

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: CHR/H/CFF 250 EC

Product name(s): Hapi 250 EC/ Turango 250 EC

Chemical active substance(s):

Florasulam, 10 g/L

Fluroxypyr-acid, 120 g/L (fluroxypyr-meptyl, 172.9 g/L)

Clopyrid, 120 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: March 2023

Update: November 2023, May 2024

MS Finalisation date: July 2024; November 2024

Version history

When	What
November 2023	Update of dRR by Applicant
May 2024	Update of dRR by Applicant (2-years stability results, corrosive properties)
July 2024	zRMS assessment of dRR
November 2024	The final Registration Report

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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:

- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Innvigo Sp. z o.o.
Address: Aleje Jerozolimskie 178, 02-486 Warsaw, Poland

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 Florasulam

Florasulam min. 970 g/kg

Relevant impurities:

2,6-DFA max. 2 g/kg

1.2.3.2 Fluroxypyr-meptyl

Flurxypyr-meptyl min. 950 g/kg

Relevant impurities:

N-methyl-2-pyrrolidone
(NMP): < 3 g/kg

1.2.3.3 Clopyralid

Clopyralid min. 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: Hapi 250 EC
Turango 250 EC

Company code number: CHR/H/CFF 250 EC

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Florasulam	10	8.5-11.5	10.2	0.92
Fluroxypyr-acid Fluroxypyr-meptyl	120 172.9	112.8-127.2 162.5-183.3	123.7 126.3 182	11.08 16.81
Clopyralid	120	112.8-127.2	126.3	11.08

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

** Based on the density of the formulation = 1.0826 (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content in the active substance (g/L or g/kg)	Maximum content in the formulation (g/L or g/kg)
2.6-DFA	2	0.02 g/L
NMP	3	0.55 g/L

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

Table 1.4-3: Information on Florasulam

Type	Name/Code Number	
ISO common name	Florasulam	-
CAS No.	145701-23-1	-
EC No.	604-488-1	--
CIPAC No.	616	

Table 1.4-4: Information on Fluroxypyr

Type	Name/Code Number	
ISO common name	Fluroxypyr	Fluroxypyr -meptyl
CAS No.	69377-81-7	69377-81-7 81406-37-3
EC No.	-	279-752-9
CIPAC No.	431	431.214

Table 1.4-5: Information on Clopyralid

Type	Name/Code Number	
ISO common name	3,6-dichloropyridine-2-carboxylic acid or 3,6dichloropicolinic acid	-
CAS No.	1702-17-6	-
EC No.	216-935-4	-
CIPAC No.	455	-

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: Emulsifiable concentrate

[Code: EC]

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 liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of 98.3 °C. It has a self ignition temperature of 390 °C. In aqueous solution, it has a pH value around 2-3 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 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least **1.2** years at ambient temperature when stored in *HDPE/PA*. Its technical characteristics are acceptable for a *EC* formulation.

The intended concentration of use is ~~0.125%~~ 0.1% to 0.25%.

Study of 2 years stability is ongoing.

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

~~Not necessary.~~

The kinematic viscosity of the formulation has value ≤ 20.5 mm²/s, measured at 40°C, therefore the formulation shall be classified in Category 1 (hazard statement H304).

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not applicable.

Compliance with FAO specifications:

~~The product CHR/H/CFF 250 EC complies with FAO specifications.~~

At the time of evaluation, no FAO specifications for formulations containing florasulam, fluroxypyr methyl, or clopyralid were allocated.

Formulation used for tests

CHR/H/CFF 250 EC
Batch No.: CHE2AC2001
Prod. Date: 16.02.2022

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)	OPPTS 830.630 2, 830.630 3 and 830.630 4	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	<p>Initial:</p> <p>Colour to Gardner's scale – 6.6</p> <p>Physical state – liquid</p> <p>Odour – intensive, characteristic</p> <p>After accelerated storage:</p> <p>Colour to Gardner's scale – 8.6</p> <p>Physical state – liquid</p> <p>Odour – intensive, characteristic</p> <p>After 1 year storage:</p> <p>Colour to Gardner's scale – 6.6</p> <p>Physical state – liquid</p> <p>Odour – intensive, characteristic</p> <p>After 2 years storage:</p> <p>Colour to Gardner's scale – 7.2</p> <p>Physical state – transparent liquid</p> <p>Odour – intensive, characteristic</p>	Y	<p>I. Knapik, Part 1, Study code: ICB/46/2022</p> <p>I. Knapik, Study code: ICB/47/2022</p> <p>I. Knapik, Study code: ICB/48/2022</p>	Accepted.
Explosive properties (KCP 2.2.1)	AE A.14	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	CHR/H/CFF 250 EC does not have explosive properties.	Y	D. Buczkowski, Study code: BW-08/22	Determination of impact sensitivity was performed with the BAM Fallhammer apparatus. Determination of thermal sensitivity was performed with the Koenen apparatus. The product does not

