

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: GLOB182F

Product name: SURRENDER

Chemical active substance:

Fludioxonil, 100 g/L

Interzonal

Zonal Rapporteur Member State: PL

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: January 2021

MS Finalisation date: August 2021 (initial Core Assessment)

March 2022 (final Core Assessment)

Version history

When	What
01/2021	Initial dRR - Globachem NV.
08/2021	Initial izRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the izRMS 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.
03/2022	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the izRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.

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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.

Noticed data gaps are:

- The two years storage stability study is ongoing and should be available in July 2022.

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

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 Fludioxonil

Fludioxonil min. 980 g/kg

The source of the active ingredient has been confirmed to be equivalent to the annex I source by the RMS the Czech Republic and Germany.

Further information relating to the 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: Please refer to Registration Report Part A for the relevant country (or)
Company code number: GLOB182F

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)

Fludioxonil 100 FS was not the representative formulation during the EU evaluation of Fludioxonil.

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

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Fludioxonil	100	90-110	102.04	9.72

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

** Based on the density of the formulation = ~~1.05~~ 1.0490

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 1.4-2: Information on Fludioxonil

Type	Name/Code Number
ISO common name	Fludioxonil
CAS No.	131341-86-1
EC No.	Not allocated
CIPAC No.	522

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: Flowable concentrate for seed treatment [Code: FS]

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 uniform bright red liquid, with a sweet solvent like odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of more than 400 °C. In aqueous solution, it has a pH value around 6.58 at 20°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 stored in HDPE bottles, neither the active ingredient content nor the technical properties were changed. The two years storage stability study is ongoing and should be available in July 2022. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE bottles. The packaging claimed in the section 4 (HDPE, f-HDPE, HDPE/PA or HDPE/EVOH) is acceptable as a storage stability study at elevated temperature for 14 days was carried out in the HDPE material and can be extrapolated. Its technical characteristics are acceptable for a flowable concentrate formulation.

The intended concentration of use is 6.25-37.5% (0.5-1.5L product in 4-8L water).

No tank mixes are required for GLOB182F.

