

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: SHA 126085 A**

**Product name: MEPCY**

**Chemical active substances:**

**Chlormequat, 345 g/L**

**Mepiquat, 115 g/L**

### **Central Zone**

**Zonal Rapporteur Member State: Poland**

**NATIONAL ASSESSMENT Poland**

**(authorization)**

**Applicant: Sharda Cropchem Ltd.**

**Submission date: February 2022**

**MS Finalisation date: May 2023, August 2023,  
January 2024, May 2024, August 2024**

## Version history

When	What
May 2023	ZRMs evaluated dRR submitted by Applicant.
August 2023	Final version of RR after commenting period.
September 2023	Updated by the Applicant
January 2024	zRMS assessment after Applicant's update
May 2024	Final version of RR after second round of commenting.
August 2024	ZRMS update

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

#### 1.1 Application background

This application is submitted by SHARDA CROPCHEM Ltd.

This application is for approval of MEPCY, a soluble concentrate containing 345 g/L of Chlormequat (as chloride) and 115 g/L of Mepiquat (as chloride) as plant growth regulator on winter wheat.

zRMS: Poland

#### 1.2 Letters of Access

Not application. Letter of access not needed.

#### 1.3 Justification for submission of tests and studies

This dossier relies on new tests and studies, providing data and information specific to the formulation Chlormequat 34.5% + Mepiquat 11.5 % SL as required by EU regulations.

#### 1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

### 2 Details of the authorization decision

#### 2.1 Product identity

Product code	SHA 126085 A
Product name in MS	MEPCY
Authorization number	First authorisation
Function	Plant growth regulator
Applicant	Sharda Cropchem España S.L.
Active substances (incl. content)	Chlormequat chloride, 345 g/L Mepiquat chloride, 115 g/L
Formulation type	Soluble concentrate [Code: SL]
Packaging	0.25, 0.5, 1, 5, 10, 20 L HDPE/PA 0.25, 0.5, 1, 5, 10, 20 L HDPE

Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

## 2.2 Conclusion

### Section physical-chemical properties:

Lack of the determination of the level of relevant impurities in the formulation (the study is ongoing and the results will be available in August 2023). No data gaps

### Section analytical methods:

Lack of developed and validated analytical method for the determination of relevant impurities in the formulation (the study is ongoing and the results will be available in August 2023). No data gaps.

**Section efficacy:** Accepted registration of MEPCY applied once a season (2.0 L/ha) against reducing of height and to prevent lodging on winter wheat crops at BBCH 29-32

### Section mammalian toxicology:

MEPCY is classified Acute Tox.4 (oral) /H302 and no risk for operator, worker and bystander/resident

### Section metabolism and residues:

The evaluation of the application for MEPCY resulted in the decision to grant the authorization.

Proposed label restriction: do not use straw from wheat treated with chlormequat as horticultural growth medium in cultivation of fungi.

### Section environmental fate and behavior:

The evaluation of the application for MEPCY resulted in the decision to grant the authorization.

**Section ecotoxicology:** The evaluation of the application for MEPCY resulted in the decision to grant the authorization.

The study on the effects of MEPCY (SHA 126085 A) on *Lemna gibba* with risk assessment should be provided by Applicant. To address the current data gap for *Lemna gibba* conducted by Applicant according to the OECD Guidelines. The new study for *Lemna gibba* with formulated product MEPCY has been accepted by zRMS. Toxicity data and risk assessment for *Lemna gibba* was available for the PPP MEPCY and a low risk was demonstrated for this species. Refinement risk assessment is not needed.

The chronic adult and chronic larvae tests for bees should be submitted by the applicant. The risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level. To address the current data gap for bees were conducted by Applicant according to the OECD Guidelines. The chronic and larval studies with formulated product MEPCY are provided by Applicant for products MEPCY. The chronic studies for bees were accepted by zRMS. The risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level.

The study on the effects of MEPCY (SHA 126085 A) on arthropods other than bees (*A. rhopalosiphi* and *T. pyri*) with risk assessment should be provided by Applicant. To address the current data gap for arthropods other than bees were conducted by Applicant according to the OECD Guidelines. The new studies for *T. pyri* and *A. rhopalosiphi* with formulated product MEPCY have been accepted by zRMS. Toxicity data and risk assessments were available for the PPP MEPCY and a low risk was demonstrated for arthropods other than bees. The in-field and off-field HQ value calculated for Chlormequat chloride and Mepiquat chloride and MEPCY formulation for the representative species *Typhlodromus pyri* and

*Aphidius rhopalosiphi* are lower than the trigger of 2 for Tier I tests, indicating no risk to non-target arthropods in vegetated off-field areas following application according to the proposed use patterns.

The study on the effects of MEPCY (SHA 126085 A) on earthworms with risk assessment should be provided by Applicant. The study on the effects of MEPCY (SHA 126085 A) on *Folsomia candida* and *Hypoaspis aculeifer* with risk assessment should be provided by Applicant. To address the current data gap for earthworms were conducted by Applicant according to the OECD Guidelines. The new study for MEPCY and earthworms have been accepted by zRMS. Toxicity data and risk assessments was available for the PPP MEPCY and a low risk was demonstrated for earth-worms. Refinement risk assessment is not needed. To address the current data gap for soil macro-organisms (*Folsomia candida* and *Hypoaspis aculeifer*) were conducted by Applicant according to the OECD Guidelines. The new studies for MEPCY and *Folsomia candida* and *Hypoaspis aculeifer* have been accepted by zRMS. Toxicity data and risk assessments were available for the PPP MEPCY and a low risk was demonstrated for soil macro-organisms such as *Folsomia candida* and *Hypoaspis aculeifer*. Refinement risk assessment is not needed.

The study on the effects of MEPCY (SHA 126085 A) on non-target terrestrial plants for the vegetative vigour test (OECD 227) and the study on the effects of MEPCY (SHA 126085 A) on non-target terrestrial plants in terms of seedling emergence and seedling growth test (OECD 208) with risk assessment should be provided by Applicant. To address the current data gap for non-target terrestrial plants (NTTPs) a seedling emergence and vegetative vigour study for MEPCY were conducted by Applicant according to the OECD Guidelines. The new studies for MEPCY have been accepted by zRMS. Toxicity data and risk assessments were available for the PPP MEPCY and a low risk was demonstrated.

The evaluators also verified whether the co-formulants contained in plant protection product Mepcy are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product Mepcy does not contain any unacceptable co-formulant/ingredient listed in the **Commission Regulation (EU) 2021/383** amending **Annex III** to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product Mepcy meets the Annex to **Regulation (EU) 2023/574** criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU)2023/574 can be found in RR Part C and annex to Part C of this submission (section 1.2.2).

## 2.3 Substances of concern for national monitoring

Not relevant.

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute Tox. 4 (oral)
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	<b>GHS07</b>
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H302</b>
Precautionary statement(s):	<b>P264, P270, P280, P301+P312, P330, P501</b>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

**See Part C for justifications of the classification and labelling proposals.**

#### **2.4.2 Standard phrases under Regulation (EU) No 547/2011**

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
-	-

#### **2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)**

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### **2.5 Risk management**

#### **2.5.1 Restrictions linked to the PPP**

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
P280	Wear protective gloves, protective clothing.
Worker protection:	
-	None.
-	Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
-	-



Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

## 2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): MEPCY / SHA 126085 A  
Active substance 1: Chlormequat chloride  
Active substance 2: Mepiquat chloride  
Safener: -  
Synergist: -  
Applicant: Sharda Cropchem Ltd.  
Zone(s): Central  
Verified by MS: yes/no

Formulation type: SL (Soluble concentrate)  
Conc. of as 1: 345 g/L  
Conc. of as 2: 115 g/L  
Conc. of safener: -  
Conc. of synergist: -  
Professional use: ☒  
Non professional use: ☐

Field of use: Plant growth regulator

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	Winter wheat	F	Reduction of height to prevent lodging	Foliar Spray	BBCH 29-32	a) 1 b) 1	NA	a) 2.0 b) 2.0	a) 0.69 chlomequat chloride + 0.23 mepiquat chlo- ride b) 0.69 chlomequat chloride + 0.23 mepiquat chlo- ride	200- 400	NA	

<b>Remarks table heading:</b>	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	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	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

### 3 Background of authorization decision and risk management

#### 3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of green beige slightly oily and opaque liquid with a characteristic odour. It has no explosive and oxidising properties. In an aqueous solution, it has a pH value around 5.37 at 21 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for a *soluble concentrate* formulation. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE/PA* commercial packaging material.

The intended concentration of use is 0.5% to 1%.

#### 3.2 Efficacy (Part B, Section 3)

MEPCY (Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL) is an Soluble Concentration (SL) formulation containing 345 grams per liter (g/L) chlormequat chloride and 115 grams per liter (g/L) mepiquat chloride for use in winter wheat.

In compliance with the GAP, the following dose rate is applied for registration:

- One application per season (BBCH 29-32) to reduce of height to prevent lodging in winter wheat, target rate: 2.0 L/ha

This document serves the registration of Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL in the Central zone of the EU. The objective of this document is to prove and support the label claims of the fungicidal and plant growth regulator efficacy and crop safety of Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL in the GAP claimed crops.

Comprehensive field trials were conducted in Poland, Czech Republic, France and Spain in 2017, 2018 and 2021. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the disease control and safety to the crop of Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL is equivalent to that of the standard reference product to which it was compared.

#### 3.3 Efficacy data

##### Preliminary tests

No results of the preliminary range-finding tests were submitted by the Applicant, however the active substances of MEPCY (product code: SHA 126085 A) – mepiquat chloride and chlormequat chloride are registered and have been commonly used in agricultural practice for many years (over 20). So, preliminary range finding tests are deemed too not be necessary in the opinion of ZRMs.

Applicant presented justification of the mixture in B3. No trials were presented. However, ZRMs agree with Applicant that using two active substances in a mixture may provide a more effective reduction than applied singly in sequence. In CEU, they are already registered PPP with both these active compounds: mepiquat and chlormequat. For example – Cyter registered in Spain and France. So, lack of studies should be accepted. Especially that Cyter has the same composition as the product under evaluation

(MEPCY). And its effectiveness and comparability were demonstrated during efficacy studies, as Cyter was used as a reference standard.

