

# **Draft Assessment Report**

## **Evaluation of Active Substances**

Plant Protection Products

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

### **Pydiflumetofen**

### **List of Endpoints**

Great Britain

September 2023

## Version History

When	What
October 2022	Initial GB DAR
June 2023	Post Expert Committee on Pesticides (ECP) Independent Scientific Advice (ISA)
September 2023	Update following consideration of new ED data for Ecotoxicology

## List of end points

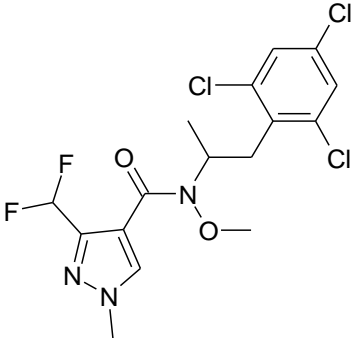
Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Pydiflumetofen
Function ( <i>e.g.</i> fungicide)	Fungicide
Evaluator	HSE

#### Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	3-(difluoromethyl)-N-methoxy-1-methyl-N-[(2E)-1-(2,4,6-trichlorophenyl)propan-2-yl]-1H-pyrazole-4-carboxamide
Chemical name (CA)	3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide
CIPAC No	999
CAS No	1228284-64-7
EC No (EINECS or ELINCS)	Not available
FAO Specification (including year of publication)	No FAO specification available
Minimum purity of the active substance as manufactured	980 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula	C <sub>16</sub> H <sub>16</sub> Cl <sub>3</sub> F <sub>2</sub> N <sub>3</sub> O <sub>2</sub>
Molar mass	426.7 g/mol
Structural formula	 <p>Pydiflumetofen consists of two enantiomers as a racemate (50:50)</p>

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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	112.7 °C (99.5%)
Boiling point (state purity)	Decomposed before boiling
Temperature of decomposition (state purity)	283°C (99.5%)
Appearance (state purity)	White powder (99.5%) Off-white powder (98.5%)
Vapour pressure (state temperature, state purity)	0.18µPa at 20°C (99.5%) 0.53µPa at 25°C (99.5%)
Henry's law constant (state temperature)	$1.51 \times 10^{-7} \text{ Pa m}^3 \text{ mol}^{-1}$ (25°C)
Solubility in water (state temperature, state purity and pH)	1.5 mg/L at 25°C (pH 6.6 ) (99.5%)
Solubility in organic solvents (state temperature, state purity)	at 25°C (98.5%): acetone 220 g/L methanol 26 g/L dichloromethane > 500 g/L octanol 7.2 g/L ethyl acetate 130 g/L toluene 67 g/L hexane 270 mg/L
Surface tension (state concentration and temperature, state purity)	71.5 mN/m at 21°C (90 % saturated solution) (99.5%)
Partition coefficient (state temperature, pH and purity)	$\log P_{OW} = 3.8$ at 25°C (pH ) (99.5%)
Dissociation constant (state purity)	Does not dissociate in water between pH 2 and pH 12 at 25 °C (99.8%).
UV/VIS absorption (max.) incl. $\epsilon$ (state purity, pH)	Purity 99.5% : Neutral solution: $\lambda_{max}$ 230 nm $\epsilon$ : 17736 (L mol <sup>-1</sup> cm <sup>-1</sup> ) Acidic solution: $\lambda_{max}$ 230 nm $\epsilon$ : 18267 (L mol <sup>-1</sup> cm <sup>-1</sup> ) Basic solution: $\lambda_{max}$ 230 nm $\epsilon$ : 17850 (L mol <sup>-1</sup> cm <sup>-1</sup> )  No absorption maxima > 290 nm
Flammability (state purity)	Not classified (98.5%)
Explosive properties (state purity)	Not classified (98.5%)
Oxidising properties (state purity)	Not classified (98.5%)

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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### Summary of representative uses evaluated, for which all risk assessments needed to be completed (pydiflumetofen) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. g/L (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	g a.s. /hL min-max (l)	Water L/ha min-max	g a.s./ha min-max (l)		
Spring and winter barley	GB	Miravis Plus	F	<i>Erysiphe graminis</i> (ERYSGR) <i>Puccinia hordei</i> (PUCCHD) <i>Pyrenophora teres</i> (PYRNTE) <i>Ramularia collo-cygni</i> (RAMUCC) <i>Rhynchosporium secalis</i> (RHYNSE)	EC	62.5	Foliar	BBCH 30-59 (or 41-59)	1	N/A	-	100-300	166	N/A	Maximum of 1 application per crop & season
Spring and winter barley and oat	GB	Miravis Plus	F	<i>Fusarium spp.</i> (FUSASP)	EC	62.5	Foliar	BBCH 55-65	1	N/A	-	100-300	200	N/A	Maximum of 1 application per crop & season
Spring and winter wheat, durum wheat, spelt, rye and triticale	GB	Miravis Plus	F	<i>Erysiphe graminis</i> (ERYSGR) <i>Puccinia recondita</i> (PUCCRE) <i>Pyrenophora tritici-repentis</i> (PYRNTR)	EC	62.5	Foliar	BBCH 30-59 (or 41-69)	1	N/A	-	100-300	166	N/A	Maximum of 1 application per crop & season

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HSE

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					Type (d-f)	Conc. a.s. g/L (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	g a.s. /hL min-max (l)	Water L/ha min-max	g a.s./ha min-max (l)		
				<i>Septoria nodorum</i> (LEPTNO) <i>Septoria tritici</i> (SEPTTR)											
Spring and winter wheat, durum wheat, spelt, rye and triticale	GB	<i>Miravis Plus</i>	F	<i>Fusarium spp.</i> (FUSASP)	EC	62.5	Foliar	BBCH 61-69	1	N/A	-	100-300	200	N/A	Maximum of 1 application per crop & season
Spring and winter oilseed rape (OSR)	GB	<i>Miravis Plus</i>	F	<i>Sclerotinia sclerotiorum</i> (SCLESC)	EC	62.5	Foliar	BBCH 57-69	1	N/A	-	100-300	200	N/A	One application every 3 years.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)  
 (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)  
 (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds  
 (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
 (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide  
 (f) All abbreviations used must be explained  
 (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
 (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).**  
 (j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  
 (k) Indicate the minimum and maximum number of applications possible under practical conditions of use  
 (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)  
 (m) PHI - minimum pre-harvest interval

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**Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (pydiflumetofen)**

**Regulation (EC) N° 1107/2009 Article 8.1(g)**

**Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses**

Crop and/or situation (a)	Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
Carrots	GB	A1964 9H (Miravis)	F	Powdery mildew (Erysiphe heraclei ERYSHE) Alternaria dauci (ALTDA)	SC	200 g/L	Foliar spray	BBCH14-49	2	14	-	300-1000	0.07	14	
Parsley roots	GB	A1964 9H (Miravis)	F	Powdery mildew (Erysiphe heraclei ERYSHE) Alternaria dauci (ALTDA)	SC	200 g/L	Foliar spray	BBCH21-49	2	14	-	200-600	0.07	14	
Parsnip	GB	A1964 9H (Miravis)	F	Powdery mildew (Erysiphe heraclei ERYSHE) Alternaria dauci (ALTDA)	SC	200 g/L	Foliar spray	BBCH14-49	2	14	-	300-1000	0.07	14	

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for

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<p>situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) <i>e.g.</i> biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) <i>e.g.</i> wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, <i>e.g.</i> overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</b></p> <p>(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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### Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### Further information, Efficacy

##### Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

The representative uses/ GAPs are supported.

##### Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

The representative uses/ GAPs are supported.

##### Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

The representative uses/ GAPs are supported.

##### Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism

Met1	Met2	Met3	Met4	Met5	Met6
N/A	N/A	N/A	N/A	N/A	N/A

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## Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

### Methods of Analysis

#### Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	HPLC-DAD
Impurities in technical a.s. (analytical technique)	HPLC-DAD GC-FID
Plant protection product (analytical technique)	HPLC-UV

#### Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

#### Residue definitions for enforcement/monitoring purposes

Food of plant origin	Pydiflumetofen (sum of isomers)
Food of animal origin	Pydiflumetofen (sum of isomers)
Soil	Pydiflumetofen (sum of isomers)
Sediment	Pydiflumetofen (sum of isomers)
Water surface	Pydiflumetofen (sum of isomers)
drinking/ground	Pydiflumetofen (sum of isomers)
Air	Pydiflumetofen (sum of isomers)
Body fluids and tissues	2,4,6- trichlorophenol (free and conjugated)

#### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS; QuEChERS method EN 15662 (pydiflumetofen) LOQ: 0.01 mg/kg for high water, high acid, high oil, high protein, high starch and “difficult to analyse” crop groups <b>Data to address extraction efficiency for high oil crops are required</b>
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS; QuEChERS method EN 15662 (pydiflumetofen) LOQ: 0.01 mg/kg for all commodities LC-MS/MS (2,4,6- trichlorophenol, free and conjugated) LOQ: 0.01 mg/kg for all commodities
Soil (analytical technique and LOQ)	LC-MS/MS (pydiflumetofen) LOQ: 0.5 µg/kg
Water (analytical technique and LOQ)	LC-MS/MS (pydiflumetofen) LOQ: 0.05 µg/L

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Air (analytical technique and LOQ)

LC-MS/MS (pydiflumetofen)

LOQ: 30 µg/m<sup>3</sup>. **An LOQ of 15 µg/m<sup>3</sup> is required.**

Body fluids and tissues (analytical technique and LOQ)

LC-MS/MS (2,4,6- trichlorophenol, free and conjugated)

LOQ: 0.01 mg/kg for blood and tissues

### Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance

Pydiflumetofen

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]<sup>1</sup>:

Peer review proposal <sup>2</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

<sup>1</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>2</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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## Section 2 Mammalian Toxicology

## Impact on Human and Animal Health

### Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability

Toxicokinetics

85-90% of oral dose absorbed in male and females rats (based on urinary (6-13%) and biliary (67-81%) excretion within 72 h, single oral gavage dose at 5 mg/kg bw). However, oral systemic availability (F) at the low dose was 50% of the administered dose. Oral absorption was reduced to 50-55% at 100 mg/kg bw and 19-24% at 300 mg/kg bw. Adjustment of AOEL and AAOEL for 50% oral systemic availability might be required.

$T_{1/2} < 2$  h following iv administration of 1 mg/kg bw. Systemic exposure ( $AUC_{(0-t)}$ ) was non-linear from 300 mg/kg bw in male rat and 100 mg/kg in female rat. Following a single oral administration,  $C_{max}$ : 0.5- 2 hours (5 mg/kg bw) and 8 hours ( $\geq 100$  mg/kg bw).  $AUC_{(0-t)}$  increased sub proportionally between 5 mg/kg bw and higher doses.

	Pharmacokinetic parameters for total radioactivity in rat plasma after oral administration with pyrazole-labelled pydiflumetofen			
	5 mg/kg bw		300 mg/kg bw	100 mg/kg bw
	M	F	M	F
$C_{max}$ (µg)	0.49	0.67	7.1	3.1
$C_{max}/D$	0.0969	0.131	0.0259	0.0365
$t_{max}$ (hours) <sup>1</sup>	2	0.5	8	2
$t_{1/2}$ (hours)	56.6*	30.4*	18.6*	10.6
$AUC_{(0-t)}$ (µg equiv.h/mL)	6.43	5.37	195	55.9
$AUC_{(0-t)}/D$	1.26	1.05	0.705	0.653
$AUC_{(0-inf)}$ (µg equiv.h/mL)	7.45*	5.81*	197*	56.2
$AUC_{(0-inf)}/D$	1.47*	1.13*	0.712*	0.658
$AUC\%$ Extrap	13.7*	7.56*	1.02*	0.678

\* = Coefficient of determination was less than 0.800 and/or the extrapolation of the AUC to infinity represents more than 20% of the total area.

<sup>1</sup> = Median reported for  $t_{max}$

Distribution

Widely distributed, with highest concentrations of radioactivity observed in the liver and kidney

Potential for bioaccumulation

No evidence for accumulation

Rate and extent of excretion

Following a single oral gavage dose, ca. 91% was excreted within 48 h with excretion complete by 168 h; predominantly in faeces via biliary excretion. The remainder of the dose was recovered from urine, with <0.1% of dose recovered in expired air or in the carcass.

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Metabolism in animals

Extensively metabolised (> 95%); in rat, unchanged parent in urine accounted for less than 3.9% of the 5 mg/kg bw oral dose.  
The primary metabolic routes included demethoxylation, N-dealkylation, single and dihydroxylation, O-demethylation and oxidative and reductive dechlorination. The majority of these metabolites were also mono and di-hydroxylated and in many cases conjugated with glucuronide or glutathione.  
Metabolic profile very similar in mouse, goat and hen.

*In vitro* metabolism

No notable difference of pydiflumetofen metabolism in a comparative *in vitro* study with rat and human liver microsome. No unique human metabolite identified.

Toxicologically relevant compounds (animals and plants)

Pydiflumetofen, 2,4,6-Trichlorophenol, SYN508272 and SYN548263

Toxicologically relevant compounds (environment)

Pydiflumetofen

## Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD<sub>50</sub> oral

> 5000 mg/kg bw

Rat LD<sub>50</sub> dermal

> 5000 mg/kg bw

Rat LC<sub>50</sub> inhalation

> 5.1 mg/L air /4h (nose-only)

Skin irritation

Non-irritant

Eye irritation

Non-irritant

Skin sensitisation

Non- sensitising (LLNA)

Phototoxicity

Not-phototoxic (*in vitro* 3T3 NRU assay)

## Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect

Body weight reduction (dog)  
Liver: increased liver weight, blood clinical chemistry parameters changes, hepatocellular hypertrophy (rat, mouse, dog)  
Thyroid: hypertrophy of thyroid follicular epithelium (rat)

Relevant oral NOAEL

90-day, rat: 18.6 mg/kg bw per day  
90-day, mouse: 17.5 mg/kg bw per day  
90-day, dog: 30 mg/kg bw per day

Relevant dermal NOAEL

28-day, rat: 1000 mg/kg bw per day

Relevant inhalation NOAEL

No data - not required

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## Section 2 Mammalian Toxicology

### Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

<i>In vitro</i> studies	Negative Ames and MLA assays, weakly positive/equivocal for clastogenicity (CA) – S9	
<i>In vivo</i> studies	Not genotoxic (negative in two mouse bone marrow micronucleus studies and in rat chromosome aberration assays)	
Photomutagenicity	Not required	
Potential for genotoxicity	Pydiflumetofen is unlikely to be genotoxic	

### Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Rat & mouse: Lower bodyweight and increased liver weight with associated histopathology changes	
Relevant long-term NOAEL	2-year, rat: 9.9 mg/kg bw per day 18-month, mouse: 9.2 mg/kg bw per day	
Carcinogenicity (target organ, tumour type)	Rat: no tumours Mouse: liver tumours in males. Mechanistic work insufficient to exclude human relevance. Pydiflumetofen is a possibly carcinogenic to humans	Cat. 2 H351
Relevant NOAEL for carcinogenicity	2-year, rat: 102 mg/kg bw per day (highest dose tested); 18-month, mouse: 9.2 mg/kg bw per day	

### Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

#### Reproduction toxicity

Reproduction target / critical effect	Parental toxicity: Liver changes (increased liver weight (>15%) and hepatocellular hypertrophy). In males only, lower bodyweight and hypertrophy of thyroid follicular epithelium. Reproductive toxicity: delayed sexual maturation in F1 male and female offspring that could not be explained by effects on body weights. Offspring's toxicity: no effects up to top dose	Cat 2 H361f
Relevant parental NOAEL	36 mg/kg bw per day	
Relevant reproductive NOAEL	36 mg/kg bw per day	
Relevant offspring NOAEL	116 mg/kg bw per day	

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### Developmental toxicity

Developmental target / critical effect

Rat:  
Maternal toxicity: reduced bodyweight gain and food consumption at highest dose (100 mg/kg bw per day) gestation days 6-10 only.  
Developmental toxicity: No treatment related effects.

Rabbit:  
Maternal toxicity: No treatment related effects.  
Developmental toxicity: increased incidence of one skeletal variant (rib costal cartilage interrupted).

Relevant maternal NOAEL

Rat: 30 mg/kg bw per day  
Rabbit: 500 mg/kg bw per day

Relevant developmental NOAEL

Rat: 100 mg/kg bw per day  
Rabbit: 10 mg/kg bw per day

### Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity

No effects in male rats at 2000 mg/kg bw per day.  
In female rats, clinical signs and effect on body temperature and locomotor activity at  $\geq$  100 mg/kg bw. All signs of toxicity resolved by day 2.

Repeated neurotoxicity

Study not required, but neurotoxicity investigated in standard 90-day rat study.

Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)

No additional studies.

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### Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance

Mechanistic study performed in the male mouse to investigate mode of action (MoA) for liver tumours. Using a WHO/IPCS MoA Framework, the key events of constitutive androstane receptor (CAR) activation and proliferation were demonstrated in the mouse and/or in vitro hepatocytes, however in vitro human hepatocytes exposed to pydiflumetofen did not elicit a proliferative response. Nevertheless, there was insufficient information to dismiss the human relevance of the mouse liver tumours.

Pydiflumetofen is considered an inducer of hepatic microsomal UDGPT in male rats.

Pydiflumetofen was not an inhibitor of rat thyroid peroxidase (TPO) *in vitro*.

No sign indicative of immunotoxicity seen in the overall data package.

Endocrine disrupting properties

The Thyroid (T) modality was sufficiently investigated and no adversity was observed. The Oestrogen, Androgen and Steroidogenesis (EAS) modalities were sufficiently investigated and no clear pattern of adversity was observed. It is concluded that pydiflumetofen is not an ED in humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.



## List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 2 Mammalian Toxicology

Studies performed on metabolites or impurities

### CSAA798670 glucuronide/sulphate

Less toxic than parent

Rat acute oral LD50 > 2000 mg/kg bw  
 Non-genotoxic (negative Ames, MLA and CA assays *in vitro*)  
 28/90-day, rat NOAEL: 1000 mg/kg bw per day (highest dose tested)  
 Developmental toxicity in rabbit: maternal and developmental NOAELs: 250 mg/kg bw per day (highest dose tested)  
 ADI: 0.25 mg/kg bw per day (rabbit developmental toxicity study, UF 1000), but parent reference values may be more appropriate  
 No ARfD needed.

### SYN508272 glucuronide/sulphate

More toxic than parent

Rat acute oral LD50 > 500 < 2000 mg/kg bw  
 Non-genotoxic (Negative in Ames, MLA and *in vivo* rat micronucleus assay; positive *in vitro* CA)  
 28-day, rat NOAEL: 37.4 mg/kg bw per day (based on lower body weight, body weight gain and food consumption)  
 ADI and ARfD: 0.04 mg/kg bw per day (28-day, rat; UF 1000)  
 Could be included in RD-RA with parent using RPF of 2.25.

### SYN545547 glucuronide/sulphate

Non-genotoxic (negative Ames, MN and MLA assays *in vitro*)  
 Database for general toxicity considered insufficient to set toxicological reference values.  
 TTC CCIII values (1.5 and 5 µg/kg bw/d) could be used in the dietary risk assessment.

### SYN548263 glucuronide/sulphate

Non-genotoxic (negative Ames, MN and MLA assays *in vitro*).  
 Major rat metabolite (as a precursor of a major rat metabolite).  
 Covered by parent. Hence, parent reference values should be used in the risk assessment.

### SYN547897

Non-genotoxic (QSAR and read-across analysis)  
 Database for general toxicity considered insufficient to set toxicological reference values. TTC CCIII values (1.5 and 5 µg/kg bw/d) could be used in the dietary risk assessment.

### SYN547891 glucuronide/sulphate

Non-genotoxic (QSAR and read-across analysis)  
 Database for general toxicity considered insufficient to set toxicological reference values. TTC CCIII values (1.5 and 5 µg/kg bw/d) could be used in the dietary risk assessment.

### 2,4,6 – TCP sulphate

Although major rat metabolite, extensive dataset should take priority. Carcinogenic in mice and rats. Less toxic than parent. Not genotoxic.

Specific ADI = 0.4 mg/kg bw/d; Specific ARfD = 1 mg/kg bw.

As less toxic than parent, the parent reference values should be used in the risk assessment.

### SYN547948, CSCD745176 (hydroxylated parent) and SYN548264 glucuronide/sulphate

Non-genotoxic (QSAR and read-across analysis)  
 Database for general toxicity considered insufficient to set toxicological reference values. TTC CCIII values (1.5 and 5 µg/kg bw/d) could be used in the dietary risk assessment.

## List of end points

Evaluator	Month and year	Active Substance (Name)
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## Section 2 Mammalian Toxicology

### Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

Limited; new active substance, no detrimental effects on health in manufacturing personnel

### Summary<sup>3</sup> (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.09	Mouse, 18-month study	100
Acute Reference Dose (ARfD)	0.3	Rat, PNDT study	100
Acceptable Operator Exposure Level (AOEL)	0.05	Rabbit, PNDT study	100*
Acute Acceptable Operator Exposure Level (AAOEL)	0.15	Rat, PNDT study	100*

\* Including correction for limited oral systemic availability (50 %).

### Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (Miravis Plus (A21857B), EC formulation containing 62.5 g/L pydiflumetofen)

Concentrate: 0.4 %  
 Spray dilution I (2 g/L): 7.3%  
 Spray dilution II (0.55 g/L): 11%  
 Results based on in vitro human skin dermal absorption study.

### Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

Use: Winter and spring cereals, winter and spring oilseed rape, vehicle mounted boom sprayer, 0.2 kg a.s./ha  
Model: EFSA calculator % of AOEL  
 No PPE (with workwear) 10  
Model: EFSA calculator % of AAOEL  
 No PPE (with workwear) 21

Workers

Use: Winter and spring cereals, winter and spring oilseed rape, vehicle mounted boom sprayer, 0.2 kg a.s./ha  
Model: EFSA calculator % of AOEL  
 No PPE (with workwear) 6  
*Acute worker exposure assessment not possible with EFSA Calculator.*

<sup>3</sup> If available include also reference values for metabolites

## List of end points

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## Section 2 Mammalian Toxicology

Bystanders and residents

<u>Use:</u> Winter and spring cereals, winter and spring oilseed rape, vehicle mounted boom sprayer, 0.2 kg a.s./ha	
<u>Model:</u> EFSA calculator	
<u>Child resident</u>	<u>% of AOEL</u>
Spray Drift	12
Vapour	2
Surface Deposits	1
Entry into Treated Crops	7
All pathways (mean)	15
<u>Adult resident</u>	<u>% of AOEL</u>
Spray Drift	3
Vapour	<1
Surface Deposits	<1
Entry into Treated Crops	4
All pathways (mean)	5
<u>Child bystander</u>	<u>% of AAEL</u>
Spray Drift	9
Vapour	1
Surface Deposits	1
Entry into Treated Crops	2
<u>Adult bystander</u>	<u>% of AAEL</u>
Spray Drift	2
Vapour	<1
Surface Deposits	<1
Entry into Treated Crops	1

## Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]<sup>4</sup> :

Peer review proposal<sup>5</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

Pydiflumetofen
<b>Carc Cat 2; H351, Repr Cat 2; H361f</b>
<b>Carc Cat 2; H351, Repr Cat 2; H361f</b>

<sup>4</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>5</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

## List of end points

Evaluator	Month and year	Active Substance (Name)
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## Section 3 Residues

### Residues in or on treated products food and feed

### Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

<b>Primary crops</b> (Plant groups covered) <b>OECD Guideline 501</b>	Crop groups	Crop(s)	Application(s)	DAT (days)
	Fruit crops	Tomato (glasshouse)	2 x 200 g as/ha (phenyl and pyrazole) foliar application  20 mg as/plant, soil application at transplanting stage	1 <b>10 14</b> (fruits)  103 (fruits)
	Root crops	-		
	Leafy crops	-		
	Cereals/grass crops	Wheat (field)	2 x 125 g as/ha (phenyl and pyrazole)	10 (forage, post app'n 1)  29 (hay, post app'n 2)  50 (straw/grain, post app'n 2)
	Pulses/Oilseeds	oilseed rape (field)	1 x 134 g as/ha (phenyl) 1 x 147 g as/ha (pyrazole)	62 (trash and seed)
	Miscellaneous	-		
Pydiflumetofen was the main component in crops; two metabolites identified in each crop were SYN545547 and SYN547891. Other peaks (low level polar components) were not identified.  The metabolism is characterised by reduction of the parent molecule and demethylation of the pyrazole ring.  The oilseed rape study is underdosed with regard to cGAP				
<b>Rotational crops</b> (metabolic pattern) <b>OECD Guideline 502</b>	Crop groups	Crop(s)	PBI (days)	Comments
	Root/tuber crops	turnip	30, 120, 270	Both phenyl and pyrazole labelled studies.
	Leafy crops	lettuce	30, 120, 270	
	Cereal (small grain)	wheat	30, 120, 270	
	Other			Application rate of 400 g as/ha to bare soil (outside); part way through the growing period containers were moved into the glasshouse.

## List of end points

Evaluator	Month and year	Active Substance (Name)
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### Section 3 Residues

Rotational crop and primary crop metabolism similar?	<p>Pydiflumetofen was the main component in the rotational crop metabolism; two metabolites identified in the rotational crops were SYN545547 and SYN547891, the same two identified metabolites in the primary crop metabolism. Other peaks (a greater number than had been observed in the primary crop metabolism study, low level polar components) were not identified.</p> <p>The metabolism is characterised by reduction of the parent molecule and demethylation of the pyrazole ring.</p> <p>Considering maximum seasonal application rate (for the requested GAPs) only, the rotational crop metabolism study <del>representing</del> represents 2N.</p> <p>[The study is underdosed 0.63 N when considering the high soil exposures arising from year on year application and accumulation in the soil due the persistence of pydiflumetofen in soil. Studies on the levels of residues in rotational crops were conducted at higher application rates of 500 and 600 g as/ha. Please see Vol 1 (and below) for further details].</p>			
<b>Processed commodities</b> (standard hydrolysis study) <b>OECD Guideline 507</b>	<b>Conditions</b>	Pydiflumetofen		
	20 min, 90°C, pH 4	Stable		
	60 min, 100°C, pH 5	Stable		
	20 min, 120°C, pH 6	Stable		
Residue pattern in processed commodities similar to residue pattern in raw commodities?	<p>Yes - The effect of processing on the nature of the residues of pydiflumetofen was investigated using the active substance radiolabelled in the Pyrazole-5-<sup>14</sup>C position. Residues of pydiflumetofen were found to be stable.</p>			
Plant residue definition for enforcement (RD-Enf) <b>OECD Guidance, series on pesticides No 31</b>	<p>Pydiflumetofen (sum of isomers)</p> <p>Also applicable to honey</p>			
Plant residue definition for risk assessment (RD-RA)	<p>Pydiflumetofen (sum of isomers)</p> <p>Also applicable to honey</p> <p>[the non-inclusion of metabolites in RD-RA (relevant to primary and rotational crops) was considered following exposure assessment versus TTC CCIII levels for SYN547891 and SYN547891; for wider future crop uses, the TTC exposure estimation should be reconsidered to confirm that the metabolite exposures remain below the TTC CCIII levels and consider the sufficiency of the toxicological data available for metabolites].</p>			
Conversion factor (enforcement to risk assessment)	-			

## List of end points

Evaluator	Month and year	Active Substance (Name)
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### Section 3 Residues

#### Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen	Phenyl label: 3.3 (56.3 mg/kg DM)	14	73N
		Pyrazole label: 3.6 (56.9 mg/kg DM)		80N
	Goat-Cow	Phenyl label: 4.6 (143.6 mg/kg DM)	7	47N (based on all sheep dietary intake)
		Pyrazole label: 4.6 (204.6 mg/kg DM)		55N (based on ewe dietary intake)
	Pig	-	-	-
	Fish	-	-	-
Goat and hen studies conducted separately with SYN545974 in two radiolabelled forms in both studies (phenyl or pyrazole labels).				
Time needed to reach a plateau concentration in milk and eggs (days)		Eggs: 6 - 10 Milk: 2 – 5		
Animal residue definition for enforcement (RD-Enf)		Pydiflumetofen (sum of isomers)		
OECD Guidance, series on pesticides No 31				

## List of end points

Evaluator	Month and year	Active Substance (Name)
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### Section 3 Residues

Animal residue definition for risk assessment (RD-RA)

Products of animal origin, except **ruminant/mammalian** kidney: Sum of pydiflumetofen (sum of isomers) and 2,4,6-trichlorophenol (free and conjugated) expressed as pydiflumetofen.

**Ruminant/mammalian** kidney: Sum of pydiflumetofen (sum of isomers), 2,4,6-trichlorophenol (free and conjugated) and SYN548263 (free and conjugated), expressed as pydiflumetofen.

On a precautionary basis, an additional assessment factor of x 2 to apply to the level of animal product residues in the consumer risk assessment is desirable. This is intended to account for possible differential metabolism of the isomers of pydiflumetofen (which is a racemic mixture), since no investigations into the enantiomeric composition of the residues took place in any of the livestock studies.

Where the methods of analysis converts the livestock product conjugated residues to their free counterparts and the analytes are determined in levels expressed as the free metabolites, the sum of residues, expressed as parent pydiflumetofen, can be calculated as follows, according to the following molecular weights: pydiflumetofen 426.7 g/mol; 2,4,6-trichlorophenol 197.45 g/mol (molecular weight adjustment factor of **x 2.161** (426.7/197.45)); SYN548263 277.2 g/mol (molecular weight adjustment factor of **x 1.539** (426.7/277.2)).

Conversion factor (enforcement to risk assessment)

All commodities except **ruminant/mammalian** kidney  
CF= x 3.2

**Ruminant/mammalian** kidney CF= x 4.7

(see above, additional x 2 factor regarding enantiomeric composition of livestock residues)

Metabolism in rat and ruminant similar (Yes/No)

Yes

Fat soluble residues (Yes/No)

Yes

(FAO, 2009)

## List of end points

Evaluator	Month and year	Active Substance (Name)
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## Section 3 Residues

### Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

#### Confined rotational crop study

(Quantitative aspect)

OECD Guideline 502

Following application to bare soil at 400 g as/ha, parent pydiflumetofen was the principal residue detected in all rotational crops samples (18.6 – 77.8 % TRR); the maximum absolute residue of parent pydiflumetofen was 0.063 mg/kg in wheat straw at 120 DALA (pyrazole label). SYN545547 and SYN547891 were detected in each of the samples at lower levels than the parent; found at up to 0.005 mg/kg and 0.012 mg/kg, respectively.

Considering maximum seasonal application rate (for the requested GAPs) only, the rotational crop metabolism study ~~representing~~ represents 2N.

The study is underdosed 0.63 N when considering the high soil exposures arising from year on year application and accumulation in the soil due the persistence of pydiflumetofen in soil. Please see Vol 1 for further details.

There was not a marked difference between the levels of pydiflumetofen found in the metabolism and the rotational crop field studies (taking account of application rate).



## List of end points

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### Section 3 Residues

#### Field rotational crop study

#### OECD Guideline 504

Pydiflumetofen was sought in rotational crop field studies, covering a range of different crops, where the application to bare soil was conducted either at a rate of 500 g as/ha or 600 g as/ha.

The plant back intervals studied were 30 to 365 days. Metabolites were not sought, although it is anticipated that at the dose rates studied, based on the ratio of metabolite(s): parent found in the rotational crop metabolism study, that no detectable levels ( $\geq 0.01$  mg/kg) of a metabolite would have been found in these field studies (had SYN545547 and SYN547891 been sought).

Pydiflumetofen was found as positive residues in these rotational field studies, in some of the samples. Most rotational crop samples taken had residues  $< 0.01$  mg/kg pydiflumetofen. Pydiflumetofen was found at positive residue levels in various crops (e.g. roots/leafy crops at up to 0.05 mg/kg, and in cereal straw at up to 0.09 mg/kg).

Considering maximum seasonal application rate (for the requested GAPs) only, the rotational crop field studies represent 2.5 or 3N.

The studies are within  $\pm 25$  % of the proposed cGAPs, considering soil accumulation and crop interception. The N rate of the rotational field trials is 0.79 N and 0.95 N, for the studies conducted at 500 g/ha and 600 g/ha, respectively.

Despite the trials falling within  $\pm 25$  % of the proposed cGAPs; to account for potential systemic bias, positive ( $> \text{LOQ}$ ) residues have been scaled to the level of the maximum estimated soil exposure.

## List of end points

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### Section 3 Residues

#### Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

##### OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Month)					
			pydiflumetofen					
High water content	Head lettuce	≤ -18	23					
High oil content	Oilseed rape seed	≤ -18	23					
High protein content	Dried adzuki bean	≤ -18	23					
High starch content	Wheat grain	≤ -18	23					
	Potato tuber	≤ -18	23					
High acid content	Orange	≤ -18	23					
	Wheat straw (dried commodity)	≤ -18	23					
<p>Pydiflumetofen was stable when stored frozen at ≤ -18°C for at least 23 months in the crop matrices tested.</p> <p>Due to the range of crops covered it can be concluded that residues of pydiflumetofen are anticipated to be stable in all other crop commodities, including processed fractions, (for at least <b>up to</b> 23 months when stored frozen at ≤ -18 °C).</p> <p>Stability in crop commodity extracts has been demonstrated to the extent needed to support all the residues magnitude of the residues studies submitted.</p>								
Animal	Animal commodity	T (°C)*	Stability (Month)					
			Pydiflumetofen (SYN545974)	2,4,6 – TCP	SYN508 272	SYN548 264	SYN547 897	SYN548 263
Bovine	Muscle	≤ -18	24	12	-	-	-	-
Bovine	Fat	≤ -18	24	12	-	-	-	-
Bovine	Liver	≤ -18	24	12	-	-	Sufficiently stable only up to 9.5	-
Bovine	Kidney	≤ -18	-	12	-	-	Sufficiently stable only up to 11	12
Bovine	Milk	≤ -18	24	12	12	12	-	-
Poultry	Egg	≤ -18	24	12	-	-	-	-

## List of end points

Evaluator	Month and year	Active Substance (Name)
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### Section 3 Residues

2,4,6 – TCP consists of free & conjugated

\*Samples containing parent pydiflumetofen were stored frozen at -20°C in the tests. Metabolites were tested at ca -18°C.

Pydiflumetofen was stable when stored frozen at -20°C for at least 24 months in the animal matrices tested (above).

Residues of 2,4,6-TCP (free and conjugated) were stable when stored frozen at -18°C for at least 12 months in the animal matrices tested (above).

SYN508272 and SYN548264 were stable when stored frozen at -18°C for at least 12 months in milk.

SYN547897 was considered to be sufficiently stable only for up to 9.5 months in bovine liver and only up to 11 months in bovine kidney. The tests were done for up to 12 months, a start of a decline in residues of SYN547897 was observed towards the end of the study.

SYN548263 was stable when stored frozen at -18°C for at least 12 months in bovine kidney.

Stability in animal commodity extracts has been demonstrated to the extent needed to support the residues magnitude of the residues studies submitted.

## List of end points

Evaluator	Month and year	Active Substance (Name)
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## Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) [OECD Guideline 509](#), [OECD Guidance, series on pesticides No 66](#) and [OECD MRL calculator](#)

Crop	Outdoor/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
<b>Representative uses</b>						
Barley grain	Outdoor	0.06, 2 x 0.08, 2 x 0.10, 0.12, 0.13 0.32	Extrapolation to oat	See below for consideration of rotational crops	See below for consideration of rotational crops	See below for consideration of rotational crops
Barley straw	Outdoor	0.27, 0.57, 1.13, 1.19, 1.20, 1.27, 1.85, 2.72	Extrapolation to oat	Not currently set for animal feed items	See below for consideration of rotational crops	See below for consideration of rotational crops
Wheat grain	Outdoor	2 x <0.01, 0.01, 3 x 0.02, 3 x 0.03, 2 x 0.04, 0.05	Extrapolation to rye	See below for consideration of rotational crops	See below for consideration of rotational crops	See below for consideration of rotational crops
Wheat straw	Outdoor	0.28, 0.40, 0.41, 0.84, 0.86, 0.88, 0.94, 1.00, 2.20, 2.39, 3.00, 4.00	Extrapolation to rye	Not currently set for animal feed items	See below for consideration of rotational crops	See below for consideration of rotational crops
Oilseed rape (seed)	Outdoor	3 x <0.01, 2 x 0.01, 0.02, 0.03, 0.04		See below for consideration of rotational crops	See below for consideration of rotational crops	See below for consideration of rotational crops
<b>MRL application</b>						
Carrot (root)	Outdoor	<0.01, 3 x 0.02, 2 x 0.03, 2 x 0.04	Extrapolation to parsnip and parsley root	See below for consideration of rotational crops	See below for consideration of rotational crops	See below for consideration of rotational crops
<b>Summary of the data on formulation equivalence OECD Guideline 509</b>						
Representative uses are early in the growing season. No further consideration required.						
Crop	Outdoor/	Residue data (mg/kg)	Recommendations/comments			

## List of end points

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### Section 3 Residues

Crop	Outdoor/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
	Indoor					
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	Outdoor/ Indoor	Residue data (mg/kg)	Recommendations/comments			
Honey	Outdoor (tunnel trials)	3 x <0.01	three tunnel trials acceptable as all residues <0.01	See below for consideration of rotational crops	See below for consideration of rotational crops	See below for consideration of rotational crops

(a): Residues trials data relevant to the agricultural practices and climatic conditions in the UK, Indoor for glasshouse/protected crops

(b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Enf/RA** to differentiate data expressed according to the residue definition for **Enforcement** and **Risk Assessment**.

(c): **HR**: Highest residue. When residue definition for enforcement and risk assessment differs, HR according to residue definition for enforcement reported in brackets (HR<sub>Enf</sub>).

(d): **STMR**: Supervised Trials Median Residue. When residue definition for enforcement and risk assessment differs, STMR according to definition for enforcement reported in brackets (STMR<sub>Enf</sub>).

# List of end points

Evaluator	Month and year	Active Substance (Name)
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## Section 3 Residues

### Total residues considering possible impact of rotational residues

Crop/crop group	Primary Crop - PC (mg/kg)			Rotational Crop - RC (mg/kg)†			RC HR >25% of the PC?	Combined adjusted residues* (mg/kg)	Overall (combined PC + RC where needed) residue levels end-points				remark	
	Summary of residues	STMR	HR	Summary of residues	STMR	HR			STMR <sup>(2)</sup> (mg/kg)	HR <sup>(1)</sup> (mg/kg)	OECD MRL unrounded (mg/kg)	OECD MRL Rounded (mg/kg)		
Representative uses:														
Barley grain → oat grain	0.06, 2x0.08, 2x0.10, 0.12, 0.13, 0.32	0.1	0.32	8 x <0.01	<0.01	<0.01	No	N/A	0.1	0.32	0.454	0.5	PC only	
Wheat grain → rye grain, triticale grain	2x<0.01, 0.01, 3x0.02, 3 x 0.03, 2 x 0.04, 0.05	0.025	0.05	8 x <0.01	<0.01	<0.01	No	N/A	0.025	0.05	0.078	0.08	PC only	
Oilseed rape seed	3x<0.01, 2 x 0.01, 0.02, 0.03, 0.04	0.01	0.04	<0.01	<0.01	<0.01	No	N/A	0.01	0.04	0.064	0.07	PC only	
MRL application:														
Carrots, parsley root and parsnip root	<0.01, 3 x 0.02, 2 x 0.03, 2 x 0.04	0.025	0.04	8x<0.01, 2x0.021, 3x0.025, 0.032, 0.042	<0.01	0.0422	Yes	0.052, 3x0.062, 2x0.072, 2x0.082	0.067	0.082	0.205	0.2	PC + RC	
Rotational commodities:														
Strawberries	-	-	-	3 x<0.01	<0.01	<0.01	N/A	N/A	<0.01	<0.01	<0.01	0.01*	RC – only Based on data on strawberries	

# List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 3 Residues

Crop/crop group	Primary Crop - PC (mg/kg)			Rotational Crop - RC (mg/kg)†			RC HR >25% of the PC?	Combined adjusted residues* (mg/kg)	Overall (combined PC + RC where needed) residue levels end-points				remark
	Summary of residues	STMR	HR	Summary of residues	STMR	HR			STMR <sup>(2)</sup> (mg/kg)	HR <sup>(1)</sup> (mg/kg)	OECD MRL unrounded (mg/kg)	OECD MRL Rounded (mg/kg)	
Potatoes	-	-	-	8x<0.01, 2x0.021, 3x0.025, 0.032, 0.042	<0.01	0.0422	N/A	N/A	<0.01	0.0422	0.059	0.06	RC only – extrapolated from data on root and tuber veg
Root crops (other than carrots/parsnip and parsley root), including sugar beet	-	-	-	8x<0.01, 2x0.021, 3x0.025, 0.032, 0.042	<0.01	0.0422	N/A	N/A	<0.01	0.0422	0.059	0.06	RC only – extrapolated from data on root and tuber veg
Bulb vegetables	-	-	-	8x<0.01, 2x0.021, 3x0.025, 0.032, 0.042	<0.01	0.0422	N/A	N/A	<0.01	0.0422	0.059	0.06	RC only – extrapolated from data on root and tuber veg
Fruit and Fruiting vegetables	-	-	-	4 x<0.01	<0.01	<0.01	N/A	N/A	<0.01	<0.01	<0.01	0.01*	RC only – data from tomatoes
Flowering brassica, kohlrabis	-	-	-	27x<0.01, 4 x 0.011, 2 x 0.013, 0.021, 0.025, 0.032, 0.053	<0.01	0.053	N/A	N/A	<0.01	0.053	0.053	0.06	RC only – data from immature and mature spinach, radish and carrot tops
Head brassicas	-	-	-	4x<0.01	<0.01	<0.01	N/A	N/A	<0.01	<0.01	<0.01	0.01*	RC only –

# List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 3 Residues

Crop/crop group	Primary Crop - PC (mg/kg)			Rotational Crop - RC (mg/kg)†			RC HR >25% of the PC?	Combined adjusted residues* (mg/kg)	Overall (combined PC + RC where needed) residue levels end-points				remark
	Summary of residues	STMR	HR	Summary of residues	STMR	HR			STMR <sup>(2)</sup> (mg/kg)	HR <sup>(1)</sup> (mg/kg)	OECD MRL unrounded (mg/kg)	OECD MRL Rounded (mg/kg)	
and leafy brassica <sup>(3)</sup>													data from kale
Leaf vegetables, herbs and edible flowers				27x<0.01, 4 x 0.011, 2 x 0.013, 0.021, 0.025, 0.032, 0.053	<0.01	0.053	N/A	N/A	<0.01	0.053	0.053	0.06	RC only – data from immature and mature spinach, radish and carrot tops
Legume vegetables				3 x <0.01	<0.01	<0.01	N/A	N/A	<0.01	<0.01	<0.01	0.01*	RC only – data from bean (seeds)
Stem vegetables				27x<0.01, 4 x 0.011, 2 x 0.013, 0.021, 0.025, 0.032, 0.053	<0.01	0.053	N/A	N/A	<0.01	0.053	0.053	0.06	RC only – data from immature and mature spinach, radish and carrot tops
Pulses <sup>(4)</sup>				4 x <0.01	<0.01	<0.01	N/A	N/A	<0.01	<0.01	<0.01	0.01*	RC only – data from bean and soybean (seeds)
Oilseeds except oilseed rape <sup>(4)</sup>				4 x <0.01	<0.01	<0.01	N/A	N/A	<0.01	<0.01	<0.01	0.01*	RC only – data from bean and soybean



# List of end points

Evaluator	Month and year	Active Substance (Name)
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## Section 3 Residues

Crop/crop group	Primary Crop - PC (mg/kg)			Rotational Crop - RC (mg/kg)†			RC HR >25% of the PC‡	Combined adjusted residues* (mg/kg)	Overall (combined PC + RC where needed) residue levels end-points				remark
	Summary of residues	STMR	HR	Summary of residues	STMR	HR			STMR <sup>(2)</sup> (mg/kg)	HR <sup>(1)</sup> (mg/kg)	OECD MRL unrounded (mg/kg)	OECD MRL Rounded (mg/kg)	
Cereal grains, except barley, oats, rice, wheat, triticale and rye	-	-	-	8 x <0.01	<0.01	<0.01	N/A	N/A	<0.01	<0.01	<0.01	0.01*	(seeds) RC only – data from barley grain
Honey ‡	3 x <0.01	<0.01	<0.01	<0.01	<0.01	<0.01	‡	3 x<0.02	<0.02	<0.02	<0.02	0.05*	PC + RC ‡
Feed commodities:													
Root and tuber tops	-	-	-	27x<0.01, 4 x 0.011, 2 x 0.013, 0.021, 0.025, 0.032, 0.053	<0.01	0.053	N/A	N/A	<0.01	0.053	N/A	N/A	RC only – data from immature and mature spinach, radish and carrot tops
Barley straw → oat straw	0.27, 0.57, 1.13, 1.19, 1.20, 1.27, 1.85, 2.72	1.195	2.72	2x <0.01 3x 0.025 0.038 0.076 0.114	0.025	0.114	No	N/A	1.195	2.72	N/A	N/A	PC only
Wheat straw → rye straw, triticale straw	0.28, 0.40, 0.41, 0.84, 0.86, 0.88, 0.94, 1.00, 2.20, 2.39, 3.00, 4.00	0.91	4.0	2x <0.01 3x 0.025 0.038 0.076 0.114	0.025	0.114	No	N/A	0.91	4.0	N/A	N/A	PC only

## List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 3 Residues

Crop/crop group	Primary Crop - PC (mg/kg)			Rotational Crop - RC (mg/kg)†			RC HR >25% of the PC‡	Combined adjusted residues* (mg/kg)	Overall (combined PC + RC where needed) residue levels end-points				remark
	Summary of residues	STMR	HR	Summary of residues	STMR	HR			STMR <sup>(2)</sup> (mg/kg)	HR <sup>(1)</sup> (mg/kg)	OECD MRL unrounded (mg/kg)	OECD MRL Rounded (mg/kg)	
Straw – other	-	-	-	2x <0.01 3x 0.025 0.038 0.076 0.114	0.025	0.114	N/A	N/A	0.032	0.114	N/A	N/A	RC only – data from barley straw
Pea/bean vines	-	-	-	3 x <0.01	<0.01	<0.01	N/A	N/A	<0.01	<0.01	N/A	N/A	RC only – data from bean vines
Forage	-	-	-	12x <0.01, 0.011, 0.025	<0.01	0.025	N/A	N/A	<0.01	0.025	N/A	N/A	RC only – data from Maize remaining plant, barley forage, soybean forage

(1): **HR**: Highest residue. When residue definition for enforcement and risk assessment differs, HR according to residue definition for enforcement reported in brackets (HR<sub>Ent</sub>).

