DRAFT REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: MEZ-HER 100 SC

Product name: MECORN 100 SC

Chemical active substance:

mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023

MS Finalisation date: May 2024

Version history

When	What
May 2024	zRMS assessment of dRR
August 2024	The final Registration Report after 1st commenting period

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6 Mammalian Toxicology (KCP 7)

Introduction

This is the application for registration of a plant protection product under working name MEZ-HER 100 SC according to Article 33 and Article 34 of Regulation 1107/2009. MEZ-HER 100 SC is a suspension concentrate, containing 100 g/L of mesotrione to be used as an herbicide to protect maize.

The reference product Callisto 100 SC was registered in Poland in 2004 (authorisation no. R-2/2004 of 02.02.2004). Then in 2009 and 2020 the authorisation was renewed with authorisation no R-25/2009 of 27.02.2009 and decision no. R-990/2020d of 29.12.2020, respectively. In accordance with above, the data for protection for the formulation Callisto 100 SC and active substance mesotrione have expired.

In respect to the above and taking into account Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009 applicant do not provide additional data and apply for using unprotected data of Callisto 100 SC.

The classification of the MEZ-HER 100 SC based on data on hazardous substances calculation method under the guidance of Regulation 1272/2008/EC (CLP) as amended, can be found in the confidential dRR Part C.

6.1 Summary

Table 6.1-1: Information on MEZ-HER 100 SC

Product name and code	MEZ-HER 100 SC
Formulation type	SC
Active substance	mesotrione 100 g/L
Function	Herbicide

Information on the detailed composition of MEZ-HER 100 SC can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

Table 6.1-2: Justified proposals for classification and labelling for MEZ-HER 100 SC according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Eye Irrit. 2 Repr. 2, H361d
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS07, GHS08
Signal word:	Warning
Hazard statement(s):	H319 Causes serious eye irritation H361d Suspected of damaging the unborn child
Precautionary statement(s):	**WARNING SECTION OF THE LABEL (first page):** P202: Do not handle until all safety precautions have been read and understood. P280: Wear protective gloves and eye /face protection. P305+P351+P338-IF IN EYES: Rinse continuously with water for several minutes. Remove contacts lenses if present and easy to do, continue rinsing. P308+P313: IF exposed or concerned: Call a POISON CENTER/doctor. Other section of the label: P270: Do no eat, drink or smoke when using this product.. P405: Store locked up. P501: Dispose of contents/container to… And P280 as follows: OPERATOR „*Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu*” “Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and protective gloves and work wear during application”. Section “First Aid” P305+P351+P338-IF IN EYES: Rinse continuously with water for several minutes. Remove contacts lenses if present and easy to do, continue rinsing. P308+P313: IF exposed or concerned: Call a POISON CENTER/doctor. For Polish version: see the label

~~As stated above the classification of the MEZ-HER 100 SC is based on the classification of Calisto 100 SC and is included in Part C.~~

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

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Exposure: None Classification: eye/face protection and work wear (coverall) Recommended: protective gloves. ~~Recomended: Gloves and work wear (arms, body and legs covered) during mixing/loading and application.~~
Workers	Acceptable	No PPE. Work wear (arms, body and legs covered) during field actvities. Recommended: Gloves during field actvities.
Residents	Acceptable	None
Bystanders		

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

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

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

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ******	**Application**		**Application rate**		**PHI (d)**	**Remarks:** **(e.g. safener/synergist (L/ha))** **critical gap for operator, worker, resident or bystander exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique *****)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha** **mesotrione**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Residents**	**Bystander**
1	Maize Spring BBCH 14-15	F	Spraying, LCTM	a) 1 b) 1	0.1	200-300	NR	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 and EFSA Journal 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

