

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: GLOB2011I

Product name(s): SANKARI

Chemical active substance:

Pelargonic acid, 650 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: 31/07/2023

RMS Assessment: 15/01/2024

After commenting period: 05/05/2024

Update list studies: 28/05/2024

Version history

When	What
January 2024	First zRMS PL evaluation.
May 2024	After commenting period
May 2024	Update list studies

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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. It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Globachem N.V.
Address: Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden

Contact: Geoffrey Wyns
Telephone number: +32 11 78 57 17
Fax: +32 11 68 15 65

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

1.2.1 Producer(s) of the preparation

Name: Globachem N.V.
Address: Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden

Contact: Koen Quaghebeur
Telephone number: +32 11 78 57 17
Fax number: +32 11 68 15 65
E-mail: koen.quaghebeur@globachem.com

Location of the manufacturing site

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 Pelargonic acid

Pelargonic acid min. 980 g/kg

Impurities of toxicological/ecotoxicological relevance (according to EFSA 2021):

None listed in EFSA Journal 2013;11(1):3023

Cross reference is made to Part C for further information.

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

Trade name: SANKARI

Company code number: GLOB2011I

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

1.4.1 Composition of the plant protection product (KCP 1.4.1)

The formulation GLOB2011I was not the representative formulation.

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)	Technical content** (%w/w)
Pelargonic acid	650	625-675	663.3	72.8

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

** Based on the density of the formulation = 0.9109 g/mL (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L)
None listed in EFSA Journal 2013;11(1):3023	-

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

Table 1.4-3: Information on pelargonic acid

Type	Name/Code Number	
ISO common name	Pelargonic acid	
IUPAC chemical name	Nonanoic acid	
CA chemical name	Nonanoic acid	
CAS No.	112-05-0	
EC No.	2039312	
CIPAC No.	888	

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

CONFIDENTIAL information is provided separately (Part C).

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

Type: Emulsifiable concentrate

[Code: EC]

1.6 Function (KCP 1.6)

Insecticide

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 free-flowing transparent clear yellow liquid, with an oily type odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 360 °C. In aqueous solution, it has a pH value around 3.27 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, neither the active ingredient content nor the technical properties were changed. The stability data (accelerated storage for 14 days at 54°C) indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE-PA*, *HDPE-F* and *HDPE-EVOH*. Its technical characteristics are acceptable for an *emulsifiable concentrate* formulation.

The intended concentration of use is 0.333% to 1.5%.

zRMS comments

The proposed by applicant shelf life of at least 2 years at ambient temperature is based on the results of accelerated storage test performed according to CIPAC MT 46.4 – 2 weeks test at 54°C. Data from real time storage tests at ambient temperature are additionally required. The ambient temperature shelf life study (2 and 3 years shelf life study) is ongoing. When the study is completed the data should be submitted to support the proposed by applicant shelf-life of the preparation (2 years).

The stability data (accelerated storage for 14 days at 54°C) indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE-PA*, *HDPE-F* and *HDPE-EVOH*.

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

The neat pH < 2 triggers a H314 classification.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Hazard statement:

H314: Causes severe skin burns and eye damage

Precautionary Statement Prevention:

P260: Do not breathe dust/fume/gas/mist/ vapours/spray.

P264: Wash hands, forearms and face thoroughly after handling.

P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

Precautionary Statement Response:

P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P363: Wash contaminated clothing before reuse.

P304 + P340: If INHALED: Remove person to fresh air and keep comfortable for breathing.

P310: Immediately call a POISON CENTER or doctor.

P321: Specific treatment (see supplemental first aid instruction on this label).

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Precautionary Statement Storage:

P405: Store locked up.

Precautionary Statement Disposal:

P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Compliance with FAO specifications:

The product GLOB2011I complies with FAO specifications.

Formulation used for tests

The product GLOB2011I used in the physico-chemical tests has the same composition as the one cited in Part C.

