

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: GLOB2021dF

Product name: PIRLANKO

Chemical active substances:

Prothioconazole, 156 g/L

Boscalid, 156 g/L

Central Zone

Zonal Rapporteur Member State:

Poland

CORE ASSESSMENT

(authorization)

Applicant: GLOBACHEM NV

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When	What
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State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- Missing storage stability study at ambient temperature – study is ongoing. It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level.
- There is no info on relevant impurities levels of active substance prothioconazole in the PPP (before and after storage). So, each member state has to consider admission of eventual provisional shelf life for the PPP. In our opinion adequate data on impurities level in the PPP may be submitted and evaluated in the post-registration at national level
- According to Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of Plant Protection Products under Regulation (EC) No. 1107/2009 for SC formulation Particle size distribution (MT 187) test is required - data required before and after storage. The study report: Raksha, V.S., 2023 AG-G0128, does not include particle distribution test. The MT 187 test is also not included in 2 years storage stability test at ambient temperature.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Globachem NV
Address: Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden
Belgium
Contact: Jan-Pieter Ploem
Telephone number: +32 11 26 38 07
E-mail: Jan-Pieter.Ploem@globachem.com

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

1.2.1 Producer(s) of the preparation

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

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

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

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

1.2.3.1 Boscalid

Boscalid min. 980 g/kg

The sources of the active ingredient has been confirmed to be equivalent to the annex I source by the RMS Poland and UK.

Further information related to impurities is confidential information – data is provided separately (Part C).

1.2.3.2 Prothioconazole

Prothioconazole min. 970 g/kg

According Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances 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 (2-(1-chlorocyclopropyl)-1- (2-chlorophenyl)-3- (1,2,4-triazol- 1-yl)-propan- 2-ol): < 0,5 g/kg (LOD).

The sources of the active ingredient has been confirmed to be equivalent to the annex I source by the RMS the Netherlands and UK.

Further information related to impurities is confidential information – data is provided separately (Part C).

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

Trade name: PIRLANCO
Company code number: GLOB2021dF

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)

GLOB2021dF was not the representative formulation during the EU evaluation of Boscalid nor for Prothioconazole.

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)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Boscalid	156	475 – 525 147 - 165	158.22 159.2	14.17 14.26
Prothioconazole	156	235 – 265 147 - 165	160.82 159.2	14.40 14.26

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

** Based on the density of the formulation = 1.1168

Toluene and prothioconazole-desthio are relevant impurities of prothioconazole. There are no toxicologically, ecotoxicologically or environmentally relevant impurities present in the formulation.

1.4.2 Information on the active substances (KCP 1.4.2)

Table 1.4-2: 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 1.4-3: Information on prothioconazole

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

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

There are no safeners or synergists in the formulation. Information regarding the co-formulants is confidential.

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)

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 white liquid, with a mild aromatic odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of > 92.9 °C. It has a self-ignition temperature of 480 °C. In aqueous solution, it has a pH value around 5.88 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 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 HDPE. Its technical characteristics are acceptable for an SC formulation. The intended concentration of use is 0.27% to 0.8%.

zRMS comments

A shelf-life of at least 2 years was evaluated based on the low and high temperature stability tests. Storage stability study at ambient temperature is ongoing. It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level.

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

Implications for labelling: None.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Implications for labelling: None.

Compliance with FAO specifications:

The product GLOB2021dF complies with FAO specifications. No specific FAO specifications applicable to plant protection products containing more than one active ingredient

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C. It contains 156 g/L boscalid and 156 g/L prothioconazole. All other co-formulants were the same and had the same concentration.

