FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: CHR/H/CFF 250 EC

Product name(s): Hapi 250 EC/ Turango 250 EC

Chemical active substance(s):

Clopyralid, 120 g/L
Fluroxypyr-acid, 120 g/L (as fluroxypyr-meptyl, 172.9 g/L)
Florasulam, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: March 2023

MS Finalisation date: August 2024; November 2024

Version history

When	What
08.2024	Assessment by ZRMS
11.2024	The final Registration Report

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8 Fate and behaviour in the environment (KCP 9)

In the following document, data for active substances - Fluroxypyr - was described during its inclusion on Annex 1 process in respectively 2009. Were reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I.

Data matching studies for florasulam have been evaluated by Poland. As a result of the assessment all reports were accepted and considered as equivalent to protected studies. Therefore, to support the authorization of CHR/H/CFF 250 EC INNVIGO is allowed to refer to EU approved reports

Data matching studies for clopyralid have been evaluated by RMS - Finland. As a result of the assessment all re-ports were accepted and considered as equivalent to protected studies. Therefore, to support the renewal of authorization of CHR/H/CFF 250 EC INNVIGO is allowed to refer to EU approved reports

8.1 Critical GAP and overall conclusions

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

GAP rev. , date: 2021-01-13

PPP product name:		Formulation type:	EC (a, b)
product code:	CHR/H/CFF		
Active substance 1:	clopyralid	Conc. of as 1:	120 g/l (c)
Active substance 2:	fluroxypyr	Conc. of as 2:	120 g/l (c)
Active substance 3:	florasulam	Conc. of as 3:	10 g/l (c)
Safener:	-	Conc. of safener:	- (c)
Synergist:	-	Conc. of synergist:	- (c)
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central (d)	Non professional use:	☐
Verified by MS:	no		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use-No. (e)	**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 (f)	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or 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	Winter wheat (TRZAW), Winter triticale (TTLWI)	F	dicotyle-donous weeds	Spray, medium sprayer	spring BBCH 21-33	a)1 b)1	n/a	a) 0.4 - 0.5 l/ha b) 0.4 - 0.5 l/ha	a) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO) b) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO)	200-400	n/a		A
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
2														
3														
Minor uses according to Article 51 (zonal uses)														
4	PL	Spelt *Triticum spelta* (3SPWC) Emmer wheat *Triticum dicoccum* (TRZDI) Einkorn wheat *Triticum monococcum (TRZMO)* Durum wheat *Triticum durum* (TRZDW) Spring Rye *Secale cereale* (SECCS)	F	Monaocots and dicots weeds	Spray, medium sprayer	BBCH 21-33	a)1 b)1	n/a	a) 0.4 - 0.5 l/ha b) 0.4 - 0.5 l/ha	a) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO) b) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO)	200-400		.	A
5														

Minor uses according to Article 51 (interzonal uses)														
6														
7														

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 Florasulam concerning the Section Environmental Fate (EFSA Journal 2015; 13(1):3984)

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	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Winter cereals (wheat, barley, rye, triticale, oats, spelt)	F	Broad leaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 00-29 (1st September to end of December)	1	N/A	0.075	3.75	70- 400	N/A	
2	EU	Winter cereals (wheat, barley, rye, triticale, oats, spelt)	F	Broad leaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 13-45 (1st January to early July)	1	N/A	0.125	6.25	70- 400	N/A	
3	EU	Spring cereals	F	Broad leaved weeds	Tractor mount-	BBCH 12-45		N/A	0.125	6.25	70- 400	N/A	

		(wheat, barley, rye, triticale, oats, spelt)			ed or self-propelled hydraulic sprayer giving overall application.	(1st February to 15th July)	1						
4	EU	Maize	F	Broad leaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 11-20 (1st April to 30th June)	1	N/A	0.1	5	70- 400	N/A	

(a) For crops, the EU and Codex classifications (both) should be used; where

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench N/A: Not applicable – PHI determined by the stage of application

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of relevant, the use situation should be described (e.g. fumigation of a structure) equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell,
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Table 8.1-3: Assessed (critical) uses during approval of Clopyralid concerning the Section Environmental Fate (EFSA Journal 2018;16(7):5389)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Winter cereal (wheat, barley oat, rye, triticale, spelt)	CEU/SEU	GF-1374	F	Broad-leaf weeds	EC	80 g/L Clopyralid + 2.5 g/L florasulam + 144.1 g/L fluroxypyr meptyl (equivalent to 100 g/L fluroxypyr)	Over all broadcast foliar spray	BBCH 13-39 (1st Feb to 30th of June)	1	n/a	Clopyralid: 0.02 to 0.1 kg as/hL + Florasulam 0.0000625 to 0.0003125 kg as/hL + Fluroxypyr meptyl: 0.036 to 0.18 kg as/hL (0.025 to 0.125 kg ae/hL)	80-400	Clopyralid 0.08 kg as/ha + Florasulam 0.0025 kg as/ha + Fluroxypyr-meptyl 0.144 kg as/ha (0.100 kg ae/ha)	n/a	Dose: 1L GF-1374/ha Due to clopyralid content, straw treated with GF-1374 must not be used for compost production (for cultivating susceptible vegetables).
Established permanent pasture	CEU/SEU	GF-1374	F	Broadleaf weeds	EC	80 g/L Clopyralid + 2.5 g/L florasulam + 144.1 g/L fluroxypyr meptyl (equivalent to 100 g/L	Over all broadcast foliar spray	1st Feb to 30th September	1	n/a	Clopyralid: 0.03 to 0.15 kg as/hL + Florasulam 0.00009375 to 0.00046875 kg as/hL + Fluroxypyr	100-400	Clopyralid 0.12 kg as/ha + Florasulam 0.00375 kg as/ha + Fluroxypyr-meptyl 0.216	7 to 14 days (see note 1)	Dose: 1.5L GF-1374/ha. Note 1: PHI: 7 days for CEU and 14 days for SEU is the interval before any crop cutting or grazing. Fluroxypyr is the limiting factor.

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

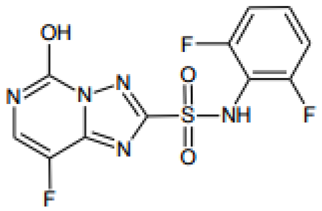
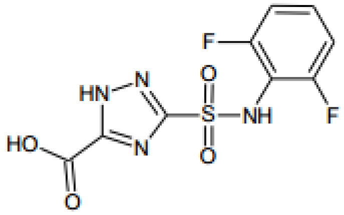
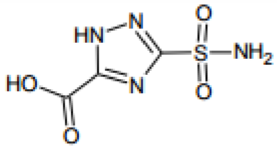
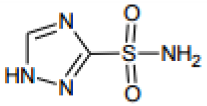
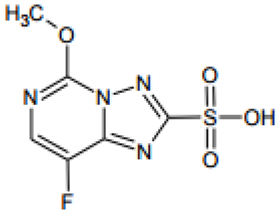
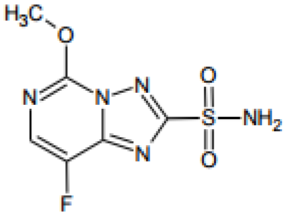
Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests Controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	kg as/hl min-max	Water L/ha min-max	kg as/ha min-max		
Cereals (winter and spring)	North Europe	Starane 200 EC	F	Broadleaved weeds	EC	200	Volume spraying	GS12-39	1	n.a.	0.05 – 0.1	200 – 400	0.200	n.a.	All concentrations in formulations and application details are reported as acid equivalents. n.a. = not applicable. [1] [2] [3]
	South Europe	Starane 200 EC	F	Broadleaved weeds	EC	200	Volume spraying	GS12-39	1	n.a.	0.05 – 0.1	200 – 400	0.200	n.a.	
	Germany	Starane 180 EC	F	Broadleaved weeds	EC	180	Volume spraying	Winter cereals: GS13–39 Spring Cereals: GS13-29	1	n.a.	0.045 – 0.09	200 – 400	0.180	n.a.	
Pasture /Amenity	North Europe	Starane 200 EC	F	Broadleaved weeds	EC	200	Medium volume	GS20-25	1	n.a.	0.1	200 – 400	0.200	7	
	South Europe	Starane 200 EC	F	Broadleaved weeds	EC	200	Medium volume	GS20-25	1	n.a.	0.1	200 – 400	0.200	14	
Maize	North Europe	Starane 200 EC	F	Broadleaved weeds	EC	200	Medium volume	GS12-16	1	n.a.	0.05 – 0.1	200 – 400	0.200	n.a.	
	South Europe	Starane 200 EC	F	Broadleaved weeds	EC	200	Medium volume	GS12-16	1	n.a.	0.05 – 0.1	200 – 400	0.200	n.a.	[1] [2] [3]

* 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

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
5-OH Florasulam	345.26		Soil/Water/Sediment: 71.6% / 99%	PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
DFP-ASTCA	304.20		Soil/Water/Sediment: 17.8% / 8.9%	PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
ASTCA	192.13		Soil/Water/Sediment: 40% / 53.8%	PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
TSA	148.14		Soil/Water/Sediment: 15.9% / 0.0001% (default value)	PEC_{gw} $PEC_{sw/sed}$
TPSA	248.17		Soil/Water/Sediment: 0.0001% (default value) / 58.0%	$PEC_{sw/sed}$
ASTP	247.20		Soil/Water/Sediment: 0.0001% (default) / 21.0%	$PEC_{sw/sed}$

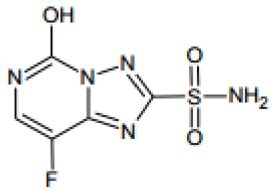
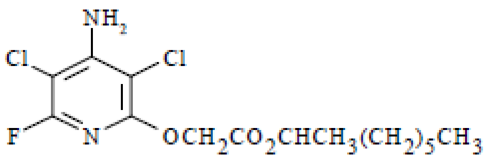
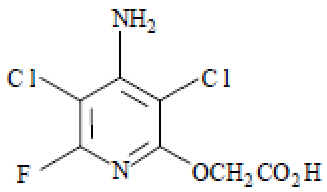
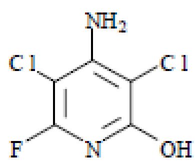
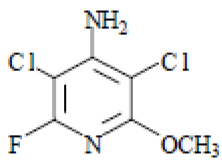
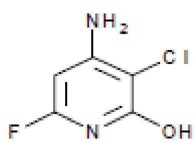
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
5-OH ASTP	233.18		Soil/Water/Sediment: 0.0001% (default) / 29.0%	$PEC_{sw/sed}$

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
Fluroxypyr-MHE	367.3 g/mol		100%	PEC soil, , PEC sw
Fluroxypyr acid	255 g/mol		Maximum occurrence observed: 100% in aquatic system (calculations performed as for parent)	PEC soil, PEC gw, PEC sw
Pyridinol	197 g/mol		Maximum occurrence observed (% molar basis with respect to the parent) Soil: 23.9 % Water: 44 Sediment: 11.5	PEC soil, PEC gw, PEC sw
Methoxypyridine	211 g/mol		Maximum occurrence observed (% molar basis with respect to the parent) Soil: 38.2 Water: not water/sediment metabolite Sediment: not water/sediment metabolite	PEC soil, PEC gw, PEC sw
3-CP	162 g/mol		Maximum occurrence observed (% molar basis with respect to the parent) Water: 17.9 Sediment: 6.5	PEC sw

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)

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion for actives substances. All relevant data are presented in:

- **Florasulam - EFSA Journal 2015; 13(1):3984**
- **Clopyralid - EFSA Journal 2018;16(7):5389**,
- **Fluroxypyr** – EFSA Journal 2011;9(3):2091

8.3.1.1 Florasulam and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for Florasulam- laboratory studies (EFSA Journal 2015; 13(1):3984)

Soil		**Soil properties**		**Incubation conditions**	**Kinetic model**	**Evaluation of the fit**		**Kinetic parameters**		**Normalised kinetic endpoints[3)]**	
Soil name	***Soil type (USDA)***	***OC***	***pH***			***χ^2 error***	***Visual fit[1)]/R^2***	***Param.***	***Value***	***DT_{50} [days]***	***DT_{90} [days]***
Andover; TP-labelling	Silt loam	3.1	7.6	20°C; 40% MWHC	SFO)	4.34	V. G./ 0.999	*k*	0.7617	0.91	3.05
Kenslow; TP-labelling	Silt loam	6.8	5.6	20°C; 40% MWHC	SFO	4.14	V. G./ 0.999	*k*	1.2006	0.58	1.92
Marcham; TP-labelling	Sandy clay loam	2.0	7.7	20°C; 40% MWHC	SFO	13.44	V.G./ 0.985	*k*	0.3290	2.14	7.10
Speyer 2.2; XDE-570, both labels	Sandy loam	3.9	7.3	20°C; 40% MWHC	Pseudo-SFO (back-calculated from FOMC)	7.48	V.G./ 0.996	*k*	0.4279	1.62	5.38
Cuckney; TP-labelling	Sandy loam	1.4	6.9	25°C; 40% MWHC	SFO	3.81	V. G./ 0.999	*k*	0.6245	1.11	3.63
Cuckney; TP-labelling	Sandy loam	1.4	6.9	20°C; Field Capacity	SFO	15.28	G./0.98 2	*k*	0.2427	2.86	9.49
Cuckney; TP-labelling; averaged - geomean	Sandy loam	1.4	6.9	----	SFO	----	----	*k*	----	**1.78**	**5.87**
Marcham; TP-labelling	Sandy clay loam	1.4	7.6	20°C; Field Capacity	SFO	12.78	G./ 0.984	*k*	0.1617	4.29	14.24
									Geometric mean:[2)]	**1.55**	**5.15**

1) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.
2) The values calculated using the geomean value determined for the experimemts in Cuckney soil (individual results for this soil were not considered in calculating geomean, following the recommendation given by PRAS 117 Expert's Meeting);
3) Normalised, where necessary, using a Q10 of 2.58 and/or Walker equation coefficient of 0.7.

Table 8.3-2: Summary of aerobic degradation rates for 5-OH Florasulam - laboratory studies (EFSA Journal 2015; 13(1):3984)

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Normalised kinetic endpoints[4)]		
Soil name	***Soil type (USDA)***	***OC***	***pH***			***χ^2 error***	***Visual fit[1)]/R^2***	***Param.***	***Value***	***DT_{50} [days]***	***DT_{90} [days]***	***Kinetic formation fraction ff***
Andover; TP-labelled XDE-570	Silt loam	3.1	7.6	20⁰C; 40% MWHC	SFO	5.14	V. G./ 0.998	*k*	0.1100	6.30	20.92	0.747
Kenslow; TP-labelled XDE-570	Silt loam	6.8	5.6	20⁰C; 40% MWHC	SFO	8.15	G./ 0.984	*k*	0.0392	17.69	58.76	0.828
Marcham ; TP-labelled XDE-570	Sandy clay loam	2.0	7.7	20⁰C; 40% MWHC	SFO	15.52	G./ 0.939	*k*	0.0567	12.22	40.57	0.717
Speyer 2.2; XDE-570, both labels	Sandy loam	3.9	7.3	20⁰C; 40% MWHC	SFO	7.70	G./ 0.982	*k*	0.0480	14.44	47.97	0.863
Cuckney; TP-labelled XDE-570	Sandy loam	1.4	6.9	25⁰C; 40% MWHC	SFO	16.52	G./ 0.951	*k*	0.0461	*15.02*	*50.02*	*0.933*
Cuckney; TP-labelled XDE-570	Sandy loam	1.4	6.9	20⁰C; Field Capacity	SFO	21.07	G./ 0.903	*k*	0.0280	*24.77*	*82.30*	*1.000*
Cuckney; TP-labelled XDE-570; averaged - geomean	Sandy loam	1.4	6.9	----	SFO	----	----	*k*	----	**19.29**	**64.16**	**0.967**
Marcham TP-labelled XDE-570	Sandy clay loam	1.4	7.6	20⁰C; Field Capacity	SFO	14.62	G./ 0.961	*k*	0.0487	14.24[#]	98.63	1.000
Geometric mean[2)]:										**14.98**	**49.74**	**----**
Arithmetic mean (for *ff* only)[3)]:										**----**	**----**	**0.854**

1) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.
2) The values calculated using the geomean value determined for the experimemts in Cuckney soil (individual results for this soil were not considered in calculating geomean, following the recommendation given by PRAS 117 Expert's Meeting);
3) The values calculated using the arithmetic mean value determined for the experimemts in Cuckney soil (individual results for this soil were not considered in calculating the mean, following the recommendation given by PRAS 117 Expert's Meeting);
4) Normalised, where necessary, using a Q10 of 2.58 and/or Walker equation coefficient of 0.7.
#) The DT50 = 14.24 was incorrectly transferred in tables B.8.1.2.1-84, -88, -89, -90, -91, -137 and -138 in the Addendum 2 (final) provided by the RMS (Poland, 2014). The correct DT50 value for metabolite 5-OH florasulam derived from the Marcham soil incubated at 20⁰C and Field Capacity is 29.75 days, because that is what results from the k = 0.0233 (the DT90 value and the final geometric mean of 14.98 are correct). The value of 29.75 days was properly reported in tables B.8.1.2.1-145 and B.8.3-1 of the same Addendum 2 (final) (Poland, 2014).

Table 8.3-3: Summary of aerobic degradation rates for DFP-ASTCA- laboratory studies (EFSA Journal 2015; 13(1):3984)

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Normalised kinetic endpoints		
Soil name	*Soil type (USDA)*	*OC*	*pH*			χ^2 *error*	*Visual fit*[1]*/R*^{2}	*Param.*	*Value*	DT_{50} *[days]*	DT_{90} *[days]*	*Kinetic formation fraction ff*[2]
Andover; TP-labelled XDE-570	Silt loam	3.1	7.6	20^{0}C; 40% MWHC	SFO, top-down	9.88	G./ 0.979	*k*	0.0356	19.45	64.60	1.000 (default)
Kenslow; TP-labelled XDE-570	Silt loam	6.8	5.6	20^{0}C; 40% MWHC	SFO, top-down	6.47	V. G./ 0.989	*k*	0.0317	21.87	72.65	1.000 (default)
Marcham ; TP-labelled XDE-570	Sandy clay loam	2.0	7.7	20^{0}C; 40% MWHC	SFO, top-down	6.47	G./	*k*	0.0150	46.16	153.33	1.000 (default)
Cuckney; TP-labelled DFP-ASTCA	Loamy sand	1.5	7.2	20^{0}C; 40% MWHC	SFO	9.95	G./ 0.985	*k*	0.0454	15.27	50.71	1.000 (default)
Marcham TP-labelled DFP-ASTCA	Sandy clay loam	3.4	7.9	20^{0}C; 40% MWHC	SFO	7.51	V. G./ 0.991	*k*	0.1637	4.23	14.06	1.000 (default)
Geometric mean:										**16.62**	**55.21**	**----**
Arithmetic mean (for *ff* only):										**----**	**----**	**1.000 (default)**

1) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.
2) Because the fitting was performed using either the top-down approach or for DFP-ASTCA applies as a parent compound, the *ff* values could not be determined experimentally; instead the default value of 1 was proposed.

