

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: GLOB1811F

Product name(s): RASPUT

Chemical active substance:

Boscalid, 500 g/kg

Poland – Art. 33

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: June 2021

MS Finalisation date: 18/03/2022

Version history

When	What
December 2021	First zRMS PL evaluation
March 2022	RR finalized by zRMS after commenting period

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Review Comments:

This application was submitted by Globachem NV for approval of Rasput (GLOB1811F) a water dispersible granule (WG) containing 500 g/kg boscalid for use as a fungicide in oilseed rape in Poland.

Boscalid was included on Annex I of Directive 91/414/EEC on 1 of August 2008 under Inclusion Directive 2008/44/EC.

This Part B document only reviews data (Annex III) and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out.

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).

No data gaps noticed.

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: XXX
Telephone number: XXX
E-mail: XXX

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 substance(s)

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 & 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: RASPUT
Company code number: GLOB1811F

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)

GLOB1811F was not the representative formulation during the EU evaluation of Boscalid.

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/Kg)	FAO Limits (min – max)	Technical content* (g/Kg)	Technical content (%w/w)
Boscalid	500	475 - 525	507.10	50.71

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

There are no toxicologically, ecotoxicologically or environmentally relevant impurities present in the formulation.

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

Table 1.4-4: Information on Boscalid

Type	Name/Code Number
ISO common name	Boscalid
CAS No.	188425-85-6

Type	Name/Code Number
EC No.	606-143-0
CIPAC No.	673

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: Water dispersible granule

[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 a light brown coloured granules less than 1 mm in size, with a musty odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 372°C. In aqueous solution, it has a pH value around 5.63 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 years at ambient temperature when stored in HDPE or silver foil bags. Its technical characteristics are acceptable for a water dispersible granule (WG) formulation. The intended concentration of use is 0.25% to 0.125%.

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 GLOB1811F complies with FAO specifications.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C. It contains 500 g/kg Boscalid. All other co-formulants were the same and had the same concentration.

The phys.-chem. properties of RASPUT (product name: GLOB1811F) have been determined under GLP and according to test methods internationally recognized such as CIPAC methods, the 'EC methods' (Regulation (EC) No. 440/2008) and OECD methods.

After 14 days storage at 54°C, neither the active ingredient content nor the technical properties were changed.

After two years storage at ambient temperature, neither the active ingredient content nor the technical properties were changed.

Appearance (physical state, colour) and odour remained unchanged over the storage period – 2 years at ambient temperature.

The user properties of the formulation are acceptable for a water dispersible granule (WG) both initially and after storage for two years at ambient temperature.

HDPE packs remain in good condition over the 2 years storage period at ambient temperature, with no corrosion and no other influence of the product on the original container.

After storage for 2 years at ambient temperature, the formulation showed good chemical and physical properties.

A minimum shelf life of 2 years (at ambient temperature) is expected for this product according to FAO specifications when stored in HDPE or silver foil bags.

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	GLOB1811F Batch: 180511	The sample consisted of uniform brown coloured granules approximately less than 1 mm. The sample was free flowing, with no signs of clumping or compactation, The granules were intact. The samples had a musty odour.	Y	XXX T., 2018. DNA4728	Accepted Visual inspection of colour, physical state and odour were performed. Observation of granule integrity is required. The granule were intact.
Explosive properties (KCP 2.2.1)	Theoretical certificate	/	No explosive properties	N	XXX T., 2019. DNA5297	Accepted The test was not performed. Theoretical evaluation based on the available information for example Safety Data Sheets, scientific information. According to CLP Regulation: “Mixture shall not be classified as explosive if: - there are no chemical groups associated with explosive properties present in the molecule”. The substances which are part of the test item are not classified as explosives. There are also no chemical groups