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 GLOB182F 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 100 g/L Fludioxonil. 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 inspection	GLOB182F Batch No PE 2004.742	The sample was a uniform bright red liquid. The sample was opaque, not allowing light to pass through and free-flowing, coating the walls of the beaker. There were no signs of separation into oil, cream, sediment, claying or suspended solids. The sample had a sweet solvent type odour.	Y	Pomeroy D., 2020a	Accepted.
Explosive properties (KCP 2.2.1)	Theoretical certificate	/	No explosive properties (theoretical certificate based on composition)	N	Pomeroy D., 2020b	Accepted.
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	/	No oxidizing properties (theoretical certificate based on composition)	N	Pomeroy D., 2020b	Accepted.
Flash point (KCP 2.3.1)	EEC A9	GLOB182F Batch No PE 2004.742	The sample did not flash below 100 °C GLOB182F is not considered to be flammable.	Y	Pomeroy D., 2020a	Accepted.
Flammability (KCP 2.3.2)	-	-	Test not required for liquids.	-	-	-
Self-heating (KCP 2.3.3)	EEC A15	GLOB182F Batch No PE 2004.742	The sample did not auto-ignite below 400 °C and is therefore considered not highly flammable.	Y	Pomeroy D., 2020a	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	GLOB182F Batch No PE 2004.742	The acidity/alkalinity of the sample was not performed as the pH of the 1 % dilution was found to be between 4 and 10. The pH of the neat formulation was found to be 6.68 at 20.0 °C.	Y	Pomeroy D., 2020a	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB182F Batch No PE 2004.742	The pH of a 1 % dilution in deionised water (pH = 6.96) was found to be 6.67 at 20.0 °C.	Y CIPAC MT 75.3	Pomeroy D., 2020a	Accepted.
Viscosity (KCP 2.5.1)	OECD 114	GLOB182F Batch No PE 2004.742	<u>At 20°C ± 0.1°C:</u> from 25830.4 to 259.61 mPa.s for shear rates going from 0.10 to 34 s ⁻¹ . <u>At 40°C ± 0.1°C:</u> from 20763.2 to 234.40 mPa.s for shear rates going from 0.10 to 34.0 s ⁻¹ .	Y	Pomeroy D., 2020a	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Surface tension (KCP 2.5.2)	EEC A5	GLOB182F Batch No PE 2004.742	At the maximum application rate (1.5 L of formulation in 8 L of water): Mean corrected surface tension at 20 °C: 34.28 mN/m ± 0.146. Mean corrected surface tension at 25 °C: 34.23 mN/m ± 1.176.	Y	Pomeroy D., 2020a	Accepted.
Relative density (KCP 2.6.1)	EEC A3	GLOB182F Batch No PE 2004.742	1.0490 g/mL at 20.0 °C.	Y	Pomeroy D., 2020a	Accepted.
Bulk density (KCP 2.6.2)	-	-	Not required for liquids.	-	-	-
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46 The sample were stored in 500 mL HDPE bottles. Analytical method for a.i. validated in the study DNA5609 (see part B5)	GLOB182F Batch No PE 2004.742	<p>Appearance: The sample remained a uniform bright red liquid. The sample was opaque, not allowing light to pass through and free-flowing, coating the walls of the beaker. There were no signs of separation into oil, cream, sediment, claying or suspended solids. The sample retained a sweet solvent type odour. The appearance of the sample remained unchanged post accelerated storage at 54° C ± 2°C for two weeks.</p> <p>[pre-storage results in square brackets]</p> <p>pH neat formulation: 6.58 [6.68] at 20.0 °C. pH 1 % dilution in deionised water (pH = 6.96): 6.56 [6.67] at 20.0°C.</p> <p>Suspensibility: High application rate (1.5/8L CIPAC water D): 101.5 % [101.5 %] Low application rate (0.5L/8L CIPAC water D): 101.5 % [101.9 %]</p> <p>Wet sieve: Sieve mesh size: 75 µm 0.0180 % [0.0125 %]</p> <p>Pourability:</p>	Y	Pomeroy D., 2020a	<p>The product showed no significant physical changes after accelerated storage and all performance properties were within acceptable limits. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary.</p> <p>The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>Poured Residue: 2.2020 % [2.1522 %] Water Rinsed Residue: 0.1288 % [0.1440 %] Acetone Rinsed Residue: 0.0031 % [0.0062 %]</p> <p>Adhesion to seeds: <u>Maize</u> For a target rate of 50 g Fludioxonil/ton seeds (5 g a.s./100 kg seeds): - Initial loading: 4.47 g a.s./ 100 kg seeds - Final loading: 4.38 g a.s./ 100 kg seeds - Retention capacity: 97.9 % <u>Sunflower</u> For a target rate of 150 g Fludioxonil/ton seeds (15 g a.s./100 kg seeds): - Initial loading: 14.33 g a.s./ 100 kg seeds - Final loading: 13.58 g a.s./100 kg seeds - Retention capacity: 94.8 %</p> <p>Distribution to seeds: <u>Maize:</u> For a target rate of 50 g Fludioxonil/ton seeds (5 g a.s./100 kg seeds): 3.88 ± 0.15 g a.s./100 kg seeds (% RSD: 19.3 %) <u>Sunflower</u> For a target rate of 150 g Fludioxonil/ton seeds (15 g a.s./100 kg seeds): 12.93 ± 0.75 g a.s./100 kg seeds (% RSD: 29.8 %)</p> <p>Dust amount: <u>Maize:</u> For a target rate of 5 g a.s./100 kg seeds: 0.17 g dust / 100 kg seeds 11.45 mg Fludioxonil / 100 kg seeds 6.6 % Fludioxonil in dust <u>Sunflower:</u> For a target rate of 15 g a.s./100 kg seeds:</p>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			2.84 g dust / 100 kg seeds 63.78 mg Fludioxonil / 100 kg seeds 2.3 % Fludioxonil in dust			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not applicable as GLOB182F was stored for 2 weeks at 54°C.	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	In house method	GLOB182F Batch No PE 2004.742	Pre-storage: 100 g/L of Fludioxonil equivalent to 100 % of the declared amount. Post-storage for 2 weeks at 54°C: 97.50 g/L of Fludioxonil equivalent to 97.50 % of the declared amount. (decrease 2.50 %)	-	-	Accepted.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	GLOB182F Batch No PE 2004.742	The sample, with the addition of a crystal of Fludioxonil after 34 hours, appeared unchanged post Low Temperature Storage for 7 days at 0 °C and 3 hours at room temperature. The sample remained a uniform red free flowing liquid, opaque, not allowing light to pass through, with no sign of separation into oil, cream, claying, sediment, claying, suspended soils or crystals. Wet sieve after storage: 0.0160%	Y	Pomeroy D., 2020a	Accepted.
