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: GLOB2007bF

Product name: Observer Pro

Chemical active substances:

Zoxamide, 67.5 g/L
Propamocarb-HCl, 450 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: November 2023

MS Finalisation date: 31/10/2024

Version history

When	What
November 2023	Initial dossier submission by applicant for approval of new product
March 2024	Dossier sent for evaluation
July 2024	zRMS finalised evaluation
October 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 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 – study is ongoing (3 years storage stability study at ambient temperature). It is required to set a shelf-life for the PPP from real time storage test at ambient temperature and may be evaluated in post-registration at national level.
- Due to low pH of the neat formulation test for the corrosion to metals should be performed.
- 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:	xxxxxxxxxxxxxxxxxxxxxxxxi
Telephone number:	xxxxxxxxxxxxxxxxxxxxxxxx
Fax:	xxxxxxxxxxxxxxxxxxxxxxxx
E-mail:	xxxxxxxxxxxxxxxxxxxxxxxx

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:	xxxxxxxxxxxx
Telephone number:	xxxxxxxxxxxx
Fax number:	xxxxxxxxxxxxx
E-mail:	xxxxxxxxxxxxx

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. 953 ~~980~~ g/kg

1.2.3.2 Propamocarb-HCl

propamocarb-HCl min. 920 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: GLOB2007bF

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)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Zoxamide	67.5	60.75 - 74.25	61.99 - 75.77	5.64 - 6.9
Propamocarb	377.1	358.245 – 395.955	389.40 – 430.39	35.44 – 39.17
Propamocarb-HCl	450	427.5 - 472.5	464.67 – 513.59	42.29 – 46.74

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers
** Based on the density of the formulation = 1.0988 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.	605-037-1 ~~Not assigned~~
CIPAC No.	640

Table 1.4-3: Information on propamocarb-HCl

Type	Name/Code Number	Variant
ISO common name	Propamocarb	Propamocarb hydrochloride
CAS No.	24579-73-5	25606-41-1
EC No.	~~399~~ Not allocated	~~399.601~~ 245-125-9
CIPAC No.	~~Not allocated~~ 399	~~245-125-9~~ 399.601

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

Overall summary: The product GLOB2007bF is a suspension concentrate. 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 liquid with a separate brown liquid layer on the top but without sediment on the bottom (no cake), homogeneous after gentle shaking, with a chemical odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of 398 °C. In aqueous solution, it has a pH value of 2.15 at 24°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °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 0.67% to 1.33%.
No tank mixtures were proposed for this formulation.

zRMS comments
A shelf-life of at least 2 years was evaluated based on the low and high temperature stability tests. Storage stability study at ambient temperature is ongoing (3 years storage stability study at ambient temperature). It is required to set a shelf-life for the PPP from real time storage test at ambient temperature and may be evaluated in post-registration at national level.

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 GLOB2007bF 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)	PA-U10-METDESCR visual method	GLOB2007bF Batch: LCM22012601	Clear opaque beige liquid with a separate brown liquid layer on the top but without sediment on the bottom (no cake) with a chemical odour .	Y	***De Ryckel, B., 2023, 25509***	**Accepted**
Explosive properties (KCP 2.2.1)	Differential Scanning Calorimetry	GLOB2007bF Batch: LCM22012601	GLOB2007bF is not a candidate for classification as a UN Class 1 explosive substance as the total heat of decomposition is < 500 J/g.	Y	***Kamran, A., 2022, GLP3016012288R1/2022***	**Accepted** Differential Scanning Calorimetry (DSC) was used to measure total heat of decomposition J/g. The exothermic decomposition energy was less than 500 J/g and the onset of exothermic decomposition was below 500ºC. Taking into account this information the PPP is not be classified as explosive according to CLP Regulation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
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	***Norris, D., 202, DNA7098***	**Accepted** The applicant delivered Theoretical Certificate of Explosive and Oxidising properties for formulation containing zoxamide and propamocarb-HCl. Zoxamide contains no "phosphore" or strong oxidising groupings, therefore represents no explosive or oxidising hazards. Propamocarb-HCl contains no "phosphore" or strong oxidising groupings, therefore represents no explosive or oxidising hazards. Based on the information of ingredients of PPP. The ingredients of test item 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 A.9	GLOB2007bF Batch: LCM22012601	> 93°C The test item is not flammable.	Y	***De Ryckel, B., 2023, 25509***	**Accepted** Flash point was determined in a closed cup. Flash point > 93ºC. 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 A.15	GLOB2007bF Batch: LCM22012601	The autoignition temperature of GLOB2007bF has been determined to be 398°C.	Y	***Kamran, A., 2022, GLP3016012288R1/2022***	**Accepted** The autoignition temperature of GLOB2007bf is 398°C.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191 CIPAC MT 75.3	GLOB2007bF Batch: LCM22012601	3.565% w/w as H_2SO_4 pH: 1.85 (at 22°C)	Y	***De Ryckel, B., 2023, 25509***	**Accepted** The pH was less than 4, the acidity was tested.
		GLOB2007bF Batch: KS080523-1*	pH: 2.15 (at 24°C) *batch adjusted to keep pH above 2 - see Part C	Y	***Fourmanoir, S., 2023, 25755***	**Accepted**
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB2007bF Batch: KS080523-1*	pH at 1% in water: 3.42 (at 22°C)	Y	***Fourmanoir, S., 2023, 25755***	**Accepted**