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	GLOB2011I, Pelargonic acid 650 g/L EC	Transparent clear yellow liquid, free flowing, with no signs of separation and with an oily type odour.	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable
Explosive properties (KCP 2.2.1)	Theoretical expert statement	GLOB2011I, Pelargonic acid 650 g/L EC	No explosive properties	N	Pomeroy D., 2023b Study No: DNA7128	Acceptable Neither the active substances nor the co-formulants of product GLOB2011I are considered as explosives. Therefore, the product GLOB2011I is considered not to be explosive.
Oxidizing properties (KCP 2.2.2)	Theoretical expert statement	GLOB2011I, Pelargonic acid 650 g/L EC	No oxidizing properties	N	Pomeroy D., 2023b Study No: DNA7128	Acceptable Neither the active substances nor the co-formulants of product GLOB2011I are considered as oxidising. Therefore, the product GLOB2011I is considered not to be oxidising.
Flash point (KCP 2.3.1)	EEC A9	GLOB2011I, Pelargonic	Flashed at 132°C and considered not highly flammable.	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		acid 650 g/L EC				The observed flash point above the CLP classification criteria. The product is not classified as flammable.
Flammability (KCP 2.3.2)	Test not required for liquids.					Acceptable
Self-heating (KCP 2.3.3)	EEC A15	GLOB2011I, Pelargonic acid 650 g/L EC	Auto-ignited at 360°C	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191, CIPAC MT 75.3	GLOB2011I, Pelargonic acid 650 g/L EC	Acidity: 22.706% m/m as sulfuric acid pH of neat formulation: 1.80 at 20°C	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable The acidity should be tested because preparation has pH < 4 (for neat formulation). The test expresses free acidity calculated as % H ₂ SO ₄ .
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB2011I, Pelargonic acid 650 g/L EC	3.27 at 20°C (diluted in deionised water)	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable
Viscosity (KCP 2.5.1)	OECD 114	GLOB2011I, Pelargonic acid 650 g/L EC	Dynamic viscosity at 20°C: 13.24 ± 0.771 mPa.s Kinematic viscosity at 20°C: 0.1455cm ² /s Dynamic viscosity at 40°C: 7.80 ± 0.260 mPa.s Kinematic viscosity at 40°C: 0.0864cm ² /s	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable Using a Brookfield DVII+ Viscometer, the spindle was submerged into the sample at equilibrated