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						have explosive properties. Accepted.
Oxidizing properties (KCP 2.2.2)	EC A.21	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	CHR/H/CFF 250 EC has not got the oxidizing properties	Y	P. Flasińska, Study code: BC-26/22	The pressure did not reach the critical value of 2070 kPa. The product does not have oxidising properties. Accepted.
Flash point (KCP 2.3.1)	EEC A.9	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	93.8°C	Y	I. Knapik, Part 1, Study code: ICB/46/2022	Pensky-Martens apparatus was used. The product is not flammable. Accepted.
Flammability (KCP 2.3.2)			Not relevant for this type of formulation.			
Self-heating (KCP 2.3.3)	EC A.15	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	CHR/H/CFF 250 EC has got auto-ignition temperature: 390°C	Y	P. Flasińska, Study code: BC-26/22	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	CHR/H/CFF 250 EC Batch No.: CHE2AC20	Initial: Acidity: 3.22% After accelerated storage:		I. Knapik, Part 1, Study code: ICB/46/2022	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		01 Prod. Date: 16.02.2022	Acidity: 3.57% After 1 year storage: Acidity: 3.21% After 2 years storage: Acidity: 3.11%		I. Knapik, Study code: ICB/47/2022 I. Knapik, Study code: ICB/48/2022	
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	Initial: 1% (w/v) pH = 2.36 After accelarted: 1% (w/v) pH = 2.45 After 1 year storage: 1% (w/v) pH = 2.39 After 2 years storage: 1% (w/v) pH= 2.34	Y	I. Knapik, Part 1, Study code: ICB/46/2022 I. Knapik, Study code: ICB/47/2022 I. Knapik, Study code: ICB/48/2022	Accepted.
Viscosity (KCP 2.5.1)	OECD 114	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	At 20.00°C: 21.49 mm ² /s At 40.00°C: 9.427 mm ² /s	Y	J. Kupiec, Study code: BF-18/22	The product contains more than 10% of co-formulants classified as H304, therefore the kinematic viscosity was determined using an Ubbelohde capillary viscometer. The kinematic viscosity of the product has a value ≤ 20.5 mm ² /s, measured at 40°C

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						therefore the product shall be classified in Category 1 (hazard statement H304). The relevant classification should be included on the label. Accepted.
Surface tension (KCP 2.5.2)	EEC A.5	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	0.25% (v/v) – 33.41 [mN/m]	Y	I. Knapik, Part 1, Study code: ICB/46/2022	The surface tension was determined at the highest in-use conc. According to SANCO/10473/2003 - rev.5, if the highest recommended rate is less than 1 g/L, the surface tension should be determined at 1 g/L as given by the test method. The surface tension is below 60 mN/m - the product is surface active. Accepted.
Relative density (KCP 2.6.1)	EEC A.3	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	1.0826	Y	I. Knapik, Part 1, Study code: ICB/46/2022	Accepted.
Bulk density (KCP 2.6.2)			Not relevant for this type of formulation.			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments			
Storage Stability after 14 days at 54° C (KCP 2.7.1)			Storage stability after 14 days at 54°C doesn't meet the criteria. Therefore storage stability after 8 weeks at 40°C was performed at point KCP 2.7.2.								
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.3	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	Study	Method	Results		Y	I. Knapik, Part 1, Study code: ICB/46/2022 I. Knapik, Part 2, Study code: ICB/46/2022	The test item was stored at 40±2°C for 8 weeks in tightly closed commercial packaging made of HDPE/PA. The content of active substances and relevant impurities was determined with methods validated according to SANCO/3030/99 rev.5; (see Part B5 of the dRR). The change of a.s. content was: - for clopyralid 0.1% - for florasulam 3.3% - for fluroxypyr 1.6% The contents of the relevant impurities determined before and after storage were below the levels of Reg. 2015/1397 and Reg. 2017/725. During storage, the packaging material proved to be resistant to its content. See KCP 2.8.6.2		
			Accelerated storage test	CIPAC MT 46.3	Accelerated storage test (8 weeks at 40°C)						
			Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour to Gardner's scale – 8.6 Physical state – liquid Odour – intensive, characteristic						
			pH	CIPAC MT 75.3	1% (w/v) emulsion – 2.45						
			Acidity	CIPAC MT 191	3.57%						
			Emulsion stability	CIPAC MT 36.3	Concentration 0.125% (v/v) at temperature 30±2°C: <i>Time</i> 30 s					<i>Water A</i> trace of oil at the bottom	<i>Water D</i> trace of oil at the bottom
					30 min					trace of solid at the bottom	trace of oil at the bottom
		2 h		trace of solid at the bottom	trace of solid at the bottom						
		24 h		trace of solid at the bottom	trace of oil and solid at the bottom						
		24h+30 s		complete	trace of oil and solid at the bottom						

