FINAL 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: GLOB2013F

Product name(s): Observer

Chemical active substance:

Zoxamide, 450 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: January 2024

MS Finalisation date: 19/12/2024

Version history

When	What
January 2024	Initial dossier submission by applicant for approval of new product
April 2024	Dossier sent for evaluation
September 2024	zRMS finalised evaluation
December 2024	zRMS finalised evaluation after commenting period

Table of Contents

zRMS comments:
The text highlighted in grey was provided by the evaluator.

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- ~~no data gap~~
- Particle size distribution (CIPAC MT 187) is required for SC formulation according to the 284/2013.

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:	xxxxxxxxxxxxxxxxxx
Telephone number:	xxxxxxxxxxxxxxxxxx
Fax:	xxxxxxxxxxxxxxxxxx
E-mail:	xxxxxxxxxxxxxxxxxx

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:	xxxxxxxxxxxxxxxxx
Telephone number:	xxxxxxxxxxxxxxxxx
Fax number:	xxxxxxxxxxxxxxxxx
E-mail:	xxxxxxxxxxxxxxxxx

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 Zoxamide

zoxamide	min. 980 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.

Company code number: GLOB2013F

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)

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 or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Zoxamide	450	427.5 - 472.5	436.22 - 482.14	38.45 - 42.49

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers
** Based on the density of the formulation = 1.1346 g/mL

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

Table 1.4-2: Information on zoxamide

Type	Name/Code Number
ISO common name	Zoxamide
CAS No.	156052-68-5
EC No.	Not assigned
CIPAC No.	640

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: Suspension concentrate [Code: SC]

1.6 Function (KCP 1.6)

Fungicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of an opaque, white, free flowing liquid, with a sweet odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of >400 °C. In aqueous solution, it has a pH value around 6.30 ~~5.71~~ 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 (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA. Its technical characteristics are acceptable for a suspension concentrate formulation.
The intended concentration of use is 0.037% to 0.37 4%.

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

The phrase "shake well before use" is recommended on the label.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None.

Compliance with FAO specifications:

The product GLOB2013F complies with FAO specifications.