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	CIPAC MT 192 Calculation (with results of density and of dynamic viscosity at 40°C)	GLOB2007bF Batch: LCM22012601	Dynamic viscosity Temperatures : 20°C ± 0.5°C 40°C ± 0.5°C Kinematic viscosity Temperature 40°C ± 0.5°C Shear stress : 26.4 s^{-1}	**No Newtonian flow behaviour** **385 mPa.s to 130 mPa.s** **231 mPa.s to 87 mPa.s** Dependent on the shear rate applied to the sample [1.32 – 26.4 s^{-1}] **80.0 mm^2/s**	Y	***De Ryckel, B., 2023, 25509***	**Accepted** The viscosity was determined at different shear rates at 20°C and 40ºC. Conclusion: no Newtonian flow behaviour. The kinematic viscosity at 40ºC is higher than 20.5 mm^2/s – the PPP is not classified for aspiration hazard according to CLP Regulation (classification criteria: A mixture which contains a total of 10 % or more of a substance or substances classified in Category 1, and has a kinematic viscosity of 20,5 mm^2/s or less, measured at 40ºC, shall be classified in Category 1).

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Surface tension (KCP 2.5.2)	PA-U10-METTENS equivalent to EEC A.5	GLOB2007bF Batch: LCM22012601	**42.2 mN/m** **The test item is surface active**	Y	***De Ryckel, B., 2023, 25509***	**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)	CIPAC MT 3.3.2	GLOB2007bF Batch: LCM22012601	at 20°C ± 0.5°C: **1.0988 ~~g/mL~~ (relative density)** at 40°C ± 0.5°C: **1.0918 g/mL (density)**	Y	***De Ryckel, B., 2023, 25509***	**Accepted**
Bulk density (KCP 2.6.2)	-	-	Not required for an SC formulation	-	-	**Accepted**
Storage Stability after 14 days at 54º C (KCP 2.7.1)		GLOB2007bF Batch: LCM22012601	**Tests** / **Initially** / **After 14 days at 54°C ± 2°C in HDPE/PA bottle (CIPAC MT 46.4)** Zoxamide content (using racemate analytical standard) (Validated HPLC method MET/25508/A) — **64.23 ± 0.07 g/L** Areas ratio of stereoisomers **49.9 ± 0.0% / 50.1 ± 0.0%** — **60.85 ± 0.09 g/L** Areas ratio of stereoisomers **49.9 ± 0.1% / 50.1 ± 0.1%** Promamocarb-HCl content (Validated HPLC method (MET/25508/A)) — **445.8 ± 1.3 g/L** — **446.9 ± 2.1 g/L** Appearance and stability of the finished package — **Outside aspect** HDPE /PA translucent white bottle of 1 L.	Y	***De Ryckel, B., 2023, 25509***	**Accepted** Based on the result of accelerated storage stability study, PPP was concluded to be stable when stored at the elevated temperature of 54ºC±2ºC for 14 days. The PPP stored at elevated temperature 54ºC±2ºC (aged dample) in HDPE /PA translucent white bottle of 1 L was analysed for ist active

