

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/FETEC-PART B 110 EC

Product name(s): Fenoxinn Max 110 EC, Herbos Max 110 EC

Chemical active substance:

Fenoxaprop-P-ethyl, 110 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: February 2023

MS Finalisation date: 10/09/2024

Version history

When	What
05/2023	Dossier sent for evaluation
07/2023	Applicant update
09/2023	Applicant update
11/2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period
September 2024	zRMS update

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are: The two years storage stability study is on-going (January 2024). It has to be assessed in the post registration at national level, but there is Shelf life test after 12 months under normal conditions at 20±2°C.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Innvigo Sp. z o. o.
Address: 178, Aleje Jerozolimskie
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 Fenoxaprop-P-ethyl

Fenoxaprop-P-ethyl min. 920 g/kg

There are no relevant impurities in formulation CHR/H/FETEC-PART B 110 EC

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: Fenoxinn Max 110 EC (or)
Herbos Max 110 EC

Company code number: CHR/H/FETEC-PART B 110 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)
Fenoxaprop-P-ethyl (source 1)	110 g/L	103.4 – 116.6 g/L	110.99 112.2 g/L	106.9 10.81% (w/w)
Fenoxaprop-P-ethyl (source 2)	110 g/L	103.4 – 116.6 g/L	111.65 111.7 g/L	107.5 10.76% (w/w)
Fenoxaprop-P-ethyl (source 3)	110 g/L	103.4 – 116.6 g/L	113.3 113.52 g/L	109.1 10.93% (w/w)

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

** Based on the density of the formulation = 1.0382 (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Cloquintocet-mexyl	55 g/L	49.5 – 60.5 g/L	-	5.3 % (w/w)

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

** Based on the density of the formulation = 1.0382 (Note: only applies if a liquid formulation – delete this comment if not needed)

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

Table 1.4-3: Information on fenoxaprop-P-ethyl

Type	Name/Code Number
ISO common name	Fenoxaprop-P-ethyl
CAS No.	71283-80-2
EC No.	615-273-7
CIPAC No.	484

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

Table 1.4-4: Information on safeners/ synergists

Type	Name/Code Number
Safener /synergist	Cloquintocet-mexyl
ISO common name	Cloquintocet-mexyl
CAS No.	99607-70-2
EC No.	619-447-3

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 (H)

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 yellow, with a intensive, characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of 58.55 °C. It has auto-ignition temperature of 470°C. In aqueous solution, it has a pH value around 5.435 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 1 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% to 0.35%.

The 2-year storage stability studies on CHR/H/FETEC-PART B 110 EC are ongoing.

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

H226: Flammable liquid and vapour. (Flam. Liq. 3)

H304: May be fatal if swallowed and enters airways. (Asp. Tox. 1)

Notifier Proposals for Risk and Safety Phrases (KCP 12)

P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

P233: Keep away from any possible contact with water, because of violent reaction and possible flash fire.

P240: Ground/bond container and receiving equipment

P241: Use explosion-proof electrical/ventilating/lighting/.../equipment.

P242: Use only non-sparking tools.

P243: Take precautionary measures against static discharge

Compliance with FAO specifications:

The product CHR/H/FETEC-PART B 110 EC complies with FAO specifications.

Formulation used for tests

Fenoxaprop-P-ethyl 110 EC (CHR/H/FETEC-PART B 110 EC)

