FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: **MEZOFLOR 103 SC**

Product names: **MEZOFLOR 103 SC, FLOCORN 103 SC**

Chemical active substances:

Mesotrione, 100 g/L
Florasulam, 3 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 07/2023

MS Finalisation date: 12/2023, 12/2024, 03/2025

Version history

When	What
07/2023	Initial dRR
12/2023	Additional data in point 8.9.2.1 and in tabels 8.9-5; 8.9-6; 8.9-9; 8.9-10; 8.9-11; 8.9-12; 8.9-13; 8.9-16; 8.9-17; 8.9-18; 8.9-19; 8.9-20; 8.9-21; 8.9-22; 8.9-23
12/2023	Assessment additional data submited by aplicant
12/2024	The final Registration Report

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

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

Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks:** **e.g. g safener/synergist per ha (f)**	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			PECgw
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Maize	F	**susceptible weeds:** *Capsella bursa-pastoris* *Galinsoga parviflora* *Thlaspi arense* *Matricaria chamomilla* *Matricaria martima* *Anthemis arvensis* *Viola arvensis* *Centaurea cyanus* *Stellaria media* *Geranium pusillum* *Polygonum convolvulus* *Brassica napus* *Persicaria maculosa"* **moderate susceptible weeds:** *Chenopodium album* *Echinochloa crus-galli* *Galium aparine* *Solanum nigrum* *Capsella bursa-pastoris* *Galinsoga parviflora* *Thlaspi arense* *Matricaria chamomilla* *Matricaria martima* *Anthemis arvensis*	Foliar spraying	BBCH 12-18	1	N/A	1.0 L/ha	Mesotrione 100 g as/ha Florasulam 3.00 g as/ha	200-300 L/ha	Not relevant		A

				Viola arvensis *Centaurea cyanus* *Stellaria media* *Geranium pusillum* *Polygonum convolvulus* *Brassica napus* *Persicaria maculosa* *Amaranthus retroflexus* *Anchusa arvensis* **medium resistance:** *Echinochloa crus-galli*										
				susceptible weeds: *Chenopodium album* *Galium aparine* *Solanum nigrum* *Capsella bursa-pastoris* *Galinsoga parviflora* *Thlaspi arense* *Matricaria chamomilla* *Matricaria martima* *Anthemis arvensis* *Viola arvensis* *Stellaria media* *Geranium pusillum* *Polygonum convolvulus* *Brassica napus* *Persicaria maculosa* *Amaranthus retroflexus* *Anchusa arvensis* **moderate susceptible weeds:** *Echinochloa crus-galli* *Galium aparine* *Solanum nigrum* *Capsella bursa-pastoris* *Galinsoga parviflora* *Thlaspi arense* *Matricaria chamomilla* *Matricaria martima* *Anthemis arvensis* *Viola arvensis* *Centaurea cyanus* *Stellaria media* *Geranium pusillum* *Polygonum convolvulus* *Brassica napus*	Foliar spraying	BBCH 12-18	1	-	1.25 L/ha	Mesotrione 125 g as/ha Florasulam 3.75 g as/ha	200-300 L/ha	Not relevant		A

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

Explanation for column 15 – 21 “Conclusion”

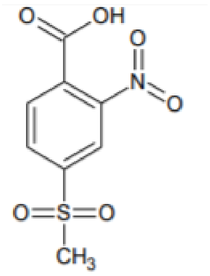
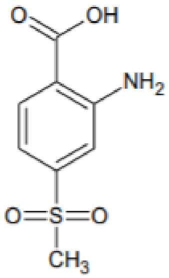
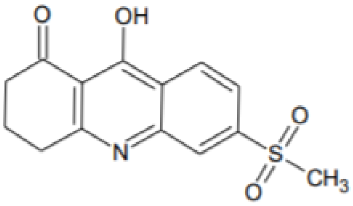
A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Critical use pattern of MEZOFLOR 103 SC grouped according to dose

Grouping according to dose		
Group	**Intended uses**	**Maximal dose**
1	Maize	1.25 L/ha

8.2 Metabolites considered in the assessment

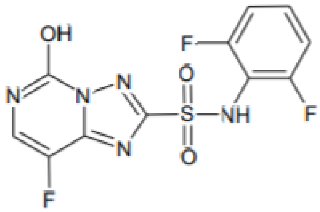
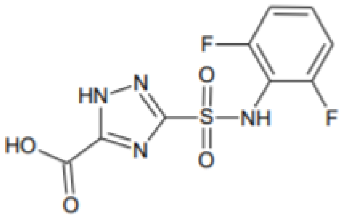
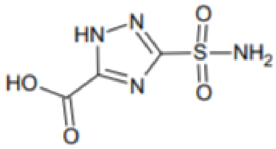
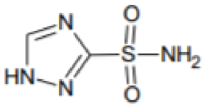
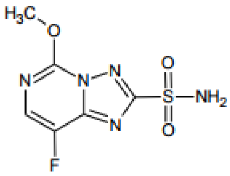
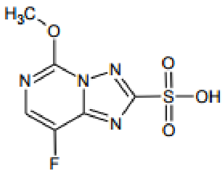
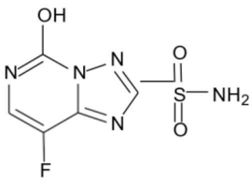
Table 8.2-1: Metabolites of mesotrione potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in com-partements	Exposue assessment required due to
MNBA	245		Soil: 57.2 % Surface water/sediment: 7.9 % groundwater : 100%	PEC_{gw}: 0.081 µg/L PEC_{soil}: 0.052 mg/kg $PEC_{sw/sed}$: 19.59 µg/L / 0.63 µg/kg
AMBA	215		Soil: 9.7 % Surface water/sediment: 24.6 % groundwater : 25%	PEC_{gw}: 0.076 µg/L PEC_{soil}: 0.008 mg/kg $PEC_{sw/sed}$: 8.99 µg/L /8.55 µg/kg
SYN 546974	291		Surface water/sediment: 33 %	$PEC_{sw/sed}$: 0.65 µg/L /88.71 µg/kg

zRMS comments

Information relating to mesotrione metabolites are in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419 and have been considered in the exposure assessment presented in this report.

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in comparte-ments	Exposue assess-ment required due to
5-OH Florasu-lam	354.26		Soil: 71.6 % Surface water/sediment: 99 % groundwater: 85%	PEC_{gw}: 0.013 µg/L PEC_{soil}: 0.003 mg/kg $PEC_{sw/sed}$: 2.04 µg/L /0.30 µg/kg
DFP-ASTCA	304.20		Soil: 17.8 % Surface water/sediment: 8.9 % groundwater :85%	PEC_{gw}: 0.002 µg/L PEC_{soil}: 0.001 mg/kg $PEC_{sw/sed}$:0.26 µg/L /0.19 µg/kg
ASTCA	192.13		Soil: 40.0 % Surface water/sediment: 53.8 % groundwater :67%	PEC_{gw}: 0.201 µg/L PEC_{soil}: 0.001 mg/kg $PEC_{sw/sed}$: 0.09 µg/L /0.10 µg/kg
TSA	248.17		Soil: 15.9 % groundwater :85%	PEC_{gw}: 0.164 µg/L PEC_{soil}: 0.000 mg/kg $PEC_{sw/sed}$:0.08 µg/L /0.02µg/kg
ASTP	247.20		Surface water: 58%	$PEC_{sw/sed}$:0.17 µg/L /0.10 µg/kg
TPSA	248.17		Surface water: 21%	$PEC_{sw/sed}$:0.49 µg/L /0.20 µg/kg
5-OH-ASTP	233.18		Surface water: 29%	$PEC_{sw/sed}$:0.22 µg/L /0.17 µg/kg

zRMS comments:

Information relating to florasulam metabolites are in line with EU agreed endpoints as reported in EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam EFSA Journal 2015; 13(1):3984 and have been considered in the exposure assessment presented in this report.

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)

Reference to:

- Peer review of the pesticide risk assessment of the active substance mesotrione EFSA Journal 2016;14(3):4419
- Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam EFSA Journal 2015; 13(1):3984

8.3.1.1 Mesotrion and its metabolites

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

Soil type	pH*) water	t. °C/% MWHC	DT_{50} /DT_{90} (days)	DT_{50} (d) 20°C pF2/ 10 kPa**)	St. (χ^2)	Method of calculation
sandy loam (EERTC)	6.4	20°C /19[a]	11.6/ 38.5	8.2	18	SFO
Loam (Toulouse)	7.7	20°C /25[a]	4.3/ 14.3	4.0	16.4	SFO
clay loam (Pickett Piece)	7.1	20°C /28[a]	5.3/ 17.7	5.3	6.5	SFO
clay loam (721)	5.6	25°C /28[a]	20.2 /(67.1)	32.3	4.1	SFO
silty clay loam (722)	5.7	25°C /30[a]	10.3/ (34.2)	16.5	3.9	SFO
silt loam (723)	5.4	25°C /26[a]	17.6/ (58.5)	28.2	3.4	SFO
loamy sand (724)	4.8	25°C /14[a]	23.8/ (78.9)	31.1	4.3	SFO
loam (725)	5.8	25°C /25[a]	6.1/ 20.3	9.5	7.6	SFO
clay loam (727)	5.1	25°C /28[a]	20.8/ (69.2)	32.4	6.4	SFO
sandy loam (728)	5.9	25°C /25[a]	7.2/ 24	9.7	5.6	SFO
silt loam (729)	5.6	25°C /26[b]	12.7/ (42.2)	20.3	1.6	SFO
clay loam (730)	5.3	25°C /28[a]	17.1/ (56.9)	26.9	8.9	SFO
Silty clay loam (731)	6.1	25°C /30[a]	14.1/ (46.9)	22.6	1.0	SFO
Silty clay loam (732)	5.0	25°C /30[a]	14.0/ (46.4)	22.4	5.3	SFO
Silty clay loam (741)	5.7	25°C /30[a]	28.7/ (95.3)	44.3	4.5	SFO
Silty clay loam (742)	7.2	25°C /34.4[a]	9.7/ (32.1)	15.5	5.5	SFO
silt loam Richmond (Vispett & ovsht-eyn,1997)	6.2	25°C /32.04[b]	13.2/ 44.0	14.68 (Average DT_{50}ref of 15.5 & 13.9	3.1	SFO
silt loam	6.2	25°C /32.04[b]	11.8/ 39.3		4.9	SFO
Richmond (Subba-Rao, 1996)				Days given identical soil descriptions in these 2		

				studies).		
silt loam Richmond (Miller, 1997)	6.1	20°C /32.04[b]	14.2/ 47.2	11.5	4.6	SFO
Geometric mean pH dependence	Yes - degradation increases with increasing pH. DT50 y = -9.766x pH + 77.692 r^2 0.4687 (non-log)					

*) Measured in [medium to be stated, usually calcium chloride solution or water]

**) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

[a] FOCUS default; [b]measured pF2

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

Soil type	pH*) water	t. ºC /% MWHC		DT_{50} /DT_{90} (days)	DT_{50} (d) 20ºC pF2/ 10kPa**)	St. (χ2)	Method of calculation
silty clay loam (722)	5.7	25°C	/30a	0.6/1.89	1.0	10	SFO
loam (725)	5.8	25°C	/25a	0.5/1.5	0.8	10.8	SFO
sandy loam (728)	5.9	25°C	/25a	5.1/16.97	6.9	3.1	Decline from peak
silt loam (729)	5.6	25°C	/26b	1.66/5.52	2.7	3.88	SFO
clay loam (730)	5.3	25°C	/28a	2.81/9.35	4.4	14.17	SFO
Silty clay loam (731)	6.1	25°C	/30a	15.7/52.3	25.2	1.6	SFO
sandy loam (ERTC)	6.4	20°C	/19a	6.2/20.7	4.4	21.89	Decline from peak
loam (Toulouse)	7.7	20°C	/25a	5/16.65	4.6	13.08	Decline from peak
silt loam Richmond (Subba-Rao, 1996)	6.2	25°C	/32.04b	1.1/3.67	1.3	11.2	SFO
silt loam Richmond (Miller, 1997)	6.1	20°C	/32.04b	6.3/21.03	5.1	20.13	Decline from peak
Geometric mean (if not pH dependent)					3.4		
pH dependence					No		

*) Measured in [medium to be stated, usually calcium chloride solution or water]

**) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

[a] FOCUS default; [b]measured pF2

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

Soil type	pH*) water	t. ºC/% MWHC	DT_{50}/DT_{90} (d)	DT_{50} (d) 20ºC pF2/ 10kPa**)	St. (χ2)	Method of calculation
Wisborough	4.9	20°C /	7.8	3.7	5.52	DFOP DT_{90}/3.32
Wisconsin	6.4	20°C /	33/109	23.5	7.98	DFOP K2
East Anglia	7.9	20°C /	58.7/195	47.4	3.66	DFOP K2
Spinks	6.7	20°C /	10.2/34	9.7	6.94	FOMC
Richmond	6.2	25°C /	13.6/45.2	16.0	14.8	SFO
Richmond	6.1	20°C /	>1000	>1000	26.6	SFO
Geometric mean (if not pH dependent)				14.5		
pH dependence				No		

Florasulam and its metabolites

The rate of degradation in soil of florasulam was evaluated during the Annex I Inclusion. No additional studies have been performed.

