DRAFT REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: A20607B

Product names: Vibrance SB

Chemical active substances:

Fludioxonil, 22.5 g/L
Metalaxyl-M, 14.4 g/L
Sedaxane, 15 g/L

~~United Kingdom~~

Great Britain (GB)

NATIONAL ASSESSMENT

~~(Renewal of authorisation)~~

Submitted to support Article 7 amendment of approval of Metalaxyl-M in GB

Applicant: Syngenta

Submission date: 21/10/2021

Finalisation date: 31/01/2024

Version history

When	What
October 2021	Applicant submission to support amendment of approval under Article 7 of retained Regulation (EC) No 1107/2009
December 2023	HSE (GB) assessment added in green boxes

This is an application from Syngenta for the renewal of VIBRANCE SB (A20607B) under Article 43 of Regulation (EC) No. 1107/2009 following the renewal of EU approval of the active substance metalaxyl-M.

No equivalence assessment is required.

This application follows the data requirements for the active substance laid down in Regulation (EU) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EU) No. 545/2011, also called ‘old’ data requirements. Metalaxyl-M is an ‘AIR-2’ substance which approval has been renewed in accordance with Regulation (EU) No 1141/2010, therefore Regulations (EU) No 283/2013 and (EU) No 284/2013 are not applicable to the renewal of authorizations for metalaxyl-M-containing plant protection products (derogation by Commission Regulation (EU) No 2015/1475; further details in the guidance document SANTE/11509/2013 rev. 5.2).

Following the renewal of EU approval of the active substance metalaxyl-M, the submission for the product renewal of VIBRANCE SB (A20607B) was made by 01 September 2020, in accordance with Article 43 of Regulation (EC) No 1107/2009.
All data relied on are provided with this application. The reference lists at Appendix 1 of dRR Part B Sections 1-10 define the data owner and data access. Data protection is a national concern and is addressed in Part A, Appendix 4.

The guidance on Renewal of Authorization according to Art 43 (SANCO/2010/13170 rev 14) requests that within the dRR ‘changes to the risk assessment are highlighted’. This is the first submission of VIBRANCE SB (A20607B) in the dRR format of April 2015, consequently all of the summary text is previously unreviewed and should be considered as ‘changed’. To facilitate the review, Syngenta has highlighted the summaries of reports not previously reviewed by the zRMS in yellow.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer’s comments	The applicant, Syngenta Crop Protection AG, submitted this application to amend the conditions of approval of metalaxyl-M in accordance to Article 7 of Regulation 1107/2009 in Great Britain (GB). On the 5 May 2020 the Commission Implementing Regulation (EU) 2020/617 renewing the approval of the active substance metalaxyl-M, and restricting the use of seed treated with a plant protection product containing it to be sown only in greenhouses, was published[1]. The renewal of metalaxyl-M applies since 1 June 2020. Since this was before

[1] Commission Implementing Regulation (EU) 2020/617 of 5 May 2020 renewing the approval of the active substance metalaxyl-M, and restricting the use of seeds treated with plant protection products containing it, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of

	UK withdrawal from the EU, the Commission Implementing Regulation for the renewal of metalaxyl-M applies direct in GB. Two representative formulations were considered in the renewal of approval for metalaxyl-M, 'Apron XL' (A9642C) and 'Ridomil Gold Mz'/68 WG Fubol Gold' (A9651D). For this Article 7 amendment application in GB, two different formulations have been considered. The formulation 'Vibrance SB' (A20607B) containing 14.4 g/L metalaxyl-M, 22.5 g/L fludioxonil and 15.0 g/L sedaxane to support the field seed treatment use on sugar and fodder beet, and the formulation 'Wakil XL' (A9873C) containing 169.6 g/Kg metalaxyl-M, 100 g/Kg cymoxanil and 50 g/Kg fludioxonil) to support the field seed treatment use on peas (vining) are the basis of this Article 7 application for metalaxyl-M to GB. The applicant has re-submitted the draft registration reports prepared for the product renewals of 'Vibrance SB' and 'Wakil XL' under Article 43 of Regulation No 1107/2009 following the renewal of approval of the active substance metalaxyl-M. The information and data submitted within these draft registration reports have been considered previously by HSE for the applications for authorisation of a new product under Article 33 of Regulation No 1107/2009. Where relevant, re-evaluation of data or information has not occurred where studies have been performed in accordance with the current requirements and the results have been deemed acceptable. This draft registration report has been provided by the applicant, where required, comments have been inserted in green boxes by HSE or the text amended by the HSE in green (applicant's text has been struck through in green where necessary). HSE notes that the product authorisations for 'Vibrance SB' and 'Wakil XL' were withdrawn in GB by the applicant. This was based on the approval restriction provided for in Commission Implementing Regulation (EU) 2020/617 that only the treatment of seeds intended to be sown in greenhouses may be authorised. Since all authorised GB uses of 'Vibrance SB' and 'Wakil XL' products are on seeds which are direct drilled in the field, these products do not comply with the restriction and therefore could not be renewed under Article 43 of Regulation No 1107/2009. HSE notes that no authorisation for 'Vibrance SB' or 'Wakil XL' is sought within this Article 7 amendment application. Therefore, HSE has only considered the information presented in the draft registration reports that relate to metalaxyl-M. For a future GB authorisation of these products a separate application would be required with a full evaluation of the data and information for all active substances present in the formulation. Note that as of 1st January 2024, The Retained EU Law (Revocation and Reform) Act 2023 has taken effect and retained EU law are now known as assimilated law. As this assessment has been prepared prior to the Retained EU Law Act taking effect, assessment may still refer to "retained" regulation as opposed to "assimilated".

plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

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8 Fate and behaviour in the environment (KCP 9)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

Name of authority: HSE Chemicals Regulation Division (CRD), UK

Fate & Behaviour Reviewer's comments

The applicant's draft registration report for product 'Vibrance SB' has been evaluated by the inclusion of green comment boxes. All HSE comments and agreed endpoints for use in the risk assessment are referenced within these boxes.

Introduction

'Vibrance SB' is a seed treatment plant protection product containing 15 g/L sedaxane, 22.5 g/L fludioxonil and 14.4 g/L metalaxyl-M for treatment of sugar beet and fodder beet seed. The application rate is 33.3 mL product/unit of seed. For these crops, a unit of seed is 100,000 seeds. The applicant has indicated that the drilling rate is 1.3 units of seed/ha, i.e. 130,000 seeds/ha. The GAP table is at Table 8.1-1. HSE has listed the critical GAP for assessment below.

As this assessment is associated only with the consideration of the Article 7 amendment of the conditions of approval of metalaxyl-M, it has been confirmed that only the metalaxyl-M component of this product needs to be taken into account. **Consequently, there is no consideration within this assessment of the environmental exposure of sedaxane and fludioxonil as a result of use of this product.**

Table HSE-01 Proposed use pattern for metalaxyl-M as applied in 'Vibrance SB'

Crop	Application rate (g a.s./ha)	Number of applications	Application timing	Crop interception
Sugar beet and fodder beet	0.62 metalaxyl-M[1]	1	BBCH 00	0%

[1] Based on 33.3 mL product/100,000 seeds; product contains 14.4 g/L metalaxyl-M. Therefore dose is 0.62 g metalaxyl-M/ha based on 130,000 seeds planted/ha.

As the use is on sugar beet and fodder beet, only a single 'application' per year in the field is considered. HSE consider it unlikely that there will be more than one crop grown in the same field each year.

Metalaxyl-M is approved in GB by virtue of being approved in the EU at the time of EU Exit.

Metalaxyl-M is subject of an EFSA Conclusion (EFSA Journal 2015;13(3):3999). The Implementing Regulation states that, with particular relevance to Environmental Fate and Behaviour assessment, Member States must pay particular attention to the potential for groundwater contamination. In addition, the Implementing Regulation stated that treated seeds could only be sown in greenhouses. The applicant is attempting to remove this restriction on the GB approval via an Article 7 submission. It should be noted that this restriction is related to ecotoxicological concerns and is not related to the Environmental Fate and Behaviour assessment. Hence no part of the Environmental Fate assessment is pertinent to the Article 7 submission.

There were no data gaps identified in the EFSA Conclusion which relate to environmental fate and behaviour.

The applicant has stated that as part of the Article 7 consideration of metalaxyl-M they wish to refine the formation fraction used in environmental exposure modelling, particularly groundwater modelling, for the metalaxyl-M metabolite SYN546520. The applicant submitted new data to support this change in formation fraction. However, the EFSA Conclusion indicates that this metabolite was not considered to be a relevant metabolite and appeared to pass the appropriate risk assessments in the EU Review with predicted concentrations of >10 µg/L. The applicant has not justified why it is necessary to refine the formation fraction of this metabolite for the GB assessment. Given the absence of an appropriate justification for attempting to refine the formation fraction, the data have not been assessed.

The applicant has not requested to risk envelope the environmental exposure of metalaxyl-M from any other authorised products.

Metabolites

With respect to metabolites, the EFSA Conclusion lists only metalaxyl-M as an ecotoxicologically relevant compound with respect to soil, water, sediment and groundwater. However, with respect to the assessment of groundwater for human health, the following metabolites are included in the assessment.

Table HSE-02 Metabolites of metalaxyl-M included in groundwater assessment

Metabolite	Considered to be toxicologically relevant
NOA 409045	Yes
CGA67868	No
SYN546520	No

Consequently, the metabolites are only considered in the assessment of groundwater exposure.

Summary of PEC values

Table HSE-03 Final PEC values for use in risk assessments for the product 'Vibrance SB'.

Substance	**PEC value**	**Notes**
PECsoil (mg/kg)		
Metalaxyl-M	0.001	
Formulation	0.060	
PECgw (µg/L)		
Metalaxyl-M	<0.001	All scenarios and models
NOA409045	0.020	PEARL, Hamburg
CGA67868	<0.001	All scenarios and models
SYN546520	0.093	PEARL, Hamburg
PECsw (µg/L) – note all values calculated only from drainage; spray drift not a relevant route of exposure due to use as seed treatment		
Metalaxyl-M	0.091	
PECsed (µg/kg) – note all values calculated only from drainage; spray drift not a relevant route of exposure due to use as seed treatment		
Metalaxyl-M	0.085	

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	10a	11	12	13	14	15
UseNo. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn,G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**				PHI (days)	Remarks: e.g. g safener / synergist per ha; pelleted seeds.	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter-val between applications (days)	ml product / seed unit	Max g a.s. / 100kg seeds 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane	Max g a.s./ha 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane	Max µg a.s. / seed 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane			Groundwater
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)															
10***	United Kingdom	Beet (Sugar (BEAVA) and fodder (BEAVC) beet)	I	Damping-off diseases (*Pythium ultimum* [PYTHUL], *Pleospora betae/P betae* [PLEOBJ], *Thanatephorus cucumeris / Rhizoctonia solani* [RHIZSO])	Seed treat-ment	BBCH 00, Jan-Dec	a) 1 b) 1	n.a.	33.3	1) 31.22 2) 19.98 3) 20.81	1) 0.97 2) 0.62 3) 0.65	1) 7.49 2) 4.80 3) 5.00	n.a.	Seed unit: 100.000 seeds Seedling rate: 1 – 1.3 seed unit/ha TGW: 24-33 g/1000 seeds Slurry volume: 8-20L/100 kg seeds Max. 43.3 ml product/ha	
			F		Sowing	BBCH 00 – March-April									
			n.a.		Transplating	n.a									

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in Column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** critical GAP covering all intended GAPs on sugar beet in Part B

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table: PHI is not relevant for seed treatment purposes.

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure).
(4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application.
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
(7) Growth stage at first and 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.
(8) The maximum number of application possible under practical conditions of use must be provided. Minimum interval (in days) between applications of the same product.
(9) This is the use pattern as typically described on the label of the product.
(10) This is the application rate in the units used to calculate exposure of operators and of birds and mammals.
(11) This is the application rate in the units used for environmental risk assessments for example leaching to ground water.
(12) This is the application rate in the units specifically requested by the German authorities.
(13) This is the application rate in the units used for environmental and ecotoxicological risk assessment.
(14) The remarks column should contain all the associated parameters that are needed to describe treating of the seeds and to derive parameters needed for risk assessment. These will include but not necessarily limited to definition of the seed unit, thousand grain weight (TGW), slurry volume for treatment and sowing density/rate of the seeds/plants.

Table 8.1-2: Assessed (critical) uses during approval of fludioxonil concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I *	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Southern and Northern Europe	Wine grapes	F	*Botrytis cinerea, Aspergillus carbonarius*	Foliar spray	BBCH 55-81	2	21	a) 1 kg/ha b) 2 kg/ha (Switch 62.5 WG)	a) 250 b) 500	100 / 1000	21	-
2	Southern Europe	Table grapes	F			BBCH 60-85						7	-
3	Southern and Northern Europe	Wheat	F	*Microdochium nivale* *Fusarium spp.* *Tiletia carie,* *Septoria sp.,* *Helminthosporium sp.*	Seed treat-ment	BBCH 00	1	-	0.35 L/ha (Celest 025 FS)	a) 5.00 b) 8.75	0 / 2.625	-	Sowing rate: 100-175 kg/ha

* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Table 8.1-3: Assessed (critical) uses during approval of metalaxyl-M concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I *	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	N-EU C-EU S-EU	Sunflower	F	*Plasmopara helianthi*	Seed treatment	-	1	-	a) 0.018 L / ha b) 0.018 L / ha	a) 6.1 b) 6.1	-	-.	Sowing rate is 40,000-80,000seeds/ha. Typical TGW is 75g. 0.0763 mg MXM/seed
2	N-EU C-EU S-EU	Spinach	F	*Peronospora farinosa, Pythium spp.*	Seed treatment	-	1	-	a) 0.240 L / ha b) 0.240 L / ha	a) 81.4 b) 81.4	-	-	Based on TGW of 10g. Sowing rate is 4,000,000-12,000,000 seeds/ha
3	N-EU C-EU	Tomato	F	*Phytophtora infestans, Alternaria spp.*	Foliar spray	BBCH 15-89	3	7	a) 2.5 kg / ha b) 7.5 kg / ha	a) 97 b) 291	200-800	3	-
4	S-EU	Tomato	F	*Phytophtora infestans, Alternaria spp.*	Foliar spray	BBCH 15-89	3	7	a) 2.5 kg / ha b) 7.5 kg / ha	a) 97 b) 291	500-1000	7	-
5	N-EU C-EU	Vines	F	*Plasmopara viticola, Pseudopezicula tracheiphila, Phomopsis viticola*	Foliar spray	BBCH 15-81	3	10	a) 2.5 kg / ha b) 7.5 kg / ha	a) 97 b) 291	500-1000	56	-
6	S-EU	Vines	F	*Plasmopara viticola*	Foliar spray	BBCH 15-81	3	10	a) 2.5 kg / ha b) 7.5 kg / ha	a) 97 b) 291	200-1000	28	-

* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Table 8.1-4: Assessed (critical) uses during approval of sedaxane concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I *	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g as/100 kg seed a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Slurry volume (ml/100 kg seed) min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	SEU and NEU	Wheat	F	*Microdochium nivale*	Seed treatment	n/a	1	n/a	a) 10 b) 10	a) 25 b) 25	400 ml – 1200 ml (20 ml A16148C/dt + 380-1180 ml water/dt)	n/a	Product A16148C (500 g a.s./L, FS) Sowing rate: max. 250 kg seeds/ha

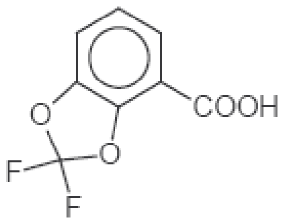
* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

Fludioxonil

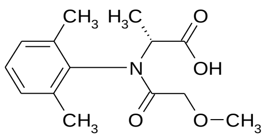
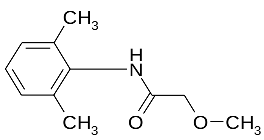
In soil, major metabolites of fludioxonil are formed through photolysis. Although endpoints are given in the EFSA conclusion for the metabolites CGA265378, CGA339833 and CGA192155, it is also stated that the degradation following seed treatment use differs to foliar use as these metabolites are formed primarily through photolysis. Since the present use is a seed treatment, exposure to light and thus formation of the metabolites in soil is not relevant. Therefore, no assessment of PEC_S and PEC_{GW} was done for these metabolites. For $PEC_{SW/SED}$ calculations, the metabolite CGA192155 was considered as relevant and assessed because it may also be formed in water.

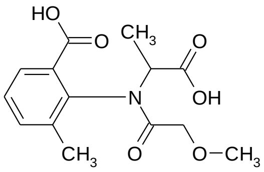
Table 8.2-1: Metabolites of fludioxonil potentially relevant for exposure assessment

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
CGA 192155	202.1		Soil: >10% of a.s. (soil photolysis study) Water: > 10 % of a.s. (water/sediment study under light exposure) Sediment: > 5 % of a.s. (water/sediment study under light exposure)	PEC_{SW}: not covered by EU assessment

Metalaxyl-M

Table 8.2-2: Metabolites of metalaxyl-M potentially relevant for exposure assessment

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
NOA409045	265.3		Soil: > 10 % of a.s. Water: > 10 % of a.s. Sediment: > 10 % of a.s.	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment.
CGA67868	193.2		Soil: >5% of a.s. in 2 sequential measurements Water: -* Sediment: -*	PEC_{GW}: not covered by EU assessment

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
SYN546520	295.3		Soil: <5 % of a.s. and maximum of formation not yet reached at the end of the study Water: -* Sediment: -*	PEC_{GW}: not covered by EU assessment

* During the EU Review the metabolites CGA67868 and SYN546520 were not included in the definition of residues that require further assessment in surface water/sediment (Metalaxyl-M, EFSA Journal 2015;13(3):3999) and thus not considered in the $PEC_{SW/SED}$ risk assessment.

The codenames for R-enantiomer parent metalaxyl-M and respective metabolites, and racemic parent metalaxyl and its metabolites are in the table below.

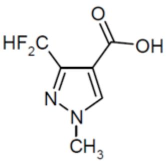
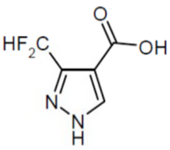
Table 8.2-3: Code names for R-enantiomer and racemic parent metalaxyl-M and their respective metabolites

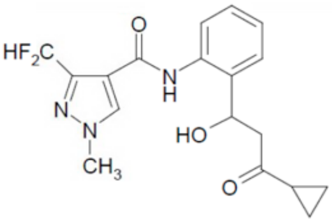
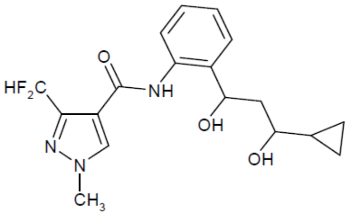
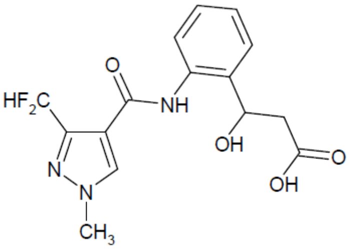
Enantiomer composition	Parent	Acid metabolite	Diacid metabolite	Amide metabolite
R-enantiomer	metalaxyl-M, CGA329351	NOA409045	SYN546520	CGA67868[a]
Racemate (R/S)	metalaxyl, CGA48988	CGA62826	CGA108906[b]	CGA67868[a]

[a] Non-chiral CGA67868 is formed from both metalaxyl-M and metalaxyl
[b] CGA108906 was used historically as a reference material in metalaxyl-M dosed studies. More recently the R-enantiomer SYN546520 was synthesised and utilized in sorption and rate of degradation studies

Sedaxane

Table 8.2-4: Metabolites of sedaxane potentially relevant for exposure assessment

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
CSAA798670	176		Soil: > 10 % of a.s. Water: > 10 % of a.s. (photolysis studies) Sediment: -	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment PEC_{SW}: not covered by EU assessment.
CSCD465008	162		Soil: > 10 % of a.s. Water: - Sediment: -	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment PEC_{SW}: not covered by EU assessment.

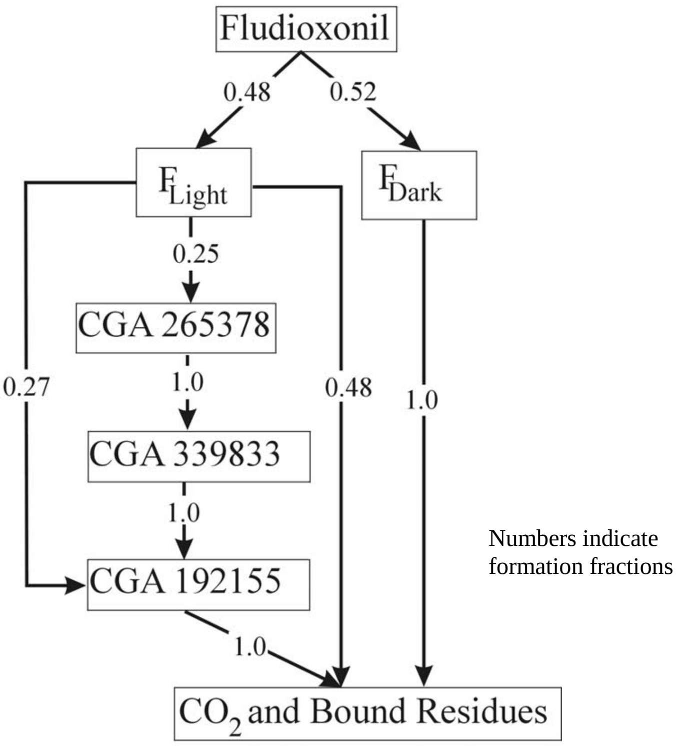
Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
CSCD728931	363.4		Soil: > 5 % of a.s. Water: - Sediment: -	PEC_{GW}: not covered by EU assessment
CSCD668094	365		Soil: - Water: > 10 % of a.s. (photolysis studies) Sediment: -	PEC_{SW}: not covered by EU assessment.
CSCD668095	339		Soil: - Water: > 10 % of a.s. (photolysis studies) Sediment: -	PEC_{SW}: not covered by EU assessment.

8.3 Rate of degradation in soil (KCP 9.1.1)

Fludioxonil

The rate of degradation in laboratory soil of fludioxonil was evaluated for Annex I Inclusion. The EU review concluded that no additional laboratory data were required at national re-registration for the rate of degradation in soils. The fate and behaviour of fludioxonil in soil is discussed in detail in the corresponding document of the EU dossier where the study references can be found. Photolysis can play a major role for the degradation pathway and degradation rate of fludioxonil in soil. Major metabolites are formed in light but not in the dark. Although endpoints are given in the EFSA Scientific Report of 2007 for the metabolites CGA265378, CGA339833 and CGA192155, it is also stated that the degradation following seed treatment use differs to foliar use as these metabolites are formed primarily through photolysis. Therefore, no assessment of PEC_S and PEC_{GW} was done for these metabolites. For PEC_{SW} calculations, the metabolite CGA192155 was considered as relevant due to formation in the water/sediment study and also assessed.

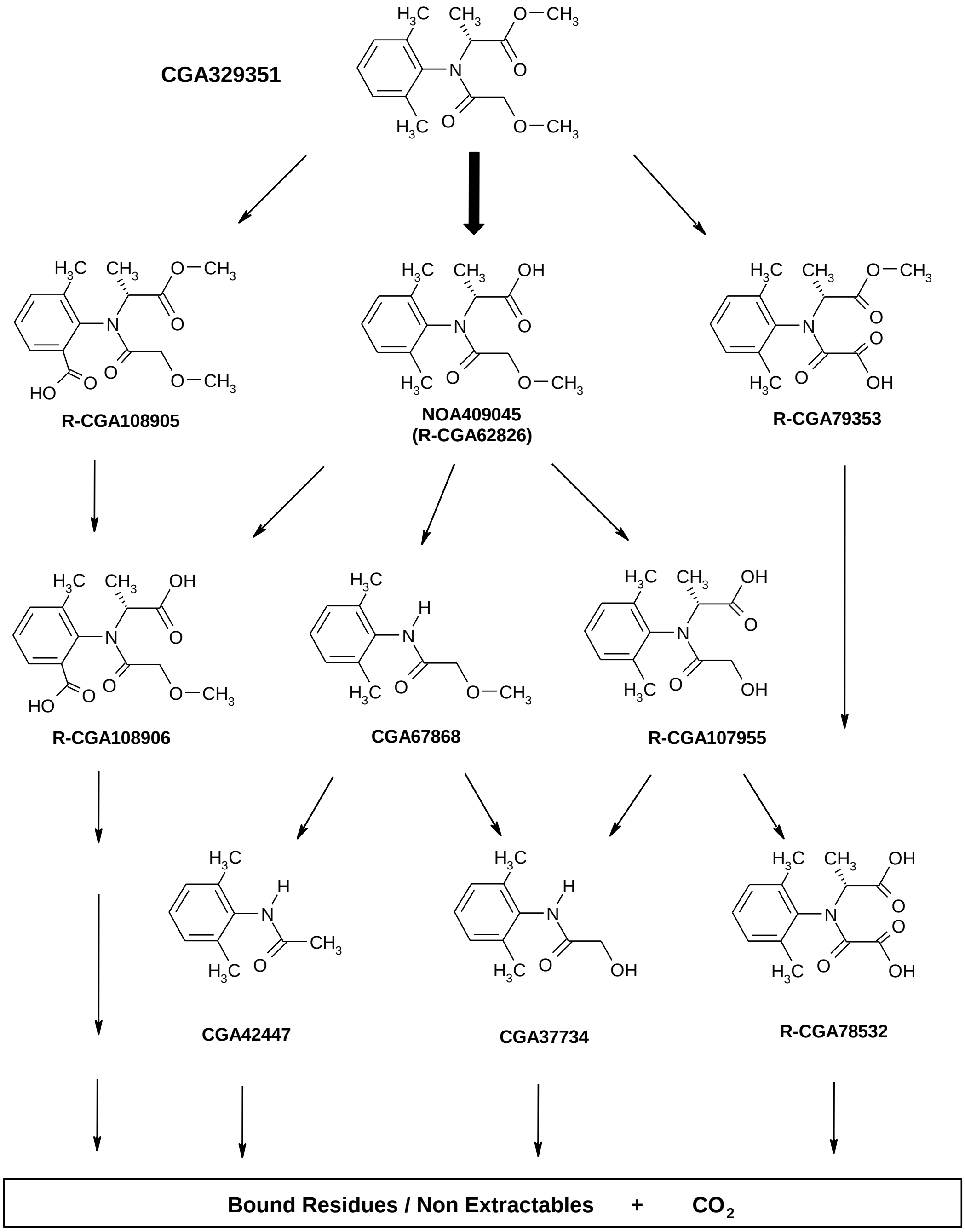
Figure 8.3-1: Proposed pathway of Fludioxonil in soil



Metalaxyl-M

The rate of degradation in soil of metalaxyl-M was evaluated during the EU Review. The fate and behaviour of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 in soil are discussed in detail in the corresponding document of the EU review dossier where the study references can be found. All other metabolites shown in the degradation pathway of metalaxyl-M in soil (see Figure 8.3-2) are minor metabolites.

Figure 8.3-2: Proposed pathway of metalaxyl-M in soil

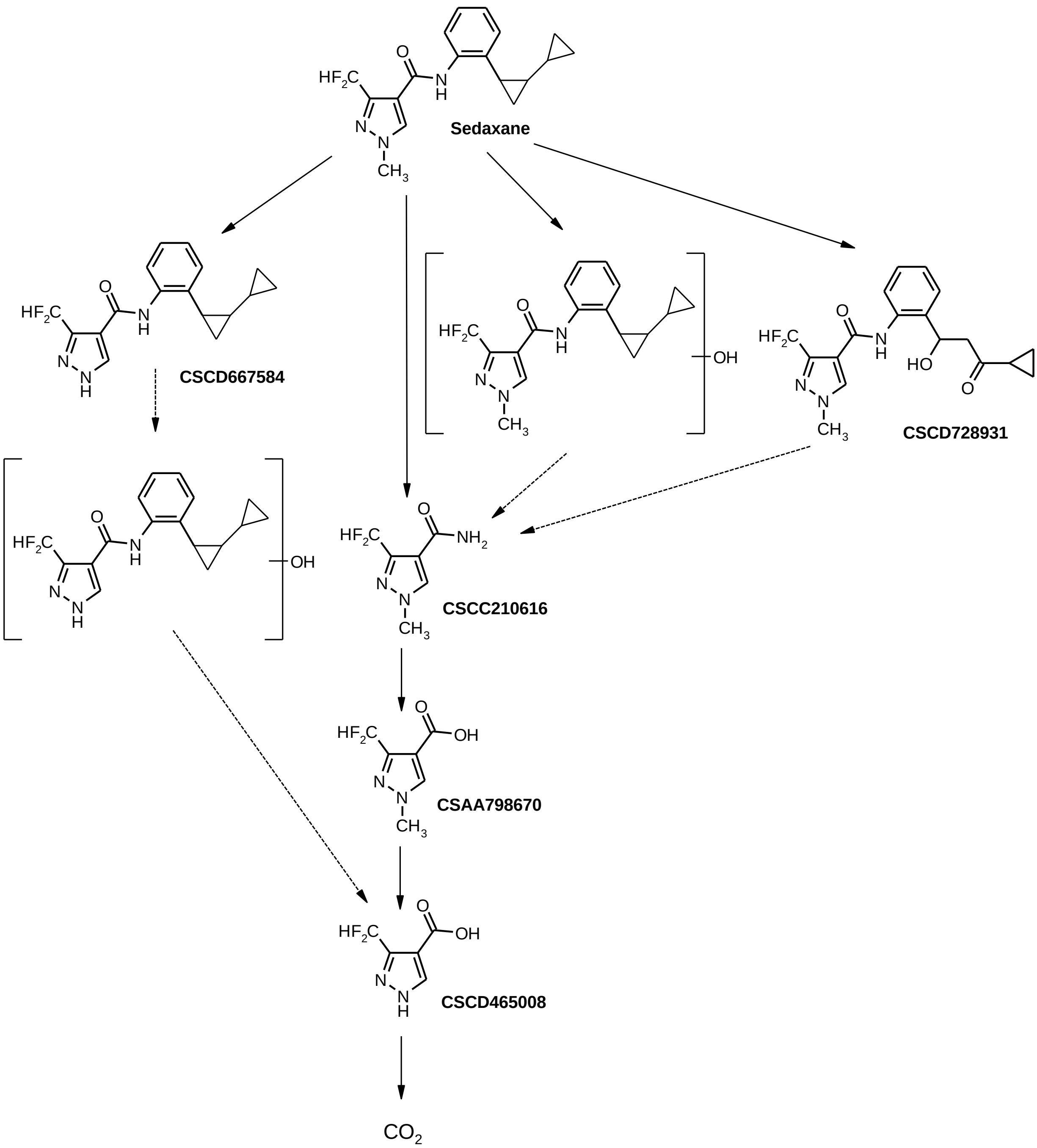


Sedaxane

The rate of degradation in soil of sedaxane was evaluated during the EU review. Two major (> 10% applied radioactivity (AR)) metabolites CSAA798670 (pyrazole acid) and CSCD465008 (N-desmethyl pyrazole acid) were identified. Metabolite CSCD465008 was measured in seed treated soil at levels up to 31.9% AR and metabolite. CSAA798670 was measured at levels up to 6.1% AR in seed treated soil and 14.5% AR in soil treated directly. All other metabolites shown in the degradation pathway of sedaxane in soil (Figure 8.3-3) are minor metabolites.

However, during EU review a data gap for the minor non-transient metabolite CSCD728931 for groundwater exposure assessment and for information on the environmental behaviour in soil was identified (**Sedaxane, EFSA Journal 2013; 11(1):3057**), thus it is treated in the present assessment for completeness only as it was observed <5% in the relevant seed applied studies. Therefore, an additional aerobic soil degradation study on the metabolite CSCD728931 was performed ([redacted] and [redacted] (2013[2]), VV-406128) and kinetically evaluated ([redacted] (2013[3]), VV-628062). These data have been provided in Appendix 2 and Appendix 3 of this document.

Figure 8.3-3: Proposed pathway of sedaxane in soil



[2] [redacted] and [redacted]. (2013): SYN546282 – Rate of Degradation of ^{14}C- SYN546282. Innovative Environmental Services (IES) Ltd Report 20120177; VV-406128.
[3] [redacted]. (2013): Sedaxane: Calculation of Kinetic Endpoints for Metabolite CSCD728931 for Modelling Purposes from Laboratory Data Accordi[3] EFSA Journal 2012; 10(1):2522; VV-628062.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Studies on aerobic degradation rates are considered to be data provided in support of the active substance.

8.3.1.1 Fludioxonil and its metabolites

Studies on the degradation rates of fludioxonil and its metabolites CGA265378, CGA339833 and CGA192155 are considered to be data provided in support of the active substance. Unless otherwise stated, all relevant detailed experimental information has been submitted for EU review of fludioxonil (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**).

Photolytic degradation in soil

The metabolic pathway for fludioxonil degradation in soil was determined from laboratory data. Fludioxonil is rapidly degraded in laboratory photolysis studies to form several degradation products, whilst degradation under the conditions of laboratory soil metabolism studies conducted in the absence of light was slower and no degradation products were isolated or identified. Therefore, for seed treatment use, these metabolites are not considered in PEC_S and PEC_{GW} assessments. For PEC_{SW} calculations, the metabolite CGA192155 was considered as relevant and also assessed since it is also formed in water.

Degradation in soil under dark conditions

The rate of degradation of fludioxonil was investigated in various soils in the laboratory, generally at 20°C and at concentrations corresponding to application rates of 0.05 *to* 10 kg a.s./ha, using [4 ^{14}C]-pyrrole- and [U ^{14}C]-phenyl-labelled material under aerobic as well as under anaerobic conditions.

The observed disappearance times for 50% of fludioxonil (DT_{50lab}) under aerobic laboratory conditions were in the range of 79 days to > 365 days, mostly based on two-compartment first order degradation kinetics. In the original EU submission, re-calculation of the data was done by applying first order one compartment kinetics and normalisation to 20°C and a moisture content of 100% at pF 2. All studies were included, taking values of >365 days as 365 days.

The RMS for the EU review proposed (DAR, 2006) that soils from the same type, which have been used in one study, were grouped together and a single mean value calculated for each soil. This further grouping of DT_{50} values for the relevant application rate subset (0.05-0.8 mg/kg) resulted in a median DT_{50lab} value of 204 days. EFSA provided another recalculation of the DT_{50lab} at pF2 and 20°C. This gave a revised median value (n = 9) of **164** days (**Fludioxonil; EFSA Scientific Report, 2007**), see Table 8.3-1 for details.

Table 8.3-1: Summary of aerobic degradation rates for fludioxonil - laboratory studies

Soil name	Soil type (USDA)	pH	t. (°C)	% FC	DT_{50} (d)	DT_{50} (d) 20°C pF2/10kPa	DT_{50} (d) grouped[a]	Chi^2 (%)	Kinetic model	Evaluated on EU level / Reference
Les Evouettes Soil	Sandy Loam	5.4	20	60 %	> 365	> 365	160	n.a.	SFO	Yes / EFSA (2007)
	Sandy Loam			30 %	365	255				
	Sandy Loam			60 %	365	352				
	Sandy Loam		10	60 %	365	347	-[b]	n.a.	-	
Stein Soil	Sandy Loam	7.0	20	58 %	373	218	186	n.a.	SFO	Yes / EFSA (2007)
Neuhofen Soil	Sand	6.6		93 %	> 365	> 365	569	n.a.	SFO	
Stein Soil	Sandy Loam	7.0	20	56 %	151	100	100	n.a.	SFO	Yes / EFSA (2007)
	Sandy Loam		30	56 %	79	123	-[b]	n.a.	SFO	
Stein Soil	Sandy Loam	7.0	20	56 %	313	204	169	n.a.	SFO	Yes / EFSA (2007)
Collombey Soil	Loamy Sand	7.2	20	61 %	350	248	177	n.a.	SFO	Yes / EFSA (2007)
Les Evouettes Soil	Silt Loam	7.3	20	52 %	342	216	151	n.a.	SFO	
Les Evouettes Soil	Silt Loam	7.0	20	75 %	143	146	120	n.a.	SFO	Yes / EFSA (2007)
	Silt Loam		20	75 %	220	200				
	Silt Loam		20	75 %	183	168				
Les Evouettes Soil	Silt Loam	7.0	20	75 %	232	190	164	n.a.	SFO	Yes / EFSA (2007)
Median (n=9)							164			
pH-dependency:							No			

[a] Grouping and re-fitting of normalised values detailed in [redacted] (2006)
[b] Duplicated trial excluded from calculation

Table 8.3-2: Summary of aerobic degradation rates for CGA192155 - laboratory studies

CGA192155, Laboratory studies, aerobic and light conditions											
Soil name	**Soil type (USDA)**	**pH**	**t. (ºC)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Silt loam	7.18 [a]	20	40	15.7	52.1	- [b]	9.56 [c]	n.a.	SFO	Yes / EFSA (2007)
Pappelacker	Loamy sand	7.43 [a]	20	40	23.8	79.1	- [b]	18.3	n.a.	SFO	
Weide	Sandy loam	7.36 [a]	20	40	16.1	53.5	- [b]	10.8	n.a.	SFO	
Arithmetic mean (n=3)								12.9			
pH-dependency:								No			

[a] Matrix of pH-measurement not stated.
[b] No data avialable, metabolite dosed study.
[c] Value from the original study report [redacted]., 2002, wrongly reported in the Fludioxonil, EFSA Scientific Report (2007); 110:1-85 as 8.56.

8.3.1.2 Metalaxyl-M and its metabolites

Studies on aerobic degradation rates of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 are considered to be data provided in support of the active substance. Unless otherwise stated, all relevant detailed experimental information has been submitted for EU review of metalaxyl-M, where all references can be found (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

Table 8.3-3: Summary of aerobic degradation rates for metalaxyl-M - laboratory studies

Metalaxyl-M, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	loam	7.25	20ºC	40%	3.97	13.2	2.6[a]	3.66	SFO	Yes / EFSA (2015)
Gartenacker	loam	7.25	20ºC	40%	5.73	19.0	3.75[a]	3.75	SFO	Yes / EFSA (2015)
Gartenacker	silt loam	7.6	20ºC	pF2	3.3	10.9	3.3	3.3	SFO	Yes / EFSA (2015)
Les Evouettes	silt loam	7.3	20ºC	40%	3.90	13.0	2.38	7.31	SFO	Yes / EFSA (2015)
Collombey	loamy sand	7.4	20ºC	40%	8.13	27.0	6.28	1.38	SFO	Yes / EFSA (2015)
Birkenheide	sandy loam	5.6	20ºC	40%	26.4	87.6	22.5	2.70	SFO	Yes / EFSA (2015)
Pappelacker	sandy loam	7.5	20ºC	40%	10.1	33.6	6.69	4.43	SFO	Yes / EFSA (2015)
Marsillargues	silty clay	8.0	20ºC	pF2	14.6	48.5	14.6	5.6	SFO	Yes / EFSA (2015)
Gardner	sandy loam	7.7	20ºC	pF2	8.2	27.3	8.2	6.5	SFO	Yes / EFSA (2015)
18 Acres	sandy clay loam	5.8	20°C	pF2	3.8	12.7	3.8	4.5	SFO	Yes / EFSA (2015)
San Miguel	Sandy loam	7.4	20°C	pF2	73.1	243	73.1	2.3	SFO	Yes / EFSA (2015)
Median (n = 10)							6.5			
pH-dependency:							No			

[a] For similar soils geometric mean values were generated before calculating the overall geometric mean DT_{50} (EFSA, 2015: arithmetic mean)

Table 8.3-4: Summary of aerobic degradation rates for NOA409045 - laboratory studies

NOA409045, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (ºC)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**ff. (-)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	loam	7.25	20ºC	40%	4.15	13.8	0.70[a]	2.72[b]	9.04	SFO	Yes / EFSA (2015)
Gartenacker	loam	7.25	20ºC	40%	15.5	51.4	0.72[a]	10.2[b]	9.80	SFO	Yes / EFSA (2015)
Gartenacker	silt loam	7.6	20°C	pF2	7.1	23.7	1	7.1	13.6	SFO	Yes / EFSA (2015)
Birkenheide	sandy loam	5.57	20ºC	40%	96.6	321	0.66	82.3[b]	2.61	SFO	Yes / EFSA (2015)
Birkenheide	sandy loam	5.57	20ºC	40%	69.4	230	-	59.1[b]	2.18	SFO	Yes / EFSA (2015)
Pappelacker	sandy loam	7.5	20ºC	40%	7.88	26.2	0.83	5.22	10.3	SFO	Yes / EFSA (2015)
Marsillargues	silty clay	8.0	20°C	pF2	161	536	0.78	161	8.8	SFO	Yes / EFSA (2015)
Gardner	Sandy loam	7.7	20°C	pF2	52.4	174	0.91	52.4	11.0	SFO	Yes / EFSA (2015)
18 Acres	sandy clay loam	5.8	20°C	pF2	32.3	107	0.81	32.3	12.8	SFO	Yes / EFSA (2015)
San Miguel	sandy loam	7.4	20°C	pF2	200	666	0.56	200	5.2	SFO	Yes / EFSA (2015)
Arithmetic mean (n=8); formed from parent							0.783				
Geometric mean (n=8)								30.5[c]			
pH-dependency								No			

[a] For similar soils arithmetic mean values were generated before calculating the overall arithmetic mean formation fraction;
[b] For similar soils geometric mean values were generated before calculating the overall geometric mean DT_{50} value (EFSA, 2015: arithmetic mean)
[c] DT_{50} value used in the modelling have been re-calculated from the list of endpoints (EFSA, 2015): the geometric mean of normalized DT_{50} values (n=8) according to FOCUS Kinetics (2014) was used (EFSA, 2015: geometric mean of 31.3 days).

