

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: SHA 7216 A

Product name: CIAZ

Chemical active substances:

Boscalid, 233 g/L

Difenoconazole, 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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Version history

When	What
02.2022	RMS Assessment
12.2022	Final Registration Report

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1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Sharda Cropchem España S.L
Address: Edificio Atalayas Business Center,
Carril Condomina nº 3, 12th Floor,
30006 Murcia, Spain
Phone: +34868127589
FAX: +34868127588

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Name: Sharda Cropchem Ltd.
Address: Prime Business Park
Dashrathlal Joshi Road
Vile Parle (West)
Mumbai – 400 056
India
Phone number: + 91 22 6678 2800
Fax number: + 91 22 6678 2828/ 2808
Email : shardaint@vsnl.com
regn@shardaintl.com

1.2.2 Producer(s) of the active substance(s)

Name: Sharda Cropchem Ltd.
Address: Prime Business Park
Dashrathlal Joshi Road
Vile Parle (West)
Mumbai – 400 056
India
Phone number: + 91 22 6678 2800
Fax number: + 91 22 6678 2828/ 2808
Email : shardaint@vsnl.com
regn@shardaintl.com

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Boscalid

Boscalid min. 970 g/kg (Sharda source; equivalence evaluated by UK)
min. ≥ 960 g/kg (Commission Directive 2008/44/EC and SAN-

CO/3919/2007 – rev. 5 (21 January 2008))

Boscalid has not relevant impurities.

1.2.3.2 Difenoconazole

Difenoconazole min. 940 g/kg (Sharda source; equivalence evaluated by Sweden)
min. 940 g/kg (Commission Directive 2008/69/EC and SANCO/830/08 – rev. 3 (13 December 2013))

According to the Regulation (EU) No 1100/2011, difenoconazole has relevant impurity – toluene (max possible content 5g/kg).

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)
Trade name: CIAZ
Company code number: SHA 7216 A
Boscalid 23.3% + Difenoconazole 6.6% SC

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Boscalid	233.0 g/L	219.0 – 247.0 g/L (± 6% of the declared content)	240.2 g/L	21.62% w/w
Difenoconazole	66.0 g/L	59.4 – 72.6 g/L (± 10% of the declared content)	70.2 g/L	6.32% w/w

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** Based on the density of the formulation = 1.111 g/mL

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Toluene	5g/kg

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-3: Information on Boscalid

Type	Name/Code Number
ISO common name	Boscalid
CAS No.	188425-85-6
EC No.	606-143-0
CIPAC No.	673

Table 1.4-4: Information on Difenoconazole

Type	Name/Code Number
ISO common name	Difenoconazole
CAS No.	119446-68-3
EC No.	601-613-1
CIPAC No.	687

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Suspension concentrate

[Code: SC]

1.6 Function (KCP 1.6)

The product Boscalid 23.3% + Difenoconazole 6.6% SC is a fungicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

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 properties were changed.

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

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Neither classification nor labelling is relevant for this section.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

P280

Compliance with FAO specifications:

The product Boscalid 23.3% + Difenconazole 6.6% SC complies with FAO specifications.

