

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 7216 A

Product name: CIAZ

Chemical active substance:

Boscalid, 233 g/L

Difenoconazole, 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

(Authorization)

Applicant: Sharda Cropchem España S.L.

Submission date: August 2021

MS Finalisation date: 03/2022; 12/2022

Version history

When	What
03/2022	Draft assessment of dRR performed by the zRMS
12/2022	ZRMs made corrections according to reviewed comments.

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Sharda Cropchem España S.L.

This application is for approval of Boscalid 23.3% + Difenoconazole 6.6% SC, a suspension concentrate containing 233 g/L of Boscalid and 66 g/L of Difenoconazole, as a fungicide on winter wheat.

zRMS: Poland
cMS: Germany

1.2 Letters of Access

Not application. Letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relies on tests and studies already evaluated and already approved in Poland for plant protection product ELANZA, providing data and information specific to the formulation Boscalid 23.3% + Difenconazole 6.6% SC as required by the EU regulations.

1.4 Data protection claims

Data protection is claimed in accordance with the Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 7216 A
Product name in MS	CIAZ
Authorization number	First authorisation
Function	Fungicide
Applicant	Sharda Cropchem España S.L.
Active substance(s) (incl. content)	Boscalid, 233 g/L Difenocoanole 66 g/L
Formulation type	Suspension Concentrate [Code: SC]
Packaging	250 mL, 500 mL, 1 L, 5 L, 10 L (PE/EV);

	20 L (Fluorinated HDPE)
Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for Boscalid 23.3% + Difenoconazole 6.6% SC (CIAZ) resulted in the decision to grant the authorization

Efficacy section: In Poland only use against SEPTTR and PUCST ~~RE~~ is accepted **conditionally**, 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). 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 ~~or/and~~ **or/and PUCST** can be acceptable.

Mammalian toxicology: 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

2.3 Substances of concern for national monitoring

Not relevant.


2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	H410 Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	
Signal word:	Warning
Hazard statement(s):	H410: Very toxic to aquatic life with long lasting effects H351- Suspected of causing cancer
Precautionary statement(s):	P260,P280, P308+P313, P501

Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazol-3(2H)-one (2634-33-5). May produce an allergic reaction. [EUH208]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains 1,2-benzisothiazol-3(2H)-one (2634-33-5). May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organism 5 m vegetative buffer strip is required to surface water bodies
SP3	To protect plants and non-target arthropods 1 m buffer zone from non-agricultural land is required.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
P280	Wear protective gloves, protective clothing.
Worker protection:	
	Without RPE/PPE.
	Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
-	-

Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
SPe3	To protect aquatic organism 5 m vegetative buffer strip is required to surfacewater bodies	-

2.6 Intended uses (only NATIONAL GAP)

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: 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 PL	Winter wheat	F	Septorio tritici spp. SEPTTR	Foliar spray	BBCH 30-59	a) 2 b) 2	14	a) 1.5 b) 3.0	a) 0.35 boscalid + 0.1 difenoconazole b) 0.7 boscalid + 0.2 difenoconazole	CEU PL	50	Metabolism and residues section: Accepted PHI: 50 days Efficacy section: in PL water volume should be 200-300 L/ha. Only SEPTTR can be accepted.
2.	CEU PL	Winter wheat	F	Puccinia striiformis spp. (PUCCST)	Foliar spray	BBCH 30-59	a) 2 b) 2	14	a) 1.5 b) 3.0	a) 0.35 boscalid + 0.1	CEU PL	50	Metabolism and residues section:

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		
										difenoconazole b) 0.7 boscalid + 0.2 difenoconazole			Accepted PHI: 50 days Efficacy section: in PL water volume should be 200-300 L/ha. Only PUCST can be accepted.
3.	CEU	Winter wheat	F	<i>Fusarium spp.</i>	Foliar spray	BBCH 39-59	a) 2 b) 2	14	a) 1.5 b) 3.0	a) 0.35 boscalid + 0.1 difenoconazole b) 0.7 boscalid + 0.2 difenoconazole	200- 400	50	Efficacy section: in PL this use is not accepted.

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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a homogenous whitish liquid with a characteristic odour. It is not explosive, has no oxidising properties. The product is surface active, not flammable/has not a flash point up to the boiling point. It has a self-ignition temperature of $\leq > 650$ °C. In water suspension, it has a pH value around 7.39 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in COEX PE/EV.

Its technical characteristics are acceptable for a Suspension concentrate formulation.

The product is not intended to be used in tank mixtures.

The intended concentration of use is 0.375% v/v to 0.75% v/v.

3.2 Efficacy (Part B, Section 3)

Boscalid 23.3% + Difenoconazole 6.6% SC is an Suspension Concentrate (SC) formulation containing 233 grams per liter (g/L) boscalid and 66 grams per liter (g/L) difenoconazole for use in winter wheat.

In this document, the information related to the efficacy of the plant protection product Boscalid 23.3% + Difenoconazole 6.6% SC is summarized for the uses in countries of the Central Zone.

To support the registration of Boscalid 23.3% + Difenoconazole 6.6% SC in the GAP claimed crops, trials have been set up in winter wheat. In winter wheat efficacy trials conducted in Italy, Poland, Germany, France, United Kingdom, Czech Republic and Hungary, the boscalid + difenoconazole formulation prepared by Sharda Cropchem España – Boscalid 23.3% + Difenoconazole 6.6% SC – was compared against a reference boscalid + difenoconazole co-formulation currently on the market in South- and Central Europe.

According to the GAP, the proposed application rate of Boscalid 23.3% + Difenoconazole 6.6% SC is 1.5 L per hectare (L/ha), with up to two applications per season. This will deliver 233 g boscalid and 66 g difenoconazole per hectare. In the current document, results obtained in field trials with Boscalid 23.3% + Difenoconazole 6.6% SC applied at 1.5 L/ha to 3.0 L/ha will be presented where these have been tested against similar dose rates of boscalid + difenoconazole reference product currently marketed in the countries where the trials were conducted.

3.3 Efficacy data

Preliminary tests

The activity of boscalid as well as difenoconazole are both well known; both actives have been marketed by e.g. Syngenta and BASF, for the use in cereals and other crops to control a wide range of foliar diseases for a number of years, i.e. difenoconazole has been used since 1989 and difenoconazole has been marketed since 2001. Based on the knowledge about the active substances and the experiences with the actives in the GAP claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and

field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose(s) (for example 60–80% of the recommended dose) to that which would be recommended. It is utilized to achieve the desired effect. In the appropriate research of efficacy were tested different doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).

Applicant for support the MED (minimum effective dose) was studied following doses:

- **Maritime EPPO zone against FUSASP, PUCCRET, PUCGST and SEPTTR-SEPTSP** – three different doses were studied: 0,8 l/ha (0,53N); 1,0 l/ha (0,67N) and 1,5 l/ha (N) in during 4 trials and two doses: 1,0 l/ha (0,67N) and 1,5 l/ha (N) in 11 trials
- **N-E EPPO zone against PUCCRET, PUCGST and SEPTTR** – two different doses were studied: 1,0 l/ha (0,67N) and 1,5 l/ha (N) during trials. Lack of trials against FUSASP.
- **S-E EPPO zone against SEPTTR, SEPTSP and FUSASP** – two different doses were studied: 1,0 l/ha (0,67N) and 1,5 l/ha (N) during trials. Lack of trials against PUCCRET.
- **MED EPPO zone against SEPTTR, PUCCRET, PUCGST and FUSASP** - two different doses were studied: 1,0 l/ha (0,67N) and 1,5 l/ha (N) during trials.

According to the presented results, the dose rate of 1.5 L/ha per application, for control of SEPTTR, SEPTSP, PUCCRET, PUCGST and FUSASP in winter wheat provided the optimal overall control and should be considered as effective against the diseases, for which activity of CIAZ (product code: SHA 7216 A) is claimed. The efficacy and crop safety of CIAZ is equivalent to the standard reference products to which it was compared.

In the opinion of ZRMs, registered the same dose (1.5 L/ha) for all diseases will make it easier for farmers to stand the product. Wheat is not endangered only by FUSASP, but also by other diseases. The dose of 1.0 L/ha was much less effective than the dose of 1.5 L/ha in the case of SEPTTR, SEPTSP, PUCCRET and PUCGST. Therefore, in our opinion, the recommended dose should be 1.5 L/ha (which showed a low, but still better efficacy than the dose of 1.0 L/ha).

The concerned member states should consider an acceptability of extrapolation from other EPPO zones results which was characterized by limited number of trials or lack of them.

Efficacy tests and conclusions regarding authorization of intended uses

Details of experiment are presented above by Applicant. All used methodology is in accordance with GEP rules, in exception of conduction studies during one growing season in MED (2017) and S-E EPPO zone (2016). Three different growing seasons were studied in the Maritime EPPO zone (2016, 2017 and 2019) and two growing seasons (2016 and 2017) in N-E EPPO zone. All trials were performed on winter wheat on different varieties.

The presented data and information about the plant protection product, active substances, crops and pests and the intended uses correspond with the provided EPPO Standards. It can be concluded to accept these data and information.

Applicant submitted in total 28 efficacy trials carried out on winter wheat in four EPPO zones: Maritime EPPO zone (15 trials: FR-4, DE-1, CZ-10), North-East EPPO zone (4 trials: PL), MED EPPO zone (5 trials: IT-4, FR-1) and South-East EPPO zone (4 trials: HU). The number of trials is sufficient and fulfil EPPO requirements for a major crop for Maritime EPPO zone. cMS form S-E should decide if 5 studies and cMS from S-E and N-E EPPO zone should decide if only 4 trials can be acceptable considering the importance of this crop. For Poland – number of trials is acceptable, because we can use trials from neighbouring countries (CZ-10 and DE-1).

The following efficacy scale was used:

- L – limiting (0-60% efficacy)
- ME – moderately efficiency (60-80%)
- E – efficiently (>80%)

We are dealing with the active substances used commonly for many years in many countries. We must emphasize that each pest should be representative by sufficient number of field efficacy tests (at least 6 for major pest and at least 3 for minor pest). PESSEV and PESINC was acceptable in all submitted trials by Applicant. Results were presented by the Applicant in the tables above and in the BAD in appendixes.

Efficacy of CIAZ (product code: SHA 7216 A):

• *Septoria spp.*

Maritime EPPO zone – 7 trials were submitted (CZ-4, FR-3). All trials were performed on SEPTSP

N-E EPPO zone – 3 trials were submitted (PL). Trials were performed on SEPTTR

S-E EPPO zone – 2 trials were submitted (HU). Trials were performed on SEPTSP.

