

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: JME-HER 12 OD

Product name(s): -

Chemical active substance:

iodosulfuron-methyl-sodium, 2 g/L

mesosulfuron-methyl, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o.o.

Submission date: December 2023, revision: April 2024

MS Finalisation date: 03/10/2024

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Version history

When	What
January 2024	Dossier sent for evaluation
04.2024	Update of dRR on evaluator's request
July 2024	zRMS evaluation of dRR
October 2024	Final version prepared by zRMS after Commenting period

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

8 Fate and behaviour in the environment (KCP 9)

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8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, 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 saf- ener/ syner- gist per ha	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			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat	F	Please refer to Part A	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	a) 1.2 l/ha b) 1.2 l/ha	a) 2.4 - iodosulfuron 12 - mesosulfuron b) same as a)	200-300	-		
2	PL	Winter triticale	F	Please refer to Part A	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	a) 0.45 L/ha b) 0.45 L/ha	a) 0.9 - iodosulfuron 4.5 - mesosulfuron b) same as a)	200-300	-		
3	PL	Winter wheat	F	Please refer to Part A	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	a) 0.45 L/ha b) 0.45 L/ha	a) 0.9 - iodosulfuron 4.5 - mesosulfuron b) same as a)	200-300	-		
4	PL	Winter triticale	F	Please refer to Part A	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	a) 0.45 L/ha b) 0.45 L/ha	a) 0.9 - iodosulfuron 4.5 - mesosulfuron b) same as a)	200-300	-		
5	PL	Rye	F	Please refer to Part A	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	a) 0.45 L/ha b) 0.45 L/ha	a) 0.9 - iodosulfuron 4.5 - mesosulfuron b) same as a)	200-300	-		

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

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

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professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

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

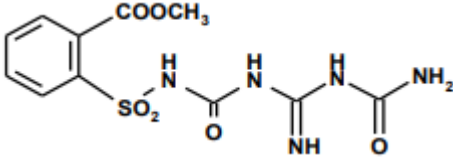
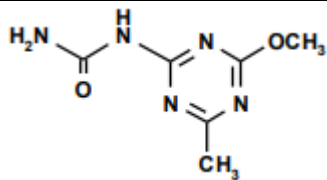
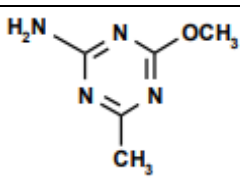
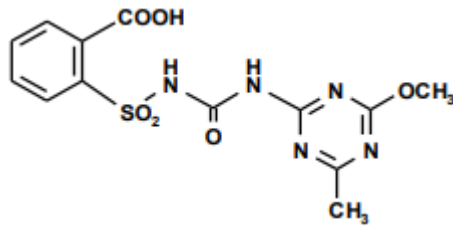
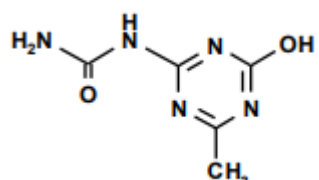
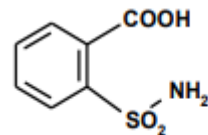
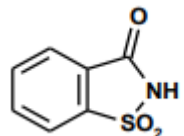
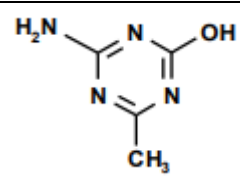
8.2 Metabolites considered in the assessment

Information concerning metabolites relevant for modelling is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

Table 8.2-1: Metabolites of iodosulfuron-methyl-sodium potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
AE F075736	381.4		Soil: 88.5% (aerobic), 67.9% (anaerobic) Water: 57.0% Sediment: 15.9% Water/sediment: 67.8%	PECsoil PECgw PECsw/sed
AE F145741	493.2		Soil: 6.9% (aerobic) Water: 7.0% Sediment: 1.9% Water/sediment: 8.7%	PECsoil PECgw PECsw/sed
AE F145740	493.2		Soil: 8.7% (aerobic) Water: 9.2% Sediment: 3.5% Water/sediment: 12.6%	PECsoil PECgw PECsw/sed
AE 0002166	397.4		Soil: 20.0% (photolysis) Water: 25.1% (photolysis in natural water)	PECsoil PECgw PECsw/sed
AE F161778	367.3		Soil: 14.5% (aerobic) Water/sediment: 2.6%	PECsoil PECgw PECsw/sed

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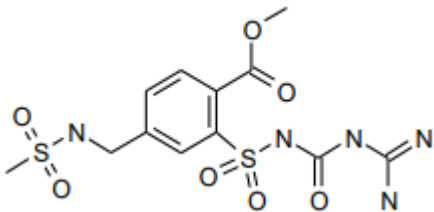
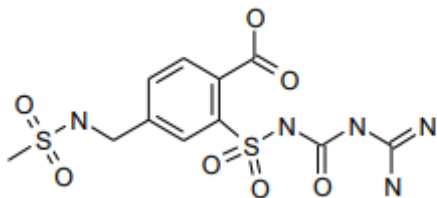
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
BCS-CW81253	343.3		Soil: 35.1% (aerobic) Water/sediment: 0.0001%	PEC _{soil} PEC _{gw} PEC _{sw/sed}
AE 0000119	183.2		Soil: 19.9% (aerobic) Water: 17.7% Sediment: 15.0% Water/sediment: 24.9%	PEC _{soil} PEC _{gw} PEC _{sw/sed}
AE F059411	140.2		Soil: 40.9% (aerobic), 23.6% (anaerobic) Water: 19.3% Sediment: 8.3% Water/sediment: 27.5%	PEC _{soil} PEC _{gw} PEC _{sw/sed}
AE 0014966	367.3		Water: 11.8% Sediment: 5.9% Water/sediment: 15.5%	PEC _{sw/sed}
AE 0034855	169.1		Water: 16.7% Sediment: 10.7% Water/sediment: 24.2%	PEC _{sw/sed}
AE 1234964	201.2		Water: 6.8% Sediment: 0.6% Water/sediment: 7.4%	PEC _{sw/sed}
AE F159737	183.2		Water: 6.1% Sediment: 1.6% Water/sediment: 7.8%	PEC _{sw/sed}
AE F154781	126.1		Water: 8.7% (aerobic mineralisation in surface water)	PEC _{sw/sed}

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
AE F154851 (mesosulfuron, mesosulfuron-acid)	489.5		Soil: 16.2% (aerobic) Water/sediment: 4.9%	PECsoil PECgw PECsw/sed
AE F160459	489.5		Soil: 8.9% (aerobic), 25.9% (anaerobic) Water/sediment: 21.6%	PECsoil PECgw PECsw/sed
AE F099095	198.2		Soil: 29.2% (aerobic) Water/sediment: 0.9%	PECsoil PECgw PECsw/sed
AE F092944	155.2		Soil: 10.1% (aerobic) Water/sediment: 3.2%	PECsoil PECgw PECsw/sed
AE F160460	475.5		Soil: 8.6% (aerobic) Water/sediment: 8.4%	PECsoil PECgw PECsw/sed
AE F140584	322.4		Soil: 5.1% (aerobic) Water/sediment: 1.9%	PECsoil PECgw PECsw/sed
AE F147447	290.3		Soil: 5.8% (aerobic), 6.5% (anaerobic) Water/sediment: 10.9%	PECsoil PECgw PECsw/sed

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Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
BCS-CO60720	407.4		Water/sediment: 13.1%	PEC _{sw/sed}
BCS-CV14885	393.4		Water/sediment: 22.0%	PEC _{sw/sed} PEC _{gw}

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)

Information concerning aerobic degradation in soil is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

The fate and behaviour of iodosulfuron-methyl-sodium in soil is discussed in detail in the corresponding document of the EU renewal assessment report where the study references can be found; presented agreed endpoints were taken from EFSA Journal 2016; 14(4): 4453, if not otherwise stated. Data requirements according to Commission Regulation (EU) No. 544/2011 apply.

Under aerobic conditions, degradation of iodosulfuron-methyl-sodium resulted in the formation of eight major metabolites, AE F075736 (up to 88.5%), AE F145740 (up to 8.7%), AE F145741 (up to 6.9% at 10 °C only), AE F161778 (up to 13.7% at 20 °C; up to 14.5% at 10 °C), BCS-CW81253 (up to 35.1%), AE 0000119 (up to 19.9%), and AE F059411 (up to 40.9%). The intermediate metabolite AE 002166 was not observed in aerobic soil but in soil photolysis with a maximum occurrence of 20.0%. The degradation pathway of iodosulfuron-methyl-sodium under aerobic conditions in soil is presented in the Figure below.

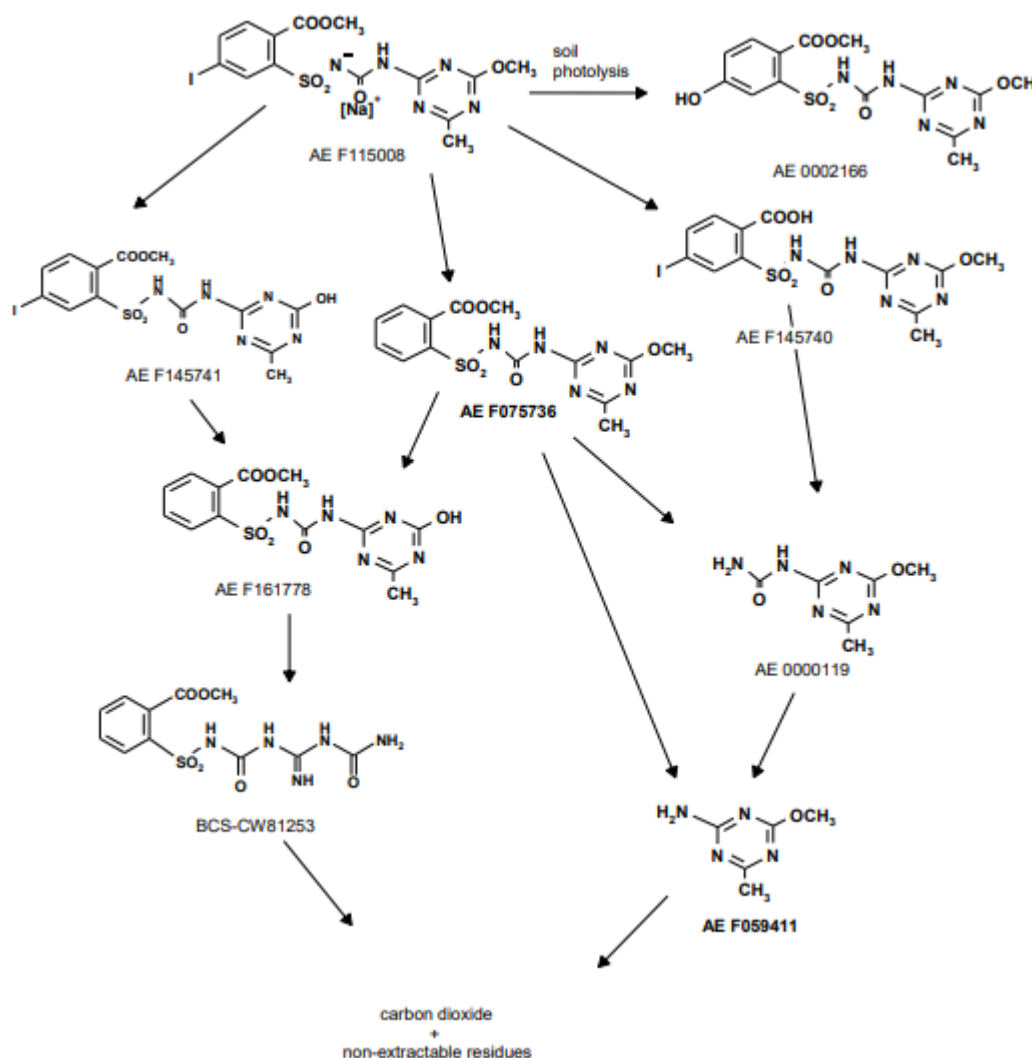


Figure 8.2-1: Proposed pathway of iodosulfuron-methyl-sodium in soil under aerobic conditions

8.3.1.1 Iodosulfuron-methyl-sodium and its metabolites

The fate and behaviour of iodosulfuron-methyl-sodium in soil is discussed in detail in the corresponding document of the EU renewal assessment report where the study references can be found; presented agreed endpoints were taken from EFSA Journal 2016; 14(4): 4453, if not otherwise stated. Data requirements according to Commission Regulation (EU) No. 544/2011 apply.

Under aerobic conditions, degradation of iodosulfuron-methyl-sodium resulted in the formation of eight major metabolites, AE F075736 (up to 88.5%), AE F145740 (up to 8.7%), AE F145741 (up to 6.9% at 10 °C only), AE F161778 (up to 13.7% at 20 °C; up to 14.5% at 10 °C), BCS-CW81253 (up to 35.1%), AE 0000119 (up to 19.9%), and AE F059411 (up to 40.9%). The intermediate metabolite AE 002166 was not observed in aerobic soil but in soil photolysis with a maximum occurrence of 20.0%. The degradation pathway of iodosulfuron-methyl-sodium under aerobic conditions in soil is presented in the Figure below.

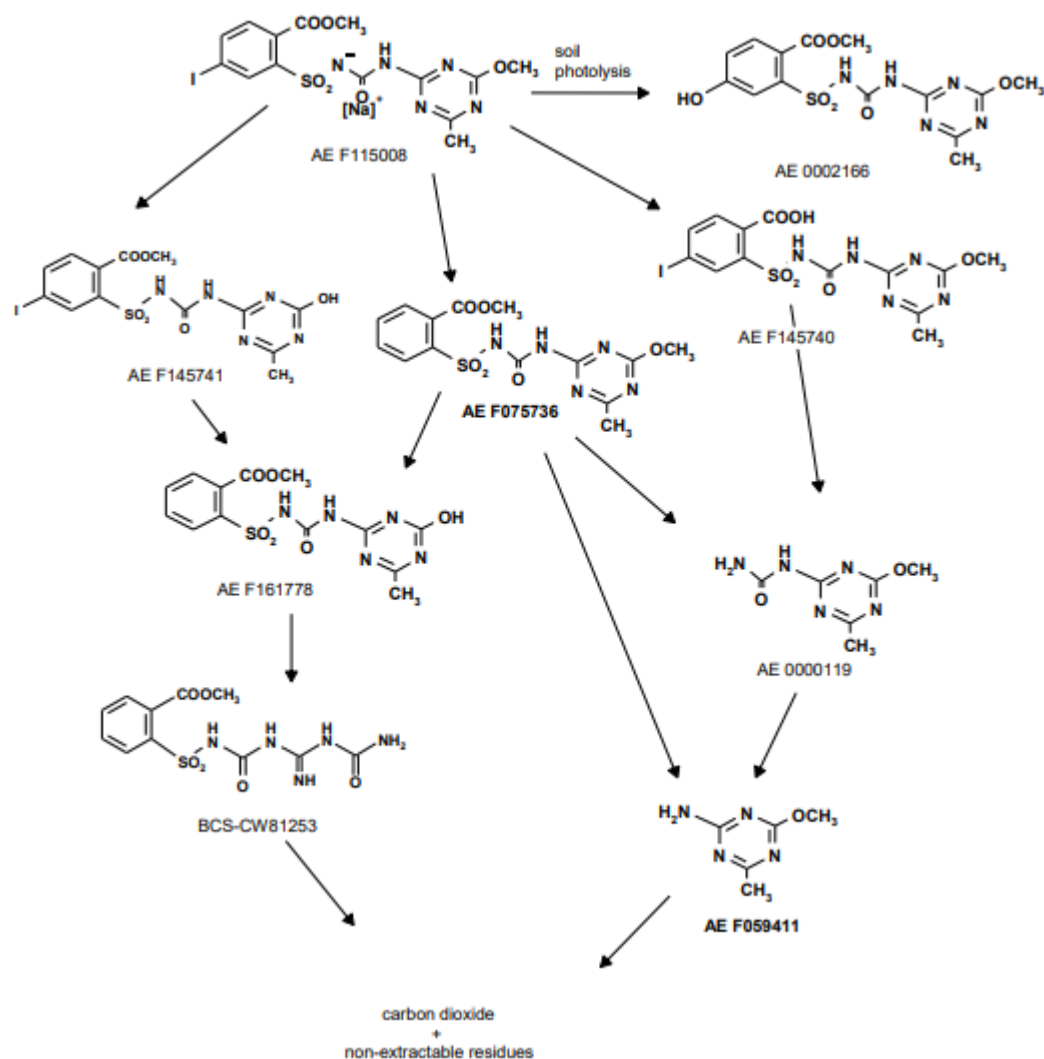


Figure 8.2-1: Proposed pathway of iodosulfuron-methyl-sodium in soil under aerobic conditions

The kinetics of aerobic degradation of iodosulfuron-methyl-sodium has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453); no additional studies are considered for this assessment.

Triggering and modelling endpoints are not explicitly specified in the EFSA conclusion (EFSA Journal 2016;14(4):4453).

Table 8.3-1: Summary of aerobic degradation rates for iodosulfuron-methyl-sodium - laboratory studies

Iodosulfuron-methyl-sodium, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/Reference
SL V	Sandy loam	6.0	20	40	1.7	7.3	1.6	4.4	FOMC: $\alpha=3.086$ $\beta=6.586$	Y/ EFSA Journal 2016;14(4)
LS 2.2	Loamy sand	5.6	20	40	1.5	5.1	1.0	5.3	SFO	Y/ EFSA Journal 2016;14(4)
S 2.1	Sand	5.6	20	40	3.1	10.2	2.9	7.1	SFO	Y/ EFSA Journal 2016;14(4)
SL 2	Silt loam	5.4	20	40	0.8	2.6	0.6	1.1	SFO	Y/ EFSA Journal 2016;14(4)
SL S	Silt loam	7.3	20	40	2.9	9.5	2.0	8.6	SFO	Y/ EFSA Journal 2016;14(4)
CL L	Clay loam ^{a)}	7.1	20	40	3.7	12.2	2.4	8.6	SFO	Y/ EFSA Journal 2016;14(4)
LS S	Loamy sand	7.1	20	40	2.7 2.7	12.2 9.1	-- 2.1	5.1 11.3	FOMC: $\alpha=2.868$ $\beta=9.945$ SFO	Y/ EFSA Journal 2016;14(4)
SL FF	Loam	7.0	20	40	4.3	26.7	5.8	2.9	FOMC: $\alpha=1.488$ $\beta=7.215$	Y/ EFSA Journal 2016;14(4)
CT	Clay	6.8	20	50	2.2	24.4	7.2	3.6	FOMC: $\alpha=0.8618$ $\beta=1.812$	Y/ EFSA Journal 2016;14(4)
CL B	Clay loam	7.2	20	50	3.0	11.7	20.8	1.9	DFOP: $k1=0.2490$ $k2=0.02819$ $g=0.9309$	Y/ EFSA Journal 2016;14(4)
Honville	Silt loam	6.2	20	40	1.4	8.0	1.9	9.8	FOMC: $\alpha=1.804$ $\beta=3.086$	Y/ EFSA Journal 2016;14(4)
Geometric mean/Median (n=11)							2.7			
pH-dependency: y/n							No			

^{a)} Stated as loamy sand in EFSA conclusion

Table 8.3-2: Summary of aerobic degradation rates for AE F075736 - laboratory studies

AE F075736, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
SL V	Sandy loam	6.0	20	40	28.5	94.8	20.6	2.3	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
LS 2.2	Loamy sand	5.6	20	40	21.5	71.6	14.2	2.5	SFO-SFO	Y/ EFSA Journal 2016;14(4)
S 2.1	Sand	5.6	20	40	71.6	238.0	66.7	2.4	SFO-SFO	Y/ EFSA Journal 2016;14(4)
SL 2	Silt loam	5.4	20	40	69.0	229.2	51.0	1.3	SFO-SFO	Y/ EFSA Journal 2016;14(4)
SL S	Silt loam	7.3	20	40	18.7	62.1	12.8	2.7	SFO-SFO	Y/ EFSA Journal 2016;14(4)
CL L	Clay loam ^{d)}	7.1	20	40	16.6	55.1	10.6	5.2	SFO-SFO	Y/ EFSA Journal 2016;14(4)
LS S	Loamy sand	7.1	20	40	69.8	232.1	52.7	1.9	SFO-SFO	Y/ EFSA Journal 2016;14(4)
SL FF	Loam	7.0	20	40	33.3	110.6	24.1	3.3	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
CT	Clay	6.8	20	50	43.5	144.6	42.4	6.0	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
CL B	Clay loam	7.2	20	50	27.8	92.2	23.4	3.8	DFOP-SFO	Y/ EFSA Journal 2016;14(4)
Honville	Silt loam	6.2	20	40	19.7	65.5	15.3	9.8	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
Matapeake, USA ^{b)}	Silt loam	5.2	20	75% of soil moisture content at 33 kPa	9.0	48	6.4	5	SFO	Y/ EFSA Journal 2016;14(4)
Speyer 2.2 Germany ^{c)}	Loamy sand	6.1	20	50% of 0 bar	26.7	88.8	26.7	6	SFO	Y/ EFSA Journal

AE F075736, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/Reference
										2016;14(4)
Tama, USA ^{c)}	Silty clay	6.8	20	50% of 0 bar	15.0	82.4	24.2 ^{a)}	1	FOMC	Y/ EFSA Journal 2016;14(4)
Lleida, Spain ^{c)}	Clay loam	7.9	20	50% of 0 bar	47.4	175.3	48.8	1	SFO	Y/ EFSA Journal 2016;14(4)
Nambsheim, France ^{c)}	Sandy loam	7.6	20	50% of 0 bar	39.9	132.6	39.9	3	SFO	Y/ EFSA Journal 2016;14(4)
Sassafras, USA ^{c)}	Sandy loam	5.5	20	50% of 0 bar	17.2	57.3	17.2	5	SFO	Y/ EFSA Journal 2016;14(4)
Speyer 3A, Germany ^{d)}	Sandy loam	6.3	20	50% of 0 bar	28.9	-	26.4	11.58	SFO	Y/ EFSA Journal 2016;14(4)
Speyer 2.3, Germany (high dose) ^{e)}	Loamy sand	6.3	20	45%	39.8	132.1	35.6	3.5	SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean/Median (n=19)							24.9			
pH-dependency: y/n							No			

^{a)} DT₅₀ back calculated as DT₉₀/3.32

^{b)} Gorman et al. (1997) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{c)} Allan (2010) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{d)} Morlock (2006) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{e)} Willems, Slangen & Hoitink (2003) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{f)} Stated as loamy sand in EFSA conclusion

Table 8.3-3: Summary of aerobic degradation rates for AE F145740 - laboratory studies

AE F145740, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/Reference
CL L	Clay loam ^{a)}	7.1	20	40	57.9	192.4	37.2	17.5	SFO-SFO	Y/ EFSA Journal 2016;14(4)
SL FF	Loam	7.0	20	40	76.9	255.5	55.8	8.1	FOMC-SFO	Y/ EFSA Journal 2016;14(4)

AE F145740, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/Reference
CL B	Clay loam	7.2	20	50	61.9	205.5	52.2	16.8	DFOP-SFO	Y/ EFSA Journal 2016;14(4)
Honville	Silt loam	6.2	20	40	53.2	176.7	41.2	23.6	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean/Median (n=4)							46.0			
pH-dependency: y/n							No			

^{a)} Stated as loamy sand in EFSA conclusion

Table 8.3-4: Summary of aerobic degradation rates for AE F145741 - laboratory studies

AE F145741, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/Reference
SL S	Silt loam	7.3	20	40	10.3	34.1	7.0	16.3	SFO-SFO	Y/ EFSA Journal 2016;14(4)
CL L	Clay loam ^{a)}	7.1	20	40	8.0	26.5	5.1	25.2	SFO-SFO	Y/ EFSA Journal 2016;14(4)
LS S	Loamy sand	7.1	20	40	2.9	9.5	2.2	31.0	SFO-SFO	Y/ EFSA Journal 2016;14(4)
SL FF	Loam	7.0	20	40	57.5	191.0	41.7	12.2	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
CL B	Clay loam	7.2	20	50	17.8	59.0	15.0	23.6	DFOP-SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean/Median (n=5)							8.7			
pH-dependency: y/n							No			

^{a)} Stated as loamy sand in EFSA conclusion

Table 8.3-5: Summary of aerobic degradation rates for AE F161778 - laboratory studies

AE F161778, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
LS 2.2	Loamy sand	5.6	20	40	5.2	17.2	3.4	14.9	SFO-SFO	Y/ EFSA Journal 2016;14(4)
S 2.1	Sand	5.6	20	40	13.2	43.7	12.3	27.2	SFO-SFO	Y/ EFSA Journal 2016;14(4)
SL S	Silt loam	7.3	20	40	22.0	73.0	15.0	8.8	SFO-SFO	Y/ EFSA Journal 2016;14(4)
LS S	Loamy sand	7.1	20	40	10.5	35.0	7.9	16.7	SFO-SFO	Y/ EFSA Journal 2016;14(4)
SL FF	Loam	7.0	20	40	26.9	89.2	19.5	8.7	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
CT	Clay	6.8	20	50	15.2	50.6	14.8	17.0	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
CL B	Clay loam	7.2	20	50	18.7	62.1	15.8	19.8	DFOP-SFO	Y/ EFSA Journal 2016;14(4)
Honville	Silt loam	6.2	20	40	2.4	7.8	1.8	16.2	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
Arrow, UK ^{a)}	Sandy loam	6.4 (H ₂ O)	20	45	30.4	100.8	30.4	6	SFO	Y/ EFSA Journal 2016;14(4)
Gross-Umstadt, Germany ^{a)}	Loam	7.4 (H ₂ O)	20	45	28.3	91.4	28.3	6	SFO	Y/ EFSA Journal 2016;14(4)
Mattapex, USA ^{a)}	Silt loam	6.9 (H ₂ O)	20	45	28.6	95.0	28.6	4	SFO	Y/ EFSA Journal 2016;14(4)
LUFA Speyer 2.2 ^{b)}	Loamy sand	5.7 (H ₂ O)	20	45	2.44	-	2.44	3.66	SFO	Y/ EFSA Journal 2016;14(4)

AE F161778, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
LUFA Speyer 3A ^{b)}	Sandy loam	7.3 (H₂O)	20	45	12.8	-	12	7.92	SFO	Y/ EFSA Journal 2016;14(4)
LUFA Speyer 6S, Germany ^{b)}	Clay	7.1 (H₂O)	20	45	29.3	-	20.2	11.2	SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean/Median (n=14)							11.4			
pH-dependency: y/n							No			

^{a)} Lewis (2000) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{b)} Morlock (2005b) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

Table 8.3-6: Summary of aerobic degradation rates for AE 0000119 - laboratory studies

AE 0000119, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
SL V	Sandy loam	6.0	20	40	124.8	414.6	89.9	10.3	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
LS 2.2	Loamy sand	5.6	20	40	11.9	39.4	7.8	9.7	SFO-SFO	Y/ EFSA Journal 2016;14(4)
CL L	Clay loam ^{b)}	7.1	20	40	4.0	13.2	2.5	15.2	SFO-SFO	Y/ EFSA Journal 2016;14(4)
CT	Clay	6.8	20	50	13.4	44.4	8.0	17.0	DFOP-SFO	Y/ EFSA Journal 2016;14(4)
Mattapex ^{a)}	Sandy loam	4.35	20	40 of 0 Bar	9.8	33	9.0	11	SFO	Y/ EFSA Journal 2016;14(4)
Lleida ^{a)}	Silty clay	7.50	20	40 of 0 Bar	6.6	22	5.6	5	SFO	Y/ EFSA Journal 2016;14(4)
Nambsheim ^{a)}	Sandy loam	7.01	20	40 of 0 Bar	3.3	11	3.3	2	SFO	Y/ EFSA Journal 2016;14(4)

AE 0000119, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Goch ^{a)}	Silt loam	5.13	20	40 of 0 Bar	16.1 M ₀ = 95.3 K ₁ = 0.008 K ₂ = 0.175 g = 0.5	204.1	71.6 (based on slow phase rate constant)	3	DFOP	Y/ EFSA Journal 2016;14(4)
Suchozebry ^{a)}	Sandy loam	5.04	20	40 of 0 Bar	24.8 M ₀ = 94.2 K ₁ = 0.003 K ₂ = 0.097 g = 0.5	542.8	231 (based on slow phase rate constant)	2	DFOP	Y/ EFSA Journal 2016;14(4)
Geometric mean/Median (n=9)							15			
pH-dependency: y/n							No			

^{a)} Tunink, A. (2009) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl and thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))

^{b)} Stated as loamy sand in EFSA conclusion

Table 8.3-7: Summary of aerobic degradation rates for BCS-CW81253 - laboratory studies

BCS-CW81253, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
LS 2.2	Loamy sand	5.6	20	40	55.6	184.6	36.6	22.2	SFO-SFO	Y/ EFSA Journal 2016;14(4)
SL S	Silt loam	7.3	20	40	13.8	46.0	9.5	9.0	SFO-SFO	Y/ EFSA Journal 2016;14(4)
SL FF	Loam	7.0	20	30	22.3	74.0	16.1	5.2	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
CT	Clay	6.8	20	50	54.2	179.9	52.7	9.1	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
CL B	Clay loam	7.2	20	50	11.4	37.8	9.6	18.3	DFOP-SFO	Y/ EFSA Journal

BCS-CW81253, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
										2016;14(4)
Honville	Silt loam	6.2	20	40	149.4	496.4	115.7	14.4	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
Arrow, UK ^{a)}	Sandy loam	6.4 (H ₂ O)	20	45	52.5	174.5	52.5	11	SFO	Y/ EFSA Journal 2016;14(4)
Gross-Umstadt, Germany ^{a)}	Loam	7.4 (H ₂ O)	20	45	16.3	54	24.7	5	SFO	Y/ EFSA Journal
Mattapex, USA ^{a)}	Silt loam	6.9 (H ₂ O)	20	45	24.7	82.2	16.3	12	SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean/Median (n=9)							26.7			
pH-dependency: y/n							No			

^{a)} Lewis (2000) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

Table 8.3-8: Summary of aerobic degradation rates for AE F059411 - laboratory studies

AE F059411, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
SL S	Silt loam	7.3	20	40	222.1	737.9	152.0	7.4	SFO-SFO	Y/ EFSA Journal 2016;14(4)
CT	Clay	6.8	20	50	143.1	475.3	139.4	13.4	FOMC-SFO	Y/ EFSA Journal 2016;14(4)
CL B	Clay loam	7.2	20	50	328.1	1089.9	276.9	4.3	DFOP-SFO	Y/ EFSA Journal 2016;14(4)
Honville ^{b)}	Silt loam	6.7 (H ₂ O)	20	40	260.1 ^{a)} (K ₁ = 0.01772 K ₂ = 0.00266 Tb = 25.9)	864 ^{a)}	201.6	3.0	HS ^{a)}	Y/ EFSA Journal 2016;14(4)
Keyport ^{c)}	Silt loam	4.3	25	70% FC	208	691	254	6.2	SFO	Y/ EFSA Journal

AE F059411, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
										2016;14(4)
Gartenacker ^{d)}	Loam	6.9	20	pF2	102.2	34	102.2	3.5	SFO	Y/ EFSA Journal 2016;14(4)
18 Acres ^{d)}	Sandy clay loam	5.0	20	pF2	249.4	828	249.4	3.2	SFO	Y/ EFSA Journal 2016;14(4)
Krone ^{d)}	Silt loam	4.9	20	pF2	190.8	634	190.8	3.7	SFO	Y/ EFSA Journal 2016;14(4)
Soil 2.2 ^{e)}	Loamy sand	5.7 (H ₂ O)	20	45	67.3	224	67.3	5.68	SFO	Y/ EFSA Journal 2016;14(4)
Soil 3A ^{e)}	Sandy loam	7.3 (H ₂ O)	20	45	188.4	626	175.7	5.64	SFO	Y/ EFSA Journal 2016;14(4)
Soil 6S ^{e)}	Clay loam	7.1 (H ₂ O)	20	45	333.2	1107	230.1	1.00	SFO	Y/ EFSA Journal 2016;14(4)
Arrow ^{f)}	Sandy loam	5.7	20	50	44.7 (K ₁ = 0, fixed lag phase K ₂ = 0.03082 Tb = 22.25d)	97	22.5	14	HS (DT ₅₀ calculated from slow phase)	Y/ EFSA Journal 2016;14(4)
Speyer 2.1 ^{g)}	Sand	5.5	20	pF2	112.5	374	112.5	2.9	SFO	Y/ EFSA Journal 2016;14(4)
Soil 115 ^{g)}	Clay loam	8.6	20	pF2	175.2	582	175.2	3.1	SFO	Y/ EFSA Journal 2016;14(4)
Soil 243 ^{g)}	Sandy loam	5.6	20	pF2	96.4	320.2	96.4	6.2	SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean/Median (n=16)							144			
pH-dependency: y/n							No			

^{a)} DT50 as well as DT90 are calculated from the slow phase rate constant (k₂).