Date of production: 01.04.2021

Batch No: 2020012

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	OPPTS 830.6302, 830.6303 and 830.6304	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	Initial preparation: Colour to Gardner's scale – 5.9 Physical state – liquid Odour – intensive, characteristic After accelerated storage: Colour to Gardner's scale – 6.4 Physical state – liquid Odour – intensive, characteristic After 1st year: Colour to Gardner's scale – 6.3 Physical state – liquid Odour – intensive, characteristic	Y	Knapik I., Study code: ICB/91/2021 Knapik I., Study code: ICB/92/2021	Acceptable
Explosive properties (KCP 2.2.1)	EEC A.14	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	CHR/H/FETEC-PART B 110 EC does not have explosive properties according to the criteria of EEC A.14 method. The formulation is considered not explosive in the sense of CLP 1272/2008/EC based on the components in the formulation.	Y	Buczkowski D., Study code: BW-36/21	Acceptable
Oxidizing properties (KCP 2.2.2)	EEC A.21	CHR/H/FETE C-PART B 110 EC Active	CHR/H/FETEC-PART B 110 EC has not got oxidizing properties according to EEC A.21 method. The formulation is considered not oxidizing in the sense of CLP 1272/2008/EC based on the components in the formulation.	Y	Flasińska P., Study code: BC-01/22	Acceptable

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
		substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012				
Flash point (KCP 2.3.1)	EEC A.9	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	Flash point is 58.55°C. The preparation is classified as H226: Flammable liquid 3 where the flashpoint is $\geq 23^{\circ}\text{C}$ but $\leq 60^{\circ}\text{C}$.	Y	Knapik I., Study code: ICB/91/2021	Acceptable
Flammability (KCP 2.3.2)	EEC A.9	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021	The preparation is classified as H226: Flammable liquid 3 where the flashpoint is $\geq 23^{\circ}\text{C}$ but $\leq 60^{\circ}\text{C}$ Not required as formulation is not a solid, gas or a preparation that is expected to liberate gas on contact with water.	Y	Knapik I., Study code: ICB/91/2021	N/A

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
		Batch No: 2020012				
Self-heating (KCP 2.3.3)	EEC A.15	- CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	Not required for this type of formulation. The auto-ignition temperature of formulation is 470°C according to criteria of EC A.15 method. The formulation is considered not to be self-heating in the sense of CLP 1272/2008/EC based on the components in the formulation.	-	Flasińska P., Study code: BC-01/22	Acceptable
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Not required. The acidity or alkalinity test should be conducted if the preparation has pH <4 or pH >10. The pH of the preparation is 5.35 5.53 .	-	-	N/A
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	Initial preparation: 1% (w/v) emulsion – 5.35 at 20.0°C After accelerated storage: 1% (w/v) emulsion – 5.53 at 20.0°C After 1st year: 1% (w/v) emulsion – 6.33 at 20.0°C	Y	Knapik I., Study code: ICB/91/2021 Knapik I., Study code: ICB/92/2021	Acceptable

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	OECD 114	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	20°C: Kinematic viscosity 48.935 mm ² /s 40°C: Kinematic viscosity 19.77 mm ² /s Calculated: 20°C: Dynamic viscosity 50.80 mPa.s 40°C: Dinamic viscosity 20.25 mPa.s The formulation is a Newtonian substance. The formulation contains of 49.7% substance that has been classified as Category 1 aspiration hazard (H304) and a kinematic density the formulation has value ≤20.5 mm ² /s, measured at 40°C. The preparation must be considered for classification as an aspiration hazard.	Y	Kupiec, J., BF-64/21	Acceptable
Surface tension (KCP 2.5.2)	EEC A.5	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	0.35% (v/v) – 28.72 [mN/m] The surface tension is below 60 mN/m, the product is surface active.	Y	Knapik I., Study code: ICB/91/2021	Acceptable
Relative density (KCP 2.6.1)	EEC A.3	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L	1.0382 at 20.0°C 1.0243 at 40.0 °C	Y	Knapik I., Study code: ICB/91/2021 I. Knapik, ICB/84/2023	Acceptable

