FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 4307 A

Product name(s): PRIMARY MX

Chemical active substances:

Rimsulfuron, 30 g/kg
Nicosulfuron, 120 g/kg
Mesotrione, 360 g/kg

Southern Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: February 2020

Update date: 06.2021; 08.2021

MS Finalisation date: 05.2022; 11.2022; 12.2022; 03.2023

Version history

When	What
June 2021	Application update
August 2021	Application update
May 2022	zRMS first evaluation
November 2022	Application update
December 2322	Final zRMS assessment
March 2022	Updated after comments

Table of Contents

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 4307 A / PRIMARY MX*

Product name and code	SHA 4307 A / PRIMARY MX
Formulation type	Water dispersible granules [Code: WG]
Active substance(s) (incl. content)	Rimsulfuron; 30 g/kg Nicosulfuron; 120 g/kg Mesotrione; 360 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 4307 A / PRIMARY MX 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 4307 A / PRIMARY MX according to Regulation (EC) No 1272/2008

Hazard class(es), categories	GHS08
Hazard pictograms or Code(s) for hazard pictogram(s)	
Signal word	Warning
Hazard statement(s)	H361d, H373(eye, nervous system
Precautionary statement(s)	P280, P308+P313, P314
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] EUH208-"Contains formaldehyde. May produce an allergic reaction"

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 4307 A / PRIMARY MX

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A None
Workers	Acceptable	Work wear (arms, body and legs covered) ~~re-entry period of 23 days~~

	Result	PPE / Risk mitigation measures
		~~after application~~ None
Residents	Acceptable	None (when ~~10~~ 5 m buffer zone is considered ~~and drift reduction used~~) None
Bystanders	Acceptable	None (when ~~10~~ 5 m buffer zone is considered ~~and drift reduction used~~) None

No unacceptable risk for workers was identified when the product is used as intended. No specific PPE is necessary.

No unacceptable risk for residents and bystanders was identified when the product is used as intended and a buffer zone of ~~10~~ 5 m from residential areas is considered ~~and drift reduction used~~. No specific PPE is necessary.

No unacceptable risk for operators was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

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 situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ******	**Application**		**Application rate**		**PHI (d)**	**Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind (incl. application technique ***| **Max. number (min. interval between applications) a) per use b) per crop/ season**	**Max. application rate kg as/ha a) a.s. 1 b) a.s. 2**	**Water L/ha min / max**				**Operator**	**Worker**	**Residents**	**Bystander**
1	Maize (BBCH 12-18)	F	Spraying, LCTM	a)1 b)1	a)~~0.0099~~ 0.0075 rimsulfuron + ~~0.0396~~ 0.03 nicosulfuron + ~~0.118~~ 0.09	200-400	-	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for				

1	2	3	4	5	6	7	8	9	10
					mesotri-one b) ~~0.0099~~ 0.0075 rimsulfu-ron + ~~0.0396~~ 0.03 nico-sulfuron + ~~0.118~~ 0.09 mesotri-one			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**	**Mesotrione**
Common Name	Rimsulfuron	Nicosulfuron	Mesotrione
CAS-No.	122931-48-0	111991-09-4	104206-82-8
Classification and proposed labelling			
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Not classified	Not classified	~~Not classified~~ **Repr.2/H361d** **STOT RE 2/H373(eyes,nervous system)**
Additional C&L proposal	-	-	-
Agreed EU endpoints			
AOEL systemic	0.07 mg/kg bw/d	0.8 mg/kg bw/d	0.005 mg/kg bw/d
Reference	EFSA Scientific Report (2005) 45	EFSA Scientific Report 2007; 120, 1-91	SANTE/11654/2016, 23 March 201

	Rimsulfuron	Nicosulfuron	Mesotrione
			Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of mesotrione. Adopted 14 September 2018 **Annex VI CLP table ATP 15 (in force from 1 March 2022)**
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 3% + Nicosulfuron 12% + Mesotrione 36% WG are derived from the classification of the active compounds 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 3% + Nicosulfuron 12% + Mesotrione 36% 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 4307 A / PRIMARY MX

	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 (3% (w/w))	Not classified	Reg. 1272/2008 / MSDS** / EFSA conclusion	-
Toxicological properties of active substance(s) (relevant for classification of product)	Nicosulfuron (12% (w/w))	Not classified	Reg. 1272/2008 / MSDS** / EFSA conclusion	-
Toxicological properties of active substance(s) (relevant	Mesotrione (36% (w/w))	~~Not classified~~ **Repr.2/H361d**	Reg. 1272/2008 / MSDS** /	**Repr.2/H361d STOT RE2 /H373(eyes,nervous**

	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)
for classification of product)		**STOT RE 2/H373(eyes,nervous system)**	EFSA conclusion **Annex VI CLP table ATP 15 (in force from 1 March 2022)**	**system)**
Toxicological properties of non-active substance(s) (relevant for classification of product)	-	-	-	-
Further toxicological information	No data – not required			EUH208: "Contains formaldehyde. May produce an allergic reaction

* 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 (Guideline)	Result	Acceptability	Reference*
In vitro gene mutation (US EPA FIFRA Subdivision F, 84-2)	non-genotoxic	Yes	Reynolds, V.L. (1989) / EU reviewed
In vitro mammalian cell mutagenicity (CHO-K cells) – (OECD 476)	non-genotoxic	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (San and Clark, 2003)
In vitro chromosomal aberration (Human lymphocytes) – (OECD 473)	non-genotoxic	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (Gudi and Rao, 2004)

Type of test, species (Guideline)	Result	Acceptability	Reference*
IN-70941, Acute oral – male rate (not a guideline study)	ALD: ≥ 11000 mg/kg bw	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (xxx, 1989)
IN-70941, Oral subacute (ten days) – male rat (not a guideline study)	NOAEL: <2200 mg/kg bw/d	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (xxx, 1989)
Rimsulfuron, Acute oral – rat (U.S. EPA FIFRA, Subdivision F, 81-1; EEC Method B.1, Directive 92/69/EEC)	LD_{50}: ≥ 5000 mg/kg bw	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 xxx, 1988a
Rimsulfuron, Oral subacute (2 week; 10 doses, weekends excluded; gavage) – male rat (not a guideline study)	NOAEL: 2200 mg/kg bw/d	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 xxx, 1988c. Study is considered as supplementary.

* indicates that a study was reviewed at EU level
ALD Approximate Lethal Dose

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 (Guideline)	Result	Acceptability	Reference*
In vitro mammalian cytogenicity test (OECD 473)	non-genotoxic	Yes	Forichon, A. (1992) / EU reviewed
In vitro gene mutation (EEC Method B.14, Directive 92/69/EEC)	non-genotoxic	Yes	Reynolds, V. L. (1989) / EU reviewed
In vivo comet assay in rats (Rat, liver and duodenum cells) – (OECD 489)	non-genotoxic	Yes / No / Supplementary	*CA 5.8.1.10, (xxx., 2016) Report No. 8346539**
IN-9260, Acute oral (OECD 401)	LD_{50}: ≥ 2000 mg/kg bw	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (xxx, 1991)
IN-9260, Oral subacute (4 weeks) (OECD 407)	≥50 mg/kg bw/d: liver weight ↑, 150 mg/kg bw/d: food consumption ↓, body weight gain ↓, food efficiency ↓, polyuria, forestomach lesions, liver weight ↑, kidney weight ↑, NOAEL: < 50 mg/kg bw/d	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (xxx, 1992)

Type of test, species (Guideline)	Result	Acceptability	Reference*
IN-9260, Acute dermal (OECD 402)	LD_{50} > 2000 mg/kg	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (xxx, 1991a)
IN-9260, Skin irritation (OECD 404)	Not irritating	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (xxx, 1992b)
IN-9260, Eye irritation (OECD 405)	Mild eye irritant	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (xxx, 1992a)
IN-9260, Skin sensitisation (OECD 406)	Not a skin senstitiser	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 (xxx, 1992c)
Rimsulfuron, Acute oral – rat (U.S. EPA FIFRA, Subdivision F, 81-1; EEC Method B.1, Directive 92/69/EEC)	LD_{50}: ≥ 5000 mg/kg bw	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 xxx, 1988a
Rimsulfuron, Oral subacute (2 week; 10 doses, weekends excluded; gavage) – male rat (not a guideline study)	NOAEL: 2200 mg/kg bw/d	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 xxx, 1988c. Study is considered as supplementary.
Oral 90-day study – rat (U.S. EPA FIFRA Subdivision F, 83-1)	≥ 1500 ppm: body weight ↓, phosphorus (females) ↓, ≥ 7500: body weight gain ↓, effects on parameters of haematology, clinical chemistry, liver morphology 20000 ppm: urinalysis NOAEL: 3.35 mg/kg bw/d	Yes / No / Supplementary	*DAR Volume 3, Annex B-B6, 2003 xxx, 1989a xxx, 1991a (supplement 1)

* 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 (Guideline)	Result	Acceptability	Reference*
Reverse mutation test (OECD 471)	non-genotoxic	Yes	xxx (2004) / EU reviewed
Gene mutation test (OECD 476)	non-genotoxic	Yes	xxx (2004) / EU reviewed
In vitro chromosome aberration (OECD 473)	non-genotoxic	Yes	Matsumoto, K. (2004) / EU 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 (Guideline)	Result	Acceptability	Reference*
Acute oral toxicity rat (OECD 401)	LD_{50}: > 2000 mg/kg bw	Yes	xxx, (1996a) / EU reviewed
Reverse mutation assay (OECD 471)	non-genotoxic	Yes	xxx, (2003) / EU reviewed
Cell mutation assay (OECD 476)	non-genotoxic	Yes	xxx, (2003) / EU reviewed
In vitro 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 (Guideline)	Result	Acceptability	Reference*
Reverse mutation assay (OCD 471)	non-genotoxic	Yes	xxx (1995) / EU reviewed
Cell mutation assay (OECD 476)	non-genotoxic	Yes	xxx (2003) / EU reviewed
In vitro chromosome aberration test (OECD 473)	non-genotoxic	Yes	Schulz, M. (2003) / EU reviewed
Acute oral toxicity rat (OECD 401)	>2000 mg/kg bw	Yes / No / Supplementary	xxx (1996) / 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 6.4-2: Summary of the results of toxicity studies for ASDM

Type of test, species (Guideline)	Result	Acceptability	Reference*
Ames test (OECD 471)	non-genotoxic	Yes	xxx (1993) / EU reviewed
Mouse micronucleus (OECD 474)	non-genotoxic	Yes	xxx (1995) / EU reviewed
In vitro clastogenicity (OECD 473)	non-genotoxic	Yes	Dance, C.A. (1993) / EU reviewed
Cell mutation assay (OECD 476)	non-genotoxic	Yes	xxx (2003) / EU reviewed
Acute oral toxicity rat	LD_{50}: > 2000 mg/kg bw	Yes / No / Supplementary	xxx (1993a) / EU reviewed
Acute oral toxicity mouse	LD_{50}: > 5000 mg/kg bw	Yes / No / Supplementary	xxx(1992a) / EU reviewed
Acute dermal toxicity rat	LD_{50}: > 2000 mg/kg bw	Yes / No / Supplementary	xxx. (1993b) / EU reviewed
28 day oral toxicity study in the rat (gavage)	NOAEL: > 1000 mg/kg bw/d	Yes / No / Supplementary	xxx (1993) / EU reviewed
90 day oral toxicity study in the rat	NOAEL: > 1000 mg/kg bw/d	Yes / No / Supplementary	xxx (1998) / EU reviewed
One generation reproduction study	NOAEL: > 1000mg/kg bw/d	Yes / No / Supplementary	xxx. (1998a) / EU reviewed
Developmental toxicity study in the rat	NOAEL maternal: > 1000 mg/kg bw/d NOAEL developmental: = 200 mg/kg bw/d	Yes / No / Supplementary	xxx. (1998b) / 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 6.4-3: Summary of the results of toxicity studies for MU-466

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral toxicity rat (OECD 401)	LD_{50}: > 2000 mg/kg bw	Yes	xxx (1996) / EU reviewed
Reverse mutation assay (OECD 471)	non-genotoxic	Yes	xxx (1996) / EU reviewed

Type of test, species (Guideline)	Result	Acceptability	Reference*
Cell mutation assay (OECD 476)	non-genotoxic	Yes	xxx (2003) / EU reviewed
In vitro chromosome aberration test (OECD 473)	non-genotoxic	Yes	Schulz, M. (2003) / EU reviewed

* indicates that a study was reviewed at EU level

6.4.8 MNBA

The metabolite MNBA is considered to be non-relevant metabolites in groundwater, therefore toxicological studies are not necessary.