Table 8.3-4: Summary of aerobic degradation rates for ASTCA - laboratory studies (EFSA Journal 2015; 13(1):3984)

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Normalised kinetic endpoints		
Soil name	*Soil type (USDA)*	*OC*	*pH*			χ^2 *error*	*Visual fit*[1]*/R*^{2}	*Param.*	*Value*	DT_{50} *[days]*	DT_{90} *[days]*	*Kinetic formation fraction ff*
Cuckney; TP-labelled DFP-ASTCA	Loamy sand	1.5	7.2	20^{0}C; 40% MWHC	SFO	n. d.[2]	n. d.[2]	*k*	n. d[2].	1000[3]	>1000[3]	Not determi-ned
Marcham TP-labelled DFP-ASTCA	Sandy clay loam	3.4	7.9	20^{0}C; 40% MWHC	SFO	4.40	V. G./ 0.992	*k*	0.0032	214.11	711.24	0.781
Cuckney; TP-labelled ASTCA	Loamy sand	1.5	7.2	20^{0}C; 40% MWHC	SFO	4.52	I./ 0.718	*k*	0.0027	259.05	860.55	Not determi-ned
Marcham TP-labelled ASTCA	Sandy clay loam	3.4	7.9	20^{0}C; 40% MWHC	SFO	7.12	G./ 0.809	*k*	0.0049	141.18	469.00	Not determi-ned
Geometric mean:										**297.47**	**659.66**[4]	**----**
Arithmetic mean (for *ff* only):										**----**	**----**	**0.781**

1) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.
2) n. d. – not determined;
3) A default value, DT50 not to be used in soil exposure assessment;
4) Calculated excluding the default values.

Table 8.3-5: Summary of aerobic degradation rates for TSA - laboratory studies (EFSA Journal 2015; 13(1):3984

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Normalised kinetic endpoints		
Soil name	*Soil type (USDA)*	*OC*	*pH*			χ^2 *error*	*Visual fit*[1]	*Param.*	*Value*	DT_{50} *[days]*	DT_{90} *[days]*	*Kinetic formation fraction ff*[2]
Calke	Sandy loam	3.54	5.4	20⁰C, 20% v/v	SFO (slow phase DFOP)	2.23	V. G.	k_2	0.0097	71.44	237.33	1.000 from ASTCA 0.219 from DFP-ASTCA
South Witham	Clay loam	3.83	7.1	20⁰C, 25.7% v/v	SFO (slow phase DFOP)	2.11	V. G.	k_2	0.0073	94.39	313.56	1.000 from ASTCA 0.219 from DFP-ASTCA
Lufa 5M	Sandy loam	0.93	7.3	20⁰C, 14% v/v	SFO	4.44	G.	*k*	0.0040	171.68	570.33	1.000 from ASTCA 0.219 from DFP-ASTCA
RefeSol 06-A	Clay loam	1.97	6.7	20⁰C, 29% v/v	SFO	12.87	G.	*k*	0.0163	42.47	141.07	1.000 from ASTCA 0.219 from DFP-ASTCA
Geometric mean:										**83.74**	**278.17**	----
Arithmetic mean (for *ff* only):										----	----	**1.000 from ASTCA** **0.219 from DFP-ASTCA**

1) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.
2) The reported *ff* values are the default values derived from the analysis of the postulated transformation scheme and the appropriate experimentally-derived *ff* values

8.3.1.2 Clopyralid and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for Clopyralid - laboratory studies (EFSA Journal 2018;16(7):5389)

Parent	**Dark aerobic conditions**						
Soil type	Biomass mgC/100 g	pH[a)]	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Parabraunerde (silt loam)	47	7.7	20 / 18.63 [c]	44.4 / 147.3	34.2	6.796	SFO
Marcham (sandy clay loam)	170	8.3	20 / 20.19 [c]	34.5 / 114.7	32.4	5.478	SFO
Castle Rising (sandy loam)	313	8	20 / 65.13 [c]	26.3 / 87.3	26.3	8.284	SFO
Speyer 2.1 (sand)	NA	6.5	20 / 12.58 [c]	64.6 / 214.6	64.6	5.466	SFO
Speyer 2.2 (sand)	110	6.3	20 / 18.56 [c]	16.2 / 53.8	16.2	7.78	SFO
Marshall county (silt loam)	11.92	6	25 / 23.42 [d]	8.6 / 28.5	11.6	6.49	SFO
A (sandy loam)	33.2	6.2	20 / 24.28 [e]	16.5 / 54.8	16.5	4.856	SFO
B (clay loam)	78.2	7.6	20 / 28.05 [e]	23 / 76.4	23.0	6.767	SFO
C (clay loam)	48.5	5.6	20 / 48.17 [e]	4.9 / 16.2	4.9	12.73	SFO
D (loam)	70.9	7.5	20 / 35.30 [e]	9.8 / 32.4	9.8	10.17	SFO
Geometric mean (if not pH dependent)					19.1		
pH dependence					No		

[a)] Measured in water
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] Reported soil moisture: 40% of maximum WHC
[d)] Reported soil moisture: 75% of 1/3 bar WHC
[e)] Reported soil moisture: 45% WHC

8.3.1.3 Fluroxypyr and its metabolites

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

Fluroxypyr-MHE	Aerobic conditions						
Soil type	X	pH	t. °C / actual soil moisture %	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa*)	χ^2	Method of calculation
Sandy loam	----	7.7	20/33.4	1.8/6.0	1.8	23.6	SFO
Clay loam	----	7.7	20/23.8	0.8/2.7	0.8	18.5	SFO
Silty clay loam	----	8.1	20/19.2	1.5/5.0	1.5	36.6	SFO
Loamy sand	----	6.7	20/23.4	1.3/4.3	1.3	24.7	SFO
Silty clay loam	----	5.9	26/20.0	0.3/1.0	0.5	7.4	SFO
Sandy loam	----	7.5	26/6.4	0.3/1.0	0.5	3.1	SFO
Clay loam	----	6.8	26/21.0	0.4/1.3	0.7	8.4	SFO
Clay	----	7.0	26/19.1	0.5/1.7	0.9	16.6	SFO
Clay loam	----	6.1	25/15.8	0.7/2.3	1.1	10.3	SFO
Clay loam	----	7.7	25/12.8	0.9/3.0	1.4	10.9	SFO
Silty clay loam	----	7.9	25/13.6	0.7/2.3	1.1	0.9	SFO
Loamy sand	----	5.7	25/9.6	0.9/3.0	1.4	2.6	SFO
Geometric mean/median				0.7/2.8**)	1.0	13.6**)	---

*) values normalised only for the temperature using Q_{10} = 2.58;

**) an arithmetic mean value;

Table 8.3-7: Summary of aerobic degradation rates for Fluroxypyr-MH+Fluroxypyr- laboratory studies

Fluroxypyr-MHE + Fluroxypyr (acid)	Aerobic conditions						
Soil type	X	pH	t. °C / actual soil moisture %	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C (Q_{10} = 2.58) pF2/10kPa	χ^2	Method of calculation
Sandy loam	----	7.7	20/33.4	10.8/35.9	10.8	10.7	SFO
Clay loam	----	7.7	20/23.8	7.2/23.9	6.4	7.7	SFO
Silty clay loam	----	8.1	20/19.2	12.7/41.2	9.3	15.8	SFO
Loamy sand	----	6.7	20/23.4	7.8/25.9	7.8	8.5	SFO
Silty clay loam	----	5.9	26/20.0	12.8/42.5	17.0	2.5	SFO
Sandy loam	----	7.5	26/6.4	30.2/100.3	25.1	4.1	SFO
Clay loam	----	6.8	26/21.0	14.4/47.8	20.9	9.5	SFO
Clay	----	7.0	26/19.1	8.8/29.2	8.1	5.8	SFO
Clay loam	----	6.1	25/15.8	20.3/67.4	21.8	8.0	SFO
Clay loam	----	7.7	25/12.8	2.9/9.6	2.7	10.2	SFO
Silty clay loam	----	7.9	25/13.6	6.90/22.91	6.3	6.52	SFO
Loamy sand	----	5.7	25/9.6	17.1/56.8	21.1	13.1	SFO
Loamy sand		n. d.[1)]	25/9.6	41.8/138.8[2)]	38.4[2)]	6.80	SFO
Sandy loam		n. d.[1)]	25/10.8	49.4/163.2[2)]	39.6[2)]	6.38	SFO
Geometric mean/median				13.3/44.0 (geomean)	13.1 (geomean)/ 13.9 (median)	8.26	

1) not determined, only the range of pH – 5.5-7.5, given in the study report
2) the kinetic endpoint for Fluroxypyr (acid) only

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

Pyridinol	Aerobic conditions							
Soil type	X	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C (Q_{10} = 2.58) pF2/10kPa	χ^2	Method of calculation
Sandy loam	----	7.7	20/33.4	16.3/54.2	0.184	16.3	28.9	SFO
Clay loam	----	7.7	20/23.8	15.7/52.1	0.089	14.0	26.6	SFO
Silty clay loam	----	8.1	20/19.2	17.2/57.1	0.152	12.6	22.7	SFO
Loamy sand	----	6.7	20/23.4	4.1/13.6	0.427	4.1	10.1	SFO
Silty clay loam	----	5.9	26/20.0	43.8/145.5	0.358	58.0	17.1	SFO
Sandy loam	----	7.5	26/6.4	13.8/45.8	0.250	11.5	20.6	SFO
Clay loam	----	6.8	26/21.0	17/56.5	0.299	24.6	18.7	SFO
Clay	----	7.0	26/19.1	9.2/30.6	0.360	8.4	13.6	SFO
Clay loam	----	6.1	25/15.8	54.5/181.0	0.666	58.7	7.1	SFO
Clay loam	----	7.7	25/12.8	12/39.8	0.280	11.2	18.4	SFO
Silty clay loam	----	7.9	25/13.6	14.7/48.8	0.117	13.5	11.2	SFO
Loamy sand	----	5.7	25/9.6	85.2/283.0	0.254	105.4	26.8	SFO
Geometric mean/median				18.3/60.7 (geomean)	0.286[1)]	18.4 (geomean) 13.8 (median)	18.5[1)]	

1) an arithmetic mean value;

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

Methoxypyridine	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C (Q_{10} = 2.58) pF2/10kPa	χ^2	Method of calculation
Sandy loam	----	7.7	20/33.4	64.5/214.2	0.183	65.4	57.0	SFO
Clay loam	----	7.7	20/23.8	208.9/692.3	0.160	185.5	27.0	SFO
Silty clay loam	----	8.1	20/19.2	743.1/ 2468.5	0.119	542.5	30.3	SFO
Loamy sand	----	6.7	20/23.4	16.7/55.5	0.118	16.7	16.2	SFO
Silty clay loam	----	5.9	26/20.0	110.5/367.1	0.149	146.4	10.5	SFO
Sandy loam	----	7.5	26/6.4	142.2/472.4	0.115	118.0	11.9	SFO
Clay loam	----	6.8	26/21.0	801.7/ 2663.2	0.420	1160.9	12.8	SFO
Clay	----	7.0	26/19.1	295.9/983.0	0.286	271.7	17.5	SFO
Clay loam	----	6.1	25/15.8	>1000/ >3322[1)]	0.221	1000[2)]	Not given	SFO
Clay loam	----	7.7	25/12.8	47.8/158.8	0.317	44.5	9.7	SFO
Silty clay loam	----	7.9	25/13.6	101.0/335.5	0.201	92.7	14.9	SFO
Loamy sand	----	5.7	25/9.6	196.7/653.4	0.126	243.3	6.4	SFO
Geometric mean/median				144.9/481.3 (geomean)	0.201[3)]	170.4 (geomean) 165.0 (median)	19.5[3)]	

1) values excluded from calculating the mean values;
2) FOCUS default value;
3) an arithmetic mean

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on anaerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Florasulam - EFSA Journal 2015; 13(1):3984**
- **Clopyralid - EFSA Journal 2018;16(7):5389**,
- **Fluroxypyr** – EFSA Journal 2011;9(3):2091

8.3.2.1 Florasulam and its metabolites

Table 8.3-10: Summary of anaerobic degradation rates for Florasulam - laboratory studies (EFSA Journal 2015; 13(1):3984

Soil		Soil properties		Incubation conditions	Selected best-fit model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints	
Soil name	*Soil type (USDA)*	*OC*	*pH*			*χ^2 error*	*Visual fit*)/R^2*	*Param.*	*Value*	*DT_{50} [days]*	*DT_{90} [days]*
Speyer 2.2; TP-labelling	Sandy loam	3.9	7.3	20°C; soil:water ratio 1:2	SFO	8.66	G./ 0.986	*k*	0.0375	18.49	61.43
Speyer 2.2; phenyl-labelling	Sandy loam	3.9	7.3	20°C; soil:water ratio 1:2	SFO	9.86	G./ 0.980	*k*	0.0376	18.46	61.31
Averaged values:									**0.03755**	**18.47**	**61.37**

*) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.

Table 8.3-11: Summary of anaerobic degradation rates for 5-OH Florasulam- laboratory studies (EFSA Journal 2015; 13(1):3984

Soil		Soil properties		Incubation conditions	Selected best-fit model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints	
Soil name	*Soil type (USDA)*	*OC*	*pH*			*χ^2 error*	*Visual fit*)/R^2*	*Param.*	*Value*	*DT_{50} [days]*	*DT_{90} [days]*
Speyer 2.2; TP-labelling	Sandy loam	3.9	7.3	20°C; soil:water ratio 1:2	SFO	7.75	G./ 0.984	*k*	5.0 E-4	1386.29	4605.17
Speyer 2.2; phenyl-labelling	Sandy loam	3.9	7.3	20°C; soil:water ratio 1:2	SFO	11.18	G./ 0.966	*k*	6.4 E-4	1083.04	3597.79
Averaged values:									**5.7 E-4**	**1234.67**	**4101.48**

*) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.

8.3.2.2 Clopyralid and its metabolites

Table 8.3-2: Summary of anaerobic degradation rates for Clopyralid - laboratory studies (EFSA Journal 2018;16(7):5389)

Parent	**Dark anaerobic conditions**						
Soil type	Biomass mgC/100 g	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Sandy loam	8.9	7.4	20 / flooded	>1 year	> 1year	n/a	First-order
Geometric mean (if not pH dependent)							

[a)] Measured in 0.01M CaCl2
[b)] Normalised using a Q10 of 2.58

8.3.2.3 Fluroxypyr and its metabolites

Anaerobic degradation ‡	
Mineralization after 100 days	<0.1 % after 365 d, at T = 25^{0}C, [^{14}C-2,6 pyridine ring]-label (n= 3); Sterile conditions: 0.3 % after 102 d at T = 25^0 C, [^{14}C-2,6 pyridine ring]-label (n= 1)
Non-extractable residues after 100 days	up to 33.5 % after *56* d, 66-85% after 356 days, at T = 25^{0}C, [^{14}C-2,6 pyridine ring]-label, (n= 3)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	The same as in case of aerobic route of degradation in soil: Pyridinol - up to 14% after 8 weeks (n= 3) Methoxypyridine – 8.0-8.4 % at 4-8 week (up to 9% after 32 weeks in one soil) (n= 3) [^{14}C-2,6 pyridine ring]-label
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	for fluroxypyr-MHE DT_{50} = 153 days; Soil photolysis is not a significant route of degradation

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)

Studies on field degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Florasulam - EFSA Journal 2015; 13(1):3984**
- **Clopyralid - EFSA Journal 2018;16(7):5389**,
- **Fluroxypyr** – EFSA Journal 2011;9(3):2091

8.4.1.1 Florasulam and its metabolites

Field dissipation of 5-OH florasulam was examined in six field trials – four in Northern Europe (Germany, UK- two trials, and North France) and two in Southern Europe (south France and Greece), in which florasulam was applied as parent compound. The results were kinetically re-examined following FOCUS Kinetics (2006), but are not reported due to the low reliability of the fitting. (EFSA Journal 2015; 13(1):3984)

8.4.1.2 Clopyralid and its metabolites

Table 8.3-3: Summary of soil dissipation for Clopyralid - field studies (EFSA Journal 2018;16(7):5389)

Parent								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm [b)]	Method of calculation
Loamy sand (bare)	Bargstedt, Germany	4.3	0-100	21	69.6	23.9	13	SFO
Loam (bare)	Wilson, UK	6.2	0-100	16.7	55.6	22.6	13.5	SFO
Silty clay loam (bare)	Sermaises, France	7	0-100	16.3	54	19.3	7.5	SFO
Silty clay loam (bare)	Ansonville, France	8.2	0-20	0.16	12.1	5.36	2.07	DFOP / SFO Norm
Clay loam (bare)	Mainbervilliers, France	7.1	0-20	6.04	28.3	7.22	2.7	DFOP / SFO Norm
Silty clay loam (bare)	Oederquart, Germany	7.5	0-20	16.2	53.9	12	5.69	SFO
Sandy clay loam (bare)	Middlefart, Denmark	7.5	0-20	23.7	78.7	13.1	8.46	SFO
Clay loam (bare)	Canals, Spain	8.0	0-100	13.7	45.5	19.2	12.3	SFO
Silty clay loam (bare)	B. Württemberg, Germany	7.4[c]	0-100	10.2	33.9	7.94	9.34	SFO
Silt loam (bare)	B. d'Islemade, France	7.3[c]	0-100	9.11	30.3	17.6	7.41	SFO
Geometric mean (if not pH dependent)							7.05	
pH dependence			No					

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
c) 0-30 cm

8.4.1.3 Fluroxypyr and its metabolites

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

Fluroxypyr-MHE	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Canada: bare soil, silty clay loam (3 locations), sandy clay loam (1 location); UK: bare soil, sandy loam, clay loam, organic soil	Canada – 4 locations/ UK – 3 locations	---	Can.: 6.2 – 7.8; UK: 6.9 – 7.6	Can: 0 – 100 cm.; UK: 0 – 25 cm	<3	n. c.**)	----*)	n. c.**)	----*)
Geometric mean/median					----	----		----	

*) value not given;
**) not calculated;

Table 8.4-2: Summary of aerobic degradation rates for Fluroxypyr acid- field studies

Fluroxypyr (acid)	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Canada: bare soil, silty clay loam (3 locations), sandy clay loam (1 location); UK: bare soil, sandy loam, clay loam, organic soil	Canada – 4 locations/ UK – 3 locations	---	Can.: 6.2 – 7.8; UK: 6.9 – 7.6	Can: 0 – 100 cm.; UK: 0 – 25 cm	34-68	n. c.**)	----*)	n. c.**)	----*)
Geometric mean/median					----	----		----	

*) value not given;
**) not calculated;

Table 8.4-3: Summary of aerobic degradation rates for Fluroxypyr-MHE + Fluroxypyr acid - field studies

Fluroxypyr-MHE + Fluroxypyr (acid)	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Canada: bare soil, silty clay loam (3 locations), sandy clay loam (1 location); UK: bare soil, sandy loam, clay loam, organic soil	Canada – 4 locations/ UK – 3 locations	---	Can.: 6.2 – 7.8; UK: 6.9 – 7.6	Can: 0 – 100 cm.; UK: 0 – 25 cm	11 - 38	n. c.**)	----*)	n. c.**)	----*)
Geometric mean/median					----	----		----	

*) value not given;
**) not calculated;

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Studies on soil accumulation testing with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Florasulam - EFSA Journal 2015; 13(1):3984**
- **Clopyralid - EFSA Journal 2018;16(7):5389**,
- **Fluroxypyr** – EFSA Journal 2011;9(3):2091

8.4.2.1 Florasulam and its metabolites

No accumulation observed in the field studies

8.4.2.2 Clopyralid and its metabolites

No accumulation observed in the field studies (EFSA Journal 2018;16(7):5389).