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						associated with the explosives properties in test item.
Oxidizing properties (KCP 2.2.2)	EEC A17	GLOB1811F Batch: 180511	Not oxidizing	Y	XXX T., 2018. DNA4728	Accepted No oxidising properties. The A17 test was performed – “Oxidising properties: Solids”. The reference mixture: barium nitrate and cellulose in a 2 to 1 ratio by weight – burned with a green flame, crackled and created sparks:oxidising properties. The mixture of test item with cellulose – did not react and no crackling or sparks were observed – no oxidising properties.
Flash point (KCP 2.3.1)	EEC A10	GLOB1811F Batch: 180511	Not highly flammable	Y	XXX T., 2018. DNA4728	Accepted The A10 test was performed “Flammability for solids”. Solid mixtures are classified as 'flammable' if they readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						removal of the source of ignition. The sample of test item was lined up in an unbroken chain. A flame was applied to the end of the sample chain. The sample charred but did not hold a flame and the flame did not travel down the chain. The test item is considered not highly flammable.
Flammability (KCP 2.3.2)	EEC A16	GLOB1811F Batch: 180511	Ignition temperature: 372°C	Y	XXX T., 2018. DNA4728	Accepted The A16 test was performed – “Relative self ignition temperature for solids”. According to A16 the self-ignition temperature for solids is the temperature of the oven at which the sample temperature reaches 400°C by self-heating. The test item self-ignited at 372°C. In view of the positive results obtained the equivalent UN test N.4 was performed to ensure the safe transport conditions in line with the current CRD requirements.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Self-heating (KCP 2.3.3)	UN Test N.4	GLOB1811F Batch: 180511	The sample did not self-ignite at 140°C for 24 hours	Y	XXX T., 2018. DNA4728	Accepted The test item did not self ignite using UN Test N.4 method, therefore test item is not considered as a spontaneously combustible material under UN classification Division 4.2.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	GLOB1811F Batch: 180511	0.2352% m/m as H ₂ SO ₄	Y	XXX T., 2018. DNA4728	Accepted The acidity or alkalinity should be tested if the preparation has pH < 4 or pH > 10 (for either 1 % dilution or neat formulation). Gnereally the test was no required. The acidity/alkalinity gives the total concentration of weak and strong acids/bases and hence is used to assess corrosive nature of formulations.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB1811F Batch: 180511	Dilution: pH 5.63	Y	XXX T., 2018. DNA4728	Accepted
Viscosity (KCP 2.5.1)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation.

