

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GLOB1817H

Product name: **Eledura**

Chemical active substance:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Halauxifen-methyl, 1.33 g/L

Cloquintocet-mexyl, 1.33 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: May 2021

MS Finalisation date: January 2022

Version history

When	What
May 2021	Initial submission by the applicant for approval of new product.
January 2022	zRMS version

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8 Fate and behaviour in the environment (KCP 9)

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	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, G, 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 saf- ener/ syner- gist per ha	Conclusion Groundwater
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg 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	PL, DE, CZ	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	Annual broad leaved weeds (BBAN) & grasses (GGAN)	Downward spraying	BBCH10- 14, (sept)oct- dec	a) 1 b) 1	/	a) 3 b) 3	a) Prosulfocarb: 2.001 Diflufenican: 0.042 Halauxifen- methyl: 0.00399 b) Prosulfocarb: 2.001 Diflufenican: 0.042 Halauxifen- methyl: 0.00399	200-300	/	Cloquintocet- mexyl: 0.00399 kg/ha	

* 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

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

Table 8.1-2: Assessed (critical) uses during approval of prosulfocarb concerning the Section Environmental Fate (EFSA Scientific Report (2007) 111, 1-81)

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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	Northern and Southern Europe	Winter wheat	F	Weeds	Boom sprayer	Pre-emergence up to BBCH 21	a) 1 b) 1	NR	a) 5 b) 5	c) 4.0 d) 4.0	200-400	NA	-
2	Northern and Southern Europe	Potatoes	F	Weeds	Boom sprayer	Pre-emergence up to BBCH 11	a) 1 b) 1	NR	a) 5 b) 5	c) 4.0 d) 4.0	200-400	NA	-

Table 8.1-3: Assessed (critical) uses during approval of diflufenican concerning the Section Environmental Fate (EFSA Scientific Report (2007) 122, 1-84)

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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Winter wheat/barley/rye	F	Annual dicot weeds, ALOMY, APESV, POAAN	Tractor mounted boom spraying	Pre-emergence; Post-emergence BBCH 10-13	a) 1 b) 1	NR	a) 0.6 b) 0.6	c) Diflufenican: 0.12, flufenacet: 0.24 d) Diflufenican: 0.12, flufenacet: 0.24	200-400	NR	Autumn use only

Table 8.1-4: Assessed (critical) uses during approval of halauxifen-methyl concerning the Section Environmental Fate (EFSA Journal 2014;12(12):3913)

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, Gp 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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	Northern zone	Winter cereals (soft wheat, barley, rye, triticale)	F	Broadleaf weeds	Overall, Broadcast foliar spray	Autumn: BBCH 09- 29 (Sep 1-Dec 31) and spring: BBCH 13- 45 (March 1 – Jun 20)	a) 2 b) 2	70 (between autumn and spring applications)	a) 1 b) 1	0.00782 followed by 0.00625	100-400	NR	Applications are made in autumn only, or in spring only or in both autumn and spring.
2	Northern zone	Spring cereals (wheat, barley)	F	Broadleaf weeds	Overall, Broadcast foliar spray	Spring: BBCH 13- 45 (March 1 – Jun 20)	a) 1 b) 1	NR	a) 0.8 b) 0.8	0.00625	100-400	NR	The application is made in spring only.
3	Central zone	Winter cereals (soft wheat, durum wheat, barley, spelt, rye, triticale)	F	Broadleaf weeds	Overall, Broadcast foliar spray	Autumn: BBCH 09- 29 (Sep 1-Dec 31) and spring: BBCH 13- 45 (Jan 1 – Jun 30)	a) 2 b) 2	70 (between autumn and spring applications)	a) 1 b) 1	0.00782 followed by 0.00625	100-400	NR	Applications are made in autumn only, or in spring only or in both autumn and spring.
4	Central zone	Spring cereals (wheat, barley)	F	Broadleaf weeds	Overall, Broadcast foliar spray	Spring: BBCH 13- 45 (Feb 1 – Jun 30)	a) 1 b) 1	NR	a) 0.8 b) 0.8	0.00625	100-400	NR	The application is made in spring only.
5	Southern zone	Winter cereals (soft wheat, durum wheat, barley, spelt, rye, triticale)	F	Broadleaf weeds	Overall, Broadcast foliar spray	Autumn: BBCH 09- 29 (Sep 1-Dec 31) and	a) 2 b) 2	70 (between autumn and spring applications)	a) 1 b) 1	0.00782 followed by 0.00625	100-400	NR	Applications are made in autumn only, or in spring only or in both autumn and spring.

						spring: BBCH 13- 45 (Jan 1 – May 31)							
6	Southern zone	Spring cereals (wheat, barley, durum wheat, rye)	F	Broadleaf weeds	Overall, Broadcast foliar spray	Spring: BBCH 13- 45 (Feb 1 – May 31)	a) 1 b) 1	NR	a) 0.8 b) 0.8	0.00625	100-400	NR	The application is made in spring only.

8.2 Metabolites considered in the assessment

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

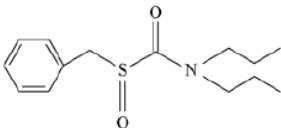
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Prosulfocarb sulfoxide	267.4		Soil: 6.8%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk to soil organisms PEC _{sw/sed} : risk to aquatic organisms

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

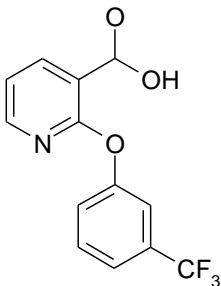
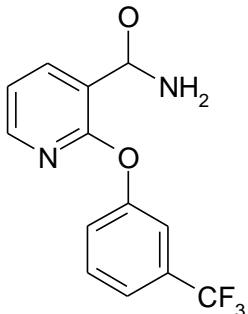
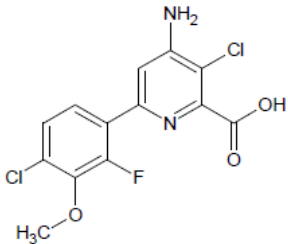
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
AE B107137	283		Soil: 16.8% Water: 32.6% Sediment: 13.3%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk to soil organisms PEC _{sw/sed} : risk to aquatic organisms
AE 0542291	282		Soil: 26.3%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk to soil organisms PEC _{sw/sed} : risk to aquatic organisms

Table 8.2-3: Metabolites of halauxifen-methyl potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
X11393729 (halauxifen)	331		Soil: 40.1% Water: 20.0% Sediment: 6.1%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk to soil organisms PEC _{sw/sed} : risk to aquatic organisms

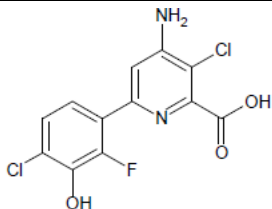
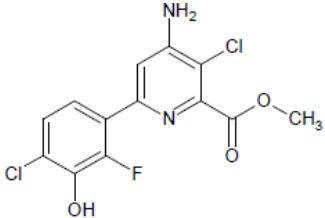
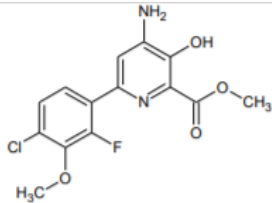
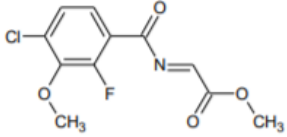
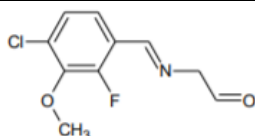
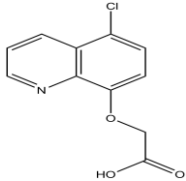
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposue assessment required due to
X11449757	317		Soil: 13.8% Water: 48.3% Sediment: 50.6%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk to soil organisms PEC _{sw/sed} : risk to aquatic organisms
X11406790	331		Soil: 1.4% Water: 16.5% Sediment: 10.6%	PEC _{sw/sed} : risk to aquatic organisms
Deg 10	326		Soil: - Water: 12.6%	PEC _{sw} : risk to aquatic organisms
Deg 11	273		Soil: - Water: 15.7%	PEC _{sw} : risk to aquatic organisms
Deg 14	229		Soil: - Water: 11.5%	PEC _{sw} : risk to aquatic organisms

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposue assessment required due to
CGA 153433 (Cloquintocet acid)	236.6		Soil: 38% Water: 38% Sediment: 27%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk to soil organisms PEC _{sw/sed} : risk to aquatic organisms

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Prosulfocarb and its metabolites

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

Prosulfocarb, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Iowa	Silty clay loam	4.8	22	26	38.4 (Q10 = 2.2) 41.6 (Q10 = 2.58)	128	40.3	0.97	SFO	Y, EFSA, 2007
Heavy loamy sand	Loamy sand	5.7	21.5	9.6	11 (Q10 = 2.2) 9.73 (Q10 = 2.58)	35	9.5	0.84	SFO	Y, EFSA, 2007
Medium loamy sand	Loamy sand	5.4	21.5	9.6	22 (Q10 = 2.2) 19.36 (Q10 = 2.58)	74	18.9	0.89	SFO	Y, EFSA, 2007
Gartenacker	Silt loam	7.0	20	49.8	6.3	21	6.3	0.955	SFO	Y, EFSA, 2007
18 Acres	Sandy clay loam	6.5	20	33.3	6.7	22	6.7	0.979	SFO	Y, EFSA, 2007
Marsillargues	Silty clay loam	7.5	20	30.9	9.3	31	9.3	0.937	SFO	Y, EFSA, 2007
Geometric mean (n=6, Q10 = 2.58)							12.1 11.9			
pH-dependency: y/n							no			

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

Prosulfocarb sulfoxide, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
18 Acres	Sandy clay loam	4.8	20	32.2	2.7	8.8	2.7	0.99	SFO	Y, EFSA, 2007
Gartenacker	Loam	7.0	20	44.0	1.5	5.2	1.6	0.99	SFO	Y, EFSA, 2007
Marsillargues	Silty clay loam	7.7	20	27.6	3.9	13.0	3.9	0.99	SFO	Y, EFSA, 2007
Geometric mean (n=3)							2.5			
pH-dependency: y/n							no			

8.3.1.2 Diflufenican and its metabolites

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

Diflufenican, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Sandy loam	7.7	22	75% of 0.33 bar	248.5	825.5	237.9	0.9980	SFO	Y, EFSA, 2007
-	Clay loam	6.6	22	75% of 0.33 bar	139.5	463.4	119.9	0.9967	SFO	Y, EFSA, 2007
-	Clay loam	6.5	20	45	232.6	772.7	193.5	0.9954	SFO	Y, EFSA, 2007
-	Clay loam	6.5	20	45	206.0	684.3	172.1	0.9975	SFO	Y, EFSA, 2007
-	Clay loam	6.5	20	45	176.3	585.8	147.3	0.9967	SFO	Y, EFSA, 2007
-	Silty clay loam	7.5	20	45	44.3	147.2	44.3	0.9819	SFO	Y, EFSA, 2007
-	Sandy loam 1	5.5	20	45	129.3	429.5	129.3	0.9836	SFO	Y, EFSA, 2007
-	Sandy loam 2	6.9	20	45	89.8	298.3	89.8	0.9890	SFO	Y, EFSA, 2007
-	Sandy loam 2	6.9	10	45	204.4	679.0			SFO	Y, EFSA, 2007

Diflufenican, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Geometric mean/Median (n=8)							128/138.3			
pH-dependency: y/n							no			

Table 8.3-4: Summary of aerobic degradation rates for AE B107137 - laboratory studies

AE B107137, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Silt loam 1	7.0	20	45	9.1	30.2	7.5	0.9919	SFO	Y, EFSA, 2007
-	Sandy loam	6.2	20	45	17.9	59.5	13.9	0.9868	SFO	Y, EFSA, 2007
-	Silt loam 2	7.4	20	45	14.5	48.1	10.4	0.9959	SFO	Y, EFSA, 2007
Geometric mean/Median (n=3)							10.3/10.4			
pH-dependency: y/n							no			

Table 8.3-5: Summary of aerobic degradation rates for AE 0542291 - laboratory studies

AE 0542291, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Silt loam 1	7.0	20	45	13.6	45.2	11.1	0.987	SFO	Y, EFSA, 2007
-	Sandy loam	6.2	20	45	58.7	194.9	45.7	0.999	SFO	Y, EFSA, 2007
-	Silt loam 2	7.4	20	45	33.2	110.2	23.8	0.991	SFO	Y, EFSA, 2007
Geometric mean/Median (n=3)							22.9/23.8			
pH-dependency: y/n							no			

8.3.1.3 Halauxifen-methyl and its metabolites

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

Halauxifen-methyl, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Clay loam	7.1	20	50	1.8 2.0	16.3 6.7	1.8 2.0	3.3 18.3	FOMC-P SFO-M	Y, EFSA, 2014
-	Loam	5.0	20	50	1.3 1.3	4.5 4.5	1.1 1.1	8.4 8.4	SFO-P SFO-M	Y, EFSA, 2014
-	Silt loam	5.9	20	50	1.1 1.2	6.1 4.0	1.1 1.2	4.4 110.9	FOMC-P SFO-M	Y, EFSA, 2014
-	Sandy loam	7.5	20	50	0.9 0.9	3.8 3.0	0.9 0.9	7.0 9.3	SFO-P SFO-M	Y, EFSA, 2014
-	Silt loam	5.9	10	50	2.2	12.2	-	4.9	FOMC-P	Y, EFSA, 2014
Geometric mean (n=4)							1.3			
pH-dependency: n										

P = Persistence endpoint, M = modelling endpoint

Table 8.3-7: Summary of aerobic degradation rates for X11393729 (halauxifen) - laboratory studies

X11393729 (halauxifen), Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Clay loam	7.1	20	50	35.9 28.7	119 95	35.9 28.7	6.0 16.4	TD SFO-P SFO IS-M	Y, EFSA, 2014
-	Loam	5.0	20	50	3.3 2.0	11 6.8	2.7 1.6	20.1 14.4	TD SFO-P SFO IS-M	Y, EFSA, 2014
-	Silt loam	5.9	20	50	7.6 4.7	25.4 15.8	7.6 4.7	13.1 14.4	TD SFO-P SFO IS-M	Y, EFSA, 2014
-	Sandy loam	7.5	20	50	13.6 11.7	45.2 38.9	13.6 11.7	11.3 14.7	TD SFO-P SFO IS-M	Y, EFSA, 2014
-	Silt loam	5.9	10	50	21.0	69.6	-	10.0	TD SFO-P	Y, EFSA, 2014
Geometric mean (n=4)							7.5			
pH-dependency: y/n							n			

Table 8.3-8: Summary of aerobic degradation rates for X11449757 - laboratory studies

X11449757, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Clay loam	7.1	20	50	76.7	255	76.7	5.2	TD SFO-& M	Y, EFSA, 2014
-	Loam	5.0	20	50	25.1	84	20.4	17.0	TD SFO-& M	Y, EFSA, 2014
-	Silt loam	5.9	20	50	31.8	106	31.8	13.8	TD SFO-& M	Y, EFSA, 2014
-	Sandy loam	7.5	20	50	47.7	158	47.7	12.3	TD SFO-& M	Y, EFSA, 2014
Geometric mean (n=4)							41.3			
pH-dependency: y/n							n			

8.3.1.4 Cloquintocet-mexyl and its metabolites

When incubated under aerobic conditions, cloquintocet-mexyl is degraded very rapidly in laboratory studies. The only major metabolite is CGA 153433 (cloquintocet acid) which represents up to 37.9% of applied radioactivity (AR) after 0.5 days. Non-extractable residues reached maximum amounts in the range of 63 to 87% AR between day 28 and day 84. Mineralization reached 3.2% AR within 28 days and 27.5% AR within 360 days.

