

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 0724 A

Product name(s): 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.

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 0724 A / COREY*

Product name and code	SHA 0724 A / COREY
Formulation type	Water dispersible granules [Code: WG]
Active substance(s) (incl. content)	Rimsulfuron; 150 g/kg Nicosulfuron; 300 g/kg
Function	Herbicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of SHA 0724 A / COREY can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for SHA 0724 A / COREY according to Regulation (EC) No 1272/2008

Hazard class(es), categories	None
Hazard pictograms or Code(s) for hazard pictogram(s)	None
Signal word	None
Hazard statement(s)	None
Precautionary statement(s)	None
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 0724 A / COREY

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) M/L and A
Workers	Acceptable	Work wear (arms, body and legs covered)
Residents	Acceptable	None
Bystanders	Acceptable	None

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use - No. *	Crops and situa- tion (e.g. growth stage of crop)	F, Fn, Fp n G, Gn, Gp n or I **	Application		Application rate		PH I (d)	Remarks: (e.g. safen- er/synergist (L/ha)) critical gap for operator, worker, resi- dent or by- stander expo- sure based on [Exposure model]	Acceptabil- ity of expo- sure assess- ment			
			Method / Kind (incl. ap- plication tech- nique ***)	Max. number (min. in- terval be- tween ap- plications) a) per use b) per crop/ sea- son	Max. ap- plication rate kg as/ha a) a.s. 1 b) a.s. 2	Wa- ter L/ha min / max			Operator	Worker	Residents	Bystander
1	Maize (BBCH 12-18)	F	Spray- ing, LCTM	a)1 b)1	a) 0.015 rimsulfu- ron + 0.03 nicosulfu- ron b) 0.015 rimsulfu- ron + 0.03 nicosulfu- ron	200- 400	-	Guidance on the assessment of exposure of operators, workers, resi- dents and by- standers in risk assessment for plant protec- tion products; EFSA Journal 2014;12(10):3 874				

* 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

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 “Acceptability of exposure assessment”

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical

areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Rimsulfuron	Nicosulfuron
Common Name	Rimsulfuron	Nicosulfuron
CAS-No.	122931-48-0	111991-09-4
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Not classified	Not classified
Additional C&L proposal	-	-
Agreed EU endpoints		
AOEL systemic	0.07 mg/kg bw/d	0.8 mg/kg bw/d
Reference	EFSA Scientific Report (2005) 45	EFSA Scientific Report 2007; 120, 1-91
Conditions to take into account/critical areas of concern with regard to toxicology		
EFSA Conclusion for active substance	The review has identified acceptable exposure scenarios for operators, workers and bystanders, which require, however, confirmation for each plant protection product.	

6.3 Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of Rimsulfuron 15% + Nicosulfuron 30% WG are derived from the classification of the active compound and co-formulants.

Justification for the proposed classification according the Regulation (EC) No 1272/2008:

Full details of the calculation methodology, co-formulants and their volumes in the product can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Classification for Rimsulfuron 15% + Nicosulfuron 30% WG was calculated based on classification of co-formulants. Based on those calculations for formulation, no classification is required for the oral, dermal and inhalation toxicity, skin irritation, eye irritation and skin sensitizer.

Table 6.3-1: Additional toxicological information relevant for classification/labelling of SHA 0724 A / COREY

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Rimsulfuron (15% (w/w))	Not classified	Reg. 1272/2008 / MSDS** / EFSA conclusion	-
Toxicological properties of active substance(s) (relevant for classification of product)	Nicosulfuron (30% (w/w))	Not classified	Reg. 1272/2008 / MSDS** / EFSA conclusion	-
Toxicological properties of non-active substance(s) (relevant for classification of product)	-	-	-	-
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

The following data on metabolites with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites is reported in Part B.10; the submitted toxicological studies are summarised in this document.

6.4.1 IN-70941

An overview of the results of the accepted toxicological studies for groundwater metabolite IN-70941 is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

Table 6.4-1: Summary of the results of toxicity studies for IN-70941

Type of test, species (Guide-line)	Result	Acceptability	Reference*
<i>In vitro</i> gene mutation (US EPA FIFRA Subdivision F, 84-2)	non-genotoxic	Yes	Reynolds, V.L. (1989) / EU reviewed

* indicates that a study was reviewed at EU level

6.4.2 IN-E9260

An overview of the results of the accepted toxicological studies for groundwater metabolite IN-E9260 is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

Table 6.4-2: Summary of the results of toxicity studies for IN-E9260

Type of test, species (Guide-line)	Result	Acceptability	Reference*
<i>In vitro</i> mammalian cytogenicity test (OECD 473)	non-genotoxic	Yes	Forichon, A. (1992) / EU reviewed
<i>In vitro</i> gene mutation (EEC Method B.14, Directive 92/69/EEC)	non-genotoxic	Yes	Reynolds, V. L. (1989) / EU reviewed

* indicates that a study was reviewed at EU level

6.4.3 HMUD

An overview of the results of the accepted toxicological studies for groundwater metabolite HMUD is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

Table 6.4-3: Summary of the results of toxicity studies for HMUD

Type of test, species (Guide-line)	Result	Acceptability	Reference*
Reverse mutation test (OECD 471)	non-genotoxic	Yes	Matsumoto, K. (2004) / EU reviewed
Gene mutation test (OECD 476)	non-genotoxic	Yes	Matsumoto, K. (2004) / EU reviewed
<i>In vitro</i> chromosome aberration	non-genotoxic	Yes/	Matsumoto, K. (2004) / EU

