FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 0724 A

Product name: COREY

Chemical active substances:

Rimsulfuron, 150 g/kg

Nicosulfuron 300 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: February 2020

MS Finalisation date: 12/2020; update 05.2021; 01.2022

Version history

When	What
December 2020	Draft assessment by RMS
February 2021	Applicant update
May 2021	Assessment update
January 2022	Final RMS Assessment after Commenting period

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

zRMS comments:

All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency.
Updated calculation are presented in yellow. Updated after commenting are presented in blue.

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	SEU	**Maize**	F	Broadleaved and grass weeds	Foliar Spray	BBCH 12-18	a) 1 b) 1	NA	a) 0.1 b) 0.1	~~a) 0.015 rimsulfuron + 0.03 nicosulfuron~~ ~~b) 0.015 rimsulfuron + 0.03 nicosulfuron~~ a) 15 g rimsulfuron + 30 g nicosulfuron b) 15 g rimsulfuron + 30 g nicosulfuron	200-400	-		R

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

Explanation for column 15 "Conclusion"

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

Table 8.1-2: Assessed (critical) uses during approval of Rimsulfuron 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 min - max	g or kg as/ha min - max	Water L/ha min/max		
1	N&S EU	**Maize**	F	Broadleaved weeds (BLW), grasses	Hydraulic sprayer overall	Up to GS 18 (8 leaves) Spring	1-2 splitting	7 days	N/A	5.0-20.0 (total 20.0)	150-500	-	+ Non-ionic surfactant at 0.1% application information covers worst-case use in EU. Max rate and latest timing vary between countries
2	N&S EU	**Potato**	F	Broadleaved weeds (BLW), grasses	Hydraulic sprayer overall	GS 30 (before closing of the rows) Spring	1-2 splitting	4-5 days	N/A	5.0-20.0 (total 20.0)	150-400	-	
3	SEU	**Tomato**	F	Broadleaved weeds (BLW), grasses	Hydraulic sprayer overall	GS 18 (8 leaves) Spring	1-2 splitting	7 days	N/A	5.0-20.0 (total 20.0)	200-500	-	

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

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

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

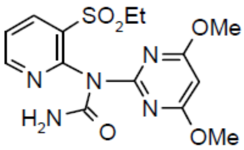
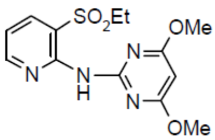
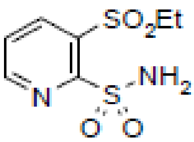
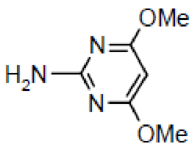
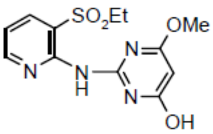
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: 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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	various	**Maize**	F	weeds	Spray application	BBCH 12-18	a) 1 b) 1	N/A	N/A	a) 60 b) 60	200-400	-	-

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

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

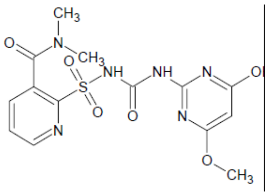
8.2 Metabolites considered in the assessment

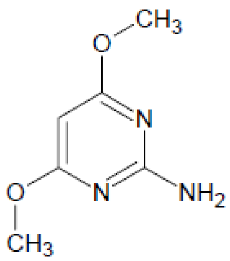
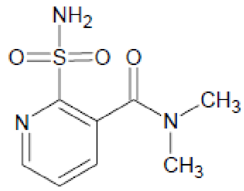
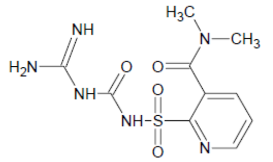
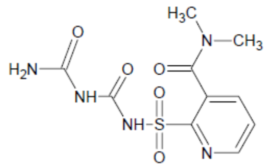
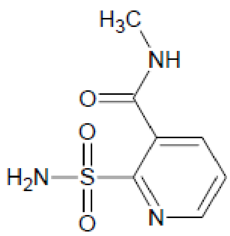
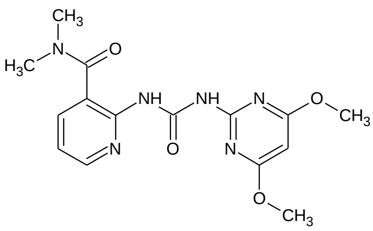
Table 8.2-1: Metabolites of Rimsulfuron potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
IN-70941 (N-(4.6-dimethoxy-2-pyrimidinyl)-N-[3-(ethylsuflonyl)-2-pyridinyl] urea)	367.4 g/mol		Soil: 54.5% Total system: 87.2%	PECgw PECsoil PECsw/sed
IN-70942 (N-[3-(ethylsulfuronyl)-2-pyridinyl]-4,6-dimethoxy-2-pyrimiinamine)	324.36 g/mol		Soil: 23.5% Total system: 83.8%*	PECgw PECsoil PECsw/sed
IN-E9260 (3-(ethylsulfuonyl)-2-pyridinesulfonamide)	250.30 g/mol		Soil: 18.9% Total system: 16.2%**	PECgw PECsoil PECsw/sed
IN-J0290 (4,6-dimethoxy-2-pyrimidinamine) a.k.a ADMP	155.20 g/mol		Soil: 12.7%*** Total system: 19.1%**	PECgw PECsoil PECsw/sed
IN-JF999 (2-[[3-ethylsulfonyl)-2-pyridinyl]amino]-6-methoxy-4(1H)-pyrimidinone)	310.33 g/mol		Soil: 1 x 10^{-10}% Total system: 24.5%	PECsw/sed

***From hydrolysis study**
****From photolysis study**
*****From soil photolysis study**

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
HMUD (2-{[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-N-dimethylpyridine-3-carboxamide)	396.4 g/mol		Soil:14.4% Water: 14.1% Sediment: 5.7% Water/sediment: 19.3%	PECgw PECsoil PECsw/sed

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
ADMP (4,6-dimethoxypyrimidin-2-amine)	155.2 g/mol		Soil: 9.8% Water: 23.1%*	PECgw PECsoil PECsw/sed
ASDM (N,N-dimethyl-2-sulfamoylpyridine-3-carboxmide)	229.2 g/mol		Soil: 63.4% Water: 61%* Sediment: 4.4% Water/sediment: 61%*	PECgw PECsoil PECsw/sed
AUSN (2-[(carbamimidoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	314.3 g/mol		Soil: 26.8% Water: 9.1% Sediment: 2.4% Water/sediment: 11.1%	PECgw PECsoil PECsw/sed
UCSN (2-[(carbamoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	315.3 g/mol		Soil: 11% Water: 5.4% Sediment: 1.4% Water/sediment: 6.5%	PECgw PECsoil PECsw/sed
MU-466 (N-methyl-2-sulfamoylpyridine-3-carboxamide)	215.2 g/mol			PECgw
DUDN 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]amino}-N,N-dimethylpyridine-3-carboxamide	346.3 g/mol		Soil: 1 x 10^{-10}% Water: 22.3%*	PECsw/sed

***From photolysis study**

zRMS comments:

Information relating to rimsulfuron metabolites are in line with EU agreed endpoints as reported in EFSA Journal, EFSA Journal 2005; 45, 1-61 and have been considered in the exposure assessment presented in this report.
Information relating to nicosulfuron metabolites are in line with EU agreed endpoints as reported in EFSA Journal EFSA Scientific Report (2007) 120, 1-91 and have been considered in the exposure assessment presented in this report.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Rimsulfuron and its metabolites

EFSA Journal 2005; 45, 1-61 was used as agreed endpoints for Rimsulfuron.

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

Rimsulfuron, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Sassafras	Sandy loam	6.7	25	75	21.3		34.2	0.87[a]/0.94[b]	SFO	Y, EFSA Journal 2005; 45, 1-61
Speyer 2.2	Loamy sand	5.6	20	40	30		23	0.977		
Middlefield	Sandy loam	6.7		40	40		26.9	0.927		
Sion Hill	Loamy sand	7.0		40	25		19.2	0.977		
	Loamy sand	7.0		60	5		5	0.982		
Geometric mean (n=5)							**18.3**			
pH-dependency: y/n							n			

[a]: Pyridine
[b]: Pyrimidine
***Normalized using a Q10 of 2.58 by the UBA Excel™ spreadsheet Input_Decision v3.3**

Table 8.3-2: Summary of aerobic degradation rates for IN-70941 - laboratory studies

IN-70941, Laboratory studies, aerobic conditions										
Soil name	**Soil type (x)**	**pH (x)**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	5.4	20	40	359		241.6	0.913	SFO	Y, EFSA Journal 2005; 45, 1-61
San Pietro en Cerro	Clay	7.9			38		21.4	0.982		
Handorf	Sandy loam	5.8			615		413.9	0.722		

IN-70941, Laboratory studies, aerobic conditions										
Soil name	**Soil type (x)**	**pH (x)**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**r²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Geometric mean (n=3)							**128.9**			
pH-dependency: y/n							n			

***Normalized using a Q10 of 2.58 by the UBA Excel™ spreadsheet Input_Decision v3.3**

Table 8.3-3: Summary of aerobic degradation rates for IN-70942 - laboratory studies

IN-70942, Laboratory studies, aerobic conditions										
Soil name	**Soil type (x)**	**pH (x)**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**r²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	5.4	20	40	214		144	0.928	SFO	Y, EFSA Journal 2005; 45, 1-61
San Pietro en Cerro	Clay	7.9			101		57	0.982		
Handorf	Sandy loam	5.8			116		78.1	0.956		
Geometric mean (n=3)							**86.2**			
pH-dependency: y/n							n			

***Normalized using a Q10 of 2.58 by the UBA Excel™ spreadsheet Input_Decision v3.3**

Table 8.3-4: Summary of aerobic degradation rates for IN-E9260 - laboratory studies

IN-70942, Laboratory studies, aerobic conditions										
Soil name	**Soil type (x)**	**pH (x)**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**r²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	5.4	20	40	744		500.7	0.814	SFO	Y, EFSA Journal 2005; 45, 1-61
San Pietro en Cerro	Clay	7.9			252		142.1	0.710		
Handorf	Sandy loam	5.8			969		652.1	0.337		
Geometric mean (n=3)							**359.3**			
pH-dependency: y/n							n			

***Normalized using a Q10 of 2.58 by the UBA Excel™ spreadsheet Input_Decision v3.3**

Table 8.3-5: Summary of aerobic degradation rates for IN-J0290 (a.k.a ADMP) - laboratory studies

IN-J0290 (ADMP), Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6	20	40	2.9	9.5	2.4	0.995	1st order non-linear	EFSA Scientiic report nicosulfuron (2007) 120, 1-91
Speyer 2.2	Loamy sand	6.0			6.1	20.4	5.4	0.980		
Les Evouettes	Loam	7.3			11.3	37.7	7.3	0.970		
Geometric mean (n=3)							**4.5**			
pH-dependency:							No			

8.3.1.2 Nicosulfuron and its metabolites

EFSA Scientific Report (2007) 120, 1-91 was used as agreed endpoints for Nicosulfuron.

