FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: MEZOT 100 SC

Product name(s): Mezot 100 SC

Chemical active substance:

Mesotrione, 100 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 28/01/2021; 02/2023;

MS Finalisation 08/2023; 12/2023

Version history

When	What
02.02.2023	Point 6.2 – Correction of data
	Point 6.3 – Deletion of table 6.3-2.
	Appendix 2, Point A.2.2. – Completion of data and information.
	Appendix 2, Point A.2.3. – Completion of data and information.
	Appendix 2, Point A.2.4. – Completion of data and information.
	Appendix 2, Point A.2.5. – Completion of data and information.
	Appendix 2, Point A.2.6. – Completion of data and information.
	Appendix 2, Point A.2.7. – Completion of data and information.
08.2023	Assessment after completion of data and information
12.2023	The final Registration Report

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on Mezot 100 SC *

Product name and code	Mezot 100 SC
Formulation type	Suspension Concentrate; SC
Active substance(s) (incl. content)	Mesotrione; 100 g/L
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 Mezot 100 SC 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 Mezot 100 SC according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Eye Dam.1; Repr.2; STOT RE 2**
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS05, GHS08
Signal word:	Danger
Hazard statement(s):	H318; H361d, H373
Precautionary statement(s):	P280- Wear protective gloves/protective clothing/eye protection/face protection. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do Ð continue rinsing. P308+P313 - IF exposed or concerned: Get medical advice/attention P314 - Get Medical advice/attention if you feel unwell. P310 - Immediately call a POISON CENTER or doctor/physician.
Additional labelling phrases:	--

** **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

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for Mezot 100 SC.

	Result	PPE / Risk mitigation measures
Operators	Acceptable	AOEM: ~~no~~ PPE
Workers	Acceptable	AOEM: PPE (working wear and gloves)
Bystanders	Acceptable	AOEM
Residents	Acceptable	AOEM BREAM

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in ** **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

Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents 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, bystander or resident exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique *****	**Max. number (min. interval between applications)**	**Max. application rate kg as/ha** **a) Mesotrione**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
1	Maize (BBCH 12-18)	F	Foliar spraying, FCTM	1 ; -	a) 0.150	200 - 300	-	Operators, workers, bystanders and residents [AOEM]				

* 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)

	Mesotrione
Common Name	Mesotrione (ISO); 2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione
CAS-No.	104206-82-8
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Repr. 2, H361d Suspected of damaging the unborn child. STOT RE 2 H373 (eyes, nervous system) Aquatic Acute 1, Aquatic Chronic 1 Code(s) for hazard pictogram(s): GHS08,GHS09 Signal word: Warning Hazard statement(s): H410 Precautionary statement(s): P273, 391, 501
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0,005 mg/kg bw/d
Reference	EFSA Journal 2016;14(3):4419
Conditions to take into account/critical areas of concern with regard to toxicology	
Review Report/EFSA Conclusion for active substance	**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**

ACCEPTED

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for Mezot 100 SC is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for product Mezot 100 SC

Type of test, species, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral, rat (OECD 423)	Not submitted, not necessary. Justification presented in Appendix 2			
LD_{50} dermal, rat	Not submitted, not necessary. Justification presented in Appendix 2			
LC_{50} inhalation, rat	Not submitted, not necessary. Justification presented in Appendix 2			
Skin corrosion, in vitro (OECD 431)	Non-corrosive		None	Krakowian D., 2019

Skin irritation, in vitro (OECD 439)	Not submitted, not necessary.			
Eye irritation/damage, in vitro (OECD 438)	Not eye damage		None	Gruszka K., 2019
Eye irritation/corrosion, in vivo (OECD 405)	Eye Damage.		**H318**	Gruszka K., 2020
Skin sensitisation, guinea pig	Not submitted, not necessary. Justification presented in Appendix 2			
Supplementary studies for combinations of plant protection products	No data – not required			

~~**Table 6.3-2: Additional toxicological information relevant for classification/labelling of Mezot 100 SC.**~~

6.4 Toxicological Evaluation of Groundwater Metabolites

According to calculation of PECgw made by PELMO and PEARL Focus models (dRR PartB Section 8), maximum con-centration results of the metabolite MNBA show a very slight exceeded of the limit value only in one scenario (Hamburg).

