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)

Applicant: Globachem NV

Submission date: September 2024

zRMS Assessment: 31/03/2025

Version after commenting: 03/07/2025

List of references update: 10/07/2025

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

Table of Contents

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
Address:	Brustem Industriepark Lichtenberglaan 2019 3800 Sint-Truiden Belgium
Contact:	Sascha Truyens
Telephone number:	+32 11 263808
E-mail:	sascha.truyens@globachem.com

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 Mesotrione	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.	~~609-064-00~~ 600-533-4
CIPAC No.	625

Table 1.4-~~45~~: Information on thiencarbazone-methyl

Type	Name/Code Number
ISO common name	Thiencarbazone-methyl
CAS No.	317815-83-1
EC No.	~~Not allocated~~ 635-659-9
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%.

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	**Accepted**
Explosive properties (KCP 2.2.1)	Theoretical certificate	-	Not explosive.	N	Norris D., 2024 DNA7397	**Accepted** 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	**Accepted** 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	**Accepted** Flash point was determined in a closed cup flash point apparatus. No flash point below 100ºC. The test item is not classified, according to CLP Regulation, as flammable.
Flammability (KCP 2.3.2)	Test not required for liquids.					**Accepted**
Self-heating (KCP 2.3.3)	EEC A15	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	**Accepted**
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC 75.3 CIPAC MT 191	GLOB2112dH Batch MAM 107683	pH neat: 1.99 7.4539% m/m as H_2SO_4	Y	Fitzmaurice T., 2023 DNA7203	**Accepted** The pH was less than 4, the acidity was tested. The pH was determined at 20°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	**Accepted** 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	**Accepted** The viscosity was determined at different shear rates at 20°C and 40ºC. Conclusion: the sample

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						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	**Accepted** The surface tension of test item was measured at 20°C and at 25°C at 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 54º 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	<table><tr><th></th><th>Before storage</th><th>After storage</th></tr><tr><td>Appearance</td><td colspan="2">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</td></tr></table>	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 40ºC for 8 weeks. The PPP stored at

<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>
<table>
<tr><td></td><td colspan="2">storage after inversion.</td></tr>
<tr><td>Thiencarbazone-methyl</td><td>77.47 g/L</td><td>76.25 g/L</td></tr>
<tr><td>Mesotrione</td><td>391.9 g/L</td><td>389.0 g/L</td></tr>
<tr><td>Cyprosulfamide</td><td>117.5 g/L</td><td>~~126.8 g/L~~ 116.8 g/L</td></tr>
<tr><td>Impurity 1 R1 (R287431)</td><td colspan="2">Not detectable above the LOQ level of 0.50 mg/kg (Equating to 1.6204 mg/kg in the active substance as manufactured)</td></tr>
<tr><td>Impurity 2 R2 (R287432)</td><td colspan="2">Not detectable above the LOQ level of 0.10 g/kg (Equating to 0.3241 g/kg in the active substance as manufactured)</td></tr>
<tr><td>Impurity 3 1,2-dichloroethane</td><td>0.0537 g/kg (Equating to 0.1740 g/kg in the active substance as manufactured)</td><td>0.0542 g/kg (Equating to 0.1757 g/kg in the active substance as manufactured)</td></tr>
<tr><td>pH neat (CIPAC MT 75.3)</td><td>~~2.19~~1.99</td><td>1.97</td></tr>
<tr><td>pH 1% dilution (CIPAC MT 75.3)</td><td>3.06</td><td>3.04</td></tr>
<tr><td>Acidity/Alkalinity (CIPAC MT 191)</td><td>7.4539% m/m as H_2SO_4</td><td>7.0373% m/m as H_2SO_4</td></tr>
<tr><td rowspan="5">Spontaneity of dispersion (CI-PAC MT 160)</td><td colspan="2">Thiencarbazone-methyl</td></tr>
<tr><td>CIPAC Water A: 99.16% CIPAC Water D: 99.66%</td><td>CIPAC Water A: 100.8% CIPAC Water D: 101.6%</td></tr>
<tr><td colspan="2">Mesotrione</td></tr>
<tr><td>CIPAC Water A: 98.65% CIPAC Water D: 99.14%</td><td>CIPAC Water A: 99.59% CIPAC Water D: 100.2%</td></tr>
<tr><td colspan="2">Cyprosulfamide</td></tr>
</table>
</td><td></td><td></td><td>elevated temperature 40ºC (aged sample) in 1L HDPE (Conventional) white bottle was analysed for 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.

