophenols. Therefore no full text was assessed and no studies were identified as potentially relevant for this submission of pydiflumetofen.

The additional 'top-up' search submitted in September 2022 did not give the breakdown in detail as given above. Excluding duplicate records, 985 new records were found. Following the same procedure, all but one record were excluded from consideration for the same reasons as with the previous searches. The single record proposed by the applicant for inclusion in the DAR is shown below:

| Data requirement (indicated by the corresponding CA and CP data point number) | Author(s) | Year | Title | Source |
|---|---|---|---|---|
| CA 6.10 | Wu X., Dong F., Xu J., Liu X., Wu X. and Zheng Y. | 2020 | Enantioselective separation and dissipation of pydiflumetofen enantiomers in grape and soil by supercritical fluid chromatography–tandem mass spectrometry | Journal of Separation Science, Vol.43, pp. 2217-2227 |

The environmental fate and behaviour relevant parts of this study are reported in section B.8.1.1.1.4.

**Conclusion:** HSE concludes that the literature searches undertaken by the applicant are acceptable in terms of databases searched and the search criteria applied.

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| KCA 6.10 | Wu X., Dong F., Xu J., Liu X., Wu X. and Zheng Y. | 2020 | Enantioselective separation and dissipation of pydiflumetofen enantiomers in grape and soil by supercritical fluid chromatography–tandem mass spectrometry.<br>Journal of Separation Science, Vol.43, pp. 2217-2227<br>No claim for GLP made.<br>Published | N | N | N/A | | N |
| KCA1 7.1.1.1 | [redacted] | 2016 | SYN545974 - Aerobic Soil Metabolism of [14C]-SYN545974<br>Report No. 3200099 including Amendment 2, September 2016<br>Document No. VV-414613 , SYN545974_50164<br>Test Facility Smithers Viscient (ESG) Ltd<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.1.2 | [redacted] | 2015a | SYN545974 - Anaerobic Soil Metabolism of 14C-SYN545974<br>Report No. 3200130<br>Document No. VV-414614 , SYN545974_50166<br>Test Facility Smithers Viscient (ESG) Ltd<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.1.2 | [redacted] | 2016 | Technical Statement - Estimation of the Anaerobic Soil DegT50 of 14C-SYN545974 Sum of Harsh and Non-Harsh Extracts<br>Report No. 3200130\|SYN545974_50166<br>Document No. VV-134434 , SYN545974_50715 | N | N | N/A | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | Test Facility Syngenta Crop Protection<br>Not GLP<br>Unpublished | | | | | |
| KCA1 7.1.1.3 | [redacted] | 2014 | SYN545974 - Soil Photolysis of 14C-SYN545974<br>Report No. 3200128<br>Document No. VV-414617 , SYN545974_50182<br>Test Facility Smithers Viscient (ESG) Ltd<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.1 | [redacted] | 2016 | Technical statement - Appropriate solvent extraction systems for determining soil degradation rates suitable for use in the calculation of the environmental exposure<br>Report No. N/A<br>Document No. VV-134291 , NA_13970<br>Test Facility Syngenta - Jealott's Hill<br>Not GLP<br>Unpublished | N | N | N/A | SYN | N |
| KCA1 7.1.2.1.1 | [redacted] | 2015a | SYN545974 - Laboratory Degradation Kinetics for Trigger and Modelling Endpoints for Parent<br>Report No. SYN/48/01-Kin01<br>Document No. VV-629825 , SYN545974_10373<br>Test Facility JSC International Ltd.<br>Not GLP<br>Unpublished<br>This is CONFIDENTIAL INFORMATION | **N** | **N** | **N/A** | **SYN** | **N** |
| KCA1 7.1.2.1.1 | [redacted] | 2016a | SYN545974 - Laboratory Degradation Kinetics for Trigger and Modelling Endpoints for Parent - Including Harsh Extraction | N | N | N/A | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | Report No. SYN/48/01-Kin02<br>Document No. VV-630255 ,<br>SYN545974_10461<br>Test Facility JSC International Ltd.<br>Not GLP<br>Unpublished<br>This is CONFIDENTIAL INFORMATION | | | | | |
| KCA1 7.1.2.2.1 | [redacted] | 2015 | SYN545974 – Bare Soil Plot Dissipation Study in Germany in 2013 - 2015<br>Report No. S13-02237-FINAL<br>Document No. VV-413308 , A19649B_10166<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.2.1 | [redacted] | 2015a | SYN545974 – Bare Soil Plot Soil Dissipation Study in Italy in 2013-2015<br>Report No. S13-02241-FINAL<br>Document No. VV-413311 , A19649B_10167<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.2.1 | [redacted] | 2015b | SYN545974 – Bare Soil Plot Dissipation Study in Northern France in 2013 - 2015<br>Report No. S13-02238-FINAL<br>Document No. VV-413312 , A19649B_10168<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.2.1 | [redacted] | 2015c | SYN545974 – Bare Soil Plot Dissipation Study in Southern France in 2013 - 2015 | N | Y | The study is necessary for | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | Report No. S13-02239-FINAL<br>Document No. VV-413238 , A19649B_10170<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | | | this regulatory decision and is eligible for data protection | | |
| KCA1 7.1.2.2.1 | [redacted] | 2015d | SYN545974 – Bare Soil Plot Dissipation Study in Spain in 2013 - 2015<br>Report No. S13-02240-FINAL<br>Document No. VV-413239 , A19649B_10171<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.2.1 | [redacted] | 2015e | SYN545974 – Bare Soil Plot Dissipation Study in UK in 2013 - 2015<br>Report No. S13-02236-FINAL<br>Document No. VV-413240 , A19649B_10172<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.2.1 | [redacted] | 2019a | SYN545974 - Preparation of Field Plot in Germany in 2016-2017<br>Report No. S16-02736<br>Document No. VV-719164<br>Test Facility Eurofins Agroscience Services GmbH<br>Not GLP<br>Unpublished | N | N | N/A | SYN | N |
| KCA1 7.1.2.2.1 | [redacted] | 2019b | SYN545974 – Soil Dissipation Study in Germany in 2016-2017<br>Report No. S16-01816 | N | Y | The study is necessary for this regulatory | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | Document No. VV-719200<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | | | decision and is eligible for data protection | | |
| KCA1 7.1.2.2.1 | [redacted] | 2020a | SYN545974 - Preparation of Field Plot in Northern France in 2016-2017<br>Report No. S16-02739<br>Document No. VV-847488<br>Test Facility Eurofins Agroscience Services GmbH<br>Not GLP<br>Unpublished | N | N | N/A | N/A | SYN |