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								temperature and spun at various speeds to give a minimum and maximum viscosity reading at 20°C and 40°C. The product is Newtonian liquid.
Surface tension (KCP 2.5.2)	EEC A5	GLOB2011I, Pelargonic acid 650 g/L EC	At 20°C: 28.52 ± 0.20 mN/m At 25°C: 27.78 ± 0.25 mN/m			Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable The surface tension was determined at the highest in use concentration at 20°C and 25°C. The surface tension was below 60 mN/m, the product is surface active.
Relative density (KCP 2.6.1)	EEC A3	GLOB2011I, Pelargonic acid 650 g/L EC	At 20°C: 0.9098 g/mL At 40°C: 0.9022 g/mL			Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable
Bulk density (KCP 2.6.2)	Test not required for liquids.							Acceptable
Storage Stability after 14 days at 54° C (KCP 2.7.1)	-	GLOB2011I, Pelargonic acid 650 g/L EC		Before storage	After storage	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable GLOB2011I was determined to be chemically and physically stable in HDPE-PA after two weeks of storage at
			Appearance (visual inspection)	Transparent clear yellow liquid, free flowing, with no signs of separation and with an oily type odour.	The sample itself became a slightly darker yellow liquid, remaining transparent and clear, which remained free flowing with no signs of separation. The sam-			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
					ple retained an oily type odour. The overall sample appearance remained unchanged post accelerated storage at 54°C±2°C for 2 weeks			<p>54°C. The sample of GLOB2011I became a slightly darker yellow liquid, remaining transparent and clear with no signs of separation into oil cream, sedimentation, claying or suspended solids after two weeks storage at 54°C compared to the pre storage sample. The overall sample appearance remained unchanged after two weeks storage at 54°C.</p> <p>The sample of GLOB2011I was stored in HDPE-PA 1-Litre tall-form bottle. The sample packaging remained unchanged after two weeks storage at 54°C (The bottle showed no signs of leaks or panneling and no sign of visual seepage). The bottle weights did not change (relative to time zero</p>
			Stability of packaging	The sample arrived with no signs of leaks or panelling and no signs of visual seepage.	The sample packaging for the sample remained unchanged Post Accelerated storage at 54°C±2°C for 2 weeks.			
			Pelargonic acid content	649.6g/L	636.7g/L			
			pH neat (CIPAC MT 75.3)	1.80 (20°C)	1.86 (20°C)			
			pH 1% dilution (CIPAC MT 75.3)	3.27 (20°C)	3.28 (20°C)			
			Acidity at 20 ± 0.5°C (CIPAC MT 191)	22.706% m/m as sulfuric acid	22.109% m/m as sulfuric acid			
			Emulsifiability (CIPAC MT 36.3) at high and low application rate (2% and 0.1% w/w dilutions, respectively)	<p>For the high application rate in CIPAC Water A, after 24 hours and 30 minutes, the Formulation remained a white emulsion with 3mL of cream and no signs of separation into oil, sediment or crystals.</p> <p>For the high application rate in CIPAC</p>	<p>For the high application rate in CIPAC Water A, after 24 hours and 30 minutes, the Formulation remained a white emulsion with 2mL of cream and no signs of separation into oil, sediment or crystals.</p> <p>For the high application rate in CIPAC Water D, after 24</p>			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
			<p>Water D, after 24 hours and 30 minutes, the Formulation remained a white emulsion with a thin layer of cream and no signs of separation into oil, sediment or crystals.</p> <p>For the low application rate in both CIPAC Water A and CIPAC Water D, after 24 hours and 30 minutes, the Formulation remained a cloudy emulsion with no signs of separation into oil, cream, sediment or crystals.</p>	<p>hours and 30 minutes, the Formulation remained a white emulsion with a thin layer of cream and no signs of separation into oil, sediment or crystals.</p> <p>For the low application rate in both CIPAC Water A and CIPAC Water D, after 24 hours and 30 minutes, the Formulation remained a cloudy emulsion with no signs of separation into oil, cream, sediment or crystals.</p>			<p>weight):</p> <ul style="list-style-type: none"> - 1003.36 g prior to storage, - 1003. 19 g post accelerated storage. <p>The analytical method which was used to determined active ingredient (Pelargonic acid) content was validated in GLP laboratory (in-house methodology method DNA7168).</p> <p>The content of active ingredient was determined by GC-FID method.</p> <p>The concentration of Pelargonic acid:</p> <p>Time zero: 649.6 g/L.</p> <p>The concentration of Pelargonic acid after two weeks storage at 54°C temperature in HDPE-PA 1-Litre tall-form bottle: 636.7 g/L equivalent to 97.95% of the declared content.</p> <p>It is recognised that a loss of up to 5 % of the active substance is</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>unlikely to adversely affect the safety or efficacy of the preparation. No significant change in content of the active substance - Pelargonic acid was observed following 2 weeks storage at 54°C in HDPE-PA container.</p> <p>Emulsifiability: results are acceptable: no signs of separation into oil, sediment or crystals at high and low application rate (2% and 0.1% w/w dilutions, respectively).</p>
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not relevant.					Acceptable
Minimum content after heat stability testing (KCP 2.7.3)	In house validated method	GLOB2011I, Pelargonic acid 650 g/L EC	Before storage: 649.6 g/L After storage: 636.7 g/L	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable The analytical method which was used to determined active ingredient (Pelargonic acid)

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>content was validated in GLP laboratory (in-house methodology method DNA7168).</p> <p>The content of active ingredient was determined by GC-FID method.</p> <p>The concentration of Pelargonic acid: Time zero: 649.6 g/L.</p> <p>The concentration of Pelargonic acid after two weeks storage at 54°C temperature in HDPE-PA 1-Litre tall-form bottle: 636.7 g/L equivalent to 97.95% of the declared content.</p> <p>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>No significant change in content of the active substance - Pelargonic acid was observed following 2 weeks storage at 54°C in HDPE-PA</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments		
						container.		
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	GLOB2011I, Pelargonic acid 650 g/L EC	The sample appearance remained unchanged post low temperature storage at 0°C±2oC for 7 days and 24 hours at room temperature.		Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable The product is stable at low temperatures.	
				Before storage				After storage
			Emulsifiability (CIPAC MT 36.3) at high and low application rate (2% and 0.1% w/w dilutions, respectively)	For the high application rate in CIPAC Water A, after 24 hours and 30 minutes, the Formulation remained a white emulsion with 3mL of cream and no signs of separation into oil, sediment or crystals.				For the high application rate in CIPAC Water A, after 24 hours and 30 minutes, the Formulation remained a white emulsion with 2mL of cream and no signs of separation into oil, sediment or crystals.
				For the high application rate in CIPAC Water D, after 24 hours and 30 minutes, the Formulation remained a white emulsion with a thin layer of cream and no signs of separation into oil, sediment or crystals.				For the high application rate in CIPAC Water D, after 24 hours and 30 minutes, the Formulation remained a white emulsion with a thin layer of cream and no signs of separation into oil, sediment or crystals.
			For the low application rate in both CIPAC Water A and CIPAC Water D, after 24 hours and 30 minutes, the Formulation remained a cloudy	For the low application rate in both CIPAC Water A and CIPAC Water D, after 24 hours and 30 minutes, the Formulation remained a cloudy emulsion with				