Table 8.3-9: Summary of aerobic degradation rates for cloquintocet-mexyl - laboratory studies

Compound	DT ₅₀	DT ₉₀	Kinetic
Cloquintocet-mexyl	0.2-2.4 d, n=7	1-8.1 d, n=7	SFO*
CGA 154433	5.5-168 d, n=5	18-64, n=4	SFO

* Except for 2 soils, DFOP

zRMS Comments:	The cloquintocet-mexyl is used as a safener and will not be evaluated in this dossier.
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8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Prosulfocarb and its metabolites

Table 8.3-10: Summary of anaerobic degradation rates for prosulfocarb - laboratory studies

Prosulfocarb, Laboratory studies, anaerobic conditions									
Soil name	Soil type	pH	t.°C	DT50 (d)	DT90 (d)		Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Silty clay loam	4.8	Not reported	96	221	Indicative values based on only 4 data points	0.95	SFO	Y, EFSA, 2007

8.3.2.2 Diflufenican and its metabolites

EFSA, 2007:

Two degradation studies under dark anaerobic conditions were performed with 2,4-difluorophenyl and 3-trifluorophenyl labelled diflufenican (one soil: pH 6.5, OM 3.1 %, clay 23.75 %) and with pyridine labelled diflufenican (one soil: pH 7.7, OM 3.6 %, clay 15.1 %). Degradation of diflufenican was seen to be relatively slow under anaerobic conditions (DT₅₀ = 87.7 d - 400 d). Degradation of AE B107137 was also investigated under anaerobic conditions. It was shown to be very high persistent under these conditions (DT₅₀ = 413 d). The transformation product 2,4-difluoroaniline (max. 34.35 % AR after 272 d) was identified as a major anaerobic metabolite.

8.3.2.3 Halauxifen-methyl and its metabolites

Table 8.3-11: Summary of anaerobic degradation rates for halauxifen-methyl - laboratory studies

Halauxifen-methyl, Laboratory studies, anaerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Clay loam	7.1	20	50% for 1 day, flooded there-after	2.8	29	-	4.9	DFOP from day of flooding	Y, EFSA, 2014
-	Loam	5.0	20	50% for 1 day, flooded there-after	1.6	5.5	-	10.3	DFOP from day of flooding	Y, EFSA, 2014
-	Silt loam	5.9	20	50% for 1 day, flooded	0.9	3.1	-	9.3	DFOP from day of flooding	Y, EFSA, 2014

Halauxifen-methyl, Laboratory studies, anaerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
				there-after						
-	Sandy loam	7.5	20	50% for 1 day, flooded there-after	1.9	6.5	-	6.5	DFOP from day of flooding	Y, EFSA, 2014

Table 8.3-12: Summary of anaerobic degradation rates for X11393729 (halauxifen) - laboratory studies

X11393729 (halauxifen), Laboratory studies, anaerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Clay loam	7.1	20	50% for 1 day, flooded there-after	77 90	257 299	-	4.7 6.3	DFOP/SFO SFO TD	Y, EFSA, 2014
-	Loam	5.0	20	50% for 1 day, flooded there-after	21 21	70 70	-	4.3 4.6	SFO/SFO SFO TD	Y, EFSA, 2014
-	Silt loam	5.9	20	50% for 1 day, flooded there-after	14 21	46 69	-	6.6 27.7	SFO/SFO SFO TD	Y, EFSA, 2014
-	Sandy loam	7.5	20	50% for 1 day, flooded there-after	106 100	352 334	-	3.4 3.8	SFO/SFO SFO TD	Y, EFSA, 2014

Table 8.3-13: Summary of anaerobic degradation rates for X11449757 - laboratory studies

X11449757, Laboratory studies, anaerobic conditions										
Soil name	Soil type	pH	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Clay loam	7.1	20	50% for 1 day, flooded there-after	92	304	-	6.0	DFOP/SFO/SFO	Y, EFSA, 2014
-	Loam	5.0	20	50% for 1 day, flooded there-after	165	549	-	13.4	SFO/SFO/SFO	Y, EFSA, 2014
-	Silt loam	5.9	20	50% for 1 day, flooded there-after	127	421	-	10.1	SFO/SFO/SFO	Y, EFSA, 2014
-	Sandy loam	7.5	20	50% for 1 day, flooded there-after	>1000	>1000	-	20.3	SFO/SFO/SFO	Y, EFSA, 2014

8.3.2.4 Cloquintocet-mexyl and its metabolites

Degradation under anaerobic conditions was investigated after 4-week aerobic conditions. Only minor amounts of the parent molecule were additionally broken down (about 1.5% AR). At the end of the study (3 months), extractable residues accounted for 7.8 % AR and the non-extractable radioactivity for 80.6 % AR.

zRMS Comments:	The cloquintocet-mexyl is used as a safener and will not be evaluated in this dossier.
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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 Prosulfocarb and its metabolites

A summary of the results of the field soil dissipation studies available in the EU review of prosulfocarb (EFSA, 2007) is given in the table below. However, based on the rapid degradation of prosulfocarb and the metabolite prosulfocarb sulfoxide in the laboratory studies (DegDT₅₀ < 60 d and DegDT₉₀ < 200 d), no field soil dissipation studies are required.

Table 8.4-1: Summary of aerobic degradation rates for prosulfocarb - field studies

Prosulfocarb, Field studies – Triggering endpoints								
Soil type	Location	pH	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	St. (σ^2)	Method of calculation	Evaluated on EU level y/n/ Reference
Sand (bare soil)	Speyer, Germany	6.4	25	6.5	22	0.83	SFO	Y, EFSA, 2007
Loam/sandy loam (bare soil)	Varendorf, Germany	6.7	10	9.9	33	0.99	SFO	Y, EFSA, 2007
Loam/sandy loam (bare soil)	Varendorf, Germany	6.7	10	10	33	0.98	SFO	Y, EFSA, 2007
Clay loam (bare soil)	Hernigersdorf, Germany	6.8	30	11	35	0.98	SFO	Y, EFSA, 2007
Silt clay loam (bare soil)	Romerberg, Germany	7.4	10	13	48	0.94	SFO	Y, EFSA, 2007
Maximum (n=5)				13	48			

8.4.1.2 Diflufenican and its metabolites

Triggering endpoints

Table 8.4-2: Summary of aerobic degradation rates for diflufenican - field studies: Triggering endpoints

Diflufenican, Field studies – Triggering endpoints								
Soil type	Location	pH	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	St. (σ^2)	Method of calculation	Evaluated on EU level y/n/ Reference
Loamy sand (b)	UK	5.8	30	621	2063	0.493	SFO	Y, EFSA, 2007
Sandy silt loam I	France	7.1	30	241	801	0.796	SFO	Y, EFSA, 2007
Sandy loam (b)	Netherlands	6.3	30	389	1292	0.495	SFO	Y, EFSA, 2007
Clay (b)	Spain	7.6	30	236	784	0.728	SFO	Y, EFSA, 2007
Clay loam (b)	Italy	6.9	30	224	744	0.748	SFO	Y, EFSA, 2007
Maximum (n=5)				621	2063			

Modelling endpoints

Table 8.4-3: Summary of aerobic degradation rates for diflufenican - field studies: Modelling endpoints

Diflufenican, Field studies – Modelling endpoints					
Soil type	Location	pH	Depth (cm)	DT50 (d) 20°C, pF2	Evaluated on EU level y/n/ Reference
Loamy sand (b)	UK	5.8	30	282.0	Y, EFSA, 2007
Sandy silt loam I	France	7.1	30	130.0	Y, EFSA, 2007
Sandy loam (b)	Netherlands	6.3	30	199.5	Y, EFSA, 2007
Clay (b)	Spain	7.6	30	122.2	Y, EFSA, 2007
Clay loam (b)	Italy	6.9	30	103.4	Y, EFSA, 2007
Geometric mean/median (n=5)				156/130*	
pH-dependency y/n				no	

* Q10 of 2.2 assumed during normalization

8.4.1.3 Halauxifen-methyl and its metabolites

Triggering endpoints

Table 8.4-4: Summary of aerobic degradation rates for halauxifen-methyl - field studies: Triggering endpoints

Halauxifen-methyl, Field studies – Triggering endpoints								
Soil type	Location	pH	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	St. (σ^2)	Method of calculation	Evaluated on EU level y/n/ Reference
Sandy loam	Germany Spring	5.73	30	18	60	18.4	SFO	Y, EFSA, 2014
Sandy loam	Germany Autumn	6.34	30	5	78	24.4	FOMC	Y, EFSA, 2014
Silt loam	UK Spring	6.94	30	43	144	19.0	SFO	Y, EFSA, 2014
Loam	UK Autumn	6.63	30	15	106	8.2	FOMC	Y, EFSA, 2014
Clay loam	Spain Spring	7.71	30	15	51	14.1	SFO	Y, EFSA, 2014
Clay loam	Spain Autumn	7.61	30	11	86	16.3	FOMC	Y, EFSA, 2014
Loam	France Spring	5.52	30	15	49	36.6	SFO	Y, EFSA, 2014
Sandy loam	France Autumn	5.25	30	2.1	51	13.0	DFOP	Y, EFSA, 2014
Maximum (n=8)				43	144			

Table 8.4-5: Summary of aerobic degradation rates for X11393729 (halauxifen) - field studies: Triggering endpoints

X11393729 (halauxifen) – top down, Field studies – Triggering endpoints							
Soil type	Location	pH	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	St. (σ^2)	Evaluated on EU level y/n/ Reference
Sandy loam	Germany Spring	5.73	30	Not used	Not used	-	Y, EFSA, 2014
Sandy loam	Germany Autumn	6.34	30	101.7	337.9	18.9	Y, EFSA, 2014
Silt loam	UK Spring	6.94	30	264.4	871.7	7.5	Y, EFSA, 2014
Loam	UK Autumn	6.63	30	163.5	543.2	12.3	Y, EFSA, 2014
Clay loam	Spain Spring	7.71	30	62	207	14.8	Y, EFSA, 2014
Clay loam	Spain Autumn	7.61	30	108	359	3.2	Y, EFSA, 2014
Loam	France Spring	5.52	30	17	56	14.8	Y, EFSA, 2014
Sandy loam	France Autumn	5.25	30	44	145	14.1	Y, EFSA, 2014
Maximum (n=8)				264.4	871.7		

Table 8.4-6: Summary of aerobic degradation rates for X11449757 - field studies: Triggering endpoints

X11449757 – top down, Field studies – Triggering endpoints							
Soil type	Location	pH	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	St. (σ^2)	Evaluated on EU level y/n/ Reference
Sandy loam	Germany Spring	5.73	30	Not used	Not used	-	Y, EFSA, 2014
Sandy loam	Germany Autumn	6.34	30	197.0	654.4	9.2	Y, EFSA, 2014
Silt loam	UK Spring	6.94	30	187.1	621.4	16.9	Y, EFSA, 2014
Loam	UK Autumn	6.63	30	Not used	Not used	-	Y, EFSA, 2014
Clay loam	Spain Spring	7.71	30	113.2	375.9	19.8	Y, EFSA, 2014
Clay loam	Spain Autumn	7.61	30	104.7	347.8	24.2	Y, EFSA, 2014
Loam	France Spring	5.52	30	146.0	484.9	13.8	Y, EFSA, 2014
Sandy loam	France Autumn	5.25	30	87.3	290.2	14.2	Y, EFSA, 2014
Maximum (n=8)				197.0	654.4		

Modelling endpoints

Table 8.4-7: Summary of aerobic degradation rates for Halauxifen-methyl - field studies: Modelling endpoints

Halauxifen-methyl, Field studies – Modelling endpoints						
Soil type	Location	pH	Depth (cm)	DT50 (d) 20°C, pF2	Fit, Kinetic	Evaluated on EU level y/n/ Reference
Sandy loam	Germany	5.73	30	17	SFO (after 10 mm rain)	Y, EFSA, 2014
Sandy loam	Germany	6.34	30	27	SFO (after 10 mm rain)	Y, EFSA, 2014
Silt loam	UK	6.94	30	26	SFO (after 10 mm rain)	Y, EFSA, 2014
Loam	UK	6.63	30	8.2	SFO (after 10 mm rain)	Y, EFSA, 2014
Clay loam	Spain	7.71	30	25	SFO (after 10 mm rain)	Y, EFSA, 2014
Clay loam	Spain	7.61	30	33	SFO (after 10 mm rain)	Y, EFSA, 2014
Loam	France	5.52	30	17	SFO (after 10 mm rain)	Y, EFSA, 2014
Sandy loam	France	5.25	30	19	SFO (after 10 mm rain)	Y, EFSA, 2014
Geometric mean (n=8)				20		
pH-dependency y/n				n		

Table 8.4-8: Summary of aerobic degradation rates for relevant metabolites - field studies: Modelling endpoints

X11393729 (halauxifen), Field studies – Modelling endpoints								
Soil type	Location	pH	Depth (cm)	Parent DT50 (SFO) (d)	Acid DT50 (SFO) (d)	f.f.	Acid DT50 (top-down SFO) (d)	Evaluated on EU level y/n/ Reference
Sandy loam	Germany	5.73	30	0.7	23	0.12	59	Y, EFSA, 2014
Sandy loam	Germany	6.34	30	2.5	42	0.44	30	Y, EFSA, 2014
Silt loam	UK	6.94	30	27	35	0.66	88	Y, EFSA, 2014
Loam	UK	6.63	30	1.1	51	0.36	59	Y, EFSA, 2014
Clay loam	Spain	7.71	30	6.4	34	0.33	62	Y, EFSA, 2014
Clay loam	Spain	7.61	30	9.1	40	0.34	85	Y, EFSA, 2014
Loam	France	5.52	30	6.6	12.6*	-	29	Y, EFSA, 2014
Sandy loam	France	5.25	30	0.7	11	0.34	28	Y, EFSA, 2014
Geometric mean (n=8)				3.3			50	
Geometric mean for acidic soils (pH 5.25-6.34, n=4 for DT50, n = 3 for					19.1	0.30		

FF)										
Geometric mean for alkaline soils (pH 7.61-7.71, n=2)				36.9	0.34					
X11449757, Field studies – Modelling endpoints										
Soil type	Location	pH	Depth (cm)	Parent DT50 (SFO) (d)	Acid DT50 (SFO) (d)	Acid f.f.	X11449757 DT50 (SFO) (d)	X11449757 f.f.	X11449757 DT50 (top-down SFO) (d)	Evaluated on EU level y/n/ Reference
Sandy loam	Germany	5.73	30	NC	NC	NC	NC	NC	NC	Y, EFSA, 2014
Sandy loam	Germany	6.34	30	1.9	43	0.41	8.9	1.00	76	Y, EFSA, 2014
Silt loam	UK	6.94	30	NC	NC	NC	NC	NC	60	Y, EFSA, 2014
Loam	UK	6.63	30	1.0	54	0.35	22	0.22	NC	Y, EFSA, 2014
Clay loam	Spain	7.71	30	NC	NC	NC	NC	NC	84	Y, EFSA, 2014
Clay loam	Spain	7.61	30	NC	NC	NC	NC	NC	60	Y, EFSA, 2014
Loam	France	5.52	30	5.8	1.9	1.00	73	0.18	107	Y, EFSA, 2014
Sandy loam	France	5.25	30	0.7	8.6	0.36	9.5	1.00	37	Y, EFSA, 2014
Geometric mean (n=4)				1.7			19		67	
Average								0.60		
Geomean for acidic soils					19.1	0.30				
Geomean for alkaline soils					36.9	0.34				

* top down including data before 10 mm rain chosen as endpoint for this site
NC = not calculated

8.4.1.4 Cloquintocet-mexyl and its metabolites

Table 8.4-9: Field degradation rates of cloquintocet-mexyl and its metabolites

Compound	Actual values		Normalised DT50	Kinetic
	DT50	DT90		
Cloquintocet-mexyl	0.9-15.7 d, n=10	3.1-52.1 d, n=10	0.2-14.8 d, n=10 median: 3.8 d	SFO
CGA 154433	27.6-117.3 d, n=9	91.8-389 d, n=9	13.4-97.1 d, n=9 median: 35.7 d	SFO

An investigation in Switzerland was performed where summer wheat was treated with 50 g/ha cloquintocet-mexyl formulated. Soil from the field plot (sandy loam) did not contain any residues of cloquintocet-mexyl, nor of CGA153433 at any depth and at any time (LOQ 0.05 mg/kg).