MED EPPO zone -1 trial was submitted (FR). Trial was carried out in SEPTTR.

Only in Maritime EPPO zone, Applicant submitted enough number of trials. cMS from N-E, S-E and MED EPPO zone should decide if limited number of trials can be acceptable or should consider possibility of extrapolation results from other EPPO zone. In Poland on the basis on 7 trials (CZ-4, PL-3), SEPTTR can be included in Polish label project

Septoria is the collective name for fungal diseases caused by fungi formerly classified as *Septoria*. And although current research based on molecular techniques has made it possible to accurately classify individual species, the name of the diseases has remained common. In Poland, two diseases belonging to this group are the most important in cereal crops. Septoriosis is caused by fungi that overwinter in crop residues, and their spores are carried with raindrops. It is worth mentioning that similar symptoms to stripe septoria are also observed in wheat chaff septoria caused by the fungus *Septoria nodorum* (the bag stage of *Phaeosphaeria nodorum*), whose current name is *Septoria glumarum*. Symptoms of this disease can also be observed already on seedlings, later on leaves, stems and ears. In the case of septoria glumarum, the spots on the leaves are usually light brown, lenticular, initially with a chlorotic border. On leaves, too, they can form very extensive necroses leading to leaf dieback. Here, however, pycnidia are less frequently observed, and are not arranged in rows, but their arrangement is usually irregular or concentric. In the opinion of ZRMS, SEPTTR can be conditionally registered in Poland on the basis on 3 trials carried out in N-E against SEPTTR and 4 trials against SEPTSP in Maritime EPPO zone. It can be concluded that CIAZ at recommended dose (1,5 L/ha) moderately effective control SEPTTR on winter wheat.

The following is a detailed assessment of the effectiveness of individual *Septoria species*.

✓ **N-E EPPO zone:**

Trial no.	Country	Variety	No. of appl	Assessm. Days after		Pest	Assess. Type	Part as-sess.	Crop GS at Assess. BBC H	Untreated		Boscalid 23,3 + Difenoconazole 6,6 SC 1.5 L/ha		Boscalid + Difeno. Ref. product 1 N	
				1st appl	2nd appl					Mean		Mean	% Control	Mean	% Control
322_Sharda_SF17PZ31 2W	PL	Sailor	1	18		SEPTTR	PESSEV	Leaf 3	75	21.9	a	10.1	b	12.9	b
347_Sharda_SF17PZ30 6W	PL	Legenda	1	15		SEPTTR	PESSEV	Leaf 3	73	28.3	a	6.63	b	5.03	b
348_Sharda_SF17PZ30 7W	PL	Sailor	1	12		SEPTTR	PESSEV	Leaf 3	73	16.3	a	4.50	b	4.75	b
										min	16.3	4.50	53.9	4.75	41.1
										max	28.3	10.1	76.5	12.9	82.2
Mean % Control (Last observation on Leaf 3 / One observation per trial, PESSEV), n=3										22.2		7.08	67.6	7.56	64.7

✓ **Maritime EPPO zone:**

Trial no.	Country	Variety	No. of appl	Assessm. Days after		Pest	Assess. Type	Part as-sess.	Crop GS at Assess. BBC H	Untreated		Boscalid 23,3 + Difenoconazole 6,6 SC 1.5 L/ha		Boscalid + Difeno. Ref. product 1 N	
				1st appl	2nd appl					Mean		Mean	% Control	Mean	% Control
PC-17-05-32-NE1	FR	SY-	2	63	35	SEPT	PESS	Leaf	75	0.65	a	0.32	a	0.5	a
													51.3		23.1

Trial no.	Country	Variety	No. of appl.	Assessm. Days after	Pest	Assess. Type	Part as-sess.	Crop GS at Asses. BBC H	Untreated	Boscalid 23,3 + Difenoconazole 6,6 SC 1.5 L/ha	Boscalid + Difeno. Ref. product 1 N			
PC 17-05-32-N01	FR	Moisson Aspache	2	40	21	SEPT SP	EV PESS EV	Leaf 1	73	80.7 a	35.9 a 55.5	39.7 b 50.8		
Mean % Control (Last observation on Leaf 1 / One observation per trial, PESSEV), n=2									min max	0.65 80.7	0.32 35.9	51.3 55.5	0.5 39.7	23.1 50.8
										40.7	18.1	53.4	20.1	36.9
SWEPL-CZE16-BOTR-TRZAW-KUJ23	CZ	Svitava	1	14	1	SEPT SP	PESS EV	Leaf 2	56	15.3 a	7.1 a b	46.5	5.7 b	55.4
F1914-TRZAW-DOM45	CZ	Bohemia	2	35	21	SEPT SP	PESS EV	Leaf 2	75	1.9 a	0.0 b	100	0.0 b	100
SWEPL-F1914-RYMA	CZ	Toras	2	49	28	SEPT SP	PESS EV	Leaf 2	73	40.2 a	0.0 d	100	0.1 c	99.5
Mean % Control (Last observation on Leaf 2 / One observation per trial, PESSEV), n=3									min max	1.9 40.2	0.0 7.1	46.5 100	0.0 5.7	55.4 100
										19.1	2.4	82.2	1.9	85.0
SWEPL-CZE16-BOTR-TRZAW-RYM1	CZ	Rumor	2	49	28	SEPT SP	PESS EV	Leaf 3	59	23.3 a	0.60 c	97.1	0.20 d	98.9
F1914-TRZAW-DOM45	CZ	Bohemia	2	35	21	SEPT SP	PESS EV	Leaf 3	75	13.1 a	4.1 c	68.4	4.4 c	66.5
SWEPL-F1914-RYMA	CZ	Toras	2	49	28	SEPT SP	PESS EV	Leaf 3	73	44.8 a	0.3 c	99.2	0.2 c	99.4
Mean % Control (Last observation on Leaf 3 / One observation per trial, PESSEV), n=3									min max	13.1 44.8	0.3 4.1	68.4 99.2	0.2 4.4	66.5 99.4
										27.1	1.7	88.2	1.6	88.3
PC 17-05-32-NE1	FR	SY-Moisson	2	63	35	SEPT SP	PESIN C	Leaf 1	75	25.0 a	13.3 a	46.7	20.0 a	38.3
PC 17-05-32-NE2	FR	Diametro	2	47	25	SEPT SP	PESIN C	Leaf 1	60	8.33 a	5.0 a	40.0	13.3 a	0.0
Mean % Control (Last observation on Leaf 1 / One observation per trial, PESINC), n=2									min max	8.33 25.0	5.0 13.3	40.0 46.7	13.3 20.0	0.0 38.3
										16.7	9.2	43.4	16.7	19.2
PC 17-05-32-NE2	FR	Diametro	2	47	25	SEPT SP	PESIN C	Leaf 2	60	16.7 a	10.0 a	40.0	11.7 a	30.0
Mean % Control (Last observation on Leaf 2 / One observation per trial, PESINC), n=1									min max	16.7 16.7	10.0 10.0	40.0 40.0	11.7 11.7	30.0 30.0
										16.7	10.0	40.0	11.7	30.0

✓ S-E EPPO zone:

Trial no.	Country	Variety	No. of appl.	Assessm. Days after		Pest	Assess. Type	Part assess.	Crop GS at Asses. BBC H	Untreated	Boscalid 23,3 + Difenoconazole 6,6 SC 1.5 L/ha		Boscalid + Difenof. Ref. product 1 N	
				1st app l.	2nd app l.					Mean	% Control	Mean	% Control	
SWEPL-HU16-BOTR-TRZAW-PLA17	HU	GK Körös	2	32	20	SEPT SP	PESS EV	Leaf 1	77	86.1 a	31.9 c	62.8	23.9 c	72.3
SWEPL-HU16-BOTR-TRZAW-PLA18	HU	MV Kokárda	2	35	20	SEPT SP	PESS EV	Leaf 1	77	39.8 a	9.50 b	76.1	4.6 c	88.4
Mean % Control (Last observation on Leaf 1 / One observation per trial, PESSEV), n=2									min	39.8	9.50	62.8	4.6	72.3
									max	86.1	31.9	76.1	23.9	88.4
										63.0	20.7	69.5	14.3	80.0

✓ MED EPPO zone:

Trial no.	Country	Variety	No. of appl	Assessm. Days after		Pest	Assess. Type	Part assess.	Crop GS at Asses. BBC H	Untreated		Boscalid 23,3 + Difenoconazole 6,6 SC 1.5 L/ha		Boscalid + Difeno. Ref. product 1 N			
				1st appl	2nd appl					Mean	% Control	Mean	% Control	Mean	% Control		
PC 17-05-32-SW1	FR	Bologna	2	43	35	SEPT R	PESSE V	Leaf 2	75-83	80.1	a	16.5	c	79.5	0.7	c	99.1
Mean % Control (Last observation on Leaf 2 / One observation per trial, PESSEV), n=1									min	80.1	16.5	79.5	0.7	99.1			
									max	80.1	16.5	79.5	0.7	99.1			
										80.1	16.5	79.5	0.7	99.1			
PC 17-05-32-SW1	FR	Bologna	2	43	35	SEPT R	PESINC	Leaf 1	75-83	10.0	a	1.67	a	83.3	0.0	b	100
Mean % Control (All observations on Leaf 1, PESINC), n=1									min	10.0	1.67	83.3	0.0	100			
									max	10.0	1.67	83.3	0.0	100			
										10.0	1.67	83.3	0.0	100			

• *Puccinia spp.*

Maritime EPPO zone – 4 trials were submitted (CZ). Trials were carried out on PUCGST

N-E EPPO zone – 2 trials were submitted (PL). 1 trial was performed against PUCGST and 1 trial against PUCCRE.

S-E EPPO zone – 0 trials

MED EPPO zone -3 trials was submitted (FR-1, IT-2). 2 trials were performed on PUCSP and 1 on PUCCRT.

All EPPO zones were characterized by limited number of efficacy trials against PUCCRT-Puccinia sp.

So, cMS from N-E, S-E, Maritime and MED EPPO zone should decide if limited number of trials can be acceptable or should consider possibility of extrapolation results from other EPPO zone. In Poland on the basis on 6 5 trials (CZ-4, PL-21), ~~PuccrT~~ PuccST can be included in Polish label project and conditionally registered. PuccRE should be deleted from Polish label (only 1 trial is not accepted). In Polish label PuccST should be registered as moderately sensitive against CIAZ used at recommended dose (in N-E efficacy was at level <60% and in Maritime at level >90%).