Please refer to the second Addendum to DAR, Revision 2 (September 2001) for mesotrione for full details of the relevance assessment performed for both metabolites MNBA and AMBA according to the "Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater" (SANCO/221/2000 rev. 10- 25 February 2003).
In brief, based on the classification of the parent active substance mesotrione and based on the available toxicological data on MNBA and AMBA, both metabolites MNBA and AMBA are con-sidered to be non-relevant metabolites in ground water.
Mesotrione does not require classification and labelling with respect to human health effects. It is not listed in Annex VI of the Regulation (EC) No 1272/2008, and during the EU evaluation of the active substance mesotrione according to Directive 91/414/EEC no classification and labelling re-garding human health effects was proposed.
A study in male rats showed that MNBA was metabolised in the gut to AMBA. Approximately 16% of the administered radioactivity was excreted in the urine, (~5% as MNBA and ~10% as AMBA), indicating either absorption of AMBA from the gut or absorption and subsequent metabolism of MNBA. MNBA was found to be of comparatively low acute toxicity, however this metabolite was identified as a potential skin sensitiser. Increased motor activity was seen in female rats in a 28-day study with MNBA, however this finding is considered to be equivocal. No effects were seen in males. Minor effects on bodyweight and food consumption were noted in males only in a 90-day study. Mild hypertyrosinaemia was also seen in males at dose levels of 650 and 3000 ppm, howev-er urinary phenolic acids were not increased at this dose level. No significant effects were seen on HPPD activity in vitro.
AMBA was found to be of low acute oral toxicity. No significant effects were seen on HPPD ac-tivity in vitro.
According to the Peer review of the pesticide risk assessment of the active substance mesotrione EFSA Journal 2016;14(3):4419
"Not extensively metabolised (~90% in urine unchanged, up to 5% hydroxylated metabolites, MNBA and AMBA); MNBA and AMBA generated by gut microflora can be reabsorbed and contribute to the hydroxylated metabolites in urine or excreted in faeces. In vitro metabolism Data gap for interspecies comparative in vitro metabolism study including human metabolism No in vitro data but a human volunteer study confirms absorption and excretion similar to rodents."

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in Mezot 100 SC are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substance in Mezot 100 SC.

	Mesotrione	
	Value	**Reference**
Concentrate	10 %	Default values for SC formulation. Guidance on dermal absorption. EFSA Journal 2017;15(6);4873.
Dilution	50 %	

6.5.1 Justification for proposed values – Mesotrione.

No data on dermal absorption for Mesotrione in Mezot 100 SC 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 Mesotrione

	Value	**Justification for value**	**Acceptability of justification**
Concentrate	10 %	Due to absence of any supporting dermal absorption studies for Mezot 100 SC and based on Guidance on dermal absorption (EFSA Journal 2017; 15(6); 4873), default values are proposed (regarding type of formulation of Mezot 100 SC): - 10 % for concentrate - 50 % for diluted product.	Yes
Dilution	50 %		Yes

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	Mezot 100 SC
Formulation type	SC
Category	Herbicide
Container size(s), short description	Bottle (HDPE): 120 ml, 250 ml, 500 ml, 1 ltr, Canister (HDPE): 5 ltr, 10 ltr, 20 ltr Drum (HDPE): 220 ltr IBC container (HDPE): 1 m^3
Active substance(s) (incl. content)	**Mesotrione** 100 g/L

AOEL systemic	0.015 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 10 % Dilution: 50 % (Default values)

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/ EU is given in Part B, Section 0.