In an additional experiment; formulated cloquintocet-mexyl was also applied once a year on four consecutive seasons. Summer barley, winter wheat and barley were treated with 50 g a.s./ha in 1987 - 1989, respectively, as well as rape with 60 g a.s./ha in 1990. Soil samples collected down to a depth of 90 cm did not reveal any residues of cloquintocet-mexyl or CGA153433 (<0.005 - 0.05 mg/kg).

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Prosulfocarb

No data or assessment is provided. The kinetic evaluation of the aerobic laboratory degradation data, for prosulfocarb and prosulfocarb sulfoxide indicate that both substances degrade rapidly, in all soils, at 20°C and pF2. In all soils tested, the DegT_{50,lab} for parent and metabolites was determined to be less than 60 days and the corresponding DegT_{90,lab} were less than 200 days. Therefore soil accumulation studies are not required.

8.4.2.2 Diflufenican

Maximum accumulation factor = 2.53

8.4.2.3 Halauxifen-methyl

The metabolites X11393729 (halauxifen) and X11449757 have a persistence DT₉₀ >365 days (lab or field), therefore accumulation PEC_{soil} values after repeated annual applications over multiple years (assuming tillage to 20 cm) were calculated for these compounds.

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 Prosulfocarb and its metabolites

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

Prosulfocarb							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
LUFA	Sand	0.5	6.0	32.8	1367	1.0	Y, EFSA, 2007 + Addendum to DAR
Itingen	Clay loam	2.4	7.3	11.7	2339	0.90	Y, EFSA, 2007 + Addendum to DAR
Borstel	Loamy sand	1.00	5.14	27.6	2760	0.92	Y, EFSA, 2007 + Addendum to DAR
18 Acres	Sandy clay loam	3.25	5.6	56.7	1743	0.92	Y, EFSA, 2007 + Addendum

Prosulfocarb									
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)		1/n (-)		Evaluated on EU level y/n/ Reference
									to DAR
Vetroz	Loam	3.49	7.3	54.1	1551		0.89		Y, EFSA, 2007 + Addendum to DAR
Les Evouettes	Silt loam	1.8	5.6	24.7	1372	1420 (geomean)	0.97	0.93 (geomean)	Y, EFSA, 2007 + Addendum to DAR
Les Evouettes	Silt loam	2.55	7.2	37.5	1469		0.89		Y, EFSA, 2007 + Addendum to DAR
Geometric mean (n=6)					1799		-		
Arithmetic mean (n=6)					-		0.93		
pH-dependency y/n					no				

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

Prosulfocarb sulfoxide							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
18 Acres	Sandy clay loam	2.9	5.9	1.98	68	0.90	Y, EFSA, 2007
Gartenacker	Loam	2.0	7.1	1.02	50	0.91	Y, EFSA, 2007
Wisborough Green	Silty clay loam	2.9	4.8	1.50	52	0.91	Y, EFSA, 2007
Geometric mean (n=3)					56.1	-	
Arithmetic mean (n=3)					-	0.91	
pH-dependency y/n					no		

8.5.2 Diflufenican and its metabolites

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

Diflufenican							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	Sandy loam	2.09	7.7	33.9	1622	0.875	Y, EFSA, 2007
-	Loamy sand	0.75	6.6	13.5	1800	0.917	Y, EFSA, 2007
-	Clay loam	1.68	6.6	39.8	2369	0.934	Y, EFSA, 2007
-	Silty clay loam	2.26	6.8	48.9	2164	0.923	Y, EFSA, 2007
Shelley Field	Clay loam	2.4	6.2	98.82	4118	0.901	Y, EFSA, 2007
Kissendorf	Silt loam	1.4	6.7	46.28	3306	0.897	Y, EFSA, 2007
Manningtree	Sandy loam	3.6	5.3	267.51	7431	0.991	Y, EFSA, 2007
Santilly	Loam	0.9	7.0	39.86	4428	0.940	Y, EFSA, 2007
Lleida	Clay loam	2.9	8.0	88.91	3066	0.917	Y, EFSA, 2007
Chazay	Clay loam	1.9	6.6	73.49	3868	0.879	Y, EFSA, 2007
Geomean (n=10)					3091	-	
Arithmetic mean (n=10)					-	0.917	
pH-dependency y/n					no		

Table 8.5-4: Summary of soil adsorption/desorption for AE B107137

AE B107137							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	Clay loam	1.9	7.0	0.22	12	0.72	Y, EFSA, 2007
-	Sand	1.6	5.8	0.11	7	0.99	Y, EFSA, 2007
-	Clay loam	4.7	7.6	0.38	8	0.54	Y, EFSA, 2007
-	Sandy loam	1.8	6.0	0.42	23	0.68	Y, EFSA, 2007
Geomean (n=4)					11	-	
Arithmetic mean (n=4)					-	0.73	
pH-dependency y/n					no		

Table 8.5-5: Summary of soil adsorption/desorption for AE 0542291

AE 0542291							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	Sandy loam	0.8	6.0	1.3	160	0.80	Y, EFSA, 2007
-	Sandy loam	1.2	5.3	1.5	127	0.84	Y, EFSA, 2007
-	Clay loam	2.6	7.0	3.6	137	0.77	Y, EFSA, 2007
-	Clay	3.9	6.0	4.0	103	0.85	Y, EFSA, 2007
Geomean (n=4)					130	-	
Arithmetic mean (n=4)					-	0.81	
pH-dependency y/n					no		

8.5.3 Halauxifen-methyl and its metabolites

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

Halauxifen-methyl							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	Clay loam	1.3	7.1	24	1812	0.89	Y, EFSA, 2014
-	Loamy sand	1.1	5.2	17	1553	0.88	Y, EFSA, 2014
-	Loam	2.5	5	28	1104	0.90	Y, EFSA, 2014
-	Silt loam	3.6	5.9	24	660	0.88	Y, EFSA, 2014
-	Sandy loam	1.4	7.5	9	652	0.89	Y, EFSA, 2014
-	Clay loam	4.4	7.2	8	190	0.76	Y, EFSA, 2014
-	Organic*	33.1	4.1	310*	936*	0.98*	Y, EFSA, 2014
Geomean (n=6)					796	-	
Arithmetic mean (n = 6)					-	0.87	
pH-dependency y/n					Very weak, not considered in modelling		

*Results excluded from calculation of mean as soil considered unrepresentative

Table 8.5-7: Summary of soil adsorption/desorption for X11393729 (halauxifen)

X11393729 (halauxifen)							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	Clay loam	1.3	7.1	1.48	113	0.83	Y, EFSA, 2014
-	Loamy sand	1.1	5.2	1.66	151	0.96	Y, EFSA, 2014
-	Loam	2.5	5	2.40	96	0.83	Y, EFSA, 2014
-	Silt loam	3.6	5.9	2.40	67	0.84	Y, EFSA, 2014
-	Sandy loam	1.4	7.5	0.41	29	0.88	Y, EFSA, 2014
-	Clay loam	4.4	7.2	1.14	26	0.88	Y, EFSA, 2014
-	Organic*	33.1	4.1	113*	341*	0.91*	Y, EFSA, 2014
Geomean (n=6)					66	-	
Arithmetic mean (n=6)					-	0.87	
pH-dependency y/n					No		

*Results excluded from calculation of mean as soil considered unrepresentative

Table 8.5-8: Summary of soil adsorption/desorption for X11449757

X11449757							
Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	Clay loam	1.3	7.1	1.84	142	0.87	Y, EFSA, 2014
-	Loamy sand	1.1	5.2	1.86	169	0.86	Y, EFSA, 2014
-	Loam	2.5	5	3.28	131	0.83	Y, EFSA, 2014
-	Silt loam	3.6	5.9	3.73	104	0.84	Y, EFSA, 2014
-	Sandy loam	1.4	7.5	0.26	19	0.90	Y, EFSA, 2014
-	Clay loam	4.4	7.2	0.66	15	0.95	Y, EFSA, 2014
-	Organic*	33.1	4.1	134*	405*	0.93*	Y, EFSA, 2014
Geomean (n=6)					67	-	
Arithmetic mean (n=6)					-	0.88	
pH-dependency y/n					No		

*Results excluded from calculation of mean as soil considered unrepresentative

8.5.4 Cloquintocet-mexyl and its metabolites

Adsorption of cloquintocet-mexyl and its metabolite was investigated in batch adsorption studies. Results are summarised below.

Table 8.5-9: Summary of soil adsorption/desorption for cloquintocet-mexyl and CGA 154433

Compound	K _{foc}	1/n
Cloquintocet-mexyl	6521-19314 mL/g, n=5 mean: 12850 mL/g	0.809-0.973 mean: 0.89
CGA 154433	1186-2870 mL/g, n=3 mean: 1772 mL/g	0.73-0.80 mean: 0.76

8.5.5 Column leaching (KCP 9.1.2.1)

8.5.5.1 Prosulfocarb

No reliable study, as the LOQ in the available study for the leachate was high at 5 µg/L, however there is no data gap as results from adequate soil batch adsorption studies are available. Leachate: < 5 µg/L (< 0.64% of applied). The result is only considered as supportive information. (EFSA, 2007)

8.5.5.2 Diflufenican

Not submitted, not required. (EFSA, 2007)

8.5.5.3 Halauxifen-methyl

Not submitted, not required. (EFSA, 2014)

8.5.5.4 Cloquintocet-mexyl

Column leaching studies confirmed the low mobility in soil of cloquintocet-mexyl and its metabolite CGA 154433.

8.5.6 Lysimeter studies (KCP 9.1.2.2)

8.5.6.1 Prosulfocarb

No studies available, not required.

8.5.6.2 Diflufenican

EFSA, 2007:

Location: Germany (Bruhl, Schwemmlöb)

Soil properties: pH = 7.7, OC = 1.05

Dates of application: 3rd December 1990

Crop: 1st year winter wheat, 2nd year barley, final green mustard

Interception estimated: none (application pre-emergent)

Number of applications: lysimeter 219 1 application each year, lysimeter 220 1 application 1st year

Duration: 2 years

Application rate: 185 g a.s./ha/year (nominal)
Average annual rainfall and irrigation: 853 mm
Average annual leachate volume: 325 mm
% radioactivity in leachate (max/year): 0.014% AR 1st year, 0.117% AR 2nd year
Individual annual average concentrations: 1st year 0.003 µg/L and 2nd year < 0.003 µg/L active substance,
< 0.003 µg/L metabolites AE B10737 and AE 0542291
Unidentified radioactivity: total max 0.01 µg/L parent equivalents

8.5.6.3 Halauxifen-methyl

Not submitted, not required.

8.5.7 Field leaching studies (KCP 9.1.2.3)

8.5.7.1 Prosulfocarb

No studies available, not required.

8.5.7.2 Diflufenican

Please refer to 8.5.5.2.

8.5.7.3 Halauxifen-methyl

Not submitted, not required.

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 Prosulfocarb and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of prosulfocarb

Prosulfocarb Distribution (max. water/sediment 84.1/80.4% after 0/14 days)										
Water/sediment system	pH water / sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic , Fit	DissT50 water (d)	DissT90 water (d)	Kinetic , Fit	DissT50 sed. (d)	Kinetic , Fit	Evaluated on EU level y/n/ Reference
Old Basin	7.9/7.5	381/331	Too long to	DFOP SFO	0.6	13.9	DFOP SFO	Not determine	-	Y, EFSA, 2007

Prosulfocarb Distribution (max. water/sediment 84.1/80.4% after 0/14 days)										
Water/sediment system	pH water / sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
			predict					d		
Virginia Water	7.9/7.2	147 139	Too long to predict	DFOP SFO	1.5	51.1	DFOP SFO	Not determined	-	Y, EFSA, 2007
Geometric mean (n=2)		214	-		0.95	26.6		-		

Table 8.6-2: Summary of degradation in water/sediment of prosulfocarb sulfoxide

Prosulfocarb sulfoxide Distribution								
Water/sediment system	pH water/ sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Pond	8.3/7.2	3.69	12.27	SFO	3.02	10.0	SFO	Y, EFSA, 2007 Addendum, April 2013
River	8.3/7.3	3.32	11.02	SFO	2.82	9.38	SFO	Y, EFSA, 2007 Addendum, April 2013
Geometric mean (n=2)		3.50	11.6		2.92	9.69		

Table 8.6-3: Summary of observed metabolites

Prosulfocarb sulfoxide Water/sediment system	Max. in water/sediment 1% after 107 d	Y, EFSA, 2007
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8.6.2 Diflufenican and its metabolites

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

Diflufenican Distribution (max. water/sediment 74.4% after 14 days)										
Water/sediment system	pH water/ sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Unter Widdersheim	8.2/7.5	90	-	SFO, 076	n.a.	n.a.	n.a.	n.a.	n.a.	Y, EFSA, 2007
Bickenbach	8.2/7.8	154	-	SFO,	n.a.	n.a.	n.a.	n.a.	n.a.	Y, EFSA,

Diflufenican Distribution (max. water/sediment 74.4% after 14 days)										
Water/sediment system	pH water/sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
				0.77						2007
Clay, UK	7.8/6.3	345	-	SFO, 0.82	n.a.	n.a.	n.a.	n.a.	n.a.	Y, EFSA, 2007
Sand, UK	6.8/5.4	195	-	SFO, 0.96	n.a.	n.a.	n.a.	n.a.	n.a.	Y, EFSA, 2007
Geometric mean (n=4)		175	-		-	-		-		

n.a.: no reliable value available

Table 8.6-5: Summary of observed metabolites

AE B107137 Water/sediment system	Max. in water/sediment 32.6/13.3% after 30 d	Y, EFSA, 2007
AE C522392 Water/sediment system	Max. in water/sediment 6.1/1.0% after 30/59 d	Y, EFSA, 2007

8.6.3 Halauxifen-methyl and its metabolites

Table 8.6-6: Summary of degradation in water/sediment of halauxifen-methyl

Halauxifen-methyl Distribution (max. sediment 7.3-12.2% after 2 days)										
Water/sediment system	pH water/sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Swiss Lake	7.0/5.8	4	12	SFO	3	9	SFO	7	SFO TD	Y, EFSA, 2014
Calwich Abbey Lake	8.3/7.7	0.8	2.9	SFO	0.67	2.24	SFO	1.3	SFO TD	Y, EFSA, 2014
Geometric mean (n=2)		1.8	5.9							Y, EFSA, 2014

Table 8.6-7: Summary of degradation in water/sediment of X11393729 (halauxifen)

X11393729 (halauxifen) Distribution (max. water 13.3-20.0% after 2-8 days; max. sediment 3.2-6.1% after 2-5 days)										
Water/sediment system	pH water / sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Swiss Lake	7.0/5.8	11	38	SFO TD	9	28	SFO TD	4	SFO TD	Y, EFSA, 2014
Calwich Abbey Lake	8.3/7.7	2	6.7	SFO TD	3	10	SFO TD	Not calculated, insufficient data	SFO TD	Y, EFSA, 2014
Geometric mean (n=2)		4.7	16							Y, EFSA, 2014

Table 8.6-8: Summary of degradation in water/sediment of X11449757

X11449757 Distribution (max. water 44.4-48.3% after 5-22 days; max. sediment 36.9-50.6% after 30-43 days)										
Water/sediment system	pH water/ sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Swiss Lake	7.0/5.8	38	125	SFO TD	22	73	SFO TD	35	SFO TD	Y, EFSA, 2014
Calwich Abbey Lake	8.3/7.7	87	289	SFO TD	23	76	SFO TD	114	SFO TD	Y, EFSA, 2014
Geometric mean (n=2)		57.5	190							Y, EFSA, 2014

Table 8.6-9: Summary of degradation in water/sediment of X11406790

X11406790 Distribution (max. water 12.8-16.5% after 2-5 days; max. sediment 7.0-10.6% after 2-5 days)										
Water/sediment system	pH water/ sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Swiss Lake	7.0/5.8	7	23	SFO TD	7	25	SFO TD	7	SFO TD	Y, EFSA, 2014
Calwich Abbey Lake	8.3/7.7	1.5	5	SFO IS	2	7	SFO TD	3	SFO TD	Y, EFSA, 2014
Geometric mean (n=2)		3.2	10.7							Y, EFSA, 2014

Table 8.6-10: Summary of observed metabolites

X11393729 (halauxifen) Water/sediment system	Max. in water/sediment 20.0/6.1% after 8/5 d	Y, EFSA, 2014
X11449757 Water/sediment system	Max. in water/sediment 48.3/50.6% after 22/43 d	Y, EFSA, 2014
X11406790 Water/sediment system	Max. in water/sediment 16.5/10.6% after 5 d	Y, EFSA, 2014

8.6.4 Cloquintocet-mexyl and its metabolites

Cloquintocet mexyl was relatively stable to hydrolysis in the pH range 7-9, with DT50 values between 134-606 days. Hydrolysis was faster at pH 5 (DT50 4.4 days). The major hydrolysis product CGA 153433 is hydrolytically stable.