The following is a detailed assessment of the effectiveness of individual *Puccinia species*.

✓ N-E EPPO zone:

Trial no.	Country	Variety	No. of appl.	Assessm. Days after		Pest	Assess. Type	Part assess.	Crop GS at Assess. BBCH	Untreated		Boscalid 23,3 + Difenconazole 6,6 SC 1.5 L/ha		Boscalid + Difen. Ref. product 1 N	
				1st appl.	2nd appl.					Mean		Mean	% Control	Mean	% Control
321_Sharda_SF17P	PL	Arkadia	1	34	-	Pucc ST	PESS EV	Leaf 1	77	13.5	a	6.0	b	0.3	c
322_Sharda_SF17P	PL	Sailor	1	32	-	Pucc RE	PESS EV	Leaf 1	77	5.9	a	1.7	b	0.6	c
Z311W															
Z312W															
min										5.9		1.7	55.6	0.3	89.8
max										13.5		6.0	71.2	0.6	97.8
Mean % Control (Last observation on Leaf 1 / One observation per trial, PESSEV), n=2										9.7		3.9	63.4	0.45	93.8

✓ Maritime EPPO zone:

Trial no.	Country	Variety	No. of appl.	Assessm. Days after		Pest	Assess. Type	Part assess.	Crop GS at Assess. BBCH	Untreated		Boscalid 23,3 + Difenconazole 6,6 SC 1.5 L/ha		Boscalid + Difen. Ref. product 1 N	
				1st appl.	2nd appl.					Mean		Mean	% Control	Mean	% Control
F1914-TRZAW-DOM46	CZ	Bohemia	2	18	14	Pucc ST	PESS EV	Leaf 1	65	15.0	a	1.3	b	1.2	b
SWEPL-CZE19-BDC-TRZAW-TRU14	CZ	Tobak	2	32	18	Pucc ST	PESS EV	Leaf 1	77	25.0	a	5.0	d	1.0	e
SWEPL-F1914-RYMC	CZ	Toras	2	49	28	Pucc ST	PESS EV	Leaf 1	73	28.3	a	0.0	d	0.1	c
SWEPL-F1914-RYMD	CZ	Bohemia	2	49	28	Pucc ST	PESS EV	Leaf 1	73	29.7	a	0.0	c	0.0	c
min										15.0		0.0	80.0	0.0	91.1
max										29.7		5.0	100	1.2	100
Mean % Control (All observations on Leaf 1, PESSEV), n=4										24.5		1.5	92.6	0.5	96.6
F1914-TRZAW-DOM46	CZ	Bohemia	2	18	14	Pucc ST	PESS EV	Leaf 2	65	5.9	a	0.4	c	0.4	c
SWEPL-F1914-RYMC	CZ	Toras	2	49	28	Pucc ST	PESS EV	Leaf 2	73	40.8	a	0.3	c	0.2	c
SWEPL-F1914-RYMD	CZ	Bohemia	2	49	28	Pucc ST	PESS EV	Leaf 2	73	44.8	a	0.2	c	0.1	c
min										5.9		0.2	92.5	0.1	92.5
max										44.8		0.4	99.4	0.4	99.7
Mean % Control (All observations on Leaf 2, PESSEV), n=3										30.5		0.4	97.0	0.2	97.2
F1914-TRZAW-DOM46	CZ	Bohemia	2	18	14	Pucc ST	PESS EV	Leaf 3	65	5.7	a	0.4	c	0.4	c
min										5.7		0.4	92.6	0.4	93.6
max										5.7		0.4	92.6	0.4	93.6
Mean % Control (All observations on Leaf 3, PESSEV), n=1										5.7		0.4	92.6	0.4	93.6

✓ MED EPPO zone:

Trial no.	Country	Variety	No. of appl.	Assessm. Days after		Pest	Assess. Type	Part assess.	Crop GS at Assess. BBCH	Untreated		Boscalid 23,3 + Difenconazole 6,6 SC 1.0 L/ha		Boscalid 23,3 + Difenconazole 6,6 SC 1.5 L/ha	
				1st appl.	2nd appl.					Mean		Mean	% Control	Mean	% Control
PC 15 SHR	IT	SY	2	28	14	PuccS	PESSE	Leaf	61	5.24	a	1.46	b	1.42	b

- *Fusasp* spp.

N-E EPPO zone – 0 trials

S-E EPPO zone – 2 trials were submitted (HU)

MED EPPO zone -2 trials was submitted (IT)

All EPPO zones were characterized by limited number of efficacy trials against FUSASP. So, cMS from N-E, S-E, Maritime, and MED EPPO zone should decide if limited number of trials can be acceptable or should consider possibility the extrapolation results from other EPPO zone. In Poland only 3 trials from neighbouring countries (DE-1, CZ-2) are not accepted, because FUSASP is a major disease in winter wheat, so at least 6 efficacy trials should be presented. FUSASP should be excluded from GAP table and Polish label project.

Boscalid 23.3% + difenoconazole 6.6% SC applied in winter wheat provided a moderate to high level control of *Puccinia spp.*, *Fusarium* and *Septoria spp.* with the recommended dose rate of 1.5 L/ha. Max. 2 application per season can be used. Results were comparable to standard reference products used during efficacy trials.

Interval between application:

- *MAR*: 7-28 days (in 5 trials interval: 13-14 days was studied)
- *N-E*: 0 days (only 1 appl. was studied)
- *MED*: 8-14 days
- *S-E*: 11-16 days

In the opinion of Evaluator, interval between application amounting to 14 days is acceptable for MAR, S-E and MED. cMS from N-E should decide if this interval (14 days) can be accepted, considering that such interval in this zone has not been tested, because only 1 application was studied. In the opinion of ZRMs, in Poland interval (14 days) can be accepted on the basis on trials from Maritime EPPO zone. During efficacy trials, assessment was made after 1st and 2nd application. Results has shown that CIAZ control fungal disease on winter wheat after 1st and 2nd application. Applicant submitted enough number of trials for efficacy after 1 application and limited number of trials for 2 applications. However, in our opinion CIAZ should be registered conditionally. Within 2 years after registration, it will be necessary to submit

studies performed in Poland to show the effectiveness of 2 applications per season. In Poland, only in one selectivity trial (351_Sharda_SF16PZ310W) – 2 application per season were studied. No negative effects on yield or its quality was observed.

In the opinion of Evaluator if one application has enough efficiency, it also be used to confirm the effectiveness of two doses per season. The lack of dose harmonization (one or two applications) was due to the following issues, which are briefly described below. Some trials were performed with one application because of various reason like:¹⁾ other diseases appeared and trials had to be stopped, ²⁾ disease pressure was reduced or weather conditions for which didn't make sense or institutes where not able to do a second application. It can be clearly observed in results over two seasons that product performed very good in all cases, and only can be expected that with a second application, the efficacy of the formulation would be increased in percentage of control and in time product protect the crop against diseases. The second application could only represent a phytotoxic problem, but as can be observed in results of trials presented, even in trials with two applications at double dose crops didn't present any phytotoxicity. Also, trials with only one application would be even more challenging than trials with two applications, so the trials with one application should be considered as valid for registration according EPPO PP 1/226(3) extrapolation is possible “from more challenging control situations to ones that pose a lower challenge”. According to this, Evaluator believes that all trials should be valid for registration purposes.

However, **in situation that we have not registered any plant protection product with boscalid and difenoconazole in Poland only conditional registration seems to be possible against SEPTTR and PUCCTR on winter wheat for two years, after which the Applicant will be required to present the missing efficacy field tests carried out twice a season, optimally in the North-East EPPO zone.**

Application widow:

- MAR: BBCH 31-61
- N-E: BBCH 45-51
- S-E: BBCH 32-65
- MED: BBCH 31-47

In the opinion of Evaluator, window application amounting to BBCH 30-59 against SEPTTR (or/and SEPTSP), PUCCTR and/or PUCCT and BBCH 39-59 against FUSASP is acceptable.

Water volume:

- MAR: 200-300 L/ha
- N-E: 200 L/ha
- S-E: 250 L/ha
- MED: 250-400 L/ha

cMS from MAR, S-E, N-E and MED should decide if this water volume can be accepted, considering that such range of water volume in this zone has not been tested. In the opinion of ZRMS, water volume for Poland should be 200-300 L/ha (because this volume was studied in trials, volume of 400 L/ha was not studied).

ZRMs agree with Applicant that: *Boscalid 23.3% + difenoconazole 6.6% SC applied in winter wheat provided a moderate to high level control of Puccinia spp., Fusarium and Septoria spp. with the recommended dose rate of 1.5 L/ha. As diseases often occur as a complex of several diseases with different susceptibility to-wards boscalid and/or difenoconazole, up to 2 applications per season of Boscalid 23.3% + difenoconazole 6.6% SC at the 1.5 L/ha rate should be used to efficiently control the diseases claimed on the label*

The applicant wishes to cite the original registrant's data on boscalid and difenoconazole now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Rapporteur extrapolate from those data. However, in the opinion of Evaluator it is not possible according to Polish regulations.

Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product (a.s. boscalid and difenoconazole) in their own Member State. It is recommended to authorize the product CIAZ (product code: SHA 7216

A) in the extent of the authorization of the reference product (a.s. boscalid and difenoconazole) at the equivalent dose rate.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

The following dossier section follows EPPO standard PP 1/213(4) *Resistance risk analysis* in particular point 6. *Registration requirements* and Appendix I of the standard.

Introduction

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the naturally-occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The fungicide-resistant population develops because the sensitive population is suppressed and the rare fungicide-resistant individual can multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of disease control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the epidemic (or disease severity) and use pattern of the fungicide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of disease control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, fungicide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential and/or possible resistance cases, the Fungicide Resistance Action Committee (FRAC) states that the term resistance be limited to situations where the conditions in both (a) and (b) below are met:

- (a) the development of resistance leads to failure of disease control under practical field conditions following application of a fungicide correctly and according to the label and
- (b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced fungicide sensitivity..

The following general recommendations can be made:

- Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- Reduced rates of SBI fungicides can contribute to accelerate the shift to less sensitive populations. It is critical to use effective rates of SBI fungicides (DMI fungicides) in order to ensure robust disease control.
- When used in mixture recommended effective rates of the SBI (DMI fungicides) should be maintained. Split and reduced rate programmes, using multiple repeated applications at dose rates below manufacture's recommendations, provide continuous selection pressure and accelerate the development of resistant populations, and therefore must not be used.
- For crop/pathogen situations where repeated spray applications (e.g. orchard crops/powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non cross-resistant fungicide are recommended.
- Where alternation or the use of mixtures is not feasible because of lack of effective or compatible non cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.
- If the performance of SBIs should decline and sensitivity testing has confirmed the presence of less sensitive isolates, SBI's should only be used in mixture or alternation with effective non cross-resistant partner fungicides.

