

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: GLOB1912H

Product name: **Jura Max**

Chemical active substances:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: November 2021

Evaluation date: August 2022

MS Finalisation date: December 2022

Version history

When	What
November 2021	Initial submission by the applicant for approval of new product.
August 2022	Version evaluated by zRMS PL
December 2022	Corrected after zonal evaluation

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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:

- The two-year study at ambient temperature is ongoing. It has to be provided for the evaluation purpose in Poland when available.

• data gap =

• data gap =

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Globachem NV
Address: Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden
Belgium

Contact: xxx
Telephone number: xxx
Fax: xxx
E-mail: xxx

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

1.2.1 Producer(s) of the preparation

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

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

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

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

1.2.3.1 Prosulfocarb

Prosulfocarb

min. 970 g/kg

1.2.3.2 Diflufenican

Diflufenican min. 975 g/kg

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)

Trade name: Jura Max

Company code number: GLOB1912H

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 GLOB1912H 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	667	642 - 692	687.6	66.07
Diflufenican	14	11.9 - 16.2	14.1 14.4	1.40

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

** Based on the density of the formulation = 1.0097 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

Table 1.4-5: Information on diflufenican

Type	Name/Code Number
ISO common name	Diflufenican
CAS No.	83164-33-4
EC No.	-

Type	Name/Code Number
CIPAC No.	462

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 light-yellow liquid, with a solvent odour. It is not explosive, has no oxidising properties. The product is not highly flammable. It has a flash point of 66.0°C. In aqueous solution, it has a pH value around 6.84 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-F*, *HDPE-EVOH* or *HDPE/PA*. Its technical characteristics are acceptable for a *emulsifiable concentrate* formulation. The intended concentration of use is 1.0% to 2.0%.

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 GLOB1912H 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	GLOB1817H (batch: KS010420)	The sample was a yellow liquid. The sample was clear and free flowing. There were no signs of separation into oil, cream, sediment or suspended solids. There were no signs of claying. The sample had an aromatic type odour similar to Solvesso.	Y	Sowle J., 2020a	Accepted
Explosive properties (KCP 2.2.1)	Theoretical certificate	-	Not explosive	N	Sowle J., 2020b	Accepted
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	-	Not oxidizing	N	Sowle J., 2020b	Accepted
Flash point (KCP 2.3.1)	EEC A9	GLOB1912H (batch: PSC0100004)	The sample flashed at 66.0 °C	Y	Sowle J., 2020a	Accepted
Flammability (KCP 2.3.2)	Not required for liquids.					
Self-heating (KCP 2.3.3)	EEC A15	GLOB1912H (batch: PSC0100004)	Not highly flammable No auto-ignition below 400 °C.	Y	Sowle J., 2020a	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191 CIPAC MT 75.3	GLOB1912H (batch: PSC0100004)	Not required as the pH was found to be between 4 and 10 pH of neat formulation: 6.50 at 20.0°C	Y	Sowle J., 2020a	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB1912H (batch: PSC0100004)	6.84 at 20.0°C	Y	Sowle J., 2020a	Accepted
Viscosity (KCP 2.5.1)	OECD 114	GLOB1912H (batch: PSC0100004)	The sample is a Newtonian liquid with a Dynamic Viscosity of 53.3 mPa.s and Kinematic Viscosity of 0.528 cm ² /s at 20.0°C.	Y	Sowle J., 2020a	Accepted Since the formulation