Formulation used for tests

The formulation 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 & Weighing of Pack	GLOB2013F Batch CES4648	The samples arrived in good condition with no signs of any leaks, visual seepage or panelling. Sample DNA6205/1 was a uniform white formulation. The sample was opaque, coating the walls of the beaker and free flowing. There were no signs of separation into oil, cream, sediment, claying, or suspended solids. The sample had a sweet odour.	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted**
Explosive properties (KCP 2.2.1)	Theoretical certificate	-	No explosive properties according to the a.s. structural formula and the rest of the co-formulants.	N	***Sowle, J., 2023, DNA6414***	**Accepted** Based on the information of ingredients of PPP. The ingredients of test item are not classified as explosive.
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	-	No oxidising properties according to the a.s. structural formula and the rest of the co-formulants.	N	***Sowle, J., 2023, DNA6414***	**Accepted** Based on the information of ingredients of PPP. The ingredients of test item are not classified as oxidising.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flash point (KCP 2.3.1)	EEC A9	GLOB2013F Batch CES4648	The SC Formulation containing 450g/L Zoxamide, pre storage sample DNA6205/1 did not flash below 100°C and is therefore considered not highly flammable.	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** Flash point was determined in a closed cup Flash Point apparatus. No flash point below 100ºC. The test item is not classified, according to CLP Regulation, as flammable.
Flammability (KCP 2.3.2)	-	-	Test not required for liquids	-	-	**Accepted**
Self-heating (KCP 2.3.3)	EEC A15	GLOB2013F Batch CES4648	The SC Formulation containing 450g/L Zoxamide, pre storage sample DNA6205/1 did not auto-ignite below 400°C and is therefore considered not highly flammable.	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted**
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191 CIPAC MT 75.3	GLOB2013F Batch CES4648	Not required as the pH was found to be between 4 and 10 pH neat formulation: 5.71 at 20°C	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** The pH was between 4 and 10, the acidity/alkalinity was not required to test.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB2013F Batch CES4648	1% dilution: pH 6.30 at 20°C	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	OECD 114	GLOB2013F Batch CES4648	Non-Newtonian Liquid	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** The viscosity was determined using DVII+ Viscometer. The viscosity was determined at different shear rates at 20°C and 40ºC. Conclusion: no Newtonian flow behaviour.
Surface tension (KCP 2.5.2)	EEC A5	GLOB2013F Batch CES4648	At 20 ± 0.1°C: 53.90 ± 0.24mN/m SD= 0.178 At 25 ± 0.1°C: 57.30 ± 0.38mN/m SD=0.218	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** The surface tension of test item was measured at maximum recommended concentration. The surface tension is below 60 mN/m, the product is surface active.
Relative density (KCP 2.6.1)	EEC A3	GLOB2013F Batch CES4648	At 20.0°C: 1.1346~~g/mL~~	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted**
Bulk density (KCP 2.6.2)	-	-	Test not required for liquids	-	-	**Accepted**
Storage Stability after 14 days at 54º C (KCP 2.7.1)		GLOB2013F Batch CES4648	**Tests** / **Pre Storage Sample DNA6205/1** / **Post Accelerated Storage Sample DNA6205/2 (2 weeks at 54°C±2°C)**	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** Based on the result of accelerated storage stability study, PPP was concluded to be stable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Appearance & Stability of Packaging Visual Assessment & Weighing of Pack: The samples arrived in good condition with no signs of any leaks, visual seepage or panelling. Sample DNA6205/1 was a uniform white formulation. The sample was opaque, coating the walls of the beaker and free flowing. There were no signs of separation into oil, cream, sediment, claying, or suspended solids. The sample had a sweet odour. — The sample appearance and packaging remained unchanged post accelerated storage for two weeks at 54ºC±2ºC, from the Pre Storage sample, DNA6205/1 after one inversion. **Active Ingredient Determination Zoxamide** David Norris In House Methodology Validated in Study DNA6208: 448.0g/L (Equating to 99.56% of the Declared Content) — 446.3g/L (Equating to 99.18% of the Declared Content) **pH Determination (at 20°C±0.5°C)** CIPAC MT 75.3: 1% Dilution: pH 6.30 at 20°C Neat: pH 5.71 at 20°C — 1% Dilution: pH 5.76 at 20°C Neat: pH 5.18 at 20°C **Acidity/ Alkalinity**: Not required as the pH was found to be between 4 and 10 **Spontaneity of Dispersion** CIPAC MT 160: In CIPAC Water A: 99.39% In CIPAC Water D: 98.93% — In CIPAC Water A: 97.49% In CIPAC Water D: 96.69% **Suspensibility** CIPAC MT 184: At the high application (0.4%) in CIPAC Water D: 101.1% At the low application (0.03%) in CIPAC Water D: 96.56% — At the high application (0.4%) in CIPAC Water D: 100.7% At the low application (0.03%) in CIPAC Water D: 95.96%			when stored at the elevated temperature of 54ºC±2ºC for 14 days. The PPP stored at elevated temperature 54ºC±2ºC (aged dample) in HDPE translucent white bottle of 0.5 L was analysed for ist active ingredient content (Zoxamide), appearance, pH, spontaneity of dispersion, suspensibility, wet sieve test, pourability and for stability of packaging and packaging/preparation interactionsat at the end of the 14 days of storage period. Based on the results of the study, it was concluded that the active ingredients content, color, physical state, pH, suspensibility, spontaneity of dispersion, wet sieve and pourability of the test item for sample

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Pourability CIPAC MT 148.1: Poured Residue: 1.8839%; Water Rinsed Residue: 0.1830%; Acetone Rinsed Residue: 0.0098% / Poured Residue: 1.6004%; Water Rinsed Residue: 0.1182%; Acetone Rinsed Residue: 0.0012% **Wet Sieve Test** CIPAC MT 185: Mean of two results: 0.0185% / Mean of two results: 0.0380%			stored at elevated temperature of 54ºC±2ºC for 14 days were well compared with that of the results obtained for the test item stored at ambient temperature. The test item found to be non-corrosive for HDPE commercial containers as there was no significant change in the weight of commercial conteiners (547.85 g pre-storage; 547.69 g post acceleratred storage) and there was not any perforations, leakage, panelling, no ballooning after storage at elevated temperature for 14 days. The content of active substance – Zoxamide - in PPP was determined by High Performance Liquid Chromatography (HPLC-PDA). The method was developed and validated in GLP laboratory. The loss of acive

