FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: DNT-162OD-R-CPd

Product name: EVRITELL 162 OD

Chemical active substance(s):
Dicamba, 110 g/L

Nicosulfuron, 40 g/L

Thifensulfuron-methyl, 12 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: QEMETICA Agricultural Solutions Poland S.A. (formerly: CIECH Sarzyna S.A.).

Submission date: 01/2024; 10/2024

MS Finalisation date: 08/2024; 10/2024; 03/2025

Version history

When	What
January 2024	First submission to zRMS
August 2024	Evaluation by zRMS
October 2024	Additional calculations for groundwater modeling performed by the applicant
October 2024	Assessment new calculations PECgw
March 2025	Final Registration Report

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp 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. safener/ synergist per ha, other dose rate expression, dose range (min-max)	**Conclusion (groundwater)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL, DE, HU, SK	Maize ZEAMX	F	Annual monocotyledonous weeds TTTMS; Annual dicotyledonous weeds TTTDS	Spraying, broadcast	Post emergence of weeds; crop BBCH 12-16	a) 1 b) 1	n.a.	a) 1 L/ha; b) 1 L/ha	a) as 1: 110 g as/ha as 2: 40 g as/ha as 3: 12 g as/ha b) as 1: 110 g as/ha as 2: 40 g as/ha as 3: 12 g as/ha	100/300	n.a.	Dose range: 0.75-1L/ha	R

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

Remarks columns:

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

Explanation for column 15 “Conclusion”

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

Table 8.1-2: Assessed (critical) uses during approval of Dicamba concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** (**crop destination / purpose of crop)**	**F, Fn, Fnp G, Gn, Gnp or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Number min.-max.	Interval between applications (min.)	kg as/hL min.-max.	kg as/ha min.-max.	Water L/ha min / max		
1	EU (N & S)	Maize	F	Dicotyledon weeds incl. *Chenopodium spp.* *Convolvulus spp.* *Polygonum spp.*	Overall sprayer	Post emergence until BBCH 16	1	-	-	0.360	100/500	-	Period between treatment and harvest is > 100 days, no PHI is applicable [1] [2]
2	EU (N & S)	Pasture	F	Dicotyledon weeds incl. *Chenopodium spp.* *Convolvulus spp.* *Polygonum spp.*	Overall sprayer	Spring/summer	1 - 2	6 weeks	-	0.480	100/500	14	[1] [2][3]

[1] Dicamba has the potential for long-range transport through the atmosphere.
[2] A detailed quantification of a group of unidentified transformation products, found in one soil incubation, was not available, therefore there are no assessments for the environmental compartments for any potentially formed soil transformation products from this group.
[3] The environmental exposure and risk assessment available for pasture covers only those situations when the pasture is already established.

Remarks table:

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

Table 8.1-3: Assessed (critical) uses during approval of Nicosulfuron concerning the Section Environmental Fate

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
					Type	Conc. of as	method kind	growth stage & season	number min/ max	interval between applications (min)	g as/hL min – max	water L/ha min – max	g as/ha min – max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)		(l)		(l)	(m)	
Maize	various	SL-950 4% SC	F	weeds	OD	40 g/L	spray application	BBCH 12-18	1	n.a.	15-30	200-400	60	n.r.	-

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	Member state(s)	Crop and/or situation (crop destination/ purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I *	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method/ Kind	Timing/ Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
n.a.	EU countries (Annex I renewal)	Maize	F	Broadleaf weeds	Tractor mounted hydraulic/trailed boom sprayer, broadcast foliar application, ground directed spraying	BBCH 12-18	1-2	7/10	-	1 x 5.6-11.25 or 5.6235+ 3.75 = 9.375 (total) or 2 x 3.75 = 7.5 (total)	150-500	n.a. except 60 (DK, SE, LI silage or feed of whole plant, cob, kernels)	With and without nonionic surfactant (i.e., Trend 90, 0.05-0.1% v/v)

8.2 Metabolites considered in the assessment

The degradation products of the active substances – dicamba, nicosulfuron and thifensulfuron methyl in the formulation are presented in the following sections. The rationale for determining the need to assess metabolites in the various exposure compartments is provided in the relevant point of the assessment.

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

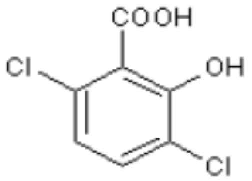
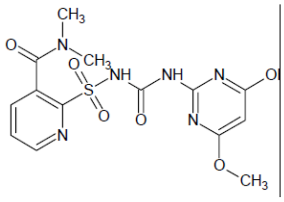
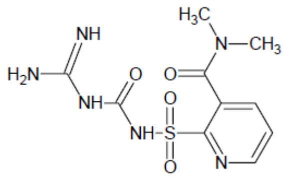
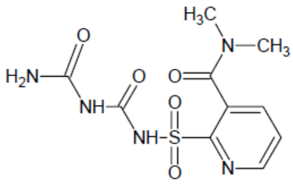
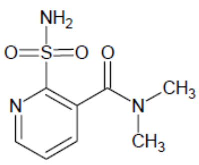
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
DCSA 3,6-0dichloro-2-hydroxybenzoic acid	207		Soil: 58.8 % Water/sediment: 31.4 %	PEC sw/sed: potential risk to aquatic and soil organisms PEC gw: leaching potential to groundwater

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
HMUD (2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-N,N-dimethylnicotinamide)	396.4		Soil: aerob; max 14.4 % on day 28 Water: max. 14.1 % on day 62 Sediment: max. 5.7 % on day 30	PEC_{gw}: leaching potential to groundwater PEC_{soil}: covered by EU assessment $PEC_{sw/sed}$: covered by EU assessment
AUSN 2-[(carbamimidoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	314.3		Soil: aerob; max 19.5 % on day 112 Water: max. 9.1 % on day 177	PEC_{gw}: leaching potential to groundwater PEC_{soil}: covered by EU assessment $PEC_{sw/sed}$: covered by EU assessment
UCSN 2-[(carbamoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	315.3		Soil: aerob; max 11 % on day 238 Water: max. 5.4 % on day 177	PEC_{gw}: leaching potential to groundwater PEC_{soil}: covered by EU assessment $PEC_{sw/sed}$: covered by EU assessment
ASDM N,N-dimethyl-2-sulfamoylpyridine-3-carboxamide	229.2		Soil: aerob; max 21.50 % on day 189 Water: max. 6.9 % on day 177	PEC_{gw}: leaching potential to groundwater PEC_{soil}: covered by EU assessment $PEC_{sw/sed}$: covered by EU assessment

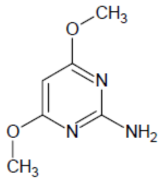
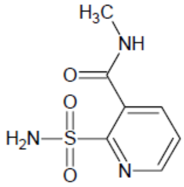
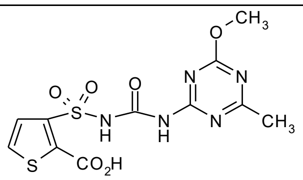
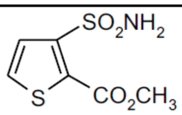
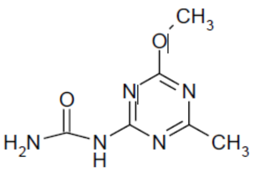
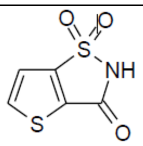
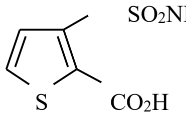
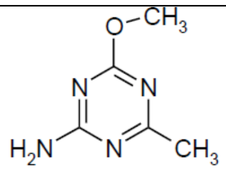
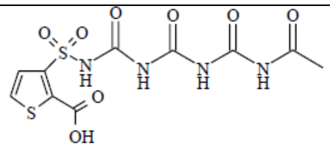
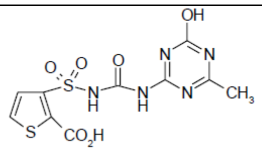
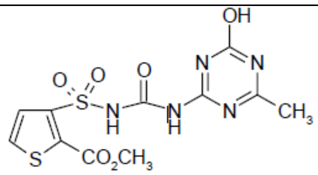
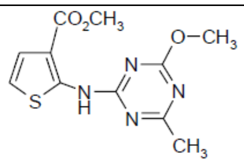
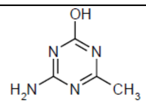
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in com-partements	Exposue assessment required due to
ADMP 4,6-dimethoxypyrimidin-2-amine	155.2		Soil: aerob; max 7.2 % on day 31 Water/Sediment study: not investigated	PEC_{gw}: leaching potential to groundwater PEC_{soil}: covered by EU assessment $PEC_{sw/sed}$: covered by EU assessment
MU-466 N-methyl-2-sulfamoylpyridine-3-carboxamide	215.1		Soil: aerob; < 5% Water/Sediment study: not investigated	PEC_{gw}: leaching potential to groundwater PEC_{soil}: covered by EU assessment $PEC_{sw/sed}$: covered by EU assessment

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

Metabolite	Molar weight (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Risk assessment required due to
IN-L9225	373.4		Soil: 94% aerobic Total Water/sediment system: 55% (water); 7.0% (Sediment)	PECgw, PECsoil, PECsw/sed
IN-A5546	221.2		Soil: 10.5% aerobic, 27.7% photolysis Hydrolysis: 64.2% (pH 4), 7.6% (pH 7)	PECgw,PECsoil, PECsw/sed
IN-V7160	183.2		Soil photolysis: 9.6% Total Water/sediment system: 25% (water); 6% (sediment)	PECgw, PECsoil, PECsw/sed
IN-W8268	189.2		Soil: 29.6%	PECgw, PECsoil, PECsw/sed
IN-L9223	207.2		Soil: 19% aerobic Total Water/sediment system: 39% (water); 8% (sediment)	PECgw, PECsoil, PECsw/sed
IN-A4098	140.1		Soil: 18% aerobic, 32.3% photolysis Total Water/sediment system: 20.0% (water); 7.0% (sediment)	PECgw, PECsoil, PECsw/sed

IN-U5F72 (2-acid-3triuret)	378.3		Soil: 17% aerobic	PECgw, PECsoil, PECsw/sed
IN-JZ789	359.3		Soil: 10% aerobic Total Water/sediment system: 21% (water) ; 4% (sediment)	PECgw, PECsw/sed, PEC_{soil}
IN-L9226	373.4		Soil: 18.5% aerobic Total Water/sediment system: 7.8% (water); 7.2% (sediment)	PECgw, PECsoil, PECsw/sed
IN-D8858	280.3		Aqueous photolysis: 15.3%	PECsw/sed
IN-B5528	126.1		Hydrolysis: 25.3% (pH 4), not formed at pH 7	PECsw/sed

zRMS comments:

Information regarding metabolites of particular active compounds provided in Tables 8.2-1 to 8.2-3 above is in line with data reported in:

- EFSA Journal 2011;9(1):1965 for dicamba,
- EFSA Scientific Report (2007) 120 for nicosulfuron..
- EFSA Journal 2015;13(7):4201 for thifensulfuron methyl

Specific formation fractions and/or maximum occurrence of particular metabolites has been considered in the exposure assessment presented in this report.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Dicamba and its metabolite

Agreed EU End-points (EFSA Journal 2011;9(1):1965)

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

Dicamba	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C & pF2	Chi^2	Method of calculation
Loamy sand (BBA 2.2)	5.5	20 ± 2°C / 40%	3.2/10.8	3.2	13.0	SFO
Loam (Gartenacker)	7.3	20 ± 2°C / 40%	3.3/11.0	3.3	13.1	SFO
Sandy loam (Pappelacker)	7.4	20 ± 2°C / 40%	4.2/13.9	4.1	10.1	SFO
Loamy sand (Borstel)	5.8	20 ± 2°C / 40%	5.5/18.4	4.6	9.7	SFO
Silt loam (Elliot)	5.1	23 ± 1°C /75% FC	3.9/12.8	4.9	16.2	SFO
Geometric mean				4.0		

pH dependence – No

Agreed EU End-points (EFSA Journal 2011;9(1):1965)

Table 8.3-2: Summary of aerobic degradation rates for metabolite DCSA - laboratory studies (metabolite dosed studies)

DCSA	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	DT_{50} (d) 20 °C & pF2	Chi[2]	Method of calculation
Loamy sand (BBA 2.2)	5.5	20 ± 2°C / 40%	12/ 39.8*	12	9.5	SFO*
Loam (Gartenacker)	7.3	20 ± 2°C / 40%	9.0/30.1*	9.0	21.4	SFO*
Sandy loam (Pappelacker)	7.4	20 ± 2°C / 40%	6.4/21.3*	6.3	7.6	SFO*
Loamy sand (Borstel)	5.8	20 ± 2°C / 40%	10.8/35.9*	9.1	9.9	SFO*
Silt loam (Elliot)	5.1	23 ± 1°C / 75% FC	9.7/32.3*	12.1	8.9	SFO*
Geometric mean				9.4		

*Calculated from day of maximum formation (peak-down)

pH dependence – No

8.3.1.2 Nicosulfuron and its metabolites

Studies on the aerobic degradation in soil have previously been evaluated within an EU peer review process. The relevant endpoints are provided in (EFSA Scientific Report (2007) 120, 1-91). Full summaries of studies are presented in respective EU DAR Nicosulfuron and its metabolites

Table 0-3: Summary of aerobic degradation rates for nicosulfuron - laboratory studies

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	Label	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Le Noron, loam	pyridine	5.3	20°C, 46.3% MWHC	20.0 / 66.4*	13.3	0.986	1st order non-linear
Le Noron, loam	pyrimi-dine	5.3	20°C, 46.3% MWHC	26.3 / 87.4*	17.4	0.901	1st order non-linear
Mean					**15.3**		
Les Evouettes, silt loam	pyridine	6.1	20 °C, 54.6% MWHC	40.5 / 134.4*	33.2	0.981	1st order non-linear
Les Evouettes, silt loam	pyrimi-dine	6.1	20 °C, 54.6% MWHC	33.1 / 110.1*	27.1	0.993	1st order non-linear
Mean					**30.1**		
Speyer 2.1, sand	pyridine	6.0	20°C, 21.1% MWHC	35.1 / 116.6*	30.6	0.989	1st order non-linear
Speyer 2.1, sand	pyrimi-dine	6.0	20°C, 21.1% MWHC	46.3 / 154.0*	40.4	0.974	1st order non-linear
Mean					**35.5**		
Speyer 2.3, sandy loam	pyridine	6.6	20°C, 31.4% MWHC	26.7 / 88.8*	20.3	0.985	1st order non-linear
Speyer 2.3, sandy loam	pyrimi-dine	6.6	20°C, 31.4% MWHC	23.2 / 77.2*	17.7	0.992	1st order non-linear
Mean					**19.0**		
Pappelacker, loamy sand	pyrimi-dine	7.0	20°C, 40% MWHC	7.0 / 23.4**	**5.7**	0.960	SFO
Karolinenhof, sand	pyrimi-dine	7.2	20°C, 40% MWHC	13.2 / 43.9**	**12.6**	0.992	SFO
Otzberg, silt loam	pyrimi-dine	7.2	20°C, 40% MWHC	18.9 / 62.8**	**14.3**	0.991	SFO
Geometric mean/median					**16.4**		

Values in bold used to calculate geometric mean DT_{50}
* values from DAR (UK, 2005)

Table 0-4: Summary of aerobic degradation rates for HMUD - laboratory studies

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

HMUD	Aerobic conditions							
Soil type	Label	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Les Evouettes, silt loam	Pyridine	6.1	20 °C, 54.6% MWHC	30.8 / 102.2	0.00752	25.2	0.983	ModelMaker based on SFO formation and decline from parent
Les Evouettes, silt loam	Pyrimi-dine	6.1	20 °C, 54.6% MWHC	27.4 / 90.0	0.00786	22.4	0.930	ModelMaker based on SFO formation and decline from parent
Mean						23.8		
The DT_{50} for HMUD are 2 values from 2 parent labels for 1 soil. Whereas for the other metabolites more than 1 soil was tested. The notifer calculated these using first-order kinetics in Modelmaker based on formation of HMUD and its subsequent degradation (HMUD formation fraction used was 0.00752 and 0.00786 respectively).								

