FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: SHA 7216 A

Product name: CIAZ

Chemical active substances:

Boscalid, 233 g/L

Difenoconazole, 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2021

MS Finalisation date: March 2022, December 2022

Version history

When	What
March 2022	Draft assessment of dRR performed by the zRMS
December 2022	ZRMs made corrections according to reviewed comments.

Table of Contents

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 CIAZ (Boscalid 23.3% + Difenoconazole 6.6% SC), a Suspension Concentrate containing 233 g/L of Boscalid and 66 g/L of Difenoconazole for use as fungicide on winter wheat 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 CIAZ	Germany CIAZ
Southern zone	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Boscalid

Table 0.1-2: Summary of regulatory history of CAS No: 188425-85-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/44/EC and Commission Implementing Regulation (EU) No 540/2011
RMS	Original RMS: Germany RMS: Slovakia Co-RMS: France
Date of Approval (or most recent renewal) of Active Substance	01.08.2008

Status	
(date of Regulation to be applied)	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.01.2009
Date of final Commission (re-registration) deadline (Step 2)	31.01.2010
Current expiration of approval	~~2022~~ 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,
- the long-term risk to birds and soil organisms,
- the risk of accumulation in soil if the substance is used in perennial crops or in succeeding crops in crop rotation

The SANCO report for Boscalid (SANCO/3919/2007 – rev. 5 – 21/01/2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is not available.

Table 0.1-3: Information on minimum purity of Boscalid

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 *, ** **
960 g/kg	minimum purity of active substance: 970 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 following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	**Active Substance**	
	EU agreed endpoint from SANCO/3919 /2007-rev. 5 – 21 January 2008	**Endpoint used**
Dermal absorption	7% for concentrate and dilution based on rat *in vivo* and rat-human *in vitro* studies (formulation BAS 510 01 F, 50% WG)	Default values for dermal absorption : 10% undiluted, 50% diluted.

0.1.3.2 Difenoconazole

Table 0.1-4: Summary of regulatory history of CAS No: 119446-68-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/69/EC and Commission Implementing Regulation (EU) No 1100/2011
RMS	Original RMS: Sweden RMS: Spain Co-RMS: UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.06.2009
Date of final Commission (re-registration) deadline (Step 2)	31.12.2013
Current expiration of approval	31.12.~~2021~~ 2023
Low risk substance or Candidate for Substitution?	CfS

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

The SANCO report for Difenoconazole (SANCO/830/08 – rev. 2 – 10/03/2008) 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 2011 (EFSA Journal 2011; 9(1):1967).

Table 0.1-5: Information on minimum purity of Difenoconazole

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 *, ** **
940 g/kg	Minimum purity of the technical active substance of 940 g/kg Equivalence report available: Y RMS: Sweden

* 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.

Endpoint	Active substance	
	EU agreed endpoint from EFSA Journal 2011;9(1):1967	**Endpoint used EFSA Journal 2017;15(6):4873**
Dermal absorption	Reference formulation values for dermal absorption: 2% undiluted, 4% diluted	Default values for dermal absorption : 10% undiluted, 50% diluted.

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: 1-3 (however, in Poland: 1-2)

Residues section: 1-3

Environmental fate and behavior section: 1-3

Ecotoxicology section: 1-3

Uses to be considered non-safe on the basis of EU methodology: none

Efficacy section: none (however, in Poland 3)

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: none

The risk mitigation measures for aquatic organisms and data for chronic risk for bees should be considered at MSs level.

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

CONCLUSIONS

Physicochemical properties section:
Shelf life – 2 years when stored in recommended packaging.

Efficacy section:

On the basis on limited number of trials, each cMS should decide if use on winter wheat against SEPTTR or/and SEPTSP, FUSASP and PUCCRE~~T~~ or/and PUCCST can be acceptable. In Poland only use against SEPTTR and PUCCST~~RT~~ is accepted, use against FUSASP and PUCCRE should be deleted from GAP table and label project. Also, in PL water volume 200-300 L/ha should be accepted (400 L/ha was not studied during trials valid for PL).

Mammalian toxicology section:
According to the Regulation (EC) 1272/2008 of SHA 7216 A/ CIAZ is classified Carc.2/H351 and with EUH208:Contains 1,2-benzisothiazol-3(2H)-one.. May produce an allergic reaction
No risk for operator, worker, bystander and resident exposure and is acceptable.

Metabolism and residues section:
Accepted PHI: 50 days

Fate Section:
No risk of groundwater contamination with Difenoconazole and Boscalid their metabolites is expected when the product is applied according to Good Agricultural Practice.

Ecotox Section:
The risk assessment is for non-target organisms is considered as acceptable.

Appendix 1 ALL intended uses

GAP rev. 0, date: August 2021

PPP (product name/code):	CIAZ (SHA 7216 A)	Formulation type:	SC (Suspension concentrate)
Active substance 1:	Boscalid	Conc. of as 1:	233 g/L
Active substance 2:	Difenoconazole	Conc. of as 2:	66 g/L
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
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	**Winter wheat**	F	*Septoria spp.* SEPTSP and/or SEPTTR)	Foliar spray	BBCH 30-59	a) 2 b) 2	14	a) 1.5 b) 3	a) 0.35 boscalid + 0.1 difenoconazole b) 0.7 boscalid + 0.2 difenoconazole	200-400	50	**Metabolism and residues section:** Accepted PHI: 50 days **Efficacy section**: in PL water volume should be 200-300 L/ha. In PL only SEPTTR can be registered.
2	CEU	**Winter wheat**	F	*Puccinia spp.* (PUCCST and/or PUCCRE)	Foliar spray	BBCH 30-59	a) 2 b) 2	14	a) 1.5 b) 3	a) 0.35 boscalid + 0.1 difenoconazole b) 0.7 boscalid + 0.2	200-400	50	**Metabolism and residues section:** Accepted PHI: 50 days **Efficacy section**: in PL water volume should

										difenoconazole			be 200-300 L/ha. In PL only PUCCST can be accepted,
3	CEU	**Winter wheat**	F	*Fusarium spp.*	Foliar spray	BBCH 39-59	a) 2 b) 2	14	a) 1.5 b) 3	a) 0.35 boscalid + 0.1 difenoconazole b) 0.7 boscalid + 0.2 difenoconazole	200-400	50	**Metabolism and residues section:** Accepted PHI: 50 days **Efficacy section:** not acceptable in Poland

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