Agreed EU Endpoints used in the Evaluation (EFSA Journal 2015; 13(1):3984)

Endpoint	Florasulam	5-OH florasulam	DFP-ASTCA	ASTCA	TSA
DT_{50} (lab) (normalised to pF2 and 20°C)	1.55 days (geometric mean, n=7)	14.98 days (geometric mean, n=7)	16.62 days (geometric mean, n=5)	297.47 days (geometric mean, n=4)	83.74 days (geometric mean, n=4)

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

Florasulam, laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH[1]**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Andover	Silt loam	7.6	20	40	1.02	3.40	0.91	4.34	SFO	Y / EFSA Journal 2015; 13(1):3984
Kenslow	Silt loam	5.6	20	40	0.58	1.92	0.58	4.14	SFO	
Marcham	Sandy clay loam	7.7	20	40	2.55	8.46	2.14	13.44	SFO	
Speyer 2.2	Sandy loam	7.3	20	40	0.71	5.38	1.62	7.48	Pseudo-SFO (back calculated from FOMC)	
Cuckney	Sandy loam	6.9	25	40	0.94	3.11	1.11	3.81	SFO	
Cuckney	Sandy loam	6.9	20	Field capacity	2.86	9.49	2.86	15.28	SFO	
Cuckney averaged - geomean	Sandy loam	6.9	20	-	-	-	1.78	-	SFO	
Marcham	Sandy clay loam	7.6	20	Field capacity	4.29	14.24	4.29	12.78	SFO	
Geometric mean (n=7)[2]							**1.55**			
pH-dependency: y/n							No			
[1] Medium measured in not stated, [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)										

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

5-OH florasulam, laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH[1]**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Andover	Silt loam	7.6	20	40	7.02	23.32	6.30	5.14	SFO	Y / EFSA Journal 2015; 13(1):3984
Kenslow	Silt loam	5.6	20	40	17.69	58.76	17.69	8.15	SFO	
Marcham	Sandy clay loam	7.7	20	40	14.56	48.36	12.22	15.52	SFO	
Speyer 2.2	Sandy loam	7.3	20	40	14.44	47.97	14.44	7.70	SFO	
Cuckney	Sandy loam	6.9	25	40	12.97	43.09	15.02	16.52	SFO	
Cuckney	Sandy loam	6.9	20	Field capacity	24.77	82.30	24.77	21.07	SFO	
Cuckney averaged - geomean	Sandy loam	6.9	20	-	-	-	19.29	-	SFO	
Marcham	Sandy clay loam	7.6	20	Field capacity	29.75	98.63	29.75	14.62	SFO	
Geometric mean (n=7)[2]							**14.98**			
pH-dependency: y/n							No			
[1] Medium measured in not stated, [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)										

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

DFP-ASTCA, laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH[1]**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Andover	Silt loam	7.6	20	40	21.68	72.02	19.45	9.88	SFO, top-down	Y / EFSA Journal 2015; 13(1):3984
Kenslow	Silt loam	5.6	20	40	21.87	72.65	21.87	6.47	SFO, top-down	
Marcham	Sandy clay loam	7.7	20	40	55.02	182.75	46.16	6.73	SFO, top-down	
Cuckney	Loamy sand	7.2	20	40	15.82	52.55	15.27	9.95	SFO	
Marcham	Sandy clay loam	7.9	20	40	4.23	14.06	4.23	7.51	SFO	
Geometric mean (n=5)							**16.62**			
pH-dependency: y/n							No			
[1] Medium measured in not stated										

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

ASTCA, laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH[1]**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Cuckney	Loamy sand	7.2	20	40	ND	ND	1000[2]	ND	SFO	Y / EFSA Journal 2015; 13(1):3984
Marcham	Sandy clay loam	7.9	20	40	214.11	711.24	214.11	4.40	SFO	
Cuckney	Loamy sand	7.2	20	40	268.45	891.76	259.05	4.52	SFO	
Marcham	Sandy clay loam	7.9	20	40	4.23	469.0	141.18	7.12	SFO	
Geometric mean (n=4)							**297.47**			
pH-dependency: y/n							No			
ND = Not determined [1] Medium measured in not stated, [2] Default value, not to be used to determine PEC_{SOIL}										

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

TSA, laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH[1]**	**t.ºC**	**Moisture content % v/v**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Calke	Sandy loam	5.4	20	20	8.11	166.91	71.44	2.23	SFO (slow phase DFOP)	Y / EFSA Journal 2015; 13(1):3984
South Witham	Clay loam	7.1	20	25.7	10.57	155.28	94.39	2.11	SFO (slow phase DFOP)	
Lufa 5M	Sandy loam	7.3	20	14	230.14	764.52	171.68	4.44	SFO	
RefeSol 06-A	Clay loam	6.7	20	29	46.21	153.51	42.47	12.87	SFO	
Geometric mean (n=4)							**83.74**			
pH-dependency: y/n							No			
[1] Medium measured in not stated										

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Reference to:

- Peer review of the pesticide risk assessment of the active substance mesotrione EFSA Journal 2016;14(3):4419

- Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam EFSA Journal 2015; 13(1):3984

Table 8.3-4: Summary of dark anaerobic degradation studies for mesotrione

Soil type	pHa)	t.oC/% MWHC	DT_{50}/ DT_{90} (days)	DT_{50} (d) 20ºCb)	St. (χ2)	Method of calculation
Wisconsin silt loam cyclo-hexane-label	6.2	25°C/	4 days / 14 days		r^2= 0.98	first order (linear least squares fit of natural log of concentration vs. Sampling interval).
Wisconsin silt loam phenyl-label	6.2	25°C/	4 days / 12 days		r^2= 0.97	first order (linear least squares fit of natural log of concentration vs. Sampling interval).
Geometric mean (if not pH dependent)						

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

Table 8.3-5: Summary of dark anaerobic degradation studies for florasulam

Soil name	Soil type (USDA)	OC	pH	condtions	Selected best-fit model	r^2 error	Visual fit*)/R^2	Param.	Value	DT50 [days]	DT90 [days]
Speyer 2.2; TP-labelling	Sandy loam	3.9	7.3	20^0C; soil: water ratio 1:2	SFO	8.66	G./ 0.986	*k*	0.0375	18.49	61.43
Speyer 2.2; phenyl- la-belling	Sandy loam	3.9	7.3	20^0C; 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 8.3-6: Summary of dark anaerobic degradation studies for 5-OH florasulam

Soil name	Soil type (USDA)	OC	pH	condtions	Selected best-fit model	r^2 error	Visual fit*)/R^2	Para m.	Value	DT50 [days]	DT90 [days]
Speyer 2.2; TP-labelling	Sandy loam	3.9	7.3	20^0C; soil: water ratio 1:2	SFO	7.75	G./ 0.984	k	5.0 E-4	1386.29	4605.17
Speyer 2.2; phenyl- label-ling	Sandy loam	3.9	7.3	20^0C; 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.

8.4 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)

Reference to:

- Peer review of the pesticide risk assessment of the active substance mesotrione EFSA Journal 2016;14(3):4419
- Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam EFSA Journal 2015; 13(1):3984

8.4.1.1 Mesotrione

Table 8.4-1: Summary of field degradation studies for mesotrione

Soil type (indicate if bare or cropped soil was used).	Location (country or USA state)	pH[a]	Depth (cm)	DT_{50} (days) actual	DT_{90} (days) actual	St. (χ^2)	DT_{50} (days) Norm[b)]	Method of calculation
clay loam(bare soil)	France	6.0	0-10	7	73	-	-	sqrt 1st order - linear regression
clay loam(bare soil)	Italy	6.1	0-10	5	59	-	-	sqrt 1st order - linear regression
sandy loam(bare soil)	Italy	8.0	0-10	4	39	-	-	sqrt 1st order - linear regression
sandy loam(bare soil)	Germany	6.2	0-10	7	78	-	-	sqrt 1st order - linear regression
loam (bare soil)	Germany	5.8	0-10	/	/	-	-	sqrt 1st order - linear regression
loam (bare soil)	Germany	7.0	0-10	3	36	-	-	sqrt 1st order - linear regression
sandy clay loam (bare soil)	Germany	6.9	0-10	3	38	-	-	sqrt 1st order - linear regression
Geometric mean (if not pH dependent)							-	
pH dependence				Not reported				

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

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

8.4.1.2 Florasulam and its metabolite

Table 8.4-2: Summary of field dissipation studies for florasulam and its metabolite

Florasulam (Parent)	Aerobic conditions. Field dissipation of 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). The results were kinetically re-examined following FOCUS Kinetics (2006), but are not reported due to the low reliability of the fitting.
5-OH Florasulam (Metabolite 1)	Aerobic conditions metabolite formed from parent – Florasulam. 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.

Table 8.4-3: The kinetic endpoints for Florasulam and its metabolites recommended to be used in the exposure assessments: Triggering endpoints

Type of assessment	Compound	Kinetic parameter		DT50 [days]	DT90 [days]	Type of value[1)2)]	Kinetic model
		symbol	value				
Soil exposure assessment (PEC_{SOIL})	Florasulam	k	0.1617	4.29	14.24	L; n	SFO
	5-OH Florasulam	k	0.0233	29.75	98.82	L; n	SFO
	DFP-ASTCA	k	0.0150	46.16	153.33	L; n	SFO
	ASTCA	k	0.0027	259.05	860.55	L; n	SFO
	TSA	k	0.0040	171.68	570.33	L; n	SFO
Groundwater exposure assessment (PEC_{GW})	Florasulam	k	0.4472	1.55	5.15	L; n	SFO
	5-OH Florasulam	k	0.0463	14.98	49.73	G; n	SFO
	DFP-ASTCA	k	0.0417	16.62	55.21	G; n	SFO
	ASTCA	k	0.0023	297.47	659.66	G; n	SFO
	TSA	k	0.0083	83.74	278.17	G; n	SFO
Surface Water exposure assessment (PEC_{SW}/PECSED)	Florasulam	k	0.4472	1.55	5.15	G; n	SFO
	5-OH Florasulam	k	0.0463	14.98	49.73	G; n	SFO
	DFP-ASTCA	k	0.0417	16.62	55.21	G; n	SFO
	ASTCA	k	0.0023	297.47	659.66	G; n	SFO
	TSA	k	0.0083	83.74	278.17	G; n	SFO

1) All values recommended for GW and SW exposure assessment are normalised.
2) L (Longest lab value), G(Geomean lab value), n (normalized)

Table 8.4-4: The maximum soil concentrations and kinetic formation fractions recommended for metabolites to be used in exposure assessment calculations.

Compound	Type of value:			
	Observed maximum in soil:		Kinetic formation fraction – ff	
	Value [%]	To be used in:	Value [%]	To be used in:
5-OH Florasulam	**71.6**	Soil and SW exposure assessment	**0.854**	GW exposure assessment
DFP-ASTCA	**17.8**	Soil and SW exposure assessment	**1.00**	GW exposure assessment
ASTCA	**40.0**	Soil and SW exposure assessment	**0.781**	GW exposure assessment
TSA	**15.9**	Soil and SW exposure assessment	**1.000** from ASTCA **0.219** from DFP-ASTCA	GW exposure assessment

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Reference to:
- Peer review of the pesticide risk assessment of the active substance mesotrione EFSA Journal 2016;14(3):4419
- Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam EFSA Journal 2015; 13(1):3984

8.4.2.1 Mesotrione

Table 8.4-5: Soil accumulation for mesotrione

Soil accumulation and plateau concentration	Not triggered. Same as initial PECsoil.

8.4.2.2 Florasulam

Table 8.4-6: Soil accumulation for florasulam

Soil accumulation and plateau concentration ‡	No accumulation observed in the field studies

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.

Reference to:
- Peer review of the pesticide risk assessment of the active substance mesotrione EFSA Journal 2016;14(3):4419
- Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam EFSA Journal 2015; 13(1):3984

8.5.1 Mesotrione and its metabolites

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

Soil Type	OC [%]	Soil pH[a)]	Kd (mL/g)	Kdoc (mL/g)	KF (mL/g)	K_{Foc} (mL/g)	1/n
Wisborough Green silty clay loam	2.63	5.1			4.46	171	0.902
Wisconsin silt loam	1.58	6.2			0.74	47	0.921
Toulouse clay	1.79	6.5			1.25	70	0.915
Garonne loam	1.03	7.8			0.15	14	0.971
Visalia sandy loam	0.53	8.2			0.13	25	0.959
Wisconsin silt loam	1.28	6.1			0.61	48	0.947
ERTC sandy loam	0.58	6.4			0.33	57	0.950
Pickett Piece clay loam	3.31	7.1			0.97	29	0.932
Garonne loam	0.87	7.7			0.16	18	0.954
Champaign (1:2 ratio) silty clay loam	3.0	4.4			6.16	354	0.94
Geometric mean (if not pH dependent)							
Arithmetic mean (if not pH dependent)							**0.94**
Median							
Worst case						**14**	
pH dependence			Yes, sorption decreases as pH increases. Kfoc y= 8583.4e^{-0785x} (log) r^2 0.8977				

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

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

Soil Type	OC%	Soil pH[a)]	Kd (mL/g)	Kdoc (mL/g)	KF (mL/g)	K_{Foc} (mL/g)	1/n
Wisborough Green silty clay loam	2.63	5.1			0.16	6.1	0.32
Wisconsin silt loam	1.58	6.2			0.05	3.2	0.61
Worst case						3.2	0.9[b]
Geometric mean (if not pH dependent)						-	
Arithmetic mean (if not pH dependent)							-
pH dependence			No				

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

b) FOCUS default

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

Soil Type	OC%	Soil pH[a)]	Kd (mL/g)	Kdoc (mL/g)	KF (mL/g)	K_{Foc} (mL/g)	1/n
Wisborough Green silty clay loam	2.63	5.1			3.2	122	0.83
Wisconsin silt loam	1.58	6.2			0.71	44.9	0.85
Toulouse clay	1.79	6.5			0.91	51.0	0.85
Garonne loam	1.03	7.8			0.18	18.1	0.82
Visalia sandy loam	0.53	8.2			0.12	23.9	0.90
Arithmetic mean (if not pH dependent)						pH dependent (51.9)	0.85
Worst case						18.1	
pH dependence			Yes, sorption decreases as pH increases. Kfoc $y = 1865e^{-0.563x}$ (log) r^2 0.9062				

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

Table 8.5-4: Summary of soil adsorption/desorption for SYN 546974

Soil Type	OC%	Soil pH[a)]	K_d (mL/g)	Kdoc (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Gartenacker Loam	1.8	7.2			30.63	1702	0.82
18 Acres Sandy Clay Loam	2.2	5.7			220.07	10003	0.96
Marysville Clay Loam	1.6	7.6			432.49	27031	0.96
Sarpy Silt loam	1.7	6.5			376.10	22124	0.88
Seven Springs Loamy sand	0.6	5.2			19.56	3260	0.84
Arithmetic mean (if not pH dependent)						13000	0.89
Worst case							
pH dependence			No				

8.5.2 Florasulam and its metabolites

Table 8.5-5: Summary of soil adsorption for florasulam

Soil type	Soil properties			Adsorption distribution		Freundlich adsorption isotherm parameters			
	Soil type (USDA)	pH	OC [%]	Kd [mL/g]	Kd 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(M444)	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**	**----**	----

Table 8.5-6: **Summary of soil desorption for florasulam**

Soil name	**Soil properties**			**Adsorption distribution**		**Freundlich adsorption isotherm parameters**			
	Soil type (USDA)	**pH**	**OC [%]**	**Kd [mL/g]**	**Kd 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 8.5-7: Summary of soil adsorption for 5-OH florasulam

Soil type	Soil properties			Adsorption distribution		Freundlich adsorption isotherm parameters			
	Soil type (USDA)	pH	OC [%]	Kd [mL/g]	Kd 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 8.5-8: Summary of soil adsorption for DFP-ASTCA

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 8.5-9: Summary of soil adsorption for ASTCA

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 8.5-10: Summary of soil adsorption for TSA

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

Aqueous photoproducts of Florasulam – values determined theoretically using KocWin:

- for ASTP: K_{OC} = **60.22** mL/g;
- for 5-OH ASTP: K_{OC} = **77.74** mL/g;
- for TPSA: K_{OC} = **41.52** mL/g.

Table 8.5-11: The adsorption parameters of Florasulam and its major degradation products recommended for use in GW and SW modelling.

Compound	Adsorption parameters			Method of determination	Remarks
	K_F [mL/g]	K_{FOC} [mL/g]	1/n		
Florasulam	0.26	10.35	0.945	batch sorption studies	none
5-OH Florasulam	0.225	14.53	0.91	batch sorption studies	none
DFP-ASTCA	1.08	75.18	0.85	batch sorption studies	none
ASTCA	1.64	104.81	0.94	batch sorption studies	none

TSA	0.38	23.46	0.94	batch sorption studies	none
TPSA	n. d.[1)]	60.22[2)]	n. d.[1)]	Value determined theoretically using KocWin tool	Value can be used only for STEP1-2 SW modelling
ASTP	n. d.[1)]	77.74[2)]	n. d.[1)]	Value determined theoretically using KocWin tool	Value can be used only for STEP1-2 SW modelling
5-OH ASTP	n. d.[1)]	41.52[2)]	n. d.[1)]	Value determined theoretically using KocWin tool	Value can be used only for STEP1-2 SW modelling

1) n. d. – not determined;
2) The presented value is Koc;

8.5.3 Column leaching (KCP 9.1.2.1)

Mesotrione:
According to information obtained from peer review EFSA Journal 2016;14(3):4419 column leaching for active substance mesotrione is not required.

