FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: CHR/H/FDF 574 SC

Product name(s): Cezaro 574 SC/ Huron 574 SC

Chemical active substance(s):

Florasulam, 12 g/L
Diflufenican, 250 g/L
Flufenacet, 312 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

MS Finalisation date: 21/11/2022

Version history

When	What
March 2022	Dossier sent for evaluation
June 2022	Updates based on feedback from zRMS Poland
September 2022	Updates based
September 2022	zRMS evaluation of dRR
November 2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:
The text highlighted in grey was provided by the evaluator.

8 Fate and behaviour in the environment (KCP 9)

In the following document, data for active substances - diflufenican and flufenacet - was described during its inclusion on Annex 1 process in respectively 2009 and 2004 . 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/FDF 574 SC 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: 2019-10-01

PPP product name:		Formulation type:	SC [a, b]
product code:	CHR/H/FDF		
Active substance 1:	flufenacet	Conc. of as 1:	312 g/l [c]
Active substance 2:	diflufenican	Conc. of as 2:	250 g/l [c]
Active substance 3:	florasulam	Conc. of as 3:	12 g/l (c)
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	PUH Chemirol Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	~~No~~ yes		
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**	**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	g or kg as/ha a) max. rate per appl. b) max. total	Water L/ha min / max			

			I						rate per crop/season	rate per crop/season				
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL, CZ	Winter wheat (TRZAW), Winter triticale (TTLWI), Winter barley (HORVW), Winter rye (SECCW)	F	dicotyledonous weeds	Spray, medium sprayer	autumn BBCH 11-25	a)1 b)1	n/a	a) 0.4 l/ha b) 0.4 l/ha	a) 0.2296 kg a.s./ha (0.1248 FLU + 0.1 D + 0.0048 FLO) b) 0.2296 kg a.s./ha (0.1248 FLU + 0.1 D + 0.0048 FLO)	200-400	n/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														
5														
Minor uses according to Article 51 (interzonal uses)														
6														
7														

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required

C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of 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 (wheat, barley, rye, triticale, oats, spelt)	F	Broad leaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 12-45 (1st February to 15th July)	1	N/A	0.125	6.25	70- 400	N/A	
4	EU	Maize	F	Broad leaved weeds	Tractor mounted or self-propelled	BBCH 11-20 (1st April to 30th June)	1	N/A	0.1	5	70- 400	N/A	

					hydraulic sprayer giving overall application.								

(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 diflufenican concerning the Section Environmental Fate

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
					Type	Conc. Of as	method kind	growth stage & season	number min/ max	interval between applications (min)	g as/hL min – max	water L/ha min – max	g as/ha min – max		
(a)			(b)	I	(d-f)	(i)	(f-h)	(j)	(k)		(l)		(l)	(m)	
Winter wheat Winter barley Winter rye	EU	Herold SC 600	F	Annual dicot weeds, ALOMY, APESV, POAAN	SC	1. 200 g/L 2. 400 g/L	Tractor mounted boom spraying	Pre-emergence; Post-emergence BBCH 10-13	1		1. 0.06 – 0.03 2. 0.12 – 0.06	200 – 400	1. 0.12 2. 0.24	#	0.6 L / ha product; Autumn use only

1 – active substance diflufenican, 2 – active substance flufenacet

* 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

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

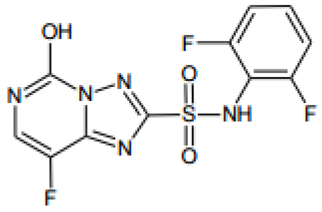
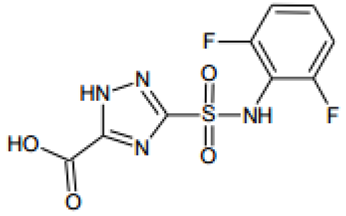
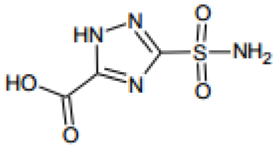
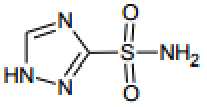
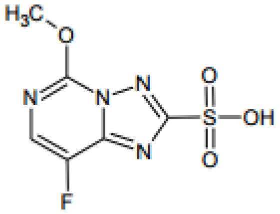
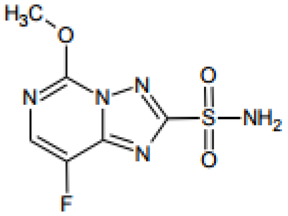
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
	Northern and Southern Europeam Countries	Corn	F	Annual grass weeds	Spray applicati on with standard field sprayers	Pre - Emergence	1	N/A	0.8-1 kg/ha	0.48 - 0.60	200 - 400	Not applicable	
	Southern Europeam Countries	Soybean, Sunflower	F	Annual grass weeds	Spray applicati on with standard field sprayers	Pre - Emergence	1	N/A	0.8-1 kg/ha	0.48 - 0.60	200 - 400	Not applicable	
	Northern Europeam Countries	Winter cereals (wheat, rye, barley , triticale)	F	Annual grass weeds	Spray applicati on with standard field sprayers	Pre - Emergence	1	N/A	0.2-04 kg/ha	0.12-0.24	200 - 400	Not applicable	

* 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%	$PEC_{sw/sed}$

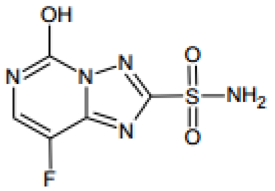
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
5-OH ASTP	233.18		Soil/Water/Sediment: 0.0001% (default) / 29.0%	PECsw/sed

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

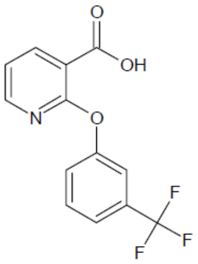
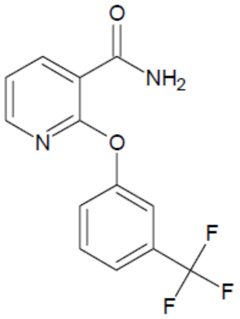
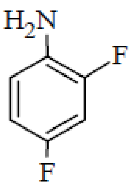
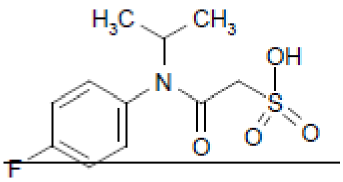
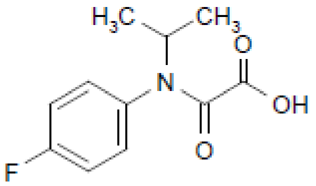
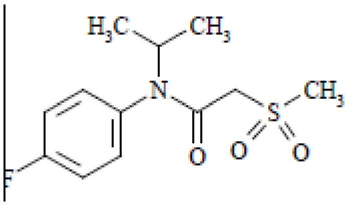
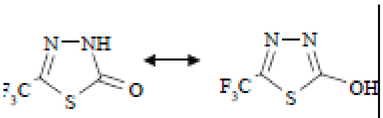
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
AE B107137	283		Soil: 16.8% Water: 32.6% Sed: 13.3%	AE PECsoil PECgw: leaching potential to groundwater PECsw/sed B107137
AE 0542291	282		Soil: 26.3% Water: 6.1% Sed: 1.0%	PECsoil PECgw: leaching potential to groundwater PECsw/sed
AE C522392	129.11		Soil: 26.3% Water: 6.1% Sed: 1.0%	PECsoil PECgw: leaching potential to groundwater PECsw/sed

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
FOE sulfonic acid	275.3g/mol		Soil (lab): max 26.3% AR	PECgw; PECsoil

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
FOE oxalate	225.2g/mol		Soil (Lab): max 15.6 % AR	PECsoil PECgw
FOE methylsulfone	273.3g/mol		Water/sediment max. 8 % in water, 3.4 % in sediment on day 157	PEC sw
FOE-thiadone	170.1g/mol		Maximum occurrence observed in sediment/ water studies: 82 % in water (55 d)	PECsw

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**
- **Diflufenican** - EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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)]/R²***	***Param.***	***Value***	***DT₅₀ [days]***	***DT₉₀ [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]/R²***	***Param.***	***Value***	***DT50 [days]***	***DT90 [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 20°C 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 Diflufenican and its metabolites

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

Diflufenican	Aerobic conditions						
Soil type	X[20]	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam		7.7 [(a)]	22°C/ 75 % of 0.33 bar	248.5/825.5	237.9	0.9980	SFO
Clay loam		6.6 [(a)]	22°C/ 75 % of 0.33 bar	139.5/463.4	119.9	0.9967	SFO
Clay loam		6.5	20°C/45 %	232.6/772.7	193.5	0.9954	SFO
Clay loam		6.5	20°C/45 %	206.0/684.3	172.1	0.9975	SFO
Clay loam		6.5	20°C/45 %	176.3/585.8	147.3	0.9967	SFO
Silty clay loam		7.5	20°C/45 %	44.3/147.2	44.3	0.9819	SFO
Sandy loam 1		5.5	20°C/45 %	129.3/429.5	129.3	0.9836	SFO
Sandy loam 2		6.9	20°C/45 %	89.8/298.3	89.8	0.9890	SFO
Sandy loam 2		6.9	10°C/45 %	204.4/679.0 [(b)]			SFO
Geometric mean/median					128 / 138.3		
Arithmetic mean					141.8		

Table 8.3-7: Summary of aerobic degradation rates for AE B107137 - laboratory studies

AE B107137	Aerobic conditions							
Soil type	X[1]	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f [(c)]	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam 1		7.0	20 °C/45 %	9.1/30.2	1	7.5	0.9919	SFO
Sandy loam		6.2	20 °C/45 %	17.9/59.5	1	13.9	0.9868	SFO
Silt loam 2		7.4	20 °C/45 %	14.5/48.1	1	10.4	0.9959	SFO
Geometric mean/median						10.3 / 10.4		
Arithmetic mean						10.6		

Table 8.3-8: Summary of aerobic degradation rates for AE 0542291 - laboratory studies

AE 0542291	Aerobic conditions							
Soil type	X[1]	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f [(c)]	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam 1		7.0	20 °C/45 %	13.6/45.2	1	11.1	0.987	SFO
Sandy loam		6.2	20 °C/45 %	58.7/194.9	1	45.7[d]	0.999	SFO

AE 0542291	Aerobic conditions							
Soil type	X[1]	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f (c)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam 2		7.4	20 °C/45 %	33.2/110.2	1	23.8	0.991	SFO
Geometric mean/median						22.9 / 23.8		
Arithmetric mean						26.9		

8.3.1.3 Flufenacet and its metabolites

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

Soil type	pH	OC (%)	DT50 (days)
loamy sand	6.2	2.58	39
silt loam	7.3	0.9	15
silt loam	5.8	2.4	27
sandy loam*	6.2	0.32	34-64 (mean 48)
* 2 labels, 21° C, 75 % FC			Normalized DT 50 used for Focus calculations: 13-24d (**geometric mean 16.5d, n=3**)

Table 8.3-10: Summary of aerobic degradation rates for FOE sulfonic acid- laboratory studies

Soil type	pH	OC (%)	DT50 (days)
sand	5.3	0.57	270
loamy sand	6.3	2.48	189
silt loam	7.3	0.9	247
			Normalized DT 50 used for Focus calculations: 119-189d (**geometric mean 140 d, n=3**)

Table 8.3-11: Summary of aerobic degradation rates for FOE oxalate- laboratory studies

Soil type	pH	OC (%)	DT50 (days)
sand	6.2	2.58	5
loamy sand	7.3	0.9	17
silt loam	5.8	2.3	12
			Normalized DT 50 used for Focus calcu-lations: 4-10 d (**geometric mean 6.6 d, n=3**)

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**
- **Diflufenican** - EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.3.2.1 Florasulam and its metabolites

Table 8.3-12: 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^{0}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^{0}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 8.3-13: 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^{0}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^{0}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 Diflufenican and its metabolites

Anaerobic degradation ‡

Mineralization after 100 days	Not available for [^{14}C-2,4-difluorophenyl]-label Not available for [^{14}C-3-trifluoromethylphenyl]-label 4.0 % after 112 d, [^{14}C-2-pyridyl]-label (n=1)
Non-extractable residues after 100 days	16.6 % after 120 d, [^{14}C-2,4-difluorophenyl]-label (n=1) 11.2 % after 120 d, [^{14}C-3-trifluoromethylphenyl]-label (n=1) 4.0 % after 112 d, [^{14}C-2-pyridyl]-label (n=1)
Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	AE C522392[19] – 10.7 % at 90 d [^{14}C-2,4-difluorophenyl]-label (n=1) AE B107137 – 48.5 % at 272 d [^{14}C-3-trifluoromethylphenyl]-label (n=2)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	None. Diflufenican was stable during the 31 d study.