- The introduction of new classes of chemistry offers opportunities for more effective resistance management. The use of different modes of action should be maximised for the most effective resistance management strategies.
- Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended use rates, or to poorly timed applications.
- Fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation, etc.
- Exclusive frequency measurements of single cyp51 mutations are not sufficient to describe the sensitivity situation towards DMIs but can help to better understand the background of sensitivity shifts.

The agronomic risk for the CIAZ (product code: SHA 7216 A) which include boscalid and difenoconazole is estimated in generally as low to medium. However, in terms of agronomic practice, the selection pressure on the intended disease target for Boscalid 23.3% + Difenoconazole 6.6% SC may be low to high in annual cereal crops like wheat (depending on whether a successful crop rotation system is applied, or mono-cropping is carried out in the crop, respectively).

The resistance management is coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided.

Generally, it can be concluded, that the proposed management strategy for the prevention of fungicide resistance can be regarded as sufficient.

Difenoconazole is a fungicide belonging to the group of SBI-Class I: De-methylation-Inhibitors (DMI) a subgroup of the Sterol Biosynthesis Inhibitors (SBI)-triazoles. The active ingredient is classified after the target site and code by FRAC to inhibition of biosynthesis in membrane G1: C14-demethylase in sterol biosynthesis. Difenoconazole is intended to be used in cereals and sugar beets. Especially the substance is active against *Erysiphe graminis*, *Puccinia spp.*, *Leptosphaeria nodorum*, *Mycosphaerella graminicola* and *Fusarium sp.* in cereals. The biochemical mode of action of the DMI is the inhibition of C14-demethylase in sterol biosynthesis. Based on the current evidence the resistance risk assessment for DMI, SBI-Class I, Triazoles will be medium. It is known a cross resistance between DMI fungicide active against the same fungus. DMI fungicides show no cross resistance to other SBI classes. For this group resistance is known in various fungus species. Several resistance mechanisms are known including target site mutations in cyp51 (erg 11) gene (Anonymous 2011a). The published use pattern for all SBI classes covered by the FRAC SBI Working Group guidelines for management strategy reflects the resistance risk assessment. Difenoconazole is a systemic active ingredient. It will be absorbed very fast by plant tissue and translocated acropetally in the transpiration stream. The active ingredient inhibits spore germination, mycelial growth, and the development of infection structures are thus prevented. Difenoconazole has a protective as well as an eradivative/curative effect. The active ingredient is selective on a wide range of dicotyledonous and monocotyledonous crop species. Difenoconazole will be used for foliar application and seed treatment. Difenoconazole is a candidate for substitution.

Boscalid is a member of the fungicide group succinate dehydrogenase inhibitors (SDHI) and pyraclostrobin belongs to the group of QoI fungicides (Quinone outside inhibitors). Mutations in several plant pathogenic fungi have been identified causing resistance against active substances of both fungicide groups. Cross resistance between SDHI fungicides is known. Cross resistance between the two fungicide groups has not been observed so far. Concerning fungicide risk FRAC describes the SDHI fungicides in general as medium to high-risk compounds and the QoI fungicides in general as high-risk compounds

Septoria tritici blotch (STB) caused by the fungal pathogen *Zymoseptoria tritici* is a global threat to sustainable wheat production. The use of fungicides against STB is considered the primary means of minimizing yield losses; however, fungicide resistance is developing, which greatly affects their effectiveness. Only a few classes of fungicides are available for STB control. DMI fungicides are seen as a major group, but growing resistance problems are calling their use into question.

Based on the current evidence the resistance risk assessment for DMI, SBI-Class I, Triazoles will be medium. It is known a cross resistance between DMI fungicide active against the same fungus. DMI fungicides show no cross resistance to other SBI classes.

For this group resistance is known in various fungus species. Several resistance mechanisms are known including target site mutations in *cyp51* (*erg 11*) gene (Anonymous 2011a). The published use pattern for all SBI classes covered by the FRAC SBI Working Group guidelines for management strategy reflects the resistance risk assessment.

Laboratory studies using single generation exposures to different SDHIs have reported several target-site mutations conferring reduced sensitivity in mutants of *Z. tritici* and other plant pathogens (Fraaije et al., 2012; Scalliet et al., 2012; Sierotzki & Scalliet, 2013; Skinner et al., 1998). The SDHI sensitivity can be differentially affected by mutations. For example, *SdhB*-H267Y mutants of *Z. tritici* are insensitive to boscalid but hypersensitive to fluopyram.

Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agronomic risk of resistance, Management of resistance, Use pattern, Proposed Risk Modifiers) has to be finalised on national level.

It is critical to use an effective disease management program to delay the emergence of resistance, so it is necessary to keep as many fungicides belonging to different modes of action or different chemical groups on the market as possible. The resistance management strategy must include changing active substances from different MoA groups during the growing season but should also consider the possibility of using the best active substance from each group in each situation. It is generally necessary to include all available MoA groups in the spray sequence and to avoid spraying products from the same group consecutively to minimize selection pressure on target diseases (and non-target diseases that may be present). Boscalid is classified by FRAC with medium to high impact on resistance, and difenoconazole with medium impact on resistance. Among the 278 PPPs, 115 can be found with high resistance, containing active ingredients such as azoxystrobin, dimoxystrobin, fluoxastrobin, kresoxim-methyl, pyraclostrobin, thiophanate-methyl, and trifloxystrobin. These substances, existing as single active substances, cannot be considered as better alternatives to CIAZ according to the resistance strategy.

zRMS considers that the following modifiers may be appropriate:

- Maximising efficacy by using the right dose at the right growth stage in the right conditions
- Monitoring success and reporting any unexpected results to [distributor]‘
- As far as possible, vary the chemicals used on the crop and alternate or combine with products having different modes of action.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

Results

Winter wheat

Crop phytotoxicity was evaluated in efficacy and selectivity trials where Boscalid 23.3% + Difenoconazole 6.6% SC was applied at one or two applications, when the crop was at growth stages ranging from

BBCH 31 to BBCH 65, at the rate of 1.0 to 3.0 L/ha in winter wheat. The 1.5 L/ha dose rate corresponds to 100% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest.

No adverse effects in regards to phytotoxicity and vigour were observed in any efficacy and selectivity trials treated with Boscalid 23.3% + Difenconazole 6.6% SC.

Effect on the yield of treated plants or plant product

The data obtained in trials harvested demonstrate that CIAZ (product code: SHA 7216A) is as safe to the crop as the reference products used in the trials. Based on this submitted data and on the expert knowledge about boscalid and difenoconazole it can be concluded to accept the data provided by the Applicant.

Effects on the quality of plants or plant products

CIAZ (product code: SHA 7216 A) applied at dose recommended did not significantly affect the quality of crop yield. Also, no phytotoxic symptoms were present in trials. Based on this submitted data and on the expert knowledge about boscalid and difenoconazole it can be concluded to accept the data provided by the Applicant.

Effect on transformation processes

Processing can include physical processing such as milling of cereals. The application of Boscalid 23.3% + Difenconazole 6.6% SC at the proposed label rate and rates above this rate has no negative effect on the quality parameters assessed in efficacy trials harvested.

Other processes depend on biological activity and are referred to as 'transformation'. These include e.g. brewing and baking and are potentially sensitive to plant protection products. Fungicides are usually only considered with regards to their potential effect on transformation processes if applied close to harvest (EPPO standard PP 1/243(1) *Effects of plant protection products on transformation processes*). It is also the case that if residues cannot be detected at harvest (dRR Part B Section 4) then it is reasonable to assume that the likelihood of an effect on transformation processes is greatly reduced.

Finally, it should be noted that currently, boscalid as well as difenconazole containing products do not have any label restrictions concerning their use on crops destined for processing. In addition, both actives are part of many products which have been used for a long time as fungicide in e.g. cereals. Since the market introduction, no effects on transformation processes have been recorded for any of these products.

Impact on treated plants or plant products to be used for propagations

Boscalid 23.3% + Difenconazole 6.6% SC is composed of boscalid and difenoconazole, which both have been widely used for several years on e.g. cereals, without identifying any issues in regard to ability of grains of treated plants to germinate.

Thus, negative effects of the two active ingredients on parts of plant used for propagating purposes can be excluded due to the fungicidal nature of the product. Furthermore, phytotoxicity assessments in the performed trials demonstrated the crop safety of the product and the absence of any negative effect on the plants or plant products in the vast majority of the trials.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

Boscalid

The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity

on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops.

Results according to Additional Report to DAR of Boscalid, point B.7.9., Published on November 08, 2002, shows the results of the report made by Hamm RT, Veit P. 2001 in Germany for Boscalid residues levels in succeeding crops.

This study was conducted with an application rate of 2.1 kg as/ha to bare soil. The application rate according to GAP is 2 x 500 g as/ha for beans and peas.

With the exception of wheat grain the major part of the residues in all other matrices was identified as parent. The concentrations of boscalid were relatively low in lettuce leaf (0.014 – 0.072 mg/kg, one sample = 0.146 mg/kg) and radish root (0.009 – 0.09 mg/kg). Higher residues were found in radish leaves (0.09 – 0.30 mg/kg) and wheat forage (0.19 – 1.47 mg/kg) and very high residues in wheat straw (0.81 – 7.99 mg/kg).

In wheat grain, the concentration of parent was low (≤ 0.028 mg/kg). The greater portion of the TRR were non extractable residues and part of these radioactive residues, especially for the pyridine label, could be detected in the starch fraction (36.2 – 48.4 % TRR for pyridine label, 0.6 – 4.3 % TRR for diphenyl label). Ammonia solubility of the residual residues in wheat grain was in the range of 12.9 – 22.9 % TRR.

Besides parent one metabolite (M510F61) could be identified in low concentrations in radish leaves/roots and in wheat straw/forage. This metabolite was a sugar conjugate of the parent compound.

Although only some of the lettuce leaf and radish root samples exceed the LOQ of the enforcement method (0.05 mg/kg) which could be assigned to an exaggerated application rate, significantly higher levels were found in radish leaves and wheat forage and very high levels in straw even after plant back intervals of 270 and 365 days. This indicates that residues of boscalid could occur above the LOQ of 0.05 mg/kg in edible parts of other crops than investigated.