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			(used for the storage) (PA-U10-METDESCR visual method)	Closing : white plastic screw-cap containing a paper layer in the bottom Sealing with plastic efficient tamper-evidence and an aluminium seal Well closed bottle without deterioration or special anomaly : no change of colour, odour (noticeable before opening of the packaging), no panelling, no ballooning, tight container, tight and resealable closure. No leak during shaking or turning : there is no seepage of solvent through the container walls or seal. No observable sign of test item contamination on the outer surface. **Inside aspect** no deformation and no observable alteration of package material **No modification of appearance or significant pack weight change**				ingredient content (Zoxamide and ~~Promamocarb~~ Propamocarb -HCl), 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 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
			Appearance of the test item (PA-U10-METDESCR visual method)	**Physical state at ambient temperature :** liquid with a separate brown liquid layer on the top but without sediment on the bottom (no cake). homogeneous after gentle shaking. **Colour** : clear opaque beige. **Odour** : chemical odour **No modification of appearance**				
			pH of the test item (CIPAC MT 75.3)	**1.85 (at 22°C)**	**1.86 (at 21-22°C)**			
			Acidity / alkalinity (CIPAC MT 191)	**3.565 % w/w (as H_2SO_4)**	**3.539 % w/w (as H_2SO_4)**			
			Pourability/rinsability Temperature : 20°C ± 2°C (CIPAC MT 148) Poured residue	 **2.04 %**	 **1.76 %**			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Wet sieve test (material retained on a 75 µm test sieve) (CIPAC MT 185)	**0.04 % w/w**	**0.04 % w/w**			be non-corrosive for HDPE /PA commercial containers as there was no significant change in the weight of commercial conteiners and there was not any perforations, leakage, panelling, no ballooning after storage at elevated temperature for 14 days. The content of active substances – Zoxamide and ~~Promamocarb~~ Propamocarb -HCl - in PPP was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory. In a first time, for the analysis before storage and after accelerated storage, the zoxamide content (including the areas ratio of both
			Suspensibility of **zoxamide** in CIPAC water D Temperature : 25°C ± 5°C after 30 minutes CIPAC MT 184.1 (by a.s. content) Concentrations : 0.67% v/v 1.33 % v/v	 **89.6%** **86.6%**	 **86.0%** **84.8%**			
			Suspensibility of **propamocarb-HCl** in CIPAC water D Temperature : 25°C ± 5°C after 30 minutes CIPAC MT 184.1 (by a.s. content) Concentrations : 0.67% v/v 1.33 % v/v	 **100.2%** **100.7%**	 **99.9%** **101.3%**			
			Spontaneity of dispersion of **zoxamide** in CIPAC water D Temperature : 30°C ± 2°C after 5 minutes CIPAC MT 160 (by a.s. content) Concentration : ± 12.5 mL/250 mL	 **94.9%**	 **97.7%**			
			Spontaneity of dispersion of **propamocarb-**	**98.3%**	**99.5%**			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			HCl in CIPAC water D Temperature : 30°C ± 2°C after 5 minutes CIPAC MT 160 (by a.s. content) Concentration : ± 12.5 mL/250 mL			stereoisomers)in the test item has been determined using racemate analytical standard (technical item) and with the sum of the peaks of each stereoisomers. In a second time, after certification of the analytical standard (technical item) with individual stereoisomers, the results of zoxamide content have been calculated again using the purity of each stereoisomers in the analytical standard (technical item) (including the % w/w ratio of both stereoisomers). The loss of acive substances after 14 days storage of test item at 54°C was almost neglible for ~~Promamocarb~~ Propamocarb -HCl and ~~lower~~ slightly larger than 5% for Zoxamide (5.26% when compared to the

