

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: MEZOFLOR 103 SC

Product names: **MEZOFLOR 103 SC/
FLOCORN 103 SC**

Chemical active substances:

mesotrione, 100 g/L

florasulam, 3 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

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MS Finalisation date: 12/2023, 12/2024

Version history

When	What
07/2023	Initial dRR
12/2023	zRMS assessment of dRR
12/2024	The final Registration Report

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on MEZOFLOR 103 SC *

Product name and code	MEZOFLOR 103 SC
Formulation type	Suspension Concentrate [Code: SC]
Active substances (incl. content)	Mesotrione; 100 g/L Florasulam, 3 g/L
Function	Herbicide
Product already evaluated as the ‘representative formulation’ during the approval of the active substances	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of MEZOFLOR 103 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 MEZOFLOR 103 SC according to Regulation (EC) No 1272/2008 in regards to mammalian toxicology

Hazard classes, categories	Repr. 2 (H361d) Aquatic Chronic 1 (H410) Aquatic Acute 1 (H400)
Hazard pictograms or Codes for hazard pictogramS	GHS08; GHS09
Signal word	Warning
Hazard statements	H361d - May damage fertility , Suspected of damaging the unborn child. H400 – Very toxic to aquatic life. H410 – Very toxic to aquatic life with long lasting effects.
Precautionary statements	WARNING SECTION OF THE LABEL (first page): P202 - Do not handle until all safety precautions have been read and understood. P273 – Avoid release to the environment. P280 - Wear protective gloves, protective clothing/ eye protection/face protection. P308 +P313 - IF exposed or concerned: Get medical advice/attention. Other sections of the label: P405 - Store locked up. P501 - Dispose of contents/ container to a hazardous waste collection point or special requirements in accordance with local regulations. And P280 as follows: Operator: „Stosować rękawice ochronne oraz odzież ochronną w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.” “Wear protective gloves, and protective clothing during mixing/loading and during application”. Worker: „Stosować rękawice ochronne oraz odzież roboczą podczas wchodzenia na teren poddany zabiegowi.” “Wear protective gloves and work wear during when entering the treated area.” Bystander/Resident: Podczas wykonywania zabiegu należy zachować 5 metrową strefę buforową oraz dysze ograniczające znos. Należy umieścić tablicę informacyjną: „Zakaz wejścia na teren poddany opryskowi do końca uprawy”. Keep a 5 meter buffer zone and drift-reduction nozzles during application. Warning board should be placed: "Do not enter the treated area till the end of the plant growth". Section “First aid”: P308 +P313 - IF exposed or concerned: Get medical advice/attention.
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains benzisothiazol-3(2OH)-one. May produce an allergic reaction. [EUH208] 1. After the treatment has been performed, place warning boards in visible places around the field, reading "No unauthorized access to the area treated with plant protection products". The boards should remain until the plants are harvested / the end of the growing season. 2. During spraying, a buffer zone of at least 5 m from residential buildings / habitats and bystanders should be applied.

	<p>3. During spraying, use techniques to reduce the drift of the product (drift-reduction nozzles, low vehicle speed, stable weather, etc.).</p> <p>4. Do not use the product when the wind speed exceeds 4 m/s (recommended up to 2 m/s).</p> <p>5. When using the PPP, do not allow drift of working liquid.</p> <p>6. Spray treatments under optimal conditions, preferably:</p> <ul style="list-style-type: none"> – using only calibrated sprayers and sprayer booms set at a height not more than 50 cm above the sprayed soil surface; – with the fan turned off in the case of using sprayers with an auxiliary air stream; – at the sprayer's speed not exceeding 8 km/h; – using nozzles for medium-drop spraying at reduced pressure in order to obtain a greater amount of coarse droplets fraction. <p>Period from application to the date when humans and animals may enter the area where the product has been applied (prevention period): Do not enter until the spray liquid is completely dry on the surface of the plants</p>
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Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for MEZOFLOR 103 SC

	Result	PPE / Risk mitigation measures
Operators	Acceptable	<p>Exposure assessment: There is no risk for operator health based on the exposure estimation (AOEM, OPEX calculator) assuming the gloves and workwear (arms, body and legs covered) are used.</p> <p>Classification: protective gloves and protective clothing</p>
Workers	Acceptable	<p>There is no risk for worker health based on the exposure estimation assuming work wear (arms, body and legs covered) and protective gloves are used.</p>
Residents	Acceptable	<p>Additional phrases according to resident and bystander safety should be used on the label of the product.</p> <ul style="list-style-type: none"> - warning boards preventing from resident/bystander entry into treated area till the end of cultivation, - min. 5-meter buffer zone during spraying - drift-reduction nozzles.
Bystanders	Acceptable	<p>Additional phrases according to resident and bystander safety should be used on the label of the product.</p> <ul style="list-style-type: none"> - warning boards preventing from resident/bystander entry into treated area till the end of cultivation, - min. 5-meter buffer zone during spraying - drift-reduction nozzles.

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

No unacceptable risk for residents and bystanders was identified when the product is used as intended. Additional phrases according to resident and bystander safety should be used on the label of the product (Table 6.1-2).

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 applications) 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 (BBCH 12-18)	F	Spraying, FCTM	1 ; 1	a) 0.125 b) 0.00375	200-300	-	Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment for plant protection products; <i>EFSA Journal</i> 2022;20(1):7032				

* 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

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

– Mesotrione:

- assessment of the toxicological relevance of individual impurities present in the technical specification in comparison with the toxicological profile of the parent mesotrione (except for the impurities already identified as relevant and solvents of known toxicological profile);
- clarification of the endocrine disrupting potential of mesotrione considering in particular level 2 and 3 tests currently indicated in the OECD Conceptual Framework (relevant for all representative uses evaluated);
- clarification of the genotoxic potential of AMBA and of its toxicological profile (relevant for all representative uses evaluated).

(EFSA Journal 2016;14(3):4419)

– Florasulam:

No critical areas of concern were identified in the mammalian toxicology section.

(EFSA Journal 2015; 13(1):3984)

6.2 Toxicological Information on Active Substances

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	Florasulam
Common Name	Mesotrione	Florasulam
CAS-No.	104206-82-8	145701-23-1
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) According to 17 th Adaptation to Technical Progress and RAC Opinion (14.09.2018).	Hazard classes, categories: Repr. 2 STOT RE 2 (eyes, nervous system) Code for hazard pictograms: GHS08 Signal word: Warning Hazard statements: H361 - Suspected of damaging the unborn child. H373 - May cause damage to organs (eyes, nervous system) through prolonged or repeated exposure. Precautionary statements: P202 - Do not handle until all safety precautions have been read and understood. P280 – Wear protective gloves/ protective clothing/eye protection/face protection. P308 + P313 – IF exposed or concerned: Get medical advice/ attention. P273 – Avoid release to the environment. P391 – Collect spillage. P501 - Dispose of contents of as hazardous waste.	Hazard classes, categories: None Code for hazard pictogram: None Signal word: Warning Hazard statements: None Precautionary statements: None
Additional C&L proposal	-	-
Agreed EU endpoints		
AOEL systemic	0.005 mg/kg bw/d (corrected for 50% oral absorption)	0.05 mg/kg bw/d (uncertainty factor of 100)
Reference	Peer review of the pesticide risk assessment of the active substance mesotrione. <i>EFSA Journal</i> 2016;14(3):4419	Peer review of the pesticide risk assessment of the active substance florasulam. <i>EFSA Journal</i> 2015; 13(1):3984
Conditions to take into account/critical areas of concern with regard to toxicology		
According to EFSA Conclusion for active substance	None	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for MEZOFLOR 103 SC is given in the following table. 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 MEZOFLOR 103 SC

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (calculation method)	(>) 2000 mg/kg bw	Yes	None	Additivity formula (calculation method)
Not submitted, not necessary. Justification presented in Appendix 2				
LD ₅₀ dermal, rat (calculation method)	-	Yes	None	Additivity formula (calculation method)
Not submitted, not necessary. Justification presented in Appendix 2				
LC ₅₀ inhalation, rat (calculation method)	-	Yes	None	Additivity formula (calculation method)
Not submitted, not necessary. Justification presented in Appendix 2)				
MEZOFLOR 103 SC: <i>In Vitro</i> Skin Corrosion: Reconstructed Human Epidermis Test Method (OECD 431)	Non-irritant	Yes	None	Krakowian D., 2021
MEZOFLOR 103 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 (OECD 438)	Non-irritant	Yes	None	Krakowian D., 2021
Skin sensitisation (calculation method)	Non-sensitising	Yes	None	Additivity formula (calculation method)
Not submitted, not necessary. Justification presented in Appendix 2.				
Supplementary studies for combinations of plant protection products	No data – not required			

Formulation does not contain any substances classified as:

- respiratory sensitizer,
- germ cell mutagenic,
- cancerogenic,
- toxic on specific target organs (single exposure),

- aspiration hazard.

Thus according to points 3.4, 3.5, 3.6, 3.8, 3.10 of Regulation (EC) 1272/2008 product MEZOFLO 103 SC does not need to be classified in above mentioned categories.

MEZOFLO 103 SC contains the active substance – mesotrione, which is classified (according to 17th Adaptation to Technical Progress) as:

- STOT RE 2 with hazard statement H373. Its concentration in the product is equal to 9.6%. This concentration is below concentration limit (10%) stated in Table 3.9.4 of Regulation (EC) 1272/2008, therefore the product is not classified as STOT RE 2 with hazard statement H373.
If a mixture contains an ingredient classified as Category 2 for specific target organ toxicant at the concentration $\geq 1.0\%$, a safety data sheet shall be available for the mixture upon request.
- Repr. 2 with hazard statement H361d. Its concentration in the product is equal to 9.6%. This concentration above concentration limit (3%) stated in Table 3.7.2 of Regulation (EC) 1272/2008, therefore the product is classified as **Repr. 2** with hazard statement **H361d**.

6.4 Toxicological Evaluation of Groundwater Metabolites

Comments of zRMS:	Taking into account toxicological data, metabolites ASTCA and TSA are considered toxicologically non-relevant (EFSA Journal 2015;13(1): 3984). The PEC _{gw} values for both metabolites are below the upper limit for metabolites (<0.75 µg/l). Consequently, the consumer risk calculations for ASTCA and TSA are not required.
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1.4.1 Mesotrione

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

Note that the relevance calculation is reported in Part ~~B.8.~~ B.10.