Florasulam:
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

Table 8.5-12: The distribution of radioactivity in soil and leachate following the column leaching

Compartment		**Results obtained column filled with:**		
		Cuckney loamy sand soil (pH 6.6) – %AR	**Elvedon sand soil (pH 7.6) - %AR**	**Marcham sandy clay loam soil (pH 7.7) -%AR**
Soil	**Soil horizon**	----	----	----
	0 – 5 cm	1.3	0.4	3.3
	5 – 10 cm	1.6	0.2	2.1
	10 – 15 cm	4.0	0.4	3.0
	15 – 20 cm	3.7	0.6	3.4
	20 – 25 cm	5.0	1.2	8.1
	25 – 30 cm	5.9	2.5	9.4
	Total AR in soil	**21.5**	**5.5**	**29.3**
Leachate	**Leachate fraction**	----	----	----

	Fraction 1 (0 – 18 hours)	n. d.[1)]	n. d.[1)]	0.1
	Fraction 2 (18 – 26.5 hours)	8.5	0.1	9.1
	Fraction 3 (26.5 – 43 hours)	56.4	82.6	44.1
	Fraction 4 (43 – 45 hours)	12.0	9.4	14.4
	Total AR in leachate	**76.9**	**92.1**	**67.7**
Total AR recovered		**98.4**	**97.6**	**97.0**

1) n. d. – not detected;

Table 8.5-13: The composition of the radioactivity in the leachates

Column	**Leachate**	**% AR in leachate**	**Composition of the leachate**					
			Expressed as % of radioactivity in leachate			**Expressed as % AR**		
			Flora. [1)] (RT 31.5 min)	**5-OH- Flo.** [2)] (RT 27.2 min.)	**Comp. 1** (RT 24.8 min.)	**Flora.** [1)] (RT 31.5 min)	**5-OH- Flo.** [2)] (RT 27.2 min.)	**Comp. 1** (RT 24.8 min.)
Cuckney loamy sand soil	2	8.5	93.2	6.8	0.0	8.0	0.6	0.0
	3	56.4	69.4	30.6	0.0	39.2	17.3	0.0
	4	12.0	59.6	40.4	0.0	7.1	4.8	0.0
	Total	76.9	----	----	----	54.3	22.7	0.0
Elvedon sand soil	3	82.6	54.8	41.9	3.3	45.3	34.6	2.7
	4	9.4	50.8	49.2	0.0	4.8	4.6	0.0
	Total	92.0	----	----	----	50.1	39.2	2.7
Marcham sandy clay loam soil	2	9.1	70.5	29.5	0.0	6.4	2.7	0.0
	3	44.1	58.0	31.4	10.7	25.6	13.8	4.7
	4	14.4	65.4	34.6	0.0	9.4	5.0	0.0
	Total	67.7	----	----	----	41.4	21.5	4.7

[1)] Flora. -Florasulam

[2)] 5-OH-Flo.- 5-OH Florasulam

Aged residues leaching ‡	Not performed, as the results of the other experiments provided suffi-

8.5.4 Lysimeter studies (KCP 9.1.2.2) and Field leaching studies (KCP 9.1.2.3)

Mesotrione:

According to information obtained from peer review EFSA Journal 2016;14(3):4419 nor column leaching neither field leaching studies for active substance mesotrione are required.

Florasulam:

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

Al remaining results presented in tables below.

Table 8.5-14: Total recovery of the Applied Radioactivity from the Lysimeters treated with [14C]-Florasulam in April 1994.

Compart-ment	Sample detail		Results obtained for the lysimeter No.				
			27	28	29	31	33
			Sandy soil; 2 x 5 g/ha	Sandy soil; 1 x 5 g/ha	Sandy soil; 1 x 25 g/ha	Loamy soil; 2 x 5 g/ha	Loamy soil; 1 x 5 g/ha
			% AR	% AR	% AR	% AR	% AR
Soil	Horizon [cm]	0 – 10	26.1	24.9	30.0	33.6	25.5
		10 – 20	18.0	11.7	14.1	29.8	30.9
		20 – 30	9.7	6.4	5.7	7.1	9.7
		0 – 30 (cumulative)	53.8	43.0	49.8	70.5	66.1

		30 – 40	3.3	3.4	5.5	1.4	3.3
		40 – 50	3.1	2.8	3.9	0.8	1.2
		50 – 60	3.2	2.9	2.4	<0.5	<0.5
		60 – 70	2.7	2.2	2.3	<0.5	<0.5
		70 – 80	2.2	1.7	2.1	<0.5	<0.5
		80 – 90	1.1	1.3	1.8	<0.5	<0.5
		90 – 100	1.5	1.1	1.9	<0.5	<0.5
	Soil – sub-total		**70.7**	**58.5**	**69.7**	**72.9**	**70.6**
Leachate	**Year 1**		4.4[1)]	3.9	4.4	1.0[1)]	0.8
	Year 2		1.5	1.8	2.4	0.3	0.8
	Year 3[2)]		0.4	----	----	0.1	----
	Leachate sub-total		**4.0**	**5.7**	**6.8**	**0.9**	**1.6**
Crops	**Year 1**		0.8[1)]	0.5	0.9	0.7[1)]	0.6
	Year 2		1.1	0.5	0.1	1.5	0.1
	Crops sub-total		**1.4**	**1.0**	**1.0**	**1.7**	**0.7**
Total AR recovered [%]			**76.1**	**65.2**	**77.5**	**75.5**	**72.9**

1) These results are expressed as % of radioactivity applied during the Year 1; all other results for these two lysimeters are expressed as % of cumulative radioactivity from the two applications;
2) Year 3 leachates were analysed for only two lysimeters, receiving double treatment with Florasulam at two consecutive years – lysimeters No. 27 and 31.

Table 8.5-15: Total recovery of the Applied Radioactivity from the Lysimeters treated with [^{14}C]-Florasulam in February 1995.

Compartment	**Sample detail**		**Results obtained for the lysimeter No.**	
			25	**26**
			Sandy soil; 1 x 5 g/ha	**Sandy soil; 1 x 5 g/ha**
			% AR	% AR
Soil	**Horizon [cm]**	0 – 10	13.2	13.0
		10 – 20	14.7	10.1
		20 – 30	15.0	8.9
		0 – 30 (cumulative)	42.9	32.0
		30 – 40	6.4	10.8
		40 – 50	5.4	4.3
		50 – 60	5.5	3.0
		60 – 70	4.3	2.5
		70 – 80	3.7	1.9

		80 – 90	2.9	1.4
		90 – 100	1.2	1.7
	Soil – sub-total		**58.9**	**44.7**
Leachate	**Year 1**		2.5	2.5
	Year 2		1.0	1.1
	Leachate sub-total		3.5	3.6
Crops	**Year 1**		9.4	0.5
	Year 2		0.1	0.1
	Crops sub-total		**0.5**	**0.6**
Total AR recovered [%]			**62.9**	**48.9**

Table 8.5-16: The total radioactivity in the leachates from the test lysimeters

Experi-mental year	**Type of value**		**Results obtained for the lysimeter**						
			27	**28**	**29**	**31**	**33**	**25**	**26**
			Sandy soil; 2 x 5 g/ha	Sandy soil; 1 x 5 g/ha	Sandy soil; 1 x 25 g/ha	Loamy soil; 2 x 5 g/ha	Loamy soil; 1 x 5 g/ha	Sandy soil; 1 x 5 g/ha	Sandy soil; 1 x 5 g/ha
Year 1[1)]	**Annual average**	µg/L[4)]	**0.05**	**0.04**	**0.27**	**0.01**	**0.01**	**0.04**	**0.004**
		%AR	**4.389**	**3.897**	**4.433**	**12.043**	**0.753**	**2.466**	**2.457**
	Minimum	µg/L[4)]	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		%AR	<0.001	<0.001	<0.001	<0.001	0.001	<0.001	<0.001
	Maximum	µg/L[4)]	0.08	0.07	0.41	0.03	0.01	0.006	0.007
		%AR	0.735	0.726	0.741	0.256	0.141	0.458	0.468
Year 2[2)]	**Annual average**	µg/L[4)]	**0.05**	**0.03**	**0.21**	**0.01**	**0.01**	**0.003**	**0.003**
		%AR	**1.519**	**1.790**	**2.388**	**0.268**	**0.758**	**0.982**	**1.076**
	Minimum	µg/L[4)]	0.03	0.02	0.18	0.01	0.01	0.002	0.002
		%AR	0.005	0.034	0.005	0.003	0.004	0.0014	0.020
	Maximum	µg/L[4)]	0.06	0.03	0.24	0.01	0.01	0.005	0.004
		%AR	0.234	0.298	0.359	0.044	0.132	0.109	0.160
Year 3[3)]	**Annual average**	µg/L[4)]	**0.04**	**n. e.**[5)]	**n. e.**[5)]	**<0.01**	**n. e.**[5)]	**n. e.**[5)]	**n. e.**[5)]
		%AR	**0.440**	**n. e.**[5)]	**n. e.**[5)]	**0.078**	**n. e.**[5)]	**n. e.**[5)]	**n. e.**[5)]
	Minimum	µg/L[4)]	0.03	n. e.[5)]	n. e.[5)]	<0.01	n. e.[5)]	n. e.[5)]	n. e.[5)]
		%AR	0.007	n. e.[5)]	n. e.[5)]	<0.01	n. e.[5)]	n. e.[5)]	n. e.[5)]
	Maximum	µg/L[4)]	0.05	n. e.[5)]	n. e.[5)]	0.01	n. e.[5)]	n. e.[5)]	n. e.[5)]
		%AR	0.124	n. e.[5)]	n. e.[5)]	0.028	n. e.[5)]	n. e.[5)]	n. e.[5)]

1) Year 1: April 1994 – March 1995 for the lysimeters No. 27 - 33 and February 1995 – February 1996 for lysimeters No. 25 and 26;
2) Year 2: April 1995 – March 1996 for the lysimeters No. 27 - 33 and February 1996 – April 1997;
3) Year 3: April 1996 – April 1997, only for the lysimeters No. 27 and 31;
4) Expressed as parent equivalent;
5) n. e. – not examined, leachates not collected

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.

Reference to:
- Peer review of the pesticide risk assessment of the active substance mesotrione *EFSA Journal* 2016;14(3):4419
- Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam *EFSA Journal* 2015; 13(1):3984

8.6.1 Mesotrione and its metabolites

Hydrolytic degradation

Hydrolytic degradation of the active substance and metabolites > 10%

pH 5: ≥ 96.3%AR parent at 25°C over 30 days

pH 4: ≥ 91.7%AR parent at 50°C over 4 days (^{14}C- Cyclohexane and ^{14}C- Phenyl-labels)

stable

pH 7: ≥ 96.8%AR parent at 25°C over 30 days

pH 7: ≥ 97.2%AR parent at 50°C over 4 days ^{14}C- Cyclohexane and ^{14}C- Phenyl-labels)

stable

pH 9: : ≥ 96.4%AR parent at 25°C over 30 days

pH 9: ≥ 95.5%AR parent at 50°C over 4 days (^{14}C- Cyclohexane and ^{14}C- Phenyl-labels)

stable

Aqueous photochemical degradation

Photolytic degradation of active substance and metabolites above 10%
Direct photolysis (Eya, B.K., 1995): DT_{50} of 81-88 days at 40ºN

DT_{50} of 89-97 days at 50ºN. No major metabolites found.

Quantum yield of direct phototransformation in water at > 290 nm
Not reported

Indirect photolytic degradation of active substance and metabolites above 10%
Indirect photolysis (Oliver, R.G., 2005): DT_{50} of 19.5 days at 40ºN

DT_{50} of 20.5 days at 50ºN
No metabolites >10%AR found

‘Ready biodegradability

Readily biodegradable (yes/no)
No data.
Not readily biodegadable

Table 8.6-1: Aerobic mineralisation in surface water of mesotrione

Parent										
System identifier (indicate fresh, estuarine or marine)	**pH water phase**	**pH sed a)**	**t.°C b)**	**DT50 /DT90 whole sys.(suspended sediment test)**		**St. (χ2)**	**DT_{50} /DT_{90} Water (pelagic test)**		**St. (χ2)**	**Method of calculation**
				At study temp (20°C)b)	**Normalised to (12°C)c)**		**At study temp (20°C^b^)**	**Normalised to 12°C^c)^**		
Group A, low conc (Natural water)	7.3	N/A	20	N/A	N/A	N/A	382/1270	712.7/2413	3.06	SFO
Group B, high conc (Natural water)	7.3	N/A	20	N/A	N/A	N/A	329/1090	613.8/2071	3.66	SFO
Group C high conc, sterilised (natural water)	7.3	N/A	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Group D, reference (Natural water)	7.3	N/A	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Group E,low conc (Natural water & sed)	7.3	7.4	20	253/842	472 /1599.8	2.63	N/A	N/A	N/A	SFO
Group F, high conc (Natural water & sediment)	7.3	7.4	20	228/758	425 /1440.2	1.87	N/A	N/A	N/A	SFO
Group G, high conc, sterilised (Natural water & sed)	7.3	7.4	20	N/A	N/A		N/A	N/A	N/A	N/A
Group H, reference (Natural water & sed	7.3	7.4	20	N/A	N/A		N/A	N/A	N/A	N/A

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

b) Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C.

c) Normalised using a Q10 of 2.58 to 12 °C for the purpose of the application of Guidance on Information Requirements and Chemical Safety Assessment. Chapter R11: PBT/vPvB assessment (ECHA, November 2014).