~~An overview of the results of the accepted toxicological studies for groundwater metabolite MNBA 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 6.4-8: Summary of the results of toxicity studies for MNBA**~~

~~Type of test, species (Guideline)~~	~~Result~~	~~Acceptability~~	~~Reference*~~
~~Bacterial reverse mutation test; Escherichia coli, reverse assay (OECD 471 and 472)~~	~~non-genotoxic~~	~~Yes~~	~~xxx. (1996a) / EU reviewed~~
~~*In vitro* chromosome aberration test (OECD 473)~~	~~non-genotoxic~~	~~Yes~~	~~Fox, V. (2000a) / EU reviewed~~
~~Test with rat liver cells *in vivo* (OECD 486)~~	~~non-genotoxic~~	~~Yes~~	~~xxxxxx (2000) / EU reviewed~~
~~Rat micronucleus test (OECD 474)~~	~~non-genotoxic~~	~~Yes~~	~~xxxx (2000 b) / EU reviewed~~
Acute oral toxicity, rat (OECD 401)	LD_{50}: > 5000 mg/kg bw	Yes	xxxx (1996) / EU reviewed
Acute dermal toxicity, rat (OECD 402)	LD_{50}: > 2000 mg/kg bw	Yes	xxxx (1996 b) / EU reviewed
Skin irritation, rabbit (OECD 404)	Non-irritating	Yes	xxxx (1996 c) / EU reviewed
Eye irritation, (OECD 405)	Moderate eye irritant	Yes	xxxx (1996 d) / EU reviewed
Skin sensitisation, LLNA	Skin sensitiser	Yes	xxxx (1996 e) / EU reviewed
28 day oral toxicity study in rats (OECD 407)	NOAEL: 1000 mg/kg bw/d	Yes	xxxx (1998) / EU reviewed
90 day oral toxicity study in rats (OECD 408)	NOAEL: 51 mg/kg bw/d	Yes	xxxx (2000) / 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 4307 A / PRIMARY MX are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SHA 4307 A / PRIMARY MX

	Rimsulfuron		Nicosulfuron		Mesotrione	
	Value	**Reference**	**Value**	**Reference**	**Value**	**Reference**
Concentrate	~~10%~~ 50%	EFSA Journal 2017;15(6):4873	10%	EFSA Journal 2017;15(6):4873	~~10%~~ 0.54%	~~EFSA Journal 2017;15(6):4873~~ New study reported in Appendix 2
Dilution	50%	EFSA Journal 2017;15(6):4873	50%	EFSA Journal 2017;15(6):4873	~~50%~~ 2.9%	~~EFSA Journal 2017;15(6):4873~~ New study reported in Appendix 2

6.5.1 Justification for proposed values - Rimsulfuron

No data on dermal absorption for Rimsulfuron in SHA 4307 A / PRIMARY MX 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%~~ 50%	~~Concentrate 10% The formulation of the product is WG: a concentrated products that is solid formulated.~~ < 5 % of a.s. Rimsulfuron in formulation	Acceptable
Dilution	50%	~~Concentrate 10% The formulation of the product is WG: a concentrated products that is solid formulated.~~ < 5 % of a.s. Rimsulfuron in formulation	Acceptable

6.5.2 Justification for proposed values - Nicosulfuron

No data on dermal absorption for Nicosulfuron in SHA 4307 A / PRIMARY MX 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%	Concentrate 10% The formulation of the product is WG: a concentrated products that is solid-formulated.	Acceptable
Dilution	50%	Concentrate 10% The formulation of the product is WG: a concentrated products that is solid-formulated.	Acceptable

6.5.3 Justification for proposed values - Mesotrione

~~No data on dermal absorption for Mesotrione in SHA 4307 A / PRIMARY MX 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 6.5-4: Default dermal absorption rates for Mesotrione~~

	~~Value~~	~~Justification for value~~	Acceptability of justification
~~Concentrate~~	~~10%~~	~~Concentrate 10% The formulation of the product is WG: a concentrated products that is solid-formulated.~~	Acceptable
~~Dilution~~	~~50%~~	~~Concentrate 10% The formulation of the product is WG: a concentrated products that is solid-formulated.~~	Acceptable

Proposed dermal absorption rates for Mesotrione are based on dermal absorption studies on PRIMARY MX. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 6.5-4: Summary of *in vitro* human dermal absorption

	Value	Justification for value	Acceptability of justification
Concentrate	0.54%	*In vitro* human skin	text
Dilution	2.9%	*In vitro* human skin	text

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 4307 A / PRIMARY MX
Formulation type	WG

Category	Herbicide		
Active substance(s) (incl. content)	**Rimsulfuron** 30 g/kg	**Nicosulfuron** 120 g/kg	**Mesotrione** 360 g/kg
AOEL systemic	0.07 mg/kg bw/d	0.8 mg/kg bw/d	0.005 mg/kg bw/d
Inhalation absorption	100%	100%	100%
Oral absorption	~~100%~~ 70%	~~100%~~ 40%	~~100%~~ 50%
Dermal absorption	Concentrate: 10% Dilution: 50% (Default)	Concentrate: 10% Dilution: 50% (Default)	Concentrate: ~~10%~~ 0.54% Dilution: ~~50% (Default)~~ 2.9%

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 4307 A / PRIMARY MX 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. ~~0.33~~ 0.25 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**		**Mesotrione**	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**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		~~0.0099~~ 0.0075 kg a.s./ha		~~0.0396~~ 0.03 kg a.s./ha		~~0.118~~ 0.09 kg a.s./ha	
Spray application	Potential exposure	~~0.0040~~ 0.0033	~~**5.74**~~ **4.7**	~~0.0117~~ 0.0094	~~**1.46**~~ **1**	~~0.0285~~ 0.0228	~~**569**~~ **455**

(AOEM; ~~95~~ 75th percentile) Body weight: 60 kg		0.0115	**16.5**			0.0022	**44**
	Work wear (arms, body and legs covered) M/L and A ~~+ gloves M/L and A~~	~~0.0024~~ 0.0020 0.0062	~~**3.50**~~ **2.9** **9**	~~0.0071~~ 0.0057	~~**0.89**~~ **0.71**	~~0.0026~~ 0.0023 0.0017	~~**53**~~ **46** **35**

Comment:
Operator exposure estimates conducted have demonstrated that an acceptable operator exposure level (AOEL) is acceptable under the conditions of intended use, taking into account that the operator will use personal protective equipment (PPE)

Conclusion
According to the EFSA AOEM Model, it can be concluded that the risk for operator using PRIMARY MX is acceptable even without personal protective equipment.

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 4307 A / PRIMARY MX 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. ~~0.33~~ 0.25 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**		**Mesotrione**	
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**	**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, Mesotrione) DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days							
Number of applications and application rate		1 x ~~0.0099~~ kg a.s./ha 0.0075		1 x ~~0.0396~~ kg a.s./ha 0.03		1 x ~~0.118~~ kg a.s./ha 0.09	
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	~~0.0062~~ 0.0047	~~**8.84**~~ **6.70**	~~0.0248~~ 0.0188	~~**3.09**~~ **2.34**	~~0.0738~~ 0.0563 0.0033	~~**1475**~~ **1125** **65**
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	~~0.0007~~ 0.0005	~~**0.99**~~ **0.75**	~~0.0028~~ 0.0021	~~**0.35**~~ **0.26**	~~0.0083~~ 0.0063 0.0004	~~**165**~~ **126** **7.31**
	Work wear (arms, body and legs covered) and gloves TC: not available for this assessment	–	–	–	–	–	–

~~Maize (Proposal of Re-entry period of 23 days)~~

		~~**Mesotrione**~~	
~~**Model data**~~	~~**Level of PPE**~~	~~**Total absorbed dose (mg/kg bw/day)**~~	~~**% of systemic AOEL**~~
~~Inspection, irrigation~~ ~~Outdoor~~ ~~Work rate: 2 hours/day,~~ ~~DT_{50}: 30 days~~ ~~DFR: 1.7633 µg/cm²/kg a.s./ha~~ ~~Interval between treatments: 365 days~~			
~~Number of applications and application rate~~		~~1 x 0.118 kg a.s./ha~~ ~~0.09~~	

Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	0.0433	**866.96**
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0049	**97.10**
	Work wear (arms, body and legs covered) and gloves TC: not available for this assessment	–	–

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/cm^2 (30 mg a.s./m^2).

Refinement

Proposal of Re-entry period

The Applicant propose to consider as refinement a re-entry period of 23 days. Therefore, we propose to calculate DFR value at 23 days for maize.

Body weight 60 kg.

DT_{50} value of 30 days is considered according to "EFSA Journal 2014;12(10):3874".

DFR_t is calculated according the following formula:

$$DFR_T = DFR_0 \times e^{-k,t}$$

Where:

DFR_T – Dislodgeable foliar residue at the time of re-entry (µg/cm^2)

DFR_0 – Dislodgeable foliar residue just after application (µg/cm^2)

k – Degradation constant (days $^{-1}$), calculated from the half life time:

$k = ln\ (2)/DT_{50}$,

DT_{50} – Foliar half-life time (days)

t – Re-entry interval (days)

– Dislodgeable foliar residue just after application is calculated as:

$DFR_0 = DFR_{def} \times MAF$

– Where:

DFR_{def} default value (If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm^2 per kg s.a/ha)

MAF_m (multiple application factor for mean residue data for *n* application) is:

$MAF = (1-e^{-nki})/(1-e^{-ki})$

where:

n is the number of applications

k is the rate constant for foliar dissipation $k = ln\ (2)/DT_{50}$,

i is the interval between applications (days)

DFR factor was calculated for each crop based on above formula and according to the EFSA Journal 2014;12(10):3874[1], corresponding to a half life $_{foliar}$ of 30 days.

Maize:
For maize, a number of 1 application (n) and 365 days interval (i) between applications is considered (worst case scenario) and MAF is 1.000. The following DFR value is calculated:
$DFR_0 = DFR_{def} \times 1.000 = 3.000$ µg/cm² (where DFR_{def} = 3 µg/cm² per kg s.a/ha)

Therefore for 23 days of re-entry interval:
$DFR_T = DFR_0 \times e^{-k,t} = 3.000$ µg/cm² × 0.5878 = 1.7633 µg/cm²
Therefore, for $DFR_T = DFR_{def\ ref} \times MAF$ = 1.7633 µg/cm² the $DFR_{def\ ref}$ = 1.7633 µg/cm² per kg s.a/ha

Conclusion
Worker activities are not relevant when considering maize on which mechanical procedures are mainly used. In case of necessity for worker to re-enter maize treated with PRIMARY MX, the risk of exposure is considered to be negligible.

Comment:
No unacceptable risk for workers was identified when the product is used as intended. No specific PPE is necessary, but will use work wear (arms, body and legs covered)

Conclusion
According to the EFSA AOEM Model, it can be concluded there is no unacceptable risk anticipated for the worker re-entering the treated crops even without suitable protective clothing.