(2): **STMR**: Supervised Trials Median Residue. When residue definition for enforcement and risk assessment differs, STMR according to definition for enforcement reported in brackets (STMR<sub>Ent</sub>).

(3): Sufficient data is available for head cabbage and kale, in line with the sub groups laid out in the ‘super’ crop group approach. All residues in kale were <LOQ.

(4): One trial on oilseeds, three on pulses – for a total of four trials <LOQ, this is sufficient to support the pulses and oilseeds ‘super group’.

(†): Rotational residues selected from the 30 and 60 day PBIs.

(‡): No specific rotational crop data is available on flowers. However, the available data on crop fractions which are produced via flowering (beans, barley grain, maize whole cobs, tomatoes and strawberries) demonstrate <LOQ residues in all cases (<0.01 mg/kg). To account for the uncertainty, the <LOQ results for primary crops have been combined with <0.01, to give an STMR of <0.02 mg/kg. The default honey MRL of 0.05\* mg/kg is considered appropriate.

# List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 3 Residues

### Inputs for animal burden calculations - (primary crops and inclusion of rotational crop residues- Tier 1—10 year use)

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Primary crop representative uses: oilseed rape, wheat, triticale, rye, barley and oats				
Primary crop (MRL assessment): carrots				
<b>Forages</b>				
Alfalfa forage, hay, meal, silage	<0.01	STMR	0.025	HR
Barley forage, silage	<0.01		0.025	
Barley straw	1.195		2.72	
Bean vines	<0.01		<0.01	
Beet, mangel fodder	<0.01		0.053	
Beet, sugar (tops)	<0.01		0.053	
Cabbage heads, leaves	<0.01		<0.01	
Clover forage, hay, silage	<0.01		0.025	
Corn, field, forage/silage	<0.01		0.025	
Corn, field (maize), pop, stover	0.032		0.114	
Cowpea, forage, hay	<0.01		0.025	
Grass, forage (fresh), hay, silage	<0.01		0.025	
Kale, leaves	<0.01		<0.01	
Lespedeza, forage, hay	<0.01		0.025	
Millet, forage	<0.01		0.025	
Millet, straw	0.032		0.114	
Oat forage, hay	<0.01		0.025	
Oat straw	1.195		2.72	
Pea vines, hay, silage	<0.01		<0.01	
Rape forage	<0.01		0.025	
Rye forage	<0.01		0.025	
Rye straw	0.91		4.0	
Sorghum forage, silage	<0.01		0.025	
Sorghum (grain), stover	0.032		0.114	
Soybean forage, hay, silage	<0.01		0.025	
Trefoil forage	<0.01		0.025	

# List of end points

Evaluator	Month and year	Active Substance (Name)
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## Section 3 Residues

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Triticale forage, hay	<0.01		0.025	
Triticale, straw	0.91		4.0	
Turnip tops, leaves	<0.01		0.053	
Vetch forage, hay	<0.01		0.025	
Wheat forage, hay	<0.01		0.025	
Wheat straw	0.91		4.0	
<b>Roots and Tubers</b>				
Carrot culls	0.067	STMR	0.082	HR
Cassava/tapioca roots	<0.01		0.042	
Potato culls	<0.01		0.042	
Swede roots	<0.01		0.042	
Turnip roots	<0.01		0.042	
<b>Cereal grains/Crop seeds</b>				
Barley grain	0.1	STMR	0.1	STMR
Bean, dry seed	<0.01		<0.01	
Corn, field (maize), pop, grain	<0.01		<0.01	
Cotton seed (undelinted)	<0.01		<0.01	
Cowpea seed	<0.01		<0.01	
Lupin seed	<0.01		<0.01	
Millet grain	<0.01		<0.01	
Oat grain	0.1		0.1	
Pea (field), dry seed	<0.01		<0.01	
Rye grain	0.025		0.025	
Sorghum grain	<0.01		<0.01	
Soybean seed	<0.01		<0.01	
Triticale grain	0.025		0.025	
Wheat grain	0.025		0.025	
<b>By-products^</b>				
Sugar beet (pulp)	<0.01	STMR	<0.01	STMR
Flaxseed/Linseed (meal)	<0.01	STMR	<0.01	STMR

## List of end points

Evaluator	Month and year	Active Substance (Name)
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### Section 3 Residues

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Rape/Canola meal	<0.01	STMR	<0.01	STMR
Safflower meal	<0.01	STMR	<0.01	STMR
Brewer's grain (dried)	0.194	STMR (barley grain) x calculated PF (1.94)	0.194	STMR (barley grain) x calculated PF (1.94)
Wheat gluten (meal)	0.0053	STMR (wheat grain) x calculated PF (0.21)	0.0053	STMR (wheat grain) x calculated PF (0.21)

^ Relevant by-products not included in the above table are included in the assessment e.g. distillers grain (dried) and wheat (milled by products) - default PFs in the animal dietary burden calculator apply, as specific processing data are not available for these. The approach populates the entries with the relevant residues from the relevant grains/seeds with the above raw commodity inputs inserted accordingly).

## List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 3 Residues

**Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4) – Tier 1 – 10-year use**

**OECD Guideline 505 and OECD Guidance, series on pesticides No 73**

MRL calculations	Ruminant				Pig/Swine		Poultry		Fish	
<b>Highest expected intake</b> (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.041	Ram/Ewe	0.083	Breeding	0.014	Broiler	0.017	Carp	-
	Dairy cattle	0.060	Lamb	0.098	Finishing	0.009	Layer	0.045	Trout	-
							Turkey	0.012	Fish intake not calculated	
Intake >0.004 mg/kg bw Feeding study submitted	Yes		Yes		Yes		Yes		-	
	Yes		No		No		Yes		No	
<b>Representative feeding level</b> (mg/kg bw/d, mg/kg DM for fish) and <b>N rates</b>	Level 0.4	Beef: 9.7 N Dairy: 6.7 N	Level 0.4	Lamb: 4.1 N Ram/Ewe: 4.8 N	Level 0.4	Finish: 44.6 N Breed: 28.8 N	Level 0.16	B or T: 9.7 N Layer: 3.5 N	Level	N rate Carp/Trout
	Estimated HR <sub>Enf</sub> <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sub>Enf</sub> <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sub>Enf</sub> <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sub>Enf</sub> <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sub>Enf</sub> <sup>(a)</sup> at 1N	MRL proposals
Muscle	<0.01	0.01*	<0.01	0.01*	<0.01	0.01*	<0.01	0.01*	-	-
Fat	0.003	0.01*	0.005	0.01*	0.001	0.01*	<0.01	0.01*	-	-
Meat <sup>(b)</sup>	<0.01		<0.01		<0.01		<0.01			
Liver	0.003	0.01*	0.005	0.01*	0.001	0.01*	<0.01	0.01*		
Kidney	<0.01	0.01*	<0.01	0.01*	<0.01	0.01*	<0.01	0.01*		
Milk <sup>(a)</sup>	<0.01	0.01*	<0.01	0.01*						
Eggs							<0.01	0.01*		
Method of calculation <sup>(c)</sup>	Tf		Tf		Tf		Tf		-	

<sup>(a)</sup>: Estimated HR calculated at 1N level (**estimated mean level for milk**), residues expressed according to the RD-Enf (Pydiflumetofen only), conversion factors (CF) for enforcement to risk assessment are provided overpage, and HR values according to the RD-RA are provided in Vol 1, section 2.7.5. See also footnote \$ with the CFs table below

<sup>(b)</sup>: HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

**List of end points**

<b>Evaluator</b>	<b>Month and year</b>	<b>Active Substance (Name)</b>
<b>HSE</b>	<b>September 2023</b>	<b>Pydiflumetofen (SYN545974)</b>

**Section 3 Residues**

- <sup>(c)</sup>: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

## List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 3 Residues

STMR calculations	Ruminant				Pig/Swine		Poultry		Fish	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.0281	Ram/Ewe	0.0491	Breeding	0.012	Broiler	0.016	Carp	-
	Dairy cattle	0.0390	Lamb	0.0532	Finishing	0.008	Layer	0.020	Trout	-
							Turkey	0.011		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level 0.4	Beef: 9.7 N Dairy: 6.7 N	Level 0.4	Lamb: 4.1 N Ram/Ewe: 4.8 N	Level 0.4	Finish: 44.6 N Breed: 28.8 N	Level 0.16	B or T: 9.7 N Layer: 3.5 N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated STMR <sub>Enf</sub> <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sub>Enf</sub> <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sub>Enf</sub> <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sub>Enf</sub> <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sub>Enf</sub> <sup>(b)</sup> at 1N
Muscle	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	-	-
Fat	0.013	0.001	0.013	0.002	0.013	<0.001	<0.01	<0.01	-	-
Meat <sup>(a)</sup>	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01		
Liver	0.013	0.001	0.013	0.002	0.013	<0.001	<0.01	<0.01		
Kidney	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01		
Milk	<0.01	<0.01	<0.01	<0.01						
Eggs							<0.01	<0.01		
Method of calculation <sup>(c)</sup>	Tf		Tf		Tf		Tf		-	

<sup>(a)</sup>: STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry, residues expressed according to the RD-Enf (Pydiflumetofen only), conversion factors (CF) for enforcement to risk assessment are provided overpage, and STMR values according to the RD-RA are provided in Vol 1, section 2.7.5. See also footnote \$ with the CFs table below

<sup>(b)</sup>: When the mean level is set at the LOQ, the STMR is set at the LOQ.

<sup>(c)</sup>: The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.



## List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 3 Residues

### Conversion Factors (CF) for enforcement to risk assessment

#### Animal products

Conversion factors derived from the livestock feeding studies at the different feeding levels <sup>s</sup>								
Study	Ruminant/Pig				Poultry			
Feeding levels	Level 1	Level 2	Level 3	-	Level 1	Level 2	Level 3	-
<b>N rate</b> (compared to sheep intake [for ruminant]^) for Tier 1 – 10 year use	<b>4.1</b>	<b>11.1</b>	<b>44.1</b>		<b>3.5</b>	<b>11.0</b>	<b>35.4</b>	
<b>N rate</b> (compared to sheep intake [for ruminant]^) for Tier 2 long term use	<b>2.4</b>	<b>6.6</b>	<b>26</b>		<b>2.4</b>	<b>7.6</b>	<b>25</b>	
Muscle	<b>3.2</b>	<b>3.2</b>	<b>3.2</b>		<b>3.2</b>	<b>3.2</b>	<b>3.2</b>	
Fat	<b>3.2</b>	1.4	1.3		<b>3.2</b>	<b>3.2</b>	<b>3.2</b>	
Liver	<b>3.2</b>	2.3	2.4		<b>3.2</b>	<b>3.2</b>	<b>3.2</b>	
Kidney	<b>4.7</b>	14.9	31.4		<b>3.2</b>	4.9	11.6	
Milk	<b>3.2</b>	3.9	16.8					
Egg					<b>3.2</b>	3.3	4.2	
Comments (up to 250 characters)	The values selected for STMR and HR calculation in this assessment are emboldened. ^sheep gave lowest N rates compared to other ruminant/mammalian livestock. <b>CFs are the same across Tier 1-10 year use and Tier 2 long term use</b>				The values selected for STMR and HR calculation in this assessment are emboldened  <b>CFs are the same across Tier 1-10 year use and Tier 2 long term use</b>			

<sup>s</sup> On a precautionary basis, an additional assessment factor of x 2 to apply to the level of animal product residues in the consumer risk assessment is desirable. This is intended to account for possible differential metabolism of the isomers of pydiflumetofen (which is a racemic mixture), since no investigations into the enantiomeric composition of the residues took place in any of the livestock studies.

## List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 3 Residues

### Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies <sup>(a)</sup>	Processing Factor (PF)		Conversion Factor (CF <sub>P</sub> ) for RA <sup>(b)</sup>
		Individual values	Median PF	
Representative uses				
Barley/Pot barley <sup>#</sup>	2 (4)	0.06, 0.06, 0.12, 0.19	0.09	NA
Barley/Pot barley bran <sup>#</sup>	2 (4)	0.15, 0.16, 0.19, 0.21,	0.18	NA
Barley/Pot barley flour <sup>#</sup>	2 (4)	2.61, 2.82, 3.03, 3.32	2.93	NA
Barley/Beer	2 (4)	< 0.01, < 0.01, < 0.01, < 0.01	< 0.01	NA
Barley/Dried brewers grain	2 (4)	1.5, 1.87, 2, 2.77	1.94	NA
Wheat/Flour (type 550)	2 (4)	0.11, 0.15, 0.17, 0.24	0.16	NA
Wheat/Whole meal flour	2 (4)	0.33, 0.39, 0.42, 0.47	0.41	NA
Wheat/Whole meal bread	2 (4)	0.48, 0.50, 0.53, 0.56	0.52	NA
Wheat/Bran*	2	4.22, 5.00	4.61	NA
Wheat/Gluten feed meal	2 (4)	0.16, 0.2, 0.22, 0.22	0.21	NA
Oilseed rape/ Extracted presscake	2 (4)	<0.09, <0.11, <0.33, <0.33	<0.22 (best estimate)	NA
Oilseed rape/ Refined extracted oil	2 (4)	1.09, 1.33, 2.00, 2.33	1.67	NA

(a): Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

(b): When the residue definition for risk assessment differs from the residue definition for enforcement

\* Bran value given is the highest of all bran samples assessed in preparation of Wheat flour (type 550), wholemeal flour and bread, wheat germs and starch and gluten.

# Covers pearl barley

### Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

**Including all uses** (representative uses and uses related to an MRL application).

A consumer risk assessment limited to the representative uses is not presented as the difference between exposures presented below covering 'representative uses + additional MRL assessment uses' and 'representative uses only' would be minimal. The MRL use/application assessed is only for uses on carrots/parsnips and parsley roots. The consumer risk assessment takes into account all residues detailed in the table titled: 'Total residues considering possible impact of rotational residues' and the potential animal residues detailed above.

<b>ADI</b>	0.09 mg/kg bw per day
<b>TMDI, according to UK model</b>	Highest TMDI: 10 % ADI (UK, toddler)
<b>TMDI according to EFSA PRIMo</b>	Highest TMDI: 3 % ADI (NL, toddler)
<b>NEDI (% ADI), according to UK model</b>	Highest NEDI: 7 % ADI (UK, infant)
<b>IEDI (% ADI), according to EFSA PRIMo</b>	Highest IEDI: 5 % ADI (NL, toddler)
<b>Factors included in the calculations</b>	PFs (where applicable); an additional assessment factor of x 2 has been applied on a precautionary basis to the residue levels in livestock (see Vol 1; enantiomeric composition of the isomers was not investigated) See Inputs to CRA

## List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 3 Residues

ARfD	0.3 mg/kg bw
NESTI (% ARfD), according to UK model	Highest NESTI: 2.5 % ARfD (milk, UK, infant)
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI: 2 % ARfD (cattle milk, children)
Factors included in IESTI and NESTI	PFs (where applicable); an additional assessment factor of x 2 has been applied on a precautionary basis to the residue levels in livestock (see Vol 1; enantiomeric composition of the isomers was not investigated) See Inputs to CRA

# List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 3 Residues

### Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code number (a)	Commodity	Proposed MRL (b) (mg/kg)
<b>Plant Commodities</b>		
<b>Representative uses, and MRL application</b>		
0213020	Carrots	0.2
0213060	Parsnips	0.2
0213070	Parsley roots/Hamburg roots parsley	0.2
0401060	Oilseed rape seed	0.07
0500010	Barley	0.5
0500050	Oat	0.5
0500070	Rye	0.08
0500090	Wheat (include triticale, spelt and durum wheat)	0.08
<b>Animal commodities</b>		
1011010	Swine – muscle	0.01*
1011020	Swine – Fat	0.01*
1011030	Swine – Liver	0.01*
1011040	Swine – kidney	0.01*
1011050	Swine – edible offals (other than liver and kidney)	0.01*
1012010	Bovine – muscle	0.01*
1012020	Bovine – Fat	0.01*
1012030	Bovine – Liver	0.01*
1012040	Bovine – kidney	0.01*
1012050	Bovine – edible offals (other than liver and kidney)	0.01*
1013010	Sheep – muscle	0.01*
1013020	Sheep – Fat	0.01*
1013030	Sheep – Liver	0.01*
1013040	Sheep – kidney	0.01*
1013050	Sheep – edible offals (other than liver and kidney)	0.01*
1014010	Goat – muscle	0.01*
1014020	Goat – Fat	0.01*
1014030	Goat – Liver	0.01*
1014040	Goat – kidney	0.01*
1014050	Goat – edible offals (other than liver and kidney)	0.01*
1015010	Equine – muscle	0.01*
1015020	Equine – Fat	0.01*
1015030	Equine – Liver	0.01*
1015040	Equine – kidney	0.01*
1015050	Equine – edible offals (other than liver and kidney)	0.01*
1016010	Poultry – muscle	0.01*
1016020	Poultry – Fat	0.01*
1016030	Poultry – Liver	0.01*
1016040	Poultry – kidney	0.01*
1016050	Poultry – edible offals (other than liver and kidney)	0.01*
1017010	Other farmed terrestrial animals – muscle	0.01*
1017020	Other farmed terrestrial animals – Fat	0.01*
1017030	Other farmed terrestrial animals – Liver	0.01*
1017040	Other farmed terrestrial animals – kidney	0.01*
1017050	Other farmed terrestrial animals – edible offals (other than liver and kidney)	0.01*
1020010	Cattle – milk	0.01*
1020020	Sheep – milk	0.01*

## List of end points

Evaluator	Month and year	Active Substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 3 Residues

1020030	Goat – milk	0.01*
1020040	Horse – milk	0.01*
1030010	Chicken – eggs	0.01*
1030020	Duck – eggs	0.01*
1030030	Geese – eggs	0.01*
1030040	Quail – eggs	0.01*
1040000	Honey	0.05*
<b>Crops potentially grown in rotation</b>		
0211000	Potatoes	0.06
0212000	Tropical root and tubers	0.06
0212020	Sweet potatoes	0.06
0213010	Beetroots	0.06
0213030	Celeriacs/turnip rooted celeries	0.06
0213040	Horseradishes	0.06
0213050	Jerusalem artichokes	0.06
0213080	Radishes	0.06
0213090	Salsifies	0.06
0213100	Swedes/rutabagas	0.06
0213110	Turnips	0.06
0213990	Root and tuber vegetables (others)	0.06
0220000	Bulb vegetables	0.06
0241000	Flowering brassica	0.06
0244000	Kohlrabis	0.06
0250000	Leaf vegetables, herbs and edible flowers	0.06
0270000	Stem vegetables	0.06
0900010	Sugar beet roots	0.06
0900030	Chicory roots	0.06
<b>All other commodities</b>		
	Default MRL at LOQ	

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

\* denotes MRL at the LOQ

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 4 Environmental fate and behaviour

#### Environmental fate and behaviour

##### Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	3.2 % after 120 d (14.5 % after 365 d), [ <sup>14</sup> C-pyrazole]-label (n <sup>6</sup> = 1) 0.2-5.3 % after 120 d (0.2-16.5 % after 365 d), [ <sup>14</sup> C-phenyl]-label (n= 5)
Non-extractable residues after 100 days	8.1% after 120 d (17.3% after 365 d), [ <sup>14</sup> C- pyrazole]-label (n= 1) 7.4-33.4% after 120 d (12.3-46.2% after 365 d), [ <sup>14</sup> C-phenyl]-label (n= 5)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	No metabolites ≥ 5%, none trigger assessment

##### Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	0.1 % after 120 d, [ <sup>14</sup> C- pyrazole]-label (n= 1) 0.1-0.4 % after 120 d, [ <sup>14</sup> C- phenyl]-label (n= 4)
Non-extractable residues after 100 days	8.3 % after 120 d, [ <sup>14</sup> C- pyrazole]-label (n= 1) 7.8-32.6% after 120 d, [ <sup>14</sup> C- phenyl]-label (n= 4)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No metabolites ≥ 5%, none trigger assessment

##### Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No metabolites ≥ 5%, none trigger assessment
Mineralisation at study end	0.2 % after 29 d in dry soil, 0.2 % after 30 d in moist soil, [ <sup>14</sup> C- pyrazole]-label (n= 1) 1.5 % after 31 d in dry soil, 0.4% after 30 d in moist soil, [ <sup>14</sup> C- phenyl]-label (n= 1)
Non-extractable residues at study end	1.4 % after 29 d in dry soil, 2.6% after 30 d in moist soil, [ <sup>14</sup> C- pyrazole]-label (n= 1) 1.7 % after 31 d in dry soil, 3.2% after 30 d in moist soil, [ <sup>14</sup> C- phenyl]-label (n= 1)

<sup>6</sup> n corresponds to the number of soils.