Table 8.3-5: Summary of aerobic degradation rates for CGA67868 - laboratory studies

CGA67868, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (ºC)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**ff. (-)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	silt loam	7.6	20°C	pF2	1.6	5.4	0.53	1.6[b]	10.9	SFO	Yes / EFSA (2015)
Gartenacker	silt loam	7.2	20°C	pF2	2.1	6.8	-	2.1[b]	9.1	SFO	Yes / EFSA (2015)
18 Acres	sandy loam	5.9	20°C	pF2	2.6	8.7	-	2.6	5.6	SFO	Yes / EFSA (2015)
Gardner	sandy loam	7.6	20°C	pF2	4.9	16.2	-	4.9	3.3	SFO	Yes / EFSA (2015)
Arithmetic mean (n=1), formed from NOA409045							0.53[a]				
Geometric mean (n=3)								2.9			
pH-dependency:								No			

[a] Kinetic formation fraction from NOA409045
[b] For similar soils geometric mean values were generated before calculating the overall geometric mean DT_{50}

Table 8.3-6: Summary of aerobic degradation rates for SYN546520 - laboratory studies

SYN546520, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (ºC)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	silt loam	7.4	20°C	pF2	42.1	139.8	-	42.1	5.5	SFO	Yes / EFSA (2015)
Marsillargues	silty clay	8.1	20°C	pF2	74.9	248.7	-	74.9	4.3	SFO	Yes / EFSA (2015)
18 Acres	sandy clay loam	6.2	20°C	pF2	287.9	956.5	-	287.9	1.9	SFO	Yes / EFSA (2015)
Geometric mean (n=3)								96.8			
Formation fraction (from NOA409045)							0.47[a] / 0.1[b]				
pH-dependency:							No				

[a] Kinetic formation fraction from NOA409045. Calculated as 1 – f.f.(CGA67868), EFSA 2015; used as Tier 1 in PEC_{GW} calculations.
[b] Formation fraction derived from inverse modelling, EFSA 2015; used as Tier 2 in PEC_{GW} calculations.

The EU active substance RMS Belgium has agreed to review the new kinetics data for deriving the for-

mation fraction for SYN546520 (as this was an open point in the EFSA conclusion). The outcome should be available in time for the product renewal evaluation.
However, if this is not the case please review the new kinetics evaluations in Appendix 3 (A 3.1 and A 3.2), leading to the conclusion that 0.1 formation fraction for SYN546520 is the appropriate modelling endpoint based on available study data.

8.3.1.3 Sedaxane and its metabolites

The overall rate of degradation of sedaxane was re-calculated taking mean values where two or more results were available for the same soil ([redacted] and [redacted], 2010a). Results are summarised in Table 8.3-7.

Table 8.3-7: Summary of aerobic degradation rates for sedaxane - laboratory studies ([redacted] and [redacted], 2010a)

Sedaxane, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. (°C)**	**Soil moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Loam	6.9	20	pF2	59.4	197	65.1[a]	5.2	SFO	Yes / EFSA (2013)
					61.8[*]	205		8.9	SFO	Yes / EFSA (2013)
					75.1	250		9.8	SFO	Yes / EFSA (2013)
North Dakota	Sandy clay loam	6.7	20	pF2	76.5	254	68.4[a]	15.8	SFO	Yes / EFSA (2013)
					61.1	203		11.2	SFO	Yes / EFSA (2013)
California	Sand	7.9	20	pF2	1000[b]	1000	1000[b]	6.4	DFOP[b]	Yes / EFSA (2013)
18 Acres	Sandy clay loam	5.8	20	pF2	90.7	301	90.7	8.7	SFO	Yes / EFSA (2013)
Marsillargues	Silty clay	7.5	20	pF2	52.4	174	52.4	9.3	SFO	Yes / EFSA (2013)
Pappelacker	Loamy sand	6.9	20	pF2	74.2	247	74.2	5.6	SFO	Yes /EFSA (2013)
Geometric mean (n=6)							108			
pH-dependency:							No			

a Geometric means of the DT_{50} for the same soils
b SFO kinetics did not describe the degradation kinetics adequately; therefore, the slow phase degradation was used from DFOP kinetics
* For one of the Gartenacker soil, incubation was conducted at 20°C but with a slightly sub-optimal soil moisture content of 32.0%w/w compared to a measured pF2 of 34.8%w/w ([redacted], 2008). A correction factor of 0.943 was applied for this soil, resulting in a normalised DT_{50} of 61.8 days.

The rate of degradation of the two isomers (trans:cis; SYN508210:SYN508211) did not change significantly over time.

CSAA798670

The behaviour of the sedaxane metabolite CSAA798670 in soil has been investigated in a soil degradation study, dosed with the primary metabolite CSCC210616, conducted on four different soils under aerobic conditions ([redacted], 2009). The data from these studies have been analysed ([redacted], 2009a) in order to derive DT_{50} values for use as modelling endpoints. Results are summarised in Table 8.3-8 ([redacted] and [redacted], 2010a).

Table 8.3-8 Summary of aerobic degradation rates for CSAA798670 - laboratory studies ([redacted] and [redacted], 2010a)

CSAA798670, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. (°C)**	**Soil mois-ture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**r^2 (-)**	**Kinetic model**	**For-mation fraction**	**Evaluated on EU level / Reference**
18 Acres	Sandy clay loam	6.4	20	pF2	6.2	20	6.2	0.99	SFO	1.000	Yes / EFSA (2013)
Gartenacker	Loam	7.1	20	pF2	3.2	11	3.2	0.98	SFO	0.961	
Marsillargues	Silty clay	7.7	20	pF2	18	59	18	0.98	SFO	1.000	
North Dakota	Sandy clay loam	6.7	20	pF2	13	44	13	0.98	SFO	0.967	
Geometric mean (n=4)							8.3			0.982	
pH-dependency:							No				

CSCD465008

The behaviour of the sedaxane metabolite CSCD465008 in soil has been investigated in three soil degradation studies conducted on four different soils (total of 10 datasets) under aerobic conditions ([redacted] and [redacted], 2007; [redacted], 2008; [redacted], 2009). In two studies ([redacted] and [redacted], 2007; [redacted], 2008) CSCD465008 was applied directly to the soil, and in a third study ([redacted], 2009) CSCD465008 was determined as a metabolite following application of CSCC210616. The data from these studies have been analysed ([redacted], 2009a & b) in order to derive DT_{50} values for use as modelling endpoints. Results are summarised in Table 8.3-9 ([redacted] and [redacted], 2010a).

Table 8.3-9 Summary of aerobic degradation rates for CSCD465008 - laboratory studies ([redacted] and [redacted], 2010a)

CSCD465008, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. (°C)**	**Soil moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Formation fraction[b]**	**Evaluated on EU level / Reference**
18 Acres	Sandy clay loam	6.4	20	pF2	112	372	70.8[a]	4.7	SFO	0.696	Yes / EFSA (2013)
		5.8			78.9	262		6.7	SFO	-	Yes / EFSA (2013)
		6.5			40.1	134		6.4	SFO	-	Yes / EFSA (2013)
Garten-acker	Loam	7.1	20	pF2	78.8	262	100 [a]	5.8	SFO	0.960	Yes / EFSA (2013)
		6.9			129	427		1.6	SFO	-	Yes / EFSA (2013)
		7.2			98.7	328		5.8	SFO	-	Yes / EFSA (2013)
Marsi-llargues	Silty clay	7.7	20	pF2	152	505	166 [a]	17	SFO	0.848	Yes / EFSA (2013)
		7.5			190	631		1.5	SFO	-	Yes / EFSA (2013)
		7.8			157	521		0.71	SFO	-	Yes / EFSA (2013)
North Dakota	Sandy clay loam	6.7	20	pF2	142	472	142	6.5	SFO	0.773	Yes / EFSA (2013)
Geometric mean (n=4)							114			0.819	
pH-dependency:							No				

[a] Geometric means of the DT_{50} for the same soils (n=3). The first value is derived from the soil degradation study ([redacted] & [redacted], 2009) where 4 soils were dosed with the minor soil metabolite CSCC210616 (precursor of metabolite CSAA798670); the other two values are derived from the studies ([redacted] and [redacted], 2007 and [redacted], 2008) where metabolite CSCD465008 was applied to three soils as parent compound.
[b] From CSAA798670

CSCD728931

The degradation behaviour of CSCD728931 in the environment was only investigated with in a single trial. Therefore, a data gap for groundwater exposure assessment and for information on the environmental behaviour in soil was identified by EFSA (2013) for the minor non-transient metabolite CSCD728931. Therefore, a new aerobic soil degradation study on the metabolite CSCD728931 was performed ([redacted] and [redacted] (2013), VV-406128) and kinetically evaluated ([redacted] (2013), VV-628062). Detailed data have been provided in Appendix 2 and Appendix 3 of this document. Results are summarised in Table 8.3-10.

Table 8.3-10 Summary of aerobic degradation rates for CSCD728931 - laboratory studies ([redacted] (2013), VV-628062)

	CSCD728931, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. (°C)**	**Soil moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Max. Chi^2 (%)**	**Kinetic model**	**Formation fraction**	**Evaluated on EU level / Reference**
California	Sand	7.9	20	pF2	79.3	263[a]	79.3	15	SFO	0.48	Yes / EFSA (2013)
18 Acres	Sandy clay loam	6.08	20	pF2	10.2[b]	33.9	10.2[b]	15	FOMC	n/a[d]	No / [redacted] and [redacted] (2013), VV-406128
Gartenacker	Loam	7.15	20	pF2	71.4[c]	237[a]	71.4[c]	15	DFOP		
East Anglia	Sandy loam	6.84	20	pF2	70.1	232.4[a]	70.1	15	SFO		
Sarpy	Silt loam	6.66	20	pF2	33.3	109.6[a]	33.3	15	SFO		
						Geometric mean (n=5)	42.3				
						pH-dependency:	No				

[a] DT_{50}*3.32
[b] DT_{90}/3.32
[c] $ln2/k_2$
[d] n/a CSCD728931 applied study

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

All studies on anaerobic degradation rates are considered to be data provided in support of the active substance. All studies on anaerobic degradation in soil of fludioxonil, metalaxyl-M, and sedaxane have been reviewed under Council Directive 91/414/EEC.

8.3.2.1 Fludioxonil and its metabolites

Studies on anaerobic degradation rates of fludioxonil and its metabolites are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of fludioxonil (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**).

The laboratory soil degradation studies of the active substance showed that under light exclusion aerobic biological degradation represents the main dissipation process, furthermore as a seed treatment the product is unlikely to be exposed to anaerobic conditions and therefore anaerobic degradation is not considered to be relevant and no anaerobic studies are required.

8.3.2.2 Metalaxyl-M and its metabolites

Studies on anaerobic degradation rates of metalaxyl-M are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

From the EU Review it was concluded that metalaxyl-M degrades more slowly under anaerobic conditions than under aerobic conditions with the same route of degradation (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

8.3.2.3 Sedaxane and its metabolites

Under anaerobic laboratory conditions sedaxane degrades slowly in soil (DT_{50} > 1 year) (**Sedaxane, EFSA Journal 2013; 11(1):3057**). Under anaerobic conditions no metabolites ≥ 0.5% of applied ^{14}C sedaxane were measured in soil. Mineralisation to carbon-dioxide was low (<5%) and unextractable residues were 30.6%.

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Fludioxonil and its metabolites

Studies on field dissipation rates, while commonly performed with a formulation, are considered to be data provided in support of the active substance. The rate of degradation in soil of fludioxonil was evaluated during the Annex I Inclusion (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**). However, the maximum DT_{50} of 43 days given by **EFSA (2007)** is not relevant for seed treatment uses as it includes photolytic degradation.

The following study on field dissipation rates performed on fludioxonil has not previously been submitted for review/reviewed under Council Directive 91/414/EEC and is provided in support of this assessment. A summary of this study is supplied in Appendix 2 of this document.

A trial was carried out in Switzerland during 2003 to compare dissipation of fludioxonil when applied as a seed treatment, a topical spray and a topical spray incorporated ([redacted] (2004), VV-330403). The residue data from the seed treatment was erratic and did not allow the calculation of a dissipation rate. The broadcast spray with incorporation, however gave a DT_{50} of 137 days and it is considered that this is an appropriately conservative value to use for field dissipation. The results of this study are summarised in Table 8.4-1.

Trigger endpoints

Table 8.4-1: Summary of aerobic degradation rates for fludioxonil - field studies: Trigger endpoints ([redacted] (2004), VV-330403)

Fludioxonil, Field studies – Trigger endpoints									
Soil type (USDA)	**Plot No./ plot type**	**pH (KCl)**	**Sampling depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Kinetic parameters**	**r^2**	**Kinetic model**	**Evaluated on EU level / Reference**
Applied as a seed treatment									
Sandy Loam	1 / bare soil	7.3[a]	0-30	NC	NC	-	NC	-	No / [redacted] (2004), VV-330403
	2 / bare soil, sterilised seed		0-30	NC	NC	-	NC	-	No / [redacted] (2004), VV-330403
	3 / over-sown with turf		0-30	NC	NC	-	NC	-	No / [redacted] (2004), VV-330403
Maximum (n=3)				-	-				
Applied and incorporated									
Sandy Loam	4 / bare soil	7.3[a]	0-30	137	NC	-	0.804	FOMC	No / [redacted] (2004), VV-330403
	5 / covered		0-30	55	NC	-	0.935	FOMC	No / [redacted] (2004), VV-330403
	6 / over-sown with turf		0-30	112	NC	-	0.761	FOMC	No / [redacted] (2004), VV-330403
Maximum (n=3)				137					
Applied and not incorporated									
Sandy Loam	7 / bare soil	7.3[a]	0-30	19	72	-	0.762	FOMC	No / [redacted] (2004), VV-330403
	8 / covered		0-30	NC	NC	-	NC	-	No / [redacted] (2004), VV-330403
	9 / over-sown with turf		0-30	12	NC	-	0.973	FOMC	No / [redacted] (2004), VV-330403
Maximum (n=3)				19					

[a] Mean value representing depth of 0-30 cm (n=3)
NC: not calculable within the 90 day timescale of the study

Modelling endpoints

Normalised field aerobic degradation modelling endpoints for fludioxonil and its metabolites are currently not available.

8.4.1.2 Metalaxyl-M and its metabolites

Studies on the field dissipation rates of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for the EU review of metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

Trigger endpoints

Table 8.4-2: Summary of aerobic degradation rates for metalaxyl-M - field studies: Trigger endpoints

Metalaxyl-M, Field studies – Trigger endpoints									
Soil type (USDA)	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Kinetic parameters**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Applied to bare ground									
Sandy loam	Elena (IT)	7.5	0-30	11.9	39.6	-	18.1	SFO	Yes / EFSA (2015)
Silty clay loam	Marsillargues (FR)	7.4	0-30	13.5	44.7	-	26.5	SFO	Yes / EFSA (2015)
Silty clay loam	Bastia di Rovolon (IT)	7.3	0-30	18.1	60.1	-	14.9	SFO	Yes / EFSA (2015)
Loam	Vouvry (CH)	7.4	0-30	4.6	15.3	-	12.5	SFO	Yes / EFSA (2015)
Silty clay	Vouvry (CH)	7.1	0-30	12.4	41.3	-	14.2	SFO	Yes / EFSA (2015)
Loamy sand	Sevilla (SP)	7.8	0-30	15.3	50.9	-	9.02	SFO	Yes / EFSA (2015)
Loam	Aimargues (FR)	7.4	0-30	30.9	102.6	-	11.4	SFO	Yes / EFSA (2015)
Loamy sand	Middelfart (DK)	6.9	0-30	20.9	69.5	-	5.74	SFO	Yes / EFSA (2015)
Loam	Sept Saux (FR)	7.8	0-30	9.3	30.7	-	14.8	SFO	Yes / EFSA (2015)
Silty loam	Lower Saxony (DE)	6.0	0-30	19.7	65.4	-	11.6	SFO	Yes / EFSA (2015)
Geometric mean (n=10)				14.1	46.7				
Maximum				**30.9**	102.6				

Table 8.4-3: Summary of aerobic degradation rates for NOA409045 - field studies: Trigger endpoints

NOA409045, Field studies – Trigger endpoints									
Soil type (USDA)	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Kinetic parameters**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Applied to bare ground									
Sandy loam	Elena (IT)	7.5	0-30	16.0	53.3	-	26.8	SFO	Yes / EFSA (2015)
Silty clay loam	Marsillargues (FR)	7.4	0-30	20.5	68.0	-	16.4	SFO	Yes / EFSA (2015)
Silty clay loam	Bastia di Rovolon (IT)	7.3	0-30	14.9	49.6	-	59.0	SFO	Yes / EFSA (2015)
Loam	Vouvry (CH)	7.4	0-30	5.8	19.2	-	25.7	SFO	Yes / EFSA (2015)
Silty clay	Vouvry (CH)	7.1	0-30	8.3	27.7	-	44.7	SFO	Yes / EFSA (2015)
Loamy sand	Sevilla (SP)	7.8	0-30	Uncertain[a]	Uncertain[a]	-	n.a.	SFO	Yes / EFSA (2015)
Loam	Aimargues (FR)	7.4	0-30	15.9	52.8	-	20.7	SFO	Yes / EFSA (2015)
Loamy sand	Middelfart (DK)	6.9	0-30	39.8	132.2	-	20.9	SFO	Yes / EFSA (2015)
Loam	Sept Saux (FR)	7.8	0-30	27.1	89.9	-	34.5	SFO	Yes / EFSA (2015)
Silty loam	Lower Saxony (DE)	6.0	0-30	30.2	100	-	22.3	SFO	Yes / EFSA (2015)
Geometric mean (n=9)				17.1	56.6				
Maximum				**39.8**	132.2				

[a] No reliable endpoint could be derived, due to poor kinetic fitting. The default value of 1000 days for an uncertain kinetic fit was not considered relevant as sufficient other data was available.

Modelling endpoints

There are no modelling endpoints from field dissipation studies available.

8.4.1.3 Sedaxane and its metabolites

Sedaxane

The field dissipation rate of sedaxane was evaluated during the EU review. No additional studies have been performed.

Residues of sedaxane were determined by analysis of the individual isomers (SYN508210 and SYN508211). As the isomer ratios did not change significantly during the course of the dissipation trials, the concentrations of sedaxane in the soil samples were calculated from the sum of the separate isomers. Soil samples were also analysed for the two major soil metabolites (CSAA798670 and CSCD465008). No residues of the metabolites CSCD465008 and CSAA798670 were measured in the soil samples at any depth. The resulting triggering and modelling endpoints are presented in Table 8.4-4 and Table 8.4-6, respectively.

CSCD465008

A field dissipation study for the sedaxane metabolite CSCD465008 was carried out at four European test sites ([redacted] et al., 2009). Two different kinetic evaluations were carried out according to FOCUS kinetics (FOCUS, 2006): analysis of un-normalised trigger endpoints ([redacted], 2009a) and analysis of time-step normalised modelling endpoints ([redacted], 2009b). The studies of [redacted] et al. (2009) and [redacted] (2009a and 2009b) have been evaluated at EU level for the approval of the active ingredient fluxapyroxad (metabolite M700F002); (**Fluxapyroxad, EFSA Journal 2012; 10(1):2522**).

A summary of DT_{50} values derived from four soils and calculated according to FOCUS kinetics (2006) is provided in Table 8.4-7.

Trigger endpoints

Table 8.4-4: Summary of aerobic degradation rates for sedaxane - field studies: Trigger endpoints ([redacted] and [redacted], 2010b)

Sedaxane, Field studies – Trigger endpoints									
Soil type (USDA)	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Kinetic parameters**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Silt loam	France (North)	7.7	0-10	125	413	-	13.7	SFO	Yes / EFSA (2013)
Silt loam	France (South)	8.2	0-20	158	521	-	18.9	SFO	Yes / EFSA (2013)
Loamy sand	Italy	6.9	0-20	129	428	-	14.9	SFO	Yes / EFSA (2013)
Silty clay loam	Germany	8.3	0-10	438	>1000	-	8.7	SFO	Yes / EFSA (2013)
Maximum (n=4)				**438**					

Table 8.4-5: Summary of aerobic degradation rates for CSCD465008 - field studies: Trigger endpoints ([redacted], 2009a)

CSCD465008, Field studies – Trigger endpoints									
Soil type (USDA)	**Location**	**pH ($CaCl_2$)**	**Depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Kinetic parameters**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Loamy sand	Middlefart (DK)	5.8	0-40	39.2	188.4	-	12.0	FOMC	Yes / EFSA (2012)[a]
Silt loam	Goch-Nierswalde (DE)	6.4	0-40	38.0	154.5	-	5.7	FOMC	Yes / EFSA (2012)[a]
Silt loam	Poggio Renatico (IT)	7.7	0-70	37.4	185.9	-	7.0	FOMC	Yes / EFSA (2012)[a]
Loam	Meauzac (FR)	5.5	0-60	25.5	84.8	-	6.9	SFO	Yes / EFSA (2012)[a]
			Maximum (n=4)	**39.2**	188.4				

[a] Fluxapyroxad, EFSA Journal 2012; 10(1):2522

Modelling endpoints

Table 8.4-6: Summary of aerobic degradation rates for sedaxane - field studies: Modelling endpoints ([redacted] and [redacted], 2010b)

Sedaxane, Field studies – Modelling endpoints									
Soil type (USDA)	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT_{50} (d) 20°C, pF2**	**DT_{90} (d) 20°C, pF2**	**Kinetic parameters**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Silt loam	France (North)	7.7	0-10	71.7	238	-	16.2	SFO	Yes / EFSA (2013)
Silt loam	France (South)	8.2	0-20	54.6	181	-	18.4	SFO	Yes / EFSA (2013)
Loamy sand	Italy	6.9	0-20	135	449	-	12.7	SFO	Yes / EFSA (2013)
Silty clay loam	Germany	8.3	0-10	188	624	-	7.8	SFO	Yes / EFSA (2013)
			Geometric mean (n=4)	**100**	331.5				
			pH-dependency	No					

Table 8.4-7: Summary of aerobic degradation rates for CSCD465008 - field studies: Modelling endpoints ([redacted], 2009b)

CSCD465008, Field studies – Modelling endpoints									
Soil type (USDA)	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT_{50} (d) 20°C, pF2**	**DT_{90} (d) 20°C, pF2**	**Kinetic parameters**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Loamy sand	Middlefart (DK)	5.8	0-40	17.9	59.4	-	13.2	SFO	Yes / EFSA (2012)[a]
Silt loam	Goch-Nierswalde (DE)	6.4	0-40	23.1	76.9	-	10.3	SFO	Yes / EFSA (2012)[a]
Silt loam	Poggio Renatico (IT)	7.7	0-70	44.1	146.4	-	11.9	SFO	Yes / EFSA (2012)[a]
Loam	Meauzac (FR)	5.5	0-60	24.6	81.7	-	9.1	SFO	Yes / EFSA (2012)[a]
Geometric mean (n=4)				**25.9**	86.0				
pH-dependency				No					

[a] Fluxapyroxad, EFSA Journal 2012; 10(1):2522

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Fludioxonil

The low use rates and the observed dissipation half-lives under environmental conditions indicate that soil accumulation of fludioxonil resulting from seed treatment is not of concern. However, given the field DT_{50} and DT_{90} of fludioxonil are > 100 d and 365 d, respectively, the potential for accumulation of fludioxonil has been assessed by calculation (see chapter 8.7).

8.4.2.2 Metalaxyl-M and its metabolites

Based on laboratory and field dissipation data, metalaxyl-M, NOA409045 and CGA67868 are not likely to accumulate in soil. Hence, calculations to estimate potential accumulation were not undertaken.
Given the longest laboratory DT_{50} and DT_{90} of SYN546520 are > 100 d and 365 d respectively, as shown in chapter 8.3.1, the potential for accumulation has been assessed by calculation under chapter 8.7.

8.4.2.3 Sedaxane

Two soil accumulation studies were started in 2007 with sedaxane applied to winter or spring wheat seeds as a seed treatment in Northern Europe (Germany/winter wheat) and Southern Europe (Italy/spring wheat). A second application was made to the Italian trial in 2008.

For each year, soil samples were taken from the treated plot (to a depth of 30 cm) immediately after the application (sowing of the seeds), at harvest, post cultivation and immediately before the sowing of the treated seeds for the following year.

No evidence of accumulation of sedaxane, CSCD465008 and CSAA798670 has been observed.

All soil accumulation studies on sedaxane have been evaluated in the EU review.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.5.1 Fludioxonil

The mobility of fludioxonil and its metabolite CGA192155 in soil was evaluated during the EU review (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**). No additional studies have been performed. The soil adsorption data for fludioxonil and CGA192155 are presented in Table 8.5-1 to Table 8.5-2.

Table 8.5-1: Summary of soil adsorption/desorption for fludioxonil

Fludioxonil							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gleadthorpe	Sand	1.7	6.4	770	46000	0.95	Yes / EFSA (2007)
Somersham	Sandy loam	2.4	6.5	290	12000	0.81	
Sandiacre	Sandy silt loam	3.5	6.9	7300	210000	1.14	
Goole	Sandy silt loam	2.8	7.9	2100	75000	0.92	
Ramsey	Silty clay loam	15.8	6.6	61000	385000	1.19	
				Arithmetic mean (n=5)	**145600**	**1.0**	
				pH-dependency	No		

Table 8.5-2: Summary of soil adsorption/desorption for CGA192155

CGA192155							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Lakeland	Sand	0.58	5.3	0.246	42.4	0.798	Yes / EFSA (2007))
Hanford	Sandy loam	0.23	7.4	0.063	27.3	0.841	
Collamer	Loam	2.15	6.5	0.266	12.4	0.811	
Niagara	Loam	2.38	6.7	0.278	11.7	0.769	
				Arithmetic mean (n=4)	**23.45**	**0.80**	
				pH-dependency:	No		

8.5.2 Metalaxyl-M and its metabolites

The mobility in soil of metalaxyl-M and its metabolites was evaluated during the EU review (**Metalaxyl-M; EFSA Journal 2015; 13(3):3999**) and unless otherwise stated all relevant experimental information and references can be found therein. Additional data were not required as a result of the review.

The soil adsorption data for metalaxyl-M, NOA409045, CGA67868 and SYN546520 are presented in Table 8.5-3 to Table 8.5-6.

Table 8.5-3: Summary of soil adsorption/desorption for metalaxyl-M

Metalaxyl-M							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Maryland	clay	2.82	5.9	8.01	283.8	1.16	Yes / EFSA (2015)
Maryland	sand	0.53	6.5	0.157	29.6	0.795	Yes / EFSA (2015)
Mississippi	loam	0.71	7.6	1.41	199.8	1.31	Yes / EFSA (2015)
Collombey	sand	1.28	7.8	0.43	33.6	0.83	Yes / EFSA (2015)
Lakeland	sand	0.696	6.3	0.48	69.0	0.79	Yes / EFSA (2015)
Les Evouettes	loam	2.09	6.1	0.87	41.6	0.77	Yes / EFSA (2015)
Vetroz	sandy clay loam	3.25	6.7	1.40	43.1	0.83	Yes / EFSA (2015)
Mississippi	clay	1.33	7.0	7.61	570	1.45	Yes / EFSA (2015)
Maryland	sand	0.348	5.4	0.0700	20	0.892	Yes / EFSA (2015)
Washington	loam	1.51	7.0	1.30	86	1.05	Yes / EFSA (2015)
Borstel	loamy sand	1.2	5.0	0.480	40.0	0.923	Yes / EFSA (2015)
Pappelacker	loamy sand	1.1	7.6	0.318	28.9	0.900	Yes / EFSA (2015)
Gartenacker	silt loam	2.08	7.3	0.644	31.0	0.908	Yes / EFSA (2015)
Vetroz	silt loam	4.7	7.2	1.67	35.5	0.928	Yes / EFSA (2015)
Illarsaz	silt loam	19.8	6.7	7.88	39.8	0.929	Yes / EFSA (2015)
Birkenheide	sandy loam	0.84	5.57	0.339	40.4	0.963	Yes / EFSA (2015)
Pappelacker	sandy loam	1.56	7.47	0.480	30.8	0.956	Yes /

Metalaxyl-M							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
							EFSA (2015)
Gartenacker	silt loam	1.81	7.30	0.700	38.7	0.937	Yes / EFSA (2015)
Vetroz	silt loam	1.77	7.70	0.717	40.5	0.934	Yes / EFSA (2015)
Birkenheide	sandy loam	0.94	5.65	0.372	39.6	0.92	Yes / EFSA (2015)
Gartenacker	silt loam	1.97	7.6	0.5	26	0.979	Yes / EFSA (2015)
18 Acres	sandy clay loam	3.19	5.8	0.9	29	0.910	Yes / EFSA (2015)
Marsillargues	silty clay	1.04	8	0.7	58	0.942	Yes / EFSA (2015)
Gardner	sandy loam	2.84	7.7	1.9	67	0.923	Yes / EFSA (2015)
Work Ranch	sandy loam	2.44	7.4	1.3	52	0.954	Yes / EFSA (2015)
				Arithmetic mean (n=25)	**78.9**	**0.955**	
				pH-dependency:	No		

Table 8.5-4: Summary of soil adsorption/desorption for NOA409045

NOA409045							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Mississippi	clay	1.22	6.1	0.875	72	0.947	Yes / EFSA (2015)
Maryland	sand	0.348	5.4	0.124	36	0.927	Yes / EFSA (2015)
California	sandy loam	0.58	6.9	0.0175	3	0.867	Yes / EFSA (2015)
Washington	loam	1.28	7.0	0.105	8	0.909	Yes / EFSA (2015)
Arizona	clay loam	0.58	7.9	0.0992	17	0.929	Yes / EFSA (2015)

NOA409045							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Les Evouettes	loam	1.4	5.5	0.3	22	0.91	Yes / EFSA (2015)
Staffort	sandy loam	0.77	5.2	0.120	15.4	0.935	Yes / EFSA (2015)
Gartenacker	loam	2.40	7.2	0.210	8.88	0.960	Yes / EFSA (2015)
Vetroz	silt loam	4.39	7.1	0.440	9.94	0.956	Yes / EFSA (2015)
Birkenheide	sandy loam	0.84	5.57	0.131	15.6	0.907	Yes / EFSA (2015)
Pappelacker	sandy loam	1.56	7.47	0.139	8.9	0.940	Yes / EFSA (2015)
Gartenacker	silt loam	1.81	7.30	0.205	11.3	0.918	Yes / EFSA (2015)
Vetroz	silt loam	1.77	7.70	0.173	9.8	0.930	Yes / EFSA (2015)
Birkenheide	sandy loam	0.94	5.65	0.122	12.9	0.956	Yes / EFSA (2015)
				Arithmetic mean (n=14)	**17.9**	**0.928**	
				pH-dependency:	No		

Table 8.5-5: Summary of soil adsorption/desorption for CGA67868

CGA67868							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	silt loam	2.0	7.6	0.4	20	0.822	Yes / EFSA (2015)
18 Acres	sandy clay loam	3.2	5.5	0.5	16	0.879	Yes / EFSA (2015)
Marsillargues	silty clay	1.2	7.8	0.2	20	0.794	Yes / EFSA (2015)
Gardner	sandy loam	2.8	7.3	0.5	19	0.816	Yes / EFSA (2015)
Madera	sandy loam	0.7	6.9	0.1	20	1.169	Yes / EFSA (2015)
				Arithmetic mean (n=5)	**19**	**0.896**	
				pH-dependency:	No		

Table 8.5-6: Summary of soil adsorption/desorption for SYN546520

SYN546520							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	silt loam	2.7	7.2	0.1	3	1.131	Yes / EFSA (2015)
18 Acres	sandy clay loam	2.4	5.9	0.4	15	0.964	Yes / EFSA (2015)
Seven Springs	loamy sand	0.5	5.8	0.2	41	0.951	Yes / EFSA (2015)
Gardner	sandy loam	2.7	7.6	0.1	2	1.366	Yes / EFSA (2015)
				Arithmetic mean (n=4)	**15.2**	**1.1**	
				pH-dependency:	No		

8.5.3 Sedaxane and its metabolites

The mobility of sedaxane and the metabolites CSAA798670 and CSCD465008 in soil was evaluated during the EU review of sedaxane and during the EU review of fluxapyroxad (metabolite CSCD465008 is the same compound as metabolite M700F002). An additional study, which has not yet been evaluated, was performed for metabolite CSCD728931 ([redacted] (2013), VV-628062). The corresponding study summary is provided in Appendix 2.

Summaries of all adsorption/desorption data for sedaxane and its metabolites CSAA798670, CSCD465008 and CSCD728931 are given in tables Table 8.5-7 to Table 8.5-10.

Table 8.5-7: Summary of soil adsorption/desorption for sedaxane

Sedaxane							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	Loam	2.6	6.8	6.82	262	0.81	Yes / EFSA (2013)
Marsillargues	Silty clay	1.04	7.5	5.72	548	0.86	
18 Acres	Sandy clay loam	2.78	5.1	16.74	602	0.91	
Visalia	Sandy loam	0.52	5.7	3.06	588	0.91	
Champaign	Silty clay	2.44	7.1	13.13	538	0.84	
Washington	Sand	0.32	7.0	2.00	666	0.86	
				Arithmetic mean (n=6)	**534**	**0.865**	
				pH-dependency	No		

Table 8.5-8: Summary of soil adsorption/desorption for CSAA798670

CSAA798670							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	Loam	2.1	6.1	0.04	2.1	0.94	Yes / EFSA (2013)
18 Acres	Sandy clay loam	2.5	7.2	0.07	2.7	0.85	
Marsillargues	Silty clay	0.7	7.6	0.02	3.6	1.02	
North Dakota	Sandy loam	3.9	6.8	0.01	0.3	0.78	
California	Loamy sand	0.4	6.8	0.02	6.1	0.93	
Arithmetic mean (n=5)					**3.0**	**0.90**	
pH-dependency					No		

Table 8.5-9: Summary of soil adsorption/desorption for CSCD465008

CSCD465008							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
18 Acres	Sandy clay loam	2.8	5.3	0.1	3.70	0.98	Yes / EFSA (2013)
Gartenacker	Loam	2.1	6.9	0.02	0.71	0.67	
Marsillargues	Silty clay loam	1.0	7.5	0.02	1.94	0.90	
LUFA 2.1	Sand	0.52	5.2	0.068	13.1	0.969	Yes / EFSA (2012)[a]
Li 10	Loamy sand	0.88	5.9	0.042	4.8	0.842	
New Jersey	Silt loam	0.90	6.3	0.127	14.1	1.165	
Nierswalde	Silt loam	1.63	6.5	0.146	9.0	0.937	
LUFA 2.3	Sandy loam	1.09	6.9	0.061	5.6	1.078	
La Gironda	Silty clay loam	3.84	7.5	0.039	1.0	0.99	
California	Sandy loam	0.41	7.6	0.023	5.6	0.764	
Arithmetic mean (n=3, EFSA 2013)					**2.1**	**0.85**	
Arithmetic mean (n=10)					**6.0**	**0.93**	
pH-dependency					No		

[a] Fluxapyroxad, EFSA Journal 2012; 10(1):2522

Table 8.5-10: Summary of soil adsorption/desorption for CSCD728931

CSCD728931							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Gartenacker	Sandy silt loam	2.09	6.6	0.938	44.9	0.9	No / [redacted] (2013), VV-628062
18 Acres	Sandy clay loam	2.15	6.3	1.648	76.8	0.9	
East Anglia	Sandy loam	2.38	7.5	2.101	88.3	0.89	
Sarpy	Silt loam	1.94	6.7	3.497	180.3	0.84	
Seven Springs	Loamy sand	0.48	5.0	0.621	129	0.91	
				Arithmetic mean (n=5)	**103.9**	**0.89**	
				pH-dependency	No		

8.5.4 Column leaching (KCP 9.1.2.1)

Studies on column leaching are considered to be data provided in support of the active substance.

Fludioxonil

All column leaching studies on fludioxonil have been evaluated in the EU review (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**). Standard soil columns with four different soils with unaged fludioxonil eluted with 200 mm artificial rain showed a leaching of 0.02-0.1% AR, confirming that fludioxonil is immobile in soil. The leaching of aged ^{14}C-fludioxonil in standard soil columns was studied in two soils. In both cases the soil residues were mainly in the top 2 cm or top 4 cm of the soil profile. The leachates contained up to 3.6% AR. The radioactivity in the leachate was not identified.

Metalaxyl-M

All column leaching studies on metalaxyl-M have been reviewed under Council Directive 1107/2009 and confirm the adsorption/desorption results, indicating the high mobility of metalaxyl-M and CGA62826, racemate of NOA409045.

Sedaxane

Column leaching studies were not conducted since reliable adsorption coefficient values were obtained from the adsorption/desorption studies reported for sedaxane and its metabolites.

8.5.5 Lysimeter studies (KCP 9.1.2.2)

Where undertaken, lysimeter studies are considered to be data provided in support of the active substance.

Fludioxonil

No lysimeter study has been performed with fludioxonil in view of the results of the soil degradation and mobility studies and of the predicted extremely low environmental concentrations in soil and groundwater.

Metalaxyl-M

The following lysimeter studies have been evaluated in the EU review (**Metalaxyl-M; EFSA Journal 2015; 13(3):3999**). Racemic metalaxyl was applied at a rate of 330 to 365 g a.s./ha on four vegetated soils. The concentrations of metalaxyl in the combined leachate of one year varied between <0.01 and 0.05 µg/L. The metabolite CGA62826 (racemate of NOA409045) was found at concentrations of 0.25 - 4.12 µg/L. CGA108906 (racemate of SYN546520) was recovered at the concentration of 0.48 – 1.11 µg/L.

Sedaxane

Based on the properties of sedaxane and the results of the soil and groundwater modelling, lysimeter studies are not required.

8.5.6 Field leaching studies (KCP 9.1.2.3)

Where undertaken, field leaching studies are considered to be data provided in support of the active substance.

Fludioxonil

No field leaching study has been performed with fludioxonil in view of the results of the soil degradation and mobility studies and of the predicted extremely low environmental concentrations in soil and groundwater.

Metalaxyl-M

Three field leaching studies have been performed, where concentrations of <1 to 2000 µg a.s./L could be observed. As the quality of the studies is questionable, the field leaching studies received low weight in the EU review (**Metalaxyl-M; EFSA Journal 2015; 13(3):3999**).

Sedaxane

Based on the properties of sedaxane and the results of the soil and groundwater modelling, field leaching studies are not required

Groundwater monitoring studies

Where undertaken, groundwater monitoring studies are considered to be data provided in support of the active substance.

Fludioxonil

No groundwater monitoring studies have been performed with fludioxonil.

Metalaxyl-M

Data on groundwater monitoring of metalaxyl-M are available from several European countries, Canada and the United States and have been submitted for the EU review of metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**). In the studies performed in Europe that did include metalaxyl, no or only few detections of this compound were made. Where quantitatively reported, the concentrations found were < 0.1 µg/L. On the whole, the conclusion can be drawn that the uses of metalaxyl over the past 20 years have not led to more than occasional detections of metalaxyl in groundwater. Hardly ever did residues exceed 0.1 µg/L.

Sedaxane

No groundwater monitoring studies have been performed with sedaxane.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.6.1.1 Fludioxonil

The rate of degradation in water/sediment systems of fludioxonil was evaluated during the EU review (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85)**. No additional studies have been performed.

Table 8.6-1: Summary of degradation in water/sediment of fludioxonil under dark conditions

Fludioxonil distribution (max. sediment 83.5% after 177 days)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Tugbach (Pond)	8.4 / 6.9[a]	699	2323	SFO	~ 1	-[b]	SFO	-	-	Yes / EFSA (2007)
River Rhine	8.4 / 7.2[a]	451	1499	SFO	~ 2	-[b]	SFO	-	-	
Fröschweiher (Pond)	7.4-9 / 7.2	>1000	>1000	SFO	6.7	21.3	SFO	-		Yes / EFSA (2007)
River Rhine	8-8.9 / 7.2	>1000	>1000	SFO	6.4	22.3	SFO	-		

[a] Matrix of pH measurement unknown.
[b] Not calculated.

Table 8.6-2: Summary of degradation in water/sediment of fludioxonil under light exposure

Fludioxonil distribution (max. water 99.3 % after 0 days, max. sediment 53.5 % after 7 days; max. sediment 85.6 % after 100 days (dark control))										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Fröschweiher (Pond)	7.4-9 / 7.2[a]	18.8	133	SFO	1.7	9.8	SFO	57.8	SFO	Yes / EFSA (2007)
River Rhine	8-8.9 / 7.2[a]	25.2	148	SFO	1.8	14.5	SFO	65.4	SFO	
Geometric mean (n=2)		21.77	140.3	-	1.75	11.92	-	61.48	-	

[a] Matrix of pH measurement unknown.

Table 8.6-3: Summary of observed metabolites

Metabolite	**Maximum observed value in water/sediment system**	**Evaluated on EU level / Reference**
CGA192155 Water/sediment system, light exposed studies	Max. in water 11.9 % after 100 days. Max. in sediment 5.5% after 100 days.	Yes / EFSA 2007

8.6.1.2 Metalaxyl-M and its metabolites

Studies on the degradation of metalaxyl-M and its aquatic metabolites CGA67868 and SYN546520 are considered to be data provided in support of the active substance. All relevant detailed experimental information on the degradation of metalaxyl-M in water/sediment systems has been submitted for EU review of metalaxyl-M **(Metalaxyl-M; EFSA Journal 2015; 13(3):3999)**. No additional studies have been performed. Data for the degradation of the metabolites CGA67868 and SYN546520 in water/sediment systems are currently not available

Table 8.6-4: Summary of degradation in water/sediment of racemic metalaxyl

Racemic metalaxyl Distribution (max. water 105.7% after 0 days, max. sediment 20.4% after 7 days)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
River	7.9 / 7.5[a]	47.1	157	SFO	37.2	124	SFO	51.7	SFO	Yes / EFSA (2015)
Pond	8.2 / 6.9[a]	21.9	72.7	SFO	16.6	55.2	SFO	19.6	SFO	Yes / EFSA (2015)
Geometric mean (n=2)		32.1	106.8		24.8	82.7		31.8		
Maximum (n=2)		**47.1**	157		37.2	124		51.7		

[a] Matrix of pH measurement unknown.

Table 8.6-5: Summary of observed metabolites

Metabolite	Maximum observed value in water/sediment system	Evaluated on EU level / Reference
CGA62826 (Racemate of NOA405049) Water/sediment system: Pond water (Ormalingen, Weiherfof-Tal, Baselland, Switzerland)	Max. in water 68.8 % after 112 d. Max. in sediment 23% after 56 days	Yes / EFSA 2015

8.6.1.3 Sedaxane and its metabolites

The rate of degradation in water/sediment systems of sedaxane was evaluated during the EU review (**Sedaxane, EFSA Journal 2013; 11(1):3057**). No additional studies have been performed.

