FINAL REGISTRATION REPORT
Part A
Risk Management

Product code: SHA 8500 A
Product name: MEPISHA
Chemical active substances:

Mepiquat chloride, 50 g/L
(Mepiquat 38 g/L)

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(Authorization)

Applicant: Sharda Cropchem España S.L.
Submission date: February 2021
Update date: March 2021
MS Finalisation date: October 2021 February 2022
April 2022

Version history

When	What
March 2021	Updated by applicant
October 2021	ZRMs evaluated version of dRR submitted by Applicant.
February 2022	RMS reply to the applicant's comment (Reporting Table)
April 2022	ZRMs (efficacy section) reply to the MRiRW comments

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application is submitted by SHARDA CROPCHEM ESPAÑA S.L. for approval of SHA 8500 A / MEPISHA, a soluble concentrate containing 50 g/L of Mepiquat chloride, equivalent to 38 g/L of Mepiquat ion, for use as plant growth regulator on winter wheat, winter barley, spring barley and winter oil seed rape in Central Europe.

zRMS: Poland

1.2 Letters of Access

Not applicable. 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 SHA 8500 A / MEPISHA as required by the 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 8500 A
Product name in MS	MEPISHA
Authorization number	First authorisation
Function	Plant growth regulator
Applicant	SHARDA Cropchem España S.L.
Active substance() (incl. content)	Mepiquat chloride 50 g/L equivalent to 38 g/L of mepiquat ion
Formulation type	Soluble concentrate [Code: SL]
Packaging	0.25, 0.5, 1, 5, 10, 20 L HDPE/EVOH; 0.25, 0.5, 1, 5, 10 L HDPE/PA; 20L HDPE/F

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

2.2 Conclusion

The evaluation of the application for SHA 8500 A / MEPISHA resulted in the decision to grant the authorization.

Efficacy section:

~~Only use on spring barley is accepted. Winter wheat, winter barley and winter oilseed rape should be excluded from label and GAP table.~~ Based on results, it can be concluded that for Mepisha (product code: SHA 8500 A) control lodging and reduces the growth when is uses according to GAP table and label project for spring barley, winter barley, winter wheat and winter oilseed rape.

Toxicology section:

SHA 8500 A/MEPISHA is unclassified. Risk for operator, worker, resident/bystander is acceptable.

Metabolism and Residues:

All uses applied for were authorised ~~except for use on Winter Oilseed rape due to following data gap : Storage stability data for high oil content commodities.~~

Section Ecotoxicology: The all uses are acceptable to non-target organism from exposure from ppp Mepisha.

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:	-

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:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	**P102, P501**
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use.

	[EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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)

-	-

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:	
-	-
Worker protection:	
-	-
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)

			GAP rev. 0, date: 2021-January-19th
PPP (product name/code):	MEPISHA / SHA 8500 A	Formulation type:	SL (Soluble concentrate)
Active substance 1:	Mepiquat chloride (mepiquat)	Conc. of as 1:	50 g/L (38 g/L)
Active substance 2:		Conc. of as 2:	
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	SHARDA Cropchem España	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: Plant growth regulator

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					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, winter barley, spring barley**	F	Reduction of crop height	Foliar Spray	BBCH 31-39	a) 1 b) 1	-	a) 0.75 b) 0.75	a) 0.0285 b) 0.0285	200-400		~~**Efficacy section:** use on winter wheat and winter barley is not accepted.~~
2	CEU	**Winter Oilseed rape**	F	Reduction of crop height	Foliar Spray	BBCH 31-39	a) 1 b) 1	-	a) 0.75 b) 0.75	a) 0.0285 b) 0.0285	200-400		~~**Efficacy and Residues sections:** use on winter oilseed rape is not accepted~~ **Metabolism and residues**: use is accepted.
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

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

(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.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
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)
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
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.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
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 off white liquid, with a mild woody odour. It is not explosive, has no oxidising properties. It has a self ignition temperature of 510.7 °C. In aqueous solution, it has a pH value around 7.58 at 25 °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. The studies on the other physico-chemical properties and 2 years storage stability are on-going and will be provided as soon as possible. Authorization can be granted for 1 year. Its technical characteristics are acceptable for a *soluble concentrate* formulation.
The intended concentration of use is 0.1875% to 0.375%.

3.2 Efficacy (Part B, Section 3)

MEPISHA is a Soluble Concentration (SL) formulation concentrate containing 50 g/L of Mepiquat chloride, equivalent to 38 g/L of Mepiquat, for use in winter wheat, winter barley, spring barley and winter oilseed rape.

To support the registration of MEPISHA in the GAP claimed crops, trials have been set up in winter wheat and spring barley field crops and winter barley and winter oilseed rape.

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

- Single application per season (BBCH 31-39) to reduction of crop height in winter wheat, winter barley and spring barley, target rate: 0.75 L/ha.
- Single application per season (BBCH 31-39) to reduction of crop height in winter oilseed rape, target rate: 0.75 L/ha

This document serves the registration of MEPISHA in the Central zone of the EU. The objective of this document is to prove and support the label claims of the plant growth regulator efficacy and crop safety of MEPISHA in the GAP claimed crops.

Comprehensive field trials were conducted in Poland in 2017 and Maritime EPPO zone in 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 MEPISHA is equivalent to that of the standard reference product to which it was compared.

3.3 Efficacy data

Preliminary tests

The activity of mepiquat is well known as it has been marketed by for the control of crop height for a number of years. Based on the knowledge about the active substance (more than 20 years) and the experiences with the actives in the GAP claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

~~MEPISHA was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with MEPISHA applied at 0.50 L/ha and 0.75 L/ha or was evaluated in 3 winter wheat and 6 spring barley trials, for reduction of crop height. The dose rates tested in winter wheat and spring barley reflects 66% and 100% of the recommended rate of MEPISHA, in accordance with the EPPO guideline PP 1/225(2) "Minimum effective dose". The dose rates are selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the North east EPPO zone (i.e Poland).~~

The trials submitted to support the MED (minimum effective dose) of Mepisha (product code: SHA 8500 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).

9 field trials carried out in one growing season on winter wheat (3 trials) and spring barley (6 trials) were established to determine the minimum effective dose of Mepiquat 3.8% SL. Trials were performed only in one EPPO zone – N-E in Poland. Two different doses were studied: 0,50 l/ha (0,66 N) and 0,75 l/ha (N dose). All results were compared to standard reference product. In the trials, specifically targeted for height reduction, single application was applied at growth stages ranging between BBCH 30 and BBCH 39. During commenting period, Applicant presented new MED trials for winter barley in Maritime EPPO zone (2 trials), and 8 trials performed on winter oilseed rape ~~in the N-E EPPO zone~~. So, in total Applicant submitted 19 MED trials carried out on winter barley (2), winter oilseed rape (8), winter wheat (3) and spring barley (6). In new trials following doses were studied: 0,40 l/ha (0,55N), 0,50 l/ha (0,66N) and 0,75 l/ha (N dose) was studied.

The proposed doses were derived from registered doses of standard reference products with mepiquat as active compound and, product safety parameters and environmental limitations. Such products are used across Europe for many years (over 20) and their MED is justified.

REDUCTION OF HEIGHT:

- **N-E EPPO zone:**

Winter wheat - During 3 trials slightly effect of reduction of height was observed (average efficacy: 2,88%) at dose 0,5 L/ha and slightly higher effect was observed at dose 0,75 L/ha – average eff. at level 7,89%.

Spring barley - During 6 trials only in 4 trials effect of reducing growth was observed. This effect was very slightly – efficacy from 0,6% to 4,60 at dose 0,5 L/ha and efficacy from 0,4% to 5,7 % at dose 0,75 L/ha. In 2 trials no effect was observed, both at 0,5 and 0,75 L/ha, because treated plants by Mepisha were higher than control plants.

