

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: GLOB1913H

Product name: Roxy XL

Chemical active substances:

Prosulfocarb, 900 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: September 2022

MS Finalisation date: 04/08/2023

After commenting period: 16/11/2023

Version history

When	What
September 2022	Initial submission by the applicant for approval of new product.
November 2023	After commenting period

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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 (real time storage test). It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level.
- **data gap 2**
- **data gap 3**

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

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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 Prosulfocarb

Prosulfocarb min. 970 g/kg

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

Trade name: Roxy XL
Company code number: GLOB1913H

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 GLOB1913H 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)
Prosulfocarb	900	875 - 925	927.8	89.4

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

** Based on the density of the formulation = 1.0375 g/mL

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

Table 1.4-2: Information on Prosulfocarb

Type	Name/Code Number
ISO common name	Prosulfocarb
CAS No.	52888-80-9
EC No.	401-730-6
CIPAC No.	539

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)

Herbicide

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 golden yellow coloured liquid, with a sweet odour. It is not explosive, has no oxidising properties. The product is not highly flammable. It has a flash point of 136.5°C. In aqueous solution, it has a pH value around 6.68 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 indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE*, *HDPE-F*, *HDPE-EVOH* or *HDPE/PA*. Its technical characteristics are acceptable for an *emulsifiable concentrate* formulation. The intended concentration of use is 1.2% to 2.8%.

zRMS comments

The proposed by applicant shelf life of at least 2 years 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 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).

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

No implications for labelling from physical chemical part.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None

Compliance with FAO specifications:

The product GLOB1913H 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.

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	GLOB1913H (batch: 200701/01)	The sample was a uniform golden yellow coloured liquid. The sample allowed light to pass through and was free flowing. There were no signs of separation into oil, cream, sediment or suspended solids. There were no signs of claying. The sample had a sweet odour.	Y	Sowle J., 2020a	Accepted
Explosive properties (KCP 2.2.1)	Theoretical certificate	-	Not explosive	N	Sowle J., 2020b	Accepted Theoretical assessment based on the information about ingredients of GLOB1913H – the active substance and co-formulants are not classified as explosive according to CLP Regulation.
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	-	Not oxidizing	N	Sowle J., 2020b	Accepted Theoretical assessment based on the information about ingredients of GLOB1913H – the active substance and co-formulants are not classified as oxidising according to CLP Regulation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flash point (KCP 2.3.1)	EEC A9	GLOB1913H (batch: 200701/01)	The sample flashed at 136.5°C and is not considered highly flammable	Y	Sowle J., 2020a	Accepted The product is not classified as flammable according to CLP Regulation (flash point obtained for GLOB1913H is higher than 60°C).
Flammability (KCP 2.3.2)	Not required for liquids.					Accepted
Self-heating (KCP 2.3.3)	EEC A15	GLOB1913H (batch: 200701/01)	The sample auto-ignited at 360°C	Y	Sowle J., 2020a	Accepted According to A15 the self-ignition temperature for liquids and gases is the lowest temperature at which the preparation will ignite when mixed with air under defined conditions. The sample auto-ignited at 360°C.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191 CIPAC MT 75.3	GLOB1913H (batch: 200701/01)	Not required as the pH was found to be between 4 and 10 pH of neat formulation: 6.20 at 20.0°C	Y	Sowle J., 2020a	Accepted The acidity/alkalinity of the sample was not performed as the pH was found to be between 4 and 10.
pH of a 1% aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	GLOB1913H (batch: 200701/01)	6.68 at 20.0°C	Y	Sowle J., 2020a	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments												
(KCP 2.4.2)																		
Viscosity (KCP 2.5.1)	OECD 114	GLOB1913H (batch: 200701/01)	The sample is a near Newtonian liquid with a Dynamic Viscosity of 41.47 mPa.s and Kinematic Viscosity of 0.3997 cm ² /s at 20.0°C. The sample is a near Newtonian liquid with a Dynamic Viscosity of 27.67 mPa.s and Kinematic Viscosity of 0.2688 cm ² /s at 40.0°C.	Y	Sowle J., 2020a	Accepted The viscosity was determined at four shear rates. Tests were conducted at 20°C and 40°C.												
Surface tension (KCP 2.5.2)	EEC A5	GLOB1913H (batch: 200701/01)	At 20°C: 35.35 mN/m SD = 0.277 mN/m At 25°C: 34.94 mN/m SD = 0.068 mN/m	Y	Sowle J., 2020a	Accepted The surface tension was determined at the highest in use concentration (4.4 L of formulation in water) at 20°C and 25°C.												
Relative density (KCP 2.6.1)	EEC A3	GLOB1913H (batch: 200701/01)	At 20°C: 1.0375 g/mL At 40°C: 1.0295 g/mL	Y	Sowle J., 2020a	Accepted Relative wensity was determined in g/L at 20°C and at 40°C.												
Bulk density (KCP 2.6.2)	Not required for liquids.					Accepted												
Storage Stability after 14 days at 54° C (KCP 2.7.1)		GLOB1913H (batch: 200701/01)	<table><tr><td></td><td>Before storage</td><td>After storage</td></tr><tr><td>Appearance</td><td colspan="2">The sample was a uniform golden yellow coloured liquid. The sample allowed light to pass through and was free flowing. There were no signs of separation into oil, cream, sediment or suspended solids. There were no signs of claying. The sample had a sweet odour.</td></tr><tr><td>Prosulfocarb</td><td>886.1 g/L</td><td>892.9 g/L</td></tr><tr><td>pH neat</td><td>6.20</td><td>6.47</td></tr></table>		Before storage	After storage	Appearance	The sample was a uniform golden yellow coloured liquid. The sample allowed light to pass through and was free flowing. There were no signs of separation into oil, cream, sediment or suspended solids. There were no signs of claying. The sample had a sweet odour.		Prosulfocarb	886.1 g/L	892.9 g/L	pH neat	6.20	6.47	Y	Sowle J., 2020a	Accepted The sample appearance remained unchanged post accelerated storage for two weeks at 54°C±2°C compare to the pre-storage sample. There we no signs of seperation into oil,
	Before storage	After storage																
Appearance	The sample was a uniform golden yellow coloured liquid. The sample allowed light to pass through and was free flowing. There were no signs of separation into oil, cream, sediment or suspended solids. There were no signs of claying. The sample had a sweet odour.																	
Prosulfocarb	886.1 g/L	892.9 g/L																
pH neat	6.20	6.47																