The degradation of ^{14}C phenyl sedaxane was investigated in two laboratory incubated aquatic sediment systems under aerobic and anaerobic conditions. Degradation of sedaxane under both aerobic and anaerobic conditions produced no metabolite > 1% AR in the total system.

Table 8.6-6: Summary of dissipation and degradation in water/sediment of sedaxane under aerobic conditions

Sedaxane Distribution (41.4% in water after 7 d.; Max. sed 88.4% after 70 d)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Möhlin (River)	7.7/7.4	847	>1000	SFO	13.5[a]	44.8	HS	847	HS	Yes / EFSA (2013)
Rothenfluh (Pond)	7.4/7.2	885	>1000	SFO	22.2[b]	74	FOMC	885	FOMC	
Geometric mean (n=2)		**866**	-	-	**17.3**	**58**	-	**866**	-	

[a] HS $DT_{90}/3.32$
[b] FOMC $DT_{90}/3.32$

Table 8.6-7: Summary of dissipation and degradation in water/sediment of sedaxane under anaerobic conditions

Sedaxane										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Möhlin (River)	7.7/7.3	>1000	>1000	SFO	96.3 [a]	-	DFOP	-	-	Yes / EFSA (2013)
Rothenfluh (Pond)	7.4/7.2	>1000	>1000	SFO	129.3 [b]	-	FOMC	-	-	

[a] DFOP "slow-phase" DT_{50}
[b] FOMC $DT_{90}/3.32$

8.7 Predicted Environmental Concentrations in soil (PEC_S) (KCP 9.1.3)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: HSE Chemicals Regulation Division (CRD), UK
Fate & Behaviour Reviewer's comments **PECsoil** This Article 7 assessment only concerns the active substance metalaxyl-M, therefore the applicant's PECsoil values for the other active substances, fludioxonil and sedaxane, have not been evaluated by HSE. As noted in the introductory green box, metalaxyl-M is considered to be the only ecotoxicologically relevant substance for soil. Therefore PECsoil values are only calculated for metalaxyl-M. Input values used in PECsoil calculations are shown in the table below. For the a.s. these are in agreement with the list of agreed endpoints in the EFSA Conclusion.

Table HSE 8.7-01: Substance input parameters used for calculating PEC_{soil} values for 'Vibrance SB' and metalaxyl-M.

Parameter	Formulation	Active
SFO Soil DT_{50} (days)	-	30.9
Application Rate (g/ha)	44.7 [a]	0.62
Crop Interception (%)	0	0

[a] Formulation application rate based on a maximum individual dose of 43.3 mL product/ha (33.3 mL product/seed unit and 1.3 seed units sown/ha) and a formulation density of 1.032 g/cm^3.

As the a.s. has a relatively short DT50, no calculation of accumulation is required.

HSE agree with the applicants calculated values in Table 8.7-4. The initial PECsoil values are reproduced below.

Table HSE 8.7-02: PECsoil values for metalaxyl-M and the formulation 'Vibrance SB'.

Substance	PECsoil (mg/kg)	PECsoil(accumulation) (mg/kg)
Formulation	0.060	N/A
Metalaxyl-M	0.001	N/A

The calculated PEC values are suitable for use in risk assessment for the product 'Vibrance SB'.

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU review of fludioxonil (**EFSA Scientific Report 2007; 110, 1-85**), metalaxyl-M (**EFSA Journal 2015; 13(3):3999**), and sedaxane (**EFSA Journal 2013; 11(1):3057**).

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8.7.1 Justification for new endpoints

Assessment of the PEC in soil (PEC_S) of fludioxonil was done following a tiered approach using the worst case laboratory DT_{50} value of 569 days reported in the **EFSA Scientific Report (2007)** (Tier I) and the maximum DT_{50} value of 137 days (Tier II) derived from field dissipation trials including soil incorporation of the substance ([redacted] (2004), VV-330403). The available EU agreed endpoint list only contains field dissipation trials in which the substance is exposed to sunlight. This type of study should not be used for the assessment of seed treatments.

EU agreed endpoints (**EFSA Journal, 2015**) were used for PEC_S calculations of metalaxyl-M and its metabolite: maximum non-normalised DT_{50} from field trials for metalaxyl-M and NOA409045.

For assessment of the PEC in soil (PEC_S) of sedaxane and its metabolites, no new endpoints were defined. PEC_S have been calculated using the unnormalised worst case field DT_{50} value of 438 days for sedaxane and maximum laboratory DT_{50} for the metabolites (**LoEP, EFSA, 2013**). Sedaxane metabolite CSCD465008 is also a metabolite of the active substance fluxapyroxad, hence additional worst case field DT_{50} from the EU review of fluxapyroxad given in **EFSA Journal 2012** for metabolite M700F002 (same as CSCD465008) was considered for PECs calculation.

8.7.2 Active substances and relevant metabolites

The following PEC_S calculations have not previously been reviewed and are provided in support of this assessment. A detailed description of the PEC_S calculations is given in Appendix 3.

Table 8.7-1: Input parameters related to application for PEC_S calculations

Use No.	Use 10
Crop	Sugar beet
Application rate (g a.s./ha)	Fludioxonil: 0.97 Metalaxyl-M: 0.62 Sedaxane: 0.65
Pseudo application rate. Metabolites (g a.s./ha)[a]	NOA409045: 0.42 CSAA798670: 0.05 CSCD465008: 0.10
Number of applications/interval (d)	1/-
BBCH growth stage	0 (seed treatment)
Crop interception (%)	0
Depth of soil layer	Initial concentration: 5 cm Plateau concentration: 20 cm (with tillage)
Models used for calculation	CRD PECsoil Excel Spreadsheet[4]

[a] Application of the parent compound adjusted for formation percentage (maximum percentage observed in soil) and molecular weight difference relative to parent

[4] https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/fate/pec-tools-2015/PEC%20Soil.xlsx (accessed 04/05/2020)

Table 8.7-2: Input parameter for active substances and relevant metabolites for PEC_S calculation

Compound	Molar mass (g/mol)	Mol weight correction factor	Max. occurrence (%)	DT_{50} (d)	Value in accordance to EU endpoint / Reference
Fludioxonil	248.2	-	-	*Tier 1: 569 d[a] (maximum lab DT_{50}) **Tier 2: 137 d[b] (maximum field DT_{50})	*Yes / EFSA (2007) / **No, [redacted] (2004), VV-330403
Metalaxyl-M	279.3	-	-	30.9 (maximum field DT_{50})	Yes / EFSA (2015)
NOA409045	265.3	0.95	72	39.8 (maximum field DT_{50})	Yes / EFSA (2015)
Sedaxane	331	-	-	438 d (maximum field DT_{50})	Yes / EFSA (2013)
CSAA798670	176	0.53	14.5	18 d (maximum lab DT_{50})	Yes / EFSA (2013)
CSCD465008	162	0.49	31.9	Tier 1: 166 d (worst case lab DT_{50}) Tier 2: 39.2 d (worst case field DT_{50}	Yes / EFSA (2013) / EFSA (2012)[c]

[a] Tier 1: worst case lab DT_{50}
[b] Tier 2: worst case non-normalised field DT_{50}
[c] Fluxapyroxad, EFSA Journal 2012; 10(1):2522

8.7.2.1 Fludioxonil

A tiered approach was followed for the PECs assessment of fludioxonil using the worst case laboratory DT_{50} value of 569 days reported in the **EFSA Scientific Report (2007)** in Tier I and the maximum DT_{50} value of 137 days in Tier II derived from field dissipation trials including soil incorporation of the substance ([redacted] (2004), VV-330403). These trials are not yet EU evaluated.

Given the DT_{50} and DT_{90} of fludioxonil are > 100 d and 365 d respectively, as shown in chapter 8.3, calculations to estimate potential accumulation of fludioxonil were undertaken.

Table 8.7-3: PEC_S for fludioxonil on sugar beet (1 x 0.97 g a.s./ha)

PEC_S (mg/kg)		Sugar beet			
		Tier I (DT_{50} 569 d)		Tier II (DT_{50} 137 d)	
		Actual	TWA	Actual	TWA
$PEC_{S,ini}$		0.001	-	0.001	-
Short term	24h	0.001	0.001	0.001	0.001
	2d	0.001	0.001	0.001	0.001
	4d	0.001	0.001	0.001	0.001
Long term	7d	0.001	0.001	0.001	0.001
	14d	0.001	0.001	0.001	0.001
	21d	0.001	0.001	0.001	0.001
	28d	0.001	0.001	0.001	0.001
	42d	0.001	0.001	0.001	0.001
	50d	0.001	0.001	0.001	0.001
	100d	0.001	0.001	0.001	0.001
$PEC_{S,plateau}$ (20 cm) with tillage after year 10 (Tier 1), year 4 (Tier 2)		<0.001	-	<0.001	-
$PEC_{S,accumulation}$ ($PEC_{S,accumulation} = PEC_{S,ini} + PEC_{S,plateau}$)		0.002	-	0.001	-

PEC_S of metabolites

The metabolic pathway for fludioxonil degradation in soil was determined from laboratory data. Fludioxonil is rapidly degraded in laboratory photolysis studies to form several degradation products, whilst degradation under the conditions of laboratory soil metabolism studies conducted in the absence of light was slower and no degradation products were isolated or identified. Since the present use is a seed treatment, exposure to light and thus formation of the metabolites is not relevant.

8.7.2.2 Metalaxyl-M and its metabolites

Given the DT_{50} and DT_{90} of metalaxyl-M are < 100d and 365d respectively, as shown in Section 8.3, calculations to estimate potential accumulation of metalaxyl-M were not undertaken.

Table 8.7-4: PEC_S for metalaxyl-M on sugar beet (1x 0.62 g a.s./ha)

PEC_S (mg/kg)		**Sugar beet**	
		Actual	**TWA**
$PEC_{S,ini}$		0.001	-
Short term	24h	0.001	0.001
	2d	0.001	0.001
	4d	0.001	0.001
Long term	7d	0.001	0.001
	14d	0.001	0.001
	21d	0.001	0.001
	28d	<0.001	0.001
	42d	<0.001	0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001

PEC_S of metabolites

Given the DT_{50} and DT_{90} of NOA409045 is < 100 d, as shown in section 8.3.1 calculations to estimate potential accumulation of NOA409045 were not undertaken.

Table 8.7-5: PEC_S for NOA409045

Crop	**PEC_S (mg/kg)**	**Single application**
Sugar beet 1 x 0.62 g a.s./ha	$PEC_{S,ini}$	0.001

8.7.2.3 Sedaxane and its metabolites

The rate of degradation in soil of sedaxane was evaluated during the EU review. Two major soil metabolites CSAA798670 (pyrazole acid) and CSCD465008 (N-desmethyl pyrazole acid) were identified. PEC_S of these metabolites has been assessed based on the initial PEC_S of the parent compound in consideration of molar mass correction and the maximum occurrence of the metabolites in soil.

Given the DT_{50} and DT_{90} of sedaxane are > 100 d and 365 d respectively, as shown in chapter 8.3, calculations to estimate potential accumulation of sedaxane were undertaken.

Table 8.7-6: PEC_S for sedaxane on sugar beet (1x 0.65 g a.s./ha)

PEC_S (mg/kg)		Sugar beet Actual	Sugar beet TWA
$PEC_{S,ini}$		0.001	-
Short term	24h	0.001	0.001
	2d	0.001	0.001
	4d	0.001	0.001
Long term	7d	0.001	0.001
	14d	0.001	0.001
	21d	0.001	0.001
	28d	0.001	0.001
	42d	0.001	0.001
	50d	0.001	0.001
	100d	0.001	0.001
$PEC_{S,plateau}$ (20 cm) with tillage after year 9		<0.001	-
$PEC_{S,accumulation}$ ($PEC_{S,accumulation} = PEC_{S,ini} + PEC_{S,plateau}$)		0.001	-

PEC_S of metabolites

Given the DT_{50} and DT_{90} of CSAA798670 and Tier 2 calculations with CSCD465008 are < 100 d, as shown in chapter 8.3.1, calculations to estimate potential accumulation were not undertaken.

Given the Tier 1 DT_{50} and DT_{90} of CSCD465008 are > 100 d and 365 d respectively, as shown in chapter 8.3.1, calculations to estimate potential accumulation of CSCD465008 were undertaken for Tier 1.

Table 8.7-7: PEC_S for CSAA798670

Crop	PEC_S (mg/kg)	Single application
Sugar beet 1 x 0.65 g a.s./ha	$PEC_{S,ini}$	<0.001

Table 8.7-8: PEC$_S$ for CSCD465008 (Tier 1)

Crop	PEC$_S$ (mg/kg)	Single application
Sugar beet 1 x 0.65 g a.s./ha	PEC$_{S,ini}$	<0.001
	Minimum plateau concentration (20 cm) with tillage (after year 4)	<0.001
	PEC$_{accumulation}$ (PEC$_{act}$ (5 cm) +PEC$_{soil\ plateau}$ (20 cm))	<0.001

Table 8.7-9: PEC$_S$ for CSCD465008 (Tier 2)

Crop	PEC$_S$ (mg/kg)	Single application
Sugar beet 1 x 0.65 g a.s./ha	PEC$_{S,ini}$	<0.001

8.7.2.4 PEC$_S$ of A20607B

Table 8.7-10: PEC$_S$ for A20607B on sugar beet

Active substance/ preparation	Application rate (g/ha)	PEC$_{S,ini}$ (mg/kg)	21 d PEC$_{S,twa}$ (mg/kg)	Tillage depth (cm)	PEC$_{S,plateau}$ (mg/kg)	PEC$_{S,accumulation}$
A20607B	44.7 [a]	0.0596	-	5	-	-

[a] The rate of formulation was based on a specific density of 1.032 g/mL with a maximum application of 43.3 mL product/ha

8.8 Predicted Environmental Concentrations in groundwater (PEC$_{GW}$) (KCP 9.2.4)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

Name of authority: HSE Chemicals Regulation Division (CRD), UK

Fate & Behaviour Reviewer's comments

PECgw

This Article 7 assessment only concerns the active substance metalaxyl-M, therefore the applicant's PECgw values for the other active substances, fludioxonil and sedaxane, have not been evaluated by HSE.

The applicant's choice of input parameters for metalaxyl-M and its soil metabolites in FOCUS groundwater modelling are shown in Table 8.8-8. Deviations from the values used in the groundwater modelling presented in the EFSA Conclusion are highlighted in Table 8.8-8 by HSE in yellow and explained below:

- Metalaxyl-M Koc, arithmetic mean of 78.9 (Kom 45.8). The EFSA Conclusion list of endpoints presents a median Koc of 40 mL/g and an arithmetic mean of 78.9 mL/g from a database of 25 values. The median of 40 mL/g was used in modelling. The guidance on selection of input parameters for FOCUSgw modelling most likely to be in place at the time of assessment (Generic guidance version 2.1 of December 2012) stated that generally the arithmetic mean Koc (or Kom for PEARL) should be used but where a large number of data points were available a median 'may be more appropriate'. A footnote gave the following clarification with respect to the circumstances in which the median might be used: "*Those carrying out simulations may wish to be aware that as a 'rule of thumb' evaluating experts from Member States competent authorities consider 9 or more reliable values constitutes a large enough number of data points to consider using a median value.*" Given the large database of values, the use of the median Koc of 40 mL/g in the EFSA Conclusion appears to be more appropriate according to the guidance in place at that time than the arithmetic mean of 78.9 mL/g. If a change were to be made to the Koc value used in modelling it is considered more appropriate to adopt the guidance on Koc selection introduced by the EFSA DegT50 guidance and adopted in Generic FOCUSgw guidance version 2.2 and later which is that the geometric mean Koc should be used, irrespective of the size of the database. This would result in a value of 50.6 mL/g. However, for the purposes of this assessment, the median Koc value of 40 mL/g (Kom 23.2 mL/g) has been used by HSE. HSE notes that this will provide a more conservative assessment of groundwater leaching potential, at least for the a.s., than the value proposed by the applicant.

- NOA409045 geometric mean DT50 of 30.5 days used instead of geometric mean DT50 of 31.3 days used in EFSA Conclusion. The difference of opinion arises from the fact that there are two soils within the laboratory dataset for this metabolite where there are two results for each soil. In the EFSA Conclusion, the arithmetic mean of the two results for each soil was taken and these were used in the calculation of the overall geometric mean for the dataset. The applicant states that this is an incorrect calculation and has calculated the geometric mean of the two results for each soil and then used these in the calculation of the overall geometric mean for the dataset. HSE notes that over the history of the EU review process there has been much discussion over the best approach to take in such situations. At the time it was common for averaging of multiple values for the same soil to be performed before the overall geomean of the data set was calculated. It is likely that there were examples where either arithmetic mean or geometric mean of the 'same' soils was calculated before calculating the overall geometric mean for the dataset. A more definitive principle to deciding on whether multiple results are from the 'same' soil has subsequently been developed by EFSA in a more general way, this being in the EFSA Opinion on Aged Sorption Guidance (EFSA Journal 2018;16(8):5382). However this guidance post-dates the EFSA Conclusion on metalaxyl-M by three years and should not be applied. In addition this EFSA Opinion does not equivocally state whether arithmetic or geometric mean should be used in these instances. The applicant's approach taken in this submission seems more consistent with the approach of calculating a geometric mean value for the entire dataset and HSE can accept the change. HSE also notes that the original motivation for adopting geometric mean of degradation parameters was that use of arithmetic mean could lead to inconsistency between averaging of DT50 values and averaging of rate constants, i.e. the DT50 calculated from the arithmetic mean of a dataset of rate constants will be different to the arithmetic mean of the same dataset of DT50 values. Use of geometric mean avoids such inconsistency. The change in DT50 from 31.3 days to 30.5 days is unlikely to result in a major change in predicted concentrations in groundwater.
- NOA409045 arithmetic mean Koc/Kom 17.9 / 10.4 mL/g. In the EFSA Conclusion List of End Points both an arithmetic mean and a median value are listed. This is because there are 14 soil adsorption data points. As noted in the discussion of Koc/Kom value for metalaxyl-M, at the time of assessment the guidance allowed the use of a median value where there were a large number of data points, i.e. 9 or more. In this case, the Koc used in groundwater modelling described in the EFSA Conclusion is 12.1 mL/g, which is the median value. However the EFSA Conclusion incorrectly states in the description of the groundwater modelling input parameters that this is the arithmetic mean

value. As the median value was used in the EFSA Conclusion modelling it is more appropriate to use the median rather than the arithmetic mean as that was the guidance at the time of assessment. HSE notes that the median value will lead to a more conservative groundwater exposure assessment for this metabolite.

- CGA67868 1/n arithmetic mean of 0.896 used instead of 0.9. The EFSA Conclusion indicates that the value of 0.9 was used as a parameter in FOCUSgw modelling . However the listing of the soil adsorption endpoints for this metabolites lists the arithmetic mean 1/n as 0.896. Thus the use of the more precise value is acceptable.
- SYN546520 Tier 2 formation fraction of 0.10. Whilst the EFSA Conclusion lists a formation fraction of 0.10 in the agreed list of endpoints, this value was not used in the FOCUSgw modelling presented in the EFSA Conclusion. The text in section 4 of the EFSA Conclusion indicates that the use of the formation fraction of 0.47 was consistent with the FOCUS Kinetics (2006) guidance. It was stated that the inverse-modelled value of 0.10 from a single lysimeter study soil could be used within the context of calculating an arithmetic mean when more data were available. Thus the EFSA Conclusion makes it clear that using the formation fraction of 0.10 is not possible without additional data. The applicant submitted new data to support this change in formation fraction. However, the EFSA Conclusion indicates that this metabolite was not considered to be a relevant metabolite and appeared to pass the appropriate risk assessments in the EU Review with predicted concentrations of >10 µg/L. The applicant has not justified why it is necessary to refine the formation fraction of this metabolite for the GB assessment. Given the absence of an appropriate justification for attempting to refine the formation fraction, the data have not been assessed. Consequently, HSE does not agree with the Tier 2 parameters for modelling SYN546520.
- Values of molecular weight and water solubility were not listed in the EFSA Conclusion with the data used for groundwater modelling. However the values were presented in the CP documents in the RAR and can be accepted.

The metabolism scheme at Figure 8.8-1 is appropriate and in accordance with the information given in the EFSA Conclusion for the conduct of the FOCUSgw modelling.

Given the difference in opinion in some input parameters, HSE performed simulations using PEARL and PELMO for all substances and with MACRO for metalaxyl-M and NOA409045. The secondary metabolites were not simulated in MACRO because CGA67868 was never predicted at >0.001 µg/L with PEARL and PELMO. In addition, SYN546520 is not a relevant metabolite and in the modelling presented in the EFSA Conclusion was predicted at concentrations >10 µg/L. The PECgw values for SYN546520 calculated using PEARL and PELMO for 'Vibrance SB' are considerably lower than 10 µg/L. Thus the concerns over CGA67868 and SYN546520 are considered to be minimal. It should also be borne in mind that as these are secondary metabolites, any attempts to model them with MACRO are likely to be compromised as the input parameters must be altered to compensate for the fact that formation via NOA409045 cannot be simulated.

Details of parameters used in HSE simulations are given below.

Table HSE 8.8-01: HSE application input parameters used for calculating PECgw values

Parameter	**Value**
Crop Type	Sugar beet
Crop Interception	0%
Dose Reaching Soil (g a.s./ha)	0.62
Number of Applications	1
Application Interval	Not applicable

(days)	
Application Date (scenario definition planting dates in FOCUSgw Generic Guidance v 2.2)	Chateaudun: 25 March (Julian day 84) Hamburg: 1 April Kremsmunster 1 April Okehampton: 10 April
Application Type	Annual
Other application details	Seed treatment, therefore residue placed at 5cm depth[1].

[1] Applicant set incorporation/injection depth to 2cm. 5cm depth chosen by HSE as conservative value for leaching assessment. British Beet Research Organisation advice is for drilling depth of 2-3.5cm. Depth used by HSE is in-line with mixing depth assumed for standard PECsoil calculations and therefore is conservative compared to the 2cm depth used by the applicant.

It is noted that the simulation of annual applications is likely to be worst-case for sugar beet as this crop would normally be grown on a longer rotation. It is not known whether fodder beet could be grown more frequently, so the assumption of annual use is appropriately precautionary.

Table HSE 8.8-02: HSE selection of substance input parameters used for calculating PECgw values.

Parameter	Metalaxyl-M	NOA409045	CGA67868	SYN546520
Molecular Mass (g/mol)	279.3	265.3	193.2	295.3
Solubility (mg/L at 25°C)	26000	265000	45800	265000
Vapour Pressure (Pa)	0.0033 (25°C)	1×10^{-5} (20°C)	1×10^{-5} (20°C)	1×10^{-5} (20°C)
DT50 (d)	6.5	30.5	2.9	96.8
Koc / Kom (mL/g)	40 / 23.2	12.1 / 7.02	19.0 / 11.0	15.2 / 8.82
1/n	0.955	0.928	0.896	1.1
Formation Fraction	-	0.783 from a.s.	0.53 from NOA409045	0.47 from NOA409045
Metabolite conversion factor for MACRO	-	0.744	Not used	Not used
Q10	2.58	2.58	2.58	2.58
Plant Uptake Factor	0	0	0	0

PECgw from HSE simulations are shown below.

Table HSE 8.8-03: PECgw values for metalaxyl-M and its soil metabolites. Calculated by the HSE evaluator using PEARL 4.4.4.

Scenario	**80th Percentile PECgw at 1 m soil depth (μg/L)**			
	Metalaxyl-M	NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	0.018	<0.001	0.062
Hamburg	<0.001	0.020	<0.001	0.093
Kremsmünster	<0.001	0.012	<0.001	0.049
Okehampton	<0.001	0.011	<0.001	0.040

Table HSE 8.8-04: PECgw values for metalaxyl-M and its soil metabolites. Calculated by the HSE evaluator using PELMO 5.5.3.

Scenario	80th Percentile PECgw at 1 m soil depth (µg/L)			
	Metalaxyl-M	NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	0.013	<0.001	0.074
Hamburg	<0.001	0.014	<0.001	0.066
Kremsmϋnster	<0.001	0.012	<0.001	0.051
Okehampton	<0.001	0.013	<0.001	0.039

Table HSE 8.8-05: PECgw values for metalaxyl-M and its soil metabolites. Calculated by the HSE evaluator using MACRO 5.5.4.

Scenario	80th Percentile PECgw at 1 m soil depth (µg/L)			
	Metalaxyl-M	NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	0.007	Not calculated	Not calculated

All PECgw values from HSE simulations were similar to those calculated by the applicant in Tables 8.8-9, -10 and -11 and were all <0.1 µg/L.

Table HSE 5.4-06: Maximum PECgw values suitable for use in the environmental risk assessment of 'Vibrance SB'.

Substance	**Max PECgw (µg/L)**	**Note**
Metalaxyl-M	<0.001	All scenarios and models
NOA409045	0.020	PEARL, Hamburg
CGA67868	<0.001	All scenarios and models
SYN546520	0.093	PEARL, Hamburg

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU review of fludioxonil (**EFSA Scientific Report 2007; 110:1-85**), metalaxyl-M, **(Metalaxyl-M; EFSA Journal 2015; 13(3):3999**), and sedaxane (**EFSA Journal 2013; 11(1):3057**).

8.8.1 Justification for new endpoints

For estimation of the PEC in groundwater (PEC_{GW}) of fludioxonil, metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 and sedaxane and its metabolite CSAA798670, no new endpoints were defined. PEC_{GW} has been assessed with FOCUS groundwater models and the endpoints proposed in Section 8.3 to 8.5 in accordance with the **EFSA Scientific Report (2007)** for fludioxonil, **EFSA Journal (2013)** for sedaxane and **EFSA Journal (2015)** for metalaxyl-M.

For sedaxane metabolite CSCD465008, it has been deemed appropriate to consider an additional field soil dissipation study ([redacted] et al., 2011), kinetic analysis ([redacted], 2009b) and adsorption study ([redacted] & [redacted], 2009) - these studies have all been reviewed for the EU approval of fluxapyroxad **EFSA Journal (2012)**.
The PEC of sedaxane metabolite CSCD728931 in groundwater (PEC_{gw}) has been assessed using endpoints proposed in Section 8.3 to 8.5 based on new degradation and sorption data provided for this as-

sessment. The CSCD728931 degradation pathway was simulated considering additional laboratory soil degradation data ([redacted] (2013), VV-406128), kinetic analysis ([redacted] (2013), VV-628062) and a sorption study ([redacted] (2013), VV-628062).

8.8.2 Active substances and relevant metabolites (KCP 9.2.4.1)

The following groundwater modelling has not previously been reviewed and is provided in support of this assessment in Appendix 3.

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	10
Crop	Sugar beet
Application rate (g a.s./ha)	Fludioxonil: 0.97 Metalaxyl-M: 0.62/0.65[a] Sedaxane: 0.65
Number of applications/interval (d)	1/-
BBCH growth stage[a]	00
Crop interception (%)	0
Application method	Seed treatment
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, MACRO v5.5.4

[a] Modelling has been performed using both 0.62 and 0.65 g a.s./ha (rate in GAP is 0.62 g a.s./ha)
[b] Application dates were chosen according to Appdate 3.06[5] (for details, see modelling report summarised in Appendix 3).

Table 8.8-2: Application dates used for groundwater risk assessment

Crop	Scenario	Application dates (absolute)
Sugar beet Use No.1	Châteaudun	25-Mar (84)*
	Hamburg	01-Apr
	Kremsmünster	01-Apr
	Okehampton	10-Apr

* Numbers in brackets indicate Julian day numbers as entered in MACRO v5.5.4 for the scenario Châteaudun

8.8.2.1 Fludioxonil and its metabolites

Major metabolites of fludioxonil are formed through photolysis. Although endpoints are given in the EFSA Conclusion for the metabolites CGA265378, CGA339833 and CGA192155, it is also stated that the degradation following seed treatment use differs to foliar use as these metabolites are formed primarily through photolysis, thus in the light rather than in the dark. Therefore, for seed treatment use, these metabolites are not considered further.

[5] [redacted] (2019). AppDate – Estimation of application dates based on crop development. Version 3.06 (28 Jun 2019).

Table 8.8-3: Input parameters related to active substance fludioxonil for PEC_{GW} calculations

Compound	Fludioxonil	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	248.2	Yes / EFSA (2007)
Water solubility (mg/L) (25°C)	1.8	Yes / EFSA (2007)
Saturated vapour pressure (Pa)	0	Worst case
DT_{50} in soil (d), laboratory data	164 Median of laboratory studies, n=9 (normalised at 20°C and pF2)	Yes / EFSA (2007)
Transformation rate[a]	0.004227 (Fludioxonil → CO_2)	Calculated
K_{FOC} / K_{FOM} (mL/g)	145600 / 84455 Arithmetic mean, n=5	Yes / EFSA (2007)
1/n	1 Arithmetic mean, n=5	Yes / EFSA (2007)
Plant uptake factor	0	Worst case
Formation fraction	-	-

[a] For PELMO; (ln(2) / DT_{50})

Table 8.8-4: PEC_{GW} for fludioxonil on sugar beet with FOCUS PEARL 4.4.4 (A 3.7, [redacted] & [redacted] 2020, VV-858626)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)
		fludioxonil
Sugar beet 1 x 0.97 g a.s./ha BBCH 00	Châteaudun	<0.001
	Hamburg	<0.001
	Kremsmünster	<0.001
	Okehampton	<0.001

Table 8.8-5: PEC_{GW} for fludioxonil on sugar beet with FOCUS PELMO v5.5.3 (A 3.7, [redacted] & [redacted] 2020, VV-858626)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)
		Fludioxonil
Sugar beet 1 x 0.97 g a.s./ha BBCH 00	Châteaudun	<0.001
	Hamburg	<0.001
	Kremsmünster	<0.001
	Okehampton	<0.001

Table 8.8-6: PEC$_{GW}$ for fludioxonil on sugar beet with MACRO v5.5.4 (A 3.7, [redacted] & [redacted] 2020, VV-858626)

Crop	Scenario	80th Percentile PECGW at 1 m Soil Depth (µg/L)
		Fludioxonil
Sugar beet 1 x 0.97 g a.s./ha BBCH 00	Châteaudun	<0.001

Table 8.8-7: Summary of maximum PEC$_{GW}$ across all models for fludioxonil (A 3.7, [redacted] & [redacted] 2020, VV-858626)

Crop	80th Percentile PECGW (µg/L)	Model and Version Number	Scenario
Sugar beet 1 x 0.97 g a.s./ha BBCH 00	<0.001	All models	All scenarios

8.8.2.2 Metalaxyl and its metabolites

Table 8.8-8: Input parameters related to active substance Metalaxyl-M and metabolites for PEC$_{GW}$ calculations

Compound	Metalaxyl-M	NOA409045	CGA67868	SYN546520	Value in accordance with EU endpoint / reference
Molar mass (g/mol)	279.3	265.3	193.2	295.3	Yes / EFSA (2015)
Water solubility (mg/L) (25°C)	26000	265000	45800 [redacted] (2012)	265000 not available, value of NOA 409045 used	Yes / EFSA (2015)
Saturated vapour pressure (Pa)	0.0033 (25°C)	1 x 10^{-5} (20°C)	1 x 10^{-5} (20°C)	1 x 10^{-5} (20°C)	Yes / EFSA (2015)
DT_{50} in soil (d), laboratory data	6.5 Median (n = 10) EFSA, 2015	30.5[c] Geometric mean, n=8 (normalised at 20°C and pF2)	2.9 Geometric mean, n=3 (normalised at 20°C and pF2)	96.8 Geometric mean, n=3 (normalised at 20°C and pF2)	Yes / EFSA (2015)
Transformation rate	0.083498 (Metalaxyl M→NOA409045) 0.023140 (Metalaxyl-M→ CO_2)	Tier 1[a]: 0.01068 (NOA409045 → SYN546520) 0.01204 (NOA409045 → CGA67868) 0 (NOA409045 → CO_2) Tier 2[a]: 0.00227	0.23902 (CGA67868 → CO_2)	0.00716 (SYN546520 → CO_2)	Calculated

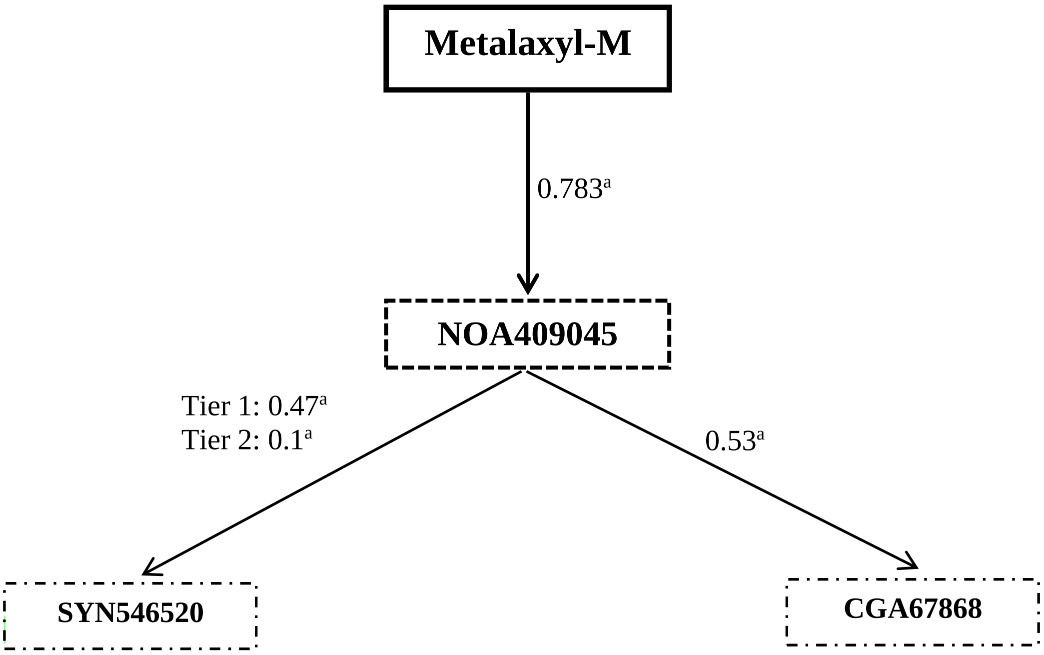
Compound	Metalaxyl-M	NOA409045	CGA67868	SYN546520	Value in accordance with EU endpoint / reference
		(NOA409045 → SYN546520) 0.01204 NOA409045 → CGA67868 0.00841 (NOA409045 → CO_2)			
K_{FOC} / K_{FOM} (mL/g)	78.9 / 45.8 Arithmetic mean, n=25	17.9 / 10.4 Arithmetic mean, n=14	19.0 / 11.0 Arithmetic mean, n=5	15.2 / 8.82 Arithmetic mean, n=4	Yes / EFSA (2015)
1/n	0.955 Arithmetic mean, n=25	0.928 Arithmetic mean, n=14	0.896 Arithmetic mean, n=5	1.1 Arithmetic mean, n=4	Yes / EFSA (2015)
Plant uptake factor	0	0	0	0	-
Formation fraction	-	0.783 from parent	0.53 from NOA409045	0.47 (Tier 1)[a] / 0.10 (Tier 2)[a] from NOA409045	Yes / EFSA (2015)
Conversion factor for MACRO[b]	-	0.744	0.287	0.389 (Tier 1)[a] / 0.083 (Tier 2)[a]	Calculated[b]

[a] As a tiered approach, the PEC_{GW} were calculated with two different formation fractions of 0.47 (Tier 1, EFSA 2015) and 0.1 (Tier 2) for SYN546520

[b] Since MACRO can only handle a single metabolite, all metabolites were calculated as primary metabolites. Conversion factors for MACRO were calculated as:
FormationFraction(Met.) x FormationFraction(PreceedingMet.) x MolarMass(Met.) / MolarMass(Parent)

[c] The geomean value of 31.3 days (EFSA, 2015) was incorrectly calculated and thus has been re-calculated.

Figure 8.8-1: Schematic diagram of the modelled route of degradation of metalaxyl-M



Simulations using FOCUS-PELMO were performed following the metabolic pathway presented in Figure 8.8-2, below.

Figure 8.8-2: Degradation scheme for metalaxyl-M and its metabolites as used in FOCUS-PELMO

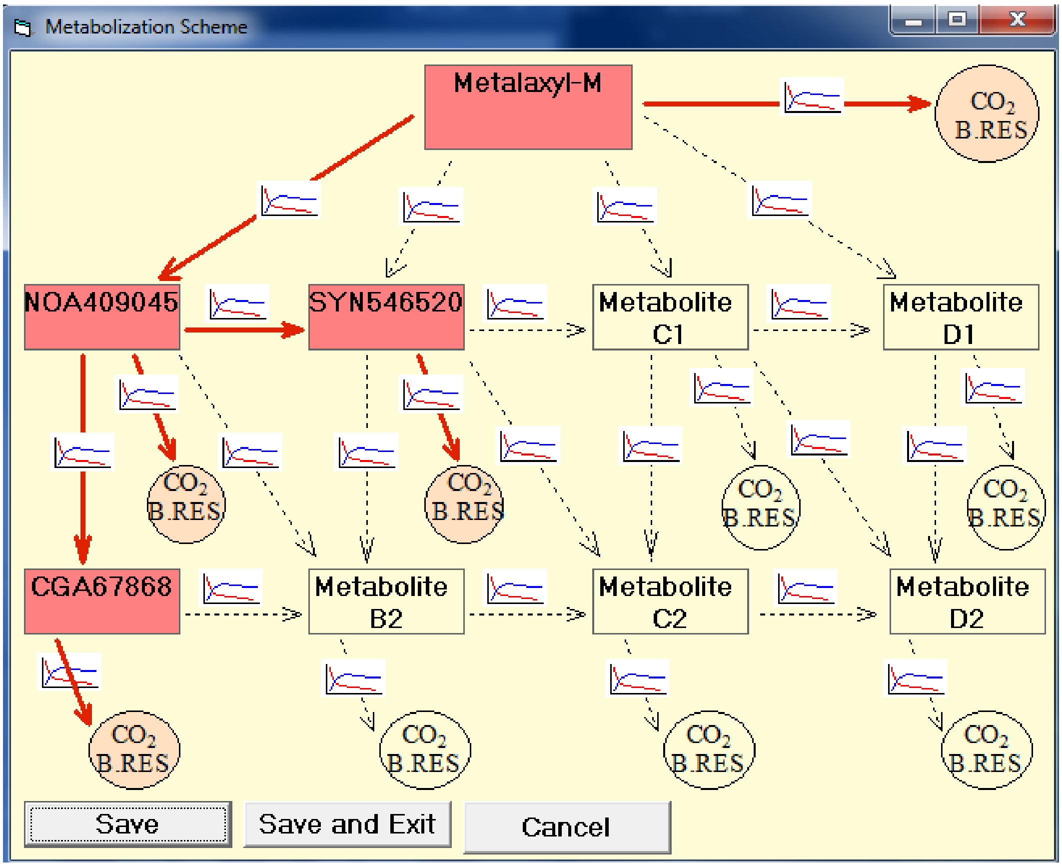


Table 8.8-9: PEC_{GW} metalaxyl-M, NOA409045, SYN546520 and CGA67868 on sugar beet with FOCUS PEARL v4.4.4 (A 3.8, [redacted] & [redacted] 2020, VV-858628)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		metalaxyl-M	NOA409045	SYN546520		CGA67868
				Tier 1	Tier 2	
Sugar beet 1 x 0.62 g a.s./ha BBCH 00	Châteaudun	< 0.001	0.012	0.063	0.014	< 0.001
	Hamburg	< 0.001	0.010	0.094	0.020	< 0.001
	Kremsmünster	< 0.001	0.007	0.048	0.010	< 0.001
	Okehampton	< 0.001	0.007	0.041	0.009	< 0.001

Table 8.8-10: PEC_{GW} metalaxyl-M, NOA409045, SYN546520 and CGA67868 on sugar beet with FOCUS PELMO v5.5.3 (A 3.8, [redacted] & [redacted] 2020, VV-858628)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	SYN546520		CGA67868
				Tier 1	Tier 2	
Sugar beet 1 x 0.62 g a.s./ha BBCH 00	Châteaudun	< 0.001	0.008	0.073	0.016	< 0.001
	Hamburg	< 0.001	0.009	0.066	0.014	< 0.001
	Kremsmünster	< 0.001	0.007	0.051	0.011	< 0.001
	Okehampton	< 0.001	0.009	0.040	0.009	< 0.001

Table 8.8-11: PEC_{GW} for metalaxyl-M, NOA409045, SYN546520 and CGA67868 on sugar beet with MACRO v5.5.4 (A 3.8, [redacted] & [redacted] 2020, VV-858628)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	SYN546520		CGA67868
				Tier 1	Tier 2	
Sugar beet 1 x 0.62 g a.s./ha BBCH 00	Châteaudun	< 0.001	0.005	0.039	0.008	< 0.001

Table 8.8-12: Summary of maximum PEC_{GW} across all models for metalaxyl-M, NOA409045, SYN546520 and CGA67868 (A 3.8, [redacted] & [redacted] 2020, VV-858628)

Crop	Substance	80th Percentile PEC_{GW} (µg/L)	Model and Version Number	Scenario
Sugar beet 1 x 0.62 g a.s./ha BBCH 00	Metalaxyl-M	<0.001	All models	All scenarios
	NOA409045	0.012	FOCUS PEARL v4.4.4	Châteaudun
	SYN546520 – Tier 1	0.094	FOCUS PEARL v4.4.4	Hamburg
	SYN546520 – Tier 2	0.020	FOCUS PEARL v4.4.4	Hamburg
	CGA67868	<0.001	All models	All scenarios

The PEC_{GW} for the metabolites NOA409045, SYN546520 and CGA67868 are all below 0.1 µg/L. Therefore, no data is required to demonstrate the non-relevance of these metabolites.