^{b)} Mündel (2001) (metabolite dosed study, accepted in the RAR for thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))

- c) Rhodes (1987) (metabolite dosed study, accepted in the RAR for thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))
- d) Jungmann, Nicollier (2006) (metabolite dosed study, accepted in the RAR for thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))
- e) Morlock (2006a) (metabolite dosed study, accepted in the RAR for thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))
- f) Scott (2000) (metabolite dosed study, accepted in the RARs for thifensulfuron methyl, metsulfuron methyl, prosulfuron and triasulfuron; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))
- g) Wonders and Melkebeke (2002) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl and thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))

Table 8.3-9: Summary of aerobic degradation rates for AE 0002166 - laboratory studies

AE 0002166, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl ₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Laacher Hof Allia	Loam	6.1	20	55	10.1	33.6	10.1	4.1	SFO	Y/ EFSA Journal 2016;14(4)
Laacher Hof AXXa	Sandy loam	6.4	20	55	9.5	31.5	9.5	4.5	SFO	Y/ EFSA Journal 2016;14(4)
Hoefchen am Hohenseh 4a	Silt loam	6.3	20	55	7.2	24.0	7.2	5.9	SFO	Y/ EFSA Journal 2016;14(4)
Dollendorf II	Clay loam	7.1	20	55	4.7	15.7	4.7	6.3	SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean/Median (n=4)							7.5			
pH-dependency: y/n							No			

8.3.1.2 Mesosulfuron-methyl and its metabolites

The aerobic degradation of mesosulfuron-methyl has been evaluated, full details of these studies are provided in the respective EU renewal assessment report and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(10): 4584); no additional studies are considered for this assessment.

Under aerobic conditions, degradation of mesosulfuron-methyl resulted in the formation of seven metabolites, AE F154851 (up to 16.2%), AE F160459 (up to 8.9%), AE F099095 (up to 29.2%), AE F092944 (up to 10.1%), AE F160460 (up to 8.6%), AE F140584 (up to 5.1%), and AE F147447 (up to 5.8%). The degradation pathway of mesosulfuron-methyl under aerobic conditions in soil is presented in the Figure below.

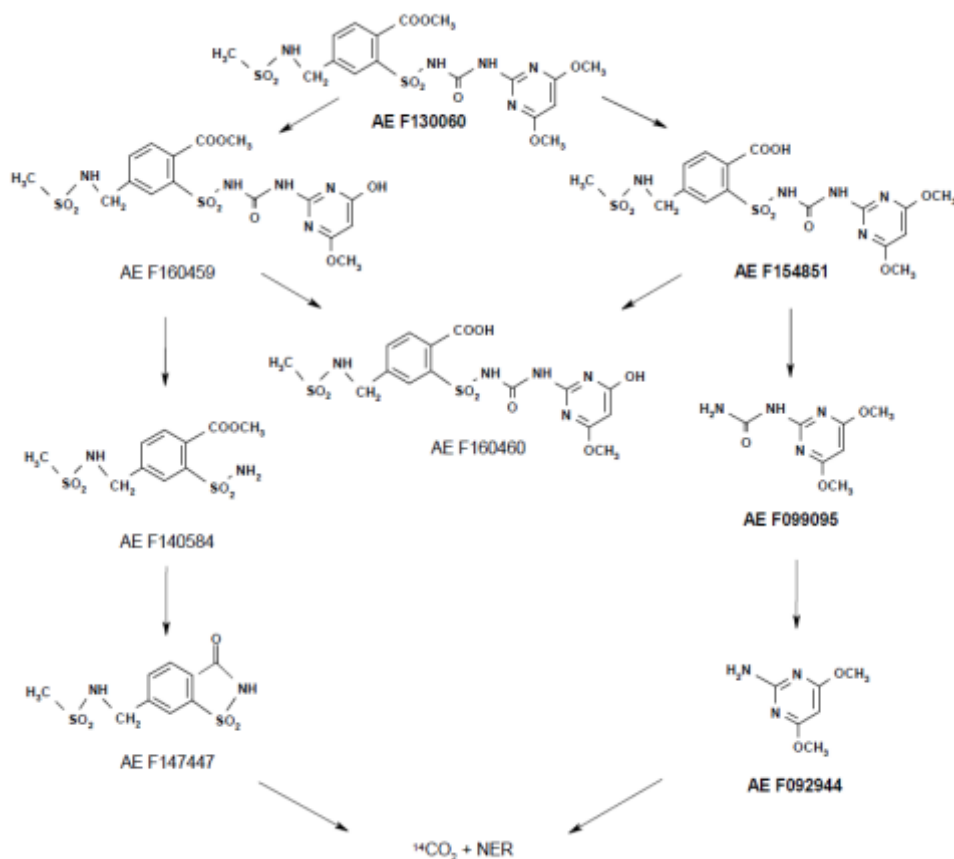


Figure 8.2-2: Proposed pathway of mesosulfuron-methyl in soil under aerobic conditions

The kinetics of aerobic degradation of mesosulfuron-methyl has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(10):4584); no additional studies are considered for this assessment.

TRIGGER ENDPOINTS:

Table 8.3-10: Summary of aerobic degradation rates for mesosulfuron-methyl - laboratory studies: Trigger points

Mesosulfuron-methyl, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl ₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
SLV	Loamy sand	6.25	20	30.8	59.9 Alpha: 0.886 Beta: 50.43	628.5	-	3.2	FOMC	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	16.0	53.0	-	2.0	SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	32.9 Alpha: 2.54 Beta: 104.7	155.0	-	2.1	FOMC	Y/ EFSA Journal 2016;14(10)

Mesosulfuron-methyl, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
SCL	Clay	7.3	20	59.8	140.10	465.40	-	14.84	SFO	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	7.6	25.3	-	18.5	SFO	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	32.14 Alpha: 0.634 Beta: 16.2	595.42	-	2.93	FOMC	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	27.9 Alpha: 2.56 Beta: 89.6	130.9	-	3.8	FOMC	Y/ EFSA Journal 2016;14(10)

Table 8.3-11: Summary of aerobic degradation rates for AE F160459- laboratory studies: Trigger points

AE F160459, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	128.64	427.34	-	10.2	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	38.60	128.23	-	14.3	SFO-SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	76.0	252.47	-	9.9	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	129.80	431.0	-	21.68	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- b)	- b)	-	- b)	- b)	Y/ EFSA Journal 2016;14(10)

AE F160459, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	- b)	- b)	-	- b)	- b)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	84.29	280.02	-	11.9	SFO-SFO	Y/ EFSA Journal 2016;14(10)

a) not observed in this soil in amounts that would allow kinetic evaluation

b) no reliable value could be determined

Table 8.3-12: Summary of aerobic degradation rates for AE F154851- laboratory studies: Trigger points

AE F154851, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	76.74	254.91	-	9.3	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	18.73	62.20	-	18.6	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	39.70	131.89	-	14.8	SFO-SFO	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	46.35	153.97	-	13.4	SFO-SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	73.93	245.59	-	14.6	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	207.38	688.91	-	19.3	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	21.52	71.49	-	26.1	SFO-SFO	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	32.95	109.46	-	11.2	SFO-SFO	Y/ EFSA Journal 2016;14(10)

^{a)} no reliable value could be determined

Table 8.3-13: Summary of aerobic degradation rates for AE F160460- laboratory studies: Trigger points

AE F160460, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	24.14	80.20	-	12.0	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	37.07	123.15	-	13.5	SFO-SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	36.23	120.3	-		SFO-SFO	Y/ EFSA Journal - 2016;14(10)
SCL	Clay	7.3	20	59.8	- b)	- b)	-	- b)	- b)	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- b)	- b)	-	- b)	- b)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	44.22	196.9	-	29.9	Decline fit	Y/ EFSA Journal 2016;14(10)

Table 8.3-14: Summary of aerobic degradation rates for AE F099095- laboratory studies: Trigger points

AE F099095, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	185.52	616.28	-	4.5	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	105.21	349.49	-	13.8	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- a)	- a)	-	- a)	- a)	Y/ EFSA

AE F099095, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
										Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	80.16	266.29	-	18.4	SFO-SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	94.19	312.89	-	9.7	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	135.08	448.71	-	25.9	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	49.1	163.1	-	7.4	Decline fit	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	27.90	92.68	-	16.28	SFO-SFO	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	- b)	- b)	-	- b)	- b)	Y/ EFSA Journal 2016;14(10)
Sandy loam ^{c)}	Sandy loam	5.3	20	pF2	58.82	195.4	-	2.73	Applied as parent SFO	Y/ EFSA Journal 2016;14(10)
Sandy clay loam ^{c)}	Sandy clay loam	6.9	20	pF2	23.16	76.93	-	3.25	Applied as parent SFO	Y/ EFSA Journal 2016;14(10)
Clay ^{c)}	Clay	7.2	20	pF2	12.2	40.51	-	4.68	Applied as parent SFO	Y/ EFSA Journal 2016;14(10)

^{a)} no reliable value could be determined

^{b)} not traced at this radiolabel position

^{c)} Sadgrove, L 2014 (accepted in the RARs for flazasulfuron; refer to the EFSA conclusion on the peer review of the active flazasulfuron, EFSA Journal 2016; 14(8): 4575)

Table 8.3-15: Summary of aerobic degradation rates for AE F140584- laboratory studies: Trigger points

AE F140584, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Sandy loam	Sandy	6.3	20	55	4.02	13.34	-	4.2	SFO	Y/ EFSA

AE F140584, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
	loam									Journal 2016;14(10)
Sand	Sand	5.8	20	55	7.04	23.38	-	2.1	SFO	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	6.4	20	55	2.35	7.81	-	6.8	SFO	Y/ EFSA Journal 2016;14(10)
Loam	Loam	7.2	20	55	1.49	4.94	-	5.4	SFO	Y/ EFSA Journal 2016;14(10)
CHL	Loamy sand	5.2	20	31.0	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	13.45	44.66	-	39.7	SFO-SFO	Y/ EFSA Journal 2016;14(10)

a) not traced at this radiolabel position

Table 8.3-16: Summary of aerobic degradation rates for AE F147447- laboratory studies: Trigger points

AE F147447, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Loam	Loam	6.1	20	55	54.83 (slow phase: 82.71) k1: 0.0159 ; k2: 8.38e-3 ; tb: 31.0	246.9	-	2.8	HS	Y/ EFSA Journal 2016;14(10)
Sandy loam	Sandy loam	6.4	20	55	75.98 (slow phase: 111.38) k1: 0.0133 ; k2: 6.223e-3 ; tb: 31.0	334.6	-	2.3	HS	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	6.3	20	55	54.76 (slow phase: 202.97) k1: 0.0147 ; k2: 3.415e-3 ; tb: 45.0	526.00	-	3.9	HS	Y/ EFSA Journal 2016;14(10)
Clay loam	Clay loam	7.1	20	55	31.12 (slow phase : 73.32) k1: 0.2054 ; k2: 9.454e-3 ; g: 0.3297	201.2	-	3.0	DFOP	Y/ EFSA Journal 2016;14(10)
CHL	Loamy sand	5.2	20	31.0	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal

AE F147447, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
										2016;14(10)
SLS	Silt loam	7.1	20	54.9	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	157.14	522.0	-	11.9	SFO- SFO	Y/ EFSA Journal 2016;14(10)

a) not traced at this radiolabel position

Table 8.3-17: Summary of aerobic degradation rates for AE F092944- laboratory studies: Trigger points

AE F092944, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	13.97	46.39	-	23.8	SFO- SFO	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	- c)	- c)	-	- c)	- c)	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- b)	- b)	-	- b)	- b)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	62.55	207.77	-	21.3	SFO- SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	82.67	274.6	-	44.1	SFO- SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2	loamy sand	5.2	20	55.4	80.52	267.49	-	27.1	SFO- SFO	Y/ EFSA

AE F092944, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
(pyrimidyl label)										Journal 2016;14(10)
LS 2.2 (phenyl label)	loamy sand	6.8	20	38.2	- b)	- b)	-	- b)	- b)	Y/ EFSA Journal 2016;14(10)
Collombey ^{d)}		7.6	20	44.2	2.9	9.6	-	6.3	SFO	Y/ EFSA Journal 2016;14(10)
Speyer 2.2 ^{d)}		6	20	44.3	4.9	34.8	-	2.3	FOMC	Y/ EFSA Journal 2016;14(10)
Les Evouettes ^{d)}		7.3	20	53.4	9.0	72.4	-	2.6	FOMC	Y/ EFSA Journal 2016;14(10)
Nambsheim ^{e)}	sandy loam	8	20	50	8.9	116	-	6	FOMC	Y/ EFSA Journal 2016;14(10)
Pavia ^{e)}	loamy sand	5.5	20	50	9.7	231.3	-	4	HS	Y/ EFSA Journal 2016;14(10)
Speyer 2.2 ^{e)}	sandy loam	6.7	20	50	2.5	12	-	4	FOMC	Y/ EFSA Journal 2016;14(10)
Vercelli ^{e)}	silt loam	6.1	20	50	6	122.3	-	5	FOMC	Y/ EFSA Journal 2016;14(10)
Pappelacker ^{f)}	sandy loam	7.3	20	40	6.4	30.3	-	5.1	FOMC	Y/ EFSA Journal 2016;14(10)
Uffholz ^{f)}	loam	6.1	20	40	5.25	34.97	-	3.6	DFOP	Y/ EFSA Journal 2016;14(10)
Otzberg ^{f)}	silt loam	7.4	20	40	5.9	19.6	-	5.7	SFO	Y/ EFSA Journal 2016;14(10)

^{a)} no reliable value could be determined

^{b)} not traced at this radiolabel position

^{c)} not observed in this soil in amounts that would allow kinetic evaluation

^{d)} Schmitt and Mikolasch, 2013 (metabolite dosed study, accepted in the RAR for foramsulfuron; refer to the EFSA conclusion on the peer review of the active substance foramsulfuron, - EFSA Journal 2016;14(3):4421)

^{e)} Shaw, D., 2002 (metabolite dosed study, accepted in the RAR for flupyrsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance flupyrsulfuron-methyl, EFSA Journal 2014;12(11):3881)

^{f)} Volkel, 2006 (metabolite dosed study, accepted in the RAR for sulfosulfuron; refer to the EFSA conclusion on the peer review of the active substance sulfosulfuron, EFSA Journal 2014;12(7):3764)

Table 8.3-18: Summary of aerobic degradation rates for BCS-CV14885- laboratory studies: Trigger points

BCS-CV14885, Laboratory studies, aerobic conditions; TRIGGER ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t, °C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Sandy loam	Sandy loam	6.5	20	55	131.3 (slow phase: 202.73) k1: 0.0106 ; k2: 3.42e-3 ; tb: 33.8	602.1	-	1.3	HS	Y/ EFSA Journal 2016;14(10)
Clay loam	Clay loam	7.3	20	55	55.34 (slow phase: 129.2) k1: 0.0514 ; k2: 0.0054; g: 0.355	347.4	-	2.5	DFOP	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	6.4	20	55	102.5 (slow phase: 129.54) k1: 0.1486 ; k2: 5.351e-3 ; g: 0.1346	403.3	-	1.4	DFOP	Y/ EFSA Journal 2016;14(10)
Sandy loam	Sandy loam	5.4	20	55	128.1 (slow phase: 154.19) k1: 0.1644 ; k2: 0.0045; g: 0.1107	486.1	-	1.4	DFOP	Y/ EFSA Journal 2016;14(10)

MODELLING ENDPOINTS

For parent active substance mesosulfuron-methyl, the EU agreed modelling endpoints comprise of 2 data sets adapted for specific purposes, see listed in Table 8.3-19 and Table 8.3-20 below.

Data in Table 8.2-19 represents a most accurate fit description of the degradation in soil considering also bi-phasic kinetic approaches, which is intended for use in modelling the behaviour of the active substance alone.

Data in Table 8.2-20 represents a single first order approximation of mesosulfuron-methyl overall degradation kinetics, which is intended for a practicable implementation of the parent active substance in pathway simulations aiming to generate conservative exposure estimates specifically for the metabolites.

The exposure simulations for the parent active substance alone, based on Table 8.2-19 data, may include 2 Tiers:

Tier 1: technically simplified but overly conservative approach of considering only the slow- phase DT50 of the bi-phasic models for an SFO-based exposure modelling.

Tier 2: accurate biphasic implementation of degradation in a DFOP-based exposure modelling.

For biphasic implementation of the degradation in exposure simulations, common DFOP parameters averaged over all soils (geometric mean normalised DT50fast, DT50slow, and arithmetic mean of g values) are needed as input parameters. These derive from the EU List of Endpoints information as

follows, see included in Table 8.2-19 in italic letters:

for soils where DFOP was already the model of choice for kinetic evaluation, the listed k_1 , k_2 , and g are used directly in form of their corresponding normalised DT50fast, DT50slow, and g .

for soils where SFO fit was the preferred kinetic model (CLF, LS2.2 phenyl label), this is expressed as a special case of DFOP, where DT50fast and DT50slow have the same value (the parameter g is left unspecified, since for this situation any value of g leads to the same fitted curve).

for soils (SLI, SLS) where the kinetic evaluation resulted in pseudo-SFO DT50 endpoints ("back- DT50" = DT90/3.32) derived from FOMC model, the same approach is applied (same value for both slow and fast phase in DFOP, and g is left unidentified).

Geometric mean DT50fast and DT50slow over all soils are 13.19 d and 49.72 d, respectively, with an arithmetic mean of $g = 0.375$. This implies that 37.5 % of the compound is associated with the fast phase and 62.5 % with the slow phase compartment. These DT50 values correspond to degradation rates of 0.0528 d⁻¹ (fast) and 0.0139 d⁻¹ (slow), respectively.

Table 8.3-19: Summary of aerobic degradation rates for mesosulfuron-methyl - laboratory studies: Modelling endpoints for modelling the active substance alone, including biphasic approaches

Mesosulfuron-methyl, Laboratory studies, aerobic conditions											
MODELING ENDPOINTS											
a) including biphasic approaches- for modelling the parent active substance alone											
Soil name	Soil type (USDA)	pH (CaCl ₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa		Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
							Tier 1 SFO DT50	Tier 2 DFOP DT50fast / DT50slow (g value)			
CHL	Loamy sand	5.2	20	31.0	60.5 <i>k</i> ₁ : 0.054 ; <i>k</i> ₂ : 0.004 ;	427	173.29 (slow phase)	12.8 / 173.29 (0.369)	2.8	DFOP	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	15.5 Back-DT50: 18.76	62.3	18.76	18.76 / 18.76 (-)	4.6	FOMC	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	61.7 <i>k</i> ₁ : 0.081 ; <i>k</i> ₂ : 0.007 ;	295.0	99.02 (slow phase)	8.56 / 99.02 (0.238)	3.2	DFOP	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	15.98	53.1	15.44	15.44 / 15.44 (-)	2.0	SFO	Y/ EFSA Journal 2016;14(10)

Mesosulfuron-methyl, Laboratory studies, aerobic conditions												
MODELING ENDPOINTS												
a) including biphasic approaches- for modelling the parent active substance alone												
Soil name	Soil type (USDA)	pH (CaCl ₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa		Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference	
							Tier 1 SFO DT50	Tier 2 DFOP DT50fast / DT50slow (g value)				
FF	Loam	7.3	20	43.2	31.9 k1: 0.059 ; k2: 0.01348; g: 0.302	144.2	46.43 (slow phase)	10.61 / 46.43 (0.302)	2.1	DFOP	Y/ EFSA Journal 2016;14(10)	
SCL	Clay	7.3	20	59.8	67.7 k1: 0.040 ; k2: 0.00205 ; g: 0.462	822.4	242.77 (slow phase)	12.44 / 242.77 (0.462)	5.7	DFOP	Y/ EFSA Journal 2016;14(10)	
SLS	Silt loam	7.1	20	54.9	7.8 Back-DT50: 7.80	25.9	7.80	7.80 / 7.80 (-)	19.3	FOMC	Y/ EFSA Journal 2016;14(10)	
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	30.6 k1: 0.062 ; k2: 0.00517 ; g: 0.503	316.1	134.07 (slow phase)	11.8 / 134.07 (0.503)	3.2	DFOP	Y/ EFSA Journal 2016;14(10)	
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	31.70	105.1	31.70	31.70 / 31.70 (-)	5.6	SFO	Y/ EFSA Journal 2016;14(10)	
Geometric mean DT50 (n=9) Arithmetic mean value g							49.72 -	13.19/49.72 (0.375)				
pH-dependency: y/n							No					

Table 8.3-20: Summary of aerobic degradation rates for mesosulfuron-methyl - laboratory studies: SFO Modelling endpoints, intended for modelling of parent active substance and metabolites

Mesosulfuron-methyl, Laboratory studies, aerobic conditions										
MODELING ENDPOINTS										
b) SFO approaches – for modelling the parent active substance and metabolites.										
Soil name	Soil type (USDA)	pH (CaCl ₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	77.3	256.9	77.3	9.1	SFO	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	16.67	55.39	16.67	6.2	SFO	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	71.6	238.0	71.6	7.2	SFO	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	16.0	53.0	15.46	2.0	SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	37.5	124.7	33.86	4.3	SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	140.10	465.40	100.59	14.8	SFO	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	7.6	25.3	7.6	18.5	SFO	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	53.56	177.91	53.56	11.1	SFO	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	31.44	104.44	31.44	5.6	SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean DT50 (n=9)							34.09			
pH-dependency: y/n							No			

Metabolites:

**Table 8.3-21: Summary of aerobic degradation rates for AE F160459- laboratory studies: SFO
Modelling endpoints**

AE F160459, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	- a)	- a)	- a)	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	128.64	427.34	128.64	10.2	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- a)	- a)	- a)	- a)	- a)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	38.60	128.23	32.29	14.3	SFO-SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	76.0	252.47	68.63	9.9	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	129.80	431.0	93.20	21.68	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- b)	- b)	- b)	- b)	- b)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	- b)	- b)	- b)	- b)	- b)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	84.29	280.02	84.29	11.9	SFO-SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean DT50 (n=5)							74.14			
pH-dependency: y/n							No			

**Table 8.3-22: Summary of aerobic degradation rates for AE F154851- laboratory studies: SFO
Modelling endpoints**

AE F154851, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	76.74	254.91	76.74	9.3	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	18.73	62.20	18.73	18.6	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	39.70	131.89	38.52	14.8	SFO-SFO	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	46.35	153.97	44.77	13.4	SFO-SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	73.93	245.59	66.76	14.6	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	207.38	688.91	148.90	19.3	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	21.52	71.49	21.52	26.1	SFO-SFO	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	32.95	109.46	32.95	11.2	SFO-SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean DT50 (n=8)							45.22			
pH-dependency: y/n							No			

^{a)} no reliable value could be determined

Table 8.3-23: Summary of aerobic degradation rates for AE F160460- laboratory studies: SFO
Modelling endpoints

AE F160460, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	- a)	- a)	- a)	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	24.14	80.20	24.14	12.0	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- a)	- a)	- a)	- a)	- a)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	37.07	123.15	35.81	30.3	SFO-SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	36.23	120.3	32.72	15.9	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	- b)	- b)	- b)	- b)	- b)	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- b)	- b)	- b)	- b)	- b)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	44.22	196.9	44.22	29.9	Decline fit	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	15.32	50.90	15.32	5.8	SFO-SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean DT50 (n=5)							28.61			
pH-dependency: y/n							No			

Table 8.3-24: Summary of aerobic degradation rates for AE F099095- laboratory studies: SFO
Modelling endpoints

AE F099095, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	185.52	616.28	185.52	4.5	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	105.21	349.49	105.21	13.8	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	_ a)	_ a)	_ a)	_ a)	_ a)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	80.16	266.29	77.43	18.4	SFO-SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	94.19	312.89	85.05	9.7	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	135.08	448.71	96.99	25.9	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	49.1	163.1	49.10	7.4	Decline fit	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	27.90	92.68	27.90	16.28	SFO-SFO	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	_ b)	_ b)	_ b)	_ b)	_ b)	Y/ EFSA Journal 2016;14(10)
Sandy loam ^{c)}	Sandy loam	5.3	20	pF2	58.82	195.4	58.82	2.73	Applied as parent SFO	Y/ EFSA Journal 2016;14(10)

AE F099095, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Sandy clay loam ^{c)}	Sandy clay loam	6.9	20	pF2	23.16	76.93	23.16	3.25	Applied as parent SFO	Y/ EFSA Journal 2016;14(10)
Clay ^{c)}	Clay	7.2	20	pF2	12.2	40.51	12.2	4.68	Applied as parent SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean DT50 (n=10)							55.6			
pH-dependency: y/n							No			

^{a)} no reliable value could be determined

^{b)} not traced at this radiolabel position

^{c)} Sadgrove, L 2014 (accepted in the RARs for flazasulfuron; refer to the EFSA conclusion on the peer review of the active flazasulfuron, EFSA Journal 2016; 14(8): 4575)

Table 8.3-25: Summary of aerobic degradation rates for AE F140584- laboratory studies: SFO Modelling endpoints

AE F140584, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Sandy loam	Sandy loam	6.3	20	55	4.02	13.34	4.02	4.2	SFO	Y/ EFSA Journal 2016;14(10)
Sand	Sand	5.8	20	55	7.04	23.38	7.04	2.1	SFO	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	6.4	20	55	2.35	7.81	2.35	6.8	SFO	Y/ EFSA Journal 2016;14(10)

AE F140584, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Loam	Loam	7.2	20	55	1.49	4.94	1.49	5.4	SFO	Y/ EFSA Journal 2016;14(10)
CHL	Loamy sand	5.2	20	31.0	_ a)	_ a)	_ a)	_ a)	_ a)	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	_ a)	_ a)	_ a)	_ a)	_ a)	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	_ a)	_ a)	_ a)	_ a)	_ a)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	_ a)	_ a)	_ a)	_ a)	_ a)	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	_ a)	_ a)	_ a)	_ a)	_ a)	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	_ a)	_ a)	_ a)	_ a)	_ a)	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	_ a)	_ a)	_ a)	_ a)	_ a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	_ a)	_ a)	_ a)	_ a)	_ a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	13.45	44.66	13.45	39.7	SFO-SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean DT50 (n=5)							4.22			
pH-dependency: y/n							No			

**Table 8.3-26: Summary of aerobic degradation rates for AE F147447- laboratory studies: SFO
Modelling endpoints**

AE F147447, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Silt loam	Silt loam	6.3	20	55	54.76 (slow phase: 202.97) k1: 0.0147 ; k2: 3.415e-3 ; tb: 45.0	526.00	202.97	3.9	HS	Y/ EFSA Journal 2016;14(10)
Clay loam	Clay loam	7.1	20	55	31.12 (slow phase : 73.32) k1: 0.2054 ; k2: 9.454e-3 ; g: 0.3297	201.2	73.32	3.0	DFOP	Y/ EFSA Journal 2016;14(10)
CHL	Loamy sand	5.2	20	31.0	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLI	Sandy loam	7.5	20	45.2	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)