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				emulsion with no signs of separation into oil, cream, sediment or crystals.	no signs of separation into oil, cream, sediment or crystals.			
Ambient temperature shelf life (KCP 2.7.5)	-	GLOB2011I, Pelargonic acid 650 g/L EC	2 and 3 years ambient temperature shelf life studies are on-going. Final reports are expected for May 2025 (study DNA7166) and for May 2026 (study DNA7167).			-	-	Data gap Missing storage stability study at ambient temperature. 2 and 3 years ambient temperature shelf life studies are on-going. 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							
Wettability (KCP 2.8.1)	Not required for liquids.							Acceptable
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB2011I, Pelargonic acid 650 g/L EC	At the low application rate (1.5L GLOB2011I in 1500L water, 0.1% v/v): After 1 minute: 0.0mL After 12 minutes: 0.0mL At the high application rate (2L GLOB2011I in 100L water, 2% v/v): After 1 minute: 5.0mL After 12 minutes: 5.0mL			Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable 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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						the preparation. Acceptable limits : Max 60 mL foam after 1 minute. The above mentioned criteria were met for low application rate and for high application rate.
Suspensibility (KCP 2.8.3.1)	Not required for an EC formulation.					Acceptable
Spontaneity of dispersion (KCP 2.8.3.2)	Not required for an EC formulation.					Acceptable
Dispersion stability (KCP 2.8.3.3)	Not required for an EC formulation.					Acceptable
Degree of dissolution and dilution stability (KCP 2.8.4)	Not required for an EC formulation.					Acceptable
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not required for an EC formulation.					Acceptable
Wet sieve test (KCP 2.8.5.1.2)	Not required for an EC formulation.					Acceptable
Dust content (KCP 2.8.5.2.1)	Not required for liquids.					Acceptable
Particle size of dust (KCP 2.8.5.2.2)	Not required for liquids.					Acceptable
Attrition	Not required for an EC formulation.					Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.3)						
Hardness and integrity (KCP 2.8.5.4)	Not required for an EC formulation.					Acceptable
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	GLOB2011I, Pelargonic acid 650 g/L EC	<p>For the high application rate (2% w/w dilution) in CIPAC Water A, after 24 hours and 30 minutes, the Formulation remained a white emulsion with 3mL of cream and no signs of separation into oil, sediment or crystals.</p> <p>For the high application rate (2% w/w dilution) in CIPAC Water D, after 24 hours and 30 minutes, the Formulation remained a white emulsion with a thin layer of cream and no signs of separation into oil, sediment or crystals.</p> <p>For the low application rate (0.1% w/w dilution) in both CIPAC Water A and CIPAC Water D, after 24 hours and 30 minutes, the Formulation remained a cloudy emulsion with no signs of separation into oil, cream, sediment or crystals.</p>	Y	Pomeroy D., 2023a Study No: DNA7165	<p>Acceptable</p> <p>No signs of separation into oil, sediment or crystals at high and low application rate (2% and 0.1% w/w dilutions, respectively).</p>
Emulsion stability (KCP 2.8.6.2)	Refer to 2.8.6.1.					Acceptable
Re-emulsifiability (KCP 2.8.6.3)	Refer to 2.8.6.1.					Acceptable
Flowability (KCP 2.8.7.1)	Not required for an EC formulation.					Acceptable
Pourability (KCP 2.8.7.2)	Not required for an EC formulation.					Acceptable
Dustability following accelerated storage (KCP 2.8.7.3)	Not required for liquids.					Acceptable
Physical compatibility of tank	Not relevant.					Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
mixes (KCP 2.9.1)						
Chemical compatibility of tank mixes (KCP 2.9.2)	Not relevant.					Acceptable
Adhesion to seeds (KCP 2.10.1)	Not applicable as GLOB2011I is not used for seed treatment.					Acceptable
Distribution to seed (KCP 2.10.2)	Not applicable as GLOB2011I is not used for seed treatment.					Acceptable
Other/special studies (KCP 2.11) Effectiveness of cleaning	David Norris In House Methodology	GLOB2011I, Pelargonic acid 650 g/L EC	0.00376% Residue	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable A mean effectiveness of cleaning result of 0.00376% residue for Pelargonic Acid using three water rinses.
Other/special studies (KCP 2.11) Stability of packaging	Visual assessment and weighing of packagings.	GLOB2011I, Pelargonic acid 650 g/L EC	The sample arrived with no signs of leaks or panelling and no signs of visual seepage.	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable
Other/special studies (KCP 2.11) Seepage data in HDPE-F and HDPE-EVOH	Visual assessment and weighing of packagings.	GLOB2011I, Pelargonic acid 650 g/L EC	The sample arrived with no signs of leaks or panelling and no signs of visual seepage.	Y	Pomeroy D., 2023a Study No: DNA7165	Acceptable