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			(CIPAC MT 75.3)					cream, sediment or suspended solids.
			pH 1% dilution (CIPAC MT 75.3)	6.68	6.52			The analytical method which was used to determined active ingredient
			Emulsifiability (CIPAC MT 36.3)	4.4L/100L water				(Prosulfocarb) content was validated in GLP laboratory (in-house methodology validated in study DNA5820.
				After 24 h and 30min: the sample formed a white emulsion with no signs of separation into oil, cream, sediment, clay- ing, suspended solids or crystals in both CIPAC Water A and CIPAC Water D	After 24 h and 30min: the sample formed a white emulsion with no signs of separation into oil, cream, sediment, clay- ing, suspended solids or crystals in both CIPAC Water A and CIPAC Water D			Analytical method used for analysing a.s. in the PPP was validated in accordance with SANCO/3030/99 rev.5). The content of active ingredient was determined by HPLC-DAD.
				3.5L/400L water				The concentration of Prosulfocarb - pre storage sample was 886.1 g/L and was equal to 98.46% of declared content.
				After 24 h and 30min: the sample formed a white emulsion with no signs of separation into oil, cream, sediment, clay- ing, suspended solids or crystals in both CIPAC Water A and CIPAC Water D	After 24 h and 30min: the sample formed a white emulsion with no signs of separation into oil, cream, sediment, clay- ing, suspended solids or crystals in both CIPAC Water A and CIPAC Water D			Concentrations of the a.s. pre storage are in the FAO/WHO tolerance.
								The concentration of Prosulfocarb after 2 weeks storage at temperature 54°C±2°C