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments									
		Production date: 01.04.2021 Batch No: 2020012													
Bulk density (KCP 2.6.2)	-	-	Not required for this formulation type.	-	-	N/A									
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	<div>The determined physicochemical properties of the tested material after accelerated storage test are comparable to the results of the initial material tests. No significant variations in active substance and Safener content was observed following the 14 day storage period at 54°C. A loss of up to 5% of the active substance (2.42%) and Safener (4.92%) is unlikely to adversely affect the safety or efficacy of the preparation.</div> <table><tr><th>Test Type</th><th>At initial preparation</th><th>After accelerated storage</th></tr><tr><td>Appearance (OPPTS 830.6302, 830.6303 and 830.6304)</td><td>Colour to Gardner's scale – 5.9 Physical state – liquid Odour – intensive, characteristic</td><td>Colour to Gardner's scale – 6.4 Physical state – liquid Odour – intensive, characteristic</td></tr><tr><td>pH 1% (w/v) emulsion (CIPAC MT 75.3)</td><td>5.35 at 20.0°C</td><td>5.53 at 20.0°C</td></tr></table>	Test Type	At initial preparation	After accelerated storage	Appearance (OPPTS 830.6302, 830.6303 and 830.6304)	Colour to Gardner's scale – 5.9 Physical state – liquid Odour – intensive, characteristic	Colour to Gardner's scale – 6.4 Physical state – liquid Odour – intensive, characteristic	pH 1% (w/v) emulsion (CIPAC MT 75.3)	5.35 at 20.0°C	5.53 at 20.0°C	Y	Knapik I., Study code: ICB/91/2021	Acceptable Remarks: Results from all studies (rhe content fenoxaprop-P-ethyl and cloquintocet-mexyl, appearance, pH, emulsion stability and stability of packing) showed that the formulation is stable for two weeks at 54°C when stored in 1 L volume commercial bottle (HDPE/PA).
Test Type	At initial preparation	After accelerated storage													
Appearance (OPPTS 830.6302, 830.6303 and 830.6304)	Colour to Gardner's scale – 5.9 Physical state – liquid Odour – intensive, characteristic	Colour to Gardner's scale – 6.4 Physical state – liquid Odour – intensive, characteristic													
pH 1% (w/v) emulsion (CIPAC MT 75.3)	5.35 at 20.0°C	5.53 at 20.0°C													

Annex point	Method used / deviations	Test material	Findings						GL P Y/N	Reference	Acceptability / comments																																																																																							
			<div>Emulsion stability (CIPAC MT 36.3)</div> <table><tr><td colspan="3">Concentration 0.125% (v/v) at temperature 30±2°C:</td><td colspan="3">Concentration 0.125% (v/v) at temperature 30±2°C:</td></tr><tr><td>Time</td><td>Water A</td><td>Water D</td><td>Time</td><td>Water A</td><td>Water D</td></tr><tr><td>30 s</td><td>complete</td><td>complete</td><td>30 s</td><td>complete</td><td>complete</td></tr><tr><td>30 min</td><td>complete</td><td>complete</td><td>30 min</td><td>complete</td><td>complete</td></tr><tr><td>2 h</td><td>complete</td><td>complete</td><td>2 h</td><td>complete</td><td>complete</td></tr><tr><td>24 h</td><td>complete</td><td>complete</td><td>24 h</td><td>complete</td><td>complete</td></tr><tr><td>24h+30 s</td><td>complete</td><td>complete</td><td>24h+30 s</td><td>complete</td><td>complete</td></tr><tr><td>24h+30 min</td><td>complete</td><td>complete</td><td>24h+30 min</td><td>complete</td><td>complete</td></tr></table> <div>Concentration 0.35% (v/v) at temperature 30±2°C:</div> <table><tr><td>Time</td><td>Water A</td><td>Water D</td><td>Time</td><td>Water A</td><td>Water D</td></tr><tr><td>30 s</td><td>complete</td><td>complete</td><td>30 s</td><td>complete</td><td>complete</td></tr><tr><td>30 min</td><td>complete</td><td>complete</td><td>30 min</td><td>complete</td><td>complete</td></tr><tr><td>2 h</td><td>complete</td><td>complete</td><td>2 h</td><td>complete</td><td>complete</td></tr><tr><td>24 h</td><td>complete</td><td>complete</td><td>24 h</td><td>complete</td><td>complete</td></tr><tr><td>24h+30 s</td><td>complete</td><td>complete</td><td>24h+30 s</td><td>complete</td><td>complete</td></tr><tr><td>24h+30 min</td><td>complete</td><td>complete</td><td>24h+30 min</td><td>complete</td><td>complete</td></tr></table>	Concentration 0.125% (v/v) at temperature 30±2°C:			Concentration 0.125% (v/v) at temperature 30±2°C:			Time	Water A	Water D	Time	Water A	Water D	30 s	complete	complete	30 s	complete	complete	30 min	complete	complete	30 min	complete	complete	2 h	complete	complete	2 h	complete	complete	24 h	complete	complete	24 h	complete	complete	24h+30 s	complete	complete	24h+30 s	complete	complete	24h+30 min	complete	complete	24h+30 min	complete	complete	Time	Water A	Water D	Time	Water A	Water D	30 s	complete	complete	30 s	complete	complete	30 min	complete	complete	30 min	complete	complete	2 h	complete	complete	2 h	complete	complete	24 h	complete	complete	24 h	complete	complete	24h+30 s	complete	complete	24h+30 s	complete	complete	24h+30 min	complete	complete	24h+30 min	complete	complete					
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			<div>Stability of package (Standard Operational Procedure SPB/38)</div> After accelerated storage study Change in packaging weight – 0.30 [%] Change in gross weight – 0.0044 [%]																																																																																															
			<div>Content of cloquintocet-mexyl and fenoxaprop-P-ethyl (Standard Operational Procedure SPB/245)</div> fenoxaprop-P-ethyl (active substance) – 108.81 g/L cloquintocet-mexyl (Safener) – 55.86 g/L	fenoxaprop-P-ethyl (active substance) – 106.18 g/L cloquintocet-mexyl (Safener) – 53.11 g/L																																																																																														
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required, not a heat sensitive preparation and the product is stable after 14 days at 54°C.						-	-	N/A																																																																																							
Minimum content after heat stability	Standard Operational Procedure SPB/245	CHR/H/FETE C-PART B 110 EC	Initial preparation: Cloquintocet-mexyl (Safener) – 55.86 g/L						Y	Knapik I., Study code: ICB/91/2021	Acceptable Remarks: A loss of up																																																																																							

