FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 8500 A

Product name(s): MEPISHA

Chemical active substance(s):

Mepiquat chloride, 50 g/L

(Mepiquat 38 g/L)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: February 2021

MS Finalisation date: 04/2021; 02/2022

Version history

When	What
April 2021	Assessment by expert
February 2022	Complement by expert

Table of Contents

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 8500 A / MEPISHA *

Product name and code	SHA 8500 A / MEPISHA
Formulation type	Soluble concentrate [Code: SL]
Active substance(s) (incl. content)	Mepiquat; 38 g/L
Function	Plant growth regulator
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of SHA 8500 A / MEPISHA can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for SHA 8500 A / MEPI-SHA according to Regulation (EC) No 1272/2008

Hazard class(es), categories	-
Hazard pictograms or Code(s) for hazard pictogram(s)	-
Signal word	-
Hazard statement(s)	-
Precautionary statement(s)	P102, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 8500 A/ MEPISHA

	Result	PPE / Risk mitigation measures
Operators	Acceptable	None
Workers	Acceptable	None
Residents & Bystanders	Acceptable	None

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

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

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

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Application**		**Application rate**		**PHI (d)**	**Remarks:** **(e.g. safener/synergist (L/ha))** **critical gap for operator, worker, resident or bystander exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique *****	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Residents**	**Bystander**
1	**Winter wheat, winter barley, spring barley** (BBCH 31-39)	F	Spraying, LCTM	a) 1 b) 1	0.0285	200-400	-	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				
2	**Winter Oilseed rape** (BBCH 31-39)	F	Spraying, LCTM	a) 1 b) 1	0.0285	200-400						

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Mepiquat
Common Name	Mepiquat chloride
CAS-No.	24307-26-4
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Acute Tox. 4;Acute Tox.3 Code(s) for hazard pictogram(s): GHS07 Signal word: Dgr Hazard statement(s): H332; H301 Precautionary statement(s): P264, P273, P301+P312, P501
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.3 mg/kg bw/d
Reference	EFSA Scientific Report (2008) 146, 1-73

	Mepiquat
	Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of mepiquat chloride Adopted 18 March 2021
Conditions to take into account/critical areas of concern with regard to toxicology	
According to EFSA Scientific Report (2008) 146, 1-73	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for SHA 8500 A / MEPISHA is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for SHA 8500 A / MEPISHA

Type of test, species, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral, rat	> 5000 mg/kg bw	Yes	None	Calculated
LD_{50} dermal, rat	> 2000 mg/kg bw	Yes	None	Calculated
LC_{50} inhalation, rat	> 5 mg/L air	Yes	None	Calculated
Skin irritation, rabbit	Non-irritant	Yes	None	Calculated
Eye irritation, rabbit	Non-irritant	Yes	None	Calculated
Skin sensitisation, guinea pig	Non-sensitising	Yes	None	Calculated
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of SHA 8500 A / MEPISHA

	Substance (concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Reg. 1272/2008)**
Toxicological properties of active substance(s) (relevant for classification of product)	Mepiquat (3.8% (w/w))	H301, H332,	Reg. 1272/2008	None
Toxicological properties of non-active substance(s) (relevant for classification of product)	Co-formulant 1 < 1% (w/w)*	H302, H318	Reg. 1272/2008	None
Further toxicological information	No data – not required			

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

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

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

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in SHA 8500 A / MEPISHA are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SHA 8500 A / MEPISHA

	Mepiquat	
	Value	**Reference**
Concentrate	50%	EFSA Journal 2017;15(6):4873
Dilution	50%	EFSA Journal 2017;15(6):4873

6.5.1 Justification for proposed values - Mepiquat

No data on dermal absorption for Mepiquat in SHA 8500 A / MEPISHA is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for Mepiquat

	Value	**Justification for value**	**Acceptability of justification**
Concentrate	50%	< 5 % of a.s Mepiquat in formulation	Acceptable
Dilution	50%	Default value (EFSA Journal 2017;15(6):4873)	Acceptable