Cloquintocet mexyl was rapidly degraded by photolysis (DT50 of 0.62 day summer sunlight at 30°N—0.17 day mid spring at 40°N—0.25 day mid spring at 50°N / no degradation observed in dark control). A number of polar breakdown products were observed (80% AR after 48 hours). In presence of acetone (1%), the amounts of polar materials were 19% after 24.5 hours, those of medium polar components were 81% AR. CGA 153433 was not detected in significant amounts.

In dark aerobic water/sediment systems, cloquintocet mexyl was rapidly degraded into the major metabolite CGA 153433 (max. 65% AR in total system after 2 days, 38% in water and 27% in sediment). Adsorption of cloquintocet mexyl on sediment reached a maximum of 19.6% AR. Non-extractable residues reached a maximum of 84% AR after 112 days. Mineralisation was low (max. 1.3% AR after 125 days).

Table 8.6-11: Summary of degradation in water/sediment of cloquintocet-mexyl and its metabolite

Compound	DT50 whole system	DissT50 water	DissT50 sediment
Cloquintocet mexyl	0.4-0.6 d, n=2	0.2-0.2 d, n=2	0.7 d, n=1
CGA 153433	36-46 d, n=2	5.6 d, n=1	Not determined

Table 8.6-12: Summary of observed metabolites

CGA 153433 Water/sediment system	Max. in water/sediment 38/27% after 2 d
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8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

zRMS Comments:	Calculations of PEC _s 's for active substances, their metabolites and formulation submitted for cereals were accepted.																																	
	The cloquintocet-mexyl is used as a safener and was not evaluated in this dossier.																																	
	The relevant endpoints used for PECs assessment were agreed at the EU level.																																	
	Prosulfocarb. The submitted PECs assessment was accepted.																																	
	Diiflufenican. In accordance with EFSA Scientific Report (2007) 122, 1-84, Conclusion on the peer review of diiflufenican in PECs assessment for metabolites the accumulation was considered. The relevant PECs values were added by evaluator.																																	
	Halauixifen-methyl. In PECs assessment the higher application rate was used (5.85 g a.s./ha); as it represents a worse case – it was accepted. The PECs's for both metabolites were corrected by evaluator.																																	
	Formulation. The formulation density of 1.0085 g/mL was considered in PECs formulation assessment.																																	
	The maximum PEC _s values for active substances and their metabolites are presented in following table:																																	
	<table><tr><th>Crop</th><th colspan="2">Winter wheat winter barley winter rye triticale</th></tr><tr><th>Compound</th><th>PECs mg/kg soil</th><th>PECs accum mg/kg soil</th></tr><tr><td>Prosulfocarb</td><td>2.668</td><td>nr</td></tr><tr><td>Prosulfocarb sulfoxide</td><td>0.1928</td><td>nr</td></tr><tr><td>Diiflufenican</td><td>0.0560</td><td>0.1417*</td></tr><tr><td>AE B107137</td><td>0.0202</td><td>0.05 mg/kg based on accumulated residues of diiflufenican in the field</td></tr><tr><td>AE 0542291</td><td>0.0315</td><td>0.08 mg/kg based on accumulated residues of diiflufenican in the field</td></tr><tr><td>Halauixifen-methyl</td><td>0.0078</td><td>nr</td></tr><tr><td>X11393729 (halauixifen)</td><td>0.0031</td><td>0.0035</td></tr><tr><td>X11449757</td><td>0.0011</td><td>0.0012</td></tr><tr><td>Formulation</td><td>4.0347</td><td>nr</td></tr></table>	Crop	Winter wheat winter barley winter rye triticale		Compound	PECs mg/kg soil	PECs accum mg/kg soil	Prosulfocarb	2.668	nr	Prosulfocarb sulfoxide	0.1928	nr	Diiflufenican	0.0560	0.1417*	AE B107137	0.0202	0.05 mg/kg based on accumulated residues of diiflufenican in the field	AE 0542291	0.0315	0.08 mg/kg based on accumulated residues of diiflufenican in the field	Halauixifen-methyl	0.0078	nr	X11393729 (halauixifen)	0.0031	0.0035	X11449757	0.0011	0.0012	Formulation	4.0347	nr
	Crop	Winter wheat winter barley winter rye triticale																																
Compound	PECs mg/kg soil	PECs accum mg/kg soil																																
Prosulfocarb	2.668	nr																																
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AE 0542291	0.0315	0.08 mg/kg based on accumulated residues of diiflufenican in the field																																
Halauixifen-methyl	0.0078	nr																																
X11393729 (halauixifen)	0.0031	0.0035																																
X11449757	0.0011	0.0012																																
Formulation	4.0347	nr																																
* in accordance with EFSA, 2007, accumulation factor = 2.53 nr – not relevant																																		
These values will be used in further risk assessment.																																		

8.7.1 Justification for new endpoints

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8.7.2 Active substance(s) and relevant metabolite(s)

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1
Crop	Winter cereals
Application rate (g as/ha)	Prosulfocarb: 2001 Diflufenican: 42 Halauxifen-methyl: 5.85* Cloquintocet-mexyl: 18.75*
Number of applications/interval	1/-
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)/20 (tillage; plateau concentration)

*Worst case calculations, performed for a higher application rate, are shown here. The associated modelling files can be found in the ongoing application for GF-3678 of Corteva Agriscience.

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Prosulfocarb	251.6	-	13 (Maximum field study, not normalized)	Y, EFSA, 2007
Prosulfocarb sulfoxide	267.4	6.8	3.9 (Maximum laboratory study, not normalized)	Y, EFSA, 2007
Diflufenican	394	-	621 (Maximum, field study, not normalized)	Y, EFSA, 2007
AE B107137	283	16.8	17.9 (Maximum, laboratory study, not normalized)	Y, EFSA, 2007
AE 0542291	282	26.3	58.7 (Maximum, laboratory study, not normalized)	Y, EFSA, 2007
Halauxifen-methyl	345	-	43 (Maximum field studies, not normalized)	Y, EFSA, 2014
X11393729 (halauxifen)	331	40.1	264	Y, EFSA, 2014
X11449757	317	13.8	197	Y, EFSA, 2014
Cloquintocet-mexyl	335.8	-	46	-
CGA 153433	236.6	38	-	-

8.7.2.1 Prosulfocarb and its metabolites

Table 8.7-3: PEC_{soil} for prosulfocarb on winter cereals

PEC _{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		2.6680	-
Short term	24h	2.5295	2.5981
	2d	2.3981	2.5307
	4d	2.1556	2.4027
Long term	7d	1.8369	2.2267
	14d	1.2647	1.8799
	21d	0.8708	1.6051
	28d	0.5995	1.3855
	50d	0.1855	0.9312
	100d	0.0129	0.4980
Plateau concentration (20 cm)		Not calculated; DT ₉₀ < 365 d	
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})			

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for prosulfocarb sulfoxide on winter cereals

PEC _{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.1928	-
Short term	24h	0.1614	0.1767
	2d	0.1351	0.1623
	4d	0.0947	0.1380
Long term	7d	0.0556	0.1103
	14d	0.0160	0.0711
	21d	0.0046	0.0504
	28d	0.0013	0.0385
	50d	0.0000	0.0217
	100d	0.0000	0.0108
Plateau concentration (20 cm)		Not calculated; DT ₉₀ < 365 d	
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})			

8.7.2.2 Diflufenican and its metabolites

Table 8.7-5: PEC_{soil} for diflufenican on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0560	-
Short term	24h	0.0559	0.0560
	2d	0.0559	0.0559
	4d	0.0558	0.0559
Long term	7d	0.0556	0.0558
	14d	0.0551	0.0556
	21d	0.0547	0.0553
	28d	0.0543	0.0551
	50d	0.0530	0.0545
	100d	0.0501	0.0530
Plateau concentration (20 cm)		0.0278	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil \text{ plateau}}$)		0.0838	-

Table 8.7-6: PEC_{soil} for diflufenican on winter cereals taking into account the accumulation factor of 2.53 from the EU review

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.1417	-
Short term	24h	0.1415	0.1416
	2d	0.1414	0.1415
	4d	0.1410	0.1414
Long term	7d	0.1406	0.1411
	14d	0.1395	0.1406
	21d	0.1384	0.1400
	28d	0.1373	0.1395
	50d	0.1340	0.1378
	100d	0.1267	0.1341

PEC_{soil} of metabolites

Table 8.7-7: PEC_{soil} for AE B107137 on winter cereals

PEC _{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0202	-
Short term	24h	0.0194	0.0198
	2d	0.0187	0.0194
	4d	0.0173	0.0187
Long term	7d	0.0154	0.0177
	14d	0.0117	0.0156
	21d	0.0090	0.0138
	28d	0.0068	0.0123
	50d	0.0029	0.0089
	100d	0.0004	0.0051

Table 8.7-8: PEC_{soil} for AE 0542291 on winter cereals

PEC _{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0315	-
Short term	24h	0.0311	0.0313
	2d	0.0308	0.0311
	4d	0.0300	0.0308
Long term	7d	0.0290	0.0302
	14d	0.0267	0.0290
	21d	0.0246	0.0279
	28d	0.0226	0.0268
	50d	0.0175	0.0238
	100d	0.0097	0.0185

8.7.2.3 Halauxifen-methyl and its metabolites

Table 8.7-9: PEC_{soil} for halauxifen-methyl on winter cereals

PEC _{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0078	-

Short term	24h	0.0077	0.0077
	2d	0.0076	0.0077
	4d	0.0073	0.0076
Long term	7d	0.0070	0.0074
	14d	0.0062	0.0070
	21d	0.0056	0.0066
	28d	0.0050	0.0063
	50d	0.0035	0.0054
	100d	0.0016	0.0039
Plateau concentration (20 cm)		Not calculated; DT ₉₀ < 365 d	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})			

PEC_{soil} of metabolites

Table 8.7-10: PEC_{soil} for X11393729 (halauxifen) on winter cereals

PEC _{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0030	-
Short term	24h	0.0030	0.0030
	2d	0.0030	0.0030
	4d	0.0030	0.0030
Long term	7d	0.0029	0.0030
	14d	0.0029	0.0029
	21d	0.0028	0.0029
	28d	0.0028	0.0029
	50d	0.0026	0.0028
	100d	0.0023	0.0026
Plateau concentration (20 cm)		0.0005	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0035	-

Table 8.7-11: PEC_{soil} for X11449757 on winter cereals

PEC _{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0010	-
Short term	24h	0.0010	0.0010
	2d	0.0010	0.0010

	4d	0.0010	0.0010
Long term	7d	0.0010	0.0010
	14d	0.0009	0.0010
	21d	0.0009	0.0010
	28d	0.0009	0.0009
	50d	0.0008	0.0009
	100d	0.0007	0.0008
Plateau concentration (20 cm)		0.0001	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0011	-

8.7.2.4 Cloquintocet-mexyl and its metabolites

Table 8.7-12: PEC_{soil} for cloquintocet-mexyl on winter cereals

PEC _{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.025	-
Long term	21d	-	0.016

PEC_{soil} of metabolites

Table 8.7-13: PEC_{soil} for CGA 153433 on winter cereals

PEC _{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.007	-
Long term	21d	-	Not relevant

8.7.2.5 PEC_{soil} of GLOB1817H

Table 8.7-14: PEC_{soil} for GLOB1817H on winter cereals

Active substance/ reparation	Application rate (g/ha)	PEC _{act} (mg/kg)	PEC _{twa21 d} (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (mg/kg)
GLOB1817H	3026	4.0347	3.9877	20	-	-

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

zRMS Comments:	<p>Calculations of PEC_{gw} for active substances, their metabolites were submitted in accordance with GAP table.</p> <p>The endpoints used for PEC_{gw} assessment were agreed at the EU level or recalculated. The recalculations were accepted.</p> <p>The cloquintocet-mexyl is used as a safener and was not evaluated in this dossier.</p> <p>Calculations of PEC_{gw} for all active substances and their relevant metabolites were provided with PUF = 0.</p> <p>The autumn application was considered and the application dates were accepted. The recommended FOCUS models were used: FOCUS PEARL, FOCUS PELMO and FOCUS MACRO.</p> <p>Prosulfocarb. It is recommended to use Soil DT_{50la} = 41.d d for modeling with PELMO model (EFSA, 2007), but ‘<i>modelling with the correct geometric mean value of 11.9 days would not have altered the result</i>’ (EFSA, 2007). The DT₅₀ = 11.9 d was accepted. The PEC_{gw} values for active substance and its metabolite for intended use presented in GAP table were accepted. The PEC_{gw} values for active substance and its metabolite were below the trigger value of 0.1 µg/L.</p> <p>Diflufenican. The PEC_{gw} values for active substance and its metabolites were accepted. The PEC_{gw} values for active substance and its metabolites were below the trigger value of 0.1 µg/L.</p> <p>Halauxifen-methyl. In PECs assessment the higher application rate was used (5.85 g a.s./ha); as it represents a worse case – it was accepted. The PEC_{gw} values for active substance and its metabolites were accepted. The PEC_{gw} values for active substance and its metabolites were below the trigger value of 0.1 µg/L.</p>
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8.8.1 Justification for new endpoints

For the Koc and DT₅₀ in soil, the geometric mean was used in accordance with EFSA Journal 2014;12(5):3662.

The values for calculating the DT₅₀ of prosulfocarb in soil were renormalised using a Q₁₀ of 2.58.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

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

Use No.	1
Crop	Winter cereals
Application rate (g as/ha)	Prosulfocarb: 2001 Diflufenican: 42 Halauxifen-methyl: 5.85** Cloquintocet-mexyl: 18.75**

Number of applications/interval (d)	1/-
Relative application date (PEARL & PELMO)	7 days after emergence
Absolute application date (MACRO)	27 Oct (300)*
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

* proposed in AppDate version 3.06

**Worst case calculations, performed for a higher application rate, are shown here. The associated modelling files for halauxifen-methyl can be found in the ongoing application for GF-3678 of Corteva Agriscience.