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
testing (KCP 2.7.3)		Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	Fenoxaprop-P-ethyl(active substance) – 108.81 g/L After accelerated storage: Cloquintocet-mexyl(Safener) – 53.11 g/L Fenoxaprop-P-ethyl (active substance) – 106.18 g/L After 1st year: cloquintocet-mexyl (Safener) – 54.47 g/L fenoxaprop-P-ethyl (active substance) – 108.05 g/L		Knapik I., Study code: ICB/92/2021	to 5% of the active substance (2.42%) and Safener (4.92%) is unlikely to adversely affect the safety or efficacy of the preparation.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	After low temperature stability 0°C for 7 days – slightly opalescent homogeneous liquid. After 24 h in room temperature and one invert – no phase separation, no sediment.	Y	Knapik I., Study code: ICB/91/2021 Knapik, I., Study code: ICB/38/2023	Acceptable

Annex point	Method used / deviations	Test material	Findings					GL P Y/N	Reference	Acceptability / comments							
			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	trace of oil at the bottom										
					30 min	complete	trace of oil at the bottom										
					2 h	complete	trace of oil at the bottom										
					24 h	complete	trace of solid at the bottom										
					24h+30 s	complete	complete										
					24h+30 min	complete	trace of solid at the bottom										
					Concentration 0.35% (v/v) at temperature 30±2°C:												
					<i>Time</i>	<i>Water A</i>	<i>Water D</i>										
					30 s	complete	trace of oil at the bottom										
					30 min	complete	trace of oil at the bottom										
					2 h	complete	trace of oil at the bottom										
					24 h	complete	trace of cream at the top and trace of solid at the bottom										
					24h+30 s	complete	complete										
			24h+30 min	complete	trace of solid at the bottom												
Ambient temperature shelf life (KCP 2.7.5)	-	-	<div>The 2-year storage stability studies on CHR/H/FETEC-PART B 110 EC are ongoing (January 2024).</div> <div>After 1st year:</div> <table><thead><tr><th>Study</th><th>Method</th><th>Results</th></tr></thead><tbody><tr><td></td><td></td><td></td></tr></tbody></table>						Study	Method	Results				Y	<div>Knapik I., Study code: ICB/92/2024</div>	
Study	Method	Results															