6.4.2 Florasulam

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

6.4.2.1 Metabolite 1 – ASTCA (5-aminosulfonyl-1H1,2,4-triazole-3-carboxylic acid)

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

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

Type of test, species (Guideline)	Result	Acceptability	Reference*
<i>Salmonella</i> <i>Escherichia coli</i> / Mammalian – microsome Reverse Mutation Assay (OECD 471 and 472)	Non-genotoxic		Mecchi M.S., 2008

Type of test, species (Guideline)	Result	Acceptability	Reference*
<i>In Vitro</i> Mammalian Cell Gene Mutation Tests using the Hprt and xprt genes (OECD 476)	Non-genotoxic		Schisler M.R., Geter D.R., 2008
<i>In Vitro</i> Chromosomal Aberration Assay Utilizing Rat Lymphocytes (OECD 473)	Non-genotoxic		Schisler M.R., Kleinert K.M., Geter D.R., 2008

* indicates that a study was reviewed at EU level

Taking into account the toxicological data the metabolite ASTCA is considered toxicologically non-relevant.

6.4.2.1 Metabolite 2 – TSA (1H-1,2,4-triazole-3-sulfonamide)

An overview of the results of the accepted toxicological studies for groundwater metabolite TSA is given in the following table.

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

Type of test, species (Guideline)	Result	Acceptability	Reference*
<i>In vitro</i> bacterial (Ames) reverse gene mutation (OECD 471)	Negative effect in the Bacterial Reverse Mutation Assay using <i>Salmonella typhimurium</i>		Nagane, R.M. (2011).
<i>In vitro</i> mammalian forward gene mutation in L5178Y cells at the <i>tk</i> locus (OECD 490)	Does not have potential to induce gene mutations at the <i>HGPRT</i> locus of CHO-K1 cells both in the absence and presence of metabolic activation system		Nagane, R.M. (2011).
<i>In vitro</i> Mammalian Chromosome Aberration Test using Human Peripheral Blood Lymphocytes (OECD 473)	Did not show any potential to induce chromosomal aberration, both in the absence and presence (2 and 4% v/v S9) of metabolic activation system		Nagane, R.M. (2011).

* indicates that a study was reviewed at EU level

Taking into account the toxicological data the metabolite TSA is considered toxicologically non-relevant.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in MEZOFLO 103 SC are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in MEZOFLO 103 SC

	Mesotrione		Florasulam	
	Value	Reference	Value	Reference
Concentrate	10% (default)	Guidance on dermal absorption. <i>EFSA Journal</i> 2017;15(6);4873.	50% (default)	1. Guidance on dermal absorption. <i>EFSA Journal</i> 2017;15(6);4873. 2. SANTE/2018/10591 (rev.1 24 October 2018).
Dilution	50% (default)		50% (default)	

Justification for proposed values – mesotrione

No data on dermal absorption for mesotrione in MEZOFLO 103 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.

Default values of dermal absorption for MEZOFLO 103 SC according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are 10% for concentrate and 50% for dilution. MEZOFLO 103 SC is water based formulation.

Regarding to Guidance on Dermal Absorption (2017), a default dermal absorption value of:

- 10% may be applied for concentrated products that are water based formulation;
- 50% may be applied for (in use) dilutions of water based formulation.

Based on above, Applicant has proposed for MEZOFLO 103 SC a default dermal absorption value of 10% for the concentrate and 50% for the spray solution.

Table 6.5-2: Default dermal absorption rates for mesotrione

	Value	Justification for value	Acceptability of justification
Concentrate	10 %	In the absence of any supporting dermal absorption data for MEZOFLO 103 SC, it is proposed a dermal absorption value of 10% for the concentrate and 50 % in-use dilution, based on Guidance on dermal absorption. EFSA Journal 2017; 15(6):4873.	Yes
Dilution	50 %		Yes

Justification for proposed values – florasulam

No data on dermal absorption for florasulam in MEZOFLO 103 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.

Default values of dermal absorption for MEZOFLO 103 SC according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are 10% for concentrate and 50% for dilution. MEZOFLO 103 SC is water based formulation.

Regarding to Guidance on Dermal Absorption (2017), a default dermal absorption value of:

- 10% may be applied for concentrated products that are water based formulation;
- 50% may be applied for (in use) dilutions of water based formulation.

Regarding to SANTE/2018/10591 (rev.1 24 October 2018) a plant protection product is considered a "dilution" when the active substance is present in the plant protection product at a concentration lower than or equal to 50 g/L (or 50 g/kg or 5%).

Based on above, Applicant has proposed for MEZOFLO 103 SC a default dermal absorption value of 50% for the concentrate and 50% for the spray solution.

Table 6.5-3: Default dermal absorption rates for florasulam

	Value	Justification for value	Acceptability of justification
Concentrate	50 %	In the absence of any supporting dermal absorption data for MEZOFLO 103 SC, it is proposed a dermal absorption value of 50% for the concentrate and 50 % in-use dilution, based on Guidance on dermal absorption. EFSA Journal 2017; 15(6):4873 and SANTE/2018/10591 (rev.1 24 October 2018).	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	MEZOFLO 103 SC	
Formulation type	SC	
Category	Herbicide	
Active substances (incl. content)	Mesotrione 100 g/L	Florasulam 3 g/L
AOEL systemic	0.005 mg/kg bw/d	0.05 mg/kg bw/d
Inhalation absorption	100%	100%
Oral absorption	100%	100%
Dermal absorption	Concentrate: 10 % (Default) Dilution: 50% (Default)	Concentrate: 50 % (Default) 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.

6.6.2. Operator exposure (KCP 7.2.1)

Comments of zRMS:	<p>The estimations of operator exposure to mesotrione and florasulam contained in MEZOFLO 103 SC (based on AOEM and OPEX calculator 1.0.1) provided by the Applicant are correct, with the exception of a small mistake in the concentration value of active substances, which should be expressed as the technical material (102 g/L for the mesotrione and 3.1 g/L for the florasulam).</p> <p>Taking into account the results of the exposure assessment to mesotrione, the use of PPP is safe for operator equipped with PPE (work wear and protective gloves during mixing/loading and application).</p> <p><u>Conclusions:</u></p> <p>According to the results of exposure estimations, the use of MEZOFLO 103 SC containing mesotrione (100 g/L) and florasulam (3 g/L) causes acceptable health risk for protected operator (work wear, protective gloves during m&l and application).</p> <p>Taking into account the results of exposure estimations and classification of the product, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:</p> <p>„Stosować rękawice ochronne oraz odzież ochronną w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.”</p> <p>“Wear protective gloves, and protecting clothing during mixing/loading and during application”.</p>
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6.6.2.1 Estimation of operator exposure



A summary of the exposure models used for estimation of operator exposure to the active substances dur-

ing application of MEZOFLO 103 SC according to the critical use 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	Maize (max. 1 x 1.25 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015
	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032. OPEX calculator ver. 1.0.0

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

		Mesotrione		Florasulam		Hazard Index (HI)
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	
Tractor mounted boom spray application outdoors to low crops Drift reduction technology: no*						
Application rate		0.125 kg a.s./ha		0.00375 kg a.s./ha		
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	No PPE	0.06768	1353.6 %	0.0208	41.6 %	
	Gloves + Work wear (arms, body and legs covered): M/L and A	0.00236	47.2 %	0.0004	0.84 %	0.48
OPEX calculator ver. 1.0.0	No PPE 	0.08	1606 %	0.007	64.9 %	
	Gloves + Work wear (arms, body and legs covered): M/L and A 	0.003	51.6 %	0.00065	1.3 %	0.53

*- worst case scenario

The results of the exposure estimations suggest that the use of MEZOFLO 103 SC according to the list of intended uses presented in GAP Table, causes no health risk for the operator assuming the gloves and workwear (arms, body and legs covered).

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)

Comments of
zRMS:

According to current requirements of Polish Authorities, if a PPP is anticipated to be used only once per season EUROPOEM II model should be used to estimate worker exposure towards active substance(s) contained in such formulation. Nevertheless, the estimations of worker exposure to the active substances contained in MEZOFLOR 103 SC performed by the Applicant are not accepted.

The results of new estimations (based on 60 kg. b.w.) are as follows:

WORKER EXPOSURE		EUROPOEM II MODEL	
form	S.C.	Re-entry in the field	
a.s.	florasulam		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.00375	kg a.s./ha	summary of intended uses
Worker			
Duration	2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		without PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.14	m ² /hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	0.0315	mg a.s./day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	3	mg a.s./day	based on 70 kg bw
Internal exposure			
	Without PPE	With PPE	
Inhalation	-	-	no model available
Dermal	0.016	0.003	DE(int) = DE x (DA/100)
Total	0.016	0.003	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	1	0	%AOEL = 100 x DE(int) / AOEL
Total	1	0	sum
* 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.			

WORKER EXPOSURE		EUROPOEM II MODEL	
form	S.C.	Re-entry in the field	
a.s.	mesotrione		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.125	kg a.s./ha	summary of intended uses
Worker			
Duration	2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		without PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.14	m ² /hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	1.05	mg a.s./day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	0.3	mg a.s./day	based on 70 kg bw
Internal exposure			
	Without PPE	With PPE	
Inhalation	-	-	no model available
Dermal	0.525	0.105	DE(int) = DE x (DA/100)
Total	0.525	0.105	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	175	35	%AOEL = 100 x DE(int) / AOEL
Total	175	35	sum
* 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.			

According to the results of new estimation, the use of MEZOFLOR 103 SC containing mesotrione (100 g/L) and florasulam (3 g/L) **causes acceptable risk for protected worker** during 2h working day (inspection, irrigation).

The exposure of protected worker (work wear, protective gloves) to active substances amounts to: 35 % and 0.3% of AOEL for mesotrione and for florasulam, respectively.

Conclusions:

According to the results of the estimations, the use of MEZOFLOR 103 SC **does not cause unacceptable health risk for a worker wearing work and protective gloves** according to EUROPOEM II.

