

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 6**

#### **Mammalian Toxicology**

Detailed summary of the risk assessment

Product code: M-100SC-OR2-C

Product name(s): Juzan Extra 100 SC

Chemical active substance:

mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 05/2022

MS Finalisation date: 01/2022; 05/2023

## Version history

When	What
May 2022	First submission for the product authorisation
January 2023	Assessment by expert
May 2023	The final version of RR after commenting period

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## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on M-100SC-OR2-C/Juzan Extra 100 SC \***

Product name and code	M-100SC-OR2-C/Juzan Extra 100 SC
Formulation type	Suspension concentrate [Code: SC]
Active substance(s) (incl. content)	mezotrione; 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 M-100SC-OR2-C/Juzan Extra 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 M-100SC-OR2-C/Juzan Extra 100 SC according to Regulation (EC) No 1272/2008**

Hazard class(es), categories	Repr. 2, <b>STOT RE 2</b>
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS08
Signal word	Warning
Hazard statement(s)	H361d, <b>H373 (eyes, nervous system)</b>
Precautionary statement(s)	P280 Wear protective gloves/ protective clothing P308 + P313 IF exposed or concerned: Get medical advice/attention P405 Store locked up
Additional labelling phrases	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH 208]

**Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for M-100SC-OR2-C/Juzan Extra 100 SC**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	<b>Workwear and gloves during mixing/loading and application</b> <b>Wear protective clothing and protective gloves when mixing, loading and handling.</b>

	Result	PPE / Risk mitigation measures
Workers	Acceptable	Workwear and gloves when handling treated crops
Residents	Acceptable	Drift reduction 5 m buffer strip Information table: “No entry for residents to area treated with plant protection product”
Bystanders	Acceptable	Drift reduction 5 m buffer strip Information table: “No entry for residents to area treated with plant protection product”

No unacceptable risk for operators, workers, residents and bystanders 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.

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. safen- er/synergist (L/ha))  critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure as- sessment			
			Method / Kind (incl. applica- tion technique ***	Max. number (min. interval between applica- tions)  a) per use b) per crop/ season	Max. applica- tion rate kg as/ha  a) a.s. 1 b) a.s. 2	Water L/ha  min / max			Operator	Worker	Residents	Bystander
1	Maize (ZEMX) sugar maize (ZEMS); Popcorn (ZEME);  BBCH 12 - 18	F	Spraying, LCTM	a) 1 b) 1	a) 0.150	200 - 400	n.a.	Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874				

\* 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

### Data gaps

N/A.

Noticed data gaps are: no

## 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)**

	Active substance
Common Name	Mezotrione
CAS-No.	104206-82-8
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended by 15 <sup>th</sup> ATP 19/05/2020; 01/03/22)  RAC opinion 14/ September 2018	<p>Hazard classes (s), categories: Repr.2 STOT RE 2</p> <p>Code(s) for hazard pictogram(s): GHS08 GHS09</p> <p>Signal word: Warning</p> <p>Hazard statement(s): H361d - Suspected of damaging the unborn child H373 - May cause damage to organs (eyes, nervous system) through prolonged or repeated exposure</p> <p>Precautionary statement(s): P280 - Wear protective gloves/protective clothing/eye protection/face protection. P260 - Do not breathe dust. P202 - Do not handle until all safety precautions have been read and understood. P308+P313-IF exposed or concerned: Get medical advice/attention. P314-Get medical advice/attention if you feel unwell P405 - Store locked up. P391 - Collect spillage. P273 - Avoid release to the environment.</p>
Additional C&L proposal	None.
AOEL systemic	0.005 mg/kg bw per day
Reference	EFSA Journal 2016;14(3):4419; RAC opinion 14/ September 2018
According to Review Report	Member States shall pay particular attention to the protection of operators

## 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for M-100SC-OR2-C/Juzan Extra 100 SC is given in the following tables. The applicant did not perform acute toxicity studies because of protection of animals used for experimental. According to Regulation (EC) No 1107/2009 “The use of non-animal test methods and

other risk assessment strategies should be promoted”. Animal testing for the purposes of registration procedure should be minimized and tests on vertebrates should be undertaken as a last resort. The same approach is strongly recommended by Regulation (EC) No 1272/2008, which advises reducing testing on vertebrate animals and the number of animals involved.