8.4.2.3 Fluroxypyr and its metabolites

No data available – EFSA Journal 2011;9(3):2091 (2003).

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. EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Florasulam - EFSA Journal 2015; 13(1):3984**
- **Clopyralid - EFSA Journal 2018;16(7):5389**,
- **Fluroxypyr** – EFSA Journal 2011;9(3):2091

8.5.1 Florasulam and its metabolites

Table 8.5-1: Summary of soil adsorption/desorption for Florasulam (EFSA Journal 2015; 13(1):3984)

Adsorption

Soil name	Soil properties			Adsorption distribution coefficients		Freundlich adsorption isotherm parameters			
	Soil type (USDA)	*pH*	*OC [%]*	*K_d [mL/g]*	*$K_{d\,OC}$ [mL/g]*	*K_f [mL/g]*	*K_{fOC} [mL/g]*	*1/n*	*R^2*
Kenslow	Loam	4.6	3.8	----	----	0.47	12.37	0.91	1.000
Fuquay (M 444)	Sand	4.7	0.64	0.35	54	0.35	54.69	1.00	0.978
RefeSol 01-A	Sandy loam	5.1	1.0	----	----	0.30	30.00	1.02	0.996
Calke	Sandy loam	5.4	3.6	----	----	0.30	8.33	0.95	1.000
Pewamo (M 445)	Clay	5.7	2.4	0.94	38	1.88	78.33	0.92	0.995
Kenslow (94/16)	Silt loam	6.1	6.8	0.90	13	1.47	21.62	0.94	0.998
Lufa 6S	Clay	6.6	1.8	----	----	0.04	2.22	1.04	0.996
RefeSol 06-A	Clay loam	6.7	1.9	----	----	0.08	4.21	0.94	0.998
Catlin (M 461)	Silty clay loam	7.0	2.2	0.33	15	0.89	40.45	0.88	0.992
South Witham	Clay loam	7.1	3.8	----	----	0.10	2.63	0.98	0.995
Longwoods	Sandy loam	7.2	1.5	----	----	0.03	2.00	0.89	0.989
Lufa 5M	Sandy loam	7.3	1.0	----	----	0.03	3.00	0.95	0.994
Speyer 2.2 (94/14)	Sandy loam	7.3	3.9	0.14	4	0.13	3.33	0.95	0.810
Hanford (M 466)	Sandy loam	7.4	1.0	0.08	8	0.22	22.00	0.86	0.943
Arithmetic mean values for the whole data set (n = 14)						0.45	20.37	**0.945**	----
Median values for the whole data set (n = 14)						0.26	**10.35**	----	----

Desorption

Soil name	Soil properties			Adsorption distribution coefficients		Freundlich adsorption isotherm parameters			
	Soil type (USDA)	*pH*	*OC [%]*	*K_d [mL/g]*	*$K_{d\,OC}$ [mL/g]*	*K_f [mL/g]*	*K_{fOC} [mL/g]*	*1/n*	*R^2*
Kenslow	Loam	4.6	3.8	----	----	0.77	20.26	0.92	0.999
Fuquay (M 444)	Sand	4.7	0.64	1.24	194	1.31	204.69	0.96	0.89
RefeSol 01-A	Sandy loam	5.1	1.0	----	----	0.51	51.00	1.05	0.993
Calke	Sandy loam	5.4	3.6	----	----	0.37	10.27	0.95	0.999
Pewamo (M 445)	Clay	5.7	2.4	2.00	82	4.25	177.08	0.89	0.98
Kenslow (94/16)	Silt loam	6.1	6.8	1.45	21	2.33	34.26	0.94	0.99
Lufa 6S	Clay	6.6	1.8	----	----	0.53	29.44	0.97	0.999
RefeSol 06-A	Clay loam	6.7	1.9	----	----	0.15	7.89	0.93	0.997
Catlin (M 461)	Silty clay loam	7.0	2.2	1.05	49	2.19	99.54	0.88	0.97
South Witham	Clay loam	7.1	3.8	----	----	0.35	9.21	0.94	0.962
Longwoods	Sandy loam	7.2	1.5	----	----	0.10	6.67	1.08	0.989
Lufa 5M	Sandy loam	7.3	1.0	----	----	0.04	4.00	0.93	0.953
Speyer 2.2 (94/14)	Sandy loam	7.3	3.9	0.50	13	3.94	101.03	0.64	0.78
Hanford (M 466)	Sandy loam	7.4	1.0	0.49	50	3.18	318.00	0.64	0.79

pH dependence, Yes or No	No

Table 8.5-2: Summary of soil adsorption/desorption for 5-OH Florasulam (EFSA Journal 2015; 13(1):3984)

Soil name	Soil properties			Adsorption distribution coefficients		Freundlich adsorption isotherm parameters			
	Soil type (USDA)	*pH*	*OC [%]*	*K_d [mL/g]*	*$K_{d\,OC}$ [mL/g]*	*K_f [mL/g]*	*K_{fOC} [mL/g]*	*1/n*	*R^2*
Fuquay (M 444)	Sand	4.7	0.64	0.20	32	0.24	37.50	0.98	0.986
Calke	Sandy loam	5.4	3.6	----	----	0.29	8.06	0.83	0.997
Pewamo (M 445)	Clay	5.7	2.4	0.72	30	1.73	72.08	0.90	0.998
Kenslow (94/16)	Silt loam	6.1	6.8	0.66	10	1.55	22.79	0.90	0.999
RefeSol 06-A	Clay loam	6.7	1.9	----	----	0.12	6.32	0.87	0.999
Catlin (M 461)	Silty clay loam	7.0	2.2	0.23	11	0.69	31.36	0.88	0.994
South Witham	Clay loam	7.1	3.8	----	----	0.16	4.21	0.79	0.997
Lufa 5M	Sandy loam	7.3	1.0	----	----	0.06	6.00	0.86	0.994
Speyer 2.2 (94/14)	Sandy loam	7.3	3.9	0.28	7	0.07	1.79	1.01	0.827
Hanford (M 466)	Sandy loam	7.4	1.0	0.16	16	0.21	21.00	0.95	0.892
Arithmetic mean values for the whole data set (n = 10)						0.51	21.11	**0.91**	----
Median values for the whole data set (n = 10)						0.225	**14.53**	----	----

pH dependence, Yes or No	No

Table 8.5-3: Summary of soil adsorption/desorption for DFP-ASTCA (EFSA Journal 2015; 13(1):3984)

Soil name	Soil properties			Freundlich adsorption isotherm parameters			
	Soil type (USDA)	*pH*	*OC [%]*	*K_f [mL/g]*	*K_{fOC} [mL/g]*	*1/n*	*R^2*
Calke	Sandy loam	5.4	3.6	0.88	24.44	0.84	0.999
South Witham	Clay loam	7.1	3.8	0.63	16.58	0.80	0.999
Lufa 5M	Sandy loam	7.3	1.0	2.36	236.00	0.91	0.999
RefeSol 06-A	Clay loam	6.7	1.9	0.45	23.68	0.86	1.000
Average values (n = 4)				**1.08**	**75.18**	**0.85**	----

pH dependence (yes or no)	No

Table 8.5-4: Summary of soil adsorption/desorption for ASTCA (EFSA Journal 2015; 13(1):3984)

Soil name	Soil properties			Freundlich adsorption isotherm parameters			
	Soil type (USDA)	*pH*	*OC [%]*	*K_f [mL/g]*	*K_{fOC} [mL/g]*	*1/n*	*R^2*
Calke	Sandy loam	5.4	3.6	1.34	37.22	0.91	1.000
South Witham	Clay loam	7.1	3.8	1.27	33.42	0.94	0.999
Lufa 5M	Sandy loam	7.3	1.0	2.97	297.00	0.95	1.000
RefeSol 06-A	Clay loam	6.7	1.9	0.98	51.58	0.94	1.000
Average values (n = 4)				**1.64**	**104.81**	**0.94**	----

pH dependence (yes or no)	No

Table 8.5-5: Summary of soil adsorption/desorption for TSA (EFSA Journal 2015; 13(1):3984)

Soil name	Soil properties			Freundlich adsorption isotherm parameters			
	Soil type (USDA)	*pH*	*OC [%]*	*K_f [mL/g]*	*K_{fOC} [mL/g]*	*1/n*	*R^2*
Calke	Sandy loam	5.4	3.6	0.26	7.22	0.98	1.000
South Witham	Clay loam	7.1	3.8	0.36	9.47	0.94	0.998
Lufa 5M	Sandy loam	7.3	1.0	0.64	64.00	0.87	1.000
RefeSol 06-A	Clay loam	6.7	1.9	0.25	13.16	0.98	0.999
Average values (n = 4)				**0.38**	**23.46**	**0.94**	----

pH dependence (yes or no)	No

8.5.2 Clopyralid and its metabolites

Table 8.5-1: Summary of soil adsorption/desorption for Clopyralid (EFSA Journal 2018;16(7):5389)

Parent							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Merzenhausen	1.00	7.19	0.051	Not Calculated	0.0057	0.57 [b]	0.9[c]
Kaldenkirchen	0.98	5.34	0.048		0.0267	2.72 [b]	0.9[c]
Lanna	2.06	6.62	0.151		0.0054	0.26 [b]	0.9[c]
Overhetfeld	0.93	6.49	0.032		0.0125	1.34[b]	0.9[c]
Calke sandy loam	3.15	5.7	0.139[b]	Not Calculated	0.01	0.5	0.489
Longwoods sandy loam	3.13	7.4	0.069 [b]		0.08	2.5	0.9[c]
LUFA 2.1 loamy sand	0.68	4.9	0.040 [b]		0.03	4.1	0.9[c]
Quilen loam	4.02	6.9	0.356 [b]		0.16	3.9	0.804
DU-L-PF clay loam	6.47	6.3	0.282 [b]		0.14	2.1	0.829
Geometric mean (if not pH dependent)*					0.026	1.41	
Arithmetic mean (if not pH dependent)							0.836
pH dependence			No				

a) Measured calcium chloride solution
b) Calculated and reported in M-CA, not in the study report
c) For modelling each soil was checked against OECD 106 reliability criterion (Kd > 0.1 for direct method and Kd > 0.3 for indirect method). Freundlich coefficient of soils not meeting the criterios was set to 0.9.
* Only relevant after implementation of the published EFSA guidance.

8.5.3 Fluroxypyr and its metabolites

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

Fluroxypyr MHE							
Soil Type	OC %	Soil pH	Kd (mL/g)	Kdoc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	2.33	5.9	260	12000	----	----	----
Sandy loam	0.22	7.5	95	43000	----	----	----
Loam	3.08	6.8	190	6200	----	----	----
Clay	1.26	7.0	210	17000	----	----	----
Arithmetic mean			188.75	19550	----	----	----
pH dependence, Yes or No			No *remark:* Fluroxypyr MHE quickly hydrolyses in water/soil slurries, therefore the Kd values are tentative.				

Table 8.5-7: Summary of soil adsorption/desorption for metabolite Fluroxypyr acid

Fluroxypyr (acid)							
Soil Type	OC %	Soil pH	Kd (mL/g)	Kdoc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	2.33	5.9	----	----	1.7	78	0.92
Sandy loam	0.22	7.5	----	----	0.11	51	0.93
Loam	3.08	6.8	----	----	1.9	62	0.95
Clay	1.26	7.0	----	----	1.0	81	0.88
Arithmetic mean			----	----	1.20	68	0.93
pH dependence, Yes or No			No				

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

Pyridinol							
Soil Type	OC %	Soil pH	Kd (mL/g)	Kdoc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	0.46	6.8	0.9	188	43.7	1791	0.85
Sand	1.68	6.4	4.3	254	28.9	1741	0.81
Clay	2.44	5.7	7.3	438	4.2	913	0.81
Silt loam	1.66	6.8	15	623	11.9	708	0.87
Sandy clay loam	1.9	7.4	1.08	41.4	----	----	----
	2.0	6.0	2.00	99.8	----	----	----
	3.8	7.7	1.39	36.5	----	----	----
	1.9	7.7	1.05	55.1	----	----	----
Arithmetic mean					22.2	1288	0.84
pH dependence (yes or no)			Yes, the adsorption is lower for alkaline soils (pH ≥7); proposed endpoints: - for acidic/neutral soils (pH < 7): K_{fOC} = 1288 mL/g, 1/n = 0.84; - for alkaline soils (pH ≥7) K_{dOC} = 44.3 mL/g, 1/n = 1.00				

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

Methoxypyridine							
Soil Type	OC %	Soil pH	Kd (mL/g)	Kdoc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy clay loam	2.6	7.0	----	----	7.14	274.6	0.81
Loamy sand	2.0	5.8	----	----	9.28	464.0	0.96
Silty clay loam	3.8	7.4	----	----	8.93	235.0	0.84
Clay soil	1.9	7.1	----	----	5.93	312.0	0.75
Arithmetic mean					7.8	321.4	0.84
pH dependence (yes or no)			No				

8.5.4 Column leaching (KCP 9.1.2.1)

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

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Florasulam - EFSA Journal 2015; 13(1):3984**
- **Clopyralid - EFSA Journal 2018;16(7):5389**,
- **Fluroxypyr** – EFSA Journal 2011;9(3):2091

8.5.4.1 Florasulam and its metabolites

The examination of the column leaching of Florasulam was performed on columns filled with three different soils:
- loamy sand (Cuckney), having the pH = 6.6 and OC = 0.8%;
- sand (Elvendon), having the pH = 7.6 and OC = 1.1%;
- sandy clay loam (Marcham), having the pH = 7.7 and OC = 2.0%.

The amount of the applied Florasulam corresponded to the application rate of 15 g/ha.
Following application the columns were leached for two days with 393 mL of 0.01 M CaCl2 solution (equivalent to 200 mm of rainfall) applied to the top of the column at a constant rate.

8.5.4.2 Clopyralid and its metabolites

Not relevant (EFSA Journal 2018;16(7):5389)

8.5.4.3 Fluroxypyr and its metabolites

Column leaching ‡	Elution (mm): 393 mL of distilled water Time period (d): 2 d (48 hours)
	Leachate: < 2 % of Fluroxypyr MHE, 18 - 74 % Fluroxypyr (acid) (a. s. equivalents);

8.5.5 Lysimeter studies (KCP 9.1.2.2)

Studies on lysimeters studies with the formulation were not performed, since it is possible to ex-trapolate from data obtained with the active substance.

EU approved endpoints were evaluated during Annex I inclusion for actives substances. All relevant data are presented in :

- **Florasulam - EFSA Journal 2015; 13(1):3984**
- **Clopyralid - EFSA Journal 2018;16(7):5389**,
- **Fluroxypyr** – EFSA Journal 2011;9(3):2091

8.5.5.1 Florasulam and its metabolites

Location: Letcombe Regis, UK
Study type: lysimeter
Soil properties:
Lysimeters No. 25, 26, 27, 28, 29, 30: texture: sand, pH = 6.2, OC= 0.6, MWHC not determined (data for 0-29 cm layer)
Lysimeters No. 31, 33: texture: sandy loam, pH = 6.5, OC= 2.49, MWHC not determined (data for 0-22 cm layer)
Dates of application :
Lysimeters No. 28, 29, 33 – 19. 04. 1994;
Lysimeters No. 27 and 31 – 19. 04 1994 and 20. 04 1995;
Lysimeters No. 25 and 26 – 16. 02. 1995
Crop : /Interception estimated: Year -1 crop: Winter cereals (Winter wheat or Winter Barley), CI = 50%

at application; Year-2 (following) crop: Winter cereals or Winter OSR; Year-3: fallow;
Number of applications:
Lysimeters No. 25, 26, 28, 29, 33: 1 year, 1 application per year
Lysimeters No. 27 and 31: 2 years, 1 application per year
Duration.: 2 years – lysimerters No. 25, 26, 28, 33; 3 years – lysimeters No. 27 and 31;
Application rate:
Lysimeters No. 25, 26, 27, 28, 31, 33: 5 g/ha/year;
Lysimeter No. 29: 25 g/ha/year
Average annual rainfall (mm):
Lysimeters No. 27-31:Year 1 (April 1994 – April 1995) 1006 mm (including irrigation), Year 2 (April 1995- April 1996) 773 mm (including irrigation); Year 3 (April 1996 – March 1997) 510 mm (including irrigation)
Lysimeters No. 25 and 26: Year 1 (February 1995 – March 1996) 792 mm , Year 2 (February 1996- April 1997) 600 mm Average annual leachate volume (mm):
Lysimeters No 27-29: Year 1: 404-426mm, Year 2: 274 – 296 mm, Year 3: 126 mm
Lysimeters No. 31 and 33: Year 1:317-335 mm, Year 2: 718mm, Year 3: 90 mm;
Lysimeters No. 25 and 26: Year 1: 312 – 325 mm; Year 2: 176 – 181 mm

8.5.5.2 Clopyralid and its metabolites

Four lysimeter studies were evaluated and reported in the EFSA conclusion for clopyralid (EFSA, 2018). Occasional exceedances of 0.1 µg/L were detected in leachate samples, but the annual average concentrations of clopyralid were below 0.1 µg/L in all studies. In one lysimeter, the annual average concentration of unidentified radioactivity was 0.113 µg/L in one year.