Table 0-5: Summary of aerobic degradation rates for ADMP - laboratory studies

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

ADMP	Aerobic conditions							
Soil type	X[27]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Collombey, loamy sand		7.6	20°C, 40% MWHC	2.9 / 9.5		2.4	0.995	1st order non-linear
Speyer 2.2, loamy sand		6.0	20°C, 40% MWHC	6.1 / 20.4		5.4	0.980	1st order non-linear
Les Evouettes, loam		7.3	20°C, 40% MWHC	11.3 / 37.7		7.3	0.970	1st order non-linear
Geometric mean						4.5		

Table 0-6: Summary of aerobic degradation rates for ASDM - laboratory studies

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

ASDM	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Collombey, loamy sand		7.6	20°C, 40% MWHC	90.5 / 300.8		73.6	0.995	1st order non-linear
Speyer 2.2, loamy sand		6.0	20°C, 40% MWHC	268.5 / 892.1		236.6	0.933	1st order non-linear
ASDM	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Les Evouettes, loam		7.3	20°C, 40% MWHC	114.8 / 381.4		73.8	0.992	1st order non-linear
Worst-case						236.6		

Table 0-7: Summary of aerobic degradation rates for AUSN - laboratory studies

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

AUSN	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Collombey, loamy sand		7.6	20°C, 40% MWHC	73.8/245.1		60.0	0.894	1st order non-linear
Speyer 2.2, loamy sand		6.0	20°C, 40% MWHC	218.2/724.8		192.3	0.907	1st order non-linear
Les Evouettes, loam		7.3	20°C, 40% MWHC	101.4/336.9		65.2	0.856	1st order non-linear
Worst-case						192.3		

Table 0-8: Summary of aerobic degradation rates for UCSN - laboratory studies

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

UCSN	Aerobic conditions							
Soil type	X^1	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Collombey, loamy sand		7.6	20°C, 40% MWHC	126.2/419.3		102.6	0.993	1[st] order non-linear
Speyer 2.2, loamy sand		6.0	20°C, 40% MWHC	307.5/1021.7		271.0.	0.962	1[st] order non-linear
Les Evouettes, loam		7.3	20°C, 40% MWHC	229.3/761.7		147.5	0.942	1[st] order non-linear
Worst-case						271.0		

Table 0-9: Summary of aerobic degradation rates for MU-466 - laboratory studies

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

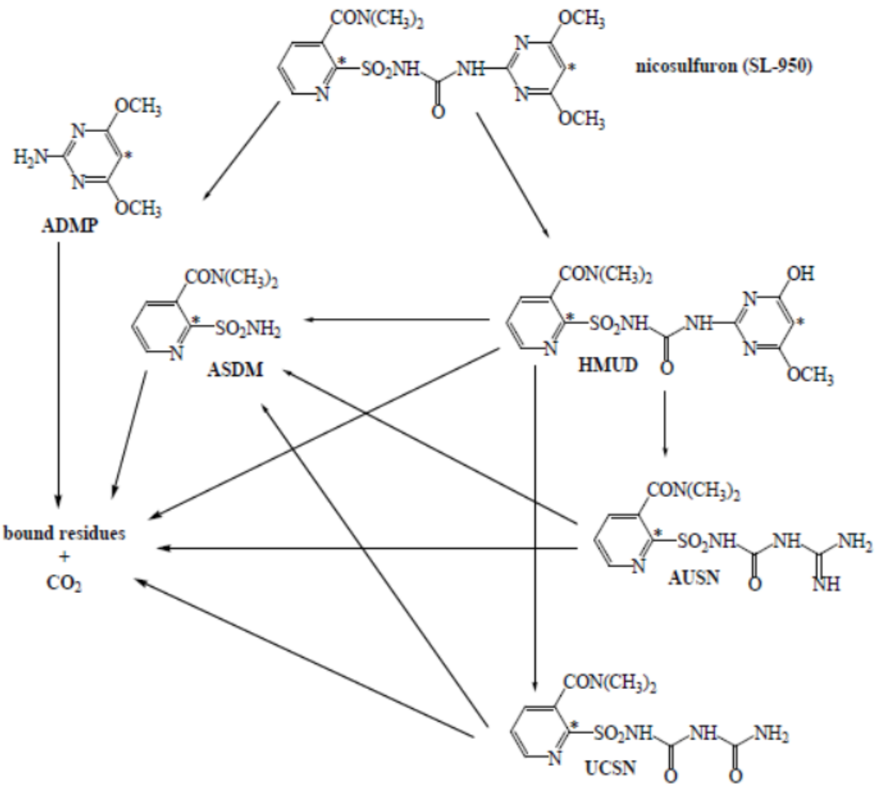
MU-466	Aerobic conditions							
Soil type	X^1	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Uffholtz		5.74	20°C, 40% MWHC	89.5 / 297		66.3	0.943	1[st] order non-linear
Speyer 2.1		6.2	20°C, 40% MWHC	84 / 279		75.5	0.975	1[st] order non-linear
MU-466	Aerobic conditions							
Soil type	X^1	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
3A		7.1	20°C, 40% MWHC	67.9 / 225.5		59.1	1.000	1[st] order non-linear
Worst-case						75.5		

The rate of degradation of nicosulfuron in soil in laboratory conditions was evaluated during the EU reviews. No additional studies have been performed. The fate and behaviour of nicosulfuron in soil is discussed in details in the corresponding documents of the EU review dossier where the study references can be found.

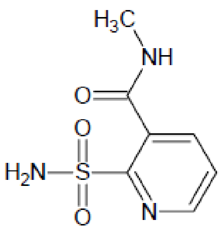
The aerobic degradation of soil was investigated in seven soils in pH range of 5,3-7,2. It was agreed that rate of degradation is not pH dependent. Nicosulfuron can be classified as low to moderate persistent in soil (DT_{50} = 7-46,3 days – 1[st] order). Moreover, the aerobic degradation of soil metabolites ADMP, ASDM, AUSN and UCSN was investigated in three soils (pH 6.0-7.3, organic carbon content 0.98-2.29%, clay content 1.1-9.3%). ADMP was rapidly degraded and therefore can be classified as low to moderate persistent (1st order DT50 = 2.9-11.3 days). Results indicated that the other 3 metabolites were medium to high (AUSN and ASDM) or high (UCSN) persistent (1st order DT50s calculated at 20ºC and 40% MWHC were in the range of 90.5-268.5 days, 73.8-218.2 days and 126.2-307.5 days for ASDM; AUSN and UCSN respectively). The DT50 of HMUD was calculated based on data from the two routes of degradation studies on one soil with the parent compound; this produced DT50 values of 27.4 and 30.8 days. Under anaerobic soil conditions degradation of nicosulfuron and its metabolites were not identified.

The soil metabolic scheme for nicosulfuron is presented below (based on the DAR for nicosulfuron).

Figure 9.1–1: Soil metabolic pathway for nicosulfuron



Additionally, the DAR noted that the possible degradation product may be ASDM MU-466 (structural formula below), although this metabolite has not been identified in the trail study and the rate of degradation in soil.



8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Dicamba

No studies on the anaerobic degradation in soil were conducted, none deemed necessary.

Nicosulfuron

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

According to EFSA Scientific Report (2007) 120, 1-91 no relevant end-points were determined due to limited degradation under anaerobic conditions (aerobic phase: 21,8 and 24,4; R2 = 0,909 – 0,998; n=2)

Thifensulfuron methyl

The degradation of thifensulfuron methyl under anaerobic conditions was investigated using compounds with ^{14}C-labeled triazine rings in AMR 1349-88 (Hawkins *et al.,* 1991) and both ^{14}C-labeled triazine and thiophene rings in WB/10/005 [CHA Doc. No. 244 TIM] by the Task Force (Simmonds, 2011a). Under anaerobic conditions, metabolite IN-B5528 was found at higher levels compared to the aerobic study (max. 8.1% AR at the study end). Since maintenance of anaerobic conditions for such prolonged periods is not considered likely in typical agricultural soils and relevant agronomic conditions for product use, this metabolite is not considered to be of relevance for the environmental exposure assessment in soil and has not been considered further (EFSA conclusion, 2015). The bound residue formed at the end of experimental period (100 days) was 18.7% in the thiophene label and 23.0% in the triazine label (Simmonds, 2011a). There was no evidence for mineralisation of thifensulfuron methyl under anaerobic conditions in both studies. The studies are summarised in the Thifensulfuron methyl RAR, Volume 3, Annex B.8, March 2015.

Table 8.3-10: Summary of anaerobic degradation rates of thifensulfuron methyl in soils

Thifensulfuron methyl, laboratory studies, anaerobic conditions							
Soil type	**pH**	**T□C**	**DT_{50} (d)**	**DT_{90} (d)**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Keyport Silt loam	7.2	25	~5.0	16.6	-	-	Y, EFSA (2015)
Farditch thiophene (complete dataset)	6.0	20	0.6	4.5	1.5	Hockey-stick	Y, EFSA (2015)
Farditch triazine (complete dataset)	6.0	20	0.7	8.8	3.9	Hockey-stick (slow phase)	Y, EFSA (2015)
Farditch thiophene (anaerobic slow phase HS)	6.0	20	15.4	51.2	-	Hockey-stick (slow phase)	Y, EFSA (2015)
Farditch triazine (anaerobic slow phase HS)	6.0	20	4.7	15.6	-	Hockey-stick (slow phase)	Y, EFSA (2015)

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

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

8.4.1.1 Dicamba and its metabolites

Field studies are available in the DAR but as these were not triggered they are not included in the agreed list of Endpoints and not required for the exposure assessment.

8.4.1.2 Nicosulfuron and its metabolites

The DT_{50} values of field dissipation studies with nicosulfuron that were evaluated during EU assessmet are summarized in Table 8.4-1.

Table 0-1: Summary of aerobic degradation rates for nicosulfuron - field studies

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OC	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Sand (bare soil)	Flackenhorst, Germany	0.8	5.7	0-10	20.7	68.8	0.86 9	N/A	1st order non-linear
Silty clay loam (bare soil)	Hünfelden, Germany	0.8	7.1	0-10	63.3	210	0.91 9	N/A	1st order non-linear
Loam (bare soil)	St. Claire, N. France	1.5	5.3	0-5	12	40	0.94 9	N/A	1st order non-linear
Clay loam, (bare soil)	Lanta, S. France	0.88	6.0	0-5	8.9	29.7	0.96 4	N/A	1st order non-linear
Geometric mean/median					19.3/16.4				
Cropped soil (maize): Niederhofen and Schifferstadt (Germany), <0.01 mg/kg after 27/28 days, Emilia Romagna (Italy) calculation of DT_{50} not possible; Lombardia and Veneto, (Italy), DT_{50s} uncertain due to non-validated LOQ.									

8.4.1.3 Thifensulfuron methyl and its metabolites

No field studies were relied upon for the regulatory assessment.

The four field dissipation studies were conducted, and evaluated in Thifensulfuron methyl RAR- Volume 3, Annex B.8. Environmental Fate and Behavior from March 2015, but not considered for exposure assessment by the RMS.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Dicamba
For active substance no studies on soil accumulation were conducted, none deemed necessary.

Nicosulfuron

No studies provided or required ((EFSA Scientific Report (2007) 120, 1-91).

Thifensulfuron methyl

None of the values of the DT_{90} in aerobic soil exceed 1 year. Consequently, no calculation of accumulation in soil for any of the compounds observed in aerobic soil is considered necessary.

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 Dicamba and its metabolite

Agreed EU End-points (EFSA Journal 2011;9(1):1965)

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

Dicamba (on 22°C)							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loam (Kenyon)	2.2	7.1	-	-	0.16	7.27	0.74
Clay loam (Cook)	2.9	6.9	-	-	0.10	3.45	0.62
Silt loam (Champaign)	2.5	5.1	-	-	0.53	21.2	0.80
Sediment loam (Winters)	1.2	7.3	-	-	0.21	17.5	0.8
Arithmetic mean (n= 4)					0.25	12.36	0.74
pH dependence, Yes or No			No				

Table 8.5-2: Summary of soil adsorption/desorption for metabolite – DCSA

DCSA (on 22°C)							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loam (Kenyon)	2.2	7.1	-	-	31.5	1432	0.72
Clay loam (Cook)	2.9	6.9	-	-	7.0	242	0.80
Silt loam (Champaign)	2.5	5.1	-	-	20.3	812	0.93
Sandy loam (Huron)	0.4	8.1	-	-	2.5	628	0.79
Sediment loam (Winters)	1.2	7.3			35.2	2930	0.77
Arithmetic mean (n=5)					19.3	1209	0.80
pH dependence (yes or no)			No				

8.5.2 Nicosulfuron and its metabolite

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

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Soil name	soil type	OC (%)	pH (n.a.)	K_F (mL/g)	K_{Foc} (mL/g)	1/n (-)	Reference
Speyer 2.1	(loamy) sand	0.48	6	0.05	10	0.9	EFSA Scientiic Report (2007) 120, 1-91
Speyer 2.2	loamy sand	2.55	6	0.2	7.9	0.92	
Itingen II	silt loam	1.42	7.7	0.73	51.3	0.94	
Les Evouettes	loam	1.4	6.1	0.19	13.7	1.01	
				Arithmetic mean (n=4)	20.7	0.93	
				pH-dependency	No, but a clay dependence of Kf values was determined		

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

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Metabolite ADMP (pyrimidine label)‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, loamy sand	5.1	2.29	7.0	-	-	1.17	50.9	0.84
Collombey, loamy sand	6.7	1.17	7.7	-	-	0.71	60.4	0.82
Sisseln, sandy loam	15.9	1.557	7.8	-	-	0.83	52.8	0.92
Vetroz, silt loam	19.4	4.05	7.3	-	-	1.70	42.0	0.91
Arithmetic mean/median						1.10	51.5	0.87
pH dependence, Yes or No			No.					

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

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Metabolite ASDM (pyridine label)‡‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, loamy sand	5.1	2.29	7.0	-	-	0.05	2.3	0.82
Collombey, loamy sand	6.7	1.17	7.7	-	-	0.08	6.7	0.81
Sisseln, sandy loam	15.9	1.557	7.8	-	-	0.12	7.7	1.07
Vetroz, silt loam	19.4	4.05	7.3	-	-	0.24	6.0	0.94
Arithmetic mean/median						0.12	5.7	0.91
pH dependence, Yes or No			Could not be clearly established					

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

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Metabolite AUSN (pyridine label)‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, loamy sand	5.1	2.29	7.0	-	-	0.30	13.0	0.98
Collombey, loamy sand	6.7	1.17	7.7	-	-	0.42	35.6	0.92
Sisseln, sandy loam	15.9	1.557	7.8	-	-	0.61	39.0	0.98
Vetroz, silt loam	19.4	4.05	7.3	-	-	0.90	22.3	0.96
Arithmetic mean/median						0.56	27.5	0.96
pH dependence, Yes or No			Could not be clearly established					

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

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Metabolite UCSN (pyridine label)‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, loamy sand	5.1	2.29	7.0	0.02	1.1	-	-	-
Collombey, loamy sand	6.7	1.17	7.7	0.07	5.6	-	-	-
Sisseln, sandy loam	15.9	1.557	7.8	0.06	3.5	-	-	-
Vetroz, silt loam	19.4	4.05	7.3	0.09	2.1	-	-	-
Arithmetic mean/median						-	-	-
pH dependence, Yes or No			No.					

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

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Metabolite HMUD (non-radiolabelled) ‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, sandy loam	8.1	2.3	5.6^{Ca}	0.12	5.07	-	-	-
Mechtildshausen, loam	17.57	1.28	7.37^{Ca}	0.14	10.75	-	-	-
Uffholtz, silt clay loam	34.04	2.67	5.42^{Ca}	0.02	0.88	-	-	-
Sawtry, clay	49.19	2.94	7.23^{Ca}	0.19	6.98	-	-	-
Bretagne 1, Silt loam	17.40	2.11	5.7^{Ca}	0.08	2.83	-	-	-
Arithmetic mean/median						-	-	-
pH dependence, Yes or No			No.					

Table 8.5-9: Summary of soil adsorption/desorption for MU-466

Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Metabolite MU-466 (non-radiolabelled) ‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, sandy loam	8.1	2.3	5.6^{Ca}	0.07	3.05	-	-	-
Mechtildshausen, loam	17.57	1.28	7.37^{Ca}	0.14	10.73	-	-	-
Uffholtz, silt clay loam	34.04	2.67	5.42^{Ca}	0.04	1.32	-	-	-
Sawtry, clay	49.19	2.94	7.23^{Ca}	0.43	16.08	-	-	-
Bretagne 1, Silt loam	17.40	2.11	5.7^{Ca}	0.17	6.50	-	-	-
Arithmetic mean/median						-	-	-
pH dependence, Yes or No			Could not be clearly established					

Based on the adsorption and desorption behaviour in soil (four soils, pH range 6-7,7) it was found that nicosulfuron moves in the soil profile (K_{foc} = 7,9-51,3 mL/g). The adsorption of nicosulfuron is not pH-dependant but clay dependent. The following metabolites ADMP, ASDM, AUSN, UCSN, HMUD and MU-46617 (metabolite identified in the lysimeter studies) were also investigated in adsorption/desorption studies in 4 or 5 soils (depends on metabolite). Metabolite ADMP may be classified as high to very high mobile and all the other metabolites exhibit very high mobility in soil. It was considered that due to the limited range of soil pH values tested, a clear correlation between adsorption and pH value could not be determined.