Type of test, species (Guide-line)	Result	Acceptability	Reference*
(OECD 473)			reviewed

* indicates that a study was reviewed at EU level

6.4.4 AUSN

An overview of the results of the accepted toxicological studies for groundwater metabolite AUSN is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

Table 6.4-4: Summary of the results of toxicity studies for AUSN

Type of test, species (Guide-line)	Result	Acceptability	Reference*
Reverse mutation assay (OECD 471)	non-genotoxic	Yes	Wollny, H. (2003) / EU reviewed
Cell mutation assay (OECD 476)	non-genotoxic	Yes	Wollny, H. (2003) / EU reviewed
<i>In vitro</i> aberration test (OECD 473)	non-genotoxic	Yes	Schulz, M. (2003) / EU reviewed

* indicates that a study was reviewed at EU level

6.4.5 UCSN

An overview of the results of the accepted toxicological studies for groundwater metabolite UCSN is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

Table 6.4-5: Summary of the results of toxicity studies for UCSN

Type of test, species (Guide-line)	Result	Acceptability	Reference*
Reverse mutation assay (OCD 471)	non-genotoxic	Yes	Wollny, H (1995) / EU reviewed
Cell mutation assay (OECD 476)	non-genotoxic	Yes/	Wollny, H (2003) / EU reviewed
<i>In vitro</i> chromosome aberration test (OECD 473)	non-genotoxic	Yes	Schulz, M. (2003) / EU reviewed

* indicates that a study was reviewed at EU level

6.4.6 ASDM

An overview of the results of the accepted toxicological studies for groundwater metabolite ASDM is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

Table 6.4-6: Summary of the results of toxicity studies for ASDM

Type of test, species (Guideline)	Result	Acceptability	Reference*
Ames test (OECD 471)	non-genotoxic	Yes	May, K.. (1993) / EU reviewed
Mouse micronucleus (OECD 474)	non-genotoxic	Yes	Edwards, C.N. (1995) / EU reviewed
<i>In vitro</i> clastogenicity (OECD 473)	non-genotoxic	Yes	Dance, C.A. (1993) / EU reviewed
Cell mutation assay (OECD 476)	non-genotoxic	Yes	Wollny, H. (2003) / EU reviewed

* indicates that a study was reviewed at EU level

6.4.7 MU-466

An overview of the results of the accepted toxicological studies for groundwater metabolite MU-466 is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

Table 6.4-7: Summary of the results of toxicity studies for MU-466

Type of test, species (Guideline)	Result	Acceptability	Reference*
Reverse mutation assay (OECD 471)	non-genotoxic	Yes	Wollny, H. (1996) / EU reviewed
Cell mutation assay (OECD 476)	non-genotoxic	Yes	Wollny, H. (2003) / EU reviewed
<i>In vitro</i> chromosome aberration test (OECD 473)	non-genotoxic	Yes	Schulz, M. (2003) / EU reviewed

* indicates that a study was reviewed at EU level

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in SHA 0724 A / COREY are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SHA 0724 A / COREY

	Rimsulfuron		Nicosulfuron	
	Value	Reference	Value	Reference
Concentrate	10%	EFSA Journal 2017;15(6):4873	10%	EFSA Journal 2017;15(6):4873
Dilution	50%	EFSA Journal 2017;15(6):4873	50%	EFSA Journal 2017;15(6):4873

6.5.1 Justification for proposed values - Rimsulfuron

No data on dermal absorption for Rimsulfuron in SHA 0724 A / COREY is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for Rimsulfuron

	Value	Justification for value	Acceptability of justification
Concentrate	10%	EFSA Journal 2017;15(6):4873	Acceptable
Dilution	50%	EFSA Journal 2017;15(6):4873	Acceptableext

6.5.2 Justification for proposed values - Nicosulfuron

No data on dermal absorption for Nicosulfuron in SHA 0724 A / COREY is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-3: Default dermal absorption rates for Nicosulfuron

	Value	Justification for value	Acceptability of justification
Concentrate	10%	EFSA Journal 2017;15(6):4873	Acceptable
Dilution	50%	EFSA Journal 2017;15(6):4873	Acceptablet

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	SHA 0724 A / COREY	
Formulation type	WG	
Category	Herbicide	
Active substance(s) (incl. content)	Rimsulfuron 150 g/kg	Nicosulfuron 300 g/kg
AOEL systemic	0.07 mg/kg bw/d	0.8 mg/kg bw/d
Inhalation absorption	100%	100%
Oral absorption	100% 70%	100% 40%
Dermal absorption	Concentrate: 10% Dilution: 50% (Default)	Concentrate: 10% Dilution: 50% (Default)

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

There is only one intended GAP.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of SHA 0724 A / COREY according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Maize (max. 0.1 kg product/ha)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-3: Estimated operator exposure (longer term exposure)

		Rimsulfuron		Nicosulfuron	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops (maize)					
Application rate		0.015 kg a.s./ha		0.03 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure	0.0055	7.85	0.0094	1.18
	Work wear (arms, body and legs covered) M/L and A	0.0033	4.76	0.0057	0.71

The operator exposure estimation performed showed that the Acceptable Operator Exposure Level (AOEL) was not exceeded under the conditions of intended use and considering work clothes but not PPE.