Ambient temperature shelf life (KCP 2.7.5)	This study is ongoing and should be available in July 2022.		GLOB182F is expected to be stable following 24 months storage at ambient temperatures, based on the accelerated storage stability data available.	-	-	This study is ongoing and should be available in July 2022.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	-	-	-	-
Wettability (KCP 2.8.1)	-	-	Test not required for liquids.	-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB182F Batch No PE 2004.742	Using CIPAC water D <u>Minimum application rate (0.5L of formulation/8L water):</u> after 1 min.: 0.0 mL after 12 min.: 0.0 mL <u>Maximum application rate (1.5L of formulation/2L water):</u> after 1 min.: 0.0 mL	Y	Pomeroy D., 2020a	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			after 12 min.: 0.0 mL			
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184 Analytical method for a.s. in study DNA5609 (for validation see part B5)	GLOB182F Batch No PE 2004.742	High application rate (1.5L/8L CIPAC water D): 101.5 %. Low application rate (0.5L/8L CIPAC water D): 101.9 %.	Y	Pomeroy D., 2020a	Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required as GLOB182F is a flowable concentrate.	-	-	-
Dispersion stability (KCP 2.8.3.3)	-	-	Not required as GLOB182F is a flowable concentrate.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required as GLOB182F is a flowable concentrate.	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required as Fludioxonil 480 FS is a flowable concentrate and Particle size distribution is already determined by means of the wet sieve test (KCP 2.8.5.1.2).	-	-	-
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	GLOB182F Batch No PE 2004.742	Sieve mesh size: 75 µm Wet sieve residue of 0.0125 %.	Y	Pomeroy D., 2020a	Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	Not required as GLOB182F is a liquid.	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required as GLOB182F is a liquid.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not required as GLOB182F is a liquid.	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required as GLOB182F is a liquid.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not required as GLOB182F is a liquid.	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not required as GLOB182F is a liquid.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required as GLOB182F is a liquid.	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Not required as GLOB182F is a liquid.	-	-	-
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	GLOB182F Batch No PE 2004.742	Poured Residue: 2.1522 % Water Rinsed Residue: 0.1440 % Acetone Rinsed Residue: 0.0062 %	Y	Pomeroy D., 2020a	Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required as GLOB182F is a liquid.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	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.	-	-	-
Adhesion to seeds (KCP 2.10.1)	CIPAC MT 194, Jeff's Test, with active substance content Analytical method for a.s. in study De Vos P., 2021a (for validation see part B5)	GLOB182F Batch No PE 2004.742	<u>Maize</u> For a target rate of 50 g Fludioxonil/ton seeds (5 g a.s./100 kg seeds): - Initial loading: 3.95 g a.s./ 100 kg seeds - Final loading: 4.03 g a.s./ 100 kg seeds - Retention capacity: 101.9 % <u>Sunflower</u> For a target rate of 150 g Fludioxonil/ton seeds (15 g a.s./100 kg seeds): - Initial loading: 13.54 g a.s./ 100 kg seeds - Final loading: 13.18 g a.s./100 kg seeds - Retention capacity: 97.4 %	Y	De Vos P., 2021a	Accepted.
Distribution to seed (KCP 2.10.2)	CIPAC MT 175, with active substance content Analytical method for a.s.	GLOB182F Batch No PE 2004.742	<u>Maize:</u> For a target rate of 50 g Fludioxonil/ton seeds (5 g a.s./100 kg seeds): 3.99 ± 0.19 g a.s./100 kg seeds (% RSD: 23.7 %)	Y	De Vos P., 2021a	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	in study De Vos P., 2021a (for validation see part B5)		<u>Sunflower</u> For a target rate of 150 g Fludioxonil/ton seeds (15 g a.s./100 kg seeds): 14.12 ± 0.92 g a.s./100 kg seeds (% RSD: 33.2 %)			
Other/special studies (KCP 2.11/01)	Heubach Test (ESA STAT Dust Working Group Method)	GLOB182F Batch No PE 2004.742	<u>Maize:</u> For a target rate of 5 g a.s./100 kg seeds: 0.26 g dust / 100 kg seeds 11.42 mg Fludioxonil / 100 kg seeds 4.4 % Fludioxonil in dust <u>Sunflower:</u> For a target rate of 15 g a.s./100 kg seed: 2.94 g dust / 100 kg seeds 58.67 mg Fludioxonil / 100 kg seeds 2.0 % Fludioxonil in dust	Y	De Vos P., 2021b	Accepted.
Other/special studies (KCP 2.11/02) Description of the effectiveness of the washing procedure.	Statement	GLOB182F Batch No PE 2004.742	Formulations are designed to form emulsions, suspensions or solutions by mixing with water at all relevant temperatures. For GLOB182F, rinsings with water are considered to be sufficient as equipment washing procedure based on the results of the pourability test performed with GLOB182F (method CIPAC MT 148.1, please refer to annex point KCP 2.8.7.2), which showed almost no acetone rinsed residue (0.0062 %) after rinsing with water.	N	Daniel Fernández Fuego, 2021	The applicant has provided a statement regarding the cleaning procedure. According to Regulation (EU) No. 284/2013, paragraph 4.2 the effectiveness of the recommended tank cleaning procedures must be addressed. Data submitted must demonstrate that residues of the plant protection product do not remain in the spray tank after cleaning such that there is a risk to the operator or crops. The method used must be fully reported and justified. Statement is not sufficient and a study report should be available. however for GLOB182F,

