

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 126085 A

Product name(s): MEPCY

Chemical active substances:

Chlormequat chloride, 345 g/L

Mepiquat chloride, 115 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem Ltd.

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Version history

When	What
May 2023	ZRMs evaluated updated dRR by Applicant
July 2023	Updated after comments
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March 2024	Applicant update
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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 126085 A / MEPCY *

Product name and code	SHA 126085 A / MEPCY
Formulation type	Soluble concentrate [Code: SL]
Active substance(s) (incl. content)	Chlormequat chloride; 345 g/L Mepiquat chloride; 115 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 126085 A / MEPCY 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 126085 A / MEPCY according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Tox., 4
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07
Signal word	Warning
Hazard statement(s)	H302
Precautionary statement(s)	P264, P270, P280, P301 + P312, P330, 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 126085 A / MEPCY

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) M/L and A + gloves during M/L None
Workers	Acceptable	None None

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	Result	PPE / Risk mitigation measures
Residents	Acceptable	None None
Bystanders	Acceptable	None None

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

No unacceptable risk for operators 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 situ- ation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/syn- ergist (L/ha)) critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure assess- ment			
			Method / Kind (incl. applica- tion technique ***	Max. number (min. interval between ap- plications) 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	Winter wheat (BBCH 29-32)	F	Spraying, LCTM	a)1 b)1	a) 0.69 0.76666 Chlomequat chloride + 0.23 0.23232 Mepi- quat chloride b) 0.69 0.76666 Chlomequat chloride + 0.23 0.23232 Mepi- quat chloride	200-400		Guidance on the assessment of ex- posure of opera- tors, workers, resi- dents and bystand- ers in risk assess- ment for plant pro- tection products; EFSA Journal 2014;12(10):3874 Guidance on the assessment of ex- posure of opera- tors, workers, resi- dents and bystand- ers in risk assess- ment for plant pro- tection products; EFSA Journal 2022;20(1):7032 EFSA OPEX cal- culator version: 1.0.2				

* 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

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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)

	Chlormequat chloride	Mepiquat chloride
Common Name	Chlormequat chloride	Mepiquat chloride
CAS-No.	999-81-5	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 (oral), Acute Tox. 4 (dermal) Code(s) for hazard pictogram(s): GHS07 Signal word: Warning Hazard statement(s): H302, H312	Hazard classes (s), categories: Acute Tox.3;Acute Tox. 4; Code(s) for hazard pictogram(s): GHS06 , GHS07 Signal word: Warning Danger Hazard statement(s): H301; H332
Additional C&L proposal	None	None
Agreed EU endpoints		
AOEL systemic	0.04 mg/kg bw/d	0.3 mg/kg bw/d
Reference	EFSA Scientific Report (2008) 179, 1-77	EFSA Scientific Report (2008) 146, 1-73 RAC opinion for mepiquat chloride, adopted March 2021
Conditions to take into account/critical areas of concern with regard to toxicology		
According to EFSA Scientific Report (2008) 179, 1-77 for Chlormequat and EFSA Scientific Report (2008) 146, 1-73 for Mepiquat	None	None

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6.3 Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of Chlormequat 34.5% + Mepiquat 11.5% SL are derived from the classification of the active compounds and co-formulants.

Justification for the proposed classification according the Regulation (EC) No 1272/2008:

Full details of the calculation methodology, co-formulants and their volumes in the product can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Classification for Chlormequat 34.5% + Mepiquat 11.5% SL was calculated based on classification of active ingredients and co-formulants. Based on those calculations for formulation, Chlormequat 34.5% + Mepiquat 11.5% SL is classified as Acute Tox. 4 (oral).

Table 6.3-1: Additional toxicological information relevant for classification/labelling of SHA 126085 A / MEPCY

	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)	Chlormequat chloride (34.5 % (w/w))	H302, H312	Reg. 1272/2008	H302
Toxicological properties of active substance(s) (relevant for classification of product)	Mepiquat chloride (11.5 % (w/w))	H302 H301; H332	Reg. 1272/2008	H302 H301; H332 H302 H301; H332
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

Not relevant, neither Chlormequat chloride nor Mepiquat chloride produce soil metabolites.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in SHA 126085 A / MEPCY are presented in the following table.

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Table 6.5-1: Dermal absorption rates for active substances in SHA 126085 A / MEPCY

	Chlormequat chloride		Mepiquat chloride	
	Value	Reference	Value	Reference
Concentrate	4% 0.44	EFSA Scientific Report (2008) 179, 1-77 New study reported in Appendix 2- Nabanita Sam, 2024	10%	EFSA Journal 2017;15(6):4873
Dilution	4% 0.90	EFSA Scientific Report (2008) 179, 1-77 New study reported in Appendix 2- Nabanita Sam, 2024	50%	EFSA Journal 2017;15(6):4873

6.5.1 Justification for proposed values – Chlormequat chloride

Proposed dermal absorption rates for Chlormequat chloride are based on dermal absorption studies on a formulation similar to SHA 126085 A / MEPCY. The study results are summarised in the following table.