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			No significant changes were observed.			<p>was 892.9 g/L and was equal to 99.21% of declared content. Concentrations of the a.s. after storage are in the FAO/WHO tolerance.</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>Based on the Emulsifiability test it can be concluded that preparation pre storage and post storage forms and maintains a stable emulsion in both CIPAC Water A and CIPAC Water D.</p> <p>Appearance and stability packaging of sample in HDPE-EVOH Bottle (1L tall form bottle): the sample packaging remained unchanged post accelerated storage for two weeks at 54°C±2°C. The bottle</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>showed no signs of leaks, vusual seepage or panelling. Weights - prior to storage: 1189.67 g - post accelerated storage: 1189.58 g</p> <p>Appearance and stability packaging of sample in HDPE-PA Bottle (1L tall form bottle): the sample packaging remained unchanged post accelerated storage for two weeks at 54°C±2°C. The bottle showed no signs of leaks, vusual seepage or panelling. Weights - prior to storage: 1136.33 g - post accelerated storage: 1136.30 g</p> <p>Appearance and stability packaging of sample in HDPE Bottle (1L tall form bottle): the sample packaging remained unchanged</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								post accelerated storage for two weeks at 54°C±2°C. The bottle showed no signs of leaks, vusual seepage or panelling. Weights - prior to storage: 1225.56 g - post accelerated storage: 1225.59 g
Stability after storage for other periods and/or temperatures (KCP 2.7.2)		GLOB1913H (batch: 200701/01)	Not required, GLOB1913H is stable after 14 days at 54°C. Nevertheless, a 3 year storage stability study at ambient temperature is ongoing.			Y	Sowle J., 2023	The ambient temperature 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).
Minimum content after heat stability testing (KCP 2.7.3)	In house method	GLOB1913H (batch: 200701/01)		Before storage	After storage	Y	Sowle J., 2020a	Accepted
			Prosulfocarb	886.1 g/L	892.9 g/L			
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	GLOB1913H (batch: 200701/01)		Before storage	After storage	Y	Sowle J., 2020a	Accepted The sample appearance remained unchanged post low temperature storage for 7 days at 0°C and 3 hours at room temperature (The sample remained a uniform golden yellow coloured liquid with no
			Emulsifiability (CIPAC MT 36.3)	4.4L/100L water				
				After 24 h and 30min: the sample formed a white emulsion with no signs of separation into oil, cream, sediment, clay-ing, suspended solids or crys-	After 24 h and 30min: the sample formed a white emulsion with no signs of separation into oil, cream, sediment, claying, suspended			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments									
			<table><tr><td></td><td>tals in both CIPAC Water A and CIPAC Water D</td><td>solids or crystals in both CIPAC Water A and CIPAC Water D</td></tr><tr><td></td><td colspan="2">3.5L/400L water</td></tr><tr><td></td><td>After 24 h and 30min the sample formed a white emulsion with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals in both CIPAC Water A and CIPAC Water D</td><td>After 24 h and 30min the sample formed a white emulsion with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals in both CIPAC Water A and CIPAC Water D</td></tr></table>				tals in both CIPAC Water A and CIPAC Water D	solids or crystals in both CIPAC Water A and CIPAC Water D		3.5L/400L water			After 24 h and 30min the sample formed a white emulsion with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals in both CIPAC Water A and CIPAC Water D	After 24 h and 30min the sample formed a white emulsion with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals in both CIPAC Water A and CIPAC Water D			signs of separation into oil, cream, sediment, claying, suspended solids or crystals). Emulsion stability was determined after storage of sample in low temperature. Based on the Emulsifiability test it can be concluded that preparation post storage at low temperature for seven days forms and maintains a stable emulsion in both CIPAC Water A and CIPAC Water D.
	tals in both CIPAC Water A and CIPAC Water D	solids or crystals in both CIPAC Water A and CIPAC Water D															
	3.5L/400L water																
	After 24 h and 30min the sample formed a white emulsion with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals in both CIPAC Water A and CIPAC Water D	After 24 h and 30min the sample formed a white emulsion with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals in both CIPAC Water A and CIPAC Water D															
			The sample remained unchanged post low temperature storage.														
Ambient temperature shelf life (KCP 2.7.5)		GLOB1913H (batch: 200701/01)	This study is ongoing.			Y	Sowle J., 2022	The ambient temperature 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). Real-time and ambient temperature testing is performed under									

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						‘normal conditions’, usually over a period of 2 years. The results produced give a more accurate description of the likely properties and do not require extrapolation. However, such tests require a prolonged testing period. These tests are also the most appropriate in producing information on the stability of the packaging for a product.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not required as GLOB1913H should be stable for at least 2 years at ambient temperature.					The ambient temperature 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).
Wettability (KCP 2.8.1)	Not required for liquids.					Accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB1913H (batch: 200701/01)	At the minimum application rate (3.5L/400L of water) After 1 minute: 7.0 mL After 12 minutes: 6.0 mL At the maximum application rate (4.4L/100L water)	Y	Sowle J., 2020a	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
			After 1 minute: 10.0 mL After 12 minutes: 8.0 mL			spray tank or other application equipment following dilution of the preparation. Acceptable limits: Max 60 mL foam after 1 minute. The above mentioned criteria was met for minimum application rate and maximum application rate.
Suspensibility (KCP 2.8.3.1)	Not required for an EC formulation.					Accepted
Spontaneity of dispersion (KCP 2.8.3.2)	Not required for an EC formulation.					Accepted
Dispersion stability (KCP 2.8.3.3)	Not required for an EC formulation.					Accepted
Degree of dissolution and dilution stability (KCP 2.8.4)	Not required for an EC formulation.					Accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not required for an EC formulation.					Accepted
Wet sieve test (KCP 2.8.5.1.2)	Not required for an EC formulation.					Accepted
Dust content (KCP 2.8.5.2.1)	Not required for liquids.					Accepted
Particle size of dust	Not required for liquids.					Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.2.2)						
Attrition (KCP 2.8.5.3)	Not required for liquids.					Accepted
Hardness and integrity (KCP 2.8.5.4)	Not required for liquids.					Accepted
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	GLOB1913H (batch: 200701/01)	For the high application rate (4.4 L in 100L) After 24 h and 30 min: the sample formed a white emulsion with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals in both CIPAC Water A and CIPAC Water D. For the low application rate (3.5 L in 400 L) After 24 h and 30 min: the sample formed a white emulsion with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals in both CIPAC Water A and CIPAC Water D.	Y	Sowle J., 2020a	Accepted Based on the Emulsifiability test it can be concluded that preparation pre storage and post storage forms and maintains a stable emulsion in both CIPAC Water A and CIPAC Water D.
Emulsion stability (KCP 2.8.6.2)	See KCP 2.8.6.1					Accepted See KCP 2.8.6.1
Re-emulsifiability (KCP 2.8.6.3)	See KCP 2.8.6.1					Accepted See KCP 2.8.6.1
Flowability (KCP 2.8.7.1)	Not required for an EC formulation.					Accepted
Pourability (KCP 2.8.7.2)	Not required for an EC formulation.					Accepted
Dustability following accelerated storage (KCP 2.8.7.3)	Not required for liquids.					Accepted
Physical compatibility of tank mixes	Not relevant: no tank mix on the label					Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.9.1)						
Chemical compatibility of tank mixes (KCP 2.9.2)	Not relevant: no tank mix on the label					Accepted
Adhesion to seeds (KCP 2.10.1)	Not applicable as GLOB1913H is not used for seed treatment.					Accepted
Distribution to seed (KCP 2.10.2)	Not applicable as GLOB1913H is not used for seed treatment.					Accepted
Other/special studies (KCP 2.11)	None					Accepted