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						substance after 14 days storage of test item at 54ºC was almost neglible for Zoxamide. (448.0 g/L pre-storage sample; 446.3 g/L post accelerated storage sample). It is recognised that a loss of up to 5 % of the active substance is unlikely to adverselyaffect the safety or efficacy of the preparation. The decrease of the pH over accelerated storage procedure was observed.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	-	-	-	

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr>
<td>Minimum content after heat stability testing (KCP 2.7.3)</td>
<td></td>
<td>GLOB2013F Batch CES4648</td>
<td>
<table>
<tr><th>Tests</th><th>Pre Storage Sample DNA6205/1</th><th>Post Accelerated Storage Sample DNA6205/2 (2 weeks at 54°C±2°C)</th><th>Post 2 Years Ambient Storage Sample DNA6206/1</th></tr>
<tr><td>Active Ingredient Determination Zoxamide

David Norris In House Methodology Validated in Study DNA6208</td><td>448.0g/L (Equating to 99.56% of the Declared Content)</td><td>446.3g/L (Equating to 99.18% of the Declared Content)</td><td>460.4g/L (Equating to 102.3% of the Declared Content)</td></tr>
</table>
</td>
<td>Y</td>
<td>Pomeroy, D., 2021, DNA6205, Pomeroy, D., 2023, DNA6206</td>
<td>Accepted
The content of active substance – Zoxamide - in PPP was determined by High Performance Liquid Chromatography (HPLC-PDA). The method was developed and validated in GLP laboratory.
The concentration of acive substance after post acceleraterd storage (2 weeks at 54±2ºC) and after 2 years storage at ambient temperature was in FAO Limits.</td>
</tr>
</table>

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr>
<td>Effect of low temperatures on stability
(KCP 2.7.4)</td>
<td></td>
<td>GLOB2013F
Batch
CES4648</td>
<td>
<table>
<tr><th>Tests</th><th>Pre Storage Sample DNA6205/1</th><th>Post Low Temperature Storage Sub Sample DNA6205/1 (7 days at 0°C±2°C)</th></tr>
<tr><td>Suspensibility
CIPAC MT 184</td><td>At the high application (0.4%) in CIPAC Water D: 101.1%
At the low application (0.03%) in CIPAC Water D: 96.56%</td><td>At the high application (0.4%) in CIPAC Water D: 101.5%
At the low application (0.03%) in CIPAC Water D: 96.65%</td></tr>
<tr><td>Low Temperature Stability
CIPAC MT 9.3</td><td colspan="2">The sample appearance remained unchanged post low temperature storage.</td></tr>
<tr><td>Wet Sieve Test
CIPAC MT 185</td><td>Mean of two results: 0.0185%</td><td>Mean of two results: 0.0120%</td></tr>
</table>
</td>
<td>Y</td>
<td>Pomeroy, D., 2021, DNA6205</td>
<td>Accepted
Based on the results of the low temperature stability test, it is concluded that test item was homogenous liquid without any phase separation when stored at 0±2ºC for 7 days.
Suspensibility and wet sieve test were determined after storage.
Suspensibility: the content of active substance – zoxamide - in suspension was determined by High Performance Liquid Chromatography (HPLC).
The method was developed and validated in GLP laboratory.
Acceptable limits:the mean measured minimum active suspensibility must not be less than 60 % or greater than 105 %.
The criteria were met for both active substance at minimum test item concentration and maximum test item concentration.
Wet sieve test: Acceptable.</td>
</tr>
</table>

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr>
<td>Ambient temperature shelf life
(KCP 2.7.5)</td>
<td></td>
<td>GLOB2013F
Batch
CES4648</td>
<td>
<table>
<tr><th>Tests</th><th>Pre Storage Sample DNA6205/1</th><th>Post 2 Years Ambient Storage Sample DNA6206/1</th></tr>
<tr><td>Appearance & Stability of Packaging