Table 6.5-2: Summary of the results of submitted dermal absorption studies for Chlormequat chloride

Test	Concen- trate	Spray dilution	Formulation in study	Acceptability of study	Justification provided on representa- tivity of study formulation for current prod- uct	Acceptability of justifica- tion	Reference*
In vivo (rat) 10 h exposure / 72 sacrifice	3.3% (7.5 mg/cm ²)	-	BAS 062 03 W (Chlormequat- chloride 750 g/L)	Yes	Similar formulation	Accepted	DAR of Chlormequat, Volume 3, Annex B, part 2/D, B.6, November 2007
In vivo (rat) 10 h exposure / 72 sacrifice	-	2.2% (1 mg/cm ²)	BAS 062 03 W (Chlormequat- chloride 750 g/L)	Yes	Similar formulation	Accepted	DAR of Chlormequat, Volume 3, Annex B, part 2/D, B.6, No- vember 2007
In vivo (rat) 10 h exposure / 72 sacrifice	-	2.3% (0.1 mg/cm ²)	BAS 062 03 W (Chlormequat- chloride 750 g/L)	Yes	Similar formulation	Accepted	DAR of Chlormequat, Volume 3, Annex B, part 2/D, B.6, No- vember 2007

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Test	Concen- trate	Spray dilution	Formulation in study	Acceptability of study	Justification provided on representa- tivity of study formulation for current prod- uct	Acceptability of justifica- tion	Reference*
In vivo (rat) 24 h exposure / 24 sacrifice	3.5%	3.5%	BAS 062 03 W (Chlormequat chloride 750 g/L)	Yes	Similar formulation	Accepted.	DAR of Chlormequat, Volume 3, Annex B, part 2/D, B.6, No- vember 2007

* indicates that a study was reviewed at EU level

†

Based on the results of an in vivo test with rats performed with the formulation Chlormequat chloride 750 g/L, the agreed dermal absorption values were 4% for both the concentrate and the field dilution (EFSA Scientific Report (2008) 179, 1-77).

Proposed dermal absorption rates for Chlormequat chloride are based on dermal absorption study on a formulation SHA 126085 A / MEPCY. The study results are summarised in the following table. Full summaries of study on the dermal absorption of SHA 126085 A / MEPCY that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2. The dermal absorption of Chlormequat chloride is summarised in Table 6.5-3.

Table 6.5-2: Summary of *in vitro* human dermal absorption

	Value	Justification for value	Acceptability of justification
Concentrate	0.44%	<i>In vitro</i> human skin	text
Dilution	0.90%	<i>In vitro</i> human skin	text

6.5.2 Justification for proposed values - Mepiquat chloride

No data on dermal absorption for Mepiquat chloride in SHA 126085 A / MEPCY 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 6.5-3: Default dermal absorption rates for Mepiquat chloride

	Value	Justification for value	Acceptability of justification
Concentrate	10%	The formulation is Soluble concentrate (SL): for dilution water-based/dispersed formulated product.	Accepted
Dilution	50%	The formulation is Soluble concentrate (SL): for dilution water-based/dispersed formulated product.	Accepted

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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 126085 A / MEPCY	
Formulation type	SL	
Category	Plant growth regulator	
Active substance(s) (incl. content)	Chlormequat chloride 345 g/L 383.33 g/L	Mepiquat chloride 115 g/L 116.16 g/L
AOEL systemic	0.04 mg/kg bw/d	0.3 mg/kg bw/d
Inhalation absorption	100%	100%
Oral absorption	100%	100%
Dermal absorption	Concentrate: 4% 0.44 Dilution: 4% 0.90 (EU Agreed / Based on product BAS 062 03 W (Chlormequat chloride 750 g/L))	Concentrate: 10% Dilution: 50% (Default)

6.6.1 Selection of critical use(s) and justification

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

Justification

There is only one intended use.

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 126085 A / MEPCY according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-2 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Winter wheat (max. 2.0 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

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	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
	EFSA OPEX calculator version: 1.0.2

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

		Chlormequat chloride		Mepiquat chloride	
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 (winter wheat)					
Application rate		0.69 kg a.s./ha		0.23 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.0850	213	0.1099	37
	Work wear (arms, body and legs covered) M/L and A + gloves M/L	0.0056	14	0.0694	23

Conclusion

According to the EFSA AOEM Model, it can be concluded that the risk for operator is acceptable, using MEPCY with tractor mounted spray application in winter wheat, with use of adequate work wear (arms, body and legs covered) M/L and A + gloves M/L

Implication for labelling: P280: Wear protective gloves, protective clothing.