8.3.2.3 Flufenacet and its metabolites

Data not provided

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**
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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 Diflufenican and its metabolites

Diflufenican	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) 20°C / pF2	Method of calculation
Loamy sand (b)	UK		5.8	30	621	2063	0.493	282.0	SFO
Sandy silt loam I	France		7.1	30	241	801	0.796	130.0	SFO
Sandy loam (b)	Netherlands		6.3	30	389	1292	0.495	199.5	SFO
Clay (b)	Spain		7.6	30	236	784	0.728	122.2	SFO
Clay loam (b)	Italy		6.9	30	224	744	0.748	103.4	SFO
Geometric mean/median					315/241			156/130*	

*Note a Q10 of 2.2 was assumed during the normalization.

8.4.1.3 Flufenacet and its metabolites

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

Location	Application and timings	DT50*
Germany	Autumn (240 g a.s/ha) Spring (480-600 g/ha)	38-43 d 15-54-31-53d
N.France	Early spring (240 g a.s/ha) Spring (480-600 g/ha)	13-16 d 16-38 d
S.France	Spring (480-600 g/ha)	30-36-34-42 d
Italy	Spring (480-600 g/ha)	38-48 d

*DT50: Germany (4 sites, bare soils), N.France (2 sites,crop), S.France (2 sites,crop), Italy (2 sites,crop).
LOD 10 µg/kg (<6%)

Metabolites not detected above LOD.

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**
- **Diflufenican** - EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph

of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.4.2.1 Florasulam and its metabolites

No accumulation observed in the field studies

8.4.2.2 Diflufenican and its metabolites

Soil accumulation and plateau concentration ‡	Maximum soil accumulation concentration of 0.405 mg/kg over top 5cm soil layer. Plateau concentration (i.e. the maximum amount of diflufenican remaining immediately prior to the following years application) would be 0.245 mg/kg. Maximum accumulation factor = 2.53

8.4.2.3 Flufenacet and its metabolites

Not relevant according with Flufenacet – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (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**
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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 Diflufenican and its metabolites

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

Diflufenican ‡								
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n	R^2
Sandy loam	2.09	7.7			33.9	1622	0.875	>0.988
Loamy sand	0.75	6.6			13.5	1800	0.917	>0.988
Clay loam	1.68	6.6			39.8	2369	0.934	>0.988
Silty clay loam	2.26	6.8			48.9	2164	0.923	>0.988
Clay loam (Shelley Field)	2.4	6.2			98.82	4118	0.901	0.998
Silt loam (Kissendorf)	1.4	6.7			46.28	3306	0.897	1.000
Sandy loam (Manningtree)	3.6	5.3			267.51	7431	0.991	0.998
Loam (Santilly)	0.9	7.0			39.86	4428	0.940	0.999
Clay loam (Lleida)	2.9	8.0			88.91	3066	0.917	0.999
Clay loam (Chazay)	1.9	6.6			73.49	3868	0.879	0.998
Arithmetic mean					75.1	3417	0.917	-
Median					47.6	3186	0.917	
pH dependence, Yes or No			No					

Table 8.5-7: Summary of soil adsorption/desorption for AE B107137

AE B107137 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay loam	1.9	7.0			0.22	12	0.72
Sand	1.6	5.8			0.11	7	0.99
Clay loam	4.7	7.6			0.38	8	0.54
Sandy loam	1.8	6.0			0.42	23	0.68
Arithmetic mean/median						13/10	0.73/0.70
pH dependence (yes or no)			No				

Table 8.5-8: Summary of soil adsorption/desorption for AE 0542291

AE 0542291							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	0.8	6.0			1.3	160	0.80
Sandy loam	1.2	5.3			1.5	127	0.84
Clay loam	2.6	7.0			3.6	137	0.77
Clay	3.9	6.0[a]			4.0	103	0.85
Arithmetic mean/median						132/132	0.81/0.82

8.5.3 Flufenacet and its metabolites

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

Soil type	pH	OC (%)	Koc	slope
silt loam	5.9	1.68	190	0.84
clay loam	6.4	1.28	211	0.90
loamy sand	6.4	0.23	696	0.87
sand	5.0	0.17	588	0.98
sandy loam	6.4	1.4	354	0.89
loam	7.1	4.3	113	0.96
silt loam	7.3	2.8	144	0.86
			Mean: 202 (for OC>0.23%)	Art mean:0.89 (for OC>0.23%)

Table 8.5-10: Summary of soil adsorption/desorption for metabolite FOE-oxalate

Soil type	pH	OC (%)	Koc	slope
sand	5.8	0.27	23	1.42
sandy loam	6.3	0.75	13	0.93
silty clay loam	6.6	2.13	7	0.82
silty clay	6.0	1.21	13	0.98
			Mean: 11 (for OC>0.27%)	Art mean:0.91 (for

				OC>0.27%)

Table 8.5-11: Summary of soil adsorption/desorption for metabolite FOE Sulfonic acid

Soil type	pH	OC (%)	Koc	slope
sand	5.8	0.27	19	0.86
sandy loam	6.3	0.75	15	1.00
silty clay loam	6.6	2.13	10	0.93
silty clay	6.0	1.21	6	1.18
			Mean: 10 (for OC>0.27%)	Art mean:1.04 (for OC>0.27%)

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**
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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 $CaCl_2$ solution (equivalent to 200 mm of rainfall) applied to the top of the column at a constant rate.

8.5.4.2 Diflufenican and its metabolites

Column leaching ‡	None submitted, none required

8.5.4.3 Flufenacet and its metabolites

No studies were provided according to the SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).

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**
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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 Diflufenican and its metabolites

Aged residues leaching ‡	None submitted, none required

8.5.5.3 Flufenacet and its metabolites

8.5.5.1 Flufenacet and metabolites.

Lysimeter/ field leaching studies	Lysimeter (sandy loam soil, < 1.41 % OC) **corn/corn rotation (2 x 480 g a.s./ha)** Total mean 0.87-0.99 µg/l, max. 2.23 µg/l (y 1) mean 0.46-0.67 µg/l, max. 1.0 µg/l (y 2) mean 0.23-0.33 µg/l, max. 0.33 µg/l (y 3) a.s. < 0.035 µg/l FOE oxalate < 0.04 µg/l FOE thioglycolate < 0.08 µg/l FOE sulfonic acid mean 0.49-0.59 µg/l, max. 1.29 µg/l (y 1) mean 0.15-0.24 µg/l (y 2) **corn/wheat rotation (480 + 180 g a.s./ha)** Total mean 2.5 µg/l, max. 5 µg/l (year 1) mean 0.24 µg/l (year 2) a.s. not identified FOE oxalate and thioglycolate < 0.1 µg/l FOE sulfonic acid : mean 1.49 µg/l, max. 3.7 µg/l (year 1) mean 0.015 µg/l (year 2)

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**
- **Diflufenican** - EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.5.6.1 Florasulam and its metabolites

Please refer to point 8.5.3.

8.5.6.2 Diflufenican and its metabolites

Lysimeter/ field leaching studies ‡	Location: Germany (Bruhl, Schwemmlob) Study type (e.g. lysimeter, field): lysimeter Soil properties: pH = 7.2, OC= 1.05 Dates of application: 3rd December 1990 Crop: 1st year winter wheat, 2nd year winter barley, final green mustard Interception estimated: None (application pre-emergent) Number of applications: lysimeter 219 1 application each year, lysimeter 220 1 application 1st year Duration: 2 years Application rate: 185 g a.s./ha/year (nominal) Average annual rainfall and irrigation (mm): 853 mm Average annual leachate volume (mm): 325 mm %radioactivity in leachate (maximum/year): 0.014 % AR 1st year, 0.117 % AR 2nd year Individual annual average concentrations: 1st year 0.003 µg /L and 2nd year <0.003 µg /L active substance, <0.003 µg /L metabolites AE B107137 and AE 0542291. Unidentified radioactivity: total max 0.01 µg /L parent equivalents.

8.5.6.3 Flufenacet and its metabolites

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**
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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 = 50^{0}C 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 = 25^{0}C 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 = 20^{0}C	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 = 20^{0}C	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 40^{0}N and at constant T = 25^{0}C	Irradiated samples	at 40^{0}N 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 = 20^{0}C	Irradiated samples	at 40^{0}N 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 40^{0}N) with artificial sunlight - Xenon lamp light having the intensity of 466 W/m^2 • nm, at constant T = 20^{0}C	Irradiated samples	at 40^{0}N 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 51.5^{0}N, at the temperature of surrounding (10 – 30^{0}C)	Irradiated samples	at 51.5^{0}N 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 – 24^{0}C	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 – 24^{0}C	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 Diflufenican and its metabolites

Degradation in water / sediment

Diflufenican	Distribution (Max. in sed 74.4 % after 14 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Unter Widdersheim	8.2	7.5	20	90	0.76	n.a.	n.a.	n.a.		SFO
Bickenbach	8.2	7.8	20	154	0.77	n.a.	n.a.	n.a.		SFO
Clay, UK	7.8	6.3	20	345	0.82	n.a.	n.a.	n.a.		SFO
Sand, UK	6.8	5.4	20	195	0.96	n.a.	n.a.	n.a.		SFO
Arithmetic mean (DT_{50})				196		n.a.		n.a.		
Geometric mean				175		n.a.		n.a.		

n.a. no reliable value available.

AE B107137	Distribution (max in water 32.6 % after 30 d, max in sed 13.3 % after 30 d)
AE C522392	Distribution (max in water 6.1 % after 30 d, max in sed 1.0 % after 59 d)

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)
Unter Widdersheim	8.2	7.5	0.6 % after 121 d	11.1 % after 121 d	11.1 % after 121 d
Bickenbach	8.2	7.8	0.2 % after 121 d	9.0 after 61 d	8.6 % after 121 d
Clay, UK	7.8	6.3	0.8 % after 365 d	35.2 % after 365 d	35.2 % after 365 d
Sand, UK	6.8	5.4	6.8 % after 365 d	27.4 % after 212 d	22.7 % after 365 d

8.6.3 Flufenacet and its metabolites

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

Degradation in water/sediment	(Days)
DT50 water	46.3-61.7d
DT90 water	154-205d
DT50 whole system	76.4-84.6 d(fluorophenyl), 20-31 d (thiadiazole)
DT90 whole system	254-281d (fluorophenyl), 67-104d (thiadiazole)

Table 8.6-3: Summary of observed metabolites

FOE methylsulfide	Max 8% in water and 3.4 % in sediment (157 d)
FOE-thiadone	Max 82 % in water (55d)

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

zRMS Comments:

The PECs assessment was accepted and corrected, if relevant.
The worst case scenario of 0% interception was used in PECs assessment (active substance and formulation).
The endpoints used for soil exposure assessment are consistent with list of endpoints for all active substances and their metabolites.
The PECs accum of active substances/metabolites, if relevant, was assessed.

Winter wheat

Compound	PECs	PECs accum
	mg/kg soil	
Florasulam	0.0064	nr
5-OH-florasulam	0.0032	nr
DFP-ASTCA	0.0008	nr
ASTCA	0.0013	0.0021
TSA	0.0004	0.0005
Diflufenican	0.1333	0.3985
AE B107137	0.0003	nr
AE 0542291	0.0010	nr
Flufenacet	0.1664	nr
FOE-sulfonic acid	0.0222	0.0412
FOE - oxalate	0.0030	nr
Formulation	0.644	nr

The relevant PECs values will be used in further risk assessment.