8.8.2.3 Sedaxane and its metabolites

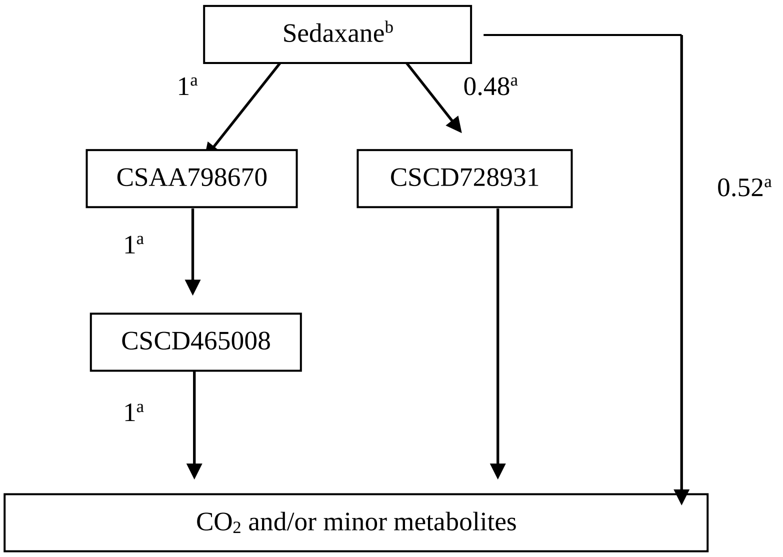
Table 8.8-13: Input parameters related to active substance sedaxane and metabolites for PEC_{GW} calculations

Compound	Sedaxane	CSAA798670	CSCD465008	CSCD728931	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	331	176	162	363.4	Yes / EFSA (2013)
Water solubility (mg/L)	14 (20°C)	100[a]	333200*	100[a]	Yes / EFSA (2013) *No[b]
Saturated vapour pressure (Pa)	1.7 x 10^{-7} (25°C)[c]	0	0	0	Worst case assumption
DT_{50} in soil (d)	100 (geomean, n=4, field, normalisation to 20°C and pF2)	8.3 (geomean, n=4, laboratory, normalisation to 20°C and pF2)	Tier 1: 114 (geomean n=4, laboratory, normalisation to 20°C and pF2) Tier 2: 25.9* (geomean n=4, field, normalisation to 20°C and pF2)	42.3** (n=5, laboratory, normalisation to 20°C and pF2)	Yes / EFSA (2013) *Yes / EFSA (2012)[d] **No / [redacted] (2013), VV-628062
Conversion factor for Macro	--	0.53	0.49	0.53	Calculated[e]
Transformation rate (1/day)	P → sink / CO_2: 0.0036 P→CSAA79867: 0.006931 P→CSCD72893: 0.00333	CSAA798670 →sink / CO_2: 0 CSAA798670→ CSCD465008 0.08351	Tier 1: CSCD465008→ sink / CO_2 0.00608 Tier 2: CSCD465008 →sink / CO_2: 0.026762	CSCD728931→ sink / CO_2: 0.01639	Calculated
K_{FOC} / K_{FOM}[f] (mL/g)	534* / 309.7 (arithmetic mean, n=6)	3.0* / 1.7 (arithmetic mean, n=5)	Tier 1: 2.1* / 1.2 (arithmetic mean, n=3) Tier 2: 6.0*/**/ 3.5 (arithmetic mean, n=10)	103.9***/ 60.3 (arithmetic mean, n=5)	*Yes / EFSA (2013) **Yes / EFSA (2012)[d] ***No / [redacted] (2013), VV-628062
1/n	0.865* (arithmetic mean, n=6)	0.9* (arithmetic mean, n=5)	Tier 1: 0.85* (arithmetic mean, n=3) Tier 2: 0.93*/** (arithmetic mean,	0.89*** (arithmetic mean, n=5)	*Yes / EFSA (2013) **Yes / EFSA (2012)[d] ***No / [redacted] (2013), VV-628062

Compound	Sedaxane	CSAA798670	CSCD465008	CSCD728931	Value in accordance to EU endpoint / Reference
			n=10)		
Plant uptake factor	0	0	0	0	Yes / EFSA (2013)
Formation fraction	-	1 from parent	1 from metabolite CSAA798670 (worst case)	0.48* from parent	Yes / EFSA (2013) *No / [redacted] (2013), VV-628062

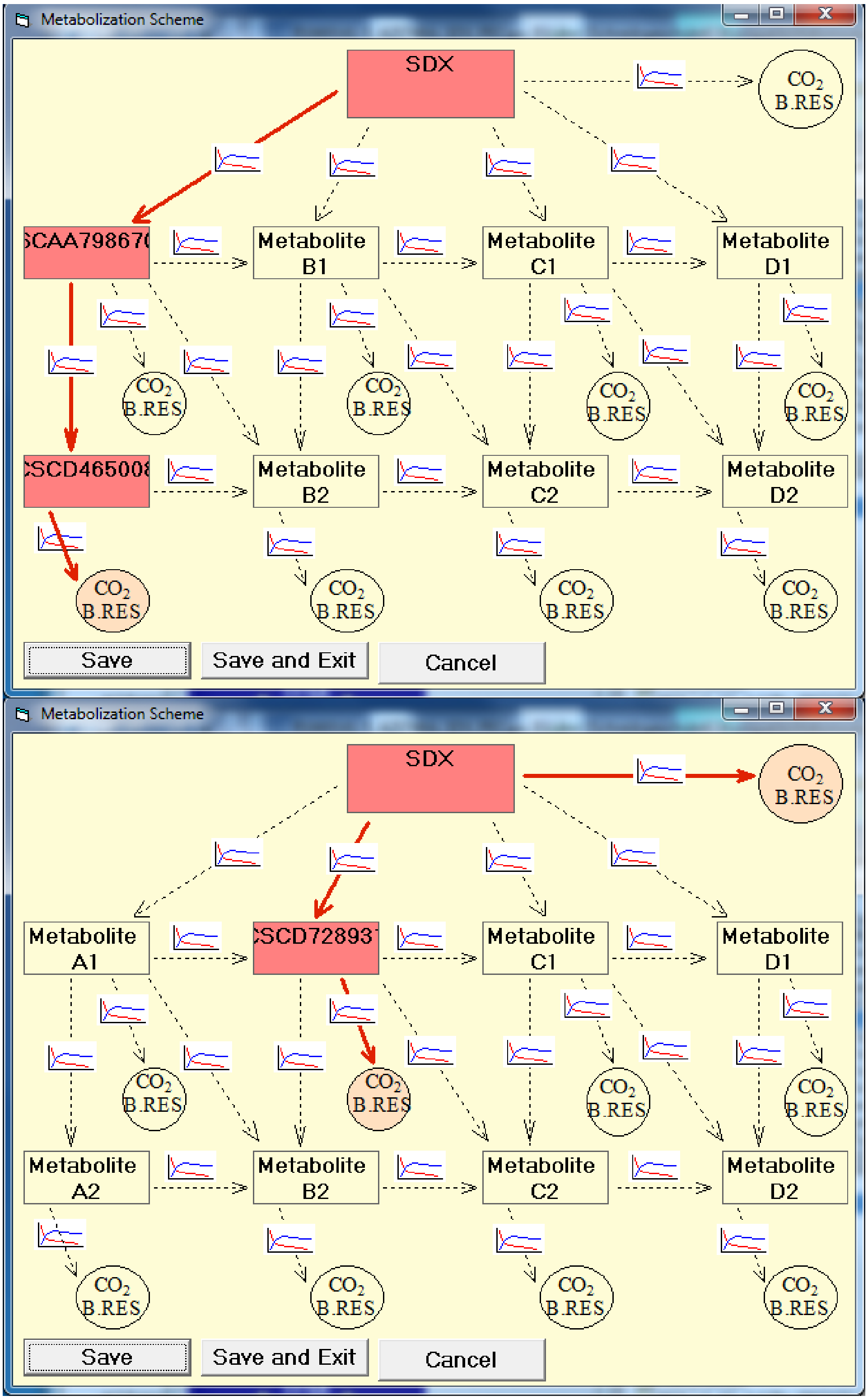
[a] Assumed as a conservative approach
[b] This value differs from the value proposed by EFSA. However, it is not a sensitive parameter and has no influence on the results
[c] Set to 0; field degradation data used for sedaxane so vaporisation should not be considered
[d] Fluxapyroxad, EFSA Journal 2012; 10 (1):2522
[e] Since MACRO can only handle a single metabolite, all metabolites were calculated as primary metabolites. Conversion factors for MACRO were calculated as:
FormationFraction(Met.) x FormationFraction(PreceedingMet.) x MolarMass(Met.) / MolarMass(Parent)
[f] Calculated: $K_{FOM} = K_{FOC} /1.724$

Figure 8.8-3: Schematic diagram of the modelled route of degradation of sedaxane



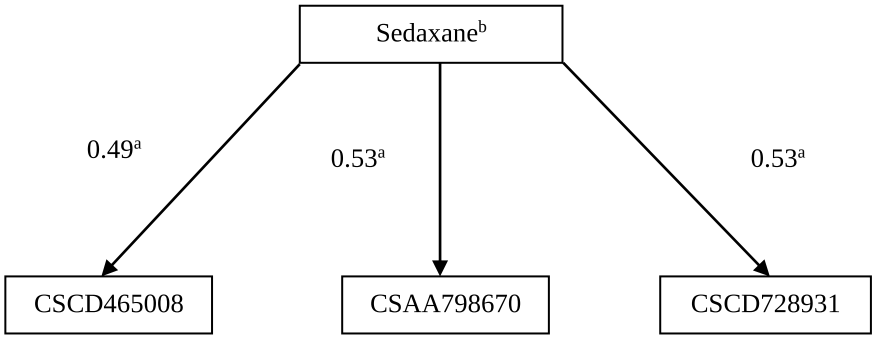
[a] Formation fraction
[b] The degradation pathways sedaxane→CSAA798670→CSCD465008 and sedaxane→CSCD728931 where simulated separately in PELMO in order to account for the worst case formation fraction for all metabolites

Figure 8.8-4: Degradation scheme for sedaxane and its metabolites as used in FOCUS-PELMO



Since MACRO can only handle a single metabolite, all metabolites were calculated as primary metabolites:

Figure 8.8-5: Degradation scheme for sedaxane and its metabolites as used in FOCUS-MACRO



[a] Conversion factor

Table 8.8-14: PEC$_{GW}$ sedaxane, CSAA798670, CSCD465008 and CSCD728931 on sugarbeet with FOCUS PEARL v4.4.4 (A 3.9, [redacted] & [redacted] 2020, VV-858630)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		sedaxane	CSAA798670	CSCD465008		CSCD728931
				Tier 1	Tier 2	
Sugar beet 1 x 0.65 g a.s./ha BBCH 00	Châteaudun	< 0.001	0.001	0.080	0.020	< 0.001
	Hamburg	< 0.001	0.004	0.129	0.036	< 0.001
	Kremsmünster	< 0.001	0.001	0.069	0.016	< 0.001
	Okehampton	< 0.001	0.002	0.057	0.017	< 0.001

Table 8.8-15: PEC$_{GW}$ sedaxane, CSAA798670, CSCD465008 and CSCD728931 on sugarbeet with FOCUS PELMO v5.5.3 (A 3.9, [redacted] & [redacted] 2020, VV-858630)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		sedaxane	CSAA798670	CSCD465008		CSCD728931
				Tier 1	Tier 2	
Sugar beet 1 x 0.65 g a.s./ha BBCH 00	Châteaudun	< 0.001	0.001	0.094	0.015	< 0.001
	Hamburg	< 0.001	0.004	0.093	0.026	< 0.001
	Kremsmünster	< 0.001	0.001	0.071	0.017	< 0.001
	Okehampton	< 0.001	0.002	0.056	0.018	< 0.001

Table 8.8-16: PEC$_{GW}$ for sedaxane, CSAA798670, CSCD465008 and CSCD728931 on sugar beet with MACRO v5.5.4 (A 3.9, [redacted] & [redacted] 2020, VV-858630)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Sedaxane	CSAA798670	CSCD465008		CSCD728931
				Tier 1	Tier 2	
Sugar beet 1 x 0.65 g a.s./ha BBCH 00	Châteaudun	< 0.001	0.001	0.055	< 0.001	< 0.001

Table 8.8-17: Summary of maximum PEC$_{GW}$ across all models for sedaxane, CSAA798670, CSCD465008 and CSCD728931 (A 3.9, [redacted] & [redacted] 2020, VV-858630)

Crop	Substance	80th Percentile PEC$_{GW}$ (µg/L)	Model and Version Number	Scenario
Sugar beet 1 x 0.65 g a.s./ha BBCH 00	Sedaxane	<0.001	All models	All scenarios
	CSAA798670	0.004	FOCUS PEARL v4.4.4 / FOCUS PELMO v5.5.3	Hamburg
	CSCD465008 – Tier 1	0.129	FOCUS PEARL v4.4.4	Hamburg
	CSCD465008 – Tier 2	0.036	FOCUS PEARL v4.4.4	Hamburg
	CSCD728931	<0.001	All models	All scenarios

The PEC$_{GW}$ for the metabolites CSAA798670 and CSCD728931 are all below 0.1 µg/L. Therefore, no data is required to demonstrate the non-relevance of these metabolites. The PEC$_{GW}$ for CSCD465008 is above 0.1 µg/L at Hamburg at Tier 1. In all other scenarios in PEARL and PELMO, PEC$_{GW}$ are below 0.1 µg/L. At Tier 2 all PEC$_{GW}$ for CSCD465008 are below 0.1 µg/L.

8.9 Predicted Environmental Concentrations in surface water (PEC$_{SW}$) and sediment (PEC$_{SED}$) (KCP 9.2.5)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: HSE Chemicals Regulation Division (CRD), UK
Fate & Behaviour Reviewer's comments **PECsw** This Article 7 assessment only concerns the active substance metalaxyl-M, therefore the applicant's PECsw values for the other active substances, fludioxonil and sedaxane, have not been evaluated by HSE. As 'Vibrance SB' is a seed treatment and not applied as a spray in the field, spray drift is not a relevant route of exposure to surface water. Standard practice for seed treatments is to assess surface water exposure via drainflow. The EFSA Conclusion lists only metalaxyl-M as an ecotoxicologically relevant compound with respect to surface water and sediment. Therefore metalaxyl-M is the only substance assessed for exposure of surface water and sediment. The applicant input parameters for drainflow assessment are shown in Table 8.9-5. The applicant has considered metabolite NOA409045 in addition to the a.s. As this metabolite is not considered to be ecotoxicologically relevant for surface water and sediment HSE have not taken the applicant

calculations for this metabolite into account.

The applicant assumptions for the a.s. of molecular weight and occurrence in sediment (20.4%) are appropriate and in-line with agreed endpoints. However they have used the Koc assumption of 78.9 mL/g. As explained in the HSE comments for the groundwater assessment in section 8.8 of this evaluation, HSE do not agree with the use of this Koc value as the EU review used a median Koc of 40 mL/g in ground- and surface water assessment.

The appropriate input parameters for metalaxyl-M are given below.

Table HSE 8.9-01: Input parameters used for calculating PECsw and PECsed values of metalaxyl-M applied by 'Vibrance SB'.

Parameter	Active
Molecular Mass (g/mol)	279.3
Peak Occurrence in Sediment (%)	20.4
Application Rate (g/ha)	0.62
K_{oc} (mL/g)	40
Crop Interception (%)	0

As the applicant calculations used a Koc value that HSE are not in agreement with, HSE do not agree with the applicant results in Table 8.9-6. Results of HSE 1st tier drainflow assessment are given below.

Table HSE 8.9-02: PECsw (drainflow) and PECsed (drainflow) values for metalaxyl-M. Calculated by the HSE evaluator using the HSE 1st tier approach.

Environmental Compartment	Active
PECsw (drainflow) (µg/L)	0.091
PECsed (drainflow) (µg/kg)	0.085

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU review of fludioxonil (**EFSA Scientific Report 2007; 110:1-85**), metalaxyl-M, **(Metalaxyl-M; EFSA Journal 2015; 13(3):3999)**, and sedaxane (**Sedaxane, EFSA Journal 2013; 11(1):3057)**.

8.9.1 Justification for new endpoints

Major soil metabolites of fludioxonil are formed through photolysis. Although endpoints are given in the EFSA Conclusion for the metabolites CGA265378, CGA339833 and CGA192155, it is also stated that the degradation following seed treatment use differs to foliar use as these metabolites are formed primarily through photolysis, thus in the light rather than in the dark. Therefore, for seed treatment use, formation of these metabolites in soil is not considered further.

For metalaxyl-M and its metabolite NOA409045, the DT_{50} and K_{FOC} values used are EU agreed endpoints.

The $PEC_{SW/SED}$ of sedaxane and its metabolites CSAA798670, CSCD465008, CSCD668094 and CSCD668095 in surface water (PEC_{SW}) has been assessed using endpoints proposed in Section 8.3 to 8.5

in accordance with the **EFSA Scientific Report (2013)**.

8.9.2 Active substances, relevant metabolites and the formulation (KCP 9.2.5)

The PEC_{SW} and PEC_{SED} of fludioxonil, metalaxyl-M and sedaxane and their respective metabolites following entry *via* drainage have been assessed according to standard Tier I calculations recommended in the national requirements in the UK[6]. For the Tier I drainage assessment, applications were assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case. The calculations used in the standard drainage Tier I assessment are specified in Appendix 3.

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	A20607B
Use No.	10
Crop	Sugar beet; seed treatment
Application rate (g a.s./ha)	Fludioxonil: 0.97 Metalaxyl-M: 0.62 Sedaxane: 0.65
Number of applications/interval (d)	1/-
Application timing (No. days until drainage period)	Application assumed to occur in drainage period
Max crop interception (%)	0

8.9.2.1 Fludioxonil and its metabolites

The following PEC_{SW} and PEC_{SED} modelling for fludioxonil has not previously been reviewed and is provided in support of this assessment in Appendix 3 of this document.

Table 8.9-2: Input parameters related to active substance fludioxonil for $PEC_{SW/SED}$ calculations

Compound	Fludioxonil	CGA192155	Value in accordance to EU endpoint / Reference
Molar mass	248.2	202.1	Yes / EFSA (2007)
K_{FOC} (mL/g)	145600 Arithmetic mean, n=5	23.5 Arithmetic mean, n=5	Yes / EFSA (2007)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: - Water: - Sediment: 85.6	Soil: - Water: 11.9 Sediment: 5.5	Yes / EFSA (2007)

6 https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/fate/pecsw-sed-via-drainflow.htm (accessed May 2020)

Fludioxonil

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I drainage

Table 8.9-3: Overall maximum $PEC_{SW/SED}$ for fludioxonil due to drainage following application of A20607B (refer to Appendix 3, A 3.10)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Sugar beet 1 x 0.97 g a.s./ha	Application in drainage period	0.001	0.002

Metabolites of fludioxonil

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I Drainage

Table 8.9-4: Overall maximum $PEC_{SW/SED}$ for CGA192155 due to formation from fludioxonil due to drainage following application of A20607B (refer to Appendix 3, A 3.10)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Sugar beet 1 x 0.97 g a.s./ha	Application in drainage period	<0.001	<0.001

8.9.2.2 Metalaxyl-M and its metabolites

The following PEC_{SW} and PEC_{SED} modelling for metalaxyl-M and NOA409045 has not previously been reviewed and is provided in support of this assessment in Appendix 3 of this document.

Table 8.9-5: Input parameters related to active substance metalaxyl-M and NOA409045 for $PEC_{SW/SED}$ calculations

Compound	Metalaxyl-M	NOA409045	Value in accordance to EU endpoint / Reference
Molecular weight	279.3	265.3	Yes / EFSA (2015)
K_{FOC} (mL/g)	78.9 Arithmetic mean, n=25	17.9 Arithmetic mean, n=14	Yes / EFSA (2015)
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 20.4	Soil: 72 Water: 68.8 Sediment: 23.0	Yes / EFSA (2015)

Metalaxyl-M

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I drainage

Table 8.9-6: Overall maximum $PEC_{SW/SED}$ for metalaxyl-M due to drainage following application of A20607B (refer to Appendix 3, A 3.11)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Sugar beet 1 x 0.62 g a.s./ha	Application in drainage period	0.033	0.031

Metabolites of metalaxyl-M

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I Drainage

Table 8.9-7: Overall maximum $PEC_{SW/SED}$ for NOA409045 due to drainage following application of A20607B (refer to Appendix 3, A 3.11)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)[a]	Initial $PEC_{SED,drainage}$ (µg/Kg)[a]
Sugar beet 1 x 0.62 g a.s./ha	Application in drainage period	0.061	0.065

[a] PECs presented represent the maximum over the fraction formed in soil and the fraction formed in water.

8.9.2.3 Sedaxane and its metabolites

The following surface water modelling on sedaxane, CSAA798670, CSCD465008, CSCD668094 and CSCD668095 has not previously been reviewed and is provided in support of this assessment in Appendix 3.

Table 8.9-8: Input parameters related to active substance sedaxane, CSAA798670, CSCD465008, CSCD668094 and CSCD668095 for $PEC_{SW/SED}$ calculations

Compound	Sedaxane	CSAA798670	CSCD465008	CSCD668094	CSCD668095	Value in accordance to EU endpoint / Reference
Molecular weight	331	176	162	365	339	Yes / EFSA (2013)
K_{FOC} (mL/g)	534 Arithmetic mean, n=6	3 Arithmetic mean, n=5	2.1 Arithmetic mean, n=5	0*	0*	Yes / EFSA (2013)
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 88.4	Soil: 14.5 Water: 25.7 Sediment: -	Soil: 31.9 Water: - Sediment: -	Soil: - Water: 15.8 Sediment: -	Soil: - Water: 15.8 Sediment: -	Yes / EFSA (2013)

* Default in absence of data

Sedaxane

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I drainage

Table 8.9-9: Overall maximum $PEC_{SW/SED}$ for sedaxane due to drainage following application of A20607B (refer to Appendix 3, A 3.12)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Sugar beet 1 x 0.65 g a.s./ha	Application in drainage period	0.025	0.102

Metabolites of sedaxane

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I drainage

Table 8.9-10: Overall maximum $PEC_{SW/SED}$ for CSAA798670 due to drainage following application of A20607B (refer to Appendix 3, A 3.12)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)[a]	Initial $PEC_{SED,drainage}$ (µg/Kg)[a]
Sugar beet 1 x 0.65 g a.s./ha	Application in drainage period	0.007	-

[a] PECs presented represent the maximum over the fraction formed in soil and the fraction formed in water.

Table 8.9-11: Overall maximum $PEC_{SW/SED}$ for CSCD465008 due to drainage following application of A20607B (refer to Appendix 3, A 3.12)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Sugar beet 1 x 0.65 g a.s./ha	Application in drainage period	0.015	-

Table 8.9-12: Overall maximum $PEC_{SW/SED}$ for CSCD668094 due to drainage following single application(s) of A20607B (refer to Appendix 3, A 3.12)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Sugar beet 1 x 0.65 g a.s./ha	Application in drainage period	0.004	-

Table 8.9-13: Overall maximum $PEC_{SW/SED}$ for CSCD668095 due to drainage following single application(s) of A20607B (refer to Appendix 3, A 3.12)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Sugar beet 1 x 0.65 g a.s./ha	Application in drainage period	0.004	-

8.9.2.4 PEC_{SW} of A20607B

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: HSE Chemicals Regulation Division (CRD), UK
Fate & Behaviour Reviewer's comments **PECair** This Article 7 assessment only concerns the active substance metalaxyl-M, therefore the applicant's PECsw values for the other active substances, fludioxonil and sedaxane, have not been evaluated by HSE. For the EU Review of metalaxyl-M the EFSA Conclusion noted that the a.s. is slightly volatile with vapour pressure of 3.3 x 10^{-3} Pa at 25°C and Henry's Law constant of 3.5 x 10^{-5} Pa.m^3/mol at 25°C. However the EFSA Conclusion did not raise any particular concerns regarding exposure of air and no attempt to quantify exposure of air, (i.e. a PECair calculation) was made. It is noted that both foliar application and seed treatment uses were included in the representative uses considered in the EU review. 'Vibrance SB' is a seed treatment and thus the majority of the substance will be buried by soil at the time of drilling the treated seed. This is likely to further reduce the potential for air exposure compared to an application method such as spraying. No further consideration of air exposure is required for this product.

Studies on fate and behaviour in the air are considered to be data provided in support of the active substance.

8.10.1.1 Fludioxonil

The fate and behaviour in air of fludioxonil was evaluated during the EU review (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**). No additional studies have been performed.

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Fludioxonil
Direct photolysis in air	Not relevant
Quantum yield of direct phototransformationa	Not relevant
Photochemical oxidative degradation in air	Latitude: standard Season: standard DT_{50}: 3.6 hours (Atkinson, 1.5 x 10^6 OH radicals/cm^3, 12 hour day)
Volatilisation	Vapour pressure (Pa): 3.9 x 10^{-7} (at 25°C) Henry's Law Constant (Pa m^3/mol): 5.4 x 10^{-5} (at 25°C)
Metabolites	No potentially volatile metabolites

Fludioxonil is directly incorporated into the soil via treated seed, since A20607B is exclusively used as seed dressing. Furthermore, the vapour pressure of fludioxonil is very low (3.9 x 10-7 Pa at 25°C), and, as expected, fludioxonil was found to be non-volatile from soil. Consequently, there will be no relevant atmospheric exposure or contamination of rainwater.

8.10.1.2 Metalaxyl-M and its metabolites

The fate and behaviour in air of metalaxyl-M was evaluated during the EU review (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**). No additional studies have been performed.

Table 8.10-2 Summary of atmospheric degradation and behaviour

Compound	Metalaxyl-M
Direct photolysis in air[a]	-
Quantum yield of direct phototransformation[a]	-
Photochemical oxidative degradation in air	DT_{50} = 4.8 hours By the Atkinson method (AOP v1.92) assuming 12 h dark/12 h light
Volatilisation	from plant surfaces: 35% volatilization (after 24 h, glasshouse conditions) from soil: rate of volatilization (TRR) was calculated at 6-10 g/ha/day (35°C, 30l/h air flow) Vapour pressure (Pa): 3.3 x 10^{-3} (at 25°C) Henry's Law Constant (Pa.m^3/mol): 3.5 x 10^{-5} (at 25°C)
Metabolites[a]	-

[a] Data not available

The vapour pressure at 25 °C of the active substance metalaxyl-M is > 10^{-5} Pa. Hence the active substance metalaxyl-M is regarded as volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance metalaxyl-M due to volatilization with subsequent deposition should be considered. Nonetheless, as mitigation measures to reduce exposure to non-target or aquatic organisms (FOCUS Surface Water Step 4) were not required, and due to the short DT_{50} (< 2 days), the exposure by volatilisation is considered negligible compared to other routes (spray drift and drainage). Moreover, A20607B is a seed treatment and the seeds are buried into soil which reduces volatilisation. Thus, PEC air is deemed not required for metalaxyl-M.

8.10.1.3 Sedaxane and its metabolites

The low vapour pressure for sedaxane (6.5 x 10^{-8} Pa at 20°C) indicates a low potential for volatilisation from soil under practical conditions of use as application is made as a seed treatment. Environmental concentrations of sedaxane in the air following application will be short lived. The calculation of half-life for the reaction of the active substance in the gas phase in the troposphere was made using the Atkinson calculation and found to be 5.1 hours (**LoEP, EFSA, 2013**). The predicted concentration in air (PEC_{AIR}) will be negligible.

Table 8.10-3 Summary of atmospheric degradation and behaviour of sedaxane

Compound	Sedaxane
Direct photolysis in air	Atkinson calculation: half-life = 5.1 h
Quantum yield of direct phototransformation	0.0277 molecules degraded/photon
Photochemical oxidative degradation in air	DT_{50}: 5.1 hours as measured by AOP
Volatilisation	Vapour pressure (Pa): 6.5 x 10^{-8} (at 20°C) Henry's Law Constant (Pa m^3/mol): 4.0 x 10^{-6} (at 25°C)
Metabolites	No data

Sedaxane is directly incorporated into the soil via treated seed, since A20607B is exclusively used as seed dressing. Furthermore, the vapour pressure of sedaxane is very low (6.5 x 10^{-8} Pa at 20°C), and, as expected, sedaxane was found to be non-volatile from soil. Consequently, there will be no relevant atmospheric exposure or contamination of rainwater. Thus, PEC air is deemed not required for the active substance sedaxane.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on (Active Substance)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Fludioxonil		
KCA1 7.1.2.2.1	[redacted]	06/09/2004	Fludioxonil : Field Study Comparing Seed Treatment Dissipation Against Field Dissipation in Switzerland During 2003 Report No. RJ3547B Document No. VV-330403 , CGA173506/5993 Test Facility Syngenta - Jealott's Hill GLP Unpublished	N	SYN
			Sedaxane		
KCA3 7.1.2.1.2	[redacted].	18/11/2013	SYN546282 – Rate of Degradation of 14C-SYN546282 Report No. 20120177 Document No. VV-406128 , SYN546282_10001 Test Facility Innovative Environmental Services GLP Unpublished	N	SYN
KCA3 7.1.3.1.2	[redacted]	07/08/2013	SYN546282 - Adsorption/Desorption Properties of 14C-SYN546282 in Five Soils Report No. 20120176 Document No. VV-405131 , SYN546282_10000 Test Facility Innovative Environmental Services GLP Unpublished	N	SYN

List of data submitted or referred to by the applicant and relied on (A20607B)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1	[redacted]	26/07/2013	Sedaxane - Calculation of Kinetic Endpoints for Metabolite CSCD728931 for Modelling Purposes from Laboratory Data According to FOCUS Kinetic Guidelines Report No. RAJ1002B Document No. VV-628062 , SYN546282_10003 Test Facility Syngenta - Jealott's Hill Not GLP Unpublished	N	SYN
KCP 9.1.1	[redacted]	10/03/2015	Metalaxyl-M - Calculation of the formation fraction of the soil degradate CGA108906 for use in environmental models Report No. RAJ1079B Document No. VV-629108 , CGA329351_11688 Test Facility Syngenta - Jealott's Hill Not GLP Unpublished	N	SYN
KCP 9.1.1	[redacted]	07/02/2020	CGA108906 – Kinetic evaluation of Formation Fraction Report No. RAJ1329B VV-862458 Document No. VV-742439 Test Facility Syngenta, Ltd. Not GLP Unpublished	N	SYN
KCP 9.2.4	[redacted]	02/06/2020	A Leaching Assessment for Fludioxonil Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Sugar beet Report No. 19-016-150-6 Document No. VV-858626 Test Facility TSG Consulting Not GLP Unpublished	N	SYN

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner
KCP 9.2.4	[redacted]	26/05/2020	A Leaching Assessment for Metalaxyl-M and its Soil Metabolites NOA409045, SYN546520 and CGA67868 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Sugar beet Report No. 19-016-150-7 Document No. VV-858628 Test Facility TSG Consulting Not GLP Unpublished	N	SYN
KCP 9.2.4	[redacted]	22/05/2020	A Leaching Assessment for Sedaxane and its Soil Metabolites CSAA798670, CSCD465008 and CSCD728931 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Sugar beet Report No. 19-016-150-8 Document No. VV-858630 Test Facility TSG Consulting Not GLP Unpublished	N	SYN

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 KCA 7.1.2.2.1: [redacted] (2004), VV-330403. Fludioxonil - Field Study Comparing Seed Treatment Dissipation Against Field Dissipation in Switzerland During 2003

Reference:	KCA1 7.1.2.2.1
Report:	Fludioxonil - Field Study Comparing Seed Treatment Dissipation Against Field Dissipation in Switzerland During 2003. [redacted] 2004 Syngenta, Environmental Sciences, Jealott's Hill, International Research Centre, Bracknell, Berkshire, RG42 6EY, UK. Laboratory Project ID 03-S602, RJ3547B Syngenta file No. VV-330403
Guideline(s):	Not applicable
Deviations:	Not applicable
GLP:	Yes
Acceptability:	Yes

A 2.1.1 Executive Summary

A field trial compared the dissipation of fludioxonil applied as a seed treatment, a topical broadcast spray and an incorporated broadcast spray. Soil samples were taken for up to 90 days after treatment. Comparisons of the fludioxonil dissipation in plots exposed to sunlight, plots covered with plastic and plots over-sown with turf were also made within each treatment.

Results were erratic for the seed treatment and no conclusions could be drawn as to degradation rate. The broadcast incorporated spray gave half-lives of 104 and 105 days for plots exposed to sunlight and under turf, respectively. The plot covered with plastic gave a half-life of 70 days and a DT_{50} of 55 days. The most rapid dissipation of fludioxonil residues occurred in the topical application trial. The half-life was determined to be 22 days, for both the plot exposed to sunlight and the plot over-sown with turf.

A 2.1.2 Test System

A trial was carried out in Switzerland during 2003 to compare the dissipation of fludioxonil when applied as a seed treatment, a topical (broadcast spray) treatment and an incorporated broadcast spray treatment. Comparisons of the fludioxonil dissipation in plots exposed to sunlight, plots covered with plastic and plots over-sown with turf were also made within each trial subset, in order to evaluate the effects of the rhizosphere and of sunlight exposure on degradation.

In the seed treatment trial fludioxonil was applied as treated spring wheat seed, treated with A8348B (a 100 g/L w/v seed formulation) at a rate of 25 g a.s./100 kg seeds. A seeding rate of 300 kg seeds/ha in the plots gave an application rate equivalent to approximately 75 g a.s./ha. The rows were spaced 12 cm apart, resulting in 8 rows per square meter, resulting in around 83 seeds/m. The seeding depth was 1.5 to 3.0 cm. In the broadcast trial a single application of fludioxonil (as A7850C, a 500 g/kg w/v wettable powder formulation) was sprayed at approximately 500 g a.s./ha to the soil surface for each of the plots in the topical and incorporated trials with water volumes of 200 L/ha and 800 L/ha.

Soil samples from all the plots were nominally taken immediately after the application and on 4, 8, 16, 33, 64 and 90 DAA (Days After Application). In the seed treatment trial samples from within the rows were taken by an 8 cm corer and all other samples were taken by a 5 cm corer. Control samples were taken from each plot immediately before application. Samples were taken from the 0-30 cm soil layer, cut into three 10 cm profiles and bulked to give composite samples. Each resulting sample was homogenised (including the seeds from the seed treatment trial) and a 10 g subsample was taken for extraction and analysis. The half-life (based on unweighted simple first order kinetics, SFO), the DT_{50} and DT_{90} values (based on a first order multicompartment model, FOMC) for fludioxonil were determined for each plot using Model Manager.

A 2.1.3 Findings

The residue values for each sampling interval in the seed treatment trial were erratic for each plot and no conclusions could be drawn as to the fludioxonil dissipation rate. The reasons for the erratic residues were that it could not be guaranteed that the number of seeds within each core was the same for every core sampled at each sampling interval (an 8 cm core would contain only 6-7 seeds). The major error, however will be due to the 10 g sub-samplings (representing an equivalent amount of 0.1 treated seed grain) from the composite samples since it could also not be guaranteed that the prepared samples were homogenous, even with thorough blending, due to the localisation of the residues around the seeds.

No measurable fludioxonil residues (limit of quantification, LOQ, 0.01 mg/kg) were determined below the 0 – 10 cm soil depth for this trial (03-S602-STR), indicating no downward movement of the fludioxonil residues from seed treatments. Residues were observed between the rows at certain sampling intervals for the sterile seed plot and the seed plot over-sown with turf. However, these residue values were all obtained at sampling intervals when no germination of the seeds had occurred. It could not be guaranteed that all the cores taken at the sampling intervals were actually between the rows and not from within a row of seeds.

The broadcast spray with incorporation trial gave half-lives of 104 and 105 days for fludioxonil dissipation, for the plot exposed to sunlight and the plot over-sown with turf, respectively. The plot covered with plastic gave a half-life of 70 days and a DT_{50} of 55 days. Water condensation (formation of droplets) under the plastic were observed from 5 DAA to the end of the field phase for this plot, leading to humid conditions. These humid conditions and the fact that the fludioxonil was incorporated into the soil led to greater biochemical breakdown of the fludioxonil, which resulted in the lower DT_{50} and half-life values. No measurable fludioxonil residues (LOQ, 0.01 mg/kg) were determined below the 10 – 20 cm soil depth for this trial.

The most rapid dissipation of fludioxonil residues occurred in the topical application trial. The half-life was determined to be 22 days, for both the plot exposed to sunlight and the plot over-sown with turf. Additionally, the plot exposed to sunlight produced a DT_{90} value of 72 days. The fludioxonil dissipation was not significant in the plot covered with plastic (i.e. kept in darkness). Apart from the application day samples from each plot, no measurable fludioxonil residues (LOQ, 0.01 mg/kg) were determined below the 10 – 20 cm soil depth for this trial.

Table A 1: Summary of half-life, DT_{50} and DT_{90} values

Trial	Plot No.	Initial (day 0) recovery [%]	Half-Life [days]	Goodness of fit [r^2]	DT_{50} [days]	Goodness of fit [r^2]	DT_{90} [days]
03-S602-STR	1 (bare soil)	47	NC	NC	NC	NC	NC
	2 (bare soil)	63	NC	NC	NC	NC	NC
	3 (turf)	89	NC	NC	NC	NC	NC
03-S602-INC	4 (bare soil)	74	104	0.726	137	0.804	NC
	5 (covered)	88	70	0.838	55	0.935	NC
	6 (turf)	67	105	0.758	112	0.761	NC
03-S602-TOP	7 (bare soil)	54	22	0.757	19	0.762	72
	8 (covered)	59	NC	NC	NC	NC	NC
	9 (turf)	60	22	0.841	12	0.973	NC

NC: Not calculable within the 90 day timescale of the study

Generally, the day zero recoveries were relatively low, which might be due to a fast initial degradation (triggered by biological and photochemical processes) before the highly lipophilic fludioxonil becomes strongly bound to the soil matrix, resulting in reduced bioavailability and increased shielding from light exposure. This same behaviour has been also observed in most field studies with fludioxonil. Since DT_{50} values were usually calculated based on the day zero recoveries, those values have to be considered consequently as worst case data as they do not include this fast initial decline.

A 2.1.4 Conclusions

- Sampling is a very critical parameter in field dissipation studies with treated seeds.
- Under field conditions usually a rapid initial decline of fludioxonil residues is observed.
- There was no significant effect of the rhizosphere on degradation.
- The most efficient degradation process is controlled by photolysis.
- After incorporation into field soil fludioxonil will be degraded significantly by biotic pathways with half lives well below those observed in laboratory studies.

A 2.2 KCA 7.1.2.1.2: [redacted] (2013), VV-406128. SYN546282 – Rate of Degradation of 14C- SYN546282

Reference:	KCA3 7.1.2.1.2
Report:	SYN546282 – Rate of Degradation of 14C- SYN546282 [redacted] 2013 Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland. Report Number 20120177 Syngenta File No. VV-406128
Guideline(s):	OECD Guideline 307: Aerobic and Anaerobic Transformation in Soil, (April 2002). EPA OPPTS 835.4100, (OPP 162-1), Aerobic Soil Metabolism, US EPA October 2008. Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. SETAC-EUROPE Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides: Section 1.1 (Laboratory Aerobic Soil Degradation Studies).
Deviations:	No
GLP:	Yes (incl. certificate)
Acceptability:	Yes

A 2.2.1 Executive summary

The rate of degradation of ^{14}C-SYN546282 (CSCD728931) was investigated in four different soils: Gartenacker (loam), 18 Acres (sandy clay loam), East Anglia (sandy loam) and Sarpy (silt loam). ^{14}C-labelled SYN546282 was applied at a dose rate of 0.043 mg/kg dry weight soil, equivalent to a single field application rate of 32.3 g /ha (assuming an incorporation depth of 5 cm and a bulk density of 1.5 g/cm^3). The soils were incubated under aerobic conditions in the laboratory and maintained at a soil moisture of pF 2 under dark conditions at 20.8°C ± 0.2°C for up to 121 days. For Gartenacker and 18 Acres, duplicate samples were taken for analysis at time 0, 7 14, 21, 59, 90 and 121 days after treatment (DAT). Corresponding intervals for East Anglia were 0, 7, 14, 28, 60, 90 and 121 DAT, and for Sarpy 0, 7, 14, 28, 59, 90 and 121 DAT.

At each sampling interval, samples were extracted at room temperature up to three times with 80:20 acetonitrile/water (v/v) and once with 80:20 acetonitrile/water (v/v) adjusted to pH 3 with concentrated formic acid, followed by reflux extraction with 80:20 acetonitrile/water (v/v) for 4 hours. The cold extracts were pooled. The pooled cold and reflux extracts were individually concentrated under reduced pressure and separately analysed by HPLC for parent compound and degradation products. Selected samples were additionally analysed by thin layer chromatography (TLC) to confirm the results obtained by HPLC. Non-extractable residues were determined by combustion. Any volatile radioactivity was continuously flushed from the incubation vessels and collected in traps. A mass balance was determined for each sample.
The overall mean mass balance values were 100.2 ± 2.4%, 99.3 ± 4.1%, 100.1 ± 4.3% and 101.0 ± 3.2% of the applied radioactivity (AR) for Gartenacker, 18 Acres, East Anglia and Sarpy, respectively, whereas

the values for all individual samples ranged from 90.4% to 107.0% AR.

The amount of total extractable radioactivity was dependent on soil type and decreased in all soils with time. At time 0, the extractable radioactivity (mean of duplicates) ranged from 99.7% AR (Gartenacker) to 100.9% AR (18 Acres). By 121 DAT, the mean readily extractable radioactivity from cold extracts continuously decreased to 32.0%, 38.8%, 45.7% and 60.7% AR in Gartenacker, 18 Acres, East Anglia and Sarpy, respectively.

Additionally, mean values up to 9.6%, 20.6%, 13.9% and 19.5% AR could be extracted in Gartenacker, 18 Acres, East Anglia and Sarpy soil, respectively, by reflux extraction for 4 hours using acetonitrile/water 80:20 (v/v).

Non-extractable radioactivity reached maximum mean values of 32.4% AR in Gartenacker at the end of incubation (121 DAT) and 35.0%, 28.7% and 15.8% AR in 18 Acres, East Anglia and Sarpy, after 90 days of incubation, respectively. At the end of the incubation period (121 DAT), corresponding mean values represented 27.6%, 28.6% and 12.6% AR, respectively.

Formation of radioactive carbon dioxide reached a maximum of 24.1% AR (mean of duplicates) by the end of the incubation (121 DAT) in Gartenacker, 9.8% and 4.0% after 90 days in 18 Acres and Sarpy, respectively, and 5.8% AR after 60 days in East Anglia. Organic volatiles did not exceed 0.5% AR in Gartenacker, 0.2% in East Anglia and 0.3% AR in Sarpy throughout the study, whereas in 18 Acres, organic volatiles remained < 0.1% AR. SYN546282 degraded quickly in Gartenacker and 18 Acres soil. Slower degradation of SYN546282 was observed in East Anglia and Sarpy soil.