6.2 Toxicological Information on Active Substance(s)

6.3 Toxicological Evaluation of Plant Protection Product

Comments of zRMS:	The product MEZ-HER 100 SC has not been tested to identify possible toxicological hazards and decide about the classification. The results of the comparative analysis of the composition indicate that the product MEZ-HER 100 SC is similar to the reference product Callisto 100 SC according to the guideline SANCO/12638/2011. Toxicological properties of the formulation MEZ-HER 100 SC have been defined based on the composition of the product and the results of acute toxicity tests performed for the representative formulation, i.e. Callisto 100 SC. Since the *in vivo* acute toxicity tests for the representative formulation already exist, their usage for this evaluation is justified. Whenever toxicological data obtained from animal studies are available, they should be used for the classification as they are more reliable than classification based on composition of the product. Taking into account above considerations, following classification and labelling regarding mammalian toxicology is proposed for the product MEZ-HER 100 SC: 1. Based on the acute toxicity test results obtained with Callisto 100 SC: • Eye Irrit. 2, H319 2. Based on harmonized classification of mesotrione (acc. to reg. 1272/2008, 15ATP): • Repr. 2, H361d

A summary of the toxicological evaluation for MEZ-HER 100 SC is given in the following tables. Full summaries of calculations 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 the final acute toxicity classification, including skin irritation and skin sensitization for MEZ-HER 100 SC

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat	> 2000 mg/kg bw	yes	none	Based on results of studies on the representative formulation (Callisto 100 SC)
LD_{50} dermal, rat	> 2000 mg/kg bw	yes	none	Based on results of studies on the representative formulation (Callisto 100 SC)
LC_{50} inhalation, ~~rat~~	> 5 mg/L	yes	none	Calculation method (additivity formula)
Skin irritation, rabbit	none	yes	none	Based on results of

				studies on the representative formulation (Callisto 100 SC)
Eye irritation, rabbit	Irritant	yes	Eye Irrit.2, H319	Based on results of studies on the representative formulation (Callisto 100 SC)
Skin sensitisation, guinea-pig	non-sensitizing	yes	None	Based on results of studies on the representative formulation (Callisto 100 SC)
Supplementary studies for combinations of plant protection products	-		-	-

Information concerning classification based on the composition of the product are provided in Part C.

Information concerning toxicological evaluation of formulation is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

6.4 Toxicological Evaluation of Groundwater Metabolites

Information concerning toxicological evaluation of groundwater metabolites is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substance in product MEZ-HER 100 SC which has the same formulation as the representative formulation is presented in the following table.

Table 6.5-1: Dermal absorption rates for active substance in MEZ-HER 100 SC

Mesotrione		
	Value	**Reference**
Concentrate	0.1%	EFSA Journal 2016;14(3):4419 (values from unprotected data for reference product Callisto 100 SC)
Spray dilution (1:200)	3%	
Spray dilution (1:400)	5%	

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	MEZ-HER 100 SC
Formulation type	SC
Category	Herbicide
Active substance (incl. content)	mesotrione 100 g/L
AOEL systemic	0.005 mg/kg bw/d (EFSA Journal 2016;14(3):4419)
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 0.1% Dilution: 3% (1:200) Dilution: 5% (1:400) (EFSA Journal 2016;14(3):4419)

6.6.1 Selection of critical uses and justification

Not relevant.

6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	The estimations of operator exposure to mesotrione contained in MEZ-HER 100 SC performed by the Applicant are acceptable. According to the estimations, the use of MEZ-HER 100 SC containing mesotrione (100 g/kg) **causes acceptable health risk for unprotected operator.** The exposure to the active substance for operator equipped with work wear amounts to 23.3% of AOEL (acc. to AOEM EFSA model v. 1.0.1). However, taking into account the classification of the product (Eye Irrit. 2, H319, Repr. Cat. 2, H361d) eye/face shield during M&L and protective gloves are mandatory. Thus, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label: „*Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu*” “Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and protective gloves and work wear during application”.