| KCA1 7.1.2.2.1 | [redacted] | 2020b | SYN545974 – Soil Dissipation Study in Northern France in 2016-2017<br>Report No. S16-02708<br>Document No. VV-856218<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.2.1 | [redacted] | 2020c | SYN545974 - Preparation of Field Plot in Southern France in 2016-2017<br>Report No. S16-02740<br>Document No. VV-847489<br>Test Facility Eurofins Agroscience Services GmbH<br>Not GLP<br>Unpublished | N | N | N/A | N/A | SYN |
| KCA1 7.1.2.2.1 | [redacted] | 2020d | SYN545974 – Soil Dissipation Study in Southern France in 2016-2017<br>Report No. S16-02711<br>Document No. VV-856216 | N | Y | The study is necessary for this regulatory decision and | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | | | is eligible for data protection | | |
| KCA1 7.1.2.2.1 | [redacted] | 2020e | SYN545974 - Preparation of Field Plot in Portugal in 2016-2017<br>Report No. S16-02741<br>Document No. VV-847490<br>Test Facility Eurofins Agroscience Services GmbH<br>Not GLP<br>Unpublished | N | N | N/A | N/A | SYN |
| KCA1 7.1.2.2.1 | [redacted] | 2020f | SYN545974 – Soil Dissipation Study in Portugal in 2016-2017<br>Report No. S16-02712<br>Document No. VV-856212<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.2.1 | [redacted] | 2020g | SYN545974 – Additional Soil Sampling and Analysis at Five Historical Field Dissipation Sites in Northern Germany, Northern France and UK in 2020<br>Report No. S20-06491<br>Document No. VV-876413<br>Test Facility Eurofins Agroscience Services GmbH<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.2.1 | [redacted] | 31/07/ 2020 | Pydiflumetofen - Similarity Assessment of Terrestrial Field Dissipation Study Sites in North America and Asia to European | N | N | N/A | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | Conditions: An Ecoregion Crosswalk Analysis<br>Report No. TK0572654<br>Document No. VV-867687<br>Test Facility Syngenta Crop Protection, LLC<br>Not GLP<br>Unpublished | | | | | |
| KCA1 7.1.2.2 | [redacted] | 2016a | SYN545974 – Kinetic Assessment of Field Dissipation Data for Persistence Endpoints<br>Report No. SYN/48/01-Kin06<br>Document No. VV-630210 , SYN545974_10445<br>Test Facility JSC International Ltd.<br>Not GLP<br>Unpublished | N | N | N/A | SYN | N |
| KCA1 7.1.2.2 | [redacted] | 2020a | Pydiflumetofen - Non-standard surface applied FOCUS EU TFD Kinetics Trigger Endpoints<br>Report No. RAJ01352B<br>Document No. VV-864726<br>Test Facility Syngenta Limited<br>Not GLP<br>Unpublished | N | N | N/A | SYN | N |
| KCA1 7.1.2.2 | [redacted] | 2020a | SYN545974 - Kinetic Modelling Evaluation of Data from EU Terrestrial Field Dissipation Studies for Calculation of Trigger Endpoints for Parent<br>Report No. NC/20/034A<br>Document No. VV-876962<br>Test Facility Battelle UK, Ltd.<br>Not GLP<br>Unpublished | N | N | N/A | SYN | N |
| KCA1 7.1.2.2 | [redacted] | 2016b | SYN545974 – Kinetic Assessment of Field Dissipation Data for Modelling Endpoints<br>Report No. SYN/48/01-Kin05 | N | N | N/A | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | Document No. VV-630209 ,<br>SYN545974_10444<br>Test Facility JSC International Ltd.<br>Not GLP<br>Unpublished | | | | | |
| KCA1 7.1.2.2.1 | [redacted] | 2015 | Stability of SYN545974 in Representative Turfgrass Clippings, Turf Thatch-Sod Layer and Soil Matrices Under Freezer Storage Conditions<br>Report No. 2K14-901-TK0228507-001<br>Document No. VV-414449 ,<br>SYN545974_50216<br>Test Facility ADPEN Laboratories Inc.<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.2.2 | [redacted] | 2021 | SYN545974 – Additional environmental fate data to support EU submission<br>Report No. RAJ1381B<br>Document No. VV-898283<br>Test Facility Syngenta Limited<br>Not GLP<br>Unpublished | N | N | N/A | SYN | N |
| KCA1 7.1.2.2 | Syngenta | 2017 | Pydiflumetofen - EU - Further clarification response to RMS on Analytical Methods Residues E- Fate - March 2017<br>Report No. N/A<br>Document No. VV-137248 ,<br>SYN545974_10495<br>Test Facility N/A<br>Not GLP<br>Unpublished | N/A | N | N/A | SYN | N |
| KCA1 7.1.3.1.1 | [redacted] | 2013 | SYN545974 - Adsorption and Desorption of 14C-SYN545974 | N | Y | The study is necessary for | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | Report No. 8252103<br>Document No. VV-404195 ,<br>SYN545974_10060<br>Test Facility Smithers Viscient (ESG) Ltd<br>GLP<br>Unpublished | | | this regulatory decision and is eligible for data protection | | |
| KCA1 7.1.3.1.2 | [redacted] | 2015 | SYN545547 - Adsorption and Desorption of [14C]-SYN545547 in Five Soils<br>Report No. SR20150709A<br>Document No. VV-414601 ,<br>SYN545547_50000<br>Test Facility Symbiotic Research<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.1.3.1.2 | [redacted] | 2009 | CSAA798670 - Adsorption Properties in Five Soils<br>Report No. 115 01 014\|SYN524464_11669<br>Document No. VV-384616 ,<br>SYN524464_11135<br>Test Facility Innovative Environmental Services<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.2.1.1 | [redacted] | 2015 | 14C-SYN545974 - Hydrolysis in Sterile Buffer at pH 4, 7 and 9<br>Report No. 3200053<br>Document No. VV-414598 ,<br>SYN545974_50052<br>Test Facility Smithers Viscient (ESG) Ltd<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.2.1.2 | [redacted] | 2015 | SYN545974 - Aqueous Photolysis of [14C]SYN545974 | N | Y | The study is necessary for | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | Report No. 3200127<br>Document No. VV-414615 ,<br>SYN545974_50168<br>Test Facility Smithers Viscient (ESG) Ltd<br>GLP<br>Unpublished | | | this regulatory decision and is eligible for data protection | | |
| KCA1 7.2.2.1 | [redacted] | 2015 | SYN545974 – Ready Biodegradability in a Manometric Respirometry Test<br>Report No. SYN-029/5-09<br>Document No. VV-411061 ,<br>SYN545974_10145<br>Test Facility Fraunhofer Institute<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.2.2.2 | [redacted] | 2015b | SYN545974 - Aerobic Mineralisation of 14C-SYN545974 in Surface Water<br>Report No. 3200503<br>Document No. VV-414448 ,<br>SYN545974_50210<br>Test Facility Smithers Viscient (ESG) Ltd<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.2.2.3 | [redacted] | 2015 | SYN545974 - Aerobic and Anaerobic Aquatic Sediment Metabolism of 14C-SYN545974<br>Report No. 3200129<br>Document No. VV-414446 ,<br>SYN545974_50204<br>Test Facility Smithers Viscient (ESG) Ltd<br>GLP<br>Unpublished | N | Y | The study is necessary for this regulatory decision and is eligible for data protection | SYN | N |
| KCA1 7.2.2.3 | [redacted] | 2015a | SYN545974 - Laboratory Water/Sediment Degradation Kinetics for Modelling and Persistence Endpoints for Parent at Level PI | N | N | N/A | SYN | N |