Results from column leaching studies under laboratory conditions and field lysimeter studies show that nicosulfuron and its metabolites move in the soil profile. Overall these results indicated that nicosulfuron and the metabolites ASDM, AUSN, UCSN and MU-466 all have the potential to leach into groundwater at annual average concentrations above 0,1 µg/L.

8.5.3 Thifensulfuron methyl and its metabolite

The adsorption coefficients (K_{foc}) of thifensulfuron methyl and its soil metabolites were derived from EFSA (2015). The K_{foc} and 1/n from the EFSA conclusion (EFSA, 2015) are summarised in Table 8.5-10 to Table 8.5-19.

Table 8.5-10: Summary of soil adsorption/desorption for thifensulfuron methyl

Thifensulfuron methyl							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Sassafras	-	0.81	4.8	0.6660	82	0.9023	Y, EFSA (2015)
Lleida	-	1.74	7.6	0.1551	9	0.9826	Y, EFSA (2015)
Drummer	-	2.96	5.7	2.5468	86	0.8211	Y, EFSA (2015)
Gross-Umstadt	-	1.39	6.6	0.2679	19	0.9599	Y, EFSA (2015)
Nambsheim	-	2.03	7.3	0.2164	11	0.8389	Y, EFSA (2015)
Long woods	-	1.3	7.3	0.08	6.0	0.967	Y, EFSA (2015)
Farditch	-	3.5	5.9	0.22	6.2	0.952	Y, EFSA (2015)
Kenslow	-	3.9	5.1	0.33	8.4	0.949	Y, EFSA (2015)
Lockington	-	2.8	5.5	0.09	3.1	1.012	Y, EFSA (2015)
Median (n=9)					9.0[a]		Y, EFSA (2015)
Arithmetic mean (n=9)					25.6	**0.932**	
pH-dependency y/n					n		

a The median K_{foc} was selected for exposure assessment in the EFSA conclusion (EFSA, 2015).

Table 8.5-11: Summary of soil adsorption/desorption for IN-L9225

IN-L9225							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Arrow	sandy loam	2.3	5.7	0.30	13.1	0.74	Y, EFSA (2015)
Gross-Umstadt	silt loam	1.2	7.7	0.083	6.9	0.62	Y, EFSA (2015)
Mattapex	silt loam	2.6	6.4	0.350	13.5	0.76	Y, EFSA (2015)
LUFA 2.2	loamy sand	1.87	5.5 ($CaCl_2$)	0.435	23[b]	-	Y, EFSA (2015)
LUFA 2.3	sandy loam	0.94	6.8 ($CaCl_2$)	0.318	34[b]	-	Y, EFSA (2015)
LUFA 6S	clay	1.64	7.1 ($CaCl_2$)	0.481	29[b]	-	Y, EFSA (2015)
Arithmetic mean (n=6)					**19.9**	**0.850[a]**	
pH-dependency y/n					n		

a In deriving an arithmetic mean, a default 1/n value of 1.0 was assumed for the three soils where no Freundlich isotherm was determined because a single concentration had been tested.

b As only one concentration was tested this value is a K_{oc} not K_{foc}

Table 8.5-12: Summary of soil adsorption/desorption for IN-L9226

IN-L9226							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Arrow	sandy loam	2.3	5.7	0.8	34	0.8	Y, EFSA (2015)
Gross-Umstadt	silt loam	1.2	7.7	2.4	199	0.81	Y, EFSA (2015)
Mattapex	silt loam	2.6	6.4	2.6	99	0.79	Y, EFSA (2015)
LUFA 2.2	loamy san	1.87	5.5 ($CaCl_2$)	1.605	86[b]	-	Y, EFSA (2015)
LUFA 2.3	sandy loam	0.94	6.8 ($CaCl_2$)	1.886	201[b]	-	Y, EFSA (2015)
LUFA 6S	clay	1.64	7.1 ($CaCl_2$)	2.193	134[b]	-	Y, EFSA (2015)
Arithmetic mean (n=6)					**126**	**0.900[a]**	
pH-dependency y/n					n		

a in deriving an arithmetic mean, a default 1/n value of 1.0 was assumed for the three soils where no Freundlich isotherm was determined because a single concentration had been tested.

b As only one concentration was tested this value is a K_{oc} not K_{foc}

Table 8.5-13: Summary of soil adsorption/desorption for IN-A5546

IN-A5546							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Sassafras	-	0.81	4.8	0.2720	34	0.8767	Y, EFSA (2015)
Drummer	-	2.96	5.7	2.5107	85	0.9004	Y, EFSA (2015)
Gross-Umstadt	-	1.28	6.8	0.3643	28	0.9521	Y, EFSA (2015)
Arithmetic mean (n=3)					**49**	**0.91**	
pH-dependency y/n					n		

Table 8.5-14: Summary of soil adsorption/desorption for IN-V7160

IN-V7160							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Stark County (Tama)	-	3.1	6.3	5.97	194	0.9297	Y, EFSA (2015)
Kent County (Sassa-fras #16)	-	1.4	6.3	0.969	69.4	0.9021	Y, EFSA (2015)
Lleida	-	1.8	7.5	1.51	84.0	0.9364	Y, EFSA (2015)
Nambsheim	-	1.6	7.0	0.908	57.9	0.9290	Y, EFSA (2015)
Suchozebry	-	0.76	5.0	1.24	164	0.8686	Y, EFSA (2015)
Arithmetic mean (n=5)					**113.9**	**0.913**	
pH-dependency y/n					n		

Table 8.5-15: Summary of soil adsorption/desorption for IN-W8268

IN-W8268							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Arrow	sandy loam	2.3	5.7	0.10	3.6	1.10	Y, EFSA (2015)
Gross-Umstadt	silt loam	1.2	7.7	0.05	4.0	1.68	Y, EFSA (2015)
Mattapex	silt loam	2.6	6.4	0.10	2.6	1.17	Y, EFSA (2015)
LUFA 2.2	loamy sand	1.87	5.5 ($CaCl_2$)	0.1652	9[b]	-	Y, EFSA (2015)
LUFA 2.3	sandy loam	0.94	6.8 ($CaCl_2$)	0.0947	10[b]	-	Y, EFSA (2015)

LUFA 6S	clay	1.64	7.1 ($CaCl_2$)	0.2536	15[b]	-	Y, EFSA (2015)
Arithmetic mean (n=6)					**7.4**	**1.160**[a]	
pH-dependency y/n					n		

a in deriving an arithmetic mean, a default 1/n value of 1.0 was assumed for the three soils where no Freundlich isotherm was determined because a single concentration had been tested.

b As only one concentration was tested this value is a K_{oc} not K_{foc}

Table 8.5-16: Summary of soil adsorption/desorption for IN-L9223

IN-L9223							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Drummer	silt loam	3.2	6.4	0.2595	8	0.9232	Y, EFSA (2015)
Longwood	sandy loam	1.3	7.9 (H_2O)	0.03	2.03	1.4090	Y, EFSA (2015)
Chelmorton	clay loam	3.3	7.3 (H_2O)	0.11	3.27	1.0931	Y, EFSA (2015)
Lockington	clay loam	2.5	6.5 (H_2O)	0.07	2.97	1.204	Y, EFSA (2015)
Arithmetic mean (n=4)					**4.07**	**1.157**	
pH-dependency y/n					n		

Table 8.5-17: Summary of soil adsorption/desorption for IN-A4098

IN-A4098							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Gross-Umstadt	Silt loam	1.2	7.7	0.2	18.8	1.05	Y, EFSA (2015)
Arrow	Sandy loam	2.3	5.7	0.7	29.7	0.94	Y, EFSA (2015)
Mattapex	Silt loam	2.6	6.4	0.4	16.7	0.96	Y, EFSA (2015)
Matapeake	-	1.1	5.3	2.36	214.2	0.841	Y, EFSA (2015)
Sassafras	-	0.46	6.3	0.621	133.8	0.784	Y, EFSA (2015)
Drummer	-	3.02	5.7	6.80	225.5	0.841	Y, EFSA (2015)
Myaka	-	0.58	6.2	0.264	45.52	0.873	Y, EFSA (2015)
Honville (Chateadun)	-	0.91	6.7	1.57	172	0.8351	Y, EFSA (2015)
Agricultural sand	-	0.35	7.9	0.2326	66.5	0.8702	Y, EFSA (2015)
-	Sandy loam	0.99	7.8	0.57	58.2	0.9024	Y, EFSA (2015)
-	Silt loam	1.74	6.5	0.9612	55.2	0.8474	Y, EFSA (2015)
-	Silty clay	0.70	6.9	1.201	171.6	0.8230	Y, EFSA (2015)
SLS	-	2.08	7.0	0.44	21.3	0.873	Y, EFSA (2015)
LS2.2	-	1.95	6.0	0.30	15.4	0.909	Y, EFSA (2015)
SLV	-	0.43	6.0	0.32	74.4	0.840	Y, EFSA (2015)
Laacher Hof Wurm-wiese	Loam	1.8	5.3	1.321	73.4	0.9183	Y, EFSA (2015)
Hoefchen Am Hohen-seh 4a	Silt loam	2.4	6.6	0.481	20.0	0.9755	Y, EFSA (2015)
Les Cayades	Clay loam	0.9	7.6	0.561	62.3	0.917	Y, EFSA (2015)
Guadalupe	Sandy Loam	0.7	6.7	0.675	96.5	0.9498	Y, EFSA (2015)
Springfield	Silt loam	1.7	6.6	3.147	185.1	0.9021	Y, EFSA (2015)
2.2	Silty sand	1.97	5.4	0.3728	18.92	0.640	Y, EFSA (2015)
3A	Sandy loam	2.42	7.3	0.4350	17.97	0.759	Y, EFSA (2015)
6S	Clay loam	1.84	6.9	0.0543	2.95	1.422	Y, EFSA (2015)

Speyer 2.1	-	0.56	6.0	0.2025	36	0.92	Y, EFSA (2015)
Standard soil no. 115	-	1.7	7.4	0.6255	37	0.89	Y, EFSA (2015)
Standard soil no. 164	-	3.0	6.5	0.645	22	0.92	Y, EFSA (2015)
Standard soil no. 243	-	1.1	4.3	0.337	31	0.91	Y, EFSA (2015)
Median (n=27)					45.5	**0.900**	
pH-dependency y/n					n		

Table 8.5-18: Summary of soil adsorption/desorption for IN-JZ789

IN-JZ789							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Drummer	clay loam	3.3	5.9	0.89	26.95	-	Y, EFSA (2015)
Gross-Umstadt	loam	1.2	6.4	0.17	13.96	-	Y, EFSA (2015)
Nambsheim	sandy loam	1.3	7.2	0.18	13.61	-	Y, EFSA (2015)
Lleida	clay	2.0	7.8	0.47	23.27	-	Y, EFSA (2015)
Sassafras	sandy loam	1.6	4.7	0.24	15.18	-	Y, EFSA (2015)
LUFA 2.2	loamy sand	1.87	5.5	0.759	41	-	Y, EFSA (2015)
LUFA 2.3	sandy loam	0.94	6.8	0.546	58	-	Y, EFSA (2015)
LUFA 6S	clay	1.64	7.1	0.901	57	-	Y, EFSA (2015)
Arithmetic mean (n=8)					**31.1**	**1.000**[a]	
pH-dependency y/n					n		

a The UK RMS considered it appropriate since no attempt to measure the Freundlich isotherm was attempted, to use a default 1/n of 1.0.

Table 8.5-19: Summary of soil adsorption/desorption for IN-U5F72 (2-acid-3-triuret)

IN-U5F72 (2-acid-3-triuret)							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
LUFA 2.2	Loamy sand	1.77	5.5	4.130	230	-	Y, EFSA (2015)
LUFA 2.3	Sandy loam	0.94	6.8	5.285	562	-	Y, EFSA (2015)
LUFA 2.4	Loam	2.26	7.2	17.620	780	-	Y, EFSA (2015)
Arithmetic mean (n=3)					**524**	**1.000**[a]	
pH-dependency y/n					n		

a The UK RMS considered it appropriate since no attempt to measure the Freundlich isotherm was attempted, to use a default 1/n of 1.0.

8.5.3 Column leaching (KCP 9.1.2.1)

Dicamba

Column leaching ‡	Eluation (mm): 200 mm Time period (d): 2 d (48 hours)
	Leachate: < 0.2 - 0.68 % dicamba equivalents < 0.12-0.48 µg/L dicamba equivalents
Aged residues leaching ‡	Aged for (d): 40.5 d Time period (d): 2 d (48 hours) Eluation (mm): 200 mm
	Analysis of soil residues post ageing was not conducted
	Leachate: Dicamba: 0.22-0.94 %, 0.39 - 1.7 µg/L DCSA: < 0.06-0.31 %, <0.1 - 0.53 µg/L

Nicosulfuron
Studies on column leaching with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. A brief summary of the these studies is provided in Table 8.5-20.
Agreed EU End-points (EFSA Scientific Report (2007) 120, 1-91)

Table 8.5-20: Summary of the results of column leaching, aged residue leaching and lysimeter studies

End-Point	Nicosulfuron
Column leaching	Eluation (mm): 508 mm Time period (d): 4 d Leachate: 62.9 – 92.2 % total residues/radioactivity in leachate 41,2-58,6% active substance, < 0,5% ADMP, ≤ 1% DMPU 1,4-5,7% total residues/radioactivity retained in top 6 cm
Aged residues leaching	Aged for (d): 28 d Time period (d): 8 d Eluation (mm): 480 mm Analysis of soil residues post ageing (soil residues pre-leaching): 43.2 % active substance, 9.0 % HMUD, 3.2 % DMPU, 2.4% ADMP Leachate: 54.8 % total residues/radioactivity in leachate 49.6 % nicosulfuron, 5.2 % others 28.5 % AR retained in soil column (8.8 % identified as nicosulfuron) 3.5% AR as nicosulfuron in the top 0 - 16.5 cm, and 5.3% AR in the bottom 16.5 - 34.5 cm of column
Lysimeter studies	3 Lysimeter studies, each with two lysimeters, 1 in Germany (Schmallenberg) and 2 in Switzerland (Itingen), each run for: (i) 2 years, (ii) 3 years, (iii) 3 years. Maize was sown in the first two years and then wheat in the final year (ii & iii) Application rates of: (i) pyridine labelled nicosulfuron: year 1 only – 1 x 40 g a.s./ha; (ii) pyridine labelled nicosulfuron: 1st lysimeter 1 x 60 g a.s/ha/ in year 1 only, 2nd lysimeter 1 x 60 g a.s/ha/ in year 1&2 only (iii) pyrimidine labelled nicosulfuron: 1st lysimeter 1 x 60 g a.s/ha/ in year 1 only, 2nd lysimeter 1 x 60 g a.s/ha/ in year 1&2 only. Average annual rainfall: (i) 600, 1039 mm; (ii & iii) 832, 1136, 1118 mm Average annual leachate volume: (i) 401 -456 and 675-700 L; (ii) 334-335, 515-529, 522-538 L, (iii) 303-346, 485-543, 434-546 L. Annual average concentrations (µg/L) (i) nicosulfuron 0.03-0.07; ASDM 0.18-0.99; AUSN 0.24-0.59; UCSN 0.03-0.22; MU-466 0.02-0.04. (ii) (2nd lysimeter with 2 applications) nicosulfuron 0.03-0.13, ASDM 0.34-2.70, AUSN 0.68-1.62, UCSN 0.06-0.94, MU-466 0.07-0.14. (iii) (2nd lysimeter with 2 applications) nicosulfuron 0.01-0.17, HMUD 0.01-0.03.

Thifensulfuron methyl

Discussion of the soil mobility of thifensulfuron methyl (soil adsorption/desorption and aged soil column leaching) can be found in the corresponding document of the EU review dossier where the study references can be found in the EFSA conclusion (EFSA, 2015). Thifensulfuron methyl and its major soil degradates demonstrated low to moderate adsorption to soil under laboratory conditions.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances. These studies have previously been evaluated within the EU peer review process.