<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></td><td></td><td></td><td></td><td></td><td></td><td>initial value).
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.
Since the results - the loss of active substance zoxamide - were acceptable in the study by De Ryckel, B., 2023, 25644, performed at 40°C for 8 weeks, zRMS recommend that the product is labelled with instructions not to store it at temperature above 40 °C.</td></tr>
<tr><td>Stability after storage for other periods and/or temperatures (KCP 2.7.2)</td><td></td><td>GLOB2007bF
Batch: LCM22012601</td><td>
<table>
<tr><th>Tests</th><th>Initially</th><th>After 8 weeks at 40°C ± 2°C in HDPE/C bottle (CIPAC MT 46.4)</th></tr>
<tr><td>Zoxamide content (using racemate analytical standard) (Validated HPLC method MET/25508/A)</td><td>64.23 ± 0.07 g/L
Areas ratio of stereoisomers
49.9 ± 0.0% / 50.1 ± 0.0%</td><td>62.73 ± 0.87 g/L
Areas ratio of stereoisomers
49.9 ± 0.1% / 50.1 ± 0.1%</td></tr>
<tr><td>Propamocarb-HCl content (Validated HPLC</td><td>445.8 ± 1.3 g/L</td><td>457.1 ± 5.4 g/L</td></tr>
</table>
</td><td>Y</td><td>De Ryckel, B., 2023, 25644</td><td>Accepted
Based on the result of accelerated storage stability study, PPP was concluded to be stable when stored at the elevated temperature of 40ºC±2ºC for 8 weeks.
The HDPE ~~C (HDPE conventional)~~ bottle is stable after 8 weeks at</td></tr>
</table>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			method (MET/25508/A))					40°C so the storage stability data obtained in this study can be extrapolated for storage in HDPE/PA, HDPE/EVOH; F-HDPE or PET bottles. The PPP stored at elevated temperature of 40ºC±2ºC (aged dample) in HDPE-C (HDPE conventional) was analysed for ist active ingredient content (Zoxamide and ~~Promamocarb~~ Propamocarb -HCl), appearance, pH, spontaneity of dispersion, suspensibility, wet sieve test, pourability and for stability of packaging and packaging/preparation interactionsat at the end of 8 weeks of storage period. Based on the results of the study, it was concluded that the active ingredients content, color, physical state, pH,
			Appearance and stability of the finished package (used for the storage) (PA-U10-METDESCR visual method)	**Outside aspect** HDPE /C opaque white bottle of 1 L. Closing : white plastic screw-cap containing a paper layer in the bottom Sealing with plastic efficient tamper-evidence and an aluminium seal Well closed bottle without deterioration or special anomaly : no change of colour, odour (noticeable before opening of the packaging), no panelling, no ballooning, tight container, tight and resealable closure. No leak during shaking or turning : there is no seepage of solvent through the container walls or seal. No observable sign of test item contamination on the outer surface. **Inside aspect** no deformation and no observable alteration of package material **No modification of appearance or significant pack weight change**				
			Appearance of the test item (PA-U10-METDESCR visual method)	**Physical state at ambient temperature :** liquid with a separate brown liquid layer on the top but without sediment on the bottom (no cake). homogeneous after gentle shaking. **Colour** : clear opaque beige. **Odour** : chemical odour **No modification of appearance after gentle shaking**				
			pH of the test item (CIPAC MT 75.3)	**1.85 (at 22°C)**	**1.82 (at 23°C)**			
			Acidity / alkalinity (CIPAC MT 191)	**3.565 % w/w (as H_2SO_4)**	**3.552 % w/w (as H_2SO_4)**			
			Pourability/rinsability					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<table><tr><td>Temperature : 20°C ± 2°C (CIPAC MT 148) Poured residue</td><td>**2.04 %**</td><td>**1.45 %**</td></tr><tr><td>Wet sieve test (material retained on a 75 µm test sieve) (CIPAC MT 185)</td><td>**0.04 % w/w**</td><td>**0.09 % w/w**</td></tr><tr><td>Suspensibility of **zoxamide** CIPAC MT 184.1 (by a.s. content) Concentrations : 0.67% v/v 1.33 % v/v</td><td>in CIPAC water D Temperature : 25°C ± 5°C after 30 minutes **89.6%** **86.6%**</td><td> **89.8%** **84.6%**</td></tr><tr><td>Suspensibility of **propamocarb-HCl** CIPAC MT 184.1 (by a.s. content) Concentrations : 0.67% v/v 1.33 % v/v</td><td>in CIPAC water D Temperature : 25°C ± 5°C after 30 minutes **100.2%** **100.7%**</td><td> **100.0%** **100.6%**</td></tr><tr><td>Spontaneity of dispersion of **zoxamide** CIPAC MT 160 (by a.s. content) Concentration : ± 12.5 mL/250 mL</td><td>in CIPAC water D Temperature : 30°C ± 2°C after 5 minutes **94.9%**</td><td> **98.3%**</td></tr><tr><td>Spontaneity of dispersion of **propamocarb-**</td><td>in CIPAC water D Temperature : 30°C ± 2°C after 5</td><td> **100.6%**</td></tr></table>			suspensibility, spontaneity of dispersion, wet sieve and pourability of the test item for sample stored at elevated temperature of 40ºC±2ºC for 8 weeks 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-C (HDPE conventional) commercial containers as there was no significant change in the weight of commercial conteiners and there was not any perforations, leakage, panelling, no ballooning after storage at 40ºC±2ºC for 8 weeks. The content of active substances – Zoxamide and ~~Promamocarb~~ Propamocarb -HCl - in PPP was