### Minimum effective dose tests

The trials submitted to support the MED (minimum effective dose) of MEPCY (product code: SHA 126085 A) are the same as the efficacy trials described under section efficacy. To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).

22 field trials carried out in different growing seasons (2017, 2018 and 2021) on winter wheat were established to determine the minimum effective dose of MEPCY. Trials were performed only in three EPPO zones – N-E in Poland (7 trials); MED in ES (4 trials) and FR (2 trials) and MAR in FR (7 trials) and CZ (2 trials). Three different doses were studied: 1,5 L/ha (0,75 N); 1,75 L/ha (0,88 N) and 2,0 L/ha (N dose). All results were compared to standard reference products. In the trials, specifically targeted for height reduction, single application was applied at growth stages ranging between BBCH 29 and BBCH 33.

The proposed doses were derived from registered doses of standard reference products with mepiquat chloride and chlormequat chloride as active compounds and, product safety parameters and environmental limitations. Such products are used across Europe for many years and their MED (minimum effective dose) is justified. The proposed dose against lodging and growth reduction is 2,0 L/ha applied once a season. Detailed results were presented by Applicant in the tables: Table 3.3-9; Table 3.3-10 and Table 3.3-1.

### Minimum effective dose results:

- **N-E EPPO zone:** During 7 trials effect of reduction of height was observed. The most effective was dose 2,0 L/ha (average efficacy of reduction height: 11,5%). Effect of dose 1,5 l/ha (average: 5,34%) and 1,75 L/ha (average: 8,72%) was lower than recommended dose. The most effective against reduction of height was dose 2,0 L/ha and this dose should be recommended for use.

Lodging was observed in 5 trials on control plants (average: 38,3%). Dose 2,0 L/ha reduce of lodging with 93,34% efficacy. Dose 1,5 L/ha reduce of lodging with 26,46% efficacy and dose 1,75 L/ha with 67,32% efficacy. The most effective against lodging in winter wheat plants was dose 2,0 L/ha and this dose should be recommended for use.

Trial no.	Country	Assess. Type	Untreated		Chlormequat + Mepiquat SL 1.5 L/ha (518 + 173g ai/ha)		Chlormequat + Mepiquat SL 1.75 L/ha (603 + 201g ai/ha)		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)	
			Mean		Mean	% Cont.	Mean	% Cont.	Mean	% Cont.
NUZ 18+19/17-1	PL	LODGING	26.0	a	22.0	ab 15.4	11.0	b 57.7	0.0	b 100
NUZ 18+19/17-3	PL	LODGING	50.0	a	35.0	b 30.0	23.0	b 54.0	0.0	c 100
NUZ 18+19/17-2	PL	LODGING	34.0	a	14.0	c 58.8	0.0	d 100	0.0	d 100
NUZ 03/21/1	PL	LODGING	45.0	a	45.0	a 0.0	33.8	b 24.9	15.0	c 66.7
SRG21-SHA52	PL	LODGING	36.3	a	16.3	a 55.1	0.0	c 100	0.0	c 100

NUZ 18+19/17-1	PL	Height	93.6	a	90.5	ab 3.31	89.1	b 4.81	85.0	c 9.20
NUZ 18+19/17-3	PL	Height	85.0	a	81.0	a 4.70	81.0	a 4.70	75.0	bc 11.8
NUZ 18+19/17-2	PL	Height	87.0	a	83.0	b 4.59	82.0	b 5.75	77.0	c 11.5
NUZ 03/21/1	PL	Height	120.2	a	119	ab 1.0	117.8	b 2.0	110.8	c 7.8
SRG21-SHA52	PL	Height	90.2	a	88.4	ab 2.0	87.0	b 3.5	80.8	c 10.4
SRG21-SHA53	PL	Height	98.8	a	85.0	b 14.0	73.8	d 25.3	82.4	c 16.6
SRG21-SHA54	PL	Height	99.9	a	92.1	b 7.8	88.4	b 11.5	86.9	b 13.0

- **Maritime EPPO zone:** During 8 trials effect of reduction of height was observed. The most effective was dose 2,0 L/ha (average efficacy of reduction height: 6,3%). Effect of dose 1,5 l/ha (average: 5,31%) and 1,75 L/ha (average: 5,43%) was lower than recommended dose. Differences between

doses were slightly, however the most effective was 2,0 L/ha. So, this dose is recommended for use against reduction of height in winter wheat plants.

Lodging was observed in 5 trials on control plants (average: 41,16%). Dose 2,0 L/ha reduce of lodging with 73,76% efficacy. Dose 1,5 L/ha reduce of lodging with 48,98% efficacy and dose 1,75 L/ha with 50,76% efficacy. The most effective against lodging in winter wheat plants was dose 2,0 L/ha and this dose should be recommended for use.

Trial no.	Country	Assess. Type	Untreated		Chlormequat + Mepiquat SL 1.5 L/ha (518 + 173g ai/ha)		Chlormequat + Mepiquat SL 1.75 L/ha (603 + 201g ai/ha)		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)	
			Mean		Mean	% Cont.	Mean	% Cont.	Mean	% Cont.
PC 17-05-31-NE2	FR	LODANG	67.5	a	61.3	a	9.18	70.0	a	0.0
PC 17-05-31-NE4	FR	LODANG	37.5	a	40.0	a	0.0	37.5	a	0.0
S17-00712-02	FR	LODGIN	37.5	a	10.0	a	73.3	12.5	a	66.7
S17-00712-03	FR	LODGIN	33.3	a	12.5	a	62.4	4.3	a	87.1
SWEPL-....-TRZAW-RYM20	CZ	LODGIN	30.0	a	0.0	a	100	0.0	a	100

PC 17-05-31-NE1	FR	Height	74.8	a	71.6	a	4.27	72.4	a	3.20
PC 17-05-31-NE2	FR	Height	92.3	a	88.9	b	3.68	90.2	ab	2.27
PC 17-05-31-NE3	FR	Height	98.7	a	92.8	b	5.97	95.4	b	3.34
PC 17-05-31-NE4	FR	Height	82.5	a	77.5	b	6.07	77.2	b	6.42
S17-00712-01	FR	Height	92.9	a	90.0	b	3.23	90.0	b	3.23
S17-00712-03	FR	Height	91.2	a	87.1	b	4.49	84.9	b	6.90
SWEPL-....-TRZAW-RYM20	CZ	Height	61.1	a	57.0	b	6.71	56.7	b	7.20
SWEPL-....-TRZAW-DOM20	CZ	Height	104	a	95.6	b	8.07	92.7	bc	10.9

- **Mediterranean EPPO zone:** During 3 trials effect of reduction of height was observed. The most effective was dose 2,0 L/ha (average efficacy of reduction height: 11,07%). Effect of dose 1,5 l/ha (average: 6,6%) and 1,75 L/ha (average: 8,87%) was lower than recommended dose.

Lodging was observed in 3 trials on control plants (average:12,52%). Dose 2,0 L/ha reduce of lodging with 43,57% efficacy. Dose 1,5 L/ha reduce of lodging with 38,4% efficacy and dose 1,75 L/ha with 51,9% efficacy. The most effective against lodging in winter wheat plants was dose 2,0 L/ha and this dose should be recommended for use.

Trial no.	Country	Assess. Type	Untreated		Chlormequat + Mepiquat SL 1.5 L/ha (518 + 173g ai/ha)		Chlormequat + Mepiquat SL 1.75 L/ha (603 + 201g ai/ha)		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)	
			Mean		Mean	% Cont.	Mean	% Cont.	Mean	% Cont.
17-SHA-476	ES	LODINT	13.8	a	7.50	b	45.5	6.25	b	54.5
17-SHA-477	ES	LODINT	8.75	a	6.25	ab	28.0	5.0	ab	42.9
17-SHA-478	ES	LODINT	15.0	a	8.75	a	41.7	6.25	a	58.3

PC 18-05-45-1	FR	Height	79.5	a	73.8	bc	7.2	73.8	bc	7.2
PC 18-05-45-2	FR	Height	82.4	a	79.4	ab	3.6	76.3	b	7.4
SHA17OP2PGR248-02	ES	Height	57.5	a	52.3	ab	9.0	50.6	ab	12.0

**Summary:** In the opinion of ZRMs, presented results and knowledge about registered doses of standard reference products with mepiquat chloride and chlormequat chloride allow to consider dose 2,0 L/ha as the most effective for winter wheat against reduction of height and lodging.

#### Efficacy tests and conclusions regarding authorization of intended uses

Lodging in cereals was evaluated in accordance with the EPPO standards PP 1/144(3). Details of experiment are presented in the table above by Applicant. All used methodology is in accordance with GEP

rules and EPPO standards, in the exception with EPPO 1/181 (4) for winter wheat in Maritime EPPO zone (all trials were carried out only in one growing season – 2017). In N-E (2017 and 2021) and MED (2017 and 2018) – two different growing seasons were studied in line to EPPO.

We are dealing with the active substances used commonly for many years in many countries. On the basis on EPPO standard Applicant should submitted for reduction height and against lodging at least six trials for each EPPO zone. For Poland trials from neighbouring countries are acceptable. Submitted documentations is sufficient in the opinion of Evaluator for winter wheat for all zones.

- **N-E EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial no.	Country	Assess. Type	Crop GS at Asses. BBCH	Untreated		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)		Medax Top 350 SL 1.25 L/ha (265 + 44g ai/ha)	
				Mean		Mean	% Cont.	Mean	% Cont.
NUZ 18+19/17-1	PL	LODGING	85	26.0	a	0.0	b 100	0.0	b 100
NUZ 18+19/17-3	PL	LODGING	85	50.0	a	0.0	c 100	0.0	c 100
NUZ 18+19/17-2	PL	LODGING	85	34.0	a	0.0	d 100	0.0	d 100
NUZ 03/21/1	PL	LODGING	85	45.0	a	15.0	c 66.7	7.5	c 83.3
SRG21-SHA52	PL	LODGING	89	36.3	a	0.0	c 100	0.0	c 100

NUZ 18+19/17-1	PL	Height	85	93.6	a	85.0	c 9.20	84.3	c 9.93
NUZ 18+19/17-3	PL	Height	85	85.0	a	75.0	bc 11.8	70.0	c 17.6
NUZ 18+19/17-2	PL	Height	85	87.0	a	77.0	c 11.5	76.0	c 12.6
NUZ 03/21/1	PL	Height	69	120.2	a	110.8	c 7.8	110.3	c 8.2
SRG21-SHA52	PL	Height	75	90.2	a	80.8	c 10.4	68.2	e 24.4
SRG21-SHA53	PL	Height	77	98.8	a	82.4	c 16.6	86.1	b 12.9
SRG21-SHA54	PL	Height	77	99.9	a	86.9	b 13.0	90.2	b 9.7

Reduction of height was observed in 7 trials carried out on winter wheat. Observed average efficacy was 11,47% and it was lower than standard ref. product eff. 13,61%.