According to EFSA Journal 2018;16(7):5389, the following Lysimeter/ field leaching study is available:
1) Germany, spring application of 150 or 200 g clopyralid/ha on oilseed rape + partly a second application of 125 g a.s./ha on winter wheat 1 year later:
A total of 935 mm of precipitation was received in year 1 and 895.5 mm in year 2. 438 – 478 L of leachate was collected in year 1 and 411-437 L in year 2.
In the first year of application the annual average concentration in leachate was < 0.050 µg/L ai equivalent, however occasional exceedings of 0.10 µg/L were detected.
In the second year the annual average concentration in leachate was < 0.055 µg/L. In the soil cores the majority of radioactivity remained in the top layers of 0 – 40 cm. 11.49 – 12.38 % of AR was found in soil 2 years after the single application.
In the third year the annual average concentration in leachate was 0.001 – 0.019 µg/L. Maximum concentration of ai equivalents in leachate of the third year was 0.043 µg/L in the lysimeter which received two applications. In the soil cores 9.82 – 10.11 % of RA was found 2 years after the second application. The total recovery of RA in the three year monitoring period was 12.81 – 17.53 % of the applied RA, considering the both applications.
2) Germany, winter oilseed rape, 120 or 141 g clopyralid/ha, 847 and 1011 mm rain in years 1 and 204 – 417 mm of leachate was collected in two lysimeters in years 1 and 2. In the lysimeter with higher application rate the annual average concentration of unidentified radioactivity was 0.127 µg/L equivalent in year 1, but taken over the whole study period of two years, the average concentration was 0.064 – 0.078 µg/L equivalent. Occasional exceedings of 0.1 µg/L were detected soon after the application in both lysimeters.
3) Germany, sugar beet, spring application of 118 g clopyralid/ha, 754 and 871 mm rainfall in years 1 and 2:113 and 196 mm of leachate was collected in years 1 and 2. Annual average concentrations of clopyralid were 0.010 and 0.002 µg/L in years 1 and 2. Unidentified radioactivity was present in the leachate at annual average concentrations of 0.113 and 0.031 µg/L equivalent in years 1 and 2, respectively. Dissolved CO2 was the major metabolite observed in the leachate. 24.6 % of AR was measured in soil after 111 days, and after 2 years 13.2 % of AR was recovered. (It was considered very unlikely that a single unknown substance would exceed an annual concentration of 0.1 µg/L.)
4) Germany, sugar beet, spring application of 99 or 185 g clopyralid/ha, ca 700 mm rainfall/year: In year

1 the leachate volume was 180 and 248 mm, and in year 2 70 to 79 mm. Annual average concentrations in the leachate were not calculated, but in individual samples the clopyralid concentrations up to 0.135 µg/L were detected occasionally. 26 months after application 20 % of AR was recovered from the soil, majority of it in tillage layer (0 – 30 cm

8.5.5.3 Fluroxypyr and its metabolites

8.5.5.1 Fluroxypyr and metabolites.

Lysimeter/ field leaching studies ‡	Study 1 Location: Germany Study type: lysimeter cropped with barley (1st year) and sugar beets (2nd year) Soil properties: texture: silty sand, pH = 6.9, OC= 0.9, Dates of application: spring Crop/Interception estimated: barley, 25% Number of applications: 1 (at the start of the first year) Duration: 2 years. Application rate: 200 - 400 g acid/ha/year Average annual rainfall (mm): 800 mm Individual annual maximum concentrations: Fluroxypyr MHE: not detected Fluroxypyr (acid): 2-years average: 0.001 µg/L and 0.0034 µg/L; maximum concentrations: 0.034 µg/L and 0.008 µg/L; Pyridinol: 2-years average: 0.0009 µg/L and <0.0001 µg/L; maximum concentrations: 0.0038 µg/L and 0.001 µg/L; Methoxypyridine: 2-years average: 0.0003 µg/L and 0.0002 µg/L; maximum concentrations: 0.0009 µg/L and 0.0006 µg/L; Study 2 Location: UK Study type (e.g. Lysimeter, field): lysimeter cropped with grass Soil properties: texture: sand Cuckney series), pH = 6.3, OC= 1.3%, Dates of application: 08. October 1998 (1st year) Crop/Interception estimated: grass, 90% Number of applications: 1 Duration. 2 years Application rate: 400 g acid/ha (576 g ester/ha Starane 200 EC) Average annual rainfall (mm): 863 mm – 1st year, 859 2nd year; Average annual leachate volume (mm): 144 - 146 mm (1st year), 153 – 156 mm (2nd year) % radioactivity in leachate (maximum/year): 0.44 – 0.47 % AR (1st year); 0.54 – 0.6% AR (2nd year)

Individual annual maximum concentrations:
dissolved CO_2: 0.22 µg/L parent equivalent – 1st year, 0.03 µg/L parent equivalent – 2nd year;
Fluroxypyr MHE: not detected;
Fluroxypyr (acid): 0.01 µg/L parent equivalent – 1st year, not detected – 2nd year;
Pyridinol: 0.02 µg/L parent equivalent – 1st year, not detected – 2nd year;
Methoxypyridine: not detected

8.5.6 Field leaching studies (KCP 9.1.2.3)

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

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Florasulam - EFSA Journal 2015; 13(1):3984**
- **Clopyralid - EFSA Journal 2018;16(7):5389**,
- **Fluroxypyr** – EFSA Journal 2011;9(3):2091

8.5.6.1 Florasulam and its metabolites

Please refer to point 8.5.3.

8.5.6.2 Clopyralid and its metabolites

Please refer to point 8.5.3.

8.5.6.3 Fluroxypyr and its metabolites

Please refer to point 8.5.3.

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.
EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Florasulam - EFSA Journal 2015; 13(1):3984**
- **Clopyralid - EFSA Journal 2018;16(7):5389**,
- **Fluroxypyr** – EFSA Journal 2011;9(3):2091

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8.6.1 Florasulam and its metabolites

Table 8.6-1: **Summary of degradation in water/sediment of Florasulam (EFSA Journal 2015; 13(1):3984)**

Process	Experimental conditions	Obtained results		
		Type of sample	*Degradation kinetics*	*Identified metabolites*
Abiotic hydrolysis	The experiment performed at T = 50⁰C on three sterilised buffer solutions: pH 4 (phthalate) buffer, pH 7 (phosphate) buffer and pH 9 (borate) buffer, incubated for up to 7 days	pH 4 sterile buffer	stable – DT_{50} > 1000 days	none detected
		pH 7 sterile buffer	stable – DT_{50} > 1000 days	none detected
		pH 9 sterile buffer	DT_{50} = 2.0 days	**"hydrated" Florasulam –** 33.8% AR (DAT 3), transient; **5-OH Florasulam –** 77.6% AR (DAT 7), hydrolytically stable
	The experiment performed at T = 25⁰C on three sterilised buffer solutions: pH 5 (citrate) buffer, pH 7 (TRIS-maleic) buffer and pH 9 (borate) buffer, incubated for up to 30 days or up to 90 days (pH 9 buffer samples); additionally pH 9 buffer incubated for up to 9 days at T = 20⁰C	pH 5 sterile buffer	stable – DT_{50} > 1000 days	none detected
		pH 7 sterile buffer	stable – DT_{50} > 1000 days	none detected
		pH 9 sterile buffer	DT_{50} = 99.1 – 100.1 days; DT_{90} = 329.2 – 332.4 days	**"hydrated" Florasulam –** 16.85% AR (DAT 90), transient; **5-OH Florasulam –** 30.82% AR (DAT 90), hydrolytically stable
		pH 9 sterile buffer T = 20⁰C	DT_{50} = 219.6 – 225.3 days; DT_{90} = 729.4 – 748.3 days	**"hydrated" Florasulam –** 12.10% AR (DAT 3), transient; **5-OH Florasulam –** 13.25% AR (DAT 7), hydrolytically stable
Direct photolysis	The experiment performed using sterilised pH 5 buffer solution irradiated for up to 32 days with natural summer sunlight at latitude 40⁰N and at constant T = 25⁰C	Irradiated samples	at 40⁰N spring DT_{50} = 80 d., summer DT_{50} = 46 d., autumn DT_{50} = 159 d.; quantum yield Φ = 0.074	**TPSA –** 17.4% AR (DAT 32); stable
		Dark control	No degradation observed	No degradation observed
	The experiment performed using sterilised pH 5 buffer solution irradiated for up to 15 days with artificial sunlight - Xenon lamp light having the intensity of 466 W/m^2 • nm, at constant T = 20⁰C	Irradiated samples	at 40⁰N spring DT_{50} = 121 d., summer DT_{50} = 64 d., autumn DT_{50} = 248 d.; quantum yield Φ = 0.0321	TPSA – 58.3% AR (DAT 15); stable
		Dark control	No degradation observed	No degradation observed
Direct and indirect photolysis	The experiment performed using non-sterile natural river water irradiated for up to 16 days (42.6 days of natural summer sunlight at 40⁰N) with artificial sunlight - Xenon lamp light having the intensity of 466 W/m^2 • nm, at constant T = 20⁰C	Irradiated samples	at 40⁰N in summer DT_{50} = 28.83 days, DT_{90} = 95.77; quantum yield not determined	**TPSA –** 21.9 % AR (DAT 16); **ASTP –** 21.9% AR (DAT 16); **DFP-ASTCA –** 7.5% AR (DAT 16); all compounds stable
		Dark control	No degradation observed	No degradation observed
	The experiment performed using non-sterile natural lake water irradiated for up to 30 days with natural summer sunlight at 51.5⁰N, at the temperature of surrounding (10 – 30⁰C)	Irradiated samples	at 51.5⁰N in summer DT_{50} = 3.23 days, DT_{90} = 10.73; quantum yield not determined	**5-OH Florasulam –** 16.6% AR (DAT 3); **5-OH ASTP –** 28.9% AR (DAT 7), **ASTP –** 9.8% AR (DAT 30), **DFP-ASTCA –** 8.9% AR (DAT 7); **ASTCA –** 53.8 % AR (DAT 30)
		Dark control	DT_{50} = 528.48 days, DT_{90} = 1771.22;	**5-OH Florasulam –** 9.7% AR (DAT 15)
Ready biodegradability	Test performed in line with OECD 301B Guideline (Modified Sturm Test) at T = 20 – 24⁰C	Florasulam as a test compound	2 % Florasulam mineralised after 29 days; **Florasulam is not readily biodegradable**	Not applicable
	Test performed in line with OECD 301B Guideline (Modified Sturm Test) at T = 20 – 24⁰C	5-OH Florasulam as a test compound	1 – 3% of 5-OH Florasulam mineralised after 29 days; **5-OH Florasulam is not readily biodegradable**	Not applicable

8.6.2 Clopyralid and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of 8.6.2 Clopyralid (EFSA Journal 2018;16(7):5389)

Parent Clopyralid	Distribution: max in water 100.13 % at 0d, max. sediment 19 % at 100 d (Loamy sand) Distribution: max in water 99.0 % at 0 d, max sediment 26 % at 100 d (Sandy silt loam)									
Water / sediment system	pH water phase	pH sed [a]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Loamy sand	6.5	5.5	20	>500 days	n/a	128	n/a	>500 days	n/a	First-order
Sandy silt loam	8.16	7.7	20	>500 days	n/a	167	n/a	>500 days	n/a	First-order
Geometric mean at 20°C[b]						148				

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Normalised using a Q10 of 2.58

Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d
Loamy sand	6.5	5.5	2% after 100 d	5% at 100 d
Sandy silt loam	8.1	7.7	5% after 100 d	5% at 100 d

(Hall & al. 2002)

- **Hydrolytic degradation**

Hydrolytic degradation of the active substance and metabolites > 10 %

pH 4, 50 °C: DT_{50} >1 year (Smith 2000)
pH 7: 50 °C: DT_{50} >1 year
pH 9: 50 °C: DT_{50} >1 year

- **Aqueous photochemical degradation**

Photolytic degradation of active substance and metabolites above 10 %

Xenon lamp for an equivalent of 41.6 days of summer sunlight at 40 ºN, DT50 ca 38000 days, no photolytic degradation products in aqueous sterile buffer could be observed. Photolysis is not a significant route of degradation of clopyralid in waters

Quantum yield of direct phototransformation in water at > 290 nm
1.01 x· 10 –6 mol · Einstein -1 (Ponte 2014)

- **Ready biodegradability**

Clopyralid isn't readily biodegradable.

In the Modified Sturm Test the cumulative CO2 production of clopyralid was 5-10% of the theoretical maximum after 27 days. (Jenkins 1991

8.6.3 Fluroxypyr and its metabolites

Table 8.6-2: Summary of degradation in water/sediment of Fluroxypyr-MHE

Fluroxypyr MHE *)	Distribution: in the system 25-50% after 1 day, almost totally disappearing from the system after 7 days; max. in sediment: 50% of the applied after 2 hours									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}/DT_{90} whole sys.	χ^2	DT_{50}/DT_{90} water	χ^2	DT_{50}/DT_{90} sed	χ^2	Method of calculation
Thornham ditch	7.5	not given	18 - 23	38.1/126.5	10.04	not calculated		not calculated		SFO
Crimplesham ditch	3.1 – 3.8	not given	18 - 23	31.3/103.9	9.55	not calculated		not calculated		SFO

Table 8.6-3: Summary of degradation in water/sediment of Fluroxypyr acid

Fluroxypyr (acid) *)	Distribution: in the system up to 88-93% after 1-2 weeks, <10% after 13 weeks; up to 80% in water phase, up to 20% in sediment phase									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}/DT_{90} whole sys.	χ^2	DT_{50}/DT_{90} water	χ^2	DT_{50}/DT_{90} sed	χ^2	Method of calculation
Thornham ditch	7.5	not given	18 - 23	38.1/126.5	10.04	not calculated		not calculated		SFO
Crimplesham ditch	3.1 – 3.8	not given	18 - 23	31.3/103.9	9.55	not calculated		not calculated		SFO
Geometric mean/median										

*) DT_{50}/DT_{90} values fro the whole system calculated for the sum of Fluroxypyr MHE and Fluroxypyr (acid)

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

Pyridinol (+Pyridi-none) *)	Distribution: max in the system 46% after 8 weeks, mainly in water phase; max. observed in water/sediment system: 55.5% (44% in water phase, 11.5% in sediment phase)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}/DT_{90} whole sys.	χ^2	DT_{50}/DT_{90} water	χ^2	DT_{50}/DT_{90} sed	χ^2	Method of calculation
Thornham ditch	7.5	not given	18 - 23	27.8/92.3	6.11	not calculated		not calculated		SFO
Crimplesham ditch	3.1 – 3.8	not given	18 - 23	35.5/118.0	2.86	not calculated		not calculated		SFO
Geometric mean/median										
*)Pyridinone is a tautomer of Pyridinol, therefore these two compounds can be regarded as one, further named "Pyridinole"										

Table 8.6-5: Summary of degradation in water/sediment of 3-CP

3-CP	Distribution: max in the system 25.2% after 4 weeks, mainly in water phase									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}/DT_{90} whole sys.	χ^2	DT_{50}/ DT_{90} water	χ^2	DT_{50}/DT_{90} sed	χ^2	Method of calculation
Brewer Lake/ ND/USA	8.2	8.1	25	not calculated		not calculated		not calculated		

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Thornham ditch	7.5	not given	14.2% after 26 weeks	48% after 26 weeks	48% after 26 weeks
Crimplesham ditch	3.1 – 3.8	not given	17.9% after 26 weeks	22% after 26 weeks	22% after 26 weeks

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- Florasulam - EFSA Journal 2015; 13(1):3984
- Clopyralid - EFSA Journal 2018;16(7):5389,
- Fluroxypyr – EFSA Journal 2011;9(3):2091

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	Cereals
Application rate (g as/ha)	Florasulam: 0.005 Clopyralid: 0.06 Fluroxypyr: 0.06 (Fluroxypyr-MHE: 0.0864)
Number of applications/interval	1/-
Crop interception (%)	20
Depth of soil layer (relevant for plateau concentration) (cm)	5

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 end-point y/n/ Reference
Florasulam	359.3	-	4.29 d	EFSA Journal 2015; 13(1):3984
5-OH Florasulam	345.26	71.6	29.75 d	EFSA Journal 2015; 13(1):3984
DFP-ASTCA	304.20	17.8	46.16 d	EFSA Journal 2015; 13(1):3984
ASTCA	192.13	40	259.05 d	EFSA Journal 2015; 13(1):3984
TSA	148.14	15.9	171.68 d	EFSA Journal 2015; 13(1):3984
Clopyralid	191.96	-	23.7 d representative worst case from field studies	(EFSA Journal 2018;16(7):5389)
Fluroxypyr-MHE	367.3	100%	DT50 = 1.8 days	EFSA Journal 2011;9(3):2091
Fluroxypyr	255	100%	DT50:39.6 d Kinetics: SFO Field or Lab: representative worst case un-normalised values from lab studies	EFSA Journal 2011;9(3):2091
Pyridinol	197	23.9%	DT50= 105.4	EFSA Journal 2011;9(3):2091
Methoxypyridine	211	38.2%	DT50=1160.9 days	EFSA Journal 2011;9(3):2091

8.7.2.1 Florasulam and its metabolites

Table 8.7-3: PECsoil for Florasulam on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0053	-	-	-
Short term	24h	0.0045	0.0049	-	-
	2d	0.0039	0.0046	-	-
	4d	0.0028	0.0039	-	-

Long term	7d	0.0017	0.0032	-	-
	14d	0.0006	0.0021	-	-
	21d	0.0002	0.0015	-	-
	28d	0.0001	0.0012	-	-
	50d	<0.0001	0.0007	-	-
	100d	<0.0001	0.0003	-	-
Plateau concentration (5 cm) after year 10		Not relevant		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)				-	-

Table 8.7-4: PEC_{soil} for 5-OH Florasulam on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0027	-	-	-
Short term	24h	0.0027	0.0027	-	-
	2d	0.0027	0.0027	-	-
	4d	0.0026	0.0027	-	-
Long term	7d	0.0025	0.0027	-	-
	14d	0.0022	0.0026	-	-
	21d	0.0019	0.0025	-	-
	28d	0.0016	0.0024	-	-
	50d	0.0010	0.0021	-	-
	100d	0.0003	0.0014	-	-
Plateau concentration (5 cm) after year 10		Not relevant		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)				-	-

Table 8.7-5: PEC_{soil} for DFP-ASTCA on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0006	-	-	-
Short term	24h	0.0006	0.0006	-	-

	2d	0.0006	0.0006	-	-
	4d	0.0006	0.0006	-	-
Long term	7d	0.0006	0.0006	-	-
	14d	0.0006	0.0006	-	-
	21d	0.0005	0.0006	-	-
	28d	0.0005	0.0006	-	-
	50d	0.0003	0.0005	-	-
	100d	0.0002	0.0004	-	-
Plateau concentration (5 cm) after year 10		Not relevant		-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)				-	-

Table 8.7-6: PEC_{soil} for ASTCA on winter cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0011	-	-	-
Short term	24h	0.0011	0.0011	-	-
	2d	0.0011	0.0011	-	-
	4d	0.0011	0.0011	-	-
Long term	7d	0.0011	0.0011	-	-
	14d	0.0010	0.0011	-	-
	21d	0.0010	0.0011	-	-
	28d	0.0010	0.0011	-	-
	50d	0.0009	0.0010	-	-
	100d	0.0008	0.0010	-	-
Plateau concentration (5 cm) after year 10		Not relevant		-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)				-	-

Table 8.7-7: **PEC_{soil} for TSA on winter cereals**

PEC_{soil} (mg/kg)	Winter cereals			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA

Initial		0.0003	-	-	-
Short term	24h	0.0003	0.0003	-	-
	2d	0.0003	0.0003	-	-
	4d	0.0003	0.0003	-	-
Long term	7d	0.0003	0.0003	-	-
	14d	0.0003	0.0003	-	-
	21d	0.0003	0.0003	-	-
	28d	0.0003	0.0003	-	-
	50d	0.0003	0.0003	-	-
	100d	0.0002	0.0003	-	-
Plateau concentration (5 cm) after year 10		Not relevant		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)				-	-

8.7.2.2 Clopyralid and its metabolites

Table 8.7-8: PEC_{soil} for Clopyralid on cereals

PEC_{soil} (mg/kg)		cereals	
		Single application	
		Actual	TWA
Initial		0.0640	-
Short term	24h	0.0622	0.0631
	2d	0.0604	0.0622
	4d	0.0569	0.0604
Long term	7d	0.0522	0.0579
	14d	0.0425	0.0525
	21d	0.0346	0.0478
	28d	0.0282	0.0437
	50d	0.0148	0.0336
	100d	0.0034	0.0207
Plateau concentration (5 cm) after year 10		<0.0001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0640	-

8.7.2.3 Fluroxypyr and its metabolites

Table 8.7-9: PEC_{soil} for Fluroxypyr-MHE on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0922	-
Short term	24h	0.0627	0.0774
	2d	0.0427	0.0651
	4d	0.0198	0.0476
Long term	7d	0.0062	0.0323
	14d	0.0004	0.0172
	21d	<0.0001	0.0115
	28d	<0.0001	0.0087
	50d	<0.0001	0.0048
	100d	<0.0001	0.00024
Plateau concentration (5 cm) after year 10		<0.0001	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.0922	-

Table 8.7-10: PEC_{soil} for Fluroxypyr acid on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0640	-
Short term	24h	0.0629	0.0634
	2d	0.0618	0.0629
	4d	0.0597	0.0618
Long term	7d	0.0566	0.0602
	14d	0.0501	0.0568
	21d	0.0443	0.0536
	28d	0.0392	0.0506
	50d	0.0267	0.0427
	100d	0.0111	0.0302
Plateau concentration (5 cm) after year 10		0.0001	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.0641	-

PEC$_{soil}$ of metabolites

Table 8.7-11: PEC$_{soil}$ for Pyridinol on winter cereals

PEC$_{soil}$ (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0066	-
Short term	24h	0.0066	0.0066
	2d	0.0066	0.0066
	4d	0.0066	0.0066
Long term	7d	0.0066	0.0066
	14d	0.0065	0.0066
	21d	0.0064	0.0066
	28d	0.0063	0.0066
	50d	0.0059	0.0065
	100d	0.0048	0.0063
Plateau concentration (5 cm) after year 10		0.0011	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		0.0077	-

Table 8.7-12: PEC$_{soil}$ for Methoypyridine on winter cereals

PEC$_{soil}$ (mg/kg)		Winter cereals	
		Single application	
Initial		0.0180	-
Short term	24h	0.0180	0.0180
	2d	0.0180	0.0180
	4d	0.0180	0.0180
Long term	7d	0.0180	0.0180
	14d	0.0179	0.0180
	21d	0.0179	0.0180
	28d	0.0179	0.0180
	50d	0.0178	0.0179
	100d	0.0174	0.0179
Plateau concentration (5 cm) after year 10		0.0795	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		0.0974	-

8.7.2.4 PEC_{soil} of CHR/H/CFF 250 EC SC

The PECsoil immediately after the first application was calculated for formulation as follows:

$$\text{Initial PECsoil (mg/kg)} = \frac{A \text{ (g/ha)}}{100 \times d \text{ (cm)} \times \rho \text{ (g/cm}^3\text{)}}$$

where: A = application rate (543.1 g formulation/ha, density product from physicochemical studies: 1.0826 g/ml)
d = depth of soil layer (5 cm)
ρ = soil bulk density (1.5 g/cm3)

Table 8.7-13: PEC_{soil} for CHR/H/CFF 250 EC SC on cereals

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
CHR/H/CFF 250 EC	541.3	0.577	-	5	0.577	0.577

zRMS comments:

Clopyralid
The calculations of PECs submitted by Applicant have been accepted.
The degradation endpoints used for clopyralid was line in the LoEP (EFSA Journal 2018;16(7):5389).
The results of calculation PECs are presented in Table 8.7-14.

Fluroxypyr
Input parameters endpoints were used from EFSA Journal 2011;9(3):2091.
The PECs calculations performed for active fluroxypyr and its metabolites have been accepted..
The calculation of PECs was based on the recommended presented in the GAP.
The results of PECs are presented from Table 8.7-15 to Table 8.7-16.

Florasulam
The calculations of PECs submitted by Applicant have been accepted.
The degradation endpoints used for florasulam and its metabolites were in line in the LoEP (EFSA Journal 2015; 13(1):3984).
The results of PECs calculation are presented from Table 8.7-3 to Table 8.7-7.

PECsoil for CHR/H/CFF 250 EC SC on cereals
Based on an application rate of 541.3 g/ha and a formulation density of 1.0826 g/ml g/ml and 20% crop interception calculated PECs was 0.577 mg/kg.

The results of PECs for the active substances clopyralid, florasulam, fluroxypyr and its metabolites were used for the ecotoxicological risk assessment.

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

8.8.1 Justification for new endpoints

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- Florasulam - EFSA Journal 2015; 13(1):3984
- Clopyralid - EFSA Journal 2018;16(7):5389,
- Fluroxypyr – EFSA Journal 2011;9(3):2091

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/Spring cereals
Application rate (g as/ha)	Florasulam: 5 Clopyralid: 60 Fluroxypyr: 60
Number of applications/interval (d)	1/-
Relative application date	161 day after evemt
Crop interception (%)	20
Frequency of application	annual
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, FOCUS MACRO v5.5.3

8.8.2.1 Florasulam and its metabolites

Table 8.8-2: Input parameters related to active substance Florasulam and metabolite(s) for PEC_{gw} calculations

Compound	Florasulam	5-OH Flo-rasulam	DFP-ASTCA	ASTCA	TSA	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	359.3	345.26	304.20	192.13	148.14	EFSA Journal 2015; 13(1):3984

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA	Value in accordance with EU endpoint y/n/ Reference*
Water solubility (mg/L):	6360	354	87400	250000	10900	EFSA Journal 2015; 13(1):3984
Saturated vapour pressure (Pa):	1.0 E-6 Pa at 20°C	2.7 E-6 Pa at 20°C	3.0 E-6 Pa at 20°C	2.0 E-6 Pa at 20°C	1.0 E-4 Pa at 20°C	EFSA Journal 2015; 13(1):3984
DT_{50} in soil (d)	1.55 d (normalisation to 10kPa or pF2, 20 ºC with Q10 of 2.58 and Walker equation coefficient 0.7)	14.98 d (normalisation to 10kPa or pF2, 20 ºC with Q10 of 2.58 and Walker equation coefficient 0.7)	16.62 d (normalisation to 10kPa or pF2, 20 ºC with Q10 of 2.58 and Walker equation coefficient 0.7)	297.47 d (normalisation to 10kPa or pF2, 20 ºC with Q10 of 2.58 and Walker equation coefficient 0.7)	83.47 d (normalisation to 10kPa or pF2, 20 ºC with Q10 of 2.58 and Walker equation coefficient 0.7)	EFSA Journal 2015; 13(1):3984
DT_{50} in soil (d) lab/field	1.55	14.98	16.62	297.47	83.47	EFSA Journal 2015; 13(1):3984
Transformation rate	0.381902/per day to 5-OH Florasulam	0.046272/per day to DFP-ASTCA	0.032572/per day to ASTCA; 0.009134/per day to TSA	0.00233/per day to TSA	0.008304/ per day to CO_2	PELMO 5.5.3
K_{foc} (mL/g)/K_{fom}	10.35	14.53	75.18	104.81	23.46	EFSA Journal 2015; 13(1):3984
1/n	0.945	0.91	0.85	0.94	0.94	EFSA Journal 2015; 13(1):3984
Plant uptake factor	0	0	0	0	0	
Formation fraction	-	0.854 from florasulam	1.00 from 5-OH florasulam	0.781 from DFP-ASTCA	0.219 from DFP-ASTCA 1.000 from ASTCA	EFSA Journal 2015; 13(1):3984

Table 8.8-3: PEC_{gw} for Florasulam and metabolite(s) on winter cereals (with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA
Winter cereals	Châteaudun	<0.0001	0.0012	0.0003	0.1847	0.1751
	Hamburg	<0.0001	0.0104	0.0027	0.2182	0.2038
	Jokioinen	<0.0001	0.0076	0.0008	0.1882	0.2226
	Kremsmünster	<0.0001	0.0105	0.0030	0.1768	0.1257

	Okehampton	<0.0001	0.0168	0.0043	0.1743	0.1089
	Piacenza	<0.0001	0.0020	0.0012	0.1550	0.1369
	Porto	<0.0001	0.0014	<0.0001	0.1144	0.1158
	Sevilla	<0.0001	<0.0001	<0.0001	0.0223	0.0666
	Thiva	<0.0001	<0.0001	<0.0001	0.2257	0.2200

Table 8.8-4: **PEC_{gw} for Florasulam and metabolite(s) on winter cereals (with FOCUS PELMO 6.6.4)**

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasu-lam	DFP-ASTCA	ASTCA	TSA
Winter cereals	Châteaudun	<0.001	0.006	0.002	0.218	0.159
	Hamburg	0.004	0.134	0.040	0.285	0.167
	Jokioinen	0.002	0.070	0.012	0.231	0.177
	Kremsmünster	0.001	0.039	0.014	0.243	0.136
	Okehampton	0.001	0.112	0.026	0.198	0.101
	Piacenza	0.002	0.061	0.020	0.226	0.151
	Porto	0.004	0.202	0.011	0.152	0.106
	Sevilla	<0.001	0.012	0.001	0.080	0.090
	Thiva	<0.001	0.006	0.001	0.222	0.164

Table 8.8-5: **PEC_{gw} for Florasulam and metabolite(s) on spring cereals (with FOCUS PEARL 5.5.5)**

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasu-lam	DFP-ASTCA	ASTCA	TSA
Winter cereals	Châteaudun	<0.0001	0.0010	0.0001	0.1626	0.1488
	Hamburg	<0.0001	0.0134	0.0036	0.2693	0.2534
	Jokioinen	<0.0001	0.0078	0.0009	0.1633	0.1808
	Kremsmünster	<0.0001	0.0114	0.0029	0.1959	0.1404
	Okehampton	<0.0001	0.0116	0.0026	0.1753	0.1106
	Porto	<0.0001	0.0012	<0.0001	0.1077	0.0924

Table 8.8-6: PEC$_{gw}$ for Florasulam and metabolite(s) on spring cereals (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasu-lam	DFP-ASTCA	ASTCA	TSA
Winter cereals	Châteaudun	<0.001	0.001	<0.001	0.165	0.153
	Hamburg	<0.001	0.006	0.001	0.242	0.200
	Jokioinen	<0.001	0.009	<0.001	0.168	0.189
	Kremsmünster	<0.001	0.010	0.001	0.212	0.166
	Okehampton	<0.001	0.012	0.001	0.190	0.118
	Porto	<0.001	0.003	<0.001	0.121	0.103

Only metabolites ASTCA and TSA PEG$_{GW}$ resulting from both PEARL and PELMO calculations all exceed the trigger value 0.1 µg L-1. No toxicological relevance according EFSA Journal 2015; 13(1):3984 for all florasulam metabolites.

8.8.2.2 Clopyralid and its metabolites

Table 8.8-7: Input parameters related to Clopyralid and metabolite(s) for PEC$_{gw}$ calculations

Compound	Clopyralid	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	191.96	(EFSA Journal 2018;16(7):5389)
Water solubility (mg/L):	1.43 x 105 at pH 7 and 20°C	(EFSA Journal 2018;16(7):5389)
Saturated vapour pressure (Pa):	set to 0 Pa as worst case	(EFSA Journal 2018;16(7):5389)
DT_{50} in soil (d)	Geometric mean parent DT50 field 7.05 d (n = 10) (normalisation to pF2, 20°C with Q10 of 2.58)	(EFSA Journal 2018;16(7):5389)
DT_{50} in soil (d) lab/field	7.05	(EFSA Journal 2018;16(7):5389)
Transformation rate	-	
K_{foc} (mL/g)/K_{fom}	geometric mean 1.41 mL/g (n = 9), arithmetic mean	(EFSA Journal 2018;16(7):5389)
1/n	1/n= 0.836 (n = 9)	(EFSA Journal 2018;16(7):5389)
Plant uptake factor	0 / 0.0002711/ 0.5[1]	(EFSA Journal 2018;16(7):5389)
Formation fraction	-	

* Delete row in case of no pH dependency
[1] Tier 1 / Tier 2; Tier 2 value according to Briggs equation (Briggs et al., 1982) with log(KOW) = -2.63 TSCF = 0.774 exp -

[(log KOW - 1.78)2/2.44] / Tier 3

Table 8.8-8: PEC$_{gw}$ for Clopyralid and metabolite(s) on winter cereals (with FOCUS PEARL 5.5.5) – TIER 1 (PUF=0)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Winter cereals	Châteaudun	0.0031
	Hamburg	0.0752
	Jokioinen	0.1463
	Kremsmünster	0.0758
	Okehampton	0.1014
	Piacenza	0.0205
	Porto	0.0024
	Sevilla	<0.0001
	Thiva	<0.0001

Table 8.8-9: PEC$_{gw}$ for Clopyralid and metabolite(s) on spring cereals (with FOCUS PEARL 5.5.5) – TIER 1 (PUF=0)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Winter cereals	Châteaudun	0.0019
	Hamburg	0.09818
	Jokioinen	0.1356
	Kremsmünster	0.06471
	Okehampton	0.04696
	Porto	0.0017

Table 8.8-10: PEC$_{gw}$ for Clopyralid and metabolite(s) on winter cereals (with FOCUS PEARL 5.5.5) – TIER 1 every other year(PUF=0)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Winter cereals	Châteaudun	0.0014
	Hamburg	0.0715
	Jokioinen	0.0572

	Kremsmünster	0.0419
	Okehampton	0.0536
	Piacenza	0.0268
	Porto	0.0087
	Sevilla	<0.0001
	Thiva	<0.0001

Table 8.8-11: PEC$_{gw}$ for Clopyralid and metabolite(s) on winter cereals (with FOCUS PEARL 5.5.5) – TIER 2 every year (PUF=0.0002711)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Winter cereals	Châteaudun	0.0031
	Hamburg	0.0752
	Jokioinen	0.1462
	Kremsmünster	0.0758
	Okehampton	0.1013
	Piacenza	0.0205
	Porto	0.0024
	Sevilla	<0.0001
	Thiva	<0.0001

Table 8.8-12: PEC$_{gw}$ for Clopyralid and metabolite(s) on winter cereals (with FOCUS PEARL 5.5.5) – TIER 3 every year (PUF=0.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Winter cereals	Châteaudun	0.0019
	Hamburg	0.0473
	Jokioinen	0.0716
	Kremsmünster	0.0521
	Okehampton	0.0587
	Piacenza	0.0164
	Porto	0.0018
	Sevilla	<0.0001
	Thiva	<0.0001

Table 8.8-13: PEC$_{gw}$ for Clopyralid and metabolite(s) on winter cereals (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Winter cereals	Châteaudun	0.002
	Hamburg	0.015
	Jokioinen	**1.031**
	Kremsmünster	0.051
	Okehampton	0.184
	Piacenza	0.007
	Porto	0.002
	Sevilla	<0.001
	Thiva	<0.001

Table 8.8-14: PEC$_{gw}$ for Clopyralid and metabolite(s) on spring cereals (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Spring cereals	Châteaudun	0.001
	Hamburg	0.018
	Jokioinen	0.197
	Kremsmünster	0.054
	Okehampton	0.065
	Porto	0.015

Table 8.8-15: PEC$_{gw}$ for Clopyralid and metabolite(s) on winter cereals (with FOCUS PELMO 6.6.4) - TIER 1 every other year (PUF=0)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Winter cereals	Châteaudun	0.001
	Hamburg	0.009
	Jokioinen	0.489
	Kremsmünster	0.023
	Okehampton	0.089

	Piacenza	0.003
	Porto	0.001
	Sevilla	<0.001
	Thiva	<0.001

Table 8.8-16: PEC$_{gw}$ for Clopyralid and metabolite(s) on winter cereals (with FOCUS PELMO 6.6.4) - TIER 2 every year (PUF=0.0002711)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Winter cereals	Châteaudun	0.002
	Hamburg	0.015
	Jokioinen	**1.031**
	Kremsmünster	0.051
	Okehampton	0.184
	Piacenza	0.007
	Porto	0.002
	Sevilla	<0.001
	Thiva	<0.001

Table 8.8-17: PEC$_{gw}$ for Clopyralid and metabolite(s) on winter cereals (with FOCUS PELMO 6.6.4) – TIER 3 every year (PUF=0.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Clopyralid
Winter cereals	Châteaudun	0.001
	Hamburg	0.004
	Jokioinen	**0.810**
	Kremsmünster	0.025
	Okehampton	0.074
	Piacenza	0.006
	Porto	0.001
	Sevilla	<0.001
	Thiva	<0.001

8.8.2.3 Fluroxypyr and its metabolites

Table 8.8-18: Input parameters related to active substance Fluroxypyr and metabolite(s) for PEC_{gw} calculations

Compound	Fluroxypyr acid	Pyridinol (DCP)	Methoxypyridine (DMP)	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	255	197	211	Fluroxypyr – Volume 3 – Confirmatory Information December 2014
Water solubility (mg/L):	91	91	91	Fluroxypyr – Volume 3 – Confirmatory Information December 2014
Saturated vapour pressure (Pa):	3.78E-09	3.78E-09	3.78E-09	Fluroxypyr – Volume 3 – Confirmatory Information December 2014
DT_{50} in soil (d)	13.9	17.6	111.14	Fluroxypyr – Volume 3 – Confirmatory Information December 2014
Formation fraction	-	0.286 from fluroxypyr 0.723 from DMP	0.201 from fluroxypyr	Fluroxypyr – Volume 3 – Confirmatory Information December 2014
K_{foc} (mL/g)/K_{fom}	68	708 for acidic/neutral coils 68.8 for alkalaine soils	321	Fluroxypyr – Volume 3 – Confirmatory Information December 2014
1/n	0.92	0.81 for acidic/neutral soils 0.72 for alkaline soils	0.84	Fluroxypyr – Volume 3 – Confirmatory Information December 2014
Plant uptake factor	0	0	0	

* Inputs used for Chateaudun, Kremsmunster, Piacenza, Sevilla and Thivia

Table 8.8-19: PEC_{gw} for Fluroxypyr and metabolite(s) on winter cereals (with FOCUS PEARL 5.5.5) – acidic/neutral soils

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Fluroxypyr	DCP	DMP
Winter cereals	Châteaudun	<0.0001	<0.0001	<0.0001
	Hamburg	0.0004	<0.0001	0.0001
	Jokioinen	<0.0001	<0.0001	<0.0001
	Kremsmünster	0.0004	<0.0001	<0.0001
	Okehampton	0.0012	<0.0001	0.0002
	Piacenza	0.0002	<0.0001	<0.0001