Based on the results of the study, it was concluded that the active ingredients content, color, physical state, pH, suspensibility,</td></tr>
</table>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<table><tr><td></td><td>CIPAC Water A: 98.97% CIPAC Water D: 99.53%</td><td>CIPAC Water A: 100.7% CIPAC Water D: 101.4%</td></tr><tr><td rowspan="6">Suspensibility (CIPAC MT 184.1)</td><td colspan="2">Thiencarbazone-methyl</td></tr><tr><td>High rate: 100.4% Low rate: 101.2%</td><td>High rate: 103.0% Low rate: 100.4%</td></tr><tr><td colspan="2">Mesotrione</td></tr><tr><td>High rate: 99.97% Low rate: 100.7%</td><td>High rate: 102.0% Low rate: 99.40%</td></tr><tr><td colspan="2">Cyprosulfamide</td></tr><tr><td>High rate: 100.3% Low rate: 100.6%</td><td>High rate: 102.2% Low rate: 99.36%</td></tr><tr><td>Pourability (CIPAC MT 148.1)</td><td>Poured Residue: 3.5680% Water Rinsed Residue: 0.1561 % Acetone Rinsed Residue: 0.0091%</td><td>Poured Residue: 3.2809% Water Rinsed Residue: 0.1023% Acetone Rinsed Residue: 0.0091%</td></tr><tr><td>Wet sieve (CIPAC MT 185)</td><td>0.0632%</td><td>0.0543%</td></tr><tr><td>Particle size (CIPAC MT 187 laser diffraction)</td><td>d10: 0.681 µm d50: 1.815 µm d90: 4.969 µm mean: 2.363 µm</td><td>d10: 0.713 µm d50: 1.974 µm d90: 5.336 µm mean:</td></tr></table>			spontaneity of dispersion, wet sieve, pourability, particle size distribution of the test item for sample stored at elevated temperature of 40ºC for 8 weeks were well compared with that of the results obtained for the test item before storage. ~~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 conteiners (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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						at 40°C for 8 weeks. ~~after inversion~~ 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 acive substances and safener after 8 weeks storage of test item at 40ºC was almost neglible. 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. Active substances and safener conetnt before and after storage meet FAO Limits. The content of Impurity

		2.578 µm

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						1 R1 (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. The content of Impurity 2 R2 (R287432) in PPP was determined by HPLC-PDA. The analytical method was developed and

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						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. 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 GLOB2112dH - pre storage contain

<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>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.</td></tr>
<tr><td>Minimum content after heat stability testing
(KCP 2.7.3)</td><td>Method validated in DNA7206</td><td>GLOB2112dH
Batch MAM 107683</td><td>Thiencarbazone-methyl: 77.47 g/L
Mesotrione: 391.9 g/L
Cyprosulfamide: 17.5 g/L</td><td>Y</td><td>Fitzmaurice T., 2023
DNA7203</td><td>Accepted</td></tr>
<tr><td>Effect of low temperatures on stability
(KCP 2.7.4)</td><td>CIPAC MT 39.3</td><td>GLOB2112dH
Batch MAM 107683</td><td><table><tr><th></th><th>Before storage</th><th>After storage</th></tr><tr><td>Appearance</td><td colspan="2">The sample appearance remained unchanged post low temperature storage.
The test was repeated with the addition of a crystal of thiencarbazone-methyl after 24 hours. The crystal dissolved, the sample appearance remained</td></tr></table></td><td>Y</td><td>Fitzmaurice T., 2023
DNA7203</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</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></td><td>
<table>
<tr><td></td><td colspan="2">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.</td></tr>
<tr><td rowspan="8">Suspensibility (CIPAC MT 184.1)</td><td colspan="2">Thiencarbazone-methyl</td></tr>
<tr><td>High rate: 100.4%
Low rate: 101.2%</td><td>High rate: 100.2%
Low rate: 101.6%</td></tr>
<tr><td colspan="2">Mesotrione</td></tr>
<tr><td>High rate: 99.97%
Low rate: 100.7%</td><td>High rate: 99.83%
Low rate: 101.1%</td></tr>
<tr><td colspan="2">Cyprosulfamide</td></tr>
<tr><td>High rate: 100.3%
Low rate: 100.6%</td><td>High rate: 100.0%
Low rate: 101.0%</td></tr>
<tr><td>Wet sieve (CI-PAC MT 185)</td><td>0.0632%</td><td>0.0502%</td></tr>
</table>
</td><td></td><td></td><td>at 0±2ºC for 7 days. Suspensibility and wet sieve test were determined after storage. 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 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</td></tr>
</table>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						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	**Data gap** 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.					**Accepted**
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 At the low application rate: After 1 min: 4mL After 12 min: 2mL	Y	Fitzmaurice T., 2023 DNA7203	**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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						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	**Accepted** 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 laboratory (validated in study DNA7206). Acceptable limits:the mean measured minimum active

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						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	**Accepted** 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 Chromatography (HPLC). The method was developed and validated in GLP laboratory (validated in study DNA7206).

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						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 remains which might cause the blockage of nozzles or filters on application equipment. Acceptable limits: Maximum 2 %

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						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 preparation and that an excessive amount of the material does not remain in the container. Acceptable Limits: Maximum 5 %

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						residue. Acceptable limiit 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 40ºC). 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 nm 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 nm 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 nm 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 nm 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

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 nm 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 00267% thiencarbazone-methyl residue, 0.00231% mesotrione residue and 0.0142% cyrposulfamide 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 thiencarbazone-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 – Thiencarbazone-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 (00267% thiencarbazone-methyl residue, 0.00231% mesotrione residue and 0.0142% cyrposulfamide 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. (thiencarbazone-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 *Confidential – filed in Part C*	Norris D.	2024	Theoretical certificate of explosive and oxidising properties for GLOB2112dH. DNA7397 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

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 Thiencarbazone-methyl

No new data submitted.

A 2.2 Mesotrione

No new data submitted.