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

[1] Guidance of EFSA (EFSA Journal 2014;12(10):3874): "Guidance on the assessment of exposure of operators. workers. residents and bystanders in risk assessment for plant protection products"

Rimsulfuron, Nicosulfuron and Mesotrione. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Maize (max. 1 x ~~0.33~~ 0.25 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**		**Mesotrione**	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**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) (Rimsulfuron, Nicosulfuron); ~~10~~ 5 (m) (Mesotrione); 2-3 (m) (Mesotrione) Drift reduction technology: no (Rimsulfuron, Nicosulfuron); ~~yes~~ no (Mesotrione), no (Mesotrione) DT_{50}: ~~3~~ 30 days (Rimsulfuron), 30 days (~~Rimsulfuron~~ Nicosulfuron, Mesotrione) DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days							
Number of applications and application rate		1 x ~~0.0099~~ kg a.s./ha 0.0075		1 x ~~0.0396~~ kg a.s./ha 0.03		1 x ~~0.118~~ kg a.s./ha 0.09	
Resident child Body weight: 10 kg	Drift (75th perc.)	~~0.0006647~~ 0.0005036	~~0.95~~ 0.72	~~0.0026589~~ 0.0020144	~~0.33~~ 0.25	~~0.0021767~~ ~~0.0026357~~ 0.0040205 0.0003598	~~43.53~~ ~~52.71~~ 80.41 7.20
	Vapour (75th perc.)	0.0010700	1.53	0.0010700	0.13	0.0010700	21.40
	Deposits (75th perc.)	~~0.0000801~~ 0.0000607 0.0000589	~~0.11~~ 0.09 0.08	~~0.0003204~~ 0.0002428 0.0002281	~~0.04~~ 0.03 0.03	~~0.0001108~~ ~~0.0001961~~ 0.0002991 0.0001111 0.0000745	~~2.22~~ ~~3.92~~ 5.98 2.22 1.49
	Re-entry (75th perc.)	~~0.0008353~~ 0.0006328	~~1.19~~ 0.90	~~0.0033413~~ 0.0025313	~~0.42~~ 0.32	~~0.0099563~~ 0.0075938 0.0004404	~~199.13~~ 151.88 8.81
	Sum (mean)	~~0.0021608~~ 0.0018964 0.0018950	~~3.09~~ 2.71 2.71	~~0.0054333~~ 0.0043755 0.0043648	~~0.68~~ 0.55 0.55	~~0.0103065~~ ~~0.0106174~~ 0.0095791 0.0017028 0.0016760	~~206.13~~ ~~212.35~~ 191.58 34.06 33.52
Resident adult Body weight: 60 kg	Drift (75th perc.)	~~0.0001591~~ 0.0001205	~~0.23~~ 0.17	~~0.0006362~~ 0.0004820	~~0.08~~ 0.06	~~0.0004114~~ ~~0.0004802~~ 0.0007325 0.0000846	~~8.23~~ ~~9.60~~ 14.65 1.69
	Vapour (75th perc.)	0.0002300	0.33	0.0002300	0.03	0.0002300	4.60

	Deposits (75th perc.)	0.0000337 0.0000256	0.05 0.04	0.0001349 0.0001022	0.02 0.01	0.0000467 0.0000826 0.0001259 0.0000178	0.93 1.65 2.52 0.36
	Re-entry (75th perc.)	0.0004641 0.0003516	0.66 0.50	0.0018563 0.0014063	0.23 0.18	0.0055313 0.0042188 0.0002447	110.63 84.38 4.89
	Sum (mean)	0.0007003 0.0005863	1.00 0.84	0.0021111 0.0016551	0.26 0.21	0.0048977 0.0049528 0.0040704 0.0004786	97.95 99.06 81.41 9.57
Refinement no.1							
Tractor mounted boom spray application outdoors to low crops (maize) Buffer zone: 2-3 (m) (Rimsulfuron, Nicosulfuron); 5 (m) (Mesotrione) Drift reduction technology: no (Rimsulfuron, Nicosulfuron); yes no (Mesotrione) Mesotrione: Refined transfer coefficient [20%]; see section 6.6.4.2. DT_{50}: 3 days (Rimsulfuron), 30 days (Nicosulfuron, Mesotrione) DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days							
Number of applications and application rate		1 x 0.0099 kg a.s./ha 0.0075		1 x 0.0396 kg a.s./ha 0.03		1 x 0.118 kg a.s./ha 0.09	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0006647 0.0005036	0.95 0.72	0.0026589 0.0020144	0.33 0.25	0.0026357 0.0040205	52.71 80.41
	Vapour (75th perc.)	0.0010700	1.53	0.0010700	0.13	0.0010700	21.40
	Deposits (75th perc.)	0.0000801 0.0000607	0.11 0.09	0.0003204 0.0002428	0.04 0.03	0.0001961 0.0002991	3.92 5.98
	Re-entry (75th perc.)	0.0008353 0.0006328	1.19 0.90	0.0033413 0.0025313	0.42 0.32	0.0019913 0.0015188	39.83 30.38
	Sum (mean)	0.0021608 0.0018964	3.09 2.71	0.0054333 0.0043755	0.68 0.55	0.0042667 0.0047353	85.33 94.71
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0001591 0.0001205	0.23 0.17	0.0006362 0.0004820	0.08 0.06	0.0004802 0.0007325	9.60 14.65
	Vapour (75th perc.)	0.0002300	0.33	0.0002300	0.03	0.0002300	4.60
	Deposits (75th perc.)	0.0000337 0.0000256	0.05 0.04	0.0001349 0.0001022	0.02 0.01	0.0000826 0.0001259	1.65 2.52
	Re-entry (75th perc.)	0.0004641 0.0003516	0.66 0.50	0.0018563 0.0014063	0.23 0.18	0.0011063 0.0008438	22.13 16.88
	Sum (mean)	0.0007003 0.0005863	1.00 0.84	0.0021111 0.0016551	0.26 0.21	0.0014246 0.0013794	28.49 27.59
Refinement no.2							
Tractor mounted boom spray application outdoors to low crops (maize) Buffer zone: 2-3 (m) (Rimsulfuron, Nicosulfuron); 5 (m) (Mesotrione) Drift reduction technology: no (Rimsulfuron, Nicosulfuron); yes no (Mesotrione) Mesotrione: Refined transfer coefficient entry into treated crops - 75th perc.: 1400 cm2/h (adult), 420 cm2/h (child). Refined transfer coefficient entry into treated crops - mean:1100 cm2/h (adult), 330 cm2/h (child); see section 6.6.4.2. DT_{50}: 3 days (Rimsulfuron), 30 days (Nicosulfuron, Mesotrione) DFR: 3 µg/cm²/kg a.s./ha							

Interval between treatments: 365 days							
Number of applications and application rate		1 x 0.0099 kg a.s./ha 0.0075		1 x 0.0396 kg a.s./ha 0.03		1 x 0.118 kg a.s./ha 0.09	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0006647 0.0005036	0.95 0.72	0.0026589 0.0020144	0.33 0.25	0.0026357 0.0040205	52.71 80.41
	Vapour (75th perc.)	0.0010700	1.53	0.0010700	0.13	0.0010700	21.40
	Deposits (75th perc.)	0.0000801 0.0000607	0.11 0.09	0.0003204 0.0002428	0.04 0.03	0.0001961 0.0002991	3.92 5.98
	Re-entry (75th perc.)	0.0008353 0.0006328	1.19 0.90	0.0033413 0.0025313	0.42 0.32	0.0018585 0.0014175	37.17 28.35
	Sum (mean)	0.0021608 0.0018964	3.09 2.71	0.0054333 0.0043755	0.68 0.55	0.0041392 0.0046381	82.78 92.76
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0001591 0.0001205	0.23 0.17	0.0006362 0.0004820	0.08 0.06	0.0004802 0.0007325	9.60 14.65
	Vapour (75th perc.)	0.0002300	0.33	0.0002300	0.03	0.0002300	4.60
	Deposits (75th perc.)	0.0000337 0.0000256	0.05 0.04	0.0001349 0.0001022	0.02 0.01	0.0000826 0.0001259	1.65 2.52
	Re-entry (75th perc.)	0.0004641 0.0003516	0.66 0.50	0.0018563 0.0014063	0.23 0.18	0.0010325 0.0007875	20.65 15.75
	Sum (mean)	0.0007003 0.0005863	1.00 0.84	0.0021111 0.0016551	0.26 0.21	0.0013538 0.0013254	27.08 26.51

Conclusion
According to the EFSA AOEM Model, when a 5 m buffer zone is considered, the risk for residents and bystanders can be considered as acceptable after accidental short-term exposure to PRIMARY MX.

Comment:
No unacceptable risk for residents and bystanders was identified when the product is used as intended and a buffer zone of 5 m from residential areas is considered and drift reduction used.

Conclusion
According to the EFSA AOEM Model, there is no risk for residents and bystanders after accidental short-term exposure to PRIMARY MX.

6.6.4.2 Refinements

The Applicant propose to consider different options for resident refinement (entry into treated crops):

Refinement no.1 for the entry into treated crop exposure:
The applicant proposal is to refine the risk by entry into the treated crop by using a refined transfer coefficient due to early growth stage of the crop (BBCH 12-18 max.). The transfer coefficient used by default for entry into crop is 2250 cm^2/h for children and 7500 cm^2/h for adult:

~~Formula[2] and exposure calculation for Dermal Exposure in Cereals:~~
~~Dermal exposure [Cereals] = d_TcEntryCh * 0.25 * d_DFR * d_MAF/1000 * MAX (dermal_abs)~~
~~= 2250 cm²/h * 0.25 h * 0.27 0.354 0.27 µg a.s./cm² * 0.001 * 70 50%~~
~~= mg a.s./day~~
~~= mg a.s./kg bw/day (given a 10 kg child)~~

~~Dermal exposure [Cereals] = d_TcEntryAd * 0.25 * d_DFR * d_MAF/1000 * MAX (dermal_abs)~~
~~= 7500 cm²/h * 0.25 h * 0.27 0.354 0.27 µg a.s./cm² * 0.001 * 70 50%~~
~~= mg a.s./day~~
~~= mg a.s./kg bw/day (given a 60 kg adult)~~

~~Refinements~~
~~The first approach for refinement is to reduce the Transfer Coefficient in Cereals to about 20 % of the child and adult surface area due to early growth stage of the crop (BBCH 12-18 max.):~~
~~Child:~~
~~Dermal exposure [Cereals] = 2250 cm²/h * 20 % * 0.25 h * 0.354 0.27 µg a.s./cm² * 0.001 * 50 %~~
~~= 0.0199125 0.0151875 mg a.s./day~~
~~= 0.0019913 0.0015188 mg a.s./kg bw/day (given a 10 kg child)~~
~~Which is 39.83% 30.38% of AOEL~~

~~Adult:~~
~~Dermal exposure [Cereals] = 7500 cm²/h * 20 % * 0.25 h * 0.354 0.27 µg a.s./cm² * 0.001 * 50 %~~
~~= 0.0663750 0.0506250 mg a.s./day~~
~~= 0.0011063 0.0008438 mg a.s./kg bw/day (given a 60 kg child adult)~~
~~Which is 22.13% 16.88% of AOEL~~

~~The second approach for refinement is to use the calculation of the Grassland. The situation is thought to be quite similar to the cereals with low BBCH. Indeed, this scenario provides nearly the same value as for the first approach:~~
~~Formula and exposure calculation for Dermal Exposure in Grassland:~~

~~Child:~~
~~Dermal exposure [Grassland] = i_AppRate/100 * d_MAF * d_Turf * d_ReTCCh * d_expDurTreatCrop * MAX (dermal_abs)~~
~~= 0.00118 0.0009 kg as/ha * 1.00 * 5 % * 2600 cm²/h * 0.25 h * 50 %~~
~~= 0.019175 0.014625 mg a.s./day~~
~~= 0.0019175 0.0014625mg a.s./kg bw/day (given a 10 kg child)~~
~~Which is 38.35 29.25 % of AOEL~~

~~Adult:~~
~~Dermal exposure [Grassland] = i_AppRate/100 * d_MAF * d_Turf * d_ReTCAd * d_expDurTreatCrop * MAX (dermal_abs)~~
~~= 0.00118 0.0009 kg as/ha * 1.00 * 5 % * 7300 cm²/h * 0.25 h * 50 %~~
~~= 0.0538375 0.0410625 mg a.s./day~~
~~= 0.00089729166 0.000684375 mg a.s./kg bw/day (given a 60 kg adult)~~
~~Which is 17.94 13.69% of AOEL~~

[2] Formulas are taken from the EFSA excel sheet based on EFSA Journal 2014, 12: 3874

Both approaches correspond to: 39.83 30.38% (child) and 38.35 29.25% (child) of the AOEL, 22.13 16.88% (adult) and 17.94 13.69% (adult) of the AOEL, respectively, thus it is concluded that the risk for child residents are lower than estimated when using refined calculation.