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			HCl CIPAC MT 160 (by a.s. content) Concentration : ± 12.5 mL/250 mL minutes **98.3%**			determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory. The loss of acive substances after 8 weeks storage of test item at 40ºC were lower than 5%. 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.
		GLOB2007bF Batch: KS080523-1*	**Tests** / **Initially** / **After 8 weeks at 40°C ± 2°C in HDPE/C bottle (CIPAC MT 46.4)** Zoxamide content (using analytical standards of both individual stereoisomers) (Validated HPLC method MET/25508/A) / **67.29 ± 0.32 g/L** % w/w of stereoisomers (R/S) **50.2 ± 0.2 % / 49.8 ± 0.2 %** / **64.57 ± 0.14 g/L** % w/w of stereoisomers (R/S) **49.8 ± 0.1 % / 50.2 ± 0.1 %** ~~Promamocarb-~~ Propamocarb-HCl content (Validated HPLC method / **461.2 ± 6.5 g/L** / **469.0 ± 2.2 g/L**	Y	***Fourmanoir, S., 2023, 25755***	**Accepted** Based on the result of accelerated storage stability study, PPP was concluded to be stable when stored at the elevated temperature of 40ºC±2ºC for 8 weeks. The HDPE bottle of 100 mL is stable after 8 weeks at 40°C so the storage stability data obtained in this study can be

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			MET/25508/A) Appearance of the test item (Test facility method PA-U10-METDESCR) **Physical state :** before homogeneisation : traces of a liquid layer on the top but without sediment on the bottom (no cake). after homogeneisation : homogeneous liquid. **Colour** : opaque, light beige. **Odour** : chemical odour . Appearance and stability of the commercial type package Appearance and stability of the commercial type package (Test facility method PA-U10-METDESCR) **Outside aspect** Description : Opaque white HDPE bottle of 100 mL. Reclosable packaging with sealing, Total height (with cap) : 10.0 cm Diameter : 6.0 cm Closing : white plastic screw-cap containing a paper layer in the bottom. Sealing : aluminium seal. - well closed container without deterioration or special anomaly. - no deformation of the container. - no observable sign of test item contamination on the outer surface. - no odour and/or modification of colour noticeable before opening. - no leak during shaking or turning. **Inside aspect** - No deformation and no observable alteration of package material by the test item. - Packaging easily reclosable after opening. **No modification of appearance or pack weight change** Density at 20°C ± 0.5°C CIPAC MT 3.3.2 **1.0832 g/mL** -			extrapolated for storage in HDPE/PA, HDPE/EVOH; F-HDPE or PET bottles. The PPP stored at elevated temperature of 40ºC±2ºC (aged dample) in HDPE bottle of 100 mL was analysed for ist active ingredient content (Zoxamide and ~~Promamocarb~~ Propamocarb-HCl), appearance, pH of test item stored at elevated temperature of 40ºC±2ºC for 8 weeks 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 bottle of 100 mL as there was no significant change in the weight of commercial conteiners and there was not any perforations, leakage, panelling, no

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			pH of the test item CIPAC MT 75.3 — **2.15 (at 24°C)** — **2.19 (at 21 and 22°C)** pH at 1% in water CIPAC MT 75.3 — **3.42 (at 22°C)** — **3.44 (at 20°C)** Acidity / alkalinity CIPAC MT 191 — **0.807 % w/w (as H_2SO_4)** — **0.807 % w/w (as H_2SO_4)**			ballooning after storage at 40ºC±2ºC for 8 weeks. The content of active substances – Zoxamide and ~~Promamocarb~~ Propamocarb-HCl - in PPP was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory. The loss of acive substances after 8 weeks storage of test item at 40ºC were lower than 5%. 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.