Formulation used for tests

The product used to determine the physical, chemical and technical properties is the one cited in Part C, Boscalid 23.3% + Difenconazole 6.6% SC.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Organoleptic (visual inspection, nasal inhalation)	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	Homogenous whitish liquid of characteristic odour	Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted
Explosive properties (KCP 2.2.1)	Software CHETAH	Boscalid 23.3% + Difenoconazole 6.6% SC	The product is not expected to exhibit explosive behaviours.	N	Mena B., 2019 SCE-023/2019	Accepted The formulation is not explosive
Oxidizing properties (KCP 2.2.2)	Standard Operating Procedure No. SPO/BC/05/b; corresponds to EEC A.21	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	The test item has not got the oxidizing properties.	Y	Flasińska P., 2017 Study No. BC-40/17	Accepted The formulation does not have oxidising properties
Flash point (KCP 2.3.1)	Standard Operating Procedure No. SPO/BC/09/b based on PN-EN ISO 2719: 2016; corresponds to EEC A.9	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	The test item has not got the flash point up to the boiling point.	Y	Flasińska P., 2017 Study No. BC-40/17	Accepted The formulation is not flammable.
Flammability (KCP 2.3.2)	-	-	Not required for liquid formulations.	-	-	Not applicable
Self-heating	Standard	Boscalid 23.3%	The test item has not got the auto-ignition temperature up to 650°C.	Y	Flasińska P.,	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
(KCP 2.3.3)	Operating Procedure No. SPO/BC/06/b based on standard DIN 51794:2003-05; corresponds to EEC A.15	+ Difenoconazole 6.6% SC (Batch No. SCL-20245)			2017 Study No. BC-40/17							
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed.	-	-	Not required						
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	pH of 1% water suspension = 7.39 The performed at 20 °C	Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted						
		Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-30305)	pH of neat formualtion = 6.50 The temperature of the sample was kept at 20 °C <table border="1"><tr><td>SAMPLE NAME:</td><td>Boscalid 23.3 % + Difenoconazole 6.6 % SC</td></tr><tr><td>• active substance:</td><td>1. Boscalid; 2. Difenoconazole</td></tr><tr><td>• active substance chemical name:</td><td>1. 2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide (IUPAC) 2. 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether (IUPAC)</td></tr><tr><td>• content of active substance:</td><td>1. 23.8 % w/v; 2. 6.56 % w/v</td></tr></table>	SAMPLE NAME:	Boscalid 23.3 % + Difenoconazole 6.6 % SC	• active substance:	1. Boscalid; 2. Difenoconazole	• active substance chemical name:	1. 2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide (IUPAC) 2. 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether (IUPAC)	• content of active substance:	1. 23.8 % w/v; 2. 6.56 % w/v	Y
SAMPLE NAME:	Boscalid 23.3 % + Difenoconazole 6.6 % SC											
• active substance:	1. Boscalid; 2. Difenoconazole											
• active substance chemical name:	1. 2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide (IUPAC) 2. 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether (IUPAC)											
• content of active substance:	1. 23.8 % w/v; 2. 6.56 % w/v											
Viscosity	Brookfield	Boscalid 23.3%	<u>At 20°C temperature:</u>	Y	Al Amin I.,	Accepted						

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments						
(KCP 2.5.1)	Test Method in accordance with OECD 114	+ Difenoconazole 6.6% SC (Batch No. SCL-20245)	At 5 s ⁻¹ was 780 mPa·s At 10 s ⁻¹ was 474 mPa·s At 25 s ⁻¹ was 248 mPa·s At 50 s ⁻¹ was 155 mPa·s <u>At 40°C:</u> At 5 s ⁻¹ was 618 mPa·s At 10 s ⁻¹ was 387 mPa·s At 25 s ⁻¹ was 206 mPa·s At 50 s ⁻¹ was 128 mPa·s				2017 Study No. BF-107/16 (Part I)	The mixture is not aspiration hazard						
Surface tension (KCP 2.5.2)	EEC A.5	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	44.45 mN/m at 20°C and 7.5 mL/L concentration			Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted According to the Reg No. 440/2008 criteria, the formulation SHA 7216 A is a surface-active material						
Relative density (KCP 2.6.1)	CIPAC MT 3.2	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	Absolute: 1.111 g/mL (20 °C) Relative: 1.111			Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted						
Bulk density (KCP 2.6.2)	-	-	Not relevant for liquid formulations.			-	-	Not applicable						
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3.1, 75.3, 148.1, 160, 184, 185 HPLC Visual	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	<table><tr><td></td><td>Initial preparation</td><td>After 14 d at 54°C</td></tr><tr><td>Physical state, colour and odour</td><td>Homogenous whitish liquid of characteristic</td><td>A solution of 25% volume appeared at the</td></tr></table>				Initial preparation	After 14 d at 54°C	Physical state, colour and odour	Homogenous whitish liquid of characteristic	A solution of 25% volume appeared at the	Y	Al Amin I., 2017 Study No. BF-107/16 (Part I) Krzysiak-	Accepted No degradation of active ingredients content after storage. The impurity (toluene)
	Initial preparation	After 14 d at 54°C												
Physical state, colour and odour	Homogenous whitish liquid of characteristic	A solution of 25% volume appeared at the												