Table 6.6 8: Refined estimated resident exposure (longer term exposure)

		Mesotrione	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops (maize) Buffer zone: 10(m) Drift reduction technology: yes DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.118 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0021767	43.53
	Vapour (75th perc.)	0.0010700	21.40
	Deposits (75th perc.)	0.0001108	2.22
	Re entry (75th perc.)	0.0019913	39.83
	Sum (mean)	0.0039557	79.11
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0004114	8.23
	Vapour (75th perc.)	0.0002300	4.60
	Deposits (75th perc.)	0.0000467	0.93
	Re entry (75th perc.)	0.0011063	22.13
	Sum (mean)	0.0013695	27.39

Refinement no.2 for the entry into treated crop exposure:

It is considered that a child re-entering the treated crop will wear clothes covering arms, body and legs. Therefore, a refinement is proposed, for resident exposure during "entry into treated crops" using the TC values for a worker re-entering the field for inspection/irrigation tasks assuming arms body and legs are covered, i.e. 1400 cm²/h (75th percentiles); 1100 cm²/h (mean). Since there are no TC values available for children, a factor of 0.3 is applied to adult TC values, i.e. 420 cm²/h (75th percentiles); 330 cm²/h (mean).

TC child = 420 cm²/h (75th percentiles), 330 cm²/h (mean)
TC adult = 1400 cm²/h (75th percentiles), 1100 cm²/h (mean)

Formula[3] and exposure calculation for Dermal Exposure in Cereals:
Dermal exposure [Cereals] = d_TcEntryCh * 0.25 * d_DFR * d_MAF/1000 * MAX (dermal_abs)

The Applicant proposes refinement estimation of resident exposure for child and adult (entry into treated crops) for maize.

Maize:

[3] Formulas are taken from the EFSA excel sheet based on EFSA Journal 2014, 12: 3874

~~Child:~~
~~Dermal exposure [Cereals] = 420 cm²/h * 0.25 h * 0.354 0.27 µg a.s./cm² * 0.001 * 50 %~~
~~= 0.0185849 0.0141749 mg a.s./day~~
~~= 0.0018585 0.0014175 mg a.s./kg bw/day (given a 10 kg child)~~
~~Which is 37.17 28.35% of AOEL~~

~~Adult:~~
~~Dermal exposure [Cereals] = 1400 cm²/h * 0.25 h * 0.354 0.27 µg a.s./cm² * 0.001 * 50 %~~
~~= 0.0619498 0.0472498 mg a.s./day~~
~~= 0.0010325 0.0007875 mg a.s./kg bw/day (given a 60 kg adult)~~
~~Which is 20.65 15.75% of AOEL~~

~~It can be concluded that there is no undue risk for resident child and adult.~~

~~In case any of refinements for entry into treated crops for residents, presented above, are not acceptable by expert, applicant proposes the following risk mitigation measure:~~

~~Re-entry into treated fields should not be allowed to the general public.~~

6.6.4.3 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, Nicosulfuron and Mesotrione 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 three active substances.

6.6.5.1 Exposure assessment of Rimsulfuron, Nicosulfuron and Mesotrion in SHA 4307 A / PRIMARY MX

It is not necessary to estimate the combined exposure considering the active substances Rimsulfuron, Nicosulfuron and Mesotrion are not classified as CMRs (carcinogenic, mutagenic or toxic for reproduction) and not having effects on the same target organ.

Even not required, the Applicant presents exposure assessment of combined exposure for Rimsulfuron, Nicosulfuron and Mesotrion as the worst and unrealistic case scenario.

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 ~~+ gloves during M/L and A~~	Rimsulfuron	~~0.0350~~ 0.029 ~~0.09~~
	Nicosulfuron	~~0.0089~~ 0.0071
	Mesotrione	~~0.53~~ 0.46 ~~0.35~~
	Cumulative risk operators (HI)	**~~0.57~~ 0.50 ~~0.39~~ ~~0.45~~**
Workers – Work wear (arms, body and legs covered)	Rimsulfuron	~~0.0099~~ 0.0075
	Nicosulfuron	~~0.0035~~ 0.0026
	Mesotrione	~~0.9710~~ 1.26 ~~0.0731~~
	Cumulative risk workers (HI)	**~~0.98~~ 1.27 ~~0.08~~**
Refinement no.1 Resident - child	Rimsulfuron	
	Drift	~~0.0095~~ 0.0072
	Vapour	0.0153
	Deposits	~~0.0011~~ 0.0009
	Re-entry	~~0.0119~~ 0.0090
	Sum of all pathways	~~0.0309~~ 0.0271
	Nicosulfuron	
	Drift	~~0.0033~~ 0.0025
	Vapour	0.0013
	Deposits	~~0.0004~~ 0.0003
	Re-entry	~~0.0042~~ 0.0032
	Sum of all pathways	~~0.0068~~ 0.0055
	Mesotrione	
	Drift	~~0.4353~~ ~~0.5271~~ 0.8041
	Vapour	0.2140
	Deposits	~~0.0222~~ ~~0.0392~~ 0.0598
	Re-entry	~~0.3983~~ 0.3038
	Sum of all pathways	~~0.7911~~ ~~0.8533~~ 0.9471
	Cumulative risk resident – child (HI)	
	Drift	~~0.4481~~ ~~0.54~~ 0.81
	Vapour	0.23~~06~~
	Deposits	~~0.0237~~ ~~0.04~~ 0.06
	Re-entry	~~0.4144~~ 0.32
	Sum of all pathways	**~~0.83~~ ~~0.89~~ 0.98**
Refinement no.1 Resident - adult	Rimsulfuron	
	Drift	~~0.0023~~ 0.0017
	Vapour	0.0033
	Deposits	~~0.0005~~ 0.0004

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Re-entry	~~0.0066~~ 0.0050
	Sum of all pathways	~~0.01~~ 0.0084
	Nicosulfuron	
	Drift	~~0.0008~~ 0.0006
	Vapour	0.0003
	Deposits	~~0.0002~~ 0.0001
	Re-entry	~~0.0023~~ 0.0018
	Sum of all pathways	~~0.0026~~ 0.0021
	Mesotrione	
	Drift	~~0.0823~~ ~~0.0960~~ 0.1465
	Vapour	0.0460
	Deposits	~~0.0093~~ ~~0.0165~~ 0.0252
	Re-entry	~~0.2213~~ 0.1688
	Sum of all pathways	~~0.2739~~ ~~0.2849~~ 0.2759
	Cumulative risk resident – adult (HI)	
	Drift	~~0.0854~~ ~~0.1~~ 0.15
	Vapour	~~0.0496~~ 0.05
	Deposits	~~0.01~~ ~~0.02~~ 0.03
	Re-entry	~~0.2302~~ 0.18
	Sum of all pathways	~~**0.29**~~ ~~**0.30**~~ **0.29**
Refinement no.2 Resident - child	Rimsulfuron	
	Drift	~~0.0095~~ 0.0072
	Vapour	0.0153
	Deposits	~~0.0011~~ 0.0009
	Re-entry	~~0.0119~~ 0.0090
	Sum of all pathways	~~0.0309~~ 0.0271
	Nicosulfuron	
	Drift	~~0.0033~~ 0.0025
	Vapour	0.0013
	Deposits	~~0.0004~~ 0.0003
	Re-entry	~~0.0042~~ 0.0032
	Sum of all pathways	~~0.0068~~ 0.0055
	Mesotrione	
	Drift	~~0.5271~~ 0.8041
	Vapour	0.2140
	Deposits	~~0.0392~~ 0.0598
	Re-entry	~~0.3717~~ 0.2835

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Sum of all pathways	~~0.8278~~ 0.9276
	Cumulative risk resident – child (HI)	
	Drift	**~~0.54~~ 0.81**
	Vapour	**0.23**
	Deposits	**~~0.04~~ 0.06**
	Re-entry	**~~0.39~~ 0.30**
	Sum of all pathways	**~~0.87~~ 0.96**
Refinement no.2 Resident - adult	Rimsulfuron	
	Drift	~~0.0023~~ 0.0017
	Vapour	0.0033
	Deposits	~~0.0005~~ 0.0004
	Re-entry	~~0.0066~~ 0.0050
	Sum of all pathways	~~0.01~~ 0.0084
	Nicosulfuron	
	Drift	~~0.0008~~ 0.0006
	Vapour	0.0003
	Deposits	~~0.0002~~ 0.0001
	Re-entry	~~0.0023~~ 0.0018
	Sum of all pathways	~~0.0026~~ 0.0021
	Mesotrione	
	Drift	~~0.0960~~ 0.1465
	Vapour	0.0460
	Deposits	~~0.0165~~ 0.0252
	Re-entry	~~0.2065~~ 0.1575
	Sum of all pathways	~~0.2708~~ 0.2651
	Cumulative risk resident – adult (HI)	
	Drift	**~~0.1~~ 0.15**
	Vapour	**0.05**
	Deposits	**~~0.02~~ 0.03**
	Re-entry	**~~0.22~~ 0.16**
	Sum of all pathways	**~~0.28~~ 0.28**
Resident – child (Buffer zone: 2-3 (m), drift reduction technology: no)	Rimsulfuron	
	Drift	~~0.0095~~ 0.0072
	Vapour	0.0153
	Deposits	~~0.0011~~ 0.0009 0.0008
	Re-entry	~~0.0119~~ 0.0090

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Sum of all pathways	~~0.0309~~ 0.0271 0.0271
	Nicosulfuron	
	Drift	~~0.0033~~ 0.0025
	Vapour	0.0013
	Deposits	~~0.0004~~ 0.0003
	Re-entry	~~0.0042~~ 0.0032
	Sum of all pathways	~~0.0068~~ 0.0055
	Mesotrione	
	Drift	0.0720
	Vapour	0.2140
	Deposits	0.0222 0.0149
	Re-entry	0.0881
	Sum of all pathways	0.3406 0.3352
	Cumulative risk resident – child (HI)	
	Drift	**0.08**
	Vapour	**0.23**
	Deposits	**0.02** **0.02**
	Re-entry	**0.10**
	Sum of all pathways	**0.37** **0.37**
Resident – adult (Buffer zone: 2-3 (m), drift reduction technology: no)	Rimsulfuron	
	Drift	~~0.0023~~ 0.0017
	Vapour	0.0033
	Deposits	~~0.0005~~ 0.0004
	Re-entry	~~0.0066~~ 0.0050
	Sum of all pathways	~~0.01~~ 0.0084
	Nicosulfuron	
	Drift	~~0.0008~~ 0.0006
	Vapour	0.0003
	Deposits	~~0.0002~~ 0.0001
	Re-entry	~~0.0023~~ 0.0018
	Sum of all pathways	~~0.0026~~ 0.0021
	Mesotrione	
	Drift	0.0169
	Vapour	0.0460
	Deposits	0.0036
	Re-entry	0.0489

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Sum of all pathways	0.0957
	Cumulative risk resident – adult (HI)	
	Drift	**0.02**
	Vapour	**0.05**
	Deposits	**0.004**
	Re-entry	**0.06**
	Sum of all pathways	**0.11**

The Hazard Index is < 1. Thus, combined exposure to all active substances in SHA 4307 A / PRIMARY MX is not expected to present a risk for operators, workers, residents and by-standers. 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
KCP 7.3	Yogeesha S.	2021	*In vitro* percutaneous dermal absorption study of Mesotrione, formulated as Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, through human skin Eurofins Advinus Limited report No.: G18510 GLP, Unpublished	N	SHARDA Cropchem Limited

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

Not relevant.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**According calculation method the acute oral toxicity of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was estimated to be > 2000 mg/kg.** **Therefore, according to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is not classified.** **No signal word or hazard statement is required for this hazard**

The classification of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was performed by calculation. The assessment of all acute toxicological properties of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is derived from the classification of the active compounds 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
Mesotrione Technical (104206-82-8)	**36.55**	> 5000 mg/kg	> 2000 mg/kg	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 1	**xxx**	500 mg/kg[2)] H302	> 3000 mg/kg	1.5 mg/l[2)], H332	Not Irritating[1)]	Eye Irrit. 2, H319	Not sensitising[1)]
Coformulant 2	**xxx**	500 mg/kg[2)] H302	> 2000 mg/kg	*	Skin Irrit. 2, H315	Eye Dam. 1, H318	Not sensitising[1)]
Coformulant 3	**xxx**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Skin Sens. 1 H317
Coformulant 4	xxx	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 5	xxx	500 mg/kg[2)] H302	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Skin Sens. 1B H317
Coformulant 6	**xxx**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Skin Irrit. 2, H315	Eye Irrit. 2, H319	Not sensitising[1)]
Coformulant 7	xxx	> 5000 mg/kg	> 2000 mg/kg[1)]	*	Skin Irrit. 2, H315	Eye Irrit. 2, H319	Not sensitising[1)]
Coformulant 8	**xxx**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]