- **Maritime EPPO zone:**

Winter barley: 2 trials – tested product reduce height in all doses tested (0,4 L/ha; 0,5 L/ha and 0,75 L/ha) in one trial (Sharda21-023). No significant differences were noted between the doses tested. But in second trial (SHA21-022) in all treatments tested plants were slightly higher than control plants. So, in this study no effect of reducing growth was observed.

Winter oilseed rape – 8 trials – Slightly effect of reducing growth was observed during 6 trials. But, in two trials (SWEPL-KUJ21-BRSNW52 and Sharda21-020) plants treated by Mepisha were higher than control ones, so no effect of reducing growth was observed.

LODGING:

- **N-E EPPO zone:**

Winter wheat – 3 trials. Lodging was observed in all 3 trials on control plants (average:11,5%). Dose 0,5 L/ha reduce of lodging with 46,5% efficacy and dose 0,75 L/ha with 100% efficacy.

Spring barley – 5 trials. Lodging was observed in all studies (average:60,3%). Dose 0,5 L/ha reduce of

lodging with 33,5% efficacy and dose 0,75 L/ha with 29,4% efficacy.

- **Maritime EPPO zone:**

Winter barley - 2 trials. Lodging was observed in all trials (average: 68,8%). Dose 0,4 L/ha reduce of lodging with 93.8%; 0,5 L/ha reduce of lodging with 100% efficacy and dose 0,75 L/ha with 92,4% efficacy.

Winter oilseed rape – 5 trials. No lodging at control area was observed. Those trials should not be assessed, because the phenomenon of lodging did not occur, and such tests should not be included in the table as a possible basis for calculating the effectiveness of the tested agents

In the opinion of ZRMs, presented results and knowledge about registered doses of standard reference products with mepiquat can allow to consider dose 0,75 l/ha as the most effective for winter wheat, winter oilseed rape, spring barley and winter barley. But, the recorded results from field trials did not allow to draw clear conclusions about tested Mepisha. Slightly reducing of growth was observed after using Mepisha on cereal crops (winter wheat and barley; spring barley) and winter oilseed rape. In most studies, a dose of 0.75 L/ha was found to be the most effective. Also, reducing of lodging was observed on cereals crops. The best effect of counteracting this phenomenon was achieved at a dose of 0.75 L/ha. But, on winter oilseed rape crops phenomenom of lodging did not occur, so we cannot assess the effect of the different doses on the risk of lodging of oilseed rape. Only, a mild reduction in growth was observed for most studies carried out on winter oilseed rape (2 trials without shortening effect). During, efficacy trials carried out in N-E EPPO zone, Applicant shown that dose 0,75 l/ha have effect on reducing growth and lodging in winter oilseed rape crops.

cMS should decide if lack of trials carried out in their EPPO zone can be accepted. In the opinion of Evaluator, each EPPO zone should be represented by enough trials. However, final decision is left to each cMS. Only for N-E EPPO zone and use on spring barley and winter oilseed rape in the Maritime EPPO zone the acceptable number of MED trials was submitted. For winter wheat (N-E EPPO zone) and winter barley (Maritime EPPO zone) only limited number of trials were presented. However, given submitted by Applicant the efficacy studies which have shown that a dosage of 0.75 l/ha has satisfactory efficacy and the comparability of the results to the standard used for spring barley and winter wheat. So, those uses should also be accepted by the N-E and Maritime EPPO zone. cMS from MED and S-E EPPO zone should decide if lack of trials and only results from another climatic zone can be accepted.

~~**Reduction of Height (CEU)**~~

~~To prove and to support the proposed dose rate of 0.75 L/ha MEPISHA [28.5 g mepiquat per hectare, per application] for the reduction of height in winter wheat and spring barley, the assessment results from 9 efficacy trials performed in the North-east EPPO zone are reported. The trials were conducted in Poland in 2017. MEPISHA was included in these trials at 0.75 L/ha to demonstrate the recommended dose rate as well as the lower dose rate (0.5 L/ha [19 g mepiquat per hectare, per application]). In the trials, specifically targeted for height reduction, single application was applied at growth stages ranging between BBCH 30 and BBCH 39.~~

~~It can be concluded that for consistent reduction of height, the intended use rate of 0.75 L/ha, with single application per season, is required.~~

Efficacy tests and conclusions regarding authorization of intended uses

Lodging in cereals was evaluated in accordance with the EPPO standards PP 1/144(3). ~~Lack of trials for winter oilseed rape.~~ Control of lodging and growth regulation in brassica oil crops was studied according to EPPO 1/153 (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 oilseed rape trials. ~~Because~~ Applicant submitted ~~only~~ results from ~~one~~ two growing seasons (2017 and 2021) for win-

ter wheat, winter barley and spring barley. ~~However,~~ Explanations for conducting surveys in only one season are included in this dRR. These explanations were accepted by the ZRMs.

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 major crops at least six trials. For Poland trials from neighbouring countries are acceptable. Submitted documentations is sufficient in the opinion of Evaluator ~~only~~ for spring barley (18 trials: PL-10, DE-4, CZ-4), winter barley (11 trials: PL-2, DE-5, CZ-4), winter wheat (14 trials: PL-9, DE-3, CZ-2) and winter oilseed rape (12 trials: PL-2, DE-4, CZ-4) for N-E EPPO zone against reduction of growth and lodging. ~~However, also lodging in spring barley should be accepted on the basis on 5 valid trials in the opinion of Evaluator. For winter wheat at least 3 additional efficacy trials are required, for winter barley – at least 2-3 phytotoxicity trials (when the number of tests for winter wheat will be acceptable, then the extrapolation results on winter barley will be possible) and at least 6 efficacy and phytotoxicity trials for winter oilseed rape.~~ For Maritime EPPO zone only for winter barley (9 trials), winter oilseed rape (8 trials) and spring barley (8 trials) sufficient number of trials were presented. Also, 5 trials for winter wheat for Maritime EPPO zone should be acceptable (extrapolation results from winter barley or/and reduction of number of trials should be consider by cMS). In the opinion of ZRMs registration in MED or S-E is not possible without any trials conducted in those zones. However, final decision is left to cMS from S-E and MED EPPO zone.

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 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 Mepisha (product code: SHA 8500 A) can be accepted by them only on the basis on extrapolation results from N-E EPPO zone and/or Maritime EPPO zone.

According to EPPO PP 1/144 Reduction of lodging in cereals, an assessment of lodging ~~(5 trials on spring barley and 3 trials on winter wheat)~~ and height ~~(6 trials on spring barley and 3 trials on winter wheat)~~ 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. Mepisha (product code: SHA 8500 A) provided an ~~high~~ acceptable level of reduction in crop height as well as control of lodging in the GAP claimed crops with the recommended dose rate of 0,75 l/ha in spring barley, winter barley, winter wheat and winter oilseed rape. Compared to the mepiquat reference product, the efficacy obtained with Mepisha were ~~comparable~~ lower in ~~all~~ most trials. However, it is worth noting that the product was tested at a dose lower than the reference standards used during trials. Mepisha is recommended for once-a-season application at a rate of 0.75 L/ha, whereas in the trials conducted in the northeast zone, the reference standard used was Canopy at a rate of 1.25 l/ha (winter wheat spring barley, winter rape, winter barley), Medax Top at 1.0-1.25 L/ha (winter wheat, spring barley, Caryx 240 SL at 1.25 L/ha (spring barley, winter rape) and in the Maritime zone: Medax Top at 1.5 l/ha (cereal trials) and Caeyx at 1.4 l/ha (rapeseed trials). It is worth noting that the tested product showed a reduction in cereal growth and in lodging, but its efficacy was lower than standard ref. products used in higher doses. Also, those standards reference products contained 6 times (300 g/L) more active substance than the tested product (50 g/L). Therefore, the effectiveness of Mepisha will always be lower than products used in higher doses. One might wonder whether Mepisha applied twice a season would not be more effective than products already on the market. However, no study was conducted in which two doses of a test product were tested. For example, in Poland no plant protection products with mepiquat for use twice a season are registered. Also, used standard reference products during trials are registered for use only once a season. When we, we change the method or number of applications, we are dealing with a new application for which efficacy studies must be presented. In our opinion, it is always advisable to register a product that contains a lower amount of active substance than those currently available on the market for environmental reasons. However, it would be worthwhile to consider applying Mepisha twice a season, the first time at BBCH 31. Then, a treatment at this stage of development would ensure a thickening of the stem base, the development of the root system and a permanent reduction in plant height as well as an even ripening of the canopy. The second growth