AE F147447, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
SCL	Clay	7.3	20	59.8	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	- a)	- a)	-	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	157.14	522.0	157.14	11.9	SFO-SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean DT50 (n=5)							102.15			
pH-dependency: y/n							No			

Table 8.3-27: Summary of aerobic degradation rates for AE F092944- laboratory studies: SFO Modelling endpoints

AE F092944, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
CHL	Loamy sand	5.2	20	31.0	13.97	46.39	13.97	23.8	SFO-SFO	Y/ EFSA Journal 2016;14(10)

AE F092944, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
SLI	Sandy loam	7.5	20	45.2	- c)	- c)	- c)	- c)	- c)	Y/ EFSA Journal 2016;14(10)
SLV	Loamy sand	6.25	20	30.8	- b)	- b)	-	- b)	- b)	Y/ EFSA Journal 2016;14(10)
CLF	Loam	7.3	20	47.5	62.55	207.77	60.42	21.3	SFO-SFO	Y/ EFSA Journal 2016;14(10)
FF	Loam	7.3	20	43.2	82.67	274.6	- a)	44.1	SFO-SFO	Y/ EFSA Journal 2016;14(10)
SCL	Clay	7.3	20	59.8	- a)	- a)	- a)	- a)	- a)	Y/ EFSA Journal 2016;14(10)
SLS	Silt loam	7.1	20	54.9	- a)	- a)	- a)	- a)	- a)	Y/ EFSA Journal 2016;14(10)
LS 2.2 (pyrimidyl label)	Loamy sand	5.2	20	55.4	80.52	267.49	80.52	27.1	SFO-SFO	Y/ EFSA Journal 2016;14(10)
LS 2.2 (phenyl label)	Loamy sand	6.8	20	38.2	- b)	- b)	- b)	- b)	- b)	Y/ EFSA Journal 2016;14(10)
Collombey ^{d)}	Not available	7.6	20	44.2	2.9	9.6	2.9	6.3	SFO	Y/ EFSA Journal 2016;14(10)
Speyer 2.2 ^{d)}	Not available	6	20	44.3	4.9	34.8	10.48	2.3	FOMC	Y/ EFSA Journal 2016;14(10)

AE F092944, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Les Evouettes^{d)}	Not available	7.3	20	53.4	9.0	72.4	19.6	2.6	FOMC	Y/ EFSA Journal 2016;14(10)
Nambsheim^{e)}	sandy loam	8	20	50	8.9	116	30.8	6	FOMC	Y/ EFSA Journal 2016;14(10)
Pavia^{e)}	loamy sand	5.5	20	50	9.7	231.3	173.3	4	HS	Y/ EFSA Journal 2016;14(10)
Speyer 2.2^{e)}	sandy loam	6.7	20	50	2.5	12	3.6	4	FOMC	Y/ EFSA Journal 2016;14(10)
Vercelli^{e)}	silt loam	6.1	20	50	6	122.3	30.6	5	FOMC	Y/ EFSA Journal 2016;14(10)
Pappelacker^{f)}	sandy loam	7.3	20	40	6.4	30.3	8	5.1	FOMC	Y/ EFSA Journal 2016;14(10)
Uffholz^{f)}	loam	6.1	20	40	5.25	34.97	11.2	3.6	DFOP	Y/ EFSA Journal 2016;14(10)
Otzberg^{f)}	silt loam	7.4	20	40	5.9	19.6	4.4	5.7	SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean DT50 (n=13)							16.93			
pH-dependency: y/n							No			

^{a)} no reliable value could be determined

^{b)} not traced at this radiolabel position

^{c)} not observed in this soil in amounts that would allow kinetic evaluation

^{d)} Schmitt and Mikolasch, 2013 (metabolite dosed study, accepted in the RAR for foramsulfuron; refer to the EFSA conclusion on the peer review of the active substance foramsulfuron, - EFSA Journal 2016;14(3):4421)

- ^{e)} Shaw, D., 2002 (metabolite dosed study, accepted in the RAR for flupyr-sulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance flupyr-sulfuron-methyl, EFSA Journal 2014;12(11):3881)
- ^{f)} Volkel, 2006 (metabolite dosed study, accepted in the RAR for sulfosulfuron; refer to the EFSA conclusion on the peer review of the active substance sulfosulfuron, EFSA Journal 2014;12(7):3764)

Table 8.3-28: Summary of aerobic degradation rates for BCS-CV14885- laboratory studies: SFO
Modelling endpoints

BCS-CV14885, Laboratory studies, aerobic conditions, MODELLING ENDPOINTS										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Sandy loam	Sandy loam	6.5	20	55	113.6	377.2	113.6	3.77	SFO	Y/ EFSA Journal 2016;14(10)
Clay loam	Clay loam	7.3	20	55	125.7	417.5	125.7	3.01	SFO	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	6.4	20	55	102.8	341.4	97.7	3.48	SFO	Y/ EFSA Journal 2016;14(10)
Sandy loam	Sandy loam	5.4	20	55	65.06	216.1	65.06	5.23	SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean DT50 (n=4)							97.6			
pH-dependency: y/n							No			

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Information concerning anaerobic degradation in soil is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

8.3.2.1 Iodosulfuron-methyl-sodium and its metabolites

The anaerobic degradation of iodosulfuron-methyl-sodium has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453); no additional studies are considered for this assessment.

Degradation in soil under anaerobic conditions follows basically the same pathways as under aerobic conditions, with generally lower levels of downstream metabolites formed after AE F075736.

Table 8.3-29: Summary of anaerobic degradation rates for iodosulfuron-methyl-sodium - laboratory studies

Iodosulfuron-methyl-sodium, Laboratory studies, anaerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	St. (r²)	Kinetic model	Evaluated on EU level y/n/ Reference
LS 2.2	Silt loam	7.0	20	flooded	28.1	93.4	-	0.997	SFO	Y/ EFSA Journal 2016;14(4)
SL S	Loamy sand	6.0	20	flooded	14.3	47.5	-	0.990	SFO	Y/ EFSA
Geometric mean/Median (n=2)							-			
pH-dependency: y/n							-			

8.3.2.2 Mesosulfuron-methyl and its metabolites

The anaerobic degradation of mesosulfuron-methyl has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(10): 4584); no additional studies are considered for this assessment.

In anaerobic soil incubations mesosulfuron-methyl transformation was slower than under aerobic conditions, with the degradation pathway being comparable to that under aerobic conditions.

Table 8.3-30: Summary of anaerobic degradation rates for mesosulfuron-methyl - laboratory studies

Mesosulfuron-methyl, Laboratory studies, anaerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t.°C	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	St. (r²)	Kinetic model	Evaluated on EU level y/n/ Reference
Sandy loam (pyrimidyl label)	Sandy loam	5.4	20	-	30.1	-	-	-	First- order	Y/ EFSA Journal 2016;14(10)
Sandy loam (phenyl label)	Sandy loam	5.4	20	-	30.5	-	-	-	First- order	Y/ EFSA Journal 2016;14(10)
Geometric mean/Median (n=2)							-			
pH-dependency: y/n							-			

Table 8.3-31: Summary of anaerobic degradation rates for AE F160459 - laboratory studies

AE F160459, Laboratory studies, anaerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl₂)	t. °C	MWHC %	DT₅₀ (d)	DT₉₀ (d)	DT₅₀ (d) 20°C pF2/10kPa	St. (r²)	Kinetic model	Evaluated on EU level y/n/Reference
Sandy loam (pyrimidyl label)	Sandy loam	5.4	20	-	70.2	-	-	-	First-order	Y/ EFSA Journal 2016;14(10)
Sandy loam (phenyl label)	Sandy loam	5.4	20	-	81.4	-	-	-	First-order	Y/ EFSA Journal 2016;14(10)
Geometric mean/Median (n=2)							-			
pH-dependency: y/n							-			

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)

Information concerning soil dissipation is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

8.4.1.1 Iodosulfuron-methyl-sodium and its metabolites

The field dissipation of iodosulfuron-methyl-sodium has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453); no additional studies are considered for this assessment.

Worst case normalised laboratory data (DT₅₀ soil = 12.2 d) was used for PEC_{soil} calculations of the parent as this value is higher than the DT₅₀ (10.3 d) measured in the field, and hence represents a more conservative approach for the PEC_{soil} calculations.

For higher tier PEC calculations (e.g. PEC_{gw}) for the parent compound and metabolite AE F075736 also the field data are considered.

No differentiation between triggering and modelling endpoints is made in the EFSA conclusion (EFSA Journal 2016;14(4):4453).

Triggering endpoints

Table 8.4-1: Summary of aerobic degradation rates for iodosulfuron-methyl-sodium - field studies

Iodosulfuron-methyl-sodium, Field studies									
Soil type	Location	pH^{a)}	Depth (cm)	DissT₅₀ (d) actual	DT₉₀ (d) actual	DT₅₀ (d) Norm^{b)}	St. (x²)	Method of calculation	Evaluated on EU level y/n/ Reference
Silt loam (Duern)	S Germany	6.9	0-30			10.3	14.3	SFO	Y/ EFSA Journal 2016;14(4)
Silt loam (Warpe)	N Germany	6.4	0-30			0.8	13.6	SFO	Y/ EFSA Journal 2016;14(4)
Silt loam (Rotgla)	Spain	7.8	0-30			4.8	10.4	SFO	Y/ EFSA Journal 2016;14(4)
Silt loam (S. Jean de)	S France	7.4	0-30			2.4	17.1	SFO	Y/ EFSA Journal 2016;14(4)
Silt (Schleithal)	N France	5.8	0-30			3.7	8.0	SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=5)						3.2			

^{a)} Medium for measurement of soil pH not stated

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7.

Table 8.4-2: Summary of aerobic degradation rates for AE F075736 - field studies

AE F075736, Field studies									
Soil type	Location	pH^{a)}	Depth (cm)	DissT₅₀ (d) actual	DT₉₀ (d) actual	DT₅₀ (d) Norm^{b)}	St. (x²)	Method of calc.	Evaluated on EU level y/n/ Reference
Silt loam (Duern)	S Germany	6.9	0-30			7.9	34.1	SFO-SFO	Y/ EFSA Journal 2016;14(4)
Silt loam (Warpe)	N Germany	6.4	0-30			19.0	38.0	SFO-SFO	Y/ EFSA Journal 2016;14(4)
Silt loam (Rotgla)	Spain	7.8	0-30			34.9	27.3	SFO-SFO	Y/ EFSA Journal 2016;14(4)
Silt loam (S. Jean de Blagnac)	S France	7.4	0-30			11.4	29.5	SFO-SFO	Y/ EFSA Journal 2016;14(4)
Silt (Schleithal)	N France	5.8	0-30	6.9	22.8	6.9	35.6	SFO-SFO	Y/ EFSA Journal 2016;14(4)
Silt loam*	N France	6.1		42.7	141.7	11.4	19	SFO best fit	Y/ EFSA Journal 2016;14(4)
Loam*	UK	6.2		39.3	378.7	37.1	13	SFO best fit	Y/ EFSA Journal 2016;14(4)

Sandy clay loam *	N Germany	7.0		20.3	67.6	10.1	9	SFO best fit	Y/ EFSA Journal 2016;14(4)
Loam *	Italy	6.6		11.1	36.8	7.3	7	SFO best fit	Y/ EFSA Journal 2016;14(4)
Geometric mean (if not pH dependent)							13.2		

* Aitken, Doig & Just (2012) (metabolite dosed study, accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{a)} Medium for measurement of soil pH not stated

^{b)} Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7.

8.4.1.2 Mesosulfuron-methyl and its metabolites

The field dissipation of mesosulfuron-methyl has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(10): 4584), no additional studies are considered for this assessment.

Although field soil dissipation studies were rated acceptable for the first approval of the active substance mesosulfuron-methyl, some deviations were identified by the EU re-review and no reliable normalised field $DegT_{50}$ could be derived based on updated risk assessment practises.

Environmental exposure simulations for risk assessments were in consequence agreed to be based on laboratory study information, cf. Section. 8.3.1.1 for tabular summaries of modelling endpoints. For conservative PEC_{soil} calculations of parent and metabolites, it was agreed to apply worst case DT_{50} values of trigger kinetic evaluations, see summarised as well in Section. 8.3.1.1.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Information concerning soil accumulation is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

8.4.2.1 Iodosulfuron-methyl-sodium and its metabolites

The accumulation of **iodosulfuron-methyl-sodium** has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453). No accumulation studies have been performed or are required. As shown in various laboratory and field degradation experiments no accumulation of iodosulfuron-methyl-sodium nor most of its metabolites is expected. For metabolite AE F059411 calculations show that accumulation can be considered negligible.

8.4.2.2 Mesosulfuron-methyl and its metabolites

The accumulation of **mesosulfuron-methyl** has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(10): 4584). No accumulation studies have been performed or are required.

8.5 Mobility in soil (KCP 9.1.2)

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

8.5.1 Laboratory studies (KCP 9.1.2.1)

8.5.1.1 Iodosulfuron-methyl-sodium and its metabolites

The plant uptake factor (PUF) of AE F075736 has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453). Additionally, the PUF of AE F075736 has been evaluated and accepted during the peer review of the active substance metsulfuron-methyl (EFSA Journal 2015;13(1):3936). The PUF for AE F075736 in wheat was agreed as 0.50. No additional studies are considered for this assessment.

The soil adsorption/desorption of iodosulfuron-methyl-sodium and its metabolites has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453). No additional studies are considered for this assessment.

Column leaching studies for iodosulfuron-methyl-sodium were not required for EU registration; no additional studies are considered for this assessment.

Table 8.5-1: Summary of soil adsorption/desorption for iodosulfuron-methyl-sodium

Iodosulfuron-methyl-sodium							
Soil name	Soil type	OC (%)	pH (-)	K _f (mL/g)	K _{foc} (mL/g)	I/n (-)	Evaluated on EU level y/n/ Reference
S 2.1	Sand	1.2	5.6 ^{a)}	0.12	10	0.70	Y/ EFSA Journal 2016;14(4)
LS 2.2	Loamy sand	2.5	5.7 ^{a)}	0.54	22	0.93	Y/ EFSA Journal 2016;14(4)
SL V	Sandy loam	1.1	6.0 ^{a)}	0.13	12	1.03	Y/ EFSA Journal 2016;14(4)
SL 2	Silt loam	0.7	5.4 ^{a)}	1.05	152	0.87	Y/ EFSA Journal 2016;14(4)
CLM	Clay loam	2.8	7.2 ^{a)}	2.47	90	0.80	Y/ EFSA Journal 2016;14(4)
SLJ	Sandy loam	2.5	7.5 ^{a)}	2.03	82	0.85	Y/ EFSA Journal 2016;14(4)
FL	Loam	3.0	7.3 ^{a)}	0.694	22.8	0.89	Y/ EFSA Journal 2016;14(4)
FB	Clay loam	2.4	7.2 ^{a)}	0.368	15.5	0.86	Y/ EFSA Journal 2016;14(4)
Honville	Loamy silt	0.9	5.9 ^{b)}	0.451	49.5	0.92	Y/ EFSA Journal 2016;14(4)

Iodosulfuron-methyl-sodium							
Soil name	Soil type	OC (%)	pH (-)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Geometric mean (n=9)					33.4	-	
Arithmetic mean (n=9)					50.6	0.87	
pH-dependency y/n					No		

^{a)} Medium for the measurement of soil pH not stated.

^{b)} In CaCl₂.

Table 8.5-2: Summary of soil adsorption/desorption for AE F075736

AE F075736							
Soil Name	Soil Type	OC (%)	pH (-)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
FL	Loam	3.0	7.3 ^{a)}	0.134	4.3	0.94	Y/ EFSA Journal 2016;14(4)
FB	Clay loam	2.4	7.2 ^{a)}	0.067	2.9	0.89	Y/ EFSA Journal 2016;14(4)
SL S	Silt loam	2.1	7.0 ^{a)}	0.106	5.1	0.86	Y/ EFSA Journal 2016;14(4)
LS 2.2	Loamy sand	2.0	6.0 ^{a)}	0.145	7.4	0.92	Y/ EFSA Journal 2016;14(4)
SL V	Sandy loam	0.4	6.0 ^{a)}	0.065	15.1	0.90	Y/ EFSA Journal 2016;14(4)
LUFA 2.2	Loamy sand	2.2	5.8 ^{a)}	0.530	24.2	0.91	Y/ EFSA Journal 2016;14(4)
Honville	Loamy silt	0.9	6.7 ^{a)}	0.241	26.5	0.96	Y/ EFSA Journal 2016;14(4)
Flanagan ^{b)}	Silt loam	2.3	6.5 ^{a)}	1.4	60	0.97	Y/ EFSA Journal 2016;14(4)
Keyport (USA) ^{b)}	Silt loam	1.6	6.4 ^{a)}	0.84	53	0.85	Y/ EFSA Journal 2016;14(4)
Cecil (USA) ^{b)}	Sand	0.2	6.1 ^{a)}	0.36	207	1.14	Y/ EFSA Journal 2016;14(4)
Bow Island (Canada) ^{c)}	Sandy loam	1.3	7.1 ^{a)}	0.05	4	0.97	Y/ EFSA Journal 2016;14(4)
Tangent (Canada) ^{c)}	Clay loam	2.6	5.3 ^{a)}	0.3	12	0.95	Y/ EFSA Journal 2016;14(4)
Dauphin (Canada) ^{c)}	Sandy clay loam	3.4	7.5 ^{a)}	0.3	9	0.95	Y/ EFSA Journal 2016;14(4)
Bradwell (Canada) ^{c)}	Loam	2.1	7.6 ^{a)}	0.15	7	1.1	Y/ EFSA Journal 2016;14(4)
Hanley Res. (Canada) ^{c)}	Loam	2.3	5.4 ^{a)}	0.65	29	1.03	Y/ EFSA Journal 2016;14(4)

AE F075736							
Soil Name	Soil Type	OC (%)	pH (-)	K _f (mL/g)	K _{foc} (mL/g)	I/n (-)	Evaluated on EU level y/n/ Reference
Foam Lake (Canada) ^{c)}	Sandy loam	3	7.7 ^{a)}	0.35	12	1.06	Y/ EFSA Journal 2016;14(4)
Fisher Branch (Canada) ^{c)}	Clay loam	4.2	7.5 ^{a)}	0.6	14	0.94	Y/ EFSA Journal 2016;14(4)
Drummer (USA) ^{d)}	Silt loam	3.2	6.4 ^{a)}	1.5	47	0.85	Y/ EFSA Journal 2016;14(4)
Lleida (Spain) ^{d)}	Silty clay	1.8	7.9 ^{a)}	0.13	6.9	0.95	Y/ EFSA Journal 2016;14(4)
Gross-Umstadt (Germany) ^{d)}	Loam	1.3	7.2 ^{a)}	0.1	7.8	0.95	Y/ EFSA Journal 2016;14(4)
Sassafras (USA) ^{d)}	Sand	1.4	5.3 ^{a)}	0.48	35	0.9	Y/ EFSA Journal 2016;14(4)
Nambsheim (France) ^{d)}	Sandy loam	1.3	7.1 ^{a)}	0.05	4	0.97	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=22)					14.0	-	
Arithmetic mean (n=22)					27.0	1.0	
pH-dependency y/n					No		

^{a)} Medium for the measurement of soil pH not stated

^{b)} Friedman (1981) (accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{c)} Yang (1987) (accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{d)} Allan (2011) (accepted in the RAR for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

Table 8.5-3: Summary of soil adsorption/desorption for AE F145740

AE F145740							
Soil Name	Soil Type	OC (%)	pH (CaCl ₂)	K _f (mL/g)	K _{foc} (mL/g)	I/n (-)	Evaluated on EU level y/n/ Reference
Laacher Hof AXXa	Sandy loam	2.0	6.5	0.27	13.5	0.91	Y/ EFSA Journal 2016;14(4)
Dollendorf II	Silty clay loam	4.9	7.4	0.61	12.5	0.91	Y/ EFSA Journal 2016;14(4)
Höfchen am Hohenseh 4a	Silt loam	2.1	6.5	0.39	18.7	0.90	Y/ EFSA Journal 2016;14(4)
Hanscheider Hof	Sandy loam	2.9	5.4	0.95	32.6	0.95	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=4)					17.9	-	
Arithmetic mean (n=4)					19.3	0.92	
pH-dependency y/n					No		

Table 8.5-4: Summary of soil adsorption/desorption for AE F161778

AE F161778							
Soil Name	Soil Type	OC (%)	pH (-)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Hattersheim	Silty loam	1.9	6.4 ^{a)}	0.754	39.7	0.96	Y/ EFSA Journal 2016;14(4)
Baumber	Loamy sand	2.2	7.3 ^{a)}	0.753	34.2	0.98	Y/ EFSA Journal 2016;14(4)
Empingham	Sandy clayey loam	4.6	7.4 ^{a)}	0.940	20.4	0.94	Y/ EFSA Journal 2016;14(4)
Gross-Umstadt (Germany) ^{c)}	Silt loam	1.2	7.7 ^{b)}	0.4	34	1.08	Y/ EFSA Journal 2016;14(4)
Arrow (UK) ^{c)}	Sandy loam	2.3	5.7 ^{b)}	0.6	24.2	0.92	Y/ EFSA Journal 2016;14(4)
Mattapex (USA) ^{c)}	Silt loam	2.6	6.4 ^{b)}	0.8	30.4	0.84	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=6)					29.7	-	
Arithmetic mean (n=6)					30.5	1.0	
pH-dependency y/n					No		

^{a)} In CaCl₂

^{b)} Medium for the measurement of soil pH not stated

^{c)} Yeomans (1999c) (accepted in the RARs for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

Table 8.5-5: Summary of soil adsorption/desorption for BCS-CW81253

BCS-CW81253							
Soil Name	Soil Type	OC (%)	pH (CaCl₂)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Laacher Hof AXXa	Loamy sand	1.6	6.4 ^{a)}	0.73	45.4	0.91	Y/ EFSA Journal 2016;14(4)
Dollendorf II	Clay loam	5.0	7.2 ^{a)}	0.99	19.9	0.89	Y/ EFSA Journal 2016;14(4)
Höfchen am Hohenseh 4a	Silt loam	1.7	6.3 ^{a)}	0.77	45.2	0.90	Y/ EFSA Journal 2016;14(4)
Hanscheider Hof	Sandy loam	2.9	5.4 ^{a)}	1.06	36.5	0.89	Y/ EFSA Journal 2016;14(4)
Gross-Umstadt (Germany) ^{c)}	Silt loam	1.2	7.7	0.97 (K _d)	81	1.0	Y/ EFSA Journal 2016;14(4)
Arrow (UK) ^{c)}	Sandy loam	2.3	5.7	0.9	41	0.86	Y/ EFSA Journal 2016;14(4)
Mattapex (USA) ^{c)}	Silt loam	2.6	6.4	1.2	45	0.92	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=7)					41.87	-	

BCS-CW81253							
Soil Name	Soil Type	OC (%)	pH (CaCl ₂)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Arithmetic mean (n=7)					44.9	0.91	
pH-dependency y/n					No		

^{a)} In CaCl₂

^{b)} Medium for the measurement of soil pH not stated

^{c)} Yeomans (1999c) (accepted in the RARs for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

Table 8.5-6: Summary of soil adsorption/desorption for AE 0000119

AE 0000119							
Soil Name	Soil Type	OC (%)	pH (CaCl ₂)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Wurmwiese	Loam	1.8	5.3	1.103	61.3	0.93	Y/ EFSA Journal 2016;14(4)
Höfchen am Hohenseh 4a	Silt loam	2.4	6.6	1.702	70.9	0.91	Y/ EFSA Journal 2016;14(4)
Guadalupe	Sandy loam	0.7	6.7	1.772	253.2	0.92	Y/ EFSA Journal 2016;14(4)
Springfield	Silt loam	1.7	6.6	5.985	352.0	0.89	Y/ EFSA Journal 2016;14(4)
Tama, (USA) ^{a)}	Silty clay loam	3.1	6.3	5.97	194	0.9297	Y/ EFSA Journal 2016;14(4)
Sassafras (USA) ^{a)}	Sand	1.4	6.3	0.969	69.4	0.9021	Y/ EFSA Journal 2016;14(4)
Lleida (Spain) ^{a)}	Silty clay	1.8	7.5	1.51	84.0	0.9364	Y/ EFSA Journal 2016;14(4)
Nambsheim (France) ^{a)}	Sandy loam	1.6	7.0	0.908	57.9	0.9290	Y/ EFSA Journal 2016;14(4)
Suchozébry (Poland) ^{a)}	Sandy loam	0.76	5.0	1.24	164	0.8686	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=9)					117.2	-	
Arithmetic mean (n=9)					145.2	0.91	
pH-dependency y/n					No		

^{a)} Elliott, T. (2009) (accepted in the RARs for metsulfuron-methyl and thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))

Table 8.5-7: Summary of soil adsorption/desorption for AE F059411

AE F059411							
Soil Name	Soil Type	OC (%)	pH (-)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
SL S	Silt loam	2.1	7.0 ^{a)}	0.443	21.3	0.87	Y/ EFSA Journal 2016;14(4)
LS 2.2	Loamy sand	2.0	6.0 ^{a)}	0.298	15.3	0.91	Y/ EFSA Journal 2016;14(4)
SL V	Sandy loam	0.4	6.0 ^{a)}	0.315	73.3	0.84	Y/ EFSA Journal 2016;14(4)
Honville	Loamy silt	0.9	6.7 ^{a)}	1.57	172.0	0.84	Y/ EFSA Journal 2016;14(4)
Laacher Hof Wurmweise	Loam	1.8	5.3 ^{b)}	1.321	73.4	0.92	Y/ EFSA Journal 2016;14(4)
Hoefchen am Hohenseh 4a	Silt loam	2.4	6.6 ^{b)}	0.481	20.0	0.98	Y/ EFSA Journal 2016;14(4)
Les Cayades	Clay loam	0.9	7.6 ^{b)}	0.561	62.3	0.92	Y/ EFSA Journal 2016;14(4)
Guadalupe	Sandy loam	0.7	6.7 ^{b)}	0.675	96.5	0.95	Y/ EFSA Journal 2016;14(4)
Springfield	Silt loam	1.7	6.6 ^{b)}	3.147	185.1	0.90	Y/ EFSA Journal 2016;14(4)
Gross-Umstadt ^{d)}	Silt loam	1.2	7.7 ^{a)}	0.2	18.8	1.05	Y/ EFSA Journal 2016;14(4)
Arrow ^{d)}	Sandy loam	2.3	5.7 ^{a)}	0.7	29.7	0.94	Y/ EFSA Journal 2016;14(4)
Mattapex ^{d)}	Silt loam	2.6	6.4 ^{a)}	0.4	16.7	0.96	Y/ EFSA Journal 2016;14(4)
Matapeake ^{e)}	Silt loam	1.1	5.3 ^{a)}	2.36	214.2	0.841	Y/ EFSA Journal 2016;14(4)
Sassafras ^{e)}	Sand	0.46	6.3 ^{a)}	0.621	133.8	0.784	Y/ EFSA Journal 2016;14(4)
Drummer ^{e)}	Silty clay loam	3.02	5.7 ^{a)}	6.8	225.5	0.841	Y/ EFSA Journal 2016;14(4)
Myaka ^{e)}	Sand	0.58	6.2 ^{a)}	0.264	45.52	0.873	Y/ EFSA Journal 2016;14(4)
Agricultural sand ^{f)}	Sand	0.35	7.9 ^{a)}	0.2326	66.5	0.87	Y/ EFSA Journal 2016;14(4)
Sandy loam ^{f)}	Sandy loam	0.99	7.8 ^{a)}	0.57	58.2	0.902	Y/ EFSA Journal 2016;14(4)
Silt loam ^{f)}	Silt loam	1.74	6.5 ^{a)}	0.9612	55.2	0.847	Y/ EFSA Journal 2016;14(4)
Silty clay loam ^{f)}	Silty clay loam	0.7	6.9 ^{a)}	1.201	171.6	0.823	Y/ EFSA Journal 2016;14(4)
2.2 ^{g)}	Silty sand	1.97	5.4 ^{a)}	0.3728	18.92	0.64	Y/ EFSA Journal 2016;14(4)

AE F059411							
Soil Name	Soil Type	OC (%)	pH (-)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
3A ^{g)}	Sandy loam	2.42	7.3 ^{a)}	0.435	17.97	0.759	Y/ EFSA Journal 2016;14(4)
6S ^{g)}	Clay loam	1.84	6.9 ^{a)}	0.0543	2.95	1.422	Y/ EFSA Journal 2016;14(4)
Speyer 2.1 ^{h)}	-	0.56	6.0 ^{c)}	0.2025	36	0.92	Y/ EFSA Journal 2016;14(4)
Standard soil no. 115 ^{h)}	-	1.7	7.4 ^{c)}	0.6255	37	0.89	Y/ EFSA Journal 2016;14(4)
Standard soil no. 164 ^{h)}	-	3	6.5 ^{c)}	0.645	22	0.92	Y/ EFSA Journal 2016;14(4)
Standard soil no. 243 ^{h)}	-	1.1	4.3 ^{c)}	0.337	31	0.91	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=27)					45.6	-	
Arithmetic mean (n=27)					71.1	0.90	
pH-dependency y/n					No		

^{a)} Medium for the measurement of soil pH not stated.

^{b)} In CaCl₂.