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Surface tension (KCP 2.5.2)	-	-	Not required for WG formulation			-	-	Accepted Not required for WG formulation.
Relative density (KCP 2.6.1)	-	-	Not required for WG formulation			-	-	Accepted Not required for WG formulation.
Bulk density (KCP 2.6.2)	CIPAC MT 186	GLOB1811F Batch: 180511	Pour density: 0.6701 g/mL Tap density: 0.7425 g/mL			Y	XXX T., 2018. DNA4728	Accepted The pour and tap density of granular formulations should be reported.
Storage Stability after 14 days at 54° C (KCP 2.7.1)		GLOB1811F Batch: 180511	Test	Before Storage	After Storage (54 °C, 2 weeks)	Y	XXX T., 2018. DNA4728	Accepted The product is stable after two weeks of storage at 54°C. The analytical method which was used to determined active ingredient (boscalid) content was validated in GLP laboratory (analytical method DNA4730). The content of active ingredient was determined by HPLC with UV detection method. The initial concentration of boscalid was 497.2 g/kg, the concentration of boscalid after 2 weeks of storage at temperature 54°C was 501.9 g/kg. It is recognised that a
			Active content	497.2 g/kg (99.44 % of declared content)	501.9 g/kg (101.4 % of declared content)			
			Appearance	Sample stored in white 0.5L tall form HDPE bottle Uniform brown coloured granules approximately less than 1 mm. Musty odour.	Sample stored in white 0.5L tall form HDPE bottle Uniform brown coloured granules approximately less than 1 mm. The sample appearance remained unchanged post accelerated 2 weeks storage after one inversion.			
			pH determination	1% dilution pH 5.63	1% dilution pH 5.63			
			Acidity/Alkalinity	0.2352% m/m as H ₂ SO ₄	0.2313% m/m as H ₂ SO ₄			
			Suspensibility	At the high	At the high			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				concentration (0.25%) in CIPAC Water D: 100.1% At the low concentration (0.125%) in CIPAC Water D: 100.3%	concentration (0.25%) in CIPAC Water D: 99.65% At the low concentration (0.125%) in CIPAC Water D: 94.22%			loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation. Appearance: before storage - the sample consisted of uniform brown coloured granules approximately less than 1 mm. The sample was free flowing, with no signs of clumping or compactation, The granules were intact. The samples had a musty odour. The sample appearance remained unchanged after storage at two weeks at 54°C. There were no difference in pH of initial product and after 2 weeks of storage at 54°C. Acidity and alkalinity were not required as pH >4 and <10, but tests were conducted. The acidity/alkalinity gives the total concentration of
			Aspontaneity of dispersion	In CIPAC Water A: 101.3% In CIPAC Water D: 102.0%	In CIPAC Water A: 101.9% In CIPAC Water D: 102.6%			
			Wet sieve test	0.0930%	0.1100%			
			Wettability	1.0 second	1.0 second			
			Particle size distribution	≥90% on the 75 sieve ≤10% on the 500 µm sieve	≥90% on the 75 sieve ≤10% on the 500 µm sieve			
			Dust content	0.5 mg	0.2 mg			
			Attrition	100.0%	100.0%			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								<p>weak and strong acids/bases and hence is used to assess corrosive nature of formulations.</p> <p>Suspensibility/dispersion stability is determined to demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying. For the determination of mass of active substance still in suspension the validated analytical method was used (HPLC method). According to CIPAC MT 184 method the mean measured active suspensibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for the test item before storage and after two weeks of storage at 54°C.</p> <p>The spontaneity of dispersion is determined</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								<p>to show the mixture is rapidly dispersed when diluted with water. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for the test item before storage and after two weeks of storage at 54°C.</p> <p>A 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 above mentioned criteria were met for the test item before storage and after two weeks of</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								<p>storage at 54°C.</p> <p>Wettability is determined to ensure the mixture is readily wetted in use. The data are required for solid preparations which are to be dispersed in water. Acceptable limits: a preparation is considered acceptable if there is complete wetting in 1 minute without swirling. The criteria were met. The product before storage and after storage for two weeks at 54°C were completely wet at 1.0 second.</p> <p>The nominal size range for solid materials for dispersion in water were determined with MT 170 (Particle size distribution) before storage and after storage at two weeks at 54°C.</p> <p>The dust content of solid mixtures must be determined to ensure there is no unacceptable risk to operators,</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								<p>residents or bystanders or potential for blockage of application equipment.</p> <p>The amount of dust (either in mg for the gravimetric method or as dust value for the optical method) must be stated.</p> <p>Products, according to MT 171.1, should be ‘nearly dust free’ (category 1) or ‘essentially non dusty’ (category 2). Based on the amount of dust content before storage - 0.5 mg and after two weeks storage at 54°C - 0.2 mg the product is considered “nearly dust free”.</p> <p>Attrition is defined as the wearing away of the surface of a granule by friction or impact, particularly by granule-to-granule interaction. These data are required to determine whether a granular material is robust under normal conditions of use and transport.</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								Acceptable limits: where the material has an attrition resistance of < 98 % then the particle size of the dust must be determined and the risk to operators, residents and bystanders must be addressed. The criteria were met. The product before storage and after two weeks of storage at 54°C had attrition resistance of 100%. The product is robust under normal conditions of use and transport.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required, GLOB1811F was found to be stable after storage for 14 days at 54 °C.			-	-	Accepted The product is stable after storage for two weeks at 54°C.
Minimum content after heat stability testing (KCP 2.7.3)	In house method	GLOB1811F Batch: 180511	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.			Y	XXX T., 2018. DNA4728	Accepted The analytical method which was used to determined active ingredient (boscalid) content was validated in GLP laboratory (analytical method DNA4730). The content of active ingredient was determined by HPLC with UV detection method.