Coformulant 9	**xxx**	10000 mg/kg	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 10	**xxx**	8394 mg/kg	> 2100 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 11	**xxx**	> 5000 mg/kg	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 12	**xxx**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Nicosulfuron technical (111991-09-4)	**12.90**	> 5000 mg/kg	> 2000 mg/kg	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 13	**xxx**	> 2000 mg/kg	> 2000 mg/kg [1)]	*	Skin Irrit. 2, H315	Eye Irrit. 2, H319	Not sensitising[1)]
Coformulant 14	xxx	> 5000 mg/kg	> 2000 mg/kg [1)]	*	Skin Irrit. 2, H315	Eye Irrit. 2, H319	Not sensitising[1)]
Coformulant 15	**xxx**	500 mg/kg[2)] H302	1100 mg/kg [2)] H312	*	Skin Irrit. 2, H315	Eye Dam. 1, H318	Not sensitising[1)]
Coformulant 16	**xxx**	29700 mg/kg	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 17	**xxx**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Rimsulfuron technical (122931-48-0)	**3.06**	5000 mg/kg	> 2000 mg/kg	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 18	**xxx**	2000 – 5000 mg/kg	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 19	**xxx**	> 2000 mg/kg [1)]	> 2000 mg/kg [1)]	*	Not Irritating[1)]	Eye Irrit. 2, H319	Not sensitising[1)]
Coformulant 20	**xxx**	500 mg/kg[2)] H302	1100 mg/kg [2)], H312	*	Skin Irrit. 2, H315	Eye Dam. 1, H318	Not sensitising[1)]
Coformulant 21	**xxx**	29700 mg/kg	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 22	**xxx**	17000 mg/kg	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 23	**xxx**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 24	**xxx**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[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; Inhalation: ATE = 1.5 mg/l is used for the calculation for co-formulant classified as Acute Tox. 4; H332.

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

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

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.

The acute oral toxicity classification for Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was calculated:

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

$$ATE_{mix} = \frac{100}{\frac{2.16}{500} + \frac{0.16}{500} + \frac{0.128}{500} + \frac{0.32}{500} + \frac{0.06}{500}} = 17680.34\ mg/kg\ bw$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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 3% + Nicosulfuron 12% + Mesotrione 36% WG was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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:	**According to the calculation method the acute dermal toxicity of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was estimated to be > 2000 mg/kg.** **Therefore, according to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is not classified.** **No signal word or hazard statement is required for this hazard.**

The acute dermal toxicity classification for Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was calculated:

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

$$ATE_{mix} = \frac{100}{\frac{0.32}{1100} + \frac{0.06}{1100}} = 290\,697.67\,mg/kg\,bw$$

Conclusion
The acute dermal toxicity of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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:	**TAccording to the calculation method the acute inhalation toxicity of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was estimated to be > 5 mg/l.** **Therefore, according to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is not classified.** **No signal word or hazard statement is required for this hazard**

The acute inhalation toxicity classification for Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was calculated:

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

$$ATE_{mix} = \frac{100}{\frac{2.16}{1.5}} = 69.44\ mg/l$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute inhalation toxicity of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion
The acute inhalation toxicity of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was estimated to be > 5 mg/l. Therefore, according to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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:	**According to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is not classified.** **No signal word or hazard statement is required for this hazard.**

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.

Conclusion

According to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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:	**According to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is not classified.** **No signal word or hazard statement is required for this hazard**.

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.

Conclusion

According to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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 of zRMS:	**According to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is not classified.** **No signal word or hazard statement is required for this hazard.**

The product contains < 1% of co-formulants considered as skin sensitiser (classified as: Skin Sens. 1; H317). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

Conclusion

According to the Regulation EC No. 1272/2008, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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).

Considering < 5 % of a.s. Rimsulfuron in formulation, dermal absorption value of 50% (concentrate) and 50% (diluted) are used for exposure calculations.

A 2.10.1 Study 1 – Mesotrione in SHA 4307 A / PRIMARY MX

Comparative dermal absorption, in vitro using rat and human skin

Comments of zRMS:	

Reference	KCP 7.3
Report	*In vitro* percutaneous dermal absorption study of Mesotrione, formulated as Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, through human skin, Yogeesha S., 2021, report No.: G18510
Guideline(s)	Yes, OECD Guideline No. 428 “Skin Absortion: in vitro Method” April 2004, OECD Guideline notes on dermal absorption No. 156, ENV/JM/MONO (2011) 36, OECD Guideline for the conduct of skin absorption studies, OECD series No. 28, 05-Mar-2004 (ENV/JM/MONO (2004)2), Guideline on dermal absorption EFSA Journal 2017;15(6):4873
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material	Name (Lot/Batch No.)	^{14}C-Mesotrione
	Test preparation	Radioformulation
	Specific activity	5.078 MBq/mg
	Radiochemical purity	98.84%
Product	Name (Lot/Batch No.)	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG (Batch no.: SCL-78944)
	Company code	S020-264
	Concentration a.s.	Mesotrione 36%
	Formulation type	Water dispersible granule (WG)
Blank product	Name (Lot/Batch No.)	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Blank Formulation (Batch no.: SCL-44756)
	Concentration a.s.	[g/L or g/kg]

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.8 ml/h
	Exposed skin area	0.64 cm²
Membrane	Skin type	isolated epidermis
	Skin thickness range	0.2-0.4 mm
	Skin donors age	35, 38, 34, 35 years
	Skin donors sex	f, f, f, f
	Location	abdomen
	Source	ZenBio Laboratory, Vendor - Life Technologies India Pvt Ltd.
	Integrity test	yes
Receptor	Receptor medium	Scintillation liquid (Ultima Gold™)
	Solubility in receptor medium	n
Sample Time	Exposure time	8 h
	Observation time	16 h post exposure
Sampling	Sample intervals	At 0-1h, 1-2h, followed by 2h intervals until 24h after application. Samping duration: 24 h.
Washing		At 8 h using water and a mild soap solution (3% Dove)
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	n
Remarks:		

Tested doses	Concentrate	Spray dilution 1
Target concentration	360 g /kg	0.3 g. L^{-1}
Area dose [µg/cm²]	1805.72 ± 4.78	3.18 ± 0.042
Specific activity [MBq.mg^{-1} / MBq.mL^{-1}]	0.00735	1.602
No. of donors	8	8

Results and discussions

Table A 1: In-vitro dermal penetration of Mesotrione formulated as SHA 4307 A / PRIMARY MX through human skin - Recovery data

Dose group	High dose (Formulation concentrate)	Low dose (Spray dilution 1:1200)
Target concentration	360 g/kg	0.3 g. L^{-1}

Mean actual applied dose [µg/cm²]	1805.72 ± 4.78		3.18 ± 0.042	
	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
Skin wash	97.70	1.83	95.35	0.95
Donor chamber wash	0.11	0.18	0.39	0.84
Dose associated to skin				
Tape strips: 1st sample, strips 1 + 2	0.11	0.04	0.38	0.06
Tape strips: 2nd sample; strips 3 - n	0.13	0.04	0.46	0.08
Stripped skin	0.06	0.03	1.84	0.17
Absorbed dose	0.32	0.12	2.36	0.11
Receptor fluid	0.24	0.10	0.50	0.22
Receptor chamber wash	0.02	0.01	0.02	0.01
Total recovery[1]	98.37	1.76	98.95	1.40
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	No [66.47% ±3.41]		No [64.77% ±3.64]	
If no: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2) [2]	0.45	0.11	2.82	0.14
If yes: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding all tape strips)	N/A	N/A	N/A	N/A
Absorption estimate normalised[3]	0.45 ± 0.84 × 0.11		2.82 ± 0.84 × 0.14	
Relevant absorption estimate[4]	0.45 ± 0.09		2.82 ± 0.12	
Absorption estimates used for risk assessment[5]	**0.54**		**2.9**	

[1] Values may not calculate exactly due to rounding of figures

[2] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

[3] According to the EFSA Guidance on Dermal Absorption, cells with insufficient recovery (< 95%) can be corrected by normalisation of absorption estimate to 100% recovery; explanation should be included.

[4] In accordance with the EFSA Guidance on Dermal Absorption, one standard deviation was added to the mean% dermal penetration in cases where the standard deviation was ≥ 25% of the mean value.

[5] Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

Conclusion/endpoint: 0.54% of dose for undiluted Mesotrione, formulated as Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG (concentrate)

2.9% of dose for actual spray strength used in the field dilution

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 2: Input parameters considered for the estimation of operator exposure

Formulation type	WG		Crop type	Maize
Application rate (AR)	~~0.0099~~ 0.0075	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	~~10~~ 50	% (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 3: 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	~~76.2918103~~ 61.6107493 308.0537466	µg/person	~~76.2918103~~ 61.6107493 308.0537466	µg/person
Systemic exposure	**~~1.2715302~~ 1.0268458 5.1342291**	**mg/kg bw/d**	**~~1.2715302~~ 1.0268458 5.1342291**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	~~75.3388233~~ 61.9817450 309.9087250	µg/person	~~0.9970506~~ 0.7795502 3.8977511	µg/person
Systemic exposure	**~~1.2556471~~ 1.0330291 5.1651454**	**mg/kg bw/d**	**~~0.0166175~~ 0.0129925 0.0649625**	**mg/kg bw/d**
Head			None	
Specific exposure value	~~0.3214217~~ 0.2435013 1.2175065	µg/person	~~0.3214217~~ 0.2435013 1.2175065	µg/person
Systemic exposure	**~~0.0053570~~ 0.0040584 0.0202918**	**mg/kg bw/d**	**~~0.0053570~~ 0.0040584 0.0202918**	**mg/kg bw/d**
Inhalation			None	
Specific exposure value	~~30.2903650~~ 27.8882784 27.8882784	µg/person	~~30.2903650~~ 27.8882784 27.8882784	µg/person
Systemic exposure	**~~0.5048394~~ 0.4648046**	**mg/kg bw/d**	**~~0.5048394~~ 0.4648046**	**mg/kg bw/d**

	~~0.4648046~~		**~~0.4648046~~**	
Application				
Hands			None	
Specific exposure value	~~36.7100365~~ 27.8106337 27.8106337	µg/person	~~36.7100365~~ 27.8106337 27.8106337	µg/person
Systemic exposure	**~~0.6118339~~** **0.4635106** **0.4635106**	**mg/kg bw/d**	**~~0.6118339~~** **0.4635106** **0.4635106**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	~~20.5258362~~ 15.5498759 15.5498759	µg/person	~~0.5630583~~ 0.4265593 0.4265593	µg/person
Systemic exposure	**~~0.3420973~~** **0.2591646** **0.2591646**	**mg/kg bw/d**	**~~0.0093843~~** **0.0071093** **0.0071093**	**mg/kg bw/d**
Head			None	
Specific exposure value	~~0.9701213~~ 0.7349404 0.7349404	µg/person	~~0.9701213~~ 0.7349404 0.7349404	µg/person
Systemic exposure	**~~0.0161687~~** **0.0122490** **0.0122490**	**mg/kg bw/d**	**~~0.0161687~~** **0.0122490** **0.0122490**	**mg/kg bw/d**
Inhalation			None	
Specific exposure value	~~0.7280959~~ 0.6335502 0.6335502	µg/person	~~0.7280959~~ 0.6335502 0.6335502	µg/person
Systemic exposure	**~~0.0121349~~** **0.0105592** **0.0105592**	**mg/kg bw/d**	**~~0.0121349~~** **0.0105592** **0.0105592**	**mg/kg bw/d**
Total				
Total systemic exposure	**~~0.0040196~~** **0.0032742** **0.0115300**	**mg/kg bw/d**	**~~0.0024479~~** **0.0020021** **0.0061777**	**mg/kg bw/d**
% of AOEL	**~~5.74~~** **4.68** **16.47**	**%**	**~~3.50~~** **2.86** **8.83**	**%**