Dicamba

A lysimeter study has been described in the List of Endpoints of the EFSA conclusion. The study was conducted in Hamburg (Germany) in a lysimeter cropped with maize (Soil properties (0-30 cm): texture, pH = 6.1-6.2, OC= 1.1-1.3, MWHC = 29.7-40.4).
A single application of 360 g a.s./ha was made per year for 2 years (8 June 1990, 3 July 1991). The duration was 2 years (for lysimeter 3), and 3 years (for lysimeter 4).
Average annual precipitation (incl. irrigation) was 922 mm (year 1-2) and the average annual leachate volume was 445 L (year 1-2). The retrieved % radioactivity in leachate (maximum/year) was 0.19 % AR and the individual annual maximum concentrations (year 1-2) was 0.17 g/L dicamba equivalents. Annual mean 0.11-0.12 dicamba equivalents. No dicamba or DCSA was identified in leachates. No dicamba or DCSA was identified in the soil residues.

Nicosulfuron

Lysimeter studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. See point 8.5.2 of this report.

Thifensulfuron methyl

A lysimeter study was not required with thifensulfuron methyl. Data from the adsorption/desorption studies, the aerobic soil degradation studies, and PEC calculations have clearly demonstrated that there is no reasonable expectation of any leaching of thifensulfuron methyl into groundwater under normal use conditions. The safe use of thifensulfuron methyl in the EU was demonstrated in modelling done in support of the various proposed uses.

Full summaries of the lysimeter studies are presented in the respective EU DARs.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Dicamba

Please refer to point 8.5.

Nicosulfuron

No field leaching studies with nicosulfuron are available.

Thifensulfuron methyl

A study was not required since the data from the adsorption/desorption studies, the aerobic soil degradation studies, and modelling done in support of the proposed use have clearly demonstrated that there is no reasonable expectation of any movement of thifensulfuron methyl into groundwater under normal use conditions.

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

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

8.6.1 Dicamba and its metabolite

Agreed EU End-points (EFSA Journal 2011;9(1):1965)

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

Dicamba	Rhine: Max. 5.5% in sediment day 7 Pond: Max. 6% in sediment day 7									
Water / sed. system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (d)	St. (r^2)	DT_{50}-DT_{90} Water (d)	St. (r^2)	DT_{50}- DT_{90} Sed (d)	St. (r^2)	Method of calculation
Rhine	8.3	7.6	20± 2	38/125*	0.93					SFO
Pond	8.3	7.4	20± 2	45/151*	0.98					SFO
Geometric mean				41/137*						

* The values are considered as uncertain

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

DCSA	Rhine: Max. 26.9% in water and 4.5% in sediment (whole system 31.4%) at day 60 Pond: Max. 12.5% in water and 3.4% in sediment (whole system 15.9%) at day 60									
Water/sed. system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (d)	St. (r^2)	DT_{50}-DT_{90} Water (d)	St. (r^2)	DT_{50}- DT_{90} sed. (d)	St. (r^2)	Method of calculation
Rhine	8.3	7.6	20±2	57.7/192*	0.89	No reliable data – not needed for the risk assessment				SFO – linear regression
Pond	8.3	7.4	20±2	58.2/193*	0.77					SFO – linear regression
Geometric mean				57.9/193*				-		-

* No lag phase included – notifier has used DT_{50} values of 53.7 d and 45.1 d (mean 49.4 d) based on a lag phase of 7 and 14 days, respectively, for Rhine and pond in the FOCUSsw modelling. However, these values are considered as uncertain.

8.6.2 Nicosulfuron and its metabolite

The fate of nicosulfuron was investigated in two water/sediment systems during EU approval. The degradation rates derived for the total system and the dissipation rates in the water phase are presented in Table 8.6-3.

Table 0-3: Summary of degradation in water/sediment of nicosulfuron [pirydine-^{14}C]

Water/sediment system	$DegT_{50}$ whole syst. (d)	$DegT_{90}$ whole syst. (d)	Kinetic/ Fit	$DissT_{50}$ water (d)	$DissT_{90}$ water (d)	Kinetic/ Fit	Reference
River Rhine	49.8	165.4	SFO/ r^2: 0.978	32.0	106.2	SFO/ r^2: 0.922	DAR, 2005
Pond Anwil	33.2	110.2	SFO/ r^2: 0.994	24.9	82.9	SFO/ r^2: 0.993	

8.6.3 Thifensulfuron methyl and its metabolite

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

Thifensulfuron methyl Distribution (max. water >99% at 0 d; max. sediment 1.08% after 31 d)										
Water/sediment system	pH water/ sed.	$DegT_{50}$ 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
Town park pond	7.8/7.2	18.2	-	SFO	18.2	-	SFO	1000	-	Y, (EFSA, 2015)
Red Oak stream	7.6/7.1	26.1	-	SFO	26.1	-	SFO	1000	-	Y, (EFSA, 2015)
Swiss lake	7.4/6.0	32.3	-	SFO	32.0	-	SFO	1000	-	Y, (EFSA, 2015)
Calwich abbey lake	8.3/7.4	17.6	-	SFO	17.3	-	SFO	1000	-	Y, (EFSA, 2015)
Geometric mean (n=4)		22.8								

Table 8.6-5: Summary of observed metabolites

Compounds	Maximum occurrences	Evaluated on EU level y/n/ Reference
All metabolites	PEC_{sw}/PEC_{sed} modeling with the worst-case assumptions: Max in water: 100% Max in sediment: 100%	y (EFSA, 2015)
IN-L9226	Max in water: 7.8% Max in sediment: 7.2%	y (EFSA, 2015)
IN-JZ789	Max in water: 21% after 125 days Max in sediment: 4%	y (EFSA, 2015)
IN-L9223	Max in water: 39% after 182 days Max in sediment: 8%	y (EFSA, 2015)
IN-V7160	Max in water: 25% after 182 days Max in sediment: 6%	y (EFSA, 2015)

IN-A4098	Max in water: 20% Max in sediment: 7%	y (EFSA, 2015)
IN-L9225	Max in water: 55% Max in sediment: 7%	y (EFSA, 2015)

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

For determination of the predicted environmental concentrations of the active substances and relevant metabolites in soil the following guideline was used: "Soil persistence models and EU registration" (The final report of the work of the Soil Modelling Work group of FOCUS).

EVRITELL 162 OD is applied to maize at a maximum rate of 110 g a.s./ha of dicamba, 40 g a.s./ha of nicosulfuron and 12 g a.s./ha of thifensulfuron methyl, which are protective for assessing the risk associated with application of EVRITELL 162 OD on maize. Input parameters related to application for PEC_{soil} calculations are presented in Table 8.7-1.

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

Use No.	1
Crop	maize
Application rate (g as/ha)	Dicamba: 110 g as/ha Nicosulfuron: 40 g as/ha Thifensulfuron- methyl: 12 g as/ha
Number of applications/interval	1/n.a.
Crop interception (%)	25% (BBCH12-16)
Depth of soil layer (cm)	5 (5 for plateau)

8.7.1 Justification for new endpoints

No new endpoints are presented in the current submission.

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

8.7.2.1 Dicamba and its metabolites

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	Maximum non-normalised DT50 (days)	Value in accordance to EU end-point y/n/ Reference
Dicamba	221		3.0*/	Yes / EFSA Journal 2011;9(1):1965
DCSA	207	58.8	4.5**/	Yes / EFSA Journal 2011;9(1):1965

*According to EFSA peer review DT50 = 4.0d is recommended to be used in PECs calculations
**According to EFSA peer review DT50 = 9.4d is recommended to be used in PECs calculations

Dicamba and its metabolites

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

PEC_{soil} (mg/kg)		Single application, maize, App. rate =110 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.1100	-	-	-
Short term	24h	0.0925	0.1012		
	2d	0.0778	0.0932		
	4d	0.0550	0.0795		
Long term	7d	0.0327	0.0639		
	14d	0.0097	0.0414		
	21d	0.0029	0.0295		
	28d	0.0009	0.0226		
	42d	0.0001	0.0151		
	50d	<0.0001	0.0127		
	100d	<0.0001	0.0064		
Plateau concentration		Not required			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not required since DT_{90} in soil is < 365d			

PEC_{soil} of metabolites

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

PEC_{soil} (mg/kg)		Single application, maize; App. rate =61 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0610			-
Short term	24h	0.0567	0.0588		
	2d	0.0526	0.0567		
	4d	0.0454	0.0529		
Long term	7d	0.0364	0.0477		
	14d	0.0217	0.0381		
	21d	0.013	0.031		
	28d	0.0077	0.0258		
	42d	0.0028	0.0188		
	50d	0.0015	0.0161		
	100d	<0.0001	0.0083		
Plateau concentration		Not required			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not required			

zRMS comments:

The application parameters of dicamba for soil exposure presented in Table 8.7-3 are in line with the EFSA Journal 2011;9(1):1965 and it is thus accepted by the zRMS.
Relevant crop interceptions in line with FOCUS groundwater guidance (2014) have been selected.

We agree with calculations performed by Applicant. Therefore, results reported in tables above 8.7-3 and 8.7-2 may be used for the soil risk assessment purposes.

8.7.2.2 Nicosulfuron and its metabolites

Table 8.7-5: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Nicosulfuron	410.4	-	63.3 d (Kinetics, Maximum, field)	EFSA Scientific Report (2007) 120, 1-91
ADMP	155.2	9.8	11.3 (SFO, max. from lab data)	EFSA Scientific Report (2007) 120, 1-91
ASDM	229.2	63.4	268.5 (SFO, max. from lab data)	EFSA Scientific Report (2007) 120, 1-91
AUSN	314.3	26.8	218.2 (SFO, max. from lab data)	EFSA Scientific Report (2007) 120, 1-91
UCSN	315.3	11	307.5 (SFO, max. from lab data)	EFSA Scientific Report (2007) 120, 1-91
HMUD	396.4	14.4	30.8 (SFO, only available value from lab studies)	EFSA Scientific Report (2007) 120, 1-91

<u>Nicosulfuron and its metabolites</u>

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

PEC_{soil} (mg/kg)		Single application, maize; App. rate =40 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0400	-		-
Short term	24h	0.0396	0.0398		
	2d	0.0391	0.0396		
	4d	0.0383	0.0391		
Long term	7d	0.0370	0.0385		
	14d	0.0343	0.0371		
	21d	0.0318	0.0357		
	28d	0.0294	0.0344		

	42d	0.0253	0.0321		
	50d	0.0231	0.0308		
	100d	0.0134	0.0243		
Plateau concentration		Not required	-		-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not required			

PEC_{soil} of metabolites

Table 8.7-7: PEC_{soil} for ADMP on maize

PEC_{soil} (mg/kg)		Single application, maize; App. rate =1.5≈2 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0020	-		-
Short term	24h	0.0019	0.0019		
	2d	0.0018	0.0019		
	4d	0.0016	0.0018		
Long term	7d	0.0013	0.0016		
	14d	0.0008	0.0013		
	21d	0.0006	0.0011		
	28d	0.0004	0.001		
	42d	0.0002	0.0007		
	50d	0.0001	0.0006		
	100d	<0.0001	0.0003		
Plateau concentration		Not required	-		-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not required			

Table 8.7- 8: PEC_{soil} for HMUD on maize

PEC_{soil} (mg/kg)		Single application, maize; App. rate =5.6≈6 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0060			-
Short term	24h	0.0059	0.0059		
	2d	0.0057	0.0059		
	4d	0.0055	0.0057		
Long term	7d	0.0051	0.0056		
	14d	0.0044	0.0051		
	21d	0.0037	0.0048		
	28d	0.0032	0.0045		
	42d	0.0023	0.0039		
	50d	0.0019	0.0036		
	100d	0.0006	0.0024		
Plateau concentration		Not required	-		-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not required			

Table 8.7-9: PEC_{soil} for UCSN on maize

PEC_{soil} (mg/kg)		Single application, maize; App. rate =3.4 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0034	-		-
Short term	24h	0.0034	0.0034		
	2d	0.0034	0.0034		
	4d	0.0034	0.0034		
Long term	7d	0.0033	0.0034		

	14d	0.0033	0.0033		
	21d	0.0032	0.0033		
	28d	0.0032	0.0033		
	42d	0.0031	0.0032		
	50d	0.003	0.0032		
	100d	0.0027	0.003		
Plateau concentration (5 cm)		0.0027	-		-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.0061			

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

PEC_{soil} (mg/kg)		Single application, maize; App. rate =14.2 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0142	-		-
Short term	24h	0.0142	0.0142		
	2d	0.0141	0.0142		
	4d	0.0141	0.0141		
Long term	7d	0.0139	0.0141		
	14d	0.0137	0.0139		
	21d	0.0135	0.0138		
	28d	0.0132	0.0137		
	42d	0.0127	0.0135		
	50d	0.0125	0.0133		
	100d	0.0110	0.0125		
Plateau concentration (5 cm)		0.0091	-		-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.0233			

Table 8.7-11: PEC_{soil} for AUSN on maize

PEC_{soil} (mg/kg)		Single application, maize; App. rate =14.2 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0082	-		-
Short term	24h	0.0082	0.0082		
	2d	0.0081	0.0082		
	4d	0.0081	0.0081		
Long term	7d	0.008	0.0081		
	14d	0.0078	0.008		
	21d	0.0077	0.0079		
	28d	0.0075	0.0078		
	42d	0.0072	0.0077		
	50d	0.007	0.0076		
	100d	0.006	0.007		
Plateau concentration (5 cm)		0.0037	-		-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.0119			

zRMS comments:

The PECs calculations has been accepted for the active substance nicosulfuron and its metabolites HMUD, ADMP, ASDM, AUSN and UCSN.
The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report EFSA (2007) 120, 1-91. Interception is appropriate to the proposed BBCH of crops (guidance 2014).
The results calculations of PECs are presented in the Table below: 8.7-6 - 8.7-11
The acceptable predicted environmental concentrations of nicosulfuron and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

8.7.2.2 Thifensulfuron- methyl and its metabolites

Thifensulfuron methyl and its metabolites

Table 8.7-12: Input parameter for thifensulfuron methyl and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	Maximum non-normalised DT50 (days)	Value in accordance to EU end-point y/n/ Reference
Thifensulfuron- methyl	387.4	-	3.1	y (EFSA, 2015)
IN-L9225	373.4	94	154.4	y (EFSA, 2015)
IN-L9223	207.2	19	272 /1000	y (EFSA, 2015)
IN-A4098	140.1	32.3	1000	y (EFSA, 2015)
IN-U5F72	378.3	17	132	y (EFSA, 2015)
IN-JZ789	359.3	9.7	1000	y (EFSA, 2015)
IN-A5546	221.2	27.7	3	y (EFSA, 2015)
IN-V7160	183.2	9.6	231	y (EFSA, 2015)
IN-L9226	373.4	18.5	3.3	y (EFSA, 2015)
IN-W8268	189.2	29.6	64.2	y (EFSA, 2015)

Table 8.7-13: PEC_{soil} for thifensulfuron methyl on maize

PEC_{soil} (mg/kg)		Single application, maize; App. rate =**12.0 g a.s./ha; CI=25%**			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0120	-	-	-
Short term	24h	0.0096	0.0108		
	2d	0.0077	0.0097		
	4d	0.0049	0.008		
Long term	7d	0.0025	0.0061		
	14d	0.0005	0.0037		
	21d	0.0001	0.0025		
	28d	<0.0001	0.0019		
	42d	<0.0001	0.0013		
	50d	<0.0001	0.0011		
	100d	<0.0001	0.0005		
Plateau concentration- tillage depth 5 cm (more conservative value)		<0.0001			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0120			

PEC_{soil} of metabolites

Table 8.7-14: PEC_{soil} for IN-L9225 on maize

PEC_{soil} (mg/kg)		Single application, maize; App.rate = 10.9 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0109	-		-
Short term	24h	0.0109	0.0109		
	2d	0.0108	0.0109		
	4d	0.0107	0.0108		
Long term	7d	0.0106	0.0107		
	14d	0.0102	0.0106		
	21d	0.0099	0.0104		
	28d	0.0096	0.0102		
	42d	0.0090	0.0099		
	50d	0.0087	0.0098		
	100d	0.0070	0.0088		
Plateau concentration- tillage depth 5 cm (more conservative value)		0.0026			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0135			

Table 8.7-15: PEC_{soil} for IN-L9223 on maize

PEC_{soil} (mg/kg)		Single application, maize; App.rate = 1.2 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0012	-		-
Short term	24h	0.0012	0.0012		
	2d	0.0012	0.0012		
	4d	0.0012	0.0012		
Long term	7d	0.0012	0.0012		
	14d	0.0012	0.0012		
	21d	0.0011	0.0012		
	28d	0.0011	0.0012		
	42d	0.0011	0.0011		
	50d	0.0011	0.0011		
	100d	0.0009	0.0011		
Plateau concentration- tillage depth 5 cm (more conservative value)		0.0008			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0020			