^{c)} In Ca/KCl₂

^{d)} Yeomans & Swales (2000) (accepted in the RARs for metsulfuron-methyl, triasulfuron, prosulfuron and thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))

^{e)} Li & McFetridge (1996) (accepted in the RARs for chlorsulfuron, metsulfuron-methyl, triasulfuron, prosulfuron and thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))

^{f)} Kersterson (1990) (accepted in the RARs for metsulfuron-methyl, triasulfuron, prosulfuron and thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))

^{g)} Morlock (2006) (accepted in the RARs for metsulfuron-methyl and thifensulfuron methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))

^{h)} Van Noorloos & Slangen (2001) (accepted in the RARs for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance thifensulfuron methyl, EFSA (2015))

8.5.1.1 Mesosulfuron-methyl and its metabolites

The soil adsorption/desorption of mesosulfuron-methyl and its metabolites has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(10): 4584); no additional studies are considered for this assessment.

Column leaching studies for mesosulfuron-methyl were not required for EU registration; no additional studies are considered for this assessment.

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

Mesosulfuron-methyl							
Soil name	Soil type	OC (%)	pH (CaCl ₂)	K _f (mL/g)	K _{foc} (mL/g)	I/n (-)	Evaluated on EU level y/n/ Reference
Hamlet Sand (EFS-8)	Hamlet Sand (EFS-8)	0.49	5.0	1.69	345	0.85	Y/ EFSA Journal 2016;14(10)
Sandy Clay Loam (EFS-15)	Sandy Clay Loam (EFS-15)	2.70	7.4	3.71	137	0.93	Y/ EFSA Journal 2016;14(10)
Loamy Sand (EFS-17)	Loamy Sand (EFS-17)	1.13	5.2	0.41	37	0.93	Y/ EFSA Journal 2016;14(10)
Loamy Sand (EFS-18)	Loamy Sand (EFS-18)	2.34	5.2	0.71	31	0.91	Y/ EFSA Journal 2016;14(10)
Sandy Loam (EFS-19)	Sandy Loam (EFS-19)	2.64	7.3	2.28	86	0.90	Y/ EFSA Journal 2016;14(10)
Sandy Loam (EFS-20)	Sandy Loam (EFS-20)	0.91	6.3	0.24	26	0.92	Y/ EFSA Journal 2016;14(10)
Clay Loam (EFS-28)	Clay Loam (EFS-28)	1.68	7.5	0.60	36	0.93	Y/ EFSA Journal 2016;14(10)
Loam (EFS-29)	Loam (EFS-29)	1.43	7.5	1.22	85	0.90	Y/ EFSA Journal 2016;14(10)
Silt Loam (EFS-30)	Silt Loam (EFS-30)	1.16	7.3	0.56	48	0.93	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=9)					64	-	
Arithmetic mean (n=9)					92	0.91	
pH-dependency y/n					No		

Table 8.5-9: Summary of soil adsorption/desorption for metabolite AE F154851

AE F154851							
Soil Name	Soil Type	OC (%)	pH (CaCl₂)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
clay loam	clay loam	3.15	5.8	3.1	98	0.92	Y/ EFSA Journal 2016;14(10)
silt loam	silt loam	1.3	7.4	0.79	61	0.94	Y/ EFSA Journal 2016;14(10)
sandy loam	sandy loam	1.65	5.1	0.75	46	0.95	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=3)					65	-	
Arithmetic mean (n=3)					68	0.94	
pH-dependency y/n					No		

Table 8.5-10: Summary of soil adsorption/desorption for metabolite AE F099095

AE F099095							
Soil Name	Soil Type	OC (%)	pH (CaCl₂)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
clay loam	clay loam	3.15	5.8	42.8	1360	0.83	Y/ EFSA Journal 2016;14(10)
silt loam	silt loam	1.3	7.4	2.94	226	0.84	Y/ EFSA Journal 2016;14(10)
sandy loam	sandy loam	1.65	5.1	2.33	141	0.86	Y/ EFSA Journal 2016;14(10)
sandy loam ^{c)}	sandy loam	1.3	5.7	3.05	235	0.777	Y/ EFSA Journal 2016;14(10)
sandy loam ^{a)}	sandy loam	4.3	5.3	4.81	112	0.737	Y/ EFSA Journal 2016;14(10)
sandy clay loam ^{a)}	sandy clay loam	3.5	7.0	4.39	126	0.78	Y/ EFSA Journal 2016;14(10)
clay ^{a)}	clay	3.8	7.1	4.94	130	0.79	Y/ EFSA Journal 2016;14(10)
sand ^{a)}	sand	1.1	3.9	2.05	186	0.801	Y/ EFSA Journal 2016;14(10)
loamy sand ^{b)}	loamy sand	14.42	3.38	126	874	0.817	Y/ EFSA Journal 2016;14(10)
clay ^{b)}	clay	0.89	7.55	33	3704	0.761	Y/ EFSA Journal 2016;14(10)
silt loam ^{b)}	silt loam	2.13	5.16	11	516	0.802	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=11)					334	-	
Arithmetic mean (n=11)					692	0.80	
pH-dependency y/n					No		

^{a)} Sadgrove, 2014, (accepted in the RARs for flazasulfuron; refer to the EFSA conclusion on the peer review of the active flazasulfuron, EFSA Journal 2016; 14(8): 4575)

^{b)} Refer to the EFSA conclusion on the peer review of the active substance orthosulfamuron, EFSA Journal 2014;12(3):3353)

Table 8.5-11: Summary of soil adsorption/desorption for metabolite AE F092944

AE F092944							
Soil Name	Soil Type	OC (%)	pH (-)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Loamy sand	Loamy sand	1.17	5.00 ^{a)}	2.47	211	0.69	Y/ EFSA Journal 2016;14(10)
Loamy sand	Loamy sand	2.91	5.00 ^{a)}	2.59	89	0.86	Y/ EFSA Journal 2016;14(10)
Sandy loam	Sandy loam	1.32	4.70 ^{a)}	8.25	625	0.65	Y/ EFSA Journal 2016;14(10)
Loamy sand	Loamy sand	0.16	8.00 ^{a)}	1.05 *	663 *	0.52 *	Y/ EFSA Journal 2016;14(10)
Sandy loam	Sandy loam	0.26	7.95 ^{a)}	1.82 *	696 *	0.63 *	Y/ EFSA Journal 2016;14(10)
Sandy loam	Sandy loam	1.04	6.10 ^{a)}	4.11	395	0.78	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	0.72	5.60 ^{a)}	81.3	11289	0.58	Y/ EFSA Journal 2016;14(10)
Silty clay	Silty clay	1.80	7.70 ^{a)}	16.5	917	0.62	Y/ EFSA Journal 2016;14(10)
Loamy sand ^{c)}	Loamy sand c)	2.1	6.4 ^{b)}	1.22	58.1	0.85	Y/ EFSA Journal 2016;14(10)
Loamy sand ^{c)}	Loamy sand c)	0.5	5.2 ^{b)}	2.26	452	0.81	Y/ EFSA Journal 2016;14(10)
Silt loam ^{c)}	Silt loam c)	3.1	5.5 ^{b)}	45.3	1460	0.71	Y/ EFSA Journal 2016;14(10)
Sandy loam ^{c)}	Sandy loam	0.7	7.8 ^{b)}	0.859	123	0.79	Y/ EFSA Journal 2016;14(10)
Silt loam ^{c)}	Silt loam	1.2	5.8 ^{b)}	2.35	196	0.82	Y/ EFSA Journal 2016;14(10)
Loamy sand ^{d)}	Loamy sand	2.29	7.0 ^{b)}	1.17	50.9	0.84	Y/ EFSA Journal 2016;14(10)
Loamy sand ^{d)}	Loamy sand	1.17	7.7 ^{b)}	0.71	60.4	0.82	Y/ EFSA Journal 2016;14(10)
Sisseln, sandy loam ^{d)}	Sandy loam	1.557	7.8 ^{b)}	0.83	52.8	0.92	Y/ EFSA Journal 2016;14(10)
Silt loam ^{d)}	Silt loam	4.05	7.3 ^{b)}	1.70	42.0	0.91	Y/ EFSA Journal 2016;14(10)
Silt loam ^{e)}	Silt loam	1.78	6.9 ^{b)}	11.54	648.3	0.72	Y/ EFSA Journal 2016;14(10)
Sandy loam ^{e)}	Sandy loam	0.58	8.0 ^{b)}	1.92	331.0	0.68	Y/ EFSA Journal 2016;14(10)

Loamy sand ^{e)}	Loamy sand	1.15	6.8 ^{b)}	2.59	225.2	0.79	Y/ EFSA Journal 2016;14(10)
Silty clay loam ^{e)}	Silty clay loam	2.0	5.8 ^{b)}	32.23	1611.5	0.56	Y/ EFSA Journal 2016;14(10)
Sandy loam ^{f)}	Sandy loam	1.1	4.9 ^{a)}	13.77	1252.0	0.632	Y/ EFSA Journal 2016;14(10)
Sandy loam ^{f)}	Sandy loam	1.4	6.2 ^{a)}	5.53	395.0	0.695	Y/ EFSA Journal 2016;14(10)
Sandy clay loam ^{f)}	Sandy clay loam	3.3	7.6 ^{a)}	3.7	112.0	0.754	Y/ EFSA Journal 2016;14(10)
Slay loam ^{f)}	Slay loam	4.0	4.9 ^{a)}	17.99	450.0	0.429	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=23)					293.9		
Arithmetic mean (n=23)					956.4	0.74	
pH-dependency y/n					No		

* Value excluded from the mean calculation

^{a)} Measured in calcium chloride solution

^{b)} Measured in water

^{c)} Aikens, P.J.; 2001 (accepted in the RARs for flupyr-sulfuron-methyl, bensulfuron and azimsulfuron; refer to the EFSA conclusion on the peer review of the active substance flupyr-sulfuron-methyl, EFSA Journal 2014;12(11):3881)

^{d)} Voelkel, W. 1995 (accepted in the RAR for nicosulfuron; refer to the EFSA conclusion on the peer review of the active substance nicosulfuron, EFSA Journal 2008;6(1):120r)

^{e)} Nadeau, R.G., Sidhu, R.S., 1996 (accepted in the RARs for sulfosulfuron and halosulfuron; refer to the EFSA conclusion on the peer review of the active sulfosulfuron, EFSA Journal 2014;12(7):3764)

^{f)} Hiler T, 2006 (accepted in the RARs for flazasulfuron; refer to the EFSA conclusion on the peer review of the active flazasulfuron, EFSA Journal 2016; 14(8): 4575)

Table 8.5-12: Summary of soil adsorption/desorption for metabolite AE F160459

AE F160459							
Soil Name	Soil Type	OC (%)	pH (CaCl ₂)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Loam	Loam	1.8	5.3	0.1978	11.2	0.9320	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	2.4	6.6	0.3797	15.7	0.9388	Y/ EFSA Journal 2016;14(10)
Clay loam	Clay loam	7.42	7.3	0.7630	16.2	0.9267	Y/ EFSA Journal 2016;14(10)
Sandy loam	Sandy loam	0.7	6.7	0.1475	21.1	0.9760	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	1.7	6.6	0.7590	44.6	0.9324	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=5)					19.3		
Arithmetic mean (n=5)					21.8	0.941	
pH-dependency y/n					No		

Table 8.5-13: Summary of soil adsorption/desorption for metabolite AE F160460

AE F160460							
Soil Name	Soil Type	OC (%)	pH (CaCl₂)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Loam	Loam	1.8	5.3	0.2069	11.5	0.9745	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	2.4	6.6	0.2258	9.4	0.8692	Y/ EFSA Journal 2016;14(10)
Clay loam	Clay loam	7.42	7.3	0.3488	7.6	0.8387	Y/ EFSA Journal 2016;14(10)
Sandy loam	Sandy loam	0.7	6.7	0.0743	10.6	0.9524	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	1.7	6.6	0.5329	31.3	0.8628	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=5)					12.2		
Arithmetic mean (n=5)					14.1	0.900	
pH-dependency y/n					No		

Table 8.5-14: Summary of soil adsorption/desorption for metabolite AE F140584

AE F140584							
Soil Name	Soil Type	OC (%)	pH (-)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Geometric mean (n=-)*					0		Y/ EFSA Journal 2016;14(10)
Arithmetic mean (n=-)*					0	1	
pH-dependency y/n					No		

* worst case assumption in absence of experimental study

Table 8.5-15: Summary of soil adsorption/desorption for metabolite AE F147447

AE F147447							
Soil Name	Soil Type	OC (%)	pH (CaCl₂)	K_d (mL/g)	K_{doc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Sandy loam	Sandy loam	2.1	6.4	0.097	4.6	-	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	2.5	6.8	0.096	3.8	-	Y/ EFSA Journal

							2016;14(10)
Loam	Loam	1.3	6.8	0.086	6.6	-	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	2.8	5.6	0.196	7.0	-	Y/ EFSA Journal 2016;14(10)
Clay loam	Clay loam	4.4	7.3	0.181	4.1	-	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=5)					5.1	-	
Arithmetic mean (n=5)					5.2	-	
pH-dependency y/n					No		

Table 8.5-16: Summary of soil adsorption/desorption for metabolite BCS-CV14885

BCS-CV14885							
Soil Name	Soil Type	OC (%)	pH (CaCl ₂)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Loamy sand	Loamy sand	1.7	6.2	0.30	17.5	1.17	Y/ EFSA Journal 2016;14(10)
Loam	Loam	5.1	7.0	0.96	18.8	1.07	Y/ EFSA Journal 2016;14(10)
Silt loam	Silt loam	2.0	6.1	0.27	13.6	1.18	Y/ EFSA Journal 2016;14(10)
Loam	loam	1.9	5.3	0.41	21.7	1.43	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)					17.7		
Arithmetic mean (n=4)					17.8	1.21	
pH-dependency y/n					No		

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Information concerning mobility in soil (lysimeter studies) is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

8.5.2.1 Iodosulfuron-methyl-sodium and its metabolites

Lysimeter studies for iodosulfuron-methyl-sodium has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453). No additional studies are considered for this assessment. The results of two lysimeter studies were only considered indicative. Even under realistic worst-case conditions for leaching, in one study an atypical leaching event has been established, and at factor 1.5 exaggerated maximum application rate, neither iodosulfuron-methyl-sodium nor its main soil metabolite AE F075736, or any other metabolite, leached at concentrations that pose a risk to ground water.

8.5.2.2 Mesosulfuron-methyl and its metabolites

Lysimeter studies for mesosulfuron-methyl have been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(10): 4584; no additional studies are considered for this assessment.

Averaged yearly concentrations in leachates (µg/L), active substance and degradates where exceeding 0.1 µg/L:

Study design	Compound	1 st year	2 nd year	3 rd year
spring application (April-May) of 15 g/ha pyrimidyl label a.s. in 2 consecutive years, silty sand soil, 2 replicate cores, yearly rainfall 874 – 1127 mm. Total duration 3 years	parent a.s.	not detected	not detected	not detected
	BCS-CV14885	0.240 µg/L	0.241 µg/L	0.269 µg/L
autumn application (November) of 15 g/ha pyrimidyl label a.s. in 2 consecutive years, silty sand soil, 2 replicate cores, yearly rainfall 823 – 1160 mm. Total duration 3 years.	parent a.s.	(not analysed)	not detected	not detected
	BCS-CV14885	(not analysed)	0.481 µg/L	0.154 µg/L

For metabolite BCS-CV14885 the average annual concentration of radioactivity in leachates was 0.2 µg/L (spring applications) and in the range of 0.15-0.48 µg/L (autumn applications). Therefore, metabolite BCS-CV14885 was included in the groundwater exposure assessment.

Since the component was not found formed to notable abundance in the standard aerobic soil metabolism studies, soil half-life information was generated separately in a metabolite-dosed test, cf. Section 8.3. In the EU review, a kinetic formation fraction from mesosulfuron-methyl (kf/kdp) of 0.096 was agreed for BCS-CV14885.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Information concerning mobility in soil (field leaching studies) is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

Field leaching studies for **iodosulfuron-methyl-sodium** were not required for EU registration as sufficient information can be derived from the existing studies; no additional studies are considered for this assessment.

Field leaching studies for **mesosulfuron-methyl** were not required for EU registration as sufficient information can be derived from the existing studies, no additional studies are considered for this assessment.

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

Information concerning degradation in the water/sediment is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

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

8.6.1 Iodosulfuron-methyl-sodium and its metabolites

The degradation of iodosulfuron-methyl-sodium in water/sediment systems has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453). No additional studies are considered for this assessment.

Table 8.6-1: Summary of degradation in water/sediment of iodosulfuron-methyl-sodium

Iodosulfuron-methyl-sodium Distribution: mainly distributed to water phase										
Water/sediment system	pH water/sed.	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Nidda	8.3 / -	20.4	68.0	SFO	19.0	63.3	SFO	21.2	SFO	Y/ EFSA Journal 2016;14(4)
Rhine	7.7 / -	11.3	37.6	SFO	10.5	34.8	SFO	2.2	FOMC	Y/ EFSA Journal 2016;14(4)
Pikeville	7.1 / 5.4 ^{a)}	33.9	112.7	SFO	28.4	94.4	SFO	- ^{b)}	SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=3)		19.8	66.1		17.8	59.2		6.8		

^{a)} measured in CaCl₂

^{b)} no reliable value determinable

Table 8.6-2: Summary of degradation in water/sediment of AE F075736

AE F075736 Distribution; max. 67.8% total system (43 d), 57% water (43 d), 15.9% sediment (14 d)										
Water/sediment system	pH water/sed.	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Nidda	8.3 / -	68.4	227.4	SFO	169.4	562.9	SFO	134.9	SFO	Y/ EFSA Journal 2016;14(4)
Rhine	7.7 / -	39.2	130.4	SFO	24.0	79.7	SFO	29.4	SFO	Y/ EFSA Journal 2016;14(4)
Pikeville	7.1 / 5.4 ^{a)}	97.8	324.9	SFO	- ^{b)}		SFO	- ^{b)}	SFO	Y/ EFSA Journal 2016;14(4)
Birkenbach ^{e)}	8 / 7.2	272.5	905.1	SFO	231.3	857.5	DFOP	>1000	FOMC	Y/ EFSA Journal 2016;14(4)

AE F075736 Distribution; max. 67.8% total system (43 d), 57% water (43 d), 15.9% sediment (14 d)										
Water/sediment system	pH water/sed.	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Unter-Widdersheim ^{e)}	7.6 / 7.6	50.2	166	SFO	45.3	150.4 ^{c)}	SFO	41.1	SFO	Y/ EFSA Journal 2016;14(4)
Pond ^{f)}	7.7 / 7.3	305.5 ^{c)}	1014 ^{c)}	SFO	180.4 ^{c)}	599.1 ^{c)}	SFO	>1000 ^{c)}	SFO	Y/ EFSA Journal 2016;14(4)
Creek ^{g)}	8.3 / -	605.5 ^{c)}	1973 ^{c,d)}	SFO/DFOP	413.4 ^{c)}	1373 ^{c)}	SFO	>1000 ^{c)}	SFO	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=7)		131.0	433.9		113.4	410.1		- ^{h)}		

^{a)} measured in CaCl₂

^{b)} no reliable value determinable

^{c)} Extrapolated beyond the study period

^{d)} Calculated from slow phase of DFOP model ($\ln(2)/k_2$)

^{e)} Knoch, E., Dust M. (1999) (accepted in the RARs for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{f)} Morlock (2006n) (accepted in the RARs for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{g)} Morlock (2006m) (accepted in the RARs for metsulfuron-methyl; refer to the EFSA conclusion on the peer review of the active substance metsulfuron-methyl, EFSA (2015))

^{h)} no geomean determinable with relative values of > 1000

Table 8.6-3: Summary of degradation in water/sediment of AE F145740

AE F145740 Distribution: max. 12.6% total system (60-79 d), 9.2% water (79 d), 3.5% sediment (60-79 d)										
Water/sediment system	pH water/sed.	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Pikeville	7.1 / 5.4 ^{a)}	45.4	150.9	SFO	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	Y/ EFSA Journal 2016;14(4)
Endpoint		45.4								

^{a)} measured in CaCl₂

^{b)} no reliable value determinable

Table 8.6-4: Summary of degradation in water/sediment of AE F145741

AE F145741 Distribution: max. 8.7% total system (46 d), 7.0% water (46 d), 1.9% sediment (79-100 d)										
Water/sediment system	pH water/sed.	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Pikeville	7.1 / 5.4 ^{a)}	73.4	243.7	SFO	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	Y/ EFSA Journal 2016;14(4)
Endpoint		73.4								

^{a)} measured in CaCl₂

^{b)} no reliable value determinable

Table 8.6-5: Summary of degradation in water/sediment of AE 0000119

AE 0000119 Distribution: max. 24.9% total system (120 d), 17.7% water (91 d), 15.0% sediment (182 d)										
Water/sediment system	pH water/sed.	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Nidda	8.3 / -	27.1	90.2	SFO	- ^{a)}	- ^{a)}	- ^{a)}	- ^{a)}	- ^{a)}	Y/ EFSA Journal 2016;14(4)
Rhine	7.7 / -	29.8	98.9	SFO	84.6	281.0	SFO	- ^{a)}	- ^{a)}	Y/ EFSA Journal 2016;14(4)
Geometric mean (n=2)		28.4								

^{a)} no reliable value determinable

Table 8.6-6: Summary of degradation in water/sediment of AE F059411

AE F059411 Distribution: max. 27.5% total system (182 d), 19.3% water (182 d), 8.3% sediment (182 d)										
Water/sediment system	pH water/sed.	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Nidda	8.3 / -	9.9	32.8	SFO	- ^{a)}	- ^{a)}	- ^{a)}	- ^{a)}	- ^{a)}	Y/ EFSA Journal 2016;14(4)
Endpoint		9.9								

^{a)} no reliable value determinable

Table 8.6-7: Summary of degradation in water/sediment of AE 0014966

AE 0014966 Distribution: max. 15.5% total system (91 d), 11.8 water (100 d), 5.9% sediment (43 d)										
Water/sediment system	pH water/sed.	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Pikeville	7.1 / 5.4 ^{a)}	43.8	145.7	SFO	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	Y/ EFSA Journal 2016;14(4)
Endpoint		43.8								

^{a)} measured in CaCl₂

^{b)} no reliable value determinable

Metabolites AE 0034855, AE F150737 and AE 1234964 are summarized in one table because no reliable values could be determined for all the metabolites and for all test systems.

Table 8.6-8: Summary of degradation in water/sediment of AE 0034855, AE F150737 and AE 1234964

AE 0034855 Distribution: max. 24.2% total system (182 d), 16.7 water (182 d), 10.7% sediment (150 d)										
AE F150737 Distribution: max. 7.8% total system (100 d = study end), 6.1 water (100 d), 1.6% sediment (100 d)										
AE 1234964 Distribution: max. 7.4% total system (100 d = study end), 6.8 water (100 d), 0.6% sediment (100 d)										
Water/sediment system	pH water/sed.	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Nidda	8.3 / -	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	Y/ EFSA Journal 2016;14(4)
Rhine	7.7 / -	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	Y/ EFSA Journal 2016;14(4)
Pikeville	7.1 / 5.4 ^{a)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	- ^{b)}	Y/ EFSA Journal 2016;14(4)
Endpoint		- ^{b)}								

^{a)} measured in CaCl₂

^{b)} no reliable value determinable

Table 8.6-9: Summary of observed metabolites

AE F075736	Max. in water/sediment: 67.8% after 43 d (Rhine, triazinyl-label)	Y/ EFSA Journal 2016;14(4)
Water/sediment system	Max. in water: 57.0% after 43 d (Rhine, triazinyl-label) Max. in sediment: 15.9% after 14 d (Rhine, triazinyl-label)	

AE F145740 Water/sediment system	Max. in water/sediment: 12.6% after 60 and 79 d (Pikeville, phenyl-label) Max. in water: 9.2% after 79 d (Pikeville, phenyl-label)Max. in sediment: 3.5% after 60 and 79 d (Pikeville, phenyl-label)	Y/ EFSA Journal 2016;14(4)
AE F145741 Water/sediment system	Max. in water/sediment: 8.7% after 46 d (Pikeville, phenyl-label) Max. in water: 7.0% after 46 d (Pikeville, phenyl-label) Max. in sediment: 1.9% after 79 and 100 d (Pikeville, phenyl-label)	Y/ EFSA Journal 2016;14(4)
AE 0000119 Water/sediment system	Max. in water/sediment: 24.9% after 120 d (Rhine, triazinyl-label) Max. in water: 17.7% after 91 d (Rhine, triazinyl-label) Max. in sediment: 15.0% after 182 d (Nidda, triazinyl-label)	Y/ EFSA Journal 2016;14(4)
AE F059411 Water/sediment system	Max. in water/sediment: 27.5% after 182 d (Rhine, triazinyl-label) Max. in water: 19.3% after 182 d (Rhine, triazinyl-label) Max. in sediment: 8.3% after 182d (Rhine, triazinyl-label)	Y/ EFSA Journal 2016;14(4)
AE 0014966 Water/sediment system	Max. in water/sediment: 15.5% after 91 d (Rhine, triazinyl-label) Max. in water: 11.8% after 100 d (Pikeville, phenyl-label) Max. in sediment: 5.9% after 43 d (Rhine, triazinyl-label)	Y/ EFSA Journal 2016;14(4)
AE 0034855 Water/sediment system	Max. in water/sediment: 24.2% after 182 d (Rhine, triazinyl-label) Max. in water: 16.7% after 182 d (Rhine, triazinyl-label) Max. in sediment: 10.7% after 150 d (Rhine, triazinyl-label)	Y/ EFSA Journal 2016;14(4)
AE F150737 Water/sediment system	Max. in water/sediment: 7.8% after 100 d (Pikeville, phenyl-label) Max. in water: 6.1% after 100 d (Pikeville, phenyl-label) Max. in sediment: 1.6% after 100 d (Pikeville, phenyl-label)	Y/ EFSA Journal 2016;14(4)
AE 1234964 Water/sediment system	Max. in water/sediment: 7.4% after 100 d (Pikeville, phenyl-label) Max. in water: 6.8% after 100 d (Pikeville, phenyl-label) Max. in sediment: 0.6% after 100 d (Pikeville, phenyl-label)	Y/ EFSA Journal 2016;14(4)

8.6.2 Mesosulfuron-methyl and its metabolites

The degradation of mesosulfuron-methyl in water/sediment systems has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(10): 4584, no additional studies are considered for this assessment.