Estimated operator exposure (longer term exposure)

		Chlormequat chloride		Mepiquat chloride	
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 field crops (winter wheat)					
Application rate		0.76666 kg a.s./ha		0.23232 kg a.s./ha	
Spray application (OPEX; 75 th percentile) Body weight: 60 kg	Potential exposure	0.01	29.9	0.1	42.1
	Work wear (arms, body and legs covered) M/L and A	0.008	18.9	0.08	27.3

Conclusion

According to the EFSA OPEX calculator, it can be concluded that the risk for the operator using MEPCY

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is acceptable even without use of personal protective equipment
 Implication for labelling: None

ACCEPTED

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SHA 126085 A / MEPCY according to the critical use(s). 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(s)	Winter wheat (max. 1 x 2.0 L product/ha)
Model	<p>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</p> <p>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 EFSA OPEX calculator version: 1.0.2</p>

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

Conclusion
According to the EFSA AOEM Model, it can be concluded there is no unacceptable risk anticipated for the worker re-entering the treated crops even without suitable protective clothing.
Implication for labelling: None

		Chlormequat chloride			Mepiquat chloride		
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL at day 0	Safe re-entry interval (days)	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL at day 0	Safe re-entry interval (days)
Inspection, irrigation							

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Outdoor Work rate: 2 hours/day, 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 0.76666 kg a.s./ha			1 x 0.23232 kg a.s./ha		
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.009	21.6	0	0.1	48.4	0
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.001	2.4	0	0.02	5.4	0
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.0009	2.2	0	0.01	4.8	0

Conclusion

According to the EFSA OPEX calculator, it can be concluded there is no unacceptable risk anticipated for the worker re-entering treated crops even without suitable protective clothing.

Implication for labelling: None

ACCEPTED

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not required.

If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm² (30 mg a.s./m²).

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.

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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 Chlormequat chloride and Mepiquat chloride. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Winter wheat (max. 1 x 2.0 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 EFSA OPEX calculator version: 1.0.2

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

		Chlormequat chloride		Mepiquat chloride	
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 (winter wheat) 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 0.69 kg a.s./ha		1 x 0.23 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0038	9.44	0.0154	5.15
	Vapour (75 th perc.)	0.0011	2.68	0.0011	0.36
	Deposits (75 th perc.)	0.0010	2.41	0.0019	0.62
	Re-entry (75 th perc.)	0.0047	11.64	0.0194	6.47
	Sum (mean)	0.0076	18.96	0.0264	8.80
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0009	2.23	0.0037	1.23
	Vapour (75 th perc.)	0.0002	0.58	0.0002	0.08
	Deposits (75 th perc.)	0.0002	0.47	0.0008	0.26
	Re-entry (75 th perc.)	0.0026	6.47	0.0108	3.59
	Sum (mean)	0.0029	7.14	0.0112	3.72

Conclusion

According to the EFSA AOEM Model, it can be concluded that there is no undue risk to any

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bystander after accidental short-term exposure nor to any resident exposure to MEPCY.

Implication for labelling: None

Estimated resident exposure (longer term exposure)

		Chlormequat chloride		Mepiquat chloride	
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 field crops (winter wheat) 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 0.76666 kg a.s./ha		1 x 0.23232 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.001	2.5	0.02	5.2
	Vapour (75 th perc.)	0.0008	2	0.0008	0.3
	Deposits (75 th perc.)	0.0007	1.8	0.002	0.6
	Re-entry (75 th perc.)	0.001	2.9	0.02	6.5
	Sum (mean)	0.003	7	0.03	8.8
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0002	0.6	0.004	1.2
	Vapour (75 th perc.)	0.0003	0.7	0.0003	0.09
	Deposits (75 th perc.)	5e-05	0.1	0.0008	0.3
	Re-entry (75 th perc.)	0.0006	1.6	0.01	3.6
	Sum (mean)	0.0009	2.3	0.01	3.8

Conclusion

According to the EFSA OPEX calculator, it can be concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to MEPCY.

Implication for labelling: None

ACCEPTED

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 Chlormequat chloride and Mepiquat chloride 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.

6.6.5.1 Exposure assessment of Chlormequat chloride and Mepiquat chloride in SHA 126085 A / MEPCY

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 Table 6.6-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-8: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – Work wear (arms, body and legs covered) M/L and A + gloves M/L	Chlormequat chloride	0.14
	Mepiquat chloride	0.23
	Cumulative risk operators (HI)	0.37
Workers – Work wear (arms, body and legs covered)	Chlormequat chloride	0.1
	Mepiquat chloride	0.054
	Cumulative risk workers (HI)	0.15
Resident - child	Chlormequat chloride	
	Drift	0.09
	Vapour	0.03
	Deposits	0.02
	Re-entry	0.12
	Sum of all pathways	0.19
	Mepiquat chloride	
	Drift	0.05
	Vapour	0.004
	Deposits	0.006
	Re-entry	0.06
	Sum of all pathways	0.09
	Cumulative risk resident – child (HI)	
	Drift	0.14
	Vapour	0.03

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Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Deposits	0.03
	Re-entry	0.18
	Sum of all pathways	0.28
Resident - adult	Chlormequat chloride	
	Drift	0.02
	Vapour	0.01
	Deposits	0.005
	Re-entry	0.06
	Sum of all pathways	0.07
	Mepiquat chloride	
	Drift	0.01
	Vapour	0.001
	Deposits	0.003
	Re-entry	0.04
	Sum of all pathways	0.04
	Cumulative risk resident – adult (HI)	
	Drift	0.03
	Vapour	0.01
	Deposits	0.01
	Re-entry	0.10
	Sum of all pathways	0.11

