

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: GPF515 / FGE03

Product name(s): Boscalid / Prothioconazole 350 / 200 WG

Chemical active substance(s):

Boscalid, 350 g/kg

Prothioconazole, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Article 33 application for a new product registration)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024

MS Finalisation date: June 2025 (initial Core Assessment)

August 2025 (final Core Assessment)

Version history

When	What
November 2024	V0 – Version from applicant for submission to z-RMS Poland in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No 1107/2009.
June 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency.
August 2025	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency.

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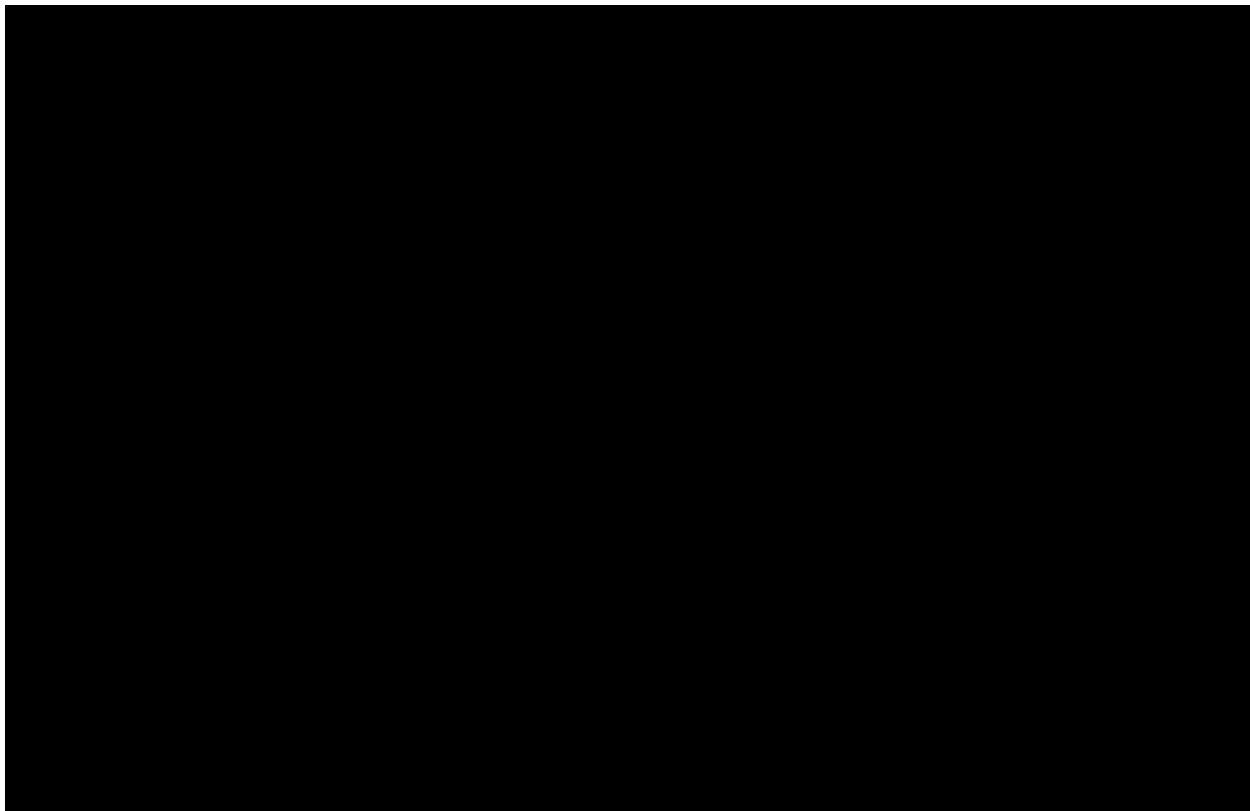
Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- The 2 and 3 years storage stability study is still ongoing upon submission of the dossier, which is a formal data GAP. Sufficient data however is available from the accelerated storage testing.

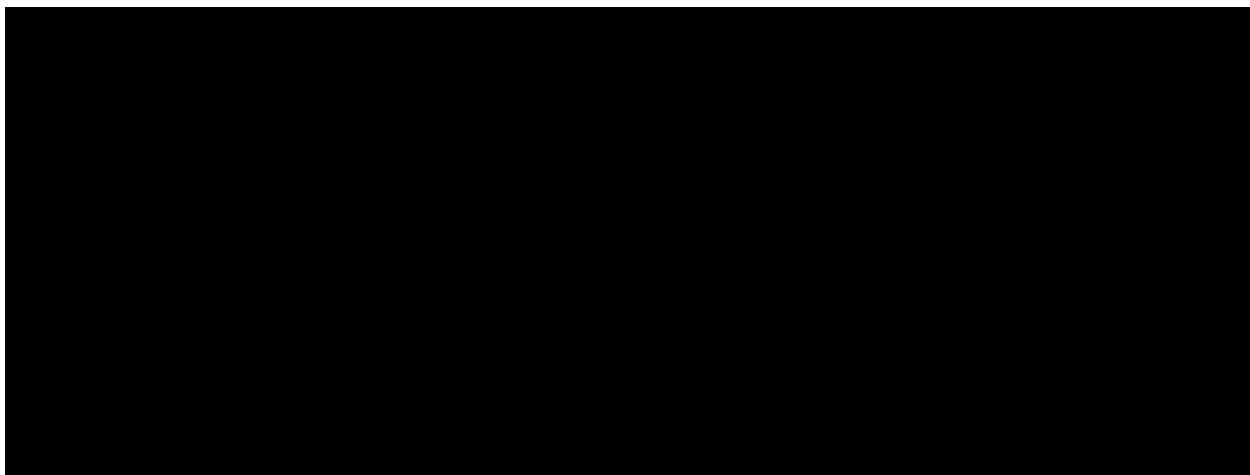
1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