A 3.1.2 Calculations for Nicosulfuron

Table A 4: Input parameters considered for the estimation of operator exposure

Formulation type	WG		Crop type	Maize
Application rate (AR)	~~0.0396~~ 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 5: 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	~~221.8001132~~ 179.1184548	µg/person	~~221.8001132~~ 179.1184548	µg/person
Systemic exposure	**~~3.6966686~~ 2.9853076**	**mg/kg bw/d**	**~~3.6966686~~ 2.9853076**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	~~199.6295658~~ 164.2365557	µg/person	~~3.4069450~~ 2.6637411	µg/person
Systemic exposure	**~~3.3271594~~ 2.7372759**	**mg/kg bw/d**	**~~0.0567824~~ 0.0443957**	**mg/kg bw/d**
Head			None	
Specific exposure value	~~1.2856868~~ 0.9740052	µg/person	~~1.2856868~~ 0.9740052	µg/person
Systemic exposure	**~~0.0214281~~ 0.0162334**	**mg/kg bw/d**	**~~0.0214281~~ 0.0162334**	**mg/kg bw/d**
Inhalation			None	
Specific exposure value	~~45.7591091~~ 42.1303201	µg/person	~~45.7591091~~ 42.1303201	µg/person
Systemic exposure	**~~0.7626518~~ 0.7021720**	**mg/kg bw/d**	**~~0.7626518~~ 0.7021720**	**mg/kg bw/d**
Application				
Hands			None	
Specific exposure value	~~146.8401461~~ 111.2425349	µg/person	~~146.8401461~~ 111.2425349	µg/person
Systemic exposure	**~~2.4473358~~ 1.8540422**	**mg/kg bw/d**	**~~2.4473358~~ 1.8540422**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	~~82.1033447~~ 62.1995035	µg/person	~~2.2522333~~ 1.7062373	µg/person
Systemic exposure	**~~1.3683891~~ 1.0366584**	**mg/kg bw/d**	**~~0.0375372~~ 0.0284373**	**mg/kg bw/d**
Head			None	
Specific exposure value	~~3.8804854~~ 2.9397616	µg/person	~~3.8804854~~ 2.9397616	µg/person
Systemic exposure	**~~0.0646748~~ 0.0489960**	**mg/kg bw/d**	**~~0.0646748~~ 0.0489960**	**mg/kg bw/d**
Inhalation			None	
Specific exposure value	~~1.4582119~~ 1.2688582	µg/person	~~1.4582119~~ 1.2688582	µg/person
Systemic exposure	**~~0.0243035~~ 0.0211476**	**mg/kg bw/d**	**~~0.0243035~~ 0.0211476**	**mg/kg bw/d**
Total				
Total systemic exposure	**~~0.0117126~~ 0.0094018**	**mg/kg bw/d**	**~~0.0071114~~ 0.0057007**	**mg/kg bw/d**
% of AOEL	**~~1.46~~ 1.18**	**%**	**~~0.89~~ 0.71**	**%**

A 3.1.3 Calculations for Mesotrione

Table A 6: Input parameters considered for the estimation of operator exposure

Formulation type	WG		Crop type	Maize
Application rate (AR)	~~0.118~~ 0.09	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	~~10~~ 0.54	% (concentr.)	Indoor/outdoor	Outdoor
	~~50~~ 2.9	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.005	mg/kg bw/d	Water soluble bag	No

Table A 7: Estimation of longer term operator exposure towards Mesotrione according to EFSA guidance

	Potential		**With work wear + PPE/RPE**	
Mixing and loading				
Hands			~~Protective gloves~~	
Specific exposure value	~~514.0495746~~ 417.2944316 22.5338993	µg/person	~~5.2494301~~ 4.4009148 22.5338993	µg/person
Systemic exposure	**~~8.5674929~~** **6.9549072** **0.3755650**	**mg/kg bw/d**	**~~0.0874905~~** **0.0733486** **0.3755650**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	~~430.0757987~~ 355.5106966 19.1975776	µg/person	~~8.9674734~~ 7.0533913 0.3808831	µg/person
Systemic exposure	**~~7.1679300~~** **5.9251783** **0.3199596**	**mg/kg bw/d**	**~~0.1494579~~** **0.1175565** **0.0063481**	**mg/kg bw/d**
Head			None	
Specific exposure value	~~3.8310870~~ 2.9220155 0.1577888	µg/person	~~3.8310870~~ 2.9220155 0.1577888	µg/person
Systemic exposure	**~~0.0638514~~** **0.0487003** **0.0026298**	**mg/kg bw/d**	**~~0.0638514~~** **0.0487003** **0.0026298**	**mg/kg bw/d**
Inhalation			None	
Specific exposure value	~~63.3279688~~ 58.4232946 58.4232946	µg/person	~~63.3279688~~ 58.4232946 58.4232946	µg/person
Systemic exposure	**~~1.0554661~~** **0.9737216** **0.9737216**	**mg/kg bw/d**	**~~1.0554661~~** **0.9737216** **0.9737216**	**mg/kg bw/d**
Application				
Hands			Protective gloves	
Specific exposure value	~~437.5539707~~ 333.7276048 19.3562011	µg/person	~~55.5522514~~ 47.9533234 19.3562011	µg/person
Systemic exposure	**~~7.2925662~~** **5.5621267** **0.3226034**	**mg/kg bw/d**	**~~0.9258709~~** **0.7992221** **0.3226034**	**mg/kg bw/d**

Body			Work wear	
Specific exposure value	~~244.6513806~~ 186.5985106 10.8227136	µg/person	~~6.7112002~~ 5.1187120 0.2968853	µg/person
Systemic exposure	**~~4.0775230~~** **3.1099752** **0.1803786**	**mg/kg bw/d**	**~~0.1118533~~** **0.0853119** **0.0049481**	**mg/kg bw/d**
Head			None	
Specific exposure value	~~11.5630624~~ 8.8192849 0.5115185	µg/person	~~11.5630624~~ 8.8192849 0.5115185	µg/person
Systemic exposure	**~~0.1927177~~** **0.1469881** **0.0085253**	**mg/kg bw/d**	**~~0.1927177~~** **0.1469881** **0.0085253**	**mg/kg bw/d**
Inhalation			None	
Specific exposure value	~~2.5199286~~ 2.2001427 2.2001427	µg/person	~~2.5199286~~ 2.2001427 2.2001427	µg/person
Systemic exposure	**~~0.0419988~~** **0.0366690** **0.0366690**	**mg/kg bw/d**	**~~0.0419988~~** **0.0366690** **0.0366690**	**mg/kg bw/d**
Total				
Total systemic exposure	**~~0.0284595~~** **0.0227583** **0.0022201**	**mg/kg bw/d**	**~~0.0026287~~** **0.0022815** **0.0017310**	**mg/kg bw/d**
% of AOEL	**~~569.19~~** **455.17** **44.40**	**%**	**~~52.57~~** **45.63** **34.62**	**%**

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Rimsulfuron

Table A 8: Input parameters considered for the estimation of worker exposure

Intended use(s)	Maize, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm²/kg a.s./ha
Application rate (AR)	~~0.0099~~ 0.0075	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	~~3~~ 30	days	TC dermal (potential)	12500	cm²/h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm²/h
AOEL	0.07	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}

Table A 9: 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			

	Potential		With work wear		With work wear and gloves	
Systemic exposure	~~0.0061875~~ 0.0046875	**mg/kg bw/d**	~~**0.0006930**~~ **0.0005250**	**mg/kg bw/d**	-	**mg/kg bw/d**
% of AOEL	~~**8.84**~~ **6.70**	**%**	~~**0.99**~~ **0.75**	**%**	-	**%**

A 3.2.2 Calculations for Nicosulfuron

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

Intended use(s)	Maize, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm²/kg a.s./ha
Application rate (AR)	~~0.0396~~ 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	cm²/h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm²/h
AOEL	0.8	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}

Table A 11: 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	~~0.0247500~~ 0.0187500	**mg/kg bw/d**	~~**0.0027720**~~ **0.0021000**	**mg/kg bw/d**	-	**mg/kg bw/d**
% of AOEL	~~**3.09**~~ **2.34**	**%**	~~**0.35**~~ **0.26**	**%**	-	**%**

A 3.2.3 Calculations for Mesotrione

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

Intended use(s)	Maize, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm²/kg a.s./ha
Application rate (AR)	~~0.118~~ 0.09	kg a.s./ha	Dermal absorption (DA)	~~50~~ 2.9	% (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	cm²/h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm²/h
AOEL	0.005	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}

Table A 13: Estimation of longer term worker exposure towards Mesotrione 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			

	Potential		With work wear		With work wear and gloves	
Systemic exposure	0.0737500 0.0562500 0.0032625	**mg/kg bw/d**	**0.0082600** **0.0063000** **0.0003654**	**mg/kg bw/d**	-	**mg/kg bw/d**
% of AOEL	**1475.00** **1125.00** **65.25**	**%**	**165.20** **126.00** **7.31**	**%**	-	**%**

Table A 14: Input parameters considered for the estimation of worker exposure for re-entry period of 23 days

Intended use(s)	Maize, outdoor		Dislodgeable foliar residue (DFR)	1.7633	µg/cm²/kg a.s./ha
Application rate (AR)	0.118	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	cm²/h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm²/h
AOEL	0.005	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}

Table A 15: Estimation of longer term worker exposure towards Mesotrione according to EFSA guidance for re-entry period of 23 days

	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	0.0433478	**mg/kg bw/d**	**0.0048550**	**mg/kg bw/d**	-	**mg/kg bw/d**
% of AOEL	**866.96**	**%**	**97.10**	**%**	-	**%**

A 3.3 Resident exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Rimsulfuron

Table A 16: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Maize, spraying		Drift reduction (DR)		%
Application rate (AR)	0.0099 0.0075	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) - 75th 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	3 30	days	Exposure duration inhal. (H_I)	24	h
Multiple application	1.0		Exposure duration entry into	0.25	h

factor (MAF)			treated crops (H_E)		
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~~ 3	µg/cm^2/kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	~~100~~ 70	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.07	mg/kg bw/d	Surface Area of Hands (SA)	20	cm^2
Spray drift dermal (SD) - 75th 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) - 75th 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 - 75th 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 17: Estimation of longer term resident exposure towards Rimsulfuron according to EFSA guidance

Adult			**Child**		
Spray drift (75th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	**~~0.0001591~~ 0.0001205**	**mg/kg bw/d**	**Systemic exposure**	**~~0.0006647~~ 0.0005036**	**mg/kg bw/d**
% of AOEL:	**~~0.23~~ 0.17**	**%**	**% of AOEL:**	**~~0.95~~ 0.72**	**%**
Vapour (75th 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 (75th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	**~~0.0000337~~ 0.0000256**	**mg/kg bw/d**	**Systemic exposure**	**~~0.0000721~~ 0.0000546**	**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	**~~0.0000053~~ 0.0000040 0.0000028**	**mg/kg bw/d**

Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
			Systemic exposure	~~**0.0000028**~~ **0.0000021** **0.0000015**	**mg/kg bw/d**
Total					
Systemic exposure	~~**0.0000337**~~ **0.0000256**	**mg/kg bw/d**	**Systemic exposure**	~~**0.0000801**~~ **0.0000607** **0.0000589**	**mg/kg bw/d**
% of AOEL:	~~**0.05**~~ **0.04**	**%**	**% of AOEL:**	~~**0.11**~~ **0.09** **0.08**	**%**
Entry into treated crops (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	~~**0.0004641**~~ **0.0003516**	**mg/kg bw/d**	**Systemic exposure**	~~**0.0008353**~~ **0.0006328**	**mg/kg bw/d**
Hand to mouth					
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**
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	~~**0.0004641**~~ **0.0003516**	**mg/kg bw/d**	**Systemic exposure**	~~**0.0008353**~~ **0.0006328**	**mg/kg bw/d**
% of AOEL:	~~**0.66**~~ **0.50**	**%**	**% of AOEL:**	~~**1.19**~~ **0.90**	**%**
All pathways (mean)					
Systemic exposure		~~**0.0007003**~~ **0.0005863**	**mg/kg bw/d**	**Systemic exposure**	~~**0.0021608**~~ **0.0018964** **0.0018950** **mg/kg bw/d**
% of AOEL:	~~**1.00**~~ **0.84**	**%**	**% of AOEL:**	~~**3.09**~~ **2.71** **2.71**	**%**