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	SHA 8500 A / MEPISHA
Formulation type	SL (Soluble concentrate)
Category	Plant growth regulator
Active substance(s) (incl. content)	**Mepiquat** 38 g/L
AOEL systemic	0.3 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	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)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of SHA 8500 A / MEPISHA according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	**Winter wheat, winter barley, spring barley** (max. 0.75 L product/ha) **Winter Oilseed rape** (max. 0.75 L product/ha)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

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

		Mepiquat	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to **low crops** (Cereals and Oilseed)			
Application rate		1 x 0.0285 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0948	**32**
	Work wear (arms, body and legs covered) M/L and A	0.0560	**19**

Estimation of operator exposure to the active substance during application of SHA 8500 A / MEPISHA indicated no risk for operator even without PPE, then the risk for operator is acceptable.

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Błąd! Nie można odnaleźć źródła odwołania.4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SHA 8500 A / MEPISHA according to the critical use(s). Outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.**5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	**Winter wheat, winter barley, spring barley** (max. 0.75 L product/ha) **Winter Oilseed rape** (max. 0.75 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

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

		Mepiquat	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Cereals and Oilseed Inspection, irrigation/Outdoor Work rate: 2 hours/day, 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 0.0285 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.0178	**6**
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.0020	**1**
	no TC available for this assessment	-	-

Estimation of worker exposure to the active substance during application of SHA 8500 A / MEPISHA indicated no risk for worker even without PPE then the risk for worker is acceptable.

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)

6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6-6 shows the exposure model(s) used for estimation of resident and bystander exposure to Mepiquat. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	**Winter wheat, winter barley, spring barley** (max. 0.75 L product/ha) **Winter Oilseed rape** (max. 0.75 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

Table 6.6-7: Estimated resident exposure (longer term exposure)

		Mepiquat	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops **(Cereals and Oilseed)** Buffer zone: 2-3 (m) Drift reduction technology: no 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 0.0285 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0019	0.64
	Vapour (75th perc.)	0.0011	0.36
	Deposits (75th perc.)	0.0002	0.08
	Re-entry (75th perc.)	0.0024	0.80
	Sum (mean)	0.0042	**1.40**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0005	0.15
	Vapour (75th perc.)	0.0002	0.08
	Deposits (75th perc.)	< 0.0001	0.03
	Re-entry (75th perc.)	0.0013	0.45
	Sum (mean)	0.0016	**0.53**

Estimation of resident/bystander (adult & child) exposure to the active substance during application of SHA 8500 A / MEPISHA indicated no risk while keeping buffor zone 2-3 m

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 Mepiquat 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

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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

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

No additional study submitted.

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	N/A

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**The acute oral toxicity of SHA 8500 A / MEPISHA was estimated to be over 2000 mg/kg.** **According to the Regulation EC No. 1272/2008, SHA 8500 A/MEPISHA is unclassified**

Acute toxicity studies for SHA 8500 A / MEPISHA were **not** evaluated as part of the EU review of Mepiquat. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of SHA 8500 A / MEPISHA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute oral toxicity of SHA 8500 A / MEPISHA was calculated as follow:

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

$$ATE_{mix} = \frac{100}{\frac{xx\%}{464} + \frac{xx\%}{500}} = > 5000\, mg/kg\, bw$$

The acute oral toxicity of SHA 8500 A / MEPISHA was estimated to be over 2000 mg/kg. Under the GHS classification system this component does not get the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, SHA 8500 A/MEPISHA is **not classified**. No signal word or hazard statement is required for this hazard.

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

Comments of zRMS:	**No co-formulant in the SHA 8500 A / MEPISHA recipe classified as danger through dermal contact.** **According to the Regulation EC No. 1272/2008, SHA 8500 A / MEPISHA is unclassified**

There is no co-formulant in the SHA 8500 A / MEPISHA recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, SHA 8500 A / MEPISHA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**No co-formulant in the SHA 8500 A / MEPISHA recipe classified as danger through inhalation.** **According to the Regulation EC No. 1272/2008, SHA 8500 A/ MEPI-SHA is unclassified**

There is no co-formulant in the SHA 8500 A / MEPISHA recipe classified as danger through inhalation.