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>double rinsing with water seems to be sufficient as equipment washing procedure based on the results of the pourability test performed with GLOB182F (method CIPAC MT 148, please refer to annex point KCP 2.8.7.2), which showed accepted rinsed residue (0.1440 %) after rinsing with water.</p> <p>Taking in to account the results of the pourability study and the statement of the applicant, double rinsing with tap water is recommended.</p>

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)

Comments of zRMS:	Ambient temperature study is currently ongoing, will be provided upon completion. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Extrapolation from HDPE to HDPE/EVOH, HDPE/PA and HDPE/F is acceptable.
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Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leak proofness, 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”. GLOB182F will be packed in the following HDPE, HDPE/PA, HDPE/F, HDPE/EVOH containers with volumes of 1, 5, 10, 15, 20, 200 or 1000 L. The specifications are presented in the tables below.

Table 4.1-1: Packaging information for 1 litre 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 4.1-2: Packaging information for 5 litre container

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

Table 4.1-3: Packaging information for 10 litre container

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

Table 4.1-4: Packaging information for 15 litre container

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 245 mm width x 294 mm length x 311 mm height
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 20 litre container

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

Table 4.1-6: Packaging information for 200 litre drum

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	cylindrical / approx. 580 mm diameter x 965 mm
Opening:	53 and 57 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 1000 litre container

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	L x W x H: approx. 1200 x 1000 x 1160 mm
Opening:	150 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Suitability of the packaging and closures:

The packaging material is standardly used for water based plant protection products like flowable concentrates for seed treatment. The 2 weeks accelerated storage stability study at 54°C was conducted in commercial HDPE packaging and showed that the product and packaging are stable and thus that the packaging is suitable.