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark aerobic conditions – Trigger endpoints					
Soil type	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (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 <sub>1</sub> =0.03734 k <sub>2</sub> = 0.000264 g=0.06232	0.41	DFOP
Sarpy (silt loam)	6.2	20°C / pF2	567/2970	k <sub>1</sub> =0.04405 k <sub>2</sub> = 0.000669 g=0.2693	3.15	DFOP
East Anglia (sandy loam)	7.1	20°C / pF2	1300/4870	k <sub>1</sub> =0.09243 k <sub>2</sub> = 0.000452 g=0.1005	0.96	DFOP
Capay (clay loam)	7.6	20°C / pF2	410/2540	k <sub>1</sub> =0.05022 k <sub>2</sub> = 0.000756 g=0.3183	2.54	DFOP
<b>Maximum</b>			<b>2380/7640</b>			<b>DFOP</b>

<sup>a)</sup> Measured in calcium chloride solution

Parent	Dark aerobic conditions – Modelling endpoints					
Soil type	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20 °C pF2/10kPa <sup>b)</sup>	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 <sup>c)</sup>	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 <sup>c)</sup>	2.54	DFOP
<b>Geometric mean</b> (if not pH dependent)				<b>930</b>		
pH dependence				No		

<sup>a)</sup> Measured in calcium chloride solution

<sup>b)</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

<sup>c)</sup> Calculated from DFOP k<sub>2</sub> parameter (ln(2)/k<sub>2</sub>)

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

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

<sup>a)</sup> Measured in calcium chloride solution

<sup>b)</sup> application to bare soil, DegT50 design

<sup>c)</sup> application to bare soil, grass cover subsequently developed

<sup>d)</sup> DT50 or DT90 extrapolated beyond study duration

Parent	Aerobic conditions – <b>Modelling endpoints</b>						
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH <sup>a)</sup>	Depth (cm)	DT <sub>50</sub> (d) Norm <sup>b)</sup> .	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 <sup>c)</sup>	k <sub>1</sub> =0.04618 k <sub>2</sub> = 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
<b>Geometric mean</b> (if not pH dependent)				<b>1334</b>			
pH dependence				No			

<sup>a)</sup> Measured in calcium chloride solution

<sup>b)</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

<sup>c)</sup> Calculated from DFOP k2 parameter (ln(2)/k2)



## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 4 Environmental fate and behaviour

#### Combined laboratory and field kinetic endpoints for modelling (when not from different populations)\*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)

Not relevant according to EFSA guidance since laboratory geomean DT50 > 240 days

#### Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

Please refer to PECsoil calculations

#### Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark anaerobic conditions					
Soil type	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20 °C <sup>b)</sup>	St. (χ <sup>2</sup> )	Method of calculation
Gartenacker (loam)	7.5	20°C / flooded	No significant degradation observed			
18 Acres (sandy clay loam)	6.1	20°C / flooded				
Sarpy (silt loam)	6.7	20°C / flooded				
Capay (clay loam)	6.7	20°C / flooded				

<sup>a)</sup> Measured in calcium chloride solution

<sup>b)</sup> Normalised using a Q10 of 2.58

#### Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Parent	Soil photolysis				
Soil type	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) calculated at summer sunlight 30-50°N	St. (χ <sup>2</sup> )	Method of calculation
18 Acres (sandy clay loam)	6.1	20°C / dry soil	154/507	1.7	SFO
		20°C / pF2	361/1198	1.0	SFO

<sup>a)</sup> Measured in calcium chloride solution

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 4 Environmental fate and behaviour

#### Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Parent							
Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (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	<b>1706</b>	
Arithmetic mean (if not pH dependent)							<b>0.876</b>
pH dependence			No				

<sup>a)</sup> Measured in calcium chloride solution

#### Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

SYN545547							
Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (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	<b>607.9</b>	
Arithmetic mean (if not pH dependent)							<b>0.862</b>
pH dependence			No				

<sup>a)</sup> Measured in calcium chloride solution

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

NOA449410							
Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (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				

<sup>a)</sup> Measured in calcium chloride solution

### Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

No data submitted, not required

### Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

No data submitted, not required

### Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies

No data submitted, not required

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 4 Environmental fate and behaviour

#### Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

Stable at pH 4, 7 and 9 at 50°C

#### Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

pH 7 buffer:  
DT<sub>50</sub> : 89 days  
Estimated DT<sub>50</sub> at summer sunlight 30-50°N: 93 days  
No metabolite ≥ 5%

Sterilised natural water:  
DT<sub>50</sub> : 33 days  
Estimated DT<sub>50</sub> at summer sunlight 30-50°N: 35 days  
SYN548261: 7.3 % AR (21 d) (minor non transient)  
NOA449410: 5.4 % (30 days) (≥ 5% at the end of the study)

Quantum yield of direct phototransformation in water at  $\Sigma > 290$  nm

0.0105 molecules degraded/photon

#### ‘Ready biodegradability’ (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable  
(yes/no)

No

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed <sup>a)</sup>	t. °C <sup>b)</sup>	DT <sub>50</sub> /DT <sub>90</sub> whole sys. (suspended sediment test)		St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> Water (pelagic test)		St. ( $\chi^2$ )	Method of calculation
				At study temp	Norma lised to x °C <sup>c)</sup>		At study temp	Norma lised to x °C <sup>c)</sup>		
Fresh water, 10 µg/L, dark	8.0	7.1	20	>1000/>1000	-	1.81	-	-	-	SFO
Fresh water, 95 µg/L, dark	8.0	7.1	20	637/>1000	-	2.14	-	-	-	SFO
Fresh water, 10 µg/L, light/dark	8.2	6.8	20	402/>1000	-	1.55	-	-	-	SFO
Fresh water, 95 µg/L, light/dark	8.2	6.8	20	662/>1000	-	1.01	-	-	-	SFO

<sup>a)</sup> Measured in usually calcium chloride solution

<sup>b)</sup> Temperature of incubation=std temperature of 20°C

<sup>c)</sup> Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

Metabolite SYN545547	Max in total system 7.3 % after 60 days (light/dark incubation, low dose 10 µg a.s./L)
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Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues. max x % after n d (suspended sediment test)	Non-extractable residues. max x % after n d (end of the study) (suspended sediment test)
Fresh water, 10 µg/L, dark	8.0	7.1	≤0.1% after 58 d	-	-
Fresh water, 95 µg/L, dark	8.0	7.1	≤0.1% after 58 d	-	-
Fresh water, 10 µg/L, light/dark	8.2	6.8	≤0.8 after 58 d	-	-
Fresh water, 95 µg/L, light/dark	8.2	6.8	≤0.5 after 58 d	-	-

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

#### Water/sediment system – Aerobic conditions

Parent	Distribution (Max in water 80.5-86.4% after 0 d. Max. sed 62.1-79.0 % after 100-30 d)
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Trigger endpoints									
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DegT <sub>50</sub> / DegT <sub>90</sub> whole sys.	St. ( $\chi^2$ )	Method of calculation	DissT <sub>50</sub> / DissT <sub>90</sub> water	St. ( $\chi^2$ )	Method of calculation
Calwich Abbey	8.4	7.6	20	270/976	2.1	HS k <sub>1</sub> : 0.01021 k <sub>2</sub> : 0.00228 t <sub>b</sub> : 9.853	0.74/33.1	9.0	DFOP k <sub>1</sub> : 2.665 k <sub>2</sub> : 0.04446 g: 0.5645
Swiss Lake	7.9	5.1	20	299/1100	0.9	HS k <sub>1</sub> : 0.01061 k <sub>2</sub> : 0.002004 t <sub>b</sub> : 10.91	8.03/86.9	4.7	HS k <sub>1</sub> : 0.087 k <sub>2</sub> : 0.0204 t <sub>b</sub> : 7.947

Modelling endpoints									
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DegT <sub>50</sub> whole sys.	St. ( $\chi^2$ )	Method of calculation	DissT <sub>50</sub> water	St. ( $\chi^2$ )	Method of calculation
Calwich Abbey	8.4	7.6	20	244 <sup>b</sup>	2.8	SFO	10 <sup>c)</sup>	9.0	DFOP k <sub>1</sub> : 2.665 k <sub>2</sub> : 0.04446 g: 0.5645
Swiss Lake	7.9	5.1	20	252 <sup>b</sup>	2.3	SFO	26.2 <sup>c)</sup>	4.7	HS k <sub>1</sub> : 0.087 k <sub>2</sub> : 0.0204 t <sub>b</sub> : 7.947

<sup>a)</sup> Measured in calcium chloride solution

<sup>b)</sup> due to lack of clear decline in sediment, default DT50 of 1000 days is used for calculation of accumulation in sediment

<sup>c)</sup> Calculated from DT90 / 3.32

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. kinetic formation fraction (k <sub>f</sub> /k <sub>dp</sub> ): from parent pydiflumetofen						
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DT <sub>50</sub> /DT <sub>90</sub> whole sys.	St. (χ <sup>2</sup> )	Formation fraction	Method of calculation
Calwich Abbey	8.4	7.6	20	455/1510 <sup>b</sup>	10.4	0.60	SFO
Swiss Lake	7.9	5.1	20	18.6/61.9	12.8	0.96	SFO

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup> due to lack of clear decline in sediment, default DT50 of 1000 days is used for calculation of accumulation in sediment

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

Mineralisation and non-extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Calwich Abbey	8.4	7.6	≤0.8% after 100 d	10.1-10.2% after 100 d	10.1-10.2% after 100 d
Swiss Lake	7.9	5.1	≤0.9% after 100 d	14.7-16.2% after 100 d	14.7-16.2% after 100 d

## Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT <sub>50</sub> of 5.85 hours derived by the Atkinson model (AOP version 1.91). OH (12h) concentration assumed = 1.5x10 <sup>6</sup> radicals/cm <sup>3</sup>
Volatilisation	No data submitted, not required.
	No data submitted, not required.

## Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: Pydiflumetofen Surface water: Pydiflumetofen, NOA449410, SYN548261 Sediment: Pydiflumetofen, SYN545547 Ground water: Pydiflumetofen Air: Pydiflumetofen
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## Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

## Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent

Method of calculation

#### 1<sup>st</sup> tier

DT<sub>50</sub> (d): 8540 days; DT<sub>90</sub> >10000 days

Kinetics: DFOP (parameters k<sub>1</sub> = 0.05381, k<sub>2</sub> = 0.000043, g = 0.2484)

Field or Lab: worst case from DegT50 design field studies.

#### 2<sup>nd</sup> tier

DT<sub>50</sub> (d): 1310 days; DT<sub>90</sub> 4360 days

Kinetics: SFO

Field or Lab: worst case from grass-cropped field studies.

Application data

See below

Crop	Cereals	Cereals	Oil Seed Rape
Application rate (g a.s./ha)	166	200	200
Number of applications/interval (d)	1/-	1/-	1/-
Relative application date/BBCH growth stage	-/30	-/55	-/57
Crop interception (%)	80	90	80
Soil loading after interception (g a.s./ha)	33.2	20	40
Depth of soil layer (relevant for PEC <sub>S,plateau</sub> ) (cm)	5 cm for 1 year and 20 years 20cm for longer term	5 cm for 1 year and 20 years 20cm for longer term	5 cm for 1 year and 20 years 20cm for longer term
Product dose l/ha	2.65	3.2	3.2
Product dose g/ha <sup>a</sup>	2907	3510.4	3510.4
Models used for calculation	PECsoil spreadsheet	PECsoil spreadsheet	PECsoil spreadsheet

<sup>a</sup> assuming formulation density of 1.097 g/cm<sup>3</sup>



## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### Tier 1

#### PECsoil for use on cereals at BBCH 30, 166 g pydiflumetofen/ha, 80% crop interception

	PECsoil
PECini	0.044
'Steady state' (mg/kg) after 20 years, 5cm depth	0.567
'Peak' (mg/kg) after 20 years (5cm)	<b>0.611</b>
'Steady state' (mg/kg) final, 20 cm depth <sup>1</sup>	0.526
'Peak' (mg/kg) final <sup>1</sup> (5 cm)	0.570

<sup>1</sup> Note: final values reflect a plateau reached after more than 100 years

#### PECsoil for use on cereals at BBCH 55, 200 g pydiflumetofen/ha, 90% crop interception

	PECsoil
PECini	0.027
'Steady state' (mg/kg) after 20 years, 5cm depth	0.341
'Peak' (mg/kg) after 20 years	<b>0.368</b>
'Steady state' (mg/kg) final, 20 cm depth <sup>1</sup>	0.317
'Peak' (mg/kg) final <sup>1</sup>	0.344

<sup>1</sup> Note: final values reflect a plateau reached after more than 100 years

#### PECsoil for use on oilseed rape at BBCH 57, 200 g pydiflumetofen/ha, 80% crop interception

	PECsoil
PECini	0.053
'Steady state' (mg/kg) after 20 years, 5cm depth	0.683
'Peak' (mg/kg) after 20 years	<b>0.736</b>
'Steady state' (mg/kg) final, 20 cm depth <sup>1</sup>	0.634
'Peak' (mg/kg) final <sup>1</sup>	0.687

<sup>1</sup> Note: final values reflect a plateau reached after more than 100 years

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### Tier 2

#### PECsoil for use on cereals at BBCH 30, 166 g pydiflumetofen/ha, 80% crop interception

		TWA
PECINI mg/kg (1st)	0.044	0.044
1	0.044	0.044
2	0.044	0.044
4	0.044	0.044
7	0.044	0.044
14	0.044	0.044
21	0.044	0.044
28	0.044	0.044
48	0.043	0.044
100	0.042	0.043
<b>Accumulated PECsoil after 20 years</b>		
‘Steady state’ (mg/kg), 5cm depth	0.202	
‘Peak’ (mg/kg)	<b>0.247</b>	
<b>Accumulated PECsoil after 36 years</b>		
‘Steady state’ (mg/kg), 20 cm depth <sup>1</sup>	0.052	
‘Peak’ (mg/kg) <sup>1</sup>	0.096	

<sup>1</sup> Note: if final accumulation was calculated over 5cm, steady state would be 0.208 mg/kg and peak 0.252 mg/kg

#### PECsoil for use on cereals at BBCH 55, 200 g pydiflumetofen/ha, 90% crop interception

		TWA
PECINI mg/kg (1st)	0.027	0.027
1	0.027	0.027
2	0.027	0.027
4	0.027	0.027
7	0.027	0.027
14	0.026	0.027
21	0.026	0.027
28	0.026	0.026
48	0.026	0.026
100	0.025	0.026
<b>Accumulated PECsoil after 20 years</b>		
‘Steady state’ (mg/kg), 5cm depth	0.122	
‘Peak’ (mg/kg)	<b>0.149</b>	
<b>Accumulated PECsoil after 32 years</b>		
‘Steady state’ (mg/kg), 20 cm depth <sup>1</sup>	0.031	
‘Peak’ (mg/kg) <sup>1</sup>	0.058	

<sup>1</sup> Note: if final accumulation was calculated over 5cm, steady state would be 0.125 mg/kg and peak 0.152 mg/kg

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### PECsoil for use on oilseed rape at BBCH 57, 200 g pydiflumetofen/ha, 80% crop interception

		TWA
PECINI mg/kg (1st)	0.053	0.053
1	0.053	0.053
2	0.053	0.053
4	0.053	0.053
7	0.053	0.053
14	0.053	0.053
21	0.053	0.053
28	0.053	0.053
48	0.052	0.053
100	0.051	0.052
<b>Accumulated PECsoil after 20 years (annual application)</b>		
‘Steady state’ (mg/kg), 5cm depth	0.244	
‘Peak’ (mg/kg)	<b>0.297</b>	
<b>Accumulated PECsoil after 39 years (annual application)</b>		
‘Steady state’ (mg/kg), 20 cm depth <sup>1</sup>	0.063	
‘Peak’ (mg/kg) <sup>1</sup>	0.116	
<b>Accumulated PECsoil after 22 years (application every 3<sup>rd</sup> year)</b>		
‘Steady state’ (mg/kg), 5cm depth	0.067	
‘Peak’ (mg/kg)	0.120	
<b>Accumulated PECsoil after 28 years (application every 3<sup>rd</sup> year)</b>		
‘Steady state’ (mg/kg), 20 cm depth <sup>2</sup>	0.017	
‘Peak’ (mg/kg) <sup>2</sup>	0.070	

<sup>1</sup> Note: if final accumulation was calculated over 5cm, steady state would be 0.250 mg/kg and peak 0.304 mg/kg

<sup>2</sup> Note: if final accumulation was calculated over 5cm, steady state would be 0.068 mg/kg and peak 0.121 mg/kg

### PECsoil for the formulation ‘Miravis Plus’

Use	PECsoil (mg formulation/kg)
Cereals, 2907 g/ha, 80% interception	0.775
Cereals, 3510.4 g/ha, 90% interception	0.468
Oilseed rape, 3510.4 g/ha, 80% interception	0.936

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)

For FOCUS gw modelling, values used –  
 Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.  
 Model(s) used: PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4  
 Crop: Cereals and oilseed rape  
 Crop uptake factor: 0  
 Water solubility (mg/L): 1.5 at 25°C  
 Vapour pressure:  $1.84 \times 10^{-7}$  (20°C)  
 $5.30 \times 10^{-7}$  (25°C)  
 Geometric mean parent  $DT_{50 \text{ field}}$  1334 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).  
 $K_{OC}$  /  $K_{OM}$ : geometric mean 1706 / 989.56 mL/g, arithmetic mean  $^{1/n}$  = 0.876.  
 No metabolites trigger assessment.

Application details

See below

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 4 Environmental fate and behaviour

Crop	Spring Cereals	Spring Cereals	Spring Cereals	Spring Cereals
Application rate (g a.s./ha)	166	166	200	200
Number of applications/interval (d)	1/-	1/-	1/-	1/-
Relative application date/BBCH growth stage	-/30	-/41	-/55	-/69
Crop interception (%)	80	90	90	90
Frequency of application	annual	annual	annual	annual
FOCUS models used for calculation	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4
Crop	Winter Cereals	Winter Cereals*	Winter Cereals	Winter Cereals
Application rate (g a.s./ha)	166	166	200	200
Number of applications/interval (d)	1/-	1/-	1/-	1/-
Relative application date/BBCH growth stage	-/30	-/41	-/55	-/69
Crop interception (%)	80	90	90	90
Frequency of application	annual	annual	annual	annual
FOCUS models used for calculation	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4
Crop	Summer Oil Seed Rape	Summer Oil Seed Rape	Winter Oil Seed Rape	Winter Oil Seed Rape
Application rate (g a.s./ha)	200	200	200	200
Number of applications/interval (d)	1/-	1/-	1/-	1/-
Relative application date/BBCH growth stage	-/57	-/69	-/57	-/69
Crop interception (%)	80	80	80	80
Frequency of application	Triennial (every third year)	Triennial (every third year)	Triennial (every third year)	Triennial (every third year)
FOCUS models used for calculation	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4

\*Relevant for extended 66 year assessment only NOTE: MACRO was not used to conduct any non-standard extended groundwater leaching assessments

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

Crop	Scenario	Application dates (absolute)
Spring Cereals BBCH 30	Châteaudun	16 April
	Hamburg	28 April
	Kremsmünster	27 April
	Okehampton	22 April
Spring Cereals BBCH 41	Châteaudun	06 May
	Hamburg	12 May
	Kremsmünster	11 May
	Okehampton	03 May
Spring Cereals BBCH 55	Châteaudun	01 June
	Hamburg	30 May
	Kremsmünster	30 May
	Okehampton	17 May
Spring Cereals BBCH 69	Châteaudun	22 June
	Hamburg	28 June
	Kremsmünster	28 June
	Okehampton	18 June
	Porto	22 June
Winter Cereals BBCH 30	Châteaudun	15 April
	Hamburg	04 May
	Kremsmünster	24 April
	Okehampton	21 April
Winter Cereals BBCH 41	Châteaudun	02 May
	Hamburg	14 May
	Kremsmunster	09 May
	Okehampton	30 April
Winter Cereals BBCH 55	Châteaudun	23 May
	Hamburg	27 May
	Kremsmünster	29 May
	Okehampton	11 May
Winter Cereals BBCH 69	Châteaudun	14 June
	Hamburg	22 June
	Kremsmünster	25 June
	Okehampton	07 June

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

Crop	Scenario	Application dates (absolute)
Summer Oil Seed Rape , BBCH 57	Okehampton	12 May
Summer Oil Seed Rape, BBCH 69	Okehampton	13 June
Winter Oil Seed Rape BBCH 57	Châteaudun	14 April
	Hamburg	02 May
	Kremsmünster	02 May
	Okehampton	27 April
Winter Oil Seed Rape BBCH 69	Châteaudun	14 May
	Hamburg	30 May
	Kremsmünster	30 May
	Okehampton	25 May

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### Standard FOCUSgw modelling

PEC<sub>GW</sub> for pydiflumetofen with FOCUS PEARL v4.4.4 /PELMO v5.5.3 and MACRO v5.5.4 from the 'standard' 26 year assessment following single application to cereals, annual application

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>GW</sub> at 1 m Soil Depth (µg/L)
Spring Cereals BBCH 30 Use no. 855a	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Spring Cereals BBCH 55 Use no. 829, 860	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Spring Cereals BBCH 69 Use no. 829, 860	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Winter Cereals BBCH 30 Use no. 861a	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Winter Cereals BBCH 55 Use no. 835, 866	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Winter Cereals BBCH 69 Use no. 835, 866	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001

\*For MACRO only Chateaudun scenario is defined



## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

**PEC<sub>GW</sub> for pydiflumetofen with FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3 and FOCUS MACRO v5.5.4 from the ‘standard’ 66 year assessment following single application to oil seed rape, application one in every three years**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>GW</sub> at 1 m Soil Depth (µg/L)		
		PEARL	PELMO	MACRO
Summer Oil Seed Rape, BBCH 57, Use no. 867	Okehampton	0.010	0.008	NA
Summer Oil Seed Rape, BBCH 69, Use no. 867	Okehampton	0.010	0.008	NA
Winter Oil Seed Rape BBCH 57 Use no. 868	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	0.008	0.003	NA
	Kremsmünster	0.002	0.001	NA
	Okehampton	0.017	0.018	NA
Winter Oil Seed Rape BBCH 69 Use no. 868	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	0.008	0.003	NA
	Kremsmünster	0.002	0.001	NA
	Okehampton	0.017	0.018	NA

NA = not applicable, scenario not parameterised in MACRO, MACRO only being parameterised for Châteaudun

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### Non-standard FOCUSgw modelling – 66 years continuous use

**PEC<sub>GW</sub> for pydiflumetofen from ‘non-standard’ FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 modelling assuming annual usage over 66 year period to cereals, highest triennial average**

Crop	Scenario	High 3 yr average PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)	
		FOCUS PEARL 4.4.4	FOCUS PELMO 5.5.3
Spring Cereals BBCH 30	Châteaudun	< 0.001	< 0.001
	Hamburg	0.097	0.031
	Kremsmünster	0.035	0.011
	Okehampton	<b>0.137</b>	<b>0.123</b>
Spring Cereals BBCH 41	Châteaudun	< 0.001	< 0.001
	Hamburg	0.025	0.006
	Kremsmünster	0.006	0.002
	Okehampton	0.038	0.033
Spring Cereals BBCH 55	Châteaudun	< 0.001	< 0.001
	Hamburg	0.037	0.009
	Kremsmünster	0.01	0.003
	Okehampton	0.055	0.048
Spring Cereals BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.037	0.009
	Kremsmünster	0.01	0.003
	Okehampton	0.054	0.048
Winter Cereals BBCH 30	Châteaudun	< 0.001	< 0.001
	Hamburg	0.093	0.046 (0.045 period 20) <sup>1</sup>
	Kremsmünster	0.041	0.024 (0.023 period 20) <sup>1</sup>
	Okehampton	<b>0.171</b>	<b>0.17 (0.167 period 20)<sup>1</sup></b>
Winter Cereals BBCH 41	Châteaudun	< 0.001	< 0.001
	Hamburg	0.025	0.009
	Kremsmünster	0.008	0.004
	Okehampton	0.051	0.049
Winter Cereals BBCH 55	Châteaudun	< 0.001	< 0.001
	Hamburg	0.036	0.014
	Kremsmünster	0.012	0.006
	Okehampton	0.072	0.069
Winter Cereals BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.036	0.014
	Kremsmünster	0.012	0.006
	Okehampton	0.071	0.069

<sup>1</sup> Values in parentheses are from HSE attempts to validate PELMO modelling. Period 20 is the average of years 64, 65 and 66.