The Hazard Index is < 1. Thus, combined exposure to all active substances in SHA 126085 A / MEPCY is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – Work wear (arms, body and legs covered) M/L and A	Chlormequat chloride	0.19
	Mepiquat chloride	0.27
	Cumulative risk operators (HI)	0.5
Workers – Work wear (arms, body and legs covered)	Chlormequat chloride	0.024
	Mepiquat chloride	0.054
	Cumulative risk workers (HI)	0.08

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Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Resident - child	Chlormequat chloride	
	Drift	0.03
	Vapour	0.02
	Deposits	0.02
	Re-entry	0.03
	Sum of all pathways	0.07
	Mepiquat chloride	
	Drift	0.05
	Vapour	0.003
	Deposits	0.006
	Re-entry	0.07
	Sum of all pathways	0.09
	Cumulative risk resident – child (HI)	
	Drift	0.08
	Vapour	0.02
	Deposits	0.02
	Re-entry	0.09
	Sum of all pathways	0.2
Resident - adult	Chlormequat chloride	
	Drift	0.006
	Vapour	0.007
	Deposits	0.001
	Re-entry	0.02
	Sum of all pathways	0.02
	Mepiquat chloride	
	Drift	0.01
	Vapour	0.0009
	Deposits	0.003
	Re-entry	0.04
	Sum of all pathways	0.04
	Cumulative risk resident – adult (HI)	
	Drift	0.02
	Vapour	0.008
	Deposits	0.004

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Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Re-entry	0.05
	Sum of all pathways	0.06

The Hazard Index is < 1. Thus, combined exposure to all active substances in SHA 126085 A / MEPCY is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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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
KCP 7.3	Nabanita S.	2024	<i>In vitro</i> percutaneous dermal absorption study of Chlormequat chloride, formulated as Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL, through human skin EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED Report No.: AG-G0670 GLP, Unpublished	N	SHARDA Cropchem Limited

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

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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

Not relevant.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	The acute oral toxicity of Chlormequat 34.5% + Mepiquat 11.5% SL was estimated to be < 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL is classified as Acute Toxicity Category 4 (oral) (H302) with pictogram GHS07 and signal word “Warning”.
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The classification of Chlormequat 34.5% + Mepiquat 11.5% SL was performed by calculation. The assessment of all acute toxicological properties of Chlormequat 34.5% + Mepiquat 11.5% SL is derived from the classification of the active compounds and co-formulants as shown below. For obvious confidentiality reasons, the names and percentages of co-formulants are disclosed in Part C:

Formulant	% of formulation	Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Dermal Irritation	Ocular Irritation	Sensitising potential
Chlormequat chloride technical (CAS no.: 999-81-5)	35.23	500 mg/kg ²⁾ H302	1100 mg/kg ²⁾ H312	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Mepiquat chloride technical (CAS no.: 24307-26-4)	10.68	500 mg/kg²⁾ H302 oral: ATE = 270 mg/kg bw H301	>2000 mg/kg	* inhalation: ATE = 2.8 mg/L H332	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 1	xxx	>38900 mg/kg	>3000 mg/kg	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 2	xxx	22000 mg/kg	>2000 mg/kg	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 3	xxx	>2000 mg/kg ¹⁾	>2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 4	xxx	>2000 mg/kg ¹⁾	>2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾

* No Information / but in their MSDS are not classified acutely inhalation toxic

¹⁾ As co-formulant is not classified

²⁾ According to the Regulation (EC) n°1272/2008, Oral: ATE = 500 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4: H302; Dermal: ATE = 1100 mg/l is used for the calculation for co-formulant classified as Acute Tox. 3; H312.

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values:

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

or

$$\frac{100 - (\sum C_{unknown} \text{ if } > 10\%)}{ATE_{mix}} = \sum_r \frac{C_i}{ATE_i}$$

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.

The acute oral toxicity classification for Chlormequat 34.5% + Mepiquat 11.5% SL is calculated:

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

$$ATE_{mix} = \frac{100}{\frac{xxx}{500} + \frac{xxx}{500}} = 1089.08 \text{ } 908.96 \text{ mg/kg bw}$$

270

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Chlormequat 34.5% + Mepiquat 11.5% SL can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

The acute oral toxicity of Chlormequat 34.5% + Mepiquat 11.5% SL was estimated to be < 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL is classified as Acute Toxicity Category 4 (oral) (H302) with pictogram GHS07 and signal word “Warning”.