Resistance of the packaging materials to its content:

The 2 weeks accelerated storage stability study at 54 °C was conducted in commercial HDPE packaging and showed that the product is stable and thus that the packaging is suitable.

4.2 Procedures for Cleaning Application Equipment (KCP 4.2)

4.2.1 Procedures for cleaning application equipment and protective clothing

After use, clean the equipment thoroughly, rising it two to three times with clean water until the foam and all traces of product have been removed.

4.2.2 Effectiveness of the cleaning procedures

Formulations are designed to form emulsions, suspensions or solutions by mixing with water at all relevant temperatures. For GLOB182F, rinsings with water are considered to be sufficient as equipment washing procedure based on the results of the pourability test performed with GLOB182F (method CI-PAC MT 148.1, please refer to annex point KCP 2.8.7.2), which showed almost no acetone rinsed residue (0.0062 %) after rinsing with water. Please refer to the point 2.11/02.

4.3 Recommended methods and precautions (KCP 4.2)

Reference is made to the submitted safety data sheet for GLOB182F where all the required information can be found. A summary is given below.

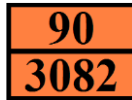
4.3.1 Procedures for storage

Keep only in the original container in a cool, well ventilated place away from: Direct sunlight. Keep container closed when not in use. Store in a well-ventilated place. Keep cool.

4.3.2 Transport

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

- UN number: 3082;
- UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (fludioxonil);
- Transport hazard class(es): 9;
- Packing group: III;
- Environmental hazards: Dangerous for the environment – Marine pollutant;
- Special precautions for user:
 - o **Overland transport**
 - Classification code (ADR): M6
 - Special provisions (ADR): 274, 335, 375, 601
 - Limited quantities (ADR): 5L
 - Excepted quantities (ADR): E1
 - Packing instructions (ADR): P001, IBC03, LP01, R001
 - Special packing provisions (ADR): PP1
 - Mixed packing provisions (ADR): MP19
 - Portable tank and bulk container instructions (ADR): T4
 - Portable tank and bulk container special provisions (ADR): TP1, TP29
 - Tank code (ADR): LGBV
 - Vehicle for tank carriage: AT
 - Transport category (ADR): 3
 - Special provisions for carriage - Packages (ADR): V12
 - Special provisions for carriage - Loading, unloading and handling (ADR): CV13
 - Hazard identification number (Kemler No.): 90



Orange plates:

Tunnel restriction code (ADR): -

EAC Code: •3Z

○ **Transport by sea**

Special provisions (IMDG): 274, 335, 969

Limited quantities (IMDG): 5 L

Excepted quantities (IMDG): E1

Packing instructions (IMDG): P001, LP001

Special packing provisions (IMDG): PP1

IBC packing instructions (IMDG): IBC03

Tank instructions (IMDG): T4

Tank special provisions (IMDG): TP2, TP29

EmS-No. (Fire): F-A

EmS-No. (Spillage): S-F

Stowage category (IMDG): A

○ **Air transport**

PCA Excepted quantities (IATA): E1

PCA Limited quantities (IATA): Y964

PCA limited quantity max net quantity (IATA): 30kgG

PCA packing instructions (IATA): 964

PCA max net quantity (IATA): 450L

CAO packing instructions (IATA): 964

CAO max net quantity (IATA): 450L

Special provisions (IATA): A97, A158, A197

ERG code (IATA): 9L

○ **Inland waterway transport**

Classification code (ADN): M6

Special provisions (ADN): 274, 335, 375, 601

Limited quantities (ADN): 5 L

Excepted quantities (ADN): E1

Carriage permitted (ADN): T

Equipment required (ADN): PP

Number of blue cones/lights (ADN): 0

○ **Rail transport**

Classification code (RID): M6

Special provisions (RID): 274, 335, 375, 601

Limited quantities (RID): 5L

Excepted quantities (RID): E1

Packing instructions (RID): P001, IBC03, LP01, R001

Special packing provisions (RID): PP1

Mixed packing provisions (RID): MP19

Portable tank and bulk container instructions (RID): T4

Portable tank and bulk container special provisions (RID): TP1, TP29

Tank codes for RID tanks (RID): LGBV

Transport category (RID): 3

Special provisions for carriage – Packages (RID): W12

Special provisions for carriage - Loading, unloading and handling (RID): CW13, CW31

