

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 9100 A

Product name : HYCOP

Chemical active substance:

Copper hydroxide, 500 g/kg (as Cu)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2019

MS Finalisation date: 02.2021; 10.2021

Version history

When	What
August 2019	Dossier submitted by Sharda
February 2021	Evaluated by RMS
October 2021	Final version of the RR after commenting

Table of Contents

0	Product background, regulatory context and GAP information	4
0.1	Introduction.....	4
0.1.1	Reason for application	4
0.1.2	Details of zRMS(s) and concerned MS	4
0.1.3	Regulatory history of the active(s).....	4
0.1.3.1	Copper hydroxide.....	4
0.1.4	Regulatory history of the product (if relevant)	6
0.2	zRMS conclusion	6
Appendix 1	ALL intended uses	9

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 ESPAÑA S.L. for approval of HYCOP, a wettable powder formulation containing 500 g/kg copper hydroxide for use as a fungicide on grapevine, potato, solanaceous fruits (tomato, aubergine) and pome fruits (apple, pear, quince) in central Europe. This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 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 HYCOP	Germany HYCOP
Southern zone	Malta HYCOP	Spain HYCOP

0.1.3 Regulatory history of the active(s)

0.1.3.1 Copper hydroxide

Table 0.1-2: Summary of regulatory history of CAS No: 20427-59-2

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Original inclusion: Commission Directive 2009/37/EC Renewal: Commission Implementing Regulation (EU) 2018/1981
RMS	RMS: France, Co-RMS: Germany
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2019
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01/04/2019

Status	
Date of final Commission (re-registration) deadline (Step 2)	01/04/2020
Current expiration of approval	31/12/2025
Low risk substance or Candidate for Substitution?	<p>The Commission considers that copper compounds are candidates for substitution for the following reasons:</p> <ul style="list-style-type: none"> • copper compounds are persistent substances (given that the half-life in soil is greater than 120 days) and • toxic substances (given the long-term no-observed effect concentration for aquatic organisms is less than 0.01 mg/L. <p>However, the applicant disagrees with this classification and is challenging the application of the 'P' criteria to inorganic substances under Reg 1107/2009 since it is not applied to such substances under Regs. (EU) 528/2012 or 1278/2008.</p>

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

Only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years shall be authorised.

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

- the operator, worker and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment and other mitigation measures as appropriate;
- the protection of water and non-target organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate;
- amounts, in terms of rates and number of applications, do not exceed the minimum necessary to achieve the desired effects and do not cause any unacceptable effect on the environment taking into account background levels of copper at the application site, and, where the information is available, copper input from other sources. Member States may in particular decide to set a maximum annual application rate not exceeding 4 kg/ha of copper.

The renewal report for copper compounds (SANTE/10506/2018 Rev. 5 - 27 November 2018) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. It is available a new EFSA scientific output approved on 20 December 2017 (EFSA Journal 2018;16(1):5152) superseding the previous output published on 22 October 2008 (EFSA Scientific Report (2008) 187, 1-101) and confirmatory data published on 21 June 2013 (EFSA Journal 2013;11(6):3235) for environmental fate and behaviour and ecotoxicology data.

Table 0.1-3: Information on minimum purity of Copper hydroxide

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalence report *, **
573 g/kg (Regulation EU 2018/1981)	<p>minimum purity of active substance: 930 g/kg as copper hydroxide, 600 g/kg expressed as total copper</p> <p>Equivalence report available: No Yes. Evaluation ongoing</p> <p>RMS: Spain</p>

- * 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 following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Table 0.1-4: Endpoints used in this submission that differ from the EU agreed endpoint

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Dermal penetration	Concentrate: 1% Spray dilution (0.33 g Cu/L): 9%	Concentrate: 1% Spray dilution (0.33 g Cu/L): 9%
Fish - Acute toxicity	Mortality, LC ₅₀ (96 h) = 0.207 mg/L total (mm); 0.0344 mg/L dissolved (mm)	ETO- RAC _{sw;ch} = 0.0048 mg/L dissolved
Fish – Chronic toxicity	Growth, EC ₁₀ (53-d) = 0.0012 mg/L (dissolved Cu)	ETO- RAC _{sw;ch} = 0.0048 mg/L dissolved
Aquatic invertebrate – Acute toxicity	Mortality, LC ₅₀ (48 h) = 0.0308 mg/L total (mm); 0.0266 mg/L dissolved (mm)	ETO- RAC _{sw;ch} = 0.0048 mg/L dissolved
Aquatic invertebrate – Chronic toxicity	Reproduction, NOEC (21 d) = 0.0076 mg/L total (gmm)	ETO- RAC _{sw;ch} = 0.0048 mg/L dissolved
Sediment dwelling organism – chronic toxicity (water spike)	NOEC (28 d) = 0.50 mg/L total (nom)	ETO- RAC _{sw;ch} = 0.0048 mg/L dissolved
Sediment dwelling organism – chronic toxicity (sediment spike)	NOEC (28 d) = 16.17 mg/kg dry weight normalized to 2.5% OC	SSD-HC5 = 40.4 mg/kg dry weight normalized to 2.5% OC
Algae – Chronic toxicity	Growth rate, ErC ₅₀ (72h) = 0.02229 mg/L total (nom)	ETO- RAC _{sw;ch} = 0.0048 mg/L dissolved
Indoor microcosm study	NOEC = 0.0048 mg/L dissolved (mm) (AF = 2 applied)	NOEC = 0.0048 mg/L dissolved (mm) (AF = 1 applied)