Annex point	Method used / deviations	Test material	Findings			GL P Y/N	Reference	Acceptability / comments																		
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Shelf life in months (if less than 2	-	CHR/H/FETE C-PART B 110	After 1 st year: <table><tr><td>Study</td><td>Method</td><td>Results</td></tr><tr><td>Appearance</td><td>OPPTS 830.6302</td><td>Colour to Gardner's scale – 6.3</td></tr></table>			Study	Method	Results	Appearance	OPPTS 830.6302	Colour to Gardner's scale – 6.3	-Y	- Knapik I., Study code: ICB/92/2021	Acceptable Remarks: Results from												
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years) (KCP 2.7.6)		EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012		830.6303 and 830.6304	Physical state – liquid Odour – intensive, characteristic			all studies (the content fenoxaprop-P-ethyl and cloquintocet-mexyl, appearance, pH, emulsion stability and stability of packing) showed that the formulation is stable for 12 months when stored in 1 L volume commercial bottle (HDPE/PA).
			pH	CIPAC MT 75.3	1% (w/v) emulsion – 6.33			
			Persistent foaming	CIPAC MT 47.3	0.125% (w/v): -after 1 minute – 10 mL - after 12 minutes – 4 mL 0.35% (w/v): -after 1 minute – 12 mL - after 12 minutes – 3 mL			
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			Content of cloquintocet-mexyl and fenoxaprop-P-ethyl	Standard Operational Procedure SPB/245	cloquintocet-mexyl – 54.47 g/L fenoxaprop-P-ethyl – 108.05 g/L			
Wettability (KCP 2.8.1)	-	-	Not required for this type of the formulation.			-	-	N/A
Persistence of foaming	CIPAC MT 47.3	CHR/H/FETE C-PART B 110	Initial preparation: 0.125% (w/v):			Y	Knapik I., Study code:	Acceptable

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
(KCP 2.8.2)		<p>EC Active substance: Fenoxaprop-P-ethyl 110 g/L</p> <p>Production date: 01.04.2021</p> <p>Batch No: 2020012</p>	<p>-after 1 minute – 10 mL - after 12 minutes – 6 mL 0.35% (w/v): -after 1 minute – 8 mL - after 12 minutes – 4 mL</p> <p>After 1st year: 0.125% (w/v): -after 1 minute – 10 mL - after 12 minutes – 4 mL 0.35% (w/v): -after 1 minute – 12 mL - after 12 minutes – 3 mL</p>		<p>ICB/91/2021</p> <p>Knapik I., Study code: ICB/92/2021</p>	
Suspensibility (KCP 2.8.3.1)	-	-	Not required for this type of the formulation.	-	-	N/A
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required for this type of the formulation.	-	-	N/A
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for this type of the formulation.	-	-	N/A
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for this type of the formulation.	-	-	N/A
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required for this type of the formulation.	-	-	N/A
Wet sieve test	-	-	Not required for this type of the formulation.	-	-	N/A