Lodging was observed in 5 trials at untreated control plants. MEPCY reduced lodging with 93,4% efficacy. Standard reference product was characterized by slightly better eff. (95,66%).

- **Maritime EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial no.	Country	Assess. Type	Crop GS at Asses. BBCH	Untreated		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)		CYTER 2.0 L/ha (690 + 230g ai/ha)		Spatial Plus 2.4 L/ha [etheponh + chlormequat] (360 + 720g ai/ha)	
				Mean		Mean	% Cont.	Mean	% Cont.	Mean	% Cont.
PC 17-05-31-NE2	FR	LODAN G	87	67.5	a	22.5	a 66.7	47.5	a 29.6	-	-
PC 17-05-31-NE4	FR	LODAN G	85	37.5	a	20.0	a 46.7	40.0	a 0.0	-	-
S17-00712-02	FR	LODGIN	83	37.5	a	7.5	a 80.0	17.0	a 54.6	-	-
S17-00712-03	FR	LODGIN	89	33.3	a	8.2	a 75.4	0.0	a 100	-	-
SWEPL-....-TRZAW-RYM20	CZ	LODGIN	85	30.0	a	0.0	a 100	-	-	0.0	a 100

PC 17-05-31-NE1	FR	Height	85	74.8	a	73.3	a 2.00	71.7	a 4.14	-	-
PC 17-05-31-NE2	FR	Height	85	92.3	a	87.8	b 4.88	88.4	b 4.23	-	-
PC 17-05-31-NE3	FR	Height	83	98.7	a	93.6	b 5.17	93.8	b 4.96	-	-
PC 17-05-31-NE4	FR	Height	85	82.5	a	77.1	b 6.54	77.7	b 5.81	-	-
S17-00712-01	FR	Height	77	92.9	a	90.5	b 7.3	90.0	b 3.12	-	-

S17-00712-03	FR	Height	77	91.2	a	85.9	b	5.81	86.2	b	5.48	-	-	
SWEPL-...-TRZAW- RYM20	CZ	Height	75	61.1	a	56.6	a	7.36	-	-	-	56.3	b	7.85
SWEPL-...-TRZAW- DOM20	CZ	Height	75	104	a	92.0	c	11.6	-	-	-	89.8	c	13.6

Reduction of height was observed in 9 trials carried out on winter wheat. Observed average efficacy was 7,23% and it was slightly higher than standard ref. product eff. 7,03%.

Lodging was observed in 5 trials at untreated control plants (average: 41,16%). MEPCY reduced lodging with 73,76% efficacy. Standard reference product was characterized by lower eff. (56,84%).

- **Mediterranean EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial no.	Country	Assess. Type	Crop GS at Asses. BBC H	Untreated		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)			CYTER 2.0 L/ha (690 + 230g ai/ha)			Hidrofertel [Chlormequat 40% SL] 3.5 L/ha (1400g ai/ha)			Moddus [Trinexapac-etyl 25% ME] 0.5 L/ha (125g ai/ha)		
				Mean		Mean		% Con t.	Mean		% Con t.	Mean		% Con t.	Mean		% Con t.
17-SHA-476	ES	LOD-INT	92	13.8	a	6.25	b	54.5	5.00	b	63.6	3.75	b	72.7	-	-	-
17-SHA-477	ES	LOD-INT	85	8.75	a	5.0	b	42.9	5.0	b	42.9	1.25	b	85.7	-	-	-
17-SHA-478	ES	LOD-INT	85	15.0	a	10.0	a	33.3	1.25	a	91.7	0.0	b	100	-	-	-

PC 18-05-45-1	FR	Height	83	79.5	a	71.3	c	10.4	73.0	b	8.2	-	-	-	-	-	-
PC 18-05-45-2	FR	Height	77	82.4	a	76.2	b	7.5	77.6	b	5.8	-	-	-	-	-	-
SHA17OP2PGR2 48-02	ES	Height	39	57.5	a	48.7	b	15.3	-	-	-	-	-	-	42.8	b	25.5

Reduction of height was observed in 3 trials carried out on winter wheat. Observed average efficacy was 11,07% and it was lower than standard ref. product eff. 13,17%.

Lodging was observed in 3 trials at untreated control plants. MEPCY reduced lodging with 43,57% efficacy. Standard reference product was characterized by better eff. (66,7% and 86,13%).

Regarding comment about number of results for each use (lodging and reduction of growth) it would be like to indicate that according to the EPPO standard PP 1/226: the full number of trials is needed particularly for plant protection products or active substances which have not been on the market in the region in which authorization is sought, or for intended uses for which no extrapolation of any aspect of efficacy from other uses is possible. Mepiquat chloride and chlormequat chloride is well known, as it has been marketed for many years for use in a broad number of crops to act as a regulation of growth. In addition, comparability of performance of the tested product with the reference is proved. So, cMS should decide if MEPCY (product code: SHA 126085 A) can be accepted by them only on the basis on extrapolation results from N-E EPPO, MED EPPO zone and/or Maritime EPPO zone.

According to EPPO PP 1/144 Reduction of lodging in cereals, an assessment of lodging and height was done during efficacy trials. The crop height reduction led to a reduction of lodging in trials where lodging was observed. The target dose reached the highest efficacy. MEPCY (product code: SHA 126085 A) provided an acceptable level of reduction in crop height as well as control of lodging in the GAP claimed crop with the recommended dose rate of 2,0 L/ha in winter wheat.

In summary, ZRMs consents to the registration of the product in Poland as stated in the GAP table. Applicant submitted enough number of trials against reduction of height (9 trials: PL-7, CZ-2) and lodging (6 trials: PL-5, CZ-1). It was demonstrated that the product reduces the height of plants (on average by several cm as compared with the control) and thus can counteract their overgrowth. The prod-



uct showed positive effect, however slightly lower than the reference standard. **It is left to the Member States to decide on the acceptability of the results presented in this dRR and to consider registration of MEPCY.**

### **3.3.1 Information on the occurrence or possible occurrence of the development of resistance**

Since Chlormequat 34.5% + Mepiquat 11.5% SL are a plant growth regulator, the crop is the target of the application and not any pests as such. It is therefore not applicable to describe the possible development of resistance or cross-resistance of the crop towards chlormequat and mepiquat.

### **3.3.2 Adverse effects on treated crops**

#### **Phytotoxicity to host crop**

The phytotoxicity trials about tested plant protection product (plant growth regulator) have been carried out in accordance with EPPO Guidelines (1/181 (4)). The conduct of the field work is principally compliant with “Good Agricultural Practice” and in accordance with EPPO Guidelines PP 1/135.

The trials were performed with the use of different agricultural practice in North-East EPPO zone, Mediterranean EPPO zone and Maritime EPPO zone. All presented trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. In all trials studied product was compared to the standard reference products. Statistical analysis of the data was performed. Also, quality of yield was evaluated in submitted trials.

Both EU Directive 91/414 (EU, 1991) and EPPO PP 1/226 (3) – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 (3) – Phytotoxicity assessment states: ‘EPPO Standards on fungicides, insecticides and plant growth regulators or seed treatments, on the other hand, include only a relatively simple special section on phytotoxicity assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent’. Selectivity trials and studied dose 2N were not required, which is in accordance with EPPO 1/135 (3).

Applicant submitted in total 22 efficacy trials in which phytotoxicity assessment was carried out on winter wheat. Trials were performed during different growing season (2017, 2018 and 2021). Only one growing season was studied during Maritime trials (2017) During MED (2017 and 2018) and N-E EPPO zone (2017 and 2021) trials two growing seasons were studied. cMS from MAR should decide if trials performed only in one season can be acceptable.

The evaluation of phytotoxicity effects was done according to EPPO Standard 1/135 (4) of plant growth regulators applied on crops of winter wheat was performed visually by comparing the condition of the plants in the plots treated with PPP – MEPCY in comparison to untreated plots (no PPP). The intensity of damage to the plant was expressed as a percentage (0%-no symptoms of phytotoxic effects of PPP, 100% - total destruction). **No negative effects were observed during all trials.**

**Assessment for Poland:** Research should be conducted in the Poland or/and in other countries from the North-East EPPO zone or neighbouring countries not belonging to the zone. According to the Polish guidelines for well-known active substance should be submitted at least 4-5 phytotoxicity studies performed in two growing seasons on 3-4 varieties. Also, Applicant can use CIRCA for the assessment, but into account must be taken issues related to data protection. Alternatively, Applicant can use the data from the records of other / neighbouring countries – but the justification for using this part by Applicant must be submitted.

In the opinion of Evaluator, the Applicant submitted enough phytotoxicity trials for winter wheat: PL-7; CZ-2. **On the basis on presented results it can be concluded that tested product is safe for winter wheat.** No negative effects are expected at recommended dose (2,0 L/ha). In the opinion of Evaluator, since no adverse symptom was observed at the recommended dose, it was not mandatory to submit doses of 2 N.

**Assessment for cMS:** Applicant submitted for MAR – 9 trials (FR-7, CZ-2) and for MED – 6 trials (ES-4, FR-2). In the opinion of ZRMs the number of trials should be accepted. **No negative effects were observed during trials at dose 2,0 L/ha** (recommended). In the opinion of Evaluator, since no adverse symptom was observed at the recommended dose, it was not mandatory to submit doses of 2 N.

#### **Effects on yield and quality**

Twenty two efficacy trials treated with Chlormequat 34.5% + Mepiquat 11.5% SL were harvested and yields recorded. Besides recording yield, assessments were also carried out on the potential impact of treatment on a range of quality parameters including moisture content, hectolitre weight or thousand grain weight. The efficacy trials were conducted as defined by EPPO Standard PP1/241(1).