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SHA 0724 A / COREY according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Maize (max. 0.1 kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-5: Estimated worker exposure (longer term exposure)

		Rimsulfuron		Nicosulfuron	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation Outdoor Work rate: 2 hours/day DT ₅₀ : 3-30 days (Rimsulfuron), 30 days (Nicosulfuron) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days					
Number of applications and application rate		1 x 0.015 kg a.s./ha		1 x 0.03 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.0094	13.39	0.0188	2.34
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0011	1.50	0.0021	0.26
	Work wear (arms, body and legs covered) and gloves TC: no TC available for this assessment	—	—	—	—

The worker exposure estimation performed showed that the Acceptable Operator Exposure Level (AOEL) was not exceeded under the conditions of intended use and considering work clothes but not PPE.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not required.

If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm² (30 mg a.s./m²).

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6-6 shows the exposure model(s) used for estimation of resident and bystander exposure to Rimsulfuron and Nicosulfuron. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure) and Table 6.6-8 (acute bystander exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Maize (max. 1 x 0.1 kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-7: Estimated resident exposure (longer term exposure)

		Rimsulfuron		Nicosulfuron	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops (maize) Buffer zone: 2-3(m) Drift reduction technology: no DT ₅₀ : 3-30 days (Rimsulfuron), 30 days (Nicosulfuron) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days					
Number of applications and application rate		1 x 0.015 kg a.s./ha		1 x 0.03 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0010072	1.44	0.0020144	0.25
	Vapour (75 th perc.)	0.0010700	1.53	0.0010700	0.13
	Deposits (75 th perc.)	0.0001214	0.17	0.0002428	0.03
	Re-entry (75 th perc.)	0.0012656	1.81	0.0025313	0.32
	Sum (mean)	0.0027228	3.89	0.0043755	0.55
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0002410	0.34	0.0004820	0.06
	Vapour (75 th perc.)	0.0002300	0.33	0.0002300	0.03
	Deposits (75 th perc.)	0.0000511	0.07	0.0001022	0.01
	Re-entry (75 th perc.)	0.0007031	1.00	0.0014063	0.18
	Sum (mean)	0.0009425	1.35	0.0016551	0.21

Table 6.6-8: Estimated bystander exposure (acute exposure)

		Rimsulfuron		Nicosulfuron	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Tractor mounted boom spray application outdoors to low crops (maize) Buffer zone: 2-3(m) Drift reduction technology: no DFR: 3 µg/cm ² /kg a.s./ha					
Application rate:		0.015 kg a.s./ha		0.03 kg a.s./ha	

Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.0022839	3.26	0.0045678	0.57
	Vapour (95 th perc.)	0.0010700	1.53	0.0010700	0.13
	Deposits (95 th perc.)	0.0003634	0.52	0.0007268	0.09
	Re-entry (95 th perc.)	0.0012656	1.81	0.0025313	0.32
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.0006208	0.89	0.0012415	0.16
	Vapour (95 th perc.)	0.0002300	0.33	0.0002300	0.03
	Deposits (95 th perc.)	0.0001541	0.22	0.0003081	0.04
	Re-entry (95 th perc.)	0.0007031	1.00	0.0014063	0.18

The performed exposure(acute and longer term) estimation bystander / resident (child & adult) is acceptable under the conditions of the intended use of COREY

6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Rimsulfuron and Nicosulfuron will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

The product is a mixture of two active substances.

6.6.5.1 Exposure assessment of Rimsulfuron and Nicosulfuron in SHA 0724 A / COREY

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Table 6.6-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-9: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – Work wear (arms, body and legs covered) M/L and A	Rimsulfuron	0.0476
	Nicosulfuron	0.0071
	Cumulative risk operators (HI)	0.05
Workers – Work wear (arms, body and legs covered)	Rimsulfuron	0.015
	Nicosulfuron	0.0026
	Cumulative risk workers (HI)	0.02
Resident - child	Rimsulfuron	
	Drift	0.0144
	Vapour	0.0153
	Deposits	0.0017
	Re-entry	0.0181
	Sum of all pathways	0.0389
	Nicosulfuron	
	Drift	0.0025
	Vapour	0.0013
	Deposits	0.0003
	Re-entry	0.0032
	Sum of all pathways	0.0055
	Cumulative risk resident – child (HI)	
	Drift	0.02
	Vapour	0.02
	Deposits	0.002
	Re-entry	0.02
	Sum of all pathways	0.04
Resident - adult	Rimsulfuron	
	Drift	0.0034
	Vapour	0.0033
	Deposits	0.0007
	Re-entry	0.01
	Sum of all pathways	0.0135
	Nicosulfuron	
	Drift	0.0006

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Vapour	0.0003
	Deposits	0.0001
	Re-entry	0.0018
	Sum of all pathways	0.0021
	Cumulative risk resident – adult (HI)	
	Drift	0.004
	Vapour	0.004
	Deposits	0.0008
	Re-entry	0.01
	Sum of all pathways	0.02
Bystander - child	Rimsulfuron	
	Drift	0.0326
	Vapour	0.0153
	Deposits	0.0052
	Re-entry	0.0181
	Nicosulfuron	
	Drift	0.0057
	Vapour	0.0013
	Deposits	0.0009
	Re-entry	0.0032
	Cumulative risk bystander – child (HI)	
	Drift	0.04
	Vapour	0.02
	Deposits	0.006
	Re-entry	0.02
Bystander - adult	Rimsulfuron	
	Drift	0.0089
	Vapour	0.0033
	Deposits	0.0022
	Re-entry	0.01
	Nicosulfuron	
	Drift	0.0016

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Vapour	0.0003
	Deposits	0.0004
	Re-entry	0.0018
	Cumulative risk bystander – adult (HI)	
	Drift	0.01
	Vapour	0.004
	Deposits	0.003
	Re-entry	0.01

The Hazard Index is < 1. Thus, combined exposure to all active substances in SHA 0724 A / COREY is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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 XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

No additional study submitted.