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 Mezot 100 SC according to the critical uses is presented in Table 6.6-2. Outcome of the estimation is presented in Table 6.6-3. Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical uses	Maize (max. 1.5 L product/ha)
Model	AOEM 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

		Mesotrione	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Vehicle mounted Application rate: 0,150 kg a.s./ha			
Maize			
AOEM Body weight: 70 kg Application volume 200 L/ha	no PPE (mixing/loading/application)	0,0781954	521,3
AOEM Body weight: 70 kg Application volume 200 L/ha	PPE (Gloves, Protective clothing) (mixing/loading/application)	0,0077406	51,6

The operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses (gloves, protective clothing)(mixing/loading/application)
Implication for labelling: P280- Wear protective gloves/protective clothing

ACCEPTED

6.6.3 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 considering above mentioned data – even without PPE protection, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 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 Mezot 100 SC according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical uses	Maize (max. 1.5 L product/ha)
Model	AOEM 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

		Mesotrione	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Number of applications and application rate: max. 1 x 150 g a.s./ha			
Maize			
AOEM Outdoor Work rate: 8 hours/day, DT_{50}: 43,4 days Initial DFR: 3 µg/cm2/kg a.s./ha Body weight: 60 kg	no PPE	0,0937500	625,0
	PPE (arm, body and legs covered)	0,0105000	70,0

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

Accepted

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

No applicable.

6.6.4.3 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.

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

Błąd! Nie można odnaleźć źródła odwołania. shows the exposure model(s) used for estimation of bystander and resident exposure to Mesotrione. Detailed calculations are in Appendix 3.

Table 6.6-6 Exposure models for intended uses

Critical uses	Maize (max. 1.5 L product/ha)
Model	AOEM 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 6.6-6-1: Estimated bystander and resident exposure – model AOEM

	Mesotrione	
Model data	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Vehicle mounted Application rate: max. 1 x 0,150 kg a.s./ha		
Maize		
Bystanders (adult) Buffer strip: 2-3 m; Drift 8,5 % Body weight: 60 kg	0,0062075	-
Bystanders (children) Buffer strip: 2-3 m; Drift 8,5 % Body weight: 16,15 kg	0,0228390	-
Residents (adult)	0,0073553	-

Buffer strip: 2-3 m; Drift 8,5 % Body weight: 60 kg		
Residents (children) Buffer strip: 2-3 m; Drift 8,5 % Body weight: 16,15 kg	0,0175977	-

Table 6.6-7-2: Estimated bystander and resident exposure – model BREAM

	Mesotrione	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted; Field crops Application rate: max. 1 x 0,150 kg a.s./ha		
Maize		
Bystanders (adult) Buffer strip: 2-3 m; Drift 8,5 % Body weight: 60 kg	0,0051944	34,63
Bystanders (children) Buffer strip: 2-3 m; Drift 8,5 % Body weight: 16,15 kg	0,0040536	27,02

The bystander and/or resident exposure estimations carried out according BREAM Model indicated that the acceptable operator exposure level (AOEL) for Mesotrione will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures

Accepted

6.6.5.2 Measurement of bystander and/or resident exposure

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

6.6.6 Combined exposure

Not relevant. The product contains only one active substance.

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 7.1.4	Krakowian D.	2019	Mezot 100 SC: In Vitro Skin Corrosion: Reconstructed Human Epidermis Test Method Study code: SCT-2/19 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP; Unpublished	Y	Elvita Sp. z o.o.
KCP 7.1.5/01	Gruszka K.	2019	Mezot 100 SC: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage Study code: ICE-5/19 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP; Unpublished	Y	Elvita Sp. z o.o.
KCP 7.1.5/02	Krakowian D.	2019	Mezot 100 SC: Short time exposure in vitro test method for identifying I) chemicals inducing serious eye damage and II) chemicals not requiring classification for eye irritation or serious eye damage Study code: STE-4/19 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP; Unpublished	Y	Elvita Sp. z o.o.
KCP 7.1.5/03	Gruszka K.	2020	Mezot 100 SC: Acute Eye Irritation/Corrosion Study on Rabbits Study code: ODR-1/20 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP; Unpublished	Y	Elvita Sp. z o.o.

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

The bridging was not necessary.

Comments of zRMS:	N/A

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**ATEmix > 2 000.** **Product is not classified as Harmful if swallowed**

No studies submitted.
Calculation method indicates that content (concentration) of raw materials classified as harmful via oral toxicity, not cause such classification for product.