<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>GLOB2007bF
Batch:
LCM22012601</td>
<td>
<table>
<tr><th>Tests</th><th>Initially</th><th>After 14 days at 54°C ± 2°C in HDPE/PA bottle (CIPAC MT 46.4)</th><th>After 8 weeks at 40°C ± 2°C in HDPE/C bottle (CIPAC MT 46.4)</th></tr>
<tr><td>Zoxamide content
(using racemate analytical standard)
(Validated HPLC method MET/25508/A)</td><td>64.23 ± 0.07 g/L
<u>Areas ratio of stereoisomers</u>
49.9 ± 0.0%
/
50.1 ± 0.0%</td><td>60.85 ± 0.09 g/L
<u>Areas ratio of stereoisomers</u>
49.9 ± 0.1%
/
50.1 ± 0.1%</td><td>62.73 ± 0.87 g/L
<u>Areas ratio of stereoisomers</u>
49.9 ± 0.1%
/
50.1 ± 0.1%</td></tr>
<tr><td>Propamocarb-HCl content
(Validated HPLC method (MET/25508/A))</td><td>445.8 ± 1.3 g/L</td><td>446.9 ± 2.1 g/L</td><td>457.1 ± 5.4 g/L</td></tr>
</table>
</td>
<td>Y</td>
<td>De Ryckel, B., 2023, 25509
De Ryckel, B., 2023, 25644</td>
<td>Accepted
Based on the result of accelerated storage stability study, PPP was concluded to be stable when stored at 54ºC±2ºC for 14 days in HDPE/PA bottle and when stored at 40ºC±2ºC for 8 weeks in HDPE/C bottle.
The content of active substances – Zoxamide and ~~Promamocarb~~ Propamocarb-HCl - in PPP was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory.
The loss of acive substances after 8 weeks storage of test item at 40ºC or after 14 days storage at 54ºC±2ºC were lower than 5%.
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.</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></td>
<td></td>
<td>GLOB2007bF
Batch:
KS080523-1*</td>
<td>
<table>
<tr><th>Tests</th><th>Initially</th><th>After 8 weeks at 40°C ± 2°C (CIPAC MT 46.4)</th></tr>
<tr><td>Zoxamide content (using racemate analytical standard) (Validated HPLC method MET/25508/A)</td><td>67.29 ± 0.32 g/L
% w/w of stereoisomers (R/S)
50.2 ± 0.2 % /
49.8 ± 0.2 %</td><td>64.57 ± 0.14 g/L
<s>67.29 ± 0.32 g/L</s>
% w/w of stereoisomers (R/S)
49.8 ± 0.1 % /
50.2 ± 0.1 %</td></tr>
<tr><td>Propamocarb-HCl content (Validated HPLC method (MET/25508/A))</td><td>461.2 ± 6.5 g/L</td><td>469.0 ± 2.2 g/L</td></tr>
</table>
</td>
<td>Y</td>
<td>Fourmanoir, S., 2023, 25755</td>
<td>Accepted
Based on the result of accelerated storage stability study, PPP was concluded to be stable when stored at 40ºC±2ºC for 8 weeks in HDPE bottle.
The content of active substances – Zoxamide and <s>Promamocarb</s> Propamocarb-HCl - in PPP was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory.
The loss of acive substances after 8 weeks storage of test item at 40ºC were lower than 5%.
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.</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>CIPAC MT 39.3, adapted</td>
<td>GLOB2007bF
Batch:
LCM22012601</td>
<td>
<table>
<tr><th>Tests</th><th>Initially</th><th>After 7 days at 0°C ± 2°C in a closed glass bottle</th></tr>
<tr><td>Appearance of the test item</td><td colspan="2">Physical state at ambient temperature :
liquid with a separate brown liquid layer on the top but without sediment on the bottom (no cake).
homogeneous after gentle shaking.
Colour : clear opaque beige.
Odour : chemical odour
No modification of appearance</td></tr>
<tr><td>Wet sieve test (material retained on a 75 µm test sieve)</td><td>0.04 % w/w</td><td>0.04 % w/w</td></tr>
<tr><td>Suspensibility of zoxamide
CIPAC MT 184.1
(by a.s. content)

in CIPAC water D
Temperature : 25°C ± 5°C
after 30 minutes

Concentrations :
0.67% v/v
1.33 % v/v</td><td>

89.6%
86.6%</td><td>

87.8%
86.5%</td></tr>
<tr><td>Suspensibility of propamocarb-HCl
CIPAC MT 184.1
(by a.s. content)