regulation period would be at BBCH 39, the flag leaf stage. A farmer does not always have to decide on a two-stage shortening of wheat or other cereals, because a properly performed first adjustment may be sufficient. The decision about the second treatment should be made in situations where the plantation is managed intensively with high nitrogen fertilization and in the case of varieties susceptible to lodging. The aim of this treatment is to shorten and strengthen the spikelet. The minimum interval between two applications should be at least 14 days. What is important, both studies on selectivity and available reference products on the market, testify that the product at a dose of 1.5 L/ha is safe for winter oilseed rape and cereals. It is only necessary to demonstrate that the effectiveness of two doses at 14 days will be more effective than one application per season. Without studies with 2 applications, it's unfortunately just a guessing game.

In summary, **ZRMs consents to the registration of the product in Poland as stated in the GAP table.** 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 product showed positive effect, however lower than the reference standard applied at a higher dose and containing more active compound. **At the same time, we point out that it is worth considering a conditional registration of Mepisha with an indication of a possible change in the number of applications in a season (with a maximum of 2 treatments, interval at least 14 days), which could visibly increase the effectiveness of the product and reduce economic losses of farmers resulting from lodging of crops.**

It is left to the Member States to decide on the acceptability of the results presented in this dRR and to consider registration of Mepisha (normal or conditional). Below are the detailed results from all submitted filed trials by Applicant, which will help cMS to make a more accurate decision.

REDUCTION IN HEIGHT and LODGING:

- ***N-E EPPO zone***

Winter wheat

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed

				Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)			Reference product 1 N		
Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Mean		Mean		% Cont.	Mean		% Cont.
NUZ 18+19/17 I	1	-	HEIGHT	93.6	a	86.4	bc	7.89	84.3	c	9.93
NUZ 18+19/17 II	1	-	HEIGHT	87.0	a	78.0	c	10.4	76.0	c	12.6
NUZ 18+19/17 III	1	-	HEIGHT	85.0	a	71.0	c	16.5	70.0	c	17.6
21-po-11-Af	1	-	HEIGHT	86,3	a	85,1	a	1.4	79,8	b	7.5
21-po-12-Af	1	-	HEIGHT	86,3	a	85,1	a	1.4	79,8	b	7.5
21-po-13-Af	1	-	HEIGHT	85,8	a	85	a	0.9	82,3	b	4.1
SRG21-SHA111	1	-	HEIGHT	94,8	a	92,8	b	2.1	87,2	e	8.0
SRG21-SHA112	1	-	HEIGHT	92,8	a	91,8	a	1.1	76,6	e	17.5
SRG21-SHA113	1	-	HEIGHT	87,8	a	85,8	b	2.3	82,8	d	5.7
NUZ 18+19/17 I	1	-	LODGING	8.8	a	0.0	b	100	0.0	b	100
NUZ 18+19/17 II	1	-	LODGING	14.0	a	0.0	d	100	0.0	d	100
NUZ 18+19/17 III	1	-	LODGING	11.8	a	0.0	b	100	0.0	b	100
21-po-11-Af	1	-	LODGING	8		0		100	0		100
21-po-12-Af	1	-	LODGING	8		0		100	0		100
21-po-13-Af	1	-	LODGING	12		8		66,67	0		100
SRG21-SHA111	1	-	LODGING	50	a	38,8	a	77,6	0	b	100
SRG21-SHA112	1	-	LODGING	70	a	38,8	b	55,43	0	c	100

Reduction of height was observed in 9 trials carried out on winter wheat. Observed average efficacy was 4,9% and it was lower than standard ref. product eff. 10%.

Lodging was observed in 8 trials at untreated control plants. In one trial lodging was not observed (SRG21-SHA113). This report was excluded from assessment and average efficacy. Mepisha reduced

lodging with 87,6% efficacy. Standard reference product was characterized by better eff. (100%).

Spring barley

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed

Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated Mean		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha) Mean		% Cont.	Reference product 1 N Mean		% Cont.
SGS/2017/032/PL01	1	-	HEIGHT	70.9	a	72.0	a	0.0	71.8	a	0.0
SGS/2017/032/PL02	1	-	HEIGHT	72.3	a	71.8	a	0.4	72.1	a	0.3
SGS/2017/032/PL03	1	-	HEIGHT	75.1	a	73.5	a	1.9	75.3	a	0.0
SGS/2017/032/PL04	1	-	HEIGHT	82.5	a	77.7	a	5.7	77.5	a	6.0
SGS/2017/032/PL05	1	-	HEIGHT	76.2	a	74.0	a	2.8	75.8	a	0.7
SGS/2017/032/PL06	1	-	HEIGHT	81.9	a	81.6	a	0.4	81.9	a	0.0
21-jj-16-Af	1	-	HEIGHT	72,6	a	68,8	b	5.3	65,4	b	0.9
21-jj-17-Af	1	-	HEIGHT	74,3	a	68,5	b	7.9	68,5	b	7.8
NUZ01-21-I	1	-	HEIGHT	85,6	a	85,1	a	0.6	73,9	d	13.7
NUZ01-21-II	1	-	HEIGHT	81,1	a	80,3	a	1.0	69,4	d	14.4
SGS/2017/032/PL01	1	-	LODGING	48.8	a	0.0	b	100	0.0	b	100
SGS/2017/032/PL02	1	-	LODGING	90.0	a	90.0	a	0.0	90.0	a	0.0
SGS/2017/032/PL03	1	-	LODGING	33.4	a	18.5	a	47.0	36.6	a	0.0
SGS/2017/032/PL04	1	-	LODGING	59.4	a	61.1	a	0.0	58.8	a	1.0
SGS/2017/032/PL06	1	-	LODGING	70.0	a	70.0	a	0.0	70.0	a	0.0
21-jj-16-Af	1	-	LODGING	11	a	0		100	0	b	100
21-jj-17-Af	1	-	LODGING	13	a	0		100	0	b	100
NUZ01-21-I	1	-	LODGING	3		2,4		80	0,4		13,33
NUZ01-21-II	1	-	LODGING	4,56	a	1,38	a	30,26	1,69	a	37,06

Reduction of height was observed in 10 trials carried out on spring barley. Observed average efficacy was 2,6% and it was compared to standard ref. product eff. 4,4%).

Lodging was observed in 9 trials. Mepisha reduced lodging with 82,1% efficacy. Standard reference product was characterized by lower eff. (70,1%).

winter barley

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging

Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated Mean		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha) Mean		% Cont.	Reference product 1 N Mean		% Cont.
21-jo-14-Af	1	-	HEIGHT	105,9	a	103,8	a	2.0	98,6	b	6.9
21-jo-15-Af	1	-	HEIGHT	106	a	102,1	b	3.7	97,3	b	8.2
21-jo-14-Af	1	-	LODGING	90	a	80		88,89	85	a	94,44
21-jo-15-Af	1	-	LODGING	13	a	4		30,77	2		15,38

Reduction of height was observed in 2 trials carried out on winter barley. Observed average efficacy was 2,9% and it was compared to standard ref. product eff. 7,6%).

Lodging was observed in 2 trials. Mepisha reduced lodging with 59,8% efficacy. Standard reference product was characterized by lower eff. (54,9%).