Table 8.6-2: Aerobic mineralisation in surface water of MNBA

Metabolite MNBA (NOA437130)*	**Max in total system 9.7% after 60 days (n=2, 11.3%, 8.1%). No DT50 values calculated; no clear decline phase observed**									
System identifier (indicate fresh, estuarine or marine)	**pH water phase**	**pH sed a)**	**t.°C b)**	**DT_{50} /DT_{90} whole sys. (suspended sediment test)**		**St. (χ2)**	**DT_{50} /DT_{90} Water (pelagic test)**		**St. (χ2)**	**Method of calculation**
				At study temp	**Normalised to x °C c)**		**At study temp**	**Normalised to x °C c)**		
Group A,low conc (Natural water)	7.3	N/A	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Group B, high conc(Natural water)	7.3	N/A	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Group E,low conc (Natural water & sed)	7.3	7.4	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Group F, high conc (Natural water & sediment)	7.3	7.4	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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

b) Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

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

* No other major metabolites observed in aerobic mineralisation study

Table 8.6-3: Mineralization and non extractable residues studies

System identifier (indicate fresh, estuarine or marine)		**pH water phase**	**pH sed**	**Mineralisation *x%* after *n* days. (end of the study).**			**Non-extractable residues. max *x%* after *n* d(suspended sediment test)**	**Non-extractable residues. Max *x%* after *n* days (end of the study) (suspended sediment test)**
Group conc (Natural	A, low water)	7.3	N/A	ND (CO_2 days)	after	60	n.r	n.r
Group B, high conc (Natural water)		7.3	N/A	0.3% (CO_2 after 60 days)			n.r	n.r
Group E, low conc (Natural water & sed)		7.3	7.4	ND (CO_2 days)	after	60	n.r	n.r

Group F, high conc (Natural water & sediment)	7.3	7.4	0.3% (CO_2 after 60 days)	n.r	n.r

n.r = Not reported

Table 8.6-4: Water / sediment study distribution of mesotrione

Parent	Distribution (max in water 98.7% after 0 d. Max. sed 4.3% after 1d)									
Water/ sediment system (radiolabel)	**pH water phase**	**pH sed a)**	**t. ºC**	**DT_{50}/ DT_{90} Whole sys.c)**	**St. (χ2)**	**DT_{50} /DT_{90} water**	**St. (χ2)**	**DT_{50} /DT_{90} sed**	**St. (χ2)**	**Method of calculation**
Basing (Phenyl)	7.86		20	2.6	6.8	2.5	6.2	n/a	n/ a	SFO
Basing (Cyclohexane)			20	4.2	13.3	4.2	13.3	n/a	n/a	SFO
Virginia (Phenyl)	7.40		20	5.5	12.3	5.3	13.5	n/a	n/ a	SFO
Virginia (Cyclohexane)			20	7.2	14.4	7.0	13.4	n/a	n/ a	SFO
Calwich (Phenyl)	8.4/7.8 (aerobic/ anaerobi c)	7.6	20	6.6	4.5	6.7	3.4	n/a	n/ a	SFO
Swiss (Phenyl)	7.4/7.5 (aerobic/ anaerobi c)	6.1	20	11.1	3.5	11.0	3.3	n/a	n/ a	SFO
Geometric mean at 20 ºC b)				**5.6**		**5.5**		**n/a**		

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

Table 8.6-5: Water / sediment study distribution of MNBA

Metabolite **MNBA**	Distribution (max in water 7.4%* after 3 days. Max. sed <1%*). Max in total system 7.4% after 3 days. *Detected in Cary., 1999. Not detected in Graham R, 2013 kinetic formation fraction (k_f/k_{dp}): Not available									
Water/ sediment system	**pH water phase**	**pH sed a)**	**t.º C**	**DT_{50} /DT_{90} whol.sys.**	**St. (χ2)**	**DT_{50} /DT_{90} water**	**St. (χ2)**	**DT_{50} /DT_{90} sed**	**St. (χ2)**	**Method of calculation**
n/a	n/a	n/a	n/a	n/a	n/ a	n/a	n/ a	n/a	n/ a	n/a
Geometric mean at 20ºC b)**				n/a		n/a		n/a		n/a

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58
** 1000 day default value used in risk assessment

Table 8.6-6: Water / sediment study distribution of AMBA

Metabolite **AMBA**	Distribution (max in water 15.8% after 46 d. Max. sed 8.8 % after 46 d). Max in total system 24.6% after 46 days, kinetic formation fraction (kf/kdp): Not available									
Water /sediment system	**pH water phase**	**pH sed a)**	**t.ºC**	**DT_{50} /DT_{90} whole sys.**	**St. (χ2)**	**DT_{50} /DT_{90} water**	**St. (χ2)**	**DT_{50} /DT_{90} sed**	**St. (χ2)**	**Method of calculation**
n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/ a	n/a	n/ a	n/a
Geometric mean at 20ºC b)*				n/a		n/a		n/a		n/a

* 1000 days default value used in risk assessment

Table 8.6-7: Water / sediment study distribution of SYN546974

Metabolite **SYN546974**	Distribution (max in water 9.4% after 29 d. Max. sed 25.6% after 102 d). Max in total sytem 33% after 29 days. Kinetic formation fraction (kf/kdp): Not available									
Water /sediment system	**pH water phase**	**pH sed a)**	**t.ºC**	**DT_{50} /DT_{90} whole sys.**	**St. (χ2)**	**DT_{50} /DT_{90} water**	**St. (χ2)**	**DT_{50} /DT_{90} sed**	**St. (χ2)**	**Method of calculation**
n/a	n/a	n/a	n/a	n/a	n/ a	n/a	n/ a	n/a	n/ a	n/a
Geometric mean at 20ºC b)*				n/a		n/a		n/a		n/a

* 1000 days default value used in risk assessment

Table 8.6-8: Mineralisation and non extractable residues studies

Water /sediment system	**pH water phase**	**pH sed**	**Mineralisation x% after n d. (end of thestudy).**	**Non-extractable resi-dues in sed. max x% after n d**	**Non-extractable residues in sed. max x% after n d (end of the study)**
Basing (Phenyl)	7.86		5.5	73.7 (101 DAT)	73.7 (101 DAT)
Basing (Cyclohexane)			27.8	63.8 (101 DAT)	63.8 (101 DAT)
Virginia (Phenyl)	7.40		15.6	64.5 (101 DAT)	64.5 (101 DAT)
Virginia (Cyclohexane)			26.8	48.4 (28 DAT)	44.7 (101 DAT)
Calwich (Phenyl)	8.4/7.8 (aerobic /anaerobic)	7.6	6.3	60.7 (102 DAT)	60.7 (102 DAT)
Swiss (Phenyl)	7.4/7.5 (aerobic /anaerobic)	6.1	11.4	45.0 (102 DAT)	(102 DAT)

8.6.2 Florasulam and its metabolites

Table 8.6-9: Route and rate of degradation in water of florasulam

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

Table 8.6-10: Distribution of the Applied Radioactivity (AR) in the test systems.

Water/ Sediment system and test compound	Characteristic of the system:			AR distribution in the system [%]:				
				Max. in water phase	Max. in sediment - extractable	NER	Mineralisation level ($^{14}CO_2$)	Identified metabolites
Sandy loam sediment system; [^{14}C]-phenyl Florasulam and [^{14}C]-TP Florasulam	**Sediment's texture class - USDA**		Sand-loam	101.83 –[^{14}C] –phenylFlorasulam, DAT 0; 99.83 – [^{14}C] –TP Florasulam,DAT 1;	35.23 – [^{14}C]–phenyl Florasulam, DAT 60; 36.44 – [^{14}C] –TP Florasulam, DAT 182;	11.49 – [^{14}C]–phenyl Florasulam, DAT 182; 9.28 – [^{14}C] –TP Florasulam,DAT 60;	8.05 – [^{14}C]–phenyl Florasulam, DAT 182; 1.93 – [^{14}C] –TP Florasulam, DAT 100 and DAT182;	5-OHFlorasulam (both labels)
	pH	Water phase	7.6					
		Sediment	5.4					
	OC-content	Water phase–DOC [%]	<0.0013					
		Sediment [%]	2.2					
	Incubation temperature [^{0}C]		20					
Clay loam sediment system; [^{14}C]-phenyl Florasulam and [^{14}C]-TP Florasulam	**Sediment's texture class - USDA**		Clay-loam	106.12 –[^{14}C] –phenylFlorasulam, DAT 0;101.00 – [^{14}C] –TP Florasulam,DAT 0;	37.87 – [^{14}C]–phenyl Florasulam, DAT 60;38.94 – [^{14}C] –TP Florasulam, DAT 182;	11.13 – [^{14}C]–phenyl Florasulam, DAT 182;8.06 – [^{14}C] –TP Florasulam, DAT 182;	No mineralisa- tion observed (both labels)	5-OHFlorasulam (both labels)
	pH	Water phase	6.6					
		Sediment	5.9					
	OC-content	Water phase–DOC [%]	0.0020					
		Sediment [%]	2.9					
	Incubation temperature [^{0}C]		20					
Calwich Abbey Lake	**Sediment's texture class - USDA**		Silt-loam	97.9 – [^{14}C]–phenyl Florasulam, DAT	31.0 – [^{14}C]–phenyl Florasulam, DAT 59;35.2 –	10.7 – [^{14}C]–phenyl Florasulam,	3.2 – [^{14}C] –phenyl Florasulam, DAT 100;0.5 –	5-OHFlorasulam (both labels)

water /sediment system;[^{14}C]-phenyl Florasulam and [^{14}C]-TP Florasulam	**pH**	Water phase	7.9	0;94.0 – [^{14}C] –TP Florasulam,DAT 0;	[^{14}C] –TP Florasulam,DAT 59;	DAT 100;10.8 – [^{14}C] –TP Florasulam, DAT 100;	[^{14}C] –TP Florasulam, DAT 100 and DAT100;	
		Sediment	7.3					
	OC-content	Water phase – TOC [ppm]	5.3					
		Sediment [%]	4.4					
	Incubation temperature [^{0}C]		20					
Swiss Lake water /sediment system;[^{14}C]-phenyl Florasulam and [^{14}C]-TP Florasulam	**Sediment's texture class - USDA**		Sand	98.8 – [^{14}C]–phenyl Florasulam, DAT 0;98.0 – [^{14}C]–TPFlorasulam, DAT 0;	27.8 – [^{14}C]–phenyl Florasulam, DAT 100;33.2 – [^{14}C] –TP Florasulam,DAT 59;	5.6 – [^{14}C] – phenyl Florasulam, DAT 100;2.9 – [^{14}C] –TP Florasulam, DAT 100;	4.1 – [^{14}C] –phenyl Florasulam, DAT 100;0.0 – [^{14}C] –TP Florasulam, DAT 100 –no mineralisatio n observed;	5-OHFlorasulam (both labels)
	pH	Water phase	6.7					
		Sediment	5.2					
	OC - content	Water phase – TOC [ppm]	10.9					
		Sediment [%]	0.8					
	Incubation temperature [^{0}C]		20					

Table 8.6-11: Distribution of the Florasulam and 5-OH Florasulam in water/sediment systems (% AR).

Water /Sediment system and test compound	Characteristic of the system:			Distribution of Florasulam in the system		Distribution of 5-OH Florasulam in the system		
				Max. in water phase [%AR]	Max. in sediment [% AR]	Max. in the system [%AR]	Max. in water phase [%AR]	Max. in sediment [% AR]
Sandy loam sediment system; [^{14}C]-phenyl Florasulam and [^{14}C]-TP Florasulam	**Sediment's texture class - USDA**		Sandy loam	101.83 – [^{14}C] – phenyl Florasulam, DAT 0; 96.24 – [^{14}C] –TP Florasulam, DAT 0;	8.73 – [^{14}C] – phenyl Florasulam, DAT 0.25; 4.22 – [^{14}C] –TP Florasulam, DAT 2;	99.00 – [^{14}C] –phenyl Florasulam, DAT 60; 91.91 – [^{14}C] –TP Florasulam, DAT 60;	83.14 – [^{14}C] –phenyl Florasulam, DAT 60; 64.36 – [^{14}C] –TP Florasulam, DAT 60;	35.06 – [^{14}C] –phenyl Florasulam, DAT 60; 32.84 – [^{14}C] –TP Florasulam, DAT 100;
	pH	Water phase	7.6					
		Sediment	5.4					
	OC content	Water phase – DOC [%]	<0.0013					
		Sediment [%]	2.2					
	Incubation temperature [^{0}C]		20					
Clay loam sediment system; [^{14}C]-phenyl Florasulam and [^{14}C]-TP Florasulam	**Sediment's texture class- USDA**		Clay loam	106.12 –[^{14}C] – phenyl Florasulam, DAT 0; 101.00 – [^{14}C] –TP Florasulam, DAT 0;	5.22 – [^{14}C] – phenyl Florasulam, DAT 7; 6.12 – [^{14}C] –TP Florasulam, DAT 7;	98.21 – [^{14}C] –phenyl Florasulam, DAT 100; 89.58 – [^{14}C] –TP Florasulam, DAT 60;	63.15 – [^{14}C] –phenyl Florasulam, DAT 100; 57.04 – [^{14}C] –TP Florasulam, DAT 60;	35.06 – [^{14}C] –phenyl Florasulam, DAT 100; 32.54 – [^{14}C] –TP Florasulam, DAT 60;
	pH	Water phase	6.6					
		Sediment	5.9					
	OC content	Water phase – DOC [%]	0.0020					
		Sediment [%]	2.9					
	Incubation temperature [^{0}C]		20					
Calwich Abbey Lake water/ sediment system; [^{14}C]-	**Sediment's texture class - USDA**		Silt loam	95.9 – [^{14}C] –phenyl Florasulam, DAT 0; 93.0 – [^{14}C] –TP Florasulam,	5.1 – [^{14}C] – phenyl Florasulam, DAT 1; 6.2 – [^{14}C] –TP Florasulam,	87.2 – [^{14}C] – phenyl Florasulam, DAT 59; 91.9 – [^{14}C] –TP Florasulam,	57.5 – [^{14}C] – phenyl Florasulam, DAT 59; 59.4 – [^{14}C] –TP Florasulam,	29.7 – [^{14}C] – phenyl Florasulam, DAT 59; 32.5 – [^{14}C] –TP Florasulam,
	pH	Water phase	7.9					
		Sediment	7.3					

phenyl Florasulam and [^{14}C]-TP Florasulam	**OC content**	Water phase – TOC [ppm]	5.3	DAT 0;	DAT 0;	DAT 59;	DAT 59;	DAT 59;
		Sediment [%]	4.4					
	Incubation temperature [^{0}C]		20					
Swiss Lake water/ sediment system; [^{14}C]-phenyl Florasulam and [^{14}C]-TP Florasulam	**Sediment's texture class – USDA**		Sand	96.5 – [^{14}C] –phenyl Florasulam, DAT 0; 97.9 – [^{14}C] –TP Florasulam, DAT 0;	3.6 – [^{14}C] – phenyl Florasulam, DAT 3; 4.0 – [^{14}C] –TP Florasulam, DAT 7;	74.9 – [^{14}C] – phenyl Florasulam, DAT 59; 73.3 – [^{14}C] –TP Florasulam, DAT 59;	53.3 – [^{14}C] – phenyl Florasulam, DAT 59; 54.9 – [^{14}C] –TP Florasulam, DAT 100;	21.6 – [^{14}C] – phenyl Florasulam, DAT 59; 28.4 – [^{14}C] –TP Florasulam, DAT 59;
	pH	Water phase	6.7					
		Sediment	5.2					
	OC content	Water phase – TOC [ppm]	10.9					
		Sediment [%]	0.8					
	Incubation temperature [^{0}C]		20					

Table 8.6-12: Endpoints for florasulam

Water/ Sediment system and test compound	**Characteristic of the system:**			**Persistence Kinetic endpoints**								
				Whole system			**Water phase**			**Sediment**		
				DT50 [days]	**DT90 [days]**	**Kinetic model**	**DT50 [days]**	**DT90 [days]**	**Kinetic model**	**DT50 [days]**	**DT90 [days]**	**Kinetic model**
Sandy loam sediment system; [^{14}C]-phenyl Florasulam	**Sediment's texture class - USDA**		Sandy loam	6.74	22.38	SFO; χ^2err = 4.45; R^2 = 0.994	6.12	20.32	SFO; χ^2err =5.27; R^2 = 0.992	0.54	1.80	Kinetic analysis performed, but its results not reported due to the low reliability
	pH	Water phase	7.6									
		Sediment	5.4									
	OC-content	Water phase– DOC [%]]	<0.0013									
		Sediment[%]	2.2									
	Incubation temperature		20									