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments																								
					<div>24h+30 min<div>trace of solid at the bottom</div><div>trace of oil and solid at the bottom</div></div> <div>Concentration 0.25% (v/v) at temperature 30±2°C:</div> <table><thead><tr><th>Time</th><th>Water A</th><th>Water D</th></tr></thead><tbody><tr><td>30 s</td><td>trace of oil at the bottom and cream at the top</td><td>trace of oil at the bottom</td></tr><tr><td>30 min</td><td>complete</td><td>trace of oil at the bottom</td></tr><tr><td>30 min</td><td>trace of solid at the bottom</td><td>trace of oil at the bottom</td></tr><tr><td>2 h</td><td>trace of solid at the bottom</td><td>trace of solid at the bottom</td></tr><tr><td>24 h</td><td>trace of solid at the bottom and cream at the top</td><td>trace of oil and solid at the bottom</td></tr><tr><td>24h+30 s</td><td>complete</td><td>trace of oil and solid at the bottom</td></tr><tr><td>24h+30 min</td><td>trace of solid at the bottom</td><td>trace of oil and solid at the bottom</td></tr></tbody></table>	Time	Water A	Water D	30 s	trace of oil at the bottom and cream at the top	trace of oil at the bottom	30 min	complete	trace of oil at the bottom	30 min	trace of solid at the bottom	trace of oil at the bottom	2 h	trace of solid at the bottom	trace of solid at the bottom	24 h	trace of solid at the bottom and cream at the top	trace of oil and solid at the bottom	24h+30 s	complete	trace of oil and solid at the bottom	24h+30 min	trace of solid at the bottom	trace of oil and solid at the bottom			comments regarding emulsion stability. Accepted.
Time	Water A	Water D																														
30 s	trace of oil at the bottom and cream at the top	trace of oil at the bottom																														
30 min	complete	trace of oil at the bottom																														
30 min	trace of solid at the bottom	trace of oil at the bottom																														
2 h	trace of solid at the bottom	trace of solid at the bottom																														
24 h	trace of solid at the bottom and cream at the top	trace of oil and solid at the bottom																														
24h+30 s	complete	trace of oil and solid at the bottom																														
24h+30 min	trace of solid at the bottom	trace of oil and solid at the bottom																														
			Stability of package	Standard Operational Procedure SPB/38	Change in packaging weight – 0.12% Change in gross weight – 0.017%																											
			Content of clopyralid, florasulam and fluroxypyr	Standard Operational Procedure SPB/258	clopyralid – 119.84 g/L florasulam – 9.10 g/L fluroxypyr -115.32 g/L																											

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																		
			<p>Table 1. Physicochemical properties of the test item – before accelerated storage test.</p> <table><tr><th>Study</th><th>Method</th><th>Results</th></tr><tr><td>Content of 2,6-difluoroaniline as impurity</td><td>Standard Operational Procedure SPB/278</td><td>2,6-difluoroaniline – <0.0106 g/kg</td></tr><tr><td>Content of 1-methyl-2-pyrrolidinone as impurity</td><td>Standard Operational Procedure SPB/271</td><td>1-methyl-2-pyrrolidinone – 0.05687 g/kg</td></tr></table> <p>Table 2. Physicochemical properties of the test item – after accelerated storage test.</p> <table><tr><th>Study</th><th>Method</th><th>Results</th></tr><tr><td>Content of 2,6-difluoroaniline as impurity</td><td>Standard Operational Procedure SPB/278</td><td>2,6-difluoroaniline – <0.0106 g/kg</td></tr><tr><td>Content of 1-methyl-2-pyrrolidinone as impurity</td><td>Standard Operational Procedure SPB/271</td><td>1-methyl-2-pyrrolidinone – 0.06144 g/kg</td></tr></table>	Study	Method	Results	Content of 2,6-difluoroaniline as impurity	Standard Operational Procedure SPB/278	2,6-difluoroaniline – <0.0106 g/kg	Content of 1-methyl-2-pyrrolidinone as impurity	Standard Operational Procedure SPB/271	1-methyl-2-pyrrolidinone – 0.05687 g/kg	Study	Method	Results	Content of 2,6-difluoroaniline as impurity	Standard Operational Procedure SPB/278	2,6-difluoroaniline – <0.0106 g/kg	Content of 1-methyl-2-pyrrolidinone as impurity	Standard Operational Procedure SPB/271	1-methyl-2-pyrrolidinone – 0.06144 g/kg			
Study	Method	Results																						
Content of 2,6-difluoroaniline as impurity	Standard Operational Procedure SPB/278	2,6-difluoroaniline – <0.0106 g/kg																						
Content of 1-methyl-2-pyrrolidinone as impurity	Standard Operational Procedure SPB/271	1-methyl-2-pyrrolidinone – 0.05687 g/kg																						
Study	Method	Results																						
Content of 2,6-difluoroaniline as impurity	Standard Operational Procedure SPB/278	2,6-difluoroaniline – <0.0106 g/kg																						
Content of 1-methyl-2-pyrrolidinone as impurity	Standard Operational Procedure SPB/271	1-methyl-2-pyrrolidinone – 0.06144 g/kg																						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)	Standard Operational Procedure SPB/258		<p>Initial:</p> <p>clopyralid – 119.67 g/L florasulam – 9.41 g/L fluroxypyr – 117.13 g/L 2,6-difluoroaniline - <0.0106 g/kg 1-methyl-2-pyrrolidinone – 0.05687 g/kg</p> <p>After Accelerated storage:</p> <p>clopyralid – 119.84 g/L florasulam – 9.10 g/L fluroxypyr -115.32 g/L 2,6-difluoroaniline - <0.0106 g/kg 1-methyl-2-pyrrolidinone – 0.06144 g/kg</p> <p>After 1 year storage:</p> <p>clopyralid – 118.23 g/L florasulam – 9.33 g/L fluroxypyr -116.18 g/L 2,6-difluoroaniline - <0.0106 g/kg 1-methyl-2-pyrrolidinone – 0.05865 g/kg</p> <p>After 2 years storage:</p> <p>clopyralid – 119.17g/L florasulam – 9.09 g/L fluroxypyr -113.65 g/L 2,6-difluoroaniline - <0.0106 g/kg 1-methyl-2-pyrrolidinone – 0.06082 g/kg</p>	Y	<p>I. Knapik, Part 1, Study code: ICB/46/2022</p> <p>I. Knapik, Part 2, Study code: ICB/46/2022</p> <p>I. Knapik, Study code: ICB/47/2022</p> <p>I. Knapik, Study code: ICB/48/2022</p>	The content of active substances and relevant impurities was determined with methods validated according to SANCO/3030/99 rev.5; (see Part B5 of the dRR). Accepted.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date:	<p>After low temperature stability 0°C for 7 days – no phase separation, no sediment.</p> <p>After 24 h in room temperature and one invert – no phase separation, no sediment.</p>	Y	I. Knapik, Part 1, Study code: ICB/46/2022	See KCP 2.8.6.2 comments regarding emulsion stability. Accepted.