**PEC<sub>GW</sub> for pydiflumetofen from ‘non-standard’ FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 modelling assuming annual usage over 66 year period to oilseed rape, highest triennial average**

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

Crop	Scenario	High 3 yr average PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)	
		FOCUS PEARL 4.4.4	FOCUS PELMO 5.5.3
Summer Oil Seed Rape, BBCH 57	Okehampton	0.026	0.024
Summer Oil Seed Rape, BBCH 69	Okehampton	0.026	0.024
Winter Oil Seed Rape  BBCH 57	Châteaudun	< 0.001	< 0.001
	Hamburg	0.019 (0.142 period 20) <sup>1</sup>	0.007 (0.075 period 20) <sup>1</sup>
	Kremsmünster	0.006 (0.070 period 20) <sup>1</sup>	0.003 (0.044 period 20) <sup>1</sup>
	Okehampton	0.036 (0.224 period 20) <sup>1</sup>	0.042 (0.261 period 20) <sup>1</sup>
Winter Oil Seed Rape  BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.019	0.007
	Kremsmünster	0.006	0.003
	Okehampton	0.036	0.042

<sup>1</sup> Values in parentheses are from HSE attempts to validate PEARL and PELMO modelling. . Period 20 is the average of years 64, 65 and 66.

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

Non-standard FOCUSgw modelling – 16 years annual use followed by 50 years with no treatment

PEC<sub>GW</sub> for pydiflumetofen with FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 from a 16 year use period on winter and spring cereals followed by 50 years with no treatment, highest triennial average

Crop	Scenario	High 3 yr average PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)	
		FOCUS PEARL 4.4.4	FOCUS PELMO 5.5.3
Spring Cereals BBCH 55	Châteaudun	< 0.001	< 0.001
	Hamburg	0.016	0.005
	Kremsmünster	0.006	0.002
	Okehampton	0.023	0.020
Spring Cereals BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.016	0.005
	Kremsmünster	0.005	0.002
	Okehampton	0.023	0.020
Spring Cereals BBCH 30	Châteaudun	< 0.001	< 0.001
	Hamburg	0.040	0.015
	Kremsmünster	0.018	0.006
	Okehampton	0.053	0.048
Winter Cereals BBCH 55	Châteaudun	< 0.001	< 0.001
	Hamburg	0.015	0.007
	Kremsmünster	0.007	0.004
	Okehampton	0.028	0.028
Winter Cereals BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.015	0.007
	Kremsmünster	0.007	0.004
	Okehampton	0.028	0.028
Winter Cereals BBCH 30	Châteaudun	< 0.001	< 0.001
	Hamburg	0.037	0.022 (0.021, period 20) <sup>1</sup>
	Kremsmünster	0.020	0.012 (0.012, period 20) <sup>1</sup>
	Okehampton	0.063	0.063 (0.062, period 19&20) <sup>1</sup>

<sup>1</sup> Values in parentheses are from HSE attempts to validate PELMO modelling. Period 20 is the average of years 64, 65 and 66; period 19 is the average of years 61, 62 and 63.

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

**PEC<sub>GW</sub> for pydiflumetofen with FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 from a 16 year use period on winter and spring oilseed rape followed by 50 years with no treatment, highest triennial average**

Crop	Scenario	High 3 yr average PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)	
		FOCUS PEARL 4.4.4	FOCUS PELMO 5.5.3
Summer Oil Seed Rape 1x200 g a.s./ha BBCH 57-69	Okehampton	0.067	0.067
Winter Oil Seed Rape 1x200 g a.s./ha, BBCH 57-69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.015 (0.057 period 19) <sup>1</sup>	0.035 (0.034 period 20) <sup>1</sup>
	Kremsmünster	0.007 (0.033 period 20) <sup>1</sup>	0.023 (0.022 period 20) <sup>1</sup>
	Okehampton	0.028 (0.081 period 18) <sup>1</sup>	0.096 (0.094 period 18) <sup>1</sup>

<sup>1</sup> Values in parentheses are from HSE attempts to validate PEARL and PELMO modelling. Period 20 is the average of years 64, 65 and 66; period 19 is the average of years 61, 62 and 63; period 18 is the average of years 58, 59 and 60.

## PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

### Substance parameters

Compound	Pydiflumetofen	SYN545547	NOA449410	SYN548261
Molar mass (g/mol)	426.7	396 (correction factor 0.928)	176 (correction factor 0.412)	291 (correction factor 0.682)
K <sub>FOC</sub> (mL/g)	1706 (geometric mean, n = 6) Assumed loss to drains = 0.02%	607.9 (geomean, n = 5)	2.1 (geomean, n = 5)	0 (worst case default)
DT <sub>50,soil</sub> (d)	8540 (worst case un-normalised, field value)	<sup>a</sup>	<sup>a</sup>	<sup>a</sup>
DT <sub>50,water</sub> (d)	26.2 (max. dissipation DT <sub>50</sub> in water, n=2)	<sup>b</sup>	1000 (default)	1000 (default)
DT <sub>50,sed</sub> (d)	1000 (default; no clear decline in sediment)	455 (max whole system)	1000 (default)	1000 (default)
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 79.0	Soil: - Water: 2.3 (aerobic water / sed study) Sediment: 12.3 (aerobic water / sed study)	Soil: - Water: 5.4 (photolysis) Sediment: -	Soil: - Water: 7.3 (photolysis) Sediment: -

<sup>a</sup> No soil metabolites of pydiflumetofen trigger assessment for PEC<sub>sw</sub> or PEC<sub>sed</sub>

<sup>b</sup> PEC<sub>sw</sub> assessment not triggered

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### GAP details for PEC<sub>sw</sub> and PEC<sub>sed</sub> calculations

Crop	Cereals (spring and winter)	Cereals (spring and winter)	Oil Seed Rape (spring and winter)
Application rate (g a.s./ha)	166	200	200
Number of applications/interval (d)	1 / -	1 / -	1 / -
Application timing (No. days until drainage period)	BBCH 30-59 (0 days until drainflow assumed)	BBCH 55-65 (0 days until drainflow assumed)	BBCH 57-69 (0 days until drainflow assumed)
Application method	Foliar spray	Foliar spray	Foliar spray
Min crop interception (%) <sup>a</sup>	80	90	80
Product dose l/ha	2.65	3.2	3.2
Product dose g/ha <sup>b</sup>	2907	3510.4	3510.4

<sup>a</sup> used in drainage calculation

<sup>b</sup> assuming formulation density of 1.097 g/cm<sup>3</sup>

### PEC<sub>sw</sub> and PEC<sub>sed</sub> from spray drift

#### Maximum PEC<sub>sw</sub> and PEC<sub>sed</sub> via spray drift for pydiflumetofen

Crop	Spray drift buffer (m)	Maximum PEC <sub>sw,spraydrift</sub> (µg/L)	PEC <sub>sed,spraydrift</sub> (µg/kg)	Accumulated PEC <sub>sed,spraydrift</sub> (µg/kg)
Winter/Spring cereals 1 x 166 g a.s./ha	1	1.533	5.589	25.003
Winter/Spring cereals 1 x 200 g a.s./ha	1	1.847	6.733	30.121
Oil Seed Rape 1 x 200 g a.s./ha	1	1.847	6.733	30.121

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 4 Environmental fate and behaviour

#### PEC<sub>sw</sub> via spray drift for 166 g pydiflumetofen/ha at various buffer distances

Distance (m)	PEC <sub>sw</sub> ini (µg/L)
1 m	1.533
5 m	0.315
6 m	0.266
7 m	0.227
8 m	0.199
9 m	0.177
10 m	0.160
11 m	0.149
12 m	0.133
13 m	0.127
14 m	0.116
15 m	0.111
16 m	0.100
17 m	0.094
18 m	0.089
19 m	0.089
20 m	0.083

#### PEC<sub>sw</sub> via spray drift for 200 g pydiflumetofen/ha at various buffer distances

Distance (m)	PEC <sub>sw</sub> ini (µg/L)
1 m	1.847
5 m	0.380
6 m	0.320
7 m	0.273
8 m	0.240
9 m	0.213
10 m	0.193
11 m	0.180
12 m	0.160
13 m	0.153
14 m	0.140
15 m	0.133
16 m	0.120
17 m	0.113
18 m	0.107
19 m	0.107
20 m	0.100

**List of end points**

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

**Section 4 Environmental fate and behaviour****Formulation PEC<sub>sw</sub> via spray drift for 2907 g 'Miravis Plus'/ha at various buffer distances**

Distance (m)	PEC <sub>sw</sub> ini (µg formulation/L)
1 m	26.841
5 m	5.523
6 m	4.651
7 m	3.973
8 m	3.488
9 m	3.101
10 m	2.810
11 m	2.616
12 m	2.326
13 m	2.229
14 m	2.035
15 m	1.938
16 m	1.744
17 m	1.647
18 m	1.550
19 m	1.550
20 m	1.454

**Formulation PEC<sub>sw</sub> via spray drift for 3510.4 g 'Miravis Plus'/ha at various buffer distances**

Distance (m)	PEC <sub>sw</sub> ini (µg formulation/L)
1 m	32.413
5 m	6.670
6 m	5.617
7 m	4.798
8 m	4.212
9 m	3.744
10 m	3.393
11 m	3.159
12 m	2.808
13 m	2.691
14 m	2.457
15 m	2.340
16 m	2.106
17 m	1.989
18 m	1.872
19 m	1.872
20 m	1.755



**List of end points**

<b>Evaluator</b>	<b>Month and year</b>	<b>Active substance (Name)</b>
<b>HSE</b>	<b>September 2023</b>	<b>Pydiflumetofen (SYN545974)</b>

**Section 4 Environmental fate and behaviour****PECsed values via spray drift for metabolite SYN545547**

<b>Crop</b>	<b>Spray drift buffer (m)</b>	<b>PECsed, spraydrift (µg/kg)</b>	<b>Accumulated PECsed, spraydrift (µg/kg)</b>
Winter/Spring cereals 1 x 166 g a.s./ha	1	0.807	3.610
Winter/Spring cereals 1 x 200 g a.s./ha	1	0.973	4.353
Oil Seed Rape 1 x 200 g a.s./ha	1	0.973	4.353

**PECsw values via spray drift for metabolite NOA449410**

<b>Crop</b>	<b>Spray drift buffer (m)</b>	<b>Maximum PECsw, spraydrift (µg/L)</b>
Winter/Spring cereals 1 x 166 g a.s./ha	1	0.034
Winter/Spring cereals 1 x 200 g a.s./ha	1	0.041
Oil Seed Rape 1 x 200 g a.s./ha	1	0.041

**PECsw values via spray drift for metabolite SYN548261**

<b>Crop</b>	<b>Spray drift buffer (m)</b>	<b>Maximum PECsw, spraydrift (µg/L)</b>
Winter/Spring cereals 1 x 166 g a.s./ha	1	0.076
Winter/Spring cereals 1 x 200 g a.s./ha	1	0.092
Oil Seed Rape 1 x 200 g a.s./ha	1	0.092

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 4 Environmental fate and behaviour

### PECsw and PECsed via drainflow

#### PECsw and PECsed via drainflow for pydiflumetofen

Crop	Maximum PECsw, drainflow (µg/L)	PECsed, drainflow (µg/kg)	Accumulated PECsed, drainflow (µg/kg)
Winter/Spring cereals 1 x 166 g a.s./ha, 80% interception	0.051	0.186	0.832
Winter/Spring cereals 1 x 200 g a.s./ha, 90% interception	0.031	0.112	0.501
Oil Seed Rape 1 x 200 g a.s./ha, 80% interception	0.062	0.224	1.002

No drainflow calculations were performed for metabolites. PECsw, drainflow concentrations for pydiflumetofen are lower than the PECsw from spray drift with the maximum 20m no spray buffer zone for both the 166 g a.s./ha and 200 g a.s./ha doses. Therefore the surface water and sediment exposure from metabolites forming from pydiflumetofen entering the water via drainflow will be lower than those predicted to occur via spray drift exposure.

### Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

No other routes of exposure considered

### PEC

Maximum concentration

No other routes of exposure considered

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

### Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
<i>Colinus virginianus</i>	a.s.	14 day acute oral study	LD <sub>50</sub>	> 2000 mg/kg body weight 3776 <sub>extrapolated</sub> mg/kg body weight
<i>Serinus canaria</i>	a.s.	14 day acute oral study	LD <sub>50</sub>	> 2000 mg/kg body weight 3776 <sub>extrapolated</sub> mg/kg body weight
<i>Colinus virginianus</i>	a.s.	8 day dietary study	EC <sub>50</sub>	> 1258 (nom.)
<i>Anas platyrhynchos</i>	a.s.	8 day dietary study (5 days exposure)	LC <sub>50</sub>	> 2437 (nom.)
<i>Colinus virginianus</i>	a.s.	21 week dietary reproductive study	NOEC	90.1
<i>Anas platyrhynchos</i>	a.s.	24 20 week dietary reproductive study	NOEC	141 (nom.)
Mammals				
<i>Rat</i>	a.s.	Acute Oral	LD <sub>50</sub>	> 5000
<i>Rat</i>	a.s.	Two generation reproduction	NOAEL (parental)	Male: 46 Female: 31.6
<i>Rat</i>	a.s.	Two generation reproduction	NOAEL (reproduction)	Male: 46 Female: 31.6 36.1
<i>Rat</i>	a.s.	Two generation reproduction	NOAEL (offspring)	Male: 276.6 Female: 116
<i>Rat</i>	a.s.	Developmental toxicity	NOAEL (maternal)	30

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

<i>Rat</i>	a.s.	Developmental toxicity	NOAEL (developmental)	100
<i>Rabbit</i>	a.s.	Developmental toxicity	NOAEL (maternal)	500
<i>Rabbit</i>	a.s.	Developmental toxicity	NOAEL (developmental)	10
<i>Rat</i>	a.s.	104 week carcinogenicity study with combined 52 week toxicity study	NOAEL (chronic)	Males: 9.9 Females: 31
<i>Rat</i>	a.s.	104 week carcinogenicity study with combined 52 week toxicity study	NOAEL (carcinogenicity)	Males: 319 Females: 102
<i>Mouse</i>	a.s.	80 week carcinogenicity study	NOAEL (chronic)	Males: 9.2 Females: 48.4
<i>Mouse</i>	a.s.	80 week carcinogenicity study	NOAEL (carcinogenicity)	Males: 9.2 Females: 306
Endocrine disrupting properties (Annex Part A, points 8.1.5) Overall, on the basis of the current dataset and EFSA/ECHA 2018 guidance document it is not possible to fully conclude for pydiflumetofen against ED criteria when considering birds.  Overall, HSE concludes that based on current EFSA/ECHA 2018 guidance, pydiflumetofen does not meet the criteria of being an ED based on T and EAS modalities when considering wild mammals.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): -				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): -				

**Bold** indicates endpoints used in risk assessment

<sup>1</sup> Extrapolation according to EFSA (2009) Chapter 2.1.2. has been applied to the acute endpoint LD<sub>50</sub> >2000 mg a.s./kg bw (■■■■■, 2016a) since 10 animals were tested and there were no mortalities at the limit dose (extrapolation factor = 1.888)

## Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

### Cereals at 200 g a.s./ha x 1 application

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small Omnivorous bird	Acute	31.76	118.89	10

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
All	Small Omnivorous bird	Long-term	6.87	13.12	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	23.68	211.15	10
All	Small herbivorous mammal	Long-term	5.18 5.12	6.10 7.05	5
<b>Risk from bioaccumulation and food chain behaviour</b>					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	0.073	1234.25	5
Earthworm-eating mammals		Long-term	0.089	405.62	5
Fish-eating birds		Long-term	0.0092	9793.48	5
Fish-eating mammals		Long-term	0.0082	4402.44	5
Higher tier : -					
<b>Risk from consumption of contaminated water</b>					
<b>Puddle scenario, Screening step</b>					
2) Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					

## Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)\*

\* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
Laboratory tests				
Fish				
<i>Oncorhynchus mykiss</i>	a.s.	Acute 96 hr (flow-through)	Mortality, LC <sub>50</sub>	<b>0.18 mg a.s./L</b> (mm)
<i>Lepomis macrochirus</i>	a.s.	Acute 96 hr (flow-through)	Mortality, LC <sub>50</sub>	0.48 mg a.s./L (mm)
<i>Pimephales promelas</i>	a.s.	Acute 96 hr (flow-through)	Mortality, LC <sub>50</sub>	0.35 mg a.s./L (mm)
<i>Cyprinus carpio</i>	a.s.	Acute 96 hr (flow-through)	Mortality, LC <sub>50</sub>	0.33 mg a.s./L (mm)
<i>Cyprinodon variegatus</i>	a.s.	Acute 96 hr (flow-through)	Mortality, LC <sub>50</sub>	0.66 mg a.s./L (mm)

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
Geometric mean endpoint (based on 5 acute studies above)	a.s.	Acute 96 hr (flow-through)	Mortality, LC <sub>50</sub>	<b>0.366 mg a.s./L</b> (mm)
<i>Oncorhynchus mykiss</i>	Miravis Plus A21857B	Acute 96 hr (static)	Mortality, LC <sub>50</sub>	<b>2.84 mg prep./L</b> (0.16 mg a.s./L <sub>(gm)</sub> )
<i>Pimephales promelas</i>	a.s.	Chronic 32- day early life stage (flow- through)	EC <sub>10</sub> (body weight)  NOEC	<b>0.13 mg a.s./L<sub>(mm)</sub></b>  0.025 mg a.s./L <sub>(mm)</sub>
<i>Cyprinodon variegatus</i>	a.s.	Chronic 34- day early life stage (flow- through)	EC <sub>10</sub> (embryo hatch success)  NOEC	0.34 mg a.s./L <sub>(mm)</sub>  0.17 mg a.s./L <sub>(mm)</sub>
<i>Oncorhynchus mykiss</i>	SYN545547	96 hr (static)	Mortality, LC <sub>50</sub>	<b>1.4 mg metab./L<sub>(gm)</sub></b>
<i>Oncorhynchus mykiss</i>	SYN548261	96 hr (static)	Mortality, LC <sub>50</sub>	<b>&gt; 100 mg metab./L<sub>(nom)</sub></b>
<i>Oncorhynchus mykiss</i>	M700F001 (NOA449410)	96 hr (static)	Mortality, LC <sub>50</sub>	<b>&gt; 100 mg metab./L<sub>(nom)</sub></b>
Aquatic invertebrates				
<i>Daphnia magna</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	0.42 mg a.s./L <sub>(mm)</sub>
<i>Chaoborus crystallinus</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	2.489 mg a.s./L <sub>(mm)</sub>
<i>Cloeon dipterum</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	>5.01 mg a.s./L <sub>(mm)</sub>
<i>Cyclops agilis speratus</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	4.168 mg a.s./L <sub>(mm)</sub>
<i>Asellus aquaticus</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	4.209 mg a.s./L <sub>(mm)</sub>
<i>Crangonyx pseudogracilis</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	1.226 mg a.s./L <sub>(mm)</sub>
<i>Lumbriculus variegatus</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	4.651 mg a.s./L <sub>(mm)</sub>
<i>Lymnaea stagnalis</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	> 7.30 mg a.s./L <sub>(mm)</sub>
<i>Chironomus riparius</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	0.691 mg a.s./L <sub>(mm)</sub>

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
<i>Hyalella Azteca</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	<b>0.12 mg a.s./L<sub>(mm)</sub></b>
<i>Americamysis bahia</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	0.16 mg a.s./L <sub>(mm)</sub>
Geometric mean endpoint (based on 11 acute studies above)	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	<b>1.037 mg a.s./L (mm)</b>
<i>Daphnia magna</i>	Miravis Plus A21857B	48 h (static)	Mortality, EC <sub>50</sub>	<b>1.90 mg prep./L (0.107 mg a.s./L<sub>(gm)</sub>)</b>
<i>Daphnia magna</i>	a.s.	21 d (semi- static)	NOEC	0.042 mg a.s./L <sub>(mm)</sub>
<i>Americamysis bahia</i>	a.s.	28 d (flow- through)	NOEC	<b>0.037 mg a.s./L<sub>(mm)</sub></b>
<i>Daphnia magna</i>	SYN545547	48 h (static)	Mortality, EC <sub>50</sub>	<b>7.3 mg metab./L<sub>(mm)</sub></b>
<i>Daphnia magna</i>	SYN548261	48 h (semi- static)	Mortality, EC <sub>50</sub>	<b>&gt; 100 mg metab./L<sub>(nom)</sub></b>
<i>Daphnia magna</i>	M700F001 (NOA449410)	48 h (static)	Mortality, EC <sub>50</sub>	<b>&gt; 100 mg metab./L<sub>(nom)</sub></b>
Sediment-dwelling organisms				
<i>Hyalella azteca</i>	a.s.	42 d spiked sediment (static renewal)	NOEC (survival)  Growth, EC <sub>10</sub>	<b>36 mg a.s./kg dry sediment (mm) &gt; 88 mg a.s./kg sediment<sub>(mm)</sub></b>
<i>Leptocheirus plumulosus</i>	a.s.	10 d (static)	LC <sub>50</sub>	> 89 mg a.s./kg dry sediment <sub>(gm)</sub>
<i>Chironomus riparius</i>	SYN545547	28 d (static)	NOEC (male development)  Female development, EC <sub>10</sub>	<b>7.2 mg metab./kg dry sediment<sub>(gm)</sub> 35.4 mg metab./kg dry sediment<sub>(gm)</sub></b>
Algae				
<i>Skeletonema costatum</i>	a.s.	96 h (static)	72 h  Growth rate: E <sub>r</sub> C <sub>50</sub> E <sub>r</sub> C <sub>10</sub> Yield: E <sub>y</sub> C <sub>50</sub> E <sub>y</sub> C <sub>10</sub>	2.7 mg a.s./L <sub>(gm)</sub> 2.5 mg a.s./L <sub>(gm)</sub> 2.7 mg a.s./L <sub>(gm)</sub> 2.5 mg a.s./L <sub>(gm)</sub>