For time 0 samples, the mean amount of SYN546282 represented 99.7% and 100.9% of AR for Gartenacker and 18 Acres, respectively, and 100.5% of AR for East Anglia and Sarpy soil. By day 7, corresponding values were 51.0%, 46.9%, 78.3% and 87.3% AR for residues in cold extracts. Additionally, after 7 days of incubation, mean values for the reflux extracts counted for 5.6%, 6.2%, 7.8% and 7.9% AR in the respective soils. After 121 days, at the end of incubation, the mean amount of SYN546282 decreased to 10.6%, 4.6%, 7.8%, and 25.5% AR in cold extracts of Gartenacker, 18 Acres, East Anglia and Sarpy soil, respectively. Corresponding values for the reflux extractions represented 4.5%, 3.0%, 3.6% and 9.9% AR.

The rate of degradation in the soils for SYN546282 was calculated using single first-order (SFO) kinetics, using the data from the pooled cold extracts. Reflux data is excluded as this is considered a harsh procedure. The calculated degradation half-life ($DegT_{50}$) and $DegT_{90}$ values obtained are shown in Table A 2 below.

Table A 2: Degradation Kinetics for SYN546282

Soil	Degradation Kinetics for SYN546282					
	$DegT_{50}$ [days]	**$DegT_{90}$ [days]**	**k value**	**$\chi2$**	**r^2**	**Prob > t**
Gartenacker	10	33	k = 0.0698	15.94	0.961	1.161E-05
18 Acres	7	22	k = 0.1034	11.78	0.987	8.44E-09
East Anglia	35	117	k = 0.0198	7.34	0.973	1.003E-08
Sarpy	70	232	k = 0.0099	4.28	0.968	1.593E-09

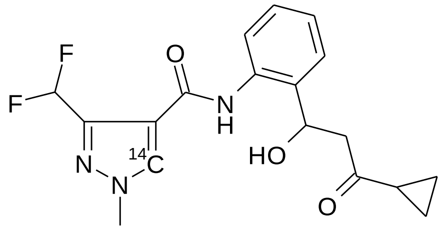
Note: SFO (single first-order kinetics; non-linear method) was applied using CAKE software (version 1.4). $DegT_{50}$: Calculated degradation half-life of parent. $\chi2$: chi-square statistical value. r^2: linear regression coefficient relating goodness of fit as value approaches unity. Soil Gartenacker (90 DAT) cold extract values were considered as outliers, and therefore excluded from parent half-life calculations.

Mean values of enantiomer levels of the unlabelled test item, as well as application solution were analysed by LC-MS/MS to be 50%:50% confirming a racemic mix. The mean values of enantiomeric fractions of the cold extracts, tested at the start and end of the incubation period, ranged from 46:54% to

66:34%. The overall mean values from the four soils were 49%:51% at 0 DAT and 54%:46% at 121 DAT.

A 2.2.2 Materials

Test Item: SYN546282



Chemical Name:	3-Difluorormethyl-1-methyl-1H-[5-^{14}C]pyrazole-4-carboxylic acid [2-(3-cyclopropyl-1-hydroxy-3-oxo-propyl)-phenyl-amide
Lot/Batch #:	5269ITH001-3
Purity:	99.0%, as re-determined by HPLC before use
Stability of Test Compound:	Stable, as determined within the study
Application Vehicle:	Water/Acetonitrile 3:1 (v/v)

Soils

Name	**Gartenacker**	**18 Acres**	**East Anglia**	**Sarpy**
Sampling location[a]	Les Barges, Vouvry Switzerland (46º19 N 6º55 E)	Jealott's Hill Farm, Bracknell, Berkshire, UK (51º27 N 0º43 W)	East Anglia, UK	Sarpy County, Lousville NE, USA (GPS 96.15085 41.03725)
Date of collection[a]	November 09, 2012	November 09, 2012	November 08, 2012	November 13, 2012
Pesticide History[a]	No treatment for 5 years	No treatment for 12 years	Not available	No treatment for 5 years
Sampling depth (cm)[a]	5-20	5-20	5-25	0-15
Storage conditions[d]	~4ºC, aerobic in the dark	~4ºC, aerobic in the dark	~4ºC, aerobic in the dark	~4ºC, aerobic in the dark
Duration of storage[d]	66/89 days	66 days	67/90 days	62 days
Soil preparation[a]	Sieved (2 mm)	Sieved (2 mm)	Sieved (2 mm)	Sieved (2 mm)
Particle size (% w/w):				
Clay (<2 µm)	12[a]	25[a]	14.26[c]	26.00[c]
Silt (50-2 µm)	43[a]	24[a]	23.70[c]	62.96[c]
Sand (2000-50 µm)	45[a]	51[a]	62.04[c]	11.04[c]
Texture (USDA) [4]	Loam[a]	Sandy clay loam[a]	Sandy loam[d]	Silt loam[d]
USA Taxonomy (order and sub-order)	Entisols/Fluvents (USBA-1975)	Alfisols Aqualf (USBA-2006)	Entisols/Aquents (USDA-2006)	Mollisols/Udolls
pH (water)[c]	7.44	6.40	7.23	7.07
pH (0.01M CaCl2)[c]	7.15	6.08	6.84	6.66
Organic matter* (%)[d]	3.48	3.84	4.98	3.50
Organic carbon* (%)[c]	2.02	2.23	2.89	2.03
CEC (meq/100 g soil)	10.8[a]	18.9[a]	20.14[c]	23.84[c]
Moisture at pF2.0 (0.1bar, w/w %)	33.2[a]	29.78[a]	28.9[b]	29.1[b]
Biomass [3] (mg carbon/kg soil), value in brackets (% of organic carbon content of the soil):[d]				
Initial (start of study)	483 (2.4)	999 (4.5)	520 (1.8)	653 (3.2)
Final (end of study)	177 (0.9)	199 (0.9)	280 (1.0)	123 (0.6)

a Parameters provided by the Sponsor.
b Parameters provided by Agvise Laboratories, Northwood, ND 58267, USA
c Parameters determined by AgroLab AG, 6037 Root, Switzerland (non-GLP).
d Parameters determined by IES Ltd, Witterswil, Switzerland.
*Organic carbon (OC) % = organic matter (OM) %/1.724.

CEC = cation exchange capacity.

A 2.2.3 Study Design and Methods

Experimental Design

Parameter	Description
Duration between collection and application	Soil I (Gartenacker): 67 and 89 days Soil II (18 Acres): 67 days Soil III (East Anglia): 66 and 90 days Soil IV (Sarpy): 63 days
Storage conditions	At approximately 4 °C in unsealed containers.
Sieving mesh size (mm)	2
Acclimation duration range (days)	7 to 30 days
Soil incubation sample weight (g, dry weight equivalent)	100
Number of replicates per sampling interval	2 (each extracted and analysed); each uniquely labelled.
Test apparatus	1000 mL size glass bottles, moist air flow through system.
Traps for organic volatiles & CO_2	One trap of ethylene glycol (for organic volatiles) followed by two 2 M NaOH traps (for CO_2).
Frequency of trap collection/replenishment	At each sampling interval (except 0 DAT) and/or at sample wt. checks.
Test substance concentration[7] as mg ai/kg soil, dry weight equivalent (and equivalent g test item/ha)	0.043 mg/kg (32 g test item/ha)
Dosing solution concentration and preparation	3.79 µg/mL in water/acetonitrile 3:1
Volume and application method of test solution	1.1 mL/sample by Hamilton syringe (1000µL size); applied drop-wise across the entire soil surface; sealed vessel shaken vigorously by hand to ensure homogeneity and allowing the organic solvent to evaporate.
% of organic solvent per sample (mL/g x 100%)	0.825% (v/w)
Incubation conditions	20.8 + 0.2oC from January 15th until June 1st, 2013 under continuous darkness.
Moisture content	Soil moisture adjusted/maintained at pF 2 during acclimation and checked prior to dosing by weighing samples and adjusting with water.
Moisture maintenance/frequency and sample handling	Vessels weighed at: 0, 9, 17, 35, 71 and 121 DAT. Deionized water added to restore original weight relative to 0 DAT. Following periodic weight checks, adjusted vessels (sealed) were shaken gently by hand to ensure uniform handling.
Incubation Duration	Soil I (Gartenacker), Soil II (18 Acres), soil III (East Anglia) and soil IV (Sarpy): 121 days
Sampling Intervals	Soil I (Gartenacker) and Soil II (18 Acres): 0, 7, 14, 21, 59, 90 and 121 DAT Soil III (East Anglia): 0, 7, 14, 28, 60, 90 and 121 DAT Soil IV (Sarpy): 0, 7, 14, 28, 59, 90 and 121 DAT
Control (untreated) samples handling	Received only equivalent volume of solvent; for microbial biomass.
Microbial biomass frequency	Initial: 6 days after application; End: 22 days after final interval.

[7] Dose concentration based on 5 cm soil depth incorporation, average soil bulk density of 1.5 g/cm^3 and max. single label rate.

Sampling

Parameter		Description
Sampling intervals	Aerobic	Soil I (Gartenacker) and Soil II (18 Acres): 0, 7, 14, 21, 59, 90 and 121 DAT Soil III (East Anglia): 0, 7, 14, 28, 60, 90 and 121 DAT Soil IV (Sarpy): 0, 7, 14, 28, 59, 90 and 121 DAT
	Untreated systems for biomass	6 and 143 DAT
Sampling procedures		Complete test systems were removed at each sampling interval. The soil was extracted using the following solvent mixtures: Acetonitrile/water 80:20 (v/v), shaken at RT at 250 rpm for 1 h, repeated up to three times. Acetonitrile/water 80:20 (v/v) adjusted to pH 3 with formic acid, shaken at RT at 250 rpm for 1 h, once. Reflux with acetonitrile/water 80:20 (v/v) if more than 10% of AR remained in the soil, 4 h, once. The amount of radioactivity recovered was quantified by LSC.
Collection of CO2 and volatile organics		Volume of solutions measured and aliquots taken for LSC.
Sample storage before analysis		Samples were extracted on the day of sampling, except Soil I and II (21 DAT) samples, which were stored at approximately -80°C for 7 days before analysis.

Description of Analytical Procedures

At each sampling interval, two replicates per soil were extracted. The extractions were performed up to three times with acetonitrile/water 80:20 (v/v) (shaken at RT at 250 rpm for 1 h) followed by one extraction with acetonitrile/water 80:20 (v/v) adjusted to pH 3 with formic acid (shaken at RT at 250 rpm for 1 h). If more than 10% of AR remained in the soil, one reflux extraction with acetonitrile/water 80:20 (v/v) for 4 hours was performed. The individual extracts were radioassayed by LSC. The cold extracts were then pooled, concentrated by a rotary evaporator (Büchi Labortechnik AG, Flawil, Switzerland) and analysed by HPLC and LC-MS/MS. The reflux extracts were concentrated and analysed, by HPLC separately and excluded from the kinetics calculations. For selected samples, the results obtained by HPLC were confirmed by TLC.

As SYN546282 is a racemic mix of two enantiomers, the levels (peak area) of each enantiomer was determined by analysis of the 0 and 121 DAT cold extracts for each soil (in triplicate), with a comparison to samples of the application solution and reference standard. This chiral analysis was performed using LC-MS/MS. The recovery of radioactivity in each soil is shown in Table A 3 to Table A 6 and the percentage of SYN546282 detected in cold extracts and reflux extraction is shown in Table A 7 and Table A 8.

Radioactive Residues in Soil Extracts

For time 0 samples, the mean amount of SYN546282 represented 99.7% and 100.9% of AR for Gartenacker and 18 Acres, respectively, and 100.5% of AR for both East Anglia and Sarpy soil. On 7 DAT, corresponding values for pooled cold extracts were 51.0%, 46.9%, 78.3% and 87.3% AR in Gartenacker, 18 Acres, East Anglia and Sarpy, respectively. Additionally, after 7 days of incubation, mean values for the reflux extractions counted for 5.6%, 6.2%, 7.8% and 7.9% AR in the respective soils. On 121 DAT, at the end of incubation, for the pooled cold soil extracts the mean amount of SYN546282 decreased to 10.6%, 4.6%, 7.8%, and 25.5% AR in Gartenacker, 18 Acres, East Anglia and Sarpy soil, respectively. Corresponding values for the reflux extractions represented 4.5%, 3.0%, 3.6% and 9.9% AR.

The identity of ^{14}C-SYN546282 was confirmed by co-chromatography with the unlabelled test item using HPLC and TLC.

The degradation rate of the parent was determined using non-linear regression and a Single First-Order kinetic model (SFO, CAKE, version 1.4). The results are presented in Table A 9.

Table A 3: Distribution and Recovery of Radioactivity in Gartenacker Soil

^{14}C-SYN546282	Replicate	Percent of applied radioactivity during incubation (days)						
		0	7	14	21	59	90	121
Extractables*	A	100.0	79.1	77.3	73.8	58.4	64.2	31.1
	B	99.4	77.5	75.5	70.2	59.9	71.0	32.8
	Mean	99.7	78.3	76.4	72.0	59.2	67.6	32.0
Reflux**	A	n.p.	9.8	5.5	8.2	9.3	8.4	8.1
	B	n.p.	8.3	5.7	8.6	9.8	7.1	7.3
	Mean	n.p.	9.1	5.6	8.4	9.6	7.8	7.7
Total Extractables	A	100.0	88.9	82.8	82.0	67.7	72.5	39.2
	B	99.4	85.8	81.2	78.8	69.6	78.1	40.1
	Mean	99.7	87.3	82.0	80.4	68.7	75.3	39.7
Non-extractables	A	2.5	12.4	16.7	18.2	24.3	21.8	32.4
	B	2.1	12.6	17.3	18.8	23.1	20.4	32.4
	Mean	2.3	12.5	17.0	18.5	23.7	21.1	32.4
Alkaline Traps (as $^{14}CO_2$)	A	n.p.	0.6	0.9	2.2	6.6	6.1	24.0
	B	n.p.	0.5	1.9	3.2	5.1	5.0	24.2
	Mean	n.p.	0.6	1.4	2.7	5.9	5.6	24.1
Other Volatiles in EG	A	n.p.	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
	B	n.p.	<0.1	<0.1	<0.1	<0.1	0.5	<0.1
	Mean	n.p.	<0.1	<0.1	<0.1	<0.1	0.3	<0.1
Total % Recovery	A	102.5	102.0	100.4	102.5	98.7	100.5	95.7
	B	101.5	99.0	100.5	100.8	97.9	104.0	96.7
Overall Mean ± SD		100.2 ± 2.4						

* Cold extraction up to four times with 80:20 Acetonitrile/water (v/v), followed by one extraction with 80:20 Acetonitrile/water (v/v) adjusted to pH 3 with formic acid.
** Reflux extraction for 4 hours using 80:20 Acetonitrile/water (v/v).
n.p. not performed.

Table A 4: Distribution and Recovery of Radioactivity in 18 Acres Soil

^{14}C-SYN546282	Replicate	Percent of applied radioactivity during incubation (days)						
		0	**7**	**14**	**21**	**59**	**90**	**121**
Extractables*	A	100.8	65.7	65.0	62.3	44.9	38.0	38.8
	B	101.1	67.0	59.4	60.0	48.1	39.2	38.8
	Mean	100.9	66.4	62.2	61.1	46.5	38.6	38.8
Reflux**	A	n.p.	17.7	8.2	15.2	19.9	19.2	20.7
	B	n.p.	16.9	8.8	15.9	19.1	20.7	20.5
	Mean	n.p.	17.3	8.5	15.6	19.5	20.0	20.6
Total Extractables	A	100.8	83.4	73.2	77.6	64.8	57.3	59.5
	B	101.1	83.9	68.2	75.8	67.2	59.9	59.3
	Mean	100.9	83.7	70.7	76.7	66.0	58.6	59.4
Non-extractables	A	1.1	15.6	27.1	22.7	27.3	32.2	26.3
	B	1.2	17.5	26.9	23.8	26.5	37.9	29.0
	Mean	1.2	16.5	27.0	23.3	26.9	35.0	27.6
Alkaline Traps (as $^{14}CO_2$)	A	n.p.	0.4	0.7	0.6	5.3	10.4	6.2
	B	n.p.	<0.1	1.3	2.0	2.6	9.3	3.5
	Mean	n.p.	0.3	1.0	1.3	4.0	9.8	4.9
Other Volatiles in EG	A	n.p.	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
	B	n.p.	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
	Mean	n.p.	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Total % Recovery	A	101.9	99.4	101.1	100.9	97.5	99.9	92.0
	B	102.3	101.4	96.4	101.7	96.3	107.0	91.9
Overall Mean ± SD		99.3 ± 4.1						

* Cold extraction up to four times with 80:20 Acetonitrile/water (v/v), followed by one extraction with 80:20 Acetonitrile/water (v/v) adjusted to pH 3 with formic acid.
** Reflux extraction for 4 hours using 80:20 Acetonitrile/water (v/v).
n.p. not performed.

Table A 5: Distribution and Recovery of Radioactivity in East Anglia Soil

^{14}C-SYN546282	Replicate	Percent of applied radioactivity during incubation (days)						
		0	**7**	**14**	**21**	**60**	**90**	**121**
Extractables*	A	100.6	85.2	83.0	74.0	61.5	51.8	44.8
	B	100.4	85.3	81.1	73.8	61.0	58.8	46.6
	Mean	100.5	85.3	82.1	73.9	61.3	55.3	45.7
Reflux**	A	n.p.	7.8	6.7	9.7	13.6	12.5	12.3
	B	n.p.	7.8	7.6	9.8	11.8	15.2	12.1
	Mean	n.p.	7.8	7.2	9.8	12.7	13.9	12.2
Total Extractables	A	100.6	93.0	89.7	83.7	75.0	64.3	57.1
	B	100.4	93.2	88.7	83.6	72.8	73.9	58.7
	Mean	100.5	93.1	89.2	83.7	73.9	69.1	57.9
Non-extractables	A	1.0	8.5	10.6	15.8	22.2	31.7	29.6
	B	1.0	8.2	11.9	14.6	26.8	25.7	27.5
	Mean	1.0	8.3	11.3	15.2	24.5	28.7	28.6
Alkaline Traps (as $^{14}CO_2$)	A	n.p.	0.2	0.2	1.2	8.6	4.4	4.4
	B	n.p.	0.2	0.2	0.8	3.1	4.1	4.1
	Mean	n.p.	0.2	0.2	1.0	5.8	4.3	4.3
Other Volatiles in EG	A	n.p.	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
	B	n.p.	<0.1	<0.1	0.2	<0.1	<0.1	<0.1
	Mean	n.p.	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Total % Recovery	A	101.5	101.7	100.5	100.8	105.8	100.4	91.1
	B	101.4	101.5	100.8	99.2	102.8	103.7	90.4
Overall Mean ± SD		100.1 ± 4.3						

* Cold extraction up to four times with 80:20 Acetonitrile/water (v/v), followed by one extraction with 80:20 Acetonitrile/water

(v/v) adjusted to pH 3 with formic acid.
** Reflux extraction for 4 hours using 80:20 Acetonitrile/water (v/v).
n.p. not performed.

Table A 6: Distribution and Recovery of Radioactivity in Sarpy Soil

^{14}C-SYN546282	Replicate	Percent of applied radioactivity during incubation (days)						
		0	7	14	21	59	90	121
Extractables*	A	99.2	90.4	89.3	85.1	73.6	67.8	57.8
	B	101.8	88.5	89.7	84.0	76.8	63.6	63.5
	Mean	100.5	89.5	89.5	84.6	75.2	65.7	60.7
Reflux**	A	n.p.	8.2	6.0	9.5	14.7	17.6	19.6
	B	n.p.	7.6	5.0	8.3	14.2	16.2	19.3
	Mean	n.p.	7.9	5.5	8.4	14.5	16.9	19.5
Total Extractables	A	99.2	98.6	95.4	94.6	88.2	85.4	77.3
	B	101.8	96.1	94.8	92.3	91.0	79.7	82.8
	Mean	100.5	97.3	95.1	93.4	89.6	82.6	80.1
Non-extractables	A	1.3	4.9	6.7	8.0	10.7	14.0	13.7
	B	1.2	6.5	5.2	6.7	10.0	17.5	11.5
	Mean	1.2	5.7	6.0	7.4	10.4	15.8	12.6
Alkaline Traps (as $^{14}CO_2$)	A	n.p.	0.1	0.2	1.1	1.6	3.3	2.7
	B	n.p.	0.3	0.2	0.4	2.2	4.6	<0.1
	Mean	n.p.	0.2	0.2	0.8	1.9	4.0	1.4
Other Volatiles in EG	A	n.p.	0.1	0.2	0.2	0.2	0.2	0.2
	B	n.p.	0.3	0.2	0.2	0.2	0.3	<0.1
	Mean	n.p.	0.2	0.2	0.2	0.2	0.2	0.1
Total % Recovery	A	100.5	103.7	102.5	103.9	100.8	102.9	93.9
	B	103.0	103.2	100.3	99.7	103.4	102.1	94.4
Overall Mean ± SD		101.0 ± 3.2						

* Cold extraction up to four times with 80:20 Acetonitrile/water (v/v), followed by one extraction with 80:20 Acetonitrile/water (v/v) adjusted to pH 3 with formic acid.
** Reflux extraction for 4 hours using 80:20 Acetonitrile/water (v/v).
n.p. not performed.

Table A 7: Summary of SYN546282 in Pooled Cold Soil Extracts as a Percentage of Applied Radioactivity

Soil	Replicate	DAT (Percent of Applied)						
		0	7	14	21	59	90	121
Gartenacker	A	100.0	49.7	37.9	31.9	13.5	29.5	10.5
	B	99.4	52.2	31.9	24.0	14.6	40.0	10.7
	Mean	99.7	51.0	34.9	27.9	14.1	34.7	10.6
18 Acres	A	100.8	43.4	22.4	19.3	4.2	2.2	4.6
	B	101.1	50.3	19.5	15.0	4.7	11.3	4.6
	Mean	100.9	46.9	20.9	17.2	4.5	6.8	4.6
East Anglia	A	100.6	77.9	66.4	50.4	31.4	20.2	7.6
	B	100.4	78.6	67.1	51.6	25.5	28.2	8.1
	Mean	100.5	78.3	66.8	51.0	28.4	24.2	7.8
Sarpy	A	99.2	87.8	79.5	69.0	54.1	49.0	27.0
	B	101.8	86.9	80.4	68.0	58.1	37.3	24.0
	Mean	100.5	87.3	79.9	68.5	56.1	43.1	25.5

Table A 8: Summary of SYN546282 in Reflux Extracts as a Percentage of Applied Radioactivity

Soil	Replicate	DAT (Percent of Applied)					
		7	14	21	59	90	121
Gartenacker	A	6.0	3.0	3.5	2.6	5.5	4.5
	B	5.2	2.2	3.4	2.6	4.7	4.5
	Mean	5.6	2.6	3.5	2.6	5.1	4.5
18 Acres	A	5.0	1.5	1.4	1.4	*	2.9
	B	7.4	1.2	1.6	1.2	0.9	3.0
	Mean	6.2	1.4	1.5	1.3	0.4	3.0
East Anglia	A	7.8	4.5	6.5	6.2	6.0	3.8
	B	7.8	6.2	7.5	5.2	7.4	3.5
	Mean	7.8	5.4	7.0	5.7	6.7	3.6
Sarpy	A	8.2	6.0	6.9	8.1	8.4	11.1
	B	7.6	5.0	8.3	8.5	8.1	8.8
	Mean	7.9	5.5	7.6	8.3	8.3	9.9

* Not detected

Table A 9: Summary of $DegT_{50}$ and $DegT_{90}$ Values

Soil	Degradation Kinetics for SYN546282					
	$DegT_{50}$ [days]	$DegT_{90}$ [days]	k value	χ^2	r^2	Prob > t
Gartenacker	10	33	k = 0.0698	15.94	0.961	1.16E-05
18 Acres	7	22	k = 0.1034	11.78	0.987	8.44E-09
East Anglia	35	117	k = 0.0198	7.34	0.973	1.00E-08
Sarpy	70	232	k = 0.0099	4.28	0.968	1.59E-09

Note: Values from reflux extracts were excluded from parent half-life calculations. Soil Gartenacker (90 DAT) cold extract values were considered as outliers, and therefore excluded from parent half-life calculations. SFO (single first-order kinetics; non-linear method) was applied using CAKE software (version 1.4).

$DegT_{50}$: Calculated degradation half-life of parent.

χ^2: chi-square statistical value.

r^2: linear regression coefficient relating goodness of fit as value approaches unity.

A 2.2.4 Conclusions

The key findings after application of ^{14}C-SYN546282 at a dose rate of 0.04 mg/kg to Gartenacker, 18 Acres, East Anglia and Sarpy soils under aerobic incubation (20 ± 2 °C, dark and pF 2 conditions) for up to 121 days are summarized below:

- The mass balance for all individual soil samples ranged from 91.1% to 107.0% AR.
- The $DegT_{50}$ values (SFO) for SYN546282 were determined to be 7, 10, 35 and 70 days in 18 Acres, Gartenacker, East Anglia and Sarpy soil, respectively. Corresponding $DegT_{90}$ values were 22, 33, 117 and 232 days.

Enantiomer levels in the soil extracts did not change significantly over the period of the study, from an average for the four soils of 49%:51% at the start of the study to 54%:46% at the end of the study.

A 2.3 KCA 7.1.3.1.2: [redacted] (2013), VV-405131. SYN546282 – Adsorption/Desorption Properties of 14C-SYN546282 in Five Soils

Reference:	KCA3 7.1.3.1.2
Report:	SYN546282 – Adsorption/Desorption Properties of 14C-SYN546282 in Five Soils. [redacted] 2013 Innovative Environmental Services (IES) Ltd, Benkenstrasse 260, 4108 Witterswil, Switzerland. Report 20120176 Syngenta File No. VV-405131
Guideline(s):	OECD Guidelines for the Testing of Chemicals, Guideline 106: Adsorption/Desorption using a Batch Equilibrium Method (adopt. 21st January 2000). US EPA, Fate, Transport and Transport and Transformation Test Guidelines, EPA 712-C-08-012, OPPTS 835.1230: Adsorption/Desorption (Batch Equilibrium) (October 2008) Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC SETAC-EUROPE Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides: Section 4.0 (Soil Adsorption and Desorption); March 1995.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

A 2.3.1 Executive Summary

The adsorption/desorption characteristics of ^{14}C-SYN546282 (CSCD728931) was studied in 5 soils differing in particle size, organic matter content, cation exchange capacity and pH: Gartenacker (sandy silt loam; Switzerland), 18 Acres (sandy clay loam; UK), East Anglia (sandy loam; UK), Sarpy (silt loam; USA) and Seven Springs (loamy sand; USA). The test was performed in the dark at 20.3 ± 0.2 °C using a standard batch equilibrium method. The chemical was added to soil:aqueous slurries to achieve five nominal rates of application (1.000, 0.500, 0.100, 0.050, 0.010 µg/mL). The soil adsorption coefficients K_d and K_{OC}, including the Freundlich adsorption constants K_F and K_{FOC}, were determined for each soil.

The mass balance showed mean recoveries of 99.7%, 96.4%, 96.2%, 99.3% and 99.7% of applied SYN546282 for Gartenacker, 18 Acres, East Anglia, Sarpy and Seven Springs soils, respectively.

SYN546282 adsorbed to all five soils with a mean K_{FOC} value of 103.9 L/kg and mean slope (1/n) of 0.89. The K_{FOC} values for desorption of SYN546282 for all five soils ranged from 54.5 to 257.3 and slopes (1/n) ranged from 0.86 to 0.92. A summary of the key values is shown in Table A 10.

K_F and K_{FOC} were higher for desorption when compared to the adsorption step, indicating a partially irreversible sorption process.

Table A 10: Soil adsorption constants for SYN546282 (CSCD728931) in 5 Soils

Parameter	Gartenacker	18 Acres	East Anglia	Sarpy	Seven Springs
Texture	Sandy silt loam	Sandy clay loam	Sandy loam	Silt loam	Loamy sand
pH (0.01M $CaCl_2$)	6.6	6.3	7.5	6.7	5.0
%OC	2.09	2.15	2.38	1.94	0.48
Adsorption					
K_F	0.938	1.648	2.101	3.497	0.621
K_{FOC}	44.9	76.8	88.3	180.3	129.0
Mean K_{FOC}	103.9				
1/n	0.90	0.90	0.89	0.84	0.91
r^2	0.9957	0.9998	0.9997	0.9990	0.9998
K_d (averaged)	1.243	2.219	3.079	5.981	0.813
K_{OC} (averaged)	59.5	103.4	129.4	308.3	168.8
Desorption					
K_F	1.138	2.180	2.821	4.992	0.981
K_{FOC}	54.5	101.6	118.5	257.3	203.8
1/n	0.89	0.92	0.90	0.86	0.92
r^2	0.9994	0.9997	0.9997	0.9985	0.9997
K_d (averaged)	1.697	2.864	4.149	8.612	1.320
K_{OC} (averaged)	81.2	133.4	174.3	443.9	274.1

A 2.3.2 Materials

Test Material:	SYN546282
Lot/Batch #:	5269ITH001-3
Purity:	98.4%, was re-determined before use
Stability of test compound:	Stable, determined within study
Application vehicle:	0.01M $CaCl_2$
Soils:	Five soils were used for the study, soils which were chosen to represent arable farming conditions in respect of soil texture and pH.

Name	Gartenacker	18 Acres	East Anglia	Sarpy	Seven Springs
Sampling location	Vouvry Switzerland 46°20'N 06°56'E	Bracknell UK 51°27'N 00°43'E	Melton Constable UK 52°51'N 01°04'E	Louisville NE, USA 41°02'N 96°09'W	Seven Springs NC, USA 35°16'N 77°53'W
Date of collection	27.05.2010	14.05.2010	20.09.2012	26.09.2012	26.10.2012
Sampling depth (cm)	2 - 20	5 - 25	5 - 30	0 - 15	0 - 15
Storage conditions	Room temperature, aerobic	Room temperature, aerobic	Room temperature, aerobic	Room temperature, aerobic	Room temperature, aerobic
Duration of storage	33 months	33 months	6 months	6 months	22 months
Particle size (% w/w; USDA):					
Clay (<2 µm)	10	25	9.5	25.9	4
Silt (50-2 µm)	44	25	32.3	62.5	12
Sand (2000-50 µm)	46	50	58.3	11.6	84
Texture (USDA)	Sandy silt loam	Sandy clay loam	Sandy loam	Silt loam	Loamy sand
Taxonomy (USDA)	Entisols (Fluvents)	Alfisols (Aqualf)	Alfisol (Xeralfs)	Mollisols (Udolls)	Ultisols (Udults)
pH (water)	7.2	6.7	7.0	7.2	5.8
pH (0.01M $CaCl_2$)	6.6	6.3	7.5	6.7	5.0
Organic matter (%)	3.6	3.7	4.1	3.3	0.83
Organic carbon (%)	2.09	2.15	2.38	1.94	0.48
Nitrogen content	Not available	Not available	0.26	0.20	0.04
C/N ratio	Not available	Not available	9.2	9.7	12.0
CEC (meq/100 g soil)	9.4	19.7	23.2	23.0	3.3
Dry-weight g water/100 g dry soil	1.38	3.24	1.36	2.77	0.29

%OM, %OC and C/N ratio were calculated as follows:
%OM = 1.724 × % organic carbon
%OC = % organic carbon / 1.724
C/N ratio = % organic carbon / % nitrogen content

A 2.3.3 Study Design and Methods

Experimental design

Based on a preliminary test, the definitive experiment was performed using all five soils, with a 48 hour adsorption step and a 24 hours desorption step. Based on a preliminary test, a soil-to-solution ratio of 1:2 was used for soils Gartenacker, 18 Acres and East Anglia. A ratio of 1:4 and 1:1 was used for soil Sarpy and Seven Springs, respectively. SYN546282 was applied to soil/aqueous slurries resulting in initial aqueous concentrations of 0.884, 0.443, 0.088, 0.045 and 0.009 µg/mL. The selected soil-to-solution ratio resulted in an adsorption of between 32% and 69% of applied SYN546282 after the 48 hour adsorption step.

Mass balance was determined after the desorption phase for each soil using the samples treated at the highest concentration (0.884 µg/mL) and for soil Sarpy, all concentrations were used.

Adsorption phase

<table>
<tr><th colspan="2">Parameter</th><th>Description</th></tr>
<tr><td colspan="2">Soil condition</td><td>Air-dried soil, passed through 2 mm sieve prior to use</td></tr>
<tr><td colspan="2">Soil sample weight</td><td>- Gartenacker, 18 Acres, East Anglia and Sarpy: 5 g (dry weight) per replicate
- Seven Springs: 10 g (dry weight) per replicate</td></tr>
<tr><td colspan="2">Equilibration solution</td><td>- Gartenacker, 18 Acres, East Anglia and Seven Springs: 9 mL0.01 M $CaCl_2$
- Sarpy: 18 mL 0.01 M $CaCl_2$</td></tr>
<tr><td colspan="2">Control conditions</td><td>No soil</td></tr>
<tr><td colspan="2">Number of replicates</td><td>2</td></tr>
<tr><td colspan="2">Test apparatus</td><td>Teflon tubes and seals</td></tr>
<tr><td rowspan="4">Test material application</td><td>Identity of solvent</td><td>Dosed in 0.01 M $CaCl_2$ solution. The amount of co-solvent in the treatment solution did not exceed 1% v/v.</td></tr>
<tr><td>Volume of test solution used/treatment</td><td>- Gartenacker, 18 Acres, East Anglia and Seven Springs: 1000 µL
- Sarpy: 2000 µL</td></tr>
<tr><td>Application method</td><td>Eppendorf pipette</td></tr>
<tr><td>Evaporation of application solvent</td><td>No</td></tr>
<tr><td rowspan="2">Test material concentration</td><td>Nominal application rates (µg/mL)</td><td>1.000
0.500
0.100
0.050
0.010</td></tr>
<tr><td>Actual application rates (µg/mL)</td><td>0.884
0.443
0.088
0.045
0.009</td></tr>
<tr><td colspan="2">Soil:Solution ratio</td><td>- Gartenacker, 18 Acres and East Anglia: 1:2
- Sarpy: 1:4
- Seven Springs: 1:1</td></tr>
<tr><td colspan="2">Indication of test material adsorbing to walls of test apparatus</td><td>No</td></tr>
<tr><td rowspan="4">Equilibration conditions</td><td>Temperature (°C)</td><td>20.3 ± 0.2 °C</td></tr>
<tr><td>Time</td><td>48 hours</td></tr>
<tr><td>Continuous darkness (Yes/No):</td><td>Yes</td></tr>
<tr><td>Shaking method</td><td>End-over-end</td></tr>
<tr><td colspan="2">Method of separation of supernatant</td><td>Centrifugation</td></tr>
<tr><td rowspan="3">Centrifugation</td><td>Speed (g)</td><td>Approx. 1640</td></tr>
<tr><td>Duration (min)</td><td>10</td></tr>
<tr><td>Method of separating supernatants</td><td>Decanting</td></tr>
</table>

Desorption phase

Parameter		Description
Soil samples from adsorption phase used		Yes
Number of desorption cycles		1
Equilibration solution		0.01 M $CaCl_2$ (10 mL/replicate)
Control conditions		Not done
Number of replicates		2
Test apparatus		Teflon tubes and seals
Soil: Solution ratio		- Gartenacker, 18 Acres and East Anglia: 1:2 - Sarpy: 1:4 - Seven Springs: 1:1
Equilibration conditions	Temperature (°C)	20.3 ± 0.2 °C
	Time	24 hours
	Continuous darkness (Yes/No):	Yes
	Shaking method	End-over-end
Method of separation of supernatant		Centrifugation
Centrifugation	Speed (g)	Approx. 1640
	Duration (min)	10
	Method of separating supernatants	Decanting

Description of analytical procedures

The quantity of radioactivity in aliquots of the aqueous solutions was quantified by Liquid Scintillation Counting (LSC). High-Performance Liquid Chromatography (HPLC) was used to determine the purity of the test item and for chromatographic profiling of selected samples. Aliquots of extracted soil samples were analysed for non-extractable radioactivity by combustion.

A 2.3.4 Results and Discussion

SYN546282 was adsorbed to the 5 soils tested with a mean K_{FOC} value of 103.9 L/kg and mean slope (1/n) of 0.89. Adsorption was not fully reversible.

The concentrations measured after the adsorption step are shown in Table A 11 to Table A 15. The K_{OC} values ranged from 45.3 – 73.8, 81.0 – 126.8, 96.1 – 166.1, 195.8 – 425.9 and 132.7 – 209.2 L/kg, for Gartenacker, East Anglia, Sarpy and Seven Springs soils respectively.

The Freundlich equations showed a good fit to the data with r^2 values of 0.9990 – 0.9998. The corresponding 1/n values ranged from 0.84 to 0.91. The Freundlich coefficients (K_F) calculated for the adsorption step were observed to be 0.938, 1.648, 2.101, 3.497 and 0.621, with corresponding K_{FOC} values of 44.9, 76.8, 88.3, 180.3 and 129.0 for Gartenacker, 18 Acres, East Anglia, Sarpy and Seven Springs soils, respectively. The concentrations measured after the desorption step are shown in Table A 11 to Table A 15. The corresponding K_{OC} values ranged from 59.9 – 101.9, 108.7 – 156.4, 138.5 – 216.3, 304.9 – 565.8 and 223.0 – 335.2 L/kg for Gartenacker, 18 Acres, East Anglia, Sarpy and Seven Springs soils, respectively. The Freundlich equation showed a good fit to the desorption data in all soils with r^2 values of 0.9985 – 0.9997. The corresponding 1/n values ranged from 0.86 to 0.92. The Freundlich coefficients (K_F) calculated for the desorption step were 1.138, 2.180, 2.821, 4.992 and 0.981, with corresponding K_{FOC} values of 54.5, 101.6, 118.5, 257.3 and 203.8 for Gartenacker, 18 Acres, East Anglia, Sarpy and Seven Springs soil, respectively. K_F and K_{FOC} were higher for desorption when compared to the adsorption step, indicating a partially irreversible sorption process.

Table A 11: Concentration of ^{14}C-SYN546282 in the supernatant and soil at the end of adsorption and desorption equilibration period in Gartenacker soil.

Nominal		Adsorption			Desorption		
dose level	Replicate	Ce	X/m	% ad-sorbed*	C1	X1/m	% desorbed as % of the adsorbed
[µg/mL]		[µg/mL]	[µg/g]		[µg/mL]	[µg/g]	
0.884	A	0.604	0.561	31.7	0.276	0.350	37.7
0.884	B	0.597	0.575	32.5	0.271	0.334	40.4
	Mean	0.601	0.568	32.1	0.274	0.342	39.1
0.443	A	0.288	0.310	35.0	0.134	0.195	37.0
0.443	B	0.285	0.315	35.6	0.135	0.203	34.3
	Mean	0.287	0.313	35.3	0.135	0.199	35.7
0.088	A	0.054	0.069	38.9	0.027	0.047	32.4
0.088	B	0.053	0.071	39.9	0.026	0.044	35.8
	Mean	0.054	0.070	39.4	0.027	0.046	34.1
0.045	A	0.027	0.036	39.9	0.013	0.024	32.9
0.045	B	0.027	0.036	40.2	0.013	0.025	29.5
	Mean	0.027	0.036	40.1	0.013	0.025	31.2
0.009	A	0.005	0.008	45.5	0.003	0.005	35.7
0.009	B	0.005	0.008	41.5	0.003	0.006	25.8
	Mean	0.005	0.008	43.5	0.003	0.006	30.8

* % adsorbed as the % of the applied

Table A 12: Concentration of ^{14}C-SYN546282 in the supernatant and soil at the end of adsorption and desorption equilibration period in 18 Acres soil.

Nominal		Adsorption			Desorption		
dose level	Replicate	Ce	X/m	% ad-sorbed*	C1	X1/m	% desorbed as % of the adsorbed
[µg/mL]		[µg/mL]	[µg/g]		[µg/mL]	[µg/g]	
0.884	A	0.476	0.817	46.2	0.257	0.598	26.8
0.884	B	0.470	0.828	46.8	0.260	0.608	25.6
	Mean	0.473	0.823	46.5	0.259	0.603	26.2
0.443	A	0.228	0.431	48.6	0.124	0.328	23.7
0.443	B	0.227	0.431	48.7	0.124	0.323	25.0
	Mean	0.228	0.431	48.7	0.124	0.326	24.4
0.088	A	0.042	0.093	52.6	0.024	0.071	23.5
0.088	B	0.041	0.095	53.8	0.025	0.070	24.6
	Mean	0.042	0.094	53.2	0.025	0.071	24.1
0.045	A	0.020	0.049	54.9	0.012	0.038	23.4
0.045	B	0.020	0.050	55.5	0.012	0.037	24.0
	Mean	0.020	0.050	55.2	0.012	0.038	23.7
0.009	A	0.004	0.010	56.3	0.002	0.008	23.3
0.009	B	0.004	0.011	59.0	0.002	0.008	21.8
	Mean	0.004	0.011	57.7	0.002	0.008	22.6

* % adsorbed as the % of the applied

Table A 13: Concentration of ^{14}C-SYN546282 in the supernatant and soil at the end of adsorption and desorption equilibration period in East Anglia soil.

Nominal		Adsorption			Desorption		
dose level	Replicate	Ce	X/m	% ad-sorbed*	C1	X1/m	% desorbed as % of the adsorbed
[µg/mL]		[µg/mL]	[µg/g]		[µg/mL]	[µg/g]	
0.884	A	0.409	0.951	53.8	0.223	0.729	23.3
0.884	B	0.416	0.936	52.9	0.224	0.744	21.8
	Mean	0.413	0.944	53.4	0.224	0.737	22.6
0.443	A	0.198	0.491	55.4	0.112	0.379	22.7
0.443	B	0.196	0.493	55.7	0.110	0.378	23.0
	Mean	0.197	0.492	55.6	0.111	0.379	22.9
0.088	A	0.034	0.109	61.9	0.021	0.087	20.3
0.088	B	0.034	0.109	61.9	0.020	0.087	20.8
	Mean	0.034	0.109	61.9	0.021	0.087	20.6
0.045	A	0.016	0.057	63.7	0.010	0.046	19.1
0.045	B	0.017	0.056	62.4	0.010	0.046	18.5
	Mean	0.017	0.057	63.1	0.010	0.046	18.8
0.009	A	0.003	0.012	67.5	0.002	0.010	20.3
0.009	B	0.003	0.012	65.3	0.002	0.010	15.1
	Mean	0.003	0.012	66.4	0.002	0.010	17.7

* % adsorbed as the % of the applied

Table A 14: Concentration of ^{14}C-SYN546282 in the supernatant and soil at the end of adsorption and desorption equilibration period in Sarpy soil.