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
		16.02.2022	Emulsion stability	CIPAC MT 36.3	Concentration 0.125% (v/v) at temperature 30±2°C:					
					<i>Time</i>	<i>Water A</i>	<i>Water D</i>			
					30 s	complete	complete			
					30 min	complete	trace of oil at the bottom			
					2 h	complete	trace of oil and solid at the bottom			
					24 h	trace of solid at the bottom	trace of oil and solid at the bottom			
					24h+30 s	complete	trace of solid at the bottom			
					24h+30 min	complete	trace of solid at the bottom			
					Concentration 0.25% (v/v) at temperature 30±2°C:					
					<i>Time</i>	<i>Water A</i>	<i>Water D</i>			
					30 s	complete	complete			
					30 min	complete	trace of oil and solid at the bottom			
					2 h	complete	trace of oil and solid at the bottom			
					24 h	trace of solid at the bottom	trace of oil and solid at the bottom			

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
					24h+30 s	complete	trace of solid at the bottom			
					24h+30 min	complete	trace of oil and solid at the bottom			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments		
Ambient temperature shelf life (KCP 2.7.5)		CHR/H/CFF 250 EC Batch No.: CHE2AC2001 Prod. Date: 16.02.2022	Study	Method	Results			Y	I. Knapik, Study code: ICB/48/2022	The test item was stored at 20±2°C for 24 months in tightly closed commercial packaging made of HDPE/PA. The content of active substances and relevant impurities was determined with methods validated according to SANCO/3030/99 rev.5; (see Part B5 of the dRR). The change of a.s. content was: - for clopyralid 0.4% - for florasulam 3.4% - for fluroxypyr 3.0% The contents of the relevant impurities determined before and after storage were below the levels of Reg. 2015/1397 and Reg. 2017/725. During storage, the packaging material proved to be resistant to its content. See KCP 2.8.6.2 comments regarding emulsion stability. Accepted.
			Colour, physical state, odour	OPPTS 830.6302, 830.6303 and 830.6304	Colour to Gardner’s scale – 7.2 Physical state – transparent liquid Odour – intensive, characteristic					
			pH	CIPAC MT 75.3	1% (w/v) emulsion – 2.34					
			Acidity	CIPAC MT 191	3.11%					
			Persistent foaming	CIPAC MT 47.3	0.125% (w/v): -after 1 minute – 5 mL - after 12 minutes – 4 mL 0.25% (w/v): -after 1 minute – 9 mL - after 12 minutes – 6 mL					
			Emulsion stability	CIPAC MT 36.3	Concentration 0.125% (v/v) at temperature 30±2°C:					
					Time	Water A	Water D			
					30 s	complete	complete			
					30 min	complete	trace of oil at the bottom			
					2 h	complete	trace of oil at the bottom			
					24 h	trace of solid at the bottom	trace of solid at the bottom			
					24h+30 s	complete	complete			
24h+30 min	complete	trace of solid at the bottom								
Concentration 0.25% (v/v) at temperature 30±2°C:										
Time	Water A	Water D								
30 s	complete	complete								
30 min	complete	trace of oil at the bottom								
2 h	complete	trace of oil at the bottom								