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

Comments of zRMS:	<p>The acute dermal toxicity of Chlormequat 34.5% + Mepiquat 11.5% SL was estimated to be > 2000 mg/kg.</p> <p>Therefore, according to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL is not classified. No signal word or hazard statement is required for this hazard.</p>
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The acute dermal toxicity classification for Chlormequat 34.5% + Mepiquat 11.5% SL is calculated:

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

$$ATE_{mix} = \frac{100}{\frac{xxx}{1100}} = 3122.36 \text{ mg/kg bw}$$

Conclusion

The acute dermal toxicity of Chlormequat 34.5% + Mepiquat 11.5% SL was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL 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:	According to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL is not classified. No signal word or hazard statement is required for this hazard
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~~Neither the active substances nor co-formulants in the Chlormequat 34.5% + Mepiquat 11.5% SL recipe are classified as danger through inhalation.~~

The acute inhalation toxicity classification for Chlormequat 34.5% + Mepiquat 11.5% SL is calculated:

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

$$ATE_{mix} = \frac{100}{\frac{10.68}{2.8}} = 26.22 \text{ mg/l}$$

The acute inhalation toxicity of Chlormequat 34.5% + Mepiquat 11.5% SL is estimated to be > 5 mg/l. Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL 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:	According to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL is not classified. No signal word or hazard statement is required for this hazard.
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Neither the active substances nor co-formulants in the Chlormequat 34.5% + Mepiquat 11.5% SL recipe are classified as danger through skin contact.

According to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL 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:	According to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL is not classified. No signal word or hazard statement is required for this hazard.
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Neither the active substances nor co-formulants in the Chlormequat 34.5% + Mepiquat 11.5% SL recipe are classified as danger through eye contact.

According to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL 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:	According to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL is not classified. No signal word or hazard statement is required for this hazard.
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Neither the active substances nor co-formulants in the Chlormequat 34.5% + Mepiquat 11.5% SL recipe are classified as skin sensitiser.

According to the Regulation EC No. 1272/2008, Chlormequat 34.5% + Mepiquat 11.5% SL 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)

Chlormequat chloride

The dermal absorption value for soluble concentrate formulations as stated in the List of endpoints of Chlormequat chloride is based on a SL formulation containing 750 g/L Chlormequat chloride. The dermal absorption is 4% for a concentrate and 4% for a spray dilution. According to EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) data on another (reference) formulation can be used if the formulation to be assessed is closely related.

This is the case for the formulation Chlormequat 34.5% + Mepiquat 11.5% SL. EU agreed endpoint can be used as BAS 062 03 W (Chlormequat chloride 750 g/L) and Chlormequat 34.5% + Mepiquat 11.5% SL are the same type of formulation and have similar dermal irritation and sensitization properties:

- Active substance content: Chlormequat chloride
- Formulation type: SL
- Skin irritation: not a skin irritant
- Skin sensitization: not a skin sensitizer

Mepiquat chloride

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).

A 2.10.1 Study 1 – Chlormequat chloride in SHA 126085 A / MEPCY

Comparative dermal absorption, in vitro using rat and human skin

Comments of zRMS:	0.44 % of dose for undiluted Chlormequat chloride formulation (concentrate). .90% of dose for actual spray strength used in the field dilution
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Reference

KCP 7.3

Report

In vitro percutaneous dermal absorption study of Chlormequat chloride, formulated as Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL, through human skin, Nabanita S., 2024, Report No.: AG-G0670

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Guideline(s)	OECD Guideline 428 “Skin Absorption: in vitro Method” April 2004
Deviations	Yes. The radiochemical purity of test item and test item formulations were determined by a combination of IC and LSC instead by radio-HPLC, as in study plan. This deviation has no impact on the outcome of the study.
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material	Name (Lot/Batch No.)	¹⁴ C-Chlormequat Chloride (S020-864)
	Test preparation	radioformulation
	Specific activity	51.58 mCi/mmol 322.9 µCi/mg
	Radiochemical purity	99.7 HPLC area%
Product	Name (Lot/Batch No.)	Chlormequat Chloride 34.5% + Mepiquat Chloride 11.5% SL (SCL-49122)
	Company code	S020-655
	Concentration a.s.	Chlormequat Chloride: 34.50% Mepiquat Chloride: 11.50%
	Formulation type	Soluble concentrate (SL)
Blank product	Name (Lot/Batch No.)	Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL (blank) (SCL-86953)
	Concentration a.s.	Chlormequat chloride 0% Mepiquat chloride 0%

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.8 mL/h
	Exposed skin area	0.64 cm²
Membrane	Skin type	isolated epidermis
	Skin thickness range	0.2-0.4 mm
	Skin donors age	59, 61, 39, 34 years
	Skin donors sex	f, f, f, f
	Location	abdomen
	Source	post mortem
	Integrity test	yes
Receptor	Receptor medium	PBS buffer supplemented with 0.01% sodium azide and 6% PEG, pH ca. 7.4
	Solubility in receptor medium	y
Sample Time	Exposure time	8 h
	Observation time	16 h post exposure
Sampling	Sample intervals	At 0-1h, 1-2h, followed by 2h intervals until 24h after application. Sampling duration: 24 h.
Washing		At 8 h using water and a mild soap solution (3% Dove)
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	n
Remarks:		

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Tested doses	Concentrate	Spray dilution 1
Target concentration [g. L ⁻¹]	345	1.725
Area dose [µg/cm ²]	3454.31 ± 10.04	17.27 ± 0.053
Specific activity [MBq.mL ⁻¹]	3.7046 ± 0.011	17.27 ± 0.053
No. of donors	4	4