Table 8.6-10: Summary of degradation in water/sediment of mesosulfuron-methyl

Mesosulfuron-methyl Distribution: Max. sed. 20.0% after 7 d										
Water/sediment system	pH water/sed. ^{a)}	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Kies ([¹⁴C-phenyl]-label)	7.2/7.2	81.15	269.6	SFO	72.7	241.5	SFO	No reliable DT50 derived	-	Y/ EFSA Journal 2016;14(10)
Kies ([¹⁴C-pyrimidyl]-label)	7.2/7.2	68.93	228.98	SFO	61.65	204.8	SFO	62.83	SFO	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴C-phenyl]-label)	7.8/6.4	26.82	89.08	SFO	12.79 (back-DT50:	68.19	FOMC	79.32	SFO	Y/ EFSA Journal 2016;14(10)

Mesosulfuron-methyl Distribution: Max. sed. 20.0% after 7 d										
Water/sediment system	pH water/sed. ^{a)}	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
					20.53					
Nidda ([¹⁴C-pyrimidyl]-label)	7.8/6.4	22.81	75.78	SFO	14.42	47.9	SFO	44.45	SFO	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)		43.01	-		33.9	-		60.51		

^{a)} measured in CaCl₂

Table 8.6-11: Summary of degradation in water/sediment of metabolite AE F154851

AE F154851 Distribution: Max in total system 4.9% after 14 days										
Water/sediment system	pH water/sed. ^{a)}	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Kies ([¹⁴C-phenyl]-label)	7.2/7.2	1000		-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Kies ([¹⁴C-pyrimidyl]-label)	7.2/7.2	100.04	332.34	SFO	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴C-phenyl]-label)	7.8/6.4	11.03	36.64	SFO	33.11	110.0	SFO	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴C-pyrimidyl]-label)	7.8/6.4	8.12	26.98	SFO	25.29	84.02	SFO	-	-	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)		54.7	-		-	-		-		

^{a)} measured in CaCl₂

Table 8.6-12: Summary of degradation in water/sediment of metabolite AE F160459

AE F160459 Distribution: Max in total system 4.9% after 14 days										
Water/sediment system	pH water/sed. ^{a)}	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Kies ([¹⁴C-phenyl]-label)	7.2/7.2	1000		-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Kies ([¹⁴C-pyrimidyl]-label)	7.2/7.2	77.39	257.08	SFO						Y/ EFSA Journal

AE F160459 Distribution: Max in total system 4.9% after 14 days										
Water/sediment system	pH water/sed. ^{a)}	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	Kinetic, Fit	DissT ₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
label)										2016;14(10)
Nidda ([¹⁴ C-phenyl]-label)	7.8/6.4	43.98	146.11	SFO						Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-pyrimidyl]-label)	7.8/6.4	17.45	57.98	SFO						Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)		87.8	-							

^{a)} measured in CaCl₂

Table 8.6-13: Summary of degradation in water/sediment of metabolite AE F160460

AE F160460 Distribution: Max in total system 8.4 % after 28 days										
Water/sediment system	pH water/sed. ^{a)}	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	Kinetic, Fit	DissT ₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Kies ([¹⁴ C-phenyl]-label)	7.2/7.2	1000		-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Kies ([¹⁴ C-pyrimidyl]-label)	7.2/7.2	1000		-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-phenyl]-label)	7.8/6.4	101.6	337.4	Peak down	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-pyrimidyl]-label)	7.8/6.4	111.0	368.7	Peak down	70.59	234.5		-	-	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)		325.9	-		-	-		-		

^{a)} measured in CaCl₂

Table 8.6-14: Summary of degradation in water/sediment of metabolite AE F147447

AE F147447 Distribution: Max in total system 10.9% after 141 days										
Water/sediment system	pH water/sed. ^{a)}	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	Kinetic, Fit	DissT ₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Kies ([¹⁴ C-	7.2/7.2	1000		-	-	-	-	-	-	Y/ EFSA

AE F147447 Distribution: Max in total system 10.9% after 141 days										
Water/sediment system	pH water/sed. ^{a)}	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
<i>phenyl</i>]-label)										Journal 2016;14(10)
Kies ([¹⁴ C-pyrimidyl]-label)	7.2/7.2	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-phenyl]-label)	7.8/6.4	1000	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-pyrimidyl]-label)	7.8/6.4	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)		1000	-		-	-		-		

^{a)} measured in CaCl₂

Table 8.6-15: Summary of degradation in water/sediment of metabolite AE F092944

AE F092944 Distribution: Max in total system 3.2% after 112 days										
Water/sediment system	pH water/sed. ^{a)}	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Kies ([¹⁴ C-phenyl]-label)	7.2/7.2	1000		-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Kies ([¹⁴ C-pyrimidyl]-label)	7.2/7.2	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-phenyl]-label)	7.8/6.4	1000		-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-pyrimidyl]-label)	7.8/6.4	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)		1000	-		-	-		-		

^{a)} measured in CaCl₂

Table 8.6-16: Summary of degradation in water/sediment of metabolite AE F099095

AE F099095 Distribution: Max in total system 3.2% after 112 days										
Water/sediment system	pH water/sed. ^{a)}	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Kies ([¹⁴ C-phenyl]-label)	7.2/7.2	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Kies ([¹⁴ C-pyrimidyl]-label)	7.2/7.2	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-phenyl]-label)	7.8/6.4	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-pyrimidyl]-label)	7.8/6.4	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)		-	-		-	-		-		

^{a)} measured in CaCl₂

Table 8.6-17: Summary of degradation in water/sediment of metabolite BCS-CVI4885

BCS-CVI4885 Distribution: Max in total system 22.0 % after 309 days										
Water/sediment system	pH water/sed. ^{a)}	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Kies ([¹⁴ C-phenyl]-label)	7.2/7.2	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Kies ([¹⁴ C-pyrimidyl]-label)	7.2/7.2	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-phenyl]-label)	7.8/6.4	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-pyrimidyl]-label)	7.8/6.4	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)		-	-		-	-		-		

^{a)} measured in CaCl₂

Table 8.6-18: Summary of degradation in water/sediment of metabolite BCS-CO60720

BCS-CO60720 Distribution: Max in total system 13.1 % after 365 days										
Water/sediment system	pH water/sed. ^{a)}	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Kies ([¹⁴ C-phenyl]-label)	7.2/7.2	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Kies ([¹⁴ C-pyrimidyl]-label)	7.2/7.2	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-phenyl]-label)	7.8/6.4	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Nidda ([¹⁴ C-pyrimidyl]-label)	7.8/6.4	-	-	-	-	-	-	-	-	Y/ EFSA Journal 2016;14(10)
Geometric mean (n=4)		-	-		-	-		-		

^{a)} measured in CaCl₂

Table 8.6-19: Summary of observed metabolites

AE F154851 Water/sediment system	Max in total system 4.9% after 14 days Nidda ([¹⁴ C-phenyl]-label)	Y/ EFSA Journal 2016;14(10)
AE F160459 Water/sediment system	Max in total system 21.6% after 112 days Kies ([¹⁴ C-pyrimidyl]-label)	Y/ EFSA Journal 2016;14(10)
AE F160460 Water/sediment system	Max in total system 8.4% after 28 days Nidda ([¹⁴ C-pyrimidyl]-label)	Y/ EFSA Journal 2016;14(10)
AE F147447 Water/sediment system	Max in total system 10.9% after 141 days Kies ([¹⁴ C-phenyl]-label)	Y/ EFSA Journal 2016;14(10)
AE F092944 Water/sediment system	Max in total system 3.2% after 112 days Nidda ([¹⁴ C-pyrimidyl]-label)	Y/ EFSA Journal 2016;14(10)
AE F099095 Water/sediment system	Max in total system 0.9% after 141 days Kies ([¹⁴ C-pyrimidyl]-label)	Y/ EFSA Journal 2016;14(10)
BCS-CV14885 Water/sediment system	Max in total system 22.0% after 309 days Kies ([¹⁴ C-pyrimidyl]-label)	Y/ EFSA Journal 2016;14(10)
BCS-CO60720 Water/sediment system	Max in total system 13.1% after 365 days Kies ([¹⁴ C-pyrimidyl]-label)	Y/ EFSA Journal 2016;14(10)

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

zRMS

Comments:

The PEC_{SOIL} assessment for active substances and their metabolites was accepted. Calculations were made for a higher dose than proposed in the GAP table. The risk envelope approach and the crop interception of 0% were taken into consideration. The submitted assessment represents a worse case.

The endpoints used for soil exposure assessment are consistent with the list of endpoints for active substances and its metabolites.

The DT₅₀ values for active substances and their metabolites used for PEC_{SOIL} assessment was accepted as it represents the worst case.

Iodosulfuron-methyl-sodium:

The PEC_{SOIL} values for active substance and its metabolites at single application for cereals are presented in the table below:

	PECs [mg/kg soil]
Iodosulfuron-methyl-sodium	0.013
AE F075736	0.009
AE F145741	0.001
AE F145740	0.001
AE 0002166	0.001
AE F161778	0.001
BCS-CW81253	0.003
	0.003*
AE 0000119	<0.001
	0.001*
AE F059411	0.001
	0.002*

*PEC_{SOIL} accum

Mesosulfuron-methyl:

The PEC_{SOIL} values for active substance and its metabolites at single application for cereals are presented in the table below:

	PECs [mg/kg soil]
Mesosulfuron-methyl	0.020
	0.022*
AE F154851	0.003
	0.004*
AE F160459	0.002
	0.002*
AE F099095	0.002
	0.003*
AE F092944	<0.001
AE F160460	0.002
AE F140584	<0.001
AE F147447	0.001
	0.002*

*PEC_{SOIL} accum

Formulation:

Calculations of PEC_{SOIL} for formulation was accepted as a worse case. For formulation PEC_{SOIL}= 2.0000 mg/kg soil.

These values will be used in further risk assessment.

Information concerning PECs for active substances and relevant metabolites is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

8.7.1 Justification for new endpoints

No new endpoints were used.

Note for mesosulfuron-methyl and metabolites: The exemplary PEC_{soil} calculations provided in the EU List of Endpoints for mesosulfuron were based on an interim set of parameters which during the review process had not been updated to reflect the final EU agreed kinetic endpoints. Since "Agreed trigger endpoints should be considered in further exposure calculations", the simulations presented here below are based on the final agreed trigger endpoints (maximum of laboratory soil DT_{50}) as summarised in Section 8.3.1 of the present dRR, sourced from pages 25-29 of Appendix A to EFSA Journal 2016;14(10):4584.

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

Not relevant. See point 8.7.

Input parameters related to application:

Iodosulfuron-methyl-sodium

For the active substance **iodosulfuron-methyl-sodium** and its metabolites risk assessments based on PEC_{soil} calculations are passed without any refinement, even if worst case PEC_{soil} values are considered. Therefore, to simplify the assessment, PEC_{soil} for this compound is calculated in a "risk envelope approach", addressing the maximum registered application rate and overall worst case exposure situation (no tillage, no crop interception) which is relevant for the compound in any product supported by Bayer AG in Europe.

The resulting PEC_{soil} calculations overestimate the actual exposure due to use of the product, and thus further increase the conservatism of the Tier 1 risk assessments.

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

Use No.	risk envelope covering all uses of iodosulfuron-methyl-sodium
Crop	cereals, maize, non-cropped area (risk envelope)
Application rate (g a.s./ha)	10 g a.s./ha (risk envelope)
Number of applications/interval	1 / -
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	10 cm (no tillage)

Mesosulfuron-methyl

For the active substance **mesosulfuron-methyl** (and metabolites) risk assessments based on PEC_{soil} calculations are passed without any refinement, even if worst case PEC_{soil} values are considered. Therefore, to simplify the assessment, PEC_{soil} is calculated in a "risk envelope approach", addressing the maximum registered application rate and overall worst case exposure situation (no tillage, no crop

interception) which is relevant for the compound in any product supported by Bayer AG in Europe. The resulting PEC_{soil} calculations may overestimate the actual exposure due to use of the present product, and thus further increase the conservatism of the Tier 1 risk assessments.

Table 8.7-2: Input parameters related to application for PEC_{soil} calculations - mesosulfuron-methyl

Use No.	risk envelope covering all uses of mesosulfuron-methyl
Crop	cereals (risk envelope)
Application rate (g a.s./ha)	15 g a.s./ha (risk envelope)
Number of applications/interval	1 / -
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	10 cm (no tillage)

Substance parameters for active substances and metabolites:

Table 8.7-3: Input parameter for iodosulfuron-methyl-sodium and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
iodosulfuron-methyl-sodium	529.3	100	20.8	Y/ EFSA Journal 2016;14(4)
AE F075736	381.4	88.5	66.7	Y/ EFSA Journal 2016;14(4)
AE F145741	493.2	6.9	41.7	Y/ EFSA Journal 2016;14(4)
AE F145740	493.2	8.7	55.8	Y/ EFSA Journal 2016;14(4)
AE 0002166	397.4	20.0	10.1	Y/ EFSA Journal 2016;14(4)
AE F161778	367.3	14.5	30.4	Y/ EFSA Journal 2016;14(4)
BCS-CW81253	343.3	35.1	115.78	Y/ EFSA Journal 2016;14(4)
AE 0000119	183.2	19.9	231	Y/ EFSA Journal 2016;14(4)
AE F059411	140.1	40.9	276.9	Y/ EFSA Journal 2016;14(4)

Table 8.7-4: Input parameter for mesosulfuron-methyl and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Mesosulfuron-methyl	503.5	100	140.1	Y/ EFSA Journal 2016;14(10):4584
AE F154851	489.5	16.2	207.4	Y/ EFSA Journal 2016;14(10):4584
AE F160459	489.5	8.9	129.8	Y/ EFSA Journal 2016;14(10):4584
AE F099095	198.2	29.2	185.5	Y/ EFSA Journal 2016;14(10):4584
AE F092944	155.2	10.1	82.7	Y/ EFSA Journal 2016;14(10):4584
AE F160460	475.5	8.6	44.2	Y/ EFSA Journal 2016;14(10):4584
AE F140584	322.4	7.1	13.5	Y/ EFSA Journal 2016;14(10):4584
AE F147447	290.3	6.5	157.1	Y/ EFSA Journal 2016;14(10):4584

8.7.2.1 Iodosulfuron-methyl-sodium and its metabolites

Table 8.7-5: PEC_{soil} for iodosulfuron-methyl-sodium

PEC_{soil} (mg/kg)		Risk envelope approach – cereals, maize, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.013	-	-	-
Short term	24h	0.013	0.013	-	-
	2d	0.012	0.013	-	-
	4d	0.012	0.012	-	-
Long term	7d	0.011	0.012	-	-
	14d	0.008	0.011	-	-
	21d	0.007	0.01	-	-
	28d	0.005	0.009	-	-
	42 d	0.003	0.007	-	-
	50d	0.003	0.006	-	-
	100d	<0.001	0.004	-	-

Table 8.7-6: PEC_{soil} for AE F075736

PEC_{soil}	Risk envelope approach – cereals, maize, non-cropped area
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(mg/kg)		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.009	-	-	-
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	0.007	0.008	-	-
	21d	0.007	0.008	-	-
	28d	0.006	0.007	-	-
	42 d	0.005	0.007	-	-
	50d	0.005	0.007	-	-
	100d	0.003	0.005	-	-

Table 8.7-7: PEC_{soil} for AE F145741

PEC_{soil} (mg/kg)		Risk envelope approach – cereals, maize, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.001	-	-	-
Short term	24h	0.001	0.001	-	-
	2d	0.001	0.001	-	-
	4d	0.001	0.001	-	-
Long term	7d	0.001	0.001	-	-
	14d	0.001	0.001	-	-
	21d	0.001	0.001	-	-
	28d	0.001	0.001	-	-
	42d	0.001	0.001	-	-
	50d	0.001	0.001	-	-
	100d	0.001	0.001	-	-

Table 8.7-8: PEC_{soil} for AE F145740

PEC_{soil} (mg/kg)		Risk envelope approach – cereals, maize, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.001	-	-	-
Short term	24h	0.001	0.001	-	-
	2d	0.001	0.001	-	-
	4d	0.001	0.001	-	-
Long term	7d	0.001	0.001	-	-
	14d	0.001	0.001	-	-

	21d	0.001	0.001	-	-
	28d	0.001	0.001	-	-
	42d	0.001	0.001	-	-
	50d	0.001	0.001	-	-
	100d	0.001	0.001	-	-

Table 8.7-9: PEC_{soil} for AE 0002166

PEC_{soil} (mg/kg)		Risk envelope approach – cereals, maize, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.001	-	-	-
Short term	24h	0.001	0.001	-	-
	2d	0.001	0.001	-	-
	4d	0.001	0.001	-	-
Long term	7d	0.001	0.001	-	-
	14d	0.001	0.001	-	-
	21d	0.001	0.001	-	-
	28d	0.001	0.001	-	-
	42d	0.001	0.001	-	-
	50d	0.001	0.001	-	-
	100d	0.001	0.001	-	-

Table 8.7-10: PEC_{soil} for AE F161778

PEC_{soil} (mg/kg)		Risk envelope approach – cereals, maize, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.001	-	-	-
Short term	24h	0.001	0.001	-	-
	2d	0.001	0.001	-	-
	4d	0.001	0.001	-	-
Long term	7d	0.001	0.001	-	-
	14d	<0.001	0.001	-	-
	21d	<0.001	0.001	-	-
	28d	<0.001	< 0.001	-	-
	42d	<0.001	< 0.001	-	-
	50d	<0.001	< 0.001	-	-
	100d	<0.001	< 0.001	-	-

Table 8.7-11: PEC_{soil} for BCS-CW81253

PEC_{soil} (mg/kg)		Risk envelope approach – cereals, maize, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.003	-	-	-
Short term	24h	0.003	0.003	-	-
	2d	0.003	0.003	-	-
	4d	0.003	0.003	-	-
Long term	7d	0.003	0.003	-	-
	14d	0.003	0.003	-	-
	21d	0.003	0.003	-	-
	28d	0.003	0.003	-	-
	42d	0.002	0.003		
	50d	0.002	0.003	-	-
	100d	0.002	0.002	-	-
Plateau concentration (10 cm)		<0.001	-	-	-
$PEC_{accumulation} (PEC_{act} + PEC_{soil\ plateau})$		0.003	-	-	-

Table 8.7-12: PEC_{soil} for AE 0000119

PEC_{soil} (mg/kg)		Risk envelope approach – cereals, maize, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		<0.001	-	-	-
Short term	24h	<0.001	<0.001	-	-
	2d	<0.001	<0.001	-	-
	4d	<0.001	<0.001	-	-
Long term	7d	<0.001	<0.001	-	-
	14d	<0.001	<0.001	-	-
	21d	<0.001	<0.001	-	-
	28d	<0.001	<0.001	-	-
	42d	<0.001	<0.001	-	-
	50d	<0.001	<0.001	-	-
	100d	<0.001	<0.001	-	-
Plateau concentration (10 cm)		<0.001	-	-	-
$PEC_{accumulation} (PEC_{act} + PEC_{soil\ plateau})$		0.001	-	-	-

Table 8.7-13: PEC_{soil} for AE F059411

PEC_{soil} (mg/kg)		Risk envelope approach – cereals, maize, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.001	-	-	-
Short term	24h	0.001	0.001	-	-
	2d	0.001	0.001	-	-
	4d	0.001	0.001	-	-
Long term	7d	0.001	0.001	-	-
	14d	0.001	0.001	-	-
	21d	0.001	0.001	-	-
	28d	0.001	0.001	-	-
	42d	0.001	0.001	-	-
	50d	0.001	0.001	-	-
	100d	0.001	0.001	-	-
Plateau concentration (10 cm)		<0.001	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		0.002	-	-	-

8.7.2.2 Mesosulfuron-methyl and its metabolites

Table 8.7-14: PEC_{soil} for mesosulfuron-methyl

PEC_{soil} (mg/kg)		Risk envelope approach – cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.020	-	-	-
Short term	24h	0.020	0.020	-	-
	2d	0.020	0.020	-	-
	4d	0.020	0.020	-	-
Long term	7d	0.019	0.020	-	-
	14d	0.019	0.019	-	-
	21d	0.018	0.019	-	-
	28d	0.017	0.019	-	-
	42d	0.016	0.018	-	-
	50d	0.016	0.018	-	-
	100d	0.012	0.016	-	-
Plateau concentration (10 cm) after year 2		0.002	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		0.022	-	-	-

Table 8.7-15: PEC_{soil} for AE F154851

PEC_{soil} (mg/kg)		Risk envelope approach – cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.003	-	-	-
Short term	24h	0.003	0.003	-	-
	2d	0.003	0.003	-	-
	4d	0.003	0.003	-	-
Long term	7d	0.003	0.003	-	-
	14d	0.003	0.003	-	-
	21d	0.003	0.003	-	-
	28d	0.003	0.003	-	-
	42d	0.003	0.003	-	-
	50d	0.003	0.003	-	-
	100d	0.002	0.003	-	-
Plateau concentration (10 cm) after year 2		<0.001	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		0.004	-	-	-

Table 8.7-16: PEC_{soil} for AE F160459

PEC_{soil} (mg/kg)		Risk envelope approach – cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.002	-	-	-
Short term	24h	0.002	0.002	-	-
	2d	0.002	0.002	-	-
	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	-	-
	42d	0.001	0.002	-	-
	50d	0.001	0.002	-	-
	100d	0.001	0.001	-	-
Plateau concentration (10 cm) after year 2		<0.001	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		0.002	-	-	-

Table 8.7-17: PEC_{soil} for AE F099095

PEC _{soil} (mg/kg)		Risk envelope approach – cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.002	-	-	-
Short term	24h	0.002	0.002	-	-
	2d	0.002	0.002	-	-
	4d	0.002	0.002	-	-
Long term	7d	0.002	0.002	-	-
	14d	0.002	0.002	-	-
	21d	0.002	0.002	-	-
	28d	0.002	0.002	-	-
	42d	0.002	0.002	-	-
	50d	0.002	0.002	-	-
	100d	0.002	0.002	-	-
Plateau concentration (10 cm) after year 2		<0.001	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.003	-	-	-

Table 8.7-18: PEC_{soil} for AE F092944

PEC _{soil} (mg/kg)		Risk envelope approach – cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		<0.001	-	-	-
Short term	24h	<0.001	<0.001	-	-
	2d	<0.001	<0.001	-	-
	4d	<0.001	<0.001	-	-
Long term	7d	<0.001	<0.001	-	-
	14d	<0.001	<0.001	-	-
	21d	<0.001	<0.001	-	-
	28d	<0.001	<0.001	-	-
	42d	<0.001	<0.001	-	-
	50d	<0.001	<0.001	-	-
	100d	<0.001	<0.001	-	-
Plateau concentration (10 cm) after year 1		<0.001	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		<0.001	-	-	-

Table 8.7-19: PEC_{soil} for AE F160460

PEC_{soil} (mg/kg)		Risk envelope approach – cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.002	-	-	-
Short term	24h	0.002	0.002	-	-
	2d	0.002	0.002	-	-
	4d	0.002	0.002	-	-
Long term	7d	0.001	0.002	-	-
	14d	0.001	0.001	-	-
	21d	0.001	0.001	-	-
	28d	0.001	0.001	-	-
	42d	<0.001	0.001	-	-
	50d	<0.001	0.001	-	-
	100d	<0.001	<0.001	-	-
Plateau concentration (10 cm) after year 1		<0.001	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		0.002	-	-	-

Table 8.7-20: PEC_{soil} for AE F140584

PEC_{soil} (mg/kg)		Risk envelope approach – cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		<0.001	-	-	-
Short term	24h	<0.001	<0.001	-	-
	2d	<0.001	<0.001	-	-
	4d	<0.001	<0.001	-	-
Long term	7d	<0.001	<0.001	-	-
	14d	<0.001	<0.001	-	-
	21d	<0.001	<0.001	-	-
	28d	<0.001	<0.001	-	-
	42d	<0.001	<0.001	-	-
	50d	<0.001	<0.001	-	-
	100d	<0.001	<0.001	-	-
Plateau concentration (10 cm) after year 2		<0.001	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		<0.001	-	-	-

Table 8.7-21: PEC_{soil} for AE F147447

PEC_{soil} (mg/kg)		Risk envelope approach – cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		<0.001	-	-	-
Short term	24h	<0.001	<0.001	-	-
	2d	<0.001	<0.001	-	-
	4d	<0.001	<0.001	-	-
Long term	7d	<0.001	<0.001	-	-
	14d	<0.001	<0.001	-	-
	21d	<0.001	<0.001	-	-
	28d	<0.001	<0.001	-	-
	42d	<0.001	<0.001	-	-
	50d	<0.001	<0.001	-	-
	100d	<0.001	<0.001	-	-
Plateau concentration (10 cm) after year 2		<0.001	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		<0.001	-		

8.7.2.3 PEC_{soil} of formulation

Not relevant. See point 8.7.

Table 8.7-22: PEC_{soil} for IMS+MSM+MPR OD 42 (2+10+30) on cereals

Active substance/ preparation	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)
IMS+MSM+MPR OD 42 (2+10+30)	1500 [#]	2.0*	-	5	-	-

* The PEC for the formulation was calculated with an interception rate of 0%

[#] density: 1.0 kg/L

PEC_{soil} is calculated using a standard approach with 5 cm mixing depth and soil density of 1.5 kg/L. No degradation data is available for the product. Therefore, TWA, plateau, and accumulation concentrations are not calculated, and tillage depth is not relevant here.

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

zRMS Comments:	<p>The PEC_{gw} assessment for active substances and their metabolites was accepted. Modelling was performed using FOCUS-PEARL v5.5.5 and FOCUS-PELMO v6.6.4 models for one application to winter cereals for application rate of 2.4 g of iodosulfuron-methyl-sodium/ha and 12.0 g of mesosulfuron-methyl/ha.</p> <p>The geometric mean of K_{foc} values, following the current EU guidance (EFSA, 2014) were used for PEC_{gw} calculations for active substances and their metabolites. For the metabolite AE F075736, a K_{foc} of 27 mL/g should have been used instead of 14 mL/g. However, since the value used by the Applicant is more conservative, it was accepted.</p> <p>Calculations of PEC_{gw} for active substance were provided in with PUF = 0.0.</p> <p>Iodosulfuron-methyl-sodium: The maximum PEC_{gw} values for active substance iodosulfuron-methyl-sodium and its metabolites are below the trigger value of 0.1 µg/L in all tested scenarios and models.</p> <p>Mesosulfuron-methyl: The maximum PEC_{gw} values for active substance mesosulfuron-methyl and its metabolites: AE F154851, AE F099095, AE F092944 and AE F140584 are below the trigger value of 0.1 µg/L in all tested scenarios and models. The maximum PEC_{gw} values for metabolites AE F160459, AE F160460, AE F147447 and BCS-CV14885 are above the trigger value of 0.1 µg/L. Assessment of the relevance of these metabolites is therefore required (please refer to dRR Part B10 – Assessment of relevance of metabolites in groundwater).</p>
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8.8.1 Justification for new endpoints

Not relevant.

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

In respect to the harmonization guidance for Poland, posted on the website of the Ministry of Agriculture and Rural Development, calculations for Predicted Environmental Concentrations in groundwater (PEC_{gw}) with the latest versions of the FOCUS-PELMO v6.6.4 FOCUS - PEARL v5.5.5 and MACRO v.5.5.4 were performed. Modeling using the EU agreed input parameters, application dates as suggested by App Date 3.06 and relevant crop interception according FOCUS groundwater guidance (2014) was conducted.

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

Use No.	1, 2, 3, 4, 5
Crop	Winter cereals
Application rate (g as/ha)	2.4 g of iodosulfuron-methyl-sodium/ha 12.0 g of mesosulfuron-methyl/ha 0.36 g of AE0002166/ha
Number of applications/interval (d)	1/-
Relative application date	-
Crop interception (%)	20

Frequency of application	annual
Models used for calculation	FOCUS PEARL, v 5.5.5; FOCUS PELMO v6.6.4, MACRO v5.5.4

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

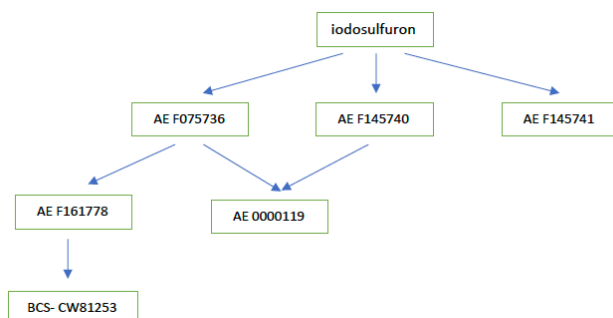
Crop	Scenario	Application dates (absolute)
Winter cereals BBCH 21	Châteaudun	06/04*
	Hamburg	25/04
	Jokioinen	05/05
	Kremsmünster	15/04
	Okehampton	12/04
	Piacenza	10/03
	Porto	03/01
	Sevilla	21/12
	Thiva	27/12

*06/04 - respective Julian day - 96

8.8.2.1 Iodosulfuron-methyl-sodium and its metabolites

Two degradation pathways were applied for iodosulfuron-methyl-sodium because of complexity of degradation and number of metabolites. Additionally, metabolite AE 0002166 as the parent was applied as a third path. The application rate of AE 0002166 was calculated assuming 20% formation from the parent and a molecular mass ratio 397.4/529.3.

Pathway no 1



Pathway no 2

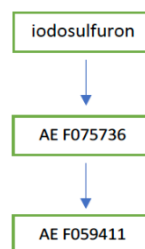


Table 8.8-3: Input parameters related to active substance iodosulfuron-methyl-sodium and its metabolites for PEC_{gw} calculations

Compound	iodosulfuron - methyl sodium	AE F075736	AE F145740	AE F145741	AE F059411	AE F161778	BCS- CW81253	AE 0000119	AE 0002166	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	529.3	381.4	493.2	493.2	140.1	367.3	343.3	183.2	397.4	Y, EFSA Journal 2016;14(4):445
Water solubility at 20° (mg/L):	25000	2790	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	200	1000 (default)	Y, EFSA Journal 2016;14(4):445
Saturated vapour pressure at 20° (Pa):	$2.6 \cdot 10^{-9}$	$1 \cdot 10^{-10}$ Pa (default)	$1 \cdot 10^{-10}$ Pa (default)	$1 \cdot 10^{-10}$ Pa (default)	$1 \cdot 10^{-10}$ Pa (default)	$1 \cdot 10^{-10}$ Pa (default)	$1 \cdot 10^{-10}$ Pa (default)	$1 \cdot 10^{-10}$ Pa (default)	$1 \cdot 10^{-10}$ Pa (default)	Y, EFSA Journal 2016;14(4):445
DT ₅₀ in soil (d)	2.7 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n=11)	24.9 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n=19)	46 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n=4)	8.7 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n=5)	144 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n=16)	11.4 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n=14)	26.7 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n=9)	15 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n=9)	7.5 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n=4)	Y, EFSA Journal 2016;14(4):445
K _{foc} / K _{fom} (mL/g)	33.4 / 19.37 (geomean, n = 9)	14.0 / 8.12 (geomean, n = 22)	17.9 / 10.4 (geomean, n = 4)	0 / 0 (worst case default)	45.6 / 26.45 (geomean, n = 27)	29.7 / 17.2 (geomean, n = 6)	41.7 / 24.2 (geomean, n = 7)	117.2 / 67.98 (geomean, n = 9)	0 / 0 (worst case default)	Y, EFSA Journal 2016;14(4):445
1/n	0.87 (arithmetic mean, n=9)	1.0 (arithmetic mean, n=22)	0.92 (arithmetic mean, n=4)	1.0 (worst case default)	0.9 (arithmetic mean, n=27)	1.0 (arithmetic mean, n=6)	0.91 (arithmetic mean, n=7)	0.91 (arithmetic mean, n=9)	1.0 (worst case default)	Y, EFSA Journal 2016;14(4):445
Plant uptake factor (PUF/TSCF)	0	0	0	0	0	0	0	0	0	Y, EFSA Journal 2016;14(4):445

Compound	iodosulfuron - methyl sodium	AE F075736	AE F145740	AE F145741	AE F059411	AE F161778	BCS- CW81253	AE 0000119	AE 0002166	Value in accordance with EU endpoint y/n/ Reference*
Transformation rate	0.25672	0.02784	0.01507	0.07967	0.00481	0.06080	0.02596	0.04621	0.09242	Y, EFSA Journal 2016;14(4):445
Formation fraction	NR	0.86 (from parent)	0.04 (from parent)	0.05 (from parent)	0.42 (from AE F075736)	0.55 (from AE F075736)	0.72 (from AE F161778)	0.33 (from AE F075736) 1 (rom AE F145740)	0.2 (from parent)	Y, EFSA Journal 2016;14(4):445

*even though geometric mean is 13.2 d, RMS proposed 12.6 d to be used in modelling (EFSA Journal 2016;14(4):445)

Table 8.8-4: PEC_{gw} for iodosulfuron-methyl-sodium and its metabolites on winter cereals (with FOCUS PELMO 6.6.4/PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)								
		iodosulfuron-methyl sodium	AE F161778	AE F145740	BCS-CW81253	AE F075736	AE F145741	AE 0000119	AE F059411	AE 0002166
PELMO 6.6.4										
Winter cereals, application rate: 2.4 g as/ha	Châteaudun	< 0.001	0.003	< 0.001	0.004	0.011	< 0.001	< 0.001	0.002	< 0.001
	Hamburg	< 0.001	0.010	< 0.001	0.009	0.039	< 0.001	< 0.001	0.003	< 0.001
	Iokioinen	< 0.001	0.011	< 0.001	0.006	0.051	< 0.001	< 0.001	0.001	< 0.001
	Kremsmünster	< 0.001	0.013	< 0.001	0.013	0.041	< 0.001	< 0.001	0.006	< 0.001
	Okehampton	< 0.001	0.012	< 0.001	0.011	0.040	< 0.001	< 0.001	0.006	< 0.001
	Piacenza	< 0.001	0.007	< 0.001	0.009	0.021	< 0.001	< 0.001	0.007	< 0.001
	Porto	< 0.001	0.010	< 0.001	0.008	0.070	0.001	< 0.001	0.006	0.004
	Sevilla	< 0.001	0.001	< 0.001	< 0.001	0.003	< 0.001	< 0.001	0.002	0.001

	Thiva	< 0 001	0 003	< 0 001	0 004	0 011	< 0 001	< 0 001	0 004	< 0 001
PEARL 5.5.5										
Winter cereals, application rate: 2.4 g as/ha	Châteaudun	< 0 001	0 004	0 001	0 005	0 014	< 0 001	< 0 001	0 015	< 0 001
	Hamburo	< 0 001	0 013	0 004	0 010	0 054	< 0 001	0 001	0 020	0 001
	Iokioinen	< 0 001	0 011	0 003	0 007	0 047	< 0 001	< 0 001	0 015	0 002
	Kremsmünster	< 0 001	0 010	0 003	0 011	0 034	< 0 001	< 0 001	0 017	0 001
	Okehamnton	< 0 001	0 011	0 003	0 011	0 037	< 0 001	< 0 001	0 016	0 001
	Piacenza	< 0.001	0.006	0.002	0.008	0.019	< 0.001	< 0.001	0.016	0.001
	Porto	< 0 001	0 008	0 002	0 008	0 036	0 002	< 0 001	0 013	0 007
	Sevilla	< 0 001	0 000	< 0 001	< 0 001	0 001	< 0 001	< 0 001	0 001	< 0 001
	Thiva	< 0 001	0 003	< 0 001	0 004	0 009	< 0 001	< 0 001	0 022	< 0 001

Table 8.8-5: PEC_{gw} for iodosulfuron-methyl-sodium and its metabolites on winter cereals (MACRO v.5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)								
		iodosulfuron-methyl sodium	AE F161778	AE F145740	BCS-CW81253	AE F075736	AE F145741	AE 0000119	AE F059411	AE 0002166
MACRO 5.5.4										
Winter cereals, application rate: 2.4 gas/ha	Châteaudun	0.000	< 0.001	< 0.001	< 0.001	0.01	< 0.001	< 0.001	0.006	< 0.001

Conclusions:

The 80th percentiles of the predicted annual average leachate concentrations of iodosulfuron-methyl sodium and its metabolites were below 0.1 µg/L in all calculated scenarios.