Difenoconazole

As per the peer review for difenoconazole (EFSA Journal 2011; 9(1):1967), average DT_{50} in the laboratory is 130 days (range 53-456 days, n=10) and in the field, average DT_{50} is 92 days (range 20-265 days, n=9). In the same field trials, conducted in Germany and Switzerland, the geometric mean of DT_{90} was 305 days (range 68-879, n=9). Data from soil dissipation studies where difenoconazole was applied using spray application at ≤ 500 g/ha (conducted in Germany (4) and Switzerland (1)) demonstrated that the average DT_{50} in the field, when using the geometric mean, was 53 days (range 22-83 days, n=5). The persistence of the two principal metabolites (CGA 205375 and CGA 71019) are considered to be medium to high (DT_{50} range: 83-152) and low to moderate (DT_{50} range: 6-12 days), respectively.

In conclusion, considering the application rates proposed and taking into account that a part of the applied substance is intercepted by the treated crops, it is concluded that significant levels of difenoconazole are not expected in rotational crops provided that Boscalid 23.3% + Difenoconazole 6.6% SC is applied according to GAP.

Boscalid and difenoconazole did not cause any symptoms of phytotoxicity. It is not probable that this product would cause damage to succeeding crops at the recommended rate.

Impact on other plants including adjacent crops

During the conduct of efficacy trials, no observations about negative or positive effects on other plants or neighbouring crops were reported. Furthermore, in efficacy trials, it was demonstrated that the co-formulation of boscalid and difenoconazole is not phytotoxic to the crop claimed in the GAP.

EPPO guidelines PP1/256(1) is intended to examine whether the active substance of a plant protection product can cause negative effects on crop which would be in contact with that product. Based on the actual drift value calculated with the Ganzelmeier model and on the bio assay results from the Vegetative vigour test, TER values are obtained.

- If the active substance has no activity against plants at the highest doses tested in the bioassays. Then field trials are unnecessary.
- If the TER values are > 1 . Then no further testing is necessary.
- If the TER values are ≤ 1 . Damage to the relevant succeeding crop is possible and further field testing is necessary as described in the EPPO guideline.

The maximum individual proposed rate of Boscalid 23.3% + Difenconazole 6.6% SC is 1.5 L/ha (equivalent to 350 g boscalid/ha and 100 g difenconazole/ha) and the maximum cumulative application rate per season is 3.0 L/ha (2 x 1.5 L/ha, equivalent to 700 g boscalid/ha and 200 g difenconazole/ha).

The applicant claims that no impact on other plants including adjacent crops have been reported in the efficacy trials and the risk to non-target plants following the use of boscalid and difenconazole are considered acceptable. Based on this submitted data and expert knowledge about boscalid and difenconazole it can be concluded to accept the data provided by the applicant.

3.4 Methods of analysis (Part B, Section 5)

Analytical methods for the determination of active substances – Boscalid and Difenconazole and the relevant impurity – Toluene in the formulation Boscalid 23.3% + Difenconazole 6.6% SC have been developed and sufficiently validated according to SANCO/3030/99 rev 5.

Analytical method for Boscalid 23.3% + Difenconazole 6.6% SC in food, feed of plant and animal origin, soil, water and air and in the formulation Boscalid 23.3% + Difenconazole 6.6% SC are available.

3.4.1 Analytical method for the formulation

An analytical method for the determination of Boscalid and Difenconazole in the formulation Boscalid 23.3% + Difenconazole 6.6% SC has been developed and sufficiently validate. The determination of the active substance is performed by HPLC using an external standard and UV detector.

	Boscalid	Difenconazole
Author(s), year	Pokrzywnicka S., 2017	
Principle of method	The method is based on determination of boscalid and difenconazole using reversed phase high performance liquid chromatography (RP-HPLC) with UV-Vis detection at wavelength 206 nm and external standard.	
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	Linear between 0.19 – 0.43 mg/mL (~ 67 - 155%) $n = 5$ $R^2 = 0.9999$ Calibration curve: $y = 21282506x + 269652$	Linear between 0.05-0.13 mg/mL (~ 68-169%) $n = 5$ $R^2 = 0.9998$ Calibration curve: $y = 22063839x - 36824$
Precision – Repeatability Mean n = 6 (%RSD)	Boscalid mean content: 20.965 % w/w SD = 0.137 %RSD = 0.65% Acceptable Horwitz RSD: $\leq 1.67\%$ H_f : 0.39	Difenconazole mean content: 5.953% w/w SD = 0.061 %RSD = 1.02% Acceptable Horwitz RSD: $\leq 2.02\%$ H_f : 0.5
Accuracy n = 6	Mean recovery = 100.54% Acceptable limit (SANCO rev. 4): 98-	Mean recovery = 100.76% Acceptable limit (SANCO rev. 4): 97-

	Boscalid	Difenoconazole
(% Recovery)	102% Acceptable limit (SANCO rev. 5): 97-103% SD = 0.67 %RDS = 0.67	103% Acceptable limit (SANCO rev. 5): 90-110% SD = 0.53 %RSD = 0.53%
Interference/ Specificity	Chromatograms submitted. No interference/ Specific.	Chromatograms submitted. No interference/ Specific.

An analytical method for the determination of the relevant impurity – Toluene in the formulation Boscalid 23.3% + Difenoconazole 6.6% SC has been developed and sufficiently validate. The determination of the impurity is performed by GC-MS analysis.

	Toluene
Author(s), year	E. Nowakowska-Bogdan, 2020
Principle of method	GC-MS
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	5.67 – 8.45 mg/L Calibration points = 5 Correlation coeff R=0.9993 Calibration curve: $y = 19291x + 44451$
Precision – Repeatability Mean n = 10 (%RSD)	%RSD: 3.46 % SD: 0.001 Acceptable Horwitz RSD: $\leq 6.67\%$ %RSDr: 4.47% H _r : 0.77
Accuracy n = 7 (% Recovery)	Analyte conc. 80% - recovery 107.4 % Analyte conc. 100% - recovery 106.7 % Analyte conc. 120% - recovery 103.1 % Acceptable limit (SANCO rev. 5): 75-125% SD = 0.002 %RDS = 4.46
Interference/ Specificity	Interference <3 % Chromatograms submitted
LOQ	5.38 mg/L
Comment	The proposed analytical method is suitable for the determination of the relevant impurity – toluene in the formulation CIAZ and fulfill requirements of SANCO/3030/99 and rev.5. Method has been validated in terms of specificity, linearity, precision and accuracy

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- none

Boscalid (minor data gaps – post registration requirement)

Animal matrices:

- ILV method for eggs
- Primary and ILV method with LOQ of 0.01 mg/kg for muscle.

An independent laboratory validation (ILV) of the analytical method for boscalid in drinking water

An analytical method for boscalid in body fluids

Difenoconazole (minor data gaps – post registration requirement)

An independent laboratory validation (ILV) of the analytical method for difenoconazole in drinking water

An analytical method for difenoconazole in body fluids

Commodity/crop	Supported/ Not supported
Winter wheat	Supported

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for Boscalid 23.3% + Difenoconazole 6.6% SC were not evaluated as part of the EU review of Boscalid and Difenoconazole. All relevant data were provided and are considered adequate. All toxicological studies have been performed.

Classification

Carc.2/H351

EUH208: Contains 1,2-benzisothiazol-3(2H)-one (CAS No. 2634-33-5). May produce an allergic reaction

3.5.1 Acute toxicity

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 423)	= 5000 mg/kg bw	Yes	None	Samruddhi Junnarkar, 2017, report No. 401-1-01-16906
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	Samruddhi Junnarkar, 2017, report No. 403-1-01-16907
LC ₅₀ inhalation, rat (OECD 403)	> 5.433 mg/L air	Yes	None	Manish R. Patel, 2017, report No. 405-1-01-16908
Skin irritation, rabbits calculation	Non-irritant	Yes	None	calculated
Eye irritation, rabbits calculation	Non-irritant	Yes	None	calculated
Skin sensitisation, guinea pi (OECD 406)	Non-sensitising	Yes	None	Vinay Bhimani, 2017, report No. 408-1-01-16911
Supplementary studies for combinations of plant protection products	No data – not required			

3.5.2 Operator exposure

Operator exposure to Boscalid 23.3% + Difenoconazole 6.6% SC was not evaluated as part of the EU review of Boscalid and Difenoconazole for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimations of potential operator exposure have been undertaken for Boscalid and Difenoconazole using the AOEM model.

Conclusions:

According to the EFSA calculator, it can be concluded that the risk for operator is acceptable using CIAZ is acceptable for boscalid with the use work wear (arms, body and legs covered) M/L and A, but for difenoconazole even without PPE. Generally operator should use work wear (arms, body and legs covered) M/L and A + gloves during M / L

Implication for labelling:

Implication for labelling:

P280: Wear protective gloves, protective clothing.

3.5.3 Worker exposure

Worker exposure to Boscalid 23.3% + Difenoconazole 6.6% SC was not evaluated as part of the EU review of Boscalid and Difenoconazole for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Calculations were made using the standard dermal absorption value and the AOEM model.

Conclusions: According to the EFSA AOEM Model, it is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and without personal protective equipment.

According to calculations, it can be concluded that the risk to the employee is acceptable for boscalid using work clothing (with arms, body and legs folded), but for difenoconazole even without appropriate work clothing. However, in this case the employee should use work clothing (covered arms, body and legs) when checking the performed procedure

~~Implication for labelling:~~

~~P280: Wear protective gloves, protective clothing.~~

3.5.4 Bystander and resident exposure

Bystander and resident exposure to Boscalid 23.3% + Difenoconazole 6.6% SC was not evaluated as part of the EU review of Boscalid and Difenoconazole for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimation of potential resident and bystander's exposures have been undertaken for Boscalid and Difenonazole using EFSA model (EFSA Journal 2014;12(10):3874).

Conclusions:

Calculations show that there is no risk for residents after accidental short-term exposure to CIAZ.

According to the EFSA AOEM Model, when a 2-3 m buffer zone is employed, the risk for bystanders can be considered as acceptable.

Implication for labelling: 2-3 m buffer

3.6 Residues and consumer exposure (Part B, Section 7)

The preparation SHA 7216 A is composed of Boscalid and Difenoconazole.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Boscalid					
ADI	EC	2008	0.04 mg/kg bw/d	Rat 2-year oral feed study	100
ARfD	EC	2008	Not allocated.		
Difenoconazole					
ADI	EFSA	2011	0.01 mg/kg bw/d	2-year rat study	100
ARfD	EFSA	2011	0.16 mg/kg bw	Developmental study in rat	1000

An acceptable acute and chronic risk for consumer is expected after the use of Boscalid 23.3% + Difenconazole 6.6% SC accordingly to the intended GAP.