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

Nicosulfuron, Laboratory studies, aerobic conditions										
Soil name (label)	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Le Noron (pyridine)	Loam	5.3	20	46.3	20.0	66.4*	13.3	0.986	1st order non-linear	EFSA Scientific Report (2007) 120, 1-91
Le Noron (pyrimidine)	Loam	5.3	20	46.3	26.3	87.4*	17.4	0.901	1st order non-linear	
Mean							**15.3**			
Les Evouettes (pyridine)	Silt loam	6.1	20	54.6	40.5	134.4*	33.2	0.981	1st order non-linear	
Les Evouettes (pyrimidine)	Silt loam	6.1	20	54.6	33.1	110.1*	27.1	0.993	1st order non-linear	
Mean							**30.1**			
Speyer 2.1 (pyridine)	Sand	6.0	20	21.1	35.1	116.6*	30.6	0.989	1st order non-linear	
Speyer 2.1 (pyrimidine)	Sand	6.0	20	21.1	46.3	154.0*	40.4	0.974	1st order non-linear	
Mean							**35.5**			
Speyer 2.3 (pyridine)	Sandy loam	6.6	20	31.4	26.7	88.8*	20.3	0.985	1st order non-linear	
Speyer 2.3 (pyrimidine)	Sandy loam	6.6	20	31.4	23.3	77.2*	17.7	0.992	1st order non-linear	

Nicosulfuron, Laboratory studies, aerobic conditions										
Soil name (label)	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
						Mean	**19.0**			
Pappelacker (pyrimidine)	Loamy sand	7.0	20	40	7.0	23.4**	**5.7**	0.960	SFO	
Karolinenhof (pyrimidine)	Sand	7.2	20	40	13.2	43.9**	**12.6**	0.992	SFO	
Otzberg (pyrimidine)	Silt loam	7.2	20	40	18.9	62.8**	**14.3**	0.991	SFO	
						Geometric mean (n=7)	**16.4**			
						pH-dependency:	No			

Values in bold used to calculated geometric mean DT_{50}
***: values from DAR (UK, 2005)**
****: values from report A39791 (Mamouni, 2006)**

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

HMUD, Laboratory studies, aerobic conditions										
Soil name (label)	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Les Evouettes (pyridine)	Silt loam	6.1	20	54.6	30.8	102.2	25.2	0.983	ModelMaker based on SFO formation and decline from parent	EFSA Scientific report (2007) 120, 1-91
					27.4	90.0	22.4	0.930		
						Geometric mean (n=2)	**23.8**			
						pH-dependency:	No			
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. This was calculated 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 8.3-8: Summary of aerobic degradation rates for ADMP - laboratory studies

ADMP, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6	20	40	2.9	9.5	2.4	0.995	1st order non-linear	EFSA Scientiic report (2007) 120,
Speyer 2.2	Loamy sand	6.0			6.1	20.4	5.4	0.980		

ADMP, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Les Evouettes	Loam	7.3			11.3	37.7	7.3	0.970		1-91
Geometric mean (n=3)							**4.5**			
pH-dependency:							No			

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

ASDM, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6	20	40	90.5	300.8	73.6	0.995	1st order non-linear	EFSA Scientiic report (2007) 120, 1-91
Speyer 2.2	Loamy sand	6.0	20	40	268.5	892.1	236.6	0.933		
Les Evouettes	Loam	7.3	20	40	114.8	381.4	73.8	0.992		
Geometric mean (n=3)							**108.7**			
pH-dependency:							No			

Table 8.3-10: Summary of aerobic degradation rates for AUSN - laboratory studies

AUSN, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6	20	40	73.9	245.1	60.0	0.894	1st order non-linear	EFSA Scientiic report (2007) 120, 1-91
Speyer 2.2	Loamy sand	6.0	20	40	218.2	724.8	192.3	0.907		
Les Evouettes	Loam	7.3	20	40	101.4	336.9	65.2	0.856		
Geometric mean (n=3)							**90.9**			
pH-dependency:							No			

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

UCSN, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r²)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6	20	40	126.2	419.3	102.6	0.993	1st order non-linear	EFSA Scientiic report (2007) 120, 1-91
Speyer 2.2	Loamy sand	6.0	20	40	307.5	1021.7	271.0	0.962		
Les Evouettes	Loam	7.3	20	40	229.3	761.7	147.5	0.942		
Geometric mean (n=3)							**160.1**			
pH-dependency:							No			

Table 8.3-12: Summary of aerobic degradation rates for MU-466 - laboratory studies

MU-466, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r²)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Uffholtz	-	5.74	20	40	89.5	297	66.3	0.943	1st order non-linear	EFSA Scientiic report (2007) 120, 1-91
Speyer 2.1	Sand	6.2	20	40	84	279	75.5	0.975		
3A	-	7.1	20	40	67.9	225.5	59.1	1.000		
Geometric mean (n=3)							**66.6**			
pH-dependency:							No			

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

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

8.3.2.1 Rimsulfuron and metabolites

The degradation of rimsulfuron was also studied in sandy loam soil in the laboratory under flooded anaerobic conditions (25°C), the route and rate of degradation observed was comparable to that observed under aerobic conditions. The summary of anaerobic degradation rates obtained under anaerobic condition is presented in Table 8.3-16.

Table 8.3-16: Summary of anaerobic degradation rates for Rimsulfuron - laboratory studies

Soil type	pH	t. ºC	DT_{50} (d)	St. (r^2)
Sandy loam	6.7	25	18.1[1]/17.9[2]	0.99[1]/0.91[2]

[1]: Pyridine
[2]: Pyrimidine

8.3.2.2 Nicosulfuron and metabolites

Table 8.3-17: Summary of anaerobic degradation rates for Nicosulfuron - laboratory studies

Nicosulfuron, Laboratory studies, anaerobic conditions										
Due to limited degradation observed under anaerobic conditions it was not possible to derive a DT_{50}/DT_{90} for this phase of the study. (Aerobic phase: 21.8, 24.4; r^2 0.909-0.998; n=2)										
Wisconsin	Silt loam	6.2	25	-	4	12	-	r^2= 0.97		

8.4 Field studies (KCP 9.1.1.2)

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

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

8.4.1.1 Rimsulfuron and its metabolites

In European field studies (2 northern trial sites and 1 southern site) rimsulfuron was degraded with single first order DT_{50}'s ranging from 6 to 14 days and in US field studies (3 sites), single first order DT_{50}values from 8 to 18 days were determined. Rimsulfuron is considered to exhibit moderate persistence.

Table 8.4-1: Summary of field dissipation values of Rimsulfuron from studies performed in Europe and USA

Country	Location	% OC	pH	DT_{50} (d)	r^2
MS, USA	Greenv.	0.75	7.0	7.9[1]-9.6[2]	0.88[1]-0.96[2]
CA, USA	Madera	0.70	7.7	8.0[1]-8.2[2]	0.99[1]-0.99[2]
IL, USA	Rochelle	2.61	7.8	15.9[1]-17.7[2]	0.94[1]-0.95[2]
Spain	Palafolls	0.8	6.7	5.6	0.95
Germany	Lindenh.	1.1	6.5	10	0.94
Denmark	Middelf.	1.1	6.6	14	0.95
			Geomean (n=3)	4*	

[1] Pyridine

[2] Pyrimidine

***Normalized value for the 3 European values (20ºC, Q10 = 2.2 and 100% relative moisture) according to Addendum to the DAR**

In the 3 field studies conducted in Europe where rimsulfuron was the applied test substance, single first order DT_{50}values for IN-70941 were 62 to 1100 days and for IN-E9620 were 25 to 294 days (calculated using a 2 compartment kinetic model, parent to metabolite, using the residues detected in all soil layers. This $DT_{50}$is therefore analogous to a degradation rate and does not represent the rate of the observed decline after the peak formation). As IN-70942 was not detected at levels greater than 10 % of the parent molar equivalence in any of the European field studies, it was not possible to estimate field $DT_{50}$for this metabolite. These data indicate that in the field, the metabolites IN-70941 and IN-E9620 have the potential to accumulate in soil when rimsulfuron applications are made every year.

Table 8.4-2: Summary of field dissipation values of IN-70941

Country	Location	% OC	pH	DT_{50} (d)	r^2
Spain	Palafolls	0.8	6.7	435	0.95
Germany	Lindenh.	1.1	6.5	62	0.94
Denmark	Middelf.	1.1	6.6	1100	0.95
			Geomean (n=3)	201*	

***Normalized value for the 3 European values (20ºC, Q10 = 2.2 and 100% relative moisture) according to Addendum to the DAR**

Table 8.4-3: Summary of field dissipation values of IN-E9260

Country	Location	% OC	pH	DT_{50} (d)	r^2
Spain	Palafolls	0.8	6.7	294	0.95
Germany	Lindenh.	1.1	6.5	25	0.94
Denmark	Middelf.	1.1	6.6	82	0.95
			Geomean (n=3)	56*	

***Normalized value for the 3 European values (20ºC, Q10 = 2.2 and 100% relative moisture) according to Addendum to the DAR**

8.4.1.2 Nicosulfuron and its metabolites

Triggering endpoints

Table 8.4-4: Summary of aerobic degradation rates for Nicosulfuron - field studies: Triggering endpoints

Nicosulfuron Field studies – Triggering endpoints								
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**St. (χ^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Sand (bare soil)	Flackenhorst, Germany	5.7	0-10	20.7	68.8	0.869	1st order non-linear	EFSA Scientific report (2007) 120, 1-91
Silty clay loam (bare soil)	Hünfelden, Germany	7.1	0-10	63.3	210	0.919		
Loam (bare soil)	St. Claire, N. France	5.3	0-5	12	40	0.949		
Clay loam (bare soil)	Lante, S. France	6.0	0-5	8.9	29.7	0.964		
Geometric mean (n=4)				**19.3**				
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_{50} uncertain due to non-validated LOQ.								

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Rimsulfuron	Based on calculation for metabolites
Nicosulfuron	No studies provided or required.

zRMS comments:

Soil degradation data for rimsulfuron its metabolites, nicosulfuron its metabolites are in line with EU agreed endpoints.