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
- Diflufenican - EFSA Scientific Report (2007) 122, 1-84,
- Flufenacet – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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: 0.0048 Diflufenican: 0.1 Flufenacet: 0.1248
Number of applications/interval	1/-
Crop interception (%)	0
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 endpoint 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
Diflufenican	394	-	621	LoEP EFSA 2007
AE B107137	283	16.8	10.6	LoEP EFSA 2007
AE 0542291	282	26.3	26.9	LoEP EFSA 2007
Flufenacet	363.34	-	DT50: 54 d Kinetics: Longest DT 50 from field studies	SANCO 7469/VI/98-Final 3 July 2003

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
FOE-sulfonic acid	275.3	26.3%	DT50:270 d Kinetics: SFO Field or Lab: representative worst case un-normalised values from lab studies	SANCO 7469/VI/98-Final 3 July 2003
FOE - oxalate	225.2	15.6%	DT50:17 d Kinetics: SFO using a fixed DT50 representative worst case un-normalised values from lab studies	SANCO 7469/VI/98-Final 3 July 2003

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		0.0064	-	-	-
Short term	24h	0.0054	0.0059	-	-
	2d	0.0046	0.0055	-	-
	4d	0.0034	0.0047	-	-
Long term	7d	0.0021	0.0038	-	-
	14d	0.0007	0.0025	-	-
	21d	0.0002	0.0018	-	-
	28d	0.0001	0.0014	-	-
	50d	<0.0001	0.0008	-	-
	100d	<0.0001	0.0004	-	-
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		0.0032	-	-	-
Short term	24h	0.0032	0.0032	-	-
	2d	0.0032	0.0032	-	-
	4d	0.0031	0.0032	-	-
Long term	7d	0.0030	0.0032	-	-
	14d	0.0027	0.0031	-	-
	21d	0.0023	0.0030	-	-
	28d	0.0020	0.0029	-	-
	50d	0.0012	0.0025	-	-
	100d	0.0004	0.0017	-	-
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		0.0008	-	-	-
Short term	24h	0.0008	0.0008	-	-
	2d	0.0008	0.0008	-	-
	4d	0.0008	0.0008	-	-
Long term	7d	0.0007	0.0008	-	-
	14d	0.0007	0.0007	-	-
	21d	0.0006	0.0007	-	-
	28d	0.0006	0.0007	-	-
	50d	0.0004	0.0006	-	-
	100d	0.0002	0.0005	-	-
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		0.0013	-	-	-
Short term	24h	0.0013	0.0013	-	-
	2d	0.0013	0.0013	-	-
	4d	0.0013	0.0013	-	-
Long term	7d	0.0013	0.0013	-	-
	14d	0.0013	0.0013	-	-
	21d	0.0012	0.0013	-	-
	28d	0.0012	0.0013	-	-
	50d	0.0011	0.0012	-	-
	100d	0.0010	0.0012	-	-
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		0.0004	-	-	-
Short term	24h	0.0004	0.0004	-	-
	2d	0.0004	0.0004	-	-
	4d	0.0004	0.0004	-	-
Long term	7d	0.0004	0.0004	-	-
	14d	0.0004	0.0004	-	-
	21d	0.0004	0.0004	-	-
	28d	0.0004	0.0004	-	-
	50d	0.0003	0.0004	-	-

	100d	0.0003	0.0003	-	-
Plateau concentration (5 cm) after year 10		Not relevant		-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)				-	-

8.7.2.2 Diflufenican and its metabolites

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

PEC_{soil} (mg/kg)		cereals	
		Single application	
		Actual	TWA
Initial		0.1333	-
Short term	24h	0.1332	0.1333
	2d	0.1330	0.1332
	4d	0.1327	0.1330
Long term	7d	0.1323	0.1328
	14d	0.1313	0.1323
	21d	0.1302	0.1318
	28d	0.1292	0.1313
	50d	0.1261	0.1297
	100d	0.1193	0.1262
Plateau concentration (5 cm) after year 10		0.2651	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.3985	-

PEC_{soil} of metabolites

Table 8.7-9: PEC_{soil} for AE B107137 on cereals

PEC_{soil} (mg/kg)		cereals	
		Single application	
		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		0.0005	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.0008	-

Table 8.7-10: PEC_{soil} for AE 0542291 on cereals

PEC_{soil} (mg/kg)		cereals	
		Single application	
		Actual	TWA
Initial		0.0010	-
Short term	24h	0.0010	0.0010
	2d	0.0010	0.0010
	4d	0.0010	0.0010
Long term	7d	0.0010	0.0010
	14d	0.0010	0.0010
	21d	0.0010	0.0010
	28d	0.0009	0.0010
	50d	0.0009	0.0010
	100d	0.0009	0.0009
Plateau concentration (5 cm) after year 10		0.0020	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.0030	-

8.7.2.3 Flufenacet and its metabolites

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

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.1664	-
Short term	24h	0.1643	0.1653

	2d	0.1622	0.1643
	4d	0.1581	0.1622
Long term	7d	0.1521	0.1591
	14d	0.1390	0.1523
	21d	0.1271	0.1459
	28d	0.1162	0.1398
	50d	0.0876	0.1228
	100d	0.0461	0.0937
Plateau concentration (5 cm) after year 10		0.0016	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.1680	-

PEC_{soil} of metabolites

Table 8.7-12: PEC_{soil} for FOE sulfonic acid on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0222	-
Short term	24h	0.0222	0.0222
	2d	0.0222	0.0222
	4d	0.0222	0.0222
Long term	7d	0.0222	0.0222
	14d	0.0221	0.0222
	21d	0.0221	0.0222
	28d	0.0219	0.0222
	50d	0.0215	0.0221
	100d	0.0199	0.0219
Plateau concentration (5 cm) after year 10		0.0190	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0412	-

Table 8.7-13: PEC_{soil} for FOE oxalate on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
Initial		0.0030	-
Short term	24h	0.0030	0.0030

	2d	0.0030	0.0030
	4d	0.0030	0.0030
Long term	7d	0.0030	0.0030
	14d	0.0029	0.0030
	21d	0.0028	0.0030
	28d	0.0027	0.0030
	50d	0.0022	0.0029
	100d	0.0012	0.0025
Plateau concentration (5 cm) after year 10		<0.0001	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.0031	-

8.7.2.4 PEC_{soil} of CHR/H/FDF 574 SC

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

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

where: A = application rate (483.08 g formulation/ha, density product from manufacturer: 1.2077 g/ml)
d = depth of soil layer (5 cm)
ρ = soil bulk density (1.5 g/cm^3)

Table 8.7-14: PEC_{soil} for CHR/H/FDF 574 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/FDF 574 SC	483.08	0.644	-	5	0.644	0.6444

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

<table>
<tr><td>Evaluator's Comments:</td><td>
The submitted PECgw assessment was accepted.
Calculations of PECgw for all active substances and its relevant metabolite were provided with PUF = 0.
The recommended FOCUS models were used: FOCUS PELMO and FOCUS PEARL.
All used endpoints were agreed at the EU level.
The autumn application was taken into consideration.
Florasulam. The PECgw assessment for active substance and its metabolites was provided.
The PECgw values for active substance were below the trigger value of 0.1 µg/L.
As PECgw for all metabolites were below trigger value of 0.75 µg/L.
<table>
<tr><th>Compound</th><th>PECgw
µg/L</th></tr>
<tr><td>Florasulam</td><td>0.001</td></tr>
<tr><td>5-OH-florasulam</td><td>0.202</td></tr>
<tr><td>DFP-ASTCA</td><td>0.472</td></tr>
<tr><td>ASTCA</td><td>0.433</td></tr>
<tr><td>TSA</td><td>0.336</td></tr>
</table>
Diflufenican. The PECgw values for active substance and its metabolites were below the trigger value of 0.1 µg/L. No tiered approach was considered (Table 8.8-6).
The active substance name in tables title (Tables 8.8-6 and 8.8-7) was corrected.
Flufenacet. The PECgw values for active substance and its metabolite FOE oxalate were below the trigger value of 0.1 µg/L.
The active substance name in table title (Tables 8.8-10) was corrected.
For metabolite FOE Sulfonic acid the PECgw values was higher than the trigger value of 10 µg/L in scenario Jokioinen; as this scenario is not relevant for Central Zone – was not taken into account.
For metabolites the following PECgw values were obtained:
<table>
<tr><th rowspan="2">Compound</th><th>PECgw</th></tr>
<tr><th>µg/L</th></tr>
<tr><td>Flufenacet</td><td>< 0.001</td></tr>
<tr><td>FOE-sulfonic acid</td><td>9.0484</td></tr>
</table>
The relevant metabolites of active substances will be considered in Section 10.
</td></tr>
</table>

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
- Diflufenican - EFSA Scientific Report (2007) 122, 1-84,
- Flufenacet – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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

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

Use No.	1
Crop	Winter Cereals
Application rate (g as/ha)	Florasulam: 5 (worst case) Diflufenican: 100 Flufenacet: 124.8
Number of applications/interval (d)	1/-
Relative application date	2 day after evemt
Crop interception (%)	0
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.3

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 Florasulam	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
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

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA	Value in accordance with EU endpoint y/n/ Reference*
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 4.4.4)

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	0.008452	0.003290	0.2856	0.2375
	Hamburg	0.00056	0.1015	0.04098	0.3481	0.1515
	Jokioinen	0.0001	0.04717	0.01105	0.2965	0.2872
	Kremsmünster	<0.0001	0.03667	0.01447	0.2714	0.1610
	Okehampton	0.000164	0.07834	0.02398	0.2242	0.1269
	Piacenza	<0.0001	0.02255	0.01492	0.2589	0.1770

	Porto	0.00026	0.07554	0.008134	0.1790	0.1436
	Sevilla	<0.0001	0.0002	<0.0001	0.04644	0.1035
	Thiva	<0.0001	0.002574	0.000663	0.4330	0.3364

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

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA
Winter cereals	Châteaudun	<0.001	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

Only metabolites 5-OH Florasulam, 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 Diflufenican and its metabolites

Table 8.8-5: **Input parameters related to active substance diflufenican and metabolite(s) for PEC_{gw} calculations**

Compound	Diflufenican	AE B107137	AE 0542291	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	394	283	282	EFSA Scientific Report (2007) 122, 1-84
Water solubility (g/mol):	0.05	0.05	0.05	EFSA Scientific Report (2007) 122, 1-84
Saturated vapour pressure (Pa):	4.25 E-06	4.25E-06	4.24E-06	EFSA Scientific Report (2007) 122, 1-84

Compound	Diflufenican	AE B107137	AE 0542291	Value in accordance with EU endpoint y/n/ Reference*
DT_{50} in soil (d)	141.8	10.6	45.7	EFSA Scientific Report (2007) 122, 1-84
DT_{50} in soil (d) field	-	-	-	EFSA Scientific Report (2007) 122, 1-84
Transformation rate	0.000821 per day to AE B107137 0.0012855 per day to AE 0542291 0.0021067 per day to CO2	0.065391 per day to CO2	0.025768 per day to CO@	EFSA Scientific Report (2007) 122, 1-84
K_{foc} (mL/g)/K_{fom}	1989/1154	13/7.5	132/76.6	EFSA Scientific Report (2007) 122, 1-84
1/n	0.91	0.73	0.81	EFSA Scientific Report (2007) 122, 1-84
Plant uptake factor	0	0	0	EFSA Scientific Report (2007) 122, 1-84
Formation fraction		0.168 from diflufenican	0.263 from diflufenica	EFSA Scientific Report (2007) 122, 1-84

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

Table 8.8-6: PEC_{gw} for ~~Florasulam~~ Diflufenican and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 1 (lab DT50)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Diflufenican	AE B107137	AE 0542291
Winter cereals	Châteaudun	<0.0001	<0.0001	<0.0001
	Hamburg	<0.0001	<0.0001	<0.0001
	Jokioinen	<0.0001	<0.0001	<0.0001
	Kremsmünster	<0.0001	<0.0001	<0.0001
	Okehampton	<0.0001	<0.0001	<0.0001
	Piacenza	<0.0001	<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 8.8-7: PEC$_{gw}$ for ~~Florasulam~~ Diflufenican and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3)

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

8.8.2.3 Flufenacet and its metabolites

Table 8.8-8: Input parameters related to active substance flufenacet and metabolite(s) for PEC$_{gw}$ calculations

Compound	Flufenacet	FOE sulfonic acid	FOE oxalate	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	363.34	275.3	225.2	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).
Water solubility (mg/L):	56	56 from parent	56 from parent	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).
Saturated vapour pressure (Pa):	9E-5 Pa at 20°C	1E-8 default	1E-8 default	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).
DT$_{50}$ in soil (d)	16.5 (geo mean normalised)	140 (geo mean normalised)	6.6 (geo mean normalised)	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate

Compound	Flufenacet	FOE sulfonic acid	FOE oxalate	Value in accordance with EU endpoint y/n/ Reference*
				and behaviour (2003).
Transformation rate	0.008359791to FOE Sulfonic acid 0.00042to FOE oxalate 0.0336072 to C02	0.004951 to CO2	0.105022 to CO2	**SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).**
K_{foc} (mL/g)/K_{fom}	349 mL/g, arithmetic mean	12.5 arithmetic mean	14 arithmetic mean	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).
1/n	0.89	1.04	0.91	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).
Plant uptake factor	0	0	0	
Max occurance	-	26.2%	15.6 %	