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)	Visual assessment	GLOB2021dF Batch: FOP5819-2	White liquid with a mild aromatic odour		Raksha, V.S., 2023 AG-G0128	Accepted
Explosive properties (KCP 2.2.1)	Theoretical certificate	/	No explosive properties	N	Augutine A., 2024	Accepted Based on the information of ingredients of PPP. The ingredients of test item are not classified as explosive. Additionally based on the structural elements of individual compounds included in the mixture the PPP has no explosive properties.
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	/	Not oxidizing	N	Augutine A., 2024	Accepted Based on the information of ingredients of PPP. The ingredients of test item are not classified as oxidising.
Flash point (KCP 2.3.1)	CIPAC MT 12 EEC A.9	GLOB2021dF Batch: FOP5819-2	Not highly flammable.	Y	Raksha, V.S., 2023 AG-G0131	Accepted The determination of flash point of test item was carried out using Pensky-Martens Flash Point test method in accordance with CIPAC Method MT 12 and EEC A.9. The flash point of test item is above 92.9°C. The test item is not classified, according to CLP Regulation, as flammable.
Flammability (KCP 2.3.2) and Self-heating	EEC A.15	GLOB2021dF Batch: FOP5819-2	The test item was found to be flammable at a temperature of 480°C with the sample volume of 0.1 mL (100 µL).	Y	Raksha, V.S., 2023 AG-G0132	Accepted Auto-ignition temperature of test item is 480°C.

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments	
(KCP 2.3.3)												
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	GLOB2021dF Batch: FOP5819-2	At 25°C: 4.31 ± 0.01						Y	Raksha, V.S., 2023 AG-G0128	Accepted The pH was not less than 4 and also not higher than 10, the acidity/alkanity was not tested.	
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB2021dF Batch: FOP5819-2	At 25°C: 5.88 ± 0.04						Y	Raksha, V.S., 2023 AG-G0128	Accepted The pH was not less than 4 and also not higher than 10, the acidity/alkanity was not tested.	
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD 114	GLOB2021dF Batch: FOP5819-2	Speed (rpm)	20.0	40.0	60.0	40.0	20.0	Y	Raksha, V.S., 2023 AG-G0133	Accepted The dynamic viscosity of test item was measured using Brookfield rotational viscometer at 20 and 40°C for the shear rate range 20 to 60 s ⁻¹ .	
			eP mPas at 20°C	1512 ± 12	980 ± 5	769 ± 3	955 ± 5	1450 ± 9				
			eP mPas at 40°C	4544 ± 93	2585 ± 62	1904 ± 44	2584 ± 61	4508 ± 103				
Surface tension (KCP 2.5.2)	EEC A.5	GLOB2021dF Batch: FOP5819-2	At 20°C: 37.496 ± 0.127 mN/m						Y	Raksha, V.S., 2023 AG-G0134	Accepted The surface tension of test item was measured at maximum recommended concentration. The surface tension is below 60 mN/m, the product is surface active.	
Relative density (KCP 2.6.1)	EEC A.3	GLOB2021dF Batch: FOP5819-2	At 20°C: 1.1168						Y	Raksha, V.S., 2023 AG-G0135	Accepted	
Bulk density (KCP 2.6.2)	-	-	Not an SC requirement.						-	-	Accepted	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	SANCO/3030/99 rev.5 HPLC Method OCSPP 830.6302 OCSPP 830.6304 OCSPP 830.6303	GLOB2021dF Batch: FOP5819-2	Test			Ambient		Aged (54°C, 2 weeks)		Y	Raksha, V.S., 2023 AG-G0128	Accepted Based on the result of accelerated storage stability study, PPP was concluded to be stable when stored at the elevated temperature of 54°C±2°C for 14 days. The PPP stored at both
			a.i. content (g/L) - boscalid - prothioconazole			155.46 ± 0.22 160.11 ± 0.23		155.31 ± 0.06 159.97 ± 0.06				
			Appearance			White Mild aromatic Liquid		White Mild aromatic Liquid				

