FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: SHA 6821 A

Product name(s): PRIORITY

Chemical active substances:

Dimethomorph, 150 g/kg
Dithianon, 350 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2019

MS Finalisation date: 03/2022; 01/2024

Version history

When	What
February 2022	Updated by Applicant
March 2022	ZMRS assessment.
January 2024	The final Registration Report

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application was submitted by Sharda Cropchem España S.L. for approval of PRIORITY (Dimethomorph 15% + Dithianon 35% WG), a water dispersible granules formulation containing 150 g/kg and 350 g/kg of Dimethomorph and Dithianon, respectively, for a use as a fungicide on grapevine.
zRMS: Poland

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)**
Northern zone	-	-
Central zone	Poland PRIORITY	-
Southern zone	Malta PRIORITY	
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Dimethomorph

Table 0.1-2: Summary of regulatory history of CAS No: 110488-70-5

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011
RMS	Netherlands
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.10.2007

Status	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.03.2008
Date of final Commission (re-registration) deadline (Step 2)	30.09.2011
Current expiration of approval	~~31.07.2018~~ 15.02.2025
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 safety of operators and workers and ensure that conditions of use prescribe the application of adequate personal protective equipment
- the protection of birds, mammals and aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones.

The SANCO report for Dimethomorph (SANCO/10040/06 – rev. 3) 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 23 June 2006 (EFSA Scientific Report (2006) 82, 1-69).

Table 0.1-3: Information on minimum purity of Dimethomorph

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 *, **
965 g/kg (E/Z isomer ratio 44/56)	Minimum purity of the technical active substance of 985 g/kg Equivalence report available: Y RMS: UK

* 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 used endpoints during the evaluation are identical to those used during the EU review.

0.1.3.2 Dithianon

Table 0.1-4: Summary of regulatory history of CAS No: 3347-22-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011
RMS	Greece
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.06.2011
Date of first Commission (re-registration) deadline (Step 1) or date of	30.11.2011

Status	
deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline (Step 2)	31.05.2015
Current expiration of approval	~~31.05.2021~~ 31.08.2024
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 protection of aquatic organisms. Conditions of use shall include risk mitigation measures, such as buffer zones, where appropriate,
- the operator safety. Conditions of use shall prescribe the application of adequate personal protective equipment, where appropriate,
- long-term risks to birds. Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for Dithianon (SANCO/10349/2011 final) 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 25 November 2010 (EFSA Journal 2010;8(11):1904).

Table 0.1-5: Information on minimum purity of Dithianon

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 *, ** **
930 g/kg	Minimum purity of active substance: 1st source 97.5% 2nd source 98%, Equivalence report available:Y RMS:UK, PL

* 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 used endpoints during the evaluation are identical to those used during the EU review.

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: 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:

Ecotox Section: The risk mitigation for aquatic organism should be considered at MSs level.

Residues section:
All uses/ GAPs are covered by established MRLs

Conclusions:

Physicochemical properties Section:
Shelf life – 2 years
Recommended packagings are accepted.
Efficacy section:
PRORITY can be registered in Poland to protect grapevine against Plasmopara viticola. Accepted dose is 1,5 kg/ha applied max. 3 per season. On the basis on results from Czech Republic and average LWA (10813), the proposed dose LWA for Poland should be: 1,39 kg/ha LWA.
Mammalian toxicology section:
According to the toxicological property classification and labelling of product under Regulation (EC) No 1272/2008: Acute Tox.4/H302, Skin SEns.1B/H317, Eye Irrit.2/H319, Repr.2/.H360F
According to the AOEM model, calculations, it can be concluded that the risk for the operator using PRIORITY is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application
It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering grapes treated with PRIORITY a time period of 15 day after application is respected or without gloves when a time period of 22 days after ap-plication is respected
It is concluded that there is no unacceptable risk anticipated for the adult residents and bystanders However, for dithianone there is a risk for children during entry into treated crops. The calculation shows that change buffer zone and drift reduction is not related as the risk for children is only when they enter into treated crop
It can be concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to PRIORITY.
NOTE: Entrance into treated crop prohibited for children.
Fate and behaviour:
Both active ingredient and their metabolites not to pose any risk for groundwater contamination.
No concerns for air compartment are expected.
Ecotoxicology: The risk for non-target organisms is considered acceptable.

Appendix 1 ALL intended uses

GAP rev. 0, date: 2016-November-28th

PPP (product name/code):	PRIORITY (Dimethomorph 15%+Dithianon 35% WG)/ SHA6821A	Formulation type:	WG (Water dispersible granules) (a, b)
Active substance 1:	Dimethomorph	Conc. of as 1:	150 g/kg (c)
Active substance 2:	Dithianon	Conc. of as 2:	350 g/kg (c)
Safener:	-	Conc. of safener:	- (c)
Synergist:	-	Conc. of synergist:	- (c)
Applicant:	Sharda Cropchem España S.L.	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	yes/no		

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: 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	**Grapevine**	F	*Plasmopara viticola*	Foliar Spray	BBCH 55-79	a) 3 b) 3	10-12	a) 1.5 b) 4.5	a) 0.225 dimethomorph + 0.525 dithianon b) 0.675 azoxystrobin + 1.575 difenoconazole	800-1000	42	

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