	Porto	<0.0001	<0.0001	<0.0001
	Sevilla	<0.0001	<0.0001	<0.0001
	Thiva	<0.0001	<0.0001	<0.0001

Table 8.8-20: PEC$_{gw}$ for Fluroxypyr and metabolite(s) on winter cereals (with FOCUS PEARL 5.5.5) – alkaline soils

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Fluroxypyr	DCP	DMP
Winter cereals	Châteaudun	<0.0001	<0.0001	<0.0001
	Hamburg	0.0004	<0.0001	0.0001
	Jokioinen	<0.0001	<0.0001	<0.0001
	Kremsmünster	0.0004	<0.0001	<0.0001
	Okehampton	0.0012	<0.0001	0.0002
	Piacenza	0.0002	<0.0001	<0.0001
	Porto	<0.0001	<0.0001	<0.0001
	Sevilla	<0.0001	<0.0001	<0.0001
	Thiva	<0.0001	<0.0001	<0.0001

Table 8.8-21: PEC$_{gw}$ for Fluroxypyr and metabolite(s) on winter cereals (with FOCUS PELMO 6.6.4) – acidic/neutral soils

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Fluroxypyr	DCP	DMP
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 8.8-22: PEC$_{gw}$ for Fluroxypyr and metabolite(s) on winter cereals (with FOCUS PELMO 6.6.4) – alkaline soils

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Fluroxypyr	DCP	DMP
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 8.8-23: PEC$_{gw}$ for Fluroxypyr and metabolite(s) on spring cereals (with FOCUS PEARL 5.5.5) – acidic/neutral soils

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Fluroxypyr	DCP	DMP
Spring cereals	Châteaudun	<0.0001	<0.0001	<0.0001
	Hamburg	0.0005	<0.0001	0.0001
	Jokioinen	<0.0001	<0.0001	<0.0001
	Kremsmünster	0.0004	<0.0001	<0.0001
	Okehampton	0.0007	<0.0001	0.0001
	Porto	<0.0001	<0.0001	<0.0001

Table 8.8-24: PEC$_{gw}$ for Fluroxypyr and metabolite(s) on spring cereals (with FOCUS PEARL 5.5.5) – alkaline soils

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Fluroxypyr	DCP	DMP
Spring cereals	Châteaudun	<0.0001	<0.0001	<0.0001
	Hamburg	0.0005	<0.0001	0.0001
	Jokioinen	<0.0001	<0.0001	<0.0001
	Kremsmünster	0.0004	<0.0001	<0.0001
	Okehampton	0.0007	<0.0001	0.0001
	Porto	<0.0001	<0.0001	<0.0001

Table 8.8-25: PEC$_{gw}$ for Fluroxypyr and metabolite(s) on spring cereals (with FOCUS PELMO 6.6.4) – acidic/neutral soils

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Fluroxypyr	DCP	DMP
Spring 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
	Porto	<0.001	<0.001	<0.001

Table 8.8-26: PEC$_{gw}$ for Fluroxypyr and metabolite(s) on spring cereals (with FOCUS PELMO 6.6.4) – alkaline soils

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Fluroxypyr	DCP	DMP
Spring 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
	Porto	<0.001	<0.001	<0.001

zRMS comments:

Clopyralid
The calculations of PECgw submitted by Applicant have been accepted.
PECgw values were calculated for clopyralid and its metabolites for proposed uses in GAP.
All input parameters for clopyralid and its metabolites were considered acceptable as they followed the LoEP EFSA Journal 2018;16(7):5389).
Calculations were performed using new version the standard FOCUS procedures. Calculations were performed using new version the standard FOCUS PEARL v5.5.5 and FOCUS PELMO v6.6.4 models.
The calculation were performed on winter cereals and recommended by GAP on spring cereals for BBCH 21-33:
on TIER 1 with PUF=0
on TIER 1 every other year with PUF=0
on TIER 2 every year with PUF=0.0002711
on TIER 3 every year with PUF=0.

Fluroxypyr
PECgw values were calculated for fluroxypyr and its metabolites for application proposed in GAP.

All input parameters were considered acceptable as they followed the EFSA Journal 2011;9(3):2091 and Addendum: Confirmatory Information December 2014.
Calculations were performed using new version the standard FOCUS PEARL v5.5.5 and FOCUS PELMO v6.6.4models.
The presented above results of the model calculations demonstrate that neither fluroxypyr nor its metabolites were presented in the leachate in amounts ≥ 0.1 µg/L, for any of the combinations of FOCUS Scenario. It can be therefore stated that neither fluroxypyr nor its major soil metabolites, pose a serious threat to the groundwater compartment, when fluroxypyr is used according to the GAP.
PECgw values were calculated for application proposed in GAP.
All input parameters were considered acceptable in line the EFSA Journal 2011;9(3):2091 and Addendum: Confirmatory Information December 2014.

Florasulam
Calculations of PECgw for active substance and its metabolites were accepted.
The endpoints agreed at the EU level (EFSA Journal 2015; 13(1):3984) were used in modeling.
Relevant active substance metabolites were considered too.
Calculations of PECgw for active substance were accepted. The recommended FOCUS models were used: FOCUS PEARL v5.5.5 and FOCUS PELMO v6.6.4 models.
The maximum PECgw for active substance is below the trigger value 0.1 µg/L for proposed patter use in spring cereals. Relevant active substance metabolites were considered too.

According to PECgw modelling with FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 a ground water contamination of the active substances florasulam, clopyralid, fluroxypyr at a concentration of ≥ 0.1 µg/L is not expected in use on winter/spring cereals for all scenarios, except Jokioinen for use of clopyralid.
For the metabolites a groundwater concentration of ≥ 0.1 µg/L cannot be excluded. However, the risk assessment for metabolites was performed in B-10 section and concluded that there is no risk to consumer.

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

8.9.1 Justification for new endpoints

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- Florasulam - EFSA Journal 2015; 13(1):3984
- Clopyralid - EFSA Journal 2018;16(7):5389,
- Fluroxypyr – EFSA Journal 2011;9(3):2091

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	CHR/H/CFF 250 EC SC
Use No.	1
Crop	Winter cereals/Spring cereals
Application rate (kg as/ha)	Florasulam: 0.005 Dilfufenican: 0.06 Fluroxypyr:0.06 (Fluroxypyr-MHE: 0.0864)

Number of applications/interval (d)	1/-
Application window	September - Febuary
Application method	annual
CAM (Chemical application method)	
Soil depth (cm)	
Models used for calculation	FOCUS SWASH v3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1

8.9.2.1 Florasulam and its metabolites

Table 8.9-2: Input parameters related to active substance Florasulam and metabolite(s) for PEC$_{sw/sed}$ calculations STEP 1/2 and 3(/4

Com-pound	Florasu-lam	5-OH Florasu-lam	DFP-ASTCA	ASTCA	TSA	TPSA	ASTP	5-OH ASTP	Value in accord-ance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	359.3	345.26	304.20	192.13	148.14	248.17	247.20	233.18	EFSA Journal 2015; 13(1):3984
Saturated vapour pressure (Pa)	1.0 E-6 Pa at 20°C	2.7 E-6 Pa at 20°C	3.0 E-6 Pa at 20°C	2.0 E-6 Pa at 20°C	1.0 E-4 Pa at 20°C	3.0 E-4 Pa at 20°C	1.0 E-8 Pa at 20°C	6.0 E-4 Pa at 20°C	EFSA Journal 2015; 13(1):3984
Water solubility (mg/L)	6360	354	87400	250000	10900	6360	6360	6360	EFSA Journal 2015; 13(1):3984
Diffusion coefficient in water (m²/d)	not required for Step 1+2/ 4.3 x 10^{-5}	not required for Step 1+2/ 4.3 x 10-5	not required for Step 1+2/ 4.3 x 10^{-5}	not required for Step 1+2/ 4.3 x 10-5	not required for Step 1+2/ 4.3 x 10-5	not required for Step 1+2/ 4.3 x 10-5	not required for Step 1+2/ 4.3 x 10-5	not required for Step 1+2/ 4.3 x 10-5	default
Diffusion coefficient in air (m²/d)	not required for Step 1+2/0.43	not required for Step 1+2/0.43	not required for Step 1+2/0.43	not required for Step 1+2/0.43	not required for Step 1+2/0.43	not required for Step 1+2/0.43	not required for Step 1+2/0.43	not required for Step 1+2/0.43	default
K_{foc} (mL/g)	10.53	14.53	78.15	104.81	23.46	41.52	60.22	77.74	EFSA Journal 2015; 13(1):3984
Freundlich Exponent 1/n	0.945	0.91	0.85	0.94	0.94	n.d.	n.d.	n.d.	EFSA Journal 2015; 13(1):3984

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA	TPSA	ASTP	5-OH ASTP	Value in accordance to EU endpoint y/n/ Reference
Plant Uptake	0	0	0	0	0	0	0	0	EFSA Journal 2015; 13(1):3984
Wash-Off factor from Winter cereals (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	EFSA Journal 2015; 13(1):3984
$DT_{50,soil}$ (d)	1.55	14.98	16.62	297.47	83.74	365	365	365	EFSA Journal 2015; 13(1):3984
$DT_{50,water}$ (d)	15.03	1000	1000	1000	1000	1000	1000	1000	EFSA Journal 2015; 13(1):3984
$DT_{50,sed}$ (d)	15.03	1000	1000	1000	1000	1000	1000	1000	EFSA Journal 2015; 13(1):3984
$DT_{50,whole\ system}$ (d)	15.03	1000	1000	1000	1000	1000	1000	1000	EFSA Journal 2015; 13(1):3984
Maximum occurrence observed (% molar basis with respect to the parent)	-	Total Water and Sediment: 99 Soil:71.6	Total Water and Sediment: 8.9 Soil: 17.8	Total Water and Sediment: 53.8 Soil: 40	Total Water and Sediment: 0.0001 Soil: 15.9	Total Water and Sediment: 58 Soil: 0.0001	Total Water and Sediment: 21 Soil: 0.0001	Total Water and Sediment: 29 Soil: 0.0001	EFSA Journal 2015; 13(1):3984
Formation fraction in soil:	-	0.854 from florasulam	1.00 from 5-OH florasulam	0.781 from DFP-ASTCA	0.219 from DFP-ASTCA 1.000 from ASTCA	n.d.	n.d.	n.d.	EFSA Journal 2015; 13(1):3984

$PEC_{sw/sed}$

Table 8.9-3: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Florasulam following single/ multiple application(s) of CHR/H/CFF 250 EC SC 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	---	1.69	drainage/run off	1.08	0.17
Step 2					
Northern Europe	March-May	0.09	drainage/run off	0.06	0.01

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-4: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Florasulam following single/ multiple application(s) of CHR/H/CFF 250 EC SC to spring 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	---	1.69	drainage/run off	1.08	0.17
Step 2					
Northern Europe	March-May	0.09	drainage/run off	0.06	0.01

* single applications should be marked.
** twa-time as required by ecotox

Metabolite(s) of Florasulam

Table 8.9-5: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for 5-OH florasulam, DFP-ASTCA, ASTCA, TSA, TPSA, ASTP and 5-OH ASTP following single application to Winter cereals

Scenario FOCUS	Metabolite	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	5-OH Florasulam	---	2.72	drainage/run off	2.70	0.40
Step 2		---		-		
Northern Europe		March-May	0.28	drainage/run off	0.28	0.04
Southern Europe		-	-	-	-	-
Step 1	DFP-ASTCA	---	0.34	drainage/run off	0.34	0.27
Step 2		---		-		

Scenario FOCUS	Metabolite	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Northern Europe		March-May	0.05	drainage/run off	0.05	0.04
Southern Europe		-	-	-	-	-
Step 1	ASTCA	---	0.75	drainage/run off	0.74	0.78
Step 2		---		-		
Northern Europe		March-May	0.09	drainage/run off	0.09	0.09
Southern Europe		-	-	-	-	-
Step 1	TSA	---	0.11	drainage/run off	0.11	0.02
Step 2		---		-		
Northern Europe		March-May	0.02	drainage/run off	0.02	0.00
Southern Europe		-	-	-	-	-
Step 1	TPSA	---	0.65	drainage/run off	0.65	0.27
Step 2		---		-		
Northern Europe		March-May	0.04	drainage/run off	0.04	0.02
Southern Europe		-	-	-	-	-
Step 1	ASTP	---	0.23	drainage/run off	0.23	0.14
Step 2		---		-		
Northern Europe		March-May	0.01	drainage/run off	0.01	0.01
Southern Europe		-	-	-	-	-
Step 1	5-OH ASTP	---	0.29	drainage/run off	0.29	0.23
Step 2		---		-		
Northern Europe		March-May	0.02	drainage/run off	0.02	0.01
Southern Europe		-	-	-	-	-

Table 8.9-6: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for 5-OH florasulam, DFP-ASTCA, ASTCA, TSA, TPSA, ASTP and 5-OH ASTP following single application to spring cereals

Scenario FOCUS	Metabolite	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	5-OH Florasulam	---	2.72	drainage/run off	2.70	0.40
Step 2		---		-		
Northern Europe		March-May	0.28	drainage/run off	0.28	0.04
Southern Europe		-	-	-	-	-
Step 1	DFP-ASTCA	---	0.34	drainage/run off	0.34	0.27
Step 2		---		-		
Northern Europe		March-May	0.05	drainage/run off	0.05	0.04
Southern Europe		-	-	-	-	-
Step 1	ASTCA	---	0.75	drainage/run off	0.74	0.78
Step 2		---		-		
Northern Europe		March-May	0.09	drainage/run off	0.09	0.09
Southern Europe		-	-	-	-	-
Step 1	TSA	---	0.11	drainage/run off	0.11	0.02
Step 2		---		-		
Northern Europe		March-May	0.02	drainage/run off	0.02	0.00
Southern Europe		-	-	-	-	-
Step 1	TPSA	---	0.65	drainage/run off	0.65	0.27
Step 2		---		-		
Northern Europe		March-May	0.04	drainage/run off	0.04	0.02
Southern Europe		-	-	-	-	-
Step 1	ASTP	---	0.23	drainage/run off	0.23	0.14
Step 2		---		-		
Northern Europe		March-May	0.01	drainage/run off	0.01	0.01
Southern Europe		-	-	-	-	-
Step 1	5-OH ASTP	---	0.29	drainage/run off	0.29	0.23

Scenario FOCUS	**Metabolite**	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominat entry route**	**21 d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 2		---		-		
Northern Europe		March-May	0.02	drainage/run off	0.02	0.01
Southern Europe		-	-	-	-	-

8.9.2.2 Clopyralid and its metabolites

Table 8.9-7: Input parameters related to Clopyralid and metabolite(s) for $PEC_{sw/sed}$ calculations STEP 1/2

Compound	**Clopyralid**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	191.96	EFSA Journal 2018;16(7):5389
Saturated vapour pressure (Pa)	1.36 × 10-3 Pa at 20°C	EFSA Journal 2018;16(7):5389
Water solubility (mg/L)	1.43 × 105	EFSA Journal 2018;16(7):5389
Diffusion coefficient in water (m²/d)	not required for Step 1+2	default
Diffusion coefficient in air (m²/d)	not required for Step 1+2	default
K_{foc} (mL/g)	1.41	EFSA Journal 2018;16(7):5389
Freundlich Exponent 1/n	0.836	EFSA Journal 2018;16(7):5389
Plant Uptake	0	EFSA Journal 2018;16(7):5389
$DT_{50,soil}$ (d)	7.05	EFSA Journal 2018;16(7):5389
$DT_{50,water}$ (d)	1000	EFSA Journal 2018;16(7):5389
$DT_{50,sed}$ (d)	1000	EFSA Journal 2018;16(7):5389
$DT_{50,whole\ system}$ (d)	1000	EFSA Journal 2018;16(7):5389
Maximum occurrence observed (% molar basis with respect to the parent)	-	-
Formation fraction in soil:	-	-

$PEC_{sw/sed}$

Table 8.9-8: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Clopyralid following single/ multiple application(s) of CHR/H/CFF 250 EC SC 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	---	20.51	Drainage/run off	20.36	0.29
Step 2					
Northern Europe	March-May	3.24	Drainage/run off	3.22	0.05

Table 8.9-9: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Clopyralid following single/ multiple application(s) of CHR/H/CFF 250 EC SC to spring 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	---	20.51	Drainage/run off	20.36	0.29
Step 2					
Northern Europe	March-May	3.24	Drainage/run off	3.22	0.05

8.9.2.3 Fluroxypyr and its metabolites

Table 8.9-10: Input parameters related to active substance Fluroxypyr and metabolite(s) for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4

Compound	Fluroxypyr-MHE	Fluroxypyr acid	DCP	DMP	**3-CP**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	367.3	255	197	211	162	EFSA Journal 2011;9(3):2091 (2003).
Saturated vapour pressure (Pa)	1.349E-06	3.78E-09	3.78E-09	3.78E-09	3.78E-09	EFSA Journal 2011;9(3):2091 (2003).
Diffusion coefficient in water (m²/d)	not required for Step 1+2	not required for Step 1+2/	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
Diffusion coefficient in air (m²/d)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default

Compound	Fluroxypyr-MHE	Fluroxypyr acid	DCP	DMP	3-CP	Value in accordance to EU endpoint y/n/ Reference
Water solubility (mg/L)	0.009	91	91	91	91	EFSA Journal 2011;9(3):2091 (2003).
KOC	19550	68	708 for acidic/neutral soils 68.5 for alkaline soils	321.4	0	EFSA Journal 2011;9(3):2091 (2003).
Plant Uptake	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/	not required for Step 1+2/	not required for Step 1+2/	not required for Step 1+2	default
$DT_{50,soil}$ (d)	0.7	13.9	17.6	111.11	0.001 (worst case)	EFSA Journal 2011;9(3):2091 (2003).
$DT_{50,water}$ (d)	38.1	38.1	35.5	1000	1000	EFSA Journal 2011;9(3):2091 (2003).
$DT_{50,sed}$ (d)	38.1	1000	1000 d	1000 d	1000	
$DT_{50,whole\ system}$ (d)	38.1	38.1	35.5d	1000 d	1000	
Maximum occurrence observed (% molar basis with respect to the parent)	-	-	Maximum occurrence observed in soil: 23.9% Max 55.5 % in water	Maximum occurrence observed in soil: 38.2 % Max 0.0001% in water	Maximum occurrence observed in soil: 0.00001 % Max 24.4% in water	EFSA Journal 2011;9(3):2091 (2003).