8.8.2.2 Mesosulfuron-methyl its metabolites

Tier 1 PEC_{gw} for mesosulfuron-methyl is derived from exposure modelling of the parent active substance alone, based on the technically simple but overly conservative procedure of considering only slow-phase SFO-DT50 where bi-phasic models were used in the original kinetic evaluation. A specific EU endpoint is dedicated to "modelling the parent active substance alone".

Tier 1 PEC_{gw} for metabolites (other than BCS-CV14885) is derived from a pathway simulation, for conservatism of which the degradation of parent is assumed to proceed faster than in the Tier 1 simulation for the parent active substance alone. This is described by a specific SFO-DT50 EU endpoint dedicated to "modelling the parent active substance and metabolites".

Tier 1 PEC_{gw} for metabolite BCS-CV14885 (detected in lysimeter leachate but not in laboratory soil metabolism studies) is derived from a separate simulation for the system parent active substance – metabolite BCS-CV14885, using the parent EU endpoint dedicated to "modelling the parent active substance and metabolites", and the EU agreed metabolite formation fraction estimate for BCS-CV14885.

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

Compound	Mesosulfuron-methyl	AE F154851	AE F160459	AE F099095	AE F092944	AE F160460	AE F140584	AE F147447	BCS-CV14885	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	503.5	489.5	489.5	198.2	155.2	475.5	322.4	290.3	393.4	Y/ EFSA Journal 2016;14(10):4584
Water solubility (mg/L):	483 (20°C) [#]	200000 (20°C) [#]	10000 (20°C) [#]	190 (20°C) [#]	5200 (20°C) [#]	100000 (20°C) [#]	100 (20°C) [#]	150000 (20°C) [#]	2000 (20°C) [#]	*Y/ EFSA Journal 2016;14(10):4584. #Y/ values listed in RAR Vol 3 – B.8
Saturated vapour pressure at 20° (Pa):	3.5 x 10 ^{-12*}	1.7 x 10 ^{-8#}	6.8 x 10 ^{-8#}	1.9 x 10 ^{-5#}	2.6 x 10 ^{-2#}	5.6 x 10 ^{-7#}	1.3 x 10 ^{-6#}	1.0 x 10 ^{-8#}	7.4 x 10 ^{-10#}	*Y/ EFSA Journal 2016;14(10):4584. #Y/ values listed in RAR Vol 3 – B.8
DT ₅₀ in soil (d)	49.72 ¹ / 34.09 ² (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n=9)	45.22 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n=8)	74.14 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 5)	55.6 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 10)	16.93 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 13)	28.61 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 5)	4.22 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 5)	102.15 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 5)	97.6 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 4)	Y/ EFSA Journal 2016;14(10):4584
K _{foc} / K _{fom} (mL/g)	64 / 37.1 (geomean, n = 9)	65.0 / 37.7 (geomean, n = 3)	19.3 / 11.2 (geomean, n = 5)	334 / 194 (geomean, n = 11)	293.9 / 170.5 (geomean, n = 23)	12.2 / 7.1 (geomean, n = 5)	0 / 0 (default)	5.1 / 2.9 (geomean, n = 5)	17.7 / 10.3 (geomean, n = 4)	Y/ EFSA Journal 2016;14(10):4584
1/n	0.91 (arithmetic mean, n = 9)	0.94 (arithmetic mean, n = 3)	0.941 (arithmetic mean, n = 5)	0.80 (arithmetic mean, n = 11)	0.74 (arithmetic mean, n = 23)	0.9 (arithmetic mean, n = 5)	1.0 (default)	1.0 (default)	1.21 (arithmetic mean, n = 4)	Y/ EFSA Journal 2016;14(10):4584
Plant uptake factor	0	0	0	0	0	0	0	0	0	Y/ EFSA Journal 2016;14(10):4584
Transformation rate	Parent -> AE F154851:	AE F154851 ->	AE F160459 ->	AE F099095 -> BR/CO ₂ :	AE F092944 -> BR/CO ₂ :	AE F160460 -> BR/CO ₂ :	AE F140584 -> BR/CO ₂ :	AE F147447 -> BR/CO ₂ :	BCS-CV14885 ->	Output of PELMO calculation

Compound	Mesosulfuron-methyl	AE F154851	AE F160459	AE F099095	AE F092944	AE F160460	AE F140584	AE F147447	BCS-CV14885	Value in accordance with EU endpoint y/n/ Reference*
	0.0042699 Parent -> AE F160459: 0.0020943 Parent -> AE F099095: 0.0008133 Parent -> AE F092944: 0.0072588 Parent -> AE F140584: 0.0043106 Parent -> AE F147447: 0.0017893 Parent -> BCS- CV14885: 0.0019520	AE F160460: 0.0153283	AE F160460: 0.0093492	0.0124667	0.0409419	0.0242274	0.1642529	0.0067856	BR/CO ₂ : 0.0071019	
Formation fraction	-	0.210 (from parent)	0.103 (from parent)	0.040 (from parent)	0.357 (from parent)	1 (from AE F154851) 1 (from AE F160459)	0.212 (from parent)	0.088 (from parent)	0.096 (from parent)	Y/ EFSA Journal 2016;14(10):4584

¹ for modelling of parent active substance alone

² for modelling of metabolites formation from parent

Table 8.8-7: PEC_{gw} for mesosulfuron-methyl and its metabolites on winter cereals (with FOCUS PELMO 6.6.4/PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)								
		Mesosulfuron-methyl *	AE F154851	AE F160459	AE F099095	AE F092944	AE F160460	AE F140584	AE F147447	BCS-CV14885
PELMO 6.6.4										
Winter cereals, application rate: 12 g as/ha	Châteaudun	< 0.001	< 0.001	0.002	< 0.001	< 0.001	0.001	0.002	0.044	0.108
	Hamburg	0.001	< 0.001	0.005	< 0.001	< 0.001	0.008	0.015	0.050	0.141
	Iokioinen	< 0.001	< 0.001	0.003	< 0.001	< 0.001	0.003	0.029	0.065	0.183
	Kremsmünster	0.002	0.001	0.005	< 0.001	< 0.001	0.007	0.006	0.037	0.101
	Okehamnton	0.003	0.001	0.005	< 0.001	< 0.001	0.009	0.008	0.031	0.085
	Piacenza	0.007	0.002	0.016	< 0.001	< 0.001	0.012	0.008	0.033	0.107
	Porto	0.009	0.002	0.018	< 0.001	< 0.001	0.009	0.015	0.028	0.091
	Sevilla	< 0.001	< 0.001	0.005	< 0.001	< 0.001	0.001	0.001	0.021	0.086
	Thiva	< 0.001	< 0.001	0.014	< 0.001	< 0.001	0.002	0.002	0.036	0.120
PEARL 5.5.5										
Winter cereals, application rate: 12 g as/ha	Châteaudun	0.009	0.007	0.075	< 0.001	< 0.001	0.091	< 0.001	0.135	0.203
	Hamburg	0.066	0.034	0.141	< 0.001	< 0.001	0.195	0.008	0.174	0.263
	Iokioinen	0.023	0.015	0.140	< 0.001	< 0.001	0.181	0.013	0.257	0.391
	Kremsmünster	0.051	0.025	0.090	< 0.001	< 0.001	0.120	0.002	0.095	0.142
	Okehamnton	0.066	0.032	0.089	< 0.001	< 0.001	0.125	0.003	0.089	0.135
	Piacenza	0.031	0.016	0.062	< 0.001	< 0.001	0.084	0.001	0.084	0.126
	Porto	0.049	0.024	0.066	< 0.001	< 0.001	0.086	0.004	0.081	0.119
	Sevilla	0.000	< 0.001	0.021	< 0.001	< 0.001	0.023	< 0.001	0.059	0.088
	Thiva	0.006	0.004	0.080	< 0.001	< 0.001	0.081	< 0.001	0.138	0.203

*Results of parent substance alone calculation

Table 8.8-8: PEC_{gw} for mesosulfuron-methyl and its metabolites on winter cereals (MACRO v.5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)								
		Mesosulfuron-methyl *	AE F154851	AE F160459	AE F099095	AE F092944	AE F160460	AE F140584	AE F147447	BCS-CV14885
MACRO 5.5.4										
Winter cereals, application rate: 12 g as/ha	Châteaudun	0.00667	0.00557	0.066	< 0.001	< 0.001	0.028	0.000479	0.116	0.177

*Results of parent substance alone calculation

Conclusions:

The relevant trigger of 0.1 µg/L mesosulfuron-methyl is not exceeded. Respect to the metabolites AE F160459, AE F160460, AE F147447 and BCS-CV14885, PEC_{gw} are greater than the regulatory threshold of 0.1 µg/L in some scenarios with a maximum of 0.391 µg/L (Jokionen). Nevertheless, these metabolites are considered non-relevant according to Sanco/221/2000 –rev.10- final. Besides, the relevance of these, has been evaluated in the RAR of mesosulfuron-methyl. The risk to groundwater is therefore low.

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

<div>zRMS</div> <div>Comments:</div>	<div>The PEC_{sw}/sed assessment for active substances and their metabolites was accepted.</div> <div>The PEC_{sw}/sed values were based on the Atlantis 12 OD renewal Registration Report (zRMS: Poland, MS finalisation: 12/02019). From environmental point of view JME-HER 12 OD is considered equivalent/comparable to already authorized Atlantis 12 OD, therefore the calculations PEC_{sw}/sed performed for Atlantis 12 OD can be used for JME-HER 12 OD.</div> <div>The submitted PEC_{sw} values represent a worse case as higher application rates than proposed in the GAP table JME-HER 12 OD and were accepted.</div> <div>STEP 1 & 2 and STEP 3 were used for PEC_{sw} and PEC_{sed} assessment.</div> <div>All used endpoints for active substances and their metabolites were agreed at the EU level.</div> <div>Formulation. The PEC_{sw} for the formulation JME-HER 12 OD for single application of 1500 g prod./ha in winter cereals was recalculated by the evaluator and is of 9.6370 µg/L.</div> <table><tr><th>Cropping scenario</th><th>FOCUS scenario</th><th>Max. PEC_{sw} (µg/L)</th></tr><tr><td rowspan="3">Potatoes</td><td>Ditch</td><td>9.6370</td></tr><tr><td>Pond</td><td>0.3286</td></tr><tr><td>Stream</td><td>7.1518</td></tr></table> <div>The relevant mitigation measure will be recommended in ecotoxicological section.</div>	Cropping scenario	FOCUS scenario	Max. PEC _{sw} (µg/L)	Potatoes	Ditch	9.6370	Pond	0.3286	Stream	7.1518
Cropping scenario	FOCUS scenario	Max. PEC _{sw} (µg/L)									
Potatoes	Ditch	9.6370									
	Pond	0.3286									
	Stream	7.1518									

Information concerning PEC_{sw} for active substances and relevant metabolites is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

8.9.1 Justification for new endpoints

Not relevant. See point 8.9.

No new endpoints were used.

Note for mesosulfuron-methyl and metabolites: The exemplary PEC_{sw} calculations provided in the EU List of Endpoints for mesosulfuron were based on an interim set of parameters which during the review process had not been updated to reflect the final EU agreed kinetic endpoints. Since "Agreed endpoints should be considered in further exposure calculations", the simulations presented here are based on final agreed modelling endpoints according Appendix A to EFSA Journal 2016;14(10):4584.

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

~~Not relevant. See point 8.9.~~

Structure of PEC_{sw} presentation

To enable a stepwise ecotoxicological risk assessment according the tiered approaches of the EFSA Aquatic Guidance Document (AGD), a comprehensive set of exposure calculations and supportive information for exposure description is presented here in dRR Part B.8, in an order consistent with the later data use for risk assessment in dRR Part B Section 9:

As a first step, a spray-drift exposure calculation for the formulated product is made, based on Ganzelmeier tabulated standard drift values.

Thereafter, exposure calculations for the individual components (active substances and metabolites) via the FOCUS_{sw} approach are made, in a structure as follows:

(a) FOCUS Steps 1-2 - PEC_{sw}/sed for a generic risk envelope use pattern covering all uses
to enable a simplified screening level assessment for components and organisms characterised by a wide margin of safety even when based on highly conservative exposure assumptions.

(b) FOCUS Step 3 – PEC_{sw}/sed (maximum and TWA) for the critical GAPs
to enable Tier 1 risk assessment based on the accurate GAP and standard FOCUS Step 3 exposure description, where assessment was not resolved at the before screening level. For the present product and uses, this applies only for the herbicidally active components iodosulfuron-methyl-sodium, metabolite AE F075736, and mesosulfuron-methyl on which all further risk assessments will concentrate.
FOCUS Step 3 PEC_{sw}/sed calculations for iodosulfuron-methyl-sodium and metabolite AE F075736 are normally prepared using laboratory data to describe the degradation kinetics in soil. Where helpful to pass the ecological risk assessment, additional calculations are provided using EU agreed soil degradation kinetics (DT₅₀ and formation fraction) based on geomean of field soil dissipation study data for parent a.s. and metabolite AE F075736, as well as the EU-agreed plant uptake factor for metabolite AE F075736.

(c) FOCUS Step 3 - Time course plots (FOCUS year) and exposure pattern analysis to selected scenarios
to enable a refined risk assessment considering time-variability of the exposure, based on AGD option Tier 2C.

(d) FOCUS Step 3 - Time course plots (multi-year simulation) and exposure pattern analysis to selected scenarios
to provide confirmative information on multi-annual representativity of the before assessments.

(e) FOCUS Step 4 – PEC_{sw}/sed (maximum and TWA) for the critical GAPs
to enable consideration of exposure mitigating measures, where required.

The same headline structure (a) to (e) is followed for each substance in the subsequent sections.

Risk envelope approach for Iodosulfuron-methyl-sodium: For iodosulfuron-methyl-sodium and its metabolites, risk assessment for most aquatic organisms is resolved with a wide margin of safety even when based on highly conservative exposure assumptions. For dossier simplicity, a screening level assessment will therefore be presented first as a “risk envelope” approach, based on a generic FOCUS Step 1-2 exposure simulation for the maximum registered application rate and overall worst case exposure situation across all iodosulfuron-methyl-sodium containing products supported by Bayer AG in Europe.

FOCUS Step 3-4 calculations are performed for the critical product GAP(s). These calculations are only provided for those components which are failing the risk assessment at screening level, i.e. for the parent active substance and its relevant metabolite AE F075736.

(a) FOCUS Step 1-2 – Risk envelope PEC_{sw/sed} [for screening level assessment]

Table 8.9-1: Risk envelope assessment (FOCUS Step 1,2): Input parameters related to application for PEC_{SW/SED} calculations - iodosulfuron-methyl-sodium

Plant protection product	risk envelope for active substance iodosulfuron-methyl-sodium and its metabolites
Use No.	covers all uses
Crop	arable crops, no interception
Application rate (kg as/ha)	10 g a.s./ha
Number of applications/interval (d)	1 / -
Application window	year-round: October – February, March – May, June – September (Step 2)
Application method	Spray application
CAM (Chemical application method)	not relevant for FOCUS Steps 1, 2
Soil depth (cm)	not relevant for FOCUS Steps 1, 2
Models used for calculation	FOCUS STEPS 1-2 v3.2

Risk envelope approach Mesosulfuron-methyl: For mesosulfuron-methyl and its metabolites, risk assessment for most aquatic organisms is resolved with a wide margin of safety even when based on highly conservative exposure assumptions. For dossier simplicity, a screening level assessment will therefore be presented first as a “risk envelope” approach, based on a generic FOCUS Step 1-2 exposure simulation for the maximum registered application rate and overall worst case exposure situation across all mesosulfuron-methyl containing products supported by Bayer AG in Europe.

FOCUS Step 3-4 calculations are performed for the critical product GAP(s). These calculations are only provided for those components which are failing the risk assessment at screening level, i.e. for the parent active substance.

Table 8.9-2: Risk envelope assessment (FOCUS Step 1,2): Input parameters related to application for PEC_{SW/SED} calculations - mesosulfuron-methyl

Plant protection product	risk envelope for active substance mesosulfuron-methyl and its metabolites
Use No.	covers all uses
Crop	arable crops, no interception
Application rate (kg as/ha)	15 g a.s./ha
Number of applications/interval (d)	1 / -

Application window	year-round: October – February, March – May, June – September (Step 2)
Application method	Spray application
CAM (Chemical application method)	not relevant for FOCUS Steps 1, 2
Soil depth (cm)	not relevant for FOCUS Steps 1, 2
Models used for calculation	FOCUS STEPS 1-2 v3.2

(b) FOCUS Step 3 – PEC_{sw/sed} (maximum and TWA) [for Tier 1 assessment]

Table 8.9-3: Input parameters related to application for PEC_{SW/SED} calculations – iodosulfuron-methyl-sodium, mesosulfuron-methyl

Plant protection product	IMS+MSM+MPR OD 42 (2+10+30)
Use No.	5
Crop	Winter cereals (arable crops)
Application rate (kg as/ha)	Iodosulfuron-methyl-sodium: 3 g a.s./ha Mesosulfuron-methyl: 15 g a.s./ha
Number of applications/interval (d)	1 / -
Application window	End of winter to spring (start of vegetation period): see specific information provided below Application window used for modelling: see Table 8.9-4
Application method	Spray application
CAM (Chemical application method)	2 (application foliar linear)
Soil depth (cm)	4 (default)
Models used for calculation	FOCUS SWASH v5.3 (FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v4.4.3)

End-of-winter to spring use in winter cereals

The application in winter cereals according to GAP is intended at the onset of the spring vegetation period, i.e. when climate conditions allow for resumption of crop and weed growth after winter dormancy, and soil moisture level allows again for field trafficability by the farmer's equipment. Treatment is made to well-established crop at the growth stage reached at that time, within the BBCH boundaries specified in the GAP. At FOCUS Step 3, actual application dates are generally determined by the PAT (pesticide application timer) included within SWASH, which within a defined time window selects an appropriate actual application date to ensure at least 10 mm of rainfall in the first 10 days after application, and at the same time less than 2 mm of rain per day in a five day period around the date of application.

No pre-defined event dates are however implemented in the FOCUS model that would directly translate the above cropping situation into discrete PAT windows for each surface water scenario setting. To generate an adequate scenario-adapted representation with relative date setting, the following approach was therefore used: the simulated treatment was referenced relative to the tabulated crop emergence date of the earliest emerging spring crop (i.e. not necessarily cereals) that was defined by FOCUS for the respective scenario. Start of the PAT window was then set to 14 days before that date, as an adequate

representation of the start of the vegetation period in the respective scenario environment.

An overview of the date selection per scenario is presented in the table below; for technical reason, such application dates must be entered to the simulation model formally as 'absolute' dates, even though referencing was in fact of relative type.

The approach and resulting model application date settings were discussed and agreed suitable during the EU review of active substance mesosulfuron-methyl (cf. DAR Vol. 3 – B.8(PPP) – Atlantis OD).

**Table 8.9-4: Application date definition used for surface water exposure assessment
– End-of-winter use in winter cereals**

Scenario	Location	Crop	Emergence date	Start of application window Julian date
D1	Lanna	spring cereals	05-May	21-Apr
D2	Brimstone	spring cereals ^{a)}	15-Mar ^{a)}	01-Mar ^{a)}
D3	Vredepeel	spring cereals	01-Apr	18-Mar
D4	Skousbo	field beans	15-Apr	01-Apr
D5	La Jailliere	spring cereals	15-Mar	01-Mar
D6	Thiva	root vegetables	25-Feb	11-Feb
R1	Weiherbach	field beans	10-Apr	27-Mar
R2	Porto	bulb vegetables	28-Feb	14-Feb
R3	Bologna	root vegetables	26-Feb	12-Feb
R4	Roujan	root vegetables	26-Feb	12-Feb

^{a)} no crop with emergence in spring defined; D5 data used instead

(c) FOCUS Step 3 – Timecourse of PEC_{sw} (FOCUS year) [for Tier 2C and Tier 3 assessment]

In dRR Part B Section 9, a refined risk assessment is presented based on an ecotoxicological interpretation of the evolution of surface concentration over time (EFSA Aquatic Guidance Document: Tier 2C). Therefore, plots of the exposure pattern were generated from the FOCUS Step 3 simulation output data for some exposure scenarios of relevance, and are shown for the complete time frame simulated by the FOCUS model (1 year). For data interpretation, a numeric pattern description is made via the EPAT tool¹, to characterise each exposure pattern by four properties which are

- the PEC_{max} ,
- the number of peak events above the Tier 1 RAC,
- the duration of these peak events, and
- the interval between these peak events.

(d) FOCUS Step 3 – Timecourse of PEC_{sw} (multi-year simulation) [for Tier 2C and Tier 3 assessment]

In response to concerns expressed by some regulators on the representativeness of the FOCUS model's single weather year in the context of a refined risk assessment based on exposure pattern analysis, additional FOCUS calculations have been conducted for an extended time period of 20 years (multi-year calculations). From this large data set, a statistically justified 90th percentile realistic worst case exposure pattern was derived for use in ecotoxicological risk assessment Tier 2C, based again on the above four exposure pattern descriptors.

¹ Bastiansen, F., Nickisch, D., Wang, M. (2016): EPAT v. 1.1 – Exposure Pattern Analysis Tool. European Crop Protection Association (ECPA), Brussels. Program Manual: RIFCON GmbH Report No. R1520392. Program download: https://www.rifcon.de/files/downloads/EPAT_1.1.1_setup.exe.

(e) FOCUS Step 4 – PEC_{sw}/sed (maximum and TWA) [for Tier 1 assessment considering mitigation options]

Exposure simulations considering options for exposure mitigation according FOCUS Step 4 methodology² were conducted for all components of biological relevance, based on the same substance and timing parameters previously used at Step 3. Where this information is not necessary to complete the aquatic risk assessment.

**8.9.2.1 Spray drift exposure calculation for the formulated product - IMS+MSM+MPR
OD 42 (2+10+30)**

The PEC_{sw} of the formulation was calculated according to the following formula:

$$PEC_{sw} [\mu g/L] = \frac{\% \text{ drift (90}^{th} \text{ percentile)} \times \text{application rate [g/ha]}}{\text{water depth (30 cm)} \times 10}$$

Application rate & frequency / Crop	1 × 1.5 L/ha, cereals
Scenario / Drift percentile	Arable crops / 90 th percentile (for 1 x application)
Entry pathways considered	Drift: yes Volatilisation: no

PEC_{sw} for formulations are based on Ganzelmeier data covering the respective crop (arable crops) and the number of applications. All loadings are considered to occur in a single pseudo-application reaching the standard static ditch (width 1 m, depth 30 cm, sediment depth 5 cm, and sediment density 0.8 kg/L). Since no degradation data is available for the product, no TWA concentrations can be calculated.

8.9.2.2 Iodosulfuron-methyl-sodium and its metabolites

For iodosulfuron-methyl-sodium, the exposure assessment may follow a tiered approach as described below, for which dedicated modelling endpoints were agreed in the EU review.

- (a) **Standard calculation³:** soil kinetics (DT₅₀ and formation fractions) for all components based on geomean of standard laboratory study data.
- (b) **Refined calculation⁴:** soil degradation kinetics for parent a.s. and metabolite AE F075736 (DT₅₀ and formation fraction) based on geomean of field soil dissipation study data; consideration of EU agreed plant uptake factor for metabolite AE F075736; kinetic parameters for other metabolites – where considered in this step - are based on laboratory studies.

For iodosulfuron-methyl-sodium, agreed endpoints were used as input to exposure modelling as follows:

² FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 2. Detailed Technical Reviews". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 436 pp.

³ cf. List of EU endpoints: "Standard calculation for parent and all metabolites"

⁴ cf. List of EU endpoints: "Higher tier calculation for parent and metsulfuron-methyl AE F075736 (using normalised field DT₅₀ and PUF 0.5 for metsulfuron-methyl AE F075736 derived from following crop metabolism studies)."