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	inspection Nasal inhalation GC/MS	Batch No. SCL-30305		odour	top. After shaking it became homogenous whitish liquid of characteristic odour		Warzała B., 2019 Study No 191/2019 E. Nowakowska-Bogdan, 2020 Study No. 112/2020	content within the limit. Regarding solution which appeared at the top after storage, thorough mixing is required before each spraying, which was taken into consideration in the draft label. As regards pourability result, it is recommended to repeat rinsing. Other properties are considered acceptable. The PE/EV packaging after storage remain unchanged.
			pH at 1%	7.39	6.53			
			pH (neat)	6.50	4.94			
			Suspension stability (3.75 mL/L Boscalid)	93.98%	92.56%			
			Suspension stability (7.50 mL/L Boscalid)	94.19%	91.33%			
			Suspension stability (3.75 mL/L Difenconazole)	93.10%	88.62%			
			Suspension stability (7.50 mL/L Difenconazole)	93.09%	86.39%			
			Dispersion spontaneity	99.18%	97.67%			
			Wet sieve test	0.00%	0.00%			
			Pourability	R = 1.06% R' = 0.35%	R= 3.36% R' = 0.16%			
			Active ingredients	Boscalid 20.97% (232.98 g/L) Difenconazole 5.95% (66.10	Boscalid 21.97% (244.09 g/L) Difenconazole 6.29% (69.88			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
				g/L)	g/L)				
			Toluene content	0.03 % w/w 0.30 g/kg 0.033% (w/v) 0.33 g/L	0.032 % w/w 0.32 g/kg 0.036 % w/v 0.36 g/L				
			Density	1.1146 g/cm³	1.1175 g/cm³				
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required.				-	-	Accepted
Minimum content after heat stability testing (KCP 2.7.3)	HPLC	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	After 14 d at 54°C: Boscalid 21.97% (244.09 g/L) Difenoconazole 6.29% (69.88 g/L)				Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted The formulation was not affected by low temperature
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	After 7 days storage at 0 °C: Homogenous white liquid, and the next properties were performed: - Suspension stability was 97.09% (3.75 mL/L) and 98.53% (7.5 mL/L); - Wet sieve test: 0.00% residue in 75µm sieve.				Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted The formulation was not affected by low temperature
Ambient temperature shelf life (KCP 2.7.5)	SPO/BF/07/b based on GIFAP No. 17	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	Test	Initial	After 1 year	After 2 years	Y	Al Amin I., Study No. BF-107/16 (Part III)	Accepted Shelf life – 2 years Regarding apperance, pH, suspension stability, dispersion
			Appearance	Homogenou whitish liquid of characteristic odour	A solution of 5% in volume appeared at the top. After shaking it becam homogenous whitish liquid	A solution of 5% in volume appeared at the top. After shaking it becam homogenous whitish liquid			
			pH at 1%	7.39	7.08	7.44			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
			Suspension stability (3.75 ml/L Boscalid)	93.98%	98.64%	97.34			<p>spontaneity and wet sieve test, there was no significant change after storage.</p> <p>Regarding solution which appeared at the top after storage, thorough mixing is required before each spraying, which was taken into consideration in the draft label.</p> <p>Based on the results of pourability, it is recommended to repeat rinsing.</p> <p>Packaging (PE/EV bottles) was stable after storage.</p>
			Suspension stability 7.50 ml/L Boscalid)	94.19%	101.13%	96.26			
			Suspension stability (3.75 ml/L Difenoconazole)	93.10%	98.17%	96.60			
			Suspension stability (7.50 ml/L Difenoconazole)	93.09%	101.16%	96.19%			
			Dispersion spontaneity	99.18%	99.69%	98.78%			
			Wet sieve test	0.00%	0.00%	0.00%			
			Pourability	R = 1.06% R' = 0.35%	R = 2.82% R' = 0.29%	R = 2.56% R' = 0.33%			
			Package	1 litre PE/EV	Stable	Stable			
			Active ingredients	Boscalid 20.97% (232.98 g/L) Difenoconazole 5.95% (66.10 g/L)	Boscalid 21.65% (240.53 g/L) Difenoconazole 6.14% (68.23 g/L)	Boscalid 21.37% (237.42 g/L) Difenoconazole 6.06% (67.33 g/L)			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	SPO/BF/07/b based on GIFAP No. 17 CIPAC MT 75.3, 148.1, 160, 184, 185	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)		Initial preparation	After 1 year at 20°C		Y	Al Amin I., 2018 Study No. BF-107/16 (Part II)	Accepted Regarding appearance, pH, suspension stability, dispersion spontaneity and wet sieve test,
			Physical state colour and odour	Homogenous whitish liquid of characteristic odour	A solution of 5% in volume appeared at the top. After shaking it				