$PEC_{sw/sed}$

Table 8.9-11: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Fluroxypyr-MHE following single/ multiple application(s) of CHR/H/CFF 250 EC SC 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	---	1.86	Drainage/runoff	0.93	209.91
Step 2					
Northern Europe	March- May	0.79	Drainage/runoff	0.06	6.02

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-12: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Fluroxypyr acid following single/ multiple application(s) of CHR/H/CFF 250 EC SC 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	---	18.89	Drainage/runoff	15.66	12.58
Step 2					
Northern Europe	March- May	3.49	Drainage/runoff	2.93	2.36

Table 8.9-13: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Fluroxypyr-MHE following single/ multiple application(s) of CHR/H/CFF 250 EC SC to spring 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	---	1.86	Drainage/runoff	0.93	209.91
Step 2					
Northern Europe	March- May	0.79	Drainage/runoff	0.06	6.02

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-14: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Fluroxypyr acid following single/ multiple application(s) of CHR/H/CFF 250 EC SC to spring 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	---	18.89	Drainage/runoff	15.66	12.58
Step 2					
Northern Europe	March- May	3.49	Drainage/runoff	2.93	2.36

Metabolite(s) of Fluroxypyr

Table 8.9-15: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for Pyridinol following single application(s) to winter cereals in acid/neutral soils

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	6.55	Drainage/runoff	5.28	44.68

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 2					
Northern Europe	March- May	1.18	Drainage/run off	104	8.23

Table 8.9-16: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for Pyridinol following single application(s) to winter cereals in alkaline soils

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	11.48	Drainage/runoff	9.40	7.70
Step 2					
Northern Europe	March- May	2.07	Drainage/run off	1.72	1.41

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-17: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for Methoxypyridine following single application(s) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	4.43	Drainage/runoff	4.39	14.22
Step 2					
Northern Europe	March- May	0.86	Drainage/run off	0.86	2.77

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-18: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for 3-CP acid following single application(s) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	3.19	Drainage/runoff	3.16	0.00
Step 2					
Northern Europe	March- May	0.59	Drainage/run off	0.59	0.00

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-19: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for Pyridinol following single application(s) to spring cereals in acid/neutral soils

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	6.55	Drainage/runoff	5.28	44.68
Step 2					
Northern Europe	March- May	1.18	Drainage/run off	104	8.23

Table 8.9-20: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for Pyridinol following single application(s) to spring cereals in alkaline soils

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	11.48	Drainage/runoff	9.40	7.70
Step 2					
Northern Europe	March- May	2.07	Drainage/run off	1.72	1.41

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-21: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for Methoxypyridine following single application(s) to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	4.43	Drainage/runoff	4.39	14.22
Step 2					
Northern Europe	March- May	0.86	Drainage/run off	0.86	2.77

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-22: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for 3-CP acid following single application(s) to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	3.19	Drainage/runoff	3.16	0.00

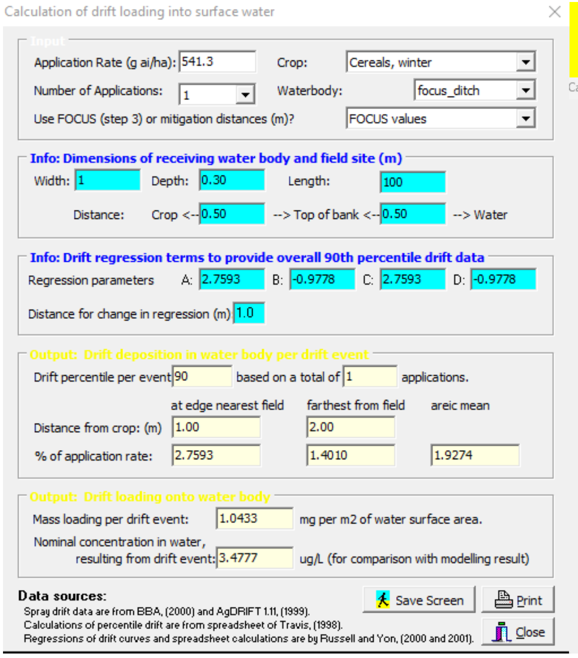
Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominat entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 2					
Northern Europe	March- May	0.59	Drainage/run off	0.59	0.00

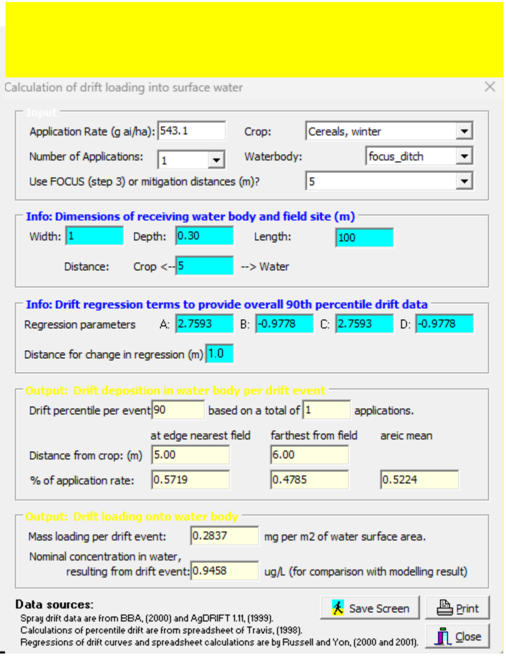
* single applications should be marked.
** twa-time as required by ecotox

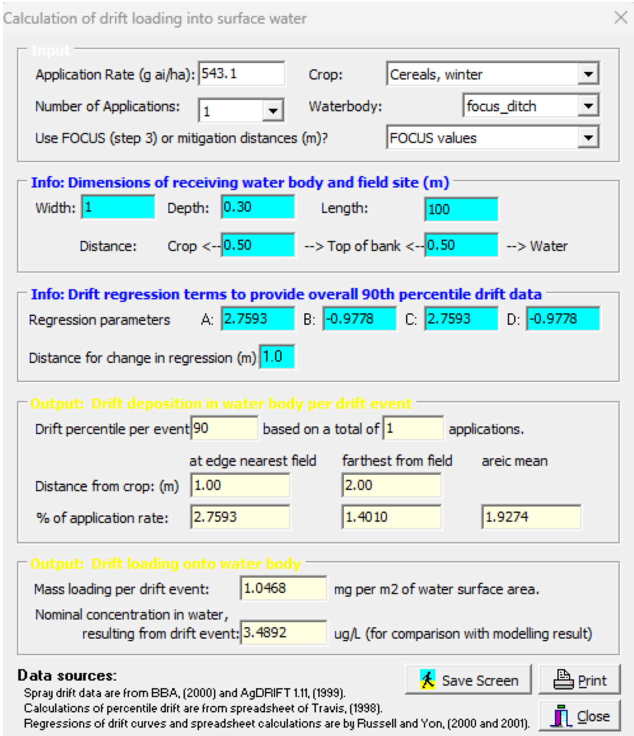
8.9.2.4 PEC$_{sw/sed}$ of CHR/H/CFF 250 EC SC

Table 8.9-23: PEC$_{sw}$ of CHR/H/CFF 250 EC SC assuming application 543.1 g prod/ha (0.5L on winter cereals) in Drift calculator into surface water from SWASH ver 5.3

Intended use	Winter cereals
Formulation	CHR/H/CFF 250 EC
Application rate (g[prod]/ha)	1 X 543.1 g
Entry into surface water via spraydrift (Drift alculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L**
1	~~3.4777~~ 3.4892
5	0.9458







ZRMS comments:

The calculations of PECsw/sed submitted by Applicant for active substances florasulam, clopyralid, fluroxypyr have been accepted. All input parameters for active substances florasulam, clopyralid, fluroxypyr and their metabolites and formulation. are considered acceptable.
PECsw values were calculated in Step 1 and 2 and Step 3 and Step 4 for active substances.
PECsw values for active substance metabolites were calculated in Step 1 and 2 and for proposed uses in GAP.

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Florasulam
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Not determined
Photochemical oxidative degradation in air	DT50 of 1.706 days hours derived by the Atkinson model (version 1.92). OH (12-h) concentration assumed = 1.6 E-6
Volatilisation	from plant surfaces (BBA guideline): 1.7 % after 24 hours from soil surfaces (BBA guideline): negligible after 24 hours
Metabolites	Not examined

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

Table 8.10-2 Summary of atmospheric degradation and behaviour for Clopyralid (EFSA Journal 2018;16(7):5389)

Compound	Clopyralid
Direct photolysis in air	No data submitted nor required
Quantum yield of direct phototransformation	Not determined
Photochemical oxidative degradation in air	Atkinson calculation using AOPWIN v.1.90 DT50 = 19.5 days (Madsen 2002)
Volatilisation	BBA guideline: from plant surfaces: ≤4 % in 24 hours (Day & Rudel 1994) BBA guideline: from soil: <2 % in 24 hours (Day & Rudel 1994)
Metabolites	Not examined

The vapour pressure at 20 °C of the Clopyralid is 1.36 × 10-3 Pa. Clopyralid is regarded as low-volatile (volatilisation from soil and from plant surface). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the Clopyralid due to volatilization with subsequent deposition is not considered.

Table 8.10-3 Summary of atmospheric degradation and behaviour

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	active substance: not applicable as for λ ≥ 290 nm ε < 10 $L \cdot mol^{-1} \cdot cm^{-1}$ (the substance does not absorb in the near UV-VIS region of spectrum).
Photochemical oxidative degradation in air ‡	Fluroxypyr MHE: DT_{50} = 9.82 h. derived by the Atkinson model (version 1.70). OH (24 h) concentration assumed = 5.0E5 rad/cm^3 Fluroxypyr acid: DT_{50} = 13.35 h. derived by the Atkinson model (version 1.70). OH (24 h) concentration assumed = 5.0E5 rad/cm^3
Volatilisation ‡	from plant surfaces (BBA guideline): not examined due to low volatility of Fluroxypyr
	from soil surfaces (BBA guideline): not examined due to low volatility of Fluroxypyr
Metabolites	None

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

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
KCP 9.1.1	Jackson R., Ghosh D.,	1997	The Aerobic Degradation of XDE-570 in Soil.; Report No. GHE-P-4710; DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1	Jackson R., Massart J.,	1998	The degradation of DFP-ASTCA and ASTCA (two metabolites of DE-570) in Soil. Report No. GHE-P-7522; Dow AgroSciences, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Cleveland C. B., Sanders L. T., Gilbert J. R.,	1997	Anaerobic Aquatic Metabolism Study of XDE-570. Study report No. ENV95137; North American Environmental Chemistry Laboratory GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Krieger M. S., Yoder R. N.,	1996	Photolysis of XDE-570 on Soil Study report No. ENV95083; Global Environmental Chemistry Laboratory – Indianapolis Lab GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Pillar F.,	1997	Effects of temperature on the degradation of DE-570 in soil. Study report No. GHE-P-6749; DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Pillar F.,	1997	Effects of moisture on the degradation of DE-570 in soil Study report No. GHE-P-6750; DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Jackson R.,	2010	Re-evaluation of the Degradation Kinetics of Florasulam and its Major Metabolites in European Soils According to Focus Guidance Report No GHE-P-12511 Dow AgroSciences, European Development Centre GLP No	N	DowAgroSciences

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
			Unpublished		
KCP 9.1.1	Simmonds R.,	2012	[14C]-TSA: Rate of Degradation in Four Soils at 20°C Study report No. YR/11/010; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Germany, 1995 – 1996. Study report No. GHE-P-6366 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Northern France - 1995. Study report No. GHE-P-6367 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, UK – 1996 Study report No. GHE-P-6368 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Southern France – 1996 Study report No. GHE-P-6369 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Greece – 1996 Study report No. GHE-P-6370 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, UK – 1995 Study report No. GHE-P-6781 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.1	Gambie A.,	1997	Residues of DE-570 and its 5-hydroxy metabolite in soil at normal harvest following application of EF-1343 to wheat and barley – Europe: 1995-1996 Study report No. GHE-P-6833 Dow Elanco Europe, Letcombe Regis GLP No Unpublished	N	DowAgroSciences
KCP 9.1.1	Ostrander J. A.	1996	Mobility Studies of XDE-570 and 5-hydroxy-XDE 570 Study report No. GH-C-3868 (study ID: ENV95020) North American Environmental Chemistry Laboratory GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.2	Simmonds R.	2011	Florasulam: Adsorption and Desorption Properties of [14C]-Florasulam in Eight Soils Study report No. YR/11/005 Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.2	Simmonds R.	2011	Florasulam: Adsorption Properties of [14C]-5-hydroxyflorasulam in Four Soils Study report No. YR/11/006	N	DowAgroSciences

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
			Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished		
KCP 9.1.2	Burgess M., Simmonds R.,	2011	Florasulam: Adsorption Properties of [14C]-DFP-ASTCA in Four Soils Study report No. YR/11/009 Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.2	Burgess M., Simmonds R.,	2011	Florasulam: Adsorption Properties of [14C]-ASTCA in Four Soils Study report No. YR/11/008; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.2	Burgess M., Simmonds R.,	2011	Florasulam: Adsorption Properties of [14C]-TSA in Four Soils Study report No. YR/11/007; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	DowAgroSciences
KCP 9.1.2	Pillar F.	1997	The non-aged column leaching of DE-570 Study report No. GHE-P-6785 DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP No Unpublished	N	DowAgroSciences
KCP 9.1.2	Jackson R., Paterson G.,	1997	The dissipation of XDE-570 in soil and crops using field lysimeters Study report No. GHE-P-6751 DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences
KCP 9.2	Jackson R., Portwood	1993	The Aqueous Hydrolysis of XR-570	N	DowAgroScience

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
	D.,		Study report No. GHE-P-3326 DowElanco Limited, Letcombe Laboratory, Letcombe Regis GLP No Unpublished		s
KCP 9.2	Phillips M.,	1996	The determination of the hydrolytic stability of radiolabelled XDE-570 Study report No. GHE-P-4986 (Inveresk Project No. 386209) Inveresk Research International Ltd. GLP Yes Unpublished	N	DowAgroSciences
KCP 9.2	Yoder R. N.	1996	Aqueous Photolysis of XDE-570 in Natural Sunlight Study report No. GH-C 3951 (study ID: ENV95023) DowElanco, North American Environmental Chemistry Laboratory GLP Yes Unpublished	N	DowAgroSciences
KCP 9.2	Yoder R. N., Balcer J. L.	2002	Aqueous Photolysis of Florasulam in pH5 Buffer under Xenon Light Study report No. GH-C 5399; Regulatory Laboratories – Indianapolis Lab, Dow AgroSciences LLC GLP Yes Unpublished	N	DowAgroSciences
KCP 9.2	Byrne S. L., Crabtree A. B., Balcer J. L., Linder S. J.	2005	Aqueous Photolysis of Florasulam in Natural Water Using a Xenon Lamp Study report No. 050024 Regulatory Laboratories – Indianapolis Lab GLP Yes Unpublished	N	DowAgroSciences
KCP 9.2	Gibson R., Portwood D.	1999	Investigation of the degradation of DE-570 in natural water Study report No. GHE-P-7468 Dow AgroSciences, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	DowAgroSciences

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	Jenkins W. R.	1994	XDE 570 (PURE): Assessment of Ready Biodegradability. Modified Sturm Test.; Study report No. GHE-P-3736 (Pharmaco study report No.: 94/DES180/0468) Pharmaco LSR Lts GLP Yes Unpublished	N	DowAgroSciences
KCP 9.2	Jenkins W. R.	1995	XDE 570 5-Hydroxy6 metabolite: Assessment of Ready Biodegradability. Modified Sturm Test Study report No. GHE-P-4552 (Pharmaco study report No.: 95/DES284/0692) Pharmaco LSR Lts GLP Yes Unpublished	N	DowAgroSciences
KCP 9.2	Phillips M.	1997	The aerobic degradation of XDE-570 in natural waters and associated sediments Study report No. GHE-P-5039 (Inveresk Project No. 12712) Inveresk Research International Ltd. GLP Yes Unpublished	N	DowAgroSciences
KCP 9.2	Lewis C., Gilbert J.,	2011	[14C]-Florasulam: Degradation in Water-Sediment Systems under Aerobic Conditions Study report No. 1000576 (Covance Study No. 8235547) Covance Laboratories Ltd GLP Yes Unpublished	N	DowAgroSciences
KCP 9.3	Knoch E.,	1997	Investigation of the Volatilization of DE-570 formulated as 50 g a. s./L SC from soil and Dwarf Runner Bean Study report No. GHE-P-6747 (Fresenius Institut Study No. IF 97/07970-00) Institut Fresenius, Chemische und Biologische Laboratorien GmbH GLP Yes Unpublished	N	DowAgroSciences
KCP 9.3	Mattock S. D.	2011	Florasulam – literature search for toxicology, environmental fate and ecotoxicology in support of Annex I renewal Study report No. GHE-P-12699 (Project number 4-16-6) TGSA Concordia House, St James Business Park	N	DowAgroSciences

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
			GLP No Unpublished		
KCP 9.1.1	Baloch, R.;Grant, R.	1991	Degradation and metabolism of Clopyralid in Soil under Aerobic Conditions DAS Report No.GHE-P-2398R Agricultural Research and Development Center, DowElanco Limited, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, U.K. GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.1	Skinner, W.; Jao, N.; Smith, J. K.	1995	Aerobic Soil Metabolism of [14C]Clopyralid DAS Report No.GHE-C-3598 PTRL West, Inc. 4123-B Lakeside Drive, Richmond, CA 94806 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.1	Wardrope, L.	2009	The Degradation of (14C)-Clopyralid in Soil Under Aerobic Conditions DAS Report No.808711 Charles River Laboratories, Tranent, East Lothian, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.1	Allan, J.; Lowrie, C. ; Hall, B. E.	2002	The Degradation of C14 Clopyralid in Soil Under Anaerobic Conditions DAS Report No.GHE-P-9563 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.1	Schubert, S.	2015	Evaluation of kinetic endpoints for clopyralid from laboratory soil degradation studies DAS Report No. 151039 Dow AgroSciences, Milton Park, UK GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Rawle, N.; Yon, D.	2002	The dissipation of clopyralid in soil following a single application of LONTREL (EF-1136),	N	DAS