The results of estimations using EFSA model for mesotrione indicate unacceptable health risk for operator equipped only with work wear (no gloves).

Bearing in minds the results of exposure assessment (EUROPOEM II), the following sentence regarding the use of PPE should to be placed in the section of precautions for the workers is mandatory:

„Stosować rękawice ochronne oraz odzież roboczą podczas wchodzenia na teren poddany zabiegowi.”

“Wear protective gloves and work wear during when entering the treated area.”

6.6.3.1. Estimation of worker exposure

Table 6.6-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with MEZOFLO 103 SC according to the critical uses. Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use	Maize (max. 1 x 1.25 L product/ha)
Model	EUROPOEM II

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

		Mesotrione		Florasulam		Hazard Index (HI)
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	
Field Crop, Trctor Mounted						
Outdoor DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days						
Number of applications and application rate		1 x 0.125kg a.s./ha		1 x 0.00375 kg a.s./ha		
EUROPOEM II Body weight: 70 kg Work rate: 6 hours/day	Potential TC: 12500 cm²/person/h	0.0225	450 %	0.00067	1.4 %	
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.0045	90 %	0.000013	0.3 %	0.90

The results of the exposure estimations suggest that the use of MEZOFLO 103 SC according to the list of intended uses presented in GAP Table, causes no health risk for the worker assuming the workwear (arms, body and legs covered). According to EUROPOEM II, the calculated exposure level to mesotrione (100 g/L) and florasulan (3 g/L) is lower than the value of AOEL for this active substances.

6.6.3.2. Refinement of generic DFR value (KCP 7.2)

Not required.

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)

<p>Comments of zRMS:</p>	<p>According to current guidelines of Polish Authorities, the calculations of bystander and resident exposure performed using Martin S. model are not accepted (for all applications submitted or updated after the 1th of March 2017). The reference values acutely toxic active substance (RVAAS) for the active substances contained in MEZOFLOR 103 SC are not allocated. Consequently, it is assumed that the estimations of bystander exposure are covered by the calculations of resident exposure towards mesotrione and florasulam. The calculations provided by Applicant are accepted.</p> <p>Summary of bystander/resident exposure to MEZOFLOR 103 SC:</p> <ul style="list-style-type: none"> - <u>Mesotrione</u>: The results of the exposure estimations suggest that the use of MEZOFLOR 103 SC according to the list of intended uses presented in GAP Table, causes unacceptable health risk for bystander and resident (both adult and child) according to EFSA model and OPEX 1.0.1. The exposure value is above the AOEL for child and adult (<u>buffer zone: 5m, drift reduction</u>). However, it should be noted that the majority of the exposure is supposed to occur if the resident/bystander enters into the treated area. Thus, the incidental short-time exposure of bystander and resident (children and adult) to mesotrione is acceptable if warning boards preventing from resident/bystander entry into treated area are installed and remain till the end of cultivation. - <u>Florasulam</u>: The results of the exposure estimations suggest that the use of MEZOFLOR 103 SC according to the list of intended uses presented in GAP Table, causes no unacceptable health risk for bystander and resident (both adult and child) according to AOEM. - <p>Conclusions: The exposure of bystander and resident (children and adult) to the formulation MEZOFLOR 103 SC causes <u>acceptable risk to human health</u> if:</p> <ul style="list-style-type: none"> - warning boards preventing from resident/bystander entry into treated area are installed and remain till the end of cultivation, - min. 5-meter buffer zone is kept during spraying - drift-reduction nozzles are used. <p>Following sentence regarding the use of risk mitigation measures should be placed in the section of precautions for the bystander/resident:</p> <p><i>Podczas wykonywania zabiegu należy zachować 5 metrową strefę buforową oraz dysze ograniczające znos. Należy umieścić tablicę informacyjną: „Zakaz wejścia na teren poddany opryskowi do końca uprawy”.</i></p> <p>Keep a 5 meter buffer zone and drift-reduction nozzles during application. Warning board should be placed: <i>"Do not enter the treated area till the end of the plant growth".</i></p>
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6.6.4.1. Estimation of resident and bystander exposure

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

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the poten-

tial to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6-6 shows the exposure model used for estimation of resident and bystander exposure to mesotrione and florasulam. The outcome of the estimation is presented in Table 6.6-7: Estimated resident exposure according to Martin S. model

	mesotrione		florasulam		Hazard Index (HI)
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	
Field crops, Tractor mounted, outdoor application to low crop					
Application rate:	1 x 0.125 kg a.s./ha		1 x 0.00375 kg a.s./ha		
Bystanders (adult) Drift rate: 3.5% (5 m) Body weight: 60 kg	0.00365	72.9 %	0.00011	0.2 %	0.73
Bystanders (children) Drift rate: 3.5% (5 m) Body weight: 16.15 kg	0.0285	56.9 %	0.000085	0.2 %	0.57
Residents (adult) Drift rate: 3.5% (5 m) Body weight: 60 kg	0.000266	5.3 %	0.000008	0.02 %	0.05
Residents (children) Drift rate: 3.5% (5 m) Body weight: 16.15 kg	0.00042	8.4 %	0.000013	0.03 %	0.08

Table 6.6-8 (acute bystander exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use	Maize, Sorghum, Common millet/proso millet (max. 1 x 1.25 L product/ha)
Models	Martin S. et al. (2008) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76.
	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.
	OPEX calculator ver. 1.0.0 Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032.

Table 6.6-7: Estimated resident exposure according to Martin S. model

	mesotrione		florasulam		Hazard Index (HI)
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	
Field crops, Tractor mounted, outdoor application to low crop					
Application rate:	1 x 0.125 kg a.s./ha		1 x 0.00375 kg a.s./ha		
Bystanders (adult) Drift rate: 3.5% (5 m) Body weight: 60 kg	0.00365	72.9 %	0.00011	0.2 %	0.73
Bystanders (children) Drift rate: 3.5% (5 m) Body weight: 16.15 kg	0.0285	56.9 %	0.000085	0.2 %	0.57
Residents (adult) Drift rate: 3.5% (5 m) Body weight: 60 kg	0.000266	5.3 %	0.000008	0.02 %	0.05
Residents (children) Drift rate: 3.5% (5 m) Body weight: 16.15 kg	0.00042	8.4 %	0.000013	0.03 %	0.08

Table 6.6-8: Estimated resident exposure according to AOEM

Model data	mesotrione		florasulam		Hazard Index (HI)
	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	
Tractor mounted boom spray application outdoors to low crops Buffer zone: 5 m Drift reduction technology: yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha					

Interval between treatments: 365 days						
Number of applications and application rate		1 x 0.125 kg a.s./ha		1 x 0.00375 kg a.s./ha		
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0028	55.84%	0.0001	0.17%	0.56
	Vapour (75 th perc.)	0.0011	21.40%	0.0011	2.14%	0.23
	Deposits (75 th perc.)	0.0002	4.15%	0.0000	0.01%	0.04
	Re-entry (75 th perc.)	0.0105	210.94%	0.0003	0.63%	2.11
	All pathways (mean)	0.0112	223.68%	0.0014	2.75%	2.26
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0005	10.17%	0.0000	0.03%	0.10
	Vapour (75 th perc.)	0.0002	4.60%	0.0002	0.46%	0.05
	Deposits (75 th perc.)	0.0001	1.75%	0.0000	0.01%	0.02
	Re-entry (75 th perc.)	0.0059	117.19%	0.0000	0.35%	1.17
	All pathways (mean)	0.0052	104.66%	0.0002	0.76%	1.05

Table 6.6-9: Estimated resident exposure according to OPEX calculator ver. 1.0.0

		mesotrione		florasulam		Hazard Index (HI)
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	
Tractor mounted boom spray application outdoors to low crops Buffer zone: 5 m Drift reduction technology: yes, 50% DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days						Hazard Index (HI)
Number of applications and application rate		1 x 0.125 kg a.s./ha		1 x 0.00375 kg a.s./ha		
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.003	56.5 %	0.0001	0.2 %	0.57
	Vapour (75 th perc.)	0.0008	16 %	0.0008	1.6 %	0.18
	Deposits (75 th perc.)	0.0002	4.2%	0.0000	0.01 %	0.04
	Re-entry (75 th perc.)	0.01	211 %	0.0003	0.6 %	2.12
	Sum (mean)	0.01	218 %	0.001	2.2 %	2.20
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0005	10.3 %	0.0000	0.03%	0.10
	Vapour (75 th perc.)	0.0003	5.4 %	0.0003	0.5%	0.06
	Deposits (75 th perc.)	0.0001	1.7 %	0.0000	0.005%	0.02
	Re-entry (75 th perc.)	0.006	117 %	0.0002	0.4%	1.17
	Sum (mean)	0.005	105 %	0.0004	0.8%	1.06

Using **Martin S. et al. (2008)** approach, there is no an unacceptable health risk to the public based on estimations of bystander and resident exposure (adults and children) for MEZOFLO 103 SC, using the critical uses.

According to the **AOEM calculator** results of the exposure estimations suggest that the use of ME-

ZOFLO 103 SC according to the intended uses presented in GAP, causes unacceptable health risk for resident (adult and child). The exposure (all pathways) was for:

- mesotrione 223.68 % and 104.66 % of AOEL
- florasulam 2.75% and 0.76 % of AOEL

for child and adult, respectively (buffer zone: 5 m; 50 % drift reduction). The majority of the exposure is supposed to occur if a resident and bystander enters into the treated area.

According to the **OPEX calculator** results of the exposure are similar to that presented according to AOEM calculator. The exposure (all pathways) was for:

- mesotrione 218 % and 105 % of AOEL
- florasulam 2.2% and 0.8 % of AOEL

for child and adult, respectively (buffer zone: 5 m; 50 % drift reduction).

Four pathways of exposure are considered (Guidance on Pesticides Exposure Assessment of Operator, Worker, Resident and Bystander, *EFSA Journal* 2014; 12 (10):3874 and *EFSA Journal* 2022; 20(1): 7032):

- spray drift (at the time of application),
- vapour (may occur after the PPP has been applied),
- surface deposits,
- entry into treated crops (walking in treated field).

