

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: GLOB1817H

Product name: **Eledura**

Chemical active substances:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Halauxifen-methyl, 1.33 g/L

Cloquintocet-mexyl, 1.33 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: May 2021

MS Finalisation date: January 2022

Revision date: April 2022

Version history

When	What
May 2021	Initial submission by the applicant for approval of new product.
January 2022	Version evaluated by zRMS PL
April 2022	Corrected after zonal evaluation (due to RT stage)

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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 ambient storage stability study is on-going. It has to be assessed in the post-registration
- ~~data gap 2~~
- ~~data gap 3~~

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Globachem NV
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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 (source 1)
min. 980 g/kg (source 2)

1.2.3.2 Diflufenican

Diflufenican min. 990 g/kg (source 1 and source 2)
 min. 975 g/kg (source 3)

1.2.3.3 Halauxifen-methyl

Halauxifen-methyl min. 930 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: Eledura
 Company code number: GLOB1817H

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 GLOB1817H 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	68.2
Diflufenican	14	11.9 - 16.2	14.1	1.40
Halauxifen-methyl	1.33	1.13 - 1.53	1.43	0.14

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

** Based on the density of the formulation = 1.0085 g/mL

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Cloquintocet-mexyl	1.33	1.13 - 1.53	1.36	0.14

* Based on the minimum purity of the safener/synergist declared for registration

** Based on the density of the formulation = 1.0085 g/mL

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

Table 1.4-3: 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.	-
CIPAC No.	462

Table 1.4-6: Information on halauxifen-methyl

Type	Name/Code Number
ISO common name	Halauxifen-methyl
CAS No.	943831-98-9
EC No.	-
CIPAC No.	970.201

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

Table 1.4-7: Information on safeners

Type	Name/Code Number
Safener	Cloquintocet-mexyl
ISO common name	Cloquintocet-mexyl
CAS No.	99607-70-2
EC No.	619-447-3

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 yellow liquid, with an aromatic odour. It is not explosive, has no oxidising properties. The product is not highly flammable. It has a flash point of 69.0°C. In aqueous solution, it has a pH value around 4.80 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*. Its technical characteristics are acceptable for a *emulsifiable concentrate* formulation. The intended concentration of use is 1% to ~~3~~ 1.5%.

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 GLOB1817H 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	XXXX D., 2020	Accepted
Explosive properties (KCP 2.2.1)	Theoretical certificate	-	Not explosive	N	XXXX D., 2020	Accepted
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	-	Not oxidizing	N	XXXX D., 2020	Accepted
Flash point (KCP 2.3.1)	EEC A9	GLOB1817H (batch: KS010420)	The sample flashed at 69.0 °C	Y	XXXX D., 2020	Accepted
Flammability (KCP 2.3.2)	Not required for liquids.					
Self-heating (KCP 2.3.3)	EEC A15	GLOB1817H (batch: KS010420)	Not highly flammable	Y	XXXX D., 2020	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191 CIPAC MT 75.3	GLOB1817H (batch: KS010420)	Not required as the pH was found to be between 4 and 10 pH of neat formulation: 5.55 at 20.0°C	Y	XXXX D., 2020	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB1817H (batch: KS010420)	4.80 at 20.0°C	Y	XXXX D., 2020	Accepted
Viscosity (KCP 2.5.1)	OECD 114	GLOB1817H (batch: KS010420)	The sample is a Newtonian liquid with a Dynamic Viscosity of 26.60 mPa.s and Kinematic Viscosity of 0.2637 cm ² /s at 20.0°C.	Y	XXXX D., 2020	Accepted Hence 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 22.39 mPa.s and Kinematic Viscosity of 0.2242 cm ² /s at 40.0°C.			contains the coformulant with H304 phrase assigned above 10% kinematic viscosity comes into the account. The kinematic viscosity at 40.0°C for the PPP is slightly above the trigger value of 20.5 mm ² /s (22.42 mm ² /s). So, this PPP cannot be classified as Asp. Tox cat.1 under CLP.												
Surface tension (KCP 2.5.2)	EEC A5	GLOB1817H (batch: KS010420)	At 20°C: 32.15 mN/m SD = 0.079 mN/m At 25°C: 32.06 mN/m SD = 0.056 mN/m	Y	XXXX D., 2020	Accepted												
Relative density (KCP 2.6.1)	EEC A3	GLOB1817H (batch: KS010420)	At 20°C: 1.0085 g/mL At 40°C: 0.9986 g/mL	Y	XXXX D., 2020	Accepted												
Bulk density (KCP 2.6.2)	Not required for liquids.																	
Storage Stability after 14 days at 54° C (KCP 2.7.1)		GLOB1817H (batch: KS010420)	<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 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.</td> </tr> <tr> <td>Prosulfocarb</td> <td>672.8 g/L</td> <td>660.7 g/L</td> </tr> <tr> <td>Diflufenican</td> <td>14.20 g/L</td> <td>14.21 g/L</td> </tr> </tbody> </table>		Before storage	After storage	Appearance	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.		Prosulfocarb	672.8 g/L	660.7 g/L	Diflufenican	14.20 g/L	14.21 g/L	Y	XXXX D., 2020	Accepted. The study was done using HDPE-F bottle. All physicochemical parameters are adequate for EC formulation
	Before storage	After storage																
Appearance	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.																	
Prosulfocarb	672.8 g/L	660.7 g/L																
Diflufenican	14.20 g/L	14.21 g/L																