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| | | | and Metabolite SYN545547 at Level MI<br>Report No. SYN/48/01-KIN03<br>Document No. VV-629861 ,<br>SYN545974_10378<br>Test Facility JSC International Ltd.<br>Not GLP<br>Unpublished | | | | | |

**Appendix I: Detailed results of the field dissipation studies**

Detailed results for the field dissipation studies summarised under B.8.1.1.2.2.1 are presented below. Note any values <LOQ were recorded a 0 g/ha. These values were not used for kinetic assessment.

**Table B.8. 300 Residues of pydiflumetofen (individual triplicates) in the individual soil layers for Germany ([redacted] 2015)**

| DAA | Subplot | Pydiflumetofen [g a.s./ha] | | |
|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm |
| -1# | 1 | 0 | 0 | NA |
| | 2 | 0 | 0 | NA |
| | 3 | 0 | 0 | NA |
| 0 | 1 | 141 | NA | NA |
| | 2 | 152 | NA | NA |
| | 3 | 141 | NA | NA |
| 3 | 1 | 182 | 0 | NA |
| | 2 | 156 | 0 | NA |
| | 3 | 133 | 0 | NA |
| 7 | 1 | 129 | 0 | NA |
| | 2 | 130 | 0 | NA |
| | 3 | 135 | 0 | NA |
| 14 | 1 | 131 | 0 | NA |
| | 2 | 165 | 0 | NA |
| | 3 | 131 | 0 | NA |
| 29 | 1 | 121 | 0 | NA |
| | 2 | 121 | 0 | NA |
| | 3 | 110 | 0 | NA |
| 58 | 1 | 94 | 0 | NA |
| | 2 | 112 | 0 | NA |
| | 3 | 109 | 0 | NA |
| 119 | 1 | 100 | 0 | NA |
| | 2 | 120 | 0 | NA |
| | 3 | 107 | 0 | NA |
| 178 | 1 | 130 | 0 | NA |
| | 2 | 126 | 0 | NA |
| | 3 | 138 | 0 | NA |
| 358 | 1 | 109 | 0 | NA |
| | 2 | 116 | 0 | NA |
| | 3 | 107 | 0 | NA |
| 533 | 1 | 117 | 0 | NA |
| | 2 | 224 | 0 | NA |
| | 3 | 90 | 0 | NA |
| 715 | 1 | 106 | 0 | NA |
| | 2 | 107 | 0 | NA |
| | 3 | 122 | 0 | NA |

DAA/DBA - days after/before application
NA - Not analysed
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).