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 75.3 CIPAC MT 160 CIPAC MT 184.1 CIPAC MT 185 CIPAC MT 148.1 OCSPP 830.6320, Visual		pH - 1% w/v aqueous suspension at 25°C - neat sample	5.88 ± 0.04 4.31 ± 0.01	5.99 ± 0.02 4.24 ± 0.02			ambient temperature and elevated temperature 54°C±2°C (aged sample) was analysed for its active ingredient content, appearance, pH, spontaneity of dispersion, suspensibility, wet sieve test, pourability and corrosion characteristics at the end of the 14 days of storage period. Based on the results of the study, it was concluded that the active ingredient content, color, odor, physical state, pH, suspensibility, spontaneity of dispersion, wet sieve and pourability of the test item for sample stored at elevated temperature of 54°C±2°C for 14 days were well compared with that of the results obtained for the test item stored at ambient temperature. The test item found to be non-corrosive for HDPE-COEX commercial containers as there was no significant change in the weight of commercial containers and there was not any perforations, leakage, discolorations and darkening was found before and after storage at elevated temperature for 14 days. The content of active substances – boscalid and prothioconazole - in PPP was determined by High Performance Liquid Chromatography (HPLC) equipped with PDA detector
			Spontaneity of dispersion (%) - boscalid - prothioconazole	98.14 ± 0.02 98.15 ± 0.01	98.10 ± 0.02 98.09 ± 0.02			
			Suspensibility (% m/m) - at minimum test item concentration - boscalid - prothioconazole - at maximum test item concentration - boscalid - prothioconazole	97.35 ± 0.02 96.97 ± 0.02 96.51 ± 0.01 96.91 ± 0.01	97.29 ± 0.01 96.18 ± 0.02 96.39 ± 0.02 96.07 ± 0.02			
			Wet sieve (% m/m retained on 75 µm sieve)	0.022 ± 0.001	0.021 ± 0.002			
			Pourability (% m/m) - Residue - Rinsed characteristics	3.897 ± 0.010 0.939 ± 0.021	3.888 ± 0.019 0.981 ± 0.007			
			Corrosion characteristics	There was no perforations, darkening, discoloration and leakage of HDPE-COEX container	There was no perforations, darkening, discoloration and leakage of HDPE-COEX container			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								at wavelength measuring 254 nm. The method was developed and validated in GLP laboratory. The loss of active substances after 14 days storage of test item at 54°C was almost negligible. It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation. There is no info on relevant impurities levels of active substance prothioconazole in the PPP (before and after storage). So, each member state has to consider admission of eventual provisional shelf life for the PPP. In our opinion adequate data on impurities level in the PPP may be submitted and evaluated in the post-registration at national level.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required, based on the two week accelerated storage study, the product is stable.			-	-	Accepted Storage stability study (2 years study) at ambient temperature is ongoing
Minimum content after heat stability testing (KCP 2.7.3)		GLOB2021dF Batch: FOP5819-2	Pre-storage: 497.2 g/kg equivalent to 99.44 % of the declared amount. Storage for 2 weeks at 54 °C: 501.9 g/L equivalent to 100.4 % of the declared amount. Boscalid Pre-storage: 155.46 g/kg Storage for 2 weeks at 54°C: 155.31 g/kg			Y	Raksha, V.S., 2023 AG-G0128, AG-G0	Accepted

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Prothioconazole Pre-storage: 160.11 g/kg Storage for 2 weeks at 54°C: 159.97 g/kg					
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 184.1 CIPAC MT 185	GLOB2021dF Batch: FOP5819-2	Test	Ambient	Low T (0°C, 7 days)	Y	Raksha, V.S., 2023 AG-G0136	Accepted Based on the results of the low temperature stability test, it is concluded that test item was homogenous liquid without any phase separation when stored at 0±2°C for 7 days. Suspensibility and wet sieve test were determined after storage. Suspensibility: the content of active substances – boscalid and prothioconazole - in suspension was determined by High Performance Liquid Chromatography (HPLC) equipped with VWD/DAD/PDA detector at wavelength measuring 254 nm. The method was developed and validated in GLP laboratory. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %. The criteria were met for both active substances at minimum test item concentration and maximum test item concentration. Wet sieve test: Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The criteria were met.
			Suspensibility (% m/m) - at minimum test item concentration - boscalid - prothioconazole	97.49 ± 0.27 97.14 ± 0.34	97.49 ± 0.27 97.14 ± 0.34			
			- at maximum test item concentration - boscalid - prothioconazole	96.14 ± 0.07 95.82 ± 0.07	96.14 ± 0.07 95.82 ± 0.07			
			Wet sieve (% m/m retained on 75 µm sieve)		0.023 ± 0.001			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
Ambient temperature shelf life (KCP 2.7.5)	SANCO/3030/99 rev.5 HPLC Method OCSPP 830.6302 OCSPP 830.6304 OCSPP 830.6303 CIPAC MT 75.3 CIPAC MT 160 CIPAC MT 184.1 CIPAC MT 185 CIPAC MT 148.1 OCSPP 830.6320, Visual	GLOB2021dF Batch: FOP5819-2	Study is ongoing, based on the two week accelerated storage study, the product is stable.		Y	Raksha, V.S., 2023 AG-G0129; Raksha, V.S., 2023 AG-G0672	Data gap Missing storage stability study at ambient temperature - study is ongoing (2 years study). It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required, based on the two week accelerated storage study, the product is stable.		-	-	Storage stability study (2 years study) at ambient temperature is ongoing
Wettability (KCP 2.8.1)	-	-	Not an SC requirement.		-	-	Accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB2021dF Batch: FOP5819-2	Nil after 1 min and 12 min for both maximum and minimum recommended concentrations of the test item.		Y	Raksha, V.S., 2023 AG-G0137	Accepted Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation. Acceptable limits: max 60 mL foam after 1 minute. The above mentioned criteria were met.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	GLOB2021dF Batch: FOP5819-2	Suspensibility (% m/m) - at 0.25% minimum test item concentration - boscalid - prothioconazole - at 1.0% maximum test item concentration	97.35 ± 0.02 96.97 ± 0.02		Raksha, V.S., 2023 AG-G0128	Accepted Suspensibility: the content of active substances – boscalid and prothioconazole - in suspension was determined