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

Table 8.8-9: PEC_{gw} for flufenacet and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE Sulfonic acid	FOE oxalate
Winter cereals	Châteaudun	<0.0001	8.6327	0.0004
	Hamburg	<0.0001	8.5117	0.0111
	Jokioinen	<0.0001	14.045	0.007117
	Kremsmünster	<0.0001	5.2870	0.0019
	Okehampton	<0.0001	4.856	0.01817
	Piacenza	<0.0001	5.1420	0.0017
	Porto	<0.0001	4.2630	0.0135
	Sevilla	<0.0001	4.034	<0.0001
	Thiva	<0.0001	9.0484	~~14.045~~ <0.0001

Table 8.8-10: PEC$_{gw}$ for Florasulam and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE Sulfonic acid	FOE oxalate
Winter cereals	Châteaudun	<0.001	5.973	<0.001
	Hamburg	<0.001	6.354	0.001
	Jokioinen	<0.001	7.677	<0.001
	Kremsmünster	<0.001	4.837	<0.001
	Okehampton	<0.001	3.731	0.001
	Piacenza	<0.001	5.466	<0.001
	Porto	<0.001	3.258	0.001
	Sevilla	<0.001	2.637	<0.001
	Thiva	<0.001	4.713	<0.001

~~**Conclusions: No scenerio predicts to exceed 0.1 µg/L for active substance and FOE oxalate. However one of the metabolite FOE Sulfonic acid is exceeding 0.75 µg/L in all 9 scenarios. On Annex I inclusion were performed Lysimeter studies, which represents worst case of application. Results are summrized below:**~~

~~Lysimeter (sandy loam soil, < 1.41 % OC)~~

- ~~**corn/corn rotation (2 x 480 g a.s./ha)**~~

~~Total mean 0.87-0.99 µg/l, max. 2.23 µg/l (y 1)~~
~~mean 0.46-0.67 µg/l, max. 1.0 µg/l (y 2)~~
~~mean 0.23-0.33 µg/l, max. 0.33 µg/l (y 3)~~
~~a.s. < 0.035 µg/l~~
~~FOE oxalate < 0.04 µg/l~~
~~FOE thioglycolate < 0.08 µg/l~~
~~FOE sulfonic acid~~
~~mean 0.49-0.59 µg/l, max. 1.29 µg/l (y 1)~~
~~mean 0.15-0.24 µg/l (y 2)~~

~~Conclusions: Under unfavourable conditions (sand soil, high rainfall), concentrations of flufenacet and of most of its degradation products are clearly < 0.1 µg/L in soil water at 1.3 m depth, for repeated applications to corn at 480 g as/ha with the exception of metabolite FOE sulfonic acid. For this compound, the maximum concentration is 1.29 µg/L (year 1) and annual mean concentrations are 0.49-0.59 µg/L (year 1) and 0.15-0.24 µg/L (year 2). This metabolit eis likely to present hazard to ground water wand this risk is similar for both single ans repeated applications. No accumulation in soi lis expected.~~

- ~~**corn/wheat rotation (480 + 180 g a.s./ha)**~~

~~Total mean 2.5 µg/l, max. 5 µg/l (year 1)~~

~~mean 0.24 µg/l (year 2)~~
~~a.s. not identified~~
~~FOE oxalate and thioglycolate < 0.1 µg/l~~
~~FOE sulfonic acid :~~
~~mean 1.49 µg/l, max. 3.7 µg/l (year 1)~~
~~mean 0.015 µg/l (year 2)~~
~~**Conclusions:** Th maximum concentration of FOE 5043 in single leachates were measured to be lower than 0.01 µg/l, however, a defined peak of the parent compound could not be observed. Therefore, FOE 5043 was not positively identified in the leachate. The same is true for FOE oxalate (M1, ≤0.04 µg/l). FOE alcohol (M3) was only positively identified in lysimeter #18, especially in the early leachates in maximum concentrations of 0.16 µg/l. Whereas FOE thioglycolate sulfoxide was only detected in amounts of 0.028 µg/l, the maximum residues of FOE sulfonic acid (M2) in the leachates of February 1994 were 3.4 µg/l (lys #17) and 3.7 µg/l (lys #18). Maximum concentrations of radioactivity remaining at the start and being spread over the whole TLC plate were 0.31 and 0.37 µg/l, respectively, and unknown single metabolites were below 0.08 µg/l.~~
~~The results of this study proved that even under worst case conditions a contamination of soil layers below 1.2 m depth by parent compound can be precluded with high probability. Most of ist relevant degradation products in soil showed a similar behaviour. Furthermore, the data confirmed that FOE 5043 is well degradable in soil.~~

Conclusions: No scenerio predicts to exceed 0.1 µg/L for active substance Florasulam, Diflufenican and Diflufenican. However metabolite TSA, ASTCA, 5-OH Florasulam, DOE sulfonic acid exceed triger value 0.1 µg/L. Therfore, Assessment of relevance of ground water metabolites is performed and presented in section b10 of dRR

Assessment of relevance of ground water metabolites is performed and presented in section b10 of dRR

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

Evaluator's Comments:	The submitted PECsw and PECsed calculations were accepted. All used endpoints for active substances and their metabolites were agreed at the EU level. The recommended FOCUS models were used: FOCUS Step 1 & 2, Step 3 and Step 4. The autumn application was taken into consideration. D1 and D2 scenarios are not relevant for Central Zone and were not taken into consideration. The max PECsw for Central zone and Poland with relevant mitigation measure are presented in the table below. **Florasulam**. **The active substance name in Section 8.9.2.1 was corrected**. The PECsw and PECsed assessment for active substance and its metabolites was provided in accordance with intended use (single use).

Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Central Zone Max PEC_{sw} (µg/L)
Winter cereals	4.8	20	20	0. R3 stream

Metabolites of florasulam. The relevant metabolites were taken into consideration; the Step 1 & 2 were used in PEC assessment. In the table below the higher values of PECsw and PECsed (from alkaline and acidic soils) are presented.

Step 1

Compound	PECsw	PECsed
	µg/L	µg/kg
5-OH-florasulam	2.62	0.38
DFP-ASTCA	0.33	0.26
ASTCA	0.72	0.75
TSA	0.10	0.02
TPSA	0.63	0.26
ASTP	0.22	0.13
5-OH ASTP	0.28	0.21

Diflufenican. The PECsw and PECsed values for active substance and its metabolites with relevant mitigation measures are presented in the table below.

Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Max PEC_{sw} (µg/l)
Winter cereals	100	20	20	0.1656 D4 stream

Metabolites of diflufenican. The relevant metabolites were taken into consideration; the Step 1 & 2 were used in PEC assessment. In the table below the higher values of PECsw and PECsed (from alkaline and acidic soils) are presented.

Step 1

Compound	PECsw	PECsed
	µg/L	µg/kg
AE B107137	12.59	1.63
AE 0542291	5.34	7.04

Flufenacet. The PECsw and PECsed values for active substance and its metabolites with relevant mitigation measures are presented in the table below.

Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Max PEC_{sw} (µg/l)
Winter cereals	124.8	20	20	0.4940 D5 stream

Metabolites of flufenacet. The relevant metabolites were taken into consideration; the Step 1 & 2 were used in PEC assessment. In the table below PECsw and PECsed are presented.

Step 1

Compound	PECsw	PECsed
	µg/L	µg/kg
FOE methylsulfide	3.67	0.00
FOE thiadone	16.41	0.00
FOE sulfonic acid	8.12	1.02

Additionally, for the ecotoxicological request, for active substances mixture risk assessment, in Step 4 (SWAN and VFSmod) the PECsw was assessed. The mitigation measures of 20 m vegetated buffer strip and 20 m non-sprayed strip with 90 % drift reduction were taken into consideration.

ZRMS is of the opinion, that relevant mitigation measures will be proposed at the Member State level.

The drift exposure was reassessed by evaluator using the Drift Calculator in SWASH model:

Crop	Application rate g product./ha	No spray buffer (m)	Max PEC_{sw} (µg/l)
Winter cereals	483.1	10 20 30 40 50 60 65	0.4462 0.2318 0.1572 0.1191 0.0960 0.0804 0.0744

The relevant mitigation measure will be recommended in ecotoxicological section.

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
- Diflufenican - EFSA Scientific Report (2007) 122, 1-84,

- Flufenacet – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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/FDF 574 SC
Use No.	1
Crop	Winter cereals
Application rate (kg as/ha)	Florasulam: 0.0048 Dilfufenican: 0.100 Flufenacet:0.1248
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

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of CHR/H/FDF 574 SC

Crop	Scenario	Application window used in modelling
Winter cereals	D3	23 Nov – 23 Dec
	D4	24 Sep – 24 Oct
	D5	12 Nov – 12 Dec
	R1	14 Nov – 14 Dec
	R3	1 Dec – 31 Dec
	R4	15 Nov – 15 Dec

8.9.2.1 ~~Penoxsualm~~ Florasulam and its metabolites

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

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA	TPSA	ASTP	5-OH ASTP	Value in accordance 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/ 4.3×10^{-5}	not required for Step 1+2/ 4.3 x 10-5	not required for Step 1+2/ 4.3×10^{-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
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)	not required for Step 1+2/ 0.05 (MACRO)	not required for Step 1+2/ 0.05 (MACRO)	not required for Step 1+2/ 0.05 (MACRO)	not required for Step 1+2/ 0.05 (MACRO)	not required for Step 1+2/ 0.05 (MACRO)	not required for Step 1+2/ 0.05 (MACRO)	not required for Step 1+2/ 0.05 (MACRO) 0.50	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**
	0.50 (PRZM)	0.50 (PRZM)	0.50 (PRZM)	0.50 (PRZM)	0.50 (PRZM)	0.50 (PRZM)	0.50 (PRZM)	(PRZM)	
$DT_{50,soil}$ (d)	1.55	14.98	16.62	297.47	23.46	41.52	60.22	77.74	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

$PEC_{sw/sed}$

New calculation (highlight in blue) was performed only for mixture toxicity for aquatic species in Section B9 to show acceptable risk assessment for this case in that scenarios. New calculation performed without vfs mod by SWAN v.5.0.1

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Florasulam following single/ ~~multiple~~ application(s) of CHR/H/FDF 574 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	---	1.62	drainage/run off	1.04	0.17
Step 2		0.17	drainage/run off	0.11	0.02
Northern Europe	Oct-Feb	0.17	drainage/run off	0.11	0.02
Southern Europe	-	-	-	-	-
Step 3					
D3 ditch	Ditch	0.03020	drainage	0.001148	0.002442
D4 pond	pond	0.001099	drainage	0.000859	0.000437
D4 stream	stream	0.02620	drainage	0.000362	0.001398
D5 pond	pond	0.001099	drainage	0.000909	0.000623
D5 stream	stream	0.02826	drainage	0.000519	0.001728
R1 pond	pond	0.001865	run off	0.001540	0.000928
R1 stream	stream	0.09043	run off	0.002003	0.006603
R3 stream	Stream	0.02820	run off	0.000475	0.001654
R4 stream	stream	0.02667	run off	0.000950	0.002300
Step 4	20 meters vegetative and 20 meters no spray buffer zone – only for aquatic mixture toxicity				
R1 stream	stream	0.02113	Run off	0.000441	0.001564
R3 stream	Stream	0.002751	run off	0.000046	0.000168
R4 stream	stream	0.006289	Run off	0.000204	0.000547
Step 4	20 meters vegetative and 20 meters no spray buffer zone and 90% nozzle reduction – only for aquatic mixture toxicity				
R1 stream	Stream	0.02113	run off	0.000427	0.001558
R3 stream	Stream	0.001378	Run off	0.000031	0.000106
R4 stream	Stream	0.006289	run off	0.000193	0.000543

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

Metabolite(s) of Florasulam

Table 8.9-5: FOCUS Step 1, 2 and 3 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	---	2.62	-	2.60	0.38
Step 2		---	0.61	-	0.61	0.09
Northern Europe		Oct -Feb	0.61	-	0.61	0.09
Southern Europe		-	-	-	-	-
Step 1	DFP-ASTCA	---	0.33	-	0.33	0.26
Step 2		---	0.10	-	0.1	0.08
Northern Europe		Oct - Feb	0.10	-	0.10	0.08
Southern Europe		-	-	-	-	-
Step 1	ASTCA	---	0.72	-	0.71	0.75
Step 2		---	0.19	-	0.19	0.20
Northern Europe		Oct-Feb	0.19	-	0.19	0.20
Southern Europe		-	-	-	-	-
Step 1	TSA	---	0.10	-	0.10	0.02
Step 2		---	0.05	-	0.04	0.01
Northern Europe		Oct-Feb	0.05	-	0.04	0.01
Southern Europe		-	-	-	-	-
Step 1	TPSA	---	0.63	-	0.62	0.26
Step 2		---	0.07	-	0.07	0.03
Northern Europe		Oct-Feb	0.07	-	0.07	0.03
Southern Europe		-	-	-	-	-
Step 1	ASTP	---	0.22	-	0.22	0.13
Step 2		---	0.02	-	0.02	0.01
Northern Europe		Oct-Feb	0.02	-	0.02	0.01