* See relevant section for a detailed explanation
(nom) nominal concentration; (mm) mean measured concentration; (gmm) geometric mean measured concentration

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: : 1-4
Residues section: 1-2
Fate section: 1-4
Ecotoxicology section: The risk assessment for all intended uses for aquatic organism is not finalised according to EFSA 2018. The risk for aquatic organism should be updated by the applicant. 1, 3 and 4 (late application). For use 2 an acceptable risk is concluded for 3 x 1200 g Cu/ha/

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

Efficacy section: none
Residues section: 3
Fate section: none
Ecotoxicology section: The risk assessment for all intended uses for aquatic organism is not finalised according to EFSA 2018. The risk for aquatic organism should be updated by the applicant. Non safe uses is identified for (potato) for 4 x 2 kg/ha and 3 x 2.4 kg /ha and for 3 x 2.4 kg product/ha for Solanaceous fruits (Tomato, aubergine). Non safe uses is identified for (potato) for 4 x 2 kg/ha ha and early application in orchards for max dose 3 x 2.4 kg/ha.

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:

Residues section: 4

The risk for aquatic organism should be updated by the applicant.

Residues section:

All uses/ GAPs are covered by established MRLs except for use in Solanaceous fruits.

Ecotoxicology Section:

The risk for aquatic organism should be considered at MSs level. Risk for sediment dwelling organism should be decided at MSs level. The risk mitigation measures to bees should be decided at MSs level.

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Physical and chemical properties section:

The equivalency report for a.s. copper hydroxide did not include assessment of the relevant impurities Co, Cr, Sb, and Hg, therefore the authorisation could be granted when the Applicant provided updated equivalency report including relevant impurities Co, Cr, Sb, and Hg.

Efficacy section:

The final decision to accept uses is left to cMS. The dose of LWA depends to a large extent on the height of the seed-lings, therefore it should be individualized by each cMS based on the average height of crops, row spacing, etc. Detailed assessment is presented in B3.

Residues section

A letter of access to protected data for copper compound allowing the renewal of approval is submitted by applicant to support the application for HYCOP.

Pome fruit (apple, pear, quince)

There is no agreement on the proposed use because the provided new studies are not in line with it.

It is possible to accept the application in line with the GAP of the provided new trials. GAP corrections were made in accordance with the GAP of this field new trials.

Solanaceous fruits (Tomato, aubergine)

The EU data (EFSA, 2008; EFSA Journal 2018;16(1):5152) are sufficient to cover proposed uses in SEU and protected uses in NEU and SEU. There is no sufficient data to cover proposed uses in outdoor NEU.

Toxicology Section:

Classification and labeling are acceptable. The assessment of the operator, **employee worker**, resident / bystander in relation to HYCOP indicates that there is no unacceptable risk when the product is used in accordance with the specified PPE for the purpose and label

Appendix 1 ALL intended uses

GAP rev. 0, date: 2016-June-23th

PPP (product name/code): Copper hydroxide 50% WP
Active substance 1: Copper hydroxide
Active substance 2: -
Safener: -
Synergist: -
Applicant: SHARDA CROP CHEM ESPAÑA S.L.
Zone(s): CENTRAL
Verified by MS: yes/no

Formulation type: WP (Wettable powder)
Conc. of as 1: 500 g/Kg (Expressed as Cu)
Conc. of as 2: -
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

Field of use: Fungicide

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		
1	CEU	Grapevine	F	Downy mildew (<i>Plasma- para viticola</i>)	Foliar Spray	BBCH 15-85	a) 4 b) 4	7-12	a) 2.0 b) 8.0	a) 1.0* b) 4.0*	800- 1000	21	* Expressed as Cu Ecotox Section: The risk is not finalised for aquatic organism.

2	CEU	Potato	F	Late blight (<i>Phytophthora infestans</i>)	Foliar Spray	BBCH 15-85	a) 3 b) 3	7-12	a) 2.0-2.4 b) 7.2-8.0	a) 1.0-1.2* b) 3.6-4.0*	500-1000	14	* Expressed as Cu Ecotox Section: The risk is not finalised for aquatic organism. Not acceptable risk for non-target arthropods for max. rates.max dose 4 x 1 kg Cu/ha.
3	CEU	Solanaceous fruits (Tomato, aubergine)	F	Late blight (<i>Phytophthora infestans</i>)	Foliar Spray	BBCH 15-85	a) 3 b) 3	7-10	a) 1.5-2.4 b) 4.5-7.2	a) 0.75-1.2* b) 2.25-3.6*	500-1000	3	* Expressed as Cu Residues section: use is not accepted Ecotox Section: The risk is not finalised for aquatic organism. The max. acceptable dose is 3 x 1.5 kg product/ha for non target arthropods.
4	CEU	Pome fruit (apple, pear, quince)	F	Scab (<i>Venturia spp.</i>)	Foliar Spray	BBCH 15-85	a) 5- 3 b) 5- 3	10	a) 1.15-2.4 b) 5.75- 7.2	a) 0.575-1.2* b) 2.875-3.6*	800-1000	14 21	* Expressed as Cu 3 applications for dose of 2.4 kg/ha, kg/ha (only for cMS) and 1.15 kg/ha (only for PL) Ecotox Section: The risk is not finalised for aquatic organism Not acceptable risk for early application for max doses 3 x 1.2 kg Cu/ha..

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.