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								The initial concentration of boscalid was 497.2 g/kg, the concentration of boscalid after 2 weeks of storage at temperature 54°C was 501.9 g/kg. 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.
Effect of low temperatures on stability (KCP 2.7.4)	-	-	Not required for WG formulation			-	-	Accepted Not requires for WG formulation.
Ambient temperature shelf life (KCP 2.7.5)		GLOB1811F Batch: 180511	Test	Before Storage	After Storage (ambient temperature, 2 years)	-	XXX T., 2020 DNA4729	Accepted The product is stable after two years of storage at ambient temperature. The analytical method which was used to determined active ingredient (boscalid) content was validated in GLP laboratory (analytical method DNA4730). The content of active ingredient was determined by HPLC
			Active content	497.2 g/kg (99.44 % of declared content)	499.2 g/kg (99.83 % of declared content)			
			Appearance	The sample consisted of uniform brown coloured granules approximately less than 1mm. the sample was free flowing, with no signs of clumping or	The sample appearance remained unchanged after 2 years ambient storage from the pre storage sample.			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				compaction. The granules were intact. The sample had a musty odour.				<p>with UV detection method. The initial concentration of boscalid was 497.2 g/kg, the concentration of boscalid after 2 years of storage at ambient temperature was 499,2 g/kg. 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.</p> <p>Appearance: before storage - the sample consisted of uniform brown coloured granules approximately less than 1 mm. The sample was free flowing, with no signs of clumping or compactation, The granules were intact. The samples had a musty odour. The sample appearance remained unchanged after storage at two years at ambient temperature.</p> <p>There were almost no</p>
			pH determination	1% dilution pH 5.63	1% dilution pH 5.69 at 20°C			
			Acidity/Alkalinity	0.2352% m/m as H ₂ SO ₄	0.2283% m/m as H ₂ SO ₄			
			Suspensibility	At the high concentration (0.25%) in CIPAC Water D: 100.1% At the low concentration (0.125%) in CIPAC Water D: 100.3%	At the high concentration (0.25%) in CIPAC Water D: 100.3% At the low concentration (0.125%) in CIPAC Water D: 99.31%			
			Aspontaneity of dispersion	In CIPAC Water A: 101.3% In CIPAC Water D: 102.0%	In CIPAC Water A: 102.1% In CIPAC Water D: 101.5%			
			Wet sieve test	0.0930%	0.0870%			
			Wettability	1.0 second	1.0 second			
			Particle size distribution	≥90% on the 75 sieve ≤10% on the 500 µm sieve	≥90% on the 75 sieve ≤10% on the 500 µm sieve			
			Dust content	0.5 mg	0.5 mg			
			Attrition	100.0%	99.81%			
			Stability of packaging bottle	The sample	The sample			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				arrived in good condition with no signs of any leaks or panelling	packaging remained unchanged post 2 years ambient storage			<p>difference in pH of initial product and after 2 years of storage at ambient temperature. Acidity and alkalinity were not required as pH >4 and <10, but tests were conducted. The acidity/alkalinity gives the total concentration of weak and strong acids/bases and hence is used to assess corrosive nature of formulations. Suspensibility/dispersion stability is determined to demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying. For the determination of mass of active substance still in suspension the validated analytical method was used (HPLC method). According to CIPAC MT 184 method the mean measured active suspensibility must not be less than 60 % or greater than 105 %.. The</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								<p>above mentioned criteria were met for the test item before storage and after two years of storage at ambient temperature.</p> <p>The spontaneity of dispersion is determined to show the mixture is rapidly dispersed when diluted with water. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for the test item before storage and after two years of storage at ambient temperature.</p> <p>A 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</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								<p>blockage of nozzles or filters on application equipment.</p> <p>Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The above mentioned criteria were met for the test item before storage and after two years of storage at ambient temperature.</p> <p>Wettability is determined to ensure the mixture is readily wetted in use. The data are required for solid preparations which are to be dispersed in water. Acceptable limits: a mixture is considered acceptable if there is complete wetting in 1 minute without swirling. The criteria were met. The product before storage and after storage for two years at ambient temperature were completely wet at 1.0 second.</p> <p>The nominal size range for solid materials for</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								<p>dispersion in water were determined with MT 170 (Particle size distribution) before storage and after storage at two years at ambient temperature.</p> <p>The dust content of solid mixtures must be determined to ensure there is no unacceptable risk to operators, residents or bystanders or potential for blockage of application equipment.</p> <p>The amount of dust (either in mg for the gravimetric method or as dust value for the optical method) must be stated. Products, according to MT 171.1, should be ‘nearly dust free’ (category 1) or ‘essentially non dusty’ (category 2). Based on the amount of dust content before storage - 0.5 mg and after two years storage at ambient temperature - 0.5 mg the product is considered “nearly dust free”.</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								<p>Attrition is defined as the wearing away of the surface of a granule by friction or impact, particularly by granule-to-granule interaction. These data are required to determine whether a granular material is robust under normal conditions of use and transport.</p> <p>Acceptable limits: where the material has an attrition resistance of < 98 % then the particle size of the dust must be determined and the risk to operators, residents and bystanders must be addressed. The criteria were met. The product before storage and after two years of storage at ambient temperature had attrition resistance of 100%. The product is robust under normal conditions of use and transport.</p> <p>The sample was stored in a white 500 ml tall form PE bottle. The</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								sample packaging showed no signs of leaks or panelling. The sample packaging remained unchanged after 2 years of storage at ambient temperature.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required as GLOB1811F is stable following more than 2 years at ambient temperature.			-	-	Accepted The product is stable after two years of storage at ambient temperature.
Wettability (KCP 2.8.1)	CIPAC 53.3	GLOB1811F Batch: 180511	1.0 second			Y	XXX T., 2018. DNA4728	Accepted Wettability is determined to ensure the mixture is readily wetted in use. The data are required for solid mixtures which are to be dispersed in water. Acceptable limits: a mixture is considered acceptable if there is complete wetting in 1 minute without swirling. The criteria were met. The product was completely wet at 1.0 second.
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB1811F Batch: 180511	Minimum application rate: 0.0mL after 1 minute 0.0mL after 12 min Maximum application rate:			Y	XXX T., 2018. DNA4728	Accepted Persistent foam is determined to measure the amount of foam likely to be present in a