A 3.3.2 Calculations for Nicosulfuron

Table A 18: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Maize, spraying		Drift reduction (DR)		%
Application rate (AR)	~~0.0396~~ 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) - 75th 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~~ 3	µg/cm^2/kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	~~100~~ 40	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.8	mg/kg bw/d	Surface Area of Hands (SA)	20	cm^2
Spray drift dermal (SD) - 75th 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) - 75th 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 - 75th 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 19: Estimation of longer term resident exposure towards Nicosulfuron according to EFSA guidance

Adult			**Child**		
Spray drift (75th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	**~~0.0006362~~ 0.0004820**	**mg/kg bw/d**	**Systemic exposure**	**~~0.0026589~~ 0.0020144**	**mg/kg bw/d**
% of AOEL:	**~~0.08~~ 0.06**	**%**	**% of AOEL:**	**~~0.33~~ 0.25**	**%**
Vapour (75th 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 (75th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	**~~0.0001349~~ 0.0001022**	**mg/kg bw/d**	**Systemic exposure**	**~~0.0002883~~ 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	~~**0.0000211**~~ **0.0000160** **0.0000064**	**mg/kg bw/d**
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
			Systemic exposure	~~**0.0000111**~~ **0.0000084** **0.0000034**	**mg/kg bw/d**
Total					
Systemic exposure	~~**0.0001349**~~ **0.0001022**	**mg/kg bw/d**	**Systemic exposure**	~~**0.0003204**~~ **0.0002428** **0.0002281**	**mg/kg bw/d**
% of AOEL:	~~**0.02**~~ **0.01**	**%**	**% of AOEL:**	~~**0.04**~~ **0.03** **0.03**	**%**
Entry into treated crops (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	~~**0.0018563**~~ **0.0014063**	**mg/kg bw/d**	**Systemic exposure**	~~**0.0033413**~~ **0.0025313**	**mg/kg bw/d**
Hand to mouth					
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**
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	~~**0.0018563**~~ **0.0014063**	**mg/kg bw/d**	**Systemic exposure**	~~**0.0033413**~~ **0.0025313**	**mg/kg bw/d**
% of AOEL:	~~**0.23**~~ **0.18**	**%**	**% of AOEL:**	~~**0.42**~~ **0.32**	**%**
All pathways (mean)					
Systemic exposure			~~**0.0021111**~~ **0.0016551**	**mg/kg bw/d**	**Systemic exposure** ~~**0.0054333**~~ **0.0043755** **0.0043648** **mg/kg bw/d**
% of AOEL:	~~**0.26**~~ **0.21**	**%**	**% of AOEL:**	~~**0.68**~~ **0.55** **0.55**	**%**

A 3.3.3 Calculations for Mesotrione

Table A 20: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Maize, spraying		Drift reduction (DR)		%
Application rate (AR)	~~0.118~~ 0.09	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) - 75th perc.	~~1.30~~ 2.30 5.60	%
Buffer strip	~~10~~ 5 ~~2-3~~	m	Drift on surface (D) - mean	~~1.00~~ 1.80 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~~ 2.9	% ('worst case')	Dislodgeable foliar residue (DFR)	~~1~~ 3	µg/cm^2/kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	~~100~~ 50	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.005	mg/kg bw/d	Surface Area of Hands (SA)	20	cm^2
Spray drift dermal (SD) - 75th perc.	~~0.20385~~ 0.23798 0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	~~0.17965~~ 0.2175 0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75th perc.	0.00009 0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	20	%
	~~0.00013~~ 0.00017 0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	~~0.10973~~ 0.12278 0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm^2/d
	~~0.1~~ 0.12 0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	~~0.00007~~ 0.00008 0.00009	mL spray dilution (adult)	TC entry into treated crops - 75th perc.	7500	cm^2/h (adult)
	~~0.00011~~ 0.00014 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 21: Estimation of longer term resident exposure towards Mesotrione according to EFSA guidance

Adult			**Child**		
Spray drift (75th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	**~~0.0004114~~ ~~0.0004802~~ ~~0.0007325~~ ~~0.0000846~~**	**mg/kg bw/d**	**Systemic exposure**	**~~0.0021767~~ ~~0.0026357~~ ~~0.0040205~~ ~~0.0003598~~**	**mg/kg bw/d**
% of AOEL:	**~~8.23~~ ~~9.60~~ ~~14.65~~ ~~1.69~~**	**%**	**% of AOEL:**	**~~43.53~~ ~~52.71~~ ~~80.41~~ ~~7.20~~**	**%**

Vapour (75th 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:	**4.60**	**%**	**% of AOEL:**	**21.40**	**%**
Surface deposits (75th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	**~~0.0000467~~ ~~0.0000826~~ 0.0001259 0.0000178**	**mg/kg bw/d**	**Systemic exposure**	**~~0.0000997~~ ~~0.0001764~~ 0.0002691 0.0000380**	**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	**~~0.0000073~~ ~~0.0000129~~ 0.0000197 0.0000479 0.0000239**	**mg/kg bw/d**
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
			Systemic exposure	**~~0.0000038~~ ~~0.0000068~~ 0.0000104 0.0000252 0.0000126**	**mg/kg bw/d**
Total					
Systemic exposure	**~~0.0000467~~ ~~0.0000826~~ 0.0001259 0.0000178**	**mg/kg bw/d**	**Systemic exposure**	**~~0.0001108~~ ~~0.0001961~~ 0.0002991 0.0001111 0.0000745**	**mg/kg bw/d**
% of AOEL:	**~~0.93~~ ~~1.65~~ 2.52 0.36**	**%**	**% of AOEL:**	**~~2.22~~ ~~3.92~~ 5.98 2.22 1.49**	**%**
Entry into treated crops (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	**~~0.0055313~~ 0.0042188 0.0002447**	**mg/kg bw/d**	**Systemic exposure**	**~~0.0099563~~ 0.0075938 0.0004404**	**mg/kg bw/d**
Hand to mouth					
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**
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	**~~0.0055313~~ 0.0042188 0.0002447**	**mg/kg bw/d**	**Systemic exposure**	**~~0.0099563~~ 0.0075938 0.0004404**	**mg/kg bw/d**
% of AOEL:	**~~110.63~~ 84.38 4.89**	**%**	**% of AOEL:**	**~~199.13~~ 151.88 8.81**	**%**

All pathways (mean)							
Systemic exposure			**0.0048977 0.0049528 0.0040704 0.0004786**	**mg/kg bw/d**	**Systemic exposure**	**0.0103065 0.0106174 0.0095791 0.0017028 0.0016760**	**mg/kg bw/d**
% of AOEL:	**97.95 99.06 81.41 9.57**	**%**	**% of AOEL:**		**206.13 212.35 191.58 34.06 33.52**	**%**	

Table A 22: Input parameters considered for the refined estimation (no. 1) of longer term resident exposure

Intended use(s)	Maize, spraying		Drift reduction (DR)		%
Application rate (AR)	0.118 0.09	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) - 75th perc.	1.30 2.30	%
Buffer strip	10 5	m	Drift on surface (D) - mean	1.00 1.80	%
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 3	$\mu g/cm^2/kg$ a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.005	mg/kg bw/d	Surface Area of Hands (SA)	20	cm^2
Spray drift dermal (SD) - 75th perc.	0.20385 0.23798	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.17965 0.2175	mL spray dilution (child)			
Spray drift inhal. (SI) - 75th perc.	0.00009	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	20	%
	0.00013 0.00017	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.10973 0.12278	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm^2/d
	0.1 0.12	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00007 0.00008	mL spray dilution (adult)	TC entry into treated crops - 75th perc.	7500 x 20%	cm^2/h (adult)
	0.00011 0.00014	mL spray dilution (child)		2250 x 20%	cm^2/h (child)
Inhalation rate (IR)	16.57	m^3/d (adult)	TC entry into treated crops -	5980 x 20%	cm^2/h (adult)

	8.31	m^3/d (child)	mean:	1794 x 20%	cm^2/h (child)

Table A 23: Refined estimation (no. 1) of longer term resident exposure towards Mesotrione according to EFSA guidance

Adult			Child		
Spray drift (75th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0004114 0.0004802 0.0007325	mg/kg bw/d	**Systemic exposure**	0.0021767 0.0026357 0.0040205	mg/kg bw/d
% of AOEL:	8.23 9.60 14.65	%	**% of AOEL:**	43.53 52.71 80.41	%
Vapour (75th 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:	4.60	%	**% of AOEL:**	21.40	%
Surface deposits (75th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	0.0000467 0.0000826 0.0001259	mg/kg bw/d	**Systemic exposure**	0.0000997 0.0001764 0.0002691	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	0.0000073 0.0000129 0.0000197	mg/kg bw/d
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
			Systemic exposure	0.0000038 0.0000068 0.0000104	mg/kg bw/d
Total					
Systemic exposure	0.0000467 0.0000826 0.0001259	mg/kg bw/d	**Systemic exposure**	0.0001108 0.0001961 0.0002991	mg/kg bw/d
% of AOEL:	0.93 1.65 2.52	%	**% of AOEL:**	2.22 3.92 5.98	%
Entry into treated crops (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	0.0011063 0.0008438	mg/kg bw/d	**Systemic exposure**	0.0019913 0.0015188	mg/kg bw/d
Hand to mouth					
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
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	0.0011063 0.0008438	mg/kg bw/d	Systemic exposure	0.0019913 0.0015188	mg/kg bw/d
% of AOEL:	22.13 16.88	%	% of AOEL:	39.83 30.38	%

All pathways (mean)							
Systemic exposure			0.0013695 0.0014246 0.0013794	mg/kg bw/d	Systemic exposure	0.0039557 0.0042667 0.0047353	mg/kg bw/d
% of AOEL:	27.39 28.49 27.59	%	% of AOEL:		79.11 85.33 94.71	%	

Table A 24: Input parameters considered for the refined estimation (no. 2) of longer term resident exposure

Intended use(s)	Maize, spraying		Drift reduction (DR)		%
Application rate (AR)	0.118 0.09	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) - 75th perc.	2.30	%
Buffer strip	5	m	Drift on surface (D) - mean	1.80	%
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)	3	$\mu g/cm^2/kg$ a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.005	mg/kg bw/d	Surface Area of Hands (SA)	20	cm^2
Spray drift dermal (SD) - 75th perc.	0.23798	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.2175	mL spray dilution (child)			
Spray drift inhal. (SI) - 75th perc.	0.00009	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	20	%
	0.00017	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.12278	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm^2/d
	0.12	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00008	mL spray dilution (adult)	TC entry into treated crops - 75th perc.	1400	cm^2/h (adult)

	0.00014	mL spray dilution (child)		420	cm^2/h (child)
Inhalation rate (IR)	16.57	m^3/d (adult)	TC entry into treated crops - mean:	1100	cm^2/h (adult)
	8.31	m^3/d (child)		330	cm^2/h (child)

Table A 25: Refined estimation (no. 2) of longer term resident exposure towards Mesotrione according to EFSA guidance

Adult			Child		
Spray drift (75th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0004802 0.0007325	mg/kg bw/d	Systemic exposure	0.0026357 0.0040205	mg/kg bw/d
% of AOEL:	9.60 14.65	%	% of AOEL:	52.71 80.41	%
Vapour (75th 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:	4.60	%	% of AOEL:	21.40	%
Surface deposits (75th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	0.0000826 0.0001259	mg/kg bw/d	Systemic exposure	0.0001764 0.0002691	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	0.0000129 0.0000197	mg/kg bw/d
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
			Systemic exposure	0.0000068 0.0000104	mg/kg bw/d
Total					
Systemic exposure	0.0000826 0.0001259	mg/kg bw/d	Systemic exposure	0.0001961 0.0002991	mg/kg bw/d
% of AOEL:	1.65 2.52	%	% of AOEL:	3.92 5.98	%
Entry into treated crops (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	0.0010325 0.0007875	mg/kg bw/d	Systemic exposure	0.0018585 0.0014175	mg/kg bw/d
Hand to mouth					
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
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~~	~~0.0010325~~ ~~0.0007875~~	~~mg/kg bw/d~~	~~Systemic exposure~~	~~0.0018585~~ ~~0.0014175~~	~~mg/kg bw/d~~	
~~% of AOEL:~~	~~20.65~~ ~~15.75~~	~~%~~	~~% of AOEL:~~	~~37.17~~ ~~28.35~~	~~%~~	
~~All pathways (mean)~~						
~~Systemic exposure~~			~~0.0013538~~ ~~0.0013254~~	~~mg/kg bw/d~~	~~Systemic exposure~~	~~0.0041392~~ ~~0.0046381~~ ~~mg/kg bw/d~~
~~% of AOEL:~~	~~27.08~~ ~~26.51~~	~~%~~	~~% of AOEL:~~	~~82.78~~ ~~92.76~~	~~%~~	

A 3.4 Combined exposure calculations for Rimsulfuron, Nicosulfuron and Mesotrione

Mesotrione.

