

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

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

MS Finalisation date: September 2021 ; February 2022

April 2022

Version history

When	What
September 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 MRiRW comments.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

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.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 for mepiquat and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	-	-
Central zone	Poland	-
Southern zone	To be confirmed	To be confirmed
Inter-zonal	-	-

0.1.3 Regulatory history of the actives

0.1.3.1 Mepiquat chloride (mepiquat)

Table 0.1-2: Summary of regulatory history of mepiquat chloride (CAS No: 24307-26-4)

Status	
Approved in EU	Y
Original Inclusion Directive Commission Implementing Regulation	Commission Directive 2008/108/EC Commission Implementing Regulation (EU) No 2021/52
RMS	RMS: Finland Co-RMS: Estonia
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.03.2009
Date of first Commission (re-registration) deadline (Step 1) or date of	31.08.2009

Status	
deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline (Step 2)	28.02.2013
Current expiration of approval	28.02.2022
Low risk substance or Candidate for Substitution?	N/A

In this overall assessment Member States must pay particular attention to the residues in food of plant and animal origin and evaluate the dietary exposure of consumers.

The SANCO report for Mepiquat (SANCO/106/08 – rev. 2 – 20 May 2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 14 April 2008 (EFSA Scientific report (2008) 143,1-73).

Table 0.1-3: Information on minimum purity of mepiquat chloride (CAS No: 24307-26-4)

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
990 g/kg	990 g/kg Equivalence report available: on-going RMS: Spain

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The information on the equivalence of the active substances sources has been provided by the Applicant to the Polish Ministry of Agriculture and Rural Development and assessed and approved by the Ministry during the completeness check.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

Efficacy section: ~~only spring barley from use no.~~ 1-2
Residues section: 1-2
Environmental fate and behavior section: 1-2
Ecotoxicology section: 1-2

Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: ~~winter barley and winter wheat from use no. 1, use no. 2~~ none

Residues section: ~~2~~ none

Environmental fate and behavior section: none

Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with assessment to be confirmed.

The following text is to be shortened or to be amended as necessary.

Metabolism and Residues section:

All uses/ GAPs are covered by established MRLs ~~except for use in Winter Oilseed rape.~~

Conclusions:

Physical and chemical properties section:

Authorization can be granted for 1 year

Efficacy section:

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 in Poland, CMS from S-E and MED should decide if Mepisha can be accepted by them on the basis on extrapolation results from N-E EPPO zone and MAR EPPO zone. CMS from Maritime should decide if Mepisha can be accepted on the basis on submitted documentation.

Mammalian toxicology section:

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

Metabolism and Residues section:

Data gap: storage stability data for high oil content commodities (post registration formal requirement - residues in samples taken in the new studies are not expected to be unstable).

Ecotoxicology Section:

All uses are acceptable for non-target organism

Appendix 1 ALL intended uses

GAP rev. 0, date: 2021-January-19th

PPP (product name/code): MEPISHA / SHA 8500 A
Active substance 1: Mepiquat chloride (mepiquat)
Active substance 2:
Safener: -
Synergist: -
Applicant: SHARDA Cropchem España
Zone(s): Central
Verified by MS: yes/no

Formulation type: SL (Soluble concentrate)
Conc. of as 1: 50 g/L (38 g/L)
Conc. of as 2:
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. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, 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 ^(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 section: use on winter oilseed rape is not accepted. Residues section: Not accepted 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	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/m³ 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