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 Rimsulfuron and its metabolites

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

Rimsulfuron							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Cecil	Sandy loam	1.2	6.5	0.23	18.9	0.9	Y, EFSA Journal 2005; 45, 1-61
Fargo	Clay loam	2.5	7.7	1.4	54.4	0.97	
Sassafras	Sandy loam	0.6	6.3	0.35	50.1	1.22	
Flanagan	Silt loam	2.5	5.4	1.58	62.8	0.99	
Geomean (n=4)					**42.4**	-	
Arithmetic mean (n=4)					-	1.02	
pH-dependency y/n					n		

Table 8.5-2: Summary of soil adsorption/desorption for IN-70941

IN-70941							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	1.2	5.4	0.47	39	0.96	Y, EFSA Journal 2005; 45, 1-61
San Pietro	Clay	1.6	7.9	1.85	116*	0.94	
Handorf	Sandy loam	1.1	5.8	0.37	34	0.92	
Frederica	Sandy loam	0.5	6.3	0.27	54	0.92	
Geomean (n=3)					**41.5**	-	
Arithmetic mean (n=4)					-	0.94	
pH-dependency y/n					n		

***Not used for geomean calculation**

Table 8.5-3: Summary of soil adsorption/desorption for IN-70942

IN-70942							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	1.2	5.4	2.68	223	0.84	Y, EFSA Journal 2005; 45, 1-61
San Pietro	Clay	1.6	7.9	3.12	195	0.85	
Handorf	Sandy loam	1.1	5.8	1.59	145	0.84	
Frederica	Sandy loam	0.5	6.3	1.07	214	0.85	
				Geomean (n=4)	**191.7**	-	
				Arithmetic mean (n=4)	-	0.85	
				pH-dependency y/n	n		

Table 8.5-4: Summary of soil adsorption/desorption for IN-E9260

IN-E9260							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	1.2	5.4	0.27	23	1.08	Y, EFSA Journal 2005; 45, 1-61
San Pietro	Clay	1.6	7.9	1.37	86*	0.96	
Handorf	Sandy loam	1.1	5.8	0.18	16	0.99	
Frederica	Sandy loam	0.5	6.3	0.17	34	0.93	
				Geomean (n=3)	**23.2**	-	
				Arithmetic mean (n=4)	-	0.99	
				pH-dependency y/n	n		

***Not used for geomean calculation**

Table 8.5-5: Summary of soil adsorption/desorption for IN-J0290*

IN-J0290						
Soil Type	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Loamy sand	2.29	7.0 [b)]	1.17	50.9	0.84	Y, EFSA Journal 2018; 16(5):5258
Loamy sand	1.17	7.7 [b)]	0.71	60.4	0.82	
Sisseln, sandy loam	1.557	7.8 [b)]	0.83	52.8	0.92	
Silt loam	4.05	7.3 [b)]	1.70	42.0	0.91	

IN-J0290						
Soil Type	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Geomean (n=4)				**51.1**	-	
Arithmetic mean (n=4)				-	0.87	
pH-dependency y/n				n		

***Also known as ADPM, Voelkel, W. 1995 (accepted in the RAR for nicosulfuron; refer to the EFSA conclusion on the peer review of the active substance nicosulfuron, EFSA (2007))**

8.5.2 Nicosulfuron and its metabolites

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

Nicosulfuron							
Soil name	**Soil type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.1	(loamy) sand	0.48	6.0	0.05	10.0	0.90	EFSA Scientific report (2007) 120, 1-91
Speyer 2.2	Loamy sand	2.55	6.0	0.20	7.9	0.92	
Itingen II	Silt loam	1.42	7.7	0.73	51.3	0.94	
Les Evouettes	Loam	1.40	6.1	0.19	13.7	1.01	
Geometric mean (n=4)					**15.4**	-	
Arithmetic mean (n=4)					-	0.94	
pH-dependency					No Clay dependence: Yes		

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

ADMP							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.29	7.0	1.17	50.9	0.84	EFSA Scientific report (2007) 120, 1-91
Collombey	Loamy sand	1.17	7.7	0.71	60.4	0.82	
Sisseln	Sandy loam	1.557	7.8	0.83	52.8	0.92	
Vetroz	Silt loam	4.05	7.3	1.70	42.0	0.91	
Geometric mean (n=4)					**51.1**	-	
Arithmetic mean (n=4)					-	0.87	
pH-dependency					No		

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

ASDM							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.29	7.0	0.05	2.3	0.82	EFSA Scientific report (2007) 120, 1-91
Collombey	Loamy sand	1.17	7.7	0.08	6.7	0.81	
Sisseln	Sandy loam	1.554	7.8	0.12	7.7	1.07	
Vetroz	Silt loam	4.05	7.3	0.24	6.0	0.94	
Geometric mean (n=4)					**5.2**	-	
Arithmetic mean (n=4)					-	0.91	
pH-dependency					Could not be clearly established		

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

AUSN							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.29	7.0	0.30	13.0	0.98	EFSA Scientific report (2007) 120, 1-91
Collombey	Loamy sand	1.17	7.7	0.42	35.6	0.92	
Sisseln	Sandy loam	1.554	7.8	0.61	39.0	0.98	
Vetroz	Silt loam	4.05	7.3	0.90	22.3	0.96	
Geometric mean (n=4)					**25.2**	-	
Arithmetic mean (n=4)					-	0.96	
pH-dependency					Could not be clearly established		

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

UCSN							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.29	7.0	0.02	1.1	-	EFSA Scientific report (2007) 120, 1-91
Collombey	Loamy sand	1.17	7.7	0.07	5.6	-	
Sisseln	Sandy loam	1.554	7.8	0.06	3.5	-	
Vetroz	Silt loam	4.05	7.3	0.09	2.1	-	
Geometric mean (n=4)				0.04	**2.6**		
pH-dependency				No			

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

HMUD							
Soil Name	**Soil Type**	**OC (%)**	**pH (Ca)**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.3	5.6	0.12	5.07	-	EFSA Scientific report (2007) 120, 1-91
Mechtildshausen	Loam	1.28	7.37	0.14	10.75	-	
Uffholtz	Silty clay loam	2.67	5.42	0.02	0.88	-	
Sawtry	Clay	2.94	7.23	0.19	6.98	-	
Bretagne 1	Silt loam	2.11	5.7	0.08	2.83	-	
Geometric mean (n=5)				0.09	**3.9**		
pH-dependenc				No			

Table 8.5-12: Summary of soil adsorption/desorption for MU-466

MU-466							
Soil Name	**Soil Type**	**OC (%)**	**pH (Ca)**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.3	5.6	0.07	3.05	-	EFSA Scientific report (2007) 120, 1-91
Mechtildshausen	Loam	1.28	7.37	0.14	10.73	-	
Uffholtz	Silty clay loam	2.67	5.42	0.04	1.32	-	
Sawtry	Clay	2.94	7.23	0.43	16.08	-	
Bretagne 1	Silt loam	2.11	5.7	0.17	6.50	-	
Geomeatric mean (n=5)				0.12	**5.4**		
pH-dependency				Could not be clearly established			

8.5.3 Column leaching (KCP 9.1.2.1)

Rimsulfuron

Column leaching studies showed a high leaching potential of Rimsulfuron with 47 - 93 % TAR in the leachate (mainly Rimsulfuron and metabolites IN-70941 and IN-70942).

Radioactivity in leachate [%]:

	^{14}C	**Rimsulfuron**	**IN-70942**	**IN-70941**
Soil 1	97.9[1]/70.7[2]	50.7[1]/60.4	27.5[1]/6.4[2]	5.7[1]/0.9[2]
Soil 2	89.6/57.3[2]	49.9[1]/45.1[2]	6.9[1]/6.1[2]	2.8[1]/2.6[2]
Soil 3	76.0[1]/62.0[2]	5.8[1]/n.d.[2]	3.0[1]/n.d.[2]	60.8[1]/59.8[2]
Soil 4	89.5[1]/79.5[2]	61.3[1]/54.0[2]	11.8[1]/10.3[2]	11.4[1]/14.1[2]

IN-9260: 1.6-3.5% in leachate (Pyridine)

Soil 1 (Speyer 2.1): sand, 0.7% C_{org}, pH6.1
Soil 2 (Speyer 2.2): loamy sand, 2.3% C_{org}, pH 6.3

<table>
<tr><td></td><td>Soil 3 (Speyer 2.3): sandy loam, 1.3% C_{prg}, pH 6.7
Soil 4 (Sassafras): sandy loam, 1.3% Corg, pH 6.2

<u>Aged residues leaching</u>
30 days ageing (20 °C, 40% MWHC, dark), radi-activity in leachate in soil [%]:
<table><tr><td>^{14}C</td><td>Rimsulfuron</td><td>IN-70942</td><td>IN-70941</td><td>IN-E9260</td></tr><tr><td>41.7[1]/29.1[2]</td><td>5.7[1]/3.0[2]</td><td>16.2[1]/7.4[2]</td><td>11.6[1]/18.7[2]</td><td>7.2[1]/n.d.</td></tr></table>[1]: Pyridine
[2]: Pyrimidine</td></tr>
<tr><td>Nicosulfuron</td><td>Eluation: 508 mm
Time period: 4d
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

<u>Aged residues leaching</u>
Aged for 28 d
Time period: 8 d
Eluation: 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 residue/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 0-46.5 cm, and 5.3% AR in the bottom 16.5-34.5 cm of column</td></tr>
</table>

8.5.4 Lysimeter studies (KCP 9.1.2.2)

<table>
<tr><td>Rimsulfuron</td><td>No data provided, not required.</td></tr>
<tr><td>Nicosulfuron</td><td>3 Lysimeter studies, each with two lysimeters, 1 in Germany (Schmallenberg) and 2 in Switzerland (Itigen), 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 0.002-0.04

(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.</td></tr>
</table>

8.5.5 Field leaching studies (KCP 9.1.2.3)

Rimsulfuron	No data provided, not required.
Nicosulfuron	Please refer to 8.5.5.

zRMS comments:

Soil mobility data for rimsulfuron and its metabolites, nicosulfuron and its metabolites are in general in line with EU agreed endpoints.

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

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

8.6.1 Rimsulfuron and its metabolites

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

Rimsulfuron Distribution (max. sediment 12.6 % after 14 days)										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Blackiston	4.3/4.8	1	3	1st order non-linear	1	3	1st order non-linear	12	1st order non-linear	Y, DAR and EFSA Journal 2005; 45, 1-61
Mills Lawn	6.7/5.7	11	35		7	26		9		
Geometric mean at 20ºC (n=2)		**3.3**	10.4		**2.6**	8.8		**10.4**		

Table 8.6-2: Summary of degradation in water/sediment of IN-70941

Distribution (max in water 74.9% after 3 d. Max. sed x 17.5 % after 7 d). Max in total system 87.2 % after 3 days,										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Blackiston	4.3/4.8	12	-	1st order non-linear	9	-	1st order non-linear	-	1st order non-linear	Y, DAR and EFSA Journal 2005; 45, 1-61
Mills Lawn	6.7/5.7	28	-		31	-		-		
Geometric mean at 20ºC (n=2)		**18.3**	-		**16.7**	-		-		

Table 8.6-3: Summary of degradation in water/sediment of IN-70942

Distribution (max in water 33.5% after 14 d. Max. sed 78.0 % after 100 d). Max in total system 79.1 % after 100 days										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Blackiston	4.3/4.8	-	-	1st order non-linear	27	-	1st order non-linear	-	1st order non-linear	Y, DAR and EFSA Journal 2005; 45, 1-61
Mills Lawn	6.7/5.7	107	-		22	-		-		
Worst case at 20ºC (n=1)		**107**	-		-	-		-		

Table 8.6-7: Summary of observed metabolites in water/sediment systems

IN-70941	Max. in water/sediment 87.2 %	Y, DAR and EFSA Journal 2005; 45, 1-61
IN-70942	Max. in water/sediment 79.1%	
IN-E9260	Max. in water/sediment < 6%	
IN-JF999	Max. in water/sediment 24.5%	

8.6.2 Nicosulfuron and its metabolites

Table 8.6-8: Summary of degradation in water/sediment of Nicosulfuron

Nicosulfuron Distribution (max. water/max. in sediment 24% after 14 days)										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Pond (Anwil)	-/6.9	33.2	110.2	1st order non-linear	24.9	82.9	1st order non-linear	-	-	~~EFSA Scientific report (2007) 120, 1-91~~ DAR
River (Rhine)	-/6.9	49.8	165.4		32.0	106.2		-	-	
Geometric mean (n=2)		**40.7**	-		**28.2**	-		-		

Table 8.6-9: Summary of observed metabolites

HMUD Water/sediment system	Max. in water 14.1% after 62 d (pyridine) Max. in sediment 5.7 % after x 30 (pyridine) Max. in water/sediment 19.3%	Y, EFSA Journal 2007; 120, 1-91
AUSN Water/sediment system	Max. in water 9.1% after 177 d (pyridine) Max. in sediment 2.4 % after x 105 (pyridine) Max. in water/sediment 11.1%	
UCSN Water/sediment	Max. in water 5.4% after 177 d (pyridine) Max. in sediment 1.4 % after x 105 (pyridine)	

system	Max. in water/sediment 6.5%	
ASMD Water/sediment system	Max. in water 6.9% after 177 d (pyridine) Max. in sediment 4.4 % after x 62 (pyridine) Max. in water/sediment 9.4%	

zRMS comments:

Information on degradation of rimsulfuron and its metabolites, nicosulfuron and its metabolites in water/sediment systems are in line with EU agreed endpoints.