3.6.1 Residues

The data available (EU unprotected data and the new studies) are considered sufficient for risk assessment.

Noticed data gaps:

TMDs (post registration requirement):

The applicant should provide data to document the stability of the TMDs in the test samples obtained from the new trials conducted in Germany and in Poland

Storage stability

Boscalid

Storage stability of Boscalid was demonstrated for a period of 16 months at -18 °C in commodities with high acid content (grape) and 24 months at -18 °C in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw. Degradation of residues during storage of the trial samples is therefore not expected.

Storage stability of Boscalid and M510F01 in milk, muscle, fat, liver and kidney and egg for up to 5 months was demonstrated, when stored deep frozen. Boscalid and M510F01 residue storage stability in poultry eggs was found to be 9 months. No additional studies are required.

Difenoconazole

According to EFSA Journal 2011;9(1):1967, residues of difenoconazole were found to be stable up to 24 months in potato, tomato, cotton (cottonseed oil) and wheat (straw, forage and grain) and up to 12 months in lettuce (head), soybean (beans) and banana when stored frozen at -20°C. Residues of difenoconazole were found to be stable at least 12 months in animal matrices (eggs, milk, poultry breast and beef liver) when stored frozen at -20°C. And difenoconazole and difenoconazole alcohol (CGA-205375) were found to be stable at least 10 months in animal matrices (milk, liver, kidney, fat and muscle) when stored frozen at -18°C.

TMDs

Storage stability data for TDMs are presented in EFSA Journal 2018;16(7):5376. Residues are stable in wheat and barley grain for 12 month - 1,2,4-Triazole, for 26 month – TA, for 26 month – TAA and for 48 month – TLA.

Residues are stable in cereal straw for 12 month - 1,2,4-Triazole, for 53 month – TA, for 40 month – TAA and there is no data for TLA.

Metabolism in plants and animals

Boscalid

Metabolism of boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-¹⁴C-diphenyl and 3-¹⁴C-pyridine labelled boscalid.

Plant residue definition for monitoring and risk assessment: boscalid

Animal residue definition for monitoring: Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney

Animal residue definition for risk assessment:

Boscalid in muscle, fat milk and eggs;

Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney;

Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates and the bound residues (measured as M510F52 or M510F53) expressed as Boscalid in Liver (ruminant and pig);

(EFSA 2014)

Difenoconazole

Plant residue definition for monitoring Difenoconazole Reg. (EU) 2019/552

Plant residue definition for risk assessment separate residue definitions (Difenoconazole, SANCO/830/08 – rev. 3, 13 December 2013, 18 May 2020):

- 1) Difenoconazole
- 2) TA and TLA, since these compounds share the same toxicity;
- 3) TAA
- 4) 1,2,4-T

Animal residue definition for monitoring: difenoconazole Reg. (EU) 2019/552

Animal residue definition for risk assessment

- 1) Difenoconazole
- 2) TA and TLA, since these compounds share the same toxicity;
- 3) TAA
- 4) 1,2,4-T

Magnitude of residues in plants

Boscalid

Proposed GAP:

Winter wheat, BBCH 30-59, 2 applications, 0.35 kg a.s/ha, PHI – not required.

Sufficient new trials according to the proposed GAP on wheat are available to support the proposed uses. The residue data are valid with regard to storage stability data. The residues arising from the proposed uses will not exceed the MRLs established for wheat (0.8 mg/kg, Reg. (EU) 2021/590).

50 days is proposed as PHI (according to the new trials).

Difenoconazole

Proposed GAP:

Winter wheat, BBCH 30-59, 2 applications, 0.10 kg a.s/ha, PHI – not required.

Sufficient new trials on wheat are available to support the proposed uses. The residue data are valid with regard to storage stability data. Trials GAP: BBCH 61-75; 2 applications, 0.100 kg a.s/ha.

The residues arising from the proposed uses will not exceed the MRLs for Difenoconazole established for cereals (0.1 mg/kg; Reg. (EU) 2019/552).

50 days is proposed as PHI (see boscalid).

TMDs

Trials GAP (new studies): 2x 0,1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, 43, outdoor.

GAP (EU unprotected data): GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d

EU data is not in line with proposed GAP. Unprotected EU residue trials are considered for informational purposes only.

The sufficient data submitted for residues TMDs in wheat are available and presented in EFSA Journal 2018;16(7):5376. Proposed GAP is within acceptable range with respect to trials GAP ($\pm 25\%$).

NEW trials:

Residues:

TA

Grain (new studies): 5 x n.d. (<0.003), 0.089, 0.14 mg/kg

Straw (new studies): 7 x n.d. (<0.003) mg/kg

TLA

Grain (new studies): 7 x n.d. (<0.003) mg/kg

Straw (new studies): 7 x n.d. (<0.003) mg/kg

TAA

Grain (new studies): 5 x n.d. (<0.003), <0.01 ($<LOQ$), 0.013 mg/kg

Straw (new studies): 7 x n.d. (<0.003) mg/kg

1,2,4-T

Grain (new studies): 0.24, 0.13, 0.11, 0.11, 0.09, 0.57, 0.098 mg/kg

Straw (new studies): 8 x n.d. (<0.003) mg/kg

Study Paszek G., 2019

The samples were analysed in November 2019. Therefore, two trials conducted in Germany (2016) could not be accepted due to lack of stability data over time from sampling to analysis. The available storage stability data does not cover that time.

Time from sampling to analysis of 1,2,4-T is more than 12 months in all other trials. The applicant should provide data to document 1,2,4-T stability in the test samples.

Study Romero S., Niewelt S., 2019

Time from sampling to analysis of 1,2,4-T is more than 12 months. The applicant should provide data to document the stability of the 1,2,4-T in the test samples.

Magnitude of residues in livestock

Boscalid

The Applicant refers to data of active ingredient since, the data protection was expired.

There is no risk for animal MRL to be exceeded (Reg. (EU) 2021/590). Additional studies are no required.

zRMS remark:

The dietary burden was calculated in the framework of the Article 12 procedure. The intended uses are covered by the uses assessed in EFSA Journal 2014;12(7):3799.

STMR/HR values from the supervised residue trials presented in this submission are lower than were used as input values stated in EFSA Journal 2014;12(7):3799 (presented below).

Wheat grain STMR: 0.12 (EFSA, 2014)

Wheat straw STMR: 33.7 and HR: 52.7 (EFSA, 2014)

No further calculation is needed.

Nevertheless, the evaluator has been performed the calculations using the currently valid calculator (animal model 2017) for the proposed uses only.

Difenoconazole

The requested uses modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

Calculation using the input data from the EFSA Journal 2021 19 (2): 64 as input; except for wheat were done (see rev. B7, point 7.3.4.1).

Input data for wheat (residue trials):

Grain

STMR – 0.02

Straw

STMR – 0.75

HR – 2.14

TMDs

Applicant refers to unprotected EU data.

EFSA Journal 2018;16(7):5376:

Data Gap: Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin.

The above requirement applies to the active substance.

Processing studies

Boscalid, Difenoconazole

No new studies for determination of residues in processed commodities have been performed. The Applicant refers to data of active ingredients since, the data protection was expired. Further processing studies are not required as they are not expected to affect the outcome of the risk assessment.

TDMs

Applicant refers to Addendum – Confirmatory Data, UK, 2018.

The TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation.

Magnitude of residues in representative succeeding crops

Boscalid

Taking relatively low application rate of boscalid into account it can be concluded that specific plant-back

restrictions related to the use of Boscalid 23.3% + Difenconazole 6.6% SC are not required, provided that the product is used according to GAP. Exceedance of the MRLs set based on rotational crops residue studies is unlikely. Waiting periods before planting following succeeding crops: not required.

Difenconazole

Waiting periods before planting following succeeding crops: not required.

TMDs:

Applicant refers to Addendum – Confirmatory Data, UK, 2018.

EFSA Journal 2018;16(7):5376: *Rotational crop field trials on cereals small grain, carrots and lettuces were submitted for the determination of all the TDMs at different plant back intervals. The maximum storage time interval of the residue samples of the trials in primary and rotational crops, however, was not provided and is required to conclude on the validity of these trials (data gap).*

The above requirement applies to the active substance.

According to the available data, the intended uses on winter wheat are considered acceptable.

3.6.2 Consumer exposure

Consumer exposure regarding Boscalid

TMDI (% ADI) according to EFSA PRIMo	398% (NL toddler) 260% (DE child) 224% (GEMS/Food G11) 223% (GEMS/Food G10) 217% (NL child) 216% (GEMS/Food G06) 213% (GEMS/Food G08) 210% (GEMS/Food G07) 187% (GEMS/Food G15) 184% (IE adult) 168% (SE general) 145% (IT adult) 144% (ES adult) 143% (FR child 3-15 yr) 140% (ES child) 131% (IT toddler) 131% (RO general) 131% (PT general) 130% (NL general) 127% (FR toddler 2-3 yr) 120% (DE women 14-50 yr) 119% (DK child) 115% (DE general) 112% (FI 3 yr) 108% (FR adult) 102% (FR infant) 102% (UK toddler)
IEDI (% ADI) according to EFSA PRIMo	85% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo	Not relevant.
NTMDI (% ADI)	-

NEDI (% ADI)	-
NESTI (% ARfD)	-

The proposed uses of Boscalid in the formulation Boscalid 23.3% + Difenconazole 6.6% SC do not represent unacceptable chronic risk for the consumer.

Consumer exposure regarding Difenconazole

TMDI (% ADI) according to EFSA PRIMo	351,3% NL toddler 282,4% DE child 240,7% GEMS/Food G06 195,0% NL child 188,2% GEMS/Food G11 182,9% GEMS/Food G10 182,5% GEMS/Food G07 179,8% PT general 177,2% GEMS/Food G08 175,5% IE adult 155,2% GEMS/Food G15 155,1% RO general 149,6% FR child 3 15 yr 136,4% DE women 14-50 yr 135,1% FR adult 128,9% FR toddler 2 3 yr 125,6% DE general 124,6% ES child 115,0% SE general 111,1% ES adult 107,7% NL general 105,3% UK toddler 103,4% IT toddler 100,4% IT adult		
IEDI (% ADI) according to EFSA PRIMo	53,3% GEMS/Food G06	tomatoes	
	32,2% GEMS/Food G10	Rice	
IESTI (% ARfD) according to EFSA PRIMo	Unprocessed commodities: Wheat: 0.9% (based on children) Wheat: 0.5% (based on adult) Processed commodities: Wheat/milling (flour): 0.8% (based on children) Wheat/bread/pizza: 0.3% (based on adult)		
NTMDI (% ADI)	-		
NEDI (% ADI)	-		
NESTI (% ARfD)	-		

Boscalid:

Consumer risk assessment has been recalculated (EFSA PRIMo rev.3.1) using as input values: MRLs (Reg. (EU) 2021/590) and in the next step STMR values (EFSA Journal 2019;17(11):5897).