Results and discussions

Table A 1: In-vitro dermal penetration of Chlormequat chloride formulated as SHA 126085 A / MEPCY through human skin - Recovery data

Dose group	High dose		Low dose	
	(Formulation concentrate)		(Spray dilution 1:200)	
Target concentration [g.L ⁻¹]	345		1.725	
Mean actual applied dose [µg.cm ²]	3454.31 ± 10.04		17.27 ± 0.053	
Number of replicates (n)	8		8	
	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
Skin washing	100.20	2.64	98.42	2.28
Donor chamber wash	0.03	0.01	0.59	0.21
Dose associated to skin				
Tape strips: 1 st sample, strips 1 + 2	0.03	0.02	0.07	0.02
Tape strips: 2 nd sample; strips 3 - n	0.18	0.05	0.40	0.07
Stripped skin	0.04	0.03	0.30	0.10
Absorbed dose	0.21	0.04	0.76	0.16
Receptor fluid	0.16	0.02	0.41	0.08
Receptor chamber wash	0.01	0.01	0.06	0.01
Total recovery¹	100.64	2.64	100.24	2.52
Absorption essentially complete at end of study (>75% absorption within half the study duration) [% Absorption at t _{0.5}]	No [54.93%]		Yes [80.36%]	
If no:				
Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²	0.38	0.07	N/A	N/A
If yes:				
Absorption estimates = absorbed dose + skin preparation	N/A	N/A	0.76	0.16
Absorption estimate normalised ³	0.38 ± 0.84 × 0.07		0.76 ± 0.84 × 0.16	
Relevant absorption estimate ⁴	0.38 ± 0.06		0.76 ± 0.13	
Absorption estimates used for risk assessment⁵	0.44		0.90	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the

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absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

³ According to the EFSA Guidance on Dermal Absorption, cells with insufficient recovery (< 95%) can be corrected by normalisation of absorption estimate to 100% recovery; explanation should be included.

⁴ In accordance with the EFSA Guidance on Dermal Absorption, one standard deviation was added to the mean% dermal penetration in cases where the standard deviation was $\geq 25\%$ of the mean value.

⁵ Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

Conclusion/endpoint: 0.44 % of dose for undiluted Chlormequat chloride formulation (concentrate).

0.90% of dose for actual spray strength used in the field dilution.

A 2.11 Other/Special Studies

No new additional other/special studies.

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Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Chlormequat chloride

Table A 1: Input parameters considered for the estimation of operator exposure

Formulation type	SL		Crop type	Winter wheat
Application rate (AR)	0.69	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	4	% (concentr.)	Indoor/outdoor	Outdoor
	4	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.04	mg/kg bw/d	Water soluble bag	No

Table A 2: Estimation of longer term operator exposure towards Chlormequat chloride according to EFSA guidance

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			Protective gloves	
Specific exposure value	2966.7384843	µg/person	13.8017985	µg/person
Systemic exposure	49.4456414	mg/kg bw/d	0.2300300	mg/kg bw/d
Body			Work wear	
Specific exposure value	1719.3692994	µg/person	21.9344477	µg/person
Systemic exposure	28.6561550	mg/kg bw/d	0.3655741	mg/kg bw/d
Head			None	
Specific exposure value	71.5993511	µg/person	71.5993511	µg/person
Systemic exposure	1.1933225	mg/kg bw/d	1.1933225	mg/kg bw/d
Inhalation			None	
Specific exposure value	10.6182993	µg/person	10.6182993	µg/person
Systemic exposure	0.1769717	mg/kg bw/d	0.1769717	mg/kg bw/d
Application				
Hands			None	
Specific exposure value	204.6862643	µg/person	204.6862643	µg/person
Systemic exposure	3.4114377	mg/kg bw/d	3.4114377	mg/kg bw/d
Body			Work wear	
Specific exposure value	114.4470865	µg/person	3.1394767	µg/person
Systemic exposure	1.9074514	mg/kg bw/d	0.0523246	mg/kg bw/d
Head			None	
Specific exposure value	5.4091614	µg/person	5.4091614	µg/person

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Systemic exposure	0.0901527	mg/kg bw/d	0.0901527	mg/kg bw/d
<u>Inhalation</u>			None	
Specific exposure value	6.1043405	µg/person	6.1043405	µg/person
Systemic exposure	0.1017390	mg/kg bw/d	0.1017390	mg/kg bw/d
Total				
Total systemic exposure	0.0849829	mg/kg bw/d	0.0056216	mg/kg bw/d
% of AOEL	212.46	%	14.05	%

A 3.1.2 Calculations for Mepiquat chloride

Table A 3: Input parameters considered for the estimation of operator exposure

Formulation type	SL		Crop type	Winter wheat
Application rate (AR)	0.23	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	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.3	mg/kg bw/d	Water soluble bag	No

