

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 126000 B

Product name: CLARA

Chemical active substances:

Chlormequat chloride, 720 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Sharda Cropchem Ltd.

Submission date: February 2022

MS Finalisation date: June 2023; October 2023 February 2024

March 2024

Version history

When	What
02/2022	Submission date
06/2023	ZRMs evaluated dRR submitted by Applicant.
10/2023	The Final Registration Report
02/2024	Efficacy section made changes in fRR in line to reviewed comments from MRiRW.
03/2024	Corrected by zRMS

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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 CLARA, a soluble concentrate containing 720 g/L of Chlormequat (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 CLARA	-
Southern zone	Spain CLARA	-

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 (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
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 Y RMS: Spain (2022)

* 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

Residues section: 1

Environmental fate and behavior section: 1

Ecotoxicology section: 1

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

Efficacy section: none

Residues section: 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:

Metabolism and residues: none

Metabolism and residues: Use/ GAP is covered by established MRL.

zRMS main conclusions:

Efficacy section:

CLARA can be registered in PL ~~only~~ against reduction of height and conditionally against preventing use against lodging ~~not accepted~~. cMS decide about possibility of granted CLARA according to claimed GAP and its national rules.

Mammalian toxicology:

SHA 126000 B / CLARA is classified Acute Tox.4/H302. No unacceptable risks to operators have been identified when the product is used as intended and with appropriate PPE

Metabolism and residues:

Use is accepted.

Fate and behaviour:

No risk for ground water is expected after application of product according proposed GAP.

Ecotoxicology section:

Use is accepted. In addition, the chronic study for adult bees and a study effects on honey bee development and other honey bee life stages was submitted by Applicant. The chronic studies were accepted by zRMS in updated RAR. However, the risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level. Final decision should be taken into account at MSs level.

[illegible]

[illegible]

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 ap-
plication

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 EPPG-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