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
			Denmark and the UK – 2000 DAS Report No. GHE-P-9370 CEMAS GLP/GEP (Y/N): Yes Published (Y/N): No		
KCP 9.1.2	Rawle, N.; Yon, D.	2002	The dissipation of clopyralid in soil following a single application of LONTREL (EF-1136), Germany and Northern France – 2000 DAS Report No. GHE-P-9371 CEMAS GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Kröger, F.	2015	Soil dissipation study with one spring application of GF-1966 (Clopyralid) at three sites to bare soil in Europe in 2013-2015 Eurofins Agroscience Services, Stade, Germany Eurofins Study S13-00312 DAS Study No. 130673 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Robinson, P.	2015	Estimation of kinetic endpoints for clopyralid from soil dissipation studies. Dr Knoell Consult Ltd., Cardiff, UK DAS Study No. 150296 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Kröger, F.	2016	Soil dissipation study with one spring application of GF-1966 (Clopyralid) at one site to bare soil in South Europe in 2015. Eurofins Agroscience Services, Stade, Germany Eurofins Study S15-02991 DAS Study No. 150672 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2	Kröger, F.	2016	Soil dissipation study with one spring application of GF-1966 (Clopyralid) at one site to bare soil in South Europe in 2015. Eurofins Agroscience Services, Stade, Germany Eurofins Study S15-02992 DAS Study No. 150673 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Robinson, P.	2016	Estimation of kinetic endpoints for clopyralid from field soil dissipation studies (Southern Europe). Dr Knoell Consult Ltd., Cardiff, UK DAS Study No. 160486 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Ahrens, C. & Kröger, F.	2017	Final report – Field soil dissipation study with one spring application of GF-1966 (Clopyralid) at one site in North EU and one site in South EU to bare soil in 2016 - 2017. Eurofins Agroscience Services, Stade, Germany; Eurofins Study S16-01795 DAS Study No. 160394 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Robinson, P.	2017	Estimation of kinetic endpoints for clopyralid from soil dissipation studies (North and South Europe). Dr Knoell Consult Ltd., Cardiff, UK DAS Study No. 170481 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Reeves, G. L. & Mittelstaedt, W.	2002	Adsorption/Desorption of Clopyralid in Soil: Corrections to Final Report of Study DW 2/92 from August 1993 DAS Report No.GHE-P-9762 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Buntain, I., Simmonds, M.	2015	[14C]-Clopyralid: Adsorption to and Desorption from Five Soils DAS Report No.130699 Battelle UK Ltd., Chelmsford, Essex, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2	Schnöder, F.	2004	[14C] Clopyralid: Leaching in outdoor lysimeters following spring application to oilseed rape – Final report DAS Report No.000136 Covarance Laboratories, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Dust, M., Führ, F.	1994	Degradation and leaching of clopyralid monoethylamine salt after post emergence application of LONTREL 100 to winter rape in German lysimeters DAS Report No.GHE-P-4037 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Brumhard, B., Führ, F., Baloch, R.	1994	Behaviour of [2,6 14C] Clopyralid (LONTREL*) in a sandy Pseudogley Braunerde after post-emergence application to sugar beet DAS Report No.GHE-P-2908 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Brumhard, B., Baloch, R., Führ, F.	1994	Behaviour of [2,6 14C] clopyralid formulated as LONTREL 100 in Parabraunerde (Orthic Luvisol) after post emergence application to sugar beet lysimeters DAS Report No.GHE-P-2580 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Smith-Drake, J. K.	2000	Hydrolysis of 14C Clopyralid in Natural Water And Buffered Water as a Function of pH DAS Report No.000132 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Hall B.E.; Allen, J.;	2002	The Aerobic Degradation of [14]-Clopyralid in Natural Waters and their Associated Sediments	N	DAS

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
	Clements B.		DAS Report No.GHE-P-9564 Inveresk Research International, Tranet, East Lothian, UK Published (Y/N): No		
KCP 9.1.2	Ponte, M.	2014	Direct Aqueous Photodegradation of [14C]Clopyralid in pH 7 Buffer DAS Report No.140077 PTRL West, Hercules, California, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.2	Jenkins, W. R.	1991	LONTREL T: Assessment of its Biodegradability - Modified Sturm Test Life Science Research, Eye, Suffolk, UK DAS Report No. GHE-P-2522 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.3	Day, S. R.; Rudel, H.	1994	The evaporation of Clopyralid acid from soil and leaf surfaces following application of LONTREL 100 DAS Report No. GHE-P-3507 Fraunhofer Institute, D-57392 Schmallenberg, Grafschaft/Hochsauerland, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.3	Madsen, S.	2002	Calculation of the Stability in Air of Clopyralid - Photochemical Degradation. DAS Report No. LLC NAFST GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1	Lehmann, R. G.	1988	Extraction of Fluroxypyr and its Metabolites from Aged Soil Dow Chemical U.S.A. GH-C 2048 GLP: No not published	N	DOW
KCP 9.1	Dawson, J	1987	An Extractability Assessment of Fluroxypyr 1- Methylheptyl Ester from Soil and Immature	N	DOW

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
			Cereal Plants Dow Chemical Europe, Oxon, UK GHE-P-1706R GLP: no not published		
KCP 9.1	Grant, R. K.	1992	Degradation and Metabolism of Fluroxypyr 1-methylheptyl ester in soil under aerobic conditions DowElanco, Oxon, UK GHE-P-2754 GLP: yes not published	N	DOW
KCP 9.1	Hawkins, D. R., Kirkpatrick, D., Conway, B., Finn, C.M., Powell, G. P. and Biggs, S.	1982	The Metabolism of 14CDOWCO 433 MHE in Laboratory Soil under Aerobic and Anaerobic Conditions Department of Chemical Metabolism and Radiosynthesis, Huntingdon Research Centre, Huntingdon, Cambridgeshire, PE18 6ES, UK Dow Chemical Europe, Norfolk, UK GHE-P-1018 GLP: yes not published	N	DOW
KCP 9.1	Lehmann, R. J. and Miller, J. R.	1989	Aerobic Soil Metabolism of Fluroxypyr-MHE Agricultural Chemistry R&D Laboratories, The Dow Chemical Co, USA GH-C 2149R GLP: yes not published	N	DOW
KCP 9.1	Ballantine, L. G. and Zabik,	1993	Aerobic Soil Metabolism of 14CFluroxypyr- MHE	N	DOW

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
	S. E.		Hazleton Wisconsin Inc, 3301 Kinsman Boulevard, Madison, Wisconsin 53704, USA Dow Elanco, USA GH-C 3026 GLP: yes not published		
KCP 9.1	Hawkins, D. R., Kirkpatrick, D., Conway, B., Finn, C.M., Powell, G. P. and Biggs, S.	1982	The Metabolism of 14CDOWCO 433 MHE in Laboratory Soil under Aerobic and Anaerobic Conditions Department of Chemical Metabolism and Radiosynthesis, Huntingdon Research Centre, Huntingdon, Cambridgeshire, PE18 6ES, UK Dow Chemical Europe, Norfolk, UK GHE-P-1018 GLP: yes not published	N	DOW
KCP 9.1	Yon, D.A.	1987	The metabolism of 14CFluroxypyr 1-MHE in laboratory stored soil – Part II. Identification of an anaerobic metabolite Dow Chemical Europe, Oxon, UK GHE-P-1670 GLP: yes	N	DOW

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
			not published		
KCP 9.1	Batzer, F. R. and Lubinski, R. N.	1992	Soil Photolysis of Fluroxypyr 1-Methylheptyl Ester in Natural Sunlight Dow Elanco, Midland, USA GH-C 2717 GLP: yes not published	N	DOW
KCP 9.1	Reeves, G.	2007	Modelling the laboratory soil degradation kinetics of Fluroxypyr meptyl, Fluroxypyr and two metabolites Dow AgroSciences, UK GHE-P-11641 GLP: no not published;	N	DOW
KCP 9.1	Hawkins, D. R. Kirkpatrick, D. Conway, B. Finn, C. M. and Powell, G. P.	1981	DOWCO 433: 1-Methylheptyl Ester Metabolism in Spring Wheat and Soil After Field Application Department of Chemical Metabolism and Radiosynthesis, Huntingdon Research Centre, Huntingdon, Cambridgeshire, PE18 6ES, UK Dow Chemical Europe, UK GHE-P-895 GLP: yes not published	N	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1	Freeman, J. M. H., Houghton, S., McAllister-Hewlings, N. and Smith, D.	1985	Degradation and leaching of fluroxypyr in soil - UK 1984 Dow Chemical Europe, UK GHE-P-1303R GLP: yes not published	N	DOW
KCP 9.1	Poletika, N. N., Roberts, D. W., Phillips, A. M. and Buttler, I. W.	1994	Terrestrial Field Dissipation of Fluroxypyr in Western Canada A & L Great Lakes Laboratories Inc., 3505 Conestoga Drive, Fort Wayne, Indiana 46808-4413, USA DowElanco, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA DowElanco Canada Inc., 9635-45th Avenue, Edmonton, Alberta, T6E 5Z8, CANADA Enviro-Quest, Box 144, Minto, Manitoba, R0K 1MO, CANADA Normac AES Ltd., Box 880, Swift Current, Saskatchewan, S9H 3W8, CANADA Dow Elanco GH-C 3210 GLP: yes not published	N	DOW
KCP 9.1	Teasdale, R.	1995	Residues of Fluroxypyr in soft wheat at harvest and residues of Fluroxypyr 1-methylheptyl ester (MHE), Fluroxypyr and two metabolites in soil following a single	N	DOW

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
			post-emergence application of Starane (EF 1018), Italy – 1993 Laboratory Phase: DowElanco Europe, UK Field Phase: DowElanco Italia SRL, Via d'Azelgio, 25, 40123 Bologna, ITALY Dow AgroSciences, Oxon, UK GHE-P-3913 GLP: yes not published		
KCP 9.1	Teasdale, R.	1995	Residues of Fluroxypyr in winter barley at harvest and residues of Fluroxypyr 1-methylheptyl ester (MHE), Fluroxypyr and two metabolites in soil following a single postemergence application of Starane (EF 1018), Italy – 1993 Laboratory Phase: DowElanco Europe, UK Field Phase: DowElanco Italia SRL, Via d'Azelgio, 25, 40123 Bologna, ITALY Dow AgroSciences, Oxon, UK GHE-P-3914 GLP: yes not published	N	DOW
KCP 9.1	Teasdale, R.	1994	Residues of Fluroxypyr in durum wheat at harvest and residues of Fluroxypyr 1-methylheptyl ester (MHE), Fluroxypyr and two metabolites in soil following a single postemergence application of Starane (EF 1018), Italy – 1993 Laboratory Phase:	N	DOW

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
			DowElanco Europe, UK Field Phase: DowElanco Italia SRL, Via d'Azelgio, 25, 40123 Bologna, ITALY Dow AgroSciences, Oxon, UK GHE-P-3912 GLP: yes not published		
KCP 9.1	Freeman, J. M. H.	1984	Residues of Fluroxypyr in Soil Following Application of STARANE Herbicides to Summer Wheat, Winter Rye and Winter Barley in Germany 1983 Dow Chemical Europe, UK GHE-P-1244 GLP: no not published	N	DOW
KCP 9.1	Hale, K. and Gardinal, P.	1995	The adsorption/desorption of [14C]-Fluroxypyr methyl ester, [14C]-Fluroxypyr butoxy-propyl ester, [14C]-Fluroxypyr, [14C]- Fluroxypyr pyridinol and [14C]-Fluroxypyr meth-oxypyridine in soil. DowElanco, Oxon, UK GHE-P-4500 R GLP: yes not published	N	DOW
KCP 9.1	Lehmann, R. G. and Miller, J. R.	1988	An Adsorption/desorption Study of Fluroxypyr The Dow Chemical Company, Midland, MI, USA	N	DOW

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
			GH-C 2124 GLP: yes not published		
KCP 9.1	Cleveland, C. B. and Ostrander, J. A.	1996	Adsorption/Desorption Batch Equilibrium Partitioning of Methoxypyridine and Dichloropyridinol Metabolites of Fluroxypyr DowElanco, USA GH-C 3854 GLP: yes not published;	N	DOW
KCP 9.1	Cleveland, C. B.	1998	Response to the U. S. EPA Data Evaluation Report on: Adsorption/Desorption Batch Equilibrium Partitioning of Methoxypyridine and Dichloropyridinol Metabolites of Fluroxypyr DowElanco, Indiana, USA GH-C 3854R GLP: yes not published;	N	DOW
KCP 9.1	Freeman, J. M.	1985	The Leaching Characteristics of Fluroxypyr in Soil Hazleton Laboratories Europe Ltd., Otley Road, Harrogate North Yorkshire, HG3 1PY, UK Dow Chemical Europe, UK GHE-P-1301 GLP: no not published	N	DOW
KCP 9.1	Freeman, J. M.	1985	The Leaching Characteristics of Starane 180 in Soil According to Merkblatt 37 Guidelines	N	DOW

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
			Hazleton Laboratories Europe Ltd., Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK Dow Chemical Europe, UK GHE-P-1355 GLP: no not published		
KCP 9.1	Freeman, J. M. H.	1985	The Leaching Characteristics of Fluroxypyr as Determined in an Aged Leaching Study Hazleton Laboratories Europe Ltd., Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK Dow Chemical Europe, UK GHE-P-1300 GLP: no not published	N	DOW
KCP 9.1	Baloch, R. I, Brumhard, B. and Fuhr, F.	1992	Behaviour of [2,6-14C] Fluroxypyr 1-Methylheptyl Ester in a Sandy Pseudogley Braunerde After Post- Emergence Application to Spring Barley Institut Für Radioagronomie, Forschungszentrum, Jülich, D-5170 Jülich, GERMANY Dow Elanco, Oxon, UK GHE-P-2803 GLP: yes not published	N	DOW
KCP 9.1	Reeves, G.	2001	The leaching of Fluroxypyr after autumn application of Starane 200 to pasture grass lysimeters Dow Agrosciences, Oxon, UK	N	DOW

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
			GHE-P-8590 GLP: yes not published;		
KCP 9.2	Lehmann, R. G.	1987	The Hydrolysis of Fluroxypyr MHE in Dilute Aqueous Solution Dow Chemical U.S.A GH-C 1910 GLP: yes not published	N	DOW
KCP 9.2	Dawson, J.	1984	The degradation of Fluroxypyr 1-methylheptyl ester and Fluroxypyr in buffered water solutions according to the BBA Protocol Merkblatt 55 Hazelton Laboratories Europe Ltd, Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK Dow Chemical Europe 3995-295/2 GLP: no not published	N	DOW
KCP 9.2	Meikle, R.W	1979	The hydrolysis rate of DOWCO 433X, 1-methylheptyl ester, in buffered dilute aqueous solution Dow Chemical, Walnut Creek, USA 1979-03-08 GS-1601 GLP: no not published	N	DOW

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	Cleveland, C. B. and Holbrook, D. L.	1992	The Aqueous Photolysis of Fluroxypyr Methylheptyl Ester and Fluroxypyr (Acid) in Natural Sunlight Dow Elanco, Midland, USA GH-C 2758 GLP: yes not published	N	DOW
KCP 9.2	Douglas, M. I. and Pell, I. B.	1986	Assessment of the Ready Biodegradability of Fluroxypyr Acid Huntingdon Research Centre Ltd., Huntingdon, Cambridgeshire, PE18 6ES, UK Dow Chemical Europe GHE-P-1582 GLP: yes not published	N	DOW
KCP 9.2	Knowles, S. J.	1991	Ready Biodegradability of Fluroxypyr-1- methylheptyl ester (Modified Sturm Test) Life Science Research Limited Eye, Suffolk, IP23 7PX, UK DowElanco, UK GHE-P-2439 GLP: yes not published	N	DOW
KCP 9.2	Yon, D. A.	1988	The Degradation of 14C Fluroxypyr 1-MHE in Ditch Waters and their Associated Sediments, 1987 Main study: Hazleton UK Ltd., Otley Road, Harrogate, North Yorkshire, UK Sediment/Water	N	DOW

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
			Characterisation MAFF, ADAS, Lawnswood, Leeds, UK Aerobic Microflora Determination: Grange Laboratories, Wetherby, West Yorkshire, UK Dow Chemical Europe GHE-P-1785 GLP: no not published		
KCP 9.2	Cleveland, C. B. and Miller, J. R.	1993	Aerobic Aquatic Metabolism of Fluroxypyr Methyl Heptyl Ester Dow Elanco, USA GH-C 3008 GLP: yes not published	N	DOW
KCP 9.1	Lehmann, R. G.	1988	Formation of Fluroxypyr from Fluroxypyr MHE by Soil Catalysis Dow Chemical, USA GH-C 2068 GLP: no not published	N	DOW
KCP 9.2	Partsch, S.	2008	Modelling the degradation kinetics of Fluroxypyr meptyl, Fluroxypyr and two metabolites from a water/sediment study Dr. Knoell Consult GmbH, Mannheim, Germany Dow AgroChemical, UK GHE-P-11831 GLP: no	N	DOW

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
			not published;		
KCP 9.2	Yon, D. A. and Müller, M.	1995	Estimation of the Atmospheric Half-Life of Fluroxypyr-1-methylheptyl ester Fraunhofer Institut für Umweltchemie und Ökotoxikologie, D-57392 Schmallenberg, Germany Dow Elanco Europe GHE-P-4736 GLP: yes not published	N	DOW
KCP 9.2	Yon, D. A. and Müller, M.	1995	Estimation of the Atmospheric Half-Life of Fluroxypyr Fraunhofer Institut für Umweltchemie und Ökotoxikologie, D-57392 Schmallenberg, Germany Dow Elanco Europe GHE-P-4738 GLP: yes not published	N	DOW
KCP 9.2	Knowles, S., Wright, K., Blackmore, K., Thorne, J. and Horth, H.	2004	Review of monitoring and occurrence of Fluroxypyr in groundwater and surface water in Europe Water Research Centre (WCR) Blagrove, Swindon, Wiltshire, UK Dow AgroSciences, UK GHE-P-10764 GLP: yes not published;	N	DOW

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	Gesell J., Balcer J.,	2011	Degradation of Fluroxypyr DMP Metabolite in Four Soils under Aerobic Conditions; Regulatory Sciences & Government Affairs, Dow AgroSciences LLC, Indianapolis, Indiana 46268-1054, USA; Study No. 101798; GLP: Yes; Unpublished study;;	N	DOW
KCP 9.2	Simmonds M., Burgess M.,	2010	Fluroxypyr: Adsorption and Desorption Properties of [14C]-Pyridinol (DCP) in Five Soils; Battelle UK Ltd., Ongar, Essex, CM5 0GZ, UK for Doow Agro Sciences, Abingdon, Oxon, OX14 4RN, UK; Study No.: Battelle Study Number YR/10/001; GLP: Yes; Unpublished study;	N	DOW
KCP 9.3	Turner B.	2010	Determination of Vapour Pressure for DMP Metabolite of Fluroxypyr; Huntingdon Life Sciences Ltd, Alconbury, Huntingdon, Cambridgeshire, PE28 4HS, UK for Dow AgroSciences LLC, Indianapolis, Indiana 46268-1054, USA; Study No.: ABY0058 (DAS Project Identity NAFST-10-70);	N	DOW

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
			GLP: Yes; Unpublished study;		
KCP 9.3	Reeves G.	2012	Estimation of the atmospheric halflife for the DMP metabolite of Fluroxypyr; Dow AgroSciences, European Development Centre, Abingdon, Oxon., OX14 4RN, UK; Report No. GHE-P-12864; GLP: No, not required (modelling study); Unpublished study;	N	DOW

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

A 2.1 Study 1

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference:	Data point
Report	Title, author(s), year, report No, document No, Authority registration No
Guideline(s):	Yes/No (If yes, give guidelines; If no, give justification, e.g., " no guidelines available" or " methods used comparable to guideline(s) xxx")
Deviations:	Yes/No (If yes, describe deviations from test guidelines)
GLP:	Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed)
Acceptability:	Yes/No/Supplementary

Materials and methods

Results and discussions

Conclusion

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