Visual Assessment & Weighing of Pack</td><td>The samples arrived in good condition with no signs of any leaks, visual seepage or panelling. Sample DNA6205/1 was a uniform white formulation. The sample was opaque, coating the walls of the beaker and free flowing. There were no signs of separation into oil, cream, sediment, claying, or suspended solids. The sample had a sweet odour.</td><td>The sample appearance and packaging remained un-changed post 2 years storage at ambient temperature, from the Pre Storage sample, DNA6205/1 after one inver-sion.</td></tr>
<tr><td>Active Ingredient Determination Zoxamide

David Norris In House Methodology Validated in Study DNA6208</td><td>448.0g/L
(Equating to 99.56% of the Declared Content)</td><td>460.4g/L
(Equating to 102.3% of the Declared Content)</td></tr>
<tr><td>pH Determination (at 20°C±0.5°C)

CIPAC MT 75.3</td><td>1% Dilution:
pH 6.30 at 20°C
Neat:
pH 5.71 at 20°C</td><td>1% Dilution:
pH 5.62 at 20°C
Neat:
pH 5.25 at 20°C</td></tr>
<tr><td>Acidity/ Alkalinity</td><td colspan="2">Not required as the pH was found to be between 4 and 10</td></tr>
<tr><td>Spontaneity of Dispersion

CIPAC MT 160</td><td>In CIPAC Water A:
99.39%
In CIPAC Water D:
98.93%</td><td>In CIPAC Water A:
98.37%
In CIPAC Water D:
101.4%</td></tr>
</table>
</td>
<td>Y</td>
<td>Pomeroy, D., 2023, DNA6206</td>
<td>Accepted
Based on the result of ambient temperature shelf life study, PPP was concluded to be stable when stored at ambient temperature for 2 years.

The PPP stored at ambient temperature in HDPE translucent white bottle of 1.0 L was analysed for ist active ingredient content (Zoxamide), appearance, pH, spontaneity of dispersion, suspensibility, wet sieve test, pourability and for stability of packaging and packaging/preparation interactionsat at the end of the 2 years of storage period.
Based on the results of the study, it was concluded that the active ingredients content, color, physical state, pH, suspensibility,</td>
</tr>
</table>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Suspensibility CIPAC MT 184: At the high application (0.4%) in CIPAC Water D: 101.1%; At the low application (0.03 %) in CIPAC Water D: 96.56%; At the high application (0.4%) in CIPAC Water D: 100.3%; At the low application (0.03%) in CIPAC Water D: 97.12% **Pourability** CIPAC MT 148.1: Poured Residue: 1.8839%; Water Rinsed Residue: 0.1830%; Acetone Rinsed Residue: 0.0098%; Poured Residue: 1.6542%; Water Rinsed Residue: 0.1645%; Acetone Rinsed Residue: 0.0053% **Wet Sieve Test** CIPAC MT 185: Mean of two results: 0.0185%; Mean of two results: 0.0706%			spontaneity of dispersion, wet sieve and pourability of the test item for sample stored at ambient temperature for 2 years were well compared with that of the results obtained for the test item stored at ambient temperature. The test item found to be non-corrosive for HDPE commercial containers as there was no significant change in the weight of commercial conteiners (1186.91 g pre-storage; 1186.76 g post 2 years storage at ambient temperature) and there was not any perforations, leakage, panelling, no ballooning after storage at ambient temperature for 2 years. The content of active substance – Zoxamide - in PPP was determined by High Performance Liquid Chromatography (HPLC-PDA). The