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
			The sample is a Newtonian liquid with a Dynamic Viscosity of 38.1 mPa.s and Kinematic Viscosity of 0.380 cm ² /s at 40.0°C.			contains more than 10% of the co-formulant classified as Asp. Tox cat.1 (with H304 phrase assigned), a kinematic viscosity parameter comes into consideration. The kinematic viscosity at 40.0°C is 38 mm ² /s for the PPP and it is slightly above the trigger value of 20.5 mm ² /s. So, the PPP doesn't meet all the criteria for Asp. Tox cat.1 assigning and cannot be classified under CLP.						
Surface tension (KCP 2.5.2)	EEC A5	GLOB1912H (batch: PSC0100004)	At 20°C: 37.34 SD = 0.151 mN/m At 25°C: 36.63 SD = 0.089 mN/m	Y	Sowle J., 2020a	Accepted The formulation is surface active						
Relative density (KCP 2.6.1)	EEC A3	GLOB1912H (batch: PSC0100004)	At 20°C: 1.0097 g/mL At 40°C: 1.0017 g/mL	Y	Sowle J., 2020a	Accepted						
Bulk density (KCP 2.6.2)	Not required for liquids.											
Storage Stability after 14 days at 54° C (KCP 2.7.1)		GLOB1912H (batch: PSC0100004)	<table border="1"> <thead> <tr> <th></th> <th>Before storage</th> <th>After storage</th> </tr> </thead> <tbody> <tr> <td>Appearance</td> <td colspan="2">The sample was a light-yellow coloured liquid. The sample allowed light to pass through and was free flowing. There</td> </tr> </tbody> </table>		Before storage	After storage	Appearance	The sample was a light-yellow coloured liquid. The sample allowed light to pass through and was free flowing. There		Y	Sowle J., 2020a	Accepted The HDPE-F bottle remained intact after storage. All the
	Before storage	After storage										
Appearance	The sample was a light-yellow coloured liquid. The sample allowed light to pass through and was free flowing. There											

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments	
				were no signs of separation into oil, cream, sediment or suspended solids. There were no signs of claying. The sample had a solvent odour.				physicochemical parameters were accepted for this EC formulation.
Prosulfocarb	680.2 g/L	671.1 g/L	Diflufenican	14.40 g/L	14.34 g/L			
pH neat (CIPAC MT 75.3)	6.50	6.41	pH 1% dilution (CIPAC MT 75.3)	6.84	6.89			
Emulsifiability (CIPAC MT 36.3)	4L/100L water			After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.	After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.			
	3L/300L water				After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into	After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation		

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.	into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.			
			No significant changes were observed.					
Stability after storage for other periods and/or temperatures (KCP 2.7.2)		GLOB1912H (batch: PSC0100004)	Not required, GLOB1912H is stable after 14 days at 54°C. Nevertheless, a 3 year storage stability study at ambient temperature is ongoing.			Y	Sowle J., 2023	Not required
Minimum content after heat stability testing (KCP 2.7.3)	In house method	GLOB1912H (batch: PSC0100004)		Before storage	After storage	Y	Sowle J., 2020a	Accepted
			Prosulfocarb	680.2 g/L	671.1 g/L			
			Diflufenican	14.40 g/L	14.34 g/L			
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	GLOB1912H (batch: PSC0100004)	Emulsifiability (CIPAC MT 36.3)	Before storage 4L/100L water After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.	After storage After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and	Y	Sowle J., 2020a	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
			<table border="1" data-bbox="862 327 1417 890"> <tr> <td data-bbox="862 327 1070 384"></td> <td data-bbox="1070 327 1243 384"></td> <td data-bbox="1243 327 1417 384">CIPAC Water D.</td> </tr> <tr> <td data-bbox="862 384 1070 416">3L/300L water</td> <td data-bbox="1070 384 1243 416"></td> <td data-bbox="1243 384 1417 416"></td> </tr> <tr> <td data-bbox="862 416 1070 890">After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.</td> <td data-bbox="1070 416 1243 890"></td> <td data-bbox="1243 416 1417 890">After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.</td> </tr> </table> <p data-bbox="862 922 1417 986">The sample remained unchanged post low temperature storage.</p> <p data-bbox="862 1018 1417 1129">The EC Formulation GLOB1912H, sample DNA5955/1 appeared unchanged post low temperature storage for 7 days at 0°C and 3 hours at room temperature. The sample remained a yellow liquid, with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals.</p>			CIPAC Water D.	3L/300L water			After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.		After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.			
		CIPAC Water D.													
3L/300L water															
After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.		After 24 h and 30min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.													
Ambient temperature shelf life (KCP 2.7.5)		GLOB1912H (batch: PSC0100004)	This study is ongoing.	Y	Sowle J., 2022	Ongoing Data GAP It has to be provided for the evaluation in Poland when available. This study can be assessed in									