Scenario FOCUS	Metabolite	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Southern Europe		-	-	-	-	-
Step 1	5-OH ASTP	---	0.28	-	0.28	0.22
Step 2		---	0.03	-	0.03	0.02
Northern Europe		Oct-Feb	0.03	-	0.03	0.02
Southern Europe		-	-	-	-	-

8.9.2.2 Diflufenican and its metabolites

Table 8.9-5: Input parameters related to active substance Diflufenican and metabolite(s) for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4

Compound	Diflufenican	AE B107137	AE 0542291	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	394	283	282	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Saturated vapour pressure (Pa)	0.425E-05	Not required for Step 1+2	Not required for Step 1+2	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Water solubility (mg/L)	50	410	100	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	Not required for Step 1+2	Not required for Step 1+2	default
Diffusion coefficient in air (m²/d)	0.43	Not required for Step 1+2	Not required for Step 1+2	default

Compound	Diflufenican	AE B107137	AE 0542291	Value in accordance to EU endpoint y/n/ Reference
K_{foc} (mL/g)	1989	13	131.9	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Freundlich Exponent 1/n	0.91	0.73	0.81	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Plant Uptake	0	Not required for Step 1+2	Not required for Step 1+2	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
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	default
$DT_{50,soil}$ (d)	141.8	10.6	20.9	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
$DT_{50,water}$ (d)	31.7	730	730	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
$DT_{50,sed}$ (d)	338.7	730	730	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
$DT_{50,whole\ system}$ (d)	214	730	730	EFSA Scientific Report (2007) 122,1-84, Conclusion on the

Compound	Diflufenican	AE B107137	AE 0542291	Value in accordance to EU endpoint y/n/ Reference
				peer review of Diflufenican, Appendix 1 – list of end points
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 16.8 Water/ Sediment: 35.7	Soil: 26.3 Water: Sediment: 0.0001	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points

$PEC_{sw/sed}$

New calculation (highlight in blue) was performed only for mixture toxicity for aquatic species in Section B9 to show acceptable risk assessment for this case in that scenarios. New calculation performed without vfs mode by SWAN v.5.0.1

Table 8.9-6: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Diflufenican following single/ multiple application(s) of CHR/H/FDF 574 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	---	10.05	Drainage/run off	9.08	185.95
Step 2					
Northern Europe	Oct-Feb	4.79	Drainage/run off	4.31	93.63
Step 3					
D3	Ditch	0.6299	Drainage	0.02287	0.3088
D4	pond	0.04667	Drainage	0.03718	0.3668
D4	stream	0.5464	Drainage	0.01610	0.1787
D5	pond	0.02189	Drainage	0.01679	0.1939
D5	stream	0.5896	Drainage	0.01078	0.1607
R1	pond	0.06265	Run off	0.04945	0.5696
R1	stream	0.4154	Run off	0.02002	0.5601
R3	stream	0.5829	Run off	0.02451	0.4198
R4	stream	0.5912	Run off	0.02899	0.5392
Step 4	10 meters vegetative buffer zone and 10 meters no-spray buffer zone				
D3	Ditch	0.09049	Drainage	0.003280	0.04528

Scenario FOCUS	**Waterbody**	**Max PEC$_{sw}$ (µg/L)***	**Dominant entry route**	**21 d- PEC$_{sw,twa}$ (µg/L)****	**Max PEC$_{sed}$ (µg/kg)***
D4	pond	0.04452	Drainage	0.03531	0.3258
D4	Stream	0.1656	Drainage	0.01610	0.1654
D5	pond	0.01363	Drainage	0.01054	0.1522
D5	stream	0.1140	Drainage	0.002155	0.03206
R1	pond	0.02718	Run off	0.02155	0.2619
R1	stream	0.1749	Run off	0.008953	0.1770
R3	stream	0.1949	Run off	0.009706	0.1375
R4	stream	0.2667	Run off	0.01228	0.1990
Step 4	20 meters vegetative buffer zone and 20 meters no-spray buffer zone – used only for mixture toxicity in aquatic speciec				
R1	Stream	0.09109	Run off	0.004660	0.08603
R3	stream	0.1018	Run off	0.005064	0.06789
R4	stream	0.1393	Run off	0.006397	0.1006
Step 4	20 meters vegetative buffer zone and 20 meters no-spray buffer zone (vfs mode) – used only for mixture toxicity in aquatic speciec				
D3	Ditch	0.04703	Drainage	0.001704	0.02368
D4	pond	0.04336	Drainage	0.03431	0.3034
D4	Stream	0.1656	Drainage	0.08817	0.1638
D5	pond	0.01229	Drainage	0.009766	0.1295
D5	stream	0.06354	Drainage	0.002155	0.02712
R1	pond	0.009043	Run off	0.006760	0.05747
R1	stream	0.04185	Run off	0.000350	0.005559
R3	stream	0.05872	Run off	0.000958	0.01546
R4	stream	0.04151	Run off	0.000312	0.005451

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

Metabolite(s) of diflufenican

Table 8.9-7: FOCUS Step 1, 2 PEC$_{sw}$ and PEC$_{sed}$ for AE B107137 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	---	12.59	Drainage/runoff	12.46	1.63
Step 2					

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Northern Europe	Oct-Feb	5.87	Drainage/runoff	5.81	0.76

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

Table 8.9-8: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE 0542291 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	---	5.34	Drainage/runoff	5.28	7.04
Step 2					
Northern Europe	Oct-Feb	2.34	Drainage/runoff	2.31	3.08

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

8.9.2.3 Flufenacet and its metabolites

Table 8.9-9: Input parameters related to active substance flufenacet and metabolite(s) for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4

Compound	Flufenacet	FOE methylsulfide	FOE thiadone	FOE Sulfonic acid	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	363.34	273.3 g/mol	170.1 g/mol	275.3 g/mol	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B-B.7 Enviromental Fate and behaviour (2003).
Saturated vapour pressure (Pa)	9E-5	9E-5	9E-5	9E-5	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B-B.7 Enviromental Fate and behaviour (2003).
Diffusion	4.3×10^{-5}	not required for	not required	not required for	default

Compound	Flufenacet	FOE methylsulfide	FOE thiadone	FOE Sulfonic acid	**Value in accordance to EU endpoint y/n/ Reference**
coefficient in water (m²/d)		Step 1+2/	for Step 1+2	Step 1+2	
Diffusion coefficient in air (m²/d)	0.43	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
Water solubility (mg/L)	56	56 from parent	56 from parent	56 from parent	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B-B.7 Enviromental Fate and behaviour (2003).
KOC	349	0	0	12.5	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B-B.7 Enviromental Fate and behaviour (2003).
Plant Uptake	0.5	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/	default
$DT_{50,soil}$ (d)	16.5 d	0.1 d	0.1 d	140	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B-B.7 Enviromental Fate and behaviour (2003).
$DT_{50,water}$ (d)	61.7 d	1000 d	1000 d	1000 d	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B-B.7 Enviromental Fate and behaviour (2003).
$DT_{50,sed}$ (d)	1000 d	1000 d	1000 d	1000 d	
$DT_{50,whole\ system}$ (d)	84.6 d (STEP 1-2)	1000 d	1000d	1000 d	
Maximum occurrence observed (% molar basis with respect to the parent)		Maximum occurrence observed in soil: 0.001% max. 8 % in water, 3.4 % in sediment	Maximum occurrence observed in soil: 0.001 % Max 82 % in water (55 d)	Maximum occurrence observed in soil: 26.2% Max 0.001% in water	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B-B.7 Enviromental Fate and behaviour (2003).

$PEC_{sw/sed}$

New calculation (highlight in blue) was performed only for mixture toxicity for aquatic species in Section B9 to show acceptable risk assessment for this case in that scenarios. New calculation performed without vfs mode by SWAN v.5.0.1

Table 8.9-10: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for flufenacet following single/ multiple application(s) of CHR/H/FDF 574 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	---	29.54	Drainage/runoff	26.81	100.98
Step 2					
Northern Europe	Oct-Feb	12.84	Drainage/runoff	11.72	44.49
Step 3					
D3	Ditch	0.7881	Drainage	0.02892	0.2752
D4	pond	0.02724	Drainage	0.02216	0.1416
D4	stream	0.6839	Drainage	0.009442	0.1218
D5	pond	0.3578	Drainage	0.3279	1.457
D5	stream	0.7378	Drainage	0.1179	0.4872
R1	pond	0.08545	Run off	0.07424	0.3978
R1	stream	2.046	Run off	0.04604	0.5613
R3	stream	2.602	Run off	0.1100	0.8316
R4	stream	2.429	Run off	0.09891	0.9011
Step 4	10 meters vegetative buffer zone and 10 meters no-spray buffer zone				
D3	Ditch	0.1134	Drainage	0.004157	0.04227
D4	pond	0.01696	Drainage	0.01401	0.1163
D4	Stream	0.1325	Drainage	0.007759	0.03325
D5	pond	0.3550	Drainage	0.3253	1.431
D5	stream	0.4940	Drainage	0.1179	0.4765
R1	pond	0.03775	Run off	0.03284	0.1888
R1	stream	0.9162	Run off	0.01941	0.2453
R3	stream	1.173	Run off	0.04956	0.3677
R4	stream	1.096	Run off	0.04350	0.4099
Step 4	20 meters vegetative buffer zone and 20 meters no-spray buffer zone – used only for mixture toxicity in aquatic species				
R1	stream	0.4774	Run off	0.01009	0.1288
R3	stream	0.6129	Run off	0.02587	0.1942
R4	stream	0.5727	Run off	0.02267	0.2188
Step 4	10 meters vegetative buffer zone and 10 meters no-spray buffer zone (vfs mode)				
D3	Ditch	0.1134	Drainage	0.004157	0.04227
D4	pond	0.01696	Drainage	0.01401	0.1163
D4	Stream	0.1325	Drainage	0.007759	0.03325
D5	pond	0.3550	Drainage	0.3253	1.431

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D5	stream	0.4940	Drainage	0.1179	0.4765
R1	pond	0.03775	Run off	0.03284	0.1888
R1	stream	0.1007	Run off	0.001208	0.01735
R3	stream	0.1413	Run off	0.001715	0.02313
R4	stream	0.09989	Run off	0.000781	0.01010
Step 4	20 meters vegetative buffer zone and 20 meters no-spray buffer zone (vfs mode) – used only for mixture toxicity in aquatic speciec				
D3	Ditch	0.05897	Drainage	0.002162	0.02245
D4	pond	0.01388	Drainage	0.01338	0.1026
D4	Stream	0.06895	Drainage	0.007759	0.03263
D5	pond	0.3535	Drainage	0.3239	1.416
D5	stream	0.4940	Drainage	0.1179	0.4752
R1	pond	0.01137	Run off	0.009455	0.04401
R1	stream	0.05242	Run off	0.000439	0.006412
R3	stream	0.07353	Run off	0.000892	0.01216
R4	stream	0.05199	Run off	0.000354	0.005288

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

Metabolite(s) of flufenacet

Table 8.9-11: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for FOE methylsulfide 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	---	3.67	Drainage/runoff	3.64	0.00
Step 2					
Northern Europe	Oct-Feb	1.61	Drainage/run off	1.59	0.00

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

Table 8.9-12: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for FOE thiadone 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	---	16.41	Drainage/runoff	16.29	0.00
Step 2					
Northern Europe	Oct-Feb	7.19	Drainage/run off	7.14	0.00

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

Table 8.9-13: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for FOE sulfonic 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	---	8.12	Drainage/runoff	8.06	0.00
Step 2					
Northern Europe	Oct-Feb	3.98	Drainage/run off	3.95	0.50