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			0.0mL after 1 minute 0.0mL after 12 min			spray tank or other application equipment following dilution of the mixture. Acceptable limits: max 60 mL foam after 1 minute. The criteria were met for the minimum application rate and for the maximum application rate.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	GLOB1811F Batch: 180511	At the high concentration in CIPAC Water D: 100.1% At the low concentration in CIPAC Water D: 100.3%	Y	XXX T., 2018. DNA4728	Accepted Suspensibility/dispersion stability is determined to demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying. For the determination of mass of active substance still in suspension the validated analytical method was used (HPLC method). According to CIPAC MT 184 method the mean measured active suspensibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						were met for the test item before storage at high concentration in CIPAC Water D (100,1%) and low concentration in CIPAC Water D (100,3%).
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174 Using HPLC	GLOB1811F Batch: 180511	In CIPAC Water A: 101.3% In CIPAC Water D: 102.0%	Y	XXX T., 2018. DNA4728	Accepted The spontaneity of dispersion is determined to show the mixture is rapidly dispersed when diluted with water. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for the test item before storage.
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation.
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation.
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 170	GLOB1811F Batch: 180511	≥90% on the 75 sieve ≤10% on the 500 µm sieve	Y	XXX T., 2018. DNA4728	Accepted The nominal size range for solid materials for dispersion in water were