Table 8.7-16: PEC_{soil} for IN-A4098 on maize

PEC_{soil} (mg/kg)		Single application, maize; App.rate = 1.4 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0014	-		-
Short term	24h	0.0014	0.0014		
	2d	0.0014	0.0014		
	4d	0.0014	0.0014		
Long term	7d	0.0014	0.0014		
	14d	0.0014	0.0014		
	21d	0.0014	0.0014		
	28d	0.0014	0.0014		
	42d	0.0014	0.0014		
	50d	0.0014	0.0014		
	100d	0.0013	0.0014		
Plateau concentration- tillage depth 5 cm (more conservative value)		0.0049			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0063			

Table 8.7-17: PEC_{soil} for IN-U5F72 on maize

PEC_{soil} (mg/kg)		Single application, maize; App.rate = 2.0 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0020	-		-
Short term	24h	0.0020	0.0020		
	2d	0.0020	0.0020		
	4d	0.0020	0.0020		
Long term	7d	0.0019	0.0020		
	14d	0.0019	0.0019		
	21d	0.0018	0.0019		
	28d	0.0017	0.0019		
	42d	0.0016	0.0018		
	50d	0.0015	0.0018		
	100d	0.0012	0.0016		
Plateau concentration- tillage depth 5 cm (more conservative value)		0.0003			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0023			

Table 8.7-18: PEC$_{soil}$ for IN-JZ789 on maize

PEC$_{soil}$ (mg/kg)		Single application, maize; App.rate = 1.1 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0011	-		-
Short term	24h	0.0011	0.0011		
	2d	0.0011	0.0011		
	4d	0.0011	0.0011		
Long term	7d	0.0011	0.0011		
	14d	0.0011	0.0011		
	21d	0.0011	0.0011		
	28d	0.0011	0.0011		
	42d	0.0011	0.0011		
	50d	0.0011	0.0011		
	100d	0.0010	0.0011		
Plateau concentration- tillage depth 5 cm (more conservative value)		0.0038			
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		0.0049			

Table 8.7-19: PEC$_{soil}$ for IN-A5546 on maize

PEC$_{soil}$ (mg/kg)		Single application, maize; App.rate = 2.0 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0020	-		-
Short term	24h	0.0016	0.0018		
	2d	0.0013	0.0016		
	4d	0.0008	0.0013		
Long term	7d	0.0004	0.001		
	14d	0.0001	0.0006		
	21d	<0.0001	0.0004		
	28d	<0.0001	0.0003		
	42d	<0.0001	0.0002		
	50d	<0.0001	0.0002		
	100d	<0.0001	0.0001		
Plateau concentration- tillage depth 5 cm (more conservative value)		<0.0001			
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		0.0020			

Table 8.7-20: PEC_{soil} for IN-V7160 on maize

PEC_{soil} (mg/kg)		Single application, maize; App.rate = 0.5 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0005	-		-
Short term	24h	0.0005	0.0005		
	2d	0.0005	0.0005		
	4d	0.0005	0.0005		
Long term	7d	0.0005	0.0005		
	14d	0.0005	0.0005		
	21d	0.0005	0.0005		
	28d	0.0005	0.0005		
	42d	0.0004	0.0005		
	50d	0.0004	0.0005		
	100d	0.0004	0.0004		
Plateau concentration- tillage depth 5 cm (more conservative value)		0.0003			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0008			

Table 8.7-21: PEC_{soil} for IN-L9226 on maize

PEC_{soil} (mg/kg)		Single application, maize; App.rate = 2.1 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0021	-		-
Short term	24h	0.0017	0.0019		
	2d	0.0014	0.0017		
	4d	0.0009	0.0014		
Long term	7d	0.0005	0.0011		
	14d	0.0001	0.0007		
	21d	<0.0001	0.0005		
	28d	<0.0001	0.0004		
	42d	<0.0001	0.0002		
	50d	<0.0001	0.0002		
	100d	<0.0001	0.0001		
Plateau concentration- tillage depth 5 cm (more conservative value)		<0.0001			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0021			

Table 8.7-22: PEC_{soil} for IN-W8268 on maize

PEC_{soil} (mg/kg)		Single application, maize; App.rate = 1.7 g a.s./ha; CI=25%			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0017	-		-
Short term	24h	0.0017	0.0017		
	2d	0.0017	0.0017		
	4d	0.0016	0.0017		
Long term	7d	0.0016	0.0016		
	14d	0.0015	0.0016		
	21d	0.0014	0.0015		
	28d	0.0013	0.0015		
	42d	0.0011	0.0014		
	50d	0.0010	0.0013		
	100d	0.0006	0.001		
Plateau concentration- tillage depth 5 cm (more conservative value)		<0.0001			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0017			

zRMS comments:

The calculations PECs cover proposed using in GAP.
Peer-reviewed endpoints for thifensulfuron-methyl and its metabolites have been presented in EFSA conclusion (EFSA Journal 2015;13(7) :4201) and used for calculations PECs.
The PECs for metabolites are presented in Tables: 8.7.14 - 8.7.22.
The acceptable predicted environmental concentrations of thifensulfuron methyl and its metabolites are appropriate to be used for the subsequent risk assessment.

8.7.1.1 PEC_{soil} of EVRITELL 162 OD

Table 8.7-23: PEC_{soil} for EVRITELL 162 OD on maize

Active substance/ reparation	Application rate (g/ha)*	Crop inter-ception (%)	PEC_{act} (mg formu-lation /kg soil)**	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
EVRITELL 162 OD	1016	25	1.02	n/a	5 cm	not required	not required

* Application rate of = 1.0 L product ha-1 x 1.016 (relative density) = 1.016 kg product/ha
** based on the recommended crop interception, soil density of 1.5 g/cm^3 and soil depth of 5 cm

zRMS comments:

The calculations PECs cover proposed using in GAP.
The acceptable predicted environmental concentrations of formulation in soil are appropriate to be used for the subsequent risk assessment.

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

8.8.1 Justification for new endpoints

No new endpoints are presented in the current submission.

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

The calculation of the predicted environmental concentrations in ground waters (PEC_{GW}) of dicamba, nicosulfuron and thifensulfuron methyl and relevant metabolites have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PEARL v.5.5.5, FOCUS PELMO v.6.6.4 and MACRO in FOCUS v5.5.4. Calculation were performed for all FOCUS scenarios (if available).

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	Dicamba: 110 g as/ha Nicosulfuron: 40 g as/ha Thifensulfuron- methyl: 12 g as/ha
Number of applications/interval (d)	1/n.a.
Relative application date	Emergence + 10 d
Crop interception (%)	25
Calculated amount of active reaching soil (kg a.s/ha)	Dicamba: 0.110 Nicosulfuron: 0.040 Thifensulfuron- methyl: 0.012
Frequency of application	annual
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, FOCUS MACRO v5.5.4

8.8.1.1 Dicamba

8.8.1.2 Dicamba and its metabolites

The following substance parameters were used.

Table 8.8-2: Input parameters related to active substance dicamba and its metabolite DCSA for PEC_{GW} calculations

Compound	Dicamba	DCSA	Value in accordance to EU end-point y/n Reference
Molecular weight (g/mol)	221	207	Yes / EFSA Journal 2011;9(1):1965
Solubility in water (mg/L) at 25°C	6600	88000	Yes / EFSA Journal 2011;9(1):1965
Henry's Law constant ($Pa \cdot m^3/mol$) at 25°C	1×10^{-4}	1×10^{-4}*	Yes / EFSA Journal 2011;9(1):1965
Saturated vapour pressure (Pa) at 25°C	1.67×10^{-3}	1×10^{-6}	Yes / EFSA Journal 2011;9(1):1965
$DT_{50,soil}$ (d) (geometric mean)	4	9.4	Yes / EFSA Journal 2011;9(1):1965
$K_{oc,foc}$ (mL/g) Geometric mean	9.8	877	Yes / EFSA Journal 2011;9(1):1965
K_{om} (mL/g)	5.7	508.5	Calculated from K_{foc} (K_{fom}= K_{foc}/1.724)
Freundlich Exponent 1/n arithmetic mean	0.74	0.80	Yes / EFSA Journal 2011;9(1):1965
Plant crop uptake	0	0	FOCUS default
Formation fraction	-	0.75	Yes / EFSA Journal 2011;9(1):1965

*value the same as parent

Table 8.8-3: PEC_{GW} for dicamba and metabolite DCSA on proposed uses (with FOCUS PEARL 5.5.5)

Crop	Scenario	80^{th} Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		Dicamba	DCSA
maize	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

Table 8.8-4: PEC_{GW} for dicamba and metabolite DCSA on proposed uses (with PELMO 6.6.4)

Crop	Scenario	80^{th} Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		Dicamba	DCSA
maize	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

zRMS comments:

Input parameters presented in Table 8.8-2 and used in the groundwater modelling are in general in line with EU agreed endpoints.
In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2014).
The calculations were performed by using FOCUS PEARL 5.5.5, PELMO 6.6.4 and FOCUS MACRO 5.5.4 with the EU input parameters. The application dates suggested by AppDate ver. 3.06 were considered.
The PECgw results were far below the threshold of 0.1 µg/L (<0.001).

Overall, no unacceptable leaching of dicamba and its metabolite is expected following application of A18032E according to the intended use pattern.

8.8.1.3 Nicosulfuron

8.8.1.4 Nicosulfuron and its metabolites

The following substance parameters were used.

Table 8.8-5: Input parameters related to active substance nicosulfuron and metabolites for PEC_{gw} calculations

Compound	Nicosulfuron	Remarks
Molar mass (g/mol)	410.4	
K_{foc} (L/kg)	Please refer to Table 8.8-6	
Freundlich Exponent 1/n (-)	0.93	Arithmetic mean
$DT50_{,soil}$ (d)	16.4	Geometric mean, lab studies at pF2 and 20 °C
Plant uptake factor (-)	0	Default

Table 8.8-6: Adsorption data for nicosulfuron used in the FOCUS modelling (taken from the EFSA Scientific Report (2007) 120, 1-91)

Adsorption data for nicosulfuron used in the FOCUS modelling					
Scenario	**Horizon**	**Depth (cm)**	**Clay content* (%)**	**Calculated $K_{F,CLAY}^{+}$ (ml/g)**	**Degradation transformation factor**
Châteaudun	1	0-25	30	0.78	1.0
	2	25-50	31	0.81	0.5
	3	50-60	25	0.65	0.5
	4	60-100	26	0.68	0.3
	5	100-120	26	0.68	0.0
	6	120-190	24	0.62	0.0
	7	190-260	31	0.81	0.0
Hamburg	1	0-30	7.2	0.19	1.0
	2	30-60	6.7	0.17	0.5
	3	60-75	0.9	0.02	0.3
	4	75-90	0	0.00	0.3
	5	90-100	0	0.00	0.3

	6	100-200	0	0.00	0.0
Kremsmünster	1	0-30	14	0.36	1.0
	2	30-50	25	0.65	0.5
	3	50-60	27	0.70	0.5
	4	60-100	27	0.70	0.3
	5	100-200	27	0.70	0.0
Okehampton	1	0-25	18	0.47	1.0
	2	25-55	17	0.44	0.5
	3	55-85	14	0.36	0.3
	4	85-100	9	0.23	0.3
	5	100-150	9	0.23	0.0
Piacenza	1	0-30	15	0.39	1.0
	2	30-40	15	0.39	0.5
	3	40-60	7	0.18	0.5
	4	60-80	7	0.18	0.3
	5	80-100	0	0.00	0.3
	6	100-170	0	0.00	0.0
Porto	1	0-35	10	0.26	1.0
	2	35-60	8	0.21	0.5
	3	60-100	8	0.21	0.3
	4	100-120	8	0.21	0.0
Sevilla	1	0-10	14	0.36	1.0
	2	10-30	13	0.34	1.0
	3	30-60	15	0.39	0.5
	4	60-100	16	042	0.3
	5	100-120	16	0.42	0.0
	6	120-180	22	0.57	0.0
Thiva (calculated by applicant because not available in the EFSA report)	1	0-30	25.3	0.65	1.0
	2	30-45	25.3	0.65	0.5
	3	45-60	29.6	0.76	0.5
	4	60-85	31.9	0.82	0.3
	5	85-100	32.9	0.85	0.3
	6	100-200	32.9	0.85	0.0

* fraction < 2 µm
\+ calculated using the equation KF CLAY = 0.026 x %clay

Table 8.8-7: Input parameters for PECgw nicosulfuron and metabolites

Parameter	Nico-sulfuron	HMUD	AUSN	ADMP	UCSN	ASDM	MU-466
Molecular weight (g/mol)	410.4	396.4	314.3	155.2	315.3	229.2	215.1
Vapour pressure (Pa, at 20°C)	8.00E-10	8.00E-10	8.00E-10	8.00E-10	8.00E-10	8.00E-10	8.00E-10
Aqueous solubility (mg/L, at 20°C)	76400	76400	76400	76400	76400	76400	76400
Koc / Kom (mL/g)[a]	Clay dependent[c]	5.3 / 3.1	13 / 7.5	51.5 / 29.9	3.1 / 1.8	2.3 / 1.3	3.62 / 2.1
1/n[a]	0.94	0.90	0.98	0.87	0.90	0.82	0.90
Koc / Kom (mL/g)[b]	Clay dependent[c]	5.3 / 3.1	37.3 / 21.6	51.5 / 29.9	3.1 / 1.8	7.2 / 4.2	13.41 / 7.8
1/n[b]	0.94	0.90	0.95	0.87	0.90	0.94	0.90
Aerobic soil DT_{50} (days)	16.4	23.8	192.3	4.5	271.0	236.6	75.5
Formation fraction (-)	-	0.442 (from parent)	0.687 (from HMUD)	0.214 (from parent)	0.313 (from HMUD)	0.214 (from parent)	0.282 (from ASDM
Plant uptake factor (-)	0.0	0.0	0.0	0.0	0.0	0.0	0.0

[a] Endpoints for pH < 7.0
[b] Endpoints for pH > 7.0
[c]For clay dependent inputs see table 8.8.6

PECgw of nicosulfuron and its metabolites

Table 8.8-8 : PECgw for metabolites of nicosulfuron for an annual application of EVRITELL 162 OD to maize. FOCUS PEARL v. 5.5.5. & PELMO v. 6.6.4 and MACRO v.5.5.4_PUF=0

Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)_ FOCUS PEARL v. 5.5.5.									
	nicosulfuron	HMUD	UCSN	ADMP	pH <7			pH >7		
					AUSN	ASDM	MU-466	AUSN	ASDM	MU-466
Châteaudun	0.088937	**0.456474**	**1.092559**	0.000000	**2.123215**	**1.201675**	0.065954	**1.500248**	**1.184417**	0.055586
Hamburg	**0.127379**	**1.236269**	**1.405736**	0.005993	**2.666281**	**1.718294**	0.071878	**1.882338**	**1.668070**	0.053274
Kremsmünster	0.016419	**0.530036**	**0.794895**	0.000388	**1.539959**	**0.940615**	0.045820	**1.318606**	**0.901677**	0.035905
Okehampton	0.018160	**0.639926**	**0.637257**	0.000869	**1.239365**	**0.800167**	0.031661	**0.978590**	**0.775198**	0.025767
Piacenza	0.083577	**0.402866**	**1.446584**	0.000805	**2.595116**	**1.520317**	0.095492	**2.148555**	**1.450350**	0.072558
Porto	0.008218	**0.173884**	**0.492131**	0.000037	**1.018441**	**0.533869**	0.030792	**0.780620**	**0.539209**	0.024646
Sevilla	0.023568	0.064399	**1.299803**	0.000000	**1.941197**	**1.167657**	**0.109245**	**1.158139**	**1.134110**	0.073132
Thiva	0.000100	**0.204600**	**2.002655**	0.000000	**3.473475**	**1.965531**	**0.157445**	**2.447598**	**1.896267**	**0.140053**
80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)_ PELMO v. 6.6.4										
Châteaudun	0.000	**0.261**	**1.304**	0.000	**2.342**	**1.329**	0.089	**1.652**	**1.281**	0.070
Hamburg	**0.160**	**0.809**	**1.117**	0.002	**2.168**	**1.317**	0.060	**1.622**	**1.293**	0.048
Kremsmünster	0.002	**0.483**	**0.902**	0.000	**1.772**	**1.011**	0.052	**1.418**	**0.982**	0.043
Okehampton	0.028	**0.509**	**0.673**	0.000	**1.241**	**0.786**	0.035	**0.962**	**0.760**	0.026
Piacenza	0.014	**0.302**	**0.710**	0.000	**1.296**	**0.774**	0.041	**1.074**	**0.741**	0.034
Porto	0.008	**0.148**	**0.514**	0.000	**1.058**	**0.545**	0.034	**0.774**	**0.555**	0.028
Sevilla	0.000	0.034	**1.067**	0.000	**1.648**	**0.991**	0.092	**1.069**	**0.977**	0.070
Thiva	0.000	0.094	**1.650**	0.000	**2.698**	**1.594**	**0.133**	**2.000**	**1.520**	**0.110**
FOCUS MACRO v.5.5.4										
Châteaudun (129 d Julian- 9.05)	0.017	0.231	1.04	0.00	2.28	1.09	0.27	1.22	1.06	0.17