Chlormequat 34.5% + Mepiquat 11.5% SL applied at the proposed dose rate, at a range of growth stages within the label recommended rate, in winter wheat did not significantly affect the quality of the harvested crop in any of the 22 trials harvested. In all efficacy trials as, Chlormequat 34.5% + Mepiquat 11.5% SL applied at recommended dose rates did not significantly affect the quality of the harvested crop either.

Furthermore, the data obtained in trials harvested demonstrate that Chlormequat 34.5% + Mepiquat 11.5% SL is as safe to the crop as the reference products used in the trials.

As this document clearly demonstrates, the efficacy and crop safety of Chlormequat 34.5% + Mepiquat 11.5% SL is equivalent to the standard reference products to which it was compared.

#### **Effect on transformation processes**

Processing can include physical processing such as milling of seeds. It has already been shown in effects on the quality of plants section that the application of Chlormequat 34.5% + Mepiquat 11.5% SL at the proposed label rate and rates above this rate has no negative effect on the quality parameters assessed in efficacy trials harvested.

Other processes depend on biological activity and are referred to as ‘transformation’. These include e.g. brewing and baking and are potentially sensitive to plant protection products. Plant growth regulators are usually only considered with regards to their potential effect on transformation processes if applied close to harvest (EPPO standard PP 1/243(1) *Effects of plant protection products on transformation processes*). It is also the case that if residues cannot be detected at harvest (dRR Part B Section 7) then it is reasonable to assume that the likelihood of an effect on transformation processes is greatly reduced.

Finally, it should be noted that currently, chlormequat and mepiquat containing products do not have any label restrictions concerning their use on crops destined for processing. In addition, both actives are part of many products which have been used for a long time as plant growth regulator in e.g. cereals. Since the market introduction, no effects on transformation processes have been recorded for any of these products.

#### **Impact on treated plants or plant products to be used for propagations**

Chlormequat 34.5% + Mepiquat 11.5% SL is composed of chlormequat + mepiquat, which both have been widely used for several years on e.g. cereals, without identifying any issues in regard to ability of grains of treated plants to germinate.

Thus, negative effects of the active ingredient on parts of plant used for propagating purposes can be excluded due to the fungicidal nature of the product. Furthermore, phytotoxicity assessments in the performed trials demonstrated the crop safety of the product and the absence of any negative effect on the plants or plant products in the vast majority of the trials.

### **3.3.3 Observations on other undesirable or unintended side-effects**

#### **Impact on succeeding crops.**

Since Chlormequat 34.5% + Mepiquat 11.5% SL is a plant growth regulator, the crop is the target of the application and not any pests as such. It is therefore not applicable to describe the possible impact of succeeding crops of the crop towards chlormequat and mepiquat.

### Impact on other plants including adjacent crops

During the conduct of efficacy trials, no observations about negative or positive effects on other plants or neighboring crops were reported. Furthermore, in efficacy trials, it was demonstrated that the formulation of chlormequat and mepiquat is not phytotoxic to the crop claimed in the GAP.

Effects on non-target terrestrial plants of Chlormequat 34.5% + Mepiquat 11.5% SL were not evaluated as part of the EU assessment of chlormequat and mepiquat.

### Effects on beneficial and other non-target organisms

From the experimentation carried out with Chlormequat 34.5% + Mepiquat 11.5% SL in 2017 and 2018, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

## 3.4 Methods of analysis (Part B, Section 5)

Analytical method for Chlormequat and Mepiquat in food and feed of plant and animal origin, soil, water and air and in the formulation Chlormequat 34.5% + Mepiquat 11.5% SL are available.

### 3.4.1 Analytical method for the formulation

	Chlormequat chloride	Mepiquat chloride
<b>Author(s), year</b>	S. Aversa, 2018	
<b>Principle of method</b>	HPLC-MS/MS	
<b>Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)</b>	5 points 99.384, 74.538, 49.692, 24.846, 9.938 µg/L  <u>First mass transition</u> $R^2 = 0.9991$ $y = 225.708810x - 495.897924$ <u>Second mass transition</u> $R^2 = 0.9990$ $y = 56.076039x - 103.137826$	5 points 101.455, 76.091, 50.728, 25.364, 10.146 µg/L  <u>First mass transition</u> $R^2 = 0.9993$ $y = 179.362204x - 315.448262$ <u>Second mass transition</u> $R^2 = 0.9988$ $y = 147.440060x - 162.124351$
<b>Precision – Repeatability Mean n = 5 (%RSD)</b>	<u>First mass transition</u> %RSD = 0.60 %RSD <sub>R</sub> = 2.38 %RSD <sub>r</sub> = 1.59 Hr = 0.377 ≤ 1  <u>Second mass transition</u> %RSD = 1.23 %RSD <sub>R</sub> = 2.38 %RSD <sub>r</sub> = 1.59 Hr = 0.774 ≤ 1	<u>First mass transition</u> %RSD = 1.52 %RSD <sub>R</sub> = 2.78 %RSD <sub>r</sub> = 1.87 Hr = 0.813 ≤ 1  <u>Second mass transition</u> %RSD = 1.67 %RSD <sub>R</sub> = 2.77 %RSD <sub>r</sub> = 1.86 Hr = 0.898 ≤ 1
<b>Accuracy (standard addition method) n = 5 (% Recovery)</b>	<b>Low level 21% w/w</b> <u>First mass transition</u> 100.65% <u>Second mass transition</u> 99.83%  <b>High level 43% w/w</b>	<b>Low level 7% w/w</b> <u>First mass transition</u> 101.34% <u>Second mass transition</u> 102.56%  <b>High level 14.5% w/w</b>

	Chlormequat chloride	Mepiquat chloride
	<u>First mass transition</u> 101.72% <u>Second mass transition</u> 101.40%	<u>First mass transition</u> 100.06% <u>Second mass transition</u> 100.55%
<b>Interference/ Specificity</b>	No interference	No interference

The method was successfully validated and is suitable to determine the content of chlormequat chloride and mepiquat chloride in the test item Chlormequat 34.5% + Mepiquat 11.5% SL.

According to Commission Implementing Regulation (EU) No 540/2011 and SANCO/175/08 final rev 2 (29 May 2015), for the active substance chlormequat chloride the manufacturing impurities 1,2-dichloroethane and chloroethene (vinylchloride) are of toxicological concern and must not exceed respectively 0.1 g/kg and 0.0005 g/kg in the technical material (based on the dry chlormequat chloride content).

According to Commission Implementing Regulation (EU) No 540/2011 and SANCO/106/08 rev 2 (20 May 2008), for the active substance mepiquat chloride no impurities are of toxicological concern.

~~A study on the development and validation of an analytical method for the determination of relevant impurities 1,2-dichloroethane and chloroethene is ongoing and the results will be available in August 2023.~~

	1,2-Dichloroethane	Vinyl chloride
<b>Author(s), year</b>	K.S. Kishora, 2023	
<b>Principle of method</b>	GC-HS	GC-MS
<b>Linearity</b> (linear between mg/L) (correlation coefficient, expressed as r)	5 points Conc. Range = 1.007 to 16.106 µg/mL (0.0010 to 0.0161%) $Y = 2774 \times + 159$ $r = 0.99950$	5 points Conc. Range = 0.025 to 0.400 µg/mL (0.000025 to 0.00040 %) $Y = 12409 \times + 587$ $r = 0.99948$
<b>Precision – Repeatability Mean</b> <b>n = 5</b> (%RSD)	Mean conc. of impurity-I = 0.00241 % w/w %RSD = 2.075 %RSD <sub>R</sub> = 9.91 %RSD <sub>r</sub> = 6.64 Hr = 0.313 ≤ 1	Mean conc. of impurity-II = 0.0001008 % w/w %RSD = 1.190 %RSD <sub>R</sub> = 15.98 %RSD <sub>r</sub> = 10.705 Hr = 0.111 ≤ 1
<b>Accuracy</b> <b>n = 5 at each of 2 levels</b> (% Recovery)	<u>Conc. of Impurity-I Standard Stock Solution used for Fortification: 1.51 µg/mL:</u> Accuracy as recovery (%): 94.905 ± 4.500 (s.d.)  <u>Conc. of Impurity-I Standard Stock Solution used for Fortification: 8.06 µg/mL:</u> Accuracy as recovery (%): 90.299 ± 4.075 (s.d.)  <u>Overall mean recovery (%): 92.602 ± 4.720</u>	<u>Conc. of Impurity-I Standard Stock Solution used for Fortification: 0.075 µg/mL:</u> Accuracy as recovery (%): 100.079 ± 3.920 (s.d.)  <u>Conc. of Impurity-I Standard Stock Solution used for Fortification: 0.220 µg/mL:</u> Accuracy as recovery (%): 97.220 ± 8.937 (s.d.)  <u>Overall mean recovery (%): 98.650 ± 6.678</u>
<b>Interference/ Specificity</b>	No interference, the method is specific The chromatograms of blank,	No interference, the method is specific The chromatograms of blank,

	1,2-Dichloroethane	Vinyl chloride
	standard, and test item were included.	standard, and test item were included.
LOQ	0.00143 % w/w	0.00006401 0.00006348 % w/w
Comment	-	-

The method was successfully validated according to SANCO/3030/99 rev. 5 guidelines and is suitable to determine content of relevant impurities – 1,2-dichloroethane and Vinyl chloride in the test item Chlormequat 34.5% + Mepiquat 11.5% SL.

### 3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

Chlormequat chloride

- Data gap (minor): ILV method for water. This data gap can be supplemented after registration.

Mepiquat chloride

- Data gap (minor): ILV method for water. This data gap can be supplemented after registration.

Missing data should be completed when the plant protection product is reassessed.

Commodity/crop	Supported/ Not supported
High starch content (winter wheat)	Supported

## 3.5 Mammalian toxicology (Part B, Section 6)

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.

### 3.5.1 Acute toxicity

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).

**Classification:** Acute Tox., 4 (oral), H302

### 3.5.2 Operator exposure

Operator exposure to MEPCY was not evaluated as part of the EU review of Chlormequat chloride and Mepiquat chloride for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimations of potential operator exposure have been undertaken for Chlormequat chloride and Mepiquat chloride using the AOEM.

## **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 clothing and gloves during mixing and loading.

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

### **3.5.3 Worker exposure**

Worker exposure to MEPCY was not evaluated as part of the EU review of Chlormequat chloride and Mepiquat chloride.