An alternative approach under Regulation (EC) No 1272/2008 may be presented. Toxicity can be determined by the calculation based on the data for relevant ingredients. Details of ingredients and content – see dRR Part C.

Sum of ingredients with classification H302 - Harmful if swallowed: 2,82 %

Equation:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

Converted acute toxicity point, according to Table 3.1.2 of regulation 1272/2008 - ATE: 500.
ATEmix = 17 730,5.
ATEmix > 2 000.
Product is not classified as Harmful if swallowed.

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

Comments of zRMS:	**The product does not contain ingredients which are classified as dermally toxic according to regulation 1272/2008**

No data on acute dermal toxicity for Mezot 100 SC. Studies not submitted, not necessary.
Results of studies:

- In Vitro Skin Corrosion: Reconstructed Human Epidermis Test Method (OECD 431); (KCP 7.1.4).

The product does not contain ingredients which are classified as dermally toxic according to regulation 1272/2008. Details of ingredients and content – see dRR Part C

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**The product does not contain ingredients which are classified as toxic via inhalation according to regulation 1272/2008**

No data on acute inhalation toxicity for Mezot 100 SC. Studies not submitted, not necessary.
The recommended way of spraying formulation Mezot 100 SC results in production of medium drops size. Mezot 100 SC contains active substance with a vapour pressure below 1×10^{-2} Pa. Thus, according to the regulations (Commission Regulation (EU) No 284/2013), the study of acute inhalation toxicity for Mezot 100 SC is not required.
Additivity formula to classification was used.
The product does not contain ingredients which are classified as toxic via inhalation according to regulation 1272/2008. Details of ingredients and content – see dRR Part C.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**Based on the results of in vitro studies product is not classified as skin irritation**

A 2.5.1 Study 1

Reference:	KCP 7.1.4
Report	In Vitro Skin Corrosion: Reconstructed Human Epidermis Test Method; [redacted] 2019. Study code: SCT-2/19
Guideline(s):	OECD Guideline No. 431 / EU Method B.40.BIS
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	Mezot 100 SC - Batch No. 190521
Species	EpiDerm™ kit (MatTek In Vitro Life Science Laboratories in Bratislava).
Study course:	Skin corrosion refers to the production of irreversible tissue damage following the application of a test item. The test consists of a topical exposure of the neat test item to a human reconstructed epidermis model followed by a cell viability test. Cell viability is measured by dehydrogenase conversion of MTT, present in cell mitochondria, into a blue formazan salt that is quantitatively measured after extraction from tissues. The percentage reduction of cell viability in comparison of untreated negative controls is used to predict the skin corrosion potential. Two inserts with tissues of the human skin model EpiDerm™ were treated with Mezot 100 SC for 3 minutes and for 60 minutes. The test item was applied directly to each tissue and spread to match the tissue size.

	Water was used as negative control and 8N KOH solution was used as positive control.
Remarks	None

Results and discussions:

All acceptance criteria (absorbance value for negative control, mean value of relative tissue viability of positive control, variation within the tissue replicates) were within the appropriate range. Therefore, the experiment is considered as valid.
After the 3-minute exposure to the test item, the mean value of relative tissue viability was equal 98 %. After the 1-hour exposure to the test item, the mean value of relative tissue viability was reduced to 32 %. These values are above the threshold of non-corrosive effects on the skin (viability ≥ 50 % after 3-minutes exposure and ≥ 15 % after 60-minutes exposure).
The test item, Mezot 100 SC, is considered to be non-corrosive to skin in the Reconstructed human Epidermis (RhE) Test Method. It can not be classified as category 1A / 1B-1C in the UN GHS classification.

An alternative approach under Regulation (EC) No 1272/2008 may be presented. Toxicity can be determined by the calculation based on the data for relevant ingredients. Details of ingredients and content – see dRR Part C.