Nominal		Adsorption			Desorption		
dose level	Replicate	Ce	X/m	% adsorbed*	C1	X1/m	% desorbed as % of the adsorbed
[µg/mL]		[µg/mL]	[µg/g]		[µg/mL]	[µg/g]	
0.884	A	0.454	1.721	48.7	0.202	1.176	31.7
0.884	B	0.453	1.724	48.7	0.198	1.192	30.8
	Mean	0.454	1.723	48.7	0.200	1.184	31.3
0.443	A	0.206	0.949	53.6	0.097	0.674	29.0
0.443	B	0.211	0.928	52.4	0.099	0.674	28.9
	Mean	0.209	0.939	53.0	0.098	0.674	29.0
0.088	A	0.035	0.214	60.5	0.018	0.160	25.1
0.088	B	0.035	0.215	60.7	0.018	0.162	24.2
	Mean	0.035	0.215	60.6	0.018	0.161	24.7
0.045	A	0.016	0.115	64.0	0.009	0.088	22.9
0.045	B	0.016	0.116	64.5	0.008	0.090	21.3
	Mean	0.016	0.116	64.3	0.009	0.089	22.1
0.009	A	0.003	0.025	68.5	0.002	0.020	21.6
0.009	B	0.003	0.024	66.3	0.002	0.020	21.7
	Mean	0.003	0.025	67.4	0.002	0.020	21.7

* % adsorbed as the % of the applied

Table A 15: Concentration of ^{14}C-SYN546282 in the supernatant and soil at the end of adsorption and desorption equilibration period in Seven Springs soil.

Nominal dose level [µg/mL]	Replicate	Adsorption Ce [µg/mL]	X/m [µg/g]	% ad-sorbed*	Desorption C1 [µg/mL]	X1/m [µg/g]	% desorbed as % of the adsorbed
0.884	A	0.544	0.341	38.5	0.245	0.263	22.8
0.884	B	0.535	0.349	39.5	0.243	0.262	23.2
	Mean	0.540	0.345	39.0	0.244	0.263	23.0
0.443	A	0.257	0.186	42.1	0.118	0.151	19.2
0.443	B	0.257	0.186	42.0	0.123	0.143	23.2
	Mean	0.257	0.186	42.1	0.121	0.147	21.2
0.088	A	0.049	0.040	45.1	0.024	0.030	23.4
0.088	B	0.049	0.039	44.6	0.024	0.031	21.0
	Mean	0.049	0.040	44.9	0.024	0.031	22.2
0.045	A	0.023	0.022	48.0	0.012	0.016	23.7
0.045	B	0.024	0.020	45.7	0.012	0.017	21.7
	Mean	0.024	0.021	46.9	0.012	0.017	22.7
0.009	A	0.004	0.005	51.0	0.002	0.004	19.1
0.009	B	0.005	0.004	49.4	0.002	0.004	20.1
	Mean	0.005	0.005	50.2	0.002	0.004	19.6

* % adsorbed as the % of the applied

Table A 16: Mass Balance

Soil	Treatment concentration [µg/mL]	% of applied amount in: Soil extract	Adsorption supernatant	Desorption supernatant	Non-extracted residue	Total
Gartenacker	0.884	19.1	49.0	31.2	0.8	100.1
	0.884	18.3	49.7	30.6	0.7	99.3
18 Acres	0.884	28.6	37.1	29.1	1.6	96.4
	0.884	30.0	35.6	29.4	1.5	96.5
East Anglia	0.884	34.5	33.6	25.2	2.5	95.7
	0.884	35.6	33.4	25.4	2.3	96.6
Sarpy	0.884	30.5	43.9	22.8	1.8	99.0
	0.884	28.7	43.8	22.4	1.8	96.8
	0.443	36.7	40.1	21.9	1.9	100.6
	0.443	34.9	40.8	22.3	1.1	99.1
	0.088	43.7	34.1	20.6	2.1	100.6
	0.088	43.6	33.6	20.3	2.2	99.7
	0.045	48.4	31.0	19.7	2.1	101.2
	0.045	45.9	30.3	18.8	2.0	97.1
	0.009	50.1	27.1	19.2	2.3	98.7
	0.009	49.5	28.7	19.9	2.1	100.2
Seven Springs	0.884	24.8	42.5	27.7	0.8	95.9
	0.884	25.2	42.0	27.5	0.8	95.4

The results showed that SYN546282 was present in aqueous supernatant solutions as well as in the soil extracts. The mass balance showed mean recoveries of 99.7%, 96.4%, 96.2%, 99.3% and 95.6% of applied SYN546282 for soil Gartenacker, 18 Acres, East Anglia, Sarpy and Seven Springs, respectively.

A 2.3.5 Conclusions

SYN546282 was adsorbed to the 5 soils tested with a mean K_{FOC} value of 103.9 L/kg and mean slope (1/n) of 0.89.

Using the McCall Classification scale to assess a chemical's potential mobility in soil (based on its K_{FOC}), SYN546282 can be classified as having a "very high" potential mobility in soil Gartenacker and a "high" potential mobility in 18 Acres, East Anglia and Seven Springs soils. For Sarpy soil a "medium" potential mobility was observed.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

A 3.1 KCP 9.1.1: [redacted] (2015), VV-629108. Metalaxyl-M: Calculation of the formation fraction of the soil degradate CGA108906 for use in environmental models, VV-629108

Reference:	KCP 9.1.1
Report:	Metalaxyl-M: Calculation of the formation fraction of the soil degradate CGA108906 for use in environmental models [redacted] 2015 Report Number RAJ1079B Syngenta Ltd, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY UK Syngenta file No. VV-629108
Guideline(s):	FOCUS (2006). Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005, version 2.0, 434 pp.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

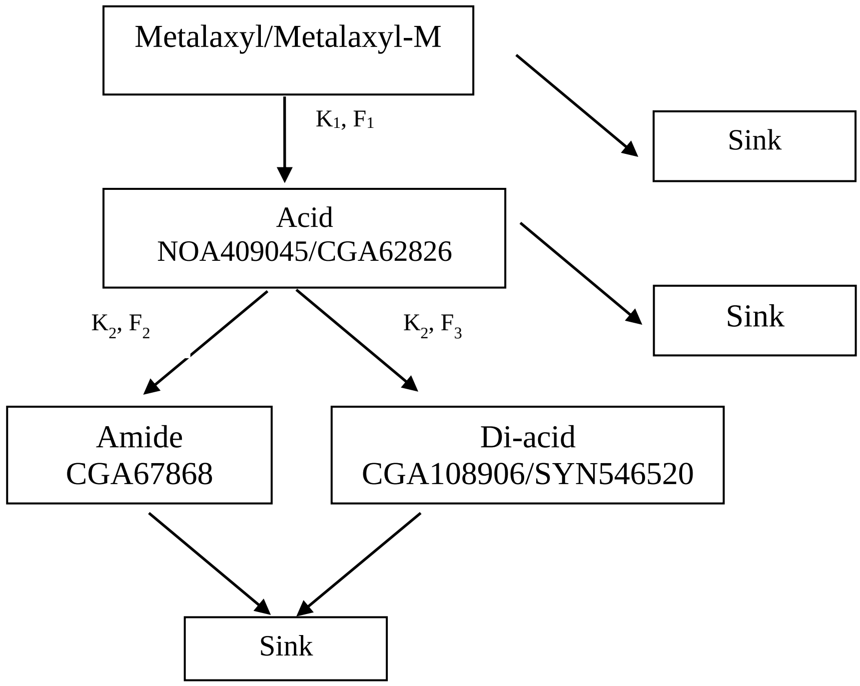
A 3.1.1 Materials and methods

This report presents the calculations to determine the degradation rate and formation fraction for the di-acid metabolite of metalaxyl/metalaxyl-M. The di-acid formed from the enantiomerically pure (R enantiomer) metalaxyl-M is referred to as SYN546520. The di-acid metabolite formed from the racemic (R/S) compound metalaxyl is also a racemic mixture and is referred to as CGA108906.

The route and rate of degradation of metalaxyl-M (R enantiomer) and metalaxyl (R/S racemate) has been studied in the laboratory in two studies in which formation and decline of di-acid was observed ([redacted] 2003, [redacted] 2003a).

The original data from these studies was used to calculate the rate of degradation of metalaxyl-M, metalaxyl and metabolites NOA409045, CGA62826, CGA67868 and CGA108906 in soil and their formation fractions, following the guidance in FOCUS Kinetics (2006). The pathway implemented for kinetic modelling is presented in Figure A 1 below.

Figure A 1: Implementation of metalaxyl-m degradation pathway for kinetic fitting



K_1 degradation rate of parent
F_1 formation fraction of acid metabolite (NOA409045/CGA62826)
K_2 degradation rate of acid metabolite (NOA409045/CGA62826)
F_2 formation fraction of amide metabolite (CGA67868) from acid metabolite.
F_3 formation fraction of di-acid metabolite (CGA108906/SYN546520) from acid metabolite

Confidence in the resulting parameters has been assessed visually and from the probability values for a t-test of the rate parameters for the single first order (SFO). Where the parameters for a particular model are not significantly different from zero at the 95th or 90th significance level, it has been concluded that the model is not appropriate to represent the degradation behaviour of metalaxyl-M in that soil. The χ^2 error% parameter has been used to determine goodness of fit and where two models are appropriate to fit the data, the choice of best fit has been based on the lowest value of this parameter.

In the first instance, the data were directly fitted unweighted with the complete data set and unconstrained initial concentration (M0) for parent and M0 fixed to zero for metabolites. The acceptability of the kinetic fits was judged as follows:

Visually using a three point scale:
Poor = an unacceptable fit, the fitted curve does not represent the trend of the data points and residuals show strong deviations from random distribution;
Acceptable = the fitted curve describes the trend of the data points, residuals may show some deviation from random distribution but it is not significant;
Good = the fitted curve closely follows all the data points, residuals are randomly distributed.

Confidence of rate constants:
The FOCUS Kinetics guidelines state that the confidence that can be assigned to a parameter must be assessed (FOCUS, 2006). Parameter estimates with a significance level greater than 95% are acceptable and, if greater than 90%, may be accepted where the visual fit is acceptable or good. Where significance levels are less than 90%, the fits are not considered acceptable.

For SFO fits the assessment was based on the t-test probability value of the estimate of the degradation rate (k).

Fit to the data points (χ^2 error%):
It is recommended that a χ^2 error% of 15% or less indicates acceptable fits, although for data that may include intrinsically variable data (metabolites at low levels compared to parent and field data) higher values can be tolerated if the visual fit is acceptable or good. Where two or more models are acceptable fits to the data, the χ^2 error% parameter has been used to assess goodness of fit. In these cases, the model with the lowest value of this parameter has been chosen as the best fit.

Metabolites:
Metabolites have been fitted in the step-wise procedure indicted by the guidance (FOCUS, 2006). Parent data were fitted with the best-fit model, the parameters were fixed for the metabolite fitting step and, finally, the parameters were un-fixed for a re-fit. The outputs from the final step only are given in Appendix 3 of the initial report.

For fits that are visually acceptable or good, but for which a robust degradation rate cannot be established, i.e. a t-test of <90% probability, then a conservative default value $DegT_{50}$ of 1000 days has been used.

A 3.1.2 Data Manipulation, Pappelacker treated with metalaxyl-M ([redacted] and [redacted] 2003)

Zero day metabolite applied radioactivity (AR) values were added to parent metalaxyl-M. Metabolite zero day values were set to zero. Preceding values of zero were set to half of LOQ for metabolite CGA108906 for Day 2a and 2b.

A 3.1.3 Data Manipulation, Pappelacker treated with metalaxyl ([redacted] and [redacted] 2003a)

Preceding values of zero were set to half of LOQ for metabolite CGA108906 for Day 7a, 7b and 14a.

A 3.1.4 Normalisation to 20ºC and pF2

These studies were performed at standard conditions.

A 3.1.5 Results

Table A 17 to Table A 19 provide a summary and the averages for persistence and modelling endpoints for metalaxyl-M, metalaxyl and soil metabolites NOA409045, CGA62826, CGA67868, SYN546520 and CGA108906. $DegT_{50}$ values derived for parent material were very similar to those previously reported ([redacted] 2007). Formation fractions are summarised in Table A 20 below.

Table A 17: Parent endpoints for metalaxyl–M[1] and metalaxyl[2] in laboratory aerobic soil

Soil	Pappelacker[1] ([redacted] and [redacted] 2003)	Pappelacker[2] ([redacted] and [redacted] 2003a)
Model	SFO[3]	SFO[3]
Visual Fit	Acceptable	Acceptable
Residuals (visual)	Acceptable	Acceptable

χ^2 error (%)	4.88	2.94
Initial value: estimate / (range) / standard error	Pini: 97.8 (97.5 - 99.2) σ: 1.047	Pini: 97.6 (98.9 – 99.0) σ: 0.917
Rate Parameters: estimate / standard error / probability (trigger: 0.05)	kP: 0.06943 σ: 0.001686 $p < 0.01$	kP: 0.02934 σ: 0.000657 $p < 0.01$
DT_{50} (days)	9.98	23.6
DT_{90} (days)	33.2	78.5
Modelling $DegT_{50}$	9.98	23.6

[1] Laboratory soil treated with metalaxyl-M

[2] Laboratory soil treated with metalaxyl

[3] Full report of selection process in [redacted] 2007

Table A 18: Modelling fits for the acid, amide and di-acid metabolites (NOA409045, CGA67868 and SYN546520) of metalaxyl-M – laboratory aerobic soil Pappelacker ([redacted] and [redacted] 2003)

Metabolite	NOA409045	CGA67868	SYN546520
Parent Model	SFO	SFO	SFO
Metabolite Model	SFO	SFO	SFO
Visual Fit	Good	Acceptable	Good
Residuals (visual)	Good	Acceptable	Good
χ^2 error (%)	10.8	29.2	37.5
Rate Parameters: estimate / standard error / probability (trigger: 0.05)	k A1: 0.08553 σ: 0.005917 $p < 0.01$	k A2: 0.1911 σ: 0.06404 $p < 0.01$	k B1: 0.00944 σ: 0.004559 $p < 0.01$
DT_{50} (days)	8.10	3.63	73.4
DT_{90} (days)	26.9	12.1	244
Formation fraction from Parent	0.805		
Formation fraction from NOA409045		0.367	**0.026**

Table A 19: Modelling fits for the acid, amide and di-acid metabolites (CGA62826, CGA67868 and CGA108906) of metalaxyl – laboratory aerobic soil Pappelacker ([redacted] and [redacted] 2003a)

Metabolite	CGA62826	CGA67868	CGA108906
Parent Model	SFO	SFO	SFO
Metabolite Model	SFO	SFO	SFO
Visual Fit	Good	Good	Acceptable

Residuals (visual)	Good	Good	Acceptable
χ^2 error (%)	10.5	16.7	22.5
Rate Parameters: estimate / standard error / probability (trigger: 0.05)	k A1: 0.1359 σ: 0.0124 $p < 0.01$	k A2: 0.1085 σ: 0.02034 $p < 0.01$	k B1: 0.0233 σ: 0.004736 $p < 0.01$
DT_{50} (days)	5.10	6.39	29.8
DT_{90} (days)	17	21.2	98.8
Formation fraction from Parent	1		
Formation fraction from CGA62828		0.203	**0.025**

Table A 20: Summary of Formation Fractions in Pappelacker Soil

Metabolite	Derivation of value	Formation Fraction Range	Formation fraction [from]
Di-acid CGA108906/SYN546520	Arithmetic mean (n=2)	0.025-0.026	0.03 (NOA409045)
Amide CGA67868	Arithmetic mean (n=2)	0.203-0.367	0.285 (NOA409045)

A 3.1.6 Conclusion

Evaluation of CGA108906 formation fraction in a third soil, as requested by EFSA 2015 (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**), has been performed for Pappelacker. The arithmetic mean CGA108906 formation fraction value of 0.03, demonstrates that the formation fraction 0.1 value proposed at Annex 1 Renewal to be conservative.

A 3.2 KCP 9.1.1: [redacted] (2020), VV-742439. CGA108906 Kinetic evaluation of Formation Fraction, VV-742439

Reference:	KCP 9.1.1
Report:	Metalaxyl-M: Kinetic evaluation of Formation Fraction. [redacted] 2020 Report Number RAJ1329B Syngenta Ltd, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY UK Syngenta file No. VV-742439
Guideline(s):	FOCUS (2006). Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005, version 2.0, 434 pp. FOCUS (2014). Generic guidance for estimating modelling and degradation kinetics from environmental fate studies on pesticides in EU registration. Version 1.1, 440 pp.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.2.1 Materials and methods

This report demonstrates how the EFSA List of Endpoints SYN546520 (metabolite of metalaxyl-M) 0.47 formation fraction (ff) is both overly conservative and unrealistic, and alternatively proposes a lower value which is based on kinetic evaluation of soil study data.

From the kinetic studies of [redacted], 2012, 2015 and [redacted] 2013, metalaxyl-M and its metabolites degrade according to a single first order (SFO) degradation model for parent and its metabolites as shown in Figure A 2. These data were used as inputs to an SFO model spreadsheet using MS Excel 365 ProPlus, which uses standard kinetic equations to represent the pathway of parent to primary metabolite to secondary metabolite.

Inputs to the spreadsheet are the initial value of the parent, DT_{50} values of the parent and metabolites, and ff of the metabolites which are presented in Table A 21 below.

Table A 21: Inputs used to determine predicted maximum occurrence and formation fraction of metabolites

Compound	$DegT_{50}$ (d)	M0 (%)	Formation fraction	Predicted maximum occurrence (%)
Metalaxyl-M	3.17 [a]	100	-	-
Acid metabolite NOA409045	5.82 [a]	0	1 [a]	48.34
Amide CGA67868	1.83 [a]	0	0.53 [a]	7.28
Diacid metabolite SYN546520	42.1 [b]	0	0.47 (Belgium RMS, Tier I) [c]	33.24
			0.1 (Tier II)	7.07

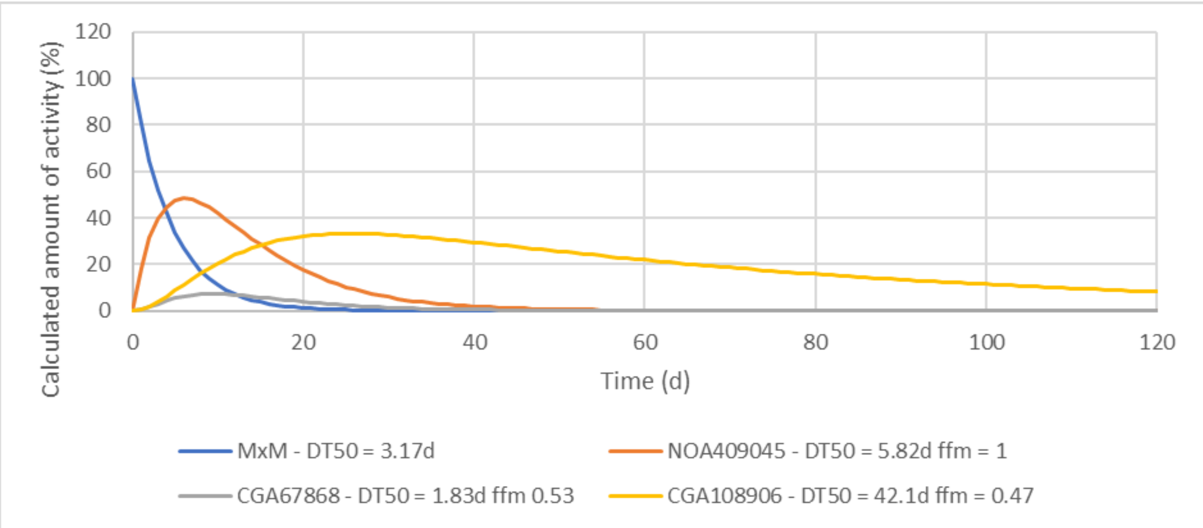
(CGA108906)			0.033	2.33

a = [redacted], 2012
b = [redacted], 2015
c = Conclusion on the peer review of the pesticide risk assessment of the active substance metalaxyl-M, 2015

Based on these inputs, the spreadsheet calculates kinetic graphs for the parent and metabolites and therefore enables analysis of the impact of ff on the maximum observed value of a metabolite.

For the Gartenacker soil, a CGA108906 ff value of 0.47 was hypothesized by RMS Belgium, whereas a value of 0.1 was proposed by Syngenta at Annex I Renewal, 2012. Both of these ff were inputted into the SFO model spreadsheet and the outputs of the model are presented in Figure A 2 and Figure A 3 below, respectively.

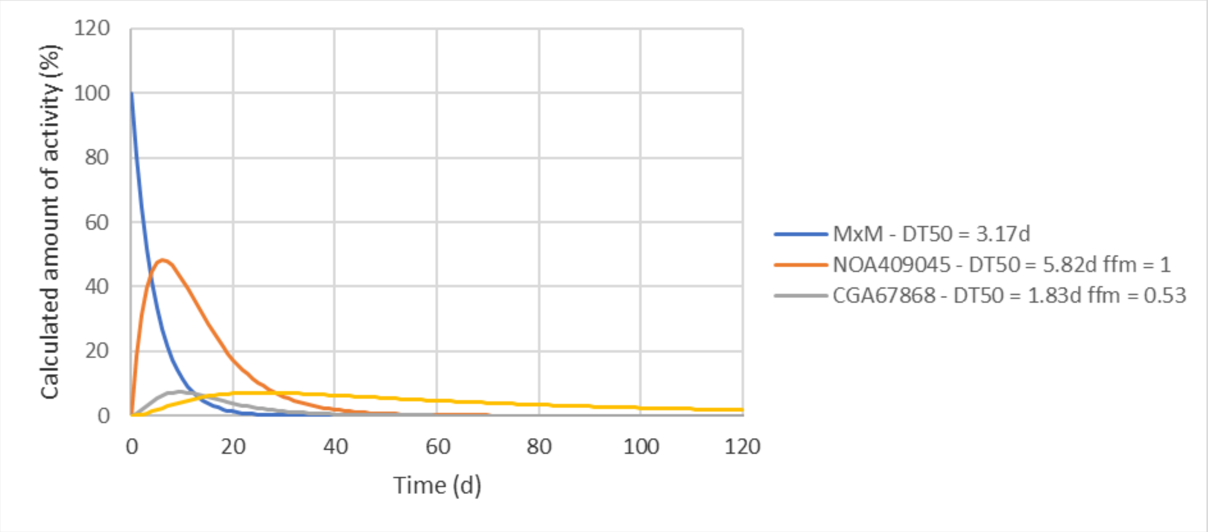
Figure A 2: Formation and decay curves of metalaxyl-M and its metabolites using CGA108906 0.47 Tier 1 ff based on DT_{50}'s derived from [redacted] 2012, 2015 and [redacted] 2013.



Max of NOA409045 predicted = 48.44%
Max of CGA67868 predicted = 7.28%
Max of CGA108906 predicted = 33.24% (overly conservative), CGA108906 was not observed <2.3%

From Figure A 2 above it can be seen that a CGA108906 ff value of 0.47 leads to a maximum predicted value of CGA108906 of 33.24%. Whereas from Figure A 3 below it can be seen that a CGA108906 ff value of 0.1 leads to a maximum predicted value of CGA108906 of 7.07%. Since CGA108906 was not observed in the Gartenacker soil and the maximum unidentified radioactive component was <2.3%, both of these ff values are therefore very conservative.

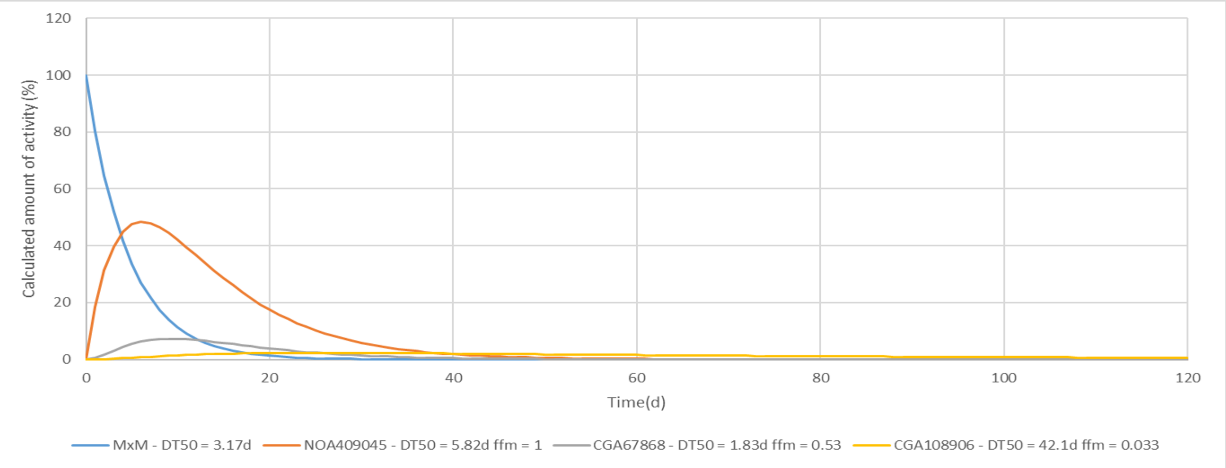
Figure A 3: **Formation and decay curves of metalaxyl-M and its metabolites using CGA108906 0.1 Tier 2 ff based on DT_{50}'s derived from [redacted] 2012, 2015 and [redacted] 2013.**



Max of NOA409045 predicted = 48.34%
Max of CGA67868 predicted = 7.28%
Max of CGA108906 predicted = 7.07% (still very conservative), CGA108906 was not observed <2.3%

Values of ff were then tested to see what is the maximum CGA108906 ff that does not lead to an exceedance of 2.3%, and Figure A 4 below shows that a CGA108906 ff of 0.033 leads to a maximum predicted value of CGA108906 of 2.3%.

Figure A 4: **Formation and decay curves of metalaxyl-M and its metabolites using estimated CGA108906 0.033 ff based on DT_{50}'s derived from [redacted] 2012, 2015 and [redacted] 2013.**

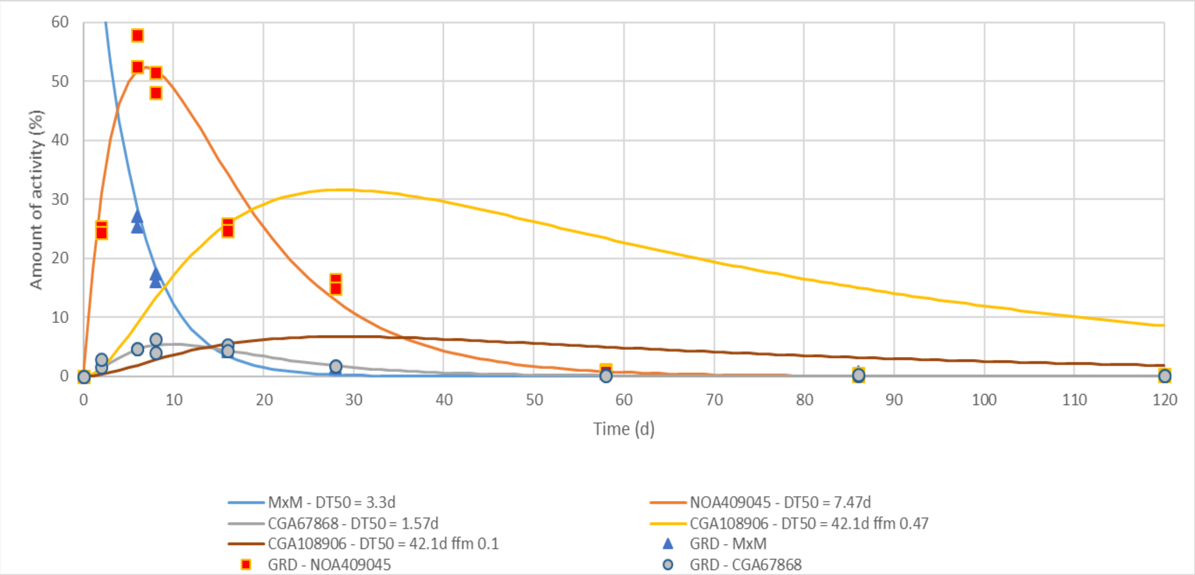


Max of NOA409045 predicted = 48.34%
Max of CGA67868 predicted = 7.28%
Max of CGA108906 predicted = 2.3%, maximum unidentified component

The CGA108906 formation fraction of 0.033 in Gartenacker soil is still considered to be conservative because CGA108906 eluted with a shorter chromatographic retention time than the maximum unidentified component in the [redacted] and [redacted], 2012a study, that is CGA108906 was <2.3% of applied radioactive residue (ARR).

Figure A 5 below shows the residue data from the Gartenacker soil superimposed onto the predicted data for metalaxyl-M and its metabolites, and it can be seen that there is good agreement between the residue data and predicted values. This indicates that the use of standard kinetic equations in the SFO model spreadsheet is valid and can be used to provide evidence for the formation fraction of CGA108906 as 0.033 and not 0.47 as proposed by Belgium RMS at Tier I.

Figure A 5: Formation and decay curves of metalaxyl-M and its metabolites using estimated CGA108906 0.033 ff with residue data from Gartenacker soil ([redacted] and [redacted], 2012a)



GRD = Gartenacker Residue Data

A 3.2.2 Conclusions

Re-evaluation of the Gartenacker soil data ([redacted], and [redacted], 2012a) demonstrated that a formation fraction for SYN546520 (CGA108906) of 0.47 is overly conservative and not supported by the study data.

Standard kinetic equations assuming SFO degradation were used to show that a formation fraction of 0.47 is not plausible, nor credible based on the experimental data. Should a formation fraction of 0.47 be valid, CGA10896 would be anticipated to be observed at >10% ARR at seven time points in the [redacted] and [redacted] 2012a study, reaching a maximum of 33% of ARR. Whereas, in the soil study, CGA108906 was never observed and the maximum unidentified component was 2.3%. Note that the origin of the 0.47 formation fraction was based on the hypothesis of one minus the amide metabolite CGA67868 formation fraction (1-0.53). However, this hypothesis fails to consider other possible sink routes, e.g. to carbon dioxide.

Assuming the maximum 2.3% unidentified component to be CGA108906, this would result in a formation fraction of 0.033 in Gartenacker soil. This is still considered to be conservative because CGA108906 eluted with a shorter chromatographic retention time than the maximum unidentified component in the [redacted] and [redacted], 2012a study, that is CGA108906 was <2.3% ARR.

The ff of 0.033 proposed in this report for Gartenacker soil is consistent with the estimations of ff in the two other soils; 0.035 in [redacted] soil ([redacted] 2013) and 0.03 in Pappelacker ([redacted] 2015).

In conclusion and to introduce a further degree of conservatism, and considering ff <0.04 in three soils, this report proposes that CGA108906 ff of 0.1 is appropriate to be used as a modelling endpoint.

A 3.3 KCP 9.1.1: [redacted] (2013), VV-628062. Sedaxane: Calculation of Kinetic Endpoints for Metabolite CSCD728931

Reference:	KCP 9.1.1
Report:	Sedaxane: Calculation of Kinetic Endpoints for Metabolite CSCD728931 for Modelling Purposes from Laboratory Data According to FOCUS Kinetic Guidelines. [redacted]. 2013 Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Syngenta Report Number RAJ1002B Syngenta File No. VV-628062
Guideline(s):	FOCUS (2006). Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005, version 2.0, 434 pp. FOCUS (2011). Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in EU Registration. Version 1.0. 23 November 2011.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.3.1 Executive summary

Laboratory studies have been carried out to investigate the rate of degradation of CSCD728931 a soil metabolite of sedaxane. The data from the studies have been used to calculate rates of degradation in soil for CSCD728931. This report presents the calculations of $DegT_{50}$ values following FOCUS Kinetics guidance (2006, 2011) for modelling endpoints.

An assessment of the confidence in the resulting parameters has been made using probability values for a t-test of the rate parameters for the single first-order (SFO) model. Where the parameters for a particular model are not significantly different from zero at the 95th or 90th significance level, it has been concluded that the model is not appropriate to represent degradation behaviour in that soil. A maximum value of the $\chi 2$ error% parameter of 15% has been used to determine an acceptable fit to the study data.

The endpoints reported here may be used in the calculation of predicted environmental concentrations. The modelling endpoint $DegT_{50}$ values for CSCD728931 are given in Table A 22 below.

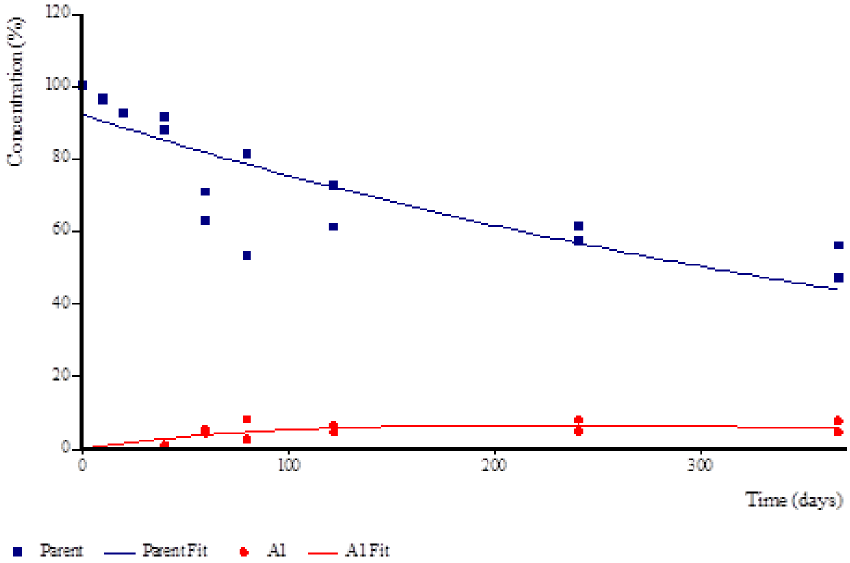
Table A 22: Modelling Endpoints for CSCD728931

Soil	**Model**	**Formation Fraction (Ffm)**	**DegT$_{50}$ (days)**
California	SFO	0.48	79.3
Gartenacker	DFOP	n/a^	71.4*
Sarpy	SFO		33.3
18 Acres	FOMC		10.2$
East Anglia	SFO		70.1
Geometric Mean		**0.48**	**42.3**

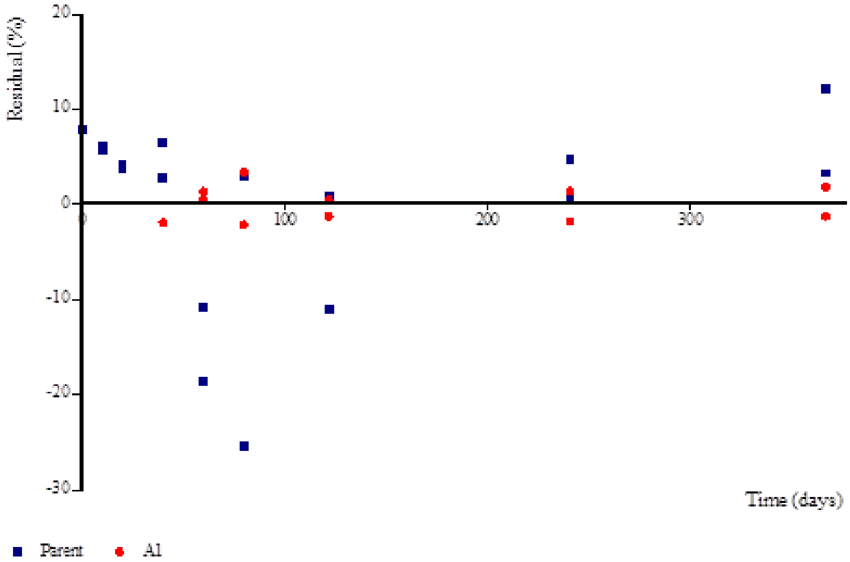
^n/a CSCD728931 applied study
*ln2/k2
$ DT$_{90}$/3.32

Figure A 6: Graphical summary California soil ([redacted] 2009)

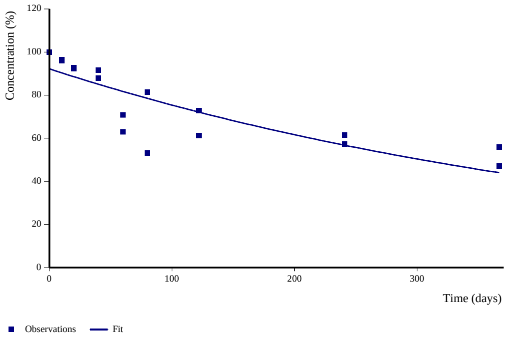
Observations and Fitted Model:

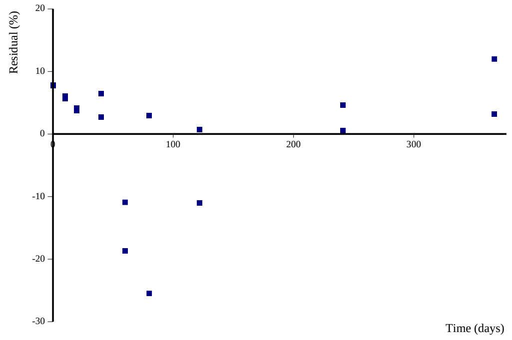


Residuals:

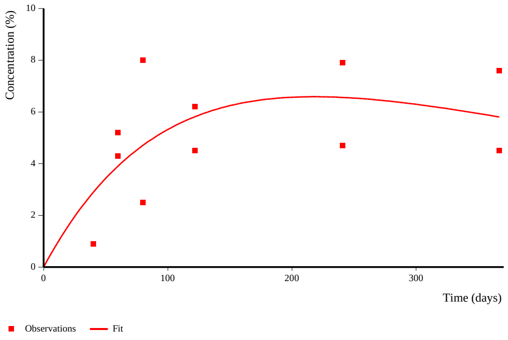


Compartment Parent:





Compartment A1:



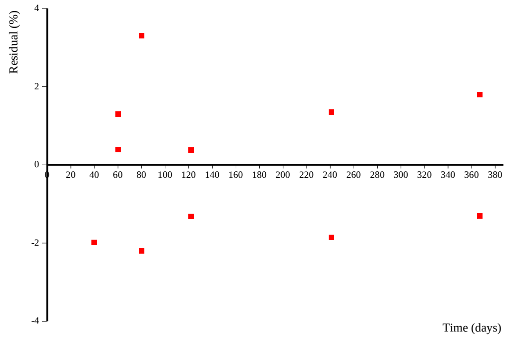
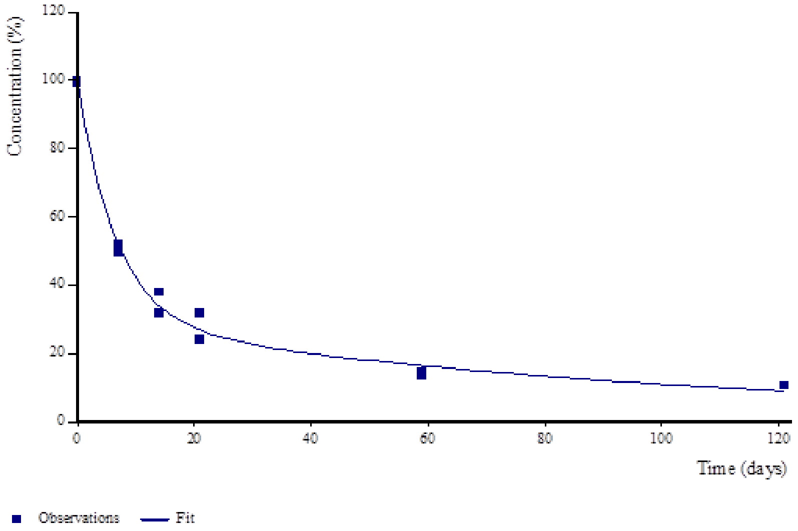


Figure A 7: Graphical summary Gartenacker soil (DFOP, [redacted] and [redacted] (2013), VV-406128)

Observations and Fitted Model:



Residuals:

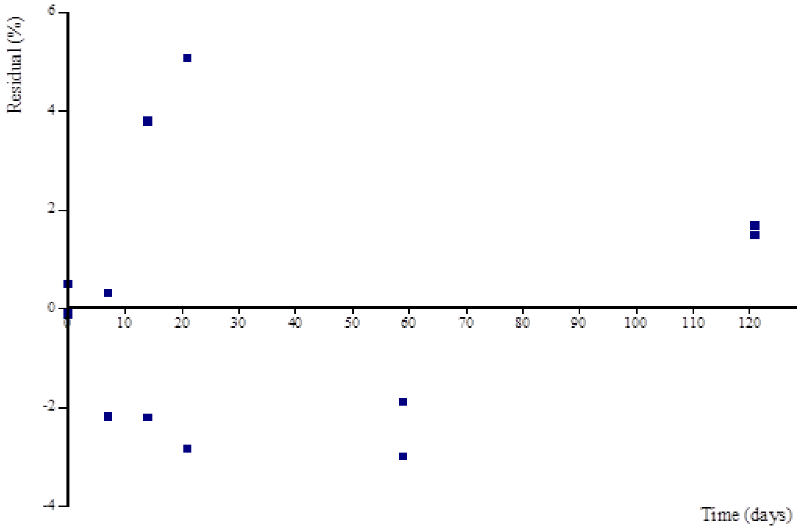
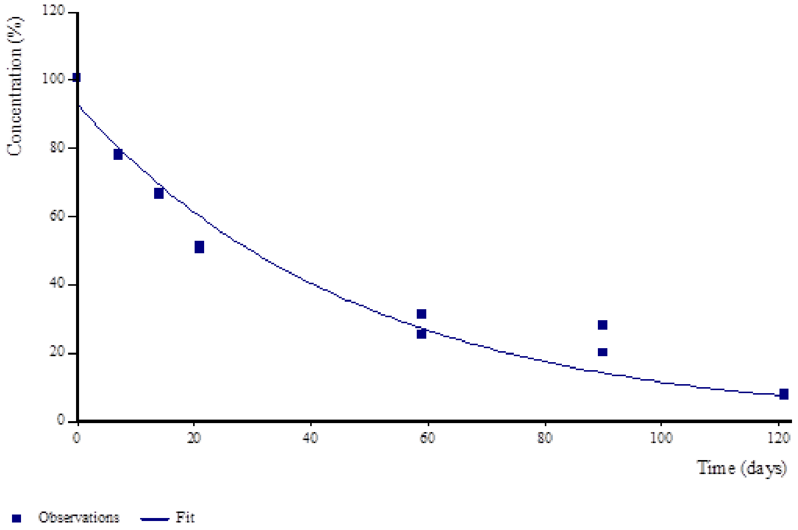