Estimations of potential worker exposure have been undertaken for Chlormequat chloride and Mepiquat chloride using the AOEM.

## **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

### **3.5.4 Bystander and resident exposure**

Bystander and resident exposures to MEPCY was not evaluated as part of the EU review of Chlormequat chloride and Mepiquat chloride.

Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the AOEM model.

## **Conclusion**

According to the EFSA AOEM Model, 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.

## **3.6 Residues and consumer exposure (Part B, Section 7)**

### **3.6.1 Residues**

The evaluator's comments and corrections are marked with a grey background colour.

#### **Chlormequat chloride**

#### **Stability of Residues**

The storage stability of chlormequat chloride in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2009). Residues of chlormequat chloride in wheat grain and straw are stable at least 24 months. In processed fractions (bran, whole grain bread, malt and beer) chlormequat chloride is stable up to a period of 13 months.

Residues of chlormequat chloride in animals products (cow meat, mild and hen eggs) are stable for at least 12 months.

#### **Metabolism in plants and animals**

The metabolism of chlormequat in primary crops belonging to the group of cereals/grass has been investigated in the framework of the EU pesticides peer review under Directive 91/414/EEC (EFSA, 2009).

Plant residue definition for monitoring Sum of chlormequat and its salts, expressed as chlormequat chloride (Reg. (EU) 2022/1290)

Plant residue definition for risk assessment Sum of chlormequat and its salts, expressed as chlormequat chloride ((only for cereals, pears and cultivated fungi) (EFSA Journal 2016;14(3):4422)

The intended uses are covered by the established residue definitions.

No additional studies are required.

The residue definition for animal products for monitoring and risk assessment is set as sum of Chlormequat and its salts expressed as Chlormequat chloride.

### **Magnitude of residues in plants**

Proposed uses:

1 application, BBCH 29-32, 0.69 kg a.s./ha (chlormequat chloride)

Applicant refers to new trials and to EU unprotected data.

Trials GAP: 1.512 kg a.s./ha, BBCH 29-31 (new studies)

1.5 kg as/ha, BBCH 34-37 (trials evaluated in the DAR)

These trials are done at higher doses than the proposed one. Despite this, the studies are accepted as “worst case situation”.

Sufficient trials on wheat are available to support the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for wheat.

Use is accepted.

### **Magnitude of residues in livestock**

The dietary burden was updated by zRMS based on trials data and European data, which was reported by EFSA in Reasoned Opinion (EFSA, 2020).

No exceedance of the current EU-MRL is expected.

### **Magnitude of residues in processed commodities**

Available EU data are sufficient to cover the proposed use.

### **Magnitude of residues in representative succeeding crops**

EFSA Journal 2020;18(1):5982:

*The available rotational crop metabolism studies demonstrated that no significant residues (residues below 0.01 mg/kg) are expected in succeeding crops (lettuces, radishes and wheat) planted in soil treated at 2 kg a.s./ha.*

Field rotational crop studies are not required.

Restrictions for succeeding crops are not required.

EFSA Journal 2020;18(1):5982:

*Considering that high residue levels are expected in cereals straw, residues in mushrooms may occur via the uptake of chlormequat from growth substrate composed of cereal straws that have been previously treated with chlormequat (EFSA, 2019b). A restriction should be considered to avoid the use of cereals straw treated with chlormequat as horticultural growth medium or as mulch.*

Proposed label restriction: do not use straw from wheat treated with chlormequat as horticultural growth medium in cultivation of fungi.

### **Other / special studies**

Wheat have not melliferous capacity. Studies are not required.

### **Estimation of exposure through diet and other means**

Calculation based on trials data (input: STMR from field trials – wheat) and MRLs for animal commodities was made by zRMS.

The proposed uses of Chlormequat chloride in the formulation Chlormequat 34.5% + Mepiquat 11.5% SL do not represent unacceptable acute and chronic risks for the consumer.

### **Mepiquat chloride**

### **Stability of Residues**

Residues of Mepiquat-chloride are stable for at least 24 months in wheat forage, wheat grain and wheat straw and for at least 12 months in bran, flour, wholemeal bread, pot barley, brewing malt and beer.

Residues of Mepiquat-chloride are stable for at least 26 months in cow liver, cow kidney, cow muscle, cow fat, chicken muscle, milk and eggs.

Additional studies are not required.

### **Metabolism in plants and animals**

The metabolism in plants and livestock for the active substance was reviewed during the Annex I inclusion process.

Plant and animal residue definition for monitoring      Mepiquat (sum of Mepiquat and its salts, expressed as Mepiquat chloride) (Reg. (EU) 2021/976)

Plant residue definition for risk assessment      Sum of Mepiquat and its salts, expressed as Mepiquat chloride (EFSA Scientific report (2008) 146, 1-73)

Animal residue definitions for risk assessment (EFSA Journal 2018;16(7):5380):

*For risk assessment, the residue definition was set as the sum of mepiquat, 4-hydroxy mepiquat and their salts, expressed as mepiquat chloride (EFSA, 2008). Based on the metabolism data, EFSA derived a conversion factor for monitoring to risk assessment of 1.7 in ruminant liver. In all other animal matrices and since the parent mepiquat was the only significant compound of the total residues, a conversion factor of 1 was deemed to be sufficient.*

Additional data are not required for the proposed uses.

### **Magnitude of residues in plants**

Proposed uses:



1 application, BBCH 29-32, 0.23 kg a.s./ha (Mepiquat chloride)

Applicant refers to EU unprotected data.

Trials GAP: 1 x 0.76 kg as/ha, BBCH 30-39

Sufficient trials on barley are available to support the proposed uses. According to the SAN-TE/2019/12752 extrapolation to wheat is possible.

The residues arising from the proposed uses will not exceed the MRLs established for wheat and barley.

Uses are accepted.

### **Magnitude of residues in livestock**

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

### **Magnitude of residues in processed commodities**

Studies investigating the magnitude of residues in processed commodities of cereals were reported in the EU review. Processing factors for enforcement and risk assessment were derived in processed products of barley, wheat and rape seed. The data provided are sufficient to support the proposed uses.

### **Magnitude of residues in representative succeeding crops**

Based on the confined rotational crop study evaluated during the peer review, significant residues are not expected in the succeeding crops. Rotational crop field trials are therefore not required.

### **Estimation of exposure through diet and other means**

The proposed uses of Mepiquat chloride in the formulation Chlormequat 34.5% + Mepiquat 11.5% SL do not represent unacceptable acute and chronic risks for the consumer. Calculation is accepted.

### **Other / special studies**

Wheat have not melliferous capacity. Studies are not required.

### **Combined exposure and risk assessment**

The Hazard Index is <1. Thus combined exposure to all active substances in Chlormequat 34.5% + Mepiquat 11.5% SL is not expected to present a consumer risk. No further refinement of the assessment is required.

## **3.6.2 Consumer exposure**

### **3.6.2.1 Chlormequat chloride**

IEDI (% ADI) according to EFSA PRIMo rev.3.1	80% NL toodler (highest contributor: milk cattle)
----------------------------------------------	---------------------------------------------------

<p>IENTI (% ARfD) according to EFSA PRIMo rev.3.1</p>	<p><b>Unprocessed commodities:</b>  <u>Results for children:</u>  Wheat: 5%</p> <p><u>Results for adults:</u>  Wheat: 3%</p> <p><b>Processed commodities:</b>  <u>Results for children:</u>  Wheat/ milling (flour): 4%  Wheat/ milling (wholemeal)-baking: 4%</p> <p><u>Results for adults:</u>  Wheat/ bread/ pizza: 1%  Wheat/ pasta: 1%  Wheat/ bread (wholemeal): 1%</p>
-------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

The proposed uses of Chlormequat chloride in the formulation Chlormequat 34.5% + Mepiquat 11.5% SL do not represent unacceptable acute and chronic risks for the consumer.

### 3.6.2.2 Mepiquat chloride

TMDI (% ADI) according to EFSA PRIMo	23% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IENTI (% ARfD) according to EFSA PRIMo	<p><b>Unprocessed commodities:</b>  <u>Based on children:</u>  Wheat: 14%</p> <p><u>Based on adults:</u>  Wheat: 8%</p> <p><b>Processed commodities:</b>  <u>Based on children:</u>  Wheat/milling (flour): 12%  Wheat/milling (wholemeal)-baking: 6%</p> <p><u>Based on adults:</u>  Wheat/bread/pizza: 4%  Wheat/pasta: 4%  Wheat/bread: 3%</p>
NTMDI (% ADI)	-
NEDI (% ADI)	-
NESTI (% ARfD)	-

The proposed uses of Mepiquat chloride in the formulation Chlormequat 34.5% + Mepiquat 11.5% SL do not represent unacceptable acute and chronic risks for the consumer.

## 3.7 Environmental fate and behaviour (Part B, Section 8)

Concentration of Chlormequat and Mepiquat in various environmental compartments are predicted according to the proposed use pattern. The predicted environmental concentrations (PEC values) in soil,

surface water, sediment and ground water are provided.

### **3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)**

PEC<sub>soil</sub> calculations have been conducted with Chlormequat using the EU agreed endpoints (EFSA Scientific Report (2008) 179, 1-77) and with Mepiquat using the EU agreed endpoints (EFSA Scientific Report (2008) 146, 1-73).

Maximum PEC<sub>soil</sub> value for Chlormequat was 0.736 mg/kg following the highest application rate of 690 g Chlormequat/ha.

Maximum PEC<sub>soil</sub> value for Mepiquat was 0.245 mg/kg following the highest application rate of 230 g Mepiquat/ha.

### **3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)**

PEC<sub>gw</sub> have been calculated for Chlormequat and Mepiquat.

The maximum PEC<sub>gw</sub> value for Chlormequat was 0.028 µg/L for the Kremsmünster FOCUS PEARL 5.5.5 scenario. PEC<sub>gw</sub> values were all below 0.001 µg/L for Mepiquat.

### **3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)**

The PEC<sub>sw/sed</sub> of Chlormequat and Mepiquat have been assessed with the model FOCUS Steps 1-2. Please refer to Part B, Section 8, Point 8.9 for more details about the results obtained.

### **3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)**

The vapour pressure at 20 °C of the active substance Chlormequat is < 10<sup>-5</sup> Pa. Hence the active substance Chlormequat is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Chlormequat due to volatilization with subsequent deposition should not be considered.