Winter oilseed rape

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed

Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated Mean		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha) Mean		% Cont.	Reference product 1 N Mean		% Cont.
21-ro-08-Af	1	-	HEIGHT	167,5	a	166,8	a	0.4	164	b	2.1
21-ro-09-Af	1	-	HEIGHT	132,1	a	130,9	a	1.0	120,4	b	8.9
21-ro-10-Af	1	-	HEIGHT	162,7	a	161	a	1.04	156,7	b	3.7
NUZ01-21-III	1	-	HEIGHT	117,4		116,3		1.0	110,8		5.6
NUZ01/21/2	1	-	HEIGHT	127	a	125,9	a	0.9	118,3	b	6.8
NUZ01/21/2	1	-	HEIGHT	132,5	a	131,3	a	0.9	123,3	b	6.9
21-ro-08-Af	1	-	LODGING	5		3		60	0		100
21-ro-09-Af	1	-	LODGING	4		1		25	0		100
21-ro-10-Af	1	-	LODGING	8		4		50	0		100
NUZ01-21-III	1	-	LODGING	40		30		75	11,3		28,25
NUZ01/21/2	1	-	LODGING	45	a	42,5	a	94,44	17,5	d	38,89
NUZ01/21/2	1	-	LODGING	32,5	a	28,8	a	88,62	7,5	c	23,08

Reduction of height was observed in 6 trials carried out on winter oilseed rape. Ob-served average efficacy was 0,9% and it was lower than standard ref. product eff. 2,1%.

Lodging was observed in 6 trials. Mepisha reduced lodging with 65,5% efficacy. Standard reference product was characterized by compared eff. (65,0%).

- **Maritime EPPO zone**

Winter barley

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging

Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated Mean		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha) Mean		% Cont.	Reference product 1 N Mean		% Cont.
Sharda21-022	1	-	HEIGHT	118	a	118,2	a	0,16	112,1	b	5,00
Sharda21-023	1	-	HEIGHT	96,2	a	91,9	a	4,47	90,9	a	5,51
Sharda21-021	1	-	HEIGHT	115	a	113,4	b	1,39	101,5	e	11,7
PGR21-HORVW-2021-DOM26	1	-	HEIGHT	84,9	a	82,9	a	2,36	75,5	b	11,7
PGR21-HORVW-2021-DOM27	1	-	HEIGHT	99,2	a	100	a	0,00	96	a	3,22
SWEPL-KUJ21-HORVW49	1	-	HEIGHT	118,4	a	114,4	b	3,38	100	d	15,5
SWEPL-RR21-WB-RYM	1	-	HEIGHT	51,2	a	51	b	0,39	48	d	6,25
Sharda21-022	1	-	LODGING	90	a	87,5	a	97,2	75	b	83,33
Sharda21-023	1	-	LODGING	47,5	a	22,5	ab	87,5	37,5	a	87,5
Sharda21-021	1	-	LODGING	85	a	80	a	94,12	85	a	100

Reduction of height was observed in 7 trials carried out on winter barley. Observed average efficacy was 1,74% and it was lower than standard ref. product eff. 8,41%.

Lodging was observed in 3 trials. Mepisha reduced lodging with 92,9% efficacy. Standard reference product was characterized by compared eff. (90,3%).

Winter oilseed rape

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging

Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated Mean		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha) Mean		% Cont.	Reference product 1 N Mean		% Cont.
Sharda21-019	1	-	HEIGHT	92,7	a	88,5	b	4,53	64,4	d	30,52

PGR21-WOSR-2021-DOM29	1	-	HEIGHT	87,3	a	86,3	a	1,15	76,2	b	12,71
PGR21-WOSR-2021-DOM30	1	-	HEIGHT	130,3	a	123,7	b	5,07	113,8	c	12,66
Sharda21-017	1	-	HEIGHT	80,1	a	77,9	a	2,75	58,2	b	27,34
Sharda21-018	1	-	HEIGHT	137,4	a	134,6	a	2,04	130,9	a	4,73
Sharda21-020	1	-	HEIGHT	155	a	157,3	a	1,48	147	b	5,16
SWEPL-KUJ21-BRSNW52	1	-	HEIGHT	144,1	a	144,9	a	0,56	135,7	b	5,83
SWEPL-KUJ21-BRSNW53	1	-	HEIGHT	111,8	a	108,2	ab	3,22	102,6	b	8,23

Reduction of height was observed in 8 trials carried out on winter barley. Observed average efficacy was 2,6% and it was much lower than standard ref. product eff. 13,4%.

No lodging was observed during 6 trials. Those trials should be excluded from assessment.

Spring barley

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging

				Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)			Reference product 1 N		
Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Mean		Mean		% Cont.	Mean		% Cont.
PGR21-HORVS-2021-DOM28	1	-	HEIGHT	63,4	a	62,5	a	1,42	57,4	a	9,46
Sharda21-026	1	-	HEIGHT	74,6	a	71,4	b	4,29	67,6	c	5,32
Sharda21-027	1	-	HEIGHT	71,7	a	70,6	a	15,3	70,1	a	0,71
SWEPL-KUJ21-HORVS50	1	-	HEIGHT	76,9	a	75,6	a	1,69	69,3	c	9,88
SWEPL-KUJ21-HORVS51	1	-	HEIGHT	86,8	a	86,2	a	0,69	79	b	8,99
SWEPL-RR21-SB-RYM	1	-	HEIGHT	41	a	41	a	0,00	39	a	4,88
Sharda21-025	1	-	HEIGHT	83,8	a	81,7	a	2,51	77,3	c	7,76
Sharda21-028	1	-	HEIGHT	87,5	a	87,6	a	0,00	86,3	b	1,37
Sharda21-026	1	-	LODGING	17,5	a	7,5	a	42,86	15	a	85,71
Sharda21-027	1	-	LODGING	10	a	3,8	a	38	5	a	50
SWEPL-KUJ21-HORVS50	1	-	LODGING	33	a	26,4	ab	80	8,3	b	25,15
Sharda21-025	1	-	LODGING	12,5	a	5	a	40	0	b	100

Reduction of height was observed in 8 trials carried out on spring barley. Observed average efficacy was 3,24% and it was lower than standard ref. product eff. 6,05%.

Lodging was observed in 4 trials. Mepisha reduced lodging with 50,2% efficacy. Standard reference product was characterized by compared eff. (65,2%).

Winter wheat

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging

				Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)			Reference product 1 N		
Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Mean		Mean		% Cont.	Mean		% Cont.
PGR21-TRZAW-2021-DOM25	1	-	HEIGHT	80,8	a	80,7	a	0,12	72,9	b	9,78
Sharda21-030	1	-	HEIGHT	98,4	a	97,8	ab	0,61	87,1	e	11,48
Sharda21-032	1	-	HEIGHT	93,9	a	94,3	a	0,43	87,1	a	7,24
SWEPL-RR21-WW-RYM	1	-	HEIGHT	58,1	a	56	b	3,61	52	e	10,5
Sharda21-029	1	-	HEIGHT	102,1	a	97,9	b	4,11	88,6	e	13,2
Sharda21-029	1	-	LODGING	30	a	15	b	50	0	b	100

Reduction of height was observed in 5 trials carried out on winter wheat. Observed average efficacy was 1,78% and it was lower than standard ref. product eff. 10,44%.

Lodging was observed in 1 trial. Mepisha reduced lodging with 50% efficacy. Standard reference product was characterized by compared eff. (100%). Studies in which lodging did not occur were not included in the evaluation and calculation of the average efficacy of the test product.