Full justifications and classification based on composition of the product (estimation method - additivity formula) 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 M-100SC-OR2-C/Juzan Extra 100 SC**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat	No study submitted	Yes	No classification based on composition of the product (estimation method - additivity formula)	Appendix 2
LD <sub>50</sub> dermal, rat	No study submitted	Yes	No classification based on composition of the product (estimation method - additivity formula)	Appendix 2
LC <sub>50</sub> inhalation, rat	No study submitted	Yes	No classification based on composition of the product (estimation method - additivity formula)	Appendix 2
Not submitted, not necessary. Justification presented in Appendix 2				
Skin irritation, model system	No study submitted	Yes	No classification based on composition of the product (estimation method - additivity formula)	Appendix 2
Eye irritation, model system	No study submitted	Yes	No classification based on composition of the product (estimation method - additivity formula)	Appendix 2
Skin sensitisation, guinea pig/mouse	Estimation based on composition of the product (additivity formula)	Yes	No classification based on composition of the product (estimation method - additivity formula)	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 M-100SC-OR2-C/Juzan Extra 100 SC**

	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)	mesotrione (9.87 76% (w/w) technical) 103.4 102g/l	Repr.2, H361d (Concentration ≥ 3 %)  STOT RE 2, H373 (Concentration ≥ 10 %)	Reg. 1272/2008	Repr.2, H361d  STOT RE 2, H373
Toxicological properties of non-active substance(s) (relevant for classification of product)	Information concerning toxicological properties of non-active substance are presented can be found in the confidential dossier of this submission (Registration Report - Part C).			
Further toxicological information	No data – not required			

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

\*\* Material safety data sheet by the applicant

## 6.4 Toxicological Evaluation of Groundwater Metabolites

During EU review of mesotrione two metabolites of the active substance were considered in the groundwater modelling: MNBA and AMBA. The same has been done for this product.

In case of assessment performed for the Juzan Extra 100 SC the predicted environmental concentrations in groundwater (PEC<sub>GW</sub>) of AMBA did not exceed 0.1µg/L and thus, no further assessment was for this metabolite needed. In a contrast, the maximum PEC<sub>GW</sub> of MNBA exceeded the trigger value of 0.1µg/L. For that reason further evaluation on its relevance is reported in the dRR Part B, Section 10.

As stated in the EU peer review on mesotrione, the MNBA metabolite has low toxicity than the parent mesotrione. The tyrosine disturbance is secondary to inhibition of p-hydroxyphenylpyruvate dioxygenase (HPPD). In a study of relative potency of HPPD inhibition, MNBA was several orders of magnitude less potent than mesotrione. It is considered that MNBA will not produce disturbance of tyrosine metabolism of sufficient magnitude to induce classifiable developmental effect

No additional toxicological studies were submitted for metabolites. The evaluation in dRR Part B, Section 10 is based on the EFSA conclusions and RAR for mesotrione.

## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in M-100SC-OR2-C/Juzan Extra 100 SC are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in M-100SC-OR2-C/Juzan Extra 100 SC**

	mesotrione	
	Value	Reference
Concentrate	10%	EFSA Guidance on dermal absorption (EFSA Journal

	mesotrione	
	Value	Reference
		2017;15(6):4873)
Dilution	50%	EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873)

### 6.5.1 Justification for proposed values - mesotrione

No data on dermal absorption for mesotrione in M-100SC-OR2-C/Juzan Extra 100 SC is available. Default values according to Guidance on Dermal Absorption 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%	Default dermal absorption value from EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873)	Yes
Dilution	50%	Default dermal absorption value from EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873)	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	Juzan Extra 100 SC / M-100SC-OR2-C
Formulation type	SC
Category	Herbicide
Active substance(s) (incl. content)	Mesotrione 100 g/L
AOEL systemic	0.005 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	<b>70% based on comparison of excretion patterns after oral vs. intravenous administrations in rats treated with 1 mg/kg bw (used in the exposure and risk assessment)</b> 50% based on radioactivity excreted in urine and cage-wash in mice treated with 1 mg/kg bw via the oral route
Dermal absorption	Concentrate:10% Dilution: 50% (Default)

### 6.6.1 Selection of critical use(s) and justification

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

#### Justification

The critical GAPs have been defined following evaluation of the individual GAPs for each crop and take into account the appropriate crop scenario and the maximum application rate applied in the minimum water volume as relevant for this zone.