The vapour pressure at 20 °C of the active substance Mepiquat is < 10<sup>-5</sup> Pa. Hence the active substance Mepiquat is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Mepiquat due to volatilization with subsequent deposition should not be considered.

## **3.8 Ecotoxicology (Part B, Section 9)**

### **3.8.1 Effects on terrestrial vertebrates**

- **Birds:**

According to the screening and first tier risk assessment for cereals, all the TER<sub>a</sub> and TER<sub>t</sub> values for Chlormequat and Mepiquat are greater than the Annex VI trigger of 10 and 5, respectively, indicating that MEPCY (Chlormequat 34.5% + Mepiquat 11.5% SL) presents no unacceptable acute and long-term risk to birds according to the intended uses on cereals.

- **Mammals:**

According to the first-tier risk assessment for cereals, the TER<sub>a</sub> values for the active substance

Chlormequat are lower than the Annex VI trigger of 10 for small omnivorous mammal 'mouse'. A refinement of the risk was done and the  $TER_a$  were above the trigger showing no risk. The  $TER_{lt}$  values for Chlormequat are greater than the Annex VI trigger of 5. According to screening and first-tier assessment for cereals, all the  $TER_a$  and  $TER_{lt}$  values for Mepiquat are greater than the Annex VI trigger of 10 and 5, respectively, indicating that MEPCY presents no unacceptable acute and long-term risk to birds according to the intended uses on cereals.

#### Updated 2024

The higher tier refinement presented by the Applicant (geomean  $LD_{50}$ ) is the same step wise approach as presented by the notifier of Chlormequat in the Addendum – Confirmatory Data (March 2014, with post-commenting changes marked in red – May 2014). The geomean  $LD_{50}$  approach was discussed in the Addendum and finally considered acceptable, demonstrating an acceptable risk for small omnivorous mammals. Moreover, as a result of the confirmatory data evaluation, the List of Endpoints was amended and the higher tier refinement for mammals was included. Therefore, the higher tier refinement submitted by Applicant in the dRR has already been evaluated an accepted at EU level. However, the refinement risk assessment for small omnivorous mammal “mouse” should be considered at MS level.

### 3.8.2 Effects on aquatic species

#### MEPCY:

The study on the effects of MEPCY (SHA 126085 A) on aquatic plants - *Lemna gibba* was not provided by Applicant. In this case, the Applicant used the available data for PPP to indicate acceptable risk for aquatic organisms such as fish, aquatic invertebrates and algae. However, in opinion RMS this approach may be questioned. The study of effects on *Lemna gibba* shall be required for Mepcy (SHA 126085 A) belongs to plant growth regulators and contains more than 1 substance active.

#### Data gap:

**The study on the effects of MEPCY (SHA 126085 A) on *Lemna gibba* with risk assessment should be provided by Applicant.**

Applicant has provided the study in September 2023.

#### January 2024 updated

To address the current data gap for *Lemna gibba* conducted by Applicant according to the OECD Guidelines. The new study for *Lemna gibba* with formulated product MEPCY has been accepted by zRMS. Toxicity data and risk assessment for *Lemna gibba* was available for the PPP MEPCY and a low risk was demonstrated for this species. Refinement risk assessment is not needed.

#### Chlormequat:

For the intended uses on winter wheat, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for invertebrate prolonged as characterised by a NOEC for *Daphnia magna* of 2.4 mg/L in connection with an assessment factor of 10) in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment is necessary.

#### Mepiquat:

For the intended uses winter wheat, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for invertebrate acute as characterised by an  $EC_{50}$  for *Daphnia magna* of 68.5 mg/L in connection with an assessment factor of 100) in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment is necessary.

### 3.8.3 Effects on bees

First-tier assessments indicate that no unacceptable risk for bees exposed to MEPCY (Chlormequat 34.5% + Mepiquat 11.5% SL) is expected according to the proposed intended uses on cereals.

The risk assessment for bees was conducted in accordance with SANCO/10329/2002 rev. 2 final. The acute oral and contact toxicity data are available for the formulation SHA 126085A/MEPCY. Based on the first-tier assessment results, the risk is acceptable (HQ values exceeded 50) for the product. In addition, the chronic study for adult bees and a study effects on honey bee development and other honey bee life stages should be submitted by Applicant. The risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level. Final decision should be taken into account at MSs level.

#### **Updated January 2024**

To address the current data gap for **bees** were conducted by Applicant according to the OECD Guidelines. The chronic and larval studies with formulated product MEPCY are provided by Applicant for products MEPCY. The chronic studies for bees were accepted by zRMS. The risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level. Final decision should be taken into account at MSs level.

### **3.8.4 Effects on other arthropod species other than bees**

The study on the effects of MEPCY (SHA 126085 A) on arthropods was not provided by Applicant. In this case, the Applicant used the available data for substance active chlormequat chloride and formulation with mepiquat chloride to indicate acceptable risk for arthropods other than bees. However, in opinion RMS this approach should be not accepted. The data requirements specify that toxicity data for PPP should be provided in the case that a PPP contain more than one active substance. In opinion RMS, the study on the effects of MEPCY (SHA 126085 A) on arthropods other than bees should be provided by RMS. Acceptable risk assessment could not be conclude without the study for PPP and arthropods other than bees.

#### **Data gap:**

The study on the effects of MEPCY (SHA 126085 A) on arthropods other than bees (*A.rhopalosiphi* and *T.pyri*) should be provided by Applicant.

Applicant has provided the studies in September 2023.

#### **Updated January 2024**

To address the current data gap for **arthropods other than bees** were conducted by Applicant according to the OECD Guidelines. The new studies for *T. pyri* and *A. rhopalosiphi* with formulated product MEPCY have been accepted by zRMS. Toxicity data and risk assessments were available for the PPP MEPCY and a low risk was demonstrated for **arthropods other than bees**. The in-field and off-field HQ value calculated for Chlormequat chloride and Mepiquat chloride and **MEPCY** formulation for the representative species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are lower than the trigger of 2 for Tier I tests, indicating no risk to non-target arthropods in vegetated off-field areas following application according to the proposed use patterns. Refinement risk assessment is not needed.

### **3.8.5 Effects on soil organisms**

- **Earthworms and other non-target soil organisms:**

#### **Earthworms:**

The study on the effects of MEPCY (SHA 126085 A) on earthworms was not provided by Applicant. In this case, the Applicant used the available data for substance active chlormequat chloride to indicate acceptable risk for earthworms. However, in opinion RMS this approach should be not accepted. The data requirements specify that toxicity data for PPP should be provided in the case that a PPP contain more than one active substance. It was acknowledged that the active substance chlormequat chloride did not show a high toxicity to earthworms. The RMS noted that the risk assessment for chlormequat chloride indicated a very high margin of safety based on the currently available exposure assessment. However,

the toxicity of the plant protection product Mepcy (SHA 126085 A) cannot be predicted on the basis of the data for the active substance. For mepiquat chloride the toxicity data for long-term toxicity are not available. In opinion RMS, the study on the effects of MEPCY (SHA 126085 A) on earthworms should be provided by RMS. Acceptable risk assessment could not be conclude without the study for PPP and earthworms.

**Data gap:**

The study on the effects of MEPCY (SHA 126085 A) on earthworms should be provided by Applicant.

Applicant has provided the study in September 2023.

**Updated January 2024**

To address the current data gap for earthworms were conducted by Applicant according to the OECD Guidelines. The new study for MEPCY and *earthworms* have been accepted by zRMS. Toxicity data and risk assessments was available for the PPP MEPCY and a low risk was demonstrated for earthworms. Refinement risk assessment is not needed.

**Other soil macro-organisms**

In accordance with the data requirements of the (EU) Regulation 284/2013 data on *Folsomia candida* and *Hypoaspis aculeifer* should be submitted. No toxicity data are available for the PPP. However, the Applicant provided a justification indicating that the data requirements indicate that an assessment is not triggered since it is of low risk to NTAs. However, the RMS noted that the data requirements specify that toxicity data should be provided in the case that a PPP contain more than one active substance.

**Data gap:**

The study on the effects of MEPCY (SHA 126085 A) on *Folsomia candida* and *Hypoaspis aculeifer* should be provided by Applicant.

Applicant has provided the studies in September 2023.

**Updated January 2024**

To address the current data gap for soil macro-organisms (*Folsomia candida* and *Hypoaspis aculeifer*) were conducted by Applicant according to the OECD Guidelines. The new studies for MEPCY and *Folsomia candida* and *Hypoaspis aculeifer* have been accepted by zRMS. Toxicity data and risk assessments were available for the PPP MEPCY and a low risk was demonstrated for soil macro-organisms such as *Folsomia candida* and *Hypoaspis aculeifer*. Refinement risk assessment is not needed.

- **Soil microorganisms:**

Risk assessments conducted with relevant  $PEC_{soil}$  for Chlormequat and Mepiquat in MEPCY (Chlormequat 34.5% + Mepiquat 11.5% SL) formulation indicate a low risk to soil microorganisms when applied according to the proposed use rates.

### 3.8.6 Effects on non-target terrestrial plants

The study on the effects of MEPCY (SHA 126085 A) on non-target terrestrial plants for the vegetative vigour test (OECD 227 "Terrestrial Plant Test: Vegetative Vigour Test) and the study on the effects of MEPCY (SHA 126085 A) on non-target terrestrial plants in terms of seedling emergence and seedling growth test (OECD Guideline for the Testing of Chemicals No. 208 "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test") were not provided by Applicant. In this case, the Applicant used the available data for substance active to indicate acceptable risk for non-target plants. However, in opinion RMS this approach may be questioned. The data requirements specify that toxicity data for PPP should be provided in the case that a PPP contain more than one active substance. It was acknowledged that both active substance did not show a high toxicity to non-target plants. The RMS noted that the risk assessment for chlormequat chloride indicated a very high margin of safety based on the currently available exposure assessment. Furthermore, mepiquat chloride was indicated not to be of high toxicity to non-target plants. However, according to Regulation 284/2013 to studies of effects on non-target plants shall

be required for herbicide and plant growth regulator plant protection products. Mepcy (SHA 126085 A) belongs to plant growth regulators and contains more than 1 substance active and toxicity data for PPP should be provided in opinion RMS (OECD 227 and OECD 208).