Mepiquat 3.8% SL applied in winter oilseed rape, winter barley, winter wheat and spring barley provided a good reduction of crop height and lodging with the recommended dose rate of 0.75 L/ha. Single application per season of Mepiquat 3.8% SL at the proposed dose rate should be used to efficiently reduce height as claimed on the label. Compared to the reference product tested in the winter oilseed rape, winter barley, winter wheat and spring barley trials, the efficacy obtained with Mepiquat 3.8% SL is comparable against the key uses tested. ~~All detailed results were correctly presented by Applicant in tables above.~~

Based on results, it can be concluded that for Mepisha (product code: SHA 8500 A) control lodging and reduces the growth when is uses according to GAP table and label project for spring barley, winter barley, winter wheat and winter oilseed rape. ~~**Winter oilseed rape, winter wheat and winter barley should be excluded from GAP table and label project**.~~

~~**Reduction of crop height on spring barley:** The mean height in untreated plots was 76.5cm (range: 70.9-82.5 cm) at the assessments chosen for evaluation. At these assessments, carried out at 29-48 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of 1.9%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 1.2%.~~

~~**Lodging of the spring barley plants:** The mean lodging in untreated plots was 60.3% (range: 33.4-90.0%) at the assessments chosen for evaluation. At these assessments, carried out at 32-81 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of 29.4%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 20.2%.~~.

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

An assessment of resistance risk is not required for a plant growth regulator. Mepiquat-chloride are on successful use since decades in plant production systems for the reduction of unwanted longitudinal shoot growth. From the type of use and the nature of the underlying mode of action it is extremely unlikely that any plant species would lose its sensitivity to this type of plant growth regulator.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

~~Data from 9 efficacy trials in winter wheat and spring barley have been presented for selectivity results conducted in the North-east EPPO zone (9, i.e Poland) have been included in this biological assessment dossier to support the label claims and recommendations on selectivity in the EU Central Registration zone.~~

~~The trials were conducted in Poland (9) in winter wheat and spring barley in 2017 to evaluate the crop safeties of MEPISHA. The Applicant submitted enough phytotoxicity trials for spring barley (6 phytotoxicity trials were presented). On the basis on presented results it can be concluded that tested product is safe for spring barley. No negative effects are expected at recommended dose (0,75 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.~~

~~For winter wheat – not sufficient documentation was presented (only 3 trials are not accepted). As winter wheat is a major crop in Poland, at least 4-5 phytotoxicity trials should be presented. Lack of trials for winter barley and winter oilseed rape (at least 4-5 are required).~~

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 spring barley (6 phytotoxicity trials were presented from efficacy trials and 12 selectivity trials: PL-4, DE-4, CZ-4), winter wheat (3 phytotoxicity trials were presented from efficacy trials and 11 selectivity trials: PL-6, DE-3, CZ-2), winter barley (2 phytotoxicity trials were presented from efficacy trials and 7 selectivity trials: PL-2, DE-1, CZ-4) and winter oilseed rape (8 ~~phytotoxicity~~ trials were presented from efficacy/selectivity trials in Maritime zone and 4 selectivity trials: PL-4). On the basis on presented results it can be concluded that tested product is safe for spring barley, winter barley, winter wheat and winter oilseed rape. No negative effects are expected at recommended dose (0,75 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. However, Applicant submitted 34 additional selectivity trials in which the double dose was studied. In all trials, no negative effect was observed. For winter oilseed rape Applicant also submitted eff./sel. trials carried out in Maritime EPPO zone (8 trials). In those trials, also dose 2 N was studied.

~~For winter wheat – not sufficient documentation was presented (only 3 trials are not accepted). As winter wheat is a major crop in Poland, at least 4-5 phytotoxicity trials should be presented. Lack of trials for winter barley and winter oilseed rape (at least 4-5 are required).~~

Assessment for cMS: ~~in the opinion of Evaluator, trials from only one EPPO zone are not representative for other EPPO zones. However, final decision about possibility of taking results from N-E EPPO zone is left to each cMS.~~ Applicant submitted additional selectivity trials carried out in the Maritime EPPO zone on winter wheat (5 trials: DE-3, CZ-2), spring barley (8 trials: DE-4, CZ-4), winter barley (5 trials: DE-1, CZ-4) and winter oilseed rape (8 trials in DE and CZ – those trials were the same as efficacy, but during them Applicant studied effect of N and 2 N dose on efficacy, phytotoxicity effect, yield and its quality). Only 6 from 8 trials carried out on winter oilseed rape were harvested. So only 6 trials were presented for effects on yield and its quality in Maritime zone. ~~Lack of trials from Maritime EPPO zone for winter oilseed rape. However, in 8 efficacy trials carried out in DE (4 trials) and CZ (4 rials) the phytotoxicity effect of recommended dose (0,75 L/ha) was studied.~~ No negative effects were observed during trials.

No trials for MED and S-E EPPO zone were presented. In the opinion of Evaluator, registration of product in MED and S-E without any trials (eff. and sel.) is not possible. However, final decision is left to cMS..

Effects on yield and quality

~~Nine efficacy trials treated with MEPISHA were harvested and yields recorded. Besides recording yield, assessments were also carried out on the potential impact of treatment on a range of quality parameter including thousand grain weight, moisture content, protein content and others. The efficacy trials were conducted as defined by EPPO Standard PP1/241(1).~~

~~MEPISHA applied at the proposed dose rate, at a range of growth stages within the label recommended rate, in winter wheat and spring barley did not significantly affect the quality of the harvested crop in any of the 9 trials harvested. In all efficacy trials as, MEPISHA 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 MEPISHA is as safe to the crop as the reference products used in the trials. Only for spring barley and N-E EPPO zone submitted documentation is sufficient.~~

No negative impact on yield was recorded during trials. Mepiquat 3.8% SL applied at the recommended dose did not significantly affect the yield. Applicant submitted in total ~~9 trials: 3 trials for winter wheat and 6 trials for spring barley~~. ~~Lack of trials for winter barley and winter oilseed rape.~~ trials for: spring barley (6 phytotoxicity trials were presented from efficacy trials and 12 selectivity trials: PL-4, DE-4, CZ-4), winter wheat (3 phytotoxicity trials were presented from efficacy trials and 11 selectivity trials: PL-6, DE-3, CZ-2), winter barley (2 phytotoxicity

trials were presented from efficacy trials and 7 selectivity trials: PL-2, DE-1, CZ-4) and winter oilseed rape (8 ~~phytotoxicity~~ efficacy/selectivity trials were presented from efficacy trials and 4 selectivity trials: PL-4). For assessing negative effect on yield in winter oilseed rape was used 6 trials from Maritime (6 from 8 trials were harvested and 4 trials from N-E EPPO zone. In the opinion, of Evaluator ~~only for spring barley and N-E EPPO zone~~ submitted documentation is sufficient for N-E and MAR EPPO zone. In the opinion of Evaluator, trials from ~~only~~ ~~one~~ two EPPO zone (N-E and MAR) are not representative for other EPPO zones. However, final decision about possibility of taking results from N-E EPPO zone and MAR EPPO zone is left to each cMS from MED and S-E..

Effect on transformation processes

The crop of cereals is not used later for any transformation process, such as calorific processes, that can alter its composition, therefore according to EPPO standard PP 1/243(1) (*Effects of plant protection products on transformation processes*) no studies are necessary in this section. It has already been shown in effects on the quality of plants section that the application of MEPISHA at the proposed label rate and rates above this rate has no negative effect on the quality parameters assessed in efficacy trials harvested.

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*).

In addition, it should be noted that currently, mepiquat containing products do not have any label restrictions concerning their use on crops destined for processing. Additionally, the active is part of many products which have been used for a long time. Since the market introduction, no effects on transformation processes have been recorded for any of these products.

Finally applicant would like to refer and present data from dRR part B7 Metabolism and Residues where is presented European data from RAR and EFSA to demonstrate to demonstrate the result of a study carried out by the UK in March 2005 and January 2008 to use of MEPISHA on cereals.