- 1 x 1.5 L of product/ ha eq. to 1 x 150 g of mesotrione/ha in 200 L of water for maize, sugar maize, popcorn (Cereals represented by cereals scenario in the EFSA calculator scenario);

### 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 M-100SC-OR2-C/Juzan Extra 100 SC 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)	Cereals – maize (max. 1.5 L product/ha) Maize (max. 1.5 L product/ha), represented by cereals scenario in the EFSA calculator
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)**

		Mesotrione	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Cereals scenario Tractor mounted boom spray application outdoors to low crops			
Application rate		0.150 kg a.s./ha	
Spray application (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.0781954	1563.91
	Work wear (arms, body and legs covered) M/L and A	0.0488838	977.68
	Work wear (arms, body and legs covered) + gloves M/L and A	0.0026995	<b>53.99</b>

According to the model calculations, it can be concluded that the risk for the operator using JU-ZAN EXTRA 100 SC on crops proposed is acceptable according to the model applied with the use of personal protective equipment. Work wear (arms, body and legs covered) Mixing/Loading and Application + gloves

### 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 M-100SC-OR2-C/Juzan Extra 100 SC according to the critical use(s). Outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed calculations are in Appendix 3.

**Table 6.6-4: Exposure models for intended uses**

Critical use(s)	Cereals maize (max. 1.5 L product/ha) <b>Maize (max. 1.5 L product/ha), represented by cereals scenario in the EFSA calculator</b>
Model(s)	Post-Application Exposure of Workers to Pesticides in Agriculture – Report of the Re-entry Working Group. EUROPOEM II Project, FAIR3-CT96-1406. December 2002

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

		Mesotrione	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals Inspection, irrigations EUROPOEM II Work rate: 2 hours/day DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha MAF: n.a.			
Number of applications and application rate		1 x 0.150 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm <sup>2</sup> /person/h	-	-
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	0.630	<b>210</b>
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm <sup>2</sup> /person/h PPE factor dermal: 5	0.126	42

**It can be concluded that exposure is acceptable for workers wearing work wear (arms, body and legs covered) and gloves wearing protective clothing and protective gloves when mixing, loading and handling**

### 6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not relevant, default value 3 µg/cm<sup>2</sup>/kg a.s./ha was applied for calculations

### 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

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- shows the exposure model(s) used for estimation of resident and bystander exposure to mesotrione. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term resident exposure). Detailed calculations are in Appendix 3.

**Table 6.6-6: Exposure models for intended uses**

Critical use(s)	<b>Cereals – maize (max. 1.5 L product/ha) Maize (max. 1.5 L product/ha), represented by cereals scenario in the EFSA calculator</b>
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)**

		mesotrione	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>Cereals – maize scenario Maize (max. 1.5 L product/ha), represented by cereals scenario in the EFSA calculator</b> Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 365 days			

MAF: n.a.			
Number of applications and application rate		1 x 0.150 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0100718	<b>201.44</b>
	Vapour (75 <sup>th</sup> perc.)	0.0010700	21.40
	Deposits (75 <sup>th</sup> perc.)	0.0011773	23.55
	Re-entry (75 <sup>th</sup> perc.)	0.0126563	<b>253.13</b>
	<b>Sum (mean)</b>	0.0175709	<b>351.42</b>
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0024100	48.20
	Vapour (75 <sup>th</sup> perc.)	0.0002300	4.60
	Deposits (75 <sup>th</sup> perc.)	0.0005110	10.22
	Re-entry (75 <sup>th</sup> perc.)	0.0070313	<b>140.63</b>
	<b>Sum (mean)</b>	0.0073553	<b>147.11</b>
<p><del>Cereals – maize scenario</del> <b>Maize (max. 1.5 L product/ha), represented by cereals scenario in the EFSA calculator</b></p> <p>Tractor mounted boom spray application outdoors to low crops  Buffer zone: 2-3 (m)  Drift reduction technology: yes  DT<sub>50</sub>: 30 days  DFR: 3 µg/cm<sup>2</sup>/kg a.s./ha  Interval between treatments: 365 days  MAF: n.a.</p>			
Number of applications and application rate		1 x 0.150 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0050359	<b>100.72</b>
	Vapour (75 <sup>th</sup> perc.)	0.0010700	21.40
	Deposits (75 <sup>th</sup> perc.)	0.0005886	11.77
	Re-entry (75 <sup>th</sup> perc.)	0.0126563	<b>253.13</b>
	<b>Sum (mean)</b>	0.0143661	<b>287.32</b>
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0012050	24.01
	Vapour (75 <sup>th</sup> perc.)	0.0002300	4.60
	Deposits (75 <sup>th</sup> perc.)	0.0002555	5.11
	Re-entry (75 <sup>th</sup> perc.)	0.0070313	<b>140.63</b>
	<b>Sum (mean)</b>	0.0065958	<b>131.92</b>
<p><del>Cereals – maize scenario</del> <b>Maize (max. 1.5 L product/ha), represented by cereals scenario in the EFSA calculator</b></p> <p>Tractor mounted boom spray application outdoors to low crops  Buffer zone: 5 (m)  Drift reduction technology: yes  DT<sub>50</sub>: 30 days  DFR: 3 µg/cm<sup>2</sup>/kg a.s./ha  Interval between treatments: 365 days  MAF: n.a.</p>			
Number of applications and application rate		1 x 0.150 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0033504	67.01
	Vapour (75 <sup>th</sup> perc.)	0.0010700	21.40
	Deposits (75 <sup>th</sup> perc.)	0.0002418	4.84

	Re-entry (75 <sup>th</sup> perc.)	0.0126563	<b>253.13</b>
	<b>Sum (mean)</b>	0.0132007	<b>264.01</b>
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0006104	12.21
	Vapour (75 <sup>th</sup> perc.)	0.0002300	4.60
	Deposits (75 <sup>th</sup> perc.)	0.0001049	2.10
	Re-entry (75 <sup>th</sup> perc.)	0.0070313	<b>140.63</b>
	<b>Sum (mean)</b>	0.0062335	<b>124.67</b>
<p><del>Cereals – maize scenario</del> <b>Maize (max. 1.5 L product/ha), represented by cereals scenario in the EFSA calculator</b>                      Tractor mounted boom spray application outdoors to low crops  <b>Buffer zone: 5 (m)</b>                      Drift reduction technology: yes                      DT<sub>50</sub>: 30 days                      DFR: 3 µg/cm<sup>2</sup>/kg a.s./ha                      Interval between treatments: 365 days                      MAF: n.a.</p> <p><b>No entry for residents to area treated with plant protection product</b></p>			
Number of applications and application rate		1 x 0.150 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0033504	67.01
	Vapour (75 <sup>th</sup> perc.)	0.0010700	21.40
	Deposits (75 <sup>th</sup> perc.)	0.0002418	4.84
	Re-entry (75 <sup>th</sup> perc.)	0.0000000	0.00
	<b>Sum (mean)</b>	0.0031095	<b>62.19</b>
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0006104	12.21
	Vapour (75 <sup>th</sup> perc.)	0.0002300	4.60
	Deposits (75 <sup>th</sup> perc.)	0.0001049	2.10
	Re-entry (75 <sup>th</sup> perc.)	0.0000000	0.00
	<b>Sum (mean)</b>	0.0006272	<b>12.54</b>

**The estimation of resident and/or bystander exposure has shown that the acceptable operator exposure level (AOEL) for mesotrione will only be not exceeded if risk mitigation measures are applied, such as drift reduction nozzles, a 5 meter buffer strip and the table states that residents and bystanders should not enter the treated area.**

#### 6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for mesotrione will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures (drift reduction nozzles, 5 m buffer strip and information table that residents and bystanders should to not enter the treated area), a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

### **6.6.5 Combined exposure**

Not relevant. The product contains only one active substance.



## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### 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
-	-	-	-	-	-

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

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

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

## Appendix 2 Detailed evaluation of the studies relied upon

### A 2.1 Statement on bridging possibilities

Bridging is not necessary since the toxicological potential of M-100SC-OR2-C/Juzan Extra 100 SC can be predicted on the basis of toxicological data available for active substance and co-formulants included in composition of the product.

### A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<b>Taking into account the composition of the product, the formulation M-100SC-OR2-C/Juzan Extra 100 SC is unclassified</b>
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Acute oral toxicity value ( $ATE_{mix}$ ) for M-100SC-OR2-C/Juzan Extra 100 SC can be estimated according to principles of Regulation 1272/2008, p. 3.1.3.6.1 (additivity formula) as follows:

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

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.

Calculations takes account data for components which are classified to acute oral toxicity class. Three components of product M-100SC-OR2-C/Juzan Extra 100 SC are classified as Acute Tox. 4 with hazard statement H302. Their concentration in the product is equal to 0.48%, 0.007%, and 0.014% respectively. Their summed concentration equal to 0.501% is below concentration limit (1%) stated in Table 1.1 of Regulation 1272/2008, therefore the product will not be classified as Acute Tox. 4 with hazard statement H302 and indicated ingredients will not significantly affect the estimated  $ATE_{mix}$  value.

None of the others co-formulants of M-100SC-OR2-C/Juzan Extra 100 SC (according to submitted MSDs) is classified as Acute Tox. with hazard statements H300, H301, H302.

Taking into account the composition of the product, the formulation M-100SC-OR2-C/Juzan Extra 100 SC does not require classification in respect to oral acute toxicity. No additional studies are required.

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

Comments of zRMS:	<b>Taking into account the composition of the product, the formulation M-100SC-OR2-C/Juzan Extra 100 SC does not require classification in respect to dermal acute toxicity</b>
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Acute dermal toxicity value ( $ATE_{mix}$ ) can be estimated according to principles of Regulation 1272/2008, p. 3.1.3.6.1 (additivity formula) as follows:

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

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.

Calculations takes account data for components which are classified to acute dermal toxicity class and are in the appropriate concentration in the mixture. None of co-formulants of M-100SC-OR2-C/Juzan Extra 100 SC is classified as Acute Tox. with hazard statements H310, H311, H312 therefore none of them is relevant for calculation  $ATE_{mix}$  for acute dermal toxicity category according to point 3.1.3.6.1 of Regulation 1272/2008.

Taking into account the composition of the product, the formulation M-100SC-OR2-C/Juzan Extra 100 SC does not require classification in respect to dermal acute toxicity. No additional studies are required.

#### A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS	<b>Taking into account the composition of the product, the formulation M-100SC-OR2-C/Juzan Extra 100 SC does not require classification in respect to inhalation acute toxicity</b>
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Acute inhalation toxicity value ( $ATE_{mix}$ ) can be estimated according to principles of Regulation 1272/2008, p. 3.1.3.6.1 (additivity formula) as follows:

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

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.

Calculations takes account data for components which are classified to acute inhalation toxicity class and are in the appropriate concentration in the mixture. None of co-formulants of M-100SC-OR2-C/Juzan Extra 100 SC is classified as Acute Tox. with hazard statements H330, H331, H332 therefore none of them is relevant for calculation  $ATE_{mix}$  for acute inhalation toxicity category according to point 3.1.3.6.1 of Regulation 1272/2008.

Taking into account the composition of the product, the formulation M-100SC-OR2-C/Juzan Extra 100 SC does not require classification in respect to inhalation acute toxicity. No additional studies are required.

## A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	<b>Taking into account it is concluded that formulation M-100SC-OR2-C/Juzan Extra 100 SC does not require classification for skin corrosion or irritation</b>
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A skin irritation potential of M-100SC-OR2-C/Juzan Extra 100 SC can be estimated according to principles of Regulation 1272/2008 by using additivity approach.

The concentration of one of the ingredient of a product M-100SC-OR2-C/Juzan Extra 100 SC classified as Skin Corr. 1B, H314 is equal to 0.14 % w/w and is below the concentration limits for classification of mixture as Skin Corr.1 (  $\geq 5\%$  ) and Skin irrit.2 (  $\geq 1\%$  ) given in table 3.2.3. of Regulation (EC) 1272/2008.

One ingredient is classified as Skin Irrit. 2, H315, and one as Skin Corr. 1A - H314, but they are both components of the above mixture ingredient already classified as Skin Corr. 1B, H314 present in the product at concentration of 0.14 %.

The sum of the concentrations of ingredients classified as Skin Corr. 1, H314 multiply by 10 (  $10 \times 0.14\%$  ) equal to 1.4 % is well below generic concentration limit of  $\geq 10\%$  for ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) defined in Table 3.2.3 of Regulation 1272/2008 that trigger classification of the mixture as irritant to skin. Above 99% of the mixture is not classified for skin corrosion or irritation.

Taking into account it is concluded that formulation M-100SC-OR2-C/Juzan Extra 100 SC does not require classification for skin corrosion or irritation. No additional studies are required.

## A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	The sum of concentration of ingredient classified as Skin Corr. 1, H314 plus concentration of ingredient classified as Eye Dam.1 multiplied is equal to 6.2 % w/w ( $10 \times (0.14 + 0.48) + 0$ ) thus it is well below the generic concentration limit of 10% for ingredients of a mixture classified for effects on the eye  <b>And then Juzan Extra 100 SC does not require classification for eye effects according this criterion.</b>
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An eye irritation potential of M-100SC-OR2-C/Juzan Extra 100 SC can be estimated according to principles of Regulation 1272/2008 by using additivity approach.

M-100SC-OR2-C/Juzan Extra 100 SC contains one constituent classified as Skin Corr. 1B, Causes severe skin burns and eye damage at concentration of 0.14 % w/w and one ingredient classified as Eye Dam. 1, H318 at concentration 0.48% w/w. Their total concentration is equal to 0.62 % w/w and is below the concentration limits for classification of mixture as Eye Dam. 1 (  $\geq 3\%$  ) or as Eye Irrit.2 (  $\geq 1\%$  but  $< 3\%$  ) given in table 3.3.3 of Regulation (EC) 1272/2008, thus M-100SC-OR2-C/Juzan Extra 100 SC does not require classification for eye effects according this criterion.

The sum of concentration of ingredient classified as Skin Corr. 1, H314 plus concentration of ingredient classified as Eye Dam.1 multiplied is equal to 6.2 % w/w ( $10 \times (0.14 + 0.48) + 0$ ) thus it is well below the generic concentration limit of 10% for ingredients of a mixture classified for effects on the eye given in Table 3.3.3 in Regulation EC 1272/2008, thus M-100SC-OR2-C/Juzan Extra 100 SC does not require classification for eye effects according this criterion. No additional studies are required.

## A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<b>. Its concentration in M-100SC-OR2-C/Juzan Extra 100 SC is equal to 0.014%, which is below its specific concentration limit of 0.05% (for H317) but above its elicitation limit of 0.005% for EUH 208 statement, therefore M-100SC-OR2-C/Juzan Extra 100 SC require labelling: EUH 208 Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.</b>
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A skin or respiratory sensitisation potential of M-100SC-OR2-C/Juzan Extra 100 SC can be estimated according to principles of Regulation 1272/2008 which indicate that if at least one ingredient has been classified as a respiratory or skin sensitizer and is present at or above the appropriate generic/specific concentration limit, the mixture shall be classified as a respiratory or skin sensitizer.

M-100SC-OR2-C/Juzan Extra 100 SC does not contain any component which is classified as respiratory sensitizer with hazard statement H334, therefore the product will not be classified as respiratory sensitizer with hazard statement H334.

One ingredient (mixture) of the product M-100SC-OR2-C/Juzan Extra 100 SC classified as Skin Sens.1B, H317 is present at concentration of 0.14% thus below a generic concentration limit of a 1% for sensitising components of a mixture that triggers classification of the whole mixture as Skin Sens. 1 (Table 3.4.5 of the Regulation 1272/2008), therefore product M-100SC-OR2-C/Juzan Extra 100 SC does not require to be classified as skin sensitizer: Skin Sens. 1 ; H317 for that reason.

In addition this mixture present in M-100SC-OR2-C/Juzan Extra 100 SC contains only one substance which is classified as Skin Sens. 1, H317. Its concentration in M-100SC-OR2-C/Juzan Extra 100 SC is equal to 0.014%, which is below its specific concentration limit of 0.05% (for H317) but above its elicitation limit of 0.005% for EUH 208 statement, therefore M-100SC-OR2-C/Juzan Extra 100 SC require labelling:

**EUH 208 Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.**

No additional studies are required.

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

Not relevant.

## 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)**

No study on dermal absorption was submitted, default values were used to risk assessment.

**A 2.11                    Other/Special Studies**

No applicable.

## Appendix 3 Exposure calculations

### A 3.1 Operator exposure calculations (KCP 7.2.1.1)

#### A 3.1.1 Calculations for mesotrione

**Table A 1: Input parameters considered for the estimation of operator exposure in cereals – tractor mounted**

<b>Substance name</b>	Mesotrione
<b>Product name</b>	Juzan Extra 100 SC
<b>Reference value non acutely toxic active substance (RVNAS)</b>	0,005 mg/kg bw/day
<b>Reference value acutely toxic active substance (RVAAS)</b>	mg/kg bw/day
<b>Crop type</b>	Cereals
<b>Substance properties</b>	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	200 L/ha
Maximum application rate of active substance	0,15 kg a.s. /ha
50% Dissipation Time DT50	30 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	70,00%
Inhalation absorption of active substance	100,00%
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa
<b>Scenario</b>	
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



**Table A 2: Estimation of longer term operator exposure towards mesotrione in cereals – tractor mounted when no PPE is applied- according to EFSA guidance**

Application rate of active substance		0,15 kg a.s./ha		L_AppRate	
Assumed area treated		50 ha/day		d_AreaTreated	
Amount of active substance applied		7,5 kg a.s./day		L_AmountAS	
Dermal absorption of the product		10,00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		50,00%		i_AbsorpInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrate, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	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	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	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	No			
	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	4,6917225	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0781954	0,0781954	
% of RVNAS	1563,91%	1563,91%	

**Table A 3: Estimation of longer term operator exposure towards mesotrione in cereals – tractor mounted when work wear during M/L and A is applied- according to EFSA guidance**

Application rate of active substance		0,15 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated		50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied		7,5 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product		10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution		50,00%	<i>i_AbsorInuse</i>
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application		Outdoor	
Application method		Downward spraying	
Application equipment		Vehicle-mounted	
Season		not relevant	

  

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	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	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

  

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	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	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		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	2,9330298	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0781954	0,0488838	
% of RVNAS	1563,91%	977,68%	

**Table A 4: Estimation of longer term operator exposure towards mesotrione in cereals – tractor mounted when work wear and gloves during M/L and A is applied- according to EFSA guidance**

Application rate of active substance		0,15 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated		50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied		7,5 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product		10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution		50,00%	<i>i_AbsorpInuse</i>
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application		Outdoor	
Application method		Downward spraying	
Application equipment		Vehicle-mounted	
Season		not relevant	

  

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	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	
	<b>Protective Equipment</b>	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	

  

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	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	
	<b>Protective Equipment</b>	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
	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	0,1619678	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0781954	0,0026995	
% of RVNAS	1563,91%	53,99%	

**A 3.2 Worker exposure calculations (KCP 7.2.3.1)**

### A 3.2.1 Calculations for mesotrione

**Table A 5:** Estimation of worker exposure towards mesotrione in all intended crops according to EUROPOEM II Model

WORKER EXPOSURE			EUROPOEM II MODEL	
form	Juzan Extra 100 S.C.		Re-entry in the field	
a.s.	Mesotrione			
Parameter		Value	Unit	References, comments
<b>Re-entry activities in the field</b>				
AR	Application rate	0,15	kg a.s./ha	summary of intended uses
<b>Worker</b>				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
<b>Inhalation Exposure</b>				
	no model available	-		without PPE
<b>Dermal Exposure</b>				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,14	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
	Dermal Exposure	1,26	mg a.s./ day	DE = DFR x AR x TC x T
<b>Internal exposure</b>				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	0,3	mg a.s./ day	based on 70 kg bw
		<b>Without PPE</b>	<b>With PPE</b>	
	<b>Internal exposure</b>	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0,630	0,126	DE(int) = DE x (DA/100)
	<b>Total</b>	<b>0,630</b>	<b>0,126</b>	<b>sum</b>
	<b>% AOEL</b>			
	Inhalation	-	-	no model available
	Dermal	210	42	%AOEL = 100 x DE(int) / AOEL
	<b>Total</b>	<b>210</b>	<b>42</b>	<b>sum</b>

\* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

### A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

#### A 3.3.1 Calculations for mesotrione

**Table A 6: Estimation of resident exposure towards mesotrione in cereals – vehicle mounted sprayer according to EFSA guidance when no buffer strip is applied**

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_Absorplnuse
Oral absorption	70,00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,45 µg a.s./cm²				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/m³				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 m³/day/kg				d_BreathRAd
Breathing rate child (1-3 year old)	1,07 m³/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 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50,00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaoHM
Frequency of hand to mouth activity	9,5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/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	0,0117726	0,1265625	0,1757092
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0100718	0,0010700	0,0011773	0,0126563	0,0175709
% of RVNAS	201,44%	21,40%	23,55%	253,13%	351,42%
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
% of RVNAS	48,20%	4,60%	10,22%	140,63%	147,11%

**Table A 7: Estimation of resident exposure towards mesotrione in cereals – vehicle mounted sprayer according to EFSA guidance when drift reduction and no buffer strip is applied**