The following tables are to be completed by MS

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

The classification of Rimsulfuron 15% + Nicosulfuron 30% WG was performed by calculation. The assessment of all acute toxicological properties of Rimsulfuron 15% + Nicosulfuron 30% WG is derived from the classification of the active compound and co-formulants as shown below. For obvious confidentiality reasons, the names and percentages of co-formulants are disclosed in Part C:

Formulant	% of formulation	Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Dermal Irritation	Ocular Irritation	Sensitising potential
Nicosulfuron technical (111991-09-4)	32.26	> 5000 mg/kg	> 2000 mg/kg	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 1	xxx	> 2000 mg/kg	> 2000 mg/kg ¹⁾	*	Skin Irrit. 2, H315	Eye Irrit. 2, H319	Not sensitising ¹⁾
XXXXXXXXXX xx	xxx	> 5000 mg/kg	> 2000 mg/kg ¹⁾	*	Skin Irrit. 2, H315	Eye Irrit. 2, H319	Not sensitising ¹⁾
Coformulant 2	xxx	500 mg/kg ²⁾ H302	1100 mg/kg ²⁾ H312	*	Skin Irrit. 2, H315	Eye Dam. 1, H318	Not sensitising ¹⁾
Coformulant 3	xxx	29700 mg/kg	> 2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 4	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Rimsulfuron technical (122931-48-0)	15.30	5000 mg/kg	> 2000 mg/kg	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 5	xxx	2000 – 5000 mg/kg	> 2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 6	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Eye Irrit. 2, H319	Not sensitising ¹⁾

Coformulant 7	xxx	500 mg/kg ²⁾ H302	1100 mg/kg ²⁾ , H312	*	Skin Irrit. 2, H315	Eye Dam. 1, H318	Not sensi- tising ¹⁾
Coformulant 8	xxx	29700 mg/kg	> 2000 mg/kg ¹⁾	*	Not Irritat- ing ¹⁾	Not Irritat- ing ¹⁾	Not sensi- tising ¹⁾
Coformulant 9	xxx	17000 mg/kg	> 2000 mg/kg ¹⁾	*	Not Irritat- ing ¹⁾	Not Irritat- ing ¹⁾	Not sensi- tising ¹⁾
Coformulant 10	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Not Irritat- ing ¹⁾	Not Irritat- ing ¹⁾	Not sensi- tising ¹⁾

* No Information / but in their MSDS are not classified acutely inhalation toxic

¹⁾ As co-formulant is not classified

²⁾ According to the Regulation (EC) n°1272/2008, Oral: ATE = 500 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4: H302; Dermal: ATE = 1100 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4: H312

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values:

$$\frac{100}{ATE_{mix}} = \sum_r \frac{C_i}{ATE_i}$$

or

$$\frac{100 - (\sum C_{unknown} \text{ if } > 10\%)}{ATE_{mix}} = \sum_r \frac{C_i}{ATE_i}$$

where:

C_i = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATE_i = Acute Toxicity Estimate of ingredient i.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p>Calculation method is acceptable</p> <p>The acute oral toxicity of COREY (Rimsulfuron 15% + Nicosulfuron 30%) was estimated to be 41 666.7 mg/kg .</p> <p>According to the Regulation EC No. 1272/2008 COREY (Rimsulfuron 15% + Nicosulfuron 30%) WG is not classified</p>
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The acute oral toxicity classification for Rimsulfuron 15% + Nicosulfuron 30% WG is calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100}{\frac{xxx}{500} + \frac{xxx}{500}} = 41666.7 \text{ mg/kg bw}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Rimsulfuron 15% + Nicosulfuron 30% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

The acute oral toxicity of Rimsulfuron 15% + Nicosulfuron 30% WG was estimated to be 41666.7 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Rimsulfuron 15% + Nicosulfuron 30% WG is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	Calculation method is acceptable The acute dermal toxicity of COREY (Rimsulfuron 15% + Nicosulfuron 30%)was estimated to be 91 701.05 mg/kg . According to the Regulation EC No. 1272/2008 COREY (Rimsulfuron 15% + Nicosulfuron 30%) WG is not classified
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The acute dermal toxicity classification for Rimsulfuron 15% + Nicosulfuron 30% WG is calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100}{\frac{xxx}{1100} + \frac{xxx}{1100}} = 91701.05 \text{ mg/kg bw}$$

Conclusion

The acute dermal toxicity of Rimsulfuron 15% + Nicosulfuron 30% WG was estimated to be 91701.05 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Rimsulfuron 15% + Nicosulfuron 30% WG is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Acceptable There is no co-formulant in the Rimsulfuron 15% + Nicosulfuron 30% WG recipe classified as danger through inhalation.
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	According to the Regulation EC No. 1272/2008, COREY (Rimsulfuron 15% + Nicosulfuron 30% WG) is not classified.
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There is no co-formulant in the Rimsulfuron 15% + Nicosulfuron 30% WG recipe classified as danger through inhalation.