Sum of ingredients with classification H314 - Causes severe skin burns and eye damage: 0,05 %
Concentration triggering classification of a mixture as H314 - Causes severe skin burns and eye damage: 5 %
Concentration triggering classification of a mixture as H315: Causes skin irritation: 1 %

Product is not classified as Causes severe skin burns ~~and eye~~ damage or Causes skin irritation.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**Based on the results of study Acute Eye Irritation/Corrosion Study on Rabbits; 2020 (study 3) classification is H318/Eye Dam,1**

None of ingredients of formulation Mezot 100 SC have classification and/or potential to eye irritation.

A 2.6.1 Study 1

Reference: KCP 7.1.5/01

Report Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing

	Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage; [redacted] 2019. Study code: ICE-5/19
Guideline(s):	OECD Guideline No. 438 / EU Method B.48
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	Mezot 100 SC - Batch No.: 190521
Species	The eyeballs were collected from chickens obtained from a licensed slaughterhouse, JAS-DROP in Krzyżowice
Study course:	In the isolated chicken eye test (in vitro), toxic effects to the cornea were measured by a qualitative assessment of damage to epithelium based on application of fluorescein to the eye (fluorescein retention), a qualitative assessment of opacity, a quantitative measurement of increased thickness (swelling), and qualitative macroscopic and histopathological evaluations of morphological damage to the surface. The study was conducted on nine eyeballs. In order to control the quality of the procedure, the eyeballs used for the purpose of the experiment were assessed for potential damage (corneal opacity, corneal thickness and fluorescein retention). The resulting score of corneal opacity and fluorescein retention for all examined eyeballs was less than 0.5. Deviation of corneal thickness for all examined eyeballs was less than 10%. Before the application of the test item and the control items, all examined and approved eyeballs were incubated at a temperature of 32 ± 1.5°C for 45-60 minutes in the superfusion apparatus in order to equilibrate them to the test system. After that, a zero reference measurement for corneal thickness and opacity was recorded. The test item and the items used in the positive (5% benzalkonium chloride) and negative (physiological saline) controls in a volume of 0.03 mL were uniformly applied to the corneal surface. Three eyeballs were used for the test item and three for each control item. The test item and the control items were applied to the corneal surface for 10 seconds and kept at ambient temperature. Then, they were rinsed from the eye with 20 mL of physiological salt solution at ambient temperature. Next, the eyeballs were placed in their holders in the superfusion apparatus in the original upright position. The corneas treated with the test item and the control items were evaluated prior to treatment and at 30, 75, 120, 180, and 240 minutes (± 5 minutes) after the post-treatment rinse. At all observation time points, corneal opacity and swelling were evaluated, whereas morphological changes of the corneal surface were recorded. The quantitative determination of fluorescein retention was performed only prior to treatment and 30 minutes after the end of the exposure. Following the final evaluation of the treated eyeballs, i.e. 240 minutes after the application of the test item and the control items, the eyeballs were preserved in a 4% solution of formaldehyde for histopathological examinations.

Remarks	None

Results and discussions

For eyeballs treated with the test item:
- the mean fluorescein retention value was equal to 1.7 (ICE class III),
- the maximal mean corneal opacity value was equal to 1.7 (ICE class III),
- the maximal mean corneal swelling value was equal to 25.1% (ICE class III),
- roughness of the corneal surface were observed,
- histopathological examinations revealed: moderate vacuolation of epithelium (eyeballs no. 1 and no. 2); moderate vacuolation of epithelium (eyeball no. 3); moderate necrosis of epithelium (eyeball no. 1); slight necrosis of epithelium (eyeballs no. 2 and no. 3) and dissection of stroma (eyeball no.2).

These results can be accepted because the concurrent positive and negative control values fell within the acceptable ranges for the method [6,7].
Interpretation of the study results:
For test item (Mezot 100 SC) the prediction can be made such as: no prediction can be made (3 x III) according to UN GHS classification criteria. The other additional researches (in vivo or in vitro) are necessary for classification of this test item.