Figure A 8: Graphical summary Sarpy soil (SFO, [redacted] and [redacted] (2013), VV-406128)

Observations and Fitted Model:



Residuals:

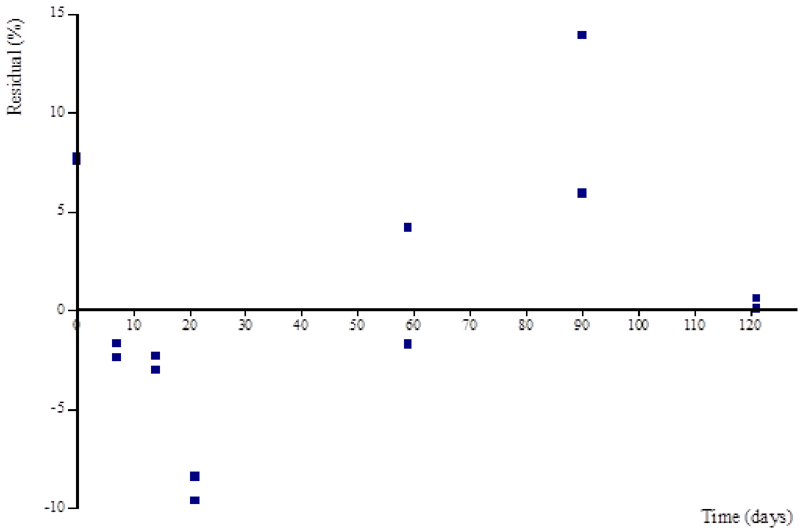
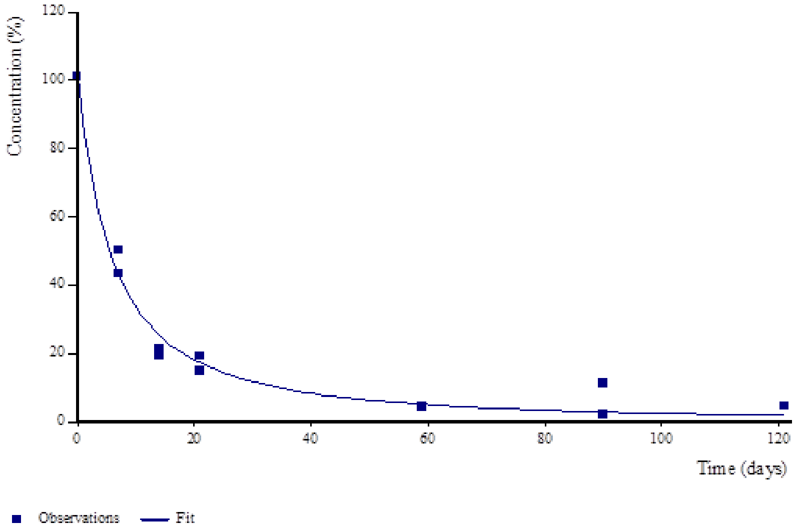


Figure A 9: **Graphical summary 18 Acres soil (FOMC, [redacted] and [redacted] (2013), VV-406128)**

Observations and Fitted Model:



Residuals:

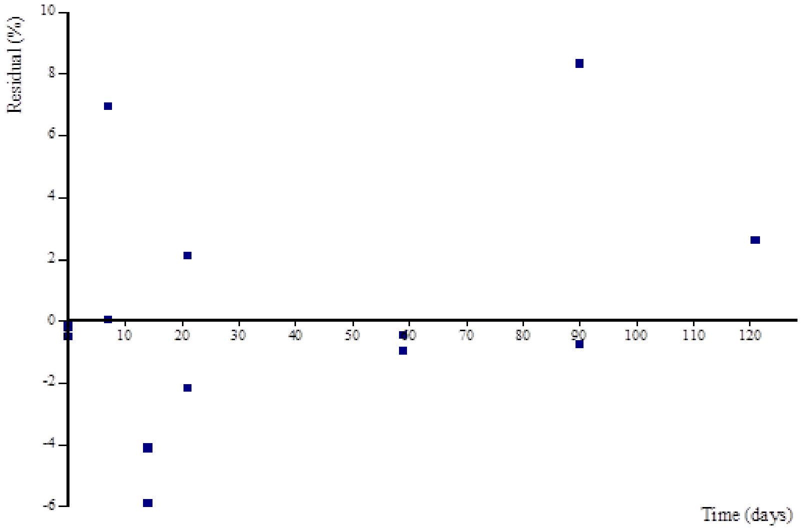
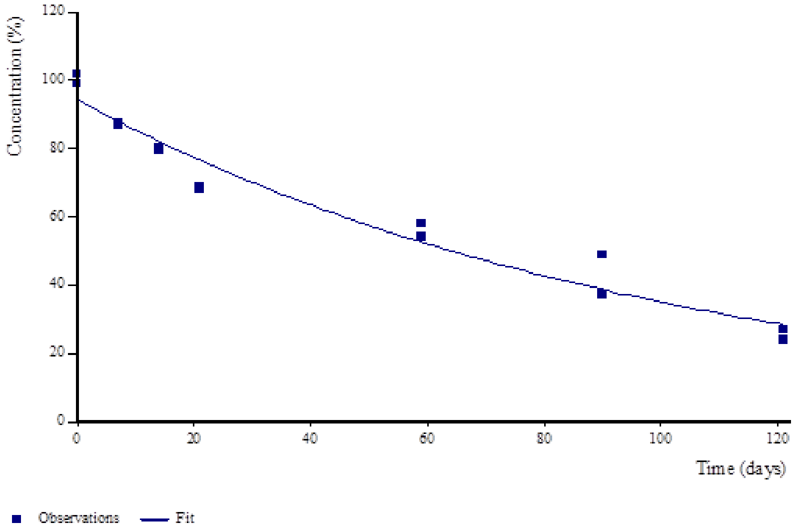
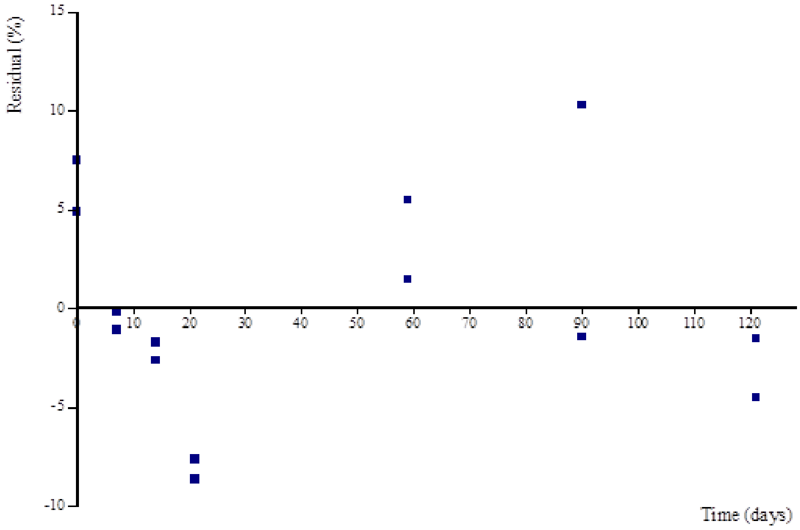


Figure A 10: Graphical summary East Anglia soil (SFO, [redacted] and [redacted] (2013), VV-406128)

Observations and Fitted Model:



Residuals:



A 3.3.2 Conclusions

Modelling endpoints representing the degradation rate of metabolite CSCD728931, in laboratory soils have been determined in accordance with FOCUS (2006, 2011) guidance, the appropriate $DegT_{50}$ and formation fraction values for model inputs are 42.3 d and 0.48, respectively.

A 3.4 PEC_S specifications

PEC_S immediately after the first application were calculated using FOCUS guidance[8] with the following equation:

$$PEC\ (mg/kg) = \frac{A(g/ha) \times (1 - F)}{100 \times d\ (cm) \times \rho\ (g/cm^3)}$$

Where:
A = Application rate
F = Fraction intercepted by crop (0.7)
d = Depth of field soil layer (5 cm)
ρ = Dry bulk density (1.5 g/cm^3)

The PEC at specific times (t) after the application is given by:

$$PEC(mg/kg) = \text{Initial } PEC_S \text{ after last application} \times e^{-kt}$$

Where:
k = first order degradation/dissipation rate constant (ln(2)/half-life)

The time weighted average (TWA) PEC values are found by calculating a set of TWA PEC over a time window that is moved along the time axis. The average PEC within a day is calculated by:

$$\text{Average PEC over a day (mg/kg)} = \frac{\text{Actual PEC at start of day} \times (1-e^{-k})}{k}$$

The TWA over the moving window is calculated from the simple numerical average of these daily values.

[8] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

A 3.5 $PEC_{S,\ accu}$ specifications

In addition to the seasonal PEC_S calculations, the potential accumulation ($PEC_{S,accumulation}$) of the active substances fludioxonil and sedaxane in soil following repeated sowings of A20607B treated sugar beet seed was calculated. Accumulation calculations were based on application every year as a worst case.

For all active substances, SFO degradation was considered. The decay of each annual application was modelled on a daily basis for up to 10 years from first application. The total daily residue was the sum of the individual residues from each application. The calculation was done for 10 years and incorporation to 5 cm depth with annual tillage to 20 cm depth.

The maximum plateau concentration ($PEC_{S,max.\ plateau}$) was calculated as follows:

$$PEC_{S,max.plateau}\ [mg/kg] = \frac{PEC_{S,ini,d}}{(1 - e^{(-tk)})}$$

Where:
$PEC_{S,ini,d}$ = $PEC_{S,ini}$ calculated for 20 cm soil depth (incorporation due to ploughing) [mg/kg]
t = time interval between the application schemes [d] (every year = 365d)

The minimum plateau concentration ($PEC_{S,plateau}$), i.e. the minimum concentration in soil before the first annual application, was calculated as:

$$PEC_{S,plateau}\ [mg/kg] = PEC_{S,max.plateau} \times e^{(-tk)}$$

Where:
t = time interval between the last annual application and the first application in the subsequent season [d]

$PEC_{S,accumulation}$ was calculated as the sum of the $PEC_{S,plateau}$ concentration before the first annual application and the $PEC_{S,ini}$ (calculated for 5 cm soil depth) immediately after the last application:

$$PEC_{S,\ accumulation}\ [mg/kg] = PEC_{S,\ plateau} + PEC_{S,ini}$$

Under these conditions, fludioxonil and sedaxane residues reached the $PEC_{S,plateau}$ concentrations given in the Table 8.7-3 and Table 8.7-6, respectively. The following figures show the $PEC_{S,accumulation}$ at 5 cm soil depth.

Figure A 11: Graphical representation of the accumulated PEC_S of fludioxonil at 5 cm soil depth for an application rate of 0.97 g a.s./ha to sugar beet (Tier 1).

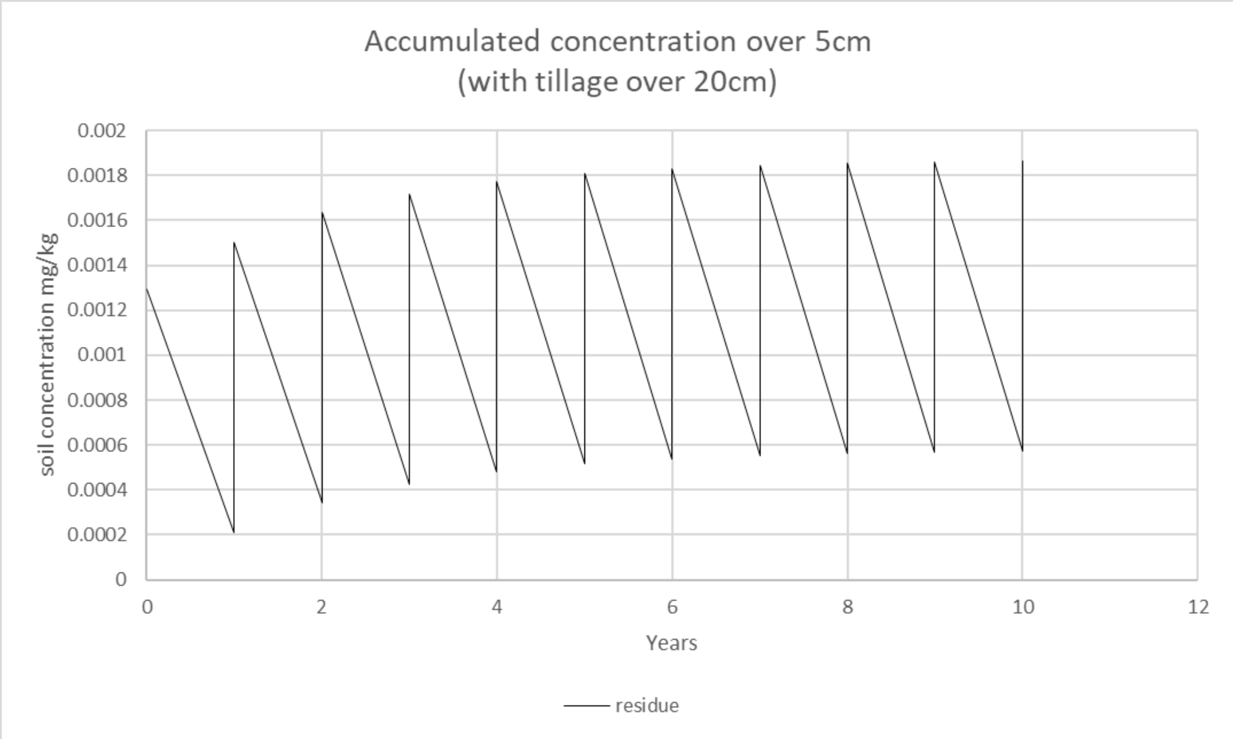


Figure A 12: Graphical representation of the accumulated PEC_S of fludioxonil at 5 cm soil depth for an application rate of 0.97 g a.s./ha to sugar beet (Tier 2).

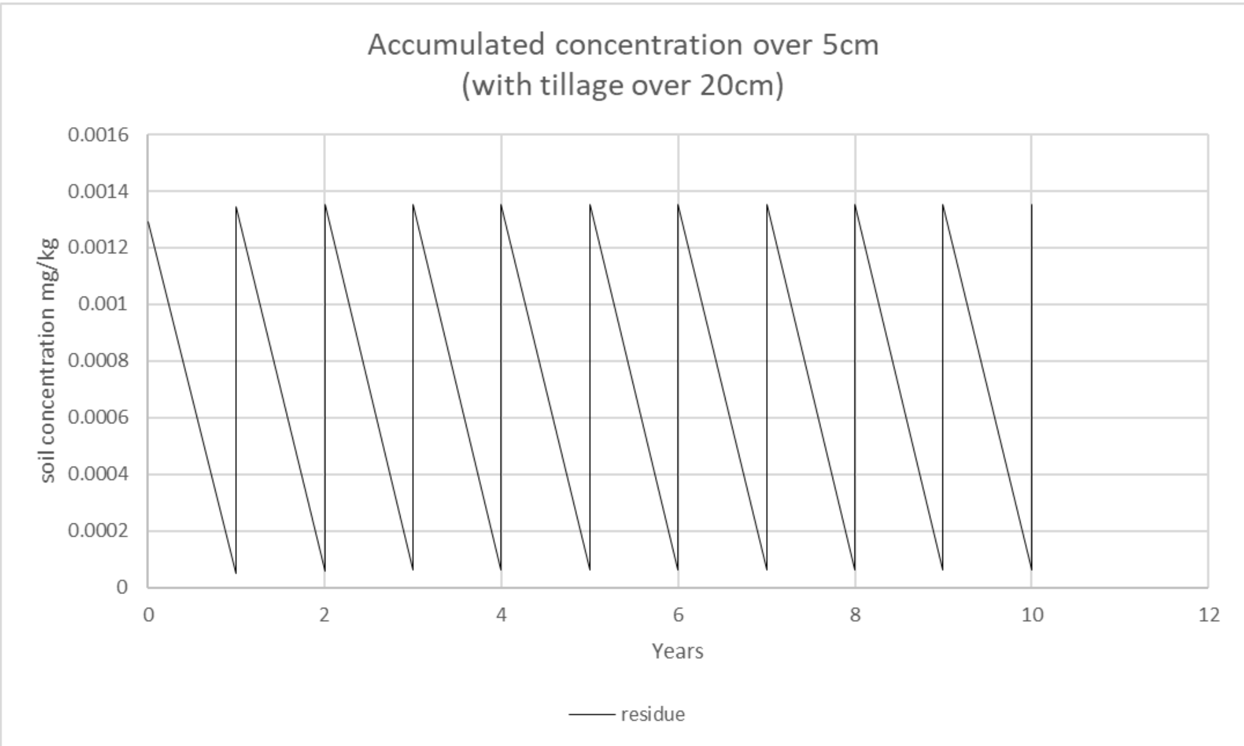


Figure A 13: Graphical representation of the accumulated PEC_S of sedaxane at 5 cm soil depth for an application rate of 0.65 g a.s./ha to sugar beet.

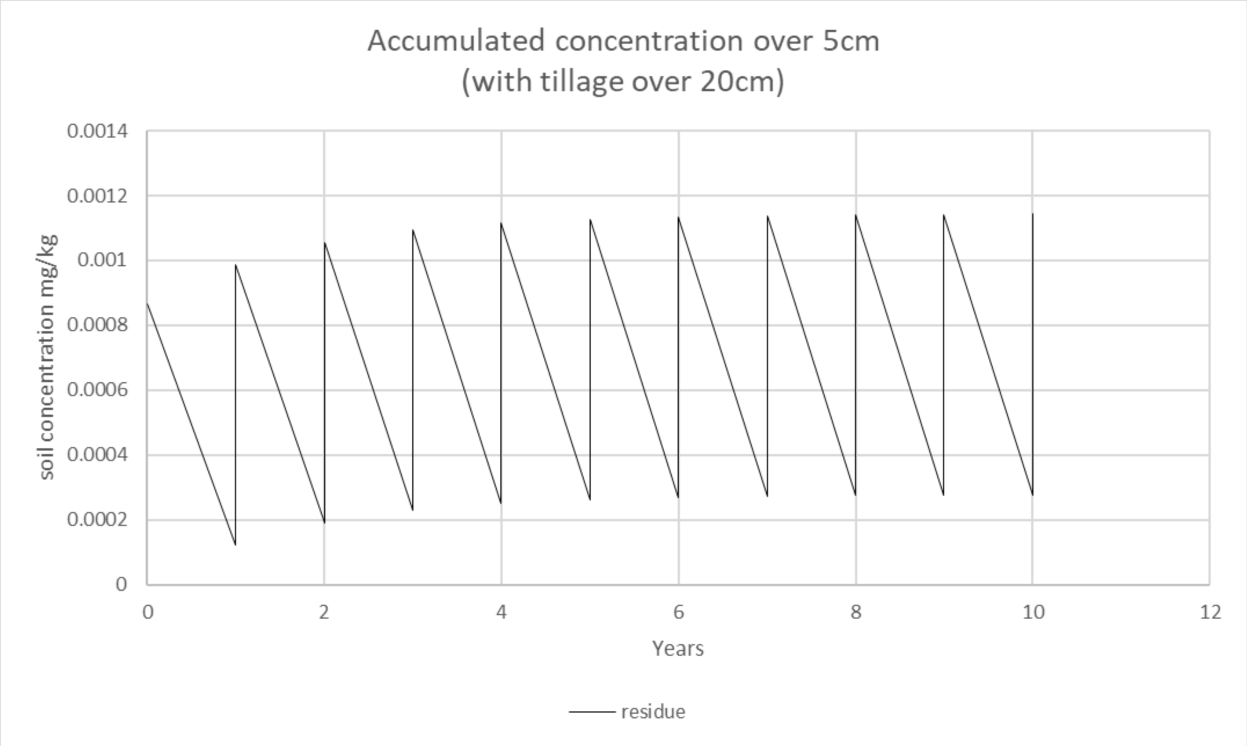
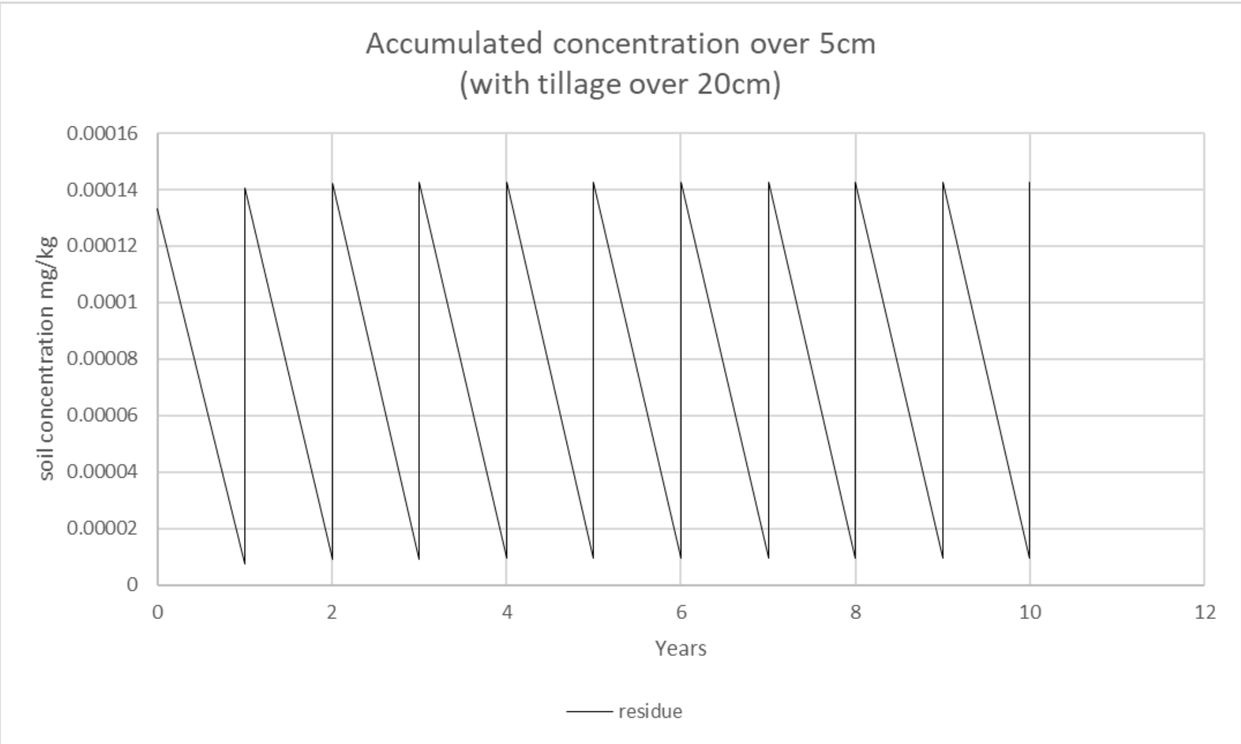


Figure A 14: Graphical representation of the accumulated PEC_S of CSCD465008 (Tier 1 PEC soil calculation) 5 cm soil depth for an application rate of 0.65 g a.s./ha to sugar beet.



A 3.6 Screenshots of the UK CRD PECsoil calculator

Fludioxonil - Tier 1

PEC SOIL

Number of applications	1

depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	569

1st Application	
Rate (g/ha)=	0.97
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.001	0.001
1	0.001	0.001
2	0.001	0.001
4	0.001	0.001
7	0.001	0.001
14	0.001	0.001
21	0.001	0.001
28	0.001	0.001
48	0.001	0.001
100	0.001	0.001

Fludioxonil - Tier 2

PEC SOIL

Number of applications	1

depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	137

1st Application	
Rate (g/ha)=	0.97
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.001	0.001
1	0.001	0.001
2	0.001	0.001
4	0.001	0.001
7	0.001	0.001
14	0.001	0.001
21	0.001	0.001
28	0.001	0.001
48	0.001	0.001
100	0.001	0.001

Metalaxyl-M

PEC SOIL

Number of applications	1

depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	30.9

1st Application	
Rate (g/ha)=	0.62
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.001	0.001
1	0.001	0.001
2	0.001	0.001
4	0.001	0.001
7	0.001	0.001
14	0.001	0.001
21	0.001	0.001
28	0.000	0.001
48	0.000	0.001
100	0.000	0.000

NOA409045

PEC SOIL

Number of applications	1

depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	39.8

1st Application	
Rate (g/ha)=	0.42
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.001	0.001
1	0.001	0.001
2	0.001	0.001
4	0.001	0.001
7	0.000	0.001
14	0.000	0.000
21	0.000	0.000
28	0.000	0.000
48	0.000	0.000
100	0.000	0.000

Sedaxane

PEC SOIL

Number of applications	1

depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	438

1st Application	
Rate (g/ha)=	0.65
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.001	0.001
1	0.001	0.001
2	0.001	0.001
4	0.001	0.001
7	0.001	0.001
14	0.001	0.001
21	0.001	0.001
28	0.001	0.001
48	0.001	0.001
100	0.001	0.001

CSAA798670

PEC SOIL

Number of applications	1

depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	18

1st Application	
Rate (g/ha)=	0.05
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.000	0.000
1	0.000	0.000
2	0.000	0.000
4	0.000	0.000
7	0.000	0.000
14	0.000	0.000
21	0.000	0.000
28	0.000	0.000
48	0.000	0.000
100	0.000	0.000

CSCD465008

PEC SOIL

Number of applications	1

depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	39.2

1st Application	
Rate (g/ha)=	0.1
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.000	0.000
1	0.000	0.000
2	0.000	0.000
4	0.000	0.000
7	0.000	0.000
14	0.000	0.000
21	0.000	0.000
28	0.000	0.000
48	0.000	0.000
100	0.000	0.000

A 3.7 KCP 9.2.4: [redacted] & [redacted] (2020) VV-858626. Fludioxonil - PEC_{GW} Following Seed Treatment Application to Sugar beet

Please note that use numbers in this summary refer to the modelling report and not to the GAP table in section 8.1 above. Use number 1 below corresponds to the use No. 10 in sections 8.1 and 8.8.2.

Reference:	KCP 9.2.4
Report:	Fludioxonil - A Leaching Assessment for Fludioxonil Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Sugar beet. [redacted], [redacted], 2020 TSG Consulting, Knaresborough, UK. Report Number 19-016-150-6 Syngenta File No. VV-858626
Guidelines:	Yes FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS groundwater scenarios workgroup, EC document reference Sanco/321/2000 rev. 2, 202 pp. FOCUS (2014a). Generic guidance for Tier 1 FOCUS groundwater assessments, version 2.2 FOCUS groundwater scenarios working group. FOCUS (2014b). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. The Final Report of the Ground Water Work Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their USe) Sanco/13144/2010, version 3, 10 October 2014.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.7.1 Materials and methods

This report describes a FOCUS groundwater modelling study that examined the potential for fludioxonil to reach groundwater following seed treatment application to sugar beet. The FOCUS simulation models FOCUS PEARL (v4.4.4), FOCUS PELMO (v5.5.3) and MACRO (v5.5.4) were used in the modelling study.

Single annual application at a rate of 0.97 g a.s./ha, at BBCH 00 was considered for sugar beets. The input parameters relating to application are shown in Table A 23 below.

Table A 23: Application patterns of fludioxonil used in modelling

Use No.	1
Crop	Sugar beet
Application rate (g a.s./ha)	0.97
Number of applications/interval (d)	1/--
Relative application date/BBCH growth stage	-/00
Crop interception (%)	0
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4

Applications were considered for the available FOCUS scenarios in PEARL and PELMO: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva to sugar beet. For MACRO, only the scenario Châteaudun is defined.

Application dates are presented in Table A 24, below. The dates were selected with the tool AppDate (v3.06). Simulations were carried out using the FOCUS standard crops as listed in Table A 23.

Simulations were carried out over 26 years, as proposed by FOCUS for pesticides that are applied annually. The first 6 years are intended to be a 'warm up' period, thus the following 20 years were taken into account for the assessment of the leaching behaviour.

The application method in FOCUS-PEARL was set to 'injection', which is representative for seed treatment. The soil depth was set to 2 cm in FOCUS-PEARL and in FOCUS-PELMO. In MACRO, it is not possible to specify a specific application method or depth.

Table A 24: Application dates of fludioxonil used in modelling

Crop	Scenario	Application dates (absolute)
Sugar beet	Châteaudun	25-Mar (84)*
	Hamburg	01-Apr
	Jokioinen	10-May
	Kremsmünster	01-Apr
	Okehampton	10-Apr
	Piacenza	01-Mar
	Porto	28-Feb
	Sevilla	31-Oct
	Thiva	15-Apr

* Numbers in brackets indicate Julian day numbers as entered in MACRO v5.5.4 for the scenario Châteaudun

The input parameters of fludioxonil used in modelling are shown in Table A 25, below. All other input values were set at the default values unless otherwise stated.

Table A 25: Summary of input parameters for fludioxonil for PEC_{GW} calculations

Compound	Fludioxonil	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	248.2	Yes / EFSA (2007)
Water solubility (mg/L)	1.8 (25°C)	Yes / EFSA (2007)
Saturated vapour pressure (Pa)	0 (25°C)	Worst case assumption
DT_{50} in soil (d)	164 (median of laboratory studies, n=9)	Yes / EFSA (2007)
Formation fraction	Not relevant	-
Transformation rate (1/day)[a]	P → sink / CO_2: 0.004227	Calculated
K_{FOC} / K_{FOM} (mL/g)	145600 / 84455 (arithmetic mean, n=5)	Yes / EFSA (2007)
1/n	1 (arithmetic mean, n=2)	Yes / EFSA (2007)
Plant uptake factor	0	Yes / EFSA (2007)

[a] For PELMO; (ln(2) / DT50) * FFm

A 3.7.2 Results

Predicted environmental concentrations for fludioxonil in groundwater (PEC_{GW}) were calculated for the use of fludioxonil on sugar beet in accordance with FOCUS guidelines (FOCUS, 2000, 2014).

The 80th percentile (at 1 m soil depth) PEC_{GW} values generated by the FOCUS PEARL, FOCUS PELMO and FOCUS MACRO simulations are given in the tables below.

Table A 26: PEC_{GW} for fludioxonil (with FOCUS PEARL v4.4.4)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)
		Fludioxonil
Use No. 1 Sugar beet 1 x 0.97 g a.s./ha	Châteaudun	<0.001
	Hamburg	<0.001
	Jokioinen	<0.001
	Kremsmünster	<0.001
	Okehampton	<0.001
	Piacenza	<0.001
	Porto	<0.001
	Sevilla	<0.001
	Thiva	<0.001

Table A 27: PEC$_{GW}$ for fludioxonil (with FOCUS PELMO v5.5.3)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)
		Fludioxonil
Use No. 1 Sugar beet 1 x 0.97 g a.s./ha	Châteaudun	<0.001
	Hamburg	<0.001
	Jokioinen	<0.001
	Kremsmünster	<0.001
	Okehampton	<0.001
	Piacenza	<0.001
	Porto	<0.001
	Sevilla	<0.001
	Thiva	<0.001

Table A 28: PEC$_{GW}$ for fludioxonil (with FOCUS MACRO v5.5.4)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)
		Fludioxonil
Use No. 1 Sugar beet 1 x 0.97 g a.s./ha	Châteaudun	<0.001

Table A 29: Summary of maximum PEC$_{GW}$ across all models for fludioxonil

Use	Substance		80th Percentile PEC$_{GW}$ (µg/L)	Model and Version Number	Scenario
Use No. 1: Sugar beet, 1 x 0.97 g a.s./ha	Fludioxonil	Arithmetic mean K_{FOC}	<0.001	All models	All scenarios

A 3.8 KCP 9.2.4: [redacted] & [redacted] (2020), VV-858628. Metalaxyl-M - PEC_{GW} Following Seed Treatment Application to Sugar beet

Please note that use numbers in this summary refer to the modelling report and not to the GAP table in section 8.1 above. Use number 1 below corresponds to the use No. 10 in sections 8.1 and 8.8.2.

Reference:	KCP 9.2.4
Report:	Metalaxyl-M - A Leaching Assessment for Metalaxyl-M and its Soil Metabolites NOA409045, SYN546520 and CGA67868 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Sugar beet. [redacted], [redacted], 2020 TSG Consulting, Knaresborough, UK. Report Number 19-016-150-7 Syngenta File No. VV-858628
Guidelines:	Yes FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS groundwater scenarios workgroup, EC document reference Sanco/321/2000 rev. 2, 202 pp. FOCUS (2014a). Generic Guidance for Tier 1 FOCUS Ground Water Assessments. Version 2.2. FOCUS groundwater scenarios working group. FOCUS (2014b). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. The Final Report of the Ground Water Work Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their USe) Sanco/13144/2010, version 3, 10 October 2014.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.8.1 Materials and methods

This report describes a FOCUS groundwater modelling study that examined the potential of metalaxyl-M and its soil metabolites NOA409045, SYN546520 and CGA67868 to reach groundwater following application to sugar beet. The FOCUS simulation models FOCUS PEARL (v4.4.4), FOCUS PELMO (v5.5.3) and MACRO (v5.5.4) were used in the modelling study.

Single annual application at a rate of 0.62 g a.s./ha, at BBCH 00 was considered for sugar beets. The input parameters relating to application are shown in Table A 30, below.

Table A 30: Application patterns of metalaxyl-M used in modelling

Use No.	1
Crop	Sugar beet
Application rate (g a.s./ha)	0.62
Number of applications/interval (d)	1/--
Relative application date/BBCH growth stage	-/00
Crop interception (%)	0
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4

Applications were considered for the available FOCUS scenarios in PEARL and PELMO: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva to sugar beet. For MACRO, only the scenario Châteaudun is defined.

Application dates are presented in Table A 31, below. The dates were selected with the tool AppDate (v3.06). Simulations were carried out using the FOCUS standard crops as listed in Table A 30.

Simulations were carried out over 26 years, as proposed by FOCUS for pesticides that are applied annually. The first 6 years are intended to be a 'warm up' period, thus the following 20 years were taken into account for the assessment of the leaching behaviour.

The application method in FOCUS-PEARL was set to 'injection', which is representative for seed treatment. The soil depth was set to 2 cm in FOCUS-PEARL and in FOCUS-PELMO. In MACRO, it is not possible to specify a specific application method or depth.

Table A 31: Application dates of sedaxane used in modelling

Crop	Scenario	Application dates (absolute)
Sugar beet	Châteaudun	25-Mar (84)*
	Hamburg	01-Apr
	Jokioinen	10-May
	Kremsmünster	01-Apr
	Okehampton	10-Apr
	Piacenza	01-Mar
	Porto	28-Feb
	Sevilla	31-Oct
	Thiva	15-Apr

* Numbers in brackets indicate Julian day numbers as entered in MACRO v5.5.4 for the scenario Châteaudun

The input parameters of metalaxyl-M and its soil metabolites NOA409045, SYN546520 and CGA67868 used in modelling are shown in Table A 32, below. All other input values were set at the default values unless otherwise stated. Schematic diagrams of the modelled route of degradation of sedaxane in soil are shown in Figure A 15 to Figure A 16.

Table A 32: Summary of input parameters for metalaxyl-M, NOA409045, SYN546520 and CGA67868 for PEC_{GW} calculations

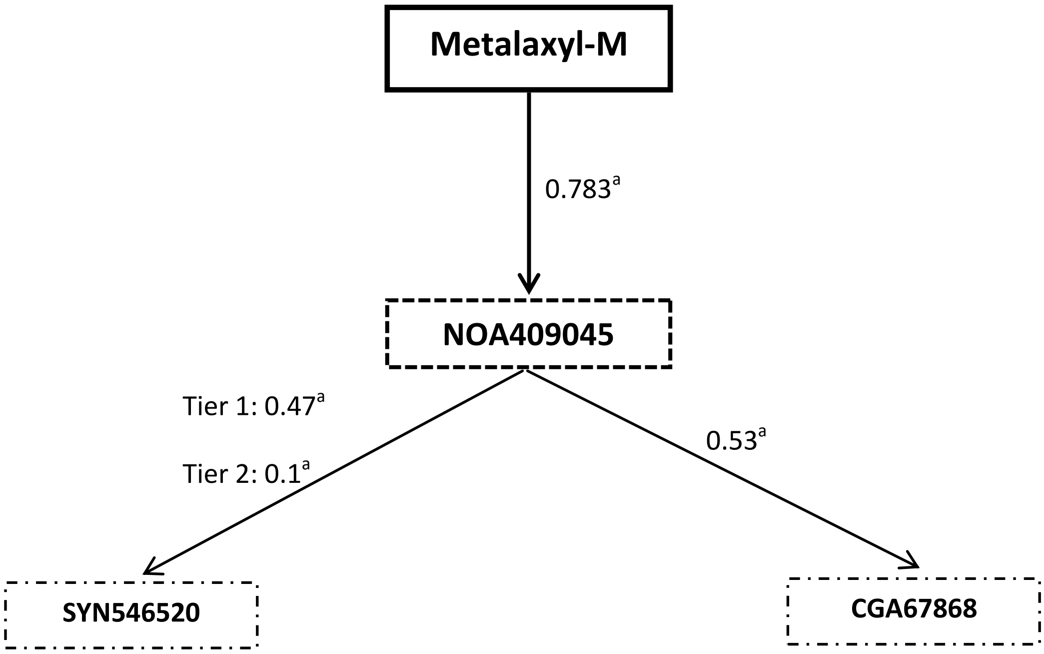
Compound	Metalaxyl-M	NOA409045	SYN546520	CGA67868	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	279.3	265.3	295.3	193.2	Yes / EFSA (2015)
Water solubility (mg/L)	26000 (25°C)	265000 (25°C)	265000 (25°C)	45800 (25°C)	Yes / EFSA (2015)
Saturated vapour pressure (Pa)	0.0033 (25°C)	1×10^{-5} (20°C)	1×10^{-5} (20°C)	1×10^{-5} (20°C)	Yes / EFSA (2015)
DT_{50} in soil (d)	6.5 (median, n=10)	30.5[a] (geometric mean, n=8)	96.8 (geometric mean, n=3)	2.9 (geometric mean, n=3)	Yes / EFSA (2015)
Formation fraction	-	0.783 from parent	Tier 1: 0.47 / Tier 2: 0.1 (from NOA409045)[b]	0.53 (from NOA409045)	Yes / EFSA (2015)
Transformation rate (1/day)[c]	P→NOA409045 0.083498 P→sink / CO_2: 0.023140	Tier 1: NOA409045 →SYN546520: 0.01068 NOA409045 →CGA67868: 0.012045 NOA409045 → sink / CO_2: 0 Tier 2: NOA409045 →SYN546520: 0.002273 NOA409045 →CGA67868: 0.012045 NOA409045 → sink / CO_2: 0.008409	SYN546520 → sink / CO_2: 0.007161	CGA67868 → sink / CO_2: 0.007161	Calculated
Conversion factor for Macro[d]	-	0.7438 (from parent)	0.3891 (Tier 1) / 0.0828 (Tier 2) (from parent)	0.2871 (from parent)	Calculated
K_{FOC} / K_{FOM}[e] (mL/g)	78.9 / 45.8 (arithmetic mean, n=25)	17.9 / 10.4 (arithmetic mean, n=14)	15.2 / 8.82 (arithmetic mean, n=4)	19.0/ 11.0 (arithmetic mean, n=5)	Yes / EFSA (2015)
1/n	0.955 (arithmetic mean, n=25)	0.928 (arithmetic mean, n=14)	1.1 (arithmetic mean, n=4)	0.896 (arithmetic mean, n=5)	Yes / EFSA (2015)
Plant uptake factor	0	0	0	0	Yes / EFSA (2015)

a Values of DT_{50} used in the modelling have been re-calculated from the list of endpoints (EFSA, 2015)
b As a tiered approach, the PEC_{GW} were calculated with two different formation fractions of 0.47 (Tier 1, EFSA 2015) and 0.1 (Tier 2) for SYN546520
c For PELMO; (ln(2) / DT50) * FFm

[d] Since MACRO can only handle a single metabolite, all metabolites were calculated as primary metabolites. Conversion factors for MACRO were calculated as:
FormationFraction(Met.) x FormationFraction(PreceedingMet.) x MolarMass(Met.) / MolarMass(Parent)

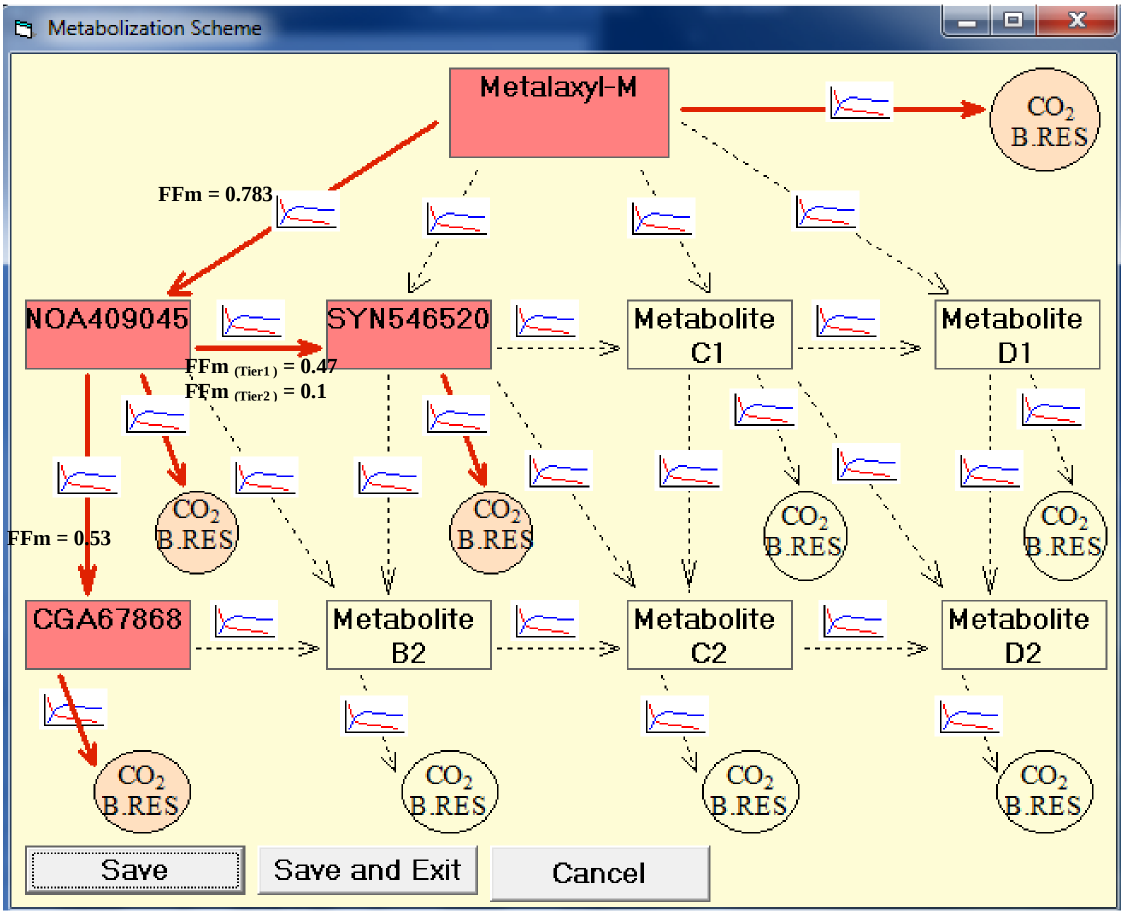
[e] Calculated: $K_{FOM} = K_{FOC} /1.724$

Figure A 15: Schematic diagram of the modelled route of degradation of metalaxyl-M



[a] Formation fraction

Figure A 16: Degradation scheme for metalaxyl-M and its metabolites as used in FOCUS-PELMO



A 3.8.2 Results

Predicted environmental concentrations for metalaxyl-M and its soil metabolites NOA409045, SYN546520 and CGA67868 in groundwater (PEC_{GW}) were calculated for the use of metalaxyl-M on sugar beet in accordance with FOCUS guidelines (FOCUS, 2000, 2014).