**Table B.8. 301 Residues of pydiflumetofen (individual triplicates) in the individual soil layers for Italy ([redacted] 2015a)**

| DAA | Subplot | Pydiflumetofen [g a.s./ha] | | | | | |
|---|---|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | 30-50 cm | 50-70 cm | 70-100 cm |
| -21# | 1 | 0 | 0 | NA | NA | NA | NA |
| | 2 | 0 | 0 | NA | NA | NA | NA |
| | 3 | 0 | 0 | NA | NA | NA | NA |
| 0 | 1 | 162 | NA | NA | NA | NA | NA |
| | 2 | 185 | NA | NA | NA | NA | NA |
| | 3 | 111 | NA | NA | NA | NA | NA |
| 3 | 1 | 130 | 7 | 3 | NA | NA | NA |
| | 2 | 115 | 3 | 1 | NA | NA | NA |
| | 3 | 74 | 3 | 1 | NA | NA | NA |
| 7 | 1 | 143 | 5 | 3 | NA | NA | NA |
| | 2 | 207 | 3 | 2 | NA | NA | NA |
| | 3 | 93 | 2 | 1 | NA | NA | NA |
| 14 | 1 | 171 | 3 | 2 | 2 | 0 | NA |
| | 2 | 150 | 6 | 1 | 2 | 0 | NA |
| | 3 | 143 | 2 | 2 | 2 | 0 | NA |
| 28 | 1 | 131 | 2 | 1 | 2 | 0 | NA |
| | 2 | 120 | 3 | 1 | 0 | NA | NA |
| | 3 | 127 | 2 | 2 | 3 | 3 | 5 |
| 58 | 1 | 119 | 3 | 2 | 2 | 0 | NA |
| | 2 | 88 | 3 | 2 | 0 | NA | NA |
| | 3 | 189 | 3 | 2 | 3 | 0 | NA |
| 121 | 1 | 85 | 0 | NA | NA | NA | NA |
| | 2 | 85 | 0 | NA | NA | NA | NA |
| | 3 | 109 | 0 | NA | NA | NA | NA |
| 182 | 1 | 128 | 0 | NA | NA | NA | NA |
| | 2 | 106 | 0 | NA | NA | NA | NA |
| | 3 | 122 | 1 | 0 | NA | NA | NA |
| 366 | 1 | 105 | 1 | 0 | NA | NA | NA |
| | 2 | 106 | 0 | NA | NA | NA | NA |
| | 3 | 126 | 5 | 5 | 0 | NA | NA |
| 542 | 1 | 100 | 2 | 0 | NA | NA | NA |
| | 2 | 96 | 0 | NA | NA | NA | NA |
| | 3 | 153 | 7 | 3 | 0 | NA | NA |
| 716 | 1 | 77 | 2 | 0 | NA | NA | NA |
| | 2 | 63 | 2 | 2 | 0 | NA | NA |
| | 3 | 67 | 8 | 3 | 6 | 0 | NA |

DAA/DBA - days after/before application
NA - Not analysed
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).

**Table B.8. 302 Residues of pydiflumetofen (individual triplicates) in the individual soil layers for Northern France ([redacted] 2015b)**

| DAA | Subplot | Pydiflumetofen [g a.s./ha] | | | | | |
|---|---|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | 30-50 cm | 50-70 cm | 70-100 cm |
| -6# | 1 | 0 | 0 | NA | NA | NA | NA |
| | 2 | 0 | 0 | NA | NA | NA | NA |
| | 3 | 0 | 0 | NA | NA | NA | NA |
| 0 | 1 | 110 | NA | NA | NA | NA | NA |
| | 2 | 125 | NA | NA | NA | NA | NA |
| | 3 | 113 | NA | NA | NA | NA | NA |
| 3 | 1 | 118 | 0 | NA | NA | NA | NA |
| | 2 | 118 | 0 | NA | NA | NA | NA |
| | 3 | 124 | 0 | NA | NA | NA | NA |
| 7 | 1 | 169 | 0 | NA | NA | NA | NA |
| | 2 | 164 | 0 | NA | NA | NA | NA |
| | 3 | 137 | 0 | NA | NA | NA | NA |
| 13 | 1 | 166 | 3 | 5 | 3 | 2 | 0 |
| | 2 | 127 | 2 | 2 | 3 | 0 | NA |
| | 3 | 105 | 3 | 2 | 0 | NA | NA |
| 27 | 1 | 102 | 2 | 0 | NA | NA | NA |
| | 2 | 142 | 3 | 2 | 0 | NA | NA |
| | 3 | 125 | 2 | 0 | NA | NA | NA |
| 62 | 1 | 124 | 5 | 3 | 0 | NA | NA |
| | 2 | 196 | 8 | 3 | 2 | 0 | NA |
| | 3 | 75 | 8 | 5 | 3 | 0 | NA |
| 119 | 1 | 151 | 10 | 0 | NA | NA | NA |
| | 2 | 129 | 0 | NA | NA | NA | NA |
| | 3 | 132 | 0 | NA | NA | NA | NA |
| 177 | 1 | 152 | 3 | 0 | NA | NA | NA |
| | 2 | 149 | 5 | 2 | 0 | NA | NA |
| | 3 | 132 | 3 | 2 | 0 | NA | NA |
| 370 | 1 | 125 | 3 | 2 | 0 | NA | NA |
| | 2 | 181 | 5 | 2 | 0 | NA | NA |
| | 3 | 119 | 5 | 0 | NA | NA | NA |
| 546 | 1 | 92 | 5 | 0 | NA | NA | NA |
| | 2 | 94 | 5 | 2 | 0 | NA | NA |
| | 3 | 87 | 5 | 0 | NA | NA | NA |
| 721 | 1 | 157 | 5 | 2 | 0 | NA | NA |
| | 2 | 95 | 13 | 0 | NA | NA | NA |
| | 3 | 102 | 5 | 2 | 0 | NA | NA |

DAA/DBA - days after/before application
NA - Not analysed
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).