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
					24 h trace of solid at the bottom trace of solid at the bottom 24h+30 s complete complete 24h+30 min complete trace of solid at the bottom			
			Stability of package (HDPE/PA)	Standard Operational Procedure SPB/38	Change in packaging weight – 0.14% Change in gross weight – 0.007% Packaging without any visible changes			
			Content of clocyralid, florasulam and fluroxypyr	Standard Operational Procedure SPB/258	clocyralid – 119.17 g/L florasulam – 9.09 g/L fluroxypyr – 113.65 g/L			
			Content of 2,6-difluoroaniline as impurity	Standard Operational Procedure SPB/278	2,6-difluoroaniline – < 0.0106 g/kg			
			Content of 1-methyl-2-pyrrolidinone as impurity	Standard Operational Procedure SPB/271	1-methyl-2-pyrrolidinone – 0.06082 g/kg			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments	
Shelf life in months (if less than 2 years) (KCP 2.7.6)		CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	Study	Method	Results				Test item was stored at 20±2°C for 12 months in a tightly closed commercial packaging made of HDPE/PA. The content of active substances and relevant impurities was determined with methods validated according to SANCO/3030/99 rev.5; (see Part B5 of the dRR). The change of a.s. content was: - for clopyralid 1.2% - for florasulam 0.9% - for fluroxypyr 0.8% See KCP 2.8.6.2 comments regarding emulsion stability. Accepted.
			Appearance, physical state, odour	OPPTS 830.6302, 830.6303 and 830.6304	Colour to Gardner's scale – 6.6 Physical state – liquid Odour – intensive, characteristic				
			pH	CIPAC MT 75.3	1% (w/v) emulsion – 2.39				
			Acidity	CIPAC MT 191	3.21%				
			Persistent foaming	CIPAC MT 47.3	0.125% (w/v): -after 1 minute – 9 mL - after 12 minutes – 7 mL 0.25% (w/v): -after 1 minute – 20 mL - after 12 minutes – 17 mL				
			Emulsion stability	CIPAC MT 36.3	Concentration 0.125% (v/v) at temperature 30±2°C:				
					Time	Water A	Water D		
					30 s	complete	complete		
					30 min	complete	trace of oil at the bottom		
					2 h	complete	trace of oil at the bottom		
24 h	trace of solid at the bottom	trace of solid at the bottom							
24h+30 s	complete	complete							
24h+30 min	complete	trace of solid at the bottom							
Concentration 0.25% (v/v) at temperature 30±2°C:									
Time	Water A	Water D							
30 s	complete	complete							
30 min	complete	trace of oil at the bottom							
2 h	complete	trace of oil at the bottom							

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments														
			<table><tr><td></td><td></td><td>24 h</td><td>trace of solid at the bottom</td><td>trace of solid at the bottom</td></tr><tr><td></td><td></td><td>24h+30 s</td><td>complete</td><td>complete</td></tr><tr><td></td><td></td><td>24h+30 min</td><td>complete</td><td>trace of solid at the bottom</td></tr></table>			24 h	trace of solid at the bottom	trace of solid at the bottom			24h+30 s	complete	complete			24h+30 min	complete	trace of solid at the bottom				
		24 h	trace of solid at the bottom	trace of solid at the bottom																		
		24h+30 s	complete	complete																		
		24h+30 min	complete	trace of solid at the bottom																		
			Stability of package (HDPE/PA)	Standard Operational Procedure SPB/38	Change in packaging weight – 0.096% Change in gross weight – 0.010%																	
			Content of clopyralid, florasulam and fluroxypyr	Standard Operational Procedure SPB/258	clopyralid – 118.23 g/L florasulam – 9.33 g/L fluroxypyr – 116.18 g/L																	
			Content of 2,6-difluoroaniline as impurity	Standard Operational Procedure SPB/278	2,6-difluoroaniline – < 0.0106 g/kg																	
			Content of 1-methyl-2-pyrrolidinone as impurity	Standard Operational Procedure SPB/271	1-methyl-2-pyrrolidinone – 0.05865 g/kg																	
Wettability (KCP 2.8.1)			Not relevant for this type of formulation.																			
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date:	0.125% (w/v): -after 1 minute – 6 mL - after 12 minutes – 4 mL 0.25% (w/v): -after 1 minute – 12 mL			Y	I. Knapik, Part 1, Study code: ICB/46/2022	Accepted.														