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
<i>Anabaena flos-aquae</i>	a.s.	96 h (static)	72 h Growth rate: E <sub>r</sub> C <sub>50</sub> E <sub>r</sub> C <sub>10</sub> Yield: E <sub>y</sub> C <sub>50</sub>	3.6 mg a.s./L <sub>(mm)</sub> 2.8 mg a.s./L <sub>(mm)</sub> 3.5 mg a.s./L <sub>(mm)</sub>
<i>Pseudokirchneriella subcapitata</i>	a.s.	96 h (static)	72 h Growth rate: E <sub>r</sub> C <sub>50</sub>  E <sub>r</sub> C <sub>10</sub> Yield: E <sub>y</sub> C <sub>50</sub> E <sub>y</sub> C <sub>10</sub>	> 5.9 mg a.s./L <sub>(mm)</sub> 2.3 mg a.s./L <sub>(mm)</sub> 3.6 mg a.s./L <sub>(mm)</sub> 1.1 mg a.s./L (mm)
<i>Navicula pelliculosa</i>	a.s.	96 h (static)	96 h Growth rate: E <sub>r</sub> C <sub>50</sub>  72 h Growth rate: E <sub>r</sub> C <sub>50</sub> E <sub>r</sub> C <sub>10</sub>  Yield: E <sub>y</sub> C <sub>50</sub> E <sub>y</sub> C <sub>10</sub>	<b>1.5 mg a.s./L<sub>(mm)</sub></b>  1.6 mg a.s./L <sub>(mm)</sub> 1.1 mg a.s./L <sub>(mm)</sub>  1.5 mg a.s./L <sub>(mm)</sub> 0.68 mg a.s./L <sub>(mm)</sub>
<i>Pseudokirchneriella subcapitata</i>	'Miravis Plus' A21857B	96 h (static)	72 h Growth rate: E <sub>r</sub> C <sub>50</sub>  E <sub>r</sub> C <sub>10</sub>  Yield: E <sub>y</sub> C <sub>50</sub>  E <sub>y</sub> C <sub>10</sub>	<b>7.38 mg prep./L<sub>(gm)</sub></b> [0.415 mg a.s./L <sub>(gm)</sub> ] 4.20 mg prep/L <sub>(gm)</sub> [0.236 mg a.s./L <sub>(gm)</sub> ] 3.93 mg prep/L <sub>(gm)</sub> [0.221 mg a.s./L <sub>(gm)</sub> ] 2.67 mg prep/L <sub>(gm)</sub> [0.150 mg a.s./L <sub>(gm)</sub> ]



## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
<i>Pseudokirchneriella subcapitata</i>	SYN545547	96 h (static)	72 h Growth rate: E <sub>r</sub> C <sub>50</sub>  E <sub>r</sub> C <sub>10</sub>  Yield: E <sub>y</sub> C <sub>50</sub>  E <sub>y</sub> C <sub>10</sub>	<b>4.1 mg metab./L<sub>(mm)</sub></b> 2.3 mg metab./L <sub>(mm)</sub> 2.9 mg metab./L <sub>(mm)</sub> 1.9 mg metab./L <sub>(mm)</sub>
<i>Pseudokirchneriella subcapitata</i>	SYN548261 (metabolite)	96 h (static)	72 h Growth rate: E <sub>r</sub> C <sub>50</sub>  Yield: E <sub>y</sub> C <sub>50</sub>	> 100 mg metab./L <sub>(nom)</sub> > 100 mg metab./L <sub>(nom)</sub>
<i>Pseudokirchneriella subcapitata</i>	M700F001 (NOA449410) (metabolite)	72 h (static)	72 h Growth rate: E <sub>r</sub> C <sub>50</sub>  E <sub>r</sub> C <sub>10</sub>  Yield: E <sub>y</sub> C <sub>50</sub>  E <sub>y</sub> C <sub>10</sub>	<b>36.31 mg metab./L<sub>(nom)</sub></b> 20.61 mg metab./L <sub>(nom)</sub> 26.42 mg metab./L <sub>(nom)</sub> 19.43 mg metab./L <sub>(nom)</sub>

Further testing on aquatic organisms

**Fish:** in addition to the acute study with *O. mykiss*, four additional acute fish studies were conducted in order to refine the Tier 1 RAC. Due to insufficient consideration of latency of effects, an SSD could not be conducted. Instead a geomean was derived from the data points, resulting in a geomean RAC of **3.66 µg SYN545974/L based on a geomean of 366 µg SYN545974/L and an assessment factor of 100.**

**Invertebrates:** in addition to *D. magna* and *A. bahia*, nine additional acute studies with aquatic invertebrates were conducted, in order to refine the Tier 1 TER. Due to insufficient latency of effects, an SSD could not be conducted. Instead a geomean was derived from the data points, resulting in a geomean RAC of **10.37 µg SYN545974/L, based on a geomean of 1037 µg SYN545974/L and an assessment factor of 100.**

**Formulation risk to aquatic invertebrates:** Formulation data was only available for *D. magna* however, when considering active substance data, the most sensitive species was *H. azteca*. To ensure the formulation risk assessment was protective of the most sensitive aquatic invertebrate species, HSE has taken into account the multispecies active substance data. Considering both active substance and formulation data for *Daphnia*, the formulation appears to be 3.925 times more toxic than the active substance. HSE has applied this factor to the aquatic invertebrate geomean RAC (10.37 µg/L), in order to better approximate the toxicity of the formulation to aquatic invertebrates by accounting for a wider range of species sensitivities. **The resulting RAC is 2.64 µg/L (expressed in terms of a.s.).**

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

### Potential endocrine disrupting properties (Annex Part A, point 8.2.3) – THIS SECTION IS SUBJECT TO THE SUBMISSION OF THE FINAL STUDY REPORT

There are no clear treatment related effects of pydiflumetofen on endocrine activity at the highest concentration tested in the FSTRA study (0.13 mg a.s./L) based on evidence from the submitted FSTRA study, and taking into consideration relevant observations from the two ELS studies. Regarding the results from the FSTRA, Effects on gonads were seen at the highest test concentration (0.13 mg a.s./L) which correlated with a significant reduction in egg production (fecundity); there was also a significant reduction in female vitellogenin (VTG) at the middle test concentration. Independent Scientific Advice (ISA) was sought from the Expert Committee on Pesticides (ECP) regarding the results from this assay and it was concluded that it was uncertain as to whether the observed effects were due to systemic toxicity or endocrine-mediated. As such, a Rapid Androgen Disruption Activity Reporter (RADAR) assay was requested to provide further mechanistic data. This is currently ongoing, therefore it is not possible to conclude at present on the endocrine disrupting potential of pydiflumetofen on Estrogen, Androgen and Steroidogenesis (EAS) modalities for aquatic organisms. However it was concluded that these results were a result of mild systemic toxicity upon consideration of the weight of evidence from the FSTRA and ELS studies. Therefore, based on submitted studies for Oestrogen, Androgen and Steroidogenesis (EAS) modalities, pydiflumetofen is not an endocrine disruptor for aquatic organisms. A draft study report for the RADAR assay was submitted by the applicant to HSE in September 2023 and whilst noting some uncertainties with the study, it was concluded that pydiflumetofen was inactive in the RADAR assay. Taken together with the results from the FSTRA, HSE considers EAS modalities have been sufficiently investigated and the results support a negative conclusion for EAS modalities.

Overall, there were no clear treatment related effects on T-mediated parameters in the submitted AMA study up to the MTC. There was a slight effect on the whole body wet weight parameter, which is sensitive to but not diagnostic of thyroid-mediated effects. This is likely due to general toxicity, meaning that overall, the case is strong enough to conclude that there is no evidence of treatment-related changes in thyroid activity. There were some uncertainties with the study design and selection of test concentrations, however this was not considered to invalidate the study. Therefore, based on the submitted study for Thyroid (T) modalities, pydiflumetofen is not an endocrine disruptor for aquatic organisms.

In conclusion, pydiflumetofen is considered not to have endocrine disruption properties, in accordance with EFSA/ECHA 2018 guidance based on available information.

<sup>1</sup> (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

**Bold** indicates endpoints used in risk assessment

**List of end points**

<b>Evaluator</b>	<b>Month and year</b>	<b>Active substance (Name)</b>
<b>HSE</b>	<b>September 2023</b>	<b>Pydiflumetofen (SYN545974)</b>

**Section 5 Ecotoxicology****Bioconcentration in fish (Annex Part A, point 8.2.2.3)**

	Active substance	Metabolite1	Metabolite2	Metabolite3
logP <sub>O/W</sub>	3.8			
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	31.1*			
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	189			
Annex VI Trigger for the bioconcentration factor	>1000			
Clearance time (days) (CT <sub>50</sub> )	0.41			
Level and nature of residues (%) in organisms after the 7 day depuration phase	4.6 %			
Higher tier study				

\* based on total <sup>14</sup>C or on specific compounds

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

**UK SPECIFIC** - TERs for pydiflumetofen – single application to oilseed rape at 200 g a.s./ha (worst case GAP for proposed use).

Group		Fish acute	Fish acute	Fish chronic	Invertebrate acute	Invertebrate acute	Invertebrate chronic	Algae		Sediment dwelling organisms <sup>1</sup>
Test species		<i>O. mykiss</i>	Geometric mean	<i>P. promelas</i>	<i>H. azteca</i>	Geometric mean	<i>A. bahia</i>	<i>N. pelliculosa</i>		<i>H. azteca</i>
Endpoint (µg a.s./L)		LC <sub>50</sub> 180	LC <sub>50</sub> 366	NOEC 130	EC <sub>50</sub> 120	EC <sub>50</sub> 1037	NOEC 37	E <sub>r</sub> C <sub>50</sub> 1600		NOEC 36000
AF		100	100	10	100	100	10	10		10
RAC (µg a.s./L)		1.8	3.66	13	1.2	10.37	3.7	160		3600
Entry pathway / Buffer zone [m] / season	PEC <sup>gl-sw max</sup> (µg a.s./L)	PEC/RAC (= ETR)							PEC sed (µg/L)	PEC/RAC (= ETR)
Spray drift Standard distance (1 m)	1.847	1.026	0.50	0.142	1.539	0.18	0.499	0.115	30.121	0.0084
Drainage	0.062	0.034	-	0.005	0.05	-	0.017	0.0004	1.002	0.00028

<sup>1</sup> Spiked sediment study; value is expressed as µg/kg sediment. AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**.

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

### UK SPECIFIC - TERs for pydiflumetofen metabolites – single application to oilseed rape at 200 g a.s./ha (worst case GAP for proposed use).

Group	Exposure	Fish (Acute)		Inverteb. acute		Sediment dwelling organisms	Algae	
Test species		<i>O. mykiss</i>		<i>D. magna</i>		<i>C. riparius</i>	<i>P. subcapitata</i>	
Metabolite:		M700F001 (NOA449410)	SYN548261	M700F001 (NOA449410)	SYN548261	SYN545547	M700F001 (NOA449410)	SYN548261
Endpoint (µg metabolite/L)		LC <sub>50</sub>	LC <sub>50</sub>	EC <sub>50</sub>	EC <sub>50</sub>	NOEC	E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
AF		100	100	100	100	10	10	10
RAC (µg metabolite/L)		10000	10000	1000	1000	720	3631	10000
Spray drift entry / Buffer zone [m]	PEC <sub>sw-ini</sub> (µg metabolite/L)	PEC/RAC (= ETR)						
M700F001 (NOA449410) standard distance (1 m)	0.041	0.000041	--	0.000041	--	--	0.00001	--
SYN548261 standard distance (1 m)	0.092	--	0.000092	--	0.000092	--	--	0.0000092
SYN545547 PEC <sub>sed</sub> (µg/kg sediment)	4.353	--	--	--	--	0.006	--	--

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentrations, -- = not applicable as different metabolite PEC

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

**UK SPECIFIC - TERs for pydiflumetofen representative formulation ('Miravis Plus')– single application to oilseed rape at 200 g a.s./ha (worst case GAP for proposed use).**

Group	Exposure	Inverteb. acute	Algae
Test species		<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg product/L)		EC <sub>50</sub> 1900	E <sub>r</sub> C <sub>50</sub> 7380
AF		100	10
RAC (µg product/L)		19.00	738
Spray drift entry / Buffer zone [m]	PEC <sub>sw-ini</sub> (µg product/L)		
standard distance (1 m)	32.413	<b>1.7</b>	0.044
standard distance (5 m)	6.670	0.35	-

*Daphnia* was not the most sensitive species when considering active substance data. The most sensitive species was *Hyalella* (EC<sub>50</sub> of 0.12 mg a.s./L vs EC<sub>50</sub> of 0.42 mg a.s./L for *Daphnia*), however no formulation data was available with this species. This raises concern as to whether the formulation risk assessment is sufficiently protective of the risk to all aquatic invertebrates. In order to address the risk of the formulation to the most sensitive aquatic invertebrate species, HSE has taken into account the multispecies active substance data as follows.

Considering both active substance and formulation data for *Daphnia*, the formulation appears to be 3.925 times more toxic than the active substance. HSE has applied this factor to the aquatic invertebrate geomean RAC (10.37 µg/L), in order to better approximate the toxicity of the formulation to aquatic invertebrates by accounting for a wider range of species sensitivities. The resulting RAC is 2.64 µg/L (expressed in terms of a.s.).

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

### Risk assessment for aquatic invertebrates considering active substance multispecies data.

Scenario	PEC (µg a.s./L)	Aquatic invertebrates
		Multispecies data
		RAC
		2.64 µg/L
Spraydrift (1 m)	1.847	0.70

An acceptable risk to aquatic invertebrates can be concluded at 1 m. This approach is considered more suitable than using the *Daphnia* formulation endpoint, since it accounts for a wider range of species sensitivities and can therefore be considered protective of species more sensitive than *Daphnia*. The risk of the formulation to aquatic invertebrates can therefore be resolved at 1 m with no risk mitigation required.

### **Overall conclusion for aquatic organisms:**

Based on the above an acceptable risk to aquatic organisms for the proposed uses can be concluded.



## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

### Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)\*

\* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	Toxicity
<i>Apis mellifera</i>	a.s.	Acute (48 h), Adult	Oral toxicity (LD <sub>50</sub> )	>116 µg a.s./bee <sub>(con)</sub>
<i>Apis mellifera</i>	a.s.	Acute (48 h), Adult	Contact toxicity (LD <sub>50</sub> )	>100 µg a.s./bee
<i>Apis mellifera</i>	Preparation 'A19649B';	Acute (48 h), Adult	Oral toxicity (LD <sub>50</sub> )	>1132 µg f.p./bee <sub>(con)</sub> (equivalent to >211 µg a.s./bee <sub>(con)</sub> )
<i>Apis mellifera</i>	Preparation 'A19649B'	Acute (48 h), Adult	Contact toxicity (LD <sub>50</sub> )	>1000 µg f.p./bee (equivalent to >186 µg a.s./bee)
<i>Apis mellifera</i>	Preparation 'A21857B' (Miravis Plus)	Acute (48 h), Adult	Oral toxicity (LD <sub>50</sub> )	>423 µg f.p./bee <sub>(con)</sub> (equivalent to >24.07 µg a.s./bee <sub>(con)</sub> )
<i>Apis mellifera</i>	Preparation 'A21857B' (Miravis Plus)	Acute (48 h), Adult	Contact toxicity (LD <sub>50</sub> )	>1000 µg f.p./bee (equivalent to >56.9 µg a.s./bee)
<i>Apis mellifera</i>	Preparation 'A19649B'	Chronic (10 d repeated exposure), Adult	LD <sub>50</sub> /LD <sub>20</sub> /LD <sub>10</sub> <sup>a</sup> LC <sub>50</sub> /LC <sub>20</sub> /LC <sub>10</sub> <sup>a</sup> NOED <sup>a</sup> NOEC <sup>a</sup>	>138.2 µg a.s./bee/day <sub>(con)</sub> <sup>a</sup> >3854 mg a.s./kg diet <sup>a</sup> 138.2 µg a.s./bee/day <sub>(con)</sub> <sup>a</sup> 3854 mg a.s./kg diet <sup>a</sup>
<i>Apis mellifera</i>	a.s.	Bee brood development (Larval 22d, repeated exposure, limit test)*	8d LD <sub>50</sub> & 22d ED <sub>50</sub> 8d LC <sub>50</sub> & 22d EC <sub>50</sub> 8d & 22d NOED <sup>b</sup> 8d & 22d NOEC <sup>b</sup>	>0.014 µg a.s./larva <sub>(con)</sub> >0.0035 µg a.s./larva/day <sub>(con)</sub> >0.09 mg a.s./kg diet <sub>(mc)</sub> <0.014 µg a.s./larva <sub>(con)</sub> <sup>b</sup> <0.0035 µg a.s./larva/day <sub>(con)</sub> <sup>b</sup> <0.09 mg a.s./kg diet <sub>(mc)</sub> <sup>b</sup>
<i>Apis mellifera</i>	Preparation 'A19649B'	Bee brood development (Larval 22d, repeated exposure)*	8d LD <sub>50</sub> <sup>c</sup> 8d NOED <sup>b</sup> 8d NOEC <sup>b</sup> 8d LD <sub>10/20</sub> & 22d ED <sub>10/20</sub>	45.24 µg a.s./larva <sub>(con)</sub> 11.31 µg a.s./larva/day <sub>(con)</sub> <0.06 µg a.s./larva <sub>(con)</sub> <sup>b</sup> <0.015 µg a.s./larva/day <sub>(con)</sub> <sup>b</sup> <0.409 mg a.s./kg diet <sub>(nc)</sub> <sup>b</sup> n.d.

## List of end points

Evaluator	Month and year	Active substance (Name)
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			22d ED <sub>50</sub> <sup>c</sup>	7.64 µg a.s./larva <sub>(con)</sub> 1.91 µg a.s./larva/day <sub>(con)</sub>
			22d NOED	0.06 µg a.s./larva <sub>(con)</sub> 0.015 µg a.s./larva/day <sub>(con)</sub>
			22d NOEC	0.409 mg a.s./kg/diet <sub>(nc)</sub>
<i>Apis mellifera</i>	Preparation 'A19649B'	Larval 8d, repeated exposure*	8d NOED <sup>d</sup>	55 µg a.s./larva <sup>d</sup> 13.75 µg a.s./larva/day <sup>d</sup>
			8d NOEC	347 mg a.s./kg diet <sub>(nc)</sub>
			8d LD/LC <sub>10/20</sub>	n.d.
			8d LD <sub>50</sub> <sup>e</sup>	>109.9 µg a.s./larva <sup>e</sup> >27.48 µg a.s./larva/day <sup>e</sup>
			8d LC <sub>50</sub>	>695 mg a.s./kg diet <sub>(nc)</sub>

A19649B: the representative product for the EU assessment of this active. Whilst not the representative product for the GB assessment, data from this formulation was used to inform the risk assessment.

A21857B (Miravis Plus): the representative product for the GB assessment of this active.

(con) = consumed dose; (mc) = measured concentration; (nc) = nominal concentration; a.s. = active substance; f.p. = formulated preparation/product; n.d. = not possible to determine.

\*These three studies with honeybee larvae were considered valid, but the results are contradictory to each other. Whilst these larval endpoints are not currently used in a quantitative manner in risk assessment (due to current lack of noted/agreed guidance), they have been included for future information.

<sup>a</sup> Note there is uncertainty in the reliability of the endpoints from this study, as no analytical measurements were provided and there were no corrections for evaporative loss of the test substance in the diet.

<sup>b</sup> Although an unbounded 'less-than' NOEC would typically be described as an undefined endpoint, the unbounded values are provided for additional information.

<sup>c</sup> There is some uncertainty with these ED/LD<sub>50</sub> endpoints due to wide confidence intervals. LC and EC<sub>10/20</sub> were also calculated in the study, but were unreliable due to extrapolation outside tested concentrations and wide confidence intervals

<sup>d</sup> This endpoint does not take into account the actual consumed dose, which may be lower, as left-over food (indicating repellence/unpalatability) and corresponding reduction in larval development was observed in 21 % of remaining larvae.

<sup>e</sup> This endpoint does not take into account the actual consumed dose, which may be lower, as left-over food (indicating repellence/unpalatability) and corresponding reduction in larval development was observed in 35 % of remaining larvae.

Potential for accumulative toxicity: -

#### Semi-field test (Cage and tunnel test)

Three studies on the honey bee *Apis mellifera* were conducted to OECD 75 (2007), with treatments of formulation A19649B applied by single spray application (max. application equivalent to 200 g a.s./ha) to full-flowering *Phacelia tanacetifolia* within tunnels to provide a 7-day exposure period of the test item to the bees. After the 7-day exposure period within tunnels, bee colonies were transferred to a monitoring site 10.5 – 22 km away for the remainder of the study in free-flying conditions (total observation period: 54 - 63 days after test item application).

Residue analysis of the active substance was carried out on nectar from forager bees, pollen, flowers and foliage in all three studies across the 7-day exposure period. Residues were found in all three studies from 4 hours after application onwards and decreased over the next 7 days. In combination with a survey of foraging activity of the bees, this demonstrated that bees were sufficiently exposed to the test item.

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

The studies were carried out at the following locations and times of year: Saxony, Germany from 27 May – 01 Aug 2017 (■■■■■, 2018); Baden-Württemberg, Germany from 10 Aug – 19 Oct 2016 (■■■■■, 2017) and Baden-Württemberg, Germany from 14 Jun – 25 Aug 2016 (■■■■■, 2017). Additional supplementary feeding was necessary up to two times once colonies were transferred to the monitoring sites, as colonies were on the verge of starvation. This was stated to be common beekeeping practice for the region and times of year the studies were carried out.

Detailed observations of foraging activity, behaviour and adult mortality were carried out for the 7 days exposure period of each study. Detailed photographic evaluation of brood development was carried out up to 22 days after test item application (DAT). Evaluations of colony strength (no. bees/colony), food and brood development by comb surface area were carried out for up to 63 days after test item application. The results did not indicate a cause for concern for honeybees at any life stage. Please see the dossier volume 3CP B9 section B.9.5.1 (study summaries/evaluation) and B.9.6.1 (discussion of semi-field studies in the context of risk assessment) for further details.

**Overall, the three semi-field tunnel tests using preparation ‘A19649B’ with exposure by single spray application (7-day exposure within tunnels) of the formulation to flowering *Phacelia* revealed no significant adverse effects of the test item on the colonies, as tested up to 200 g a.s./ha.**

### Field tests

One colony-feeding study on the honey bee *Apis mellifera*, broadly conducted to the ‘Oomen method’, was carried out using the technical active substance (a.s.). The study involved chronic oral exposure for 9 days via an in-hive application of treated sucrose solution (max. test concentration 32.30 mg a.s./kg diet) under field conditions where bees are free flying. Food consumption was monitored and demonstrated sufficient exposure of bees to the test item.

The study was conducted in late summer from 23 Jun – 28 Aug 2017 (■■■■■, 2018). Detailed observation of adult and pupal mortality and behaviour was carried out for 26 days after first treatment. Detailed photographic measurement of brood development was carried out up to 20 days after first treatment. Colony strength (no. bees/colony) and general food and brood development by comb surface area was carried out up to 61 days after first treatment. The results did not indicate a cause for concern for honeybees at any life stage. Please see the dossier volume 3CA B9 section B.9.3.1 (study summary/evaluation) and dossier volume 3CP B9 section B.9.6.1 (discussion of colony-feeding study in the context of risk assessment) for further details.