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
			- boscalid - prothioconazole	96.51 ± 0.01 96.91 ± 0.01			by High Performance Liquid Chromatography (HPLC) equipped with PDA detector at wavelength measuring 254 nm. The method was developed and validated in GLP laboratory. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %. The criteria were met for both active substances at minimum test item concentration and maximum test item concentration.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	GLOB2021dF Batch: FOP5819-2	Spontaneity of dispersion (%) - boscalid - prothioconazole	98.14 ± 0.02 98.15 ± 0.01	Y	Raksha, V.S., 2023 AG-G0128	Accepted The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water. The content of active substances – boscalid and prothioconazole - in dispersion was determined High Performance Liquid Chromatography (HPLC) equipped with PDA detector at wavelength measuring 254 nm. The method was developed and validated in GLP laboratory. Acceptable limits: the mean measured minimum active spontaneity of dispersion must not be less than 60 % or greater than 105 %. The criteria were met.
Dispersion stability	-	-	Not an SC requirement.		-	-	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.3.3)						
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not an SC requirement.	-	-	Accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	GLOB2021dF Batch: FOP5819-2		Y	Raksha, V.S., 2023 AG-G0128	Data gap According to Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of Plant Protection Products under Regulation (EC) No. 1107/2009 for SC formulation Particle size distribution (MT 187) test is required - data required before and after storage. The study report: Raksha, V.S., 2023 AG-G0128, does not include particle distribution test. The MT 187 test is also not included in 2 years storage stability test at ambient temperature.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	GLOB2021dF Batch: FOP5819-2	0.022 ± 0.001 on 75 µm sieve	Y	Raksha, V.S., 2023 AG-G0128	Accepted Wet sieve test is required for water dispersible products. The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on application equipment. Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The criteria were met.
Dust content (KCP 2.8.5.2.1)	-	-	Not an SC requirement.	-	-	Accepted

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not an SC requirement.		-	-	Accepted
Attrition (KCP 2.8.5.3)	-	-	Not an SC requirement.		-	-	Accepted
Hardness and integrity (KCP 2.8.5.4)	-	-	Not an SC requirement.		-	-	Accepted
Emulsifiability (KCP 2.8.6.1)	-	-	Not an SC requirement.		-	-	Accepted
Emulsion stability (KCP 2.8.6.2)	-	-	Not an SC requirement.		-	-	Accepted
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not an SC requirement.		-	-	Accepted
Flowability (KCP 2.8.7.1)	-	-	Not an SC requirement.		-	-	Accepted
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	GLOB2021dF Batch: FOP5819-2	Pourability (% m/m) - Residue - Rinsed characteristics	3.897 ± 0.010 0.939 ± 0.021	Y	Raksha, V.S., 2023 AG-G0128	With respect to rinsed residue the reported result is above the normally accepted value. The pourability method recommended and used for the assessment (CIPAC MT148) gives, however, only an estimate of the actual rinsed residue that would occur in a practical situation and is almost certainly an over estimate. Pack rinsing in the field will inevitably be performed more vigorously than that represented by the inversion technique specified in CIPAC MT148 and that rinsing will normally be performed to completion. The study in order to assess the effectiveness of cleaning of PPP (GLOB2021Df) was performed. The effectiveness of cleaning test of