Summing all the exposure pathways, each one being conservative (considering high percentiles of exposure), would result in an overly conservative and unrealistic result.

Resident represents the worst case scenario. The four estimated exposures are presented separately because, it is unlikely and unrealistic that all the different exposures from the different pathways will occur contemporaneously in the case of bystanders or resident. It should be noted that the majority of the exposure is supposed to occur if a resident and bystander enters into the treated area (according to the AOEM).

It should be taking into account that MEZOFLO 103 SC can be applied post emergence (BBCH 12-18), when maize is low. In this case the risk to exposure to MEZOFLO 103 SC is limited, especially in the case of entry into treated crop (dermal exposure), resident and bystander do not have possibility to dermal (physical) contact with crop or weeds which was treated by MEZOFLO 103 SC.

In the case of MEZOFLO 103 SC application time, enters into the treated area is not a main pathways of exposure. It seems that spray drift and surface deposits, which may occur after the PPP application are more realistic pathways of exposure.

In the case of early post emergence application (BBCH 12-18), maize is low crop. According to the practice, maize is not hay densely, but in rows with an appropriate spacing of 70 cm, sowing density of 7-8 plants per m² (depended on soil condition). Main goals of the application of MEZOFLO 103 SC is to fight weeds between the maize. Main amount of MEZOFLO 103 SC is applied on soil and weeds with the use of a special nozzels type with drift reduction.

The re-entry exposure of residents (adult/child) according to the AOEM and OPEX calculator is over-estimates considering the height of the crop (BBCH scale) and the clothes worn by the resident at this period of the year.

According to Ecotoxicological protection, post-emergence use to protect aquatic organisms respect a buffer zone and drift reduction nozzle should be used (50 % or 75%). AOEM or OPEX calculator do not assume higher drift reduction that 50 %. Application of the boom sprayer with 75 % drift reduction nozzle, in the significant way reduce the systemic exposure.

Risk for a resident and bystander can be minimize if:

- min. 5-meter buffer zone is kept during spraying,
- drift-reduction nozzles (min. 50 %) are used,
- warning boards preventing from resident/bystander entry into treated area are installed and remain until the plants are harvested/ the end of the growing season “No unauthorized access to the area treated with plant protection products”.

In this case, the incidental short-time exposure of bystander and resident (children and adult) to mesotrione and florasulam can be acceptable.

It is worth to mention that also spray drift and surface deposits can be successfully reduced by the application of the PPP according to Good Plant Protection Practice

Following sentence regarding the use of risk mitigation measures is recommended to be placed in the section of precautions for the bystander/resident:

- After the treatment has been performed, place warning boards in visible places around the field, reading "No unauthorized access to the area treated with plant protection products". The boards should remain for 30 days (according to assumed DT₅₀ value);
- During spraying, a buffer zone of at least 5 m from residential buildings / habitats and bystanders should be applied;
- During spraying, use techniques to reduce the drift of the product (drift-reduction nozzles, low vehicle speed, stable weather, etc.);
- Do not use the product when the wind speed exceeds 4 m/s (recommended up to 2 m/s);
- When using the PPP, do not allow drift of working liquid;
- Spray treatments under optimal conditions, preferably:
 - using only calibrated sprayers and sprayer booms set at a height not more than 50 cm above the sprayed soil surface;
 - with the fan turned off in the case of using sprayers with an auxiliary air stream;
 - at the sprayer's speed not exceeding 8 km/h;
 - using nozzles for medium-drop spraying at reduced pressure in order to obtain a greater amount of coarse droplets fraction.

Period from application to the date when humans and animals may enter the area where the product has been applied (prevention period): Do not enter until the spray liquid is completely dry on the surface of the plants

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 and florasulam will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5. Combined exposure

The product is a mixture of two active substances.

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

6.6.5.1. Exposure assessment of mesotrione and florasulam in MEZOFLOR 103 SC

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

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from **Błąd! Nie można odnaleźć źródła odwołania.**⁸ con-

verted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-10: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators (AOEM)	mesotrione	0.47
	florasulam	0.008
	Cumulative risk operators (HI)	0.48
Operators (OPEX)	mesotrione	0.52
	florasulam	0.001
	Cumulative risk operators (HI)	0.53
Workers (EUROPOEM II)	mesotrione	0.90 0.35
	florasulam	0.003 0.003
	Cumulative risk workers (HI)	0.90 0.353
Bystander – child (Martin S. model)	mesotrione	0.57
	florasulam	0.002
	Cumulative risk workers (HI)	0.57
Bystander – adult (Martin S. model)	mesotrione	0.73
	florasulam	0.002
	Cumulative risk workers (HI)	0.73
Residents – child (Martin S. model)	mesotrione	0.08
	florasulam	0.00
	Cumulative risk workers (HI)	0.08
Residents - adult (Martin S. model)	mesotrione	0.05
	florasulam	0.00
	Cumulative risk workers (HI)	0.05
Residents – child (AOEM)	mesotrione	
	Drift	0.56
	Vapour	0.21
	Deposits	0.04
	Re-entry	2.11
	All pathways (mean)	2.24
	florasulam	
	Drift	0.00
	Vapour	0.02
	Deposits	0.00
	Re-entry	0.01

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	All pathways (mean)	0.03
	Cumulative risk resident– child (HI)	
	Drift	0.56
	Vapour	0.23
	Deposits	0.04
	Re-entry	2.11
	All pathways (mean)	2.26
Residents – adult (AOEM)	mesotrione	
	Drift	0.10
	Vapour	0.05
	Deposits	0.02
	Re-entry	1.17
	All pathways (mean)	1.05
	florasulam	
	Drift	0.00
	Vapour	0.00
	Deposits	0.00
	Re-entry	0.00
	All pathways (mean)	0.01
	Cumulative risk resident – adult (HI)	
	Drift	0.10
	Vapour	0.05
	Deposits	0.02
	Re-entry	1.17
	All pathways (mean)	1.05
Residents – child (OPEX calculator ver. 1.0.0)	mesotrione	
	Drift	0.56
	Vapour	0.16
	Deposits	0.04
	Re-entry	2.11
	Sum (mean)	2.18
	florasulam	
	Drift	0.00
	Vapour	0.02
	Deposits	0.00

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Re-entry	0.01
	Sum (mean)	0.02
	Cumulative risk resident– child (HI)	
	Drift	0.57
	Vapour	0.18
	Deposits	0.04
	Re-entry	2.12
	Sum (mean)	2.20
Residents – adult (AOEM)	mesotrione	
	Drift	0.10
	Vapour	0.05
	Deposits	0.02
	Re-entry	1.17
	Sum (mean)	1.05
	florasulam	
	Drift	0.00
	Vapour	0.00
	Deposits	0.00
	Re-entry	0.00
	Sum (mean)	0.01
	Cumulative risk resident – adult (HI)	
	Drift	0.10
	Vapour	0.06
	Deposits	0.02
	Re-entry	1.17
	Sum (mean)	1.06

The Hazard Index is < 1. Thus, combined exposure to all active substances in MEZOFLO 103 SC is not expected to present a risk for operators, workers, residents and bystanders (Martins S. model). No further refinement of the assessment is required.

In the case of cumulative risk for resident (adult and child) calculated according to AOEM and OPEC calculator, the Hazard Index is > 1.

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
KCP 7.1.4	Krakowian D.	2021	MEZOFLOR 103 SC: <i>In vitro</i> Skin Corrosion: Reconstructed Human Epidermis Test Method. Study code: SCT-1/21. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Synthos Agro Sp z.o.o Oświęcim
KCP 7.1.5	Krakowian D.	2021	MEZOFLOR 103 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-01/21. Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Synthos Agro Sp z.o.o Oświęcim

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

Data point	Authors	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Mecchi M.S.	2008	<i>Salmonella Escherichia coli</i> / Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with ASTCA Metabolite of Florasulam Covance Laboratories Inc DAS Report No.: 071120 (Accession Number) 257169 GLP/GEP Published	N	Dow AgroScience
	Schisler M.R., Geter D.R.	2008	Evaluation of Florasulam ASTCA Metabolite in the Chinese Hamster ovary Ell/hypoxanthine-guanine-phosphoribosyl Transferase (CHO/HGPRT) Forward Mutation Assay Toxicology & Environmental Research and Consulting DAS Report No.: 071133 (Accession Number) 25174 GLP/GEP Published	N	Dow AgroScience
	Schisler M.R., Kleinert K.M. Geter D.R.	2008	Evaluation of Florasulam ASTCA Metabolite in an <i>in vitro</i> Chromosomal Aberration Assay Utilizing Rat Lymphocytes Toxicology & Environmental Research and Consulting DAS Report No.: 071132 (Accession Number) 257142 GLP/GEP Published	N	Dow AgroScience
	Nagane R.M.	2011	Bacterial Reverse Mutation Test of TSA Metabolite of Florasulam using <i>Salmonella typhimurium</i> Jai Research Foundation DAS Report No.: 110432 (Accession Number) 2010127 GLP Published	N	Dow AgroScience
	Nagane R.M.	2011	<i>In vitro</i> Mammalian Cell Gene Forward Mutation Test at the hprt Locus of the Chinese Hamster Ovary (CHO)-K1 Cell Line using TSA metabolite of florasulam Jai Research Foundation DAS Report No: 110430 (Accession Number) 2010107 GLP/GEP Published	N	Dow AgroScience

Data point	Authors	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Nagane R.M.	2011	<i>In vitro</i> Mammalian Chromosome Aberration Test of TSA Metabolite of Florasulam in Human Peri Blood Lymphocytes Jai Research Foundation DAS Report No: 110431 (Accession Number) 2010112 GLP/GEP Published	N	Dow AgroScience

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	Comment on statement; acceptable or not
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The bridging was not necessary.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Conclusion: Taking into account the composition of the product, the formulation MEZOFLOR 103 SC does not require classification in regards to acute oral toxicity.
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Calculation method (Regulation (EC) No 1272/2008)

MEZOFLOR 103 SC contains:

- one component (co-formulant) which is classified as Acute Tox. 4 with hazard statement H302. Its concentration in the product is equal to 0.018 %.
- one component which is classified as Acute Tox 3, H301. Its concentration in the product is equal to 0,00019%

Acute oral toxicity value (ATE_{mix}) for MEZOFLOR 103 SC can be estimated according to principles of Regulation (EC) 1272/2008, formula in section 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.