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(KCP 2.8.5.1.2)																																																
Dust content (KCP 2.8.5.2.1)	-	-	Not required for this type of the formulation.	-	-	N/A																																										
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for this type of the formulation.	-	-	N/A																																										
Attrition (KCP 2.8.5.3)	-	-	Not required for this type of the formulation.	-	-	N/A																																										
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for this type of the formulation.	-	-	N/A																																										
Emulsifiability (KCP 2.8.6.1)	MT 36.3	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No: 2020012	Initial preparation: <div>Concentration 0.125% (v/v) at temperature 30±2°C:</div> <table><tr><td>Time</td><td>Water A</td><td>Water D</td></tr><tr><td>30 s</td><td>complete</td><td>complete</td></tr><tr><td>30 min</td><td>complete</td><td>complete</td></tr><tr><td>2 h</td><td>complete</td><td>complete</td></tr><tr><td>24 h</td><td>complete</td><td>complete</td></tr><tr><td>24h+30 s</td><td>complete</td><td>complete</td></tr><tr><td>24h+30 min</td><td>complete</td><td>complete</td></tr></table> <div>Concentration 0.35% (v/v) at temperature 30±2°C:</div> <table><tr><td>Time</td><td>Water A</td><td>Water D</td></tr><tr><td>30 s</td><td>complete</td><td>complete</td></tr><tr><td>30 min</td><td>complete</td><td>complete</td></tr><tr><td>2 h</td><td>complete</td><td>complete</td></tr><tr><td>24 h</td><td>complete</td><td>complete</td></tr><tr><td>24h+30 s</td><td>complete</td><td>complete</td></tr><tr><td>24h+30 min</td><td>complete</td><td>complete</td></tr></table> After low temperature:	Time	Water A	Water D	30 s	complete	complete	30 min	complete	complete	2 h	complete	complete	24 h	complete	complete	24h+30 s	complete	complete	24h+30 min	complete	complete	Time	Water A	Water D	30 s	complete	complete	30 min	complete	complete	2 h	complete	complete	24 h	complete	complete	24h+30 s	complete	complete	24h+30 min	complete	complete	Y	Knapik I., Study code: ICB/91/2021 Knapik I., Study code: ICB/92/2021 Knapik, I., Study code: ICB/38/2023	Acceptable
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Re-emulsifiability (KCP 2.8.6.3)	MT 36.3	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L	Initial preparation:	Y	Knapik I., Study code: ICB/91/2021	Acceptable																																																																																				

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Flowability (KCP 2.8.7.1)	-	-	Not required for this type of formulation.	-	-	N/A																																										
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Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for this type of formulation.	-	-	N/A																																										
Physical compatibility of tank mixes (KCP 2.9.1)	-ASTM E 1518-05	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021 Batch No:	<div>The study is ongoing.</div> <div>Tank mix w Galaper 200 EC:</div>	-	<div>I. Knapik, Study code: ICB/71/2023</div> <div>I. Knapik, Study code: ICB/72/2023</div>	Acceptable																																										

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Tank Mix with Triben Super 50 SG (CHR/H/1TR 50 SG):																							

Annex point	Method used / deviations	Test material	Findings			GL P Y/N	Reference	Acceptability / comments
			Study	Method	Results			
			Compatibility	ASTM E 1518 - 05	Components of Mixture I are compatible. (0.006% (w/v) TRIBEN SUPER 50 SG (CHR/H/1TR 50 SG) and 0.125% (v/v) CHR/H/FETEC-PARTB 110 EC			
			Compatibility	ASTM E 1518 - 05	Components of Mixture II are compatible. (0.0125% (w/v) TRIBEN SUPER 50 SG (CHR/H/1TR 50 SG) and 0.125% (v/v) CHR/H/FETEC-PARTB 110 EC			
			Compatibility	ASTM E 1518 - 05	Components of Mixture III are compatible. (0.006% (w/v) TRIBEN SUPER 50 SG (CHR/H/1TR 50 SG) and 0.25% (v/v) CHR/H/FETEC-PARTB 110 EC			
			Compatibility	ASTM E 1518 - 05	Components of Mixture IV are compatible. (0.0125% (w/v) TRIBEN SUPER 50 SG (CHR/H/1TR 50 SG) and 0.25% (v/v) CHR/H/FETEC-PARTB 110 EC			
Chemical compatibility of tank mixes (KCP 2.9.2)	-SPB/282, SPB/280	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production	The study is ongoing. Tank mix w Galaper 200 EC:			Y	- I. Knapik, Study code: ICB/85/2023 I. Knapik, Study code: ICB/86/2023	Acceptable

Annex point	Method used / deviations	Test material	Findings			GL P Y/N	Reference	Acceptability / comments																									
		<div>date: 01.04.2021</div> <div>Batch No: 2020012</div> <div>Triben Super 50 SG (CHR/H/1TR 50 SG)</div> <div>Batch No: 0210/22</div> <div>Prod. Date: 01.10.2022</div> <div>Expiry date: 01.10.2024</div> <div>Galaper 200 EC</div> <div>Batch No.: CHR/18</div> <div>Prod. Date: 30.01.2021</div> <div>Expiry date: 30.01.2024</div>	<table><thead><tr><th>Study</th><th>Method</th><th>Results</th></tr></thead><tbody><tr><td>Determination of active ingredients in 0.125% (v/v) emulsion of test item CHR/H/FETEC-PARTB 110 EC</td><td>SPB/282</td><td>cloquintocet- mexyl – 0.055 [%] fenoxaprop-P-ethyl – 0.112 [%]</td></tr><tr><td>Determination of active ingredients in 0.25% (v/v) emulsion of test item CHR/H/FETEC-PARTB 110 EC</td><td>SPB/282</td><td>cloquintocet- mexyl – 0.053 [%] fenoxaprop-P-ethyl – 0.107 [%]</td></tr><tr><td>Determination of active ingredient in 0.1% (v/v) emulsion of test item GALAPER 200 EC</td><td>SPB/282</td><td>fluroxypyr – 0.221 [%]</td></tr><tr><td>Determination of active ingredient in 0.2% (v/v) emulsion of test item GALAPER 200 EC</td><td>SPB/282</td><td>fluroxypyr – 0.209 [%]</td></tr><tr><td>Chemical Compatibility of Mixture I</td><td>SPB/282</td><td>cloquintocet- mexyl – 0.053 [%] fenoxaprop-P-ethyl – 0.112 [%] fluroxypyr – 0.220 [%]</td></tr><tr><td>Chemical Compatibility of Mixture II</td><td>SPB/282</td><td>cloquintocet- mexyl – 0.051 [%] fenoxaprop-P-ethyl – 0.106 [%] fluroxypyr – 0.219 [%]</td></tr><tr><td>Chemical Compatibility of Mixture III</td><td>SPB/282</td><td>cloquintocet- mexyl – 0.055 [%] fenoxaprop-P-ethyl – 0.115 [%] fluroxypyr – 0.209 [%]</td></tr><tr><td>Chemical Compatibility of Mixture IV</td><td>SPB/282</td><td>cloquintocet- mexyl – 0.050 [%] fenoxaprop-P-ethyl – 0.105 [%] fluroxypyr – 0.203 [%]</td></tr></tbody></table> <div>Tank Mix with Triben Super 50 SG (CHR/H/1TR 50 SG):</div>	Study	Method	Results	Determination of active ingredients in 0.125% (v/v) emulsion of test item CHR/H/FETEC-PARTB 110 EC	SPB/282	cloquintocet- mexyl – 0.055 [%] fenoxaprop-P-ethyl – 0.112 [%]	Determination of active ingredients in 0.25% (v/v) emulsion of test item CHR/H/FETEC-PARTB 110 EC	SPB/282	cloquintocet- mexyl – 0.053 [%] fenoxaprop-P-ethyl – 0.107 [%]	Determination of active ingredient in 0.1% (v/v) emulsion of test item GALAPER 200 EC	SPB/282	fluroxypyr – 0.221 [%]	Determination of active ingredient in 0.2% (v/v) emulsion of test item GALAPER 200 EC	SPB/282	fluroxypyr – 0.209 [%]	Chemical Compatibility of Mixture I	SPB/282	cloquintocet- mexyl – 0.053 [%] fenoxaprop-P-ethyl – 0.112 [%] fluroxypyr – 0.220 [%]	Chemical Compatibility of Mixture II	SPB/282	cloquintocet- mexyl – 0.051 [%] fenoxaprop-P-ethyl – 0.106 [%] fluroxypyr – 0.219 [%]	Chemical Compatibility of Mixture III	SPB/282	cloquintocet- mexyl – 0.055 [%] fenoxaprop-P-ethyl – 0.115 [%] fluroxypyr – 0.209 [%]	Chemical Compatibility of Mixture IV	SPB/282	cloquintocet- mexyl – 0.050 [%] fenoxaprop-P-ethyl – 0.105 [%] fluroxypyr – 0.203 [%]			
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Annex point	Method used / deviations	Test material	Findings			GL P Y/N	Reference	Acceptability / comments
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			Determination of active ingredient in 0.006% (w/v) solution of test item TRIBEN SUPER 50 SG (CHR/H/1TR 50 SG)	SPB/280	tribenuron-methyl – 0.46 [%]			
			Determination of active ingredient in 0.0125% (w/v) solution of test item TRIBEN SUPER 50 SG (CHR/H/1TR 50 SG)	SPB/280	tribenuron-methyl – 0.46 [%]			
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			Determination of active ingredients in 0.25% (v/v) emulsion of test item CHR/H/FETEC-PARTB 110 EC	SPB/280	cloquintocet- mexyl – 0.052 [%] fenoxaprop-P-ethyl – 0.104 [%]			
			Chemical Compatibility of Mixture I	SPB/280	tribenuron-methyl – 0.42 [%] cloquintocet- mexyl – 0.056 [%] fenoxaprop-P-ethyl – 0.109 [%]			
			Chemical Compatibility of Mixture II	SPB/280	tribenuron-methyl – 0.49 [%] cloquintocet- mexyl – 0.056 [%] fenoxaprop-P-ethyl – 0.110 [%]			
			Chemical Compatibility of Mixture III	SPB/280	tribenuron-methyl – 0.47 [%] cloquintocet- mexyl – 0.052 [%] fenoxaprop-P-ethyl – 0.102 [%]			
			Chemical Compatibility of Mixture IV	SPB/280	tribenuron-methyl – 0.45 [%] cloquintocet- mexyl – 0.051 [%] fenoxaprop-P-ethyl – 0.102 [%]			
Adhesion to seeds (KCP 2.10.1)	-	-	Not required for this type of formulation.			-	-	N/A