	[^{0}C]											
Sandy loam sediment system; [^{14}C]-TP Florasulam	**Sediment's texture class -USDA**		Sandy loam	11.29	37.49	SFO; **χ2**err =5.44; R^2 = 0.986	10.51	34.91	SFO; **χ2**err =5.65; R^2 = 0.987	1.37	4.55	Kinetic analysis performed, but its results not reported due to the low reliability
	pH	Water phase	7.6									
		Sediment	5.4									
	OC-content	Water phase–DOC [%]	<0.0013									
		Sediment[%]	2.2									
	Incubation temperature [^{0}C]		20									
Clay loam sediment system; [^{14}C]-phenyl Florasulam	**Sediment's texture class - USDA**		Clay-loam	26.9	89.34	SFO; **χ2**err = 9.58; R^2 = 0.964	23.29	77.38	SFO; **χ2**err = 7.97; R^2 = 0.972	4.31	14.33	Kinetic analysis performed, but its results not reported due to the low reliability
	pH	Water phase	6.6									
		Sediment	5.9									
	OC-content	Water phase–DOC [%]	0.0020									
		Sediment [%]	2.9									
	Incubation temperature [^{0}C]		20									
Clay loam sediment system; [^{14}C]-TP Florasulam	**Sediment's texture class - USDA**		Clay-loam	24.42	81.13	SFO; **χ2**err =5.46 R^2 = 0.988	22.07	73.31	DFOP; **χ2**err =4.28; R^2 = 0.992	3.82	12.68	Kinetic analysis performed, but its results not reported due to the low reliability
	pH	Water phase	6.6									
		Sediment	5.9									
	OC-content	Water phase–DOC [%]	0.0020									
		Sediment [%]	2.9									
	Incubation temperature [^{o}C]		20									

<table>
<tr><td rowspan="6">Calwich Abbey Lake water/ sediment system; [14C]-phenyl Florasulam</td><td colspan="2">Sediment's texture class - USDA</td><td>Silt loam</td><td rowspan="6">8.25</td><td rowspan="6">27.41</td><td rowspan="6">SFO;
χ2err =4.76;
R^2 = 0.995</td><td rowspan="6">7.98</td><td rowspan="6">26.53</td><td rowspan="6">SFO;
χ2err =3.28;
R^2 = 0.997</td><td rowspan="6">0.41</td><td rowspan="6">1.35</td><td rowspan="6">Kinetic analysis performed, but its results not reported due to the low reliability</td></tr>
<tr><td rowspan="2">pH</td><td>Water phase</td><td>7.9</td></tr>
<tr><td>Sediment</td><td>7.3</td></tr>
<tr><td rowspan="2">OC-content</td><td>Water phase–TOC[ppm]</td><td>5.3</td></tr>
<tr><td>Sediment[%]</td><td>4.4</td></tr>
<tr><td colspan="2">Incubation temperature[0C]</td><td>20</td></tr>
<tr><td rowspan="6">Calwich Abbey Lake water/ sediment system; [14C]-TPFlorasulam</td><td colspan="2">Sediment's texture class -USDA</td><td>Silt loam</td><td rowspan="6">9.89</td><td rowspan="6">32.85</td><td rowspan="6">SFO;
χ2err = 4.50;
R^2 = 0.995</td><td rowspan="6">9.98</td><td rowspan="6">33.15</td><td rowspan="6">SFO;
χ2err = 4.08;
R^2 = 0.996</td><td rowspan="6">0.42</td><td rowspan="6">1.40</td><td rowspan="6">Kinetic analysis performed, but its results not reported due to the low reliability</td></tr>
<tr><td rowspan="2">pH</td><td>Water phase</td><td>7.9</td></tr>
<tr><td>Sediment</td><td>7.3</td></tr>
<tr><td rowspan="2">OC-content</td><td>Water phase–TOC[ppm]</td><td>5.3</td></tr>
<tr><td>Sediment[%]</td><td>4.4</td></tr>
<tr><td colspan="2">Incubation temperature[0C]</td><td>20</td></tr>
<tr><td rowspan="6">Swiss Lake water/ sediment system; [14C]-phenyl Florasulam</td><td colspan="2">Sediment's texture class -USDA</td><td>Sand</td><td rowspan="6">25.05</td><td rowspan="6">89.19</td><td rowspan="6">SFO;
χ2err =4.71;
R^2 = 0.988</td><td rowspan="6">24.01</td><td rowspan="6">79.76</td><td rowspan="6">SFO;
χ2err =3.97;
R^2 = 0.992</td><td rowspan="6">1.85</td><td rowspan="6">6.15</td><td rowspan="6">Kinetic analysis performed, but its results not reported due to the low reliability</td></tr>
<tr><td rowspan="2">pH</td><td>Water phase</td><td>6.7</td></tr>
<tr><td>Sediment</td><td>5.2</td></tr>
<tr><td rowspan="2">OC-content</td><td>Water phase–TOC[ppm]</td><td>10.9</td></tr>
<tr><td>Sediment[%]</td><td>0.8</td></tr>
<tr><td colspan="2">Incubation temperature[0C]</td><td>20</td></tr>
<tr><td>Swiss Lake</td><td colspan="2">Sediment's texture class</td><td>Sand</td><td>25.49</td><td>84.66</td><td>SFO;</td><td>24.30</td><td>80.72</td><td>SFO;</td><td>4.56</td><td>15.16</td><td></td></tr>
</table>

water /sediment system; [14C]-TP Florasulam	**-USDA**					$\chi 2$err =.45 R^2 = 0.985			$\chi 2$err =4.30; R^2 = 0.991			Kinetic analysis performed, but its results not reported due to the low reliability
	pH	Water phase	6.7									
		Sediment	5.2									
	OC-content	Water phase–TOC[ppm]	10.9									
		Sediment[%]	0.8									
	Incubation temperature [0C]		20									
Geometric mean				**15.03**	**50.36**	-----	**14.05**	**46.74**	-----	**1.44**	**4.76**	----
Water /Sediment system and test compound	**Characteristic of the system:**			**Modelling Kinetic endpoints**								
				Whole system			**Water phase**			**Sediment**		
				DT50 [days]	**DT90 [days]**	**Kinetic model**	**DT50 [days]**	**DT90 [days]**	**Kinetic model**	**DT50 [days]**	**DT90 [days]**	**Kinetic model**
Sandy loam sediment system; [14C]-phenyl Florasulam	**Sediment's texture class -USDA**		Sandy loam				Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation
	pH	Water phase	7.6	6.74	22.38	SFO; $\chi 2$err = 4.45; R^2 = 0.994						
		Sediment	5.4									
	OC content	Water phase – DOC [%]]	<0.0013									
		Sediment[%]	2.2									
	Incubation temperature [0C]		20									
Sandy loam sediment system; [14C]-TP Florasulam	**Sediment's texture class -USDA**		Sandy loam				Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation
	pH	Water phase	7.6	11.29	37.49	SFO; $\chi 2$err =5.44; R^2 = 0.986						
		Sediment	5.4									
	OC	Water phase – DOC [%]	<0.0013									

	content	Sediment[%]	2.2									
	Incubation temperature [^{0}C]		20									
Clay loam sediment system; [^{14}C]-phenyl Florasulam	**Sediment's texture class -USDA**		Clay loam				Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation
	pH	Water phase	6.6	26.89	89.34	SFO; $\chi 2$err =9.58; R^2 = 0.964						
		Sediment	5.9									
	OC content	Water phase – DOC [%]	0.0020									
		Sediment[%]	2.9									
	Incubation temperature [^{0}C]		20									
Clay loam sediment system; [^{14}C]-TP Florasulam	**Sediment's texture class -USDA**		Clay loam				Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation
	pH	Water phase	6.6	24.42	81.13	SFO; $\chi 2$err =5.46 R^2 = 0.988						
		Sediment	5.9									
	OC content	Water phase – DOC [%]	0.0020									
		Sediment[%]	2.9									
	Incubation temperature [^{0}C]		20									
Calwich Abbey Lake water/ sediment system; [^{14}C]-phenyl Florasulam	**Sediment's texture class -USDA**		Silt loam				Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation
	pH	Water phase	7.9	8.25	27.41	SFO; $\chi 2$err =4.76; R^2 = 0.995						
		Sediment	7.3									
	OC	Water phase – TOC[ppm]	5.3									

	content	Sediment[%]	4.4									
	Incubation temperature [^{0}C]		20									
Calwich Abbey Lake water/ sediment sys-tem; [^{14}C]-TP Florasulam	**Sediment's texture class - USDA**		Silt loam				Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation
	pH	Water phase	7.9	9.89	32.85	SFO; $\chi2$err =4.50; R^2 = 0.995						
		Sediment	7.3									
	OC content	Water phase – TOC[ppm]	5.3									
		Sediment[%]	4.4									
	Incubation temperature [^{0}C]		20									
Swiss Lake water/ sedi-ment system; [^{14}C]-phenyl Florasulam	**Sediment's texture class -USDA**		Sand				Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation
	pH	Water phase	6.7	25.05	89.19	SFO; $\chi2$err =4.71; R^2 = 0.988						
		Sediment	5.2									
	OC content	Water phase – TOC[ppm]	10.9									
		Sediment [%]	0.8									
	Incubation temperature [^{0}C]		20									
Swiss Lake water/ sedi-ment system; [^{14}C]-TP Florasulam	**Sediment's texture class - USDA**		Sand				Not determined - dissi-pation	Not determined - dissi-pation	Not determined - dissi-pation	Not determined - dissi-pation	Not determined - dissi-pation	Not determined - dissi-pation
	pH	Water phase	6.7	25.49	84.66	SFO; $\chi2$err == 5.45 R^2 = 0.985						
		Sediment	5.2									
	OC content	Water phase – TOC [ppm]	10.9									

		Sediment [%]	0.8									
	Incubation temperature [^{0}C]		20									
Geometric mean				**15.03**	**50.36**	**-----**	**-----**	**-----**	**-----**	**-----**	**-----**	**-----**

Table 8.6-13: The kinetic endpoints for Florasulam and its major degradation products determined in aquatic environment.

Compound	Maximum detected in aquatic environment	Kinetic endpoints – DT_{50} [days] to be used in SW modelling		
		Whole system	Water phase	Sediment Phase
Florasulam	Not applicable – parent compound	15.03	15.03	15.03
5-OH Florasulam	99.0%	1000	1000	1000
DFP-ASTCA	8.9%	1000	1000	1000
ASTCA	53.8%	1000	1000	1000
TPSA	58.3%	1000	1000	1000
ASTP	21.9%	1000	1000	1000
5-OH ASTP	28.9%	1000	1000	1000

In case of florasulam the geomean whole system DT_{50} value was proposed to be used as input parameter for both water and sediment phase. This was due to the fact that in both water/sediment studies although this compound was found predominantly in water phase, where it underwent degradation to 5-OH Florasulam, its small amounts, up to 9% AR, were found also in sediment phase, where it quickly dissipated. The kinetic examination of the data showed that this process was much faster than in water phase, but the reliability of the derived kinetic endpoints was low, due to the low concentrations of Florasulam in sediment. It may be postulated that the process of dissipation of Florasulam from sediment was a mixed process, partly being degradation to 5-OH Florasulam (the indication for this is the fact that the formation pattern of 5-OH metabolite in sediment is correlated with the dissipation of Florasulam from sediment) and partly the release to water column. Therefore the use of FOCUS default DT_{50} = 1000 days for Florasulam in sediment does not seem supported by experimental results. Similar justification can be given to use the same value for water phase – detection of Florasulam in sediment in quantifiable amounts may indicate that at least at the beginning of the study, despite low adsorption properties, Florasulam partly migrates to sediment from where it is either back-released to water or degrades to 5-OH Florasulam. Therefore the determined net kinetic endpoints for water phase represent rather dissipation than degradation. It shall be pointed out however that due to low adsorption properties and high solubility in water Florasulam is expected to be found mainly in water phase. For this reason it can be stated that there is enough evidence for using the whole system geomean DT_{50} as an input parameter for both water and sediment in SW modelling at all tiers at which it was carried out. As for the metabolites the proposed values are FOCUS defaults mainly due to the fact that no clear decline was observed for any of them, hence it was not possible to determine the kinetic endpoints.

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

8.7.1 Justification for new endpoints

Studies on concentrations in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.
Reference to:
- Peer review of the pesticide risk assessment of the active substance mesotrione EFSA Journal 2016;14(3):4419
- Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam EFSA Journal 2015; 13(1):3984

8.7.2 Active substances and relevant metabolites

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	Mesotrione 125 g/ha Florasulam 3.75 g/ha
Number of applications/interval	1/0
Crop interception (%)	25
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU end-point y/n/ Reference
Mesotrione	339.3	-	44.3	EFSA Journal 2016;14(3):4419
MNBA	245	57.2	25.2	
AMBA	215	9.7	1000	
Florasulam	359.29	-	4.29	EFSA Journal 2015;13(1): 3984
5-OH Florasulam	345.26	71.6	29.75	
DFP-ASTCA	304.20	17.8	46.16	
ASTCA	192.13	40.0	259.05	
TSA	148.14	15.9	171.68	

8.7.2.1 Mesotrione and its metabolites

Table 8.7-3: PEC_{soil} for mesotrione on maize

PEC_{soil} (mg/kg)	maize	
	Single application	
	Actual	TWA
Initial	0.125	0.125

Short term	24h	0.123	0.124
	2d	0.121	0.123
	4d	0.117	0.121
Long term	7d	0.112	0.118
	14d	0.100	0.112
	21d	0.090	0.107
	28d	0.081	0.101
	50d	0.057	0.087
	100d	0.026	0.063
Plateau concentration (5) after year 20		0.0 (no accumulation)	-

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for MBMA on maize

PEC_{soil} (mg/kg) Application 51.6		Maize	
		Single application	
		Actual	TWA
Initial		0.052	0.052-
Short term	24h	0.050	0.051
	2d	0.049	0.050
	4d	0.046	0.049
Long term	7d	0.043	0.047
	14d	0.035	0.043
	21d	0.029	0.039
	28d	0.024	0.036
	50d	0.013	0.028
	100d	0.003	0.018
Plateau concentration (5) after year 20		0.0 (no accumulation)	-

Table 8.7-5: PEC_{soil} for AMBA on maize

PEC_{soil} (mg/kg) Application 7.7		Maize	
		Single application	
		Actual	TWA
Initial		0.008	0.008
Short term	24h	0.008	0.008
	2d	0.008	0.008
	4d	0.008	0.008
Long term	7d	0.008	0.008
	14d	0.008	0.008

	21d	0.008	0.008
	28d	0.008	0.008
	50d	0.007	0.008
	100d	0.007	0.007
Plateau concentration (5) after year 20		0.027	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.035	-

zRMS comments

Mesotrione

PEC_{soil} calculations has been accepted for the active substance mesotrione and its metabolites MNBA and AMBA. The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific EFSA Journal 2016;14 (3):4419. Interception is appropriate to the proposed BBCH of crops (guidance 2014). It is noted that for mesotrione the maximum non-normalised laboratory DT_{50} of 34.3 days was recommended for calculation of the soil exposure in EFSA report. However, DT_{50} used by the Applicant was accepted by zRMS because it does not affect the outcome of the PECs. Moreover, due to lack of potential mesotrione for accumulation in soil (DT_{50} <60 days) the soil risk assessment is based on initial PEC_{soil} values.