According to the Regulation EC No. 1272/2008, Rimsulfuron 15% + Nicosulfuron 30% WG is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Acceptable The product contains < 10% of co-formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008 therefore COREY (Rimsulfuron 15% + Nicosulfuron 30% is not classified
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The product contains < 10% of co-formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Rimsulfuron 15% + Nicosulfuron 30% WG is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Acceptable Acceptable The product contains < 3% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318) and < 10% of co-formulants considered as eye irritation (classified as: Eye Irrit. 2, H319). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008, therefore therefore COREY (Rimsulfuron 15% + Nicosulfuron 30% is not classified
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The product contains < 3% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318) and < 10% of co-formulants considered as eye irritation (classified as: Eye Irrit. 2, H319). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Rimsulfuron 15% + Nicosulfuron 30% WG is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments zRMS:	of Acceptable There is no co-formulant in the Rimsulfuron 15% + Nicosulfuron 30% WG recipe classified as skin sensitiser. According to the Regulation EC No. 1272/2008, Rimsulfuron 15% + Nicosulfuron 30% WG is not classified
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There is no co-formulant in the Rimsulfuron 15% + Nicosulfuron 30% WG recipe classified as skin sensitiser.

According to the Regulation EC No. 1272/2008, Rimsulfuron 15% + Nicosulfuron 30% WG is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are necessary.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

Rimsulfuron, Nicosulfuron

According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 10% (concentrate) and 50% (diluted) of may be applied for products that are water-based/dispersed ^(c) or solid-formulated^(d)

^(c): Formulation types: soluble concentrate (SL), suspension concentrate (SC), flowable concentrate for seed treatment (FS), flowable (FL) (SC).

^(d): Formulation types: wettable powder (WP), water-dispersible granules (WG/WDG), water-soluble granules (SG), water-soluble powder (SP), powder for dry seed treatment (DS).

Acceptable

A 2.11 Other/Special Studies

Not relevant.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Rimsulfuron

Table A 1: Input parameters considered for the estimation of operator exposure

Formulation type	WG		Crop type	Cereals
Application rate (AR)	0.015	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	50	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.07	mg/kg bw/d	Water soluble bag	No

Table A 2: Estimation of longer term operator exposure towards Rimsulfuron according to EFSA guidance

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			None	
Specific exposure value	105.0505698	µg/person	105.0505698	µg/person
Systemic exposure	1.7508428	mg/kg bw/d	1.7508428	mg/kg bw/d
Body			Work wear	
Specific exposure value	100.8943424	µg/person	1.4410135	µg/person
Systemic exposure	1.6815724	mg/kg bw/d	0.0240169	mg/kg bw/d
Head			None	
Specific exposure value	0.4870026	µg/person	0.4870026	µg/person
Systemic exposure	0.0081167	mg/kg bw/d	0.0081167	mg/kg bw/d
Inhalation			None	
Specific exposure value	34.2774284	µg/person	34.2774284	µg/person
Systemic exposure	0.5712905	mg/kg bw/d	0.5712905	mg/kg bw/d
Application				
Hands			None	
Specific exposure value	55.6212675	µg/person	55.6212675	µg/person
Systemic exposure	0.9270211	mg/kg bw/d	0.9270211	mg/kg bw/d
Body			Work wear	
Specific exposure value	31.0997518	µg/person	0.8531187	µg/person
Systemic exposure	0.5183292	mg/kg bw/d	0.0142186	mg/kg bw/d
Head			None	
Specific exposure value	1.4698808	µg/person	1.4698808	µg/person

Systemic exposure	0.0244980	mg/kg bw/d	0.0244980	mg/kg bw/d
<u>Inhalation</u>			None	
Specific exposure value	0.8965966	µg/person	0.8965966	µg/person
Systemic exposure	0.0149433	mg/kg bw/d	0.0149433	mg/kg bw/d
Total				
Total systemic exposure	0.0054966	mg/kg bw/d	0.0033349	mg/kg bw/d
% of AOEL	7.85	%	4.76	%

A 3.1.2 Calculations for Nicosulfuron

Table A 3: Input parameters considered for the estimation of operator exposure

Formulation type	WG		Crop type	Cereals
Application rate (AR)	0.03	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	50	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.8	mg/kg bw/d	Water soluble bag	No

Table A 4: Estimation of longer term operator exposure towards Nicosulfuron according to EFSA guidance

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			None	
Specific exposure value	179.1184548	µg/person	179.1184548	µg/person
Systemic exposure	2.9853076	mg/kg bw/d	2.9853076	mg/kg bw/d
Body			Work wear	
Specific exposure value	164.2365557	µg/person	2.6637411	µg/person
Systemic exposure	2.7372759	mg/kg bw/d	0.0443957	mg/kg bw/d
Head			None	
Specific exposure value	0.9740052	µg/person	0.9740052	µg/person
Systemic exposure	0.0162334	mg/kg bw/d	0.0162334	mg/kg bw/d
Inhalation			None	
Specific exposure value	42.1303201	µg/person	42.1303201	µg/person
Systemic exposure	0.7021720	mg/kg bw/d	0.7021720	mg/kg bw/d
Application				
Hands			None	
Specific exposure value	111.2425349	µg/person	111.2425349	µg/person
Systemic exposure	1.8540422	mg/kg bw/d	1.8540422	mg/kg bw/d
Body			Work wear	
Specific exposure value	62.1995035	µg/person	1.7062373	µg/person
Systemic exposure	1.0366584	mg/kg bw/d	0.0284373	mg/kg bw/d