Table 8.9-5: Input parameters related to active substance iodosulfuron-methyl-sodium and metabolites for PEC_{sw/sed} calculations STEP 1/2 and 3/4

Compound	iodosulfuron-methyl-sodium	AE F075736	AE F145741	AE F145740	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	529.3	381.4	493.2	493.2	Y / EFSA 2016;14(4)
Saturated vapour pressure (Pa)	2.6x10 ⁻⁹ # (20°C)	1x10 ⁻¹⁰ b	1x10 ⁻¹⁰ Pa b	1x10 ⁻¹⁰ Pa b	# Y / EFSA 2016;14(4)
Water solubility (mg/L)	25000 (20°C)	2790 (20°C)	1000 mg/L b	1000 mg/L b	Y / EFSA 2016;14(4)
Diffusion coefficient in water (m ² /d)	4.3 x 10 ⁻⁵	4.3 x 10 ⁻⁵	- ^a	- ^a	default
Diffusion coefficient in air (m ² /d)	0.43	0.43	- ^a	- ^a	default
K _{foc} (mL/g)	33.45 (geomean, n = 9)	14.0 (geomean, n = 22)	0	17.9 (geometric mean, n = 4)	Y / EFSA 2016;14(4)
Freundlich Exponent 1/n	0.87 (arithmetic mean, n = 9)	1.0 (arithmetic mean, n = 22)	1.0	0.92 (arithmetic mean, n = 4)	Y / EFSA 2016;14(4)
Plant Uptake	0	0	- ^a	- ^a	N / Worst case assumption
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	- ^a	- ^a	Default
DT _{50,soil} (d)	2.7 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 11)	24.9 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 19)	8.7 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 5)	46.0 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 4)	Y / EFSA 2016;14(4)
DT _{50,water} (d)	19.8 (Step 2+3)	131 (Step 2+3)	73.4	45.4	Y / EFSA 2016;14(4)
DT _{50,sed} (d)	19.8 (Step 2) / 1000 (Step 3)	131 (Step 2) / 1000 (Step 3)	73.4	45.4	Y / EFSA 2016;14(4)
DT _{50,whole system} (d)	19.8 (geomean, n = 3)	131 (geomean, n = 3)	73.4 (geomean, n = 2)	45.4 (geomean, n = 2)	Y / EFSA 2016;14(4)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 88.5 Water/sediment: 67.8	Soil: 6.9 Water/sediment: 8.7	Soil: 8.7 Water/sediment: 12.6	Y / EFSA 2016;14(4)
Formation fraction in soil:	-	0.86 (from IMS)	0.05 (from IMS)	0.04 (from IMS)	Y / EFSA 2016;14(4)

^a not required for Steps 1-2 simulations

^b Not measured. Default value used

Table 8.9-6: Input parameters related to iodosulfuron-methyl-sodium metabolites for PEC_{sw/sea} calculations STEP 1/2 (continued)

Compound	AE 0002166	AE F161778	BCS-CW81253	AE 0000119	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	397.4	367.3	343.3	183.2	Y / EFSA 2016;14(4)
Saturated vapour pressure (Pa)	1×10^{-10} Pa ^b	1×10^{-10} Pa ^b	1×10^{-10} Pa ^b	1×10^{-10} Pa ^b	N / Worst case assumption
Water solubility (mg/L)	1000 mg/L ^b	1000 mg/L ^b	1000 mg/L ^b	200 (20°C)	Y / EFSA 2016;14(4)
Diffusion coefficient in water (m ² /d)	- ^a	- ^a	- ^a	- ^a	default
Diffusion coefficient in air (m ² /d)	- ^a	- ^a	- ^a	- ^a	default
K _{foc} (mL/g)	0	29.7 (geomean, n = 6)	41.8 (geometric man, n = 7)	117.2 (geometric man, n = 9)	Y / EFSA 2016;14(4)
Freundlich Exponent 1/n	1.0	1.0 (arithmetic mean, n = 6)	0.91 (arithmetic mean, n = 7)	0.91 (arithmetic mean, n = 9)	Y / EFSA 2016;14(4)
Plant Uptake	- ^a	- ^a	- ^a	- ^a	-
Wash-Off factor from Crop (1/mm)	- ^a	- ^a	- ^a	- ^a	-
DT _{50,soil} (d)	7.5 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 4)	11.4 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 14)	26.7 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 10)	15.0 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 9)	Y / EFSA 2016;14(4)
DT _{50,water} (d)	1000	1000	1000	28.4	Y / EFSA 2016;14(4)
DT _{50,sea} (d)	1000	1000	1000	28.4	Y / EFSA 2016;14(4)
DT _{50,whole system} (d)	1000 (default)	1000 (default)	1000 (default)	28.4 (geomean, n = 2)	Y / EFSA 2016;14(4)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 20 Water/sediment: 25.1	Soil: 14.5 Water/sediment: 2.6%	Soil: 35.1 Water/sediment: 0.0001%	Soil: 19.9 Water/sediment: 24.9	Y / EFSA 2016;14(4)
Formation fraction in soil:	-	0.55 (from AE F075736)	0.72 (from AE F161778)	0.33 (from AE F075736)	Y / EFSA 2016;14(4)

^a not required for Steps 1-2 simulations

^b Not measured. Default value used

Table 8.9-7: Input parameters related to iodosulfuron-methyl-sodium metabolites for PEC_{sw/sed} calculations STEP 1/2 (continued)

Compound	AE F059411	AE 0014966	AE 0034855	AE 1234964	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	140.1	367.3	169.1	201.2	Y / EFSA 2016;14(4)
Saturated vapour pressure (Pa)	$1 \times 10^{-10}^b$	$1 \times 10^{-10} \text{ Pa}^b$	$1 \times 10^{-10} \text{ Pa}^b$	$1 \times 10^{-10} \text{ Pa}^b$	N / Worst case assumption
Water solubility (mg/L)	1000 mg/L ^b	1000 mg/L ^b	1000 mg/L ^b	1000 mg/L ^b	Y / EFSA 2016;14(4)
Diffusion coefficient in water (m ² /d)	- ^a	- ^a	- ^a	- ^a	-
Diffusion coefficient in air (m ² /d)	- ^a	- ^a	- ^a	- ^a	-
K _{foc} (mL/g)	45.6 (geomean, n = 27)	0	0	0.0001	Y / EFSA 2016;14(4)
Freundlich Exponent 1/n	0.9 (arithmetic mean, n = 27)	1.0	1.0	1.0	Y / EFSA 2016;14(4)
Plant Uptake	- ^a	- ^a	- ^a	- ^a	-
Wash-Off factor from Crop (1/mm)	- ^a	- ^a	- ^a	- ^a	-
DT _{50,soil} (d)	144 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 16)	0.0001	0.0001	0.0001	Y / EFSA 2016;14(4)
DT _{50,water} (d)	9.9	43.8	1000	1000	Y / EFSA 2016;14(4)
DT _{50,sed} (d)	9.9	43.8	1000	1000	Y / EFSA 2016;14(4)
DT _{50,whole system} (d)	9.9 (geomean, n = 2)	43.8 (geomean, n = 2)	1000 (default)	1000 (default)	Y / EFSA 2016;14(4)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 64.5 Water/sediment: 27.5	Soil: 0.0001 Water/sediment: 15.5	Soil: 0.0001 Water/sediment: 24.2	Soil: 0.0001 Water/sediment: 7.4	Y / EFSA 2016;14(4)
Formation fraction in soil:	0.42 (from AE F075736)	-	-	-	-

^a not required for Steps 1-2 simulations

^b Not measured. Default value used

Table 8.9-8: Input parameters related to iodosulfuron-methyl-sodium metabolites for PEC_{sw/sed} calculations STEP 1/2 (continued)

Compound	AE F159737	AE F154781	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	183.2	126.1	Y / EFSA 2016;14(4)
Saturated vapour pressure (Pa)	1×10^{-10} Pa ^b	1×10^{-10} Pa ^b	N / Worst case assumption
Water solubility (mg/L)	1000 mg/L ^b	1000 mg/L ^b	Y / EFSA 2016;14(4)
Diffusion coefficient in water (m ² /d)	- ^a	- ^a	default
Diffusion coefficient in air (m ² /d)	- ^a	- ^a	default
K _{oc} (mL/g)	0	0.0001	Y / EFSA 2016;14(4)
Freundlich Exponent 1/n	1.0	1.0	Y / EFSA 2016;14(4)
Plant Uptake	- ^a	- ^a	-
Wash-Off factor from Crop (1/mm)	- ^a	- ^a	-
DT _{50,soil} (d)	0.0001	0.0001	Y / EFSA 2016;14(4)
DT _{50,water} (d)	1000	1000	Y / EFSA 2016;14(4)
DT _{50,sed} (d)	1000	1000	Y / EFSA 2016;14(4)
DT _{50,whole system} (d)	1000 (default)	1000 (default)	Y / EFSA 2016;14(4)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 0.0001 Water/sediment: 7.8	Soil: 0.0001 Water/sediment: 8.7	Y / EFSA 2016;14(4)
Formation fraction in soil:	-	-	-

^a not required for Steps 1-2 simulations

^b Not measured. Default value used

For the presentation of a refined ecotoxicological assessment for iodosulfuron-methyl-sodium and its metabolite AE F075736, for selected uses additional calculations are provided using EU agreed soil degradation kinetics (DT₅₀ and formation fraction) based on geomean of field soil dissipation study data for parent a.s. and metabolite AE F075736, as well as the EU-agreed plant uptake factor for metabolite AE F075736:

Table 8.9-9: Refined input parameters related to active substance iodosulfuron-methyl-sodium and metabolite AE F075736 for $PEC_{sw/sed}$ calculation STEP 3/4, - for calculations using soil kinetics from field dissipation studies

Compound	iodosulfuron-methyl-sodium	AE F075736	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	529.3	381.4	Y / EFSA 2016;14(4)
Saturated vapour pressure (Pa)	2.6×10^{-9} [#] (20°C)	1×10^{-10} ^b	[#]) Y / EFSA 2016;14(4) ^b) default value
Water solubility (mg/L)	25000 (20°C)	2790 (20°C)	Y / EFSA 2016;14(4)
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	4.3×10^{-5}	default
Diffusion coefficient in air (m ² /d)	0.43	0.43	default
K_{foc} (mL/g)	33.45 (geomean, n = 9)	14.0 (geomean, n = 22)	Y / EFSA 2016;14(4)
Freundlich Exponent 1/n	0.87 (arithmetic mean, n = 9)	1.0 (arithmetic mean, n = 22)	Y / EFSA 2016;14(4)
Plant Uptake	0	0.5	Y / EFSA 2016;14(4)
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	default
$DT_{50,soil}$ (d)	3.2 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n = 5)	13.2 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n = 16)	Y / EFSA 2016;14(4)
$DT_{50,water}$ (d)	19.8	131	Y / EFSA 2016;14(4)
$DT_{50,sed}$ (d)	1000	1000	Y / EFSA 2016;14(4)
$DT_{50,whole\ system}$ (d)	19.8 (geomean, n = 3)	131 (geomean, n = 3)	Y / EFSA 2016;14(4)
Formation fraction in soil:	-	0.55 (from IMS) (arithmetic mean, n=10)	Y / EFSA 2016;14(4)

(a) FOCUS Steps 1-2 – Risk envelope $PEC_{sw/sed}$ of iodosulfuron-methyl-sodium and all metabolites [for screening level assessment]

Table 8.9-10: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for iodosulfuron-methyl-sodium following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC_{sw} (µg/L) *	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L) **	21 d- $PEC_{sw,twa}$ (µg/L) **	Max PEC_{sed} (µg/kg) *
FOCUS						
Step 1	---	3.2832	Run-off/Drain	2.9087	2.3222	1.0659
Step 2						

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7 d- PEC _{sw, twa} (µg/L) **	21 d- PEC _{sw, twa} (µg/L) **	Max PEC _{sed} (µg/kg) *
FOCUS						
Spring	N-Europe	0.3062*	Run-off/Drain	0.2707**	0.2161**	0.0984*
	S-Europe	0.5348*	Run-off/Drain	0.4734**	0.3780**	0.1721*
Summer	N-Europe	0.3062*	Run-off/Drain	0.2707**	0.2161**	0.0984*
	S-Europe	0.4205*	Run-off/Drain	0.3721**	0.2970**	0.1353*
Autumn	N-Europe	0.6491*	Run-off/Drain	0.5748**	0.4589**	0.2090
	S-Europe	0.3062*	Run-off/Drain	0.2707**	0.2161**	0.0984*

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-11: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F075736 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7 d- PEC _{sw, twa} (µg/L) **	21 d- PEC _{sw, twa} (µg/L) **	Max PEC _{sed} (µg/kg) *
FOCUS						
Step 1	---	3.7303	Run-off/Drain	3.6613	3.5298	0.5194
Step 2						
Spring	N-Europe	0.5313*	Run-off/Drain	0.5214**	0.5026**	0.0740*
	S-Europe	1.0192*	Run-off/Drain	1.0003**	0.9644**	0.1419*
Summer	N-Europe	0.5313*	Run-off/Drain	0.5214**	0.5026**	0.0740*
	S-Europe	0.7753*	Run-off/Drain	0.7608**	0.7335**	0.1079*
Autumn	N-Europe	1.2631*	Run-off/Drain	1.2398**	1.1952**	0.1759*
	S-Europe	1.0192*	Run-off/Drain	1.0003**	0.9644**	0.1419*

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-12: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F145741 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7-d- PEC _{sw, twa} (µg/L) **	21 d- PEC _{sw, twa} (µg/L) **	Max PEC _{sed} (µg/kg) *
FOCUS						
Step 1	---	0.4920	Run-off/Drain	0.4761	0.4463	<0.001
Step 2						
Spring	N-Europe	0.0577*	Run-off/Drain	0.0558**	0.0523**	<0.0001*
	S-Europe	0.1082*	Run-off/Drain	0.1047**	0.0982**	<0.0001*
Summer	N-Europe	0.0577*	Run-off/Drain	0.0558**	0.0523**	<0.0001*
	S-Europe	0.0830*	Run-off/Drain	0.0803**	0.0753**	<0.0001*
Autumn	N-Europe	0.1335*	Run-off/Drain	0.1292**	0.1211**	<0.0001*
	S-Europe	0.1082*	Run-off/Drain	0.1047**	0.0982**	<0.0001*

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-13: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F145740 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7-d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
Step 1	---	0.6570	Run-off/Drain	0.6228	0.5618	0.1158
Step 2						
Spring	N-Europe	0.0871 *	Run-off/Drain	0.0825 **	0.0744 **	0.0153 *
	S-Europe	0.1642 *	Run-off/Drain	0.1556 **	0.1404 **	0.0289 *
Summer	N-Europe	0.0871 *	Run-off/Drain	0.0825 **	0.0744 **	0.0153 *
	S-Europe	0.1256 *	Run-off/Drain	0.1191 **	0.1074 **	0.0221 *
Autumn	N-Europe	0.2027 *	Run-off/Drain	0.1922 **	0.1733 **	0.0357 *
	S-Europe	0.1642 *	Run-off/Drain	0.1556 **	0.1404 **	0.0289 *

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-14: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE 0002166 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7-d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
Step 1	---	1.1460	Run-off/Drain	1.1433	1.1377	<0.001
Step 2						
Spring	N-Europe	0.1315 *	Run-off/Drain	0.1311 **	0.1305 **	<0.0001 *
	S-Europe	0.2456 *	Run-off/Drain	0.2450 **	0.2438 **	<0.0001 *
Summer	N-Europe	0.1315 *	Run-off/Drain	0.1311 **	0.1305 **	<0.0001 *
	S-Europe	0.1885 *	Run-off/Drain	0.1881 **	0.1872 **	<0.0001 *
Autumn	N-Europe	0.3027 *	Run-off/Drain	0.3020 **	0.3005 **	<0.0001 *
	S-Europe	0.2456 *	Run-off/Drain	0.2450 **	0.2438 **	<0.0001 *

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-15: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F161778 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7-d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
Step 1	---	0.3821	Run-off/Drain	0.3812	0.3793	0.1134
Step 2						
Spring	N-Europe	0.0564 *	Run-off/Drain	0.0562 **	0.0559 **	0.0167 *
	S-Europe	0.1111 *	Run-off/Drain	0.1108 **	0.1103 **	0.0330 *
Summer	N-Europe	0.0564 *	Run-off/Drain	0.0562 **	0.0559 **	0.0167 *

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7-d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
	S-Europe	0.0837*	Run-off/Drain	0.0835**	0.0831**	0.0248*
Autumn	N-Europe	0.1385*	Run-off/Drain	0.1381**	0.1374**	0.0411*
	S-Europe	0.1111*	Run-off/Drain	0.1108**	0.1103**	0.0330*

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-16: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BCS-CW81253 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7-d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
Step 1	---	0.7188	Run-off/Drain	0.7171	0.7136	0.3005
Step 2						
Spring	N-Europe	0.1296*	Run-off/Drain	0.1293**	0.1286**	0.0542*
	S-Europe	0.2592*	Run-off/Drain	0.2585**	0.2573**	0.1083*
Summer	N-Europe	0.1296*	Run-off/Drain	0.1293**	0.1286**	0.0542*
	S-Europe	0.1944*	Run-off/Drain	0.1939**	0.1930**	0.0813*
Autumn	N-Europe	0.3240*	Run-off/Drain	0.3232**	0.3216**	0.1354*
	S-Europe	0.2592*	Run-off/Drain	0.2585**	0.2573**	0.1083*

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-17: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE 0000119 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7-d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
Step 1	---	0.4549	Run-off/Drain	0.4173	0.3551	0.5239
Step 2						
Spring	N-Europe	0.0573*	Run-off/Drain	0.0524**	0.0446**	0.0652*
	S-Europe	0.1081*	Run-off/Drain	0.0992**	0.0844**	0.1242*
Summer	N-Europe	0.0573*	Run-off/Drain	0.0524**	0.0446**	0.0652*
	S-Europe	0.0827*	Run-off/Drain	0.0758**	0.0645**	0.0944*
Autumn	N-Europe	0.1335*	Run-off/Drain	0.1225**	0.1043**	0.1540*
	S-Europe	0.1081*	Run-off/Drain	0.0992**	0.0844**	0.1242*

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-18: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F059411 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC_{sw} ($\mu\text{g/L}$)*	Dominant entry route	7-d- $PEC_{sw, twa}$ ($\mu\text{g/L}$)**	21 d- $PEC_{sw, twa}$ ($\mu\text{g/L}$)**	Max PEC_{sed} ($\mu\text{g/kg}$)*
FOCUS						
Step 1	---	0.5756	Run-off/Drain	0.4548	0.3013	0.2594
Step 2						
Spring	N-Europe	0.0880*	Run-off/Drain	0.0695**	0.0461**	0.0394*
	S-Europe	0.1711*	Run-off/Drain	0.1353**	0.0896**	0.0773*
Summer	N-Europe	0.0880*	Run-off/Drain	0.0695**	0.0461**	0.0394*
	S-Europe	0.1295*	Run-off/Drain	0.1024**	0.0678**	0.0583*
Autumn	N-Europe	0.2127*	Run-off/Drain	0.1681**	0.1114**	0.0962*
	S-Europe	0.1711*	Run-off/Drain	0.1353**	0.0896**	0.0773*

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-19: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE 0014966 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC_{sw} ($\mu\text{g/L}$)*	Dominant entry route	7-d- $PEC_{sw, twa}$ ($\mu\text{g/L}$)**	21 d- $PEC_{sw, twa}$ ($\mu\text{g/L}$)**	Max PEC_{sed} ($\mu\text{g/kg}$)*
FOCUS						
Step 1	---	0.3684	Run-off/Drain	0.3488	0.3135	<0.001
Step 2						
Spring	N-Europe	0.0350*	Run-off/Drain	0.0331**	0.0298**	<0.0001*
	S-Europe	0.0606*	Run-off/Drain	0.0574**	0.0516**	<0.0001*
Summer	N-Europe	0.0350*	Run-off/Drain	0.0331**	0.0298**	<0.0001*
	S-Europe	0.0478*	Run-off/Drain	0.0453**	0.0407**	<0.0001*
Autumn	N-Europe	0.0735*	Run-off/Drain	0.0696**	0.0625**	<0.0001*
	S-Europe	0.0606*	Run-off/Drain	0.0574**	0.0516**	<0.0001*

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-20: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE 0034855 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC_{sw} ($\mu\text{g/L}$) *	Dominant entry route	7-d- $PEC_{sw, twa}$ ($\mu\text{g/L}$) **	21 d- $PEC_{sw, twa}$ ($\mu\text{g/L}$) **	Max PEC_{sed} ($\mu\text{g/kg}$) *
FOCUS						
Step 1	---	0.2648	Run-off/Drain	0.2642	0.2629	<0.001
Step 2						
Spring	N-Europe	0.0256 *	Run-off/Drain	0.0255 **	0.0254 **	<0.0001 *
	S-Europe	0.0440 *	Run-off/Drain	0.0439 **	0.0437 **	<0.0001 *
Summer	N-Europe	0.0256 *	Run-off/Drain	0.0255 **	0.0254 **	<0.0001 *
	S-Europe	0.0348 *	Run-off/Drain	0.0347 **	0.0345 **	<0.0001 *
Autumn	N-Europe	0.0532 *	Run-off/Drain	0.0531 **	0.0529 **	<0.0001 *
	S-Europe	0.0440 *	Run-off/Drain	0.0439 **	0.0437 **	<0.0001 *

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-21: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE 1234964 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC_{sw} ($\mu\text{g/L}$) *	Dominant entry route	7-d- $PEC_{sw, twa}$ ($\mu\text{g/L}$) **	21 d- $PEC_{sw, twa}$ ($\mu\text{g/L}$) **	Max PEC_{sed} ($\mu\text{g/kg}$) *
FOCUS						
Step 1	---	0.0964	Run-off/Drain	0.0961	0.0957	<0.001
Step 2						
Spring	N-Europe	0.0093 *	Run-off/Drain	0.0093 **	0.0092 **	<0.0001 *
	S-Europe	0.0160 *	Run-off/Drain	0.0160 **	0.0159 **	<0.0001 *
Summer	N-Europe	0.0093 *	Run-off/Drain	0.0093 **	0.0092 **	<0.0001 *
	S-Europe	0.0127 *	Run-off/Drain	0.0126 **	0.0126 **	<0.0001 *
Autumn	N-Europe	0.0194 *	Run-off/Drain	0.0193 **	0.0192 **	<0.0001 *
	S-Europe	0.0160 *	Run-off/Drain	0.0160 **	0.0159 **	<0.0001 *

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-22: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F159737 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC_{sw} ($\mu\text{g/L}$) *	Dominant entry route	7-d- $PEC_{sw, twa}$ ($\mu\text{g/L}$) **	21 d- $PEC_{sw, twa}$ ($\mu\text{g/L}$) **	Max PEC_{sed} ($\mu\text{g/kg}$) *
FOCUS						
Step 1	---	0.0925 *	Run-off/Drain	0.0923	0.0918	<0.001
Step 2						
Spring	N-Europe	0.0089 *	Run-off/Drain	0.0089 **	0.0089 **	<0.0001 *
	S-Europe	0.0154 *	Run-off/Drain	0.0153 **	0.0153 **	<0.0001 *
Summer	N-Europe	0.0089 *	Run-off/Drain	0.0089 **	0.0076 **	<0.0001 *

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7-d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
	S-Europe	0.0121 *	Run-off/Drain	0.0121 **	0.0121 **	<0.0001 *
Autumn	N-Europe	0.0186 *	Run-off/Drain	0.0185 **	0.0185 **	<0.0001 *
	S-Europe	0.0154 *	Run-off/Drain	0.0153 **	0.0153 **	<0.0001 *

* single applications should be marked.

** two-time as required by ecotox

Table 8.9-23: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F154781 following single application to cereals - for generic risk envelope covering all uses

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7-d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
Step 1	---	0.0710	Run-off/Drain	0.0708	0.0705	<0.001
Step 2						
Spring	N-Europe	0.0069 *	Run-off/Drain	0.0068 **	0.0068 **	<0.0001 *
	S-Europe	0.0118 *	Run-off/Drain	0.0118 **	0.0117 **	<0.0001 *
Summer	N-Europe	0.0069 *	Run-off/Drain	0.0068 **	0.0068 **	<0.0001 *
	S-Europe	0.0093 *	Run-off/Drain	0.0093 *	0.0093 **	<0.0001 *
Autumn	N-Europe	0.0143 *	Run-off/Drain	0.0142 **	0.0142 **	<0.0001 *
	S-Europe	0.0118 *	Run-off/Drain	0.0118 **	0.0117 **	<0.0001 *

* single applications should be marked.

** two-time as required by ecotox

(b) FOCUS Step 3 – PEC_{sw/sed} (maximum and TWA) of iodosulfuron-methyl-sodium and metabolite AE F075736 [for Tier 1 assessment]

**Table 8.9-24: FOCUS Step 3 PEC_{sw} and PEC_{sed} for iodosulfuron-methyl-sodium following application of IMS+MSM+MPR OD 42 (2+10+30)
- Use: winter cereals, 1 × 3 g iodosulfuron-methyl-sodium/ha, end of winter to spring application**

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
Step 3: winter cereals, 1 × 3 g iodosulfuron-methyl-sodium/ha, end of winter to spring application ¹⁾						
D1	ditch	0.0197 *	Spray drift	0.0170	0.0093	0.0159 *
D1	stream	0.0165 *	Spray drift	0.0009	0.0006	0.0029 *
D2	ditch	0.1540 *	Drainage	0.0639	0.0449	0.0515 *
D2	stream	0.0962 *	Drainage	0.0332	0.0234	0.0290 *
D3	ditch	0.0191 *	Spray drift	0.0025	0.0008	0.0036 *
D4	pond	0.0007 *	Spray drift	0.0006	0.0006	0.0010 *

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
D4	stream	0.0144 *	Spray drift	< 0.0001	< 0.0001	0.0004 *
D5	pond	0.0007 *	Spray drift	0.0006	0.0006	0.001 *
D5	stream	0.0149 *	Spray drift	< 0.0001	< 0.0001	0.0003 *
D6	ditch	0.019 *	Spray drift	0.0013	0.0005	0.0027 *
R1	pond	0.0007 *	Spray drift	0.0006	0.0006	0.0012 *
R1	stream	0.0139 *	Runoff	0.0008	0.0005	0.0023 *
R3	stream	0.0428 *	Runoff	0.0030	0.0013	0.0068 *
R4	stream	0.0292 *	Runoff	0.0035	0.0013	0.0063 *

* single applications should be marked.

** two-time as required by ecotox

data origin (modelling report & crop no.): 1) EnSa-17-0475, Winter cereals 1.

Table 8.9-25: Refined FOCUS Step 3 PEC_{sw} and PEC_{sed} for iodosulfuron-methyl-sodium following application of IMS+MSM+MPR OD 42 (2+10+30)
- Use: winter cereals, 1 × 3 g iodosulfuron-methyl-sodium/ha, end of winter to spring application

Step 3: winter cereals, 1 × 3 g iodosulfuron-methyl-sodium/ha, end of winter to spring application - refined simulation based on field soil kinetics data ²⁾						
D1	ditch	0.0198 *	Spray drift	0.0171	0.0093	0.0161 *
D1	stream	0.0165 *	Spray drift	0.0009	0.0006	0.0030 *
D2	ditch	0.1788 *	Drainage	0.0760	0.0548	0.0625 *
D2	stream	0.1119 *	Drainage	0.0398	0.0288	0.0354 *
D3	ditch	0.0191 *	Spray drift	0.0025	0.0008	0.0036 *
D4	pond	0.0007 *	Spray drift	0.0006	0.0006	0.0010 *
D4	stream	0.0144 *	Spray drift	<0.001	<0.001	0.0004 *
D5	pond	0.0007 *	Spray drift	0.0006	0.0006	0.0010 *
D5	stream	0.0149 *	Spray drift	<0.001	<0.001	0.0003 *
D6	ditch	0.0190 *	Spray drift	0.0013	0.0005	0.0027 *
R1	pond	0.0007 *	Runoff	0.0006	0.0006	0.0012 *
R1	stream	0.0149 *	Runoff	0.0009	0.0006	0.0025 *
R3	stream	0.0453 *	Runoff	0.0032	0.0014	0.0072 *
R4	stream	0.0314 *	Runoff	0.0038	0.0014	0.0067 *

* single applications should be marked.

** two-time as required by ecotox

data origin (modelling report & crop no.): 2) EnSa-18-0880, Winter Cereals 1.

Table 8.9-26: *FOCUS Step 3 PEC_{sw} and PEC_{sed} for AE F075736 following application of IMS+MSM+MPR OD 42 (2+10+30)*
- Use: winter cereals, 1 × 3 g iodosulfuron-methyl-sodium/ha, end-of winter-application

Scenario	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
FOCUS						
metabolite AE F075736						
Step 3: winter cereals, 1 × 3 g iodosulfuron-methyl-sodium/ha, end-of winter-spring application¹⁾						
D1	ditch	0.0348 *	-	0.0342	0.0312	0.0211 *
D1	stream	0.0282 *	-	0.0201	0.0127	0.0098 *
D2	ditch	0.1583 *	-	0.1122	0.0995	0.0559 *
D2	stream	0.1302 *	-	0.0697	0.061	0.0353 *
D3	ditch	0.0053 *	-	0.0053	0.0053	0.006 *
D4	pond	0.0123 *	-	0.0123	0.0122	0.0122 *
D4	stream	0.0065 *	-	0.0062	0.0057	0.0049 *
D5	pond	0.0024 *	-	0.0024	0.0023	0.0024 *
D5	stream	0.0013 *	-	0.0011	0.0011	0.0008 *
D6	ditch	0.001 *	-	0.001	0.0008	0.0006 *
R1	pond	0.0003 *	-	0.0003	0.0003	0.0002 *
R1	stream	0.0071 *	-	0.0004	0.0003	0.0005 *
R3	stream	0.0133 *	-	0.0009	0.0003	0.0009 *
R4	stream	0.0111 *	-	0.0013	0.0004	0.001 *

* single applications should be marked.

** two-time as required by ecotox

data origin (modelling report & crop no.): 1) EnSa-17-0475, Winter cereals 1.

Table 8.9-27: *Refined FOCUS Step 3 PEC_{sw} and PEC_{sed} for AE F075736 following application of IMS+MSM+MPR OD 42 (2+10+30)*
- Use: winter cereals, 1 × 3 g iodosulfuron-methyl-sodium/ha, end-of winter-application

metabolite AE F075736						
Step 3: winter cereals, 1 × 3 g iodosulfuron-methyl-sodium/ha, end-of winter-spring application						
- Refined simulation based on field soil kinetics data ²⁾						
D1	ditch	0.0156 *	-	0.0154	0.0142	0.0087 *
D1	stream	0.0134 *	-	0.0091	0.0058	0.0039 *
D2	ditch	0.0880 *	-	0.0618	0.0554	0.0308 *
D2	stream	0.0867 *	-	0.0442	0.0384	0.0215 *
D3	ditch	0.0002 *	-	0.0002	0.0002	0.0002 *
D4	pond	0.0006 *	-	0.0006	0.0006	0.0006 *
D4	stream	0.0003 *	-	0.0003	0.0003	0.0002 *
D5	pond	0.0002 *	-	0.0002	0.0002	0.0002 *
D5	stream	0.0002 *	-	<0.001	<0.001	<0.001 *

D6	ditch	0.0003	*	-	0.0003	0.0003	0.0002	*
R1	pond	0.0002	*	-	0.0002	0.0002	0.0002	*
R1	stream	0.0040	*	-	0.0002	0.0001	0.0003	*
R3	stream	0.0090	*	-	0.0006	0.0002	0.0006	*
R4	stream	0.0062	*	-	0.0007	0.0002	0.0006	*

* single applications should be marked.

** two-time as required by ecotox

data origin (modelling report & crop no.): 2) EnSa-18-0880, Winter cereals 1.

(c) FOCUS Step 3 – Timecourse of PEC_{sw} (FOCUS year) of iodosulfuron-methyl-sodium and metabolite AE F075736 [for Tier 2C and Tier 3 assessment]

For iodosulfuron-methyl-sodium use with the present formulation, for all FOCUS scenarios that are characterised by a pronounced time-variability of their exposure (i.e. stream or ditch type water bodies exposed via runoff or drift entry), the aquatic risk assessment in dRR Part B Section 9 is resolved already at Tier 1 level, based on FOCUS Step 3 PEC_{sw,max}. An EPAT-analysis of the underlying exposure patterns for these scenarios would not identify any 'events' of PEC_{sw} > RAC⁵, and is therefore not presented.

(d) FOCUS Step 3 – Timecourse of PEC_{sw} (multi-year simulation) for iodosulfuron-methyl-sodium and metabolite AE F075736 [for Tier 2C and Tier 3 assessment]

In response to concerns expressed by some regulators on the representativeness of the FOCUS model's single weather year in the context of a refined risk assessment based on exposure pattern analysis, additional calculations have been run for iodosulfuron-methyl and its metabolite AE F075736 over a period of 20 years (multi-year calculations). The full detailed electronic information of hourly exposure values over the simulated 20-year period for all FOCUS scenarios served as basis for ecological modelling approaches (TK/TD population effect simulation), which are described in dRR Part B Section 9.