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

8.7.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

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

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

Use No.	1
Crop	**Maize**
Application rate (g as/ha)	Rimsulfuron: 15 Nicosulfuron: 30
Number of applications/interval	1/-
Crop interception (%)	25%
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (Tillage)

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

Compound	**Molecular weight (g/mol)**	**Max. occurrence (%)**	**DT50 (days)**	**Value in accordance to EU endpoint y/n/ Reference**
Rimsulfuron	431.45	-	9.8 (field studies)	Y, EFSA Journal 2005; 45, 1-61
IN-70941	367.4	54.5	615 (Maximum non normalised, laboratory studies)	
IN-70942	324.36	23.5	214 (Maximum non normalised, laboratory studies)	
IN-E9260	250.3	18.9	969 (Maximum non normalised, laboratory studies)	

Compound	**Molecular weight (g/mol)**	**Max. occurrence (%)**	**DT50 (days)**	**Value in accordance to EU end-point y/n/ Reference**
IN-J0290	155.2	12.7	11.3 (Maximum, non normalised laboratory studies)	
Nicosulfuron	410.4	-	63 d (longest value from field study, n=4)	EFSA Scientific report (2007) 120, 1-91
HMUD	396.4	14.4	30.8 (longest value from lab. study, n=2)	
ADMP	155.2	9.8	11.3 d (longest value from lab study, n=3)	
ASDM	229.3	63.4	268.5 (longest value from lab. study, n=3)	
AUSN	314.3	26.8	218.28 (longest value from lab. study, n=3)	
UCSN	315.3	11	307.5 d (longest value from lab. study, n=3)	

8.7.2.1 Rimsulfuron and its metabolites

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

PEC_{soil} (mg/kg)		**Maize**	
		Single application	
		Actual	TWA
Initial		0.015	-
Short term	24h	0.014	0.014
	2d	0.013	0.014
	4d	0.011	0.013
Long term	7d	0.009	0.012
	14d	0.006	0.010
	21d	0.003	0.008
	28d	0.002	0.007
	50d	<0.001	0.004
	100d	<0.001	0.002
Plateau concentration (20 cm) after year		-	-

$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)	-	-

PEC_{soil} of metabolites

PEC_{soil} values for the metabolites were determined as for the parent with an application rate corrected taking into account the molecular weights (MW) and the maximum occurrence of the metabolite in soil as following:

Application $rate_{metabolite}$ = ($MW_{metabolite}$/ MW_{parent}) x (% maximum occurrence/100) x application $rate_{parent}$

The corresponding application rates for each metabolite are summarized in the table below.

Table 8.7-4: Corrected application rates for the metabolites

Metabolite	Application rate of the parent (g/ha)	MW_{parent}	$MW_{metabolite}$	Maximum occurrence in soil (%)	Corrected application rate (g/ha)
IN-70941	15	431.45	367.4	54.5	6.962
IN-70942			324.36	23.5	2.650
IN-E9260			250.3	18.9	1.644
IN-J0290			155.2	12.7	0.685

The results of PEC_{soil} calculations are presented in the tables below.

Table 8.7-5: PEC_{soil} for IN-70941 on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.007	-
Short term	24h	0.007	0.007
	2d	0.007	0.007
	4d	0.007	0.007
Long term	7d	0.007	0.007
	14d	0.007	0.007
	21d	0.007	0.007
	28d	0.007	0.007
	50d	0.007	0.007
	100d	0.006	0.007
Plateau concentration (20 cm) after year 5		0.003	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.010	-

Table 8.7-6: PEC_{soil} for IN-70942 on maize

PEC_{soil} (mg/kg)	Maize	
	Single application	
	Actual	TWA

Initial		0.003	-
Short term	24h	0.003	0.003
	2d	0.003	0.003
	4d	0.003	0.003
Long term	7d	0.003	0.003
	14d	0.003	0.003
	21d	0.002	0.003
	28d	0.002	0.003
	50d	0.002	0.002
	100d	0.002	0.002
Plateau concentration (20 cm) after year 1		<0.001	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.003	-

Table 8.7-7: PEC_{soil} for IN-E9260 on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.002	-
Short term	24h	0.002	0.002
	2d	0.002	0.002
	4d	0.002	0.002
Long term	7d	0.002	0.002
	14d	0.002	0.002
	21d	0.002	0.002
	28d	0.002	0.002
	50d	0.002	0.002
	100d	0.002	0.002
Plateau concentration (20 cm) after year 3		0.001	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.003	-

Table 8.7-8: PEC_{soil} for IN-J0290 on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.001	-
Short term	24h	0.001	0.001
	2d	0.001	0.001

	4d	0.001	0.001
Long term	7d	<0.001	0.001
	14d	<0.001	<0.001
	21d	<0.001	<0.001
	28d	<0.001	<0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001
Plateau concentration (20 cm) after year		-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		-	-

zRMS comments:

Rimsulfuron

PEC_{soil} calculations has been accepted for the active substance rimsulfuron and its metabolites IN-70941, IN-70942 and IN-E9260 and for the major metabolite from photolysis study IN-J0290.
The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (EFSA Journal 2005; 45, 1-61. Interception is appropriate to the proposed BBCH of crops (guidance 2014).
The acceptable predicted environmental concentrations of rimsulfuron and its metabolites in soil are appropriate to be used for the subsequent risk assessment.
Agreed PECsoil:
Rimsulfuron:
PECs = 0.015 mg/kg
IN-70491: PECs = 0.007 mg/kg; PECs acc = 0.01 mg/kg
IN-70942: PECs = 0.003 mg/kg; PECs acc = 0.003 mg/kg
IN-E9260: PECs = 0.002 mg/kg; PECs acc 0.003 mg/kg
IN-J0290: PECs < 0.001mg/kg.

8.7.2.2 Nicosulfuron and its metabolites

Table 0-1: PEC_{soil} for Nicosulfuron on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.030	-
Short term	24h	0.030	0.030
	2d	0.029	0.030
	4d	0.029	0.029
Long term	7d	0.028	0.029
	14d	0.026	0.028

	21d	0.024	0.027
	28d	0.022	0.026
	50d	0.017	0.023
	100d	0.010	0.018
Plateau concentration (20 cm) after year 1		<0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

PEC_{soil} of metabolites

PEC_{soil} values for the metabolites were determined as for the parent with an application rate corrected taking into account the molecular weights (MW) and the maximum occurrence of the metabolite in soil as following:

Application $rate_{metabolite}$ = ($MW_{metabolite}$/ MW_{parent}) x (% maximum occurrence/100) x application $rate_{parent}$

The corresponding application rates for each metabolite are summarized in the table below.

Table 0-2: Corrected application rates for the metabolites

Metabolite	Application rate of the parent (g/ha)	MW_{parent}	$MW_{metabolite}$	Maximum occurrence in soil (%)	Corrected application rate (g/ha)
HMUD	30	410.4	396.4	14.4	4.174
ADMP			155.2	9.8	1.113
ASDM			229.3	63.4	10.629
AUSN			314.3	26.8	6.159
UCSN			315.3	11.0	2.538

Table 0-3: PEC_{soil} for HMUD on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.004	-
Short term	24h	0.004	0.004
	2d	0.004	0.004
	4d	0.004	0.004
Long term	7d	0.004	0.004
	14d	0.003	0.004
	21d	0.003	0.003
	28d	0.002	0.003
	50d	0.001	0.003
	100d	<0.001	0.002
Plateau concentration (20 cm) after year		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 0-4: PEC_{soil} for ADMP on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.001	-
Short term	24h	0.001	0.001
	2d	0.001	0.001
	4d	0.001	0.001
Long term	7d	0.001	0.001
	14d	<0.001	0.001
	21d	<0.001	0.001
	28d	<0.001	0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001
Plateau concentration (20 cm) after year		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 0-5: PEC_{soil} for ASDM on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.011	-
Short term	24h	0.011	0.011
	2d	0.011	0.011
	4d	0.011	0.011
Long term	7d	0.010	0.011
	14d	0.010	0.010
	21d	0.010	0.010
	28d	0.010	0.010
	50d	0.009	0.010
	100d	0.008	0.009
Plateau concentration (20 cm) after year 2		0.002	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.013	-

Table 0-6: PEC_{soil} for AUSN on maize

PEC_{soil} (mg/kg)	Maize
	Single application

		Actual	TWA
Initial		0.006	-
Short term	24h	0.006	0.006
	2d	0.006	0.006
	4d	0.006	0.006
Long term	7d	0.006	0.006
	14d	0.006	0.006
	21d	0.006	0.006
	28d	0.006	0.006
	50d	0.005	0.006
	100d	0.004	0.005
Plateau concentration (20 cm) after year 3		0.001	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.007	-

Table 0-7: PEC_{soil} for UCSN on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.003	-
Short term	24h	0.003	0.003
	2d	0.003	0.003
	4d	0.003	0.003
Long term	7d	0.002	0.003
	14d	0.002	0.002
	21d	0.002	0.002
	28d	0.002	0.002
	50d	0.002	0.002
	100d	0.002	0.002
Plateau concentration (20 cm) after year 1		<0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.003	-

zRMS comments:

Nicosulfuron

PEC_{soil} 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 acceptable predicted environmental concentrations of nicosulfuron and its metabolites in soil are appropriate to be used for the subsequent risk assessment
Nicosulfuron: PECs = 0.030 mg/kg
HMUD:PECs = 0.004 mg/kg
ADMP :PECs = 0.001 mg/kg
ASDM :PECs = 0.011 mg/kg; PECs, acc = 0.013 mg/kg
AUSN :PECs = 0.006 mg/kg; PECs, acc = 0.007 mg/kg
UCSN: PECs = 0.003 mg/kg; PECs, acc = 0.003 mg/kg

8.7.2.3 PEC_{soil} of COREY

Since COREY is rapidly broken down into its constituent parts on contact with soil and/or crop material, it is appropriate to calculate the PEC_{Soil} following a single application only, using the following equation:

$$PEC_S(mg/kg) = \frac{Application\ \text{rate (g/ha)} \times \text{(1-F)}}{100 \times \text{Soil depth (cm)} \times \text{Soil dry bulk density (g/cm}^3\text{)}}$$