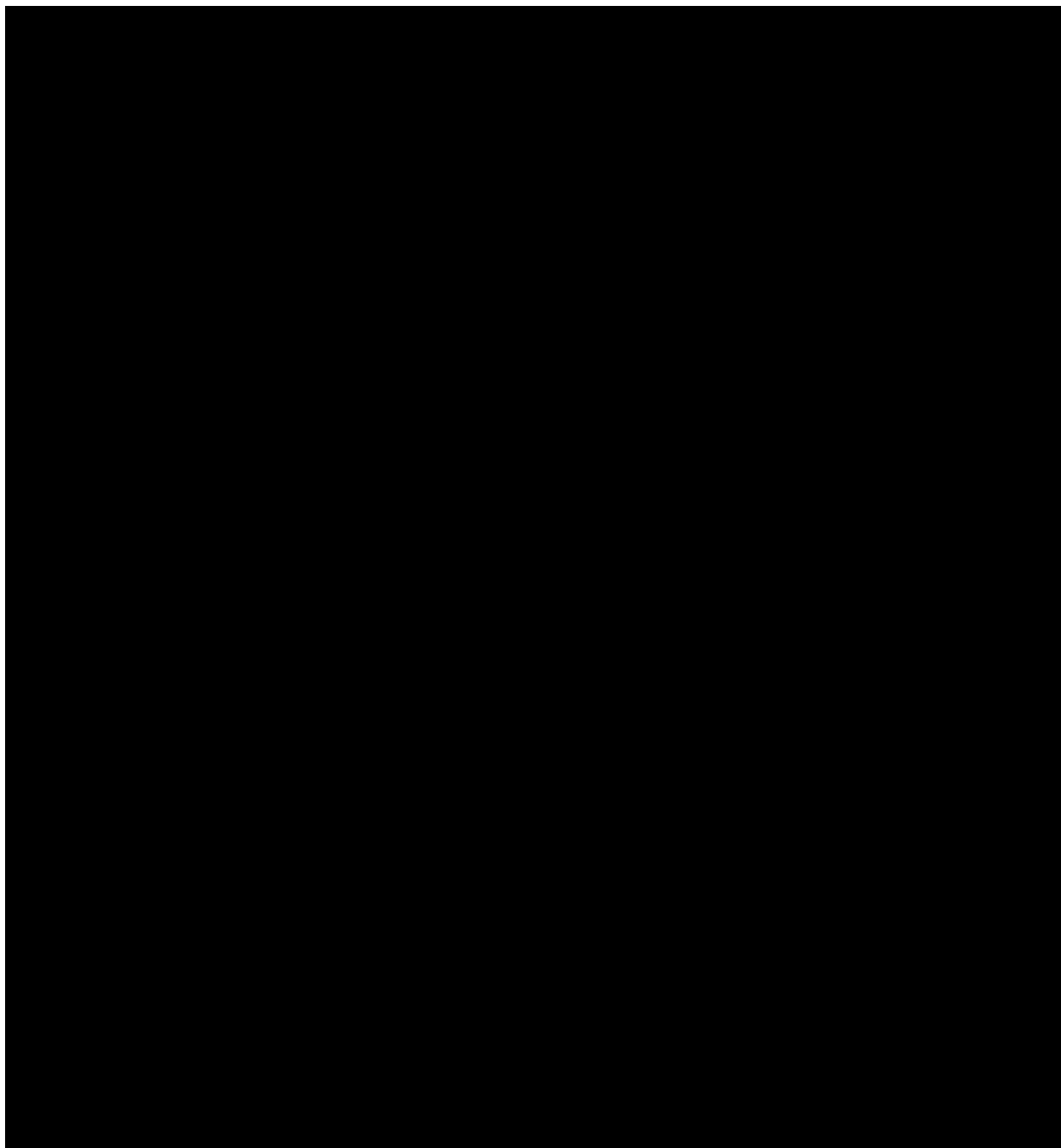


1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation



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



Manufacturing plants:

Confidential information or data are provided separately (Part C).

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

1.2.3.1 Boscalid

According to Commission Implementing Regulation (EU) No 540/2011, the minimum purity of Boscalid technical is 960 g/kg.

Boscalid– Source UPL min. 980 g/kg

Boscalid does not contain impurities of toxicological, ecotoxicological or environmental concern.

Further information/justification is provided in Part C.

1.2.3.2 Prothioconazole

According to Commission Implementing Regulation (EU) No 540/2011, the minimum purity of Prothioconazole technical is 970 g/kg.

Prothioconazole– Source 1,2,3 UPL min. 980 g/kg

According to the Commission Implementing Regulation (EU) No 540/2011 (amending Regulation (EU) No 1107/2009), for Prothioconazole the following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material:

Toluene	≤ 5 g/kg
Prothioconazole-desthio	≤ 0.5 g/kg (LOD)

Further information/justification is provided in Part C.

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

Trade name: FGE03. Please refer to Registration Report Part A for more details

Company code number: GPF515

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)

The preparation FGE03 was not the representative formulation in the EU revision of the active ingredients Boscalid and Prothioconazole. Therefore, physico chemical properties were provided for this preparation.

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/kg)	Technical content* (%w/w)
Boscalid	350 g/kg	332.5-367.5 g/kg	357.1 g/kg	35.71 %
Prothioconazole	200 g/kg	188.0-212.0 g/kg	~~204.1 g/kg~~ 206.2 g/kg	~~20.41 %~~ 20.62 %

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

The formulation does not contain any safeners or synergists.

Further information on the active substance and on the certified limits of formulants is considered confidential and is provided separately (Part C).

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Toluene	According to Regulation (EU) No 540/2011: 5 g/kg a.s. (equivalent to 1 g/kg or 0.1% w/w GPF515 / GPE03)
Prothioconazole-desthio	According to Regulation (EU) No 540/2011: 0.5 g/kg a.s. (equivalent to 0.1 g/kg or 0.01% w/w GPF515 / GPE03)

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 1.4-5: Information on Prothioconazole

Type	Name/Code Number
ISO common name	Prothioconazole
CAS No.	178928-70-6
EC No.	605-841-2
CIPAC No.	745

Please refer also to the Safety Data Sheet of the active substances (KCP 1.4.2/01 and KCP 1.4.2/02)

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

The formulation does not contain any safeners or synergists.

CONFIDENTIAL information is provided separately (Part C).