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	HPLC Visual inspection Nasal inhalation				becam homogenous whitish liquid			there was no significant change after storage.
			pH at 1%	7.39	7.08			Regarding solution which appeared at the top after storage, thorough mixing is required before each spraying, which was taken into consideration in the draft label.
			Suspension stability (3.75 ml/L Boscalid)	93.98%	98.64%			
			Suspension stability 7.50 ml/L Boscalid)	94.19%	101.13%			
			Suspension stability (3.75 ml/L Difenconazole)	93.10%	98.17%			
			Suspension stability (7.50 ml/L Difenconazole)	93.09%	101.16%			Based on the results of pourability, it is recommended to repeat rinsing.
			Dispersion spontaneity	99.18%	99.69%			Packaging (PE/EV bottles) was stable after storage.
			Wet sieve test	0.00%	0.00%			
			Pourability	R = 1.06% R' = 0.35%	R = 2.82% R' = 0.29%			
			Package	1 litre PE/EV	Stable			
			Active ingredients	Boscalid 20.97% (232.98 g/L) Difenconazole 5.95% (66.10 g/L)	Boscalid 21.65% (240.53 g/L) Difenconazole 6.14% (68.23 g/L)			
Wettability (KCP 2.8.1)	-	-	Not relevant for liquid.			-	-	Not applicable
Persistence of	CIPAC MT	Boscalid 23.3%	At 3.75 mL/L:			Y	Al Amin I.,	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
foaming (KCP 2.8.2)	47.3	+ Difenoconazole 6.6% SC (Batch No. SCL-20245)	10 mL after 1 min and 0 mL after 12 min <u>At 7.5 mL/L:</u> 11 mL after 1 min and 8 mL after 12 min		2017 Study No. BF-107/16 (Part I)	Highest and lowest concentration was tested. Results within the limit
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	At 3.75 mL/L, Boscalid: 93.98% At 7.50 mL/L, Boscalid: 94.19% At 3.75 mL/L, Difenoconazole: 93.10% At 7.50 mL/L, Difenoconazole: 93.09%	Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	99.18%	Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant for a SC formulation.	-	-	Not required
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant for a SC formulation.	-	-	Not required
Particle size distribution / nominal size range of granules	-	-	Not relevant for a SC formulation.	-	-	Not required

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.1.1)						
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Boscalid 23.3% + Difenoconazole 6.6% SC (Batch No. SCL-20245)	0.00%	Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant for a SC formulation.	-	-	Not required
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant for a SC formulation.	-	-	Not required
Attrition (KCP 2.8.5.3)	-	-	Not relevant for a SC formulation.	-	-	Not required
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant for a SC formulation.	-	-	Not required
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant for a SC formulation.	-	-	Not required
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant for a SC formulation.	-	-	Not required
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant for a SC formulation.	-	-	Not required
Flowability (KCP 2.8.7.1)	-	-	Not relevant for a SC formulation.	-	-	Not required
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Boscalid 23.3% + Difenoconazole 6.6% SC	R = 1.06% R' = 0.35%	Y	Al Amin I., 2017 Study No. BF-107/16 (Part I)	Accepted Based on the result of rinsed

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		(Batch No. SCL-20245)				residue, it is recommended to repeat rinsing.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant for a SC formulation.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant.	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant.	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant, not used for seed treatment.	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not relevant, not used for seed treatment.	-	-	-
Other/special studies (KCP 2.11)	-	-	Not relevant.	-	-	-

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.1-1: Packaging information for 0.250 liter bottle

Type	Description
Material:	COEX PE/EV
Shape/size:	Round bottle / approx. 61 mm diameter x 138.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.500 liter bottle

Type	Description
Material:	COEX PE/EV
Shape/size:	Round bottle / approx. 69 mm diameter x 199.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 1 liter bottle

Type	Description
Material:	COEX PE/EV
Shape/size:	Round bottle / approx. 88.5 mm diameter x 239.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 5 liter bottle

Type	Description
Material:	COEX PE/EV
Shape/size:	jerrycan / approx. 136 mm x 192 mm x 285 mm
Opening:	54.7 mm inner diameter

Type	Description
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 10 liter bottle

Type	Description
Material:	COEX PE/EV
Shape/size:	jerrycan / approx. 174 mm x 226 mm x 368 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 20 liter bottle

Type	Description
Material:	Fluorinated HDPE
Shape/size:	jerrycan / approx. 245 mm x 294 mm x 400 mm
Opening:	55.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextruded
UN/ADR	compliant

RMS :

Recommended packagings are accepted

4.2 Procedures for cleaning application equipment (KCP 4.4.2)

Tank cleaning

Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom and nozzles three times with clean water until the foam and all traces of product have been removed.