According to the Regulation EC No. 1272/2008, SHA 8500 A / MEPISHA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**No co-formulant in the SHA 8500 A / MEPISHA recipe classified as skin irritant.** **According to the Regulation EC No. 1272/2008, SHA 8500 A / MEPI-SHA is unclassified**

There is no co-formulant in the SHA 8500 A / MEPISHA recipe classified as skin irritant.

According to the Regulation EC No. 1272/2008, SHA 8500 A / MEPISHA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**SHA 8500 A / MEPISHA contains < 3% of co-formulants considered as eye damage.** **According to the Regulation EC No. 1272/2008, SHA 8500 A / MEPI-SHA is unclassified**

The product contains < 3% of co-formulants considered as eye damage (classified as: Eye Dam.; H318). Under the GHS classification system this component does not trigger the value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, SHA 8500 A / MEPISHA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**No co-formulant in the SHA 8500 A / MEPISHA recipe classified as skin sensitiser.** **According to the Regulation EC No. 1272/2008, SHA 8500 A / MEPI-SHA is unclassified**

There is no co-formulant in the SHA 8500 A / MEPISHA recipe classified as skin sensitiser.

According to the Regulation EC No. 1272/2008, SHA 8500 A / MEPISHA is **not classified**. No signal word or hazard statement is required for this hazard.

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

No supplementary studies are necessary.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 10% (concentrate) and 50% (diluted) of may be applied for products that are water-based/dispersed [(c)] or solid-formulated[(d)]

[(c)]: Formulation types: soluble concentrate (SL), suspension concentrate (SC), flowable concentrate for seed treatment (FS), flowable (FL) (SC).

[(d)]: Formulation types: wettable powder (WP), water-dispersible granules (WG/WDG), water-soluble granules (SG), water-soluble powder (SP), powder for dry seed treatment (DS).

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

Acceptable

A 2.11 Other/Special Studies

No data submitted.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

Table A 1: Input parameters considered for the estimation of operator exposure - Cereals and Oilseed

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0948	% of RVNAS	31,60%
	Acute systemic exposure mg/kg bw/day		0,8945	% of RVAAS	
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0,0560	% of RVNAS	18,66%
	Acute systemic exposure mg/kg bw/day		0,2260	% of RVAAS	

Table A 2: Estimation of longer term operator exposure towards Mepiquat according to EFSA guidance - Cereals and Oilseed

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5,6873329	3,3583149	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0947889	0,0559719	
% of RVNAS	31,60%	18,66%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

Table A 3: Input parameters considered for the estimation of worker exposure - Cereals and Oilseed

Worker exposure from residues on foliage for MEPISHA			
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	0,0285	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	50,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0855	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*

Table A 4: Estimation of longer term worker exposure towards Mepiquat according to EFSA guidance - Cereals and Oilseed

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,0687500	0,1197000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0178125	0,0019950		
% of RVNAS	5,94%	0,67%		

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

Table A 5: Input parameters considered for the estimation of longer term resident exposure - Cereals and Oilseed

Resident exposure for MEPISHA			
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	0,0285	kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,1425	g a.s./l	d_ConcAS
Dermal absorption of product	50,00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50,00%		i_Absorpinuse
Oral absorption	100,00%		i_AbsorpOralinuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0855	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) - adu	7500	cm^2/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chil	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

Table A 6: Estimation of longer term resident exposure towards Mepiquat according to EFSA guidance – Cereals and Oilseed

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)	0,0191363	0,0107000	0,0023062	0,0240469	0,0421026
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0019136	0,0010700	0,0002306	0,0024047	0,0042103
% of RVNAS	0,64%	0,36%	0,08%	0,80%	1,40%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0274740	0,0138000	0,0058254	0,0801563	0,0950284
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0004579	0,0002300	0,0000971	0,0013359	0,0015838
% of RVNAS	0,15%	0,08%	0,03%	0,45%	0,53%

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

None.