Table 0-8: PEC$_{soil}$ for COREY on maize

Active substances/Preparation	Application rate (g/ha)	Crop interception (%)	PEC$_{act}$ (mg/kg)
Rimsulfuron + Nicosulfuron / COREY	100	25	0.100

zRMS comments:

PECs, formulation **Corey** = 0.100 mg/kg

8.8 Predicted Environmental Concentrations in groundwater (PEC$_{gw}$) (KCP 9.2.4)

8.8.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

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

Table 8.8-1: Input parameters related to application for PEC$_{gw}$ calculations

Use No.	1
Crop	Maize
Application rate (g as/ha)	Rimsulfuron: 15 Nicosulfuron: 30
Number of applications/interval (d)	1/-
Crop interception (%)	25
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

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

Scenario	Application dates (absolute)*
Châteaudun	09/05
Hamburg	12/05
Kremsmünster	12/05
Okehampton	29/05
Piacenza	21/05
Porto	09/05
Sevilla	15/03
Thiva	25/04

***According to AppDate v3.06 28 June 2019**

8.8.2.1 Rimsulfuron and its metabolites

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

Compound	Rimsulfuron	IN-70941	IN-70942	IN-E9260	IN-J0290	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	431.45	367.4	324.36	250.3	155.2	Y, EFSA Journal 2005; 45, 1-61
Water solubility (mg/L):	7300 @ 25ºC 6062 @ 20ºC*					
Saturated vapour pressure (Pa):	8.9×10^{-7} @ 20ºC					
DT_{50} in soil (d)	18.3 (geomean, lab studies n=5, normalized at 20°C, Q_{10} 2.58 and pF2)	128.9 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	86.2 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	359.3 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	4.5 (geomean lab studies, n=3, normalized at 20 °C, Q_{10} 2.58 and pF2)	
K_{foc}/K_{fom} (mL/g)	42.4/24.6 (geomean, n=4)	41.5/24.1 (geomean, n=3, higher adsorption value from clay soil was excluded)	191.7/111.2 (geomean, n=4)	23.2/13.5 (geomean, n=3, higher adsorption value from clay soil was excluded)	51.1/29.6(geo mean, n=4)	
1/n	1.02 (arithmetic mean, n =4)	0.94 (arithmethic mean, n=4)	0.85 (arithmethic mean, n=4)	0.99 (arithmethic mean, n=4)	0.87 (arithmetic mean, n= 4)	
Plant uptake factor	0 (default)					
Formation fraction	-	0.57 from parent	1 from IN-70941	0.18 from parent	0.03 from parent	

***Calcualted by UBA Excel™ spreadsheet EVA 3.0 rev 2h used in PELMO claulations.**

Table 8.8-4: PEC_{gw} for Rimsulfuron and metabolites on maize with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3

Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)									
	Rimsulfuron		IN-70941		IN-70942		IN-E9260		IN-J0290	
	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL
Châteaudun	0.016	0.025	0.671	0.688	0.062	0.060	0.423	0.405	<0.001	<0.001
Hamburg	0.050	0.063	0.783	0.924	0.063	0.072	0.432	0.509	<0.001	<0.001
Kremsmünster	0.040	0.038	0.661	0.654	0.058	0.057	0.338	0.303	<0.001	<0.001
Okehampton	0.060	0.065	0.568	0.577	0.042	0.045	0.237	0.252	<0.001	<0.001
Piacenza	0.022	0.015	0.535	0.659	0.050	0.073	0.251	0.431	<0.001	<0.001

Porto	0.008	0.008	0.362	0.349	0.016	0.017	0.204	0.192	<0.001	<0.001
Sevilla	0.001	0.001	0.286	0.313	0.017	0.023	0.383	0.474	<0.001	<0.001
Thiva	0.007	0.009	0.754	0.888	0.076	0.101	0.603	0.817	<0.001	<0.001

Conclusion

The Rimsulfuron and IN-J0290 PECgw were below 0.1 µg/L. IN-70942 given a maximum PECgw value of 0.101 µg/L in Thiva scenario from PEARL model, but according to the field dissipation studies this metabolite was considered as minor metabolite and no field DT_{50} could be derived. Furthermore, EFSA considered that the endpoints used to risk assessment calculations represent a worst case for the metabolites IN-70942 and IN-E9260. Whilst the use of laboratory values has uncertainty as DT_{50} were extrapolated beyond the study durations, the use of formation fractions and DT_{50} values from the laboratory studies for these 2 metabolites clearly results in more conservative PECs being calculated than would result if the data from the field studies had been used as the basis for the calculations. Besides, metabolite IN-70942 was screened for herbicidal activity in 17 species giving no activity. The Applicant has done QSAR's predictions for mutagenicity and carcinogenicity to support the non risk for ground water using Toxtree v 2.6.13 (submitted separately) being predicted as non mutagenic nor carcinogenic. Therefore, the metabolite IN-70942 doesn't pose an unacceptable risk for ground water as the relevance assessment dRR Part B 10 concluded.

However, the non-relevant metabolites IN-70941 and IN-E9260 shown PECgw's greater than 0.1 but below 1 µg/L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document will be done and reported in the dRR Part B10.

zRMS comments:

Rimsulfuron

The PEC_{gw} calculations have been provided for the active substance rimsulfuron and its metabolites IN-70941, IN-70942 and IN-E9260. PEC_{gw} has been provided also for the major metabolite, in the soil photolysis study IN-J0290. Input parameters used for calculations can be considered acceptable (Y, EFSA Journal 2005; 45, 1-61). In opinion of zRMS interception is appropriate to the proposed BBCH of crops (guidance 2014). 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.

The Rimsulfuron, and IN-70942 and IN-J0290 PECgw were below 0.1 µg/L. However, the non-relevant metabolites IN-70941 and IN-E9260 shown $PEC_{gw's}$ greater than 0.1 but below 0.75 µg/L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document is reported in the dRR Part B10.

Additional simulations may be required by the MS that do not accept calculations performed using FOCUS models.

8.8.2.2 Nicosulfuron and its metabolites

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

Compound	Nicosulfuron	HMUD	ADMP	ASDM	AUSN	UCSN	MU-466	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	410.4	396.4	155.2	229.3	314.3	315.3	215.2	EFSA Scientific Report (2007) 120, 1-91
Water solubility (mg/L):	9500 at 19.7°C and pH 6.7 9508 at 20ºC pH 6.7*							
Saturated vapour pressure (Pa):	8 x 10^{-10} at 25°C 4.16 x 10^{-10} at 20ºC*	0 at 20°C (default)						
DT_{50} in soil (d)	16.4 d (geomean, normalisation to 10 kPa or pF2, 20 °C, n =7)	23.8 (geomean normalisation to pF2, 20°C, n=2)	4.5 (geomean normalisation to pF2, 20°C, n=3)	108.7 (geomean normalisation to pF2, 20°C, n=3)	90.9 (geomean normalisation to pF2, 20°C, n=3)	160.1 (geomean normalisation to pF2, 20°C, n=3)	66.6 (geomean normalisation to pF2, 20°C, n=3)	
K_{foc} (mL/g)/K_{fom}	15.4 / 8.9 (geomean, n=4)	3.9 / 2.3 (geomean, n=5)	51.1 / 29.6 (geomean, n=4)	**	**	2.6 / 1.5 (geomean, n=4)	**	
1/n	0.94 (arithmetic mean, n=4)	0.9 (default)	0.87 (arithmetic mean, n=4)	**	**	0.9 (default)	0.9 (default)	
Plant uptake factor	0							
Formation fraction	-	0.442 from parent	0.214 from parent	0.214 from parent	0.687 from HMUD	0.313 from HMUD	0.282 from ASDM	

***Calculated by UBA Excel™ spreadsheet EVA 3.0 rev 2h used on PELMO calculations**
****: cf. Table: Scenario specific adsorption values for PECgw modelling for metabolites**

Table 8.8-6: Scenario specific adsorption values for PEC_{gw} modelling for metabolites

Compound	DT_{50} (days)	**pH ≤ 6** Hamburg, Okehampton, Porto		**6 < pH < 7** Piacenza, Sevilla		**pH ≥ 7** Châteaudun, Krems-münster, Thiva	
		K_{oc}	1/n	K_{oc}	1/n	K_{oc}	1/n
AUSN	90.9[a]	13	0.98	P=13 S=22.3	P=0.98 S=0.96	37.3	0.95
ADSM	108.7[a]	2.3	0.82	P=2.3 S=6.0	P=0.82 S=0.94	7.2	0.94
MU-466	66.6[a]	3.62	0.9*	7.5	0.9*	13.41	0.9*

*: FOCUS default value
[a]: Geometric mean DT_{50} values, normalized to 20°C and pF2 (lab.)

ASDM and AUSN have pH dependant adsorption and tests were conducted at the same pH as the topsoil in these two scenarios: P= Piacenza, S= Sevilla. Although pH dependency on adsorption cannot be clearly established, the introduction of the scenario specific adsorption values for AUSN, ASDM and MU-466 in $FOCUS_{gw}$ modelling will not affect the results.

Table 8.8-7: 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	0.64	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	0.42	0.3
	5	100-120	16	0.42	0.0
	6	120-180	22	0.57	0.0
Thiva	1	0-30	25.3	0.66	1.0
	2	30-45	25.3	0.66	0.5
	3	45-60	29.6	0.77	0.5
	4	60-85	31.9	0.83	0.3
	5	85-100	32.9	0.86	0.3
	6	100-200	32.9	0.86	0.0

*: fraction < 2µm
+: calculated using the equation $K_{F\ CLAY} = 0.026 \times \%_{clay}$

Table 8.8-8: PEC$_{gw}$ for Nicosulfuron and metabolites on maize (with FOCUS PEARL v4.4.4)

Scenario	pH [KCl]	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)						
		Nicosulfuron	**HMUD**	**AUSN**	**ADMP**	**UCSN**	**ASDM**	**MU-466**
Châteaudun	7.3	<0.001	0.340	0.706	<0.001	0.773	0.639	0.071
Hamburg	5.7	**0.226**	0.990	1.526	0.002	0.947	0.986	0.097
Kremsmünster	7.0	0.004	0.431	0.651	<0.001	0.542	0.499	0.046
Okehampton	5.1	0.027	0.499	0.750	<0.001	0.452	0.472	0.045
Piacenza	6.3	0.009	0.206	0.947	<0.001	0.711	0.509	0.082
Porto	4.2	0.009	0.145	0.538	<0.001	0.321	0.278	0.038
Sevilla	6.6	<0.001	0.032	0.399	<0.001	0.611	0.346	0.066
Thiva	7.0	<0.001	0.145	0.862	<0.001	1.298	0.824	0.130

Table 8.8-9: PEC$_{gw}$ for Nicosulfuron and metabolites on maize (with FOCUS PELMO v. 5.3.3)

Scenario	pH [KCl]	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)						
		Nicosulfuron	**HMUD**	**AUSN**	**ADMP**	**UCSN**	**ASDM**	**MU-466**
Châteaudun	7.3	<0.001	0.211	0.680	<0.001	0.876	0.598	0.076
Hamburg	5.7	**0.117**	0.335	1.041	<0.001	0.774	0.628	0.062
Kremsmünster	7.0	0.003	0.170	0.463	<0.001	0.569	0.404	0.050
Okehampton	5.1	0.026	0.192	0.630	<0.001	0.466	0.364	0.049
Piacenza	6.3	0.014	0.061	0.501	<0.001	0.429	0.281	0.046
Porto	4.2	0.009	0.043	0.397	<0.001	0.317	0.200	0.037
Sevilla	6.6	<0.001	0.007	0.137	<0.001	0.361	0.142	0.028
Thiva	7.0	<0.001	0.008	0.144	<0.001	0.452	0.196	0.039

Conclusion

The Nicosulfuron PECgw was below 0.1 μg/L with the exception of Hamburg scenario where the concentration was 0.226 ug/L. Metabolites HMUD, AUSN and ASDM shown PECgw greater than 0.75 but below 10 μg/L, metabolite MU-466 had PECgw greater than 0.1 but below 0.75 μg/L and metabolite ADMP reported PECgw's well below 0.1 μg/L.