8.8.2.1 Prosulfocarb and its metabolites

Table 8.8-2: Input parameters related to active substance prosulfocarb and metabolite prosulfocarb sulfoxide for PEC_{gw} calculations

Compound	Prosulfocarb	Prosulfocarb sulfoxide	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	251.4	267.4	Y, EFSA, 2007
Water solubility (mg/L):	13.2 (at 20°C) 26.4 (at 30°C)	2332	Y, EFSA, 2007
Saturated vapour pressure (Pa):	7.9 x 10 ⁻⁴ (at 20°C) 3.16 x 10 ⁻³ (at 30°C)	0	Y, EFSA, 2007
DT ₅₀ in soil (d)	12.1 (geomean, normalisation to pF2, 20°C with Q ₁₀ of 2.58, n = 6)	2.5 (geomean, normalisation to pF2, 20°C with Q ₁₀ of 2.58, n = 3)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662. Values for prosulfocarb renormalised using Q ₁₀ of 2.58.
Transformation rate	-	0.0573 (prosulfocarb → prosulfocarb sulfoxide) 0.2773 (prosulfocarb sulfoxide → sink)	Calculated (ln2/DT ₅₀ *f.f.)
K _{foc} (mL/g)/K _{fom}	1799/1043 (geomean, n = 6)	56.1/32.5 (geomean, n = 3)	Y, EFSA, 2007 Addendum, March 2011 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
1/n	0.93 (arithmetic mean, n = 6)	0.91 (arithmetic mean, n = 3)	Y, EFSA, 2007 Addendum, March 2011
Plant uptake factor	0	0	Worst case
Formation fraction	-	1.0 from parent	Y, EFSA, 2007

Table 8.8-3: PEC_{gw} for prosulfocarb and metabolite on winter cereals (with FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Prosulfocarb	Prosulfocarb sulfoxide
Winter cereals	Châteaudun	< 0.000001	< 0.000001
	Hamburg	< 0.000001	0.000002
	Jokioinen	< 0.000001	< 0.000001
	Kremsmünster	< 0.000001	< 0.000001
	Okehampton	< 0.000001	0.000008
	Piacenza	< 0.000001	< 0.000001
	Porto	< 0.000001	0.000017
	Sevilla	< 0.000001	< 0.000001
	Thiva	< 0.000001	< 0.000001

Table 8.8-4: PEC_{gw} for prosulfocarb and metabolite on winter cereals (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Prosulfocarb	Prosulfocarb sulfoxide
Winter cereals	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8-5: PEC_{gw} for prosulfocarb on winter cereals (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)
		Prosulfocarb
Winter cereals	Châteaudun	0

8.8.2.2 Diflufenican and its metabolites

Table 8.8-6: Input parameters related to active substance diflufenican and metabolites for PEC_{gw} calculations

Compound	Diflufenican	AE 0542291	AE B107137	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	394	282	283	Y, EFSA, 2007
Water solubility (mg/L):	0.05 (at 20°C) 0.1 (at 30°C)	100	410	Y, EFSA, 2007
Saturated vapour pressure (Pa):	4.25 x 10 ⁻⁶ (at 25°C) 1.72 x 10 ⁻⁵ (at 35°C)	10 ⁻¹⁰	10 ⁻¹⁰	Y, EFSA, 2007
DT ₅₀ in soil (d)	128 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n =8)	22.9 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 3)	10.3 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n =3)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
Transformation rate	-	0.0054	0.0054	Calculated (ln2/DT ₅₀ *f.f.)
K _{foc} (mL/g)/K _{fom}	3091/1793 (geomean, n = 10)	130/75 (geomean, n = 4)	11/6.4 (geomean, n = 4)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
1/n	0.917 (arithmetic mean, n = 10)	0.81 (arithmetic mean, n = 4)	0.73 (arithmetic mean, n = 4)	Y, EFSA, 2007
Plant uptake factor	0	0	0	worst case
Formation fraction	-	1 from parent	1 from parent	Y, EFSA, 2007

Table 8.8-7: PEC_{gw} for diflufenican and metabolites on winter cereals (with FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Diflufenican	AE 0542291	AE B107137
Winter cereals	Châteaudun	< 0.000001	< 0.000001	< 0.000001
	Hamburg	< 0.000001	< 0.000001	0.000019
	Jokioinen	< 0.000001	< 0.000001	< 0.000001
	Kremsmünster	< 0.000001	< 0.000001	< 0.000001
	Okehampton	< 0.000001	< 0.000001	0.000012
	Piacenza	< 0.000001	< 0.000001	0.000001
	Porto	< 0.000001	< 0.000001	< 0.000001
	Sevilla	< 0.000001	< 0.000001	< 0.000001
	Thiva	< 0.000001	< 0.000001	< 0.000001

Table 8.8-8: PEC_{gw} for diflufenican and metabolites on winter cereals (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Diflufenican	AE 0542291	AE B107137
Winter cereals	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Table 8.8-9: PEC_{gw} for diflufenican and AE 0542291 on winter cereals (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Diflufenican	AE 0542291
Winter cereals	Châteaudun	0	0

8.8.2.3 Halauxifen-methyl and its metabolites

Table 8.8-10: Input parameters related to active substance halauxifen-methyl and metabolites for PEC_{gw} calculations

Compound	Halauxifen-methyl	X11393729 (halauxifen)	X11449757	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	345	331	317	Y, EFSA, 2014
Water solubility (mg/L):	1.7 (at 20°C) 3.4 (at 30°C)	3070 (at 20°C)	265 (at 20°C)	Y, EFSA, 2014 Solubility at 30°C = 2 x solubility at 20°C
Saturated vapour pressure (Pa):	5.9 x 10 ⁻⁹ (at 20°C) 2.36 x 10 ⁻⁸ (at 30°C)	2 x 10 ⁻⁵ (at 20°C)	5 x 10 ⁻⁵ (at 20°C)	Y, EFSA, 2014 Vapour pressure at 30°C = 4 x vapour pressure at 20°C
DT ₅₀ in soil (d)	Simulating parent only: 20 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of	36.9 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58	19 (normalisation to pF2, 20 °C with Q ₁₀ of 2.58)	Y, EFSA, 2014

Compound	Halauxifen-methyl	X11393729 (halauxifen)	X11449757	Value in accordance with EU endpoint y/n/ Reference*
	2.58, n = 8) Sequential modelling of parent + X11393729: 3.3 (normalisation to pF2, 20 °C with Q ₁₀ of 2.58) Sequential modelling of parent + X11393729 + X11449757: 1.7 (normalisation to pF2, 20 °C with Q ₁₀ of 2.58)	alkaline soils as worst-case, n = 2) Sequential modelling of parent + X11393729 + X11449757: 19.1 (normalisation to pF2, 20 °C with Q ₁₀ of 2.58, acidic soils)		
Transformation rate	-	Sequential modelling of parent + X11393729: Parent > Acid: 0.0714 Parent > CO ₂ : 0.1386 Sequential modelling of parent + X11393729 + X11449757 (alkaline soils): Parent > Acid: 0.1386 Parent > CO ₂ : 0.2691 Sequential modelling of parent + X11393729 + X11449757 (acidic soils): Parent > Acid: 0.1223 Parent > CO ₂ : 0.2854	Sequential modelling of parent + X11393729 + X11449757 (alkaline soils): X11393729 > X11449757: 0.0113 X11393729 > CO ₂ : 0.0075 Sequential modelling of parent + X11393729 + X11449757 (acidic soils): X11393729 > X11449757: 0.00218 X11393729 > CO ₂ : 0.0145	Y, EFSA, 2014
K _{foc} (mL/g)/K _{fom}	796/462 (geomean, n = 9)	66/38.3 (geomean, n = 6)	67.3/39 (geomean, n = 6)	Y, EFSA, 2014 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
1/n	0.87 (arithmetic mean, n = 6)	0.87 (arithmetic mean, n = 6)	0.88 (arithmetic mean, n = 6)	Y, EFSA, 2014

Compound	Halauxifen-methyl	X11393729 (halauxifen)	X11449757	Value in accordance with EU endpoint y/n/ Reference*
Plant uptake factor	0*	0	0	Y, EFSA, 2014
Formation fraction	-	0.34 from parent (alkaline soils) Sequential modelling of parent + X11393729 + X11449757: 0.3 (acidic soils)	0.60 from X11393729	Y, EFSA, 2014

Separate model runs were carried out for parent alone using at DT₅₀ of 20 days, and then using a DT₅₀ of either 3.3 days or 1.7 days for the formation of X11393729 (halauxifen) or X11449757, respectively.

Table 8.8-11: PEC_{gw} halauxifen-methyl and metabolites on winter cereals (with FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Halauxifen-methyl	X11393729 (halauxifen)	X11449757
Winter cereals	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

Table 8.8-12: PEC_{gw} halauxifen-methyl and metabolites on winter cereals (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Halauxifen-methyl	X11393729 (halauxifen)	X11449757
Winter cereals	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001
	Okehampton	<0.001	0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001

	Porto	<0.001	0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

8.8.2.4 Cloquintocet-mexyl and its metabolites

Table 8.8-13: Input parameters related to active substance cloquintocet-mexyl and metabolite for PEC_{gw}-calculations

Compound	Cloquintocet-mexyl	CGA 153433
Molecular weight (g/mol)	335.8	236.6
Water solubility (g/mol):	0.59	-
Saturated vapour pressure (Pa):	5.31×10^{-6}	-
DT ₅₀ in soil (d)	3.8	35.7
Transformation rate	-	0.1824
$K_{foe} \text{ (mL/g)}/K_{fom}$	12850/7454	1772/1028
1/n	0.89	0.76
Plant uptake factor	0	0
Formation fraction	-	1 from parent

Table 8.8-14: PEC_{gw}-cloquintocet-mexyl and metabolite on winter cereals (with FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} -at 1 m Soil Depth (µg/L)	
		Cloquintocet-mexyl	CGA 153433
Winter cereals	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Jokioinen	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

Table 8.8-15: PEC_{gw}-cloquintocet-mexyl and metabolite on winter cereals (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} -at 1 m Soil Depth (µg/L)	
		Cloquintocet-mexyl	CGA 153433
Winter	Châteaudun	<0.001	<0.001

cereals	Hamburg	<0.001	<0.001
	Jokioinen	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

zRMS Comments:	Calculations of PEC _{sw} and PEC _{sed} for active substances, their metabolites and formulation were submitted. The endpoints used for PEC _{sw} assessment were agreed at the EU level or recalculated (e.g. K _{foc} , the geometric mean).
	Calculations of PEC _{sw} for active substances and their relevant metabolites were provided with PUF = 0. The recommended FOCUS models were used: FOCUS Step 1 & 2, Step 3 and Step 4. The autumn application was considered and the application dates were accepted.
	Prosulfocarb. The PEC _{sw} and PEC _{sed} assessment was provided in Step 1 & 2 and Step 3 and Step 4 (SWAN model). The mitigation measures were proposed.
	Metabolite of prosulfocarb. The tiered approach was submitted: at Tier 1 the metabolite prosulfocarb sulfoxide was implemented as a normal metabolite of prosulfocarb in SWASH and at Tier 2 – the metabolite was treated as a pseudo-parent. The worst case was accepted (Tier 1) and the Tier 2 could be accepted at the Member State level.
	The max PEC _{sw} for Central Zone and Poland with relevant mitigation measure are presented in the table below.

Central Zone. Step 4. max PEC_{sw} in winter cereals, BBCH 10.					
Compound	Application rate g a.s./ha	Tier	Vegetative strip (m)	No spray buffer (m)	Max PEC_{sw} (µg/L)
Prosulfocarb	2001	nr	10	10	6.302 R4 stream
Prosulfocarb sulfoxide	nr	1	-	20	68.65 D2 ditch
	144.7*	2	-	-	7.483 D1 ditch

* at Tier 2 approach;

The submitted calculations using EVA 3.0 rev2h was not evaluated. This approach could be considered at the Member State level.
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Diffenican. The PEC_{sw} values for active substance and its metabolites were accepted. The relevant metabolites AE 0542291 and AE B107137 were taken into consideration. The geometric mean of DT₅₀ for active substance and its metabolites were used and accepted.

The EPAT analysis was not evaluated. This approach could be considered at Member State level.

The mitigation measures were proposed.

Central Zone. Step 4. max PEC_{sw} in winter cereals, BBCH 10.

Compound	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Max PEC _{sw} (µg/L)
Diffenican	42	-	20	0.1445 D2 ditch

Metabolites of diffenican. For relevant metabolites AE 0542291, AE B107137 the PEC_{sw} and PEC_{sd} were assessed in Step 1 & 2.

Step 2 max PEC_{sw} assessment

Compound	Max PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)
AE 0542291	1.00	1.29
AE B107137	2.46	0.27

Halaxifen-methyl. In PECs assessment the higher application rate was used (5.85 g a.s./ha); as it represents a worse case – it was accepted.

The relevant metabolites X11393729 (halaxifen), X11449757, X11406790 were taken into consideration.

Central Zone. Step 4. max PEC_{sw} in winter cereals, BBCH 10.

Compound	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Max PEC _{sw} (µg/L)
Halaxifen-methyl	5.85	10	10	0.02183 R4 stream
		20	20	0.0114 R4 stream

Metabolites of Halaxifen-methyl. For relevant metabolites X11449757, X11406790 and X11393729 (halaxifen), the PEC_{sw} and PEC_{sd} were assessed in Step 1 & 2:

Step 2 PEC_{sw} assessment

Compound	Max PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)
X11449757	0.42	0.28

	X11406790	0.16	0.68	
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Additionally, for metabolite X11393729 (halauxifen) the mitigation measures in Step 4 were proposed: 10 m vfs and 10 no spray zone.

Compound	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Max PEC _{sw} (µg/L)
Halauxifen-	nr	10	10	0.01681 R4 stream

Formulation. The submitted PEC_{sw} assessment was accepted.

Crop	Application rate g formul./ha	Buffer strip m	PEC _{sw} (µg/L)
Winter cereals	3025.5	1	23.33
		5	6.32

The relevant PEC_{sw} and PEC_{sed} values will be used in further risk assessment at national level.
The relevant mitigation measure will be recommended in ecotoxicological section.

National assessment for Poland

Prosulfocarb The Tier 1 was accepted. Based on submitted assessment the following max PEC values were accepted.
For scenarios D3, D4 and R1 (relevant for Poland) the max PEC_{sw} = 4.261 µg/L in R1 stream scenario if 10 m vfs and 10 no spray buffer are applied.

Prosulfocarb sulfoxide. No mitigation measure was proposed; the max PEC_{sw} = 8.658 µg/L (R1 stream) and PEC_{sed} = 2.455 µg/kg (D4 pond).

Diflufenican For scenarios D3, D4 and R1 (relevant for Poland) the max PEC_{sw} = 0.05014 µg/L in R1 stream scenario if 10 m vfs and 10 no spray buffers are applied.

Halauxifen-methyl. For scenarios D3, D4 and R1 (relevant for Poland) the max PEC_{sw} = 0.01289 µg/L in R1 stream scenario if 10 m vfs and 10 no spray buffers are applied.

Metabolites of Halauxifen-methyl. For scenarios D3, D4 and R1 (relevant for Poland) the max PEC_{sw} = 0.009646 µg/L in R1 stream scenario if 10 m vfs and 10 no spray buffers are applied.

8.9.1 Justification for nw endpoints

For the Koc and DT50 in soil, the geometric mean was used in accordance with EFSA Journal 2014;12(5):3662.