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

MEPISHA is composed of mepiquat, which has been widely used for several years on e.g. cereals, without identifying any issues in regards to the ability of treated plant part to be used for propagating purposes.

Thus, negative effects of the active ingredient on parts of plant used for propagating purposes can be excluded due to the plant growth regulator nature of the product. Furthermore, phytotoxicity assessments in the performed trials demonstrated the crop safeties 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.

The impact on succeeding crops is determined in accordance with guidance provided by EPPO standard PP 1/207(2) *'Effect on succeeding crops'*.

The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops.

Therefore, the Applicant presents the assessment of the possible effect of Mepiquat on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance to the EPPO Standard *Efficacy evaluation of plant protection products Effects on succeeding crops (PP 1/207 (2))*. This standard is intended as a general standard on the methods used to examine whether the active

substance of a plant protection product can cause negative effects on crops grown after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.

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 mepiquat is not phytotoxic to the crop claimed in the GAP.

Effects on non-target terrestrial plants of MEPISHA were not evaluated as part of the EU assessment of Mepiquat.

Effects on beneficial and other non-target organisms

From the experimentation carried out with MEPISHA in 2017, 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 MEPISHA in food, fed of plant and animal origin, soil, water and air are available.

3.4.1 Analytical method for the formulation

	Mepiquat chloride
Author(s), year	S. Srinivas, 2019
Principle of method	Ion chromatography
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	5 points 0.0400 mg/mL to 0.4997 mg/mL R = 0.9995 y=6.8382x-0.1136
Precision – Repeatability Mean n = 5 (%RSD)	%RSD = 1.20%
Accuracy n = 6 (% Recovery)	Overall mean recovery: 98.84 ±1.14%
Interference/ Specificity	No interference the method is specific
Comment	LOD = 0.0176 mg/mL LOQ = 0.0198 mg/mL

According to SANCO/3030/99 rev.4 the method was successfully validated and is suitable for determination of mepiquat chloride content in the product MEPISHA/SHA 8500 A.

3.4.2 Analytical methods for residues

3.4.2.1 Mepiquat

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

- none

Commodity/crop	**Supported/ Not supported**
High starch content (Winter wheat, winter barley, spring barley)	Supported
High oil content (Winter oilseed rape)	Supported

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity for MEPISHA was not evaluated as part of the EU review of Mepiquat. Therefore, all relevant data were provided and are considered adequate.

The toxicological classification of MEPISHA is derived from calculations.

3.5.1 Acute toxicity

All relevant data were provided and are considered adequate.

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

3.5.2 Operator exposure

Operator exposure to MEPISHA was not evaluated as part of the EU review of Mepiquat for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential operator exposure have been undertaken for Mepiquat using EFSA AOEM Model and default dermal absorption values (10% concentrate and 50% dilution).

Conclusions: According to the EFSA AOEM Model, it can be concluded that the risk for operator is ac-

ceptable.

Implication for labelling: None.

3.5.3 Worker exposure

Worker exposure to MEPISHA was not evaluated as part of the EU review of Mepiquat for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential worker exposure have been undertaken for Mepiquat using EFSA AOEM Model and default dermal absorption values (10% concentrate and 50% dilution).

Conclusion: According to EFSA AOEM Model, it can be concluded that the risk for worker is acceptable.

Implication for labelling: None.

3.5.4 Bystander and resident exposure

Bystander and resident exposure to MEPISHA was not evaluated as part of the EU review of Mepiquat for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential residents and bystander's exposures have been undertaken for Mepiquat using EFSA AOEM Model and default dermal absorption value (10% concentrate and 50% dilution).

Conclusion: According to the EFSA AOEM Model, it can be concluded that the risk for residents and bystanders is acceptable.

Implication for labelling: None.

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

Toxicological reference values for the dietary risk assessment of Mepiquat chloride

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mepiquat chloride					
ADI	EFSA	2008	0.2 mg/kg bw/d	12-month dietary study in dogs	100
ARfD	EFSA	2008	0.3 mg/kg bw	Development neurotoxicity study in rats	100

Unprotected data were sufficient to support all the uses of Mepiquat 3.8% SL..

3.6.1 Residues

3.6.1.1 Mepiquat

Stability of Residues

Mepiquat chloride has been demonstrated to be stable for a period up to 24 months when stored at ≤ -20°C in high-water content and high starch content matrices.

Data gap: storage stability data for high oil content commodities.

RMS reply to the applicant's comment (Reporting Table)

Applicant provided storage stability data only for wheat matrices. These matrices do not belong to the group high oil content commodities. Extrapolation is not possible.

Nevertheless stability studies on oil matrices were presented in EFSA Journal 2015;13(8):4214. These studies cover the stability of mepiquat for a period of 25 months. Therefore, residues in samples taken in the studies submitted by the applicant are not expected to be unstable (harvest: 07/2020, extraction and analysis: 09/2020).

However, it is the responsibility of the applicant to document the stability of the residues. Applicant can refer to the EFSA, 2015 document if mentioned studies are not protected. This should be checked.

Considering that the applicant has initiated storage stability studies, the evaluator accepts the use on oil seed rape, provided that the study report is submitted after registration.

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

Winter wheat, winter barley, spring barley

Proposed uses:

1 application, BBCH 31-39, 0.0285 kg as/ha (mepiquat) it is equal 0.0375 kg as/ha (mepiquat chloride)

EU GAP (representative use):

1 application, BBCH 31-49, 0.7625 kg as/ha (mepiquat chloride) - SANCO/106/08 – rev. 2; 20 May 2008

Proposed GAP is less critical than EU GAP.

The applicant refers to the trials evaluated in the DAR. These trials are done at higher doses than the proposed use.

GAP on which EU a.s. assessment is based: 1 x 0.76 kg as/ha (mepiquat chloride), BBCH 30-39, PHI 50-57d, outdoor.

Sufficient trials on barley are available to support the proposed uses. According to the SANTE/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.

Winter Oilseed rape

New studies (overdosed) on the magnitude of residue have been submitted by the applicant in the framework of this application. Trials are independent. Analytical method used is accepted. LOQ: 0.01 mg/kg. ~~The studies are not accepted due to the lack of stability data.~~

Considering that the applicant has initiated storage stability studies, the evaluator accepts the use on oil seed rape, provided that the study report is submitted after registration (post registration formal requirement - residues in samples taken in the new studies are not expected to be unstable.)

Magnitude of residues in livestock

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.

3.6.2 Consumer exposure

3.6.2.1 Mepiquat

Consumer risk assessment (EFSA PRIMo rev. 3.1, input: Reg. (EU) 2021/976)

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	23% (based on NL toddler, rape seed/canola seeds (7%))
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	**Unprocessed commodities:** **Based on children:** 14 % Wheat 7% Barley 7% Rapeseeds/canola seeds **Based on adults:** 8% Wheat 6% Barley 3% Rapeseeds/canola seeds **Processed commodities:** **Based on children:** 12% Wheat / milling (flour) 6% Wheat / milling (wholemeal)-baking 5% Barley / cooked 3% Rapeseeds / oils 2% Barley / milling (flour) **Based on adults:** 10% Barley / beer 4% Wheat / bread/pizza 4% Wheat / pasta 4% Wheat / bread (wholemeal)
NTMDI (% ADI)	-

NEDI (% ADI)	-
NESTI (% ARfD)	-

The proposed uses of Mepiquat in the formulation Mepiquat 3.8% SL do not represent unacceptable acute and chronic risks for the consumer.

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

Concentration of Mepiquat and Mepiquat chloride in various environmental compartment are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment and ground water are provided.
For risk assessment was set the sum of mepiquat, 4-hydroxy mepiquat and their salts, expressed as mepiquat chloride (EFSA, 2008).