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
							GLOB2021dF was carried out in accordance with the guideline PSD efficacy guideline 305, EPPO PP1/292. The analytical method used for active ingredient analysis was validated by establishing linearity range, limit of detection (LOD), limit of quantification(LOQ), specificity, accuracy and precision. The samples were analyzed for the active ingredient content using HPLC method. The percentage of active ingredients content removed for the test item GLOB2021dF was found to be 99.998% and 99.998% for boscalid and Prothiconazole respectively. It demonstrates that only a very limited amount of residue remains in the spray tank after cleaning.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not an SC requirement.		-	-	Accepted
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required since no tank mixes are recommended on the label.		-	-	Accepted
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required since no tank mixes are recommended on the label.		-	-	Accepted
Adhesion to seeds (KCP 2.10.1)	-	-	Not required as GLOB2021dF is no seed treatment.		-	-	Accepted
Distribution to seed (KCP 2.10.2)	-	-	Not required as GLOB2021dF is no seed treatment.		-	-	Accepted
Other/special studies (KCP 2.11)	-	-	Not necessary.		-	-	Accepted

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)

zRMS comments

The HDPE-COEX bottle was used in accelerated storage study (14 days at 54°C). The HDPE-COEX bottle was stable in accelerated storage study so the storage stability data obtained in these study can be extrapolated for storage in HDPE, HDPE-EVOH; HDPE-F, HDPE/PA bottles.

(According to SANCO/10473/2003 rev.5 “Guidance Document for the Generation and Evaluation of Data on The Physical, Chemical And Technical Properties of Plant Protection Products Under Regulation (EC) No. 1107/2009” and Technical Monograph N°17 3RD Edition Guidelines for Specifying and Managing Shelf Life and Expiry Date of Crop Protection Products, Crop Life International” the following extrapolations are acceptable: for water-based formulations (e.g. SC, FS, SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of the others).

Table 4.1-1: Packaging information for 100 mL bottle

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	cylindrical / approx. 45 mm diameter x 90 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-2: Packaging information for 150 mL bottle

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	cylindrical / approx. 60 mm diameter x 90 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 250 mL bottle

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	cylindrical / approx. 60 mm diameter x 125 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap

Type	Description
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 500 mL bottle

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	cylindrical / approx. 60 mm diameter x 185 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 1L bottle

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 2L container

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 106 mm width x 155 mm length x 189 mm height
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 3L container

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 160 mm width x 262 mm length x 115 mm height
Opening:	63 mm inner diameter

Type	Description
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8: Packaging information for 5 litre container

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 140 mm x 190 mm x 313 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information for 10 litre container

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 179 mm x 240 mm x 375 mm
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for 15 litre container

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	Height: 311 mm, Width: 245 mm, Length: 294 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant
Content product in the bottle	10 kg

Table 4.1-11: Packaging information for 20 litre container

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 263 mm width x 292 mm length x 372 mm height
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

4.2 Procedures for Cleaning Application Equipment

4.2.1 Procedures for cleaning application equipment and protective clothing

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.

4.2.2 Effectiveness of the cleaning procedures (KCP 4.2)

The effectiveness of cleaning procedures was assessed in the EFFECTIVENESS OF CLEANING TEST OF GLOB2021dF (Amaljoy, A., 2023). After three tank washes with 10 mL water, 99.998 ± 0.000 of boscalid and 99.998 ± 0.000 of prothioconazole was removed from the bottles. This demonstrates that only a very limited amount of residue remains in the spray tank after cleaning.

zRMS comment

Accepted

The study in order to assess the effectiveness of cleaning of PPP (GLOB2021dF) was performed. The effectiveness of cleaning test of GLOB2021dF was carried out in accordance with the guideline PSD efficacy guideline 305, EPPO PP1/292. The analytical method used for active ingredient analysis was validated by establishing linearity range, limit of detection (LOD), limit of quantification(LOQ), specificity, accuracy and precision.