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

Type: Water dispersible granules

[Code: WG]

1.6 Function (KCP 1.6)

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 beige solid (granules) having characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature > 400 °C °C. In aqueous solution, it has a pH value around 7.2 at 20 °C. There is no effect of 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 3 years at ambient temperature when stored in commercial container trilaminated aluminium pouch. Results are available after 1 year storage (237-2-11-33020 (Interim Report-I). and the 3 years shelf-life final report will be provided as soon as possible. Its technical characteristics are acceptable for a WG formulation.

The intended concentration of use is 0.175% w/v to 0.7 % w/v.

The product is not intended to be mixed in the tank.

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

Classification according to	DPD (Directive 67/845/EEC)	CLP (Regulation (EC) No 1272/2008)
	Hazard symbol(s)	Pictograms
	Not required to be provided	None
	Indications of danger	Signal word
	Not required to be provided	None
		Hazard class and hazard category
		None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

With respect to physical/chemical data	Risk phrases:	Hazard statements:
	Not required to be provided	Not classified
	Safety phrases:	Precautionary statements
	Not required to be provided	None

Compliance with FAO specifications:

The product GPF515complies with FAO specifications of the respective formulation type.

Formulation used for tests

All tests have been conducted with the preparation GPF515.

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

Table 2-17: 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)	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg	Boscalid 350 g/kg + Prothioconazole 200 g/kg WG was beige solid (granules) having characteristic odour at 20 ± 1 °C.	Y	Desai, H. 2023a JFR 201-2-11-33001 (UPL/2022/21111)	Accepted.	
			Physical state				Solid (granules)
			Colour				Beige
			Odour				Characteristic
Explosive properties (KCP 2.2.1)	OCSPP 830.6316	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg	The thermal stability of the test item was investigated by Differential Scanning Calorimetry (DSC). In case the exothermal decomposition energy is < 500J/g and the onset of exothermic decomposition is < 500 °C, further test do not need to be performed according to UN Manual of Test and Criteria. Since there was no exothermic decomposition peak up to 430 °C, Explodability of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG is considered to be ‘non-explosive’. Since the product does not need to be classified as explosive, no test according to UN RTDG is required.	Y	Desai, H. 2023b JFR 238-2-11-33006 (UPL/2023/0027)	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.	
Oxidizing properties (KCP 2.2.2)	EC A.17	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg	Based on the results of the preliminary test, it is concluded that, “Boscalid 350 g/kg + Prothioconazole 200 g/kg WG is Non-Oxidising in Nature”. Since the product does not need to be classified as oxidizing, no UN test method is required.	Y	Desai, H. 2023c JFR 230-2-11-33005 (UPL/2022/21116)	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.	
Flash point (KCP 2.3.1)	-	-	Not required for WG formulation	-	-	-	
Flammability (KCP 2.3.2)	EC A.10 OCSPP 830.6315	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19	In the “Preliminary Screening Test”, it was observed that, Boscalid 350 g/kg + Prothioconazole 200 g/kg WG powder train did not ignite or combust but only charred up to 12 cm, when a hot flame from the gas burner was applied to it, for a period of 2 minutes	Y	Desai, H. 2023d JFR 213-2-11-33003 (UPL/2022/21113)	Accepted. The formulation does not need to be classified according to Reg.	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments												
		Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg	(maximum period). Also, there was no smouldering observed along 200 mm test item powder train within 4 minutes of total testing period after the withdrawal of flame. In view of the above test, it is concluded that Boscalid 350 g/Kg + Prothioconazole 200 g/Kg WG is ‘Not Highly Flammable’ (Non-flammable). Since no positive result as a flammable mixture was obtained with EC method, no additional UN test method is required.			(EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.												
Self-heating (KCP 2.3.3)	EC A.16	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg	There was no abrupt rise in the temperature of the sample cube while the oven temperature was raised up to 400 °C (maximum specified temperature) with a controlled heating of 0.5 °C/minute. Therefore, it is concluded that the relative self-ignition temperature of Boscalid 350 g/Kg + Prothioconazole 200 g/Kg WG was > 400 °C. Since no positive result was obtained as a shelf-heating mixture with the EC method, no additional UN test method is required.	Y	Desai, H. 2023e JFR 229-2-11-33004 (UPL/2023/0051)	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.												
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Please refer to point 2.4.2	-	-	-												
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	OCSPP 830.7000 OECD 122 CIPAC MT 75.3	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg	The mean pH of 1.0% (w/v) aqueous solution of Boscalid 350 g/Kg + Prothioconazole 200 g/Kg WG is summarised below: <table><tr><td colspan="2">After 1 Minute</td><td colspan="2">After 2 Minutes</td></tr><tr><td>Temperature (°C)</td><td>pH</td><td>Temperature (°C)</td><td>pH</td></tr><tr><td>20.1 ± 0.5</td><td>7.18 ± 0.03</td><td>20.3 ± 0.3</td><td>7.19 ± 0.03</td></tr></table>	After 1 Minute		After 2 Minutes		Temperature (°C)	pH	Temperature (°C)	pH	20.1 ± 0.5	7.18 ± 0.03	20.3 ± 0.3	7.19 ± 0.03	Y	Desai, H. 2023f JFR 210-2-11-33002 (UPL/2022/21112)	Accepted.
After 1 Minute		After 2 Minutes																
Temperature (°C)	pH	Temperature (°C)	pH															
20.1 ± 0.5	7.18 ± 0.03	20.3 ± 0.3	7.19 ± 0.03															
Viscosity (KCP 2.5.1)	-	-	Not applicable for WG formulations	-	-	-												
Surface tension (KCP 2.5.2)	-	-	Not applicable for WG formulations	-	-	-												
Relative density	-	-	Not applicable for WG formulations	-	-	-												