The Applicant would like to mention the Sharda's monitoring study for Nicosulfuron and its metabolites HMUD, AUSN, UCSN and ASDM performed on Italy during almost 3 years (January 2016-November 2018), where all of the monitoring regions are typical for cultivation of maize in Italy. The monitoring regions were Piemonte, Lombardia, Veneto, Emilia-Romagna and Friuli-Venezia Giulia. Within these five selected regions, seven key maize-growing areas of Northern Italy were identified and the 23 wells were distributed throughout these areas. During the study, groundwater sampling was conducted 12 times for 240 samples (20 wells × 12 sampling events) were analyzed for Nicosulfuron and its four metabolites (3 out 23 wells were used as backup samples). According to the study the Nicosulfuron application rate used in the maize crops were 40 g as/ha in all Italian regions.

The results of the study shown that the concentration of Nicosulfuron and its four metabolites were all < 0.1 μg/L except for UCSN which showed 4 detections at 1 location up to 0.111 μg/L, AUSN which showed 26 detections at 6 locations up to 0.657 μg/L and also ASDM which showed 4 detections at 1 location up to 0.447 μg/L. A summary of Nicosulfuron and metabolites (UCSN, HMUD, AUSN and ASDM) concentrations in groundwater (μg/L) detected during the study is presented below:

Nicosulfuron < 0.1 μg/L.
UCSN ranged from < 0.1 μg/L to 0.111 μg/L.
HMUD < 0.1 μg/L.
AUSN ranged from < 0.1 μg/L to 0.657 μg/L.
ASDM ranged from < 0.1 μg/L to 0.447 μg/L.

In the next table are given the range of concentrations for Nicosulfuron at its metabolites from FOCUS models *vs* monitoring stud.

Substance	**FOCUS models**		**Monitoring study**	
	PECgw min (μg/L)	**PECgw max (μg/L)**	**PECgw min (μg/L)**	**PECgw max (μg/L)**
Nicosulfuron	<0.001	0.226	-	<0.1
HMUD	0.007	0.990	-	<0.1
AUSN	0.137	1.526	<0.1	0.657
ADMP	<0.001	0.002	-	-
UCSN	0.317	1.298	<0.1	0.111
ASDM	0.142	0.986	<0.1	0.477
MU-466	0.028	0.130	-	-

The monitoring study results shown that the Nicosulfuron at its monitored metabolites concentrations are not in agreement with the model predicted values and it can be concluded that the use of Nicosulfuron in maize crops are safe and doesn't pose an unacceptable risk for ground water. Furthermore, the concentration of the monitored non-relevant metabolites was below 0.75 µg/L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document will be done and reported in the dRR Part B10.

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**						
		Nicosulfuron	**HMUD**	**AUSN**	**UCSN**	**ASDM**	**MU-466**	**ADMP**
Every other year application								
Maize, 1 x 40 g a.s./ha, interception 25 %	Châteaudun	< 0.001	0.230	0.926	0.472	0.517	0.029	< 0.001
	Hamburg	0.099	0.419	1.038	0.590	0.666	0.033	0.001
	Kremsmünster	0.002	0.301	0.654	0.331	0.411	0.018	< 0.001
	Okehampton	0.014	0.269	0.484	0.241	0.302	0.013	< 0.001
	Piacenza	0.005	0.125	0.824	0.461	0.483	0.032	< 0.001
	Porto	0.003	0.054	0.370	0.195	0.201	0.013	< 0.001
	Sevilla	< 0.001	0.008	0.571	0.433	0.377	0.036	< 0.001
	Thiva	< 0.001	0.091	1.998	1.209	1.139	0.101	< 0.001

zRMS comments:

Nicosulfuron

The PEC$_{gw}$ calculations provided for the active substance nicosulfuron and its metabolites HMUD, AUSN and ASDM, ADMP has been accepted by zRMS.

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

The results of the FOCUS PELMO and PEARL modelling show that the expected concentration of nicosulfuron was above the 0.1 µg/L in scenario Hamburg. Hamburg scenario is considered a relevant scenario for CZ so refinement of the assessment must be developed by the applicant in order to achieve PEG$_{gw}$ values below 0.1 ug/L. In this way, leaching of nicosulfuron in above scenarios are linked to soil parameters, where Hamburg is the scenario with lowest clay content. Moreover, a soil refinement and development of different scenarios at member state level have to be carried out by the applicant.

The nicosulfuron PEC$_{gw}$ was below 0.1 µg/L with the exception of Hamburg scenario where the concentration was > 0.1 ug/L. Metabolites HMUD, AUSN and ASDM and UCSM shown PEC$_{gw}$ greater than greater than 0.1 µg L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document is reported in the dRR Part B10. Three lysimeter studies were conducted in Germany and Switzerland with pyridine and pyrimidine labelled nicosulfuron. All lysimeters were cropped with maize in the first and second years and with rye in the third year. Applications were made at 60 and 40 g a.s./ ha. Level of nicosulfuron in the leachate of lysimeters treated at 40 g a.s./ha were <0.1 µg L (EFSA (2007) 120, 1-91). Lysimeter studies may be accepted as higher tier risk assessment.

The Applicant has submitted its own monitoring study for nicosulfuron and to the study the nicosulfuron application rate used in the maize crops were 40 g as/ha in all Italian regions. The results of monitoring study shown that the nicosulfuron and its metabolites concentrations are lower than the predicted values obtained from modelling. The monitoring study results 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.

The monitoring study was accepted by RMS, however, the other MS should decide whether the monitoring studies can be used to assess the PEC_{gw}.
Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

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

8.9.1 Justification for new endpoints

Not relevant as there is no deviation to 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	COREY
Use No.	1
Crop	**Maize**
Application rate (kg as/ha)	Rimsulfuron: 0.015 Nicosulfuron: 0.03
Number of applications/interval (d)	1/-
Application window	March-May Minimal crop canopy
Application method	Foliar spray
CAM (Chemical application method)	CAM 2
Soil depth (cm)	4 cm
Models used for calculation	FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v 5.0.0

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

Scenario	Application window used in modelling*
D3	12/05 – 11/06
D4	18/05 – 17/06
D5	15/05 – 14/06
D6	25/04 – 25/05
R1	10/05 – 9/06
R2	09/05 – 8/06
R3	08/05 – 7/06
R4	15/04 – 15/05

***According to AppDate v3.06 28 June 2019**

8.9.2.1 Rimsulfuron and its metabolites

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

Compound	**Rimsulfuron**	**IN-70941**	**IN-70942**	**IN-E9260**	**IN-JF999**	**IN-J0290 a.ka. ADMP**	**Value in accordance to EU end-point y/n/ Reference**
Molecular weight (g/mol)	431.45	367.4	324.36	250.3	310.33	155.2	Y, EFSA Journal 2005; 45, 1-61 EFSA Scientific report (2007) 120, 1-91
Saturated vapour pressure (Pa)	8.9×10^{-7} (20°C)	not required for Step 1+2					
Water solubility (mg/L)	7300 (25°C)						
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	not required for Step 1+2					
Diffusion coefficient in air (m²/d)	0.43						
K_{foc} (mL/g)	42.4/24.6 (geomean, n = 4)	41.5/24.1 (geomean (n=3) higher adsorption value from clay soil was excluded)	191.7/111.2 (geomean, n=4)	23.2/13.5 (geomean (n=3) higher adsorption value from clay soil was excluded)	34/19.7 Calculated from $\log K_{OW}$=0.95 14 due to SRC $\log K_{OW}$ v.1.66 for chemical class 4	51.1/29.6(geomean, n=4)	
Freundlich Exponent 1/n	1.02 (arithmetic mean, n= 4)	not required for Step 1+2					
Plant Uptake	0						
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)						
$DT_{50,soil}$ (d)	18.3 (geomean, lab studies n=5, normalized at 20°C, Q_{10} 2.58 and pF2)	128.9 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	86.2 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	359.3 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	1000 (default)	4.5 (geomean lab studies, n=3, normalized at 20 °C, Q_{10} 2.58 and pF2)	
$DT_{50,water}$ (d)	11 (Max. value, n = 2)	28 (Max. value, n = 2)	107 (Max. value, n = 2)	1000 (default)	86 (Max. value, n = 2	1000 (default)	
$DT_{50,sed}$ (d)	1000 (default)						
$DT_{50,whole\ system}$ (d)	11 (Max. value, n = 2)	28 (Max. value, n = 2)	107 (Max. value, n = 2)	1000 (default)	86 (Max. value, n = 2	1000 (default)	
Maximum occurrence observed (% molar basis with respect to the	Sediment: 12.6	Soil: 54.5 Total system: 82.7	Soil: 23.5 Total system: 83.8*	Soil: 18.9 Total system: 16.2**	Soil: 1×10^{-10} Total system: 24.5	Soil: 12.7*** Total system: 19.1%**	

Compound	Rimsulfuron	IN-70941	IN-70942	IN-E9260	IN-JF999	IN-J0290 a.ka. ADMP	Value in accordance to EU end-point y/n/ Reference
parent)							
Formation fraction in soil:	-	0.57 from parent	1 from IN-70941	0.18 from parent	-	0.03 from parent	

***From hydrolysis study**
****From photolysis study**
*****From soil photolysis study**

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Rimsulfuron following single application of COREY to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	4.87	Drainage/Runoff	2.70	2.01
Step 2					
Southern Europe	March-May	1.32	Drainage/Runoff	0.75	0.56
Northern Europe		0.71		0.41	0.30
Step 3					
D3	ditch	0.083	Drainage	0.009	0.016
D4	pond	0.013		0.013	0.014
D4	stream	0.070		0.009	0.010
D5	pond	0.006		0.006	0.006
D5	stream	0.072		0.005	0.006
D6	ditch	0.079		0.004	0.009
R1	pond	0.007	Runoff	0.005	0.003
R1	stream	0.174		0.006	0.013
R2	stream	0.417		0.013	0.050
R3	stream	0.619		0.022	0.063
R4	stream	0.625		0.025	0.081

FOCUS Step 4

Table 8.9-5 **Global maximum PEC_{sw} values for Rimsulfuron, following single application of COREY to maize according to the central EU zone GAP according to surface water Step 4**

PEC_{sw} (µg/L)	Scenario	STEP 4 Nicosulfuron	
Nozzle reduction	Vegetative strip (m)	5*	10
	No spray buffer (m)	5	10
None	R3 stream	0.402	0.280
	R4 stream	0.408	0.284

