

**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: GLOB2112dH

Product name: Walkover Trio

Chemical active substances:

Mesotrione, 375 g/L

Thiencarbazone-methyl, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**

(authorization)

**Update February 2026**

Applicant: Globachem NV

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zRMS Assessment: 31/03/2025

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List of references update: 10/07/2025

zRMS assessment of new pH measurement study: 05/03/2026

Version after commenting: 12/04/2026

## Version history

When	What
September 2024	Initial dossier submission by applicant for approval of new product.
March 2025	ZRMS assessment
July 2025	zRMS – after commenting period
July 2025	List of references update
February 2026	Update by applicant to include new pH measurement
March 2026	zRMS assessment of new pH measurement study
April 2026	After commenting period

After the comment period, the documentation does not require any additional corrections.

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State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

Sufficient data on identity, physical and chemical properties and other information are not available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- data gap 1: 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.

## 1 Section 1: Identity of the plant protection product

### 1.1 Applicant (KCP 1.1)

Name: Globachem NV  
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### 1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

#### 1.2.1 Producer(s) of the preparation

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

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

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

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

##### 1.2.3.1 Mesotrione

Mesotrione	min. 940 930 g/kg
Relevant impurity	
R287431	Max 2 mg/kg
R287432	Max 2 g/kg

1,2-dichloroethane

Max 1 g/kg

Further information relating to the impurities is confidential information – data is provided separately (Part C)

### 1.2.3.2 Thiencarbazone-methyl

Thiencarbazone-methyl

min. 990 950 g/kg

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

Trade name: Please refer to Registration Report Part A for the relevant country (or)

Trade name: Walkover Trio

Company code number: GLOB2112dH

## 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)

GLOB2112dH 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)
Mesotrione	375	356.25-393.75	399	32.83
Thiencarbazone-methyl	75	67.5-82.5	75.8	6.24

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

\*\* Based on the density of the formulation = 1.2153 g/mL

**Table 1.4-2: Safener and synergists**

Safener / synergist	Declared content of the safener / synergist (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Cyprosulfamide	112	105.28-118.72	115.5	9.50

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

\*\* Based on the density of the formulation = 1.2153 g/mL

**Table 1.4-3: Relevant impurities**

Relevant impurity <b>Mesotrione</b>	Maximum content (g/L)
R287431	0.00075
R287432	0.75
1,2-dichloroethane	0.375

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

**Table 1.4-4: Information on mesotrione**

Type	Name/Code Number
ISO common name	Mesotrione
CAS No.	104206-82-8
EC No.	<del>609-064-00</del> <b>600-533-4</b>
CIPAC No.	625

**Table 1.4-45: Information on thien carbazon-methyl**

Type	Name/Code Number
ISO common name	Thien carbazon-methyl
CAS No.	317815-83-1
EC No.	<del>Not allocated</del> <b>635-659-9</b>
CIPAC No.	797

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

**Table 1.4-56: Information on cyprosulfamide**

Type	Name/Code Number
Safener/Synergist	Safener
ISO common name	Cyprosulfamide
CAS No.	221667-31-8
EC No.	Not allocated
CIPAC No.	796

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)**

Herbicide

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of uniform white liquid, with an emulsion paint odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature more than 100°C. In aqueous solution, it has a pH value around 3.06 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 8 week 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*. Its technical characteristics are acceptable for a *suspension concentrate* formulation. The intended concentration of use is 0.043% to 0.2%.

### zRMS comments

The new pH study was provided by applicant. The study was performed in GLP laboratory and according to CIPAC MT 75.3 method.

The study is acceptable.

The sample of a Suspension Concentrate Formulation, product code GLOB2112dH containing 75 g/L Thiencarbazone-methyl, 375 g/L Mesotrione and 112 g/L Cyprosulfamide had a mean pH of the neat Formulation determined as 2.23 at 20.1°C.