in CIPAC water D
Temperature : 25°C ± 5°C
after 30 minutes

Concentrations :
0.67% v/v
1.33 % v/v</td><td>

100.2%
100.7%</td><td>

99.5%
100.8%</td></tr>
</table>
</td>
<td></td>
<td></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 substances – zoxamide and propamocarb-HCl - 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 spontaneity of dispersion or dispersibility must not</td>
</tr>
</table>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						be less than 60 % or greater than 105 %. The criteria were met for both active substances at minimum test item concentration and maximum test item concentration. Wet sieve test: Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The criteria were met.
Ambient temperature shelf life (KCP 2.7.5)			Study ongoing			**Data gap** Missing storage stability study at ambient temperature - study is ongoing (3 years storage stability study). It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level. The expected date of the finalization of the 3-years storage stability study is June 2026.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	-	-	-	
Wettability (KCP 2.8.1)	-	-	Not required as GLOB2007bF is not a solid formulation.	-	-	**Accepted**
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB2007bF Batch: LCM22012601	in CIPAC water D Temperature : 25°C ± 5°C <u>Concentration: 0.67 % v/v</u> after 10 seconds: 27 mL after 1 minute: 25 mL after 3 minutes: 22 mL after 12 minutes: 16 mL <u>Concentration: 1.33 % v/v</u> after 10 seconds: 28 mL after 1 minute: 25 mL after 3 minutes: 20 mL after 12 minutes: 14 mL	Y	***De Ryckel, B., 2023, 25509***	**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 184.1 (by a.s. content)	GLOB2007bF Batch: LCM22012601	Suspensibility of **zoxamide** in CIPAC water D Temperature : 25°C ± 5°C after 30 minutes Concentrations : 0.67% v/v : **89.6%** 1.33 % v/v : **86.6%** Suspensibility of **propamocarb-HCl** in CIPAC water D Temperature : 25°C ± 5°C after 30 minutes Concentrations : 0.67% v/v : **100.2%** 1.33 % v/v : **100.7%**	Y	***De Ryckel, B., 2023, 25509***	**Accepted** Suspensibility: the content of active substances – zoxamide and propamocarb-HCl - 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 spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %. The criteria were met for both active substances 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 (by a.s. content)	GLOB2007bF Batch: LCM22012601	**zoxamide** in CIPAC water D Temperature : 30°C ± 2°C after 5 minutes Concentration : ± 12.5 mL/250 mL: **94.9%** **propamocarb-HCl** in CIPAC water D Temperature : 30°C ± 2°C after 5 minutes Concentration : ± 12.5 mL/250 mL: **98.3%**	Y	***De Ryckel, B., 2023, 25509***	**Accepted** The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water. The content of active substances – zoxamide and propamocarb-HCl - in dispersion was determined 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.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not applicable for a suspension concentrate.	-	-	**Accepted**
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	GLOB2007bF Batch: LCM22012601	**0.04 % w/w**	Y	***De Ryckel, B., 2023, 25509***	**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**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
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.
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**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Pourability (KCP 2.8.7.2)	CIPAC MT 148	GLOB2007bF Batch: LCM22012601	Poured residue: 2.04 %	Y	***De Ryckel, B., 2023, 25509***	**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: Maximum 5 % residue. The criteria were met.
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)	-	-	GLOB2007bF is not used for seed treatment.	-	-	**Accepted**
Distribution to seed (KCP 2.10.2)	-	-	GLOB2007bF is not used for seed treatment.	-	-	**Accepted**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Other/special studies (KCP 2.11)	-	-	-	-	-	**Not required**

*batch adjusted to keep pH above 2 - see Part C

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)

GLOB2007bF 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 and HDPE/PA bottles were used in accelerated storage studies (14 days at 54ºC and 8 weeks at 40ºC). The HDPE and HDPE/PA bottles were stable in accelerated storage studies so the storage stability data obtained in these studies can be extrapolated for storage in HDPE/EVOH; F-HDPE or PET bottles.
(According to SANCO/10473/2003 – rev.5 (Guidance Document for the Generation and Evaluation of Data on the Physical, Chemical and Technical Properties of Plant Protection Products Under Regulation (EC) No. 1107/2009) ~~(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

Type A	Description
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

Type	Description
Closure:	polyethylene screw cap
Seal:	Induction seal
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 two to three times with clean water until the foam and all traces of product have been removed.