A 2.6.2 Study 2

Reference:	KCP 7.1.5/02
Report	Short time exposure in vitro test method for identifying I) chemicals inducing serious eye damage and II) chemicals not requiring classification for eye irritation or serious eye damage; [redacted], 2019. Study code: STE-4/19
Guideline(s):	OECD Guideline No. 491
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	Mezot 100 SC - Batch No.: 190521
Species	SIRC (ECACC 89090404) cell line
Study course:	The short time exposure (STE) test method is a cytotoxicity-based in vitro assay, that is performed on a confluent monolayer of SIRC cells, cultured on a 96-well microplate. This test method involves exposing SIRC cells to 5% and 0.05% concentrations of test item for 5 minutes. After five-minute exposure to a test item, the cytotoxicity is quantitatively measured as the relative viability of the cells using the MTT assay. Decreased cell viability is used to predict potential adverse effects leading to ocular damage. Saline was used as solvent control and 0.01 % SDS solution was used as positive control.
Remarks	None

Results and discussions

All acceptance criteria (absorbance value for medium control, viability of the solvent control and positive

control, standard deviation between repetition) were within the appropriate range. Therefore, the experiment is considered as valid.
The mean cell viability (from 3 independent runs) was 2.4 ± 0.1 % and 90.8 ± 5.6 % for concentrations of 5 % and 0,05 % respectively. The first value is below the threshold for "category 1" (≤ 70%) and the second value is above the threshold for "no category" (≥ 70%).
No prediction can be made for the test item, Mezot 100 SC, in the STE test method. Other study is necessary to classify this test item.

A 2.6.3 Study 3

Reference:	KCP 7.1.5/03
Report	Acute Eye Irritation/Corrosion Study on Rabbits; [redacted], 2020. Study code: ODR-1/20
Guideline(s):	OECD Guideline No. 405 / EU Method B.5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	Mezot 100 SC - Batch No.: 190521
Species	Albino males rabbits of the New Zealand strain obtained from the Charles River Laboratory, France
Study course:	Before the application of the test item the animals were given anesthetics. The study started with a preliminary study on one animal. The test item in volume of 0.1 mL was applied to the conjunctival sac of one eye of the animal (rabbit no. 1). The other eye, which remained untreated, served as a control. The animal was observed everyday of observation period. General clinical observations of the animal were performed daily during the entire experiment. The detailed clinical observations of the cornea, iris, and conjunctiva in rabbit were performed 1, 24, 48 and 72 hours after the application of the test item and next day until the the end of the experiment. Body weights of the animal were determined on the application day (day 0), i.e. directly before the application, and on the last day of the experiment. After the observation period, the animal was euthanized.
Remarks	None

Results and discussions

After application of the test item, changes in the cornea, iris and conjunctiva in the first rabbit were observed until the end of observation period. Because reversibility of ocular lesions was not seen before 21 days, the experiment were terminated at that time and experiment was not continued.
The results of the study were evaluated according to the Annex to the Regulation of the Minister of Health of August 10, 2012 on classification of chemical substances and their mixtures (Journal of Laws, item 1018) [6] and according to the Comission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures [7] and according to the Globally Harmonized System (GHS), Seventh revised edition

(2017) [8].
On the grounds of the study results, the test item, i.e. Mezot 100 SC can be classified into the following categories:
- agents category 1 (irreversible effects on the eye) – according to the Comission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures,
- category 1 (Substances that cause serious eye damage/ irreversible effect on the eye) – according to the Globally Harmonized System (GHS).

An alternative approach under Regulation (EC) No 1272/2008 may be presented. Toxicity can be determined by the calculation based on the data for relevant ingredients. Details of ingredients and content – see dRR Part C.

Sum of ingredients with classification H318 - Causes serious eye damage: 0,92 %
Concentration triggering classification of a mixture as H318 - Causes serious eye damage: 3 %
Concentration triggering classification of a mixture as H319 – Causes serious eye irritation: 1 %

Product is not classified as Causes serious eye damage or Causes serious eye irritation.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**The product does not contain ingredients which are classified as skin sensitiser according to regulation 1272/2008.**

No data on acute inhalation toxicity for Mezot 100 SC. Studies not submitted, not necessary.
None of ingredients of formulation Mezot 100 SC have classification and/or potential to skin sensitization.
The product does not contain ingredients which are classified as skin sensitiser according to regulation 1272/2008. Details of ingredients and content – see dRR Part C.