The values for calculating the DT₅₀ of prosulfocarb in soil were renormalised using a Q₁₀ of 2.58.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for PEC_{sw/sed} calculations

Plant protection product	GLOB1817H
Use No.	1
Crop	Winter cereals
Application rate (g as/ha)	Prosulfocarb: 2001 Diflufenican: 42 Halauxifen-methyl: 5.85* Cloquintocet-mexyl: 18.75*
Number of applications/interval (d)	1/-
Application window	October – February (relevant for STEP 1 and 2 only)
Application method	Ground spray
CAM (Chemical application method)	CAM 2 – foliar linear
Soil depth (cm)	4
Models used for calculation	STEPS 1-2 v 3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v5.0.0, EPAT v1.2

*Worst case calculations, performed for a higher application rate, are shown here. The associated modelling files for cloquintocet-mexyl can be found in the ongoing application for GF-3678 of Corteva Agriscience.

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC_{sw/sed} calculations for the application of GLOB1817H

Crop	Scenario	Application window used in modelling*
Winter cereals	D1	26/09 – 26/10 (269 - 299)
	D2	26/10 – 25/11 (299 – 329)
	D3	22/11 – 22/12 (326 – 356)
	D4	23/09 – 23/10 (266 – 296)
	D5	11/11 – 11/12 (315 – 345)
	D6	01/12 – 31/12 (335 – 365)
	R1	13/11 – 13/12 (317 – 347)
	R3	02/12 – 01/01 (336 – 1)
	R4	11/11 – 11/12 (315 - 345)

* window proposed in AppDate version 3.06 at BBCH 10

8.9.2.1 Prosulfocarb and its metabolites

Table 8.9-3: Input parameters related to active substance prosulfocarb and metabolite prosulfocarb sulfoxide for PEC_{sw/sed} calculations STEP 1/2 and 3(/4)

Compound	Prosulfocarb	Prosulfocarb sulfoxide	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	251.4	267.4	Y, EFSA, 2007

Compound	Prosulfocarb	Prosulfocarb sulfoxide	Value in accordance to EU endpoint y/n/ Reference
Saturated vapour pressure (Pa)	7.9×10^{-4} (at 20°C)	0	Y, EFSA, 2007
Water solubility (mg/L)	13.2	2332	Y, EFSA, 2007
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	4.3×10^{-5}	default
Diffusion coefficient in air (m ² /d)	0.43	0.43	default
K _{foc} (mL/g)	1799 (geomean, n = 6)	56.1 (geomean, n = 3)	Y, EFSA, 2007 Addendum, March 2011 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
Freundlich Exponent 1/n	0.93 (arithmetic mean, n = 6)	0.91 (arithmetic mean, n = 3)	Y, EFSA, 2007 Addendum, March 2011
Plant Uptake	0	0	Worst case
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	default
DT _{50,soil} (d)	12.1 (geomean, normalisation to pF ₂ , 20 °C with Q ₁₀ of 2.58, n = 6)	2.5 (geomean, normalisation to pF ₂ , 20 °C with Q ₁₀ of 2.58, n = 3)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662. Values for prosulfocarb renormalised using Q ₁₀ of 2.58.
DT _{50,water} (d)	1000 (default) or 331 (worst case from sediment water studies)	3.5	Y, EFSA, 2007 Addendum, April 2013
DT _{50,sed} (d)	331 (worst case from sediment water studies) or 1000 (default)	1000	Y, EFSA, 2007
DT _{50,whole system} (d)	331 (worst case from sediment water studies)	3.5	Y, EFSA, 2007 Addendum, April 2013
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 6.8 Water: Sediment: 1	Y, EFSA, 2007
Formation fraction in soil	-	1 (from parent)	Y, EFSA, 2007

Since the prosulfocarb K_{foc} is within the range 100-2000, two sets of Step 3 and 4 simulations with different water/sediment DT₅₀ inputs are required; one with the whole system DT₅₀ of 331 days applied to the water (DT₅₀ of 1000 days for sediment) (= “water degradation”) and one with the whole system DT₅₀ of 331 days applied to the sediment (DT₅₀ of 1000 days for water) (= “sediment degradation”).

At the results of Step 3, the concentrations shown are the maximum obtained from either the “water degradation” or “sediment degradation” analyses. In practice, the two different approaches can be considered equivalent. There were some small differences noted, mainly between the PEC_{sed} values, however, these have no impact on the risk assessment.

Step 4 calculations were not needed for prosulfocarb. The Step 4 calculations for the metabolite prosulfocarb sulfoxide in Table 8.9-7 are based on the “sediment degradation” Step 3 calculations, since these are equal to or worst-case compared to the “water degradation” Step 3 calculations.

PEC_{sw/sed}

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb following single application of GLOB1817H to winter cereals

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	214.66	-	192.99	3620
Step 2					
Northern Europe	Oct-Feb	85.11	-	80.60	1500
Southern Europe	Oct-Feb	69.51	-	65.52	1220
Step 3					
D1	ditch	12.81	Drainage	8.448	41.46
D1	stream	11.20	Drainage	0.4851	5.972
D2	ditch	12.74	Drainage	1.865	18.03
D2	stream	10.34	Drainage	0.04546	0.7057
D3	ditch	12.62	Drainage	0.4617	5.725
D4	pond	0.4369	Drainage	0.3650	2.953
D4	stream	10.95	Drainage	0.1511	2.215
D5	pond	0.4382	Drainage	0.3710	2.733
D5	stream	11.81	Drainage	0.2168	3.062
D6	ditch	12.77	Drainage	3.843	24.16
R1	pond	1.217	Runoff	1.034	10.20
R1	stream	9.514	Runoff	0.3647	6.993
R3	stream	12.11	Runoff	0.6095	6.890
R4	stream	13.96	Runoff	0.6652	9.874

Metabolite of prosulfocarb

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to winter cereals

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	51.68	-	12.24	28.88
Step 2					
Northern Europe	Oct-Feb	10.11	-	2.55	5.67
Southern Europe	Oct-Feb	8.11	-	2.04	4.55

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 3					
D1	ditch	46.13	Drainage	31.59	36.98
D1	stream	28.92	Drainage	20.68	23.70
D2	ditch	68.65	Drainage	23.42	38.12
D2	stream	43.39	Drainage	13.55	22.75
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	2.637	Drainage	2.249	2.455
D4	stream	4.907	Drainage	2.173	2.255
D5	pond	5.584	Drainage	4.077	5.120
D5	stream	8.462	Drainage	2.523	4.008
D6	ditch	18.23	Drainage	4.972	6.577
R1	pond	0.2447	Runoff	0.1532	0.1988
R1	stream	8.658	Runoff	0.1776	1.115
R3	stream	8.076	Runoff	0.2993	1.213
R4	stream	9.563	Runoff	0.3025	1.411

FOCUS Step 4

Step 4 calculations for prosulfocarb were done with the following mitigation measures:

- buffer zones of 5 m, 10 m and 20 m
- vegetated filter strip of 10 m

These calculations were not needed for the aquatic risk assessment of the active substance, but the values were used to calculate PEC_{mix} in the aquatic mixture toxicity risk assessment.

Step 4 calculations for prosulfocarb sulfoxide were done with the following mitigation measures:

- spray drift reduction of 50%, 75% and 90% drift reducing nozzles
- spray drift reduction by buffer zones of 5 m, 10 m and 20 m

Since prosulfocarb is volatile, dry deposition was implemented in the Step 4 calculations using deposition rates calculated with the UBA tool EVA 3.0 rev2h (see table below).

Table 8.9-6: Dry deposition rates for prosulfocarb in Step 4 calculations (from EVA 3.0 rev2h)

Application pattern	Spray drift scenario/interception	Time after application (hours)	Deposition rates (g/ha)			
			1 m	5 m	10 m	20 m
1 x 2001 g a.s./ha, early post- emergence	Arable crops/0%	0-4	0.0134	0.0108	0.0082	0.0047
		4-12	0.0067	0.0054	0.0041	0.0024
		12-24	0.0033	0.0027	0.0020	0.0012

Table 8.9-7: Global maximum PEC_{sw} values for prosulfocarb, following single application of GLOB1817H to winter cereals according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb	
Nozzle reduction	Vegetative strip (m)	None	10
	No spray buffer (m)	5	10
None	D1 ditch	3.563	-
None	D1 stream	4.096	-
None	D2 ditch	3.452	-
None	D2 stream	3.834	-
None	D3 ditch	3.419	-
None	D4 stream	4.015	-
None	D5 stream	4.319	-
None	D6 ditch	3.564	-
None	R1 stream	-	4.261
None	R3 stream	-	5.454
None	R4 stream	-	6.302

Table 8.9-8: Global maximum PEC_{sw} values for prosulfocarb sulfoxide, following single application of GLOB1817H to winter cereals according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb sulfoxide		
Nozzle reduction	Vegetative strip (m)	None	None	None
	No spray buffer (m)	5	10	20
None	D1 ditch	46.13	46.13	46.13
50 %		46.13	-	-
75 %		46.13	-	-
90 %		46.13	46.13	46.13
None	D1 stream	28.92	28.92	28.92
50 %		28.92	-	-
75 %		28.92	-	-
90 %		28.92	28.92	28.92
None	D2 ditch	68.65	68.65	68.65
50 %		68.65	-	-
75 %		68.65	-	-

PEC _{sw} (µg/L)	Scenario	STEP 4 Prosulfocarb sulfoxide		
Nozzle reduction	Vegetative strip (m)	None	None	None
	No spray buffer (m)	5	10	20
90 %		68.65	68.65	68.65
None	D2 stream	43.39	43.39	43.39
50 %		43.39	-	-
75 %		43.39	-	-
90 %		43.39	43.39	43.39
None	D6 ditch	18.23	18.23	18.23
50 %		18.23	-	-
75 %		18.23	-	-
90 %		18.23	18.23	18.23

For prosulfocarb sulfoxide, a tiered approach was followed at Step 3-4: At Tier 1, prosulfocarb sulfoxide was implemented as a normal metabolite of prosulfocarb in SWASH. However, since the true formation fraction of prosulfocarb sulfoxide in soil is uncertain, a refined simulation for prosulfocarb sulfoxide was undertaken, as a ‘Tier 2’, simulating the metabolite as a pseudo-parent. This approach is consistent with that previously established at EU level.

Prosulfocarb sulfoxide is a metabolite of prosulfocarb forming in soil but not in water or sediment. The maximum observed amount of prosulfocarb sulfoxide in laboratory soil degradation studies was 6.8%. The application rate of prosulfocarb was factored to account for the difference in molar mass between prosulfocarb (251.4 g/mol) and prosulfocarb sulfoxide (267.4 g/mol) and the maximum observed amount of prosulfocarb sulfoxide in soil, leading to an application rate of 144.7 g/ha for prosulfocarb sulfoxide.

In the Step 3 simulations, ground spray was considered and the application method was set to CAM-1 because prosulfocarb sulfoxide is a metabolite formed in soil but not on plants. Since spray drift is not a possible route of exposure for metabolites formed in soil, a SWAN run with 100% drift reduction was performed in order to eliminate drift entries.

The maximum amount of prosulfocarb sulfoxide was found in laboratory degradation studies at day 18 after application of the parent substance prosulfocarb. Thus, for the present calculations for prosulfocarb sulfoxide, the appropriate application window for the metabolite starts 18 days later than the respective window for the parent substance. The length of the window was set to 30 days.

The results can be found in Table 8.9-9 below.

Table 8.9-9: FOCUS Step 3 Scenario related input parameters for PEC_{sw/sed} calculations for the application of GLOB1817H

Crop	Scenario	Application window used in modelling
Winter cereals	D1	14/10 – 13/11 (287 - 317)
	D2	13/11 – 13/12 (317 – 347)
	D3	10/12 – 09/01 (344 – 9)

Crop	Scenario	Application window used in modelling
	D4	11/10 – 10/11 (284 – 314)
	D5	29/11 – 29/12 (333 – 363)
	D6	19/12 – 18/01 (353 – 18)
	R1	01/12 – 31/12 (335 – 365)
	R3	20/12 – 19/01 (354 – 19)
	R4	29/11 – 29/12 (333 - 363)

Table 8.9-10: Tier 2 PEC_{sw} and PEC_{sed} for prosulfocarb sulfoxide following single application to winter cereals

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
D1	ditch	7.483	Drainage	3.697	5.419
D1	stream	4.917	Drainage	2.767	3.551
D2	ditch	6.194	Drainage	1.635	1.648
D2	stream	4.004	Drainage	0.9508	0.9955
D3	ditch	< 0.000001	Drainage	< 0.000001	< 0.000001
D4	pond	0.2016	Drainage	0.1646	0.1902
D4	stream	0.3594	Drainage	0.1536	0.1885
D5	pond	0.03400	Drainage	0.02929	0.04952
D5	stream	0.2090	Drainage	0.04310	0.06191
D6	ditch	0.7003	Drainage	0.07671	0.1633
R1	pond	0.000987	Run-off	0.000592	0.000950
R1	stream	0.8509	Run-off	0.003907	0.04173
R3	stream	7.155	Run-off	0.1826	1.009
R4	stream	1.443	Run-off	0.04317	0.2281

8.9.2.2 Diflufenican and its metabolites

Table 8.9-11: Input parameters related to active substance diflufenican and metabolites for PEC_{sw/sed} calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Diflufenican	AE 0542291	AE B107137	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	394	282	283	Y, EFSA, 2007
Saturated vapour pressure (Pa)	0.425 x 10 ⁻⁵ (20°C)	10 ⁻¹⁰	10 ⁻¹⁰	Y, EFSA, 2007
Water solubility (mg/L)	0.05 (20°C)	100	410	Y, EFSA, 2007
Diffusion coefficient in water	4.3 x 10 ⁻⁵	4.3 x 10 ⁻⁵	4.3 x 10 ⁻⁵	default

Compound	Diflufenican	AE 0542291	AE B107137	Value in accordance to EU endpoint y/n/ Reference
(m ² /d)				
Diffusion coefficient in air (m ² /d)	0.43	0.43	0.43	default
K _{foc} (mL/g)	3091 (geomean, n = 10)	130 (geomean, n = 4)	11 (geomean, n = 4)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
Freundlich Exponent 1/n	0.917 (arithmetic mean, n = 10)	0.81 (arithmetic mean, n = 4)	0.73 (arithmetic mean, n = 4)	Y, EFSA, 2007
Plant Uptake	0	0	0	worst case
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	default
DT _{50,soil} (d)	128 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n =8)	22.9 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 3)	10.3 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n =3)	Y, EFSA, 2007 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
DT _{50,water} (d)	175 (geomean, n = 4)	1000 (worst case)	1000 (worst case)	Y, EFSA, 2007
DT _{50,sed} (d)	1000 (worst case)	1000 (worst case)	1000 (worst case)	Y, EFSA, 2007
DT _{50,whole system} (d)	175	1000 (worst case)	1000 (worst case)	Y, EFSA, 2007
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 26.3 Water: - Sediment: - Total system: 0.01	Soil: 16.8 Water: 32.6 Sediment: 13.3 Total system: 35.7	Y, EFSA, 2007
Formation fraction in soil	-	1 (from parent)	1 (from parent)	Y, EFSA, 2007

PEC_{sw/sed}

Table 8.9-12: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for diflufenican following single application of GLOB1817H to winter cereals

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	---	3.12	-	2.70	86.49
Step 2					
Northern Europe	Oct-Feb	1.44	-	1.39	43.63
Southern Europe	Oct-Feb	1.17	-	1.13	35.36

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 3					
D1	ditch	0.2699	Drainage	0.1510	1.379
D1	stream	0.2345	Drainage	0.02787	0.6183
D2	ditch	0.2929	Drainage	0.07998	1.301
D2	stream	0.2282	Drainage	0.01801	0.6593
D3	ditch	0.2641	Drainage	0.009577	0.1361
D4	pond	0.009133	Drainage	0.007068	0.1160
D4	stream	0.2291	Drainage	0.003150	0.04906
D5	pond	0.009170	Drainage	0.007220	0.08208
D5	stream	0.2472	Drainage	0.004517	0.06892
D6	ditch	0.2672	Drainage	0.07367	0.6939
R1	pond	0.02146	Run-off	0.01726	0.2998
R1	stream	0.1742	Run-off	0.006395	0.3144
R3	stream	0.2444	Run-off	0.007625	0.3012
R4	stream	0.1728	Run-off	0.008463	0.2827