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		16.02.2022	- after 12 minutes – 9 mL			
Suspensibility (KCP 2.8.3.1)			Not relevant for this type of formulation.			
Spontaneity of dispersion (KCP 2.8.3.2)			Not relevant for this type of formulation.			
Dispersion stability (KCP 2.8.3.3)			Not relevant for this type of formulation.			
Degree of dissolution and dilution stability (KCP 2.8.4)			Not relevant for this type of formulation.			
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)			Not relevant for this type of formulation.			
Wet sieve test (KCP 2.8.5.1.2)			Not relevant for this type of formulation.			
Dust content (KCP 2.8.5.2.1)			Not relevant for this type of formulation.			
Particle size of dust (KCP 2.8.5.2.2)			Not relevant for this type of formulation.			
Attrition (KCP 2.8.5.3)			Not relevant for this type of formulation.			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																											
Hardness and integrity (KCP 2.8.5.4)			Not relevant for this type of formulation.																														
Emulsifiability (KCP 2.8.6.1)			Not relevant for this type of formulation.																														
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	CHR/H/CFF 250 EC Batch No.: CHE2AC20 01 Prod. Date: 16.02.2022	<div>Initial: Concentration 0.125% (v/v) at temperature 30±2°C:</div> <table><tr><th>Time</th><th>Water A</th><th>Water D</th></tr><tr><td>30 s</td><td>trace of oil at the bottom</td><td>trace of oil at the bottom</td></tr><tr><td>30 min</td><td>complete</td><td>trace of oil at the bottom</td></tr><tr><td>2 h</td><td>trace of solid at the bottom</td><td>trace of oil at the bottom</td></tr><tr><td>24 h</td><td>trace of solid at the bottom</td><td>trace of oil and solid at the bottom</td></tr><tr><td>24h+30 s</td><td>complete</td><td>trace of solid at the bottom</td></tr><tr><td>24h+30 min</td><td>trace of solid at the bottom</td><td>trace of solid at the bottom</td></tr></table> <div>Concentration 0.25% (v/v) at temperature 30±2°C:</div> <table><tr><th>Time</th><th>Water A</th><th>Water D</th></tr><tr><td>30 s</td><td>trace of oil at the bottom</td><td>trace of oil at the bottom</td></tr></table>	Time	Water A	Water D	30 s	trace of oil at the bottom	trace of oil at the bottom	30 min	complete	trace of oil at the bottom	2 h	trace of solid at the bottom	trace of oil at the bottom	24 h	trace of solid at the bottom	trace of oil and solid at the bottom	24h+30 s	complete	trace of solid at the bottom	24h+30 min	trace of solid at the bottom	trace of solid at the bottom	Time	Water A	Water D	30 s	trace of oil at the bottom	trace of oil at the bottom	Y	I. Knapik, Part 1, Study code: ICB/46/2022 I. Knapik, Study code: ICB/47/2022 I. Knapik, Study code: ICB/48/2022	The preparation did not show significant levels of cream, free oil or solid matter. However, in the label the recommendations for ensuring thorough mixing before and during spraying should be included. Accepted.
Time	Water A	Water D																															
30 s	trace of oil at the bottom	trace of oil at the bottom																															
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Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments																					
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			After 1 year storage:																								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																
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Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments																																									
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		2 h	complete	trace of oil at the bottom																																													
		Re-emulsifiability (KCP 2.8.6.3)			Please see point KCP. 2.8.6.2																																												
Flowability (KCP 2.8.7.1)			Not relevant for this type of formulation.																																														
Pourability (KCP 2.8.7.2)			Not relevant for this type of formulation.																																														
Dustability			Not relevant for this type of formulation.																																														

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
following accelerated storage (KCP 2.8.7.3)						
Physical compatibility of tank mixes (KCP 2.9.1)			Not relevant for this application.			
Chemical compatibility of tank mixes (KCP 2.9.2)			Not relevant for this application.			
Adhesion to seeds (KCP 2.10.1)			Not relevant for this type of formulation.			
Distribution to seed (KCP 2.10.2)			Not relevant for this type of formulation.			
Other/special studies (KCP 2.11)	Standard Operational Procedure SPB/38	CHR/H/CFF 250 EC Batch No.: CHE2AC2001 Prod. Date: 16.02.2022	Stability of package: After accelerated storage: Change in packaging weight – 0.12% Change in gross weight – 0.017% After 1 year of storage: Change in packaging weight – 0.096% Change in gross weight – 0.010% After 2 years storage: Change in packaging weight – 0.14% Change in gross weight – 0.007% Packaging without any visible changes	Y	I. Knapik, Part 1, Study code: ICB/46/2022 I. Knapik, Study code: ICB/47/2022 I. Knapik, Study code: ICB/48/2022	The commercial packaging made of HDPE/PA was stored at 40±2°C for 8 weeks. The packaging was stable during the storage. Accepted.