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

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)

Comments of zRMS:	**Accepted**

According requirements from Reg. No. 284/2013/WE the study shall be conducted when dermal exposure is a significant exposure route and no acceptable risk is estimated using default absorption value.
In order to make assessment of exposure, for Mezot 100 SC has proposed a default dermal absorption value of 10 % for the concentrate and 50 % for the spray solution, based on Guidance on Dermal Absorption (EFSA Journal 2017;15(6)4873).
Use of plant protection product Mezot 100 SC is safe for operator, taking into account proposed dose of product, type of usage, type of personal protective equipment (gloves, protective garment and sturdy footwear). Using vehicle mounted sprayer and maintain general rules of safety and hygiene of working with plant protection products and comply with requirements enclosed in label, risk during employ Mezot 100 SC is acceptable, absorbed dose of Mesotrione have safe value, below AOEL for this active ingredient.
According to above there isn't necessity to do tests of dermal absorption for Mezot 100 SC.

A 2.11 Other/Special Studies

No additional studies.

Appendix 3 Exposure calculations

Data Entry:

Substance name	Mesotrione	
Product name	Mezot 100 SC	
Reference value non acutely toxic active substance (RVNAS)	0.015	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Cereals	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	200	L/ha
Maximum application rate of active substance	0.15	kg a.s. /ha
50% Dissipation Time DT50	43.4	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10.00%	
Dermal absorption of in-use dilution	50.00%	
Oral absorption of active substance	100.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

Operator exposure for Mezot 100 SC outdoor spray applications

Application rate of active substance	0.15	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	7.5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

Outdoor;Soluble concentrates, emulsifiable concentrate, etc.;Downward spraying;Vehicle-mounted;

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	22909	85448	AOEM	
	Body	14704	129332	AOEM	
	Head	389	2134	AOEM	
	Protected hands (gloves)	128	1486	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	142	1097	AOEM	
	Protected head (hood and face shield)	6	121	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	1112	10024	AOEM	
	Body	622	3206	AOEM	
	Head	29	89	AOEM	
	Protected hands (gloves)	127	4216	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	17	42	AOEM	
	Inhalation	3	9	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.6917225	0.4644341	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0781954	0.0077406	
% of RVNAS	521.30%	51.60%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

Worker exposure from residues on foliage for Mezot 100 SC			
Crop type	Cereals		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.15	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	43.4	days	*d_HalflifeAS*
Multiple application factor	1.0		*d_MAF*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50.00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.45	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	5.6250000	0.6300000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0937500	0.0105000		
% of RVNAS	625.00%	70.00%		

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

Resident exposure for Mezot 100 SC			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	2-3	m	*i_Buffer*
Application rate of the product	0.15	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	0.75	g a.s./l	*d_ConcAS*
Dermal absorption of product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorpInuse*
Oral absorption	100.00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.45	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0.47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0.327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0.00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0.00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0.22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0.18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0.00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0.00017	ml spray dilution/person	
Exposure duration dermal	2	hours	*d_ReExpDur*
Exposure duration inhalation	24	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	5.60%		
Drift percentage on surface (mean)	4.10%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	9.5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adı	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h	*d_TcEntryCh*

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1007175	0.0107000	0.0121380	0.1265625	0.1759768
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0100718	0.0010700	0.0012138	0.0126563	0.0175977

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1446000	0.0138000	0.0306600	0.4218750	0.4413179
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0024100	0.0002300	0.0005110	0.0070313	0.0073553