Therefore, ATE_{mix} value is equal to:

$$ATE_{mix} = \frac{100}{\frac{0.018}{500}} = 2\,777\,778\,mg/kg\,bw$$

ATE_{mix} value is equal to $[100 \div (0.018 \div 500)] + [100 \div (0.00019 \div 100)] = 55409356.64$

The estimated value ATE_{mix} of acute oral toxicity for MEZOFLOR 103 SC is higher than 2000 mg/kg bw. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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

Comments of zRMS:	Conclusion: Taking into account the composition of the product, the formulation MEZOFLOR 103 SC does not require classification in regards to acute dermal toxicity.
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MEZOFLOR 103 SC does not contain any component which is classified as acute dermal toxicity, therefore the product will not be classified as acute dermal toxicity.
 Therefore, no classification is required.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Conclusion: Taking into account the composition of the product, the formulation MEZOFLOR 103 SC does not require classification in regards to acute inhalation toxicity.
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No data on acute inhalation toxicity for mezotrione and florasulam in MEZOFLOR 103 SC is available. The recommended way of spraying formulation in MEZOFLOR 103 SC results in production of medium drops size. MEZOFLOR 103 SC contains active substances with a vapour pressure below 1×10^{-2} Pa (vapour pressure of mesotrione: $<5.7 \times 10^{-6}$ at 20°C (99.7% pure); vapour pressure of florasulam 1×10^{-5} Pa at 25 °C (99.7% pure). MEZOFLOR 103 SC will not be used as a fumigant or an aerosol.

~~MEZOFLOR 103 SC does not contain any component which is classified as acute inhalation toxicity, therefore the product will not be classified as acute inhalation toxicity.~~
~~Therefore, no classification is required.~~

MEZOFLOR 103 SC contains

- one component (co-formulant) which is classified as Acute Tox. 2 with hazard statement H330. Its concentration in the product is equal to 0.00019 %.

ATE_{mix} value is equal to $100 \div (0.00019 \div 0.05) = 26315.79$

The estimated value ATE_{mix} for the acute inhalation toxicity for MEZOFLOR 103 SC is higher than 0.5. Consequently, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	The results of the study by Krakowian D. (2021) are accepted without reservation. MEZOFLOR 103 SC is identified as non-corrosive in the reconstructed human epidermis (RHE) test method. However, the irritation potential of the product had to be verified by another method. The results of calculation method indicate that the sum of the ingredients which were taken into account for the purpose of product classification, is below the concentration limit triggering the classification. Conclusion: Taking into account the results of the study and composition of the product, MEZOFLOR 103 SC does not required classification in regards to corrosive/irritant effect to the skin.
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A 2.5.1 Study 1

Reference KCP 7.1.4

Report MEZOFLOR 103 SC: *In vitro* Skin Corrosion: Reconstructed Human Epidermis Test Method. Krakowian D., 2021. Study code: SCT-1/21.

Guideline(s)	OECD 431 (2019)/EU Methods B.40
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	MEZOFLOR 103 SC (Batch No. SNS-F-05-15)
Species	EpiDerm™ tissues (human reconstructed epidermis model)
No. of animals (group size)	2 inserts with tissues of the human skin model EpiDerm
Initial test using one animal	No
Exposure time	3 min., 60 min.
Negative control	sterile deionized water
Positive control	8 N potassium hydroxide
Viability Test	MTT Viability Test
Vehicle/Dilution	None
Remarks	None

Results and discussions

Table A 1: Tissue viability [%] – 1-hour exposure

	Negative control	Positive control	MEZOFLOR 103 SC
Tissue no. 1 viability	104.1	1.6	79.2
Tissue no. 2 viability	95.9	1.5	99.3
Mean Tissue viability	100.0	1.5	89.2
SD (±)	4.1	0	10

Table A 2: Tissue viability [%] – 3-minute exposure

	Negative control	Positive control	MEZOFLOR 103 SC
Tissue no. 1 viability	101.9	1.8	90.4
Tissue no. 2 viability	98.1	1.6	104.2
Mean Tissue viability	100.0	1.7	97.3
SD (±)	1.9	0.1	6.9

Conclusion

After the 3-minute exposure to the test item, the mean value of relative tissue viability was equal to 97.3 %. After the 1-hour exposure to the test item, the mean value of relative tissue viability was equal to 89.2%. 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, MEZOFLOR 103 SC, is considered to be **non-corrosive to skin** in the Reconstructed human Epidermis (RhE) Test Method. It can not be classified as any category in the UN GHS

classification.

No classification is required according to Regulation (EC) No. 1272/2008

A 2.5.2 Calculation method (Regulation (EC) No 1272/2008)

Result of the study presented in point A.2.5.1 (Krakowian D., 2021, Study code: SCT-1/21) does not exclude the irritation potential of tested formulation. Further *in vitro* test was not carried out, thus the additive formula (calculation method) was used to finalize the assessment.

MEZOFLOR 103 SC contains:

- one component (co-formulant) which is classified as Skin Corr.1 with hazard statement H314. Its concentration in the product is equal to 0.009 %. This concentration is below concentration limit that triggers classification of the mixture in regards to the skin corrosion (5%) or skin irritation (1%).
- one component (co-formulant) which is classified as Skin Irrit.2 with hazard statement H315. Its concentration in the product is equal to 0.018 %. This concentration is below concentration limit (10%) that triggers classification of the mixture in regards to the skin irritation.

MEZOFLOR 103 SC contains:

- one component (co-formulant) which is classified as Skin Corr.1A with hazard statement H314. Its concentration in the product is equal to 0.009 %. This concentration is below concentration limit that triggers classification of the mixture in regards to the skin corrosion and below the lower border of SCL 5%.
- one component (co-formulant) which is classified as Skin Corr.1B with hazard statement H314. Its concentration in the product is equal to 0.00019 %. This is below concentration limit that triggers classification of the mixture in regards to the skin corrosion
- one component (co-formulant) which is classified as Skin Irrit.2 with hazard statement H315. Its concentration in the product is equal to 0.018 %. This concentration is below concentration limit that triggers classification of the mixture in regards to the skin irritation.

The sum of concentration values is below concentration limit (10%) that triggers classification of the mixture in regards to the skin irritation.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	The results of the study by Krakowian D. (2021) are accepted without reservation. MEZOFLOR 103 SC is identified as non- corrosive and non-irritant according to the Isolated Chicken Eye Test Method. Therefore, the additional study was not necessary for classification of the product. Conclusion: Taking into account the results of the study (ICE test), MEZOFLOR 103 SC does not required classification in regards to corrosive/irritant effect to the eye.
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A 2.6.1 Study 1

Reference	KCP 7.1.5
Report	MEZOFLOR 103 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. Krakowian D.,

	2021, Study code: ICE-1/21.
Guideline(s)	OECD Guideline No 438 (2018)/ EU Method B.48. Council Regulation (EC) No. 440/2008
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	MEZOFLOR 103 SC (Batch No. SNS-F-05-15)
Species	Chickens, eyeballs
No. of animals (group size)	9 eyeballs
Initial test using one animal	No
Exposure	0.03 mL (single instillation) for 10 sec.
Irrigation (time point)	10 sec., physiological salt
Post exposure observation period	4 hours
Remarks	None

Results and discussions

Table A 3: Eye irritation of MEZOFLOR 103 SC

Observation after time (min.)	Corneal opacity		Corneal swelling (%)		Fluorescein retention	
	Mean scores	ICE class	Mean scores	ICE class	Mean scores	ICE class
30 min.	0.5	I	0.8	I	0.5	I
75 min.	0.8	II	-3.2	I	-	-
120 min.	0.8	II	-9.2	I	-	-
180 min.	1.0	II	-9.0	I	-	-
240 min.	1.0	II	-7.8	I	-	-

Table A 4: Eye irritation of DIFLUD 050 FS – Summary of the results

	Maximal ICE Class			UN GHS Classification
	Fluorescein retention	Corneal opacity	Corneal swelling	
MEZOFLOR 103 SC	I	II	I	No category
Positive control	IV	IV	IV	Category 1
Negative control	I	I	I	No category

Clinical signs:	Roughness of the corneal surface was observed
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Conclusion

MEZOFLOR 103 SC don't cause eye irritation or serious eye damage.
 Based on histopathology decision criteria for the identification of UN GHS Cat. 1 (Epithelium - necrosis

≥ moderate, observed in at least 2 out of 3 eyes), it can be concluded that the test item may have not a negative effect on the chicken cornea in the ICE and can be classified into “No category”.

According to UN GHS classification criteria “no category” (1 x I, 1 x II and 1 x I) it can be concluded that the test item should be not classified as category 1.

According to overall *in vitro* irritancy classification: 1 x I, 1 x II and 1 x I (No category.) – the combination of the above results with histopathological evaluation makes it possible to classify test item to “No category”.

Under the experimental conditions, MEZOFLOR 103 SC **is not an eye irritant**. Thus, no classification is required according to Regulation (EC) No. 1272/2008. The other additional researches (*in vivo* or *in vitro*) are not necessary for classification of MEZOFLOR 013 SC.

A 2.6.1 Calculation method (Regulation (EC) No 1272/2008)

Result of the study presented in point A.2.5.1 (Krakowian D., 2021, Study code: ICE-1/21) does not exclude the irritation potential of tested formulation. Further *in vitro* test was not carried out, thus the additive formula (calculation method) was used to finalize the assessment.

MEZOFLOR 103 SC contains:

- one component (co-formulant) which is classified as Eye Dam.1 with hazard statement H318. Its concentration in the product is equal to 0.018 %. This concentration is below concentration limit that triggers classification of the mixture in regards to the eye damage (3%) or eye irritation (1%).
- ~~– two components (co-formulants) which are classified as Eye Irrit.2 with hazard statement H319. Their concentrations in the product is equal to 0.019 % and 0.14%. The sum of concentration values is below concentration limit (10%) that triggers classification of the mixture in regards to the eye irritation.~~
- one component (co-formulant) which is classified as Eye Irrit.2 with hazard statement H319. Its concentration in the product is equal to 0.14%. This concentration is below concentration limit that triggers classification of the mixture in regards to the eye irritation (1%).
- one component (co-formulant) which is classified as Skin Corr.1A with hazard statement H314. Its concentration in the product is equal to 0.009%. This concentration is below concentration limit that triggers classification of the mixture in regards to the eye irritation (1%).
- one component (co-formulant) which is classified as Skin Corr.1B with hazard statement H314. Its concentration in the product is equal to 0.00019 %. This concentration is below concentration limit that triggers classification of the mixture in regards to the eye irritation (1%).
-

The sum of the concentration values is below concentration limit (10%) that triggers classification of the mixture in regards to the eye irritation.

A 2.7 Skin/respiratory sensitisation (KCP 7.1.6)

Comments of zRMS:	Conclusion: Taking into account the composition of the product MEZOFLOR 103 SC, the formulation MEZOFLOR 103 SC does not require classification in regards to skin sensitization. The additional phrase should be placed in the label: EUH208 Contains benzisothiazol-3(2OH)-one. May produce an allergic reaction.
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Calculation method (Regulation (EC) No 1272/2008)

~~MEZOFLOR 103 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.~~

MEZOFLOR 103 SC contains one components which are classified as Resp Sens. 1 with hazard statement H334. The concentration is equal to 0.00019%. This concentration is below concentration limit stated in Table 3.4.5 of Regulation 1272/2008.

MEZOFLOR 103 SC contains

- one component which are classified as Skin Sens. 1 with hazard statement H317. The concentration is equal to 0.018%. This concentration is below concentration limit (1%) stated in Table 3.4.5 of Regulation 1272/2008.

- one component which is classified as Skin Sens. 1A with hazard statement H317. Its concentration is equal to 0.00019%. This concentration is below the concentration limit (0.1%) stated in Table 3.4.5 of Regulation 1272/2008.

The mixture is not classified in category respiratory / skin sensitisation. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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

A.2.8.1 Specific target organ toxicity

Comments of zRMS:	Conclusion: Taking into account the composition of the product, the formulation MEZOFLOR 103 SC does not require classification in regards to specific target organ toxicity.
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Specific target organ toxicity - single exposure (STOT SE3, H335)

MEZOFLOR 103 SC contains one component which is classified as STOT SE 3 with hazard statement H335. Its concentration is equal 0.00019 % .This concentrations is significantly lower than the specific concentrations limit triggering classification. According to the point 3.8.3.4.5. of CLP Regulation, the formulation is not classified as STOT SE 3, H335.

Specific target organ toxicity - repeated exposure (STOT RE2, H373)

MEZOFLOR 103 SC contains the active substance – mesotrione, which is classified as STOT RE 2 with hazard statement H373. Its concentration in the product is equal to 9.6%. This concentration is below the concentration limit (10%) stated in Table 3.9.4 of the Regulation (EC) 1272/2008. Therefore the product is not classified as STOT RE 2 with hazard statement H373. However, please note that if an ingredient classified as Category 2 for the specific target organ toxicity is present in a mixture at the concentration \geq 1.0 %, a safety data sheet shall be available for the mixture upon request.

A.2.8.2 Reproductive toxicity

Comments of zRMS:	Conclusion: Taking into account the composition of the product, the formulation MEZOFLOR 103 SC requires classification in regards to reproductive toxicity(Repr 2 H361d).
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MEZOFLOR 103 SC contains one components which is classified as Repr. 2 with hazard statement H361d. Its concentration in the product is equal to 9.6%. This concentration above concentration limit (3%) stated in Table 3.7.2 of Regulation (EC) 1272/2008, therefore the product requires classification as

Repr. 2 with hazard statement H361d

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:	The default values of dermal absorption are accepted and consequently used for the exposure estimations.
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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, Applicant for MEZOFLOR 103 SC has proposed a default dermal absorption value of:

- 10 % for the concentrate and 50 % for the spray solution in the case of mesotrione,
- 50 % for the concentrate and 50 % for the spray solution in the case of florasulam,

based on Guidance on Dermal Absorption (*EFSA Journal* 2017;15(6)4873) and SANTE/2018/10591 (rev.1 24 October 2018).

Use of plant protection product MEZOFLOR 103 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). Maintain general rules of safety and hygiene of working with plant protection products and comply with requirements enclosed in label, risk during employ MEZOFLOR 103 SC is acceptable, absorbed dose of mesotrione and florasulam have safe value, below AOEL for this active ingredient.

According to above there isn't necessity to do tests of dermal absorption for MEZOFLOR 103 SC.

A 2.11 Other/Special Studies

Appendix 3

Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for mesotrione

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

Formulation type	SC		Crop type	Maize
Application rate (AR)	0.125	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	50	% (dilution)	Closed cabin	Yes
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.005	mg/kg bw/d	Water soluble bag	No
AAOEL	-	mg/kg bw/d		

Table A 6: Estimation of longer term operator exposure towards mesotrione according to EFSA guidance

Operator exposure for MEZOFLO 103 S.C. outdoor spray applications







Application rate of active substance	0,125 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	6,25 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	
	OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	19909	74139	AOEM	
	Body	12935	122660	AOEM	
	Head	324	1778	AOEM	
	Protected hands (gloves)	113	1238	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	121	914	AOEM	
	Protected head (hood and face shield)	5	101	AOEM	
	Inhalation	6	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	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	927	8771	AOEM	
	Body	518	2672	AOEM	
	Head	24	74	AOEM	
	Protected hands (gloves)	115	4127	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	14	35	AOEM	
	Inhalation	3	8	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
	Closed cab	Yes		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)	4,0607789	0,1414955
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0676796	0,0023583
% of RVNAS	1353,59%	47,17%

Table A 7: Estimation of operator exposure towards mesotrione and florasulam according to OPEX Calculator (ver. 1.0.0) - Outdoor, normal, downward spraying, vehicle-mounted; Summary data - Short term exposure

Mixing/loading	Application	Mezotrione (% AOEL)	Florasulam (% AOEL)	Combined (hazard index)
		1606	64.9	16.71
		1057	47.5	11.05
		51.6	1.3	0.529

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Mezotrione	Number of applications and application rate: 1 x 0.125 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear + Protected hands	0.003	51.6
	App: Workwear + Protected hands		
Florasulam	Number of applications and application rate: 1 x 0.00375 kg a.s./ha Dermal absorption (concentrate): 50 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear	0.02	47.5
	App: Workwear		
Combined exposure			Hazard index
M/L: Workwear + Protected hands			0.5
App: Workwear + Protected hands			

A 3.1.2 Calculations for florasulam

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

Formulation type	SC		Crop type	Maize
Application rate (AR)	0.00375	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	50	% (concentr.)	Indoor/outdoor	Outdoor
	50	% (dilution)	Closed cabin	Yes
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.05	mg/kg bw/d	Water soluble bag	No
AAOEL	-	mg/kg bw/d		

Table A 9: Estimation of longer term operator exposure towards florasulam according to EFSA guidance

Application rate of active substance	0,00375 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0,1875 kg a.s./day	<i>L_AmountAS</i>
Dermal absorption of the product	50,00%	<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	
	OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	1339	4833	AOEM	
	Body	1100	44286	AOEM	
	Head	10	53	AOEM	
	Protected hands (gloves)	12	37	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	27	AOEM	
	Protected head (hood and face shield)	0	3	AOEM	
	Inhalation	2	28	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	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	28	672	AOEM	
	Body	16	80	AOEM	
	Head	1	2	AOEM	
	Protected hands (gloves)	17	2742	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	0	1	AOEM	
	Inhalation	0	1	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
	Closed cab	Yes		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)	1,2488598	0,0251645
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0208143	0,0004194
% of RVNAS	41,63%	0,84%

A 3.2 Worker exposure calculation (KCP 7.2.3.1)

A 3.2.1 Calculations for mesotrione

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

Intended use(s)	Maize/ outdoor	Dislodgeable foliar residue (DFR)	3	$\mu\text{g}/\text{cm}^2/\text{kg a.s.}/\text{ha}$
Application rate (AR)	0.125 kg a.s./ha	Dermal absorption (DA)	50	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	365 days	Work rate per day (WR)	6	h/d
Half-life of active substance	30 days	TC dermal (potential)	12500	cm^2/h
Multiple application factor (MAF)	0	TC dermal (work wear)	1400	cm^2/h
Body weight (BW)	70 kg/person	TC dermal (work wear, gloves)	-	cm^2/h
AOEL	0.005 mg/kg bw/d	Task specific factor inhalation	-	$\text{ha}/\text{h} \times 10^{-3}$
AAOEL	-			

Table A 11: Estimation of longer term worker exposure towards mesotrione according to EU-ROPOEM II

WORKER EXPOSURE			EUROPEM II MODEL	
form	MEZOFLOR 103 S.C.		Re-entry in the field	
a.s.	mesotrione			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0,125	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		6	hours / day	default: 6 h (Europepm II)
Inhalation Exposure				
	no model available	-		without PPE
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europepm II)
TC	Transfer coefficient	0,14	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europepm II)
Dermal Exposure		3,15	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	0,005	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
Internal exposure		[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	1,575	0,315	DE(int) = DE x (DA/100)
	Total	1,575	0,315	sum
		% AOEL		
	Inhalation	-	-	no model available
	Dermal	31500	6300	%AOEL = 100 x DE(int) / AOEL
	Total	31500	6300	sum
		Total absorbed dose (mg/kg bw/day)		% of systemic AOEL
No PPE		0.0225		450 %
With PPE		0.0045		90 %

A 3.2.2 Calculations for florasulam

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

Intended use(s)	Maize/ outdoor	Dislodgeable foliar residue (DFR)	3	µg/cm²/kg a.s./ha
Application rate (AR)	0.00375 kg a.s./ha	Dermal absorption (DA)	50	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	365 days	Work rate per day (WR)	6	h/d
Half-life of active substance	30 days	TC dermal (potential)	12500	cm²/h
Multiple application factor (MAF)	0	TC dermal (work wear)	1400	cm²/h
Body weight (BW)	70 kg/person	TC dermal (work wear, gloves)	-	cm²/h
AOEL	0.05 mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-			

Table A 13: Estimation of longer term worker exposure towards florasulam according to EUROPEM II

WORKER EXPOSURE			EUROPEM II MODEL	
form	MEZOFLO 103 S.C.		Re-entry in the field	
a.s.	florasulam			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0,00375	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		6	hours / day	default: 6 h (Europepm II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europepm II)
TC	Transfer coefficient	0,14	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europepm II)
Dermal Exposure		0,0945	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	0,05	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0,047	0,009	DE(int) = DE x (DA/100)
	Total	0,047	0,009	sum
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	95	19	%AOEL = 100 x DE(int) / AOEL
	Total	95	19	sum
		Total absorbed dose (mg/kg bw/day)		% of systemic AOEL
No PPE		0.00067		1.4 %
With PPE		0.000013		0.3 %

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for mesotrione

Table A 14: Input parameters considered for the bystander exposure according to Martin S. et al. (2008).

Intended use(s):	Maize		Drift (D):	3,50	% (FCTM, 5 m)
Application rate (AR):	0,125	kg a.s./ha	Exposed Body Surface Area (BSA):	1	m ² (adults)
				0,21	m ² (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):	50,00	% ('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:	0,005	mg/kg bw/d			

Table A 15: Estimation of bystander exposure towards mesotrione according to Martin S. et al. (2008).

Bystander exposure towards Mezotrion					
Adults			Children		
Bystander: Dermal exposure after application in Maize (via spray drift)					
SDE _B = (AR x D x BSA x DA) / BW			SDE _B = (AR x D x BSA x DA) / BW		
(12,5 x 3,5% x 1 x 50%) / 60			(12,5 x 3,5% x 0,21 x 50%) / 16,15		
External exposure	0,4375	mg/person	External exposure	0,091875	mg/person
External exposure	0,0072917	mg/kg bw/d	External exposure	0,0056889	mg/kg bw/d
Absorbed dose:	0,0036458	mg/kg bw/d	Absorbed dose:	0,0028444	mg/kg bw/d
Bystander: Inhalation exposure after application in Maize					
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		
(0,001 / 360 x 0,125 x 20 x 5 x 100%) / 60			(0,001 / 360 x 0,125 x 20 x 5 x 100%) / 16,15		
External exposure	3,472E-05	mg/person	External exposure	1,996E-05	mg/person
External exposure	5,787E-07	mg/kg bw/d	External exposure	1,236E-06	mg/kg bw/d
Absorbed dose:	0,0000006	mg/kg bw/d	Absorbed dose:	0,0000012	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)	0,2187847	mg/person	Total systemic exposure (absorbed dose)	0,0459575	mg/person
Total systemic exposure (absorbed dose)	0,0036464	mg/kg bw/d	Total systemic exposure (absorbed dose)	0,0028457	mg/kg bw/d
% of AOEL:	72,93	%	% of AOEL:	56,91	%

Table A 16: Input parameters considered for the resident exposure according to Martin S. et al. (2008).

Intended use(s):	Maize		Drift (D):	3,50	% (FCTM, 5 m)
Application rate (AR):	0,125	kg a.s./ha	Transfer coefficient (TC):	7300	cm ² /h (adults)
				2600	cm ² /h (children)
Number of applications (NA):	1		Turf Transferable Residues (TTR):	5	%
Body weight (BW):	60	kg/person (adults)	Exposure Duration (H):	2	h
	16,15	kg/person (children)	Airborne Concentration of Vapour (ACV):	none	
Dermal absorption (DA):	50,00	% ('worst case')	Inhalation Rate (IR):	16,57	m ³ /d (adults),
Inhalation absorption (IA):	100	%		8,31	m ³ /d (children)
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE):	50	%
AOEL	0,005	mg/kg bw/d	Surface Area of Hands (SA):	20	cm ²
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm ² /d

Table A 17: Estimation of resident exposure towards mesotrione according to Martin S. et al. (2008).

Resident exposure towards Mezotrion					
Adults			Children		
Residents: Dermal exposure after application in Maize (via deposits caused by spray drift)					
SDE _R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE _R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0,00125 x 1 x 0,57% x 5% x 7300 x 2 x 50%) / 60			(0,00125 x 1 x 0,57% x 5% x 2600 x 2 x 50%) / 16,15		
External exposure	0,0319375	mg/person	External exposure	0,011375	mg/person
External exposure	0,0005323	mg/kg bw/d	External exposure	0,0007043	mg/kg bw/d
Absorbed dose:	0,0002661	mg/kg bw/d	Absorbed dose:	0,0003522	mg/kg bw/d
Residents: Inhalation exposure to vapour					
SIE _R = (AC _V x IR x IA) / BW			SIE _R = (AC _V x IR x IA) / BW		
(0 x 16,57 x 100%) / 60			(0 x 8,31 x 100%) / 16,15		
External exposure		mg/person	External exposure		mg/person
External exposure		mg/kg bw/d	External exposure		mg/kg bw/d
Absorbed dose:		none	Absorbed dose:		none
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE _H = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0,00125 x 1 x 0,57% x 5% x 50% x 20 x 20 x 2 x 100%) / 16,15		
			External exposure	0,000875	mg/person

			External exposure	5,418E-05	mg/kg bw/d
			Absorbed dose	0,0000542	mg/kg bw/d
			Residents: Oral exposure (object-to-mouth transfer)		
			$SOE_O = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$		
			FALSZ		
			External exposure	0,0002188	mg/person
			External exposure	1,354E-05	mg/kg bw/d
			Absorbed dose	0,0000135	mg/kg bw/d
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_H + SOE_O$		
Total systemic exposure (absorbed dose)	0,0159688	mg/person	Total systemic exposure (absorbed dose)	0,0067813	mg/person
Total systemic exposure (absorbed dose)	0,0002661	mg/kg bw/d	Total systemic exposure (absorbed dose)	0,0004199	mg/kg bw/d
% of AOEL:	5,32	%	% of AOEL:	8,40	%

Table A 18: Input parameters considered for the estimation of resident exposure according to EFSA guidance

Croptype	Cereals
Application method	Downward spraying
Application equipment	Vehicle-mounted-Drift Reduction
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	5 m
Application rate of the product	0,125 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,625 g a.s./l
Dermal absorption of product	10,00%
Dermal absorption of in-use dilution	50,00%
Oral absorption	100,00%
Dislodgeable foliar residue ($i_AppRate \times i_DFR$)	0,375 $\mu\text{g a.s./cm}^2$
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of $<5 \times 10^{-3}$ Pa
Concentration in air	0,001 mg/m^3
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
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 $\text{m}^3/\text{day/kg}$
Breathing rate child (1-3 year old)	1,07 $\text{m}^3/\text{day/kg}$
Drift percentage on surface (75th percentile)	2,30%
Drift percentage on surface (mean)	1,80%
Turf transferable residues percentage	5,00%
Transfer coeff. of surface deposits-adult	7300 cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm^2/hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm^2
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm^2/h

Table A 19: Estimation of resident exposure towards mesotrione according to EFSA guidance

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0,0028	% of RVNAS	55,84%
	Vapour (75th percentile) mg/kg bw/day	0,0011	% of RVNAS	21,40%
	Surface deposits (75th percentile) mg/kg bw/day	0,0002	% of RVNAS	4,15%
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0105	% of RVNAS	210,94%
	All pathways (mean) mg/kg bw/day	0,0112	% of RVNAS	223,68%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0,0005	% of RVNAS	10,17%
	Vapour (75th percentile) mg/kg bw/day	0,0002	% of RVNAS	4,60%
	Surface deposits (75th percentile) mg/kg bw/day	0,0001	% of RVNAS	1,75%
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0059	% of RVNAS	117,19%
	All pathways (mean) mg/kg bw/day	0,0052	% of RVNAS	104,66%

Table A 20: Estimation of resident exposure towards mesotrione and florasulam according to OPEX Calculator (ver. 1.0.0)

Model data		Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
				Season: Not relevant Buffer zone: 5 m Drift reduction technology: 50 % Interval between treatments: NA Minimum volume of water: 200 l
Mezotriol				Number of applications and application rate: 1 x 0.125 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days
Resident child Body weight: 10 kg	Drift (75th perc.)		0.003	56.5
	Vapour (75th perc.)		0.0008	16
	Deposits (75th perc.)		0.0002	4.2
	Re-entry (75th perc.)		0.01	211
	Sum (mean)		0.01	218
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.0005	10.3
	Vapour (75th perc.)		0.0003	5.4
	Deposits (75th perc.)		9e-05	1.7
	Re-entry (75th perc.)		0.006	117
	Sum (mean)		0.005	105
Florasulam				Number of applications and application rate: 1 x 0.00375 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days
Resident child Body weight: 10 kg	Drift (75th perc.)		8e-05	0.2
	Vapour (75th perc.)		0.0008	1.6

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident adult Body weight: 60 kg	Deposits (75th perc.)	6e-06	0.01
	Re-entry (75th perc.)	0.0003	0.6
	Sum (mean)	0.001	2.2
	Drift (75th perc.)	2e-05	0.03
	Vapour (75th perc.)	0.0003	0.5
	Deposits (75th perc.)	3e-06	0.005
	Re-entry (75th perc.)	0.0002	0.4
	Sum (mean)	0.0004	0.8
	Combined exposure		
	Hazard index		
Resident child Body weight: 10 kg	Drift (75th perc.)		0.6
	Vapour (75th perc.)		0.2
	Deposits (75th perc.)		0.04
	Re-entry (75th perc.)		2.1
	Sum (mean)		2.2
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.1
	Vapour (75th perc.)		0.06
	Deposits (75th perc.)		0.02
	Re-entry (75th perc.)		1.2
	Sum (mean)		1.1

A 3.3.2 Calculations for florasulam

Table A 21: Input parameters considered for the bystander exposure according to Martin S. et al. (2008).

Intended use(s):	Maize		Drift (D):	3,50	% (FCTM, 5 m)
Application rate (AR):	0,00375	kg a.s./ha	Exposed Body Surface Area (BSA):	1	m ² (adults)
				0,21	m ² (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):	50,00	% ('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:	0,05	mg/kg bw/d			

Table A 22: Estimation of bystander exposure towards florasulam according to Martin S. et al. (2008).