Head			None	
Specific exposure value	2.9397616	µg/person	2.9397616	µg/person
Systemic exposure	0.0489960	mg/kg bw/d	0.0489960	mg/kg bw/d
Inhalation			None	
Specific exposure value	1.2688582	µg/person	1.2688582	µg/person
Systemic exposure	0.0211476	mg/kg bw/d	0.0211476	mg/kg bw/d
Total				
Total systemic exposure	0.0094018	mg/kg bw/d	0.0057007	mg/kg bw/d
% of AOEL	1.18	%	0.71	%

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Rimsulfuron

Table A 5: Input parameters considered for the estimation of worker exposure

Intended use(s)	Maize, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.015	kg a.s./ha	Dermal absorption (DA)	50	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm ² /h
AOEL	0.07	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 6: Estimation of longer term worker exposure towards Rimsulfuron according to EFSA guidance

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0093750	mg/kg bw/d	0.0010500	mg/kg bw/d	-	mg/kg bw/d
% of AOEL	13.39	%	1.50	%	-	%

A 3.2.2 Calculations for Nicosulfuron

Table A 7: Input parameters considered for the estimation of worker exposure

Intended use(s)	Maize, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.03	kg a.s./ha	Dermal absorption (DA)	50	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm ² /h

Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm ² /h
AOEL	0.8	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 8: Estimation of longer term worker exposure towards Nicosulfuron according to EFSA guidance

	Potential	With work wear	With work wear and gloves
Worker (re-entry): Dermal exposure after application			
(DFR x TC x WR x AR x MAF x DA) / BW			
Systemic exposure	0.0187500	mg/kg bw/d	0.0021000
% of AOEL	2.34	%	0.26

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Rimsulfuron

Table A 9: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Maize, spraying		Drift reduction (DR)		%
Application rate (AR)	0.015	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	365	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	20	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.0		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	50	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.07	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			

Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 10: Estimation of longer term resident exposure towards Rimsulfuron according to EFSA guidance

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0002410	mg/kg bw/d	Systemic exposure	0.0010072	mg/kg bw/d
% of AOEL:	0.34	%	% of AOEL:	1.44	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	0.33	%	% of AOEL:	1.53	%
Surface deposits (75 th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0000511	mg/kg bw/d	Systemic exposure	0.0001092	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure	0.0000080	mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
			Systemic exposure	0.0000042	mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.0000511	mg/kg bw/d	Systemic exposure	0.0001214	mg/kg bw/d
% of AOEL:	0.07	%	% of AOEL:	0.17	%
Entry into treated crops (75 th perc.)					
<u>Dermal</u>					
AR x MAF x TC x H _D x DFR x DA / BW					
Systemic exposure	0.0007031	mg/kg bw/d	Systemic exposure	0.0012656	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x 100% x DR _{OM} x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Total</u>					

Systemic exposure	0.0007031	mg/kg bw/d	Systemic exposure	0.0012656	mg/kg bw/d
% of AOEL:	1.00	%	% of AOEL:	1.81	%
All pathways (mean)					
Systemic exposure	0.0009425	mg/kg bw/d	Systemic exposure	0.0027228	mg/kg bw/d
% of AOEL:	1.35	%	% of AOEL:	3.89	%

Table A 10: Input parameters considered for the estimation of acute bystander exposure

Intended use(s)	Maize, spraying		Drift on surface (D) – 90 th pere.	8.50	%
Application rate (AR)	0.015	kg a.s./ha	Turf transferable residues (TTR)	5	%
Minimum water volume (V)	200	L/ha	Exposure duration dermal (H _d)	2	h
Buffer strip	2-3	m	Exposure duration inhal. (H _i)	24	h
Body weight (BW)	60	kg/person (adults)	Exposure duration entry into treated crops (H _e)	0.25	h
	16	kg/person (children)			
Dermal absorption (DA)	50	% (worst case)	Airborne concentration of vapour (VC)	0.004	mg/m ³
Inhalation absorption (IA)	100	%	Dislodgeable foliar residue (DFR)	4	µg/cm ² /kg a.s.
Oral absorption (OA)	100	%	Light clothing adjustment factor (CF)	18	%
AAOEL	0.07	mg/kg bw/d	Saliva extraction factor (SE)	50	%
Spray drift dermal (SD) – 95 th pere.	1.24	mL spray dilution (adult)	Surface area of hands (SA)	20	cm ²
	0.74	mL spray dilution (child)			
Spray drift inhal. (SI) – 95 th pere.	0.00050	mL spray dilution (adult)	Frequency of hand to mouth (freq)	20	events/h
	0.00112	mL spray dilution (child)			
Inhalation rate (IR)	0.23	m ³ /d (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	1.07	m ³ /d (child)			
Drift reduction (DR)		%	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
Transfer coefficient surface deposits (TC)	14500	cm ² /h (adult)	TC entry into treated crops – 95 th pere.	7500	cm ² /h (adult)
	5200	cm ² /h (child)		2250	cm ² /h (child)

Table A 11: Estimation of acute bystander exposure towards Rimsulfuron according to EFSA guidance

Adult			Child		
Spray drift (95 th perc.)					
(SD x DA x (1 - CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0006208	mg/kg bw/d	Systemic exposure	0.0022839	mg/kg bw/d
% of AAOEL	0.89	%	% of AAOEL	3.26	%
Vapour (95 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AAOEL	0.33	%	% of AAOEL	1.53	%