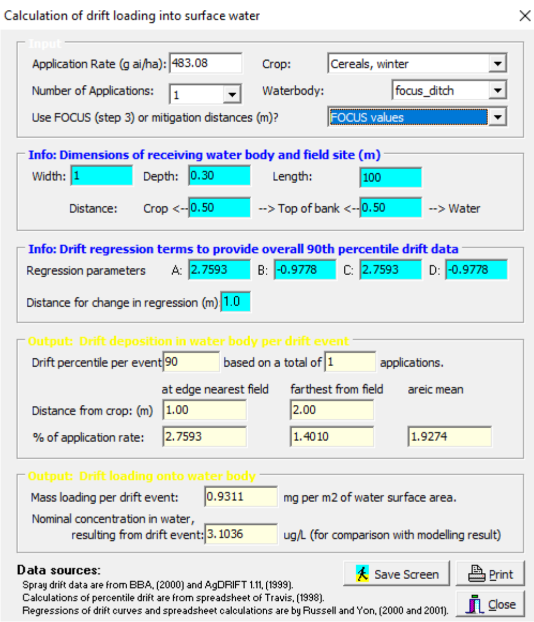
* single applications should be marked.
** twa-time as required by ecotox

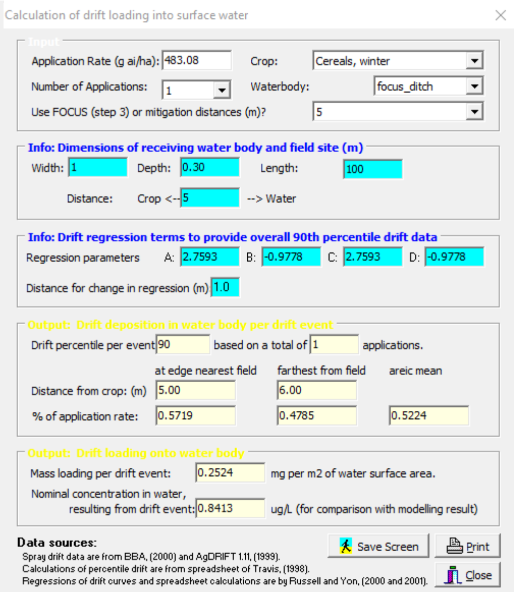
8.9.2.4 PEC$_{sw/sed}$ of CHR/H/FDF 574 SC

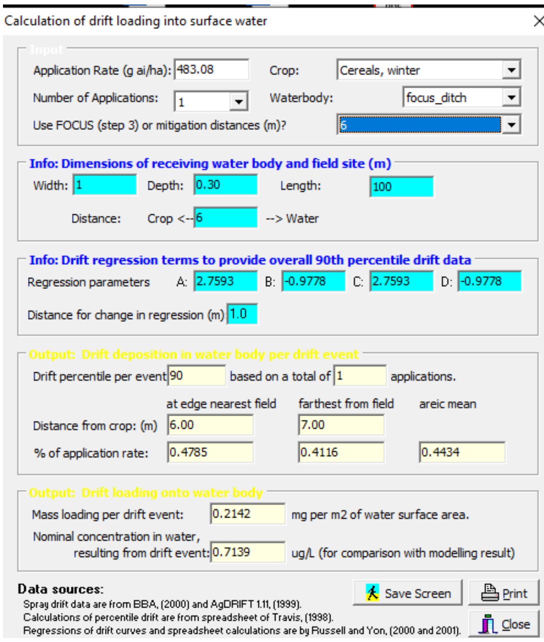
New calculation (highlight in blue) was performed to show acceptable buffer zone for formulation.

Table 8.9-14: PEC$_{sw}$ of CHR/H/FDF 574 SC assuming application 483.08 g prod/ha (0.4L on winter cereals) in Drift calculator into surface water from SWASH ver 5.3

Intended use **Formulation** **Application rate (g[prod]/ha)**	Winter cereals CHR/H/FDF 574 SC 1 X 483.08g
Entry into surface water via spraydrift (Drift alculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L**
1	3.1036
5	0.8413
6	0.7139
16	0.2867
20	0.2318
30	0.1572
35	0.1355
65	0.0744






Calculation of drift loading into surface water
Application Rate (g ai/ha): 483.08
Crop: Cereals, winter
Number of Applications: 1
Waterbody: focus_ditch
Use FOCUS (step 3) or mitigation distances (m)? 6
Info: Dimensions of receiving water body and field site (m)
Width: 1
Depth: 0.30
Length: 100
Distance: Crop <-- 6 --> Water
Info: Drift regression terms to provide overall 90th percentile drift data
Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778
Distance for change in regression (m) 1.0
Output: Drift deposition in water body per drift event
Drift percentile per event 90 based on a total of 1 applications.
at edge nearest field
farthest from field
areic mean
Distance from crop: (m) 6.00 7.00
% of application rate: 0.4785 0.4116 0.4434
Output: Drift loading onto water body
Mass loading per drift event: 0.2142 mg per m2 of water surface area.
Nominal concentration in water, resulting from drift event: 0.7139 ug/L (for comparison with modelling result)
Data sources:
Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
Calculations of percentile drift are from spreadsheet of Travis, (1998).
Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 2001).
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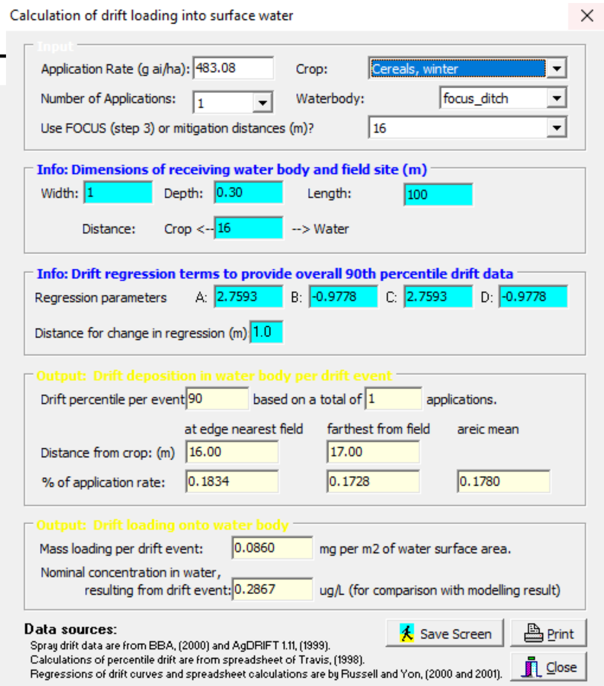
Calculation of drift loading into surface water
Application Rate (g ai/ha): 483.08
Crop: Cereals, winter
Number of Applications: 1
Waterbody: focus_ditch
Use FOCUS (step 3) or mitigation distances (m)? 16
Info: Dimensions of receiving water body and field site (m)
Width: 1
Depth: 0.30
Length: 100
Distance: Crop <-- 16 --> Water
Info: Drift regression terms to provide overall 90th percentile drift data
Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778
Distance for change in regression (m) 1.0
Output: Drift deposition in water body per drift event
Drift percentile per event 90 based on a total of 1 applications.
at edge nearest field
farthest from field
areic mean
Distance from crop: (m) 16.00 17.00
% of application rate: 0.1834 0.1728 0.1780
Output: Drift loading onto water body
Mass loading per drift event: 0.0860 mg per m2 of water surface area.
Nominal concentration in water, resulting from drift event: 0.2867 ug/L (for comparison with modelling result)
Data sources:
Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
Calculations of percentile drift are from spreadsheet of Travis, (1998).
Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 2001).
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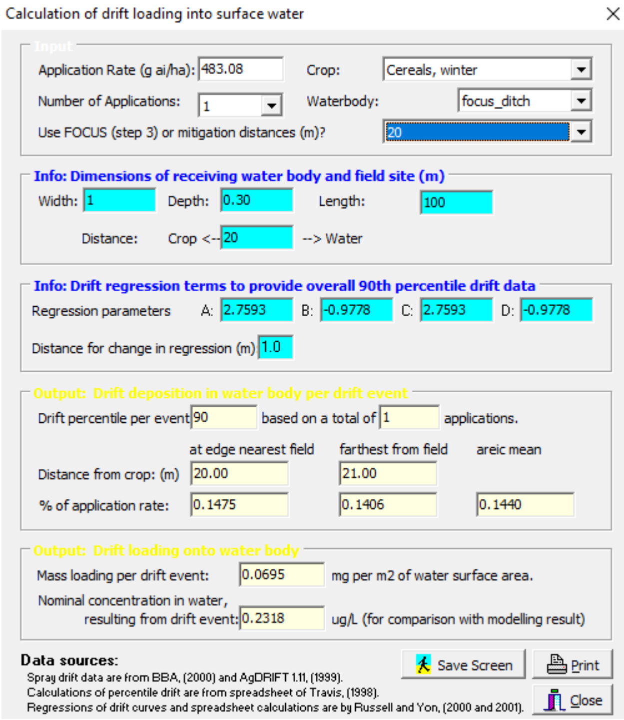
Calculation of drift loading into surface water
Application Rate (g ai/ha): 483.08
Crop: Cereals, winter
Number of Applications: 1
Waterbody: focus_ditch
Use FOCUS (step 3) or mitigation distances (m)? 20
Info: Dimensions of receiving water body and field site (m)
Width: 1
Depth: 0.30
Length: 100
Distance: Crop <-- 20 --> Water
Info: Drift regression terms to provide overall 90th percentile drift data
Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778
Distance for change in regression (m) 1.0
Output: Drift deposition in water body per drift event
Drift percentile per event 90 based on a total of 1 applications.
at edge nearest field
farthest from field
areic mean
Distance from crop: (m) 20.00 21.00
% of application rate: 0.1475 0.1406 0.1440
Output: Drift loading onto water body
Mass loading per drift event: 0.0695 mg per m2 of water surface area.
Nominal concentration in water, resulting from drift event: 0.2318 ug/L (for comparison with modelling result)
Data sources:
Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
Calculations of percentile drift are from spreadsheet of Travis, (1998).
Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 2001).
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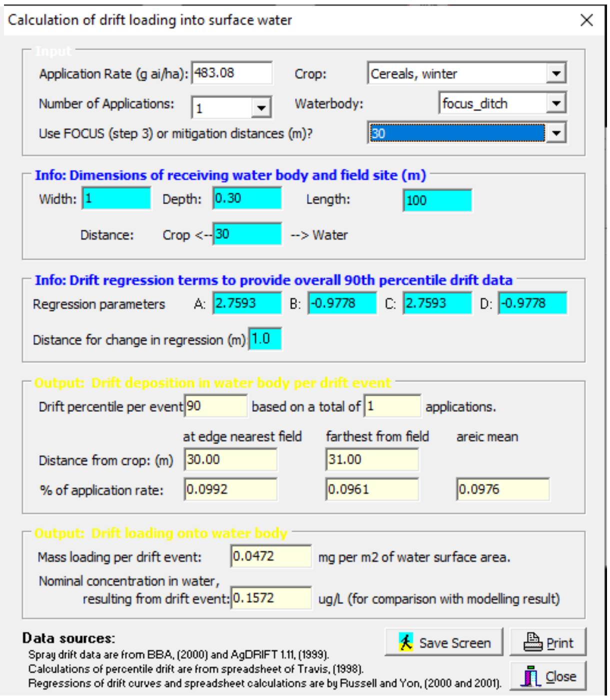
Calculation of drift loading into surface water
Application Rate (g ai/ha): 483.08
Crop: Cereals, winter
Number of Applications: 1
Waterbody: focus_ditch
Use FOCUS (step 3) or mitigation distances (m)? 30
Info: Dimensions of receiving water body and field site (m)
Width: 1
Depth: 0.30
Length: 100
Distance: Crop <-- 30 --> Water
Info: Drift regression terms to provide overall 90th percentile drift data
Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778
Distance for change in regression (m) 1.0
Output: Drift deposition in water body per drift event
Drift percentile per event 90 based on a total of 1 applications.
at edge nearest field
farthest from field
areic mean
Distance from crop: (m) 30.00 31.00
% of application rate: 0.0992 0.0961 0.0976
Output: Drift loading onto water body
Mass loading per drift event: 0.0472 mg per m2 of water surface area.
Nominal concentration in water, resulting from drift event: 0.1572 ug/L (for comparison with modelling result)
Data sources:
Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
Calculations of percentile drift are from spreadsheet of Travis, (1998).
Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 2001).
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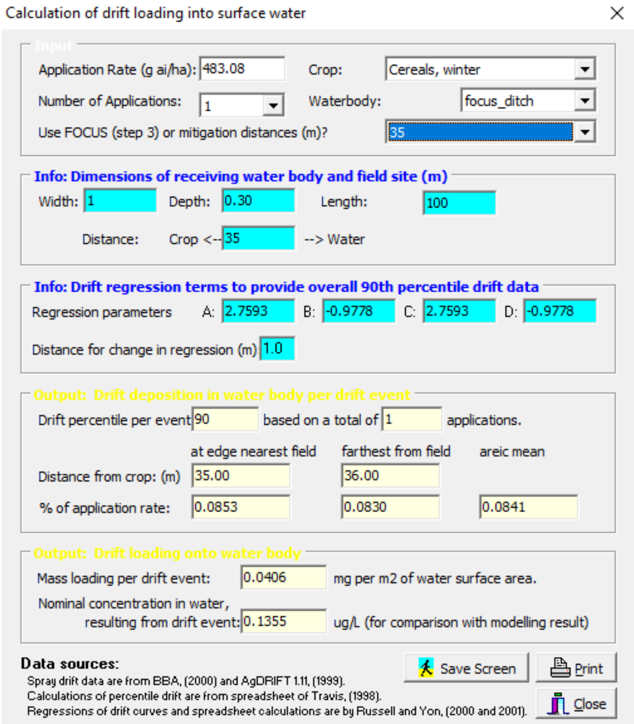