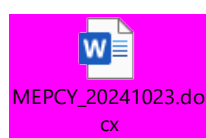
Table A 4: Estimation of longer term operator exposure towards Mepiquat chloride according to EFSA guidance

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			None	
Specific exposure value	3183.5891685	µg/person	3183.5891685	µg/person
Systemic exposure	53.0598195	mg/kg bw/d	53.0598195	mg/kg bw/d
Body			Work wear	
Specific exposure value	1985.7580551	µg/person	20.7090771	µg/person
Systemic exposure	33.0959676	mg/kg bw/d	0.3451513	mg/kg bw/d
Head			None	
Specific exposure value	59.6661259	µg/person	59.6661259	µg/person
Systemic exposure	0.9944354	mg/kg bw/d	0.9944354	mg/kg bw/d
Inhalation			None	
Specific exposure value	7.6570887	µg/person	7.6570887	µg/person
Systemic exposure	0.1276181	mg/kg bw/d	0.1276181	mg/kg bw/d
Application				
Hands			None	
Specific exposure value	852.8594344	µg/person	852.8594344	µg/person
Systemic exposure	14.2143239	mg/kg bw/d	14.2143239	mg/kg bw/d
Body			Work wear	
Specific exposure value	476.8628604	µg/person	13.0811529	µg/person

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Systemic exposure	7.9477143	mg/kg bw/d	0.2180192	mg/kg bw/d
Head			None	
Specific exposure value	22.5381725	µg/person	22.5381725	µg/person
Systemic exposure	0.3756362	mg/kg bw/d	0.3756362	mg/kg bw/d
Inhalation			None	
Specific exposure value	3.5204728	µg/person	3.5204728	µg/person
Systemic exposure	0.0586745	mg/kg bw/d	0.0586745	mg/kg bw/d
Total				
Total systemic exposure	0.1098742	mg/kg bw/d	0.0693937	mg/kg bw/d
% of AOEL	36.62	%	23.13	%

Please, refer to summary of OPEX calculations.



A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Chlormequat chloride

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

Intended use(s)	Winter wheat, inspection, irrigation, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.69	kg a.s./ha	Dermal absorption (DA)	4	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm ² /h
AOEL	0.04	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 6: Estimation of longer term worker exposure towards Chlormequat chloride according to EFSA guidance

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0345000	mg/kg bw/d	0.0038640	mg/kg bw/d	-	mg/kg bw/d
% of AOEL	86.25	%	9.66	%	-	%

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A 3.2.2 Calculations for Mepiquat chloride

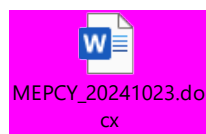
Table A 7: Input parameters considered for the estimation of worker exposure

Intended use(s)	Winter wheat, inspection, irrigation, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.23	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)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm ² /h
AOEL	0.3	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 8: Estimation of longer term worker exposure towards Mepiquat chloride according to EFSA guidance

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.1437500	mg/kg bw/d	0.0161000	mg/kg bw/d	-	mg/kg bw/d
% of AOEL	47.92	%	5.37	%	-	%

Please, refer to summary of OPEX calculations.



A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Chlormequat chloride

Table A 9: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Winter wheat, downward spraying		Drift reduction (DR)		%
Application rate (AR)	0.69	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	365	days	Exposure duration dermal (H _D)	2	h

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Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.0		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	4	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.04	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 10: Estimation of longer term resident exposure towards Chlormequat chloride according to EFSA guidance

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0008922	mg/kg bw/d	Systemic exposure	0.0037762	mg/kg bw/d
% of AOEL:	2.23	%	% of AOEL:	9.44	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	0.58	%	% of AOEL:	2.68	%
Surface deposits (75 th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0001880	mg/kg bw/d	Systemic exposure	0.0004019	mg/kg bw/d
<u>Hand to mouth</u>					

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AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure	0.0003671	mg/kg bw/d		
<u>Object to mouth</u>							
AR x MAF x D x DR _{OM} x IgR x OA / BW							
			Systemic exposure	0.0001932	mg/kg bw/d		
<u>Total</u>							
Systemic exposure	0.0001880	mg/kg bw/d	Systemic exposure	0.0009621	mg/kg bw/d		
% of AOEL:	0.47	%	% of AOEL:	2.41	%		
Entry into treated crops (75 th perc.)							
<u>Dermal</u>							
AR x MAF x TC x H _D x DFR x DA / BW							
Systemic exposure	0.0025875	mg/kg bw/d	Systemic exposure	0.0046575	mg/kg bw/d		
<u>Hand to mouth</u>							
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Object to mouth</u>							
AR x MAF x 100% x DR _{OM} x IgR x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Total</u>							
Systemic exposure	0.0025875	mg/kg bw/d	Systemic exposure	0.0046575	mg/kg bw/d		
% of AOEL:	6.47	%	% of AOEL:	11.64	%		
All pathways (mean)							
Systemic exposure			0.0028569	mg/kg bw/d	Systemic exposure	0.0075835	mg/kg bw/d
% of AOEL:	7.14	%	% of AOEL:		18.96	%	

