

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 126085 A

Product name: MEPCY

Chemical active substances:

Chlormequat chloride, 345 g/L

Mepiquat chloride, 115 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem Ltd.

Submission date: February 2022

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

Version history

When	What
May 2023	ZRMS assessment of dRR.
August 2023	Final version of RR after commenting period.
January 2024	Update of the final version of RR (point 0.1.3 and 0.2)
May 2024	Final version of RR after second round of commenting.

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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 CROP CHEM Ltd. for approval of MEPCY, a soluble concentrate containing 345 g/L of Chlormequat (as chloride) and 115 g/L of Mepiquat (as chloride) for use as plant growth regulator on winter wheat in Central Europe.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 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)
Central zone	Poland MEPCY	-
Southern zone	Spain MEPCY	-

0.1.3 Regulatory history of the actives

0.1.3.1 Chlormequat chloride

Table 0.1-2: Summary of regulatory history of CAS No: 999-81-5 (Chlormequat chloride)

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2010/2/EU Commission Implementing Regulation (EU) No 540/2011 Commission Implementing Regulation (EU) 2021/1449 2022/1480 2023/1757 (extension of approval)
RMS	UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.12.2009

Status	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	28.05.2010
Date of final Commission (re-registration) deadline (Step 2)	31.05.2014
Current expiration of approval	30.11.2022 30.11.2023 28.02.2027
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment.
- the protection of birds and mammals.

The SANCO report for Chlormequat (SANCO/175/08 final rev 2 – 29 May 2015) 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 29 September 2008 (EFSA Scientific Report (2008) 179, 1-77).

Table 0.1-3: Information on minimum purity of Chlormequat

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 *, **
636 g/kg	900 g/kg (Chlormequat chloride) Equivalence report available: On-going Yes 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.

0.1.3.2 Mepiquat **chloride**

Summary of regulatory history of CAS No: 24307-26-4 (Mepiquat chloride)

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/108/EC Commission Implementing Regulation (EU) No 540/2011 Commission Implementing Regulation (EU) 2021/2068 2023/114 2024/324 (extension of approval)
RMS	UK
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 deadline for renewal of authorization (renewal)	31.08.2009

Status	
Date of final Commission (re-registration) deadline (Step 2)	28.02.2013
Current expiration of approval	28.02.2023 29.02.2024 15.10.2025
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the residues in food of plant and animal origin and evaluated 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) 146, 1-73).

Table 0.1-4: Information on minimum purity of Mepiquat

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 (mepiquat chloride) Equivalence report available: Yes 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.

0.1.4 Regulatory history of the product (if relevant)

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: 1

Metabolism and residues: 1

Fate: 1

Ecotoxicology: 1

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

Efficacy section: none

Metabolism and residues: none

Fate: none

Ecotoxicology: 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:

Metabolism and residues: none

Metabolism and residues: Use/ GAP is covered by established MRLs except for use in crop.

Section physical-chemical properties:

~~Lack of the determination of the level of relevant impurities in the formulation (the study is ongoing).~~

None

Section analytical methods:

~~Lack of developed and validated analytical method for the determination of relevant impurities in the formulation (the study is ongoing).~~

Efficacy section:

Accepted registration of MEPCY applied once a season (2.0 L/ha) against reducing of height and to prevent lodging on winter wheat crops at BBCH 29-32 in PL. Decision about acceptance of MEPCY left to each cMS on the basis on submitted documentation.

Mammalian toxicology:

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

Metabolism and residues:

Use is accepted.

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

Fate:

The result of the MEPCY evaluation indicates that it does not pose risk to groundwater when is used in accordance with the product label. No further evaluation is required.

Ecotoxicology:

Use is not accepted.

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

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

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

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

Appendix 1 ALL intended uses

PPP (product name/code): MEPCY /SHA 126085 A
Active substance 1: Chlormequat chloride
Active substance 2: Mepiquat chloride
Safener: -
Synergist: -
Applicant: Sharda Cropchem Ltd.
Zone(s): Central
Verified by MS: yes

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

Field of use: Plant growth regulator

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(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: 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	F	Reduction of height to prevent lodging	Foliar Spray	BBCH 29-32	a) 1 b) 1	NA	a) 2.0 b) 2.0	a) 0.69 chlomequat chloride + 0.23 mepiquat chlo- ride b) 0.69 chlomequat chloride + 0.23 mepiquat chlo- ride	200- 400		

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:	<p>1 Numeration necessary to allow references</p> <p>2 Use official codes/nomenclatures of EU Member States</p> <p>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)</p> <p>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</p> <p>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.</p> <p>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.</p>	<p>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</p> <p>8 The maximum number of application possible under practical conditions of use must be provided.</p> <p>9 Minimum interval (in days) between applications of the same product</p> <p>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.</p> <p>11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.</p> <p>13 PHI - minimum pre-harvest interval</p> <p>14 Remarks may include: Extent of use/economic importance/restrictions</p>