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						method was developed and validated in GLP laboratory. The concentration of acive substance after 2 years storage at ambient temperature was in FAO Limits. The decrease of the pH over 2 years of storage at ambient tempearature was observed.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	-	-	-	
Wettability (KCP 2.8.1)	-	-	Not required as GLOB2013F is not a solid formulation.	-	-	**Accepted**
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB2013F Batch CES4648	in CIPAC water D Temperature : 25°C ± 5°C At the High Application Rate (0.4%) After 1 minute: 0.0mL After 12 minutes: 0.0mL At the Low Application Rate (0.03%) After 1 minute: 0.0mL After 12 minutes: 0.0mL	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** 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 the preparation. Acceptable limits: max 60 mL foam after 1 minute. The above mentioned criteria were met.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	GLOB2013F Batch CES4648	At the high application (0.4%) in CIPAC Water D: 101.1% At the low application (0.03%) in CIPAC Water D: 96.56%	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** Suspensibility: the content of active substance – zoxamide - in suspension was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory. Acceptable limits:the mean measured minimum active suspensibility must not be less than 60 % or greater than 105 %. The criteria were met for active substance at minimum test item concentration and maximum test item concentration.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	GLOB2013F Batch CES4648	In CIPAC Water A: 99.39% In CIPAC Water D: 98.93%	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water. The content of active substance – zoxamide - in dispersion was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory. Acceptable limits: the mean measured minimum active spontaneity of dispersion must not be less than 60 % or greater than 105 %. The criteria were met.
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not applicable for a suspension concentrate.	-	-	**Accepted**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	GLOB2013F Batch CES4648	Mean of two results: 0.0185%	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** Wet sieve test is required for water dispersible products. The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on application equipment. Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The criteria were met.
Dust content (KCP 2.8.5.2.1)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for an SC formulation.	-	-	~~**Accepted**~~ **Data gap** Particle size distribution (CIPAC MT 187) is required for SC formulation according to the 284/2013.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Attrition (KCP 2.8.5.3)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Flowability (KCP 2.8.7.1)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	GLOB2013F Batch CES4648	Poured Residue: 1.8839% Water Rinsed Residue: 0.1830% Acetone Rinsed Residue: 0.0098%	Y	***Pomeroy, D., 2021, DNA6205***	**Accepted** The data are required to demonstrate that the user can make use of the maximum amount of the preparation and that an excessive amount of the material does not remain in the container. Acceptable Limits: poured Residue: Maximum 5 % residue. Rinsed Residue: Maximum 0.25% residue. The criteria were met.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant: no tank mix on the label.	-	-	**Accepted** No tank mix on the label.
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant: no tank mix on the label.	-	-	**Accepted** No tank mix on the label.
Adhesion to seeds (KCP 2.10.1)	-	-	GLOB2013F is not used for seed treatment.	-	-	**Accepted**
Distribution to seed (KCP 2.10.2)	-	-	GLOB2013F is not used for seed treatment.	-	-	**Accepted**
Other/special studies (KCP 2.11)	-	-	-	-	-	

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)

GLOB2013F is to be marketed in 100-150-250-500 mL and 1-2-3-5-10-15-20 litre HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA containers. These containers meet the ADR requirements.

zRMS comments
The HDPE bottles were used in accelerated storage study (14 days at 54ºC) and 2 years storage study at ambient temperature. The HDPE bottles were stable in accelerated storage study and 2 years storage stability study at ambient temperature so the storage stability data obtained in these studies can be extrapolated for storage in HDPE/EVOH; F-HDPE or HDPE/PA bottles.
(According to Technical Monograph N°17 3RD Edition Guidelines for Specifying and Managing Shelf Life and Expiry Date of Crop Protection Products, Crop Life International) the following extrapolations are acceptable: for water-based formulations (e.g. SC, FS, SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of the others).

Details of the packaging are given in the tables below.