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The PEC_{soil} of MEPISHA and Mepiquat chloride in soil have been assessed with the focus groundwater interception values and the DT_{50} values established in the EU review. Based on application rate of 28.5 g mepiquat/ha, the maximum initial predicted environmental concentration in soil (PEC_{soil}) of mepiquat was 0.008 mg/kg
Maximum PEC_{soil} value will be used in ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PEC of mepiquat in groundwater has been assessed for with the models FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3. The interception values and the DT_{50} and the soil sorption values established in the EU DAR and/or review.
Maximum PEC_{GW} for mepiquat was lower than **0.1 µg/L** following application on all crops, which is under the 0.1µg/L EU limit for drinking water.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The surface water PEC values for mepiquat were calculated with FOCUS STEPS 1-2 v. 3.2 models as well as physical-chemical properties and data on fate in environment established in the EU review of mepiquat. The maximum PEC_{sw} values in surface water were used for the ecotoxicological risk assessment of aquatic organisms.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance Mepiquat is $< 10^{-5}$ 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 assessment, all the TERa and TERlt values for the active substance mepiquat are greater than the annex VI trigger of 10 and 5, respectively, indicating that MEPISHA presents no unacceptable acute and long-term risk to birds according to the intended uses.

Moreover, the risk for birds due to uptake of contaminated drinking water was considered as low and mepiquat chloride shows low potential for bioaccumulation, hence, there is no risk to earthworm-eating and fish-eating birds according to the intended uses of MEPISHA.

• Mammals:
According to the screening and first tier assessment, all the TERa and TERlt values for the active substance mepiquat chloride are greater than the annex VI trigger of 10 and 5, respectively, indicating that MEPISHA presents no unacceptable acute and long-term risk to mammals according to the intended uses.

Moreover, the risk for mammals due to uptake of contaminated drinking water was considered as low and mepiquat chloride shows low potential for bioaccumulation, hence, there is no risk to earthworm-eating and fish-eating mammals according to the intended uses of MEPISHA.

3.8.2 Effects on aquatic species

For all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Daphnia* acute as characterised by an EC_{50} of 68500 µg/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

Studies on the toxicity to honeybees show that hazard quotients (oral and contact) for mepiquat chloride and the formulation MEPISHA are clearly under the cut-off value. An application of MEPISHA to cereals and oilseed rape in respect of the GAP does not present an unacceptable risk for honeybees. According to EU Reg. 284/2009 the chronic tests for bees and larvae should be submitted by the applicant to the end of 2021 when GD for bees will be implemented at EU level.

3.8.4 Effects on other arthropod species other than bees

The in-field and off-field HQ values calculated for the representative species *T. pyri* and *A. rhopalosiphi*, are lower than the trigger of 2 for first-tier tests, indicating no risk to non-target arthropods in vegetated in-field and off-field areas following application of MEPISHA according to the proposed use patterns.

3.8.5 Effects on soil organisms

• Earthworms and other non-target soil organisms
The a~~cute~~ and chronic TER for Mepiquat chloride are above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, according to the risk assessment and the effects on other soil arthropods, it is concluded that Mepiquat chloride and MEPISHA formulation do not pose acute and long-term risk to earthworms and other soil macro- and mesofauna.

• Soil microorganisms
Risk assessments conducted with relevant PEC_{soil} for the active substance mepiquat indicate a low risk to soil microorganisms when applied according to the proposed use rates. The use of MEPISHA at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

3.8.6 Effects on non-target terrestrial plants

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for mepiquat chloride shows that the Annex VI trigger value of 5 is reached, indicating that MEPISHA poses a low risk to non-target plants when applied according to the proposed use rates.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Mepiquat:
Effects on biological methods for sewage treatment:
Activated sludge respiration > 1000 g mepiquat chloride/L

3.9 Relevance of metabolites (Part B, Section 10)

No metabolite is predicted to occur in groundwater at concentration above 0.1 µg/L (see dRR Part B8, Chapter 8.8).

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

MEPISHA contains Mepiquat which is not approved as a candidate for substitution.
No assessment is required.

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

Authorization can be granted for 1 year.

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

Metabolism and Residues:

Brak uwag. Zastosowania zaakceptowane.~~Zastosowanie w ochronie upraw rzepaku nie zostało zaakceptowane.~~

Sekcja skuteczności:

Wszystkie wnioskowane zastosowania zaakceptowano~~.~~

Załącznik do decyzji MRiRW nr R …z dnia …2021 r.

Posiadacz zezwolenia:
Sharda Cropchem España S.L., Edificio Atalayas Business Center, Carril Condomina nº 3, 12th Floor, 30006 Murcja, Królestwo Hiszpanii, tel.: +34868127589, fax.: +34868127588, e-mail: eu.regn@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
Sharda Cropchem Ltd., Prime Business Park, Dashrathlal Joshi Road, Vile Parle (West), Mumbai – 400 056, Indie, Tel.: + 91 22 6261 5615, Fax: + 91 22 6678 2828/ 2808, Email: regn@shardaintl.com

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

MEPISHA

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
Chlorek mepikwatu (substancja z grupy piperydyn)- 50 g/l (4.91%)

Zezwolenie MRiRW nr R- /2021 z dnia . .2021 r.

EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P102	Chronić przed dziećmi
P501	*Zawartość/pojemnik usuwać do…*

OPIS DZIAŁANIA

MEPISHA jest środkiem z grupy regulatorów wzrostu i rozwoju roślin w formie koncentratu rozpuszczalnego w wodzie, o działaniu układowym w celu zapobiegania nadmiernemu wyrastaniu roślin oraz skracania i wzmacniania łodyg (ograniczenie wylegania). Przeznaczony jest do w pszenicy i jęczmieniu ozimym, jęczmieniu jarym oraz rzepaku ozimym.
Środek MEPISHA przeznaczony jest do stosowania przy użyciu opryskiwaczy polowych.

STOSOWANIE ŚRODKA

Pszenica ozima
Maksymalna dawka dla jednorazowego zastosowania: 0.75 l/ha
Zalecana dawka dla jednorazowego zastosowania: 0.75 l/ha
Liczba zabiegów: 1
Termin stosowania środka: Stosować przed odnotowaniem jakichkolwiek objawów wylegania, od fazy pierwszego kolanka do fazy liścia flagowego (BBCH 31-39)
Zalecana ilość wody: 200-400 l/ha.
Zalecane opryskiwanie: średniokropliste

Jęczmień ozimy
Maksymalna dawka dla jednorazowego zastosowania: 0.75 l/ha
Zalecana dawka dla jednorazowego zastosowania: 0.75 l/ha
Liczba zabiegów: 1
Termin stosowania środka: Stosować przed odnotowaniem jakichkolwiek objawów wylegania, od fazy pierwszego kolanka do fazy liścia flagowego (BBCH 31-39)
Zalecana ilość wody: 200-400 l/ha.
Zalecane opryskiwanie: średniokropliste

Jęczmień jary
Maksymalna dawka dla jednorazowego zastosowania: 0.75 l/ha
Zalecana dawka dla jednorazowego zastosowania: 0.75 l/ha
Liczba zabiegów: 1
Termin stosowania środka: Stosować przed odnotowaniem jakichkolwiek objawów wylegania, od fazy pierwszego kolanka do fazy liścia flagowego (BBCH 31-39)
Zalecana ilość wody: 200-400 l/ha.
Zalecane opryskiwanie: średniokropliste

Rzepak ozimy
Maksymalna dawka dla jednorazowego zastosowania: 0.75 l/ha
Zalecana dawka dla jednorazowego zastosowania: 0.75 l/ha
Liczba zabiegów: 1
Termin stosowania środka: Stosować przed odnotowaniem jakichkolwiek objawów wylegania, od fazy pierwszego kolanka do fazy liścia flagowego (BBCH 31-39)
Zalecana ilość wody: 200-400 l/ha.
Zalecane opryskiwanie: średniokropliste

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ
Środka nie stosować:
- na rośliny osłabione i uszkodzone przez przymrozki, suszę, szkodniki lub choroby
- na plantacjach nasiennych.
Podczas stosowania środka nie dopuścić do:
- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.
Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego do połowy 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 nie wyposażonego 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

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- 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.
Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

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

Środki ostrożności dla osób stosujących środek: (pracowników oraz osób postronnych)

Nie jeść, nie pić ani nie palić podczas używania produktu.
Stosować rękawice ochronne i odzież **roboczą** (kombinezon), 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.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
Nie dotyczy

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

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0ºC - 30ºC, z dala od źródeł ciepła.