Bystander exposure towards florasulam					
Adults			Children		
Bystander: Dermal exposure after application in Maize (via spray drift)					
SDE _B = (AR x D x BSA x DA) / BW			SDE _B = (AR x D x BSA x DA) / BW		
(0,375 x 3,5% x 1 x 50%) / 60			(0,375 x 3,5% x 0,21 x 50%) / 16,15		
External exposure	0,013125	mg/person	External exposure	0,0027563	mg/person
External exposure	0,0002188	mg/kg bw/d	External exposure	0,0001707	mg/kg bw/d
Absorbed dose:	0,0001094	mg/kg bw/d	Absorbed dose:	0,0000853	mg/kg bw/d
Bystander: Inhalation exposure after application in Maize					
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		
(0,001 / 360 x 0,00375 x 20 x 5 x 100%) / 60			(0,001 / 360 x 0,00375 x 20 x 5 x 100%) / 16,15		
External exposure	1,042E-06	mg/person	External exposure	5,987E-07	mg/person
External exposure	1,736E-08	mg/kg bw/d	External exposure	3,707E-08	mg/kg bw/d
Absorbed dose:	0,0000000	mg/kg bw/d	Absorbed dose:	0,0000000	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)	0,0065635	mg/person	Total systemic exposure (absorbed dose)	0,0013787	mg/person
Total systemic exposure (absorbed dose)	0,0001094	mg/kg bw/d	Total systemic exposure (absorbed dose)	0,0000854	mg/kg bw/d
% of AOEL:	0,22	%	% of AOEL:	0,17	%

Table A 23: Input parameters considered for the resident exposure according to Martin S. et al. (2008).

Intended use(s):	Maize		Drift (D):	3,50	% (FCTM, 5 m)
Application rate (AR):	0,00375	kg a.s./ha	Transfer coefficient (TC):	7300	cm ² /h (adults)
				2600	cm ² /h (children)
Number of applications (NA):	1		Turf Transferable Residues (TTR):	5	%
Body weight (BW):	60	kg/person (adults)	Exposure Duration (H):	2	h
	16,15	kg/person (children)	Airborne Concentration of Vapour (ACV):	none	
Dermal absorption (DA):	50,00	% ('worst case')	Inhalation Rate (IR):	16,57	m ³ /d (adults),
Inhalation absorption (IA):	100	%		8,31	m ³ /d (children)
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE):	50	%
AOEL	0,05	mg/kg bw/d	Surface Area of Hands (SA):	20	cm ²
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm ² /d

Table A 24: Estimation of resident exposure towards florasulam according to Martin S. et al. (2008).

Resident exposure towards florasulam					
Adults			Children		
Residents: Dermal exposure after application in Maize (via deposits caused by spray drift)					
$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$			$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$		
$(0,0000375 \times 1 \times 0,57\% \times 5\% \times 7300 \times 2 \times 50\%) / 60$			$(0,0000375 \times 1 \times 0,57\% \times 5\% \times 2600 \times 2 \times 50\%) / 16,15$		
External exposure	0,0009581	mg/person	External exposure	0,0003413	mg/person
External exposure	1,597E-05	mg/kg bw/d	External exposure	2,113E-05	mg/kg bw/d
Absorbed dose:	0,0000080	mg/kg bw/d	Absorbed dose:	0,0000106	mg/kg bw/d
Residents: Inhalation exposure to vapour					
$SIE_R = (AC_V \times IR \times IA) / BW$			$SIE_R = (AC_V \times IR \times IA) / BW$		
$(0 \times 16,57 \times 100\%) / 60$			$(0 \times 8,31 \times 100\%) / 16,15$		
External exposure		mg/person	External exposure		mg/person
External exposure		mg/kg bw/d	External exposure		mg/kg bw/d
Absorbed dose:		none	Absorbed dose:		none
			Residents: Oral exposure (hand-to-mouth transfer)		
			$SOE_H = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) / BW$		
			$(0,0000375 \times 1 \times 0,57\% \times 5\% \times 50\% \times 20 \times 20 \times 2 \times 100\%) / 16,15$		
			External exposure	2,625E-05	mg/person
			External exposure	1,625E-06	mg/kg bw/d
			Absorbed dose	0,0000016	mg/kg bw/d
			Residents: Oral exposure (object-to-mouth transfer)		
			$SOE_O = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$		
			FAŁSZ		
			External exposure	6,563E-06	mg/person
			External exposure	4,063E-07	mg/kg bw/d
			Absorbed dose	0,0000004	mg/kg bw/d
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_H + SOE_O$		
Total systemic exposure (absorbed dose)	0,0004791	mg/person	Total systemic exposure (absorbed dose)	0,0002034	mg/person
Total systemic exposure (absorbed dose)	0,0000080	mg/kg bw/d	Total systemic exposure (absorbed dose)	0,0000126	mg/kg bw/d
% of AOEL:	0,02	%	% of AOEL:	0,03	%

Table A 25: Input parameters considered for the estimation of resident exposure according to EFSA guidance

Resident exposure for MEZOFLOR 103 S.C.			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted-Drift Reduction		<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		<i>i_FormVal</i>
Buffer strip	5 m		<i>i_Buffer</i>
Application rate of the product	0,00375 kg a.s./ha		<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0,01875 g a.s./l		<i>d_ConCAS</i>
Dermal absorption of product	50,00%		<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%		<i>i_AbsorpInuse</i>
Oral absorption	100,00%		<i>i_AbsorpOralinuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0,01125 µg a.s./cm ²		<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa		<i>i_Volat</i>
Concentration in air	0,001 mg/m ³		<i>d_AirCon</i>
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		<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours		<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0,25 hours		<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18,0%		<i>d_ClothAF</i>
Breathing rate adult	0,23 m ³ /day/kg		<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg		<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	2,30%		
Drift percentage on surface (mean)	1,80%		
Turf transferable residues percentage	5,00%		<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm ² /hour		<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour		<i>d_ReTCCh</i>
Saliva extraction percentage	50,00%		<i>d_SalExt</i>
Surface area of hands mouthed	20 cm ²		<i>d_AreaHM</i>
Frequency of hand to mouth activity	9,5 events/hour		<i>d_ReFreqHM</i>
Ingestion rate for mouthings of grass per day	25 cm ²		<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20,00%		<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm ² /h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm ² /h		<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h		<i>d_TcEntryCh</i>

Table A 26: Estimation of resident exposure towards florasulam according to EFSA guidance

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0,0001	% of RVNAS	0,17%
	Vapour (75th percentile) mg/kg bw/day	0,0011	% of RVNAS	2,14%
	Surface deposits (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	0,01%
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0003	% of RVNAS	0,63%
	All pathways (mean) mg/kg bw/day	0,0014	% of RVNAS	2,75%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	0,03%
	Vapour (75th percentile) mg/kg bw/day	0,0002	% of RVNAS	0,46%
	Surface deposits (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	0,01%
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0002	% of RVNAS	0,35%
	All pathways (mean) mg/kg bw/day	0,0004	% of RVNAS	0,76%

A 3.4 Combined exposure calculations for mesotrione and florasulam

Table A 27 Risk assessment from combined exposure - operator

	Mesotione (AOEL = 0,005 mg/kg bw/ day)		Florasulam (AOEL = 0,05 mg/kg bw/ day)		Cumulative risk
Application scenario	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	HI
Hight crop - tractor mounted					
AOEM, With PPE	0.00236	0.47	0.0004	0.008	0.48
OPEX With PPE	0.003	0.52	0.00065	0.01	0.53

Table A 28 Risk assessment from combined exposure – worker

	Mesotione (AOEL = 0,005 mg/kg bw/ day)		Florasulam (AOEL = 0,05 mg/kg bw/ day)		Cumulative risk
Application scenario	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	HI
Hight crop - tractor mounted					
EUROPOEM II With PPE	0.0045	0.90	0.000013	0.003	0.90

Table A 29 Risk assessment from combined exposure – resident/bystander

	Mesotione (AOEL = 0,005 mg/kg bw/ day)		Florasulam (AOEL = 0,05 mg/kg bw/ day)		Cumulative risk
Application scenario	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	Estimated exposure (mg/kg/day)	Estimated exposure / AOEL (HQ)	HI
Hight crop - tractor mounted (Martins S. (2008))					
Bystander - child	0.0285	0.57	0.000085	0.002	0.57
Bystander - adult	0.00365	0.73	0.00011	0.002	0.73
Resident - child	0.00042	0.08	0.000013	0.00	0.08
Resident - adult	0.000266	0.05	0.000008	0.00	0.05
Hight crop - tractor mounted - AOEM					
Resident - child					
Drift	0.0028	0.56	0.0001	0.00	0.56
Vapour	0.0011	0.21	0.0011	0.02	0.23
Deposits	0.0002	0.04	0.0000	0.00	0.04
Re-entry	0.0105	2.11	0.0003	0.01	2.11
All pathways (mean)		2.24		0.03	2.26
Resident - adult					
Drift	0.0005	0.10	0.0000	0.00	0.10
Vapour	0.0002	0.05	0.0002	0.00	0.05
Deposits	0.0001	0.02	0.0000	0.00	0.02
Re-entry	0.0059	1.17	0.0000	0.00	1.17
All pathways (mean)		1.05		0.01	1.05
Hight crop - tractor mounted – OPEX calculator (1.0.0)					
Resident - child					
Drift	0.003	0.56	0.0001	0.00	0.57
Vapour	0.0008	0.16	0.0008	0.02	0.18
Deposits	0.0002	0.04	0.0000	0.00	0.04
Re-entry	0.0105	2.11	0.0003	0.01	2.12
Sum (mean)	0.01	2.18	0.001	0.02	2.20
Resident - adult					
Drift	0.0005	0.10	0.0000	0.00	0.10
Vapour	0.0003	0.05	0.0003	0.00	0.06
Deposits	0.0001	0.02	0.0000	0.00	0.02

Re-entry	0.006	1.17	0.0002	0.00	1.17
Sum (mean)	0.005	1.05	0.0004	0.01	1.06

Appendix 4 (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)