**Table B.8. 303 Residues of pydiflumetofen (individual triplicates) in the individual soil layers for Southern France ([redacted] 2015c)**

| DAA | Subplot | Pydiflumetofen [g a.s./ha] | | | | |
|---|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | 30-50 cm | 50-70 cm |
| -0# | 1 | 0 | 0 | NA | NA | NA |
| | 2 | 0 | 0 | NA | NA | NA |
| | 3 | 0 | 0 | NA | NA | NA |
| 0 | 1 | 262 | NA | NA | NA | NA |
| | 2 | 194 | NA | NA | NA | NA |
| | 3 | 195 | NA | NA | NA | NA |
| 3 | 1 | 132 | 1 | 0 | NA | NA |
| | 2 | 191 | 1 | 1 | NA | NA |
| | 3 | 215 | 3 | 0 | NA | NA |
| 7 | 1 | 209 | 12 | 8 | NA | NA |
| | 2 | 208 | 26 | 12 | NA | NA |
| | 3 | 128 | 12 | 19 | NA | NA |
| 15 | 1 | 131 | 8 | 3 | 1 | NA |
| | 2 | 72 | 3 | 3 | 3 | NA |
| | 3 | 77 | 3 | 1 | 1 | NA |
| 29 | 1 | 120 | 7 | 0 | NA | NA |
| | 2 | 102 | 0 | NA | NA | NA |
| | 3 | 110 | 0 | NA | NA | NA |
| 59 | 1 | 81 | 0 | NA | NA | NA |
| | 2 | 121 | 0 | NA | NA | NA |
| | 3 | 83 | 0 | NA | NA | NA |
| 121 | 1 | 118 | 0 | NA | NA | NA |
| | 2 | 106 | 0 | NA | NA | NA |
| | 3 | 76 | 0 | NA | NA | NA |
| 172 | 1 | 80 | 0 | NA | NA | NA |
| | 2 | 72 | 0 | NA | NA | NA |
| | 3 | 103 | 0 | NA | NA | NA |
| 366 | 1 | 69 | 1 | 0 | NA | NA |
| | 2 | 87 | 1 | 0 | NA | NA |
| | 3 | 97 | 1 | 0 | NA | NA |
| 533 | 1 | 56 | 1 | 0 | NA | NA |
| | 2 | 81 | 0 | NA | NA | NA |
| | 3 | 51 | 1 | 0 | NA | NA |
| 721 | 1 | 63 | 1 | 3 | 0 | NA |
| | 2 | 36 | 3 | 0 | NA | NA |
| | 3 | 40 | 0 | NA | NA | NA |

DAA/DBA - days after/before application
NA - Not analysed
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).

**Table B.8. 304 Residues of pydiflumetofen (individual triplicates) in the individual soil layers for Spain ([redacted] 2015d)**

| DAA | Subplot | Pydiflumetofen [g a.s./ha] | | | |
|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | 30-50 cm |
| -4# | 1 | 0 | 0 | NA | NA |
| | 2 | 0 | 0 | NA | NA |
| | 3 | 0 | 0 | NA | NA |
| 0 | 1 | 186 | NA | NA | NA |
| | 2 | 185 | NA | NA | NA |
| | 3 | 196 | NA | NA | NA |
| 3 | 1 | 264 | 0 | NA | NA |
| | 2 | 222 | 4 | 0 | NA |
| | 3 | 208 | 0 | NA | NA |
| 7 | 1 | 268 | 0 | N/A | NA |
| | 2 | 169 | 3 | 0 | NA |
| | 3 | 192 | 1 | 0 | NA |
| 14 | 1 | 45 | 0 | NA | NA |
| | 2 | 37 | 0 | NA | NA |
| | 3 | 113 | 0 | NA | NA |
| 29 | 1 | 122 | 0 | NA | NA |
| | 2 | 57 | 0 | NA | NA |
| | 3 | 64 | 4 | 0 | NA |
| 62 | 1 | 93 | 4 | 0 | NA |
| | 2 | 112 | 1 | 0 | NA |
| | 3 | 124 | 1 | 0 | NA |
| 119 | 1 | 107 | 2 | 0 | NA |
| | 2 | 101 | 32 | 0 | NA |
| | 3 | 110 | 0 | N/A | NA |
| 178 | 1 | 118 | 0 | NA | NA |
| | 2 | 143 | 0 | NA | NA |
| | 3 | 177 | 0 | NA | NA |
| 358 | 1 | 118 | 0 | N/A | NA |
| | 2 | 182 | 4 | 0 | NA |
| | 3 | 132 | 1 | 0 | NA |
| 538 | 1 | 71 | 0 | N/A | NA |
| | 2 | 89 | 7 | N/A | NA |
| | 3 | 79 | 2 | N/A | NA |
| 714 | 1 | 70 | 0 | 0 | NA |
| | 2 | 108 | 8 | 0 | NA |
| | 3 | 95 | 8 | 0 | NA |

DAA/DBA - days after/before application
NA - Not analysed
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).

**Table B.8. 305 Residues of pydiflumetofen (individual triplicates) in the individual soil layers for UK ([redacted] 2015e)**

| DAA | Subplot | Pydiflumetofen [g a.s./ha] | | | |
|---|---|---|---|---|---|
| | | 0–10 cm | 10–20 cm | 20–30 cm | 30-50 cm |
| -1# | 1 | 0 | 0 | NA | NA |
| | 2 | 0 | 0 | NA | NA |
| | 3 | 0 | 0 | NA | NA |
| 0 | 1 | 132 | NA | NA | NA |
| | 2 | 132 | NA | NA | NA |
| | 3 | 110 | NA | NA | NA |
| 3 | 1 | 133 | 0 | NA | NA |
| | 2 | 143 | 0 | NA | NA |
| | 3 | 119 | 0 | NA | NA |
| 7 | 1 | 151 | 0 | NA | NA |
| | 2 | 163 | 0 | NA | NA |
| | 3 | 130 | 0 | NA | NA |
| 15 | 1 | 113 | 0 | NA | NA |
| | 2 | 127 | 0 | NA | NA |
| | 3 | 93 | 2 | 0 | NA |
| 27 | 1 | 122 | 1 | 0 | NA |
| | 2 | 92 | 1 | 0 | NA |
| | 3 | 101 | 1 | 0 | NA |
| 59 | 1 | 144 | 1 | 0 | NA |
| | 2 | 106 | 0 | N/A | NA |
| | 3 | 147 | 1 | 0 | NA |
| 118 | 1 | 128 | 0 | NA | NA |
| | 2 | 94 | 0 | NA | NA |
| | 3 | 102 | 0 | NA | NA |
| 182 | 1 | 167 | 0 | NA | NA |
| | 2 | 151 | 0 | NA | NA |
| | 3 | 143 | 2 | 0 | NA |
| 372 | 1 | 135 | 0 | NA | NA |
| | 2 | 148 | 0 | NA | NA |
| | 3 | 114 | 1 | 0 | NA |
| 539 | 1 | 145 | 0 | 0 | NA |
| | 2 | 112 | 0 | NA | NA |
| | 3 | 99 | 2 | 0 | NA |
| 718 | 1 | 127 | 4 | 0 | NA |
| | 2 | 70 | 2 | 0 | NA |
| | 3 | 57 | 0 | NA | NA |