Table 8.8-9 : PEC_{gw} for metabolites of nicosulfuron for an annual application of EVRITELL 162 OD to maize. FOCUS PEARL v. 5.5.5. & PELMO v. 6.6.4 _PUF=0.5*

Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)_ FOCUS PEARL v. 5.5.5.									
	nicosulfuron	HMUD	UCSN	ADMP	pH <7			pH >7		
					AUSN	ASDM	MU-466	AUSN	ASDM	MU-466
Châteaudun	0.067697	0.418138	1.023278	0.000000	1.988202	1.122012	0.061991	1.396604	1.106543	0.052106
Hamburg	0.086369	1.012003	1.212226	0.004068	2.297570	1.459228	0.062638	1.607680	1.418765	0.045504
Kremsmünster	0.012634	0.475702	0.733998	0.000295	1.416871	0.862131	0.042411	1.216549	0.832184	0.033347
Okehampton	0.013651	0.567197	0.581015	0.000651	1.141272	0.726441	0.029156	0.887632	0.704462	0.023740
Piacenza	0.061001	0.336300	1.291763	0.000589	2.321485	1.354739	0.086233	1.907997	1.292543	0.064862
Porto	0.004754	0.140373	0.416462	0.000021	0.855054	0.448364	0.026295	0.666624	0.451007	0.021420
Sevilla	0.007718	0.028221	0.879575	0.000000	1.281906	0.780135	0.074891	0.753842	0.750655	0.049447
Thiva	0.000069	0.183947	1.835835	0.000000	3.194039	1.798485	0.145478	2.240858	1.742597	0.129242
80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)_ PELMO v. 6.6.4										
Châteaudun	0.000	0.244	1.244	0.000	2.235	1.266	0.085	1.572	1.222	0.067
Hamburg	0.070	0.469	0.788	0.001	1.525	0.892	0.043	1.106	0.882	0.034
Kremsmünster	0.001	0.424	0.814	0.000	1.620	0.908	0.048	1.289	0.889	0.039
Okehampton	0.021	0.439	0.602	0.000	1.112	0.714	0.031	0.859	0.680	0.024
Piacenza	0.008	0.235	0.579	0.000	1.049	0.625	0.034	0.888	0.599	0.028
Porto	0.004	0.096	0.400	0.000	0.814	0.421	0.027	0.600	0.426	0.021
Sevilla	0.000	0.023	0.793	0.000	1.237	0.733	0.069	0.795	0.724	0.053
Thiva	0.000	0.089	1.576	0.000	2.568	1.521	0.127	1.903	1.450	0.105

**Literature data (Gubbiga et al., 1996, Novosel and Renner, 1995; Kalnay and Glenn, 2000) indicates root uptake of nicosulfuron by corn sugar beet and hemp plants. A default plant uptake factor of 0.5 was therefore used for nicosulfuron.*

PECgw of nicosulfuron and its metabolites

Table 8.8-10 :PECgw for metabolites of nicosulfuron for one application of EVRITELL 162 OD to maize only every second year. FOCUS PEARL v. 5.5.5. & PELMO v. 6.6.4_PUF=0

Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)_ FOCUS PEARL v. 5.5.5.									
	nicosulfuron	HMUD	UCSN	ADMP	pH <7			pH >7		
					AUSN	ASDM	MU-466	AUSN	ASDM	MU-466
Châteaudun	0.045087	0.239530	0.504821	0.000000	0.995021	0.565516	0.029735	0.800814	0.561184	0.024822
Hamburg	0.051064	0.572440	0.707357	0.003014	1.252623	0.820528	0.038108	0.860068	0.759352	0.022534
Kremsmünster	0.007213	0.306185	0.391833	0.000165	0.782270	0.466074	0.022358	0.641460	0.461682	0.018542
Okehampton	0.008352	0.327692	0.306235	0.000396	0.605740	0.382443	0.015711	0.494205	0.374274	0.012451
Piacenza	0.038104	0.233340	0.601816	0.000365	1.120305	0.633684	0.041412	0.808964	0.622450	0.031369
Porto	0.004716	0.082723	0.238867	0.000020	0.454633	0.257197	0.015049	0.374462	0.253236	0.012120

Sevilla	0.013221	0.035782	**0.812858**	0.000000	**1.165763**	**0.732063**	0.069335	**0.539351**	**0.700736**	0.039209
Thiva	0.000060	**0.112489**	**1.541660**	0.000000	**2.202430**	**1.426418**	**0.123903**	**1.442965**	**1.318971**	0.087846
80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)_ PELMO v. 6.6.4										
Châteaudun	0.000	**0.136**	**0.703**	0.000	**1.300**	**0.729**	0.048	**0.833**	**0.713**	0.040
Hamburg	0.092	**0.383**	**0.531**	0.001	**1.038**	**0.612**	0.028	**0.812**	**0.610**	0.023
Kremsmünster	0.001	**0.266**	**0.451**	0.000	**0.924**	**0.509**	0.027	**0.771**	**0.505**	0.023
Okehampton	0.016	**0.276**	**0.307**	0.000	**0.598**	**0.371**	0.016	**0.482**	**0.364**	0.013
Piacenza	0.011	**0.152**	**0.327**	0.000	**0.640**	**0.354**	0.021	**0.536**	**0.350**	0.018
Porto	0.004	**0.071**	**0.241**	0.000	**0.463**	**0.260**	0.016	**0.375**	**0.254**	0.013
Sevilla	0.000	0.025	**0.589**	0.000	**0.804**	**0.511**	0.050	**0.475**	**0.474**	0.029
Thiva	0.000	0.048	**1.015**	0.000	**1.648**	**0.936**	0.087	**1.066**	**0.914**	0.070

Results of modelling with FOCUS PEARL v. 5.5.5. & PELMO v. 6.6.4, using PUF=0 show that the active substance nicosulfuron does not exceed groundwater concentrations of 0.1 µg/L in the 8 FOCUS groundwater scenarios in the intended maize applications.
Groundwater concentrations remained below 0.1 µg/L in all relevant FOCUS scenarios when applying nicosulfuron only every second year.

Conclusions

Appropriate endpoints from the EU review were used to calculate PEC_{GW} for the active substance and their metabolites for the intended use patterns. The risk assessment for the metabolites of nicosulfuron has already been performed for EU approval (see list of endpoints 2007).

Modeling results for PEC_{GW} show that the active substance nicosulfuron can leach into groundwater at concentrations ≥ 0.1 µg/L with intended use in maize. An unacceptable risk of groundwater contamination was observed only in the Hamburg scenario (value of 0.13 µg/L; Tier 1/PUF=0).
However, considering the results from three lysimeter studies with nicosulfuron (reported in DAR: Kurth, 1995, Marmouni & Burgener (1996a & b), which were conducted at an application rate of 40 g nicosulfuron/ha, it shows that the active substance nicosulfuron has no potential to enter groundwater at annual average concentrations above 0.1 µg/L.

~~At Tier 2, the EU agreed endpoint (PUF=0.5) for nicosulfuron was used in the simulation. Consideration of endpoint reported in EFSA Journal (2007) 120, 1-91 in groundwater modelling showed that groundwater concentrations of < 0.1µg/L in Hamburg scenario.~~

None of groundwater metabolites was predicted to be exceed the trigger of 10 µg/L. The lysimeter studies indicate that the level of 0.1 µg /L is exceeded by ASDM (i.e. 0.88-0.99 µg/L in the first year and 0.18-0.3 µg/L in the second year), AUSN (i.e. 0.24 µg/L in the first year and 0.43-0.59 µg/L in the second year) and UCSN (i.e. 0.18-0.22 µg/L in the first year and no contamination in the second year).

Taking all above information into account it can be concluded that application of EVRITELL 162 OD to maize at a maximum rate of 1 L/ha (equivalent to 40 g a.s./ha) will not pose a risk of groundwater contamination by nicosulfuron. Moreover, during EU review of nicosulfuron none of the groundwater metabolites (HMUD, AUSN, UCSN, ASDM and MU-466) was considered to be relevant according to the current EU guidance document on relevance of metabolites.

zRMS comments:
The calculations PECgw were performed using programs PEARL ver. 5.5.5 and FOCUS PELMO ver. 6.6.4 FOCUS models. The input parameters used in calculations were taken from the end-points available in the EFSA conclusion on Scientific Report EFSA (2007) 120, 1-91. In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. Interception used is appropriate to the proposed BBCH of crops (guidance 2014). The results for PECgw show that the active substance nicosulfuron can leach into groundwater at concentrations ≥ 0.1 µg/L with intended use in maize. An unacceptable risk of groundwater contamination was observed only in the Hamburg scenario (value of 0.13 µg/L). In Tier II the EU agreed endpoint (PUF=0.5) for nicosulfuron was used in the simulation. Consideration of endpoint reported in EFSA Journal (2007) 120, 1-91 in groundwater modelling showed that groundwater concentrations of < 0.1µg/L in Hamburg scenario. According last harmonisation PL, PUF 0,5 can be used if study appropriate study is available. The Applicant submitted new data on the PECgw calculation performed for an application every other year on the same field. The results were accepted. They indicate that the application of nicosulfuron every other year on the same field does not pose a risk for PECgw and in all scenarios does not exceed the limit value of 0.1 µg/L. PECgw values for metabolites HMUD, ASDM, AUSN, UCSN and MU-466 were above 0.1 µg/L for most scenarios and for some scenarios also above 0.75 µg/L. The assessment relevance of the all metabolites in ground water according to SANCO/221/2000 –rev.10 document was reported in the dRR Part B10. The Applicant referred to the lysimeter tests carried out and approved by the DAR. The lysimeter study results (Germany) shown that concentrations of nicosulfuron following single application in maize at a dose of 40 g / ha doesn't pose an unacceptable risk for ground water. Annual average concentrations of nicosulfuron did not exceed 0.1 µg/L in either year (maximum 0.07 µg/L).

Member States concerned by scenarios exceeding the PECgw for nicosulfuron should decide on the possibility of using the results of lysimeter studies for assessment.
However the sMS should be take into account national PECgw concentrations from local monitoring..

8.8.1.5 Thifensulfuron methyl

8.8.1.6 Thifensulfuron methyl and its metabolites

The following substance parameters were used.

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

Compound	Thifensulfuron methyl	IN-L9225	IN-L9223	IN-A4098	IN-U5F72	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	387.4	373.4	207.2	140.1	378.3	Yes/EFSA, 2015
Water solubility (mg/L) (pH 7.0, 20 °C)	2240	2240	2240	2240	2240	Yes/EFSA, 2015
Saturated vapour pressure (Pa) (20 °C)	5.2×10^{-9}	5.2×10^{-9}	5.2×10^{-9}	5.2×10^{-9}	5.2×10^{-9}	Yes/EFSA, 2015
K_{foc} (L/kg)	9.0 (median, n = 9) 13.3	19.9 (arithmetic, n = 6)	4.07 (arithmetic, n = 4)	45.5 (median, n = 27)	524.0 (arithmetic, n = 3)	Yes/EFSA, 2015
Freundlich Exponent 1/n (-)	0.932 (arithmetic mean, n = 9)	0.85 (arithmetic mean, n = 6)	1.157 (arithmetic mean, n = 4)	0.9 (arithmetic mean, n = 27)	1.0 (arithmetic mean, n = 3)	Yes/EFSA, 2015
Plant uptake factor (-)	0	0	0	0	0	FOCUS default
$DT50_{,soil}$ (d)	1.39 (geometric mean, n = 6)	32.3 (geometric mean, n = 11	178 (geometric mean, n = 3)	167.9 (geometric mean, n = 16)	73.0 (Geometric mean, n = 8)	Yes/EFSA, 2015
Formation fraction	-	0.95 from Parent	0.3 from IN-L9225	0.05 from Parent and 0.14 from IN-L9225	1.0 from IN-JZ789 and 0.22 from IN-L9225	Yes/EFSA, 2015
Maximum occurrence in soil (%)	-	-	-	-	-	Yes/EFSA, 2015

Table 8.8-11: Input parameters related to active substance thifensulfuron methyl and metabolites for PECgw calculations (continued)

Compound	IN-JZ789	IN-A5546[a]	IN-V7160[a]	IN-L9226[a]	IN-W8268[a]	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	359.3	221.2	183.2	373.4	189.2	Yes/EFSA, 2015
Water solubility (mg/L) (pH 7.0, 25 °C)	2240	2240	2240	2240	2240	Yes/EFSA, 2015
Saturated vapour pressure (Pa) (20 °C)	5.2×10^{-9}	5.2×10^{-9}	5.2×10^{-9}	5.2 × 10-9	5.2×10^{-9}	Yes/EFSA, 2015
K_{foc} (L/kg)	31.1 (arithmetic, n = 8)	49.0 (arithmetic, n = 3)	113.94 (arithmetic, n = 5)	126 (arithmetic, n = 6)	7.4 (arithmetic, n = 6)	Yes/EFSA, 2015
Freundlich Exponent 1/n (-)	1.0 (arithmetic mean, n = 8)	0.91 (arithmetic mean, n = 3)	0.913 (arithmetic mean, n = 5)	0.900 (arithmetic mean, n = 6)	1.16 (arithmetic mean, n = 6)	Yes/EFSA, 2015
Plant uptake factor (-)	0	0	0	0	0	FOCUS default
$DT50_{soil}$ (d)	60 (Geometric mean, n = 5)	3 (Geometric mean, n = 5)	19.4 (Geometric mean, n = 5)	0.95 (Geometric mean, n = 6)	18.7 (Geometric mean, n = 6)	Yes/EFSA, 2015
Formation fraction	0.26 from IN-L9225	-	-	-	-	Yes/EFSA, 2015
Maximum Occurrence in soil (%)	-	100[b]	9.6	100[b]	29.6	Yes/EFSA, 2015

a *Metabolites IN-A5546, IN-L9226, IN-V7160 and IN-W8268 were simulated as a pseudo-parent, thus, there are no formation fraction values given.*

b *The worst-case of 100% occurrence is assumed as in the EFSA conclusion (2015).*

Table 8.8-12: PEC_{gw} for thifensulfuron methyl and metabolites on maize at the application rate of 1×12.0 g a.s./ha at BBCH 12-16 (with FOCUS PEARL 5.5.5, FOCUS PELMO 6.6.4 and FOCUS MACRO 5.5.4)

Crop	Scenario	Thifensulfuron methyl	IN-L9225	IN-L9223	IN-A4098	IN-U5F72	IN-JZ789	IN-L9226	IN-A5546	IN-V7160	IN-W8268
Maize/ FOCUS PEARL 5.5.5	Châteaudun	<0.001	0.041125	**0.477602**	0.059550	0.051523	**0.200251**	<0.001	<0.001	<0.001	0.022986
	Hamburg	<0.001	0.096729	**0.648900**	0.076510	0.070495	**0.309326**	<0.001	<0.001	<0.001	0.066864
	Kremsmünster	<0.001	0.069720	**0.349471**	0.054318	0.054359	**0.191077**	<0.001	<0.001	<0.001	0.030884
	Okehampton	<0.001	0.092787	**0.322142**	0.054833	0.046793	**0.191176**	<0.001	<0.001	<0.001	0.035782
	Piacenza	<0.001	0.044711	**0.421606**	0.058517	0.050873	**0.169152**	<0.001	<0.001	<0.001	0.010735
	Porto	<0.001	0.017537	**0.198942**	0.030246	0.014101	**0.101395**	<0.001	<0.001	<0.001	0.005386
	Sevilla	<0.001	0.002075	**0.388442**	0.025325	0.013333	0.062382	<0.001	<0.001	<0.001	0.000643

	Thiva	<0.001	0.021713	**0.782004**	0.077963	0.057457	**0.192268**	<0.001	<0.001	<0.001	0.008071
Maize/ FOCUS PELMO 6.6.4	Châteaudun	<0.001	0.029	**0.504**	0.058	0.049	**0.184**	<0.001	<0.001	<0.001	0.015
	Hamburg	<0.001	0.067	**0.530**	0.067	0.057	**0.256**	<0.001	<0.001	<0.001	0.037
	Kremsmünster	<0.001	0.064	**0.390**	0.056	0.052	**0.198**	<0.001	<0.001	<0.001	0.034
	Okehampton	<0.001	0.086	**0.315**	0.054	0.042	**0.182**	<0.001	<0.001	<0.001	0.038
	Piacenza	<0.001	0.049	**0.302**	0.047	0.042	**0.161**	<0.001	<0.001	<0.001	0.015
	Porto	<0.001	0.019	**0.197**	0.031	0.013	**0.105**	<0.001	<0.001	<0.001	0.006
	Sevilla	<0.001	0.001	**0.345**	0.020	0.010	0.062	<0.001	<0.001	<0.001	0.001
	Thiva	<0.001	0.015	**0.586**	0.067	0.040	**0.165**	<0.001	<0.001	<0.001	0.004
Maize/ FOCUS MACRO 5.5.4	Châteaudun (131d Julian-11.05)	<0.001	0.017	0.414	0.040	0.021	0.130	<0.001	<0.001	<0.001	0.01

Conclusions

Results of the groundwater modelling show that the active substance thifensulfuron methyl and its major soil metabolite IN-L9225, IN-A4098, IN-U5F72, IN-L9226, IN-A5546, IN-V7160 and IN-W8268 are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the groundwater FOCUS scenarios. On the basis of the obtained results PECgw values for metabolites IN-L9223 & IN-JZ789 were > 0.1 µg/L for application. These metabolites are toxicologically non-relevant and not likely to pose leaching risk to groundwater.