The 80th percentile (at 1 m soil depth) PEC_{GW} values generated by the FOCUS PEARL, FOCUS PELMO and FOCUS MACRO simulations are given in the tables below.

Table A 33: PEC$_{GW}$ for metalaxyl-M, NOA409045, SYN546520 and CGA67868 (with FOCUS PEARL v4.4.4)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		metalaxyl-M	NOA409045	SYN546520		CGA67868
				Tier 1	Tier2	
Use No. 1 Sugar beet 1 x 0.62 g a.s./ha	Châteaudun	< 0.001	0.012	0.063	0.014	< 0.001
	Hamburg	< 0.001	0.010	0.094	0.020	< 0.001
	Jokioinen	< 0.001	0.008	0.102	0.023	< 0.001
	Kremsmünster	< 0.001	0.007	0.048	0.010	< 0.001
	Okehampton	< 0.001	0.007	0.041	0.009	< 0.001
	Piacenza	< 0.001	0.005	0.053	0.011	< 0.001
	Porto	< 0.001	0.003	0.042	0.009	< 0.001
	Sevilla	< 0.001	0.006	0.049	0.011	< 0.001
	Thiva	< 0.001	0.004	0.106	0.023	< 0.001

Table A 34: PEC$_{GW}$ for metalaxyl-M, NOA409045, SYN546520 and CGA67868 (with FOCUS PELMO v5.5.3)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		metalaxyl-M	NOA409045	SYN546520		CGA67868
				Tier 1	Tier 2	
Use No. 1 Sugar beet 1 x 0.62 g a.s./ha	Châteaudun	< 0.001	0.008	0.073	0.016	< 0.001
	Hamburg	< 0.001	0.009	0.066	0.014	< 0.001
	Jokioinen	< 0.001	0.009	0.085	0.019	< 0.001
	Kremsmünster	< 0.001	0.007	0.051	0.011	< 0.001
	Okehampton	< 0.001	0.009	0.040	0.009	< 0.001
	Piacenza	< 0.001	0.006	0.050	0.011	< 0.001
	Porto	< 0.001	0.006	0.038	0.008	< 0.001
	Sevilla	< 0.001	0.007	0.053	0.011	< 0.001
	Thiva	< 0.001	0.003	0.066	0.014	< 0.001

Table A 35: PEC$_{GW}$ for metalaxyl-M, NOA409045, SYN546520 and CGA67868 (with FOCUS MACRO v5.5.4)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		metalaxyl-M	NOA409045	SYN546520		CGA67868
				Tier 1	Tier 2	
Use No. 1: Sugar beet, 1 x 0.62 g a.s./ha	Châteaudun	< 0.001	0.005	0.039	0.008	< 0.001

Table A 36: Summary of maximum PEC$_{GW}$ across all models for metalaxyl-M, NOA409045, SYN546520 and CGA67868

Use	Substance		80th Percentile PEC$_{GW}$ (µg/L)	Model and Version Number	Scenario
Use No. 1: Sugar beet, 1 x 0.62 g a.s./ha	Metalaxyl-M		<0.001	All models	All scenarios
	NOA409045		0.012	FOCUS PEARL v4.4.4	Châteaudun
	SYN546520	Tier 1	0.106	FOCUS PEARL v4.4.4	Thiva
		Tier 2	0.023	FOCUS PEARL v4.4.4	Jokioinen
	CGA67868		<0.001	All models	All scenarios

A 3.9 KCP 9.2.4: [redacted] & [redacted] (2020), VV-858630. Sedaxane - PEC_{GW} Following Seed Treatment Application to Sugar beet

Please note that use numbers in this summary refer to the modelling report and not to the GAP table in section 8.1 above. Use number 1 below corresponds to the use No. 10 in sections 8.1 and 8.8.2.

Reference:	KCP 9.2.4
Report:	Sedaxane - A Leaching Assessment for Sedaxane and its Soil Metabolites CSAA798670, CSCD465008 and CSCD728931 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Sugar beet. [redacted], [redacted], 2020 TSG Consulting, Knaresborough, UK. Report Number 19-016-150-8 Syngenta File No. VV-858630
Guidelines:	Yes FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS groundwater scenarios workgroup, EC document reference Sanco/321/2000 rev. 2, 202 pp. FOCUS (2014a). Generic Guidance for Tier 1 FOCUS Ground Water Assessments. Version 2.2. FOCUS groundwater scenarios working group. FOCUS (2014b). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. The Final Report of the Ground Water Work Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their USe) Sanco/13144/2010, version 3, 10 October 2014.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.9.1 Materials and methods

This report describes a FOCUS groundwater modelling study that examined the potential for sedaxane and its metabolites CSAA798670, CSCD465008 and CSCD728931 to reach groundwater following seed treatment application to sugar beet. The FOCUS simulation models FOCUS PEARL (v4.4.4), FOCUS PELMO (v5.5.3) and MACRO (v5.5.4) were used in the modelling study.

Single annual application at a rate of 0.65 g a.s./ha, at BBCH 00 was considered for sugar beets. The input parameters relating to application are shown in Table A 37, below.

Table A 37: Application patterns of sedaxane used in modelling

Use No.	1
Crop	Sugar beet
Application rate (g a.s./ha)	0.65
Number of applications/interval (d)	1/--
Relative application date/BBCH growth stage	-/00
Crop interception (%)	0
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4

Applications were considered for the available FOCUS scenarios in PEARL and PELMO: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva to sugar beet. For MACRO, only the scenario Châteaudun is defined.

Application dates are presented in Table A 38, below. The dates were selected with the tool AppDate (v3.06). Simulations were carried out using the FOCUS standard crops as listed in Table A 37.

Simulations were carried out over 26 years, as proposed by FOCUS for pesticides that are applied annually. The first 6 years are intended to be a 'warm up' period, thus the following 20 years were taken into account for the assessment of the leaching behaviour.

The application method in FOCUS-PEARL was set to 'injection', which is representative for seed treatment. The soil depth was set to 2 cm in FOCUS-PEARL and in FOCUS-PELMO. In MACRO, it is not possible to specify a specific application method or depth.

Table A 38: Application dates of sedaxane used in modelling

Crop	Scenario	Application dates (absolute)
Sugar beet	Châteaudun	25-Mar (84)*
	Hamburg	01-Apr
	Jokioinen	10-May
	Kremsmünster	01-Apr
	Okehampton	10-Apr
	Piacenza	01-Mar
	Porto	28-Feb
	Sevilla	31-Oct
	Thiva	15-Apr

* Numbers in brackets indicate Julian day numbers as entered in MACRO v5.5.4 for the scenario Châteaudun

The input parameters of sedaxane and its metabolites CSAA798670, CSCD465008 and CSCD728931 used in modelling are shown in Table A 39, below. All other input values were set at the default values unless otherwise stated. Schematic diagrams of the modelled route of degradation of sedaxane in soil are shown in Figure A 17 to Figure A 19.

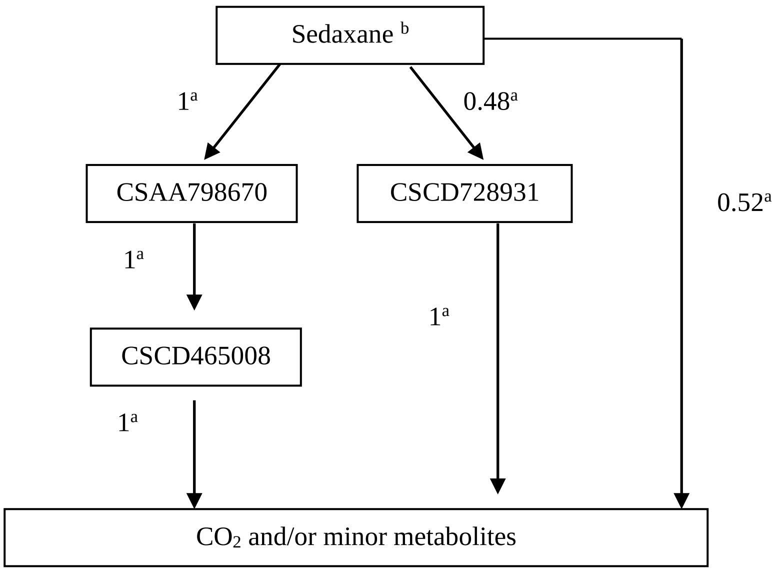
Table A 39: Summary of input parameters for sedaxane, CSAA798670, CSCD465008 and CSCD728931 for PEC_{GW} calculations

Compound	Sedaxane	CSAA798670	CSCD465008	CSCD728931	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	331	176	162	363.4	Yes / EFSA (2013)
Water solubility (mg/L)	14 (20°C)	100 (20°C)[a]	333200 (20°C)[b]	100 (20°C)[a]	Yes / EFSA (2013)
Saturated vapour pressure (Pa)	1.7 x 10-7 (25°C)[c]	0	0	0	Worst case assumption
DT_{50} in soil (d)	100* (geomean, n=4, field, normalisation to 20°C and pF2)	8.3* (geomean, n=4, laboratory, normalisation to 20°C and pF2)	Tier 1: 114* (geomean n=4, laboratory, normalisation to 20°C and pF2) Tier 2: 25.9** (geomean n=4, field, normalisation to 20°C and pF2)	42.3*** (geomean n=5, laboratory, normalisation to 20°C and pF2)	*Yes / EFSA (2013) **Yes / EFSA (2012)[d] / [redacted] et al. (2009), [redacted], (2009) *** No / [redacted] (2013)
Formation fraction[e]	-	Route 1: 1* from parent	Route 1: 1* from metabolite CSAA798670	Route 2: 0.48** from parent	*Worst case **No / [redacted] (2013)
Transformation rate (1/day)[f]	Route 1: P→CSAA798670 0.006931 Route 2: P→ CSCD728931 0.00333 P → sink / CO_2: 0.0036	Route 1: CSAA798670→ CSCD465008: 0.08351 CSAA798670→sink / CO_2: 0	Tier 1: CSCD465008 →sink / CO_2: 0.00608 Tier 2: CSCD465008 →sink / CO_2: 0.026762	Route 2: CSCD728931→ sink / CO_2: 0.01639	Calculated
Conversion factor for Macro[g]	-	0.53	0.49	0.53	Calculated
K_{FOC} / K_{FOM}[h] (mL/g)	534* / 309.7 (arithmetic mean, n=6)	3.0* / 1.7 (arithmetic mean, n=5)	Tier 1: 2.1* / 1.2 (arithmetic mean, n=3) Tier 2: 6.0*/** / 3.5 (arithmetic mean, n=10)	103.9***/ 60.3 (arithmetic mean, n=5)	*Yes / EFSA (2013) **Yes / EFSA (2012)[c] / [redacted] & [redacted] (2009) ***No / [redacted] (2013)
1/n	0.865* (arithmetic mean, n=6)	0.9* (arithmetic mean, n=5)	Tier 1: 0.85* (arithmetic mean, n=3) Tier 2: 0.93*/** (arithmetic mean, n=10)	0.89*** (arithmetic mean, n=5)	*Yes / EFSA (2013) **Yes / EFSA (2012)[d] / [redacted] & [redacted] (2009) ***No / [redacted] (2013)

Compound	Sedaxane	CSAA798670	CSCD465008	CSCD728931	Value in accordance to EU endpoint / Reference
Plant uptake factor	0	0	0	0	Yes / EFSA (2013)

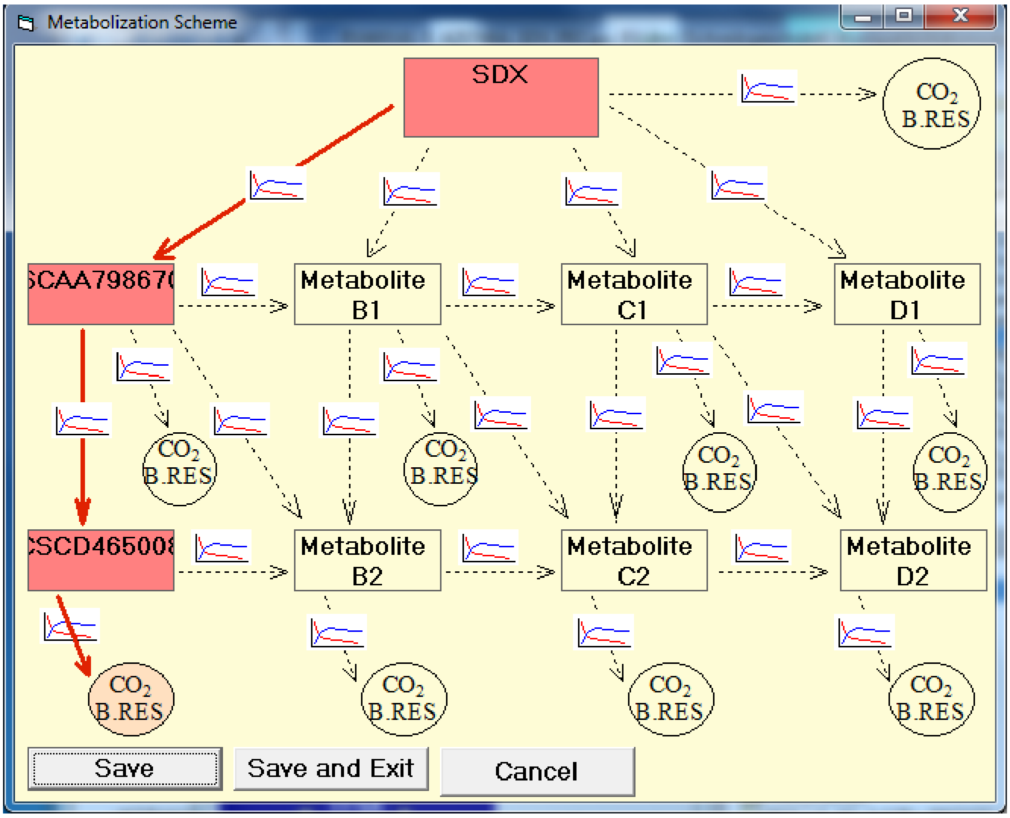
[a] Assumed as a conservative approach
[b] This value differs from the value proposed by EFSA. However, it is not a sensitive parameter and has no influence on the results
[c] Set to 0; field degradation data used for sedaxane so vaporisation should not be considered
[d] Fluxapyroxad, EFSA Journal 2012; 10(1):2522
[e] Two formation routes were analysed; Route 1: Sedaxane→CSAA798670→CSCD465008→sink/CO_2; and Route 2: SedaxaneCSCD728931→ sink / CO_2.
[f] For PELMO; (ln(2) / DT50) * FFm
[g] Since MACRO can only handle a single metabolite, all metabolites were calculated as primary metabolites. Conversion factors for MACRO were calculated as:
FormationFraction(Met.) x FormationFraction(PreceedingMet.) x MolarMass(Met.) / MolarMass(Parent)
[h] Calculated: $K_{FOM} = K_{FOC}$ /1.724

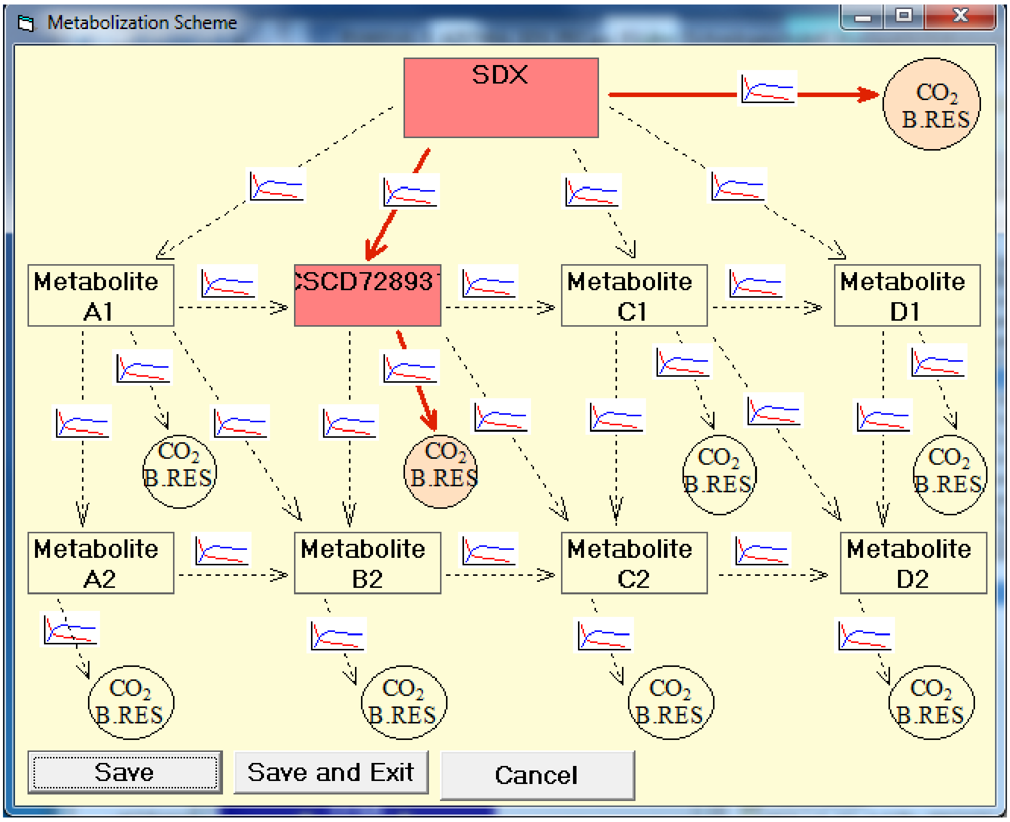
Figure A 17: Schematic diagram of the modelled route of degradation of sedaxane



[a] Formation fraction
[b] The degradation pathways sedaxane→CSAA798670→CSCD465008 and sedaxane→CSCD728931 where simulated separately in PELMO in order to account for the worst case formation fraction for all metabolites

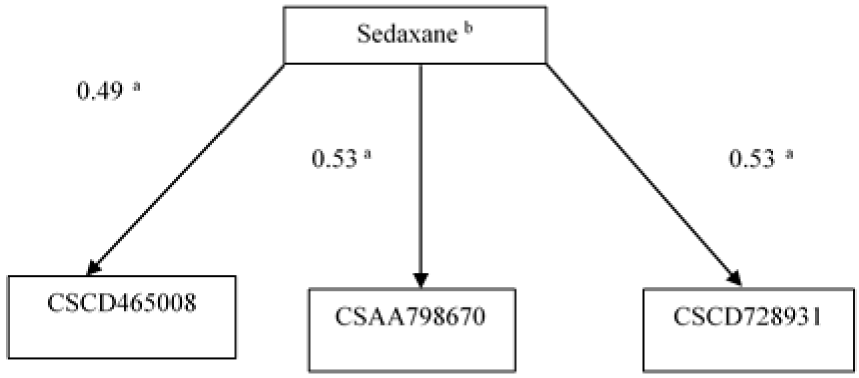
Figure A 18: **Degradation scheme for sedaxane and its metabolites as used in FOCUS-PELMO**





Since MACRO can only handle a single metabolite, all metabolites were calculated as primary metabolites:

Figure A 19: Degradation scheme for sedaxane and its metabolites as used in FOCUS-MACRO



[a] Conversion factor

A 3.9.2 Results

Predicted environmental concentrations for sedaxane and its metabolites CSAA798670, CSCD465008 and CSCD728931 in groundwater (PEC_{GW}) were calculated for the use of sedaxane on sugar beet in accordance with FOCUS guidelines (FOCUS, 2000, 2014).

The 80th percentile (at 1 m soil depth) PEC_{GW} values generated by the FOCUS PEARL, FOCUS PELMO and FOCUS MACRO simulations are given in the tables below.

Table A 40: PEC_{GW} for sedaxane, CSAA798670, CSCD465008 and CSCD728931 (with FOCUS PEARL v4.4.4)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		sedaxane	CSAA798670	CSCD465008		CSCD728931
				Tier 1	Tier2	
Use No. 1 Sugar beet 1 x 0.65 g a.s./ha	Châteaudun	< 0.001	0.001	0.080	0.020	< 0.001
	Hamburg	< 0.001	0.004	0.129	0.036	< 0.001
	Jokioinen	< 0.001	0.005	0.130	0.032	< 0.001
	Kremsmünster	< 0.001	0.001	0.069	0.016	< 0.001
	Okehampton	< 0.001	0.002	0.057	0.017	< 0.001
	Piacenza	< 0.001	0.001	0.074	0.010	< 0.001
	Porto	< 0.001	0.001	0.056	0.010	< 0.001
	Sevilla	< 0.001	0.001	0.063	0.006	< 0.001
	Thiva	< 0.001	< 0.001	0.138	0.009	< 0.001

Table A 41: PEC$_{GW}$ for sedaxane, CSAA798670, CSCD465008 and CSCD728931 (with FOCUS PELMO v5.5.3)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Sedaxane	CSAA798670	CSCD465008		CSCD728931
				Tier 1	Tier 2	
Use No. 1 Sugar beet 1 x 0.65 g a.s./ha	Châteaudun	< 0.001	0.001	0.094	0.015	< 0.001
	Hamburg	< 0.001	0.004	0.093	0.026	< 0.001
	Jokioinen	< 0.001	0.006	0.110	0.032	< 0.001
	Kremsmünster	< 0.001	0.001	0.071	0.017	< 0.001
	Okehampton	< 0.001	0.002	0.056	0.018	< 0.001
	Piacenza	< 0.001	0.001	0.064	0.011	< 0.001
	Porto	< 0.001	0.002	0.050	0.010	< 0.001
	Sevilla	< 0.001	0.001	0.062	0.007	< 0.001
	Thiva	< 0.001	< 0.001	0.090	0.007	< 0.001

Table A 42: PEC$_{GW}$ for sedaxane, CSAA798670, CSCD465008 and CSCD728931 (with MACRO v5.5.4)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		sedaxane	CSAA798670	CSCD465008		CSCD728931
				Tier 1	Tier 2	
Use No. 1: Sugar beet, 1 x 0.65 g a.s./ha	Châteaudun	< 0.001	0.001	0.055	< 0.001	< 0.001

Table A 43: Summary of maximum PEC$_{GW}$ across all models for sedaxane, CSAA798670, CSCD465008 and CSCD728931

Use	Substance		80th Percentile PEC$_{GW}$ (µg/L)	Model and Version Number	Scenario
Use No. 1: Sugar beet, 1 x 0.65 g a.s./ha	Sedaxane		<0.001	All models	All scenarios
	CSAA798670		0.006	FOCUS PELMO v5.5.3	Jokioinen
	CSCD465008	Tier 1	0.138	FOCUS PEARL v4.4.4	Thiva
		Tier 2	0.036	FOCUS PEARL v4.4.4	Hamburg
	CSCD728931		<0.001	All models	All scenarios

A 3.10 Tier I drainage assessments for fludioxonil and its relevant metabolites

A20607B is to be applied on sugarbeets within the drainflow period of 1st October to 30th April. As fludioxonil has a 'long' soil DT_{50} of 569 d, the PEC_{SW} and PEC_{SED} values of fludioxonil and its metabolite CGA192155 following entry via drainage have been determined according to standard Tier I calculations recommended for such applications in the UK national requirements (CRD, 2018).

Active substance

The PEC_{SW} and PEC_{SED} values of fludioxonil following entry *via* drainage has been calculated using the CRD 'PEC $_{sw\text{-}sed}$ (drainage)' spreadsheet (v 1.0). The Tier I drainage assessment assumes that following a rainfall event, a proportion of the applied compound in a given hectare will be lost in 10 mm of drainflow (equivalent to 100,000L water). The percentage of compound lost is assumed to be dependent on its soil adsorption (K_{OC}), and is defined in the national guidance (CRD, 2018). The 100,000 L of drainflow is then added to a stream on 30,000 L (same as the standard water body used in the drift assessment) to give a total volume of 130,000 L. By definition these concentrations are transitory as dilution and adsorption to sediments quickly dissipate the compounds. Bulk density of sediment is assumed to be 1.3g/cm^3.

The soil residue available for drainage, R, was calculated following SFO kinetics according to the following equation:

$$R\,[\mathrm{g/ha}] = A \cdot (1 - I) \cdot \frac{(1 - e^{-n \cdot k \cdot i})}{(1 - e^{-k \cdot i})}$$

Where:
A = application rate [g a.s./ha]
I = fraction crop interception [-]
k = degradation rate constant in soil (= ln(2) / DT_{50}) [1/d]
i = minimum interval between applications [d]
n= maximum number of applications [-]

The PEC_{SW} *via* drainage is calculated as follows:

$$PEC_{SW,drainage}\,[\mu g/L] = \frac{R \cdot Flux \cdot 10^6}{130000}$$

Where:
R = soil residue available for drainage [g/ha]
Flux = fraction of pesticide loss in drainflow [-]

The PEC_{SED} *via* drainage is calculated as follows:

$$PEC_{SED,drainage}[\mu g/Kg] = \left(PEC_{SW,drainage} \cdot \text{ Fraction in sediment } / (1000 \cdot 5000 \cdot 1.3)\right) \cdot 30000$$

Table A 44: Percentage of fludioxonil loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
Fludioxonil	145600	0.008

[a] In accordance with CRD guidance

Table A 45: Overall maximum $PEC_{SW/SED}$ for fludioxonil due to drainage following single application of A20607B to sugarbeet

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Initial PEC_{SW} (µg/L)	Initial PEC_{SED} (µg/Kg)
Sugar beet	1	0	0.001	0.97	0.00008	0.001	0.002

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above

Metabolites

The formation of CGA192155 was observed in soil and water (please refer to section 8.6). The formation of the metabolite in soil is considered not relevant for seed treatment use, since CGA192155 is formed only through photolysis. As such, the $PEC_{SW/SED}$ drainflow of CGA192155 has only been determined for the pathway where the metabolite is formed in the waterbody after the parent substance entered *via* drain-age.

For metabolites formed in the waterbody

PEC_{SW} and PEC_{SED} values of CGA192155 following formation in the waterbody after the parent sub-stance entered *via* drainage, were calculated based on the maximum parent PEC_{SW} value, adjusted for the maximum occurrence in the surface water and sediment, respectively, and corrected for the molecular weight difference relative to parent according to the following equations:

$$PEC_{SW,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SW,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

$$PEC_{SED,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SED,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}} \cdot 4.615$$

Where:
$PEC_{SW,parent}$ = PEC_{SW} of the parent after entry via drainage [µg/L]
$MaxAR_{SW,metabolite}$ = maximum percentage of metabolite observed in water [%]
$MaxAR_{SED,metabolite}$ = maximum percentage of metabolite observed in sediment [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Table A 46: Percentage of pesticide loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
CGA192155	23.5	1.90

[a] In accordance with CRD guidance

Table A 47: Overall maximum $PEC_{SW/SED}$ for CGA192155 due to drainage following single applications of A20607B to sugarbeet

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[ab]	Mass of comp. lost to drainage (g/ha)[a]	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							Fraction formed in soil[a]	Fraction formed in water	Fraction formed in soil[a]	Fraction formed in sedi-ment
Sugar beet	1	0	not relevant	not relevant	not relevant	0.001	not relevant	<0.001	not relevant	<0.001

[a] CGA192155 metabolite is not detected in soil
[b] Soil residue available for drainage (R), see equation above for active substance

A 3.11 Tier I drainage assessments for metalaxyl-M and its metabolite NOA409045

A20607B is to be applied on sugarbeet within the drainflow period of 1st October to 30th April. The PEC_{SW} and PEC_{SED} values of metalaxyl-M and its metabolite NOA409045 following entry *via* drainage have been determined according to standard Tier I calculations recommended for such applications in the UK national requirements (CRD, 2018).

Active substance

The PEC_{SW} and PEC_{SED} values of metalaxyl-M following entry *via* drainage has been calculated using the CRD 'PEC $_{sw\text{-}sed}$ (drainage)' spreadsheet (v 1.0). The Tier I drainage assessment assumes that following a rainfall event, a proportion of the applied compound in a given hectare will be lost in 10 mm of drainflow (equivalent to 100,000L water). The percentage of compound lost is assumed to be dependent on its soil adsorption (K_{OC}), and is defined in the national guidance (CRD, 2018). The 100,000L of drainflow is then added to a stream on 30,000L (same as the standard water body used in the drift assessment) to give a total volume of 130,000L. By definition these concentrations are transitory as dilution and adsorption to sediments quickly dissipate the compounds. Bulk density of sediment is assumed to be 1.3g/cm^3.

The soil residue available for drainage, R, was calculated following SFO kinetics according to the following equation:

$$R\,[\mathrm{g/ha}] = A \cdot (1 - I) \cdot \frac{(1 - e^{-n \cdot k \cdot i})}{(1 - e^{-k \cdot i})}$$

Where:
A = application rate [g a.s./ha]
I = fraction crop interception [-]
k = degradation rate constant in soil (= ln(2) / DT_{50}) [1/d]
i = minimum interval between applications [d]
n= maximum number of applications [-]

The PEC_{SW} *via* drainage is calculated as follows:

$$PEC_{SW,drainage}\,[\mu g/L] = \frac{R \cdot Flux \cdot 10^6}{130000}$$

Where:
R = soil residue available for drainage [g/ha]
Flux = fraction of pesticide loss in drainflow [-]

The PEC_{SED} *via* drainage is calculated as follows:

$$PEC_{SED,drainage}\,[\mu g/Kg] = \left(PEC_{SW,drainage} \cdot \text{ Fraction in sediment } \middle/ (1000 \cdot 5000 \cdot 1.3)\right) \cdot 30000$$

Table A 48: Percentage of metalaxyl-M loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
Metalaxyl-M	78.9	0.7%

[a] In accordance with CRD guidance

Table A 49: Overall maximum $PEC_{SW/SED}$ for metalaxyl-M due to drainage following single application of A20607B to sugarbeet

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Initial PEC_{SW} (µg/L)	Initial PEC_{SED} (µg/Kg)
Sugar beet	1	0[c]	0.001	0.62	0.0043	0.033	0.031

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm³ soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Metabolites

The formation of NOA409045 was observed in soil and water (please refer to section 8.6).

As such, the $PEC_{SW/SED}$ drainflow of NOA409045 has been determined for two pathways: the formation of the metabolite in soil and the subsequent entry into the waterbody *via* drainage and; the formation of the metabolite in the waterbody after the parent substance entered *via* drainage. The highest $PEC_{SW/SED}$ value obtained across the two routes is then reported.

For metabolites formed via the soil pathway

PEC_{SW} values of NOA409045 following formation in soil and subsequent entry into the water body *via* drainage, were calculated based on maximum PEC_S values after application and using the equation given above for the active substance. Thereby the PEC_S of NOA409045 is calculated on the basis of the maximum total dose of metalaxyl-M, adjusted for the maximum occurrence in the soil and corrected for the molecular weight difference relative to parent. Pseudo-application rates used to calculate PEC_S of NOA409045 were calculated according to the following equation:

$$A_{metabolite}\,[g/ha] = A_{parent} \times \frac{MaxAR_{metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

Where:
A_{parent} = application rate of parent substance [g/ha]
$MaxAR_{metabolite}$ = maximum percentage of metabolite observed in soil [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Otherwise, the PEC_{SW} and PEC_{SED} values of NOA409045 following entry *via* drainage have been calculated using the CRD ‘PEC $_{sw\text{-}sed}$ (drainage)’ spreadsheet (v 1.0), in the same way as the active substance metalaxyl-M.

For metabolites formed in the waterbody

PEC_{SW} and PEC_{SED} values of NOA409045 following formation in the waterbody after the parent substance entered *via* drainage, were calculated based on the maximum parent PEC_{SW} value, adjusted for the maximum occurrence in the surface water and sediment, respectively, and corrected for the molecular weight difference relative to parent according to the following equations:

$$PEC_{SW,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SW,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

$$PEC_{SED,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SED,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}} \cdot 4.615$$

Where:
$PEC_{SW,parent}$ = PEC_{SW} of the parent after entry via drainage [µg/L]
$MaxAR_{SW,metabolite}$ = maximum percentage of metabolite observed in water [%]
$MaxAR_{SED,metabolite}$ = maximum percentage of metabolite observed in sediment [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Table A 50: Percentage of pesticide loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
NOA409045	17.9	1.9

[a] In accordance with CRD guidance

Table A 51: Overall maximum $PEC_{SW/SED}$ for NOA409045 due to drainage following single application of A20607B to sugarbeet

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drainage (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							Formation in soil	Formation in water body	Formation in soil	Formation in water body
Sugar beet	1	0[c]	0.001	0.42	0.008	0.033	0.061	0.022	0.065	0.023

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

A 3.12 Tier I drainage assessments for sedaxane and its metabolites

A20607B is to be applied on sugarbeet within the drainflow period of 1st October to 30th April. As sedaxane has a 'long' soil DT_{50} of 438 d, the PEC_{SW} and PEC_{SED} values of sedaxane and its relevant metabolites CSAA798670, CSCD465008, CSCD668094 and CSCD668095 following entry *via* drainage have been determined according to standard Tier I calculations recommended for such applications in the UK national requirements (CRD, 2018).

Active substance

The PEC_{SW} and PEC_{SED} values of sedaxane following entry *via* drainage has been calculated using the CRD 'PEC $_{sw\text{-}sed}$ (drainage)' spreadsheet (v 1.0). The Tier I drainage assessment assumes that following a rainfall event, a proportion of the applied compound in a given hectare will be lost in 10 mm of drainflow (equivalent to 100,000 L water). The percentage of compound lost is assumed to be dependent on its soil adsorption (K_{OC}), and is defined in the national guidance (CRD, 2018). The 100,000 L of drainflow is then added to a stream on 30,000 L (same as the standard water body used in the drift assessment) to give a total volume of 130,000 L. By definition these concentrations are transitory as dilution and adsorption to sediments quickly dissipate the compounds. Bulk density of sediment is assumed to be 1.3g/cm^3.

The soil residue available for drainage, R, was calculated following SFO kinetics according to the following equation:

$$R\,[\mathrm{g/ha}] = A \cdot (1 - I) \cdot \frac{(1 - e^{-n \cdot k \cdot i})}{(1 - e^{-k \cdot i})}$$

Where:
A = application rate [g a.s./ha]
I = fraction crop interception [-]
k = degradation rate constant in soil (= ln(2) / DT_{50}) [1/d]
i = minimum interval between applications [d]
n= maximum number of applications [-]

The PEC_{SW} *via* drainage is calculated as follows:

$$PEC_{SW,drainage}\,[\mu g/L] = \frac{R \cdot Flux \cdot 10^6}{130000}$$

Where:
R = soil residue available for drainage [g/ha]
Flux = fraction of pesticide loss in drainflow [-]

The PEC_{SED} *via* drainage is calculated as follows:

$$PEC_{SED,drainage}\,[\mu g/Kg] = \left(PEC_{SW,drainage} \cdot \text{ Fraction in sediment } \middle/ (1000 \cdot 5000 \cdot 1.3)\right) \cdot 30000$$

Table A 52: Percentage of pesticide loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
Sedaxane	534	0.500

[a] In accordance with CRD guidance

Table A 53: Overall maximum $PEC_{SW/SED}$ for sedaxane due to drainage following single application of A20607B to sugarbeet

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Initial PEC_{SW} (µg/L)	Initial PEC_{SED} (µg/Kg)
Sugar beet	1	0	0.001	0.65	0.0033	0.025	0.102

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above

Metabolites

The formation of metabolite CSAA798670 was observed in soil and water. The metabolite CSCD465008 was detected only in soil. The formation of CSCD668094 and CSCD668095 was observed only in water (please refer to section 8.6). As such, the $PEC_{SW/SED}$ drainflow of CSAA798670 has been determined for two pathways: the formation of the metabolite in soil and the subsequent entry into the waterbody *via* drainage and; the formation of the metabolite in the waterbody after the parent substance entered *via* drainage. The highest $PEC_{SW/SED}$ value obtained across the two routes is then reported. The $PEC_{SW/SED}$ drainflow of CSCD465008 has only been determined for the pathway where the metabolite is formed in soil and subsequently enters the waterbody *via* drainage. The $PEC_{SW/SED}$ drainflow of CSCD668094 and CSCD668095 metabolites has only been determined for the pathway where the metabolite is formed in the waterbody after the parent substance entered *via* drainage.

For metabolites formed via the soil pathway

PEC_{SW} values of CSAA798670 and CSCD465008 metabolites following formation in soil and subsequent entry into the water body *via* drainage, were calculated based on maximum PEC_S values after application and using the equation given above for the active substance. Thereby the PEC_S of CSAA798670 and CSCD465008 are calculated on the basis of the maximum total dose of sedaxane, adjusted for the maximum occurrence in the soil and corrected for the molecular weight difference relative to parent. Pseudo-application rates used to calculate PEC_S of CSAA798670 and CSCD465008 were calculated according to the following equation:

$$A_{metabolite}\,[g/ha] = A_{parent} \times \frac{MaxAR_{metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

Where:
A_{parent} = application rate of parent substance [g/ha]
$MaxAR_{metabolite}$ = maximum percentage of metabolite observed in soil [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Otherwise, the PEC_{SW} and PEC_{SED} values of CSAA798670and CSCD465008 following entry *via* drainage have been calculated using the CRD 'PEC $_{sw\text{-}sed}$ (drainage)' spreadsheet (v 1.0), in the same way as the active substance sedaxane.

For metabolites formed in the waterbody

PEC_{SW} and PEC_{SED} values of CSAA798670, CSCD668094 and CSCD668095 following formation in the waterbody after the parent substance entered *via* drainage, were calculated based on the maximum parent PEC_{SW} value, adjusted for the maximum occurrence in the surface water and sediment, respectively, and corrected for the molecular weight difference relative to parent according to the following equations:

$$PEC_{SW,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SW,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

$$PEC_{SED,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SED,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}} \cdot 4.615$$

Where:
$PEC_{SW,parent}$ = PEC_{SW} of the parent after entry via drainage [µg/L]
$MaxAR_{SW,metabolite}$ = maximum percentage of metabolite observed in water [%]
$MaxAR_{SED,metabolite}$ = maximum percentage of metabolite observed in sediment [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Table A 54: Percentage of pesticide loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
CSAA798670	3	1.90
CSCD465008 Tier 1	2.1	1.90
CSCD465008 Tier 2	6	1.90
CSCD668094	-	Not relevant, metabolite not formed in soil
CSCD668095	-	Not relevant, metabolite not formed in soil

[a] In accordance with CRD guidance

Table A 55: Overall maximum $PEC_{SW/SED}$ for CSAA798670 due to drainage following single application of A20607B to sugarbeet

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drainage (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)[c]	
							Fraction formed in soil	Fraction formed in water	Fraction formed in soil	Fraction formed in water
Sugar beet	1	0	<0.001	0.05	0.00095	0.025	0.007	0.003	not relevant	

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above
[c] CSAA798670 is not formed in sediment

Table A 56: Overall maximum $PEC_{SW/SED}$ for CSCD465008 due to drainage following single applications of A20607B to sugarbeet

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drainage (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)[c]	Initial PEC_{SED} (µg/Kg)[c]
Sugar beet	1	0	<0.001	0.1	0.0019	0.025	0.015	not relevant

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above
[c] CSCD465008 is not detected in water and sediment; CSCD465008 is formed only in soil and subsequently enters the waterbody via drainage

Table A 57: Overall maximum $PEC_{SW/SED}$ for CSCD668094 due to drainage following single application of A20607B to sugarbeet

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[ac]	Available comp. (g/ha)[bc]	Mass of comp. lost to drainage (g/ha)[c]	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)	Initial PEC_{SED} (µg/Kg)[c]
Sugar beet	1	0	not relevant	not relevant	not relevant	0.025	0.0044	not relevant

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above
[c] CSCD668094 is not detected in soil and sediment

Table A 58: Overall maximum $PEC_{SW/SED}$ for CSCD668095 due to drainage following single of application of A20607B to sugarbeet

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[ac]	Available comp. (g/ha)[bc]	Mass of comp. lost to drainage (g/ha)[c]	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)	Initial PEC_{SED} (µg/Kg)[c]
Sugar beet	1	0	not relevant	not relevant	not relevant	0.025	0.0037	not relevant

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above
[c] CSCD668095 is not detected in soil and sediment