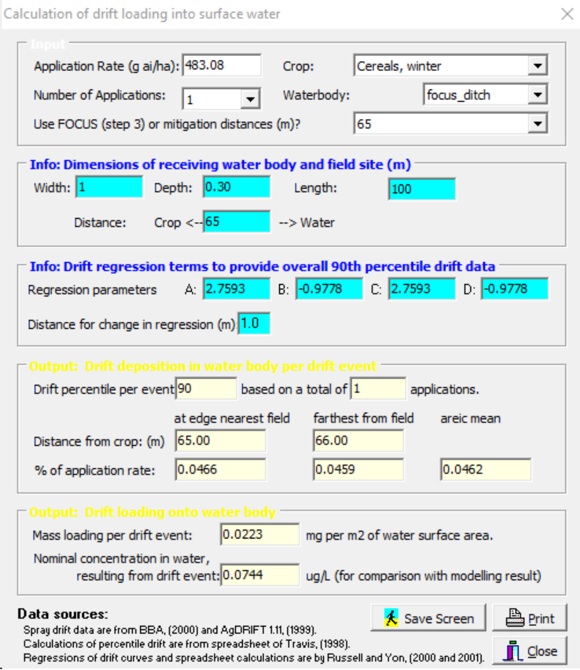

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

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

Compound	Diflufenican

Direct photolysis in air ‡	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air ‡	DT_{50} of 5.0 d (EU), 3.3 d (USA) derived by the Atkinson method of calculation
Volatilisation ‡	From plant surfaces (BBA guideline): negligible (max. 0.3 %) after 24 hours
	from soil (BBA guideline): negligible (<0.01 %) after 24 hours
Metabolites	Metabolite AE C522392 was found to be volatile in an anaerobic soil degradation study (peak of 28.11% AR in volatile traps). However because its DT_{50} in air is 10.5 hours (via Atkinson calculation), it is unlikely to persist in the troposphere or be subject to long range transport.

The vapour pressure at 20 °C of the active substance diflufenican is < 10^{-5} Pa. Hence the active substance diflufenican is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance diflufenican due to volatilization with subsequent deposition should be considered.

Table 8.10-3 Summary of atmospheric degradation and behaviour

Compound	Flufenacet
Direct photolysis in air	No data provided, not required (no absorbance above 290 nm)
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air	4.7 h (according to Atkinson)
Volatilisation	from plant surfaces: no data, not required from soil: up to 29 % within 1 day
Metabolites	None

The vapour pressure at 20 °C of the active substance Flufenacet is between 10^{-5} and 10^{-4} Pa. Hence the active substance flufenacet is regarded as semivolatile (volatilisation only from plant surfaces. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance flufenacet due to volatilization with subsequent deposition should be considered.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.3	-	2016	CHR/H/FDF 574 SC Predicted environmental concentration of flufenacet and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: CHR/H/PENDIF-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.4	-	2016	CHR/H/FDF 574 SC Predicted environmental concentration of flufenacet and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: CHR/H/PENDIF-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.5	-	2016	CHR/H/FDF 574 SC Predicted environmental concentration of flufenacet and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: CHR/H/PENDIF-B8 Non GLP Unpublished	N	Chemirol

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
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	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
			Study report No. GHE-P-6750; DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished		s
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 Unpublished	N	DowAgroSciences
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	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
			application of EF-1343, UK – 1996 Study report No. GHE-P-6368 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished		s
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
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	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	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 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]-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	2011	Florasulam: Adsorption Properties of [14C]-TSA in Four Soils	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
	R.,		Study report No. YR/11/007; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished		s
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	DowAgroScience s
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	DowAgroScience s
KCP 9.2	Jackson R., Portwood D.,	1993	The Aqueous Hydrolysis of XR-570 Study report No. GHE-P-3326 DowElanco Limited, Letcombe Laboratory, Letcombe Regis GLP No Unpublished	N	DowAgroScience 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	DowAgroScience s
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	N	DowAgroScience s

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 9.2	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
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	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
			Study report No. GHE-P-5039 (Inveresk Project No. 12712) Inveresk Research International Ltd. GLP Yes Unpublished		s
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 GLP No Unpublished	N	DowAgroSciences
KCP 9.1/09	Buys M., Chabassol Y.	1985	Diflufenican (MB38544) Aerobic soilmetabolism study. Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro, Lyon, France; Centre de Recherche de la Dargoire Document No: R008121 GLP / GEP: No unpublished	N	BCS

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 9.1/10	Slater B.J., McClenaghan I.	1987	Diflufenican - Structure of soil metabolite Generated by: Rhone-Poulenc; May & Baker Ltd., Dagenham, Essex, GBR; Radiochemistry & Analytical Chemistry Laboratories Document No: R008226 GLP / GEP: No unpublished	N	BCS
KCP 9.1/11	Unsworth R.H., Clarke D.E.	2000	(2-pyridine-14C)-diflufenican: Route of aerobic degradation in one soil type at 20 degrees Celsius. Generated by: Rhone-Poulenc; Aventis CropScience U.K., Ltd.; Document No: R008059 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/12	Mahay N., Lowden P.	2000	(14C)-Diflufenican: route of degradation in one soil (using (14C)-2,4-difluorophenyl ringlabelled and (14C)-3-trifluoromethylphenyl ring-labelled diflufenican) Code: AE F088657 Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010668 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/13	Oddy A.M., Hatcher G.	2000	(14C)-diflufenican anaerobic soil degradation Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010707 GLP / GEP Yes	N	BCS

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 9.2/07	Chabassol Y.	1985	MB 38544 Anaerobic aquatic metabolism study. Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Lyon, France; Centre de Recherche de La Dargoire Document No: R008125 GLP / GEP: No unpublished	N	BCS
KCP 9.1/14	Hobbs D., Savage E.A.	1986	Herbicides: Diflufenican-14C:Photodegradation study on soil Generated by: Rhone-Poulenc; May & Baker Ltd., Ongar, Essex, GBR; Environmental Chemistry Document No: R008188 GLP / GEP: No unpublished	N	BCS
KCP 9.1/15	Chabassol Y.	1985	Diflufenican (MB38544) Rate of degradation in soil. Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro, Lyon, France; Centre de Recherche de la Dargoire Document No: R008123 GLP / GEP: No unpublished	N	BCS
KCP 9.1/16	Mahay N., Burr C.M.	2001	Rate of degradation in three soils at 20 degrees C and one at 10 degrees C (14C)-Diflufenican Generated by: Aventis CropScience UK Limited, GBR; Environmental Chemistry, Ongar Document No: C014862 GLP / GEP Yes	N	BCS

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 9.1/17	Fliege R.	2002	Rate of degradation of (pyridyl-2-14C)-AE 0650274 in three European soils at 20 degrees C under laboratory conditions Code: AE 0650274 (= AE B107137 = M&B 38181) Generated by: Aventis CropScience GmbH, DEU; Oekochemie, Frankfurt Document No: C022808 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/18	Fliege R.	2002	Rate of degradation of (pyridyl-2-14C)-AE 0542291 in three European soils at 20 degrees C under laboratory conditions Code: AE 0542291 (= M&B 43625) Generated by: Aventis CropScience GmbH, DEU; Oekochemie, Frankfurt Document No: C022809 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/19	Oddy A.M., Hatcher G.	2000	(14C)-diflufenican anaerobic soil degradation Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010707 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/20	Lowden P., Mahay N.	1999	Anerobic soil degredation (14C)-M&B 38181 Generated by: Rhone-Poulenc Agriculture Ltd, Ongar, GBR; Rhone-Poulenc Agriculture Ltd, Ongar, GBR; Document No: C010709 GLP / GEP Yes	N	BCS

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 9.1/21	Hardy I.	2003	Kinetic evaluation of a laboratory anaerobic soil study with diflufenican using TopFit 2.0 to derive degradation data for the metabolite M&B40401 Code AE F088657 AE C522392 Generated by: Batelle AgriFood Ltd., Ongar, UK; BCS S.A., FRANCE; Environmental Chemistry Document No: C031450 GLP / GEP: Not required unpublished	N	BCS
KCP 9.1/22	Duncan P., Doran A., Livingstone K.	2004	Terrestrial field dissipation of diflufenican and its metabolites M&B 43625 and M&B 38181 at 4 Northern and 2 Southern European locations Generated by: Bayer CropScience GmbH, DEU Inveresk Research, Tranent, Scotland; Document No: C031887 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/23	Brumhard B.	2004	Determination of the storage stability of diflufenican and its metabolites M&B38181 and M&B43625 in soil from the dissipation study Generated by: Bayer CropScience AG, Monheim, DEU Document No: C031487 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/24	Hardy I.A.J.	2004	Diflufenican: Kinetic modelling analysis of data from field soil dissipation studies conducted at ten locations in Europe Generated by: Battelle AgriFood Ltd., Ongar, UK; Bayer CropScience AG, DEU	N	BCS

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
			Document No: C031888 GLP / GEP: Not required Unpublished		
KCP 9.1/25	Maycey P.A., Savage E.A.	1990	Herbicides: Diflufenican - Investigation of behaviour under field conditions after treatment with Fenikan, West Germany, 1987/ 89 Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture, Essex, England; Analytical Chemistry Department Document No: R007601 GLP / GEP: No unpublished	N	BCS
KCP 9.1/26	Cooper I., Hardy I.	2003	Kinetic evaluation of data from a diflufenican field dissipation study in Germany. Generated by: Batelle Agrifood Ltd, Ongar, UK; Bayer Crop Science, Lyon,FRA; Batelle Agrifood Ltd, Ongar, UK; Document No: C031449 GLP / GEP: Not required unpublished	N	BCS
KCP 9.1/27	Brockelsby C.H., Maycey P.A., Savage E.A.	1990	Herbicides: Diflufenican - Determination of M&B38181 in soil after treatment with Fenikan, West Germany, 1987 / 89. Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture, Ongar, Essex, GBR; Analytical Chemistry Department Document No: R008141 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/28	Imbroglini G.	1997	Long term field dissipation studydiflufenican Generated by: Inst. Sperimentale per la	N	BCS

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
			patologia vegetale, ITA ; Rhone-Poulenc AGRO Italy; Document No: C010715 GLP / GEP Yes unpublished		
KCP 9.1/29	Maycey P.A., Savage E.A.	1991	Herbicides: Diflufenican - Behaviour in soil under field conditions: A five year study, United Kingdom, 1985 - 1990. Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture Ltd., Ongar, Essex, GBR; Analytical Chemistry Department Document No: R008167 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/30	Parsons R.G.	1991	Herbicides: Diflufenican - Long term soil residue study: Methods used and effect on following rape and beet crops U.K., 1985 - 90 Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture Ltd., Essex, U.K.; Aldhams Farm, Manningtree Document No: R008165 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/31	Giraud J.P., Plewa A.	1984	Diflufenican (MB 38544): Soil sorption study. Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Lyon; Centre de Recherche de la Dargoire Document No: R006369 GLP / GEP: No Unpublished	N	BCS

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 9.1/32	Burr C.M.	2000	(14C)-M&B38181 adsoption to and from four soils Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010711 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/33	Unsworth R., McGhee I.	2002	[14C]-M&B 43625: Adsorption / Desorption on Soil Generated by: Huntingdon Life Sciences Ltd.; Document No: C023990 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/08	Hardy I.A.J.	2003	Predicted environmental concentrations in groundwater (PECgw) of diflufenican, M&B38181 and M&B43625 for the use of the formulation Fenikan using the FOCUS groundwater scenarios Generated by: Battelle AgriFood Ltd., Ongar, UK; BCS S.A., FRANCE; Environmental Chemistry Document No: C031460 GLP / GEP: Not required unpublished	N	BCS
KCP 9.2/09	Stork A., Fuehr F.	1994	Verhalten von (Pyridin-2-14C) Diflufenican in einer Parabraunerde nach Vorauflaufspritzungen zu Winterweizen und Wintergerste - Abschlußbericht. Generated by: Rhone-Poulenc; Forschungszentrum Juelich GmbH, DEU; Institut fuer Radioagronomie Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R008229 GLP / GEP Yes unpublished	N	BCS