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.6.1)						
Bulk density (KCP 2.6.2)	CIPAC MT 186	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole: 199.9 ± 0.8 g/kg	The mean pour density and tap bulk density of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG was 0.6073 ± 0.0000 g/mL and 0.6296 ± 0.0001 g/mL. Pour Density: 0.6073 g/mL Tap Density: 0.6296 g/mL	Y	Desai, H. 2023g JFR 264-2-11-33015 (UPL/2023/0054)	Accepted.
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.4 Analytical method validated in Part B5 (JRF Study Number: 228-2-12-33016, UPL/2023/0300)	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole: 199.9 ± 0.8 g/kg	Accelerated storage stability of the test substance was tested by storing the test substance Boscalid 350 g/kg + Prothioconazole 200 g/kg WG in a tri-laminated Aluminium pouch (provided by Sponsor) containing 1000 g test item at 54 ± 2°C for 14 days. On completion of storage the test substance was tested for appearance (colour, physical state, and odour), pH, active ingredients content, wet sieve test, suspensibility, wettability, dispersibility, dust content, attrition resistance, and particle size distribution with the same methods used as before storage. The test item was also found to be non-corrosive to the tri-laminated aluminium pouch while in storage, with respect to the parameters tested. See Table 2-2 for a summary of before and after parameter measurements.	Y	Desai, H. 2023h JFR 234-2-11-33019 (UPL/2023/0417)	Accepted. The product showed no significant physical changes after accelerated storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (trilaminated aluminium pouch) container.
	CIPAC MT 46.4	GPF515 Boscalid 350 g/kg +	Accelerated storage stability of the test substance was tested by storing the test substance Boscalid 350 g/kg	Y	Desai, H. 2023h 2024a JFR 234-2-11-37859	Accepted. The product showed no

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																							
	Analytical methods validated in Part B5 (JRF Study Number: 228-2-12-33016, UPL/2023/0300) And (JRF Study Number: 228-2-12-37860, UPL/2024/1238)	Prothioconazole 200 g/kg WG Batch No. BDPT/WG/240607/550/23/PP Content: Boscalid: 357.8 ± 1.1 g/kg Prothioconazole: 199.0 ± 0.7 g/kg	+ Prothioconazole 200 g/kg WG in a tri-laminated Aluminium pouch (provided by Sponsor) containing 100 g test item at 54 ± 2°C for 14 days. On completion of storage the test substance was tested for active ingredients content and relevant impurities Toluene* and Prothioconazole-Desthio content as well as weight loss of container. *Toluene content was determined in before Storage (0 Day) sample only. <table><tr><th colspan="2">Parameters</th><th colspan="2">Results</th></tr><tr><th colspan="2"></th><th>Before Storage (0 Day)</th><th>After Storage at 54 ± 2 °C for 14 Days</th></tr><tr><td rowspan="4">Active Ingredients Content</td><td rowspan="2">Boscalid</td><td>35.76% w/w (357.6 g/Kg)</td><td>35.75% w/w (357.5 g/Kg)</td></tr><tr><td colspan="2">The loss of active ingredient at a temperature of 54 ± 2 °C after a period of 14 days: 0.03%</td></tr><tr><td rowspan="2">Prothioconazole</td><td>19.89% w/w (198.9 g/Kg)</td><td>19.87% w/w (198.7 g/Kg)</td></tr><tr><td colspan="2">The loss of active ingredient at a temperature of 54 ± 2 °C after a period of 14 days: 0.10%</td></tr><tr><td>Impurities</td><td>Prothioconazole-</td><td>0.00382%</td><td>0.00390%</td></tr></table>	Parameters		Results				Before Storage (0 Day)	After Storage at 54 ± 2 °C for 14 Days	Active Ingredients Content	Boscalid	35.76% w/w (357.6 g/Kg)	35.75% w/w (357.5 g/Kg)	The loss of active ingredient at a temperature of 54 ± 2 °C after a period of 14 days: 0.03%		Prothioconazole	19.89% w/w (198.9 g/Kg)	19.87% w/w (198.7 g/Kg)	The loss of active ingredient at a temperature of 54 ± 2 °C after a period of 14 days: 0.10%		Impurities	Prothioconazole-	0.00382%	0.00390%		(UPL/2024/1237)	significant physical changes after accelerated storage. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (trilaminated aluminium pouch) container.
Parameters		Results																											
		Before Storage (0 Day)	After Storage at 54 ± 2 °C for 14 Days																										
Active Ingredients Content	Boscalid	35.76% w/w (357.6 g/Kg)	35.75% w/w (357.5 g/Kg)																										
		The loss of active ingredient at a temperature of 54 ± 2 °C after a period of 14 days: 0.03%																											
	Prothioconazole	19.89% w/w (198.9 g/Kg)	19.87% w/w (198.7 g/Kg)																										
		The loss of active ingredient at a temperature of 54 ± 2 °C after a period of 14 days: 0.10%																											
Impurities	Prothioconazole-	0.00382%	0.00390%																										

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
			Content	Desthio	w/w	w/w			
				Toluene	0.01399% w/w	-			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Please refer to point 2.7.1				-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Please refer to point 2.7.1				-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	-	-	Not applicable for WG formulation				-	-	-
Ambient temperature shelf life (KCP 2.7.5)	CLI Technical Monograph 17, 3 rd edition OCSPP 830.6320 OCSPP 830.6317 Analytical method validated in Part B5 (JRF Study Number: 228-2-12-33016, UPL/2023/0300)	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg	On going study. See Table 2-3 for a summary of before and after 1 year storage parameter measurements.				Y	Desai, H. 2024b JFR 237-2-11-33020 (UPL/2023/1452)	Ambient temperature shelf life study is on going. The product showed no significant physical changes after one year of storage storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. The stability data indicate a shelf life of at least 2 years at ambient temperature