For the reasons outlined under point (c) before, no statistical evaluation / EPAT analysis of the data is required in the present case.

(e) FOCUS Step 4 – PEC_{sw/sed} (maximum and TWA) of iodosulfuron-methyl-sodium and metabolite AE F075736 [for Tier 1 assessment considering mitigation options]

For the use of iodosulfuron-methyl-sodium with the present formulation, an exposure calculation at FOCUS Step 4 is not deemed relevant: The only scenarios left unresolved in a risk assessment based on FOCUS Step 3 are driven by the entry route drainage, which is not mitigated by the options considered at FOCUS Step 4.

⁵ RAC = Regulatory Acceptable Concentration

8.9.2.3 Mesosulfuron-methyl and its metabolites

Table 8.9-28: Input parameters related to active substance mesosulfuron-methyl and metabolites for $PEC_{sw/sea}$ calculations STEP 1/2 and 3/4

Compound	Mesosulfuron-methyl	AE F154851	AE F160459	AE F099095	AE F092944	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	503.5	489.5	489.5	198.2	155.2	Y/ EFSA Journal 2016;14(10): 4584
Saturated vapour pressure (Pa)	Step 1+2: not required Step 3/4: 3.5×10^{-12} (20°C)	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Y/ EFSA Journal 2016;14(10): 4584
Water solubility (mg/L)	483 (20°C, pH 7)*	200000 (20°C, pH 7)#	10000 (20°C, pH 7)#	190 (20°C, pH 7)#	5200 (20°C, pH 7)#	*Y/ EFSA Journal 2016;14(10): 4584. #Y/ KCA 2.14/05,07, 15,17; values listed in RAR Vol 3 – B.8 (PPP) – Atlantis OD (07/2016)
Diffusion coefficient in water (m ² /d)	Step 1+2: not required Step 3/4: 4.3×10^{-5}	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	default
Diffusion coefficient in air (m ² /d)	Step 1+2: not required Step 3/4: 0.43	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	default
K_{foc} (mL/g)	64 (geomean, n = 9) [†]	65 (geomean, n = 3)	19.3 (geomean, n = 5)	334 (geomean, n = 11)	293.9 (geomean, n = 23)	Y/ EFSA Journal 2016;14(10): 4584
Freundlich Exponent 1/n	Step 1+2: not required Step 3/4: 0.91 (arithmetic mean, n = 9)	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Y/ EFSA Journal 2016;14(10): 4584
Plant Uptake	Step 1+2:	Step 1+2:	Step 1+2:	Step 1+2:	Step 1+2:	Y/ EFSA

Compound	Mesosulfuron-methyl	AE F154851	AE F160459	AE F099095	AE F092944	Value in accordance to EU endpoint y/n/ Reference
	not required Step 3/4: 0	not required	not required	not required	not required	Journal 2016;14(10): 4584
Wash-Off factor from Crop (1/m)	Step 1+2: not required Step 3/4: 50	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	default
DT _{50,soil} (d)	Tier 1 – SFO: 49.72 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 9)	45.22 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 8)	74.14 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 5)	55.6 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 10)	16.93 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 13)	Y/ EFSA Journal 2016;14(10): 4584
DT _{50,water} (d)	43 (geomean, total system, n = 4)	54.7 (geomean, total system, n = 4)	87.8 (geomean, total system, n = 4)	1000 (default)	1000 (default)	Y/ EFSA Journal 2016;14(10): 4584
DT _{50,sed} (d)	Step 1+2: 43 (geomean, total system, n = 4) Step 3/4: 1000 (default)	54.7 (geomean, total system, n = 4)	87.8 (geomean, total system, n = 4)	1000 (default)	1000 (default)	Y/ EFSA Journal 2016;14(10): 4584
DT _{50,whole system} (d)	43 (geomean, total system, n = 4)	54.7 (geomean, total system, n = 4)	87.8 (geomean, total system, n = 4)	1000 (default)	1000 (default)	Y/ EFSA Journal 2016;14(10): 4584
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 16.2 Water/ sediment: 4.9	Soil: 8.9 Water/ sediment: 21.6	Soil: 29.2 Water/ sediment: 0.9	Soil: 10.1 Water/ sediment: 3.2	Y/ EFSA Journal 2016;14(10): 4584

¹ K_{om} = 37.1 ml/g

Table 8.9-29: Input parameters related to active substance mesosulfuron-methyl metabolites for PEC_{sw/sed} calculations STEP 1/2 (continued)

Compound	AE F160460	AE F140584	AE F147447	BCS-CV14885	BCS-CO60720	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	475.5	322.4	290.3	393.4	407.4	Y/ EFSA Journal

Compound	AE F160460	AE F140584	AE F147447	BCS-CV14885	BCS-CO60720	Value in accordance to EU endpoint y/n/ Reference
						2016;14(10):4584
Saturated vapour pressure (Pa)	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	
Water solubility (mg/L)	100000 (20°C, pH 7)*	100 (20°C, pH 7)*	150000 (20°C, pH 7)*	2000 (20°C, pH 7)*	1000 (default value)*	*Y/ KCA 2.14/09,11,13,19; values listed in RAR of mesosulfuron-methyl, Vol 3 – B.8 (PPP) – Atlantis OD (07/2016)
Diffusion coefficient in water (m ² /d)	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	
Diffusion coefficient in air (m ² /d)	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	
K _{foc} (mL/g)	12.2 (geomean, n = 5)	0 (default)	5.1 (geomean, n = 5)	17.7 (geomean, n = 4)	0 (default)	Y/ EFSA Journal 2016;14(10):4584
Freundlich Exponent 1/n	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	
Plant Uptake	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	
Wash-Off factor from Crop (1/m)	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	Step 1+2: not required	
DT _{50,soil} (d)	28.61 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 5)	4.22 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 5)	102.15 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 5)	97.6 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 4)	0.001 (default)	Y/ EFSA Journal 2016;14(10):4584
DT _{50,water} (d)	325.9 (geomean, total system, n = 4)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Y/ EFSA Journal 2016;14(10):4584
DT _{50,sed} (d)	325.9 (geomean, total system, n = 4)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Y/ EFSA Journal 2016;14(10):4584
DT _{50,whole system} (d)	325.9	1000	1000	1000	1000	Y/ EFSA

Compound	AE F160460	AE F140584	AE F147447	BCS-CV14885	BCS-CO60720	Value in accordance to EU endpoint y/n/ Reference
	(geomean, total system, n = 4)	(default)	(default)	(default)	(default)	Journal 2016;14(10):4 584
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 8.6 Water/ sediment: 8.4	Soil: 7.1 Water/ sediment: 1.9	Soil: 5.8 Water/ sediment: 10.9	Soil: 5.0 Water/ sediment: 22.0	Soil: 0.001 Water/ sediment: 13.1	Y/ EFSA Journal 2016;14(10):4 584

(a) **FOCUS Steps 1-2 – Risk envelope PEC_{sw}/sed of mesosulfuron-methyl and all metabolites [for screening level assessment]**

Table 8.9-30: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for mesosulfuron-methyl following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
Step 1	---	4.7448 -	RunOff/Drain.	4.4775	4.0162	2.9813 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.9938 * 1.8652 *	RunOff/Drain. RunOff/Drain	0.9370 1.7610	0.8404 1.5797	0.6238 * 1.1726 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.9938 * 1.4295 *	RunOff/Drain. RunOff/Drain	0.9370 1.3490	0.8404 1.2100	0.6238 * 0.8982 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	2.3009 * 1.8652 *	RunOff/Drain. RunOff/Drain	2.1731 1.7610	1.9493 1.5797	1.4470 * 1.1726 *
Step 3	Not required					

* single applications marked.

** two-time as required by ecotox

Table 8.9-31: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F154851 following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
Step 1	-	0.9504 -	RunOff/Drain.	0.9090	0.8340	0.6135 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.1837 * 0.3615 *	RunOff/Drain. RunOff/Drain.	0.1756 0.3458	0.1611 0.3172	0.1181 * 0.2337 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.1837 * 0.2726 *	RunOff/Drain. RunOff/Drain.	0.1756 0.2607	0.1611 0.2392	0.1181 * 0.1759 *
N-Europe	Oct. - Feb.	0.4503 *	RunOff/Drain.	0.4308	0.3953	0.2914 *

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
S-Europe	(Autumn)	0.3615 *	RunOff/Drain.	0.3458	0.3172	0.2337 *
Step 3	Not required					

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-32: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F160459 following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	-	1.4744 -	RunOff/Drain.	1.4337	1.3580	0.2822 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.3025 * 0.5774 *	RunOff/Drain. RunOff/Drain.	0.2941 0.5615	0.2785 0.5318	0.0579 * 0.1105 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.3025 * 0.4399 *	RunOff/Drain. RunOff/Drain.	0.2941 0.4278	0.2785 0.4052	0.0579 * 0.0842 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.7148 * 0.5774 *	RunOff/Drain. RunOff/Drain.	0.6952 0.5615	0.6585 0.5318	0.1368 * 0.1105 *
Step 3	Not required					

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-33: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F099095 following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	-	0.4104 -	RunOff/Drain.	0.4093	0.4073	1.3692 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.0784 * 0.1563 *	RunOff/Drain. RunOff/Drain.	0.0781 0.1559	0.0778 0.1552	0.2614 * 0.5217 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.0784 * 0.1173 *	RunOff/Drain. RunOff/Drain.	0.0781 0.1170	0.0778 0.1165	0.2614 * 0.3915 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.1953 * 0.1563 *	RunOff/Drain. RunOff/Drain.	0.1948 0.1559	0.1939 0.1552	0.6520 * 0.5217 *
Step 3	Not required					

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-34: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F092944 following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	-	0.1486	RunOff/Drain.	0.1479	0.1472	0.4354
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.0268 0.0525	RunOff/Drain. RunOff/Drain.	0.0266 0.0522	0.0265 0.0520	0.0783 0.1538
N-Europe S-Europe	Jun. - Sep. (Summer)	0.0268 0.0396	RunOff/Drain. RunOff/Drain.	0.0266 0.0394	0.0265 0.0392	0.0783 0.1160
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.0653 0.0525	RunOff/Drain. RunOff/Drain.	0.0651 0.0522	0.0647 0.0520	0.1915 0.1538
Step 3	Not required					

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-35: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F160460 following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	-	0.8008	RunOff/Drain.	0.7947	0.7830	0.0975
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.1571 0.3035	RunOff/Drain. RunOff/Drain.	0.1559 0.3012	0.1536 0.2967	0.0191 0.0369
N-Europe S-Europe	Jun. - Sep. (Summer)	0.1571 0.2303	RunOff/Drain. RunOff/Drain.	0.1559 0.2285	0.1536 0.2252	0.0191 0.0280
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.3766 0.3035	RunOff/Drain. RunOff/Drain.	0.3738 0.3012	0.3683 0.2967	0.0459 0.0369
Step 3	Not required					

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-36: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F140584 following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)**	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	-	0.2898	RunOff/Drain.	0.2891	0.2877	<0.001
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.0368 0.0718	RunOff/Drain. RunOff/Drain.	0.0367 0.0717	0.0365 0.0713	<0.0001 <0.0001
N-Europe S-Europe	Jun. - Sep. (Summer)	0.0368 0.0543	RunOff/Drain. RunOff/Drain.	0.0367 0.0542	0.0365 0.0539	<0.0001 <0.0001
N-Europe	Oct. - Feb.	0.0894	RunOff/Drain.	0.0891	0.0887	<0.0001

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
S-Europe	(Autumn)	0.0718 *	RunOff/Drain.	0.0717	0.0713	<0.0001 *
Step 3	Not required					

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-37: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE F147447 following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	-	0.4868 -	RunOff/Drain.	0.4856	0.4833	0.0248 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.1000 * 0.1913 *	RunOff/Drain. RunOff/Drain.	0.0997 0.1909	0.0992 0.1899	0.0051 * 0.0098 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.1000 * 0.1457 *	RunOff/Drain. RunOff/Drain.	0.0997 0.1453	0.0992 0.1446	0.0051 * 0.0074 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.2370 * 0.1913 *	RunOff/Drain. RunOff/Drain.	0.2364 0.1909	0.2353 0.1899	0.0121 * 0.0098 *
Step 3	Not required					

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-38: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BCS-CV14885 following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	-	1.0542 -	RunOff/Drain.	1.0285	0.9806	0.1852 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.2186 * 0.4145 *	RunOff/Drain. RunOff/Drain.	0.2133 0.4045	0.2033 0.3856	0.0384 * 0.0728 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.2186 * 0.3166 *	RunOff/Drain. RunOff/Drain.	0.2133 0.3089	0.2033 0.2945	0.0384 * 0.0556 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.5125 * 0.4145 *	RunOff/Drain. RunOff/Drain.	0.5001 0.4045	0.4768 0.3856	0.0901 * 0.0728 *
Step 3	Not required					

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-39: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BCS-CO60720 following single application to cereals - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
Step 1	-	0.5446	RunOff/Drain.	0.5433	0.5407	<0.001
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.1148 0.2151	RunOff/Drain. RunOff/Drain.	0.1146 0.2146	0.1140 0.2135	<0.0001 <0.0001
N-Europe S-Europe	Jun. - Sep. (Summer)	0.1148 0.1650	RunOff/Drain. RunOff/Drain.	0.1146 0.1646	0.1140 0.1638	<0.0001 <0.0001
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.2652 0.2151	RunOff/Drain. RunOff/Drain.	0.2646 0.2146	0.2633 0.2135	<0.0001 <0.0001
Step 3	Not required					

* single applications should be marked.

** twa-time as required by ecotox

(b) FOCUS Step 3 – PEC_{sw/sed} (maximum and TWA) of mesosulfuron-methyl [for Tier 1 assessment]

**Table 8.9-40: FOCUS Step 3 PEC_{sw} and PEC_{sed} for mesosulfuron-methyl following single application of IMS+MSM+MPR OD 42 (2+10+30)
– Use: winter cereals, 1 × 15 g mesosulfuron-methyl/ha, end of winter to spring application**

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L) *	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)**	21 d- PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg) *
Step 3: winter cereals, 1 × 15 g mesosulfuron-methyl/ha, end of winter to spring application ¹⁾						
D1	ditch	0.2187	Drainage	0.1926	0.1504	0.4013
D1	stream	0.1410	Drainage	0.1264	0.0996	0.2351
D2	ditch	1.6040	Drainage	0.9150	0.7687	1.0930
D2	stream	1.0230	Drainage	0.5414	0.4361	0.6295
D3	ditch	0.0982	Spray drift	0.0156	0.0074	0.0276
D4	pond	0.0412	Drainage	0.0410	0.0400	0.1044
D4	stream	0.0770	Spray drift	0.0306	0.0260	0.0417
D5	pond	0.0198	Spray drift	0.0194	0.0187	0.0511
D5	stream	0.0827	Spray drift	0.0097	0.0092	0.0241
D6	ditch	0.1009	Spray drift	0.0133	0.0092	0.0250
R1	pond	0.0063	Runoff	0.0059	0.0055	0.0105
R1	stream	0.1008	Runoff	0.0099	0.0055	0.0179
R3	stream	0.3099	Runoff	0.0217	0.0088	0.0494
R4	stream	0.2646	Runoff	0.0321	0.0113	0.0565

* single applications should be marked.

** twa-time as required by ecotox

data origin (modelling report & crop no.): 1) Ensa-17-0403, Winter cereals 1.

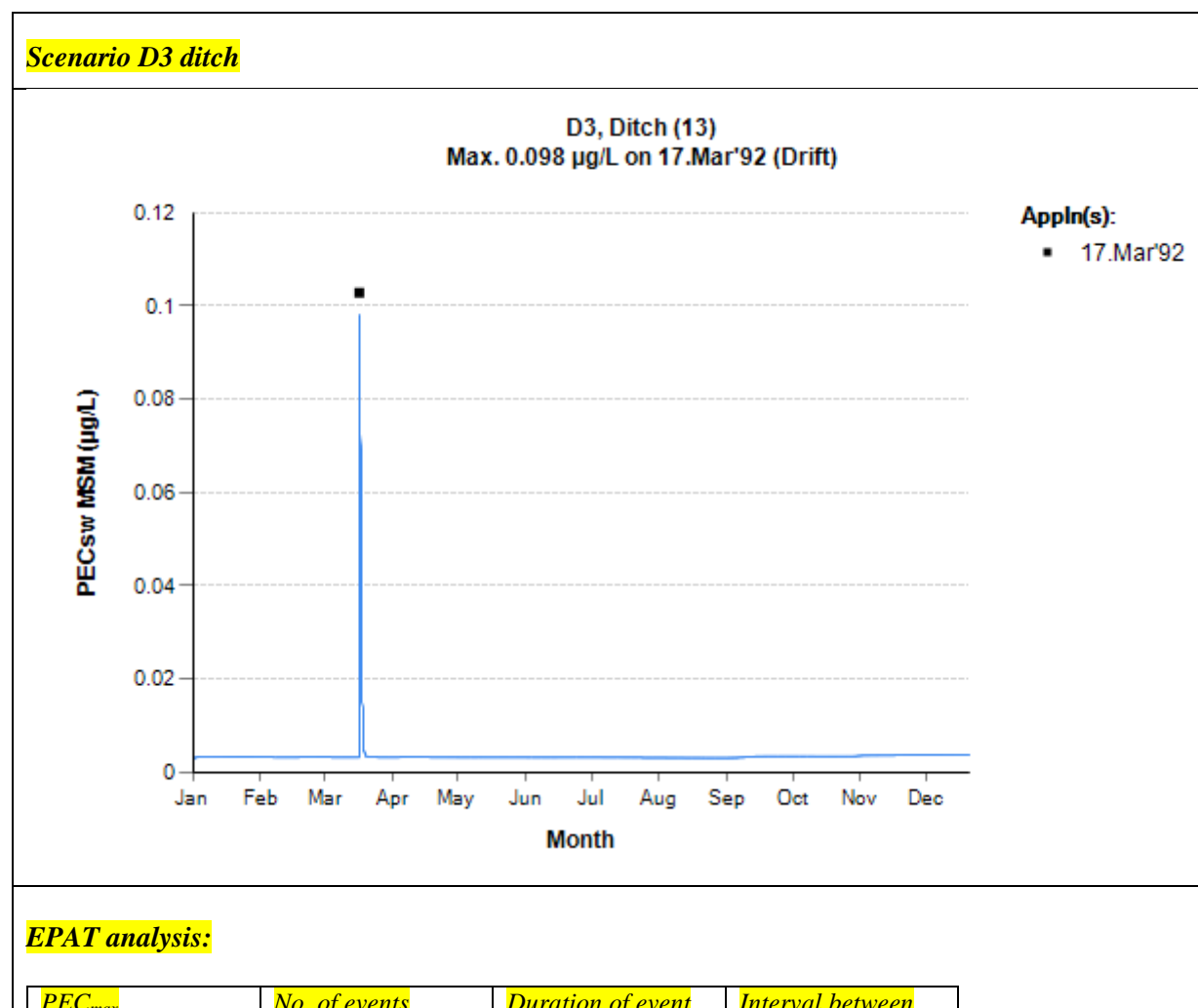
(c) FOCUS Step 3 – Timecourse of PEC_{sw} (FOCUS year) of mesosulfuron-methyl [for Tier 2C and Tier 3 assessment]

For the present formulation, a higher tier / refined risk assessment is presented for mesosulfuron-methyl exposure in selected FOCUS surface water scenarios in dRR Part B Section 9, based on an ecotoxicological interpretation of the evolution of surface concentration over time. As prerequisite, time-course plots were generated from the FOCUS Step 3 model output, and numerically characterised via EPAT tool analysis for the following parameters:

- the PEC_{max} ,
- the number of peak events above the Tier 1 RAC,
- the duration of these peak events, and
- the interval between these peak events.

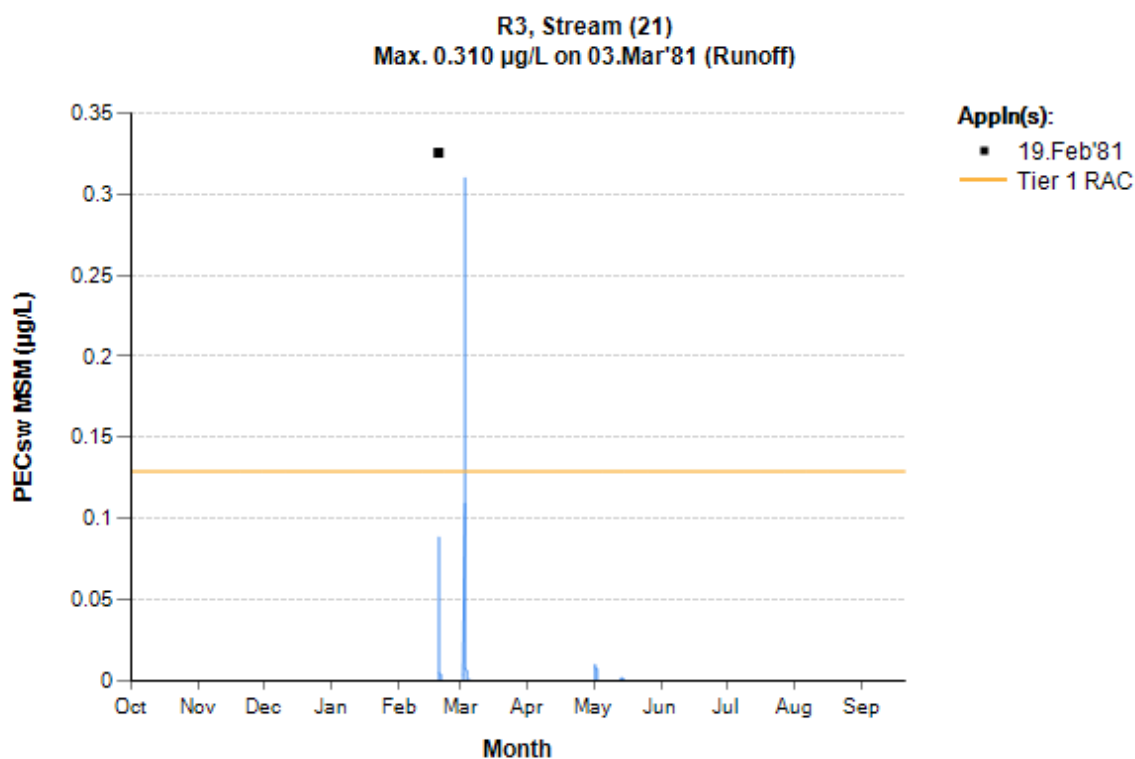
Moreover, the modelling output files containing full detailed information on exposure over the simulated FOCUS year period in hourly resolution for all FOCUS scenarios were transferred electronically into ecological modelling approaches (TK/TD population effect simulation), which are described in dRR Part B Section 9.

Table 8.9-41: Timecourse of FOCUS Step 3 PEC_{sw} for mesosulfuron-methyl following single application of IMS+MSM+MPR OD 42 (2+10+30)
– Use: winter cereals, 1 × 15 g mesosulfuron-methyl/ha, end of winter to spring application



$[\mu\text{g a.s./L}]$	$> \text{Tier 1-RAC}$	$[\text{days}]$	$\text{events} [\text{days}]$
0.09816	0	N/A	N/A
[event recognition threshold: 0.129 $\mu\text{g/L}$]			
Exposure in this scenario situation does NOT exceed the Tier 1 RAC, however analysis of timecourse was triggered by combined toxicity assessment of all active substances. Visual assessment of the plotted time course clearly shows a peak exposure profile for this drift-driven scenario.			

Scenario R3 stream

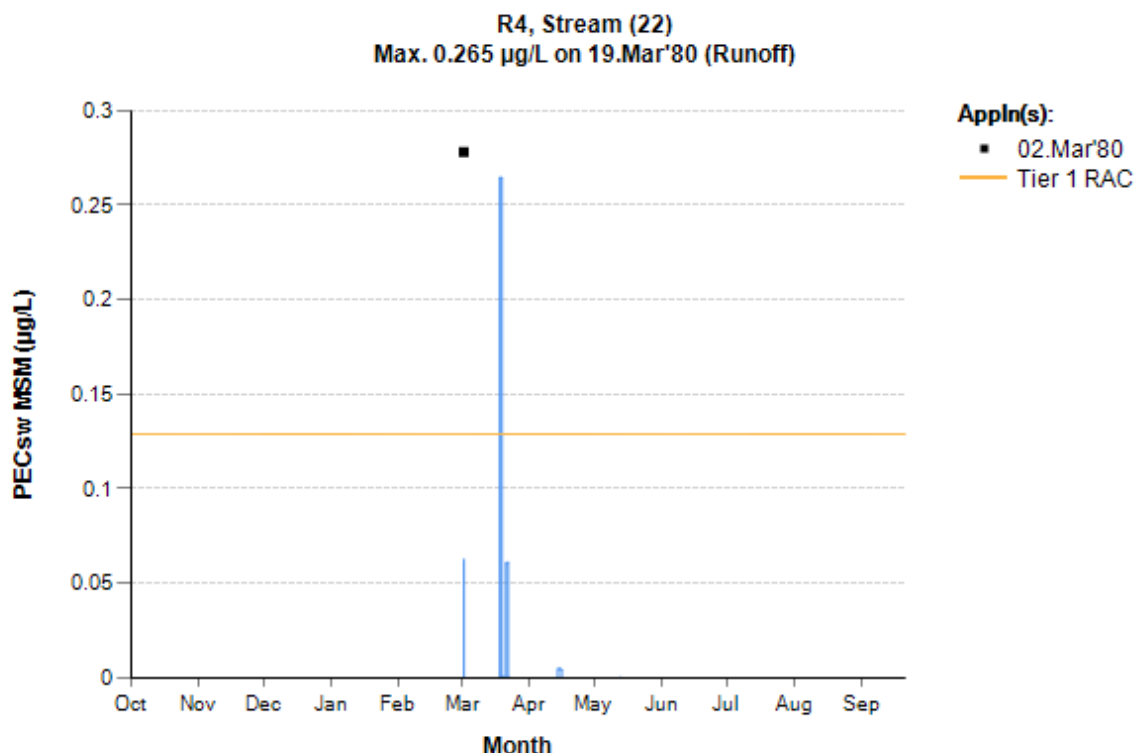


Tier 1-RAC = 0.129 $\mu\text{g/L}$

EPAT analysis:

PEC_{max} $[\mu\text{g a.s./L}]$	No. of events $> \text{Tier 1-RAC}$	Duration of event $[\text{days}]$	Interval between events $[\text{days}]$
0.3099	1	0.5	Not relevant
[event recognition threshold: 0.129 $\mu\text{g/L}$]			

Scenario R4 stream



Tier 1-RAC = 0.129 µ/L

EPAT analysis:

PEC _{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.2646	1	0.75	Not relevant

[event recognition threshold: 0.129 µg/L]

(d) FOCUS Step 3 – Timecourse of PECsw (multi-year simulation) for mesosulfuron-methyl [for Tier 2C and Tier 3 assessment]

In response to concerns expressed by some regulators on the representativeness of the FOCUS model's single weather year in the context of a refined risk assessment based on exposure pattern analysis, additional calculations have been run for mesosulfuron-methyl over a period of 20 years (multi-year calculations). From this large data set, 90th percentile realistic worst case exposure patterns were derived for those critical GAP situations previously addressed for the FOCUS medium year under point (c) above.

Moreover, the full detailed electronic information of hourly exposure values over the simulated 20-year period for all FOCUS scenarios served as basis for ecological modelling approaches (TK/TD population effect simulation), which are described in dRR Part B Section 9.

(e) FOCUS Step 4 – PECsw/sed (maximum and TWA) of iodosulfuron-methyl-sodium and metabolite AE F075736 [for Tier 1 assessment considering mitigation options]

For the use of mesosulfuron-methyl with the present formulation, an exposure calculation at FOCUS Step

4 was not deemed relevant: The only scenarios left unresolved in a risk assessment based on FOCUS Step 3 were driven by the entry route drainage, which is not mitigated by the options considered at FOCUS Step 4.

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

Information concerning fate and behaviour in air is included in RR for the reference product Atlantis 12 OD. Please refer to Renewal RR prepared for Atlantis 12 OD. No further data are required.

8.10.1 Fate and behaviour of iodosulfuron-methyl-sodium in air

The fate of iodosulfuron-methyl-sodium in air has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453), no additional studies are considered for this assessment.

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Iodosulfuron-methyl-sodium
Direct photolysis in air	Not studied, no data required
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	DT ₅₀ (h): 152 derived by the Atkinson model OH (24h) concentration assumed = 0.5×10^6 OH/cm ³
Volatilisation	Not available, not requested
Metabolites	Not available, not requested

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

8.10.2 Fate and behaviour of mesosulfuron-methyl in air

The fate of mesosulfuron-methyl in air has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(10):4584), no additional studies are considered for this assessment.

Table 8.10-2 Summary of atmospheric degradation and behaviour

Compound	Mesosulfuron-methyl
Direct photolysis in air	Not studied, no data required
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	DT ₅₀ (d): 0.05 derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 OH/cm ³
Volatilisation	Not available, not requested
Metabolites	AE F099095: DT ₅₀ (d): 0.053 derived by the Atkinson model; OH (12h) concentration assumed = 1.5×10^6 OH/cm ³ AE F092944: DT ₅₀ (d): 0.053 derived by the Atkinson model; OH (12h) concentration assumed = 1.5×10^6 OH/cm ³

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4/01	Hara-Skrzypiec A.	2023	JME-HER 12 OD- calculation of Predicted Environmental Concentrations of iodosulfuron-methyl-sodium and mesosulfuron-methyl and their metabolites in ground water using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models. Company Report No: EST/21/2023 Source: ESTICON Sp. z o.o., Poland non GLP unpublished	N	Pestila*

*Pestila Spółka z ograniczoną odpowiedzialnością (Pestila Sp. z o.o.)

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

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

Not relevant. No new studies submitted.

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

Not relevant. No new data submitted.