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 and HDPE/PA
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 and HDPE/PA
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 and HDPE/PA
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 and HDPE/PA
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 1L bottle

Type A	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA
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
Type B	**Description**
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA
Shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 2L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA
Shape/size:	rectangular / Height: 189 mm, Width: 106 mm, Length: 155 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 3L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA
Shape/size:	rectangular / approx. 160 mm x 262 mm x 115 mm
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 5L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA
Shape/size:	rectangular / Height: 313 mm, Width: 140 mm, Length: 190 mm
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 10L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA
Shape/size:	rectangular / Height: 375 mm, Width: 179 mm, Length: 240 mm
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal

Type	Description
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for 15L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA
Shape/size:	rectangular / Height: 311 mm, Width: 245 mm, Length: 294 mm
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 20L container

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA
Shape/size:	rectangular / Height: 372 mm, Width: 263 mm, Length: 292 mm
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

Description	Raw Data File	Retention Time (Minutes)	Unit Area	Response Factor	Concentration (mg/mL)	Volume (mL)	Weight of Active Ingredient in 8L spray tank (mg)	Weight of Active Ingredient in collected 100mL residue (mg)	Percentage Residue

0.10mg/mL Zoxamide	Z1506S22	10.98	1828268	0.0000000548					
DNA6205/1A Effectiveness of Cleaning	Z1506T1	10.98	954632		0.0521	32	14400	5.206	0.0362
DNA6205/1B Effectiveness of Cleaning	Z1506T2	10.97	942523		0.0514	32	14400	5.140	0.0357
0.10mg/mL Zoxamide	Z1506S23	10.98	1824294					**Mean of 2 Results**	0.0359

The SC Formulation containing 450g/L Zoxamide, pre storage sample DNA6205/1 has a mean Effectiveness of Cleaning result of 0.0359% residue for Zoxamide using three Water rinses.

zRMS comment
Accepted
The study in order to assess the effectiveness of cleaning of PPP (GLOB2013F) was performed. The effectiveness of cleaning test of GLOB2013F was carried out in accordance with test facility method DNA/A/028 “Determination of the concentration of active ingredient remaining in a garden sprayer following tank washing”.
Analytical method of determination of residue of zoxamide: validated HPLC-PDA method.

4.3 Recommended methods and precautions

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

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	Pomeroy, D.	2021	Determination of Storage Stability and Shelf Life Specification Data for a Suspension Concentrate Formulation containing Zoxamide stored at 54°C±2°C for Two Weeks, in Compliance With Good Laboratory Practice, Report No.: DNA6205, David Norris Analytical Laboratories Ltd., GLP, Unpublished	N	Globachem NV
KCP 2.2 (filed in part C)	Sowle, J.	2023	Theoretical certificate of explosive and oxidising properties for a suspension concentrate for formulation containing zoxamide, Report No.: DNA6414, David Norris Analytical Laboratories Ltd., Unpublished	N	Globachem NV
KCP 2.7	Pomeroy, D.	2023	Determination of Storage Stability and Shelf Life Specification Data for a Suspension Concentrate Formulation containing Zoxamide stored at ambient temperature for 2 years, in Compliance With Good Laboratory Practice, David Norris Analytical Laboratories Ltd., Report No.: DNA6206, GLP, Unpublished	N	Globachem NV
KCA 2.7	de Ryckel, B.	2022	Octanol/water partition coefficient (Kow) according to EEC A24 (HPLC method) for Zoxamide metabolite RH-150721, Centre Wallon De Recherches Agronomiques, Report No.: 25488, 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

*Studies in the table below were generated to data match the AIR protected studies from the main notifier. The data matching package has been evaluated at EU level by the RMS Latvia and a copy was already sent to all MS.

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
KCA 1.11	Pomeroy, D.	2021	Analysis of Five batches of Zoxamide Technical Material to determine the content of the Active Ingredient and specified impurities, with associated validation, in compliance with Good Laboratory Practice, David Norris Analytical Laboratories Ltd., Report No.: DNA6314, GLP, Unpublished	N	Globachem NV
KCA 2.7	de Ryckel, B.	2022	Octanol/water partition coefficient (Kow) according to EEC A24 (HPLC method) for Zoxamide metabolite RH-24549, Centre Wallon De Recherches Agronomiques, Report No.: 25489, GLP, Unpublished	N	Globachem NV
KCA 2.7	de Ryckel, B.	2022	Octanol/water partition coefficient (Kow) according to EEC A8 (shake-flask method) for Zoxamide metabolite RH-141452, Centre Wallon De Recherches Agronomiques, Report No.: 25675, GLP, Unpublished	N	Globachem NV

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

A 2.1 Zoxamide

Not applicable.