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						determined with MT 170 (Praticle size distribution) before storage.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	GLOB1811F Batch: 180511	0.0930%	Y	XXX T., 2018. DNA4728	Accepted A 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 above mentioned criteria was met for the test item before storage.
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171.1	GLOB1811F Batch: 180511	0.5 mg	Y	XXX T., 2018. DNA4728	Accepted The dust content of solid mixtures must be determined to ensure there is no unacceptable risk to operators, residents or bystanders or potential for blockage of application equipment. The amount of dust

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						(either in mg for the gravimetric method or as dust value for the optical method) must be stated. Products, according to MT 171.1, should be 'nearly dust free' (category 1) or 'essentially non dusty' (category 2). Based on the amount of dust content – 0.5 mg – the product is considered "nearly dust free".
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation.
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	GLOB1811F Batch: 180511	100.0%	Y	XXX T., 2018. DNA4728	Accepted Attrition is defined as the wearing away of the surface of a granule by friction or impact, particularly by granule-to-granule interaction. These data are required to determine whether a granular material is robust under normal conditions of use and transport. Acceptable limits: where the material has an attrition resistance of < 98 % then the particle

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						size of the dust must be determined and the risk to operators, residents and bystanders must be addressed. The criteria were met. The product before storage had attrition resistance of 100%. The product is robust under normal conditions of use and transport.
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation.
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation.
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation.
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation.
Flowability (KCP 2.8.7.1)	CIPAC MT 172.1	GLOB1811F Batch: 180511	Did not clump or compact. Sample passed through 4.75mm sieve with no taps required.	Y	XXX T., 2018. DNA4728	Accepted The data are required to demonstrate that granular materials remain free flowing after storage under pressure. Acceptable limits: Report whether the sample drops through

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						the sieve spontaneously. The sample should flow through the sieve after a maximum of 5 liftings. Test item passed through 4.75 mm sieve with no taps required – the criteria were met.
Pourability (KCP 2.8.7.2)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for WG formulation	-	-	Accepted Not required for WG formulation
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant – no tank mix on the label	-	-	Accepted Not relevant – no tank mix on the label
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant – no tank mix on the label	-	-	Accepted Not relevant – no tank mix on the label
Adhesion to seeds (KCP 2.10.1)	-	-	Not applicable as GLOB1811F is not used for seed treatment.	-	-	Accepted Not applicable as product is not used for seed treatment.
Distribution to seed (KCP 2.10.2)	-	-	Not applicable as GLOB1811F is not used for seed treatment.	-	-	Accepted Not applicable as product is not used for seed treatment.
Other/special studies (KCP 2.11)	-	-	Not required	-	-	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)

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

The packaging has been designed according to the FAO “Guidelines for the Packaging and Storage of Pesticides”.

GLOB1811F is to be marketed in 0.25, 0.5, 1, 2, 3, 5, 10, 15, 20 L HDPE containers or in silver foil bags.

Details of the packaging are given in the table below. The dimensions of the silver foil bags are not relevant as the product is a solid.

Table 4.1-1: Packaging information for 0.25 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	cylindrical / approx. 62.5 mm diameter x 127 mm
Opening:	41 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.5 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
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 4.1-3: Packaging information for 1 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm

Type	Description
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 2 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	Height: 189 mm, Width: 106 mm, Length: 155 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 3 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	Height: 115 mm, Width: 160 mm, Length: 262 mm
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 5 litre container

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	Height: 313 mm, Width: 140 mm, Length: 190 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 10 litre container

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	Height: 375 mm, Width: 179 mm, Length: 240 mm
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8: Packaging information for 15 litre container

Type	Description
Material:	HDPE (High Density PolyEthylene)
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

Table 4.1-9: Packaging information for 20 litre container

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	Height: 372 mm, Width: 263 mm, Length: 292 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for silver foil bags

Type	Description
Material:	Layers from inside to outside: PE – Aluminium – PET or PP
Seal:	Heat-sealing
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 storage stability study of GLOB1811F (XXX T., 2018 2019). After three tank washes with 400 mL water 0.0113% residue remained in the tank. This demonstrates that only a very limited amount of residue remains in the spray tank after cleaning.