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments	
			Halauxifen-methyl	1.323 g/L	1.323 g/L			
			Cloquintocet-mexyl	1.349 g/L	1.322 g/L			
			pH neat (CIPAC MT 75.3)	5.55	5.68			
			pH 1% dilution (CIPAC MT 75.3)	4.80	5.07			
			Emulsifiability (CIPAC MT 36.3)	3L/100L water				
				After 24 h and 30min: the sample remained a uniform 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 uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D			
				3L/400L water				
				After 24 h and 30min: the sample remained a uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water	After 24 h and 30min: the sample remained a uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				D	CIPAC Water D			
			No significant changes were observed.					
Stability after storage for other periods and/or temperatures (KCP 2.7.2)		GLOB1817H (batch: KS010420)	Not required, GLOB1817H is stable after 14 days at 54°C. Nevertheless, a 3 year storage stability study at ambient temperature is ongoing.			Y	XXXX D., 2023	Not required
Minimum content after heat stability testing (KCP 2.7.3)	In house method	GLOB1817H (batch: KS010420)		Before storage	After storage	Y	XXXX D., 2020	Accepted
			Prosulfocarb	672.8 g/L	660.7 g/L			
			Diflufenican	14.20 g/L	14.21 g/L			
			Halauxifen-methyl	1.323 g/L	1.323 g/L			
			Cloquintocet-mexyl	1.349 g/L	1.322 g/L			
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	GLOB1817H (batch: KS010420)		Before storage	After storage	Y	XXXX D., 2020	Accepted
				3L/100L water				
			Emulsifiability (CIPAC MT 36.3)	After 24 h and 30min: the sample remained a uniform 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 uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D			
					3L/400L water			
			After 24 h and	After 24 h and				

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments			
			<table border="1"> <tr> <td></td> <td>30min: the sample remained a uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D</td> <td>30min: the sample remained a uniform 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>The sample remained unchanged post low temperature storage.</p>		30min: the sample remained a uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D	30min: the sample remained a uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D			
	30min: the sample remained a uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D	30min: the sample remained a uniform 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)		GLOB1817H (batch: KS010420)	This study is ongoing.	Y	XXXX D, 2022	On-going			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not required as GLOB1817H 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	GLOB1817H (batch: KS010420)	<p>At the minimum application rate (3L/400L of water) After 1 minute: 4.0mL After 12 minutes: 4.0mL</p> <p>At the maximum application rate (3L/100L water) After 1 minute: 10.0mL After 12 minutes: 6.0mL</p>	Y	XXXX D, 2020	Accepted			
Suspensibility	Not required for an EC formulation.								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.3.1)						
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.					
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	GLOB1817H (batch: KS010420)	For the high application rate (3% v/v) After 24 h and 30 min: the sample remained a uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D. For the low application rate (0.75% v/v)	Y	XXXX D, 2020	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After 24 h and 30 min: the sample remained a uniform white emulsion with no signs of separation into oil, cream, sediment or crystals in both CIPAC Water A and CIPAC Water D.			
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.					
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 GLOB1817H is not used for seed treatment.					
Distribution to seed (KCP 2.10.2)	Not applicable as GLOB1817H 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 all the presented below f-HDPE packs are accepted for the PPP

Table 4.1-1: Packaging information for 100 mL bottle

Type	Description
Material:	HDPE-F (Fluorinated High Density PolyEthylene)
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)
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)
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-F (Fluorinated High Density PolyEthylene)
Shape/size:	cylindrical / approx. 60 mm diameter x 185 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 1 L bottle

Type	Description
Material:	HDPE-F (Fluorinated High Density PolyEthylene)
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)
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)
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

Type	Description
UN/ADR	compliant

Table 4.1-8: Packaging information for 5 L container

Type	Description
Material:	HDPE-F (Fluorinated High Density PolyEthylene)
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)
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)
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 GLOB1817H (XXXX D., 2020). The procedure is summarized below.

1. A 8 L garden sprayer is filled up to top with GLOB1817H and water at the concentration of 3 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. 20 mL acetonitrile is added to the sprayer which is then agitated to collect any remaining residue. The collected residue us assayed by LC-QQQ.

After three tank washes with 400 mL water 0.000086% prosulfocarb, 0.00011% diflufenican, 0.00023% halauxifen-methyl and 0.00011% cloquintocet-mexyl residue remained in the tank. This demonstrates that only a very limited amount of residue remains in the spray tank after cleaning.

RMS conclusion

Based on given information it may be concluded that proposed cleaning procedure removes residues of the active substances in a satisfactory manner.

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	XXXX D.	2020	Determination of Storage Stability and Shelf Life Specification an Data for Emulsifiable Concentrate Formulation containing Prosulfocarb, Diflufenican, Halauxifen-methyl and Cloquintocet-Mexyl, stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice. DNA5653 David XXXX Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP 2.2.1 and 2.2.2 <i>Confidential – submitted in Part C.</i>	XXXX D.	2020	Theoretical certificate of explosive and oxidizing properties for an EC formulation containing 667 g/L prosulfocarb, 14g/L diflufenican, 1.33 g/L halauxifen-methyl and 1.33 g/L cloquintocet-mexyl. DNA5959 David XXXX Analytical Laboratories Ltd. Not GLP Unpublished	N	Globachem NV
KCP 2.7.2	XXXX D.	2023	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Prosulfocarb, Diflufenican, Halauxifen-methyl and Cloquintocet-Mexyl, stored at ambient temperature for 3 Years, in Compliance with Good Laboratory Practice. DNA5655 David XXXX Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP 2.7.5	XXXX D.	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, Diflufenican, Halauxifen-methyl and Cloquintocet-Mexyl, stored at ambient temperature for 2 Years, in Compliance with Good Laboratory Practice. DNA5654 David XXXX 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

A 2.3 Halauxifen-methyl

None