**Overall, the chronic brood colony feeding study under field conditions using the technical active substance (a.s.) with exposure via repeated oral administration (9-day exposure, 61-day observation) did not adversely affect colony development and survival, as tested up to 32.0 mg a.s./kg diet.**

**Risk assessment** for – ‘A21857B’ at to cereals and oilseed rape at 200 g a.s./ha, single application (worst-case GAP use)

Species	Test substance	Risk quotient	HQ/ETR	Trigger
<i>Apis mellifera</i>	a.s. pydiflumetofen	HQcontact	<2.000	50
<i>Apis mellifera</i>	a.s. pydiflumetofen	HQoral	<1.724	50
<i>Apis mellifera</i>	Preparation ‘A21857B’	HQcontact	<3.515	50
<i>Apis mellifera</i>	Preparation ‘A21857B’	HQoral	<8.309	50
<i>Apis mellifera</i>	Preparation ‘A19649B’	HQcontact	<1.075	50
<i>Apis mellifera</i>	Preparation ‘A19649B’	HQoral	<0.950	50

## List of end points

Evaluator	Month and year	Active substance (Name)
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## Section 5 Ecotoxicology

-	a.s., preparation	ETRacute adult oral	-	-
-	a.s., preparation	ETRchronic adult oral	-	-
-	a.s., preparation	ETRlarvae	-	-
-	a.s., preparation	ETRhpg	-	-

### Qualitative consideration of chronic risk

In the absence of GB noted/adopted guidance for chronic risk to honeybees, a qualitative assessment of available data was carried out, as the chronic risk to honeybees still requires consideration nevertheless.

On the basis of low **and comparable** acute toxicity of both A21857B (representative formulation - GB), A19649B (alternative formulation – EU – not the representative GB product), and the technical active substance, it was considered feasible to use the A19649B data to support the risk assessment.

**The ECP advised it is incorrect to take the view that the two formulations are of comparable toxicity based on evidence from unbounded toxicity values, although the Committee agreed that both formulations do not appear to be very toxic based on the acute toxicity dataset. The Committee accepted the interpretation and use of semi-field data to support the conclusion on honeybee larvae. The availability of the colony-feeding field study using the technical active substance rather than the EU formulation, adds weight to the conclusion.**

An illustrative margin of safety calculation was carried out by comparing estimated exposure by diet from residue data of semi-field studies, and by estimated daily-dose exposure from values in Appendix J1 of EFSA (2013) bee guidance (not yet noted by GB), with the relevant toxicity endpoints from laboratory studies. This yielded a margin of safety for chronic exposure of pydiflumetofen to adult bees on the basis of first-tier data. Additional information from the semi-field studies added some weight to this conclusion.

Due to the contradictory nature of the larval laboratory study dataset, there was no reliable larval toxicity endpoint and therefore consideration relied on the semi-field and colony-feeding studies. These studies indicate that pydiflumetofen poses low risk to honeybee colonies through all life-stages, including the larval stage, as tested up to 200 g a.s./ha or 32 mg a.s./kg food.

Please see dossier volume 3CP section B.9.6.1 for further details and the full risk assessment of pydiflumetofen to bees.

### Conclusion of the risk assessment

**Overall, when considering both the lower and higher tier risk assessment, HSE considers an acceptable risk to honeybees can be concluded for the proposed use.**

**The advice of the ECP was sought regarding the risk to bees. Overall, based on the evidence put before it, the ECP advised that bees are not driving the risk assessment (bees are not the most sensitive organism group), and that based on the data available, are not a cause for concern.**

## Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

### Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
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## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Species	Test Substance	End point	Toxicity
<i>Typhlodromus pyri</i>	Preparation ‘A21857B’	Mortality, LR <sub>50</sub>	1.667 L f.p./ha
		Reproduction, ER <sub>50</sub>	>1.250 L f.p./ha
		NOER(mortality, reproduction)	0.625 L f.p./ha
<i>Aphidius rhopalosiphi</i>	Preparation ‘A21857B’	Mortality, LR <sub>50</sub>	>0.375 L f.p./ha
		Rate at which < 50 % effect on reproduction occurred	>0.375 L f.p./ha
Additional species			
-			
-			

f.p. = formulated preparation/product

**First tier risk assessment** for – 'A21857B' to cereals and oilseed rape at 200 g a.s./ha, single application (worst-case GAP use)

Test substance	Species	Effect (LR <sub>50</sub> L/ha)	HQ in-field	HQ off-field <sup>1</sup>	Trigger
Preparation 'A21857B'	<i>Typhlodromus pyri</i>	1.667	1.91	0.0531	2
Preparation 'A21857B'	<i>Aphidius rhopalosiphi</i>	>0.375	<b>&lt;8.53</b>	<0.236	2

<sup>1</sup> Using drift rate of 2.77 % (1m). Values in **bold** indicate failing HQ value.

## Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (L/ha) <sup>1,2</sup>	Corrected mortality (%) <sup>3</sup>	% Effect on reproduction <sup>3</sup>	End point	ER <sub>50</sub> (L/ha) <sup>2,4</sup>
<i>Aphidius rhopalosiphi</i>	Adult	Preparation 'A21857B', barley seedlings (3D exposure)	Mortality: 48 h	0.9526	0.0	n.d.	Mortality	8.087
				1.715	6.7	4.5		
			Fecundity: 24 h	3.086	3.3	-11.1	Reproduction	<b>5.556</b>
			Mummy development: 10 d	5.556	10.0	3.1		
				10.00	73.3	n.d.		

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Species	Life stage	Test substance, substrate	Time scale	Dose (L/ha) <sup>1,2</sup>	Corrected mortality (%) <sup>3</sup>	% Effect on reproduction <sup>3</sup>	End point	ER <sub>50</sub> (L/ha) <sup>2,4</sup>
<i>Typhlodromus pyri</i>	Proto-nymphs	Preparation 'A21857B', dwarf French bean leaf discs (2D exposure)	Mortality: 7 d Fecundity: 7 d Total: 14 d	0.3125 0.625 1.250 2.500 5.00	-2 2 10 21 50	n.d. n.d. -18.8 9.9 33.3	Mortality  Reproduction	5.000  <b>5.000</b>
<i>Chrysoperla carnea</i>	First instar larvae	Preparation 'A21857B', French bean leaf discs (2D exposure)	Total: 40 d	0.000 0.200 0.400 0.800 1.600 3.200	n.a. -2.8 -5.6 -8.3 8.3 5.6	90.0* n.d.* n.d.* 89.3* 90.8* 90.0*	Mortality  Reproduction	>3.200  <b>3.200</b>

f.p. = formulated preparation/product; n.d. = not determined; n.a. = not applicable

<sup>1</sup> Initial/fresh residues

<sup>2</sup> Expressed in terms of L formulated product/ha

<sup>3</sup> A negative value indicates an increase relative to the control, a positive value a decrease.

<sup>4</sup> The reproductive endpoint is defined as the 'highest tested rate with < 50 % effect on reproduction' as opposed to a true ER<sub>50</sub> value

\*values are mean egg viability (%) and are not control-corrected.

**Risk assessment** for – 'A21857B' to cereals and oilseed rape at 200 g a.s./ha (3.2 L product/ha), single application (worst-case GAP use) based on extended lab test or aged residue tests

Species	ER <sub>50</sub> (L f.p./ha) <sup>1</sup>	In-field predicted environmental rate (L f.p./ha)	Off-field rate <sup>2</sup>
<i>Aphidius rhopalosiphii</i> (3D exposure scenario)	5.556	3.2	-
<i>Typhlodromus pyri</i> (2D exposure scenario)	5.0	3.2	-
<i>Chrysoperla carnea</i> (2D exposure scenario)	3.2	3.2	-

f.p. = formulated preparation/product

<sup>1</sup> Worst case value from LR<sub>50</sub> mortality endpoint or reproductive endpoint ('highest tested rate with < 50 % effect on reproduction')

<sup>2</sup> Off-field rate calculation not required as risk was resolved using standard laboratory test endpoints.

Semi-field tests
-
Field studies
-
Additional specific test

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

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## Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance <sup>1</sup>	Application method of test a.s./ OM	Time scale	End point	Toxicity mg f.p./kg soil d.w. (mg a.s./kg soil d.w)
Earthworms					
<i>Eisenia foetida</i>	Preparation 'A21857B'	Mixed into soil / 5 % peat	56 d Chronic	Mortality/biomass          Reproduction	EC <sub>10</sub> >1000 (56.2) EC <sub>20</sub> >1000 (56.2) NOEC 1000 (56.2) EC <sub>10CORR</sub> <sup>2</sup> >500 (28.1) EC <sub>20CORR</sub> <sup>2</sup> > 500 (28.1) NOEC <sub>CORR</sub> <sup>2</sup> 500 (28.1)  EC <sub>10</sub> 194 (10.9) EC <sub>20</sub> 302 (16.97) NOEC 309 (17.37) <b>EC<sub>10CORR</sub><sup>2</sup> 97 (5.45)</b> EC <sub>20CORR</sub> <sup>2</sup> 151 (8.49) NOEC <sub>CORR</sub> <sup>2</sup> 154.5 (8.69)
Other soil macroorganisms					
<i>Folsomia candida</i>	Preparation 'A21857B'	Mixed into soil / 5 % peat	28 d Chronic	Mortality/reproduction	EC <sub>10</sub> >1000 (56.2) EC <sub>20</sub> >1000 (56.2) NOEC 1000 (56.2) EC <sub>10CORR</sub> <sup>2</sup> >500 (28.1) EC <sub>20CORR</sub> <sup>2</sup> > 500 (28.1) <b>NOEC<sub>CORR</sub><sup>2</sup> 500 (28.1)</b>

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Test organism	Test substance <sup>1</sup>	Application method of test a.s./ OM	Time scale	End point	Toxicity mg f.p./kg soil d.w. (mg a.s./kg soil d.w)
<i>Hypoaspis aculeifer</i>	Preparation 'A21857B'	Mixed into soil / 5 % peat	14 d Chronic	Mortality/reproduction	EC <sub>10</sub> >1000 (56.2) EC <sub>20</sub> >1000 (56.2) NOEC 1000 (56.2) EC <sub>10CORR</sub> <sup>2</sup> >500 (28.1) EC <sub>20CORR</sub> <sup>2</sup> > 500 (28.1) <b>NOEC<sub>CORR</sub><sup>2</sup> 500 (28.1)</b>

f.p.=formulated preparation/product.

<sup>1</sup>) No study available with the active substance pydiflumetofen

<sup>2</sup>) Corrected by a factor of 2 due to log<sub>Pow</sub> > 2

Bold values used in risk assessment

Higher tier testing (e.g. modelling or field studies)
-

Nitrogen transformation	a.s. pydiflumetofen	-1.3 % effect at day 28 at 0.54 mg a.s./kg d.w. soil <b>-4.4 % effect from day 28 at 2.71 mg a.s./kg d.w. soil</b>
Nitrogen transformation	a.s. pydiflumetofen	+3.3 % effect at day 28 at 5.4 mg a.s./kg d.w. soil +2.4 % effect from day 28 at 13.5 mg a.s./kg d.w. soil

- = inhibition, + = stimulation, bold values used in risk assessment

## Toxicity/exposure ratios for soil organisms

Oilseed rape at 1 x 200 g a.s./ha (worst-case GAP for proposed uses)

Test organism	Test substance	Time scale	Soil PEC (max)	TER	Trigger
Earthworms					
<i>Eisenia foetida</i>	Preparation 'A21857B' (expressed as a.s. content) <sup>1</sup>	56 d Chronic	0.736 mg a.s./kg soil d.w.	7.4	5
	Preparation 'A21857B'	56 d Chronic	0.936 mg f.p./kg soil d.w.	103.6	5



## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

## Section 5 Ecotoxicology

Test organism	Test substance	Time scale	Soil PEC (max)	TER	Trigger
Other soil macroorganisms					
<i>Folsomia candida</i>	Preparation 'A21857B' (expressed as a.s. content) <sup>1</sup>	28 d Chronic	0.736 mg a.s./kg soil d.w.	38.2	5
	Preparation 'A21857B'	28 d Chronic	0.936 mg f.p./kg soil d.w.	534.2	5
<i>Hypoaspis aculeifer</i>	Preparation 'A21857B' (expressed as a.s. content) <sup>1</sup>	14 d Chronic	0.736 mg a.s./kg soil d.w.	38.2	5
	Preparation 'A21857B'	14 d Chronic	0.936 mg f.p./kg soil d.w.	534.2	5

<sup>1</sup> No chronic active substance study was available, therefore the active substance risk assessment used the study endpoints represented in terms of the active substance content (5.62 % w/v in the formulation) along with the active substance PECsoil values

## Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

### Screening data

One non-target plant screening study was submitted for the representative product 'Miravis Plus' (A21857B). This is acceptable, as the active substance is not a herbicide, and does not demonstrate a herbicidal mode of action.

There were no observations of phytotoxicity in any of the six tested plants in the seedling emergence part of the screening assessment, at rates up to and including 3,200 mL A21857B /ha.

For the vegetative vigour part of the screening assessment, onion, wheat, sugar beet, and oilseed rape did not show any phytotoxic effects at rates up to and including 3,200 mL A21857B /ha. Observations of mild phytotoxic effects were recorded for soybean, and cucumber, none of which exceeded 50%.

The results from the screening assessment can be qualitatively supported by conclusions from studies conducted using the EU representative formulation 'Miravis' (A19649B). Although a certain level of uncertainty surrounds the extrapolation of these data as the two products have been deemed non-comparable (see Volume 4), both contain the same active substance, which was applied at 200 g a.s. /ha in the respective studies, and so it is likely that any effects resulting from exposure to the active substance would be similar in magnitude.

A total of three studies were carried out using 'Miravis' (A19649B), including one vegetative vigour study, and two seedling emergence studies. Each study tested ten species of plant, at or exceeding the maximum proposed application rate of 'Miravis Plus' (A21857B) from the GAP table. No effects > 50 % were observed for any of the tested plants at any concentration in any of the three studies, supporting the conclusions from the screening assessment.

## List of end points

Evaluator	Month and year	Active substance (Name)
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### Section 5 Ecotoxicology

#### Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	EC <sub>50</sub> (3h) > 1.5 mg a.s./L

<sup>1</sup>Limit of solubility of the active substance in water

#### Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s. None submitted Available monitoring data concerning effect of the PPP. None submitted
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#### Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds<sup>1</sup>

Compartment	
soil	Pydiflumetofen
water	Pydiflumetofen
sediment	Pydiflumetofen
groundwater	Pydiflumetofen

<sup>1</sup> metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

## List of end points

Evaluator	Month and year	Active substance (Name)
HSE	September 2023	Pydiflumetofen (SYN545974)

### Section 5 Ecotoxicology

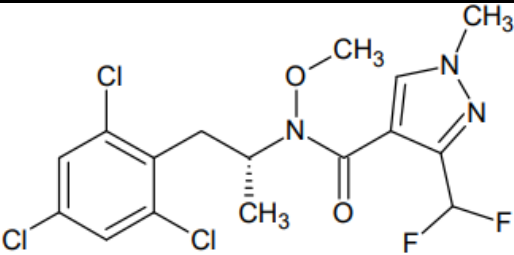
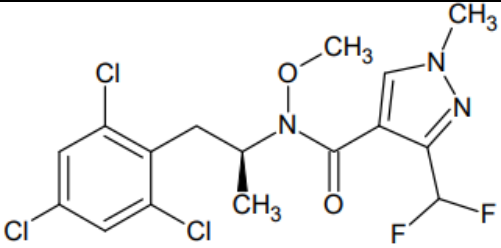
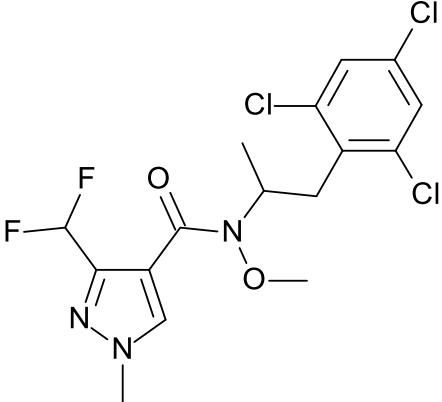
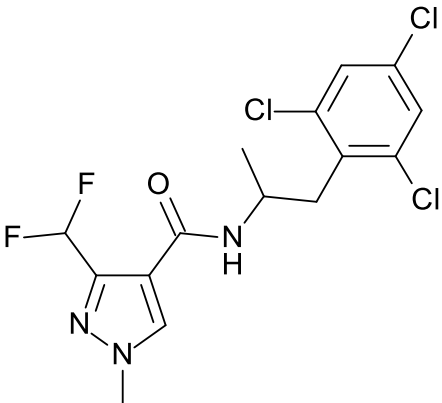
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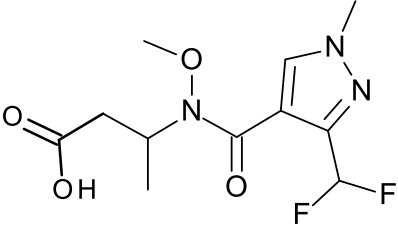
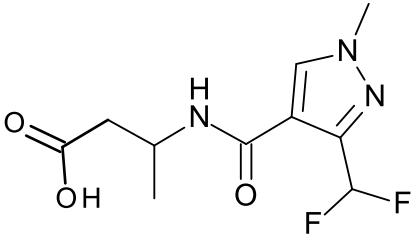
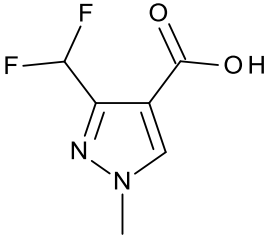
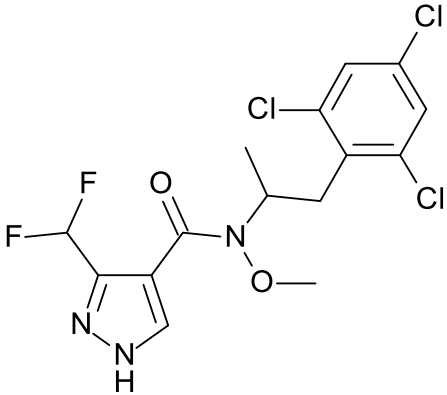
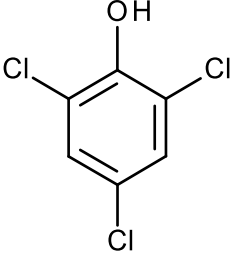
Substance	Pydiflumetofen
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] <sup>7</sup> :	Draft assessment not complete
Peer review proposal <sup>8</sup> for harmonised classification according to Regulation (EC) No 1272/2008:	Acute category 1, H400 'Very toxic to aquatic life' (M factor: 1) Chronic category 1, H410 'Very toxic to aquatic life with long lasting effects' (M factor: 1)

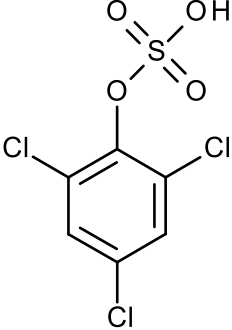
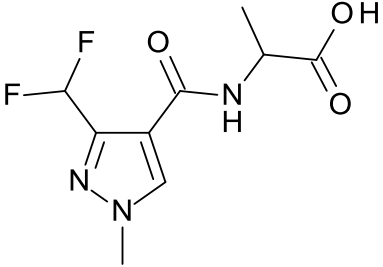
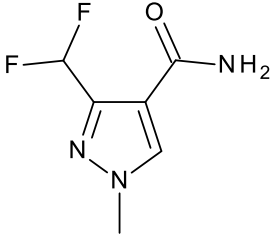
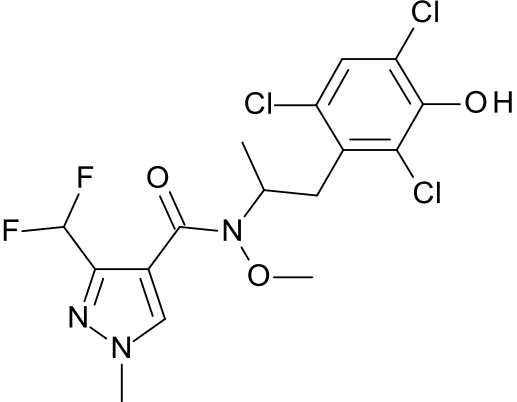
<sup>7</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

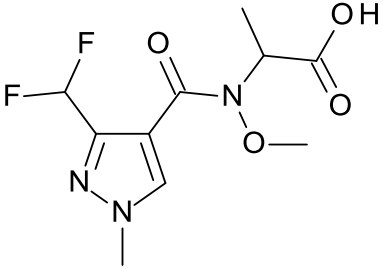
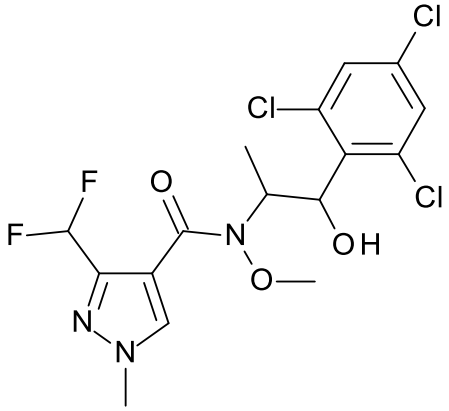
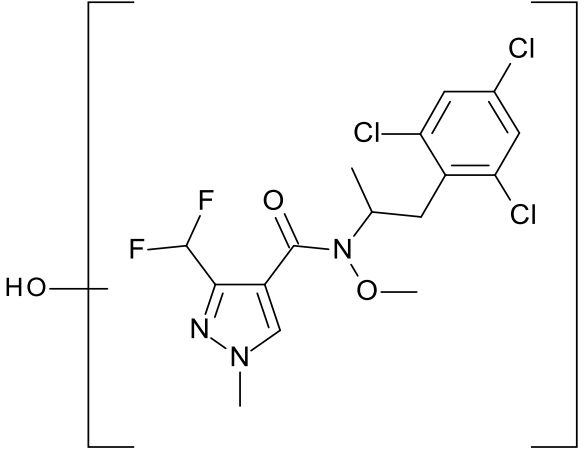
<sup>8</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

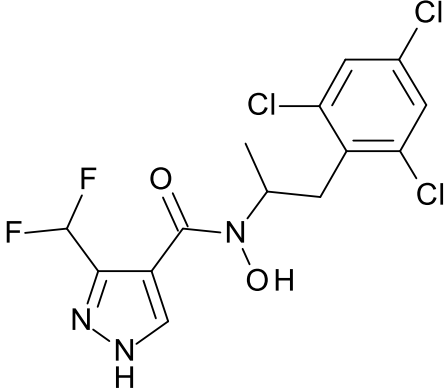
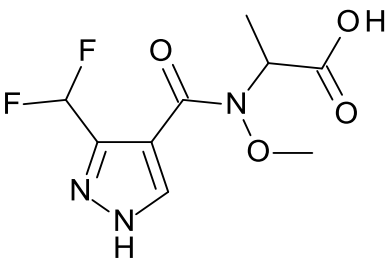
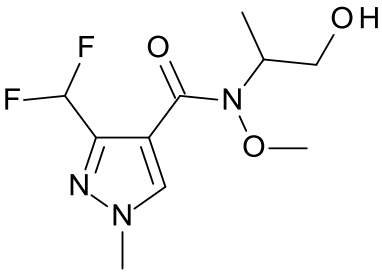
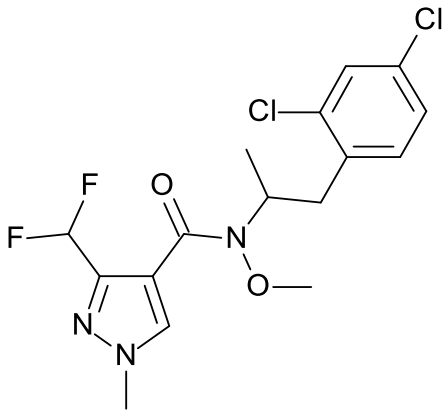
Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula
SYN546969 CSCD746375	(R)-3-Difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid methoxy-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-amide	
SYN546968 CSCD746374	(S)-3-Difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid methoxy-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-amide	
Pydiflumetofen SYN545974 CSCD678790	N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide  1H-Pyrazole-4-carboxamide, 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-	
SYN545547 CSCD550897	3-(difluoromethyl)-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]pyrazole-4-carboxamide	