Overall, the RMS considered that a low risk from the substance active such as mepiquat chloride and chlormequat chloride can be concluded. Furthermore, it should be noted that additional justification (data and/or risk assessment) for PPP may be needed for risk assessments at product registration.

**Data gap:** The study on the effects of MEPCY (SHA 126085 A) on non-target terrestrial plants for the vegetative vigour test (OECD 227) and the study on the effects of MEPCY (SHA 126085 A) on non-target terrestrial plants in terms of seedling emergence and seedling growth test (OECD 208) should be provided by Applicant.

Applicant has provided the studies in September 2023.

#### Updated January 2024

To address the current data gap for non-target terrestrial plants (NTTPs) a seedling emergence and vegetative vigour study for MEPCY were conducted by Applicant according to the OECD Guidelines. The new studies for MEPCY have been accepted by zRMS. Toxicity data and risk assessments were available for the PPP MEPCY and a low risk was demonstrated.

### 3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

### 3.9 Relevance of metabolites (Part B, Section 10)

Not relevant, there are no Chlormequat nor Mepiquat metabolites in soil.

## 4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant. MEPCY contains the active substances Chlormequat and Mepiquat which are not candidate for substitution.

## 5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

~~Developed and validated analytical method for the determination of relevant impurities 1,2-dichloroethane and chloroethene in the formulation.~~  
~~Determination of the content of relevant impurities in the formulation.~~

## **Appendix 1    Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.
----------------------------------------------------------------------------



## Appendix 2 Copy of the product label

### Section physical-chemical properties:

Brak uwag.

### Sekcja skuteczności:

Nic nie zmieniono w etykiecie, wszystkie proponowane zapisy perz Aplikanta zostały zaakceptowane.

### Metabolizm i pozostałości:

Proponowany zapis w etykiecie:

Nie stosować słomy z pszenicy traktowanej chloromekwatem jako ogrodniczego podłoża wzrostowego w uprawie grzybów.

### Los i zachowanie w środowisku:

Brak uwag

### Ekotokykologia:

Po przedstawionych dodatkowych danych wraz z uaktualnioną oceną ryzyka zastosowania zostały zaakceptowane.

Załącznik do zezwolenia MRiRW nr R-...../2022 z dnia .....2022 r.

Posiadacz zezwolenia: Sharda Cropchem Limited z siedzibą Prime Business Park Dashrathlal Joshi Road, Vile Parle (West), Mumbai – 400 056, Indie, Tel. + 91 22 6678 2800, Fax : + 91 22 6678 2828 / + 91 22 6678 2808, email: regn@shardaintl.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: (.....).

## MEPCY


Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

**chlorek chloromekwatu – 345 g/l**

**chlorek mekwipatu – 115 g/l**

**Zezwolenie MRiRW nr R -..../2022 z dnia ..... 2022 r.**

	
<b>Uwaga</b>	
H302	Działa szkodliwie po połknięciu.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P264	Dokładnie umyć ręce po użyciu.
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P270	Nie jeść, nie pić ani nie palić podczas używania produktu.

P301+P312	W PRZYPADKU POŁKNIECIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUCIE/lekarzem/....
P330	Wypłukać usta.
P501	Zawartość/pojemnik usuwać zgodnie z przepisami krajowymi.

## OPIS DZIAŁANIA

REGULATOR WZROSTU I ROWOJU ROŚLIN w formie koncentratu rozpuszczalnego w wodzie (SL) przeznaczony do stosowania w celu zapobiegania nadmiernemu wyrastaniu roślin i ich wyleganiu.

Środek zawiera substancje czynne chlorek chloromekwatu (związek z grupy czwartorzędowej soli amoniowej) oraz chlorek mepikwatu (związek z grupy piperydyn). Chlorek chloromekwatu hamuje wzrost, skraca i usztywnia łodygę pszenicy, w rezultacie zapobiegając wyleganiu. Chlorek mepikwatu stosowany wiosną w zbożach w celu redukcji wzrostu zapobiega wyleganiu.

Hamuje biosyntezę giberelin.

Działanie środka powoduje ograniczanie wzrostu międzywęzła i uzyskanie roślin o bardziej zwartym pokroju, poprawia się kwitnienie i zawiązywanie nasion.

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych..

### Pszenica ozima

*regulacja wzrostu, przeciwdziałanie wyleganiu*

Termin stosowania: środek stosować wiosną, w fazie wzrostu pędu głównego do fazy widocznych dwóch kolanek (BBCH 29-32).

Środek stosować zapobiegawczo, w celu skrócenia oraz wzmocnienia pędów roślin (zapobieganie wyleganiu).

Maksymalna /zalecana dawka dla jednorazowego zastosowania: 2,0 l/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 200 - 400 l/ha

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: średniokropliste.

## ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Pszenica ozima - nie dotyczy

Środka nie stosować:

- na glebach o niskiej zasobności, w warunkach niskiego nawożenia azotowego
- w temperaturze powietrza poniżej 10°C i powyżej 25°C
- podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie pola
- na rośliny mokre

Podczas stosowania nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach

**Uwaga:** Nie stosować słomy z pszenicy traktowanej chloromekwatem jako ogrodniczego podłoża wzrostowego w uprawie grzybów.

### **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Zawartość opakowania przed użyciem wstrząsnąć.

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

### **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.
- Po pracy aparaturę dokładnie wymyć.

### **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas stosowania środka.

Unikać wdychania rozpylonej cieczy.

Stosować rękawice ochronne (nitrylowe), odzież roboczą oraz ochronę oczu w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

### **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

**OKRES KARENCEJ** (okres od dnia ostatniego zabiegu do dnia zbioru i przeznaczenia do konsumpcji)

**NIE DOTYCZY**

**OKRES PREWENNCJI DLA LUDZI, ZWIERZĄT** (okres zapobiegający zatruciu)

**NIE DOTYCZY**

## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 5°C – 30°C,
- w suchym i dobrze wentylowanym miejscu.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku narażenia lub styczości: zasięgnąć porady/ zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

### **Appendix 3 Letter of Access**

No letter of access is required.

## Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.4	Stefano Aversa	2018	Physical-chemical characterization and accelerated storage stability (2 weeks/54±2°C) of test item Chlormequat 345 g/L + Mepiquat 115 g/L SL Biotechnologie BT report No. BT022/18 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.2.1 KCP 2.2.2/02	B. Mena	2022	Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL Determination of the oxidizing properties and explosive properties. Sharda Cropchem España S.L. Report No. SCE-048/2022 Non-GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.2/01	Antonella Mazzei	2018	Determination of Oxidizing properties (liquids) n the sample Chlormequat 345 g/L + Mepiquat 115 g/L SL Innovhub – Stazioni Sperimentali per l'Industria report No. 1800928 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.3.1 KCP 2.3.3	M. Kurka	2020	Chlormequat 345 g/L + Mepiquat 115 g/L SL Determination of Flash point (A.9) and Flammability (A.15) Institute of Heavy Organic Synthesis "Blachownia" Report No. 137/2020 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.7.1	K.S. Kishora	2023	Accelerated storage stability test of Chlormequat 34.5% + Mepiquat 11.5% SL, Report No.: AG-G0028 EUROFINS ADVINUS AGROSCIENCES SERVICES GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.7.5	Stefano Aversa	2020	Physical-chemical properties of test item Chlormequat 345 g/L + Mepiquat 115 g/L SL after 2 years shelf life (2 years/20±2°C) Biotechnologie BT report No. BT023/18 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.11	Stefano Aversa	2018	Effectiveness of cleaning procedure of test item Chlormequat 345 g/L + Mepiquat 115 g/L SL Biotechnologie BT report No. BT024/18 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1	Stefano Aversa	2018	Physical-chemical characterization and accelerated storage stability (2 weeks/54±2°C) of test item Chlormequat 345 g/L + Mepiquat 115 g/L SL Biotechnologie BT report No. BT022/18 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 5.1.1-2	K.S. Kishora	2023	Accelerated storage stability test of Chlormequat 34.5% + Mepiquat 11.5% SL, Report No.: AG-G0028 EUROFINS ADVINUS AGROSCIENCES SERVICES GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 5.1.2	D. Gąszczyk	2021	Validation of method for determination of Chlormequat chloride by Liquid Chromatography (LC-MS/MS), Report No.: PW-2021-05 and amendment No. 1 Fertico Sp z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 5.1.3	K. Zagibajło	2022	Validation of the method for determination of mepiquat chloride in cotton and wheat by liquid chromatography Report No.: 21/FSL/07/V Food Safety Laboratory The National Institute of Horticultural Research GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.0-001	Anonymous	2023	Biological Assessment Dossier: Chlormequat 34.5% + Mepiquat 11.5% SL (345 g/L chlormequat and 115 g/L mepiquat SL) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2.1-01 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Pallares Martinez, C.	2017	Efficacy of Chlormequat + Mepiquat 34.5 + 11.5 SL, Spain 2017. Laboratory: Daye desarrollo agricola, ES Trial number: 17-SHA-476 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-02 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Pallares Martinez, C.	2017	Efficacy of Chlormequat + Mepiquat 34.5 + 11.5 SL, Spain 2017. Laboratory: Daye desarrollo agricola, ES Trial number: 17-SHA-477 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-03 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Pallares Martinez, C.	2017	Efficacy of Chlormequat + Mepiquat 34.5 + 11.5 SL, Spain 2017. Laboratory: Daye desarrollo agricola, ES Trial number: 17-SHA-478 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-04 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Guillaume, G.	2017	DIV 24 protocole Efficacy PGR, France 2017. Laboratory: Agrostation, FR Trial number: PC 17-05-31-NE1 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-05 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Guillaume, G.	2017	DIV 24 protocole Efficacy PGR, France 2017. Laboratory: Agrostation, FR Trial number: PC 17-05-31-NE2 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2.1-06 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Guillaume, G.	2017	DIV 24 protocole Efficacy PGR, France 2017. Laboratory: Agrostation, FR Trial number: PC 17-05-31-NE3 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-07 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Guillaume, G.	2017	DIV 24 protocole Efficacy PGR, France 2017. Laboratory: Agrostation, FR Trial number: PC 17-05-31-NE4 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-08 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Le Roux, R.	2018	DIV 24 protocole Efficacy PGR, France 2018. Laboratory: Agrostation, FR Trial number: PC 18-05-45-1 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-09 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Le Roux, R.	2018	DIV 24 protocole Efficacy PGR, France 2018. Laboratory: Agrostation, FR Trial number: PC 18-05-45-2 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-10 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Kroniewicz, L.	2017	Determination of Efficacy of CHLORMEQUAT+MEPIQUAT 34.5+11.5 SL against lodging in winter wheat in France in 2017. Laboratory: Eurofins agrosience services, FR Trial number: S17-00712-01 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2.1-11 <u>Also cited in:</u> KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Kroniewicz, L.	2017	Determination of Efficacy of CHLORMEQUAT+MEPIQUAT 34.5+11.5 SL against lodging in winter wheat in France in 2017. <b>Laboratory:</b> Eurofins agrosience services, FR <b>Trial number:</b> S17-00712-02 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-12 <u>Also cited in:</u> KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Kroniewicz, L.	2017	Determination of Efficacy of CHLORMEQUAT+MEPIQUAT 34.5+11.5 SL against lodging in winter wheat in France in 2017. <b>Laboratory:</b> Eurofins agrosience services, FR <b>Trial number:</b> S17-00712-03 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-13 <u>Also cited in:</u> KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Orrico Marin, A.	2017	Study of the efficacy of plants growth regulators on winter wheat, Spain 2017. <b>Laboratory:</b> Sicop, ES <b>Trial number:</b> SHA17OP2PGR248-02 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-14 <u>Also cited in:</u> KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Konvalinkova, J.	2017	Efficacy of CCC mepiquat 34,5 + 11,5 SL on winter wheat in the Czech Republic 2017. <b>Laboratory:</b> Zkusebni stanice Rymarov, s.r.o., CZ <b>Trial number:</b> SWEPL-CZE17-CCC-TRZAW-RYM20 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-15 <u>Also cited in:</u> KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Konvalinkova, J.	2017	Efficacy of CCC mepiquat 34,5 + 11,5 SL on winter wheat in the Czech Republic 2017. <b>Laboratory:</b> Zkusebni stanice Rymarov, s.r.o., CZ <b>Trial number:</b> SWEPL-CZE17-CCC-TRZAW-DOM20 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2.1-16 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Grabinski, J. Nieróbca, P.	2017	The effectiveness the CCCmepiquat 34,5-11,5 SL in the cultivation of winter wheat ( <i>Triticum aestivum</i> ). <b>Laboratory:</b> Institute of soil science and plant cultivation, national research institute, PL <b>Trial number:</b> NUZ 18+19/17-1 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-17 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Grabinski, J. Nieróbca, P.	2017	The effectiveness the CCCmepiquat 34,5-11,5 SL in the cultivation of winter wheat ( <i>Triticum aestivum</i> ). <b>Laboratory:</b> Institute of soil science and plant cultivation, national research institute, PL <b>Trial number:</b> NUZ 18+19/17-3 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-18 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Grabinski, J. Nieróbca, P.	2017	The effectiveness the CCCmepiquat 34,5-11,5 SL in the cultivation of winter wheat ( <i>Triticum aestivum</i> ). <b>Laboratory:</b> Institute of soil science and plant cultivation, national research institute, PL <b>Trial number:</b> NUZ 18+19/17-2 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-19 Also cited in: KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Grabinski, J. Wyzińska, M.	2021	Efficacy of the Chlormequat 34.5% + mepiquat 11.5% SL in the cultivation of winter wheat ( <i>Triticum aestivum</i> ). <b>Laboratory:</b> Institute of soil science and plant cultivation, national research institute, PL <b>Trial number:</b> NUZ 03/21/1 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2.1-20 <u>Also cited in:</u> KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Walczak, K.	2021	Efficacy study of plant growth regulator Chlormequat 34,5% + Mepiquat 11,5% SL on winter wheat <b>Laboratory:</b> Sharda Poland, PL <b>Trial number:</b> SRG21-SHA52 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-21 <u>Also cited in:</u> KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Jakobsze, A.	2021	Efficacy study of plant growth regulator Chlormequat 34,5% + Mepiquat 11,5% SL on winter wheat <b>Laboratory:</b> Sharda Poland, PL <b>Trial number:</b> SRG21-SHA53 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-22 <u>Also cited in:</u> KCP 6.2.2 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Jakobsze, A.	2021	Efficacy study of plant growth regulator Chlormequat 34,5% + Mepiquat 11,5% SL on winter wheat <b>Laboratory:</b> Institute of soil science and plant cultivation, national research institute, PL <b>Trial number:</b> SRG21-SHA54 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.1.1	D. Gąsczyk	2021	Quantitative analysis of Chlormequat chloride residues in winter wheat in field conditions (Raw Agricultural Commodity) after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline trials in Northern Europe – Poland, 2020, Report No.: PB-2021-35 Fertice Sp z o.o. – Laboratorium GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1.2	D. Gąsczyk	2021	Quantitative analysis of Chlormequat chloride residues in winter wheat in field conditions (Raw Agricultural Commodity) after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline trials in Northern Europe – Hungary, 2020, Report No.: PB-2021-31 Fertice Sp z o.o. – Laboratorium GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.1.1-2	Michał Tartanus	2022	Magnitude of the residue of chlormequat chloride in winter wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline curve trials in Northern Europe – Poland, 2020, Report No.: D-2020-27 Fertico Sp. z o.o. Agricultural Research Service GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.1.2-2	Gábor Wágner	2022	Determination of the residues of chlormequat chloride in/on winter wheat after one application of chlormequat chloride 720 SL in Northern Europe - Hungary in 2020, Report No.: 065CPRHU20R28 CPR Europe Kft. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-01	xxxxxxx	2021	Chlormequat 345 g/L + Mepiquat 115 g/L SL: Fish, Acute toxicity test with rainbow trout. Report No. G14214 xxxxxxxxxxx GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1-02	Saiqa Nazhath, M.	2021	Chlormequat 345 g/L + Mepiquat 115 g/L SL: alga, growth inhibition test with <i>Raphidocelis subcapitata</i> . Report No. G14215 Eurofins Advinus Limited GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-03	Saiqa Nazhath, M.	2021	Chlormequat 345 g/L + Mepiquat 115 g/L SL: <i>Daphnia magna</i> , Acute immobilisation test. Report No. G14216 Eurofins Advinus Limited GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-04	Kanchana, P.	2023	Study of <i>Lemna gibba</i> growth inhibition with Chlormequat 345 g/L + Mepiquat 115g/L SL Report No. 13004/2023 Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.1.1	Likith, N.G.	2020	Chlormequat 345 g/L + Mepiquat 115 g/L SL. Acute oral toxicity test in honey bees Report No. G14217 Eurofins Advinus Limited GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.2-01	Lakshmi Prabha, K.	2023	Chronic Oral Toxicity Study of Chlormequat 345 g/L + Mepiquat 115 g/L SL on adult honey bee ( <i>Apis mellifera</i> ) Report No. 11510/2022 Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.3-01	Lakshmi Prabha, K.	2023	Effect of Chlormequat 345 g/L + Mepiquat 115 g/L SL on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure Report No. 11511/2022 Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.1-01	Parkavi, B	2023	A laboratory test for evaluating the effects of Chlormequat 345g/l + Mepiquat 115g/l SL on the predatory mite, <i>Typhlodromus pyri</i> (Scheuten)". Report No. 13006/2023 Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.1-02	Angayarkanni, V	2023	A laboratory test for evaluating the effects of Chlormequat 345g/l + Mepiquat 115 g/l SL on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani Perez Report No. 13005/2023 Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.1.1-01	Parkavi, B.	2023	Effect of Chlormequat 345g/l + Mepiquat 115g/l SL on reproduction of the earthworm ( <i>Eisenia fetida</i> ) in artificial soil Report No. 13007/2023 Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.2.1-01	Angayarkanni, V.	2023	Effect of Chlormequat 345 g/l + Mepiquat 115 g/l SL on reproduction of the collembolans ( <i>Folsomia candida</i> ) in artificial soil Report No. 13009/2023. Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.2.1-02	Angayarkanni, V.	2023	Effect of Chlormequat 345 g/L + Mepiquat 115 g/L SL on the reproductive output of the predatory soil mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in artificial soil Report No. 13008 /2023 Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.1.2	Likith, N.G.	2020	Chlormequat 345 g/L + Mepiquat 115 g/L SL. Acute contact toxicity test in honey bees Report No. G14218 Eurofins Advinus Limited GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.5.01	Anand, H.S.	2020	Soil microorganisms: nitrogen transformation test of Chlormequat 345 g/L + Mepiquat 115 g/L SL Report No. G14222 Eurofins Advinus Limited GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.5.02	Anand, H.S.	2020	Soil microorganisms: carbon transformation test of Chlormequat 345 g/L + Mepiquat 115 g/L SL Report No. G14221 Eurofins Advinus Limited GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.6.2-01	Radha, S.	2023	Effect of Chlormequat 345 g/L + Mepiquat 115 g/L SL on seedling emergence and seedling growth of terrestrial plants. Report No: 13010/2023. Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.6.2-02	Radha, S.	2023	Effect of Chlormequat 345 g/L + Mepiquat 115 g/L SL on vegetative vigor on terrestrial plants. 2023. Report No: 13011/2023 Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Raunft, E. Mackenroth, C.	2005	Study on the residue behaviour of chlormequat-chlorid in wheat after application of BAS 062 00 W and BAS 062 03 W under field conditions in Germany, France (N&S) and the United Kingdom, 2004 (study code 176257). BASF AG, Report no. 2005/1014176 GLP, Published	N	CCC Task Force
	Schulz, H	2005	Study on the residue behaviour of BAS 062 W in cereals after application of BAS 062 24 W and BAS 062 03 W under field conditions in France (S and N), Germany and United Kingdom, 2003 (study code 161200). BASF AG, DocID 2004/1015956 GLP, Published	N	CCC Task Force
	Mackenroth, C.	2003	Residue data symmary from supervised fird trials in cereals BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. 2003/1004687 Published	N	BASF
	Oberdorf K.	2004	Supplementary residues information BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. 2004 Published	N	BASF
	Rawle N.W.	2006	Residues of mepiquat chloride in barley at harvest following a single application of Terpal, France – 2005 Report Number CEMR-2632 GLP, published	N	BASF

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	Verte- brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

**List of data relied on and 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	Verte- brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner