

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: GLOB2106cF

Product name: Revus Pro

Chemical active substances:

Propamocarb-HCl, 450 g/L

Mandipropamid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: March 2023

MS Finalisation date: 06/03/2024

Version history

When	What
March 2023	Initial submission by applicant for approval of new product
July 2023	Dossier sent for evaluation
November 2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period

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Evaluator 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:

- Missing storage stability study at ambient temperature. A 2 and 3 year storage stability study at ambient temperature is ongoing. A shelf-life for the PPP may be evaluated in post-registration at national level.

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: xxxxxxxxxxxxxxxxxxxxxxxx
Telephone number: 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

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 Propamocarb-HCl

Propamocarb-HCl min. 950 g/kg

1.2.3.2 Mandipropamid

Mandipropamid min. 930 g/kg

SYN 545038 max. 0.1 g/kg
(N-{2-[4-(2-chloro-allyloxy)-3-methoxy-phenyl]-ethyl}-2-(4-chloro-phenyl)-2-prop-2-ynyloxy-acetamide)

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

Trade name: Revus Pro

Company code number: GLOB2106cF

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 GLOB2106cF 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)
Propamocarb-HCl	450	427.5-472.5	472.5-489.1	43.8-45.3
Mandipropamid	75	67.5-82.5	80.36	7.45

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

** Based on the density of the formulation = 1.08 g/mL

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L)
SYN 545038 (N-{2-[4-(2-chloro-allyloxy)-3-methoxy-phenyl]-ethyl}-2-(4-chloro-phenyl)-2-prop-2-ynyloxy-acetamide)	0.00875

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

Table 1.4-3: Information on Propamocarb-HCl

Type	Name/Code Number
ISO common name	Propamocarb hydrochloride
CAS No.	25606-41-1
EC No.	247-125-9

Type	Name/Code Number
CIPAC No.	399.601

Table 1.4-4: Information on Mandipropamid

Type	Name/Code Number
ISO common name	Mandipropamid
CAS No.	374726-62-2
EC No.	n/a
CIPAC No.	783

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 a uniform white, opaque liquid formulation, with a solvent odour. It is not explosive, has no oxidising properties. The product is not highly flammable. It has a self ignition temperature of above 400°C. In aqueous solution, it has a pH value around 5 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*. Its technical characteristics are acceptable for a *suspension concentrate* formulation. The intended concentration of use is 0.63% to 1.3%.

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The accelerated storage stability test (14 days at 54° C) was performed to generate information on the expected Shelf Life. No significant chemical, physical or packaging changes occur in the accelerated storage test. Accelerated storage stability test indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE*.

A 2 and 3 year storage stability study at ambient temperature is ongoing. A shelf-life for the PPP should be evaluated based on the results of real time data in post-registration at national level.

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

None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None

Compliance with FAO specifications:

The product GLOB2106cF 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	GLOB2106cF Batch BRN 3891	The sample was an opaque uniform white formulation. The sample was free flowing and coated the walls of a beaker. There were no signs of separation into oil, cream, sediment, claying or suspended solids. The sample had a solvent type odour.	Y	Sowle J., 2022 DNA6686	Accepted
Explosive properties (KCP 2.2.1)	Theoretical certificate	-		N	Norris D., 2023	Accepted No explosive properties The a.s and each co-formulant have no explosive properties.
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	-		N	Norris D., 2023	Accepted No oxidizing properties The a.s and each co-formulant have no oxidizing properties.
Flash point (KCP 2.3.1)	EEC A9	GLOB2106cF Batch BRN 3891	The sample did not flash below 100°C and is therefore considered not highly flammable.	Y	Sowle J., 2022 DNA6686	Accepted A closed cup flash point apparatus was used to determined the flash point of GLOB2106cF. The sample of GLOB2106cF did not flash below 100°C and it is therefore not considered highly

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						flammable.
Flammability (KCP 2.3.2)	Test not required for liquids.					
Self-heating (KCP 2.3.3)	EEC A15	GLOB2106cF Batch BRN 3891	The sample did not auto-ignite below 400°C and is therefore considered not highly flammable.	Y	Sowle J., 2022 DNA6686	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	GLOB2106cF Batch BRN 3891	Not required as the pH was found to be between 4 and 10. pH of neat formulation: 4.97 at 20.1°C	Y	Sowle J., 2022 DNA6686	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB2106cF Batch BRN 3891	5.78 at 20.1°C	Y	Sowle J., 2022 DNA6686	Accepted
Viscosity (KCP 2.5.1)	OECD 114	GLOB2106cF Batch BRN 3891	The sample is a non-Newtonian liquid.	Y	Sowle J., 2022 DNA6686	Accepted Using a Brookfield DVII+ Viscometer, a spindle was submerged into the sample at equilibrated temperature and spun at various speeds to give a minimum and maximum Viscosity reading at 20°C and 40°C. At 20 °C: from 5200.5 to 206.1 mPa.s for shear rates going from 0.20 to 34.0 s ⁻¹ . At 40 °C: from 4899.1 to 189.8 mPa.s for shear

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
						rates going from 0.20 to 34.0 s ⁻¹ . The sample is a non-Newtonian liquid.									
Surface tension (KCP 2.5.2)	EEC A5	GLOB2106cF Batch BRN 3891	At 20°C: 53.91mN/m ±0.347, SD= 0.253 At 25°C: 52.78mN/m ±0.163, SD = 0.075	Y	Sowle J., 2022 DNA6686	Accepted The surface tension was determined at the highest in use concentration (2L Formulation in 150 L water) at 20°C.and at 25°C. The product is considered as a surface active (the surface tension is below 60 mN/m).									
Relative density (KCP 2.6.1)	EEC A3	GLOB2106cF Batch BRN 3891	At 20°C: 1.0799 g/mL	Y	Sowle J., 2022 DNA6686	Accepted									
Bulk density (KCP 2.6.2)	Test not required for liquids.														
Storage Stability after 14 days at 54° C (KCP 2.7.1)		GLOB2106cF Batch BRN 3891	<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 uniform white, opaque liquid. The sample was free flowing and coated the walls of the beaker. There were no signs of separation into oil, cream, sediment, claying or suspended solids. The sample had a solvent type odour.</td> </tr> <tr> <td>Propamocarb-</td> <td>448.0 g/L</td> <td>449.4 g/L</td> </tr> </tbody> </table>		Before storage	After storage	Appearance	The sample was a uniform white, opaque liquid. The sample was free flowing and coated the walls of the beaker. There were no signs of separation into oil, cream, sediment, claying or suspended solids. The sample had a solvent type odour.		Propamocarb-	448.0 g/L	449.4 g/L	Y	Sowle J., 2022 DNA6686	Accepted The product was stable after 2 weeks storage at 54°C. Stability pf packaging – the sample was stored in a white 1.0 L HDPE
	Before storage	After storage													
Appearance	The sample was a uniform white, opaque liquid. The sample was free flowing and coated the walls of the beaker. There were no signs of separation into oil, cream, sediment, claying or suspended solids. The sample had a solvent type odour.														
Propamocarb-	448.0 g/L	449.4 g/L													

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
			HCl				bottle. After 2 weeks of storage at 54°C the bottle showed no sign of leaks or visual seepage and no signs of panelling. The sample packaging remained unchanged post 2 weeks storage at 54°C. The sample remained a uniform white opaque liquid. The sample remained free-flowing and coated the walls of the beaker. Any separation or sedimentation/claying occurs. The appearance of sample remained unchanged post 2 weeks storage at 54°C from the pre storage sample. Weight change of bottle containing test item after two weeks of storage at 54°C: - 1279.46 g (prior to storage) - 1279.17 g (post 2 week accelerated storage). Analytical methods
			Mandipropamid	76.21 g/L	74.60 g/L		
			Impurity 1	< LOQ*	< LOQ*		
			pH neat (CIPAC MT 75.3)	4.97	5.01		
			pH 1% dilution (CIPAC MT 75.3)	5.78	6.20		
			Spontaneity of dispersion (CIPAC MT 160)	Propamocarb-HCl			
				In CIPAC Water A: 101.0%	In CIPAC Water A: 99.46%		
				In CIPAC Water D: 100.5%	In CIPAC Water D: 100.8%		
				Mandipropamid			
			Suspensibility (CIPAC MT 184.1) High rate: 2L Formulation in 150L of water Low rate: 2L Formulation in 150 L of water	Propamocarb-HCl			
				High rate: 101.8%	High rate: 101.0%		
				Low rate: 100.2%	Low rate: 100.4%		
				Mandipropamid			
			Pourability (CIPAC MT 148.1)	High rate: 100.9%	High rate: 99.22%		
				Low rate: 100.4%	Low rate: 100.8%		
				Poured Residue: 2.1850%	Poured Residue: 3.1637%		
				1st Water Rinsed Residue:	1st Water Rinsed Residue:		

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments	
				0.4500% 2nd Water Rinsed Residue: 0.1397% Acetone Rinsed Residue: 0.0038%	0.5964% 2nd Water Rinsed Residue: 0.1688% Acetone Rinsed Residue: 0.0076%			<p>used for analysing a.s. and relevant impurity in the PPP are assessed in B5 section. They are validated in accordance with SANCO/3030/99 rev.5.</p> <p>The analytical method which was used to determined active ingredient (Propamocarb-HCl) content was validated in GLP laboratory (in-house methodology validated in study DNA6689). The content of active ingredient - Propamocarb-HCl - was determined by LC-QQQ method.</p> <p>The concentration of Propamocarb-HCl after 2 weeks storage at 54°C was equal to 99.86% of declared content. Concentrations of the a.s. after storage are in the FAO/WHO tolerance.</p> <p>The analytical method which was used to determined active</p>
			Wet sieve (CI-PAC MT 185)	0.0060%	0.0104%			
			Dilution stability (CIPAC MT 41.1)	No separation seen post 24 hours at 20.0°C ±2°C				
			*Impurity 1 LOQ = 0.004 g/kg, equivalent to 0.0533 g/kg in Mandipropamid a.s. as manufactured					
			No significant changes were observed.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>ingredient (Mandipropamid) content was validated in GLP laboratory (in-house methodology validated in study DNA6689). The content of active ingredient - Mandipropamid - was determined by HPLC-PDA method. The concentration of Mandipropamid after 2 weeks storage at 54°C was equal to 99.47% of declared content. Concentrations of the a.s. after storage are in the FAO/WHO tolerance.</p> <p>The analytical method which was used to determined relevant impurity (SYN 545038 – impurity 1) content was validated in GLP laboratory (in-house methodology validated in study DNA6689). The content of SYN 545038 was determined by LC-QTOF. The concentration of SYN 545038 before and</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>after 2 weeks storage at 54°C in sample was < 0.004 g/kg equivalent to < 0.0533 g/kg relative to the active ingredient content (Mandipropamid). The requirements of Commission Implementing Regulation (EU) No 188/2013 were met. According to above mentioned Regulation the maximum content of SYN 545038 in Mandipropamid is 0.1 g/kg.</p> <p>There were no difference in pH of initial product and after 2 weeks of storage at 54°C. Acidity and alkalinity were not required as pH >4 and <10.</p> <p>The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water. As for the determination of</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>suspensibility, chemical assay ('active spontaneity') is the only reliable means to measure the mass of active substance in dispersion in the spontaneity test according to MT 160. The LC-QQQ (for Propamocarb-HCl) and HPLC-PDA (for Mandipropamid) analytical methods for spontaneity of dispersion were validated in study DNA6689. According to CIPAC MT 160 method The mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %. The above mentioned criteria were met for active substances after two weeks of storage at 54°C.</p> <p>Suspensibility is determined to</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying. For the determination of mass of active substances still in suspension the validated analytical method was used. The LC-QQQ for Propamocarb-HCl and HPLC-PDA for Mandipropamid. According to CIPAC MT 184 method the mean measured active suspensibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for the active substances after two weeks of storage at 54°C.</p> <p>The data of Pourability are required to demonstrate that the user can make use of the maximum amount of the preparation and</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>that an excessive amount of the material does not remain in the container. Acceptable limits: Maximum 5 % residue. The above mentioned criteria were met for the test item before and after two weeks storage at 54°C.</p> <p>A 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 above mentioned criteria were met for the test item after two weeks storage at 54°C.</p>
Stability after storage for other periods and/or temperatures			Not required, GLOB2106cF is stable after 14 days at 54°C.			Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																			
(KCP 2.7.2)																									
Minimum content after heat stability testing (KCP 2.7.3)	Method validated in DNA6689	GLOB2106cF Batch BRN 3891	<table border="1"> <thead> <tr> <th></th> <th>Before storage</th> <th>After storage</th> </tr> </thead> <tbody> <tr> <td>Propamocarb-HCl</td> <td>448.0 g/L</td> <td>449.4 g/L</td> </tr> <tr> <td>Mandipropamid</td> <td>76.21 g/L</td> <td>74.60 g/L</td> </tr> </tbody> </table>		Before storage	After storage	Propamocarb-HCl	448.0 g/L	449.4 g/L	Mandipropamid	76.21 g/L	74.60 g/L	Y	Sowle J., 2022 DNA6686	Accepted										
	Before storage	After storage																							
Propamocarb-HCl	448.0 g/L	449.4 g/L																							
Mandipropamid	76.21 g/L	74.60 g/L																							
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	GLOB2106cF Batch BRN 3891	<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 appearance remained unchanged post low temperature storage.</td> </tr> <tr> <td rowspan="2">Suspensibility (CIPAC MT 184.1) High rate: 2L Formulation in 150L of water Low rate: 2L Formulation in 150 L of water</td> <td colspan="2">Propamocarb-HCl</td> </tr> <tr> <td>High rate: 101.8% Low rate: 100.2%</td> <td>High rate: 100.9% Low rate: 100.3%</td> </tr> <tr> <td rowspan="2"></td> <td colspan="2">Mandipropamid</td> </tr> <tr> <td>High rate: 100.9% Low rate: 100.4%</td> <td>High rate: 99.23% Low rate: 101.0%</td> </tr> <tr> <td>Wet sieve (CI-PAC MT 185)</td> <td>0.0060%</td> <td>0.0114%</td> </tr> </tbody> </table> <p>The sample remained unchanged post low temperature storage.</p>		Before storage	After storage	Appearance	The sample appearance remained unchanged post low temperature storage.		Suspensibility (CIPAC MT 184.1) High rate: 2L Formulation in 150L of water Low rate: 2L Formulation in 150 L of water	Propamocarb-HCl		High rate: 101.8% Low rate: 100.2%	High rate: 100.9% Low rate: 100.3%		Mandipropamid		High rate: 100.9% Low rate: 100.4%	High rate: 99.23% Low rate: 101.0%	Wet sieve (CI-PAC MT 185)	0.0060%	0.0114%	Y	Sowle J., 2022 DNA6686	Accepted
	Before storage	After storage																							
Appearance	The sample appearance remained unchanged post low temperature storage.																								
Suspensibility (CIPAC MT 184.1) High rate: 2L Formulation in 150L of water Low rate: 2L Formulation in 150 L of water	Propamocarb-HCl																								
	High rate: 101.8% Low rate: 100.2%	High rate: 100.9% Low rate: 100.3%																							
	Mandipropamid																								
	High rate: 100.9% Low rate: 100.4%	High rate: 99.23% Low rate: 101.0%																							
Wet sieve (CI-PAC MT 185)	0.0060%	0.0114%																							
Ambient temperature shelf life (KCP 2.7.5)		GLOB2106cF Batch BRN 3891	A 2 and 3 year storage stability study at ambient temperature is ongoing.	Y	Sowle J., 2024 DNA6687 Sowle J., 2025 DNA6688	Missing storage stability study at ambient temperature.																			
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not applicable.																						
Wettability (KCP 2.8.1)	Test not required for liquids.																								
Persistence of foaming	CIPAC MT 47.3	GLOB2106cF	At the high application rate: 2L Formulation in	Y	Sowle J., 2022	Accepted																			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.2)		Batch BRN 3891	150L of water After 1 minute: 1.0mL After 12 minutes: 0.0mL At the low application rate: Low rate: 2L Formulation in 150 L of water After 1 minute: 0.0mL After 12 minutes: 0.0mL		DNA6686	
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	GLOB2106cF Batch BRN 3891 High rate: 2L Formulation in 150L of water Low rate: 2L Formulation in 150 L of water	Propamocarb-HCl: At the high application rate: 101.8% At the low application rate: 100.2% Mandipropamid: At the high application rate: 100.9% At the low application rate: 100.4%	Y	Sowle J., 2022 DNA6686	Accepted
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	GLOB2106cF Batch BRN 3891	Propamocarb-HCl: CIPAC Water A: 101.0% CIPAC Water D: 100.5% Mandipropamid: CIPAC Water A: 101.1% CIPAC Water D: 100.7%	Y	Sowle J., 2022 DNA6686	Accepted
Dispersion stability (KCP 2.8.3.3)	Test not required for an SC formulation.					
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41.1	GLOB2106cF Batch BRN 3891	The sample remained a uniform white solution with no signs of separation into oil, cream, sediment, claying or suspended solids post 24 hours at 20.0°C ±2°C at the high and low application rate. High application rate: 2L Formulation in 150L of water	Y	Sowle J., 2022 DNA6686	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Low application rate: 2L Formulation in 150 L of water			
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Test not required for an SC formulation.					
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	GLOB2106cF Batch BRN 3891	Using a 75 µm sieve: 0.0060%	Y	Sowle J., 2022 DNA6686	Accepted A 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 above mentioned criteria were met.
Dust content (KCP 2.8.5.2.1)	Test not required for an SC formulation.					
Particle size of dust (KCP 2.8.5.2.2)	Test not required for an SC formulation.					
Attrition (KCP 2.8.5.3)	Test not required for an SC formulation.					
Hardness and integrity	Test not required for an SC formulation.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.4)						
Emulsifiability (KCP 2.8.6.1)	Test not required for an SC formulation.					
Emulsion stability (KCP 2.8.6.2)	Test not required for an SC formulation.					
Re-emulsifiability (KCP 2.8.6.3)	Test not required for an SC formulation.					
Flowability (KCP 2.8.7.1)	Test not required for an SC formulation.					
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	GLOB2106cF Batch BRN 3891	Poured Residue: 2.1850% 1st Water Rinsed Residue: 0.4500% 2nd Water Rinsed Residue: 0.1397% Acetone Rinsed Residue: 0.0038%	Y	Sowle J., 2022 DNA6686	Accepted The data of Pourability 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 above mentioned criteria were met.
Dustability following accelerated storage (KCP 2.8.7.3)	Test not required for liquids.					
Physical compatibility of tank mixes (KCP 2.9.1)	Not relevant: no tank mix on the label.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
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: no seed treatment.					
Distribution to seed (KCP 2.10.2)	Not applicable: no seed treatment.					
Other/special studies (KCP 2.11)	Not required.					

3 Section 3 is presented as a separate document

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

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

zRMS conclusion

Based on the accelerated storage study (14 days at 54°C) in HDPE pack, all packs, listed below, are accepted. In case of aqueous formulations like SC extrapolation from HDPE is allowed for other plastics (used as PPP packaging materials).

Table 4.1-1: Packaging information for 100 mL bottle

Type	Description
Material:	PET or HDPE (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:	PET or HDPE (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:	PET or HDPE (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:	PET or HDPE (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:	PET or HDPE (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:	PET or HDPE (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:	PET or HDPE (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
UN/ADR	compliant

Table 4.1-8: Packaging information for 5 L container

Type	Description
Material:	PET or HDPE (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:	PET or HDPE (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 15 L container

Type	Description
Material:	PET or HDPE (High Density PolyEthylene)
Shape/size:	rectangular / approx. 245 mm width x 294 mm length x 311 mm height
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information for 20 L container

Type	Description
Material:	PET or HDPE (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 GLOB2106cF (Sowle J., 2022). The procedure is summarized below.

106.67mL of pre storage sample DNA6686/1 was dissolved in 8 Litres of Water in the spray tank. After spraying, the tank was washed with three 400mL water rinses followed by collection of remaining residue with 100mL of Acetonitrile. The collected residue was then assayed by LC-QQQ for Propamocarb HCl and by HPLC-PDA for Mandipropamid.

Conclusion:

The sample of GLOB2106cF SC formulation containing Propamocarb HCl and Mandipropamid has a mean Effectiveness of Cleaning result of <0.0042% (0.00251%) residue for Propamocarb HCl using three Water rinses.

The sample of GLOB2106cF SC formulation containing Propamocarb HCl and Mandipropamid has a mean Effectiveness of Cleaning result of 0.00963% residue for Mandipropamid using three Water rinses.

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

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	Sowle J.	2022	Determination of storage stability and shelf life specification data for a formulation GLOB2106cF containing Propamocarb HCl and Mandipropamid stored at 54°C±2°C for two weeks, in compliance with good laboratory practice DNA6686 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP2.2.1-2.2.2	Norris D.	2023	Theoretical certificate of explosive and oxidising properties for a formulation containing propamocarb HCl and mandipropamid	N	Globachem NV
KCP 2.7.5	Sowle J.	2024	Determination of storage stability and shelf life specification data for a formulation GLOB2106cF containing Propamocarb HCl and Mandipropamid stored at ambient temperature for 2 years, in compliance with good laboratory practice DNA6687 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP 2.7.5	Sowle J.	2025	Determination of storage stability and shelf life specification data for a formulation GLOB2106cF containing Propamocarb HCl and Mandipropamid stored at ambient temperature for 3 years, in compliance with good laboratory practice DNA6688 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV

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

A 2.1 Propamocarb-HCl

No new data submitted.

A 2.2 Mandipropamid

No new data submitted.