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the mesotrione during application of MEZ-HER 100 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. Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use	Maize (max. 1 L product/ha)
Models	**AOEM EFSA 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) OPEX version: 30/03/2015 **AOEM EFSA model** (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 version: 1.0.1

Table 6.6-3: Estimated operator exposure

Mesotrione			
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Maize Outdoor Area: 50 ha/day Downward spraying Vehicle-mounted			
Application rate		0.1 kg a.s./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg *OPEX version: 30/03/2015*	Potential exposure	0.0015862	31.72
	Work wear (arms, body and legs covered) M/L and A	0.0010675	21.35
	Work wear (arms, body and legs covered) M/L and A + gloves	0.0002563	5.13
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg *OPEX version: 1.0.1*	Work wear (arms, body and legs covered) M/L and A	0.001	23.3

Conclusion

According to the model calculations, it can be concluded that the risk for the operator using product MEZ-HER 100 SC according to the GAP table is acceptable even if operator is not equipped with work wear (arms, body and legs covered) and gloves during mixing/loading and application.

However, work wear (arms, body and legs covered) and gloves are recommended for operator during mixing/loading and application.

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, 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:	The estimations of worker exposure to mesotrione contained MEZ-HER 100 SC performed by the Applicant are acceptable. According to the estimation results (AOEM, EUROPOEM II), the use of MEZ-HER 100 SC containing mesotrione (100 g/kg) **causes acceptable health risk for a worker wearing work wear** during 2 hour working day (inspection). However, bearing in minds the hygienic rules, the use of protective gloves is recommended when entering treated area. Following sentence is recommended by the evaluator to be placed in the **section of precautions for the workers**: „*Stosować rękawice ochronne oraz odzież robocza podczas wchodzenia na teren poddany opryskowi* .” “Wear protective gloves and work wear when entering treated area.”

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure models used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with MEZ-HER 100 SC according to the GAP table. Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use	Maize (max. 1 L product/ha)
Model	**AOEM EFSA 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) OPEX version: 30/03/2015 **AOEM EFSA model** (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 version: 1.0.1 **EUROPOEM II re-entry model** [Hemmen et al (2002) Post-application exposure of workers to pesticides in agriculture. Report of the re-entry working group. EUROPOEM II project. FAIR3 CT96-1406]

Table 6.6-5: Estimated worker exposure

mesotrione			
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Maize (cereals) Outdoor Downward spraying Vehicle-mounted Inspection, irrigation Work rate: 2 hours/day DT50: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: NA			
EFSA model AOEM			
Application rate		1x 0.1 kg a.s./ha	
Body weight: 60 kg *OPEX version: 30/03/2015*	Potential TC: 12500 cm^2/person/h	0.0062500	125.00
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0007000	14.00
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-
Body weight: 60 kg *OPEX version: 1.0.1*	Potential TC: 12500 cm^2/person/h	0.006	125
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0007	14
	Work wear (arms, body and legs covered) and gloves TC: 1250	0.0006	12.5
EUROPOEM II re-entry model			
Number of applications and application rate		1 x 0.1 kg a.s./ha	
Model data	**Level of PPE**	**Total absorbed dose (mg a.s./day)**	**% of systemic AOEL**
Body weight: 60 kg TC: 0.14 m^2/h	Without PPE	0.042	14
	With PPE (gloves)	0.0008	3

Conclusion

The results of the exposure calculations performed by AOEM EFSA models and EUROPOEM II re-entry model show that the use of MEZ-HER 100 SC according to the GAP Table, causes no health risk for the worker assuming the work wear (arms, body and legs covered) is used.

However, it's recommended for worker to wear also protective gloves during field activities.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not relevant.

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)

Comments of zRMS:	The AAOEL value for mesotrione is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards the active substance. The results of exposure estimations demonstrate that the use of MEZ-HER 100 SC according to the list of intended uses and anticipating the introduction of buffer zone presented in GAP Table, **cause acceptable health risk for bystander/resident (adult and child)** according to AOEM.

6.6.4.1 Estimation of resident and bystander exposure

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

Table 6.6-6 shows the exposure models used for estimation of resident and bystander exposure to mesotrione. The outcome of the estimation is presented in Table 6.6-7.Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use	Maize (max. 1 L product/ha)
Model	**AOEM EFSA 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) OPEX version: 30/03/2015 **AOEM EFSA model** (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 version: 1.0.1

Table 6.6-7: Estimated resident exposure

Mesotrione			
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Maize (cereals) Outdoor Downward spraying Vehicle-mounted Buffer zone: 2-3(m) Drift reduction technology: not applicable DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: NA			
Number of applications and application rate		1x 0.1 kg a.s./ha	
Resident child Body weight: 10 kg *OPEX version: 30/03/2015*	Drift (75th perc.)	0.0006814	13.63
	Vapour (75th perc.)	0.0010700	21.40
	Deposits (75th perc.)	0.0001540	3.08
	Re-entry (75th perc.)	0.0008438	16.88
	Sum (mean)	**0.0022330**	**44.66**
Resident adult Body weight: 60 kg *OPEX version: 30/03/2015*	Drift (75th perc.)	0.0001614	3.23
	Vapour (75th perc.)	0.0002300	4.60
	Deposits (75th perc.)	0.0000341	0.68
	Re-entry (75th perc.)	0.0004688	9.38
	Sum (mean)	**0.0007057**	**14.11**
Resident child Body weight: 10 kg *OPEX version: 1.0.1*	Drift (75th perc.)	0.0007	13.7
	Vapour (75th perc.)	0.0008	16
	Deposits (75th perc.)	0.0002	3.1
	Re-entry (75th perc.)	0.0008	16.9
	Sum (mean)	**0.002**	**39.2**
Resident adult Body weight: 60 kg *OPEX version: 1.0.1*	Drift (75th perc.)	0.0002	3.2
	Vapour (75th perc.)	0.0003	5.4
	Deposits (75th perc.)	3e-05	0.7
	Re-entry (75th perc.)	0.0005	9.4
	Sum (mean)	**0.0007**	**14.9**

Conclusion

All estimated values are below the systemic AOEL for mesotrione. It can be concluded that the exposure of bystander and resident (children and adult) to mesotrione contained in the formulation MEZ-HER 100 SC causes no risk to human health if the product is used in accordance with the intended uses listed in the GAP table.

6.6.4.2 Measurement of resident and/or bystander exposure

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

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

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

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

Not relevant. No new studies provided.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1)

AOEM EFSA model - OPEX version: 30/03/2015

Operator exposure for MEZ-HER 100 SC outdoor spray applications

Application rate of active substance	0,1	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	5,00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	16767	62314	AOEM	
	Body	11058	114960	AOEM	
	Head	259	1423	AOEM	
	Protected hands (gloves)	98	990	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	99	731	AOEM	
	Protected head (hood and face shield)	4	81	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	742	7449	AOEM	
	Body	415	2138	AOEM	
	Head	20	59	AOEM	
	Protected hands (gloves)	102	4021	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	11	28	AOEM	
	Inhalation	2	7	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,0951730	0,0640501	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0015862	0,0010675	
% of RVNAS	31,72%	21,35%	

Operator exposure for MEZ-HER 100 SC outdoor spray applications

Application rate of active substance	0,1	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	5,00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

Outdoor/Soluble concentrates, emulsifiable concentrate, etc./Downward spraying/vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	16767	62314	AOEM	
	Body	11058	114960	AOEM	
	Head	259	1423	AOEM	
	Protected hands (gloves)	98	990	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	99	731	AOEM	
	Protected head (hood and face shield)	4	81	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	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	742	7449	AOEM	
	Body	415	2138	AOEM	
	Head	20	59	AOEM	
	Protected hands (gloves)	102	4021	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	11	28	AOEM	
	Inhalation	2	7	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	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,0951730	0,0153783	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0015862	0,0002563	
% of RVNAS	31,72%	5,13%	

AOEM EFSA model - OPEX version: 1.0.1

Information on product and active substance(s)