Bystander exposure for Mezot 100 SC			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	luble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.15	kg a.s./ha	i_AppRate
Buffer strip	2-3	m	i_Buffer
Concentration of active substance (in-use dilution for liquid applications)	0.75	g a.s./l	d_ConcAS
Dermal absorption of product	10.00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50.00%		i_AbsorpInuse
Oral absorption	100.00%		i_AbsorpOralInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.45	µg a.s./cm^2	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	i_Volat
Concentration in air	0.001	mg/m^3	d_AirCon
Bystander dermal spray drift exposure - adult	1.21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0.74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00112	ml spray dilution/person	
Exposure duration	2	hours	d_ByExpDur
Exposure duration entry into treated crops	0.25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%		d_ClothAF
Breathing rate adult	0.23	m^3/kg bw/day	d_BreathRAd
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	d_BreathRCh
Drift percentage on surface (90th percentile)	8.50%		
Turf transferable residues percentage	5.00%		d_Turf
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	d_ByTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	d_ByTCCh
Saliva extraction percentage	50.00%		d_SalExt
Surface area of hands mouthed	20	cm^2	d_AreaHM
Frequency of hand to mouth activity	20	events/hour	d_ByFreqHM
Ingestion rate for mouthing of grass per day	25	cm^2	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%		d_DRP
Transfer coefficient for entry into treated crops - a	7500	cm^2/h	d_TcEntryAd
Transfer coefficient for entry into treated crops - c	2250	cm^2/h	d_TcEntryCh

1. Total

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.2283900	0.0107000	0.0363375	0.1265625
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0228390	0.0010700	0.0036338	0.0126563

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.3724500	0.0138000	0.0924375	0.4218750
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0062075	0.0002300	0.0015406	0.0070313

Estimation of bystander and resident exposure (adults and children)

Active substance (a.s.)	**Mesotrione**	
Product	**Mezot 100 S.C.**	
Intended uses	**Field Crops, Tractor Mounted (FCTM)**	
Treated area per day (A)	**20**	**ha/d**
Application rate (AR)	**0.15**	kg a.s./ha
Number of applications (NA)	**1**	1)

1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).

Dermal absorption (DA)	**75**	% (worst case, e.g. during application)
Inhalation absorption (IA)	**100**	%
Oral absorption (OA)	**100**	%
Systemic AOEL	**0.015**	mg/kg bw/d
Body weight (BW)	**60**	kg/person (adults)
	16.15	kg/person (children)

Estimation of bystander exposure during/after application in Field Crops, Tractor Mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):			**Drift (D):**	2.77	% (FCTM, 1 m)
Application rate (AR):	0.15	kg a.s./ha	**Exposed Body Surface Area (BSA):**	1	m² (adults)
				0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.00057	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75.00	% ('worst case')	**Area Treated (A):**	20	ha/d (based on Field Crops, Tractor Mounted (FCTM))
Inhalation absorption (IA):	100	%	**Exposure duration (T):**	5	min
AOEL:	0.015	mg/kg bw/d			

Bystander exposure towards Mesotrione					
Adults			**Children**		
Bystander: Dermal exposure after application in (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(15 x 2.77% x 1 x 75%) / 60			(15 x 2.77% x 0.21 x 75%) / 16.15		
External exposure	0.4155	mg/person	External exposure	0.087255	mg/person
External exposure	0.006925	mg/kg bw/d	External exposure	0.00540279	mg/kg bw/d
Absorbed dose:	**0.0051938**	**mg/kg bw/d**	**Absorbed dose:**	**0.0040521**	**mg/kg bw/d**
Bystander: Inhalation exposure after application in					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0,000 / 360 x 0.15 x 20 x 5 x 100%) / 60			(0,000 / 360 x 0.15 x 20 x 5 x 100%) / 16.15		
External exposure	4.1667E-05	mg/person	External exposure	2.3946E-05	mg/person
External exposure	6.9444E-07	mg/kg bw/d	External exposure	1.4827E-06	mg/kg bw/d
Absorbed dose:	**0.0000007**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000015**	**mg/kg bw/d**
Total systemic exposure: SE_B = SDE_B + SIE_B			Total systemic exposure: SE_B = SDE_B + SIE_B		
Total systemic exposure (absorbed dose)	0.31166667	mg/person	Total systemic exposure (absorbed dose)	0.0654652	mg/person
Total systemic exposure (absorbed dose)	**0.0051944**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0040536**	**mg/kg bw/d**
% of AOEL:	**34.63**	**%**	**% of AOEL:**	**27.02**	**%**

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)

No additional data.