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	Efficacy Guideline 305	CHR/H/CFF 250 EC Batch No.: CHE2AC2001 Prod. Date: 16.02.2022	Effectiveness of cleaning without tank-cleaner	Efficacy Guideline 305	<p>Single rinse procedure:</p> <p>>99.96 [%] clopyralid removed from the bottle 99.32 [%] florasulam removed from the bottle < 88.20 [%] fluroxypyr removed from the bottle</p> <p>Double rinse procedure:</p> <p>>99.96 [%] clopyralid removed from the bottle >99.56 [%] florasulam removed from the bottle 92.65 [%] fluroxypyr removed from the bottle</p> <p>Triple rinse procedure:</p> <p>>99.96 [%] clopyralid removed from the bottle >99.56 [%] florasulam removed from the bottle 93.26 [%] fluroxypyr removed from the bottle</p>	Y	I. Knapik, Study code: ICB/130/2023	General cleanout with tank-cleaner consisted of rinsing with the tap water and 0.2% (v/v) solution of tank cleaner: 1) 10 mL of tap water was added, the bottle was inverted twice, and the rinsing was poured out, 2) 100 mL of 0.2% (v/v) solution of tank cleaner was added, the bottle was inverted twice and allowed to stand for 15 minutes; then the bottle was inverted twice and the rinsing was poured out, 3) point 1) was repeated. The alternate cleanout with tank-cleaner consisted of adding 100 mL of 0.2% (v/v) solution of tank cleaner to the bottle, then inverting twice and allowing to stand for 15 minutes; then the bottle was inverted twice and the rinsing was poured out. The general cleanout
			Effectiveness of cleaning with tank-cleaner	Efficacy Guideline 305	<p>General cleanout with tank-cleaner:</p> <p>>99.96 [%] clopyralid removed from the bottle >99.56 [%] florasulam removed from the bottle 98.71 [%] fluroxypyr removed from the bottle</p> <p>Alternative cleanout with tank-cleaner:</p> <p>>99.96 [%] clopyralid removed from the bottle >99.56 [%] florasulam removed from the bottle 95.61 [%] fluroxypyr removed from the bottle</p>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						with tank-cleaner was most effective – it should be recommended on the label. Accepted.
	EU test C.1	CHR/H/CFF 250 EC Batch No.: CHE2AC2001 Prod. Date: 16.02.2022	After 7 days, no corrosion was detected in any aluminium sample in CHR/H/CFF 250 EC at 55°C. The weight loss of each aluminium sample was 0.00%. The corrosion rate of steel in CHR/H/CFF 250 EC at the temperature of 55°C after 7 days was below the threshold of 6.25 mm/year, since the greatest mass loss was of 0.31%, i.e. below the threshold of 13.5%. Based on these results and according to UN test C.1 criteria, the test material is not considered to be corrosive to metals.	Y	M. Petryka, Studycode: BC-24/24	Accepted.
						Due to the hydrocarbon content and the results of kinematic viscosity ($\leq 20.5 \text{ mm}^2/\text{s}$, measured at 40°C), the product shall be classified in Category 1, hazard statement H304 . The product is not explosive, not flammable, not oxidising, and has got the auto-ignition temperature 390°C – none of these end-points meets the criteria for physical-chemical classification according to CLP. The product is EC for-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>mulation to be used in water solution, it is not pyrophoric and does not emit flammable gases when in contact with water.</p> <p>The formulation is not an organic peroxide.</p> <p>The formulation contains no mutually reactive groups, sulphonyl halides/ cyanides/ hydrazides, phosphites, strained rings, olefins or cyanates so it is not a self-reactive substance.</p> <p>The formulation is not corrosive to metals.</p>

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)

Comments of zRMS:	<p>In the accelerated storage and shelf-life stability study, the formulation was stored in commercial packaging (the bottles made of HDPE/PA) and the packaging remained stable during the storage. Therefore, the proposed commercial packs of HDPE/PA are considered acceptable.</p> <p>According to the SANCO/10473/2003 –rev.5, extrapolation from HDPE/PA to HDPE/F, HDPE/EVOH for EC formulation is only possible with acceptable seepage data in the required packaging. Since the Applicant did not submit relevant seepage results for HDPE/F and HDPE/EVOH packaging, these types of packaging cannot be accepted and were crossed out.</p>
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Table 4.1-1: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	62.5±1 mm/131.3±1 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	323 ± 5 ml

Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information

Packaging information for 500 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA
size:	65 mm/234.8 mm \pm 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	69 mm \pm 2 mm/186.5 mm \pm 2 mm
Opening:	45.65 \pm 3 mm
Closure:	screw cap with seal
Capacity	574 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	74 \pm 1 mm/177 \pm 1 mm/
Opening:	41.7 \pm 0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	74 \pm 1 mm/177 \pm 1 mm/
Opening:	41.7 \pm 0.7 mm
Closure:	screw cap with seal

Capacity	550 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	88 mm \pm 2 mm/238 mm \pm 2 mm
Opening:	50 mm \pm 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	248.5 \pm 3 mm/84 \pm 1.5mm
Opening:	50 mm \pm 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	248.5 \pm 3 mm/84 \pm 1.5mm
Opening:	50 mm \pm 5 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	234 mm \pm 2 mm/88.5mm \pm 2 mm
Opening:	42 mm \pm 2 mm

Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-12: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	238± 1 mm/88 ± 1 mm/
Opening:	41.7±0,7 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	84± 1.5 mm/248.5 ± 3 mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-14: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	233.5± 1.5 mm/88.5 ± 1 mm/
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-15: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	84± 1.5 mm/248.5 ± 3 mm

Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-161: Packaging information

Type	CONTAINER
Material:	HDPE/PA
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ±5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-17: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	195 ± 3/ 130 ± 5 mm/310,5 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-18: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	193 ± 3/ 142 ± 5 mm/320 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-19: Packaging information

Type	CANNISTER
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Material:	HDPE/PA
size:	313± 5mm/190±3/140±5mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-20: Packaging information

Type	CONTAINER
Material:	HDPE/PA
size:	305mm/193 mm/142 mm ± 5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-21: Packaging information

Type	CONTAINER
Material:	HDPE/PA
size:	377,7mm/178 mm/239,5 mm ± 5 mm
Opening:	54 mm min ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

According to guideline from Ministry of Agriculture and Rural Development (*Wytęczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin*) data of stability in the material HDPE/PA are extrapolable to the all materials (HDPE/F and HDPE/EvOH). Therefore, no further studies are required for the additional packaging materials.