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						post registration at national level.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not required as GLOB1912H should be stable for at least 2 years at ambient temperature.					
Wettability (KCP 2.8.1)	Not required for liquids.					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB1912H (batch: PSC0100004)	At the minimum application rate (3L/300L of water) After 1 minute: 2.0mL After 12 minutes: 2.0mL At the maximum application rate (4L/100L water) After 1 minute: 4.0mL After 12 minutes: 4.0mL	Y	Sowle J., 2020a	Accepted
Suspensibility (KCP 2.8.3.1)	Not required for an EC formulation.					
Spontaneity of dispersion (KCP 2.8.3.2)	Not required for an EC formulation.					
Dispersion stability (KCP 2.8.3.3)	Not required for an EC formulation.					
Degree of dissolution and dilution stability (KCP 2.8.4)	Not required for an EC formulation.					
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not required for an EC formulation.					
Wet sieve test (KCP 2.8.5.1.2)	Not required for an EC formulation.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dust content (KCP 2.8.5.2.1)	Not required for liquids.					
Particle size of dust (KCP 2.8.5.2.2)	Not required for liquids.					
Attrition (KCP 2.8.5.3)	Not required for liquids.					
Hardness and integrity (KCP 2.8.5.4)	Not required for liquids.					
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	GLOB1912H (batch: PSC0100004)	<p>For the high application rate (4L in 100L) After 24 h and 30 min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.</p> <p>For the low application rate (3L in 300L) After 24 h and 30 min: the sample remained a complete white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.</p>	Y	Sowle J., 2020a	Accepted
Emulsion stability (KCP 2.8.6.2)	See KCP 2.8.6.1					
Re-emulsifiability (KCP 2.8.6.3)	See KCP 2.8.6.1					
Flowability (KCP 2.8.7.1)	Not required for an EC formulation.					
Pourability (KCP 2.8.7.2)	Not required for an EC formulation.					
Dustability following accelerated storage (KCP 2.8.7.3)	Not required for liquids.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
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)	Not applicable as GLOB1912H is not used for seed treatment.					
Distribution to seed (KCP 2.10.2)	Not applicable as GLOB1912H is not used for seed treatment.					
Other/special studies (KCP 2.11)	None					

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)

RMS conclusion:

Based on the accelerated study, the HDPE-F/HDPE-EvOH, and HDPE/PA packages are accepted for the PPP.

Table 4.1-1: Packaging information for 100 mL bottle

Type	Description
Material:	HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded 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-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded 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-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded with polyamide)
Shape/size:	cylindrical / approx. 60 mm diameter x 125 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal

Type	Description
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 500 mL bottle

Type	Description
Material:	HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded 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-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded 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-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded with polyamide)
Shape/size:	rectangular / approx. 106 mm width x 155 mm length x 189 mm height
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 3 L container

Type	Description
Material:	HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded 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-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded 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-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded with polyamide)
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
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for 20 L container

Type	Description
Material:	HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene coextruded with ethylene vinyl alcohol), HDPE/PA (High Density PolyEthylene coextruded with polyamide)

Type	Description
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)

RMS conclusion:

The effectiveness of cleaning procedures has been confirmed.

The effectiveness of cleaning procedures was assessed in the storage stability study of GLOB1912H (Sowle J., 2020a). The procedure is summarized below.

1. 320 mL of GLOB1912H was dissolved in 8 L of water in the spray tank. 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. 20 mL acetonitrile is added to the sprayer which is then agitated to collect any remaining residue. The collected residue was assayed by LC-QQQ.

After three tank washes with 400 mL water 0.000037% prosulfocarb and 0.000092% diflufenican residue remained in the tank. This demonstrates that only a very limited amount of residue remains in the spray tank after cleaning.

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 Data for an Emulsifiable Concentrate Formulation containing Prosulfocarb, and Diflufenican stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice. DNA5955 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 an EC formulation containing 667 g/L prosulfocarb and 14g/L diflufenican. DNA6103 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, and Diflufenican stored at ambient temperature for 3 Years, in Compliance with Good Laboratory Practice. DNA5957 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	N	Globachem

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Formulation containing Prosulfocarb, and Diflufenican stored at ambient temperature for 2 Years, in Compliance with Good Laboratory Practice. DNA5956 David Norris Analytical Laboratories Ltd. GLP Unpublished		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 Source	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
			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 Prosulfocarb

None

A 2.2 Diflufenican

None