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

Based on the accelerated storage study (14 days at 54°C) in HDPE-PA and seepage data in HDPE-F and HDPE-EVOH all packs, listed below, are accepted (HDPE-PA, HDPE-F and HDPE-EVOH).

Table 4.1-1: Packaging information for 100 mL bottle

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
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/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
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/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
Shape/size:	cylindrical / approx. 60 mm diameter x 125 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded

Type	Description
UN/ADR	compliant

Table 4.1-4: Packaging information for 500 mL bottle

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
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 600 mL bottle

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
Shape/size:	cylindrical / approx. 69 mm diameter x 204 mm
Opening:	39 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 1 L bottle

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
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 4.1-7: Packaging information for 2 L container

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F

Type	Description
	(Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
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 4.1-8: Packaging information for 3 L container

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
Shape/size:	rectangular / approx. 160 mm width x 262 mm length x 115 mm height
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information for 5 L container

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
Shape/size:	rectangular / approx. 140 mm width x 190 mm length x 313 mm height
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 10 L container

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
Shape/size:	rectangular / approx. 179 mm width x 240 mm length x 375 mm height
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal

Type	Description
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information for 15 L container

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
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 4.1-12: Packaging information for 20 L container

Type	Description
Material:	HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
Shape/size:	rectangular / approx. 292 mm width x 263 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 tank cleaning was assessed in the study to determine the physico-chemical properties of the product (Pomeroy D., 2023a (Study No: DNA7165)).

It was concluded that the formulation GLOB2011I (using pre-storage sample) has a mean effectiveness of cleaning result of 0.00376% residue for pelargonic acid using three Water rinses.

4.3 Recommended methods and precautions (KCP 4.2)

Reference is made to the submitted SDS (filed as KCP 4) where all the required and detailed 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

Not regulated in accordance with ADN / ADR / IATA / IMDG / RID.

4.3.3 Firefighting measures

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

Hazardous decomposition products in case of fire: 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

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

4.3.5 Environmental precautions

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.

4.4.1 Accidental release measures

For non-emergency personnel: Ventilate spillage area. Avoid contact with skin, eyes and clothing.

For emergency responders: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

For containment: collect spillage.

Methods for cleaning up: take up liquid spill into absorbent material.

Other information: dispose of materials or solid residues at an authorized site.

4.4.2 First aid measures

General: Call a poison center or a doctor if you feel unwell.

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. Take off contaminated clothing.
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.

4.5 Procedures for destruction and neutralisation (KCP 4.5)

Please refer to point 4.4.1.

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- 2.3.1- 2.4.1- 2.4.2- 2.5.1- 2.5.2- 2.6.1- 2.7.1- 2.7.3- 2.7.4- 2.8.2- 2.8.6.1- 2.8.6.2- 2.8.6.3- 2.11.	Pomeroy, D.	2023a	Determination of Storage Stability and Shelf Life Specification Data for GLOB2011I stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice Study number: DNA7165 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem nv
KCP 2.2.1- 2.2.2 (filed in Part C)	Pomeroy, D.	2023b	Theoretical certificate of explosive and oxidising properties for GLOB2011I Study number: DNA7128 David Norris Analytical Laboratories Ltd. Non 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 4	Anonymous	2023	Sankari/GLOB2011I Safety Data Sheet - Globachem NV Non 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
None					

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	Y/N	Owner

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
			Source GLP/non GLP/GEP/non GEP Published/Unpublished		

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

A 2.1 Pelargonic acid

None