The proposed uses of Boscalid in the formulation Boscalid 23.3% + Difenconazole 6.6% SC do not represent unacceptable chronic risks for the consumer.

TMDs:

Results from Sharda field trials were not used in the risk assessment calculations and can be considered as additional.

Applicant's statement: *Time between sampling and extraction varies from 28 to 39 months. Such long period has been a result of hard-to-reach situation with TDMs standards on the market at the time of performing study. Therefore applicant wants to refer to Confirmatory Data on Triazole Derivative Metabolites and its addendum (February 2018) already evaluated and accepted at EU level.*

The proposed uses of Difenoconazole in the formulation Boscalid 23.3% + Difenoconazole 6.6% SC do not represent unacceptable acute and chronic risk for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

Concentration of Boscalid and Difenoconazole in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentration (PEC values) in soil, surface water, sediment and ground water are provided.

Intended use pattern of Boscalid 23.3% + Difenoconazole 6.6% EC

Crop	Application rate (kg a.s./ha)	Application method	Max. number of applications	Min. application interval	Application timing
Winter wheat	Boscalid: 0.35 Difenoconazole: 0.1	Foliar spray	2	14 days	BBCH 30-59
Winter wheat	Boscalid: 0.35 Difenoconazole: 0.1	Foliar spray	2	14 days	BBCH 30-59
Winter wheat	Boscalid: 0.35 Difenoconazole: 0.1	Foliar spray	2	14 days	BBCH 39-59

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} calculations have been conducted with Boscalid using the EU agreed endpoints (Review Report, 2008) and with Difenoconazole and its relevant metabolites 1,2,4-triazole (CGA 71019) and Difenoconazole alcohol (CGA 205375) using the EU agreed endpoints (EFSA Journal 2010;8(11):1967 and Triazole LoEP January 2013).

Maximum *initial* PEC_{soil} value for Boscalid was 0.182 mg/kg following the highest application rate of 350 g Boscalid/ha.

Maximum *initial* PEC_{soil} value for difenoconazole was 0.052 mg/kg, 0.002 mg/kg for 1,2,4-triazole (CGA 71019) and 0.005 mg/kg for Difenoconazole alcohol (CGA 205375), following the highest application rate of 100 g of Difenoconazole/ha.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} have been realised for Boscalid and for Difenoconazole and its relevant metabolites 1,2,4-triazole (CGA 71019) and Difenoconazole alcohol (CGA 205375) with standard FOCUS scenarios to obtain outputs from FOCUS PELMO 5.5.3 and PEARL 4.4.4 models and the Koc values established in the EU review. Nine realistic worst-case standard weather, soil and crop scenarios that collectively represent major agricultural areas in the European Union were used as recommended by FOCUS (2000, 2009).

Modelling was done for two applications of 1.5 L product/ha (equivalent to 0.350 kg Boscalid /ha and 0.1 kg of Difenoconazole/ha) to winter cereals. It should be noted that as recommended in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (FOCUS 2011), a corrected application rate is calcu-

lated taking into account the interception by the crop canopy. Absolute application dates, calculated according to AppDate v 3.05 (30 April 2019), were used for modelling.

For Boscalid, the maximum PEC_{gw} value is $< 0.001 \mu\text{g/L}$ for relevant scenarios in Poland.

PEC_{gw} values were all below $0.001 \mu\text{g/L}$ for Difenconazole and its metabolite Difenconazole alcohol (CGA 205375). For the metabolite 1,2,4-triazole (CGA 71019), the maximum PEC_{gw} values PELMO and PEARL scenarios are $0.032 \mu\text{g/L}$.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The $PEC_{sw/sed}$ of Boscalid and Difenconazole and its relevant metabolites 1,2,4-triazole (CGA 71019) and Difenconazole alcohol (CGA 205375) have been assessed with the models FOCUS STEPS 1, 2, 3 and 4 (when necessary) and the DT_{50} water/sediment values established in the EU review.

Since the aquatic organisms risk assessments using Step 2 PEC_{sw} values still show unacceptable risks for the active substances Boscalid and Difenconazole, further calculations were conducted at Step 3 using the models FOCUS SWASH v5.3, FOCUS PRZM v 4.3.1, FOCUS MACRO v5.5.4 and FOCUS TOXWA v5.5.3. However, Step 3 refinements were sufficient to show acceptable risk for the substance Boscalid and Difenconazole for scenarios important for Poland.

The results for PEC surface water (Step 1 to 4) for the active substance and its metabolites were used for the eco-toxicological risk assessment. Please refer to Part B, Section 9, Point 8.9 for more details about the results obtained.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20°C of the active substance Boscalid is $< 10^{-5} \text{ Pa}$. Hence the active substance Boscalid is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Boscalid due to volatilization with subsequent deposition should not be considered.

The vapour pressure at 20°C of the active substance Difenconazole is $< 10^{-5} \text{ Pa}$. Hence the active substance Difenconazole is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Difenconazole due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

- Birds

According to the screening and first-tier assessment for winter wheat, all the TER_a and TER_{lt} values for active substances Boscalid and Difenconazole are greater than the Annex VI trigger of 10 and 5, respectively, indicating that CIAZ presents no unacceptable acute and long-term risk to birds according to the intended uses on winter wheat. In addition, no unacceptable acute and long-term risk is expected due to combined exposure.

Difenconazole has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm-eating and fish-eating birds according to the intended uses of CIAZ.

- Mammals

According to the screening assessment for winter wheat, all the TERa and TERlt values for active substances Boscalid and Difenconazole are greater than the Annex VI trigger of 10 and 5, respectively, indicating that CIAZ presents no unacceptable acute and long-term risk to mammals according to the intended uses on winter wheat. In addition, no unacceptable acute and long-term risk is expected due to combined exposure.

Difenconazole have been shown to have the potential for bioaccumulation, however, there is no risk to earthworms-eating and fish-eating mammals according to the intended uses of CIAZ.

3.8.2 Effects on aquatic species

For the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for invertebrate as characterised by a NOEC for *Daphnia magna* of 5.6 µg/L in connection with an assessment factor of 10).

The PEC_{sw}/RAC ratio for the most sensitive organism – long term exposure for aquatic invertebrates for difenconazole for scenarios D3 (ditch), on winter cereals indicated an acceptable risk for aquatic organisms only with 5 meter buffer zone, calculated by FOCUS STEP 4 programme.

For remained scenarios the risk for difenconazole is acceptable already with PEC_{sw} FOCUS STEP 3 calculations. Taking into account the PEC_{sed}/RAC ratio for *Cironomus riparius* for difenconazole for R1 (stream) stream on winter cereals indicated an acceptable risk for aquatic organisms with 5 meter vegetative buffer zone, calculated by FOCUS STEP 4 programme. The PEC_{sw}/RAC ratio for boscalid for all scenarios passed the trigger below 1 with PEC_{sw} STEP1-3 calculations on winter cereals.

The PEC/RAC ratio for metabolites of difenconazole and boscalid for all scenarios passed the trigger below 1 with PEC_{sw} STEP1- 2 calculations on winter cereals.

For **metabolites** 1,2,4-triazole and CGA 205375 step 1 calculations reached an acceptable risk for aquatic organisms in all crops.

CIAZ

Regarding the formulation, calculated PEC/RAC ratios indicated an acceptable risk for the most sensitive group of aquatic organisms (risk for acute fish as characterised by a LC₅₀ for *Oncorhynchus mykiss* of 14030 µg f.p./L in connection with an assessment factor of 100). No mitigation measures will be needed.

In addition, a risk assessment for the combinations of a.s. in the formulation was performed and no unacceptable risk was obtained.

3.8.3 Effects on bees

First-tier assessments indicate that no unacceptable risk for bees exposed to CIAZ is expected according to the intended uses.

According to EU Reg. 284 /2009, the chronic toxicity test for adult bees, the chronic test for larvae should be provided for authorization of plant protection product.

Therefore the studies should be provided to Ministry of Agriculture in Poland when new EFSA GD for Bees will be applied at EU level..

3.8.4 Effects on other arthropod species other than bees

No in-field and off-field risk to non-target arthropods is expected after the application of CIAZ according to the proposed GAP.

3.8.5 Effects on soil organisms

The acute and chronic TER values for Boscalid and Difenconazole were above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that the active substances do not pose an acute

and long-term risk to earthworms and other soil macro- and mesofauna when applied according to the proposed uses rates.

Moreover, an application of CIAZ in respect of the GAP should not represent an acute and long term risk to earthworm and the other soil meso/microfauna.

Risk assessment conducted with relevant PEC_{soil} for the active substances Boscalid and Difenoconazole indicate a low risk to soil microorganisms when applied according to the proposed use rates.

3.8.6 Effects on non-target terrestrial plants

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for CIAZ shows that the Annex VI trigger value of 5 is not exceeded, indicating that CIAZ poses a low risk to non-target plants when applied according to the proposed use rates.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites 1,2,4-triazole (CGA 71019) and Difenoconazole alcohol (CGA 205375) are predicted to occur in groundwater at concentrations below 0.001 µg/L (see Part B8, chapter 8.8 – KCP 9.2.4). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

CIAZ (Boscalid 23.3% + Difenoconazole 6.6% SC) contains Difenoconazole which is approved as a candidate for substitution because two of PBT.

As a conclusion of the comparative assessment, CIAZ is not suitable for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Sekcja toksykologii:

Dodać H351 i EUH208; strefa buforowa 2-3 m

Sekcja pozostałości:

Okres karencji: 50 dni

Okres od ostatniego zastosowania środka na rośliny do dnia, W którym można siać lub sadzić rośliny uprawiane następnie:

Nie dotyczy w normalnym cyklu rozwojowym rośliny chronionej.

W przypadku wcześniejszej likwidacji plantacji w tym samym sezonie wegetacyjnym można sadzić pszenicę.

Sekcja skuteczności: Tylko zastosowanie przeciw rdzy żółtej i septoriozie paskowanej liści pszenicy może zostać warunkowo zaakceptowane. Środek wykazuje średni stopień zwalczania septoriozy paskowanej liści pszenicy i rdzy żółtej. Fuzarioza i rdza brunatna zostały wykreślone z etykiety. Zalecana ilość wody to 200-300 L/ha.