The acceptable predicted environmental concentrations of mesotrione and its metabolites in soil are appropriate to be used for the subsequent risk assessment
Mesotrione: PECs = 0.125 mg/kg
MNBA: PECs = 0.052 mg/kg
AMBA: PECs = 0.008 mg/kg

8.7.2.2 Florasulam and its metabolites

Table 8.7-6: PEC_{soil} for florasulam on maize

PEC_{soil} (mg/kg)		maize	
		Single application	
		Actual	TWA
Initial		0.004	0.004-
Short term	24h	0.003	0.003
	2d	0.003	0.003
	4d	0.002	0.003
Long term	7d	0.001	0.002
	14d	0.000	0.001
	21d	0.000	0.001
	28d	0.000	0.001
	50d	0.000	0.000
	100d	0.000	0.000
Plateau concentration (5)		0.0 (no	-

after year 20	accumulation)	

PEC_{soil} of metabolites

Table 8.7-7: PEC_{soil} for 5-OH florasulam on maize

PEC_{soil} (mg/kg) Application 2.58 g/ha		Maize	
		Single application	
		Actual	TWA
Initial		0.003	0.003-
Short term	24h	0.003	0.003
	2d	0.002	0.003
	4d	0.002	0.002
Long term	7d	0.002	0.002
	14d	0.002	0.002
	21d	0.002	0.002
	28d	0.001	0.002
	50d	0.001	0.002
	100d	0.000	0.001
Plateau concentration (5) after year 20		0.0 (no accumulation)	-

Table 8.7-8: PEC$_{soil}$ for DFP-ASTCA on maize

PEC$_{soil}$ (mg/kg) Application 0.56 g/ha		Maize	
		Single application	
		Actual	TWA
Initial		0.001	0.001
Short term	24h	0.001	0.001
	2d	0.001	0.001
	4d	0.001	0.001
Long term	7d	0.001	0.001
	14d	0.000	0.001
	21d	0.000	0.000
	28d	0.000	0.000
	50d	0.000	0.000
	100d	0.000	0.000
Plateau concentration (5) after year 20		0.0 (no accumulation)	-

Table 8.7-9: PEC$_{soil}$ for ASTCA on maize

PEC$_{soil}$ (mg/kg) Application 0.8 g/ha		Maize	
		Single application	
		Actual	TWA
Initial		0.001	0.001-
Short term	24h	0.001	0.001
	2d	0.001	0.001
	4d	0.001	0.001
Long term	7d	0.001	0.001
	14d	0.001	0.001
	21d	0.001	0.001
	28d	0.001	0.001
	50d	0.001	0.001
	100d	0.001	0.001
Plateau concentration (5) after year 20		0.000	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		0.001	-

Table 8.7-10: PEC_{soil} for TSA on maize

PEC_{soil} (mg/kg) Application 0.25 g/ha	Maize	
	Single application	
	Actual	TWA
Initial	0.000	0.000-

zRMS comment:

Forasulam
The calculations of PECs submitted by Applicant have been accepted.
The degradation endpoints used for florasulam and its metabolites were in line in the LoEP (EFSA Journal 2015; 13 (1):3984).
The results of PECs calculation are presented from Table 8.7-6 to Table 8.7-9.

8.7.2.3 PEC_{soil} of MEZOFLOR 103 SC

Table 8.7-11: PEC_{soil} for MEZOFLOR 103 SC on maize

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)
Mesotrione	125	0.125	0.107	5	-	-
Florasulam	3.75	0.00375	0.001	5	-	-
MEZOFLOR 103 SC	1328	1.328	-	-	-	-

zRMS comments:

Based on an application rate of 1328 g/ha and 25 % crop interception calculated PECs is 1.328 mg/kg
The results of PECs for the active substances and its metabolites will and formulation are used for the ecotoxicological risk assessment.

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

8.8.1 Justification for new endpoints

Studies on concentrations in groundwater with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.
Reference to:

- Peer review of the pesticide risk assessment of the active substance mesotrione EFSA Journal 2016;14(3):4419
- Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam

EFSA Journal 2015; 13(1):3984

8.8.2 Mesotrione, florasulam and relevant metabolites (KCP 9.2.4.1)

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	Mesotrione 125 g/ha Florasulam 3.75 g/ha
Number of applications/interval (d)	1/0
Relative application date	7 d after emergence
Crop interception (%)	25
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4,

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

Crop	Scenario	Application dates (absolute)
Maize	Châteaudun	09.05 – 30.05
	Hamburg	12.05 – 29.05
	Kremsmünster	12.05 – 29.05
	Okehampton	29.05 – 08.06
	Piacenza	21.05 – 05.06
	Porto	09.05 – 30.05
	Sevilla	15.03 – 03.04
	Thiva	25.04 – 06.05

8.8.2.1 Mesotrione and its metabolites

Table 8.8-3: Input parameters related to active substance mesotrione and metabolites for PEC_{gw} calculations

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU end-point y/n/ Reference*
Molecular weight (g/mol)	339	245	215	EFSA Journal 2016;14(3):4419
Water solubility (mg/L):	160	160	160	
Saturated vapour pressure (Pa):	0	0	0	

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU endpoint y/n/ Reference*
DT_{50} in soil (d)	27.9 – pH < 7 5.4 – pH > 7 4 – worst case	3.4	14.5	
Transformation rate	0.0249– pH < 7 0.1284 – pH > 7 0.173 – worst case	0.0510 to AMBA, 0.1529 to CO_2	0.0478 to CO2	
K_{foc} (mL/g)/K_{fom}	156.6 / 90.8 – pH < 7 17.39 / 10.12 – pH > 7 14 / 8.12 – worst case	3.2 / 1.86	105.6 / 61.3 – pH < 7 21.8 / 12.6 – pH > 7 18.1 / 10.5 – worst case	
1/n	0.94– pH < 7 0.94 – pH > 7 0.97 – worst case	0.90	0.82	
Plant uptake factor	0.0	0.0	0.0	
Formation fraction	-	1 form mesotrione	0.25 from MNBA	

* Delete row in case of no pH dependency

Table 8.8-4: PEC$_{gw}$ for mestorione and metabolites on maize (with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize (pH <7)	Châteaudun	< 0.001	0.006	< 0.001
	Hamburg	0.005	0.081	0.019
	Kremsmünster	0.002	0.014	0.002
	Okehampton	0.006	0.039	0.006
	Piacenza	0.004	0.012	0.003
	Porto	< 0.001	0.011	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	0.001	< 0.001
Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**		
		Mesotrione	**MNBA**	**AMBA**
Maize (pH >7)	Châteaudun	< 0.001	< 0.001	0.004
	Hamburg	0.002	0.010	0.036
	Kremsmünster	< 0.001	0.003	0.031
	Okehampton	0.005	0.011	0.076
	Piacenza	< 0.001	< 0.001	0.006
	Porto	< 0.001	< 0.001	< 0.001

	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione	**MNBA**	**AMBA**
Maize (worst case)	Châteaudun	< 0.001	< 0.001	0.002
	Hamburg	< 0.001	0.005	0.026
	Kremsmünster	< 0.001	0.002	0.028
	Okehampton	0.002	0.007	0.067
	Piacenza	< 0.001	< 0.001	0.004
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Table 8.8-5: PEC_{gw} for mestorione and metabolites on maize (with FOCUS PELMO 6.6.4)

Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione	**MNBA**	**AMBA**
Maize (pH <7)	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.004	0.001
	Kremsmünster	< 0.001	0.002	< 0.001
	Okehampton	< 0.001	0.005	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
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione	**MNBA**	**AMBA**
Maize (pH >7)	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.001	0.004
	Kremsmünster	< 0.001	0.002	0.013
	Okehampton	0.002	0.009	0.038
	Piacenza	< 0.001	< 0.001	0.003
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize (worst case)	Châteaudun	< 0.001	< 0.001	0.001
	Hamburg	< 0.001	< 0.001	0.007
	Kremsmünster	< 0.001	0.001	0.022
	Okehampton	0.002	0.009	0.059
	Piacenza	< 0.001	< 0.001	0.005
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

ZRMS comments:

Mesotrione

The PECgw results are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in groundwater. All input parameters considered in the groundwater modelling for mesotrione and its metabolites were EU agreed values (EFSA Scientific Report 2016;14(3):4419. In simulations PUF value of 0 was assumed for all compounds is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

PECgw for mesotrione and its metabolites AMBA and MNBA are below 0.1 µg/L for all modelled scenarios.

Therefore, no unacceptable risk of groundwater contamination is expected for the formulated product according to the intended uses.

The assessment relevance of the non-relevant metabolites in ground water according to SANCO/221/2000 –rev.10 document was reported in the dRR Part B10.

Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

8.8.2.2 Florasulam and its metabolites

Table 8.8-6: Input parameters related to active substance florasulam and metabolites 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	345	304	192	148	Yes / EFSA

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA	Value in accordance with EU end-point y/n/ Reference*
Water solubility (mg/L):	6360	354	87400	250000	10900	Journal 2015; 13(1):3984
Saturated vapour pressure (Pa):	1.0 * 10^{-6}	2.7 * 10^{-6}	3.0* 10^{-6}	2.0 * 10^{-6}	1.0 * 10^{-4}	
DT_{50} in soil (d)	1.55	14.98	16.62	297.47	83.47	
Transformation rate	0.382 to 5-OH Florasulam 0.065 to CO_2	0.046 to DFP-ASTCA	0.0326 to ASTCA; 0.0091 to TSA	0.0023 to TSA	0.0083 to CO_2	
K_{foc} (mL/g)/K_{fom}	10.35 / 6.0	14.53 / 8.43	75.18 / 43.61	104.81 / 60.79	23.46 / 13.61	
1/n	0.945	0.91	0.85	0.94	0.94	
Plant uptake factor	0.0	0.0	0.0	0.0	0.0	
Formation fraction	-	0.854 form florasulam	1.0 from 5-OH florasulam	0.781 from DFP-ASTCA	0.219 from DFP-ASTCA 1.0 from ASTCA	

Table 8.8-7: PEC_{gw} for florasulam and metabolites on maize (with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH florasulam	DFP-ASTCA	ASTCA	TSA
Maize	Châteaudun	< 0.001	0.002	< 0.001	0.125	0.023
	Hamburg	< 0.001	0.008	0.002	0.151	0.033
	Kremsmünster	< 0.001	0.005	< 0.001	0.116	0.023
	Okehampton	< 0.001	0.010	0.002	0.117	0.022
	Piacenza	< 0.001	0.002	< 0.001	0.136	0.021
	Porto	< 0.001	< 0.001	< 0.001	0.065	0.012
	Sevilla	< 0.001	< 0.001	< 0.001	0.053	0.009
	Thiva	< 0.001	< 0.001	< 0.001	0.175	0.025

Table 8.8-8: PEC_{gw} for florasulam and metabolites on maize (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH florasulam	DFP-ASTCA	ASTCA	TSA
Maize	Châteaudun	< 0.001	0.002	< 0.001	0.158	0.139
	Hamburg	< 0.001	0.007	0.001	0.168	0.152

	Kremsmünster	< 0.001	0.007	0.001	0.152	0.126
	Okehampton	< 0.001	0.013	0.002	0.143	0.089
	Piacenza	< 0.001	0.003	0.001	0.125	0.097
	Porto	< 0.001	0.001	< 0.001	0.086	0.074
	Sevilla	< 0.001	< 0.001	< 0.001	0.057	0.082
	Thiva	< 0.001	< 0.001	< 0.001	0.201	0.164

The Predicted Environmental Concentrations (PECgw) of mesotrione, florasulam and their major metabolites, were calculated with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 on the basis of EU agreed endpoints. Eight scenarios were taken into consideration: Châteaudun, Hamburg, Okehampton, Kremsmünster, Piacenza, Porto, Sevilla and Thiva.

Obtained PECgw of mesotrione and its metabolites (MNBA, AMBA) as well as PECgw of florasulam and its metabolites (5-OH florasulam, DFP-ASTCA) in each scenario are significant below the trigger value of 0.1 µg/L and therefore the use of MEZOFLOR 103 SC according to recommendations does not pose a risk of groundwater contamination.

Obtained PECgw of ASTCA (3/8 scenarios in PEARL, 5/8 scenarios in PELMO) and TSA (2/8 scenarios in PEARL, 3/8 scenarios in PELMO) are slightly over the trigger value of 0.1 µg/L and therefore the use of this plant protection product according to recommendations may pose a risk of groundwater contamination. Therefore, further justifications are summarised in dRR Section 10 – Assessment of the relevance of metabolites in groundwater.

zRMS comments:

Forasulam

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

The assessment of the relevance metabolites is performed in B-10 section.

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

8.9.1 Justification for new endpoints

Studies on concentrations in groundwater with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.
Reference to:

- Peer review of the pesticide risk assessment of the active substance mesotrione EFSA Journal

2016;14(3):4419
- Conclusion on the peer review of the pesticide risk assessment of the active substance florasulam EFSA Journal 2015; 13(1):3984

8.9.2 Mesotrione, florasulam, relevant metabolites and the formulation (KCP 9.2.5)

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

Plant protection product	MEZOFLOR 103 SC
Use No.	1
Crop	Maize
Application rate (g as/ha)	Mesotrione: 125 Florasulam: 3.75
Number of applications/interval (d)	1 / 0
Application window	March - May (relevant for STEP 1 and 2 only)
Application method	Foliar spraying
Models used for calculation	FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, FOCUS SWAN v5.0.1,

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of MEZOFLOR 103 SC

Crop	Scenario	Application window used in modelling
Maize	D3	12 May – 11 Jun
	D4	17 May – 16 Jun
	D5	17 May – 16 Jun
	D6	27 Apr – 27 May
	R1	10 May – 09 Jun
	R2	08 May – 07 Jun
	R3	08 May – 07 Jun
	R4	17 Apr – 17 May

8.9.2.1 Mesotrione and its metabolites

$PEC_{sw/sed}$

Table 8.9-3 Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (EFSA Journal)

Compound	Ecotoxicology lowest regulatory acceptable concentration
Mesotrione	**0.77 µg/L (*Lemna gibba*)**
MNBA	**4200 µg/L (*Pseudokirchneriella subcapitata*)**

AMBA	**1400 µg/L (*Pseudokirchneriella subcapitata*)**
SYN546974	**9500 µg/L (*Lemna gibba*)**

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

Compound	**Mesotrione**	**MNBA**	**AMBA**	**SYN 546974**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	339	245	215	291	EFSA Journal 2016;14(3):4419
Saturated vapour pressure (Pa)	0	0	0	0	
Water solubility (mg/L)	160	160	160	160	
Diffusion coefficient in water (m²/d)	not required for Step 1+2/ 4.3 x 10^{-5}	not required for Step 1+2/ 4.3 x 10^{-5}	not required for Step 1+2/ 4.3 x 10^{-5}	not required for Step 1+2/ 4.3 x 10^{-5}	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	default
K_{foc} / K_{fom} (mL/g)	156.6 / 90.8 – pH < 7 17.39 / 10.12 – pH > 7	3.2 / 1.86	105.6 / 61.3 – pH < 7 21.8 / 12.6 – pH > 7	27031 / 7438.5	EFSA Journal 2016;14(3):4419
Freundlich Exponent 1/n	0.94– pH < 7 0.94 – pH > 7	0.90	0.82	0.94	
Plant Uptake	0	0	0	0	
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	
$DT_{50,soil}$ (d)	27.9 – pH < 7 5.4 – pH > 7	3.4	14.5	0.1	
$DT_{50,water}$ (d)	5.5	1000	1000	1000	
$DT_{50,sed}$ (d)	5.6	1000	1000	1000	
$DT_{50,whole\ system}$ (d)	5.6	1000	1000	1000	
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 57.2 Water:7.9 Sediment:7.9 Total system: 7.9	Soil:9.7 Water: 24.6 Sediment:24.6 Total system: 24.6	Water: 33.0 Sediment 33.0	