4.2.2 Effectiveness of the cleaning procedures

Tests	Methods	Initially

Tests	Methods	Initially
<u>Zoxamide</u> Effectiveness of cleaning procedure (n=6) Concentration : 1.33 % v/v Water : Water CIPAC D First rinsate Second rinsate Third rinsate Remaining residue after triplicate rinsing	PA-U10-METCLEAN	**% w/w of the initial amount of active substance in the spray tank** **7.52 ± 1.54 (RSD : 19.53%)** **0.304 ± 0.064 (RSD : 19.90%)** **0.029 ± 0.003 (RSD : 10.71%)** **0.024 ± 0.009 (RSD : 34.12%)**
<u>Propamocarb-HCl</u> Effectiveness of cleaning procedure (n=6) Concentration : 1.33 % v/v Water : Water CIPAC D First rinsate Second rinsate Third rinsate Remaining residue after triplicate rinsing	PA-U10-METCLEAN	**% w/w of the initial amount of active substance in the spray tank** **0.198 ± 0.0090 (RSD : 4.53%)** **0.0042 ± 0.0006 (RSD : 13.31%)** **0.0006 ± 0.0003 (RSD : 49.58%)** **0.0003 ± 0.0002 (RSD : 51.59%)**

zRMS comment

Accepted

The study in order to assess the effectiveness of cleaning of PPP (GLOB2007bF) was performed. The effectiveness of cleaning test of GLOB2007bF was carried out in accordance with test facility method PA-U10-METCLEAN based on PSD Efficacy Guideline 305 “Cleaning application equipment – small scale jar test protocol - Triple rinse procedure, without tank-cleaner”.

Analytical method of determination of residue of zoxamide (sum of both stereoisomers) MET/25509/A: method based on HPLC method developed and validated for the determination of active substance in the test item in study 25508, adapted by the test facility for the determination of active substance content in the rinsed residue after the test of effectiveness of cleaning procedure. The method has been validated on its specificity and non-analyte interference, LOQ, linearity and accuracy. The repeatability of the analytical method of determination of residue in the rinsing waters is not determined because it is not possible to analyse the same rinsing water several times.

The precision (repeatability) of the full method was checked with 6 replicates of the cleaning test.

Analytical method of determination of residue of propamocarb-HCl MET/25509/B: LC-MS/MS method developed and validated by the test facility for the determination of propamocarb-HCl in the rinsed residue after the test of effectiveness of cleaning procedure. The method has been validated on its specificity and non-analyte interference, LOQ, linearity and accuracy. The repeatability of the analytical method of determination of residue in the rinsing waters is not determined because it is not possible to analyse the same rinsing water several times.

The precision (repeatability) of the full method was checked with 6 replicates of the cleaning test.

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	De Ryckel, B.	2022	Physico-chemical properties and storage stability of a formulation suspension concentrate (SC) containing 67.5 g/L zoxamide and 450 g/L propamocarb-HCl, first interim report, Centre Wallon De Recherches Agronomiques, Report No.: 25509, GLP, Unpublished	N	Globachem NV
KCP 2.1-2.8	Kamran, A.	2022	Physico / Chemical Testing on a Sample of GLOB2007bF, Dekra Uk Ltd., Report No.: GLP3016012288R1/2022, GLP, Unpublished	N	Globachem NV
KCP 2.1-2.8	De Ryckel, B.	2022	Accelerated storage stability or 8 weeks at 40°C of GLOB2007bF, a formulation suspension concentrate (SC) containing 67.5 g/L zoxamide and 450 g/L propamocarb-HCl, Centre Wallon De Recherches Agronomiques, Report No.: 25644, GLP, Unpublished	N	Globachem NV
KCP 2.1-2.8	Fourmanoir, S.	2023	Accelerated storage stability for 8 weeks at 40°C and shelf-life storage for 2 and 3 years at 20°C of GLOB2007bF (batch: KS080523-1), a formulation suspension concentrate (SC) containing 67.5 g/L zoxamide and 450 g/L propamocarb-HCl, second interim report, Centre Wallon De Recherches Agronomiques, Report No.: 25755, GLP, Unpublished	N	Globachem NV
KCP 2.2.1-2.2.2 (filed in Part C)	Norris, D.	2022	THEORETICAL CERTIFICATE OF EXPLOSIVE AND OXIDISING PROPERTIES FOR A FORMULATION CONTAINING ZOXAMIDE AND PROPAMOCARB HCl, David Norris Analytical Laboratories Ltd., Report No.: DNA7098, 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 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 particion 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

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 Published/Unpublished	Y/N	Owner

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 Zoxamide

Not applicable.

A 2.2 Propamocarb-HCl

Not applicable.