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

zRMS comments

Based on the accelerated storage stability study in HDPE/ HDPE-EVOH/HDPE-PA pack, all packs, listed below, are accepted. In case of formulations like EC extrapolation from HDPE is allowed for other plastics (used as PPP packaging materials) and stability data generated for one of the materials can be used in support of any of the others.

Table 4.1-1: Packaging information for 100 mL bottle

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

Type	Description
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
UN/ADR	compliant

Table 4.1-4: Packaging information for 500 mL bottle

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

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
Shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 2 L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
Shape/size:	rectangular / approx. 106 mm width x 155 mm length x 189 mm height

Type	Description
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 3 L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
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 4.1-8: Packaging information for 5 L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
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 4.1-9: Packaging information for 10 L container

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

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

Table 4.1-10: Packaging information for 15 L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
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 4.1-11: Packaging information for 20 L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
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 cleaning procedures was assessed in the storage stability study of GLOB1913H (Sowle J., 2020a). The procedure is summarized below.

1. A 8 L garden sprayer is filled up to top with GLOB1913H and water at the concentration of 4.4 L/100L. The sprayer is shaken well.
2. The content is then sprayed using a normal spraying action to simulate that used in the field until the sprayer is empty.
3. 400 mL tap water is then poured into the sprayer. The sprayer is then shaken several times before spraying the contents to waste.
4. The step 3 is repeated twice so that the sprayer has been rinsed three times.
5. 100 mL methanol is added to the sprayer which is then agitated to collect any remaining residue. The collected residue is assayed by HPLD-DAD.

After three tank washes with 400 mL water 0.0123% prosulfocarb residue remained in the tank. This demonstrates that only a very limited amount of residue remains in the spray tank after cleaning.

zRMS comments

Accepted

Determination of the concentration of active ingredient – prosulfocarb – remaining in a garden sprayer following tank washing was performed by validated HPLC-DAD method (in-house methodology validated in study DNA5820).

4.3 Recommended methods and precautions (KCP 4.2)

4.3.1 Procedures for storage

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

4.3.2 Transport

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

4.3.3 Firefighting measures

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

4.3.4 Exposure control

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

4.3.5 Environmental precautions

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

4.4 Emergency measures (KCP 4.3)

4.4.1 Accidental release measures

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

4.4.2 First aid measures

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

4.5 Procedures for destruction and neutralisation (KCP 4.5)

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

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 2.1-2.8, KCP 4.2	Sowle J.	2020a	Determination of Storage Stability and Shelf Life Specification an Data for Emulsifiable Concentrate Formulation containing Prosulfocarb, stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice. DNA5818 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP 2.2.1 and 2.2.2 <i>Confidential – submitted in Part C.</i>	Sowle J.	2020b	Theoretical certificate of explosive and oxidizing properties for a formulation containing prosulfocarb. DNA5818 David Norris Analytical Laboratories Ltd. Not GLP Unpublished	N	Globachem NV
KCP 2.7.2	Sowle J.	2023	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Prosulfocarb, stored at ambient temperature for 3 Years, in Compliance with Good Laboratory Practice. DNA5863 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP 2.7.5	Sowle J.	2022	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Prosulfocarb, stored at ambient temperature for 2 Years, in Compliance with	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
			Good Laboratory Practice. DNA5819 David Norris Analytical Laboratories Ltd. GLP 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
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 Source GLP/non GLP/GEP/non GEP	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
			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 Prosulfocarb

None