ZRMS comments:

The PECgw calculations for thifensulfuron-methyl and its metabolites were accepted.
PECgw have been calculated for all scenarios according to the GAP using the models FOCUS PELMO v 6.6.4 and FOCUS PEARL 5.5.5.

Peer- reviewed endpoints for thifensulfuron-methyl and its metabolites have been presented in EFSA conclusion EFSA Journal 2015;13(7) :4201) and were used in modelling.
Interception has been appropriate to the proposed BBCH of crops (EFSA guidance was published, (2014;12(5):3662).
PECgw values for thifensulfuron-methyl are below the trigger value of 0.1 µg/L.
PECgw values for IN-L9225, IN-A4098, IN-U5F72, IN-L9226, IN-A5546, IN-V7160 and IN-W8268 metabolites are below the trigger value of 0.1 µg/L in PEARL and PELMO models. The PECgw values for metabolites IN-L9223 & IN-JZ789 were > 0.1 µg/L trigger value of 0.1 µg/L and but below the trigger value of 0.75 µg/L.

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

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

8.9.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.

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

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

Plant protection product	EVRITELL 162 OD
Use No.	1
Crop	Maize
Application rate (kg as/ha)	Dicamba: 0.110 Nicosulfuron: 0.040 Thifensulfuron- methyl: 0.012
Number of applications/interval (d)	1/n.a.
Application window	Spring spraying, March-May (relevant for step 1 and 2 only)
Application method	Spraying
CAM (Chemical application method)	2 - appln foliar linear (in case of R scenario)
Crop interception	Minimal crop cover (25%)
Models used for calculation	Step 1 and 2: STEPS 1-2 in FOCUS v.3.2 Step 3: FOCUS SWASH v.5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXSWA v5.5.3 Step 4: SWAN v.5.0.1

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of EVRITELL 162 OD

Crop	Scenario	Application window used in modelling	
		Date	Julian day
Maize	D3/ ditch	12May- 11Jun	132 - 162
	D4/ pond, stream	18 May-17Jun	138-168
	D5/ pond, stream	15May-14Jun	135-165
	D6/ ditch	24 Apr-25May	115-145
	R1/ pond, stream	10May-9Jun	130-160
	R2/ stream	9May-8Jun	129-159
	R3/ stream	8May-7Jun	128-158
	R4/ stream	15Apr-15May	105 – 135

8.9.1.1 Dicamba and its metabolites

Table 8.9-3: Input parameters related to active substance Dicamba and metabolite DCSA for $PEC_{sw/sed}$ calculations STEP 1, 2

Compound	dicamba	DCSA	Value in accordance to EU end-point y/n Reference
Molecular weight (g/mol)	221	207	Yes / EFSA Journal 2011;9(1):1965
Water solubility (mg/L) at 25°C	6600	88000	Yes / EFSA Journal 2011;9(1):1965
$K_{oc,foc}$ (mL/g) Geometric mean	9.8	877	Yes / EFSA Journal 2011;9(1):1965
Freundlich Exponent 1/n	0.74	0.80	Yes / EFSA Journal 2011;9(1):1965
$DT_{50,soil}$ (d) (geometric mean)	4.0	9.4	Yes / SANCO/4062/2001 - final of 11.07.2008 Based on studies on degradation route (i.e. DT50 = 24d, 25°C, 75% 33kPa) (n= 1, normalized at 20°C and pF2)
$DT_{50,water}$ (d)	41	1000*	Yes / EFSA Journal 2011;9(1):1965
$DT_{50,sed}$ (d)	1000	1000	FOCUS default value
$DT_{50,whole\ system}$ (d) Geometric mean	41	57.9	Yes / EFSA Journal 2011;9(1):1965
Maximum occurrence observed (%)	-	Soil: 58.8 Water: 26.9 Water/sediment: 31.4	Yes / EFSA Journal 2011;9(1):1965

* FOCUS default value

Table 8.9-4: FOCUS Step 1 and 2 PECsw and PECsed for dicamba following single application of EVRITELL 162 OD to maize

Scenario FOCUS	Period/ Waterbody	Max PEC_{sw} (µg/L)	7d-PECsw,twa (µg/L)[a]	Max PEC_{sed} (µg/kg)
		Step 1		
	-	37.2054	35.0770	3.5470
		Step 2		
Northern Europe	Mar-May	3.6522	3.4429	0.3573
Northern Europe	Jun-Sep	3.6522	3.4429	0.3573

a *Time as required by ecotox.*

PECsw and PECsed of metabolite

During degradation studies of dicamba in soil a major metabolite DCSA was found. The PEC_{SW} and PEC_{SED} values are presented in the table below.

Table 8.9-5: FOCUS Step 1 and 2 PECsw and PECsed for metabolite DCSA following single application of EVRITELL 162 OD to maize

Scenario FOCUS	Period/ Waterbody	Max PEC_{sw} (µg/L)	7d-PECsw,twa (µg/L)[a]	Max PEC_{sed} (µg/kg)
Step 1				
	-	14.5776	13.8411	125.2360
Step 2				
Northern Europe	Mar-May	1.5794	1.5477	13.5777
Northern Europe	Jun-Sep	1.5794	1.5477	13.5777

b *Time as required by ecotox.*

zRMS comments:

The calculations PECsw/sed of dicamba and its metabolite were performed by use Step1 and Step2
Input parameters considered in the surface water modelling for dicamba and its metabolite were in line with EU agreed values.

8.9.1.2 Nicosulfuron and its metabolites

Table 8.9-6: Input parameters related to active substance Nicosulfuron for $PEC_{sw/sed}$ calculations STEP 1, 2 and 3

Compound	Nicosulfuron	AUSN	UCSN	ASDM	HMUD	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	410.4	314.3	315.3	229.2	396.4	Y/ EFSA Scientific Report
Saturated vapour pressure (Pa)	8 x 10^{-10} (25°C)	not required for Step 1+2				Y/ EFSA Scientific Report
Water solubility (mg/L)	9500 (19.7°C)	9500 (19.7°C)	9500 (19.7°C)	9500 (19.7°C)	9500 (19.7°C)	Y/ EFSA Scientific Report
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	not required for Step 1+2				default
Diffusion coefficient in air (m²/d)	0.43	not required for Step 1+2				default
K_{foc} (mL/g)	20.7 Arithmetic mean (n=4)	13 (the lowest value)	1.1 (the lowest value)	2.3 (the lowest value)	0.88 (the lowest value)	Y/ EFSA Scientific Report
K_{om} [mL g^{-1}]	12.01	not required for Step 1+2				Value calculated on the basis of Kom=·Koc/1.724
Freundlich Exponent 1/n	0.94 (arithmetic mean, n=4))	not required for Step 1+2				Y/ EFSA Scientific Report
Plant Uptake	0 (worst case)	not required for Step 1+2				FOCUS default value
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2				FOCUS default value
$DT_{50,soil}$ (d)	16.4 (geometric mean n=7 , 20°C, pF2)	192.3	271	236.6	25.2	Y/ EFSA Scientific Report
$DT_{50,water}$ (d)	65 (geometric mean)	1000	1000	1000	1000	FOCUS recommendations Default value
$DT_{50,sed}$ (d)	13.9 (geometric mean)	1000	1000	1000	1000	FOCUS recommendations Default value
$DT_{50,whole\ system}$ (d)	42.3 (geometric mean)	1000	1000	1000	1000	FOCUS recommendations Default value
Maximum occurrence observed (% molar basis	-	Soil: 26.8 Total	Soil:11 Total system:	Soil:63.4 Total system:	Soil:14.4 Total system:	Y/ EFSA Scientific Report

Compound	Nicosulfuron	AUSN	UCSN	ASDM	HMUD	Value in accordance to EU endpoint y/n/ Reference
with respect to the parent)		system:11.1	6.5	9.4	19.3	

$PEC_{sw/sed}$

Table 8.9-7: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Nicosulfuron following single application of EVRITELL 162 OD to maize_Tier 1– PUF=0 (worst case).

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 1-2	maize			
Step 1	-	13.3431	spray drift, runoff, drainage	2.6859
Step 2	ditch	1.9890		0.3910
Northern Europe	March-May, spring spraying			
Step 3	maize			
D3	ditch	0.2193	Drift	0.03336
D4	pond	0.03311	Drainage	0.03479
D4	stream	0.1864	Drift	0.01564
D5	pond	0.01823	Drainage	0.01340
D5	stream	0.1909	Drift	0.008701
D6	ditch	0.2107	Drift	0.02419
R1	pond	0.01621	Run-off	0.009181
R1	stream	0.4547	Drift	0.03311
R2	stream	1.273	Drift	0.1435
R3	stream	1.640	Drift	0.1584
R4	stream	1.708	Drift	0.2072

FOCUS Step 4 (nicosulfuron)

Table 0-8: Global maximum PEC_{sw} values for nicosulfuron, following single application(s) of EVRITELL 162 OD to maize according to surface water Step 4 (buffer zone of 5 m)_ Tier 1– PUF=0 (worst case).

Nozzle reduction	STEP 4 nicosulfuron		
	Vegetative strip (m)	None	
	Buffer width	**5 m**	
	Scenario	PEC_{sw} (Global max.)	PEC_{sed}
		(µg/L)	(µg/kg)
None	D3 ditch	0.07816	0.01671
None	D4 pond	0.03305	0.03473
None	D4 stream	0.08231	0.01564
None	D5 pond	0.01733	0.01340
None	D5 stream	0.08237	0.006917
None	D6 ditch	0.06986	0.008780
None	R1 pond	0.01543	0.008714
50 %		0.01217	0.006762
75 %		0.01054	0.005789
90 %		0.009566	0.005207
None	R1 stream	**0.4547**	0.03270
50 %		**0.4547**	0.03254
75 %		**0.4547**	0.03246
90 %		**0.4547**	0.03242
None	R2 stream	**1.273**	0.1431
50 %		**1.273**	0.1429
75 %		**1.273**	0.1428
90 %		**1.273**	0.1428
None	R3 stream	**1.640**	0.1573
50 %		**1.640**	0.1568
75 %		**1.640**	0.1566
90 %		**1.640**	0.1565
None	R4 stream	**1.708**	0.2068
50 %		**1.708**	0.2066
75 %		**1.708**	0.2065
90 %		**1.708**	0.2065

Table 0-9: Global maximum PEC_{sw} and PEC_{sed} values for nicosulfuron following a single application of EVRITELL 162 OD to maize according to surface water Step 4 (vegetative buffer of 10-12 m and 18-20 m) _Tier 1– PUF=0 (worst case).

Nozzle reduction	**STEP 4 nicosulfuron**		
	Width of planted buffer strip (m)	**10-12 m**	
	Scenario	PEC_{sw} (Global max.)	PEC_{sed}
		(µg/L)	(µg/kg)
None	R1 pond	0.008286	0.004877
None	R1 stream	0.1867	0.01364
None	R2 stream	**0.5620**	0.06382
None	R3 stream	**0.7414**	0.07253
None	R4 stream	**0.7766**	0.09489
		18-20 m	
None	R1 pond	0.004939	0.002979
None	R1 stream	0.09413	0.006965
None	R2 stream	**0.2910**	0.03346
None	R3 stream	**0.3880**	0.03847
None	R4 stream	**0.4070**	0.05030

Table 0-10: Global maximum PEC_{sw} and PEC_{sed} values for nicosulfuron following a single application of EVRITELL 162 OD to maize according to surface water Step 4 (VFSmod model) _Tier 1– PUF=0 (worst case).

Nozzle reduction	**STEP 4 nicosulfuron**		
	Vegetative strip	**VFSmod = 5 m**	
	Scenario	PEC_{sw} (Global max.)	PEC_{sed}
		(µg/L)	(µg/kg)
None	R1 pond	0.007567	0.004493
None	R1 stream	0.06008	0.002654
None	R2 stream	0.08191	0.003065
None	R3 stream	0.08596	0.005853
None	R4 stream	0.06105	0.003345

Metabolites of nicosulfuron

Table 0-11: FOCUS Step 1, 2 and PEC_{sw} and PEC_{sed} for metabolite AUSN following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	3.8354	runoff, drainage	0.4945
Step 2	ditch	0.5697		0.0740
Northern Europe	March -May			

Table 0-12: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for metabolite UCSN following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	1.8084	runoff, drainage	0.0197
Step 2	ditch	0.2696		0.0030
Northern Europe	March -May			

Table 0-13: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for metabolite ASDM following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	5.4237	runoff, drainage	0.1243
Step 2	ditch	0.8054		0.0185
Northern Europe	March -May			

Table 0-14: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for metabolite HMUD following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	4.4035	runoff, drainage	0.0381
Step 2	ditch	0.6317		0.0056
Northern Europe	March -May			

zRMS comments:

Input parameters considered in the surface water modelling for nicosulfuron and its metabolites were in general in line with EU agreed values,
For metabolites DT_{50} in water and sediment of 300 days is given in the LoEP, while DT_{50} of 1000 days was used by the Applicant. This deviation is agreed by the zRMS as representing worst case and being in line with current default DT_{50} values indicated in FOCUS surface water guidance.
In order to mitigate the risk, Step 4 simulations were performed with assumption of 5, 10 and 20 m spray drift buffer and 10 m and 20 m vegetative filter strips and 5 m VFSmod (for run-off scenarios). The run-off reduction was assumed to be in line with FOCUS Landscape and Mitigation recommendations (FOCUS, 2007).