The samples were analyzed for the active ingredient content using HPLC method.

The percentage of active ingredients content removed for the test item GLOB2021dF was found to be 99.998% and 99.998% for boscalid and Prothiconazole respectively.

4.3 Recommended methods and precautions (KCP 4.2)

Reference is made to the submitted SDS (KCP 1.4.3) where all the required and detailed information can be found. A summary is given below:

4.3.1 Procedures for storage

Storage conditions: Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.

Incompatible products: Strong bases. Strong acids.
Incompatible materials: Sources of ignition. Direct sunlight

4.3.2 Transport

In accordance with ADN / ADR / IATA / IMDG / RID

- UN number is 3082.
- UN Proper shipping name is “ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
- Transport hazard class is 9.
- Packaging group is III

4.3.3 Firefighting measures

Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent firefighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

4.3.4 Exposure control

All unnecessary exposure should be avoided. For personal protection measures reference is made to dRR Part B Section 6.

4.3.5 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

4.4 Emergency measures (KCP 4.3)

Reference is made to the submitted SDS for KCP 4.3 where all the required and detailed information can be found.

A short summary is given below:

4.4.1 Accidental release measures

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment

Evacuate unnecessary personnel. Equip clean-up crew with proper protection. Ventilate area.

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

Avoid release to the environment.

4.4.2 First aid measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Assure fresh air breathing. Allow the victim to rest.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.5 Procedures for destruction and neutralisation (KCP 4.5)

In the event of accidental spillages the neutralisation procedures are as follows: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials (reference is also made to 4.4.1 above).

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 2.4.1 KCP 2.4.2 KCP 2.7.1 KCP 2.7.3 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2	Raksha V.S.	2023	ACCELERATED STORAGE STABILITY TEST BY HEATING AT $54 \pm 2^{\circ}\text{C}$ OF GLOB2021dF AG-G0128 Eurofins Advinus Agrosiences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV
KCP 2.7.5	Raksha V.S.	Ongoing	Long term storage stability test of GLOB2021dF AG-G0129 Eurofins Advinus Agrosiences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV
KCP 2.7.3	Raksha V.S.	2023	Purity analysis of GLOB2021dF AG-G0130 Eurofins Advinus Agrosiences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV
KCP 2.3.1	Raksha V.S.	2023	Determination of flash point of GLOB2021dF	N	Globachem

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
			AG-G0131 Eurofins Advinus Agrosciences Services India Pvt. Ltd GLP Unpublished		NV
KCP 2.3.2 KCP 2.3.3	Raksha V.S.	2023	Determination of auto ignition temperature of GLOB2021dF AG-G0132 Eurofins Advinus Agrosciences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV
KCP 2.5.1	Raksha V.S.	2023	Determination of viscosity of GLOB2021dF AG-G0133 Eurofins Advinus Agrosciences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV
KCP 2.5.2	Raksha V.S.	2023	Determination of surface tension of GLOB2021dF AG-G0134 Eurofins Advinus Agrosciences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV
KCP 2.6.1	Raksha V.S.	2023	Determination of relative density of GLOB2021dF AG-G0135 Eurofins Advinus Agrosciences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV
KCP 2.7.4	Raksha V.S.	2023	Low temperature stability of GLOB2021dF AG-G0136 Eurofins Advinus Agrosciences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV

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 2.8.2	Raksha V.S.	2023	Determination of persistent foam of GLOB2021dF AG-G0137 Eurofins Advinus Agrosiences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV
KCP 2.7.5	Raksha V.S.	Ongoing	Three years storage stability test of GLOB2021dF AG-G0672 Eurofins Advinus Agrosiences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV
KCP 4.2	Amaljoy A.	2023	Effectiveness of cleaning test of GLOB2021dF AG-G2302 Eurofins Advinus Agrosiences Services India Pvt. Ltd GLP Unpublished	N	Globachem NV

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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Not required.