***0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Metabolites of Rimsulfuron

Table 8.9-6: **FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IN-70941 following single application to maize**

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	5.63	Drainage/Runoff	4.39	2.30
Step 2					
Southern Europe	March-May	1.59	Drainage/Runoff	1.25	0.66
Northern Europe		0.84		0.66	0.35

Table 8.9-7: **FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IN-70942 following single application to maize**

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	3.30	Drainage/Runoff	3.07	6.25
Step 2					
Southern Europe	March-May	0.92	Drainage/Runoff	0.87	1.76
Northern Europe		0.50		0.47	0.94

Table 8.9-8: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IN-E9260 following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	1.00	Drainage/Runoff	0.99	0.23
Step 2					
Southern Europe	March-May	0.29	Drainage/Runoff	0.29	0.07
Northern Europe		0.15		0.15	0.03

Table 8.9-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IN-JF999 following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	0.87	Drainage/Runoff	0.80	0.29
Step 2					
Southern Europe	March-May	0.24	Drainage/Runoff	0.22	0.08
Northern Europe		0.13		0.12	0.04

Table 8.9-10: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IN-J0290 following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	0.54	Drainage/Runoff	0.54	0.28
Step 2					
Southern Europe	March-May	0.13	Drainage/Runoff	0.13	0.06
Northern Europe		0.07		0.07	0.03

zRMS comments

Rimsulfuron

$PEC_{sw/sed}$ calculations performed at Step 1-2 and Step 3-4 or the active substance rimsulfuron and at Step 1-2 and for its relevant metabolites IN-70941, IN-70942 and IN-E9260 and soil photolysis metabolite IN-J0290. $PEC_{sw/sed}$ have been accepted. Input parameters and $PEC_{sw/sed}$ calculations can be considered acceptable.

The PECsw calculations have been approved for applications proposed in GAP. PECsw and PECsed calculations were carried out according to the FOCUS guidance recommendations.

The calculations at Step 4 were performed according to FOCUS L&M Guidance for 10m buffer zone. The simulation, according to the Austrian Environmental Agency AGES were carried out for 5m buffer zone.

The Applicant has been used FOCUS models: STEPS1-2 and Step3. Nevertheless, additional simulations may be required by the MS that do not accept calculations performed using FOCUS models.

The acceptable predicted environmental concentrations of rimsulfuron and its metabolites are appropriate to be used for the subsequent risk assessment

8.9.2.2 Nicosulfuron and its metabolites

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

Compound	**Nicosulfuron**	**HMUD**	**ASDM**	**AUSN**	**UCSN**	**ADMP**	**DUDN**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	410.4	396.4	229.3	314.3	315.3	155.2	346.3	EFSA Scientific report (2007) 120, 1-91
Saturated vapour pressure (Pa)	8 x 10^{-10} at 25°C	not required for Step 1+2						
Water solubility (mg/L)	9500 at 19.7°C and pH 6.7	1000 at 20ºC (default)						
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							
K_{foc} (mL/g)	15.4 (geomean, n=4)	3.9 (geomean, n=5)	5.2 (geomean, n=4)	25.2 (geomean, n=4)	2.6 (geomean, n=4)	51.1 (geomean, n=4)	1 (default)	EFSA Scientific report (2007) 120, 1-91
Freundlich Exponent 1/n	0.94 (arithmetic mean, n=4)	not required for Step 1+2						
Plant Uptake	0	not required for Step 1+2						default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2						default
$DT_{50,soil}$ (d)	16.4 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=7)	23.8 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=2)	108.7 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=3)	90.9 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=3)	160.1 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=3)	4.5 (geomean normalisation to 10 kPa or pF2, 20 °C, n=3)	1000 (default)	EFSA Scientific report (2007) 120, 1-91
$DT_{50,water}$ (d)	40.7 (geomean, n=2)	1000 (default)						
$DT_{50,sed}$ (d)	1000 (default)							

Compound	**Nicosulfuron**	**HMUD**	**ASDM**	**AUSN**	**UCSN**	**ADMP**	**DUDN**	**Value in accordance to EU endpoint y/n/ Reference**
$DT_{50,whole\ system}$ (d)	40.7 (geomean, n=2)	1000 (default)						
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 24	Soil: 14.4 Water: 14.1 Sediment: 5.7 Total system: 19.3	Soil: 63.4 Water: 61* Sediment: 4.4 Total system: 61*	Soil: 26.8 Water: 9.1 Sediment: 2.4 Total system: 11.1	Soil: 11 Water: 5.4 Sediment:1.4 Total system: 6.5	Soil: 9.8 Total system: 23.1	Soil: 1 x 10^{-10} (no soil metabolite) Total system: 22.3*	

***Worst case from photolysis study**

$PEC_{sw/sed}$

Table 8.9-6: **FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Nicosulfuron following single application of Rimsulfuron 3% + Nicosulfuron12% + Mesotrione 36% WG to maize**

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	10.07	Drainage/Runoff	9.49	1.52
Step 2					
Southern Europe	March-May	2.74	Drainage/Runoff	2.58	0.42
Northern Europe		1.50		1.41	0.23
Step 3					
D3	ditch	0.170	Drainage	0.040	0.035
D4	pond	0.033		0.032	0.043
D4	stream	0.143		0.022	0.021
D5	pond	0.014		0.013	0.015
D5	stream	0.144		0.008	0.009
D6	ditch	0.158		0.023	0.017
R1	pond	0.011	Runoff	0.010	0.007
R1	stream	0.334		0.022	0.022
R2	stream	1.015		0.091	0.105
R3	stream	1.215		0.116	0.108
R4	stream	1.296		0.143	0.144

FOCUS Step 4

Table 8.9-13: Global maximum PEC_{sw} values for Nicosulfuron, following single application of COREY to maize according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Nicosulfuron				
Nozzle reduction	Vegetative strip (m)	None	5*	10	15**	20
	No spray buffer (m)	5	5	10	15	20
None	D3 ditch	0.065	-	-	-	-
	R1 stream	-	0.204	0.137	-	-
	R2 stream	-	0.649	0.448	0.342	0.232
	R3 stream	-	0.789	0.550	0.421	0.287
	R4 stream	-	0.846	0.589	0.452	0.309

***0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**
****0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Due to requirements on B9 by the ecotox expert application patterns for scenarios R3 and R4 at 20m with non spray buffer plus 20m of vegetative buffer have been calculated by EPAT v1.1.1 in order to clarify that only one peak is greater than the RAC value from Lemna. Furthermore, VFSMOD calculations have been done as refinement for all R scenarios, with the exception of R1 pond scenario. The results are given below.

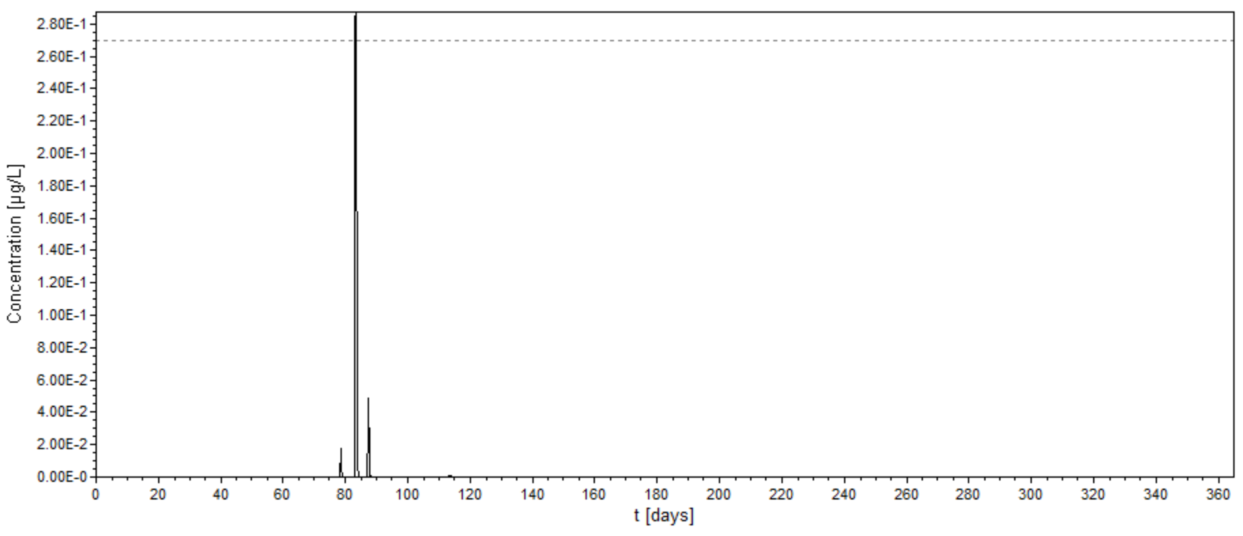


Figure 1: R3 stream application pattern at 20m of non spray buffer, plus 20 m of vegetative strip. Dotted line is the RAC value of 0.27 µg/L.

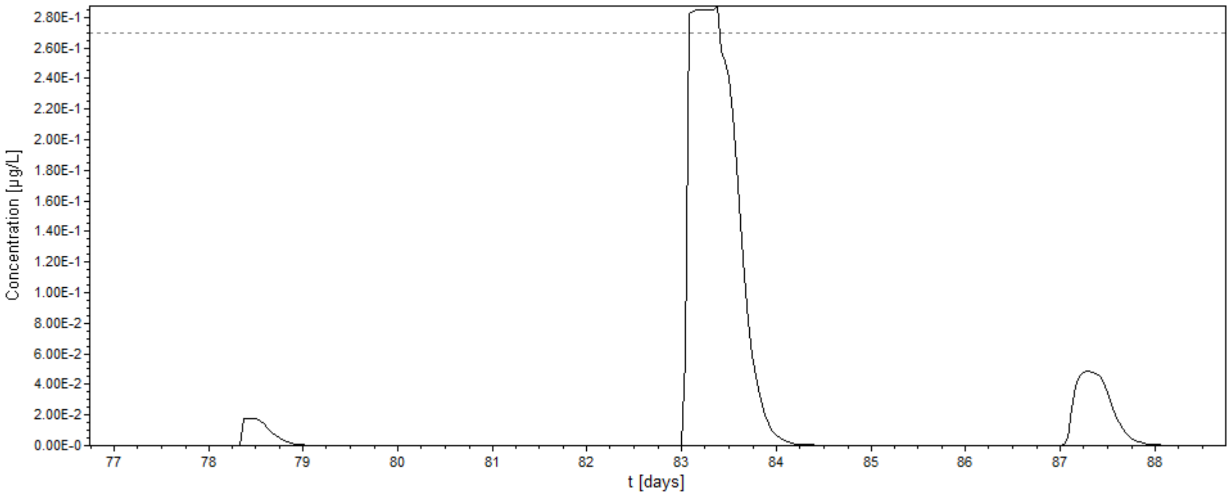


Figure 2: Detailed R3 stream application pattern at 20m of non spray buffer, plus 20 m of vegetative strip. Dotted line is the RAC value of 0.27 µg/L.