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						when stored in commercial packaging (trilaminated aluminium pouch) container.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Please refer to point 2.7.5	-	-	-
Wettability (KCP 2.8.1)	CIPAC MT 53.3.1	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole: 199.9 ± 0.8 g/kg	The mean wettability of Boscalid 350 g/Kg + Prothioconazole 200 g/Kg WG was less than one second in all replications.	Y	Desai, H. 2023i JFR 246-2-11-33010 (UPL/2023/0052)	Accepted.
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole: 199.9 ± 0.8 g/kg	Minimum dose (0.175% w/v, CIPAC water D): - Initial Volume: 24.8 mL - 1 Minutes ± 10 Seconds: 0.0 mL - 12 Minutes ± 10 Seconds: 0.0 mL Maximum Dose (2% w/v, CIPAC water D): - Initial Volume: 49.4 mL - 1 Minutes ± 10 Seconds: 11.8 mL - 12 Minutes ± 10 Seconds: 0.0 mL	Y	Desai, H. 2023j JFR 248-2-11-33011 (UPL/2023/0256)	Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole: 199.9 ± 0.8 g/kg	The mean suspensibility of Boscalid 350 g/Kg + Prothioconazole 200 g/Kg WG was: Minimum dose (0.175% w/v, CIPAC water D): 99.91 ± 1.87% w/w Maximum Dose (2% w/v, CIPAC water D): 98.23 ± 0.39% w/w	Y	Desai, H. 2023k JFR 251-2-11-33013 (UPL/2023/0392)	Accepted.
Spontaneity of	CIPAC MT 174	GPF515	The mean dispersibility of Boscalid 350 g/kg +	Y	Desai, H. 2023l	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
dispersion (KCP 2.8.3.2)		Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole: 199.9 ± 0.8 g/kg	Prothioconazole 200 g/kg WG was 99.20 ± 0.84%.		JFR 247-2-11-33017 (UPL/2023/0253)	
Dispersion stability (KCP 2.8.3.3)	-	-	Not applicable for WG formulations	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not applicable for WG formulations	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187 CIPAC MT 166	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole: 199.9 ± 0.8 g/kg	The mean particle size of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG was: 0.74 µm d [0.1(10%)], 2.19 µm d [0.5(50%)] and 4.12 µm d [0.9(90%)].	Y	Desai, H. 2023m JFR 250-2-11-33018 (UPL/2023/0254)	Accepted.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole: 199.9 ± 0.8 g/kg	There was no residue of the test item retained on the 75 µm test sieve within 10 minutes of washing time in all replications.	Y	Desai, H. 2023n JFR 245-2-11-33009 (UPL/2022/21114)	Accepted.
Dry sieve test (KCP 2.8.5.1.3)	CIPAC MT 170 Sampling (CIPAC MT 166)	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content:	X ₁ (µm) where R _x ≥ 90%: 710 X ₂ (µm) where R _x ≥ 90%: 1400 710 (R _{x1} ≥ 90%) to 1400 µm (R _{x2} ≤ 10%)	Y	Desai, H. 2024b JFR 237-2-11-33020 (UPL/2023/1452)	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg				
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171.1	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg	The mean dust content of Boscalid 350 g/Kg + Prothioconazole 200 g/Kg WG was 1.36 ± 0.11 mg. Therefore it is classified as “Nearly dust-free”.	Y	Desai, H. 2023o JFR 243-2-11-33007 (UPL/2023/0250)	Accepted.
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not applicable as the product is considered as “nearly dusty free”. Please refer to point 2.8.5.2.1	-	-	-
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No. BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole:199.9 ± 0.8 g/kg	The mean attrition resistance of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG was 99.93 ± 0.01%.	Y	Desai, H. 2023p JFR 249-2-11-33012 (UPL/2023/0053)	Accepted.
Hardness and integrity (KCP 2.8.5.4)	-	-	Not applicable for WG formulations	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not applicable for WG formulations	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not applicable for WG formulations	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not applicable for WG formulations	-	-	-
Flowability (KCP 2.8.7.1)	CIPAC MT 172.1	GPF515 Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Batch No.	After five liftings 8.80 ± 0.62% residue retained on sieve (4.75 mm mesh size). However, the test item dropped through the sieve (4.75 mm mesh size) spontaneously after twenty liftings and no residue of	Y	Desai, H. 2023q JFR 244-2-11-33008 (UPL/2023/0391)	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		BDPT/WG/220819/550/19 Content: Boscalid: 358.8 ± 0.7 g/kg Prothioconazole: 199.9 ± 0.8 g/kg	the test item retained on the sieve.			
Pourability (KCP 2.8.7.2)	-	-	Not applicable for WG formulations	-	-	-
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not applicable for WG formulations	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	It is not intended to apply GPF515 / FGE03 with other plant protection protects, therefore, no physical compatibility studies with other products are required.	-	-	No data generated.
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	It is not intended to apply GPF515 / FGE03 with other plant protection protects, therefore, no physical compatibility studies with other products are required.	-	-	No data generated.
Adhesion to seeds (KCP 2.10.1)	-	-	Not applicable for WG formulations	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not applicable for WG formulations	-	-	-
Other/special studies (KCP 2.11)	-	-	None	-	-	-

Table 2-2: Summary of ~~FGE01~~ GPF515 / FGE03 properties before and after accelerated temperature storage (14 days at 54°C) period (Study No.: 234-2-11-33019, UPL/2023/0417, Desai, H. 2023h)

Test/method	Measurement/parameter		Results	
			Before Storage	After Storage at 54 ± 2°C for 14 Days
Visual observation	Corrosion characteristics	Perforation	No	No
		Splitting at the seam	No	No
		Distortion	No	No
Visual observation	Appearance of the Commercial Container (visual) [Tri-laminated aluminium Pouch]	Shape	Rectangular	Rectangular
		Colour	Silver	Silver
		Crack	No	No