FOCUS Step 4

Table 8.9-13: Global maximum PEC_{sw} values for diflufenican, following single application of GLOB1817 to winter cereals according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 diflufenican				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	5	10	20	10	20
None	D1 ditch	0.07438	0.06633	0.06633	-	-
50 %		0.06633	0.06633	-	-	-
75 %		0.06633	-	-	-	-
90 %		-	-	-	-	-
None	D1 stream	0.08565	0.04541	0.04177	-	-
50 %		0.04284	0.04177	-	-	-
75 %		-	-	-	-	-
90 %		-	-	-	-	-
None	D2 ditch	0.1445	0.1445	0.1445	-	-
50 %		0.1445	0.1445	-	-	-

PEC _{sw} (µg/L)	Scenario	STEP 4 diflufenican				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	5	10	20	10	20
75 %	D2 stream	0.1445	-	-	-	-
90 %		-	-	-	-	-
None		0.09124	0.09124	0.09124	-	-
50 %		0.09124	0.09124	-	-	-
75 %	D3 ditch	0.09124	-	-	-	-
90 %		-	-	-	-	-
None		0.07155	0.03795	-	-	-
50 %		0.03576	-	-	-	-
75 %	D4 stream	-	-	-	-	-
90 %		-	-	-	-	-
None		0.08367	0.04435	-	-	-
50 %		0.04184	-	-	-	-
75 %	D5 stream	-	-	-	-	-
90 %		-	-	-	-	-
None		0.09028	0.04785	0.02486	-	-
50 %		0.04514	0.02392	-	-	-
75 %	D6 ditch	0.02256	-	-	-	-
90 %		-	-	-	-	-
None		0.1006	0.1006	0.1006	-	-
50 %		0.1006	0.1006	-	-	-
75 %	R1 stream	0.1006	-	-	-	-
90 %		-	-	-	-	-
None		0.1120	0.1120	0.1120	0.05014	0.02611
50 %		0.1120	0.1120	-	-	-
75 %	R3 stream	0.1120	-	-	-	-
90 %		-	-	-	-	-
None		0.1146	0.1146	0.1146	0.05160	0.02697
50 %		0.1146	0.1146	-	-	-
75 %	R4 stream	0.1146	-	-	-	-
90 %		-	-	-	-	-
None		0.1627	0.1627	0.1627	0.07341	0.03833
50 %		0.1627	0.1627	-	-	-
75 %	R4 stream	0.1627	-	-	-	-
90 %		-	-	-	-	-

From the aquatic risk assessment in section B9, it is clear that algae are the most sensitive aquatic organism when exposed to diflufenican. Based on higher-tier laboratory studies with peak exposure followed by a recovery phase, it was decided at the EU level that the risk for algae may be considered acceptable provided that:

- The peak exposure is below 0.42 µg diflufenican /L
- The other exposure peaks do not exceed the overall NOEC for all species tested, 0.1 µg/L within 3 days.
- The exposure does not persist for > 3 days (the duration of exposure in the study on which these assumptions were based). The exposure above the overall NOEC of 0.1 µg/L should be then ≤ 3 days.

Scenarios with a maximum PEC_{sw} below 0.1 µg/L automatically fulfil these conditions. However, FOCUS profiles of scenarios with a maximum PEC_{sw} above 0.1 µg/L (but below 0.42 µg/L) were analysed using EPAT v1.2 in order to check if they fulfil these conditions. The results can be found in the table below. Graphs of each FOCUS profile with plotted thresholds of 0.42 µg/L and 0.1 µg/L can be found in Appendix 3.

Table 8.9-14: Analysis of FOCUS profiles with a maximum PEC_{sw} above 0.1 µg/L but below 0.42 µg/L using EPAT v1.2

Scenario		Peaks above 0.1 µg/L	Max. peak concentration if above 0.1 µg/L	Interval between peaks above 0.1 µg/L (days)	Duration of peak above 0.1 µg/L (days)	Total duration of peaks above 0.1 µg/L (days)
STEP 4—5m	D2 ditch	1	0.117	-	0.167	3.75
		2	0.108	5.833	0.084	
		3	0.108	0.916	0.084	
		4	0.115	0.875	0.166	
		5	0.113	18.875	0.167	
		6	0.101	34.917	0.041	
		7	0.106	18.917	0.083	
		8	0.114	3.917	0.167	
		9	0.108	17.833	0.083	
		10	0.106	0.875	0.125	
		11	0.111	3.917	0.083	
		12	0.115	25	0.334	
		13	0.104	4.625	0.041	
		14	0.102	164.959	0.041	
		15	0.110	13.875	0.167	
		16	0.121	5.833	0.209	
		17	0.118	1.791	0.167	
		18	0.103	2.833	0.084	
		19	0.104	16.916	0.084	
		20	0.119	2.916	0.167	
		21	0.123	15.833	0.209	
		22	0.105	64.833	0.042	
		23	0.117	0.916	0.125	
		24	0.131	18.917	0.25	
		25	0.145	8.708	0.375	

		26	0.133	2.625	0.209	
	D6 ditch	1	0.101	-	0.042	0.042
	R1 stream	1	0.112	-	0.292	0.292
	R3 stream	1	0.115	-	0.375	0.709
		2	0.111	9.625	0.334	
	R4 stream	1	0.163	-	0.541	1.583
		2	0.152	0.5	0.417	
		3	0.114	87.542	0.625	

Metabolites of diflufenican

Table 8.9-15: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE 0542291 following single application to winter cereals

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	2.25	2.23	2.92
Step 2				
Northern Europe	Oct-Feb	1.00	0.99	1.29
Southern Europe	Oct-Feb	0.80	0.79	1.04

Table 8.9-16: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE B107137 following single application to winter cereals

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	5.30	5.26	0.58
Step 2				
Northern Europe	Oct-Feb	2.46	2.45	0.27
Southern Europe	Oct-Feb	1.99	1.98	0.22

8.9.2.3 Halauxifen-methyl and its metabolites

Table 8.9-17: Input parameters related to active substance halauxifen-methyl and metabolites for PEC_{sw/sed} calculations STEP 1/2 and 3/4

Compound	Halauxifen-methyl	X11393729 (halauxifen)	X11449757	X11406790	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	345	331	317	331	Y, EFSA, 2014
Saturated vapour pressure (Pa)	5.9×10^{-9}	2.0×10^{-5}	-	-	Y, EFSA, 2014
Water solubility (mg/L)	1.67	3070	265	3070***	Y, EFSA, 2014
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	4.3×10^{-5}	-	-	default
Diffusion coefficient in air (m ² /d)	0.43	0.43	-	-	default
K _{foc} (mL/g)	796 (geomean, n = 7)	66.0 (geomean, n = 6)	67.3 (geomean)	0/1000****	Y, EFSA, 2014 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
Freundlich Exponent 1/n	0.87 (arithmetic mean, n = 7)	0.87 (arithmetic mean, n = 6)	-	-	Y, EFSA, 2014
Plant Uptake	0	0	-	-	Worst-case default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	-	-	default
DT _{50,soil} (d)	20 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 8) [worst-case when modelling parent alone] 3.3 (geomean field) [worst-case when modelling formation of metabolites]	36.9 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 2, highest pH field sites) [worst-case when modelling formation of acid]*	67 (worst-case geomean field top down SFO value)	1000 (default)	Y, EFSA, 2014
DT _{50,water} (d)	1.8 (geomean whole system value, n = 2) or 1000 (default)	4.7 (geomean whole system value, n = 2)	57.5 (geomean whole system value, n = 2)	3.2 (geomean whole system value, n = 2)	Y, EFSA, 2014
DT _{50,sed} (d)	1000 (default) or 1.8 (geomean whole system value, n = 2)	1000 (default)	1000 (default)	1000 (default)	Y, EFSA, 2014

DT _{50,whole system} (d)	1.8 (geomean whole system value, n = 2)	4.7 (geomean whole system value, n = 2)	57.5 (geomean whole system value, n = 2)	3.2 (geomean whole system value, n = 2)	Y, EFSA, 2014
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 40.1 Water: 20.0 Sediment: 6.1 Total system: 23.5	Soil: 13.8 Water: 48.3 Sediment: 50.6 Total system: 76.7	Soil: 1.4 Water: 16.5 Sediment: 10.6 Total system: 33.4	Y, EFSA, 2014
Formation fraction in soil	-	0.34 (arithmetic mean field, high pH soil)**	-	-	Y, EFSA, 2014

* Longest DT₅₀ for X11393729 (halauxifen) from high pH soils together with the highest formation fraction will be worst-case.

** Value associated with alkaline soil used, but very similar to formation fraction from acidic soil (0.30).

*** Value for X11393729 (halauxifen) used in absence of data.

**** Two sets of analyses performed to maximise water and sediment concentrations, respectively.

Since the halauxifen-methyl K_{foc} is within the range 100-2000, two sets of Step 3 and 4 simulations with different water/sediment DT₅₀ inputs are required; one with the whole system DT₅₀ of 1.8 days applied to the water (DT₅₀ of 1000 days for sediment) (= “water degradation”) and one with the whole system DT₅₀ of 1.8 days applied to the sediment (DT₅₀ of 1000 days for water) (= “sediment degradation”).

At the results of Steps 3 and 4, the concentrations shown are the maximum obtained from either the “water degradation” or “sediment degradation” analyses. In practice, the two different approaches can be considered equivalent. There were some small differences noted between the PEC_{sed} values, however, these have no impact on the risk assessment.

Halauxifen-methyl and X11393729 (halauxifen) were analysed to Step 3, and then to Step 4 if required for risk assessment. However, when the dominant exposure route for the D scenarios was drainflow, then mitigation at Step 4 was not possible. Where run-off was the dominant exposure route, Step 4 mitigation was possible and so run-off reduction for an inclusive 10 m and 20 m VFS was implemented with reduction factors for the aqueous phase of 0.6 and 0.8 respectively, and reduction factors for the sediment phase of 0.85 and 0.95 respectively. The 10 m NSZ was also implemented to manage drift in the drainflow scenarios.

Due to lower toxicity, the X11449757 and X11406790 metabolites were evaluated at Steps 1 and 2 only. Both substances were input as a metabolite of halauxifen-methyl.

The three major aquatic photoproducts of halauxifen-methyl, referred to as Deg 10, Deg 11 and Deg 14, are rapidly formed and degraded with DT₅₀ values of 2-3 hours for Deg 10 and Deg 11, and *ca* 1 day for Deg 14. Therefore, they can be considered transient and unlikely to pose a significant aquatic risk. However, for completeness, the Step 1 and 2 PEC_{sw} values for these photoproducts were calculated from the maximum Step 1 and 2 PEC_{sw} values for parent, taking into account the % AR formed and the molecular weight difference. The following input parameters were used. Time-aged values were not calculated.

Table 8.9-18: Inputs for aquatic photoproducts for PEC_{sw/sed} (STEPS 1 and 2)

Aquatic photoproduct	mw metab/ mw parent	Max. occurrence in water (% AR)
Deg 10	326/345	12.6%
Deg 11	273/345	15.7%
Deg 14	229/345	11.5%

PEC_{sw/sed}

Table 8.9-19: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for halauxifen-methyl following single application of GLOB1817H to winter cereals

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	Max PEC _{sed} (µg/kg)*
Step 1	---	1.00	-	7.53
Step 2				
Northern Europe	Oct-Feb	0.42	-	3.37
Southern Europe	Oct-Feb	0.34	-	2.71
Step 3				
D1	ditch	0.03744	Drift	0.06474
D1	stream	0.03274	Drift	0.01787
D2	ditch	0.03722	Drift	0.04730
D2	stream	0.03020	Drift	0.002284
D3	ditch	0.03687	Drift	0.01684
D4	pond	0.001276	Drift	0.002895
D4	stream	0.03199	Drift	0.006472
D5	pond	0.001276	Drift	0.003294
D5	stream	0.03452	Drift	0.009048
D6	ditch	0.03731	Drift	0.05389
R1	pond	0.003595	Run-off	0.01095
R1	stream	0.02879	Run-off	0.02587
R3	stream	0.03644	Run-off	0.02316
R4	stream	0.04836	Run-off	0.03552

FOCUS Step 4

Table 8.9-20: Global maximum PEC_{sw} values for halauxifen-methyl, following single application of GLOB1817H to winter cereals according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 halauxifen-methyl			
Nozzle reduction	Vegetative strip (m)	None	None	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	0.00538	0.002795	-	-
	D1 stream	0.00634	0.003295	-	-
	D2 ditch	0.005354	0.002784	-	-
	D2 stream	0.005849	0.00304	-	-
	D3 ditch	0.005299	0.002752	-	-
	D4 pond	0.000793	0.00053	-	-
	D4 stream	0.006195	0.003219	-	-
	D5 pond	0.000793	0.00053	-	-
	D5 stream	0.006684	0.003473	-	-
	D6 ditch	0.02787	0.02787	-	-
	R1 pond	-	-	0.001547	0.000817
	R1 stream	-	-	0.01289	0.006712
	R3 stream	-	-	0.01642	0.008577
	R4 stream	-	-	0.02183	0.0114

Metabolites of halauxifen-methyl

Table 8.9-21: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for X11393729 (halauxifen) following single application to winter cereals

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	Max PEC _{sed} (µg/kg)*
FOCUS				
Step 1	---	1.11	-	0.72
Step 2				
Northern Europe	Oct-Feb	0.41	-	0.27
Southern Europe	Oct-Feb	0.33	-	0.22
Step 3				
D1	ditch	0.1551	Drainflow	0.2427
D1	stream	0.09722	Drainflow	0.1563

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	Max PEC _{sed} (µg/kg)*
D2	ditch	0.1821	Drainflow	0.2157
D2	stream	0.1135	Drainflow	0.1351
D3	ditch	0.00150	Drift	0.000501
D4	pond	0.0137	Drainflow	0.02339
D4	stream	0.02333	Drainflow	0.01844
D5	pond	0.01493	Drainflow	0.02609
D5	stream	0.02373	Drainflow	0.01767
D6	ditch	0.05376	Drainflow	0.04081
R1	pond	0.000706	Run-off	0.001137
R1	stream	0.02153	Run-off	0.004372
R3	stream	0.02194	Run-off	0.005297
R4	stream	0.03723	Run-off	0.008597

Table 8.9-22: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for X11449757 following single application to winter cereals

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	1.53	1.01
Step 2			
Northern Europe	Oct-Feb	0.42	0.28
Southern Europe	Oct-Feb	0.37	0.24

Table 8.9-23: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for X11406790 following single application to winter cereals

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	0.67*	2.79**
Step 2			
Northern Europe	Oct-Feb	0.16*	0.68**
Southern Europe	Oct-Feb	0.12*	0.55**

* K_{foc} = 0

** K_{foc} = 1000

Table 8.9-24: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Deg 10, Deg 11 and Deg 14 following single application to winter cereals

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*		
		Deg 10	Deg 11	Deg 14
Step 1	---	0.12	0.12	0.08
Step 2				
Northern Europe	Oct-Feb	0.06	0.06	0.03
Southern Europe	Oct-Feb	0.04	0.04	0.02