Sekcja Ekotoksykologii:

Wszystkie proponowane w GAP zastosowania zostały zaakceptowane. Wprowadzono zwrot P501.

Wykreślono zwrot 280

Załącznik do zezwolenia MRiRW nr R-/2021 z dnia2021 r.

Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalayas Business Center, Carril Condomina nº 3, 12th Floor, 30006 Murcia, Królestwo Hiszpanii, tel.: +34868127589, fax.: +34868127588, e-mail: eu.regn@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Cropchem Ltd., Prime Business Park, Dashrathlal Joshi Road, Vile Parle (West), Mumbai – 400 056, Indie, Tel.: + 91 22 6261 5615, Fax: + 91 22 6678 2828/ 2808, Email: regn@shardaintl.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: (...)

CIAZ

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

boskalid (związek z grupy anilidów) –233 g/l (20,97 %)

difenokonazol (związek z grupy triazoli) –66 g/l (5,94 %)

Zezwolenie MRiRW nr R-/2021 z dnia2021 r.



Uwaga	
H351	Podejrzewa się, że powoduje raka
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH208	Zawiera 1,2-benzisothiazol-3(2H)-one. Może powodować wystąpienie reakcji alergicznej
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P280 P501	Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach.
P391	Zebrać wyciek.

OPIS DZIAŁANIA

FUNGICYD w formie stężonej zawiesiny do rozcieńczania wodą do stosowania zapobiegawczego i interwencyjnego w zwalczaniu chorób powodowanych przez grzyby.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Pszenica ozima

Septorioza paskowana liści pszenicy, rdza **żółta** liści pszenicy, ~~fuzarioza~~

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,5 l/ha

Termin stosowania: środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, od początku fazy strzelania w źdźbło do końca fazy kłoszenia (BBCH 30-59).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 200-300-400 l/ha.

Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie wymagany

1. Środek może wykazywać średni poziom zwalczania septoriozy paskowanej liści pszenicy.
2. Środek stosować w temperaturze powietrza powyżej 12°C.
3. Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiadujące rośliny uprawne oraz nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
4. Środek zawiera dwie substancje czynne o różnych mechanizmach działania: boskalid z grupy anilidów (fungicydy inhibitory dehydrogenazy bursztynianowej – SDHI, wg FRAC grupa 7) oraz difenokonazol z grupy triazoli (fungicydy inhibitory biosyntezy steroli – inhibitory demetylacji (SBI – DMI), wg FRAC grupa 3). W ramach strategii przeciwdziałania odporności sprawców chorób środki grzybobójcze zawierające substancje czynne z tych grup należy stosować maksymalnie w dwóch

zabiegach w sezonie na danej plantacji zbóż. Należy również przestrzegać zasad integrowanej ochrony przed chrobami, w tym stosowania innych niż chemiczne metod ochrony np. upraw odmian odpornych.

5. Ponadto zaleca się stosować środek:

- głównie w zabiegach zapobiegawczych (profilaktycznie),
- wyłącznie w zalecanych dawkach,
- zgodnie z zaleceniami zamieszczonymi na etykiecie.

6. Środek wykazuje średni stopień zwalczania septoriozy paskowanej liści pszenicy i rdzy żółtej.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość wraz z objętością środka. Przed otwarciem opakowania wstrząsnąć jego zawartością.

Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego do połowy wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wleciu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe, lub,
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub,
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Bezpośrednio po pracy aparaturę dokładnie wymyć oraz co najmniej trzykrotnie przepłukać wodą.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić, ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin

Strefa buforowa 2-3 m

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA DO DNIA ZBIORU ROŚLINY UPRAWNEJ (okres karencji):

50 dni.

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA NA ROŚLINY DO DNIA, W KTÓRYM MOŻNA SIAĆ LUB SADZIĆ ROŚLINY UPRAWIANE NASTĘPCZO:

Nie dotyczy w normalnym cyklu rozwojowym rośliny chronionej.

W przypadku wcześniejszej likwidacji plantacji w tym samym sezonie wegetacyjnym można sadzić pszenicę.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający: kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych. Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności –2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

No letter of Access to protected data are required.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1, KCP 2.4.2, KCP 2.5.1, KCP 2.5.2, KCP 2.6.1, KCP 2.7.1, KCP 2.7.3, KCP 2.7.4, KCP 2.8.2, KCP 2.8.3.1, KCP 2.8.3.2, KCP 2.8.5.1.2, KCP 2.8.7.2	Al Amin I.	2017	Boscalid 23.3% + Difenconazole 6.6% SC. Part I: Determination of physicochemical properties of the initial preparation and after accelerated storage Institute of Industrial Organic Chemistry, Report No. BF-107/16 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.4.2	Krzysiak-Warżala B.	2019	Boscalid 23.3% + Difenconazole 6.6% SC. Analysis of pH of neat formulation (initial formulation and after accelerated storage) Łukasiewicz Research Network, Report No. 191/2019 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.7.1	E. Nowakowska-Bogdan	2020	Boscalid 23.3 % + Difenconazole 6.6 % SC – Analysis of relevant impurity content of initial preparation and preparation after accelerated procedure. Łukasiewicz Research Network, Report No. 112/2020 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.7.5	Al Amin I.	2019	Boscalid 23.3% + Difenconazole 6.6% SC. Part III: Evaluation of physicochemical properties after the first year of storage Institute of Industrial Organic Chemistry, Report No. BF-107/16 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.6	Al Amin I.	2018	Boscalid 23.3% + Difenconazole 6.6% SC. Part II: Evaluation of physicochemical properties after the first year of storage Institute of Industrial Organic Chemistry, Report No. BF-107/16 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.2.2, KCP 2.3.1, KCP 2.3.3	Flasinska P.	2017	Boscalid 23.3% + Difenconazole 6.6% SC. Determination of flash point, auto-ignition temperature and oxidizing properties. Institute of Industrial Organic Chemistry, Report No. BC-40/17 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.2.1	Mena B.	2019	Boscalid 23.3% + Difenconazole 6.6% SC: Determination of the oxidizing properties and explosive properties. Sharda Cropchem España S.L., Report No. SCE-023/2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
CP 6.0-001	Anonymous	2019	Biological Assessment Dossier: Boscalid 23.3% + Difenconazole 6.6% SC (233 g/L boscalid + 66 g/L difenconazole SC) – EU South zone Sharda Cropchem España - - Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 5.1.1	Pokrzywnicka S.	2017	Boscalid 23.3% + Difenconazole 6.6% SC – Method validation for determination the content of active substances Institute of Industrial Organic Chemistry report No. BA-27/17 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 5.1.2	E. Nowakowska-Bogdan	2020	Boscalid 23.3 % + Difenconazole 6.6 % SC – Analysis of relevant impurity content of initial preparation and preparation after accelerated procedure. Łukasiewicz Research Network, Report No. 112/2020 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 7.1.1	xxxxxxxxx	2017	Acute oral toxicity study of Boscalid 23.3% + Difenconazole 6.6% SC in rats xxxxxxxxxxx report No. 401-1-01-16906 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 7.1.2	xxxxxxxxx	2017	Acute dermal toxicity study of Boscalid 23.3% + Difenconazole 6.6% SC in rats xxxxxxxxxxx report No. 401-1-01-16907 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.3	xxxxxxx	2017	Acute inhalation toxicity study of Boscalid 23.3% + Difenconazole 6.6% SC in rats xxxxxxx report No. 401-1-01-16908 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 7.1.6	xxxxxxx	2017	Skin sensitisation study of Boscalid 23.3% + Difenconazole 6.6% SC in Guinea pigs [Guinea pig maximization test] xxxxxxx report No. 401-1-01-16911 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 9.1.3 KCP 9.2.4 KCP 9.2.5	Anonymous	2019/2020	Calculations of PECsoil, PECgw and PECsw. Sharda Non GLP Unpublished	N	N	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-01	xxxxxxx	2018	Boscalid 23.3% + Difenconazole 6.6% SC: Rainbow Trout, Acute Toxicity Test Report No. W/95/17 xxxxxxxxxxxxxxx GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-02	Ewa Nierzędska	2018	Boscalid 23.3% + Difenconazole 6.6% SC: <i>Daphnia magna</i> , acute immobilization test Report No. W/97/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-03	Ewa Nierzędska	2017	Boscalid 23.3% + Difenconazole 6.6% SC: <i>Pseudokirchneriella subcapitata</i> SAG 61.81 Growth Inhibition Test Report No. W/96/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-04	Ewa Nierzędska	2018	Boscalid 23.3% + Difenconazole 6.6% SC <i>Lemna gibba</i> L. CPCC 310, Growth inhibition test Report No. W/98/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.1.1	Natalia Lemańska	2018	Boscalid 23.3% + Difenconazole 6.6% SC Honeybees (<i>Apis mellifera</i> L.), Acute Oral Toxicity Test Report No. B/80/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.1.2	Natalia Lemańska	2018	Boscalid 23.3% + Difenconazole 6.6% SC Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test Report No. B/81/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.2-01	Natalia Lemańska	2018	An extended laboratory test for evaluating the effects of Boscalid 23.3% + Difenconazole 6.6% SC on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Report No. B/83/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.2-02	Natalia Lemańska	2018	An extended laboratory test for evaluating the effects of Boscalid 23.3% + Difenconazole 6.6% SC on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani-Perez) Report No. B/82/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.4.1.1	Paweł Pieczka	2018	Boscalid 23.3% + Difenconazole 6.6% SC: Earthworm Reproduction Test (<i>Eisenia andrei</i>) Report No. G/129/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.4.2.1-01	Paweł Pieczka	2018	Boscalid 23.3% + Difenconazole 6.6% SC: Collembolan (<i>Folsomia candida</i>) Reproduction Test Report No. G/130/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.5.1	Paweł Pieczka	2018	Boscalid 23.3% + Difenconazole 6.6% SC: Soil Microorganisms: Nitrogen Transformation Test Report No. G/128/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.5.2	Paweł Pieczka	2017	Boscalid 23.3% + Difenconazole 6.6% SC: Soil Microorganisms: Carbon Transformation Test Report No. G/127/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.6.2-01	Paweł Pieczka	2018	Boscalid 23.3% + Difenconazole 6.6% SC: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Report No. G/132/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.6.2-02	Paweł Pieczka	2018	Boscalid 23.3% + Difenconazole 6.6% SC: Terrestrial Plant Test: Vegetative Vigour Test Report No. G/133/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-