OPPTS 830.6302, 830.6303 and 830.6304	Appearance		Beige solid granules having characteristic odour	Beige solid granules having characteristic odour
CIPAC MT 75.3	pH (1% w/v Aqueous Dispersion)	1 Minute	7.31 at 20.5 °C	7.31 at 20.2 °C
		2 Minute	7.31 at 20.4 °C	7.31 at 20.2 °C
In house method validated in part B5 [JRF Study Number: 228-2-12-33016]	Active Ingredient Content	Boscalid	35.91% w/w (359.1 g/kg)	35.85% w/w (358.5 g/kg)
			The loss of active ingredient at a temperature of 54 ± 2 °C after a period of 14 days: 0.17%	
		Prothioconazole	20.02% w/w (200.2 g/kg)	19.98% w/w (199.8 g/kg)
			The loss of active ingredient at a temperature of 54 ± 2 °C after a period of 14 days: 0.20%	
CIPAC MT 185	Wet Sieve Test [Material Retained on the Sieve (%)]		There was no residue of the test item retained on the 75 µm test sieve within 10 minutes	There was no residue of the test item retained on the 75 µm test sieve within 10 minutes
CIPAC MT 184.1	Suspensibility (%)	Minimum Dose (0.175% w/v)	98.67	100.09
		Maximum Dose (2% w/v)	99.71	98.61
CIPAC MT 53.3.1 Without Swirling	Wettability [Wetting Time (s)]		< 1	< 1
CIPAC MT 174	Dispersibility (%)		99.31	98.97
CIPAC MT 171.1 Sampling (CIPAC MT 166)	Dust Content (mg)		1.62 (Nearly dust-free)	1.61 (Nearly dust-free)
CIPAC MT 178.2	Attrition Resistance (%)		99.93	99.93
CIPAC MT 187 Sampling (CIPAC MT 166)	Particle Size Distribution (Dry Sieve Analysis)		0710 (Rx1 ≥ 90%) to 1400 µm (Rx2 ≤ 10%)	710 (Rx1 ≥ 90%) to 1400 µm (Rx2 ≤ 10%)

Table 2-3: Summary of FGE03 properties before and after long term storage in commercial packaging (ongoing study, Study No.: 237-2-11-33020 (Interim Report-I), UPL/2023/1452, Patel D. 2024)

Test/method	Measurement/parameter		Results			
			Before Storage (0 Day)	3-Months	6-Months	12-Months
Visual observation	Corrosion characteristics	Perforation	No	No	No	No
		Splitting at the seam	No	No	No	No
		Distortion	No	No	No	No
Visual observation	Appearance of the Commercial Container (visual) [Tri-laminated aluminium Pouch]	Shape	Rectangular	Rectangular	Rectangular	Rectangular
		Colour	Silver	Silver	Silver	Silver
		Crack	No	No	No	No
OPPTS 830.6302, 830.6303 and 830.6304	Appearance		Beige solid granules having characteristic odour	Beige solid granules having characteristic odour	Beige solid granules having characteristic odour	Beige solid granules having characteristic odour
CIPAC MT 75.3	pH (1% w/v Aqueous solution)	After 1 Minute	7.26 at 20.1 °C	7.43 at 20.2 °C	7.28 at 20.3 °C	7.19 at 19.9 °C
		After 2 Minutes	7.23 at 20.1 °C	7.40 at 20.2 °C	7.24 at 20.1 °C	7.17 at 19.8 °C

In house method validated in part B5 [JRF Study Number: 228-2-12-33016]	Active Ingredients Content	Boscalid	35.84% w/w (358.4 g/Kg)	35.82% w/w (358.2 g/Kg)	35.84% w/w (358.4 g/Kg)	35.83% w/w (358.3 g/Kg)
		Prothioconazole	19.95% w/w (199.5 g/Kg)	19.92% w/w (199.2 g/Kg)	19.95% w/w (199.5 g/Kg)	19.93% w/w (199.3 g/Kg)
CIPAC MT 185	Wet Sieve Test [Material Retained on the Sieve (%)]		There was no residue of the test item retained on the 75 µm test sieve within 10 minutes of washing time	There was no residue of the test item retained on the 75 µm test sieve within 10 minutes of washing time	There was no residue of the test item retained on the 75 µm test sieve within 10 minutes of washing time	There was no residue of the test item retained on the 75 µm test sieve within 10 minutes of washing time
CIPAC MT 184.1	Suspensibility (%)	Minimum Dose	99.56	100.49	98.90	98.28
		Maximum Dose	98.23	100.14	98.51	98.30
CIPAC MT 53.3.1 (Without Swirling)	Wettability [Wetting Time (s)]		< 1	< 1	< 1	< 1
CIPAC MT 174	Dispersibility (%)		99.66	99.02	99.86	98.54
CIPAC MT 171.1 Sampling (CIPAC MT 166)	Dust Content (mg)		0.32	1.18	1.33	1.41
CIPAC MT 178.2	Attrition Resistance (%)		99.33	99.97	99.91	99.96
CIPAC MT 170 Sampling (CIPAC MT 166)	Particle Size Distribution (Dry Sieve Analysis)		710 (Rx1 ≥ 90%) to 1400 µm (Rx2 ≤ 10%)	710 (Rx1 ≥ 90%) to 1400 µm (Rx2 ≤ 10%)	710 (Rx1 ≥ 90%) to 1400 µm (Rx2 ≤ 10%)	710 (Rx1 ≥ 90%) to 1400 µm (Rx2 ≤ 10%)

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 Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1)

Waiting period (in days) between last application and sowing or planting succeeding crops

The recommendation from the renewal process of the active substance boscalid (Slovakia, 2018-AIR 3, RAR Volume 3CP BAS 510 01 F) is applicable to the intended formulation FGE03.

“Boscalid has been applied since many years with several different formulations across a wide range of crops without any reports of phytotoxic effects on succeeding crops. Due to the broad range of crops, in which the product has been used, most rotational crop possibilities have been appeared in practice. Hence no negative impact on succeeding crops is expected.

Consequently, there is no necessity for restrictions (related an eventual phytotoxicity) in the choice of following crops, even in the event of crop failure on a field, which has been treated with BAS 510 01 F.”

For prothioconazole, the recommendation from the renewal process of the active substance (UK, 2018-AIR 3, RAR Volume 1) is applicable to the intended formulation FGE03.

“under practical conditions of use of prothioconazole according to the representative uses and considering that a fraction of the applied rate is intercepted by the cereal crop, no residue of any metabolite above 0.01 mg/kg is expected in rotational crops and no plant back restriction needs to be proposed”.

Recommended methods and precautions (KCP 4.2)

Comments of zRMS:	Proposed tank cleaning procedure is considered sufficient.
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Precautions for safe handling: Ensure good ventilation of the work station. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Limit quantities of product at the minimum necessary for handling and limit the number of exposed workers. Provide local exhaust or general room ventilation. Wear personal protective equipment. Floors, walls and other surfaces in the hazard area must be cleaned regularly.

Hygiene measures: Separate working clothes from town clothes. Launder separately. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

A study on the effectiveness of the cleaning procedures for the test substance at the recommended concentration is summarized below.