Product name	MEZ-HER 100 SC
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Product category	Herbicide
Name of active substance	Mesotrione
Concentration of active substance [g a.s./l or kg]	100
AOEL [mg/kg bw/day]	0.005
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	0.1
Dermal absorption [%] (dilution) 0.48 [g a.s./l or kg]	3
Dermal absorption [%] (dilution) 0.24 [g a.s./l or kg]	5

Short term exposure

Mixing/loading	**Application**	**Mesotrione (% AOEL) Normal & vehi-cle-mounted**
		**34**
		23.3

Outdoor, normal, downward spraying, vehicle-mounted

Summary data - Short term exposure

Model data		**Level of PPE**	**Total ab-sorbed dose [mg/kg bw per day]**	**% of sys-temic AOEL**
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal				
Mesotrione	Number of applications and application rate: 1 x 0.1 kg a.s./ha Dermal absorption (concentrate): 0.1 % Dermal absorption (in-use dilution): 5 %			
		M/L: Workwear App: Workwear	0.001	23.3

A 3.2 Worker exposure calculations (KCP 7.2.3)

AOEM EFSA model - OPEX version: 30/03/2015

Worker exposure from residues on foliage for MEZ-HER 100 SC			
Crop type	Cereals		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,1	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	5,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,3	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	0,3750000	0,0420000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0062500	0,0007000		
% of RVNAS	125,00%	14,00%		

EUROPOEM II re-entry model

WORKER EXPOSURE			EUROPOEM II MODEL	
form	MEZ-HER 100 SC		Re-entry in the field	
a.s.	mesotrione			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,1	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,14	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**0,84**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	5	%	
	PPE-factor dermal	5		gloves*
	AOEL	0,3	mg a.s./ day	based on 60 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0,042	0,008	DE(int) = DE x (DA/100)
	Total	**0,042**	**0,008**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	14	3	%AOEL = 100 x DE(int) / AOEL
	Total	**14**	**3**	**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.

AOEM EFSA model - OPEX version: 1.0.1

Use 1: Field crops

Scenario 1: Outdoor, normal

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
			Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 1400 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h TC (gloves): NA cm²/h
Mesotrione			Number of applications & application rate: 1 x 0.1 kg a.s./ha Dermal absorption: 5 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days
Potential	0.006	125	10
Workwear	0.0007	14	0
Workwear and gloves	0.0006	12.5	0

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

AOEM EFSA model - OPEX version: 30/03/2015

Resident exposure for MEZ-HER 100 SC			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	2-3	m	*i_Buffer*
Application rate of the product	0,1	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	0,5	g a.s./l	*d_ConcAS*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	5,00%		*i_AbsorpInuse*
Oral absorption	100,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,3	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person	
Exposure duration dermal	2	hours	*d_ReExpDur*
Exposure duration inhalation	24	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adı	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h	*d_TcEntryCh*

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0068135	0,0107000	0,0015400	0,0084375	0,0223300
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0006814	0,0010700	0,0001540	0,0008438	0,0022330
% of RVNAS	13,63%	21,40%	3,08%	16,88%	44,66%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0096850	0,0138000	0,0020440	0,0281250	0,0423417
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0001614	0,0002300	0,0000341	0,0004688	0,0007057
% of RVNAS	3,23%	4,60%	0,68%	9,38%	14,11%

AOEM EFSA model - OPEX version: 1.0.1

Use 1: Field crops

Scenario 1: Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
			Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 l
Mesotrione			Number of applications and application rate: 1 x 0.1 kg a.s./ha Dermal absorption: 5 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0007	13.7
	Vapour (75th perc.)	0.0008	16
	Deposits (75th perc.)	0.0002	3.1
	Re-entry (75th perc.)	0.0008	16.9
	Sum (mean)	0.002	39.2
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0002	3.2
	Vapour (75th perc.)	0.0003	5.4
	Deposits (75th perc.)	3e-05	0.7
	Re-entry (75th perc.)	0.0005	9.4
	Sum (mean)	0.0007	14.9

A 3.4 Combined exposure calculations

Not relevant.

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

Not relevant.