Colis express (express parcels) (RID): CE8

Hazard identification number (RID): 90

- Transport in bulk: Not applicable.

4.3.3 Firefighting measures

- Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray. Sand;
- Special hazards arising from the substance or mixture: Toxic fumes may be released;
- Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment;
- Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection. 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;
- Personal protective equipment: Avoid all unnecessary exposure.
- Hand protection: Wear protective gloves;
- Eye protection: Chemical goggles or safety glasses. Safety glasses;
- Skin and body protection: Wear suitable protective clothing;
- Respiratory protection: Wear appropriate mask;
- 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 GLOB182F where all the required information can be found. A summary is given below.

4.4.1 Accidental release measures

Ventilate spillage area. Evacuate unnecessary personnel. Avoid contact with skin and eyes. Do not attempt to take action without suitable protective equipment. Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection". Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment. Take up liquid spill into absorbent material. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials. Dispose of materials or solid residues at an authorized site.

4.4.2 First aid measures

- 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: Remove person to fresh air and keep comfortable for breathing. Allow affected person to breathe fresh air. 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. Wash skin with plenty of water;
- First-aid measures after eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately;
- First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a poison center or a doctor if you feel unwell;
- Treat symptomatically.

4.5 Procedures for destruction and neutralisation (KCP 4.5)

Take up liquid spill into absorbent material. Soak up spills with inert solids, such as clay or diatomaceous

earth as soon as possible. Collect spillage. Store away from other materials. 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.

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- 2.3.1- 2.3.3- 2.4.1- 2.4.2- 2.5.1- 2.5.2- 2.6.1- 2.7.1- 2.7.4- 2.8.2- 2.8.3.1- 2.8.5.1.2- 2.8.7.2	Pomeroy, D.	2020a	Determination of Storage Stability and Shelf Life Specification Data for a Flowable Concentrate for Seed Treatment FS Formulation Containing Fludioxonil Stored at 54°C±2°C for 2 weeks, in Compliance with Good Laboratory Practice. Laboratory: David Norris Analytical Laboratories Ltd. Study number: DNA5607 GLP Unpublished	N	Globachem NV
KCP 2.2.1- 2.2.2 (filled in Part C)	Pomeroy, D.	2020b	Theoretical certificate of explosive and oxidizing properties for a formulation containing fludioxonil. Laboratory: David Norris Analytical Laboratories Ltd. Not GLP Unpublished	N	Globachem NV
KCP 2.10.1- 2.10.2	De Vos P.	2021a	Fludioxonil 100 FS. Adhesion to and distribution on treated maize and sunflower seeds. Laboratory: CRA-W – Centre wallon de Recherches agronomiques Study number: 25152 GLP Unpublished	N	Globachem NV
KCP 2.11/01	De Vos P.	2021b	Fludioxonil 100 FS. Residues in dust of on treated maize and sunflower seeds. Laboratory: CRA-W – Centre wallon de Recherches agronomiques Study number: 25155 GLP Unpublished	N	Globachem NV
KCP 2.11/02	Daniel Fernández Fuego	2021	Statement: Description of the effectiveness of the washing procedure for GLOB182F. Not GLP	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
			Unpublished		

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
-	-	-	-	-	-

List of data submitted by the applicant and not relied on

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

List of data relied on and not submitted by the applicant but necessary for evaluation

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

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

A 2.1 Fludioxonil

Not applicable.