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.

Okres ważności – ~~2 lata.~~ 1 rok
Data produkcji -
Zawartość netto -
Nr partii –
UFI –

Appendix 3 Letter of Access

No letter of Access to protected data 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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.4.2 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.8.4	S. Srinivas	2019	Accelerated storage stability test by heating at elevated temperature of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL. Eurofins Advinus Limited Report No. G16596 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 2.2.1	S. Srinivas	2019	Determination of explosive properties of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL. Eurofins Advinus Limited Report No. G16587 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 2.2.2	S. Srinivas	2019	Oxidation/reduction: Chemica incompatibility of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL. Eurofins Advinus Limited Report No. G16588 GLP	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited

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
			Unpublished				
KCP 2.3.3	S. Srinivas	2019	Determination of auto ignition temperature of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL. Eurofins Advinus Limited Report No. G16595 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 2.5.1	S. Srinivas	2019	Determination of viscosity of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL. Eurofins Advinus Limited Report No. G16590 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 2.6.1	S. Srinivas	2019	Determination of density of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL. Report No. G16592 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 2.8.2	S. Srinivas	2019	Determination of peristent foam of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL. Report No. G16593 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 2.11	S. Srinivas	2019	Determination of effectiveness of cleaning by small scale jar test with mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL. Report No. G16594 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 5.1.1	S. Srinivas	2019	Accelerated storage stability test by heating at elevated temperature of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL. Eurofins Advinus Limited	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited

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
			Report No. G16596 GLP Unpublished				
CP 6.0-001	Anonymous	2021	Biological Assessment Dossier: Mepiquat 3.8% SL (38 g/L mepiquat SL) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 8.3.1	R. Figurski	2020	Magnitude of the residue of mepiquat in oilseed rape (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product Mepiquat 21% + Metconazole 3% SL – two harvest and two decline curve trials in Northern Europe – Poland, 2020. Report No. D-2020-04 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 8.3.2	K. Zagibajło	2020	Determination of the residues of mepiquat chloride in oilseed rape after one application of mepiquat 21% + Metconazole 3% SL in four trials (2 DCS and 2 HS), Poland – 2020. Report No. 20/FSL/12/1PL GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 8.3.3	G. Wagner	2020	Determination of the residues of mepiquat in/on oilseed rape after one application of Mepiquat 21% + Metconazole 3% SL in Northern Europe – Hungary in 2020. Report No. 065CPRHU20R04 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 8.3.4	K. Zagibajło	2020	Determination of the residues of Mepiquat chloride in oilseed rape after one application of Mepiquat 21% + Metconazole 3% SL in four trials (2DCS and 2 HS), Hungary – 2020. Report No. 20/FSL/12/1HU GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited

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
KCP 10.2.1-01	xxxxxxxxx	2021	Mepiquat chloride 5.105% w/v equivalent to Mepiquat ion 3.89% w/v SL: Fish, acute toxicity test with rainbow trout. xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP Unpublished	Y		Data/study report never submitted before	Sharda Cropchem Limited
KCP 10.2.1-02	Nazhath, S.	2021	Mepiquat chloride 5.105% w/v equivalent to Mepiquat ion 3.89% w/v SL: Alga, Growth Inhibition Test with *Raphidocelis subcapita*. Eurofins Advinus Limited. Report No. G14245 GLP Unpublished	N		Data/study report never submitted before	Sharda Cropchem Limited
KCP 10.2.1-03	Nazhath, S.	2021	Mepiquat chloride 5.105% w/v equivalent to Mepiquat ion 3.89% w/v SL: *Daphnia magna*, Acute Immobilizaion Test. Eurofins Advinus Limited. Report No. G14246 GLP Unpublished	N		Data/study report never submitted before	Sharda Cropchem Limited
KCP 10.2.1-04	Radha, S.	2021	Study of *Lemna gibba* growth inhibition with Mepiquat Chloride 5.105% w/v equivalent to Mepiquat ion 3.89 w/v SL. Bioscience Research Foundation. Report No. 6090/2019 GLP Unpublished	N		Data/study report never submitted before	Sharda Cropchem Limited
KCP 10.3.1.1.1	Nazhath, S.	2019	Mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL: acute oral toxicity test in honey bees Eurofins Advinus Limited. Report No. G14247 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.3.1.1.2	Nazhath, S.	2019	Mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL: acute contact toxicity test in honey bees Eurofins Advinus Limited. Report No. G14248 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.3.2.1-01	Sonali, G.	2020	A laboratory test for evaluating the effects of Mepiquat Chloride 5.105% w/v equivalent to Mepiquat ion 3.89 w/v SL on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani -	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited

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
			Perez) Bioscience research foundation. 6050/2019 GLP Unpublished				
KCP 10.4.1.1	Murali, K.	2021	Effect of Mepiquat Chloride 5.105% w/v equivalent to Mepiquat ion 3.89 w/v SL on reproduction of the earthworms (*Eisenia fetida*) in artificial soil. Bioscience research foundation. 9549/2021 GLP Unpublished	N	Sharda Cropchem Limited	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.3.2.1-02	Bala, P.	2020	A laboratory test for evaluating the effects of Mepiquat Chloride 5.105% equivalent to Mepiquat ion 3.89 w/v on the predatory mite, *Typhlodromus pyri* (Scheuten) Bioscience research foundation. 6051/2019 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.4.2.1-01	Murali, K.	2020	Effect of Mepiquat Chloride 5.105% w/v equivalent to Mepiquat ion 3.89 w/v SL on the collembolans (*Folsomia candida*) in artificial soil. Bioscience research foundation. 6091/2019 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.4.2.1-02	Rajeshwari, S.	2020	Effect of Mepiquat Chloride 5.105% w/v equivalent to Mepiquat ion 3.89 w/v SL on the Reproductive Output of the Predatory Soil Mite *Hypoaspis* (*Geolaelaps*) *aculeifer* Canestrini (Acari: Laelapidae) in Artificial Soil Bioscience research foundation. 6092/2019 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.5.1	Anand, H. S.	2020	Soil microorganisms: nitrogen transformation test of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL.	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited

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			Eurofins Advinus Limited. Report No. G14252 GLP Unpublished				
KCP 10.5.2	Anand, H. S.	2020	Soil microorganisms: carbon transformation test of mepiquat chloride 5.105% w/v equivalent to mepiquat ion 3.89% w/v SL Eurofins Advinus Limited. Report No. G14251 GLP Unpublished	N	Y	Data/study report never submit-ted before	SHARDA Cropchem Limited
KCP 10.6.2-01	Radha, S.	2020	Effect of Mepiquat Chloride 5.105% w/v equivalent to Mepiquat ion 3.89% w/v SL on seedling emergence and seedling growth of terrestrial plants. Bioscience Research Foundation. Report No. 6093/2019 GLP Unpublished	N	Sharda Cropchem Limited	Data/study report never submit-ted before	SHARDA Cropchem Limited
KCP 10.6.2-02	Radha, S.	2020	Effect of Mepiquat Chloride 5.105% w/v equivalent to Mepiquat ion 3.89 w/v SL on vegetative vigour of terrestrial plants Bioscience Research Foundation. Report No. 6094/2019 GLP Unpublished	N	Sharda Cropchem Limited	Data/study report never submit-ted before	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	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