Surface deposits (95 th perc.)					
Derma					
$AR \times MAF \times D \times TTR \times TC \times H_D \times DA / BW$					
Systemic exposure	0.0001541	mg/kg bw/d	Systemic exposure	0.0003315	mg/kg bw/d
Hand to mouth					
$AR \times MAF \times D \times TTR \times SE \times SA \times Freq \times H_D \times OA / BW$					
			Systemic exposure	0.0000255	mg/kg bw/d
Object to mouth					
$AR \times MAF \times D \times DR_{GM} \times IgR \times OA / BW$					
			Systemic exposure	0.0000064	mg/kg bw/d
Total					
Systemic exposure	0.0001541	mg/kg bw/d	Systemic exposure	0.0003634	mg/kg bw/d
% of AAOEL	0.22	%	% of AAOEL	0.52	%
Entry into treated crops (95 th perc.)					
Derma					
$AR \times MAF \times TC \times H_D \times DFR \times DA / BW$					
Systemic exposure	0.0007031	mg/kg bw/d	Systemic exposure	0.0012656	mg/kg bw/d
Hand to mouth					
$AR \times MAF \times 100\% \times TTR \times SE \times SA \times Freq \times H_D \times OA / BW$					
			Systemic exposure		mg/kg bw/d
Object to mouth					
$AR \times MAF \times 100\% \times DR_{GM} \times IgR \times OA / BW$					
			Systemic exposure		mg/kg bw/d
Total					
Systemic exposure	0.0007031	mg/kg bw/d	Systemic exposure	0.0012656	mg/kg bw/d
% of AAOEL	1.00	%	% of AAOEL	1.81	%

A 3.3.2 Calculations for Nicosulfuron

Table A 13: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Maize, spraying		Drift reduction (DR)		%
Application rate (AR)	0.03	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	365	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.0		Exposure duration entry into treated crops (H _E)	0.25	h

Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	50	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.8	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 14: Estimation of longer term resident exposure towards Nicosulfuron according to EFSA guidance

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0004820	mg/kg bw/d	Systemic exposure	0.0020144	mg/kg bw/d
% of AOEL:	0.06	%	% of AOEL:	0.25	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	0.03	%	% of AOEL:	0.13	%
Surface deposits (75 th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0001022	mg/kg bw/d	Systemic exposure	0.0002184	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure	0.0000160	mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
			Systemic exposure	0.0000084	mg/kg bw/d

<u>Total</u>							
Systemic exposure	0.0001022	mg/kg bw/d	Systemic exposure	0.0002428	mg/kg bw/d		
% of AOEL:	0.01	%	% of AOEL:	0.03	%		
Entry into treated crops (75 th perc.)							
<u>Dermal</u>							
AR x MAF x TC x H _D x DFR x DA / BW							
Systemic exposure	0.0014063	mg/kg bw/d	Systemic exposure	0.0025313	mg/kg bw/d		
<u>Hand to mouth</u>							
AR x MAF x 100% x TTR x x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Object to mouth</u>							
AR x MAF x 100% x DR _{OM} x IgR x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Total</u>							
Systemic exposure	0.0014063	mg/kg bw/d	Systemic exposure	0.0025313	mg/kg bw/d		
% of AOEL:	0.18	%	% of AOEL:	0.32	%		
All pathways (mean)							
Systemic exposure		0.0016551	mg/kg bw/d	Systemic exposure		0.0043755	mg/kg bw/d
% of AOEL:	0.21	%	% of AOEL:		0.55	%	

Table A 12: Input parameters considered for the estimation of acute bystander exposure

Intended use(s)	Maize, spraying		Drift on surface (D) – 90 th perc.	8.50	%
Application rate (AR)	0.03	kg a.s./ha	Turf transferable residues (TTR)	5	%
Minimum water volume (V)	200	L/ha	Exposure duration dermal (H _D)	2	h
Buffer strip	2-3	m	Exposure duration inhal. (H _I)	24	h
Body weight (BW)	60	kg/person (adults)	Exposure duration entry into treated crops (H _E)	0.25	h
	16	kg/person (children)			
Dermal absorption (DA)	50	% (worst case)	Airborne concentration of vapour (VC)	0.001	mg/m ³
Inhalation absorption (IA)	100	%	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Oral absorption (OA)	100	%	Light clothing adjustment factor (CF)	18	%
AAOEL	0.8	mg/kg bw/d	Saliva extraction factor (SE)	50	%
Spray drift dermal (SD) – 95 th perc.	1.24	mL spray dilution (adult)	Surface area of hands (SA)	20	cm ²
	0.74	mL spray dilution (child)			
Spray drift inhal. (SI) – 95 th perc.	0.00050	mL spray dilution (adult)	Frequency of hand to mouth (freq)	20	events/h
	0.00112	mL spray dilution (child)			
Inhalation rate (IR)	0.23	m ³ /d (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	1.07	m ³ /d (child)			

Drift reduction (DR)		%	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ³ /d
Transfer coefficient surface deposits (TC)	14500	cm ³ /h (adult)	TC entry into treated crops – 95 th perc.	7500	cm ³ /h (adult)
	5200	cm ³ /h (child)		2250	cm ³ /h (child)

Table A 13: Estimation of acute bystander exposure towards Nicosulfuron according to EFSA guidance

Adult			Child		
Spray drift (95 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0012415	mg/kg bw/d	Systemic exposure	0.0045678	mg/kg bw/d
% of AAOEL	0.16	%	% of AAOEL	0.57	%
Vapour (95 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AAOEL	0.03	%	% of AAOEL	0.13	%
Surface deposits (95 th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0003081	mg/kg bw/d	Systemic exposure	0.0006630	mg/kg bw/d
Hand to mouth					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure	0.0000510	mg/kg bw/d
Object to mouth					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
			Systemic exposure	0.0000128	mg/kg bw/d
Total					
Systemic exposure	0.0003081	mg/kg bw/d	Systemic exposure	0.0007268	mg/kg bw/d
% of AAOEL	0.04	%	% of AAOEL	0.09	%
Entry into treated crops (95 th perc.)					
Dermal					
AR x MAF x TC x H _D x DFR x DA / BW					
Systemic exposure	0.0014063	mg/kg bw/d	Systemic exposure	0.0025313	mg/kg bw/d
Hand to mouth					
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure		mg/kg bw/d
Object to mouth					
AR x MAF x 100% x DR _{OM} x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
Total					
Systemic exposure	0.0014063	mg/kg bw/d	Systemic exposure	0.0025313	mg/kg bw/d
% of AAOEL	0.18	%	% of AAOEL	0.32	%

A 3.4 Combined exposure calculations for Rimsulfuron and Nicosulfuron

In tables below are presented calculations for combined exposure for Rimsulfuron and Nicosulfuron.

Operator exposure:

		Rimsulfuron (AOEL = 0.07 mg/kg bw/d)		Nicosulfuron (AOEL = 0.8 mg/kg bw/d)		Cumulative risk Operators (HI) ¹
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	
Tractor mounted boom spray application outdoors to low crops (maize)						
Application rate		0.015 kg a.s./ha		0.03 kg a.s./ha		
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure	0.0055	0.0785	0.0094	0.0118	0.09
	Work wear (arms, body and legs covered) M/L and A	0.0033	0.0476	0.0057	0.0071	0.05

The Hazard Index is < 1 for the estimation without the use of personal protective equipment during mix/loading and application.

Worker exposure:

¹ The Hazard Index (HI) is the sum of the individual HQs for Rimsulfuron and Nicosulfuron

		Rimsulfuron (AOEL = 0.07 mg/kg bw/d)		Nicosulfuron (AOEL = 0.8 mg/kg bw/d)		Cumulative risk Operators (HI)*
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	
Number of applications and application rate		1 × 0.015 kg a.s./ha		1 × 0.03 kg a.s./ha		
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.0094	0.1339	0.0188	0.0234	0.16
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0011	0.015	0.0021	0.0026	0.02
	Work wear (arms, body and legs covered) and gloves TC: not available	–	–	–	–	–

The estimated exposure for workers presents that the Hazard Index is < 1 for the estimation without the use of personal protective equipment.

Bystander and resident exposure:

		Rimsulfuron (AOEL = 0.07 mg/kg bw/d)		Nicosulfuron (AOEL = 0.8 mg/kg bw/d)		Cumulative risk Operators (HI)*
Model data		Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	
Number of applications and application rate		1 × 0.015 kg a.s./ha		1 × 0.03 kg a.s./ha		
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0010	0.0144	0.0020	0.0025	0.02
	Vapour (75 th perc.)	0.0011	0.0153	0.0011	0.0013	0.02
	Deposits (75 th perc.)	0.0001	0.0017	0.0002	0.0003	0.002
	Re-entry (75 th perc.)	0.0013	0.0181	0.0025	0.0032	0.02
	Sum (mean)	0.0027	0.0389	0.0044	0.0055	0.04
Resident adult Body	Drift (75 th perc.)	0.0002	0.0034	0.0005	0.0006	0.004
	Vapour (75 th perc.)	0.0002	0.0033	0.0002	0.0003	0.004

weight: 60 kg	perc.)					
	Deposits (75 th perc.)	0.00005	0.0007	0.0001	0.0001	0.0008
	Re-entry (75 th perc.)	0.0007	0.01	0.0014	0.0018	0.01
	Sum (mean)	0.0009	0.0135	0.0017	0.0021	0.02
						0.14

		Rimsulfuron (AOEL = 0.07 mg/kg bw/d)		Nicosulfuron (AOEL = 0.8 mg/kg bw/d)		Cumulative risk Operators (HI)
Model data		Total ab-sorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	Total ab-sorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	
Tractor mounted boom spray application outdoors to low crops (maize)						
Application rate:		0.015 kg a.s./ha		0.03 kg a.s./ha		
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.0023	0.0326	0.0046	0.0057	0.04
	Vapour (95 th perc.)	0.0011	0.0153	0.0011	0.0013	0.02
	Deposits (95 th perc.)	0.0004	0.0052	0.0007	0.0009	0.006
	Re-entry (95 th perc.)	0.0013	0.0181	0.0025	0.0032	0.02
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.0006	0.0089	0.0012	0.0016	0.01
	Vapour (95 th perc.)	0.0002	0.0033	0.0002	0.0003	0.004
	Deposits (95 th perc.)	0.0002	0.0022	0.0003	0.0004	0.003
	Re-entry (95 th perc.)	0.0007	0.01	0.0014	0.0018	0.01
						0.113

The Hazard Index is < 1. Thus, combined exposure to all active substances in product COREY is not expected to present a risk for bystanders and residents.

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

None.