Reference:	KCP 4.2/01
Report	Effectiveness of Cleaning Procedures of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG. Prajapati, P.N., 2024 JRF Study Number: 284-2-11-36678, UPL EUROPE LTD (UPL/2024/0501)
Guideline(s):	Pesticide Safety Directorate, 2004: Pesticide Safety Directorate (PSD) Efficacy Guideline 305 “Cleaning Application Equipment – Small scale jar test protocol”.
Deviations:	No

GLP: No, not subject to GLP regulations

Acceptability: Yes

This study was performed to determine the effectiveness of cleaning procedures of Boscalid 350 g/Kg + Prothioconazole 200 g/kg WG. The study was conducted in compliance with the OECD Principles of GLP (1998).

Tank mix preparation:

A volume of 300 mL of CIPAC water D was placed into a 500 mL beaker and stirred and the appropriate amount of the product was added 6 ± 0.1 g test item, calculated from the maximum recommended dose of 2 kg product in 100 L water/ha). After 2 min of stirring, 100 mL aliquots are poured into three polyethylene bottles (about 45 mm in diameter and 90 mm high). The bottles were capped and allowed to stand for 24 hours at room temperature.

Tank cleaning procedure:

After 24 hours, the bottles stored above were inverted twice and shaken to re-suspend any sealed material and the tank mix were discarded.

Three procedures were performed:

- Bottle 1-Single Rinse Procedure: A volume of 10 mL tap water was added, and the bottle was inverted twice. The rinse was discarded.
- Bottle 2-Double Rinse Procedure: The rinse procedure as described for bottle-1 was performed twice for double rinse.
- Bottle 3-Triple Rinse Procedure: The rinse procedure as described for bottle-1 was performed thrice for triple rinse.

After discarding the rinse, a volume of 10 mL Acetonitrile was added to each of the bottles and the bottles were shaken to coat all surfaces to extract residual pesticide from the bottle surfaces and the sample were filtered through 0.22 μ m nylon syringe filter and analysed by HPLC for determination of the active substances (a.i.) content.

The experiment was carried out in triplicate and the mean value along with standard deviation was reported.

Analysis

The content of the active ingredient was determined by HPLC. The analytical method was validated according to guidance SANCO/3030/99 rev.5 (22/03/2019).

Table 4.1-1: results of analytical method validation

Parameters		Boscalid		Prothioconazole	
Specificity (Non-analyte Interference)		Non-analyte interference		Non-analyte interference	
LOD (mg/L) (based on S/N ratio)		0.06		0.11	
LOQ (%w/w) (based on S/N ratio)		0.11		0.21	
Linearity (For Effectiveness Cleaning Procedure)	Concentration Range (mg/L)	0.0.8 to15.88		0.16 to 10.38	
	Intercept (a)	-448.08		467.61	
	Slope (b)	20929.30		10192.72	
	Correlation Coefficient (r)	0.999		0.999	
Linearity (For % Recovery)	Concentration Range (mg/L)	0.0.8 to15.88		0.16 to 10.38	
	Intercept (a)	-27.5		-373.74	
	Slope (b)	20802.4		10105.46	
	Correlation Coefficient (r)	0.999		0.999	
Recovery (Accuracy)	Level / Mean Recovery (%)	I	II	I	II
		97.22	103.24	98.89	97.12
	Overall Mean Recovery (%)	100.23		98.00	
	% RSD	3.41		1.17	
	% RSD (%w/w)	2.04	1.41	1.03	1.95

	Acceptable % RSD (Extended Horwitz)	5.38	2.23	4.85	2.53
	Horrat Value (H_r)	0.3792	0.6323	0.2124	0.7708
	Acceptable Horrat Value (H_r)	≤ 1	≤ 1	≤ 1	≤ 1

Evaluation

The “% Removed from the bottle by cleaning” was calculated as follows:

$$\% \text{ removed} = \{1 - (\text{mg pesticide AI recovered}) / (\text{mg pesticide AI charged (added)})\} \times 100$$

Table 4.1-2: Effectiveness of Cleaning Procedures (at 2 kg product in 100 L water) [Rinsing / % Active Substance Removed from Bottle]

Rinsing	% Active Substance Removed from Bottle	
	Boscalid	Prothioconazole
Single	99.95	99.96
Double	99.99	99.99
Triple	99.99	99.99

4.2 Emergency measures in the case of an accident (KCP 4.3)

Reference: KCP 4.3/01

Report Boscalid/Prothioconazole(350+200) WDG
Safety Data Sheet

Guideline(s): REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Deviations: No

GLP: No, not subject to GLP regulations

Acceptability: Yes

The safety data sheet contains advice for emergency measures in case of an accident with ~~PH-FGG03~~
GPF515 / FGE03 , based on scientific tests.

4.3 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	Shelf-life study is on-going. The accelerated data and results after one year of storage indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging trilaminated aluminium pouch. Containers for powders and granules: Extrapolation is possible between all container types.
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Table 4.3-1: Packaging information for 2.5 kg JERRY CAN

Type	Description
Material:	HDPE JERRY CAN
Shape/size:	Rectangular shape carboy & with two grooves on the body (118 x 178 x 302)
Opening:	63 mm
Closure:	HDPE Screw Cap
Seal:	Induction sealing
Manner of construction	Extrusion Blow Molded Jar
UN/ADR	Compliant

Table 4.3-2: Packaging information for 10 kg JERRY CAN

Type	Description
Material:	HDPE JERRY CAN
Shape/size:	Rectangular shape carboy & with two grooves on the body (278 x 266 x 368)
Opening:	63 mm
Closure:	HDPE Screw Cap
Seal:	Induction sealing
Manner of construction	Extrusion Blow Molded Jar
UN/ADR	Compliant

Reference:	KCP 4.4/01 / (KCP 2.7.5)
Report	Three years storage stability and corrosion characteristics study of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG (Interim Report-I), Desai, H., 2024 JRF Study Number: 237-2-11-33020), UPL EUROPE LTD (UPL/2023/1452)
Guideline(s):	OCSPP 830.6317, 830.6320, CRD 3.9.2
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Summary:

Stability of packaging along with the corrosion characteristics was determined according to Test Guideline OCSPP 830.6317, 830.6320, CRD 3.9.2 by observing the appearance of the container and weighting them before and after storage under specified conditions. Seven bags (Trilaminated Aluminium Pouch) of the same composition as the commercial container with test item (1000 g) were stored at ambient temperature for 3 years. One bag (Trilaminated Aluminium Pouch) of the test item was drawn initially (0 day) and after 3, 6, 9, and 12 months of storage and the test item was evaluated for corrosion characteristics (perforation, distortion, discoloration, splitting at the seam), appearance of the container (Trilaminated Aluminium Pouch) (by visual: shape, colour and crack if any), appearance of the test item (colour, physical state and odour), pH, and active ingredients content of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG. The packaging material of test substance remained stable without any damage and no significant weight change was observed during the 1-year storage period.