A 3.3.2 Calculations for Mepiquat chloride

Table A 11: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Winter wheat, downward spraying		Drift reduction (DR)		%
Application rate (AR)	0.23	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	365	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h

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Multiple application factor (MAF)	1.0		Exposure duration entry into treated crops (H_E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	50	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.3	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

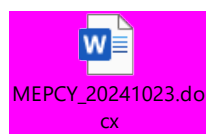
Table A 12: Estimation of longer term resident exposure towards Mepiquat chloride according to EFSA guidance

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0036953	mg/kg bw/d	Systemic exposure	0.0154434	mg/kg bw/d
% of AOEL:	1.23	%	% of AOEL:	5.15	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	0.08	%	% of AOEL:	0.36	%
Surface deposits (75 th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0007835	mg/kg bw/d	Systemic exposure	0.0016744	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure	0.0001224	mg/kg bw/d

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Object to mouth					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
			Systemic exposure	0.0000644	mg/kg bw/d
Total					
Systemic exposure	0.0007835	mg/kg bw/d	Systemic exposure	0.0018612	mg/kg bw/d
% of AOEL:	0.26	%	% of AOEL:	0.62	%
Entry into treated crops (75 th perc.)					
Dermal					
AR x MAF x TC x H _D x DFR x DA / BW					
Systemic exposure	0.0107813	mg/kg bw/d	Systemic exposure	0.0194063	mg/kg bw/d
Hand to mouth					
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure		mg/kg bw/d
Object to mouth					
AR x MAF x 100% x DR _{OM} x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
Total					
Systemic exposure	0.0107813	mg/kg bw/d	Systemic exposure	0.0194063	mg/kg bw/d
% of AOEL:	3.59	%	% of AOEL:	6.47	%
All pathways (mean)					
Systemic exposure			0.0111555	mg/kg bw/d	
% of AOEL:	3.72	%	% of AOEL:	8.80	%

Please, refer to summary of OPEX calculations.



A 3.4 Combined exposure calculations for Chlormequat chloride and Mepiquat chloride

In tables below are presented calculations for combined exposure for Chlormequat chloride and Mepiquat chloride.

Operator exposure:

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		Chlormequat chloride (AOEL = 0.04 mg/kg bw/d)		Mepiquat chloride (AOEL = 0.3 mg/kg bw/d)		Cumulative risk Operators (HI) ¹
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	
Tractor mounted boom spray application outdoors to low crops (winter wheat)						
Application rate		0.69 kg a.s./ha		0.23 kg a.s./ha		
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.0850	2.13	0.1099	0.37	2.5
	Work wear (arms, body and legs covered) M/L and A + gloves M/L	0.0056	0.14	0.0694	0.23	0.37

The Hazard Index is < 1 for the estimation using gloves during mix/loading.

Worker exposure:

¹ The Hazard Index (HI) is the sum of the individual HQs for Chlormequat chloride and Mepiquat chloride

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		Chlormequat chloride (AOEL = 0.04 mg/kg bw/d)		Mepiquat chloride (AOEL = 0.3 mg/kg bw/d)		Cumulative risk Operators (HI)*
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	
Winter wheat						
Number of applications and application rate		1 × 0.69 kg a.s./ha		1 × 0.23 kg a.s./ha		
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.0345	0.86	0.1438	0.48	1.34
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.0039	0.1	0.0161	0.054	0.15
	Work wear (arms, body and legs covered) and gloves TC: not available for this assessment	–	–	–	–	–

The estimated exposure for workers presents that the Hazard Index is < 1 for the estimation without the use of personal protective equipment.

Bystander and resident exposure:

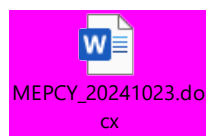
		Chlormequat chloride (AOEL = 0.04 mg/kg bw/d)		Mepiquat chloride (AOEL = 0.3 mg/kg bw/d)		Cumulative risk Operators (HI)*
Model data		Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	
Winter wheat						
Number of applications and application rate		1 × 0.69 kg a.s./ha		1 × 0.23 kg a.s./ha		
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0038	0.09	0.0154	0.05	0.14
	Vapour (75 th perc.)	0.0011	0.03	0.0011	0.004	0.03
	Deposits (75 th perc.)	0.0010	0.02	0.0019	0.006	0.03
	Re-entry (75 th perc.)	0.0047	0.12	0.0194	0.06	0.18

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	Sum (mean)	0.0076	0.19	0.0264	0.09	0.28
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0009	0.02	0.0037	0.01	0.03
	Vapour (75 th perc.)	0.0002	0.01	0.0002	0.001	0.01
	Deposits (75 th perc.)	0.0002	0.005	0.0008	0.003	0.01
	Re-entry (75 th perc.)	0.0026	0.06	0.0108	0.04	0.10
	Sum (mean)	0.0029	0.07	0.0112	0.04	0.11

The Hazard Index is < 1. Thus, combined exposure to all active substances in product MEPCY is not expected to present a risk for bystanders and residents.

Please, refer to summary of OPEX calculations.



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.