$PEC_{sw/sed}$

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for mesotrione (pH<7) following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	35.62	0	Spray drift, run off, drainage	12.62	53.98
Step 2						
Northern Europe	March-May	5.29	4	Spray drift, run off, drainage	1.85	7.97
Southern Europe	March-May	9.97	4	Spray drift, run off, drainage	3.5	15.30
Step 3						
D3	ditch	0.6559	135	drainage	0.03520	0.1659
D4	pond	0.07121	351	drainage	0.06655	0.09835
D4	stream	0.5649	150	drainage	0.05815	0.08510
D5	pond	0.04820	409	drainage	0.03865	0.05555
D5	stream	0.5976	147	drainage	0.02292	0.04109
D6	ditch	0.6553	117	drainage	0.03291	0.1612
R1	pond	0.09593	81	Run off and erosion	0.05941	0.07797
R1	stream	**2.014**	81	Run off and erosion	0.08428	0.4518
R2	stream	**1.564**	74	Run off and erosion	0.04940	0.4138
R3	stream	**4.181**	84	Run off and erosion	0.1644	0.8845
R4	stream	**4.523**	58	Run off and erosion	0.2100	1.224

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

Table 8.9-6: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for mesotrione (pH>7) following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	41.87	0	Spray drift, run off, drainage	14.91	7.09
Step 2						
Northern Europe	March-May	4.34	4	Spray drift, run off, drainage	1.52	0.72
Southern	March-May	7.99	4	Spray drift, run off,	2.81	1.35

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Europe				drainage		
Step 3						
D3	ditch	0.6560	135	drainage	0.03543	0.06782
D4	pond	0.02653	150	drainage	0.01322	0.006637
D4	stream	0.5618	150	drainage	0.002535	0.01829
D5	pond	0.02649	147	drainage	0.01253	0.006410
D5	stream	0.5862	147	drainage	0.001807	0.01453
D6	ditch	0.6552	117	drainage	0.03288	0.06589
R1	pond	0.02868	81	Run off and erosion	0.02088	0.01057
R1	stream	**1.324**	75	Run off and erosion	0.02814	0.08876
R2	stream	**3.193**	74	Run off and erosion	0.09651	0.3302
R3	stream	**3.975**	84	Run off and erosion	0.1294	0.3521
R4	stream	**4.32**	58	Run off and erosion	0.1664	0.4823

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

FOCUS Step 4

Table 8.9-7: Global maximum PEC_{sw} values for mesotrione (pH < 7), following single application of MEZOFLOR 103 SC to maize according to the central EU zone GAP according to surface water Step 4

RAC = 0.77 µg/L	Scenario	STEP 4 florasulam	
Nozzle reduction	Vegetative strip (m)	1	3
	No spray buffer (m)	1	3
None	R1 Stream	0.72	0.3012
None	R2 Stream	**0.9441**	0.3997
None	R3 Stream	**1.211**	0.4195
None	R4 Stream	**1.923**	0.6654

PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 8.9-8: Global maximum PEC_{sw} values for mesotrione (pH > 7), following single application of MEZOFLOR 103 SC to maize according to the central EU zone GAP according to surface water Step 4

RAC = 0.77 µg/L	Scenario	STEP 4 florasulam	
Nozzle reduction	Vegetative strip (m)	3	4
	No spray buffer (m)	3	4
None	R1 Stream	0.2932	0.2287
None	R2 Stream	0.3998	0.3118
None	R3 Stream	0.4195	0.3273
None	R4 Stream	**0.924**	0.2324

PEC/RAC ratios above the relevant trigger of 1 are shown in bold

In Step 4 the SWAN model was used. In modeling, all scenarios were taken into consideration. Simulations were provided for mesotrione (pH<7) for 1m and 3 m buffer zones, and for mesotrione (pH>7) for 3 and 4 m buffer zones.

Taking into consideration risk mitigation calculations for MEZOFLOR 103 SC use in maize, following risk mitigation measures should be applied:

- 4 m buffer non-spray zone with 4 meter vegetated filter strip.

Metabolites of mesotrione

Table 8.9-9: FOCUS Step 1 PEC_{sw} and PEC_{sed} for MNBA (pH <7) following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	~~Dominant entry route~~ Day nr (since start simulation	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	19.59	0	Spray drift, run off, drainage	19.44	0.63

Table 8.9-10: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for MNBA (pH >7) following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	~~Dominant entry route~~ Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	19.59	0	Spray drift, run off, drainage	19.44	0.63

Table 8.9-11: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for AMBA (pH <7) following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	~~Dominant entry route~~ Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	8.12	0	Spray drift, run off, drainage	8.04	8.55

Table 8.9-12: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for AMBA (pH >7) following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	~~Dominant entry route~~ Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	8.99	0	Spray drift, run off, drainage	8.92	1.96

Table 8.9-13: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for SYN 546974 following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	~~Dominant entry route~~ Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.65	0	Spray drift, run off, drainage	0.33	88.71

zRMS comments

Mesotrione

The PECsw/sed calculations for mesotrione have been approved for applications proposed in GAP. PECsw and PECsed calculations were carried out according to the FOCUS recommendations. The Applicant has been used FOCUS models: STEPS1-2 and Step 3. PECsw/sed were also carried out at Step

4 according to FOCUS L&M Guidance. The Applicant used the geometric mean value. In opinion of the zRMS this is acceptable, as being in line with current requirements concerning selection of Kfoc to be used for modelling purposes.

PECsw/sed are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in surface water and sediment and are appropriate to be used for the subsequent risk assessment for aquatic and sediment organisms.

MS should identify risk reduction measures at the national level.

Poland
In accordance with national requirements, only D3, D4 and R1 scenarios were taken into consideration. The max PECsw and proposed mitigation measures are presented in the tables above.

8.9.2.2 Florasulam and its metabolites

Table 8.9-14: Input parameters related to active substance florasulam and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2

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	345	304	192	148	248	247	233	EFSA Journal 2015;13(1): 3984
Saturated vapour pressure (Pa at 20°C)	1.0 E-6	2.7 E-6	3.0 E-6	2.0 E-6	1.0 E-4	0	0	0	
Water solubility (mg/L)	6360	354	87400	250000	10900	6360	6360	6360	
K_{foc} (mL/g)/K_{fom}	10.35 / 6.0	14.53 / 8.43	75.18 / 43.61	104.81 / 60.79	23.46 /13.61	41.52/24.08	60.22/34.93	77.74/ 45.09	
Freundlich Exponent 1/n	0.945	0.91	0.85	0.94	0.94	0.945	0.945	0.945	
$DT_{50,soil}$ (d)	1.55	14.98	16.62	297.47	83.47	1000	1000	1000	
$DT_{50,water}$ (d)	15.03	1000	1000	1000	1000	1000	1000	1000	
$DT_{50,sed}$ (d)	15.03	1000	1000	1000	1000	1000	1000	1000	
$DT_{50,whole\ system}$ (d)	15.03	1000	1000	1000	1000	1000	1000	1000	
Maximum	-	Water and	Total	Total	Total	Total	Total	Total	

Compound	**Florasulam**	**5-OH Florasulam**	**DFP-ASTCA**	**ASTCA**	**TSA**	TPSA	ASTP	5-OH ASTP	**Value in accordance to EU endpoint y/n/ Reference**
occurrence observed (% molar basis with respect to the parent)		Sediment: 99 Soil:71.6	Water and Sediment: 8.9 Soil: 17.8	Water and Sediment: 53.8 Soil: 40	Water and Sediment: 0.0001 Soil: 15.9	Water and Sediment: 58 Soil: 0.0001	Water and Sediment: 21 Soil: 0.0001	Water and Sediment: 29 Soil: 0.0001	

$PEC_{sw/sed}$

Table 8.9-15 Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (EFSA Journal)

Compound	Ecotoxicology lowest regulatory acceptable concentration
Florasulam	**0.118 µg/L (*Lemna gibba*)**
5-OH-florasulam	**3.78 µg/L (*Lemna gibba*)**
DFP-ASTCA	**0.3 µg/L (*Daphnia magna*)**
ASTCA	**0.3 µg/L (*Daphnia magna*)**
TSA	**0.3 µg/L (*Daphnia magna*)**
TPSA	**100 00 µg/L (*Pseudokirchneriella subcapitata*)**
ASTP	**88 00 µg/L (*Lemna gibba*)**
5-OH ASTP	**100 00 µg/L (*Pseudokirchneriella subcapitata*)**

Table 8.9-16: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for florasulam following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)***	~~Dominant entry route~~ **Day nr (since start simulation**	**Dominant entry route**	**21 d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 1	---	1.27	0	Spray drift, run off, drainage	0.81	0.13
Step 2						
Northern Europe	March-May	0.06	4	Spray drift, run off, drainage	0.04	0.01
Southern Europe	March-May	0.09	4	Spray drift, run off, drainage	0.06	0.01

Table 8.9-17: FOCUS Step 1 PEC_{sw} and PEC_{sed} for 5-OH-florasulam following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	~~Dominant entry route~~ Day nr (since start simulation	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	2.04	0	Spray drift, run off, drainage	2.03	0.30

Table 8.9-18: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for DFP-ASTCA following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	~~Dominant entry route~~ Day nr (since start simulation	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.26	0	Spray drift, run off, drainage	0.26	0.19

Table 8.9-19: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for ASTCA following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	~~Dominant entry route~~ Day nr (since start simulation	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.56	0	Spray drift, run off, drainage	0.55	0.59
Step 2						
Northern Europe	March-May	0.05	4	Spray drift, run off, drainage	0.05	0.05
Southern Europe	March-May	0.09	4	Spray drift, run off, drainage	0.09	0.10

Table 8.9-20: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for TSA following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	~~Dominant entry route~~ Day nr (since start simulation	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.08	0	Spray drift, run off, drainage	0.08	0.02

Table 8.9-21: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for TPSA following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.49	0	Spray drift, run off, drainage	0.48	0.20

Table 8.9-22: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for ASTP following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.17	0	Spray drift, run off, drainage	0.17	0.10

Table 8.9-23: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for 5-OH ASTP following single application of MEZOFLOR 103 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route Day nr (since start simula-tion	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.22	0	Spray drift, run off, drainage	0.22	0.17

ZRMS comments:

The calculations of PECsw/sed for florasulam and its metabolites submitted by Applicant have been accepted. All input parameters for active substances and its metabolites are in line EFSA conclusion 2015;13(1): 3984.
PECsw values were calculated in Step 1 and 2 for active substances and their metabolites for proposed uses in GAP. No further calculation was needed.

$PEC_{sw/sed}$ of MEZOFLOR 103 SC

RAC for mesotrione is 0.77 µg/L (Lemna gibba), whereas calculated concentration of active substance in water obtained using drift loading calculator is 0.596 µg/L when using 1.5 m mitigation distance.

RAC for florasulam is 0.118 µg/L (Lemna gibba), whereas calculated concentration of active substance in water obtained using drift loading calculator is 0.018 µg/L when using 1.5 m mitigation distance.

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	Mesotrione
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Not determined
Photochemical oxidative degradation in air	DT_{50} of 17.635 hours (1.5 days) derived by the Atkinson model (AOP version 1.8). OH (12h) concentration assumed = 1.5 x 10^6 OH/cm^3
Volatilisation	from soil surfaces and plant surface (BBA guideline): <10% after 24 hours Vapour pressure (Pa): <5.7 x 10^{-6} Pa at 20°C (99.7% pure) Henry's Law Constant (Pa.m3/mol): <5.1 x 10^{-7} Pa m^3/ mol at 20ºC
Metabolites	not applicable

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

Table 8.10-2 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	DT_{50} of 1.706 days hours derived by the Atkinson model (version 1.92). OH (12-h) concentration assumed = 1.6 E-6
Volatilisation	from soil surfaces (BBA guideline): negligible after 24 hours from plant surface (BBA guideline): 1.7% after 24 hours Vapour pressure (Pa): 1 x 10-5 Pa at 25 °C (99.7 %) Henry's Law Constant (Pa.m3/mol): 3.29 x 10-5 Pa.m3/mol (pH 5) at 20°C 4.35 x 10-7 Pa.m3/mol (pH 7) at 20°C 2.94 x 10-8 Pa.m3/mol (pH 9) at 20°
Metabolites	not applicable

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 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

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
KCA 7.1 / 01	Fish L.	2013	GIS study of the proportion of acid and alkaline soils under maize crop in Europe Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ1012B Not GLP, not published Syngenta File No ZA1296_10160 This is CONFIDENTIAL INFORMATION	N	Syngenta
KCA 7.1.2 (IIA 7.1.1)	Lay, M.M	2000	[Phenyl-U-14C] AMBA : Rate of Degradation in Soil under Aerobic Laboratory Conditions Zeneca Ag products Western Research Center Report No RR 99-096B	N	Syngenta
IIA 7.1.1.1.1/01, IIA 7.1.1.2.1/ 01 (OECD Annex IIA	Jackson R., Ghosh D.,	1997	The Aerobic Degradation of XDE-570 in Soil.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Report No. GHE-P-4710;	No	Dow AgroSciences

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
point: 7.1, 7.2,)			GLP: Yes; Unpublished report;		
KCA 7.1.2 (II, 7.1.1.1.1/01)	Vispetto, A.R., Tovshteyn, M.	1997	Addendum to: [Cyclohexane-2-14C]ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-047B ADD	N	Syngenta
IIA 7.1.1.1.1/02, IIA 7.1.1.2.1/ 02 (OECD Annex IIA point: 7.1, 7.2,)	Jackson R., Massart J.,	1998	The degradation of DFP-ASTCA and ASTCA (two metabolites of DE-570) in Soil.; Dow AgroSciences, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Report No. GHE-P-7522; GLP: Yes; Unpublished report;	No	Dow AgroScience
KCA 7.1.2 (II, 7.1.1.1.1/02)	Subba-Rao, R.V.	1996	[Phenyl 14C-ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-082B	N	Syngenta
KCA 7.1.1 & 7.1.2 (II, 7.1.1.1.1/03)	Miller, M.M.	1997	[Phenyl-U-14C]ZA 1296: Route and Rate of Degradation in Wisconsin Silt Loam Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-033B	N	Syngenta
IIA 7.1.1.1.2/01 IIA 7.1.1.2.1/ 07 (OECD Annex II point: 7.1.2)	Cleveland C. B., Sanders L. T., Gilbert J. R.,	1997	Anaerobic Aquatic Metabolism Study of XDE-570.; North American Environmental Chemistry Laboratory, DowElanco, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA; Study report No. ENV95137; GLP: Yes; Unpublished report;	No	Dow AgroScience
KCA 7.1.1.2 / 01	Hand L.	2013	Mesotrione - Assessment of the significance of unidentified components from harsh extraction of soil residues in 14C-cyclohexanedione labelled mesotrione soil metabolism studies Syngenta Syngenta - Jealott’s Hill, Bracknell, United Kingdom, Not GLP, not published Syngenta File No ZA1296_10185 This is CONFIDENTIAL INFORMATION	N	Syngenta
KCA 7.1.2 (II, 7.1.1.2.1/02)	Tarr, J.B.	1997	[phenyl-U-14C]ZA 1296. Metabolism in Thirteen Soils Under Aerobic Conditions. Zeneca Agrochemicals Report No: RR93-092B	N	Syngenta