Croptype	Cereals			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			
Buffer strip	2-3 m			
Application rate of the product	0,15 kg a.s./ha			
Concentration of active substance (in-use dilution for liquid applications)	0,75 g a.s./l			
Dermal absorption of product	10,00%			
Dermal absorption of in-use dilution	50,00%			
Oral absorption	70,00%			
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,45 µg a.s./cm <sup>2</sup>			
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa			
Concentration in air	0,001 mg/m <sup>3</sup>			
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			
Exposure duration inhalation	24 hours			
Exposure duration entry into treated crops	0,25 hours			
Light clothing adjustment factor	18,0%			
Breathing rate adult	0,23 m <sup>3</sup> /day/kg			
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg			
Drift percentage on surface (75th percentile)	5,60%			
Drift percentage on surface (mean)	4,10%			
Turf transferable residues percentage	5,00%			
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour			
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour			
Saliva extraction percentage	50,00%			
Surface area of hands mouthed	20 cm <sup>2</sup>			
Frequency of hand to mouth activity	9,5 events/hour			
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>			
Dislodgeable residues percentage transferability for object to mouth	20,00%			
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h			
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h			
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h			
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h			
<b>1. Total</b>				
<b>1.1 1-3 year old child</b>				
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)
Total systemic exposure (mg a.s./day)	0,0503588	0,0107000	0,0058863	0,1265625
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0050359	0,0010700	0,0005886	0,0126563
% of RVNAS	100,72%	21,40%	11,77%	253,13%
<b>1.2 Adult</b>				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0,0723000	0,0138000	0,0153300	0,4218750
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0012050	0,0002300	0,0002555	0,0070313
% of RVNAS	24,10%	4,60%	5,11%	140,63%

**Table A 8: Estimation of resident exposure towards mesotrione in cereals – vehicle mounted sprayer according to EFSA guidance when drift reduction and 5 m buffer strip is applied**

Croptype	Cereals			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			i_FormVal
Buffer strip	5 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_Absorplnuse
Oral absorption	70,00%			i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,45 µg a.s./cm <sup>2</sup>			d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa			i_Volat
Concentration in air	0,001 mg/m <sup>3</sup>			d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,23798 ml spray dilution/person			
Resident dermal spray drift exposure 75th percentile - child	0,2175 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - adult	0,00009 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - child	0,00017 ml spray dilution/person			
Resident dermal spray drift exposure mean - adult	0,12278 ml spray dilution/person			
Resident dermal spray drift exposure mean - child	0,12 ml spray dilution/person			
Resident inhal. spray drift exposure mean - adult	0,00008 ml spray dilution/person			
Resident inhal. spray drift exposure mean - child	0,00014 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 <sup>3</sup> /day/kg			d_BreathRad
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg			d_BreathRCh
Drift percentage on surface (75th percentile)	2,30%			
Drift percentage on surface (mean)	1,80%			
Turf transferable residues percentage	5,00%			d_Turf
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour			d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour			d_ReTCCh
Saliva extraction percentage	50,00%			d_SalExt
Surface area of hands mouthed	20 cm <sup>2</sup>			d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour			d_ReFreqHM
Ingestion rate for mouth of grass per day	25 cm <sup>2</sup>			d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%			d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h			d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h			d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h			d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h			d_TcEntryCh
<b>1. Total</b>				
<b>1.1 1-3 year old child</b>				
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)
Total systemic exposure (mg a.s./day)	0,0335044	0,0107000	0,0024176	0,1265625
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0033504	0,0010700	0,0002418	0,0126563
% of RVNAS	67,01%	21,40%	4,84%	253,13%
<b>1.2 Adult</b>				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0,0366232	0,0138000	0,0062963	0,4218750
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0006104	0,0002300	0,0001049	0,0070313
% of RVNAS	12,21%	4,60%	2,10%	140,63%

**Table A 9: Estimation of resident exposure towards mesotrione in cereals – vehicle mounted sprayer according to EFSA guidance when drift reduction, 5 m buffer strip is applied together with no-entry table (all pathways – mean)**

Total systemic exposure per day (mg/ kg bw/day)		
	Children	Adult
Spray drift	0.0018503	0.0003151
Vapour	0.0010700	0.0002300
Surface deposits		
Dermal	0.0001755	0.0000821
Hand to mouth	0.0000090	-
Object to mouth	0.0000047	-
Entry into treated crops		

Dermal	0.0000000	0.0000000
<b>Sum</b>	<b>0.0031095</b>	<b>0.0006272</b>
<b>%AOEL</b>	<b>62.19</b>	<b>12.54</b>

**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)**

Not applicable.