DAA/DBA - days after/before application
NA - Not analysed
Residue value of 0 g a.s./ha was given for analysed soil layers where the wet weight soil residue was <LOQ (0.5 µg/kg).

## Appendix II Field dissipation study results used in kinetic analysis – non normalised results

**Table B.8. 306 Study data and model input data (g a.s./ha) for Ohrensen (DE), [redacted] (2015a)**

| Time (DAT) | 0-10 cm | 10-20 cm | Sum (input) |
|---|---|---|---|
| 0 | 141.2 | - | 141.2 |
| 0 | 152.3 | - | 152.3 |
| 0 | 140.9 | - | 140.9 |
| 3 | 182.6 | 0.1[a] | 182.7 |
| 3 | 155.8 | 0.1[a] | 156.0 |
| 3 | 133.0 | 0.1[a] | 133.1 |
| 7 | 128.8 | 0.1[a] | 129.0 |
| 7 | 130.0 | 0.5[b] | 130.5 |
| 7 | 134.6 | 0.1[a] | 134.7 |
| 14 | 130.6 | 0.6[b] | 131.1 |
| 14 | 164.5 | 0.1[a] | 164.6 |
| 14 | 131.1 | 0.1[a] | 131.2 |
| 29 | 120.5 | 0.1[a] | 120.7 |
| 29 | 121.0 | 0.1[a] | 121.1 |
| 29 | 109.9 | 0.1[a] | 110.0 |
| 58 | 93.6 | 0.1[a] | 93.7 |
| 58 | 111.7 | 0.1[a] | 111.8 |
| 58 | 108.6 | 0.1[a] | 108.7 |
| 119 | 100.0 | 0.6[b] | 100.6 |
| 119 | 120.4 | 0.1[a] | 120.6 |
| 119 | 107.4 | 0.1[a] | 107.5 |
| 178 | 130.2 | 0.1[a] | 130.4 |
| 178 | 126.7 | 0.1[a] | 126.9 |
| 178 | 138.2 | 0.1[a] | 138.4 |
| 358 | 109.2 | 0.1[a] | 109.3 |
| 358 | 115.2 | 0.1[a] | 115.4 |
| 358 | 107.0 | 0.6[b] | 107.7 |
| 533 | 117.1 | 0.1[a] | 117.3 |
| 533 | *223.3*[c] | 0.2[a] | *223.5*[c] |
| 533 | 89.9 | 0.6[b] | 90.6 |
| 715 | 106.4 | 0.2[a] | 106.5 |
| 715 | 107.2 | 0.2[a] | 107.3 |
| 715 | 121.9 | 0.7[b] | 122.6 |

a - <LOD b - <LOQ c – value identified as a clear outlier; not included in optimisations

**Table B.8. 307 Study data and model input data (g a.s./ha) for Emilia Romagna (IT), [redacted] (2015b)**

| Time (DAT) | 0-10 cm | 10-20 cm | 20-30 cm | 30-50 cm | 50-70 cm | 70-100 cm | Sum (input) |
|---|---|---|---|---|---|---|---|
| 0 | 161.4 | | | | | | 161.4 |
| 0 | 184.6 | | | | | | 184.6 |
| 0 | 111.5 | | | | | | 111.5 |
| 3 | 130.1 | 6.8 | 3.4 | | | | 140.3 |
| 3 | 115.6 | 3.5 | 1.1 | | | | 120.3 |
| 3 | 73.9 | 3.2 | 1.4 | | | | 78.4 |
| 7 | 142.8 | 4.2 | 3.5 | | | | 150.5 |
| 7 | 207.4 | 3.2 | 2.2 | | | | 212.8 |
| 7 | 93.8 | 2.6 | 1.0 | | | | 97.5 |
| 14 | 170.6 | 2.9 | 2.7 | 2.2 | 0.3[b] | | 178.7 |
| 14 | 149.7 | 5.9 | 1.4 | 2.1 | 0.3[b] | | 159.4 |
| 14 | 143.3 | 2.4 | 2.0 | 2.2 | 1.2b | | 151.1 |
| 28 | 131.9 | 2.2 | 1.6 | 2.1 | 1.2b | | 139.0 |
| 28 | 119.6 | 3.0 | 1.0 | 1.1b | | | 124.8 |
| 28 | 126.4 | 2.7 | 2.2 | 3.9 | 2.9 | 4.1 | 142.3 |
| 58 | 118.4 | 3.8 | 2.1 | 2.3 | 1.2b | | 127.9 |
| 58 | 88.0 | 3.0 | 2.0 | 1.1b | | | 94.2 |
| 58 | 188.5 | 3.7 | 2.8 | 3.2 | 1.2b | | 199.3 |
| 121 | 85.5 | 0.1[b] | | | | | 85.7 |
| 121 | 84.9 | 0.6[b] | | | | | 85.5 |
| 121 | 109.6 | 0.1[b] | | | | | 109.8 |
| 182 | 127.4 | 0.6b | | | | | 128.0 |
| 182 | 106.2 | 0.6b | | | | | 106.8 |
| 182 | 122.4 | 1.4 | 0.1[b] | | | | 123.9 |
| 366 | 105.4 | 1.2 | 0.1[b] | | | | 106.7 |
| 366 | 105.9 | 0.6b | | | | | 106.6 |
| 366 | 126.0 | 4.7 | 4.2 | 1.2b | | | 136.2 |
| 542 | 99.8 | 1.7 | 0.6b | | | | 102.2 |
| 542 | 95.7 | 0.7b | | | | | 96.3 |
| 542 | 152.7 | 7.2 | 3.4 | 1.1b | | | 164.5 |
| 716 | 77.7 | 2.2 | 0.6b | | | | 80.6 |
| 716 | 62.8 | 2.2 | 2.0 | 1.3b | | | 68.3 |
| 716 | 67.4 | 8.2 | 3.7 | 5.3 | 0.3[b] | | 84.9 |