FOCUS Step 4

Table 8.9-25: Global maximum PEC_{sw} values for X11393729 (halauxifen), following single application of GLOB1817H to winter cereals according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 X11393729 (halauxifen)	
Nozzle reduction	Vegetative strip (m)	None	10
	No spray buffer (m)	10	10
None	D1 ditch	0.1551	-
	D1 stream	0.09722	-
	D2 ditch	0.1821	-
	D2 stream	0.1135	-
	D3 ditch	0.00021	-
	D4 pond	0.0137	-
	D4 stream	0.02333	-
	D5 pond	0.01493	-
	D5 stream	0.02373	-
	D6 ditch	0.05376	-
	R1 pond	-	0.000286
	R1 stream	-	0.009646
	R3 stream	-	0.0009861
	R4 stream	-	0.01681

8.9.2.4 Cloquintocet-mexyl and its metabolites

Table 8.9-26: Input parameters related to active substance cloquintocet-mexyl and metabolite CGA 153433 for PEC_{sw/sed} calculations STEP 1/2

Compound	Cloquintocet-mexyl	CGA 153433
Molecular weight (g/mol)	335.8	236.6
Water solubility (mg/L)	0.59	1 (surrogate)
K _{foe} (mL/g)	12850	1772
DT _{50,soil} (d)	3.8	35.7
DT _{50,water} (d)	1000 (default)	1000 (default)
DT _{50,sed} (d)	+	1000 (default)
DT _{50,whole system} (d)	+	1000 (default)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 38 Water: 38 Sediment: 27 Total system: 65

PEC_{sw/sed}

Table 8.9-27: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for cloquintocet-mexyl following single application of GLOB1817H to winter cereals

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS			
Step 1	—	0.517	44.290
Step 2			
Northern Europe	Oct-Feb	0.172	8.142
Southern Europe	Oct-Feb	0.172	6.541

Metabolite of cloquintocet-mexyl

Table 8.9-28: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for CGA 153433 following single application to winter cereals

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS			
Step 1	—	0.577	8.818
Step 2			
Northern Europe	Oct-Feb	0.203	3.472
Southern Europe	Oct-Feb	0.169	2.861

8.9.2.5 PEC_{sw/sed} of GLOB1817H

The PEC_{sw} of the formulation GLOB1817H was also calculated. The calculator tool from the FOCUS SWASH model was used for this purpose. The density of the product is 1.0085 g/mL, so the application rate of the formulation is 3026 g/ha. These PEC_{sw} were calculated for the ditch, pond and stream scenarios. On top, to allow for the 20% spray drift contribution from the upstream catchment in the case of streams, the drift values of the calculator have been multiplied with a factor 1.2 for the stream scenario. The results of these calculations are provided below in the table below.

Table 8.9-29: Maximum PEC_{sw} for GLOB1817H

Scenario	FOCUS scenario	% drift	Max. PEC _{sw} (µg/L)
Winter cereals, 1 x 3 L/ha – 1 m	Ditch	1.9274	19.4410
	Pond	0.3282	0.9931
	Stream	1.9274	19.4410
		-	23.3292*
Winter cereals, 1 x 3 L/ha – 5 m	Ditch	0.5224	5.2696
	Pond	0.1896	0.5736
	Stream	0.5224	5.2696
		-	6.3235*
Winter cereals, 1 x 3 L/ha – 10 m	Ditch	0.2771	2.7948
	Pond	0.1363	0.4124
	Stream	0.2771	2.7948
		-	3.3538*

*taking into account the 20% contribution from the upstream catchment

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

Table 8.10-1 Summary of atmospheric degradation and behaviour - prosulfocarb

Compound	Prosulfocarb
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not required
Photochemical oxidative degradation in air	DT50 (h): 3.9 derived by the Atkinson model
Volatilisation	From plant surfaces: 46.7% had volatilised from leaf surfaces after 24 h From soil surfaces: 18% had volatilised after 24 h
Metabolites	No available data – no data requested

The vapour pressure at 20 °C of the active substance prosulfocarb is $> 10^{-4}$ Pa. Hence the active substance prosulfocarb is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance prosulfocarb due to volatilization with subsequent deposition should be considered. However, due to the short half-life of prosulfocarb (3.9 hours), its transport via air is expected to be low.

Table 8.10-2 Summary of atmospheric degradation and behaviour - diflufenican

Compound	Diflufenican
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	DT50 (d): 3.3 derived by the Atkinson model OH (12h) concentration assumed = $1.5 \times 10^6 \text{ cm}^{-3}$
Volatilisation	Vapour pressure (Pa): 4.25×10^{-6} Henry's Law Constant (Pa.m ³ /mol): $> 1.18 \times 10^{-2}$ Volatilisation from plant surfaces and soil was negligible (plants: 0.3% AR after 24 h, soil: 0.0-0.005% AR after 24 h)
Metabolites	Soil anaerobic metabolite 2,4-difluoroaniline was found to be very volatile and may need to be assessed for the air compartment and for transport through air when prolonged anaerobic conditions are expected to occur in soil.

The vapour pressure at 20 °C of the active substance diflufenican is $< 10^{-5}$ Pa. Hence the active substance diflufenican is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance diflufenican due to volatilization with subsequent deposition should not be considered.

Table 8.10-3 Summary of atmospheric degradation and behaviour – halauxifen-methyl

Compound	Halauxifen-methyl
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Active substance: 5.6
Photochemical oxidative degradation in air	DT50 (d): 2.2 derived by the Atkinson model OH (12h) concentration assumed = $1.5 \times 10^6 \text{ radicals/cm}^3$
Volatilisation	Vapour pressure (Pa): 5.9×10^{-9} Pa Henry's Law Constant (Pa.m ³ /mol): 1.11×10^{-6}
Metabolites	X11393729 (halauxifen) unlikely to be volatile

The vapour pressure at 20°C of the active substance halauxifen-methyl is $< 10^{-5}$ Pa. Hence the active substance halauxifen-methyl is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance halauxifen-methyl due to volatilization with subsequent deposition should not be considered.

Table 8.10-4 Summary of atmospheric degradation and behaviour – cloquintocet-mexyl

Compound	Cloquintocet-mexyl
Direct photolysis in air	Not studied – no data requested
Photochemical oxidative degradation in air	DT50 (d): 0.3-1.8 derived by the Atkinson model OH (12h) concentration assumed = $5 \times 10^5 \text{ radicals/cm}^3$
Volatilisation	Vapour pressure (Pa): 5.3×10^{-6} Pa

Cloquintocet-mexyl has a vapour pressure of $5.3 \cdot 10^{-6}$ Pa at 25°C, indicating that it has no potential for volatilisation according to FOCUS Air guidance criteria. This was confirmed by laboratory experiments where no significant volatilisation from plants and soil surfaces was observed within 24 hours.

~~DT₅₀ for photochemical oxidative degradation in air was estimated by the Atkinson model to be 0.3–1.8 day (assuming OH concentration of 5×10^5 radicals/cm³, day length not reported). Therefore long range transport is not of concern.~~

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and 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
KCP 9.2.4	XXXX, S	2021	Estimations of the PEC _{gw} of prosulfocarb, diflufenican, halauxifen-methyl, cloquintocet-mexyl and relevant metabolites GLOB1817HGW Globachem NV non GLP Unpublished	N	Globachem NV
KCP 9.2.5	XXXX, S	2021	Estimations of the PEC _{sw} of prosulfocarb, diflufenican, halauxifen-methyl, cloquintocet-mexyl and relevant metabolites GLOB1817HSW Globachem NV non GLP Unpublished	N	Globachem NV

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
None					

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

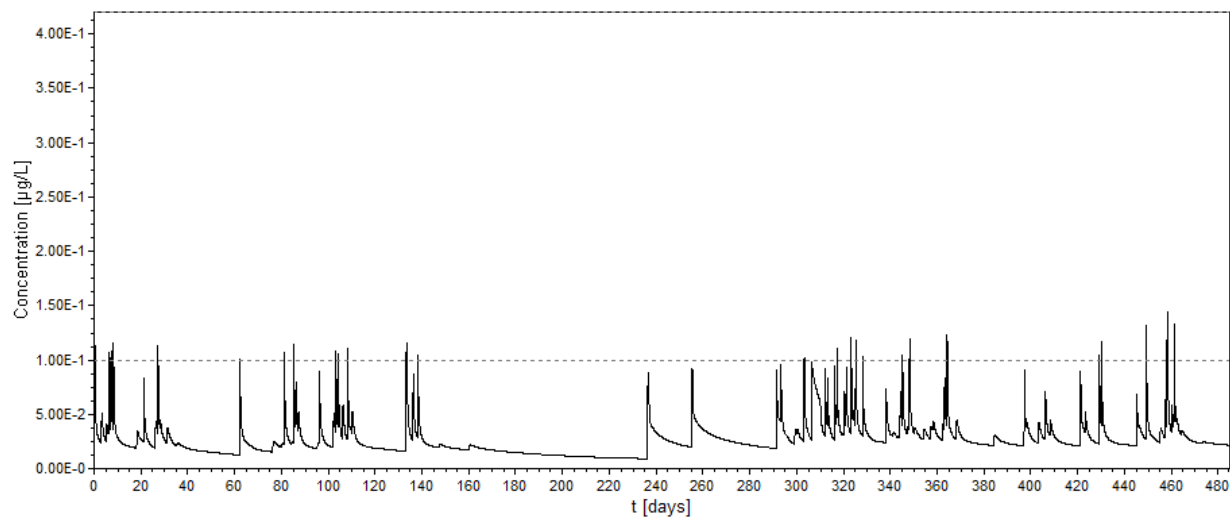
Appendix 2 Detailed evaluation of the new Annex II studies

No new studies were submitted.

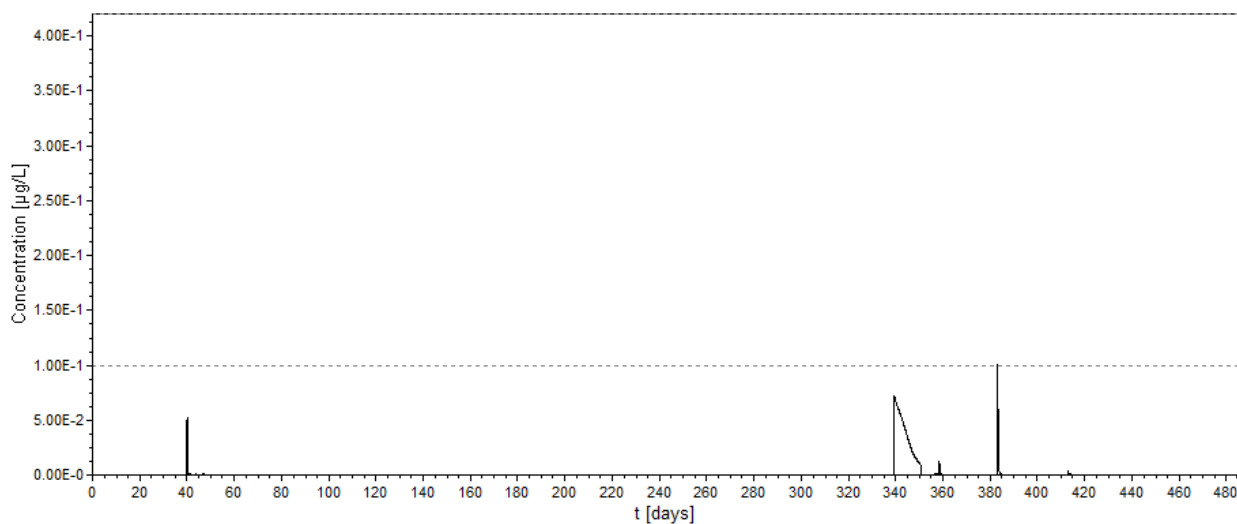
Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

FOCUS profiles - EPAT graphs

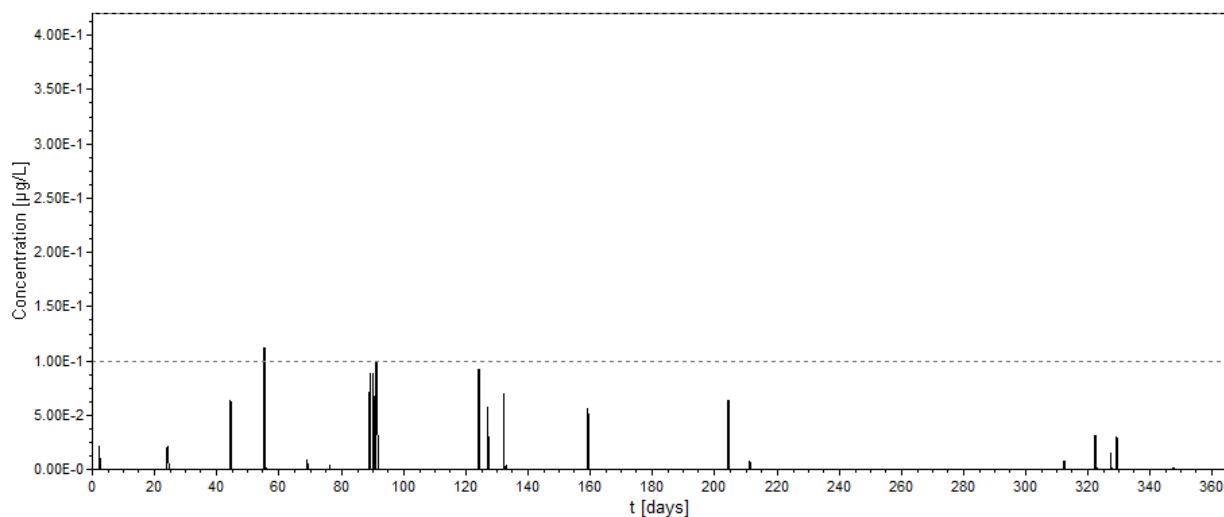
D2 ditch



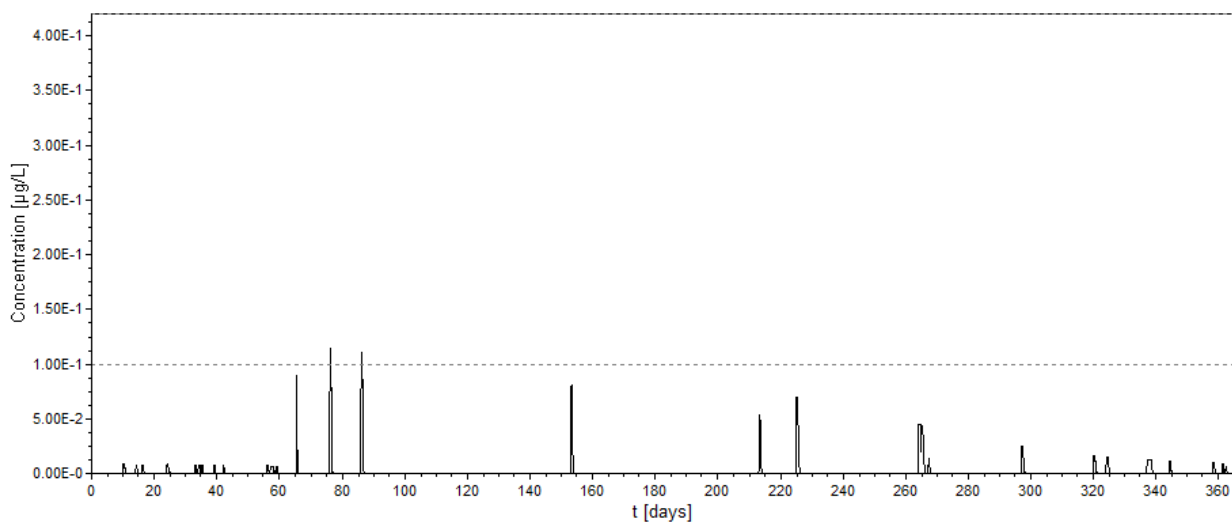
D6 ditch



R1 stream



R3 stream



R4 stream