### 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 GLOB2112dH 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	GLOB2112dH Batch MAM 107683	The sample was a uniform white liquid. It was opaque and free flowing, coating the walls of a beaker. It showed no signs of separation into cream, oil, sedimentation, claying or suspended solids. It had an odour similar to emulsion paint.	Y	Fitzmaurice T., 2023 DNA7203	<b>Accepted</b>
Explosive properties (KCP 2.2.1)	Theoretical certificate	-	Not explosive.	N	Norris D., 2024 DNA7397	<b>Accepted</b> Based on the information of active substances (no explosive properties according to the a.s. structural formula) and ingredients of PPP. The active substances and ingredients of test item are not classified according to CLP Regulation as explosive.
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	-	Not oxidising.	N	Norris D., 2024 DNA7397	<b>Accepted</b> Based on the information of active substances (no oxidising properties according to the a.s. structural formula) and ingredients of PPP. The active substances and ingredients of test item are not classified according to CLP

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						Regulation as oxidising.
Flash point (KCP 2.3.1)	EEC A9	GLOB2112dH Batch MAM 107683	The sample did not flash below 100°C and is therefore considered not highly flammable.	Y	Fitzmaurice T., 2023 DNA7203	<b>Accepted</b> Flash point was determined in a closed cup flash point apparatus. No flash point below 100°C. The test item is not classified, according to CLP Regulation, as flammable.
Flammability (KCP 2.3.2)	Test not required for liquids.					<b>Accepted</b>
Self-heating (KCP 2.3.3)	EEC A15	GLOB2112dH Batch MAM 107683	The sample did not auto-ignite below 400°C and is therefore considered not highly flammable.	Y	Fitzmaurice T., 2023 DNA7203	<b>Accepted</b>
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC 75.3 CIPAC MT 191  CIPAC 75.3	GLOB2112dH Batch MAM 107683 – <i>small-scale production</i>  GLOB2112dH Batch CHE24GLO10S01-4118046 – <i>large-scale industrial production</i>	pH neat: 1.99 7.4539% m/m as H <sub>2</sub> SO <sub>4</sub>  pH neat: 2.23	Y  Y	Fitzmaurice T., 2023 DNA7203  Norris D., 2026 DNA8467	<b>Accepted</b> The pH was less than 4, the acidity was tested. The pH was determined at 20°C.  <b>Accepted</b> The new pH study was provided by applicant. The study was performed in GLP Laboratory. The study was performed according to CIPAC

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						MT 75.3 method. The pH at 20°C±0.5°C of neat formulation was measured. The pH meter was calibrated using a three point calibration at pH 4, 7 and 9 at the temperature associated to the test required, in this case 20°C. The pH of the deionised water was measured at 20°C and accurately recorded. Mean of 2 results: pH 2.23 at 20.1°C
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB2112dH Batch MAM 107683	pH 1% dilution: 3.06	Y	Fitzmaurice T., 2023 DNA7203	<b>Accepted</b> The pH was determined at 20°C.
Viscosity (KCP 2.5.1)	OECD 114	GLOB2112dH Batch MAM 107683	Non-Newtonian liquid.	Y	Fitzmaurice T., 2023 DNA7203	<b>Accepted</b> The viscosity was determined at different shear rates at 20°C and 40°C. Conclusion: the sample of GLOB2112dH is a Non-Newtonian liquid.
Surface tension (KCP 2.5.2)	EEC A5	GLOB2112dH Batch MAM 107683	At 20°C: 44.78mN/m ±0.45 SD: 0.273 At 25°C: 45.73mN/m ±0.74 SD: 0.324	Y	Fitzmaurice T., 2023 DNA7203	<b>Accepted</b> The surface tension of test item was measured at 20°C and at 25°C at

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments		
						maximum recommended concentration (application rate 0.2 L in 100 L Water). The surface tension is below 60 mN/m, the product is surface active.		
Relative density (KCP 2.6.1)	EEC A3	GLOB2112dH Batch MAM 107683	At 20°C: 1.2153 g/mL	Y	Fitzmaurice T., 2023 DNA7203	Accepted		
Bulk density (KCP 2.6.2)	Test not required for liquids.					Accepted		
Storage Stability after 14 days at 54° C (KCP 2.7.1)	Not performed							
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	8 weeks at 40°C	GLOB2112dH Batch MAM 107683		Before storage	After storage	Y	Fitzmaurice T., 2023 DNA7203	Accepted Based on the result of accelerated storage stability study, PPP was concluded to be stable when stored at the elevated temperature of 40°C for 8 weeks.  The PPP stored at elevated temperature 40°C (aged sample) in 1L HDPE (Conventional) white bottle was analysed for
			Appearance	The sample was a uniform white liquid. It was opaque and free flowing, coating the walls of a beaker. It showed no signs of separation into cream, oil, sedimentation, claying or suspended solids. It has an odour similar to emulsion paint.  The sample appearance remained unchanged post accelerated storage after inversion.				
			Thiencarbazone-methyl	77.47 g/L	76.25 g/L			
			Mesotrione	391.9 g/L	389.0 g/L			
			Cyprosulfamide	117.5 g/L	126.8 g/L 116.8 g/L			
			Impurity 1	Not detectable above the LOQ				

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			R1 (R287431)	level of 0.50 mg/kg (Equating to 1.6204 mg/kg in the active substance as manufactured)				<p>ist active ingredient content (Thiencarbazone-methyl and Mesotrione),content of safener - Cyprosulfamide, content of relevant impurity of Mesotrione, appearance, stability, pH, spontaneity of dispersion, suspensibility, wet sieve test, pourability, particle size and for stability of packaging and packaging/preparation interactionsat before storage and at the end of the 8 weeks of storage period.</p> <p>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, pourability, particle size distribution of the</p>
			Impurity 2 R2 (R287432)	Not detectable above the LOQ level of 0.10 g/kg (Equating to 0.3241 g/kg in the active substance as manufactured)				
			Impurity 3 1,2-dichloroethane	0.0537 g/kg (Equating to 0.1740 g/kg in the active substance as manufactured)	0.0542 g/kg (Equating to 0.1757 g/kg in the active substance as manufactured)			
			pH neat (CIPAC MT 75.3)	2.191.99	1.97			
			pH 1% dilution (CIPAC MT 75.3)	3.06	3.04			
			Acidity/Alkalinity (CIPAC MT 191)	7.4539% m/m as H <sub>2</sub> SO <sub>4</sub>	7.0373% m/m as H <sub>2</sub> SO <sub>4</sub>			
			Spontaneity of dispersion (CIPAC MT 160)	Thiencarbazone-methyl				
				CIPAC Water A: 99.16% CIPAC Water D: 99.66%	CIPAC Water A: 100.8% CIPAC Water D: 101.6%			
				Mesotrione				
				CIPAC Water A: 98.65% CIPAC Water D: 99.14%	CIPAC Water A: 99.59% CIPAC Water D: 100.2%			
				Cyprosulfamide				
				CIPAC Water A: 98.97% CIPAC Water D: 99.53%	CIPAC Water A: 100.7% CIPAC Water D: 101.4%			
				Thiencarbazone-methyl				
				High rate: 100.4%	High rate: 103.0%			
			Suspensibility (CIPAC MT 184.1)					

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
				Low rate: 101.2% Mesotrione High rate: 99.97% Low rate: 100.7% Cyprosulfamide High rate: 100.3% Low rate: 100.6%	Low rate: 100.4% High rate: 102.0% Low rate: 99.40% High rate: 102.2% Low rate: 99.36%		<p>test item for sample stored at elevated temperature of 40°C for 8 weeks were well compared with that of the results obtained for the test item before storage.</p> <p>The test item found to be non-corrosive for HDPE commercial containers as After the study there was no significant change in the weight of commercial containers (1L HDPE bottle) (Weight – Prior to Storage: 1259,34 g, Weight – post Accelerated Storage: 1258,95 g) and the bottle showed no signs of leaks, visual seepage or panneling after storage at elevated temperature for 8 weeks. The sample appearance remained unchanged post accelerated storage at 40°C for 8 weeks. after inversion</p>
			Pourability (CI-PAC MT 148.1)	Poured Residue: 3.5680% Water Rinsed Residue: 0.1561 % Acetone Rinsed Residue: 0.0091%	Poured Residue: 3.2809% Water Rinsed Residue: 0.1023% Acetone Rinsed Residue: 0.0091%		
			Wet sieve (CI-PAC MT 185)	0.0632%	0.0543%		
			Particle size (CIPAC MT 187 laser diffraction)	d10: 0.681 µm d50: 1.815 µm d90: 4.969 µm mean: 2.363 µm	d10: 0.713 µm d50: 1.974 µm d90: 5.336 µm mean: 2.578 µm		



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>The content of active substances – Thiencarbazone-methyl and Mesotrione and safener – Cyprosulfamide - in PPP was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory (validated in study DNA7206). The loss of active substances and safener after 8 weeks storage of test item at 40°C was almost negligible. It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation. Active substances and safener content before and after storage meet FAO Limits.</p> <p>The content of Impurity 1 R1</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>(R287431) in PPP was determined by LC-  QQQ. The analytical method was developed and validated in GLP laboratory (validated in study DNA7206). The sample of GLOB2112dH - pre storage and after 8 weeks storage at 40°C – did not contain Impurity 1 above the LOQ level of 0.50 mg/Kg in the Formulation, equating to 1.6204 mg/Kg in the Active substance as manufactured. Specification Limit for Impurity 1: Maximum 2 mg/Kg in the active substance (Mesotrione) as manufactured, equivalent to 0.75 mg/Kg in the formulation.</p> <p>The content of Impurity 2 R2 (R287432) in PPP was determined by HPLC-PDA. The analytical method was developed</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>and validated in GLP laboratory (validated in study DNA7206). The sample of GLOB2112dH - pre storage and after 8 weeks storage at 40°C – did not contain Impurity 2 above the LOQ level of 0.10 g/Kg in the Formulation, equating to 0.3241 g/Kg in the Active substance as manufactured. Specification Limit for Impurity 2: Maximum 2 g/Kg in the active substance (Mesotrione) as manufactured, equivalent to 0.75 g/Kg in the formulation.</p> <p>The content of Impurity 3 - 1,2-dichloroethane in PPP was determined by GC-MSD. The analytical method was developed and validated in GLP laboratory (validated in study DNA7206). The sample of</p>

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								GLOB2112dH - pre storage contain Impurity 3 in concentration of 0.0537 g/Kg equivalent to 0.174 g/Kg in the active substance as manufactured. The sample of GLOB2112dH - post storage contain Impurity 3 in concentration of 0.0542 g/Kg equivalent to 0.176 g/Kg in the active substance as manufactured. Specification Limit for Impurity 3: Maximum 1 g/Kg in the active substance (Mesotrione) as manufactured, equivalent to 0.375 g/Kg in the formulation.
Minimum content after heat stability testing (KCP 2.7.3)	Method validated in DNA7206	GLOB2112dH Batch MAM 107683	Thiencarbazone-methyl: 77.47 g/L Mesotrione: 391.9 g/L Cyprosulfamide: 17.5 g/L			Y	Fitzmaurice T., 2023 DNA7203	Accepted
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	GLOB2112dH Batch MAM 107683		Before storage	After storage	Y	Fitzmaurice T., 2023 DNA7203	Accepted Based on the results of the low temperature stability test, it is
			Appearance	The sample appearance remained unchanged post low temperature storage. The test was repeated with the				

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
				addition of a crystal of thien carbazole-methyl after 24 hours. The crystal dissolved, the sample appearance remained unchanged post low temperature storage. The test was repeated with the addition of a crystal of cyprosulfamide after 24 hours. The crystal dissolved, the sample appearance remained unchanged post low temperature storage.			concluded that test item was homogenous liquid without any phase separation when stored at 0±2°C for 7 days. Suspensibility and wet sieve test were determined after storage. Suspensibility: the content of active substances – Thien carbazole-methyl and Mesotrione and safener – Cyprosulfamide - in suspension was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory (validated in study DNA7206). Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.
				Thien carbazole-methyl			
				High rate: 100.4%	High rate: 100.2%		
				Low rate: 101.2%	Low rate: 101.6%		
				Mesotrione			
				High rate: 99.97%	High rate: 99.83%		
				Low rate: 100.7%	Low rate: 101.1%		
				Cyprosulfamide			
				High rate: 100.3%	High rate: 100.0%		
				Low rate: 100.6%	Low rate: 101.0%		
				Wet sieve (CI-PAC MT 185)	0.0632%	0.0502%	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						The criteria were met for both active substances and safener 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)		GLOB2112dH Batch MAM 107683	A 2 and 3 year storage stability study at ambient temperature is ongoing.	Y	Fitzmaurice T., 2025 DNA7204 Fitzmaurice T., 2026 DNA7205	<b>Data gap</b> Missing storage stability study at ambient temperature - study is ongoing (2 and 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.
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.					<b>Accepted</b>
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB2112dH Batch MAM 107683	At the high application rate: After 1 min: 14mL After 12 min: 12mL	Y	Fitzmaurice T., 2023 DNA7203	<b>Accepted</b> Persistent foam is determined to measure

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			At the low application rate: After 1 min: 4mL After 12 min: 2mL			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 for maximum application rate (0.2 litres of GLPB2112dH in 100 Litres water) and minimum application rate (0.1 litres of GLPB2112dH in 300 Litres water)
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	GLOB2112dH Batch MAM 107683	Thiencarbazone-methyl: High Application Rate: 100.4% Low Application Rate: 101.2%  Mesotrione: High Application Rate: 99.97% Low Application Rate: 100.7%  Cyprosulfamide: High Application Rate: 100.3% Low Application Rate: 100.6%		Fitzmaurice T., 2023 DNA7203	<b>Accepted</b> Suspensibility: the content of active substances – Thiencarbazone-methyl and Mesotrione and safener – Cyprosulfamide - in suspension was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						laboratory (validated in study DNA7206). 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 and safener at minimum test item concentration and maximum test item concentration.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	GLOB2112dH Batch MAM 107683	Thiencarbazone-methyl: In CIPAC Water A: 99.16% In CIPAC Water D: 99.66%  Mesotrione: In CIPAC Water A: 98.65% In CIPAC Water D: 99.14%  Cyprosulfamide: In CIPAC Water A: 98.97% In CIPAC Water D: 99.53%		Fitzmaurice T., 2023 DNA7203	<b>Accepted</b> The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water.  The content of active substances – Thiencarbazone-methyl and Mesotrione and safener – Cyprosulfamide - in dispersion was determined by High Performance Liquid



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						Chromatography (HPLC). The method was developed and validated in GLP laboratory (validated in study DNA7206). 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)	Test not required for an SC formulation.					Accepted
Degree of dissolution and dilution stability (KCP 2.8.4)	Test not required for an SC formulation.					Accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187 laser diffraction	GLOB2112dH Batch MAM 107683	d10: 0.681µm d50: 1.815µm d90: 4.969µm  Overall Mean Particle size: 2.363µm	Y	Fitzmaurice T., 2023 DNA7203	Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	GLOB2112dH Batch MAM 107683	0.0632%		Fitzmaurice T., 2023 DNA7203	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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						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)	Test not required for an SC formulation.					Accepted
Particle size of dust (KCP 2.8.5.2.2)	Test not required for an SC formulation.					Accepted
Attrition (KCP 2.8.5.3)	Test not required for an SC formulation.					Accepted
Hardness and integrity (KCP 2.8.5.4)	Test not required for an SC formulation.					Accepted
Emulsifiability (KCP 2.8.6.1)	Test not required for an SC formulation.					Accepted
Emulsion stability (KCP 2.8.6.2)	Test not required for an SC formulation.					Accepted
Re-emulsifiability (KCP 2.8.6.3)	Test not required for an SC formulation.					Accepted
Flowability (KCP 2.8.7.1)	Test not required for an SC formulation.					Accepted
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	GLOB2112dH Batch MAM 107683	Poured Residue: 3.5680% Water Rinsed Residue: 0.1561% Acetone Rinsed Residue: 0.0091%		Fitzmaurice T., 2023 DNA7203	Accepted The data are required to demonstrate that the user can make use of the maximum amount of the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						preparation and that an excessive amount of the material does not remain in the container. Acceptable Limits: Maximum 5 % residue. Acceptable limit for rinsed residue: 0.25 %. The criteria were met.
Dustability following accelerated storage (KCP 2.8.7.3)	Test not required for liquids.					Accepted
Physical compatibility of tank mixes (KCP 2.9.1)	Test not required.					Accepted
Chemical compatibility of tank mixes (KCP 2.9.2)	Test not required.					Accepted
Adhesion to seeds (KCP 2.10.1)	Not applicable: no seed treatment.					Accepted
Distribution to seed (KCP 2.10.2)	Not applicable: no seed treatment.					Accepted
Other/special studies (KCP 2.11)	None					Accepted

### 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 comments

The HDPE bottle was used in accelerated storage studies (8 weeks at 40°C). The HDPE bottle was stable in accelerated storage studies so the storage stability data obtained in these studies can be extrapolated for storage in HDPE-EVOH; HDPE-F, HDPE/PA 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” and 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).

**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 (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
Shape/size:	cylindrical / approx. 45 mm diameter x 90 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 150 mL bottle**

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
Shape/size:	cylindrical / approx. 60 mm diameter x 90 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-3: Packaging information for 250 mL bottle**

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

**Table 4.1-5: Packaging information for 500 mL bottle - SPACK**

Type	Description
Material:	High density polyethylene (HDPE) or co-extruded High density polyethylene / Polyamide (HDPE/PA)
Shape/size:	Bottle (cylindrical) / approx. 76 mm x 170 mm
Opening, closure and seal:	Screw cap closure (45 mm diameter) with induction heat seal or compression wad and tamper evident ring
Manner of construction	Extrusion blow-molded
UN/ADR	compliant

**Table 4.1-6: Packaging information for 600 mL bottle**

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
Shape/size:	cylindrical / approx. 69 mm diameter x 204 mm
Opening:	39 mm inner diameter

Type	Description
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-7: Packaging information for 1 L bottle**

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
Shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	42 or 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 1 L bottle - SPACK**

Type	Description
Material:	High density polyethylene (HDPE) or co-extruded High density polyethylene / Polyamide (HDPE/PA) or Polyethylene terephthalate (PET)
Shape/size:	Bottle (cylindrical) / approx. 89 mm x 231 mm
Opening, closure and seal:	Screw cap closure (45 mm diameter) with induction heat seal or compression wad and tamper evident ring
Manner of construction	Extrusion blow-molded
UN/ADR	compliant

**Table 4.1-9: Packaging information for 1 L bottle – Evo Pack**

Type	Description
Material:	High density polyethylene (HDPE) or co-extruded High density polyethylene / Polyamide (HDPE/PA) or Polyethylene terephthalate (PET)
Shape/size:	Bottle (cylindrical) / approx. 91 mm x 221 mm
Opening, closure and seal:	Screw cap closure (63 mm diameter) with compression wad and tamper evident ring
Manner of construction	Blow-molded
UN/ADR	compliant

**Table 4.1-10: Packaging information for 2 L container**

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)

Type	Description
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 4.1-11: Packaging information for 3 L container**

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
Shape/size:	rectangular / approx. 160 mm width x 262 mm length x 115 mm height
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-12: Packaging information for 5 L container**

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
Shape/size:	rectangular / approx. 140 mm width x 190 mm length x 313 mm height
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-13: Packaging information for 5 L container - SPACK**

Type	Description
Material:	High density polyethylene (HDPE) or fluorinated high density polyethylene (f-HDPE)
Shape/size:	Canister (rectangular) / approx. 190 mm x 134 mm x 317 mm (L x W x H)
Opening, closure and seal:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring
Manner of construction	Extrusion blow-molded
UN/ADR	compliant



**Table 4.1-14: Packaging information for 5 L container – Evo Pack**

Type	Description
Material:	High density polyethylene (HDPE) or fluorinated high density polyethylene (f-HDPE)
Shape/size:	Rectangular / approx.. 189 x 137 x 309 mm (L x W x H)
Opening, closure and seal:	Screw cap closure (63 mm diameter) with compression wad and tamper evident ring
Manner of construction	Blow-molded
UN/ADR	compliant

**Table 4.1-15: Packaging information for 10 L container**

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
Shape/size:	rectangular / approx. 179 mm width x 240 mm length x 375 mm height
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-16: Packaging information for 10 L container - SPACK**

Type	Description
Material:	High density polyethylene (HDPE) or fluorinated high density polyethylene (f-HDPE)
Shape/size:	Canister (rectangular) / approx. 240 mm x 180 mm x 376 mm (L x W x H)
Opening, closure and seal:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring
Manner of construction	Extrusion blow-molded
UN/ADR	compliant

**Table 4.1-17: Packaging information for 10 L container – Evo Pack**

Type	Description
Material:	High density polyethylene (HDPE) or fluorinated high density polyethylene (f-HDPE)
Shape/size:	Rectangular / approx. 226 x 186 x 393 mm (L x W x H)
Opening, closure and seal:	Screw cap closure (63 mm diameter) with compression wad and tamper evident ring
Manner of construction	Blow-molded
UN/ADR	compliant

**Table 4.1-18: Packaging information for 15 L container**

Type	Description
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Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
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 4.1-19: Packaging information for 20 L container**

Type	Description
Material:	HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol), HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide)
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 GLOB2112dH (Fitzmaurice T., 2023). The procedure is summarized below.

The formulation was added to 8 L of Water in the spray tank at the required application rate. After spraying, the tank was washed with three 400 mL water rinses followed by collection of remaining residue with 100 mL Acetonitrile. The collected residue was then assayed by HPLC-UV.

Conclusion:

After three tank washes with 400 mL water 0.0267% thien carbazole-methyl residue, 0.00231% mesotri- one residue and 0.0142% cyposulfamide residue remained in the tank. This demonstrates that only a very limited amount of residue remains in the spray tank after cleaning.

#### **ZRMS comment**

##### **Accepted**

The effectiveness of cleaning of PPP (GLOB2112dH) was performed in the study DAN7203 “Determination of storage stability and shelf life specification data for GLOB2112dH, a suspension concentrate formulation containing thien carbazole-methyl, mesotrione and cyprosulfamide at accelerated temperatures.” The effectiveness of cleaning test of GLOB2112dH was carried out in accordance with test facility method: SOP DNA/A/028 “Determination of the concentration of active ingredient remaining in a garden sprayer following tank washing”. The formulation was diluted according to manufacturer’s instructions in a garden sprayer and sprayed until the sprayer is completely empty. Tank washing was then carried out using a suitable washing method - three tank washes with 400 mL water.

The residue of active substances – Thien carbazole-methyl and Mesotrione and safener – Cyprosulfamide - in the spray tank after cleaning was determined by High Performance Liquid Chromatography (HPLC). The method was developed and validated in GLP laboratory (validated in study DNA7206).

Only a very limited amount of residue remains in the spray tank after cleaning (0.0267% thien carbazole-methyl residue, 0.00231% mesotrione residue and 0.0142% cyprosulfamide residue remained in the tank).

### **4.3 Recommended methods and precautions (KCP 4.2)**

Reference is made to the submitted SDS where all the required and detailed information can be found. A summary is given below.

#### **4.3.1 Procedures for storage**

Storage conditions:	Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.
Incompatible products:	Strong bases. Strong acids.
Incompatible materials:	Sources of ignition. Direct sunlight.

#### **4.3.2 Transport**

In accordance with ADN / ADR / IATA / IMDG / RID

- UN number is 3082.
- Proper shipping name is “ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (thien carbazole-methyl, mesotrione)”
- Transport hazard class is 9.
- Packaging group is III

#### **4.3.3 Firefighting measures**

Suitable extinguishing media:	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media:	Do not use a heavy water stream.
Firefighting instructions:	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting:	Do not enter fire area without proper protective equipment, including respiratory protection.

#### **4.3.4 Exposure control**

All unnecessary exposure should be avoided. For personal protection measures reference is made to dRR

Part B Section 6.

#### **4.3.5 Environmental precautions**

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.  
Avoid release to the environment.

#### **4.4 Emergency measures (KCP 4.3)**

Reference is made to the submitted SDS where all the required and detailed information can be found.  
A summary is given below.

##### **4.4.1 Accidental release measures**

For non-emergency personnel:

Emergency procedures: Evacuate unnecessary personnel.

For emergency responders:

Protective equipment: Equip cleanup crew with proper protection.

Emergency procedures: Ventilate area.

##### **4.4.2 First aid measures**

General: Never give anything by mouth to an unconscious person. If exposed or concerned: get medical advice/attention.

After inhalation: Allow affected person to breath fresh air. Allow the victim to rest.

After skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

After eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

After ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

#### **4.5 Procedures for destruction and neutralisation (KCP 4.5)**

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage.  
Store away from other materials.

## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1-2.9	Fitzmaurice T.	2023	Determination of storage stability and shelf life specification data for GLOB2112dH, a suspension concentrate formulation containing thiencarbazone-methyl, mesotrione and cyprosulfamide at accelerated temperatures. DNA7203 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP 2.2 <i>Confidential – filed in Part C</i>	Norris D.	2024	Theoretical certificate of explosive and oxidising properties for GLOB2112dH. DNA7397 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP 2.4.1	Norris D.	2026	Analysis of GLOB2112dH, a suspension concentrate formulation containing thiencarbazone-methyl, mesotrione and cyprosulfamide to determine the pH, in compliance with good laboratory practice. DNA8467 David Norris Analytical Laboratories Ltd. 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**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
None					

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source 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**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
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                    Thiencarbazone-methyl**

No new data submitted.

### **A 2.2                    Mesotrione**

No new data submitted.