a - <LOD b - <LOQ

**Table B.8. 308 Study data and model input data (g a.s./ha) for Bas Rhin (N. FR), [redacted] (2015d)**

| Time (DAT) | 0-10 cm | 10-20 cm | 20-30 cm | 30-50 cm | 50-70 cm | 70-100 cm | Sum (input) |
|---|---|---|---|---|---|---|---|
| 0 | 109.9 | | | | | | 109.9 |
| 0 | 125.2 | | | | | | 125.2 |
| 0 | 113.5 | | | | | | 113.5 |
| 3 | 118.0 | 0.6[b] | | | | | 118.6 |
| 3 | 118.2 | 0.6[b] | | | | | 118.8 |
| 3 | 124.0 | 0.6[b] | | | | | 124.6 |
| 7 | 168.5 | 0.6[b] | | | | | 169.1 |
| 7 | 164.2 | 0.6[b] | | | | | 164.7 |
| 7 | 137.0 | 0.6[b] | | | | | 137.6 |
| 13 | 165.4 | 3.8 | 4.2 | 3.1 | 2.2 | 1.4[b] | 180.2 |
| 13 | 126.8 | 2.2 | 2.1 | 2.9 | 1.1[b] | | 135.2 |
| 13 | 105.8 | 2.9 | 1.1 | 1.2[b] | | | 111.0 |
| 27 | 101.8 | 2.4 | 0.7[b] | | | | 105.0 |
| 27 | 142.3 | 3.4 | 1.9 | 1.1[b] | | | 148.7 |
| 27 | 124.7 | 1.5 | 0.7[b] | | | | 126.9 |
| 62 | 123.3 | 4.2 | 2.5 | 1.2[b] | | | 131.2 |
| 62 | 196.1 | 8.3 | 3.7 | 2.1 | 1.1[b] | | 211.4 |
| 62 | 75.8 | 8.5 | 4.5 | 3.5 | 1.1[b] | | 93.4 |
| 119 | 150.3 | 10.9 | 0.7[b] | | | | 161.9 |
| 119 | 129.4 | 0.7[b] | | | | | 130.0 |
| 119 | 131.5 | 0.7[b] | | | | | 132.2 |
| 177 | 152.3 | 3.7 | 0.7[b] | | | | 156.7 |
| 177 | 148.1 | 5.3 | 1.8 | 0.2[a] | | | 155.4 |
| 177 | 131.7 | 2.5 | 1.3 | 1.1[b] | | | 136.7 |
| 370 | 125.2 | 2.8 | 1.0 | 1.2[b] | | | 130.2 |
| 370 | 180.8 | 4.8 | 1.0 | 1.1[b] | | | 187.8 |
| 370 | 119.4 | 4.7 | 0.6[b] | | | | 124.8 |
| 546 | 91.8 | 4.9 | 0.7[b] | | | | 97.4 |
| 546 | 93.7 | 4.2 | 1.8 | 0.3[a] | | | 100.0 |
| 546 | 87.2 | 4.8 | 0.7[b] | | | | 92.7 |
| 721 | 156.4 | 4.4 | 2.2 | 1.5[b] | | | 164.4 |
| 721 | 96.1 | 14.1 | 0.8[b] | | | | 110.9 |
| 721 | 101.8 | 5.6 | 2.4 | 1.4[b] | | | 111.3 |

a - <LOD b - <LOQ

**Table B.8. 309 Study data and model input data (g a.s./ha) for Midi-Pyrénées (S. FR), [redacted] (2015d)**

| Time (DAT) | 0-10 cm | 10-20 cm | 20-30 cm | 30-50 cm | Sum (input) |
|---|---|---|---|---|---|
| 0 | 261.9 | | | | 261.9 |
| 0 | 193.9 | | | | 193.9 |
| 0 | 195.2 | | | | 195.2 |
| 3 | 132.9 | 0.8 | 0.5[b] | | 134.1 |
| 3 | 191.1 | 2.0 | 1.3 | | 194.4 |
| 3 | 214.6 | 2.1 | 0.5[b] | | 217.2 |
| 7 | 209.4 | 11.9 | 8.1 | | 229.4 |
| 7 | 208.4 | 26.6 | 12.9 | | 247.9 |
| 7 | 128.7 | 12.7 | 19.8 | | 161.3 |
| 15 | 131.1 | 7.7 | 3.4 | 1.5 | 143.7 |
| 15 | 71.9 | 3.1 | 2.6 | 3.0 | 80.6 |
| 15 | 76.8 | 2.8 | 1.8 | 1.5 | 82.9 |
| 29 | 119.2 | 6.7 | 0.1[a] | | 126.0 |
| 29 | 101.8 | 0.1[a] | | | 102.0 |
| 29 | 110.2 | 0.1[a] | | | 110.4 |
| 59 | 81.2 | 0.5[b] | | | 81.8 |
| 59 | 120.6 | 0.6[b] | | | 121.2 |
| 59 | 82.8 | 0.1[a] | | | 83.0 |
| 121 | 118.8 | 0.6[b] | | | 119.3 |
| 121 | 105.8 | 0.1[a] | | | 105.9 |
| 121 | 75.5 | 0.1[a] | | | 75.7 |
| 172 | 80.6 | 0.6[b] | | | 81.1 |
| 172 | 72.1 | 0.6[b] | | | 72.7 |
| 172 | 103.8 | 0.6[b] | | | 104.3 |
| 366 | 68.8 | 0.8 | 0.5[b] | | 70.1 |
| 366 | 86.6 | 1.3 | 0.6[b] | | 88.4 |
| 366 | 96.8 | 1.5 | 0.6[b] | | 98.9 |
| 533 | 56.8 | 1.0 | 0.5[b] | | 58.3 |
| 533 | 81.5 | 0.5[b] | | | 82.0 |
| 533 | 51.0 | 0.9 | 0.5[b] | | 52.5 |
| 721 | 63.5 | 1.6 | 2.9 | 0.3[a] | 68.3 |
| 721 | 35.5 | 2.3 | 0.6[b] | | 38.4 |
| 721 | 40.3 | 0.6[b] | | | 40.9 |