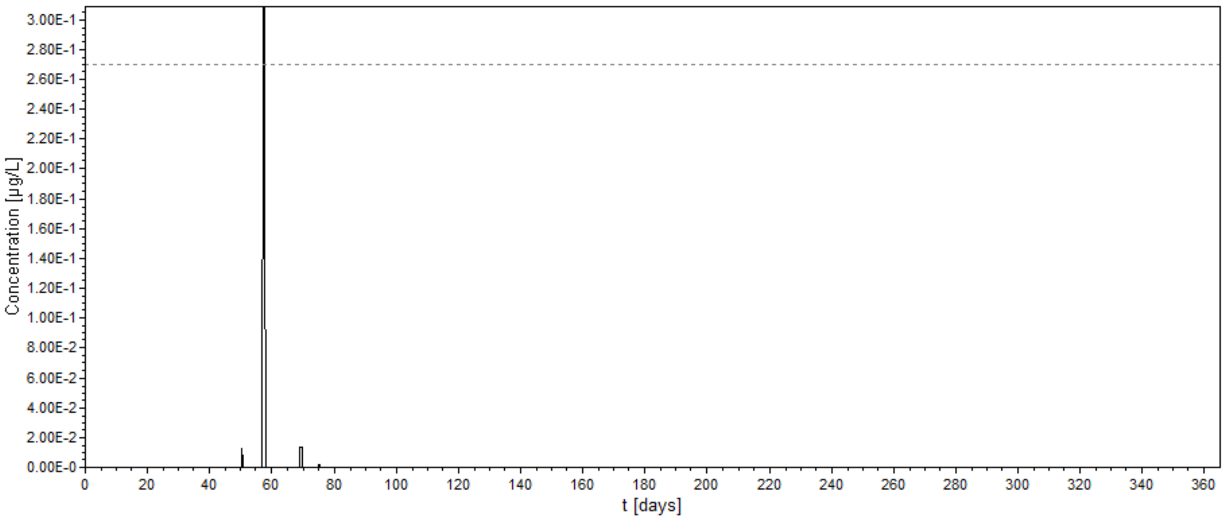


Figure 3: R4 stream application pattern at 20m of non spray buffer, plus 20m of vegetative strip. Dotted line is the RAC value of 0.27 µg/L.

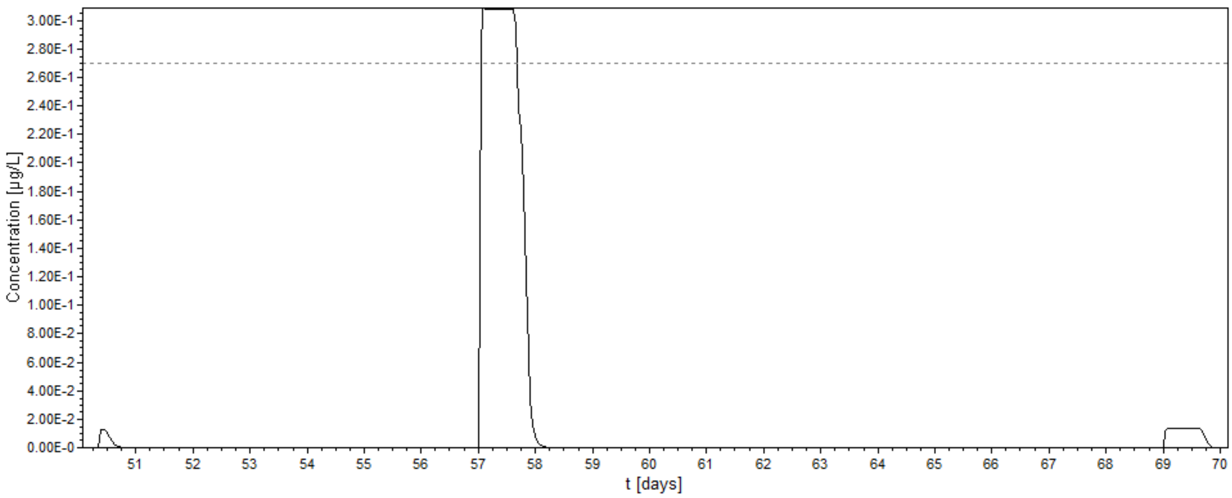


Figure 4: Detailed R4 stream application pattern at 20m of non spray buffer, plus 2 m of vegetative strip. Dotted line is the RAC value of 0.27 µg/L.

Table 8.9-13 bis: VFSMOD Global maximum PEC_{sw} values for Nicosulfuron, following single application of COREY to maize according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Nicosulfuron	
Nozzle reduction	Vegetative strip (m)	5	10
	No spray buffer (m)	5	10
None	R1 stream	0.045	0.024
50%		0.023	-
None	R2 stream	0.061	0.033
50%		0.031	-
None	R3 stream	0.064	0.034
50%		0.032	-
None	R4 stream	0.046	0.024
50%		0.023	-

Metabolites of Nicosulfuron

Table 8.9-7: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for HMUD following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	3.29	Drainage/Runoff	3.27	0.13
Step 2					
Southern Europe	March-May	0.89	Drainage/Runoff	0.88	0.03
Northern Europe		0.47		0.47	0.02

Table 8.9-8: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for ASDM following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	7.00	Drainage/Runoff	6.95	0.36
Step 2					
Southern Europe	March-May	1.98	Drainage/Runoff	1.97	0.10
Northern Europe		1.04		1.03	0.05

Table 8.9-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AUSN following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	2.83	Drainage/Runoff	2.81	0.71
Step 2					
Southern Europe	March-May	0.81	Drainage/Runoff	0.80	0.20
Northern Europe		0.42		0.41	0.10

Table 8.9-17: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for UCSN following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	1.35	Drainage/Runoff	1.34	0.04
Step 2					
Southern Europe	March-May	0.39	Drainage/Runoff	0.39	0.01
Northern Europe		0.20		0.20	

Table 8.9-18: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for ADMP following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	1.19	Drainage/Runoff	1.18	0.61
Step 2					
Southern Europe	March-May	0.29	Drainage/Runoff	0.28	0.15
Northern Europe		0.15		0.15	0.08

Table 8.9-19: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for DUDN following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	1.93	Drainage/Runoff	1.92	0.02
Step 2					
Southern Europe	March-May	0.53	Drainage/Runoff	0.52	0.01
Northern Europe		0.29		0.29	<0.01

zRMS comments

Nicosulfuron

The submitted by Applicant calculations were accepted. The input parameters for active substance were used in accordance with the List of Endpoints. The PEC_{sw} and PEC_{sed} of nicosulfuron have been assessed with standard FOCUS scenarios at Step 1-2 and Step 3 and Step 4 for the active substance nicosulfuron and at Step 1-2 and for its relevant metabolites. Input parameters and $PEC_{sw/sed}$ calculations can be considered acceptable. The $PEC_{sw/sed}$ for nicosulfuron were also carried out at Step 4 according to FOCUS L&M Guidance for 10m and 20m buffer zone. The simulation, according to the Austrian Environmental Agency AGES were carried out for 5m and 15m buffer zone.

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

The acceptable predicted environmental concentrations of nicosulfuron and its metabolites are appropriate to be used for the subsequent risk assessment.

MS should identify risk reduction measures at the national level.

The calculated by EPAT v1.1.1 in order to clarify that only one peak is greater than the RAC value from Lemna were accepted. VFSMOD calculations have been done as refinement for all R scenarios, with the exception of R1 pond scenario were accepted.

The acceptable predicted environmental concentrations of nicosulfuron are appropriate to be used for the subsequent risk assessment.

8.9.2.3 $PEC_{sw/sed}$ of COREY

The PEC_{SW} for COREY was calculated using the following equation:

$$PEC_{SW}\,(\mu g/L) = \frac{\%Drift_{90th\,\%ile} \times Application\,rate\,(g/ha)}{Water\,depth\,(cm) \times 10}$$

The application of COREY is 1 x 100 g/ha. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PEC_{SW} value is presented in the table 8.9-20.

Table 8.9-20: PEC_{sw} COREY following single application to maize

Crop	Distance (m)	Drift (%)	Max PEC_{SW} (µg/L)
Maize	1	2.77	0.923

The PEC_{sed} for COREY was calculated using the following equation:

$$PEC_{sed}\,(\mu g/kg\,dw) = \frac{\%Drift_{90th\,\%ile} \times Application\,rate\,(g/ha) \times \%Active\,substance\,in\,sediment}{1000 \times sediment\,density\,(g/cm^3) \times sediment\,height\,(cm)}$$

The application of COREY is 1 x 100 g/ha, for all crops included in the GAP. The maximum percentages of Rimsulfuron and Nicosulfuron in the sediment are 12.6 and 24% respectively.

The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm^3. The resulting maximum instantaneous PEC_{sed} value is presented in the table 8.9-21.

Table 8.9-21: PEC_{sed} for COREY following single application to maize

Crop	Distance (m)	Drift (%)	% of a.s. in sediment	Max PEC_{sed} (µg/kg) (based on maximum occurrence)
Maize	1	2.77	Rimsulfuron: 12.6	0.537
			Nicosulfuron: 24	1.023

zRMS comments

PECsw and PECsed was accepted.

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

Table 8.10-1: Rimsulfuron summary of atmospheric degradation and behaviour

Compound	Rimsulfuron
Direct photolysis in air	No data, not required.
Quantum yield of direct phototransformation	Rimsulfuron: Φ = 0.0047 IN-70942: Φ = 0.00072
Photochemical oxidative degradation in air	DT50 0.611 h (12 hour day, Atkinston calculation)
Volatilisation	From plant surface: 0.3-3.5% in 24 h From soil: 0-2.2% in 24 h Vapour pressure (Pa): 3.8×10^{-11} @ 20ºC Henry's Law Constant (Pa.m3/mol): 4.5×10^{-10} $Pa.m^3.mol^{-1}$ (pH 5, 25°C) 8.3×10^{-12} $Pa.m^3.mol^{-1}$ (pH 7, 25°C) 1.1×10^{-11} $Pa.m^3.mol^{-1}$ (pH 9, 25°C)
Metabolites	None.

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

Table 8.10-2: Nicosulfuron summary of atmospheric degradation and behaviour

Compound	Nicosulfuron
Direct photolysis in air	Not studies – no data requested
Quantum yield of direct phototransformation	No data submitted – not rquired.
Photochemical oxidative degradation in air	Atkinson (1988) method used, assuming a rate constant of 1.5×10^6 OH radicals/cm^3 photochemical 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 surface: 8.3% over 24 hours From soil: 6.2% over 24 hours Vapour pressure (Pa): < 8×10^{-10} Pa at 25°C (99.8%) Henry's Law Constant (Pa.m3/mol): 1.48×10^{-11} $Pa.m^3.mol^{-1}$ at 20°C
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. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Nicosulfuron due to volatilization with subsequent deposition should not be considered.

zRMS comments

Accepted.

Appendix 1 Lists of data considered in support of the evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.8-01	Ferrari, F.	2019	Title: Groundwater Monitoring for Nicosulfuron and 4 Metabolites in Maize Growing Regions of Italy. Company Report No 37/2016 Source Sharda Cropchem Ltd. GLP Unpublished	N	Sharda Cropchem Ltd.

Appendix 2 Detailed evaluation of the new Annex II studies

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