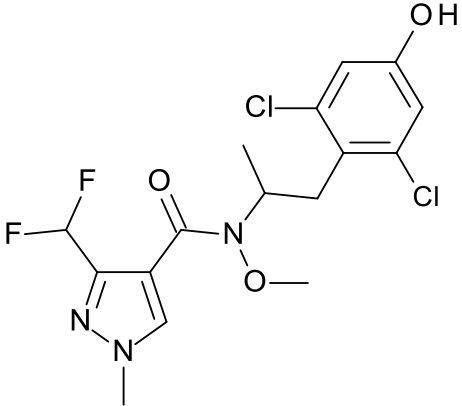
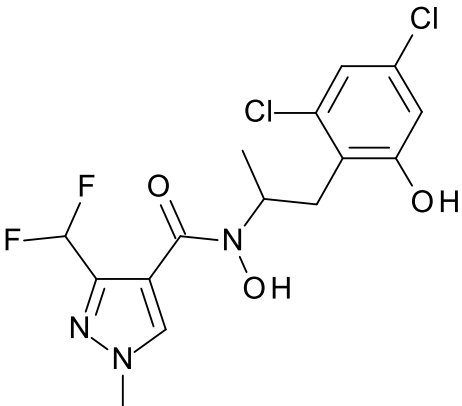
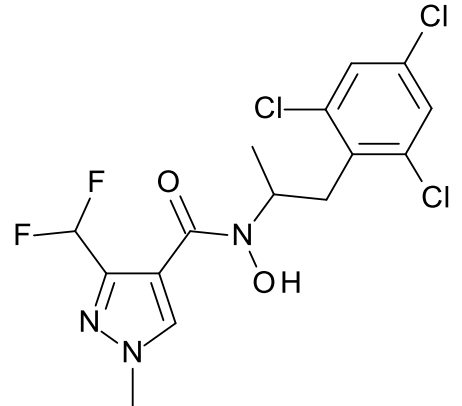
SYN548261	3-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]-methoxy-amino]butanoic acid	
SYN548262	3-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]amino]butanoic acid	
NOA449410 CSAA798670 R648993	3-(difluoromethyl)-1-methyl-pyrazole-4-carboxylic acid	
SYN547891 CSCV764139	3-(difluoromethyl)-N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]pyrazole-4-carboxamide	
2,4,6-Trichlorophenol 2,4,6-TCP	2,4,6-trichlorophenol	

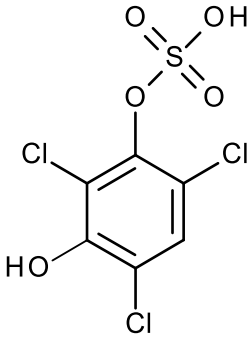
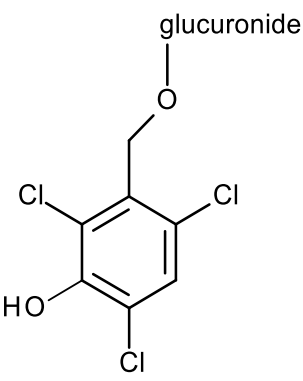
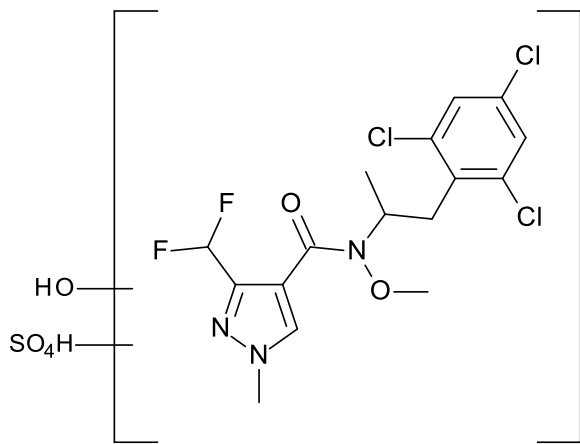
Sulphate conjugate of 2,4,6-trichlorophenol	Sulphate conjugate of 2,4,6-trichlorophenol	
SYN548264 CSCD548196 N-desmethoxy SYN548263	2-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]amino]propanoic acid	
SYN508272 CSCC210616 R423363	3-(difluoromethyl)-1-methyl-pyrazole-4-carboxamide	
SYN547897 CSCV764146	3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxyphenyl)ethyl]pyrazole-4-carboxamide	

<p>SYN548263 CSCZ159698</p>	<p>2-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]-methoxy-amino]propanoic acid</p>	
<p>SYN547948 CSCY608054</p>	<p>3-(difluoromethyl)-N-[2-hydroxy-1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-N-methoxy-1-methyl-pyrazole-4-carboxamide</p>	
<p>Hydroxylated SYN545974</p>	<p>Hydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide</p>	

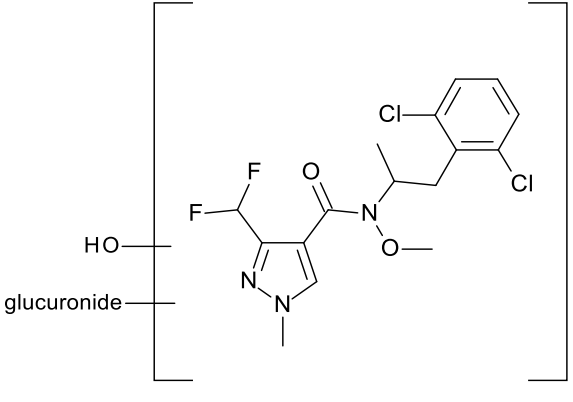
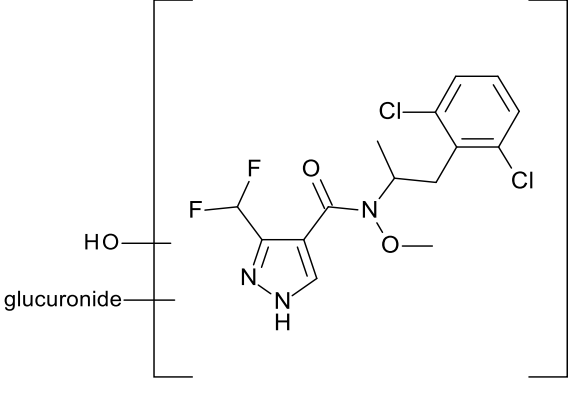
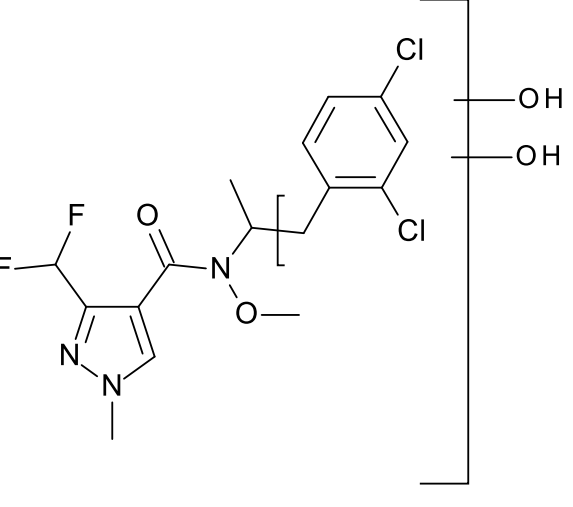
<p>N-Desmethyl SYN547890</p>	<p>3-(difluoromethyl)-N-hydroxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide</p>	
<p>Desmethyl SYN548263 CSCZ159698</p>	<p>Desmethyl 2-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]-methoxy-amino]propanoic acid</p>	
<p>SYN548265</p>	<p>3-(difluoromethyl)-N-(2-hydroxy-1-methyl-ethyl)-N-methoxy-1-methyl-pyrazole-4-carboxamide</p>	
<p>SYN547893 CSCD677133</p>	<p>N-[2-(2,4-dichlorophenyl)-1-methyl-ethyl]-3-(difluoromethyl)-N-methoxy-1-methyl-pyrazole-4-carboxamide</p>	



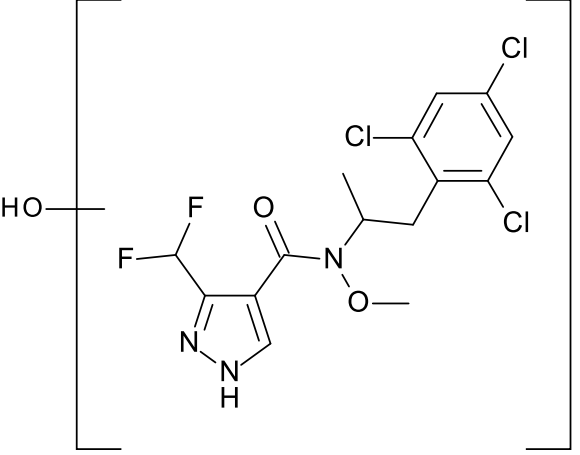
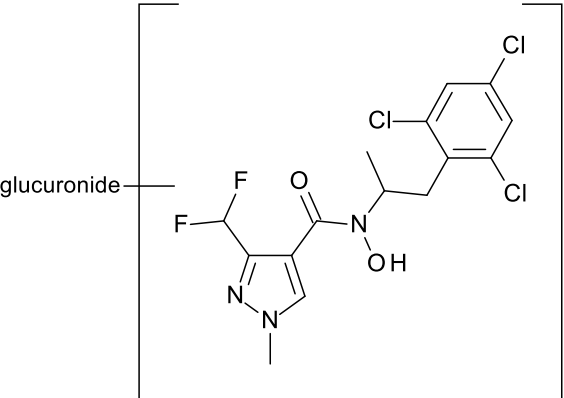
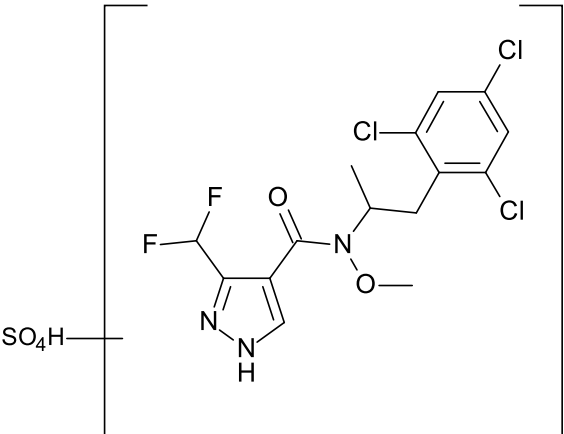
<p>SYN547894 CSCV764141</p>	<p>N-[2-(2,6-dichloro-4-hydroxy-phenyl)-1-methyl-ethyl]-3-(difluoromethyl)-N-methoxy-1-methyl-pyrazole-4-carboxamide</p>	
<p>Dechlorinated hydroxyl SYN545974</p>	<p>N-[2-(2,4-dichloro-6-hydroxy-phenyl)-1-methyl-ethyl]-3-(difluoromethyl)-N-hydroxy-1-methyl-pyrazole-4-carboxamide</p>	
<p>SYN547890</p>	<p>3-(difluoromethyl)-N-hydroxy-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]pyrazole-4-carboxamide</p>	

Hydroxylated TCP-sulphate HTCP Sulphate	(2,4,6-trichloro-3-hydroxy-phenyl) hydrogen sulfate	
TCPM glucuronide	2,4,6-trichloro-3-(methoxymethyl)phenol glucuronide	
Hydroxylated SYN545974 Sulphate conjugate	Hydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide Sulphate conjugate	

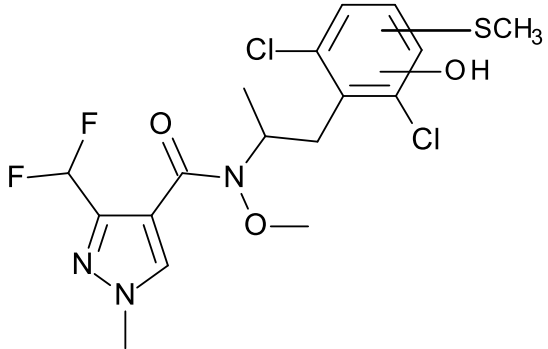
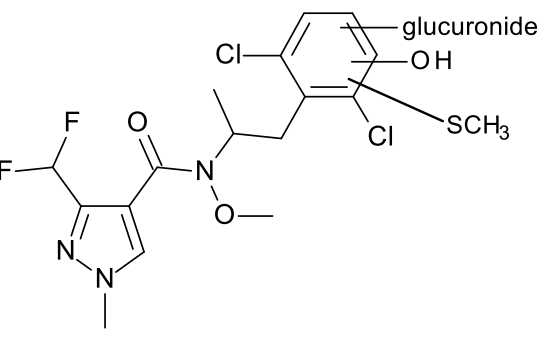
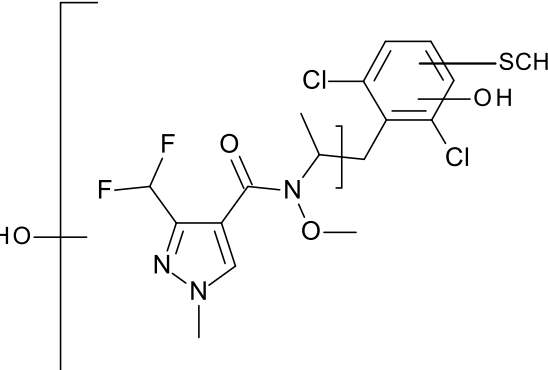
Hydroxylated SYN545974 Sulphate conjugate Glucuronide conjugate	Hydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide Sulphate conjugate Glucuronide conjugate	
Dihydroxy SYN545974	Dihydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide	
Dihydroxy SYN545974 Glucuronide conjugate	Dihydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide Glucuronide conjugate	

<p>Dechlorinated hydroxy SYN545974 Glucuronide conjugate</p>	<p>Dechlorinated hydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide Glucuronide conjugate</p>	
<p>Dechlorinated hydroxy desmethyl SYN545974 Glucuronide conjugate</p>	<p>Desmethyl Dechlorinated hydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide Glucuronide conjugate</p>	
<p>Dihydroxy dechlorinatedSYN545974</p>	<p>Dihydroxy dechlorinated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide</p>	

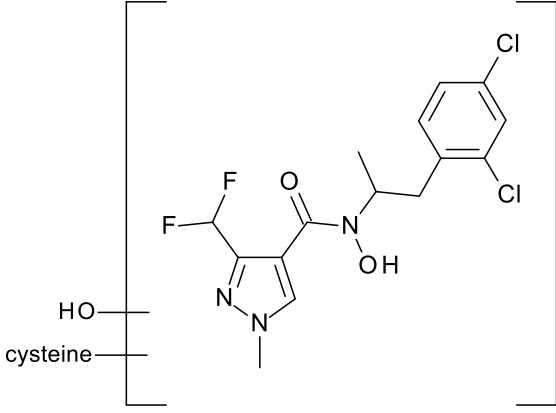
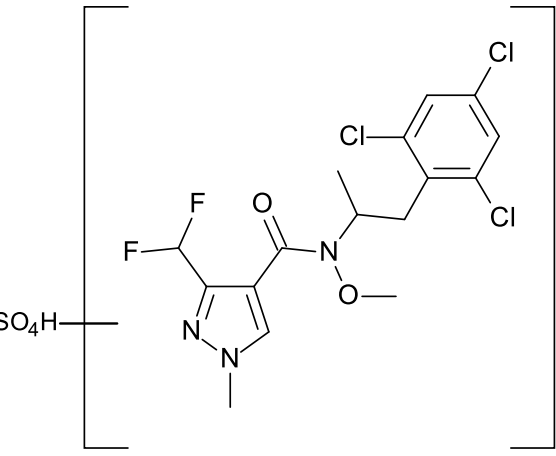
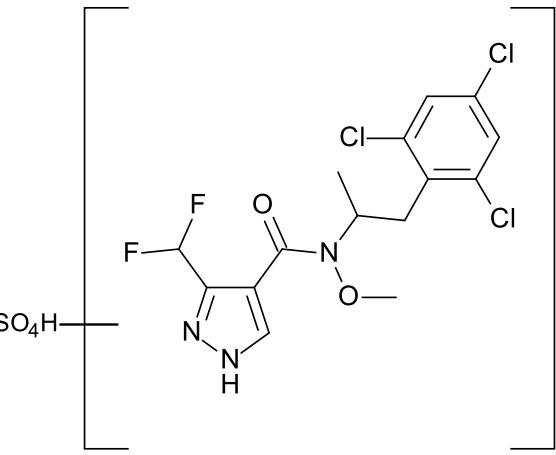
Hydroxy SYN545547	Hydroxylated 3-(difluoromethyl)-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]pyrazole-4-carboxamide	
Hydroxy SYN547891	Hydroxylated 3-(difluoromethyl)-N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide	
SYN547891 Glucuronide conjugate	3-(difluoromethyl)-N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide Glucuronide conjugate	

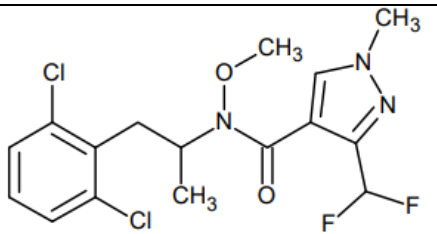
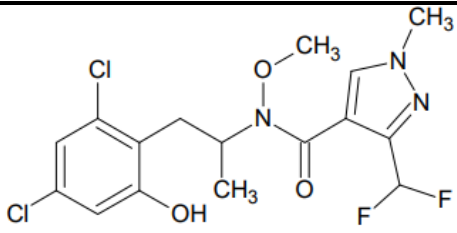
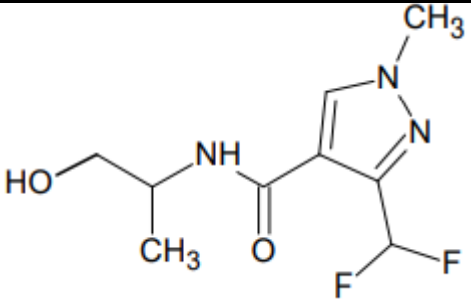
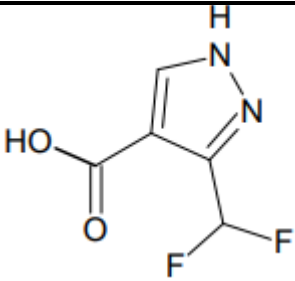
Desmethyl hydroxyl SYN545974	Hydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide	 <p>The structure shows a pyrazole ring with a methyl group at position 1 and a difluoromethyl group at position 3. At position 4, there is a carboxamide group. The nitrogen of this amide is bonded to a methoxy group and a 1-methyl-2-(2,4,6-trichlorophenyl)ethyl group. A hydroxyl group (HO-) is shown attached to the pyrazole ring at position 5, indicating a hydroxylated form.</p>
Desmethyl SYN545974 Glucuronide	Desmethyl N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide glucuronide	 <p>The structure is identical to the one above, but the hydroxyl group at position 5 of the pyrazole ring is replaced by a glucuronide group, indicating a glucuronidated metabolite.</p>
Desmethyl hydroxy SYN545974 sulphate	3-(difluoromethyl)-N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide Sulphate conjugate	 <p>The structure is identical to the one above, but the hydroxyl group at position 5 of the pyrazole ring is replaced by a sulphate group (SO<sub>4</sub>H-), indicating a sulphate conjugate metabolite.</p>

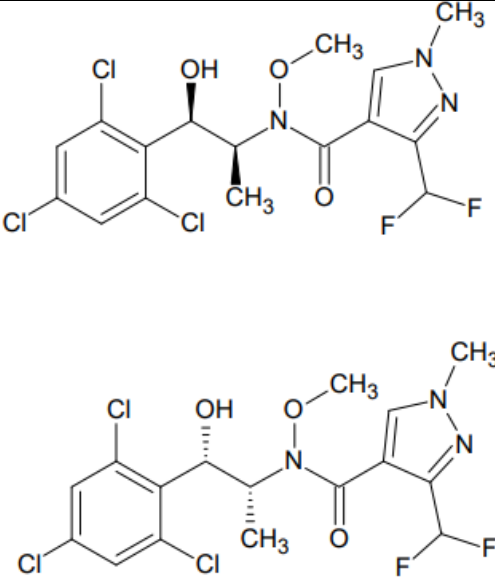
Desmethyl hydroxy SYN545974 glucuronide	Hydroxylated N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide Glucuronide conjugate	
Desmethyl SYN545974 glucuronide	3-(difluoromethyl)-N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide Glucuronide conjugate	
Desmethyl SYN548265 Glucuronide conjugate	Desmethyl 3-(difluoromethyl)-N-(2-hydroxy-1-methyl-ethyl)-N-methoxy-1-methyl-pyrazole-4-carboxamide Glucuronide conjugate	
SYN548265 Glucuronide conjugate	3-(difluoromethyl)-N-(2-hydroxy-1-methyl-ethyl)-N-methoxy-1-methyl-pyrazole-4-carboxamide Glucuronide conjugate	

Dechlorinated hydroxy thiomethyl SYN545974	Dechlorinated hydroxy thiomethyl N-methoxy-N-[1- methyl-2-(2,4,6- trichlorophenyl)-ethyl]-3- (difluoromethyl)-1- methylpyrazole-4-carboxamide	
Dechlorinated hydroxy thiomethyl SYN545974 glucuronide	Dechlorinated hydroxy thiomethyl N-methoxy-N-[1- methyl-2-(2,4,6- trichlorophenyl)-ethyl]-3- (difluoromethyl)-1- methylpyrazole-4- carboxamide glucuronide conjugate	
Dechlorinated dihydroxy thiomethyl SYN545974	Dechlorinated dihydroxy thiomethyl N-methoxy-N-[1- methyl-2-(2,4,6- trichlorophenyl)-ethyl]-3- (difluoromethyl)-1- methylpyrazole-4- carboxamide glucuronide	



Dechlorinated hydroxy SYN545974 cysteine	Dechlorinated hydroxy N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide cysteine	
Hydroxy SYN545974 sulphate	Hydroxy N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide sulphate	
Hydroxy SYN547891 sulphate	Hydroxy 3-(difluoromethyl)-N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide sulphate	

SYN547892	Not provided	
SYN547895	Not provided	
SYN548266	Not provided	
SYN545720 R958945	Not provided	

<p>SYN547949 (two enantiomers of the compound)</p>	<p>Not provided</p>	
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\* The compound code / trivial name in bold is the name used in the list of endpoints.