a - <LOD b - <LOQ

**Table B.8. 310 Study data and model input data (g a.s./ha) for Valencia (ES), [redacted] (2015e)**

| Time (DAT) | 0-10 cm | 10-20 cm | 20-30 cm | Sum (input) |
|---|---|---|---|---|
| 0 | 186.0 | | | 186.0 |
| 0 | 184.8 | | | 184.8 |
| 0 | 196.2 | | | 196.2 |
| 3 | 264.5 | 0.6[b] | | 265.1 |
| 3 | 221.3 | 3.7 | 0.1[a] | 225.1 |
| 3 | 207.8 | 0.6[b] | | 208.4 |
| 7 | 267.9 | 0.6[b] | | 268.6 |
| 7 | 168.4 | 3.3 | 0.6[b] | 172.2 |
| 7 | 191.8 | 1.1 | 0.6[b] | 193.5 |
| 14 | 44.4 | 0.1[a] | | 44.5 |
| 14 | 37.7 | 0.1[a] | | 37.8 |
| 14 | 113.2 | 0.6[b] | | 113.9 |
| 29 | 121.8 | 0.6[b] | | 122.4 |
| 29 | 56.7 | 0.6[b] | | 57.3 |
| 29 | 63.5 | 3.7 | 0.1[a] | 67.3 |
| 62 | 92.8 | 3.3 | 0.6[b] | 96.6 |
| 62 | 112.2 | 1.2 | 0.1[a] | 113.6 |
| 62 | 123.4 | 1.1 | 0.6[b] | 125.1 |
| 119 | 107.3 | 2.4 | 0.1[a] | 109.9 |
| 119 | 101.4 | 31.9 | 0.1[a] | 133.4 |
| 119 | 109.4 | 0.1[a] | | 109.6 |
| 178 | 118.1 | 0.7[b] | | 118.7 |
| 178 | 143.3 | 0.6[b] | | 144.0 |
| 178 | 177.4 | 0.6[b] | | 178.0 |
| 358 | 118.5 | 0.7[b] | | 119.1 |
| 358 | 181.1 | 3.8 | 0.2[a] | 185.1 |
| 358 | 131.8 | 1.4 | 0.2[a] | 133.4 |
| 538 | 71.4 | 0.7[b] | | 72.0 |
| 538 | 89.0 | 6.7 | 0.7[b] | 96.4 |
| 538 | 79.2 | 2.4 | 0.1[a] | 81.7 |

a - <LOD b - <LOQ

**Table B.8. 311 Study data and model input data (g a.s./ha) for Wilson (UK), [redacted] (2015f)**

| Time (DAT) | 0-10 cm | 10-20 cm | 20-30 cm | Sum (input) |
|---|---|---|---|---|
| 0 | 132.3 | | | 132.3 |
| 0 | 132.0 | | | 132.0 |
| 0 | 110.0 | | | 110.0 |
| 3 | 133.3 | 0.1a | | 133.4 |
| 3 | 142.8 | 0.1a | | 143.0 |
| 3 | 119.4 | 0.1a | | 119.5 |
| 7 | 151.0 | 0.1a | | 151.2 |
| 7 | 163.2 | 0.1a | | 163.3 |
| 7 | 129.5 | 0.6b | | 130.1 |
| 15 | 113.3 | 0.6b | | 113.8 |
| 15 | 126.7 | 0.6b | | 127.3 |
| 15 | 92.9 | 2.0 | 0.6b | 95.5 |
| 27 | 122.0 | 0.9 | 0.1a | 123.1 |
| 27 | 91.9 | 0.9 | 0.1a | 92.9 |
| 27 | 101.3 | 1.3 | 0.1a | 102.7 |
| 59 | 143.9 | 1.3 | 0.1a | 145.3 |
| 59 | 105.9 | 0.6b | | 106.5 |
| 59 | 146.7 | 1.1 | 0.1a | 148.0 |
| 118 | 128.2 | 0.6b | | 128.7 |
| 118 | 94.2 | 0.6b | | 94.7 |
| 118 | 101.8 | 0.6b | 0.6b | 102.4 |
| 182 | 167.5 | 0.6b | | 168.1 |
| 182 | 151.2 | 0.1a | | 151.4 |
| 182 | 143.3 | 1.7 | | 145.6 |
| 372 | 135.4 | 0.6b | | 136.0 |
| 372 | 147.7 | 0.6b | | 148.3 |
| 372 | 114.2 | 1.1 | 0.6b | 115.9 |
| 539 | 145.1 | 2.1 | 0.6b | 147.8 |
| 539 | 112.4 | 8.4 | 0.6b | 121.3 |
| 539 | 98.8 | 2.0 | 0.1a | 100.9 |
| 718 | 127.0 | 4.3 | 0.6b | 131.9 |
| 718 | 70.0 | 1.7 | 0.6b | 72.3 |
| 718 | 57.2 | 0.6b | | 57.8 |

a - <LOD b - <LOQ