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 9.2/10	Stork A., Fuehr F.	1994	The behaviour or (pyridine-2-14C)diflufenican in parabrown earth following pre-emergence application to winter wheat and winter barley, definitive report Generated by: Rhone-Poulenc; Forschungszentrum Juelich GmbH, DEU; Institut fuer Radioagronomie Rhone-Poulenc Secteur Agro, Lyon, France; Document No: C036280 GLP / GEP: No unpublished	N	BCS
KCP 9.2/11	Reeves G.L., Savage E.A.	1986	Diflufenican-14C: Hydrolysis in aqueous conditions at 22 degrees Celsius. Generated by: Rhone-Poulenc; May & Baker Ltd., GBR; Environmental Chemistry Document No: R008078 GLP / GEP: No (QA statement included) unpublished	N	BCS
KCP 9.2/12	Reeves G.L., Savage E.A.	1986	Diflufenican-14C: Hydrolysis in aqueous conditions at 50 degrees and 70 degrees Celsius. Generated by: Rhone-Poulenc; May & Baker Ltd., England; Environmental Chemistry Document No: R008080 GLP / GEP: No (QA statement included) unpublished	N	BCS
KCP 9.2/13	Simmonds M.B., Burr C.M.	1999	(14C)-M&B38181: Aqueous hydrolysis Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture Ltd., Ongar, UK; Document No: R015177 GLP / GEP Yes Unpublished	N	BCS

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 9.2/14	SimmondsM.B., Mills E.A.M	2002	(14C)-Diflufenican: Aqueous photolysis and quantum yield at pH7 Generated by: BCS S.A., FRA; Battelle-AgriFood Ltd., Essex, GBR; Document No: C026217 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/15	Simmonds M.B., Mills E.A.M.	2003	(14C)-Diflufenican: Aqueous photolysis and quantum yield at pH7 (amendment) Generated by: BCS S.A., FRA; Environmental Chemistry, Lyon Battelle-AgriFood Ltd., Essex, GBR; Document No: C029716 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/16	Buntain I.G.	2003	Diflufenican: Estimation of environmental photolytic half-life in water Model calculation according to Frank and Kloepffer Generated by: Battelle AgriFood Ltd., Essex, GBR; BCS S.A., FRA; Environmental Chmiestry, Lyon Document No: C030899 GLP / GEP: Not required unpublished	N	BCS
KCP 9.2/17	McGhee I.	2000	(14C)-M&B 38181: Photodegradation in water Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010713 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/18	Lebertz H.	1989	Diflufenican: Biodegradability according to closed bottle test, (OECD guideline 301D for testing	N	BCS

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			chemicals) Generated by: Rhone-Poulenc; Battelle Europe, Frankfurt; Rhone-Poulenc Agro GmbH, Kerpen, Germany; Document No: R003371 GLP / GEP: yes unpublished		
KCP 9.2/19	Knoch E.	1996	Degradation and metabolism of diflufenican in water / sediment systems Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro; Analytical Chemistry ORS Institut Fresenius Chem.und Biolog. Lab. GmbH; Document No: R000436 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/20	Hardy I.	2002	Kinetic evaluation of a water / sediment study with diflufenican using Topfit 2.0 Generated by: BCS S.A., FRANCE; Battelle AgriFood Ltd, UK; Document No: C023585 GLP / GEP: Not required unpublished	N	BCS
KCP 9.2/21	Crowe A.	2003	Diflufenican: Degradability and fate in the water/sediment system Generated by: Huntingdon Life Sciences Ltd., Suffolk, GBR; Eye Research Centre Huntingdon Life Sciences Ltd., Suffolk, GBR; Eye Research Centre BCS; Document No: C031677 GLP / GEP Yes	N	BCS

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 9.2/22	Hardy I.	2003	Kinetic modelling evaluation of a diflufenican water sediment study. Generated by: Battelle AgriFood Ltd, Ongar, UK; Battelle AgriFood Ltd, Ongar, UK; BCS, Monheim, DEU; Document No: C031461 GLP / GEP: Not required unpublished	N	BCS
KCP 9.3/01	Maurer T.	2002	Estimation of the reaction with photochemically produced hydroxyl radicals in the atmosphere Diflufenican Code: AE F088657 Generated by: Aventis CropScience GmbH, DEU; Environmental Chemistry, Frankfurt Document No: C019306 GLP / GEP: Not required unpublished	N	BCS
KCP 9.3/02	Kubiak R.	1994	Investigation of the volatilization of 14Cdiflufenican formulated according to EXP30052 (RPA30052H) with a total amount of 21 g/l diflufenican from plant surfaces under laboratory conditions. Generated by: Rhone-Poulenc; SLFA, FB Phytomedizin, Neustadt, DEU; Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R008194 GLP / GEP Yes unpublished	N	BCS
KCP 9.3/03	Jendrzejczak N.H., Turier G.P., Maestracci M.P.	1992	Soil surface volatility study of diflufenican formulated as EXP30052 (official German Ref.No. RPA30052H). Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro, Lyon, France;	N	BCS

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
			Analytical Department Document No: R008180 GLP / GEP Yes unpublished		
KCP 9.3/04	Jendrzejczak N.H., Turier G.P., Maestracci M.P.	1992	Soil surface volatility study of diflufenican formulated as EXP04072 (official German Ref.No. RPA40720H). Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro, Lyon, France; Analytical Department Document No: R008178 GLP / GEP Yes unpublished	N	BCS
KCP 9.3/05	Buntain I.G.	2003	2,4-difluoroaniline (AE C522392 = M&B 40401) Estimation of degradation by photooxidation in air Model calculation according to Atkinson Generated by: BCS, Monheim, Germany; Battelle AgriFood Ltd, UK; Document No: C032943 GLP / GEP: Not required unpublished	N	BCS
KCP 9.2/23	Parsons R.G.	1999	Diflufenican: Residues in drainage sediment - Monitoring study Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture Ltd., Essex, U.K.; Rhone-Poulenc Secteur Agro; Document No: R006364 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/34	Pangilinan, N. C.; Smith, D. M.	1994	Aerobic soil metabolism of [Phenyl-U-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA	N	Bayer CropScience

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
			Bayer CropScience, Date: 1994-05-12 GLP/GEP: yes, unpublished		
KCP 9.1/35	Pangilinan, N. C.; Smith, D. M..	1994	Aerobic soil metabolism of [Thiadiazole-2-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/36	Kelley, I. V.; Wood, S.; McKinney, M.	1995	Degradation of [Phenyl-UL-14C]FOE 5043 in three soil types Bayer Corporation, Stilwell, KS, USA Bayer CropScience, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/37	Kasper, A. M.; Shadrick, B. A.	1995	Photolysis of [Phenyl-U-14C]FOE 5043 on sandy loam Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106247, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/38	Hellpointner, E.	1995	Evolution of the microbial biomass in the biometer flask system (supportive to study no. F3042102 (MR106408), aerobic soil metabolism of FOE 5043) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF4066, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/39	Pangilinan, N. C.; Smith, D. M.	1994	Aerobic soil metabolism of [Phenyl-U-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR106408, GLP/GEP: yes, unpublished	N	Bayer CropScience

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 9.1/40	Pangilinan, N. C.; Smith, D. M.	1994	Aerobic soil metabolism of [Thiadiazole-2-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR106420, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/41	Kelley, I. V.; Wood, S.; McKinney, M..	1995	Degradation of [Phenyl-UL-14C]FOE 5043 in three soil types Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106664, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/42	Hellpointner, E.	1996	Degradation of [phenyl-UL-14C]FOE 5043-sulfonic acid in three soils Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107515, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/43	Schaefer, H.	1995	Calculation of DT-50 values of two metabolites of FOE 5043 in soil under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-037/98, GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1/44	Sommer, H.	1995	Dissipation of FOE 5043 in soil under field conditions (France, Italy) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107721, Report includes Trial Nos.:	N	Bayer CropScience

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
			40163/3 40164/1 40494/2 40495/0 GLP/GEP: yes, unpublished		
KCP 9.1/45	Sommer, H.	1995	Dissipation of FOE 5043 in soil under field conditions (Germany) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107722, Report includes Trial Nos.: 30499/9 30500/6 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/46	Sommer, H.	1995	Dissipation of FOE 5043 in soil under field conditions (France) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107723, Report includes Trial Nos.: 30254/6 30455/7 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/47	Sommer, H.	1995	Dissipation of FOE 5043 in soil under field conditions (Germany, France) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107724, Report includes Trial Nos.:	N	Bayer CropScience

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
			30159/0 30162/0 30163/9 30164/7 30248/1 30250/3 30251/1 30253/8 GLP/GEP: yes, unpublished		
KCP 9.1/48	Kelley, I. V.; Wood, S.	1992	Adsorption/desorption of FOE 5043 to soil - Addendum to Miles report no. 103903 - Adsorption/desorption of FOE 5043 to soil Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR103903, GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/49	Christensen, K. P.; Yen, P. Y.	1994	FOE 5043 - Determination of the adsorption and desorption properties in Canadian soils Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: MR106578, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/50	Blumhorst, M. R.; Yen, P. Y.; Marlow, V. A.	1994	Soil adsorption/desorption of FOE 5043 degradates: FOE Sulfonic Acid, FOE Methyl Sulfoxide, FOE Oxalate, FOE Alcohol, and Thiadone EPL Bio-Analytical Service, Inc., Harristown, IL, USA Bayer CropScience, Report No.: MR106598, GLP/GEP: yes, unpublished	N	Bayer CropScience

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 9.1/51	Kelley, I. V.; Wood, S.	1993	Leaching of aged FOE 5043 through soil columns Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR105018, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/52	Kelley, I. V.; Wood, S.	1993	Leaching of aged FOE 5043 through soil columns Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR105018, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/53	Hellpointner, E.	1996	Lysimeter study on the translocation of FOE 5043 into the subsoil after use as pre-emergence herbicide in a maize/winter wheat crop rotation Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107688, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/54	Hellpointner, E.	1995	Lysimeter study on the translocation of FOE 5043 into the underground after 2-year application as pre-emergence herbicide in corn Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107728, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/55	Hellpointner, E.	1995	Lysimeter study on the translocation of FOE 5043 into the underground after 2-year application as pre-emergence herbicide in corn Bayer AG, Leverkusen, Germany	N	Bayer CropScience

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
			Bayer CropScience, Report No.: PF4024, GLP/GEP: yes, unpublished		
KCP 9.1/56	Hellpointner, E.	1995	Lysimeter study on the translocation of FOE 5043 into the underground after the use as pre-emergence herbicide in a corn/winter wheat crop rotation Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF4025, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/57	Hellpointner, E..	1997	Lysimeter study on the translocation of FOE 5043 into the subsoil after 2-year use as pre-emergence herbicide in corn Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF4188, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/24	Kasper, A. M.; Shadrick, B. A.	1995	Aqueous photolysis of [Phenyl-U-14C]FOE 5043 Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106246, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/25	Hellpointner, E.	1993	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of FOE 5043 in water Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF3919, GLP/GEP: yes, unpublished	N	Bayer CropScience

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 9.2/26	Pangilinan, N. C.; Smith, D. M.	1995	Anaerobic aquatic metabolism of [Thiadiazole-2-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR106440, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/27	Kelley, I. V.; Wood, S.; McKinney, M.	1995	Degradability and fate of [Phenyl-UL-14C]FOE 5043 in two sediment/water systems Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106928, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/28	Halarnkar, P. P.; Irwin, D. W.	1997	Aerobic aquatic metabolism of [Thiadiazole-2-14C]FOE 5043 in two water/sediment systems Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 107822, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.3/06	Hellpointner, E.	1995	Determination of the volatilisation behavior of FOE 5043 (60 WG) in a field trial Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107281, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.3/07	Hellpointner, E.	1995	Calculation of the chemical lifetime of thiafluamide (FOE 5043) in the troposphere Bayer AG, Leverkusen, Germany Bayer CropScience,	N	Bayer CropScience

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
			Report No.: PF4069, GLP/GEP: no, unpublished		

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 Study 1

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)