The acceptable predicted environmental concentrations of nicosulfuron and its metabolites are appropriate to be used for the subsequent risk assessment.
However MS should identify risk reduction measures at the national level.
Nevertheless, additional simulations may be required by the cMS that do not accept calculations performed using FOCUS models

8.9.1.3 Thifensulfuron- methyl and its metabolites

Table 8.9-15: Input parameters related to active substance thifensulfuron- methyl for $PEC_{sw/sed}$ calculations STEP 1, 2 and 3

Compound	Thifensulfuron methyl	IN-L9225	IN-L9223	IN-A4098	2-acid-3triuret (IN-U5F72)	IN-B5528	Value in accordance to EU endpoint y/n/ Reference
Molar mass (g/mol)*	387.4	373.4	207.2	140.1	378.3	126.1	Yes/EFSA, 2015
Water solubility (mg/L) (20 °C)	2240	1000	1000	1000	1000	1000	Yes/EFSA, 2015
Saturated vapour pressure (Pa) (20 °C)	5.20×10^{-9}	-	-	-	-	-	Yes/EFSA, 2015
Diffusion coefficient in water (m^2/d)	4.3×10^{-5}	-	-	-	-	-	FOCUS default
Diffusion coefficient in air (m^2/d)	0.43	-	-	-	-	-	FOCUS default
Freundlich Exponent 1/n (-)	0.932 (arithmetic mean)	-	-	-	-	-	Yes/EFSA, 2015
Plant uptake factor (-)	0 (FOCUS default)	-	-	-	-	-	default
Wash-off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	-	-	-	-	-	FOCUS default
K_{foc} (mL/g)	9.0 (median)	0 (default)	0 (default)	0 (default)	0 (default)	0 (default)	Yes/EFSA, 2015
$DT_{50,soil}$ (d)	1.39 (geometric mean)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes/EFSA, 2015
$DT_{50,water}$ (d)	22.8	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes/EFSA, 2015
$DT_{50,sed}$ (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes/EFSA, 2015
$DT_{50,whole\ system}$ (d)	22.8 (geometric mean)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes/EFSA, 2015
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 100 (worstcase) Total system: 100 (worstcase)	Soil: 100 (worstcase) Total system: 100 (worstcase)	Soil: 100 (worstcase) Total system: 100 (worstcase)	Soil: 100 (worstcase) Total system: 100 (worstcase)	Soil: 100 (worstcase) Total system: 100 (worstcase)	Yes/EFSA, 2015

Table 8.9-16: Input parameters related to active substance thifensulfuron methyl and metabolite(s) for PECsw/sed calculations STEP 1/2 and 3 (Continued)

Compound	IN-JZ789	IN-A5546	IN-V7160	IN-L9226	IN-W8268	IN-D8858	Value in accordance to EU endpoint y/n/ Reference
Molar mass (g/mol)[a]	359.3	221.2	183.2	373.4	189.2	280.3	Yes/EFSA, 2015
Water solubility (mg/L) (20 °C)	1000	1000	1000	1000	1000	1000	Yes/EFSA, 2015
Saturated vapour pressure (Pa) (20 °C)	-	-	-	-	-	-	Yes/EFSA, 2015
Diffusion coefficient in water (m^2/d)	-	-	-	-	-	-	FOCUS default
Diffusion coefficient in air (m^2/d)	-	-	-	-	-	-	FOCUS default
Freundlich Exponent 1/n (-)	-	-	-	-	-	-	Yes/EFSA, 2015
Plant uptake factor (-)	-	-	-	-	-	-	default
Wash-off factor from Crop (1/mm)	-	-	-	-	-	-	FOCUS default
K_{foc} (mL/g)	0 (default)	0 (default)	0 (default)	0 (default)	0 (default)	0 (default)	Yes/EFSA, 2015
$DT_{50,soil}$ (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes/EFSA, 2015
$DT_{50,water}$ (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes/EFSA, 2015
$DT_{50,sed}$ (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes/EFSA, 2015
$DT_{50,whole\ system}$ (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes/EFSA, 2015
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 100 (worst-case) Total system: 100 (worst-case)	Soil: 100 (worst-case) Total system: 100 (worst-case)	Soil: 100 (worst-case) Total system: 100 (worst-case)	Soil: 100 (worst-case) Total system: 100 (worst-case)	Soil: 100 (worst-case) Total system: 100 (worst-case)	Soil: 100 (worst-case) Total system: 100 (worst-case)	Yes/EFSA, 2015

*in the Step 1&2 modeling for metabolite, the parent molecular weight of 387.4 was used for all metabolites.

Thifensulfuron methyl - Steps 1, 2, 3 and 4

Maize, 1 × 12 g a.s./ha, BBCH 12-16

Table 8.9-17: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for thifensulfuron methyl following application of 1 × 12 g a.s./ha to maize, BBCH 12-16

Scenario FOCUS	Season/ Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	7 d - $PEC_{sw,twa}$ (µg g/L)[a]	Max PEC_{sed} (µg g/kg)
Step 1					
	-	4.0629	-	3.6587	0.3557
Step 2					
Northern Europe	Mar-May	0.1777	-	0.1599	0.0159
	Jun-Sep	0.1777	-	0.1599	0.0159
Step 3					
D3	ditch	0.06298	Drift	0.01074	0.006109
D4	pond	0.002543	Drift	0.002348	0.001209
D4	stream	0.05392	Drift	0.000688	0.001557
D5	pond	0.002543	Drift	0.002338	0.001186
D5	stream	0.05627	Drift	0.000514	0.001235
D6	ditch	0.06285	Drift	0.008971	0.005631
R1	pond	0.002895	Runoff	0.002697	0.001618
R1	stream	0.09669	Runoff	0.005054	0.005811
R2	stream	0.1559	Drift	0.01455	0.01458
R3	stream	0.1797	Runoff	0.01771	0.01476
R4	stream	0.1667	Runoff	0.01843	0.01693

a *Time as required by ecotox.*

FOCUS Step 4 (thifensulfuron methyl)

Table 0-18: Global maximum PEC_{sw} values for thifensulfuron methyl, following single application(s) of EVRITELL 162 OD to maize according to surface water Step 4 (buffer zone of 5 m)

Nozzle reduction	**STEP 4 thifensulfuron methyl**		
	Vegetative strip (m)	None	
	Buffer width	**5 m**	
	Scenario	PEC_{sw} (Global max.)	PEC_{sed}
		(µg/L)	(µg/kg)
None	D3 ditch	0.02064	0.002046
50 %		0.01032	0.001037
75 %		0.005159	0.000526
90 %		0.002064	0.000214
None	D4 pond	0.002272	0.001083
50 %		0.001135	0.000550
75 %		0.000568	0.000280
90 %		0.000227	0.000115

None	D4 stream	0.02270	0.000666
50 %		0.01135	0.000337
75 %		0.005676	0.000171
90 %		0.002270	0.000070
None	D5 pond	0.002272	0.001063
50 %		0.001135	0.000540
75 %		0.000568	0.000275
90 %		0.000227	0.000112
None	D5 stream	0.02369	0.000526
50 %		0.01185	0.000267
75 %		0.005923	0.000135
90 %		0.002369	0.000055
None	D6 ditch	0.02060	0.001887
50 %		0.01030	0.000958
75 %		0.005150	0.000487
90 %		0.002061	0.000200
None	R1 pond	0.002681	0.001494
50 %		0.001780	0.000973
75 %		0.001330	0.000711
90 %		0.001060	0.000553
None	R1 stream	0.09669	0.005703
50 %		0.09669	0.005664
75 %		0.09669	0.005644
90 %		0.09669	0.005631
None	R2 stream	0.1559	0.01447
50 %		0.1559	0.01443
75 %		0.1559	0.01441
90 %		0.1559	0.01440
None	R3 stream	0.1797	0.01444
50 %		0.1797	0.01432
75 %		0.1797	0.01426
90 %		0.1797	0.01422
None	R4 stream	0.1667	0.01681
50 %		0.1667	0.01676
75 %		0.1667	0.01674
90 %		0.1667	0.01673

Table 0-19: Global maximum PEC_{sw} and PEC_{sed} values for thifensulfuron methyl following a single application of EVRITELL 162 OD to maize according to surface water Step 4 (vegetative buffer of 10-12 m and 18-20 m)

Nozzle reduction	STEP 4 thifensulfuron methyl		
	Width of planted buffer strip (m)	**10-12 m**	
	Scenario	PEC_{sw} (Global max.)	PEC_{sed}
		(µg/L)	(µg/kg)
None	D3 ditch	0.01095	0.001099
None	D4 pond	0.001633	0.000785
None	D4 stream	0.01204	0.000357
None	D5 pond	0.001633	0.000770
None	D5 stream	0.01256	0.000282
None	D6 ditch	0.01093	0.001015
None	R1 pond	0.001653	0.000955
None	**R1 stream**	0.03968	0.002379
None	**R2 stream**	0.06883	0.006467
None	**R3 stream**	0.08117	0.006662
None	**R4 stream**	0.07577	0.007722
		18-20 m	
None	D3 ditch	0.005689	0.000579
None	D4 pond	0.001091	0.000529
None	D4 stream	0.006256	0.000188
None	D5 pond	0.001090	0.000519
None	D5 stream	0.006528	0.000149
None	D6 ditch	0.005679	0.000535
None	R1 pond	0.001090	0.000617
None	R1 stream	0.02002	0.001214
None	**R2 stream**	0.03565	0.003389
None	**R3 stream**	0.04248	0.003529
None	**R4 stream**	0.03971	0.004090

Nozzle reduction	Vegetative strip	` **VFSmod = 5 m**	
	Scenario	PEC_{sw} (Global max.)	PEC_{sed}
		(µg/L)	(µg/kg)
None	D3 ditch	0.02064	0.002046
None	D4 pond	0.002272	0.001083
None	D4 stream	0.02270	0.000666
None	D5 pond	0.002272	0.001063
None	D5 stream	0.02369	0.000526
None	D6 ditch	0.02060	0.001887
None	R1 pond	0.002270	0.001115
None	R1 stream	0.01802	0.000647
None	R2 stream	0.02457	0.000770
None	R3 stream	0.02579	0.001419
None	R4 stream	0.01831	0.000813
VFSmod = 10 m			
None	D3 ditch	0.01095	0.001099
None	D4 pond	0.001633	0.000785
None	D4 stream	0.01204	0.000357
None	D5 pond	0.001633	0.000770
None	D5 stream	0.01256	0.000282
None	D6 ditch	0.01093	0.001015
None	R1 pond	0.001632	0.000789
None	R1 stream	0.009558	0.000347
None	R2 stream	0.01303	0.000413
None	R3 stream	0.01368	0.000762
None	R4 stream	0.009713	0.000437

PECsw and PECsed of metabolites (IN-L9225, IN-L9223, IN-A4098, IN-U5F72 (2-acid-3-triuret), INJZ789, IN-A5546, IN-V7160, IN-L9226, IN-W8268, IN-B5528, IN-D8858) Steps 1-2 summary results:

Table 0-20: FOCUS Step 1, 2 and PEC_{sw} and PEC_{sed} for metabolites (IN-L9225, IN-L9223, IN-A4098, IN-U5F72 (2-acid-3-triuret), INJZ789, IN-A5546, IN-V7160, IN-L9226, IN-W8268, IN-B5528, IN-D8858) following single application(s) to maize

Scenario FOCUS	Period/ Waterbody	Max PEC_{sw} (µg/L)	7d-PECsw,twa (µg/L)*	Max PEC_{sed} (µg/kg)**
		Step 1		
	-	8.1104	8.0907	<0.001
		Step 2		
Northern Europe	Mar-May	1.3067	1.3036	<0.001
Northern Europe	Jun-Sep	1.3067	1.3036	<0.001

**Time as required by ecotox.*
***The PECsed of 0.0 is due to the assumed worst-case Kfoc of 0.0.*

Step 1 and Step 2 PEC_{sw} and PEC_{sed} values were simulated for the following major soil and water metabolites of thifensulfuron methyl: IN-L9225, IN-L9226, IN-A5546, IN-V7160, IN-W8268, IN-L9223, IN-A4098, IN-JZ789, IN-B5528, IN-U5F72, and IN-D8858.

It is concluded that all metabolites of thifensulfuron methyl were characterised as being of extremely low risk to aquatic organisms. Based on the Step 1 to Step 4 PECsw and PECsed results of thifensulfuron methyl, it can be concluded that safe uses exist in relevant agricultural areas for EVRITELL 162 OD in Europe, if product is applied in compliance with the label recommendations.

zRMS comments:

Evaluator agree with Applicant calculations of PECsw/sed.
Predicted environmental concentrations of active substance in surface water (PECsw) and sediment (PECsed) were calculated using the simulation models FOCUS.
Applicant used endpoints in accordance EFSA endpoints (Journal 2015; 13(7):4201).

In opinion of zRMS-PL calculations at Step 4 PEC_{sw} were accepted only for calculations carried out in accordance to Working Document of the Central Zone in the Authorisation of Plant Protection Products (2018), the following approaches for simulating in Step 4 were performed according Landscape And Mitigation Factors In Aquatic Risk Assessment and Working Document of the Central Zone in the Authorisation of Plant Protection Products (Environmental Fate and Behaviour. Ver.1.rev1. 2018.

The calculation to surface water performed according VFSMOD Step 4 can be accepted in National Level.

8.9.1.4 $PEC_{sw/sed}$ of EVRITELL 162 OD

The PEC values of EVRITELL 162 OD in surface water have been assessed with the FOCUS SWASH model.

Table 8.9-21: The PEC_{SW} values for EVRITELL 162 OD on maize

Application Scenarios			PEC_{sw} of product (ug/L)								
Timing (BBCH)	Rate	Nr of	No buffer			10 m buffer			20 m buffer		
	(g /ha)	appls.	Pond	Ditch	Stream	Pond	Ditch	Stream	Pond	Ditch	Stream
12-16	1016*	1	0.2156	5.3969	4.2037	0.1385	0.9384	0.9384	0.0925	0.4876	0.4876

** Application rate of = 1.0 L product ha-1 x 1.016 (relative density) = 1.016 kg product/ha*

zRMS comments:

Evaluator agree with Applicant calculations of PECsw/sed for formulation Evritell 162 OD.

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

The fate and behaviour in air of dicamba, nicosulfuron and thifensulfuron- methyl were evaluated in the approval process of these substances at EU level. No additional studies have been performed.

Dicamba

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

Compound	Dicamba
Vapour pressure	1.67×10^{-3} at 25°C
Henry’s Law constant	1 x 10^{-4} Pa·m^3/mol at 25°C
Direct photolysis in air	No data, not required
No data, not required	No data, not required
Photochemical oxidative degradation in air	DT_{50} of 3.6 days were derived by the Atmospheric Oxidation Programme (AOP, ver 1.85) based on Atkinson model. OH (12 h) concentration assumed = 1.5x106 [OH x cm-3]
Volatilisation	from plant surfaces (BBA guideline): 0.12 % after 24 hours (negligible)
	from soil surfaces (BBA guideline): 0.07 - 1.15 % after 24 hours (negligible)

The values of vapour pressure and Henry’s law constant of the active substance indicate that the active substance of dicamba has low volatility.
On the basis of the physicochemical properties of the active substance, it can be concluded that the probability of air pollution by dicamba after application of **EVRITELL 162 OD** is negligible. Therefore, there is no need to calculate PEC in air.

Nicosulfuron

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

Compound	nicosulfuron
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	No data submitted – nor required
Photochemical oxidative degradation in air	Atkinson (1988) method used, assuming a rate constatnt of 1.5 x 10^6 OH radicals/cm^3 photochemiacl produced during a 12 hour-photo phase day with temperature and solar light intensity typically found at sea level gave an atmospheric DT_{50} of 0.587 hours.
Volatilisation	From plant surfaces: ‡ 8.3 % over 24 hours
	from soil: ‡ 6.2 % over 24 hours
	Vapour pressure (Pa): at 25°C: 8 x 10^{-10} Henry's Law Constant (Pa.m3/mol): (at 20°C): 1,48 x 10^{-11}
Metabolites	none

The vapour pressure at 20 °C of the active substance nicosulfuron is < 10^{-5} Pa. Hence the active substance nicosulfuron is regarded as non-volatile. The photochemical oxidative degradation of nicosulfuron in air is extremely rapid (half-life 0.587 hours derived by Atkinson model. Based on these data, the risk of atmosphere pollution by above active substance following the application with **EVRITELL 162 OD** is low. Therefore, there was no need to calculate PEC in air.

Thifensulfuron methyl

The low vapour pressure (5.2 x10^{-9} Pa at 20ºC) and Henry's law constant (3.23 x 10^{-9} Pa m^3/mol at pH 7) of the active substance thifensulfuron methyl indicate a low potential for volatilisation of the active substance from soil under practical conditions of use.

zRMS comments:
Substance dicamba indicate a low potential for volatilisation from soil under practical conditions of use (EFSA Journal 2011;9(1):1965 for dicamba) Substance nicosulfuron indicate a low potential for volatilisation from soil under practical conditions of use (EFSA Scientific Report (2007) 120 for nicosulfuron) Substance thifensulfuron methyl indicate a low potential for volatilisation from soil under practical conditions of use. EFSA Journal 2015;13(7):4201 for thifensulfuron methyl

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	Łożuk I.	2023	Calculation of the predicted environmental concentrations of dicamba, nicosulfuron and thifensulfuron-methyl and its metabolites in groundwater after application of EVRITELL 162 OD (FOCUS PEARL, FOCUS PELMO and MACRO in FOCUS) CIECH Sarzyna S.A., Poland RR/18/23 non GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 9.2.4/1	Łożuk I.	2024	Calculation of the predicted environmental concentrations of dicamba, nicosulfuron and thifensulfuron- methyl and its metabolites in groundwater after application of EVRITELL 162 OD (FOCUS PEARL and FOCUS PELMO in FOCUS) QEMETICA Agricultural Solutions Poland S.A RR/10/24 non GLP Unpublished	N	QEMETICA Agricultural Solutions Poland S.A
KCP 9.2.5	Łożuk I.	2023	Calculation of the predicted environmental concentrations of dicamba, nicosulfuron and thifensulfuron-methyl and its metabolites in surface water and water sediment after application of EVRITELL 162 OD (STEPS 1-2 in FOCUS, SWASH & SWAN) CIECH Sarzyna S.A., Poland RR/17/23 non GLP Unpublished	N	CIECH Sarzyna S.A.

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
None					

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
none					

Appendix 2 Detailed evaluation of the new Annex II studies

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