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
KCA 7.1.2 (II, 7.1.1.1.2/01)	Vispetto, A.R., Tovshteyn, M.	1996	[cyclohexane-2-14C]ZA 1296. Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR95-048B	N	Syngenta
KCA 7.1.2 (II, 7.1.1.1.2/02)	Carley, S.E.	1996	[phenyl-U-14C]ZA 1296 Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR96-033B	N	Syngenta
IIA 7.1.1.1.2/02 (OECD Annex II point: 7.1.3)	Krieger M. S., Yoder R. N.,	1996	Photolysis of XDE-570 on Soil.; Global Environmental Chemistry Laboratory – Indianapolis Lab, DowElanco, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA; Study report No. ENV95083; GLP: Yes; Unpublished report;	No	Dow AgroScience
KCA 7.1.2.1.1 / 01	Hardy I.	2013	Mesotrione - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies to Derive Modelling and Persistence Endpoint DT50 Values Syngenta Battelle UK Ltd., Ongar, United Kingdom, NC/11/059C Not GLP, not published Syngenta File No ZA1296_10135 This is CONFIDENTIAL INFORMATION	N	Syngenta
KCA 7.1.2 (II, 7.1.1.2.1/01)	Miller, M.M., Wilson, W.R.	1997	[phenyl-U-14C]ZA 1296. Rate of Degradation in Three Soils Under Aerobic Laboratory Condition. Zeneca Agrochemicals Report No: RR96-099B	N	Syngenta
IIA 7.1.1.2.1/ 03 (OECD Annex IIA point: 7.2)	Pillar F.,	1997	Effects of temperature on the degradation of DE-570 in soil.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6749; GLP: Yes; Unpublished report;	No	Dow AgroScience
KCA 7.1.2 (II, 7.1.1.2.1/04)	Marth, J.L.	1997	[14C]AMBA, a Metabolite of ZA 1296: Rate of Degradation in Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-032	N	Syngenta
IIA 7.1.1.2.1/ 04 (OECD Annex IIA	Pillar F.,	1997a	Effects of moisture on the degradation of DE-570 in soil.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon OX12 9JT, UK;	No	Dow AgroScience

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
point: 7.2)			Study report No. GHE-P-6750; GLP: Yes; Unpublished report;		
IIA 7.1.1.2.1/ 05 (OECD Annex IIA point: 7.2)	Jackson R.,	2010	Re-evaluation of the Degradation Kinetics of Florasulam and its Major Metabolites in European Soils According to Focus Guidance.; Dow AgroSciences, European Development Centre, 3 Milton Park, Abingdon, OX14 4RN, UK; Report No GHE-P-12511; GLP: no, not required (modelling study); Unpublished report;	No	Dow AgroScience
IIA 7.1.1.2.1/ 06 (OECD Annex IIA point: 7.2)	Simmonds R.,	2012	[^{14}C]-TSA: Rate of Degradation in Four Soils at 20^{0}C.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/010; GLP: Yes; Unpublished report	No	Dow AgroScience
KCA 7.1.2.2 (II, 7.1.1.2.2/01 III, 9.2.2.2/01)	Graham, D.G. et al	1997a	Field Soil Dissipation Study Carried Out in France During 1995-1996. Zeneca Agrochemicals Report No: RR97-026B	N	Syngenta
KCA 7.1.2.2 (II, 7.1.1.2.2/02 III, 9.2.2.2/02)	Graham, D.G. et al	1997b	Field Dissipation Study Carried Out in Italy During 1995-1996. Zeneca Agrochemicals Report No: RR97-025B	N	Syngenta
KCA 7.1.2.2 (II, 7.1.1.2.2/03 III, 9.2.2.2/03)	Graham, D.G. et al	1997c	Field Dissipation Study Carried Out in Germany During 1995-1996. Zeneca Agrochemicals Report No: RR97-051B	N	Syngenta
KCA 7.1.2.2 (II, 7.1.1.2.2/04 III, 9.2.2.2/04)	Graham, D.G. et al	1998a	Field Dissipation Study Carried Out in Germany During 1996-1997. Zeneca Agrochemicals Report No: RR97-067B	N	Syngenta
KCA 7.1.2.2 (II, 7.1.1.2.2/05	Graham, D.G. et al	1998b	Field Dissipation Study Carried Out in Italy During 1996-1997. Zeneca Agrochemicals Report No: RR97-070B	N	Syngenta

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
III, 9.2.2.2/05)					
IIA 7.1.1.2.2/ 01 (OECD Annex IIA point: 7.3.1)	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.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6366; GLP: Yes; Unpublished report	No	Dow AgroScience
IIA 7.1.1.2.2/ 02 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997a	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Northern France - 1995.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6367; GLP: Yes; Unpublished report;	No	Dow AgroScience
IIA 7.1.1.2.2/ 03 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997b	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, UK – 1996.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6368; GLP: Yes; Unpublished report;	No	Dow AgroScience
IIA 7.1.1.2.2/ 04 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997c	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Southern France - 1996.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6369; GLP: Yes; Unpublished report;	No	Dow AgroScience
IIA 7.1.1.2.2/ 05 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997d	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Greece - 1996.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6370; GLP: Yes;	No	Dow AgroScience

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 report;		
IIA 7.1.1.2.2/ 06 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997e	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, UK - 1995.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6781; GLP: Yes; Unpublished report;	No	Dow AgroScience
KCA 7.1.2.2 (II, 7.1.1.2.2/06)	Wiebe, L.A., Yeh, S. M.	1999	ZA 1296: Stability of ZA 1296 and the metabolites MNBA and AMBA in Frozen Soil (WRC-98-158). (WINO 12775). Zeneca Agrochemicals Report No: RR98-065B	N	Syngenta
IIA 7.1.1.2.2/ 07 (OECD Annex IIA point: 7.3.2)	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"; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6833; GLP: No; Unpublished report;	No	Dow AgroScience
KCA 7.1.3 (IIA 7.1.2)	Hand, L.H	1999a	MNBA (R169649) : Absorption Properties in Four Soils Zeneca Agrochemicals Jealott's Hill Research Station Report No RJ2885B	N	Syngenta
KCA 7.1.3 (II, 7.1.2/01)	Diaz, D.G.	1995	[14C]ZA 1296. Adsorption and Desorption Properties in Soil. Zeneca Agrochemicals Report No: RR95-070B	N	Syngenta
KCA 7.1.3 (II, 7.1.2/02)	Rowe, D., Lane, M.C.G.	1997a	ZA 1296: Adsorption and Desorption properties of ZA 1296 in 4 soils. Zeneca Agrochemicals Report No: RJ2340B	N	Syngenta
KCA 7.1.3 (II, 7.1.2/04)	Diaz, D.G.	1996a	[14C]MNBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-008B	N	Syngenta
KCA 7.1.3 (II, 7.1.2/05)	Diaz, D.G.	1996b	[14C]AMBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-009B	N	Syngenta
IIA 7.1.2/01	Ostrander J. A.	1996	Mobility Studies of XDE-570 and 5-hydroxy-XDE 570;.	No	Dow AgroScience

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
(OECD Annex IIA points: 7.4.1 and 7.4.2)			North American Environmental Chemistry Laboratory, Dow Elanco, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA; Study report No. GH-C-3868 (study ID: ENV95020); GLP: Yes; Unpublished report;		
IIA 7.1.2/02 (OECD Annex IIA point: 7.4.2)	Simmonds R.	2011	Florasulam: Adsorption and Desorption Properties of [^{14}C]-Florasulam in Eight Soils.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/005; GLP: Yes; Unpublished report;	No	Dow AgroScience
IIA 7.1.2/03 (OECD Annex IIA point: 7.4.2)	Simmonds R.	2011a	Florasulam: Adsorption Properties of [^{14}C]-5-hydroxyflorasulam in Four Soils.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/006; GLP: Yes; Unpublished report;	No	Dow AgroScience
IIA 7.1.2/04 (OECD Annex IIA point: 7.4.2)	Burgess M., Simmonds R.,	2011	Florasulam: Adsorption Properties of [^{14}C]-DFP-ASTCA in Four Soils.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/009; GLP: Yes; Unpublished report;	No	Dow AgroScience
IIA 7.1.2/05 (OECD Annex IIA point: 7.4.2)	Burgess M., Simmonds R.,	2011b	Florasulam: Adsorption Properties of [^{14}C]-ASTCA in Four Soils.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/008; GLP: Yes; Unpublished report;	No	Dow AgroScience
IIA 7.1.2/06	Burgess M.,	2011c	Florasulam: Adsorption Properties of [^{14}C]-TSA in Four Soils.;	No	Dow AgroScience

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
(OECD Annex IIA point: 7.4.2)	Simmonds R.,		Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/007; GLP: Yes; Unpublished report;		
IIA 7.1.3.1 (OECD Annex IIA point: 7.4.3)	Pillar F.	1997	The non-aged column leaching of DE-570.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report No. GHE-P-6785; GLP: No; Unpublished report;	No	Dow AgroScience
IIA 7.1.3.3; IIIA 9.1.2.2; (OECD Annex IIA point: 7.4.7)	Jackson R., Paterson G.,	1997	The dissipation of XDE-570 in soil and crops using field lysimeters.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report No. GHE-P-6751; GLP: Yes; Unpublished report;	No	Dow AgroScience
IIA 7.2.1.1/01 (OECD Annex IIA points: 2.9.1 and 7.5)	Jackson R., Portwood D.,	1993	The Aqueous Hydrolysis of XR-570.; DowElanco Limited, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report No. GHE-P-3326; GLP: No; Unpublished report;	No	Dow AgroScience
IIA 7.2.1.1/02 (OECD Annex IIA points: 2.9.1 and 7.5)	Phillips M.,	1996	The determination of the hydrolytic stability of radiolabelled XDE-570.; Inveresk Research International Ltd., Tranent, EH33 2NE, UK *for* DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report No. GHE-P-4986 (Inveresk Project No. 386209); GLP: Yes; Unpublished report	No	Dow AgroScience
IIA 7.2.1.2/01 (OECD Annex IIA points: 2.9.2 and 7.6)	Yoder R. N.	1996	Aqueous Photolysis of XDE-570 in Natural Sunlight.; DowElanco, North American Environmental Chemistry Laboratory, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA; Study report No. GH-C 3951 (study ID: ENV95023);	No	Dow AgroScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP: Yes; Unpublished Report		
IIA 7.2.1.2/02 (OECD Annex IIA points: 2.9.2 and 7.6)	Yoder R. N., Balcer J. L.	2002	Aqueous Photolysis of Florasulam in pH5 Buffer under Xenon Light.; Regulatory Laboratories – Indianapolis Lab, Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, USA; Study report No. GH-C 5399; GLP: Yes Unpublished report	No	Dow AgroScience
IIA 7.2.1.2/03 (OECD Annex IIA points: 2.9.2 and 7.6)	Byrne S. L., Crabtree A. B., Balcer J. L., Linder S. J.	2005	Aqueous Photolysis of Florasulam in Natural Water Using a Xenon Lamp.; Regulatory Laboratories – Indianapolis Lab, Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, USA Study report No. 050024; GLP: Yes Unpublished report	No	Dow AgroScience
IIA 7.2.1.2/04 (OECD Annex IIA points: 2.9.2 and 7.6)	Gibson R., Portwood D.	1999	Investigation of the degradation of DE-570 in natural water.; Dow AgroSciences, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-7468; GLP: Yes; Unpublished report	No	Dow AgroScience
IIA 7.2.1.3.1/01 (OECD Annex IIA point 7.7)	Jenkins W. R.	1994	XDE 570 (PURE): Assessment of Ready Biodegradability. Modified Sturm Test.; Pharmaco LSR Lts, Eye, Suffolk IP 23 7 PX, UK, *for* DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxfordshire OX12 9JT, UK; Study report No. GHE-P-3736 (Pharmaco study report No.: 94/DES180/0468) GLP: Yes Unpublished report;	No	Dow AgroScience
IIA 7.2.1.3.1/02 (OECD Annex IIA point 7.7)	Jenkins W. R.	1995	XDE 570 5-Hydroxy6 metabolite: Assessment of Ready Biodegradability. Modified Sturm Test. Pharmaco LSR Lts, Eye, Suffolk IP 23 7 PX, UK, *for* DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxfordshire OX12 9JT, UK; Study report No. GHE-P-4552 (Pharmaco study report No.: 95/DES284/0692); GLP: Yes;	No	Dow AgroScience

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 report;		
IIA 7.2.1.3.2/01 (OECD Annex IIA point 7.8.3)	Phillips M.	1997	The aerobic degradation of XDE-570 in natural waters and associated sediments.; Inveresk Research International Ltd., Tranent, EH33 2NE, UK *for* DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report No. GHE-P-5039 (Inveresk Project No. 12712); GLP: Yes; Unpublished report	No	Dow AgroScience
IIA 7.2.1.3.2/02 (OECD Annex IIA point 7.8.3)	Lewis C., Gilbert J.,	2011	[^{14}C]-Florasulam: Degradation in Water-Sediment Systems under Aerobic Conditions.; Covance Laboratories Ltd, Otley Road, Harrogate, HG3 1PY, UK for Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, OX14 4RN, UK; Study report No. 1000576 (Covance Study No. 8235547); GLP: Yes Unpublished report	No	Dow AgroScience
IIA 7.2.2/01 (OECD Annex IIA point 7.10)	Knoch E.,	1997	Investigation of the Volatilization of DE-570 formulated as 50 g a. s./L SC from soil and Dwarf Runner Bean.; Institut Fresenius, Chemische und Biologische Laboratorien GmbH, Konrad-Adenauer-Strasse 9-13, 45699 Herten, Germany *for* DowElanco Europe, Letcombe Laboratories, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6747 (Fresenius Institut Study No. IF 97/07970-00); GLP: Yes; Unpublished Report;	No	Dow AgroScience
KCA 7.3 (II, 7.2.2/01)	Patel, A., Benner, J.	1997	ZA 1296: Volatilisation from Soil and Leaf Surfaces Following Application as a Suspension concentrate Formulation Containing a Build in Wetter. Zeneca Agrochemicals Report No: RJ2374B	N	Syngenta
IIA 7 (OECD Annex IIA point 7)	Mattock S. D.	2011	Florasulam – literature search for toxicology, environmental fate and ecotoxicology in support of Annex I renewal.; TGSA Concordia House, St James Business Park, Grimbald Crag Court, Knaresborough, North Yorkshire, UK, *for* Dow AgroSciences European R&D Centre, 3 Milton Park, Abingdon, Oxfordshire, UK; Study report No. GHE-P-12699 (Project number 4-16-6);	No	Dow AgroScience

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

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

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