Comments of zRMS:	The study is accepted. The study demonstrated that only a very limited amount of residue remains in the spray tank after cleaning. This submitted study has been validated in a proper manner.
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4.3 Recommended methods and precautions (KCP 4.2)

Reference is made to the submitted safety data sheet for GLOB1811F where all the required information can be found. A summary is given below.

4.3.1 Procedures for storage

Store in a well-ventilated place. Keep cool.

4.3.2 Transport

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

- UN number: Not applicable;
- UN proper shipping name: Not applicable;
- Transport hazard class(es): Not applicable;
- Packing group: Not applicable;
- Environmental hazards: Not applicable;
- Special precautions for user: Not applicable;
- Transport in bulk: Not applicable.

4.3.3 Firefighting measures

- Suitable extinguishing media: Water spray. Dry powder. Foam.
- Special hazards arising from the substance or mixture: Toxic fumes may be released;
- Protection during firefighting: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

4.3.4 Exposure control

- Appropriate engineering controls: Ensure good ventilation of the work station;
- Hand protection: Protective gloves;
- Eye protection: Safety glasses;
- Skin and body protection: Wear suitable protective clothing;
- Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment;
- Environmental exposure controls: Avoid release to the environment

4.3.5 Environmental precautions

Avoid release to the environment.

4.4 Emergency measures (KCP 4.3)

Reference is made to the submitted safety data sheet for GLOB1811F where all the required information can be found. A summary is given below.

4.4.1 Accidental release measures

Ventilate the spillage area. Do not attempt to take action without suitable protective equipment as described in Section 4.3.4. Avoid release to the environment. To clean up, mechanically recover the product and dispose of materials or solid residues at an authorised site.

4.4.2 First aid measures

- First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breathing;
- First-aid measures after skin contact: Wash skin with plenty of water;
- First-aid measures after eye contact: Rinse eyes with water as a precaution;
- First-aid measures after ingestion: Call a poison center or a doctor if you feel unwell.
- Treat symptomatically.

4.5 Procedures for destruction and neutralisation (KCP 4.5)

In the event of accidental spillages, the neutralisation procedures are as follows: mechanically recover the product and dispose of materials or solid residues at an authorized site. Reference is also made to Section 4.4.1 above. Dispose of contents/container in accordance with licensed collector's sorting instructions. Controlled incineration is the preferred method of disposal for the plant protection product as well as contaminated materials and packaging.

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 2.1 2.2.2 2.3.2 2.3.3 2.4.1 2.4.2 2.6.2 2.7.1 2.7.2 2.7.3 2.8.1 2.8.2 2.8.3.1 2.8.3.2 2.8.5.1.1 2.8.5.1.2 2.8.5.2.1 2.8.5.3 2.8.7.1	XXX, T.	2018	Determination of storage stability and shelf life specification data for a water dispersible granule formulation containing Boscalid stored at 54±2°C for two weeks, in compliance with good laboratory practice. DNA4728 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP 2.2.1 (Filled in in Part C)	XXX, T.	2019	Theoretical certificate of explosive properties for a formulation containing Boscalid. DNA5297 David Norris Analytical Laboratories Ltd. Not 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 2.7.5	XXX, T.	2020	Determination of storage stability and shelf life specification data for a water dispersible granule formulation containing Boscalid stored at ambient temperature for two years, in compliance with good laboratory practice. DNA4729 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV

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

A 2.1 Boscalid

None.