4.4 Procedures for the destruction or decontamination of the plant protection product and its packaging (KCP 4.5)

Comments of zRMS:	Accepted.
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Reference:	KCP 4.5/01 / (KCP 4.3/01)
Report	Boscalid / Prothioconazole (350+200) WDG Safety Data Sheet
Guideline(s):	REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Deviations:	No
GLP:	No, not subject to GLP regulations

The safety data sheet contains advice for the destruction or decontamination of the plant protection product and its packaging.

Product/Packaging disposal recommendations: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials: Avoid release to the environment.

Appendix 1 Lists of data considered in support of the evaluation

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 1.4.2/01	Anonymous	2024	Boscalid technical Safety Data Sheet Version: 2.2 GLP: no Published	N	UPL EUROPE LTD.
KCP 1.4.2/02	Anonymous	2024	Prothioconazole technical Safety Data Sheet Version: 1.3 GLP: no Published	N	UPL EUROPE LTD.
KCP 2.1	Desai, H.	2023a	Appearance (colour, physical state and odour) of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 201-2-11-33001) UPL EUROPE LTD (UPL/2022/21111) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.2.1	Desai, H.	2023b	Explodability of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 238-2-11-33006) UPL EUROPE LTD (UPL/2023/0027) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.2.2	Desai, H.	2023c	Oxidising properties of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 230-2-11-33005) UPL EUROPE LTD (UPL/2022/21116) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.3.2	Desai, H.	2023d	Flammability of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 213-2-11-33003) UPL EUROPE LTD (UPL/2022/21113) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.3.3	Desai, H.	2023e	Relative self-ignition temperature of Boscalid 350 g/kg + prothioconazole 200 g/Kg WG Shelf heating of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG	N	UPL EUROPE

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
			JAI RESEARCH FOUNDATION (JRF Study Number: 229-2-11-33004) UPL EUROPE LTD (UPL/2023/0051) GLP Unpublished		LTD.
KCP 2.4.2	Desai, H.	2023f	pH of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 210-2-11-33002) UPL EUROPE LTD (UPL/2022/21112) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.6.2	Desai, H.	2023g	Bulk density of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 264-2-11-33015) UPL EUROPE LTD (UPL/2023/0054) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.7.1/01	Desai, H.	2023h	Accelerated storage stability and corrosion characteristics of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 234-2-11-33019) UPL EUROPE LTD (UPL/2023/0417) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.7.1/02	Desai, H.	2024a	Accelerated storage stability of boscalid 350 g/kg + prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 234-2-11-37859) UPL EUROPE LTD (UPL/2024/1237) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.7.5	Desai, H.	2024b	Three years storage stability and corrosion characteristics study of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Interim Report-I JAI RESEARCH FOUNDATION (JRF Study Number: 237-2-11-33020) UPL EUROPE LTD (UPL/2023/1452) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.8.1	Desai, H.	2023i	Wettability of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 246-2-11-33010) UPL EUROPE LTD (UPL/2023/0052)	N	UPL EUROPE LTD.

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
			GLP Unpublished		
KCP 2.8.2	Desai, H.	2023j	Persistent foaming of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 248-2-11-33011) UPL EUROPE LTD (UPL/2023/0256) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.8.3.1	Desai, H.	2023k	Suspensibility of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 251-2-11-33013) UPL EUROPE LTD (UPL/2023/0392) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.8.3.2	Desai, H.	2023l	Dispersibility of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 247-2-11-33017) UPL EUROPE LTD (UPL/2023/0253) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.8.5.1.1	Desai, H.	2023m	Particle size distribution of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 250-2-11-33018) UPL EUROPE LTD (UPL/2023/0254) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.8.5.1.2	Desai, H.	2023n	Wet sieve test of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 245-2-11-33009) UPL EUROPE LTD (UPL/2022/21114) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.8.5.1.3	Desai, H.	2024b	Three years storage stability and corrosion characteristics study of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Interim Report-I JAI RESEARCH FOUNDATION (JRF Study Number: 237-2-11-33020) UPL EUROPE LTD (UPL/2023/1452) GLP Unpublished	N	UPL EUROPE LTD.

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 2.8.5.2.1	Desai, H.	2023o	Dust content of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 243-2-11-33007) UPL EUROPE LTD (UPL/2023/0250) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.8.5.3	Desai, H.	2023p	Attrition resistance of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 249-2-11-33012) UPL EUROPE LTD (UPL/2023/0053) GLP Unpublished	N	UPL EUROPE LTD.
KCP 2.8.7.1	Desai, H.	2023q	Flowability of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 244-2-11-33008) UPL EUROPE LTD (UPL/2023/0391) GLP Unpublished	N	UPL EUROPE LTD.
KCP 4.2/01	Prajapati, P.N.	2024	Effectiveness of Cleaning Procedures of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 284-2-11-36678) UPL EUROPE LTD (UPL/2024/0501) GLP: no Unpublished	N	UPL EUROPE LTD.
KCP 4.3/01 KCP 4.5/01	Anonymous	2024	Boscalid/Prothioconazole(350+200) WDG Safety Data Sheet Version: 2.0 GLP: no Published	N	UPL EUROPE LTD.

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

A 2.1 Boscalid

Not applicable.

A 2.2 Prothioconazole

Not applicable.