Effectiveness of the cleaning procedures

At the time of compilation of this dossier, no specific study was conducted for the product Boscalid 23.3% + Difenconazole 6.6% SC to investigate the effectiveness of the cleaning procedure.

Experience in use of plant protection products based on Boscalid and Difenconazole have not indicated any particular problems. Low levels of residues of CIAZ (Boscalid 233 g/L and Difenconazole 66 g/L, SC) in the equipment are not expected to present any particular risk to crops to be treated from a tank that has previously been used for the product.

The efficacy of cleaning of the application equipment with regard to impacts on “other” crops can be estimated on the basis of the PSD Efficacy Guideline 302 (December 2001). As worst case, the following prerequisites were considered:

Application rate: 1.5 L product/ha, (349.5 g boscalid/ha and 99 g difenoconazole/ha)
Tank volume: 2000 L
Volume remaining in spray lines and pump after spraying: 20 L
Spray volume: 200 L/ha (lowest spray volume corresponding to the maximum concentration of CIAZ in diluted spray)

Based on these prerequisites and in consideration of 3 rinses with each 500 – 1000 L of water based on good agricultural cleaning procedures, Boscalid and Difenconazole residues remaining in the tank after spraying will be diluted to the following levels:

Cleaning step	Water volume [L]	Concentration of residues		
		Product [L PPP/L water]	active substance 1 [g as1/L]	active substance 2 [g as2/L]
Tank filling:	2000			
Residues after spraying:	20	0.0075	1.7475	0.495
1 st step: 1/10 dilution of residual spray volume:	200			
Residues after spraying:	20	0.00075	0.17475	0.0495
2 nd step: 20% of tank volume added:	400			
Residues after spraying:	20	3.75×10^{-5}	0.0087375	0.002475
3 rd step: 20% of tank volume added:	400			
Residues after spraying:	20	1.875×10^{-6}	4.36875×10^{-4}	1.2375×10^{-4}
Addition of fresh spray solution:	2000			
Residues in the tank filling:	20	1.875×10^{-8}	4.36875×10^{-6}	1.2375×10^{-6}

PPP = CIAZ; as1 = Boscalid; as2 = Difenconazole

Residues remaining in the last cleaning solution were calculated to be 4.36875×10^{-4} g/L of Boscalid resulting in residue concentration of 4.36875×10^{-6} g/L Boscalid after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 500 – 1000 L/ha applied to succeeding crops, residues of 8.7375×10^{-3} g Boscalid will be applied per ha.

Compared to the effect levels on non-target plants, these residues are clearly below the lowest ER₅₀ found in the studies conducted with the test item for emergence and vegetative vigour of > 3600 g/ha (Document N2 – BASF DocID 2015/1046841). Thus, any detrimental effect on plants from tank residues can be excluded.

Residues remaining in the last cleaning solution were calculated to be 1.2375×10^{-4} g/L of Difenconazole resulting in residue concentration of 1.2375×10^{-6} g/L Difenconazole after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 500 – 1000 L/ha applied to succeeding crops, residues 2.475×10^{-3} g Difenconazole will be applied per ha.

Compared to the effect levels on non-target plants, these residues are clearly below the lowest ER₅₀ found in the studies conducted with the test item for emergence and vegetative vigour of > 100 g a.s./ha (EFSA Journal 2011;9(1):1967). Thus, any detrimental effect on plants from tank residues can be excluded.

Appendix 1 Lists of data considered in support of the evaluation

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	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% + Difenoconazole 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	Sharda Cropchem Limited
KCP 2.4.2	Krzysiak-Warzała B.	2019	Boscalid 23.3% + Difenoconazole 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	Sharda Cropchem Limited
KCP 2.7.1	E. Nowakowska-Bogdan	2020	Boscalid 23.3 % + Difenoconazole 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	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	Owner
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	Sharda Cropchem Limited
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	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	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	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	Owner
-	-	-	-	-	-

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	Owner
-	-	-	-	-	-

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	Owner
-	-	-	-	-	-

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Boscalid

Not relevant. There is no additional data on the active substance.

A 2.2 Difenoconazole

Not relevant. There is no additional data on the active substance.