Operator exposure:

		Rimsulfuron (AOEL = 0.07 mg/kg bw/d)		Nicosulfuron (AOEL = 0.8 mg/kg bw/d)		Mesotrione (AOEL = 0.005 mg/kg bw/d)		Cumulative risk Operators (HI)[4]
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)**	**Total absorbed dose (mg/kg/day)**	**Estimated exposure / AOEL (HQ)**	
Tractor mounted boom spray application outdoors to low crops (maize)								
Application rate		~~0.0099~~ kg a.s./ha 0.0075		~~0.0396~~ kg a.s./ha 0.03		~~0.118~~ kg a.s./ha 0.09		
Spray application (AOEM**;** ~~95~~ 75th percentile) Body weight: 60 kg	Potential exposure	~~0.0040~~ 0.0033 0.0115	~~**0.0574**~~ **0.047** **0.165**	~~0.0117~~ 0.0094	~~**0.0146**~~ **0.01**	~~0.0285~~ 0.0228 0.0022	~~**5.69**~~ **4.55** **0.44**	~~**5.762**~~ **4.607** **0.50** **0.62**
	Work wear (arms, body and legs covered) M/L and A ~~+ gloves M/L and A~~	~~0.0024~~ 0.0020 0.0062	~~**0.0350**~~ **0.029** **0.09**	~~0.0071~~ 0.0057	~~**0.0089**~~ **0.0071**	~~0.0026~~ 0.0023 0.0017	~~**0.53**~~ **0.46** **0.35**	~~**0.5739**~~ **0.4961** **0.39** **0.45**

The Hazard Index is < 1 for the estimation using gloves during mix/loading and application.

The Hazard Index is < 1 for the estimation even without personal protective equipment.

Worker exposure:

[4] The Hazard Index (HI) is the sum of the individual HQs for Rimsulfuron, Nicosulfuron and Mesotrione

		Rimsulfuron (AOEL = 0.07 mg/kg bw/d)		Nicosulfuron (AOEL = 0.8 mg/kg bw/d)		Mesotrione (AOEL = 0.005 mg/kg bw/d)		Cumula-tive risk Operators (HI)*
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**Estimated exposure / AOEL (HQ)**	**Total absorbed dose (mg/kg bw/day)**	**Estimated exposure / AOEL (HQ)**	**Total absorbed dose (mg/kg bw/day)**	**Estimated exposure / AOEL (HQ)**	
Number of applications and application rate		1× ~~0.0099 kg~~ a.s./ha 0.0075		1× ~~0.0396~~ kg a.s./ha 0.03		1× ~~0.118~~ kg a.s./ha 0.09		
Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	~~0.0062~~ 0.0047	~~**0.0884**~~ **0.0670**	~~0.0248~~ 0.0188	~~**0.0309**~~ **0.0234**	~~0.0738~~ 0.0563 0.0033	~~**14.75**~~ **11.25** **0.65**	~~**14.87**~~ **11.34** **0.74**
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	~~0.0007~~ 0.0005	~~**0.0099**~~ **0.0075**	~~0.0028~~ 0.0021	~~**0.0035**~~ **0.0026**	~~0.0083~~ 0.0063 0.0004	~~**1.65**~~ **1.26** **0.0731**	~~**1.66**~~ **1.27** **0.08**
	Work wear (arms, body and legs covered) and gloves TC: no TC available for this assessment cm^2/person/h	–	–	–	–	–	–	

~~The estimated exposure for workers presents that the Hazard Index is < 1.~~
The estimated exposure for workers presents that the Hazard Index is < 1.

Resident exposure:

		Rimsulfuron (AOEL = 0.07 mg/kg bw/d)		Nicosulfuron (AOEL = 0.8 mg/kg bw/d)		Mesotrione (AOEL = 0.005 mg/kg bw/d)		Cumulative risk Operators (HI)*
Model data		**Total absorbed dose (mg/kg bw/day)**	**Estimated exposure / AOEL (HQ)**	**Total absorbed dose (mg/kg bw/day)**	**Estimated exposure / AOEL (HQ)**	**Total absorbed dose (mg/kg bw/day)**	**Estimated exposure / AOEL (HQ)**	
Number of applications and application rate		1× ~~0.0099~~ kg a.s./ha 0.0075		1× ~~0.0396~~ kg a.s./ha 0.03		1× ~~0.118~~ kg a.s./ha 0.09		
~~Refinement no.1~~								
Resident child Body weight: 10 kg	~~Drift (75th perc.)~~	~~0.0006647~~ ~~0.0005036~~	~~**0.0095**~~ ~~**0.0072**~~	~~0.0026589~~ ~~0.0020144~~	~~**0.0033**~~ ~~**0.0025**~~	~~0.0021767~~ ~~0.0026357~~ ~~0.0040205~~	~~**0.4353**~~ ~~**0.5271**~~ ~~**0.8041**~~	~~**0.4481**~~ ~~**0.54**~~ ~~**0.8138**~~
	~~Vapour (75th perc.)~~	~~0.0010700~~	~~**0.0153**~~	~~0.0010700~~	~~**0.0013**~~	~~0.0010700~~	~~**0.2140**~~	~~**0.2306**~~

	Deposits (75th perc.)	0.0000801 0.0000607	**0.0011** **0.0009**	0.0003204 0.0002428	**0.0004** **0.0003**	0.0001108 0.0001961 0.0002991	**0.0222** **0.0392** **0.0598**	**0.0237** **0.04** **0.061**
	Re-entry (75th perc.)	0.0008353 0.0006328	**0.0119** **0.0090**	0.0033413 0.0025313	**0.0042** **0.0032**	0.0019913 0.0015188	**0.3983** **0.3038**	**0.4144** **0.316**
	Sum (mean)	0.0021608 0.0018964	**0.0309** **0.0271**	0.0054333 0.0043755	**0.0068** **0.0055**	0.0039557 0.0042667 0.0047353	**0.7911** **0.8533** **0.9471**	**0.8288** **0.89** **0.98**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0001591 0.0001205	**0.0023** **0.0017**	0.0006362 0.0004820	**0.0008** **0.0006**	0.0004114 0.0004802 0.0007325	**0.0823** **0.0960** **0.1465**	**0.0854** **0.1** **0.15**
	Vapour (75th perc.)	0.0002300	**0.0033**	0.0002300	**0.0003**	0.0002300	**0.0460**	**0.0496** **0.05**
	Deposits (75th perc.)	0.0000337 0.0000256	**0.0005** **0.0004**	0.0001349 0.0001022	**0.0002** **0.0001**	0.0000467 0.0000826 0.0001259	**0.0093** **0.0165** **0.0252**	**0.01** **0.02** **0.03**
	Re-entry (75th perc.)	0.0004641 0.0003516	**0.0066** **0.0050**	0.0018563 0.0014063	**0.0023** **0.0018**	0.0011063 0.0008438	**0.2213** **0.1688**	**0.2302** **0.18**
	Sum (mean)	0.0007003 0.0005863	**0.01** **0.0084**	0.0021111 0.0016551	**0.0026** **0.0021**	0.0013695 0.0014246 0.0013794	**0.2739** **0.2849** **0.2759**	**0.2865** **0.30** **0.29**
Refinement no.2								
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0006647 0.0005036	**0.0095** **0.0072**	0.0026589 0.0020144	**0.0033** **0.0025**	0.0026357 0.0040205	0.5271 **0.8041**	**0.54** **0.81**
	Vapour (75th perc.)	0.0010700	**0.0153**	0.0010700	**0.0013**	0.0010700	0.2140	**0.23**
	Deposits (75th perc.)	0.0000801 0.0000607	**0.0011** **0.0009**	0.0003204 0.0002428	**0.0004** **0.0003**	0.0001961 0.0002991	0.0392 **0.0598**	**0.04** **0.06**
	Re-entry (75th perc.)	0.0008353 0.0006328	**0.0119** **0.0090**	0.0033413 0.0025313	**0.0042** **0.0032**	0.0018585 0.0014175	0.3717 **0.2835**	**0.39** **0.30**
	Sum (mean)	0.0021608 0.0018964	**0.0309** **0.0271**	0.0054333 0.0043755	**0.0068** **0.0055**	0.0041392 0.0046381	0.8278 **0.9276**	**0.87** **0.96**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0001591 0.0001205	**0.0023** **0.0017**	0.0006362 0.0004820	**0.0008** **0.0006**	0.0004802 0.0007325	0.0960 **0.1465**	**0.1** **0.15**
	Vapour (75th perc.)	0.0002300	**0.0033**	0.0002300	**0.0003**	0.0002300	0.0460	**0.05**
	Deposits (75th perc.)	0.0000337 0.0000256	**0.0005** **0.0004**	0.0001349 0.0001022	**0.0002** **0.0001**	0.0000826 0.0001259	0.0165 **0.0252**	**0.02** **0.03**
	Re-entry (75th perc.)	0.0004641 0.0003516	**0.0066** **0.0050**	0.0018563 0.0014063	**0.0023** **0.0018**	0.0010325 0.0007875	0.2065 **0.1575**	**0.22** **0.16**
	Sum (mean)	0.0007003 0.0005863	**0.01** **0.0084**	0.0021111 0.0016551	**0.0026** **0.0021**	0.0013538 0.0013254	0.2708 **0.2651**	**0.28** **0.28**
Buffer zone: 2-3 (m), drift reduction technology: no								
Resident child Body weight:	Drift (75th perc.)	0.0006647 0.0005036	**0.0095** **0.0072**	0.0026589 0.0020144	**0.0033** **0.0025**	0.0003598	**0.0720**	**0.08**
	Vapour (75th perc.)	0.0010700	**0.0153**	0.0010700	**0.0013**	0.0010700	**0.2140**	**0.23**

10 kg	Deposits (75th perc.)	~~0.0000801~~ 0.0000607 0.0000589	~~**0.0011**~~ **0.0009** **0.0008**	~~0.0003204~~ 0.0002428 0.0002281	~~**0.0004**~~ **0.0003** **0.0003**	0.0001111 0.0000745	**0.0222** **0.0149**	**0.02** **0.02**
	Re-entry (75th perc.)	~~0.0008353~~ 0.0006328	~~**0.0119**~~ **0.0090**	~~0.0033413~~ 0.0025313	~~**0.0042**~~ **0.0032**	0.0004404	**0.0881**	**0.10**
	Sum (mean)	~~0.0021608~~ 0.0018964 0.0018950	~~**0.0309**~~ **0.0271** **0.0271**	~~0.0054333~~ 0.0043755 0.0043648	~~**0.0068**~~ **0.0055** **0.0055**	0.0017028 0.0016760	**0.3406** **0.3352**	**0.37** **0.37**
Resident adult Body weight: 60 kg	Drift (75th perc.)	~~0.0001591~~ 0.0001205	~~**0.0023**~~ **0.0017**	~~0.0006362~~ 0.0004820	~~**0.0008**~~ **0.0006**	0.0000846	**0.0169**	**0.02**
	Vapour (75th perc.)	0.0002300	**0.0033**	0.0002300	**0.0003**	0.0002300	**0.0460**	**0.05**
	Deposits (75th perc.)	~~0.0000337~~ 0.0000256	~~**0.0005**~~ **0.0004**	~~0.0001349~~ 0.0001022	~~**0.0002**~~ **0.0001**	0.0000178	**0.0036**	**0.004**
	Re-entry (75th perc.)	~~0.0004641~~ 0.0003516	~~**0.0066**~~ **0.0050**	~~0.0018563~~ 0.0014063	~~**0.0023**~~ **0.0018**	0.0002447	**0.0489**	**0.06**
	Sum (mean)	~~0.0007003~~ 0.0005863	~~**0.01**~~ **0.0084**	~~0.0021111~~ 0.0016551	~~**0.0026**~~ **0.0021**	0.0004786	**0.0957**	**0.11**

The Hazard Index is < 1. Thus, combined exposure to all active substances in product PRIMARY MX is not expected to present a risk for 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.