Table 4.1-22: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	63.5±1 mm/126±1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	318 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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Table 4.1-23: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	63.5±1 mm/126±1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	312 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-24: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	570 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-25: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	575 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-26: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	580 ± 12.5 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Table 4.1-27: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	585 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-28: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1150 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-29: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1160 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-30: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1170 ± 20 ml

Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-31: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1185 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-32: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1200 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-33: Packaging information

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34: Packaging information

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	63 mm

Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	54,2 mm ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-36: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	63.4 mm min ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-37: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	67,5 mm ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-38: Packaging information

Type	CANNISTER
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Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	54,2 mm min \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-39: Packaging information

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	63,4 mm min \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-40: Packaging information

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	67,5 mm min \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-41: Packaging information

Type	Cannister
Material:	HDPE/F
size:	240 \pm 2 mm/179 \pm 2mm/375 \pm 3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	10 000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-42: Packaging information

Type	BOTTLE
Material:	HDPE/ EVOH
Body diameter / total height:	62,50 +- 0,50 / 126,50 +- 1,50
External thread diameter:	49,65 +- 0,35
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

Table 4.1-43: Packaging information

Type	BOTTLE
Material:	HDPE / EVOH
Body diameter / total height:	59 +- 1 mm / 143 +- 1 mm
External thread diameter:	41.7 +- 0,4 mm
Closure:	screw cap with seal
Capacity	310 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

Table 4.1-44: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	42±3 mm
Closure:	screw cap with cutter
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-45: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
size:	65 mm/234.8 mm ± 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Table 4.1-46: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
size:	69 mm \pm 1 mm/190 mm \pm 1.5 mm
Opening:	49.5 mm \pm 0.3 mm
Closure:	screw cap with seal
Capacity	579 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-47: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
size:	234 \pm 3 mm/88.5 \pm 2mm
Opening:	42 mm \pm 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-48: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
size:	234 \pm 3 mm/88.5 \pm 2mm
Opening:	42 mm \pm 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-49: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
size:	234 \pm 3 mm/88.5 \pm 2mm
Opening:	50 mm \pm 3 mm

Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-50: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
size:	242±1.5 mm/88.5±1mm
Opening:	49.5 mm ± 0.3 mm
Closure:	screw cap with cutter
Capacity	1200± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-51: Packaging information

Type	CONTAINER
Material:	HDPE/EvOH
size:	165 mm ± 2 mm/195 mm ± 2 mm/228mm± 2 mm
Opening:	48 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-52: Packaging information

Type	CANNISTER
Material:	HDPE/EvOH
size:	142 mm ± 1.5 mm/193 mm ± 2 mm/307mm± 3 mm
Opening:	63.3 mm ± 0.3 mm
Closure:	screw cap with cutter
Capacity	5650 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-53: Packaging information

Type	CONTAINER
Material:	HDPE/EvOH
size:	195 mm ± 2 mm/225mm± 2 mm/306mm± 2 mm
Opening:	48 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-54: Packaging information

Type	CONTAINER
Material:	HDPE/EvOH
size:	375 mm ± 2 mm/290mm± 2 mm/245mm± 2 mm
Opening:	85mm ± 2 mm
Closure:	screw cap with cutter
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

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 2.5.1	J. Kupiec	2022	CHR/H/CFF 250 EC Viscosity determination Study code: BF-18/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland, GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.2.2 KCP 2.3.3	P. Flasińska	2022	CHR/H/CFF 250 EC Determination of auto-ignition temperature and oxidizing properties Study code: BC-26/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland, GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.2.1	D. Buczkowski	2022	CHR/H/CFF 250 EC Determination of explosive properties Study code: BW-08/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland, GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.1	I. Knapik	2023	Final Report – Part 1 Determination of physicochemical properties of CHR/H/CFF 250 EC before and	N	Chemirol Sp.

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 2.3.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP 2.7.2 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.2 KCP 2.11			after accelerated storage test Study code: ICB/46/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished		Z O.O.
KCP 2.7.3	I. Knapik	2023	Final Report – Part 2 Determination of physicochemical properties of CHR/H/CFF 250 EC before and after accelerated storage test Study code: ICB/46/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.3.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP 2.7.2 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.2 KCP 2.11	I. Knapik	2023	Determination of physicochemical properties of CHR/H/CFF 250 EC after 12 months shelf-life test Study code: ICB/47/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.11	I. Knapik	2023	Determination of physicochemical property of CHR/H/CFF 250 EC	N	Chemirol Sp.

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
			Study code: ICB/47/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished		Z O.O.
KCP 2.11	M. Petryka	2024	CHR/H/CFF 250 EC Test for determining the corrosive properties to metals Study code: BC-24/24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland. GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.3.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP 2.7.2 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.2 KCP 2.11	I. Knapik	2024	Determination of physicochemical properties of CHR/H/CFF 250 EC after 24 months shelf-life test Study code: ICB/48/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Chemirol Sp. z o.o.

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
-	-	-	-	-	-
-	-	-	-	-	-

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
-	-	-	-	-	-
-	-	-	-	-	-

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
-	-	-	-	-	-

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
-	-	-	-	-	-

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

Not relevant.