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
Distribution to seed (KCP 2.10.2)	-	-	Not required for this type of formulation.	-	-	N/A
Other/special studies (KCP 2.11)	Effectiveness of cleaning (Efficacy Guideline 305)	CHR/H/FETE C-PART B 110 EC Active substance: Fenoxaprop-P-ethyl 110 g/L Production date: 01.04.2021	Single rinse procedure: 99.82 [%] cloquintocet-mexyl removed from the bottle 99.78 [%]fenoxaprop-P-ethyl removed from the bottle Double rinse procedure: 99.82 [%] cloquintocet-mexyl removed from the bottle 99.76 [%] fenoxaprop-P-ethyl removed from the bottle Triple rinse procedure: 99.84 [%] cloquintocet-mexyl removed from the bottle 99.80 [%] fenoxaprop-P-ethyl removed from the bottle	Y	Knapik I., Study code: ICB/91/2021 Knapik I., Study code: ICB/92/2021	Acceptable
	Stability of package (own method SPB/38)	Batch No: 2020012	Initial preparation: Stability of packaging test has been performed. No relevant interactions between formulation and its package were observed. Stability of the commercial used packaging material (HDPE/PE) has been confirmed. After 1st year: Change in packaging weight – 0.14 [%] Change in gross weight – 0.0044 [%]	Y		Acceptable

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)

Packaging information for 250 ml BOTTLE	
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

Packaging information for 250 ml BOTTLE	
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

Packaging information for 250 ml BOTTLE	
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

Packaging information for 500 ml BOTTLE	
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

Packaging information for 500 ml BOTTLE	
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

Packaging information for 500 ml BOTTLE	
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

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

Packaging information for 1000 ml	
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BOTTLE	
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

Packaging information for 1000 ml BOTTLE	
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

Packaging information for 1000 ml BOTTLE	
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

Packaging information for 1000 ml BOTTLE	
Type	BOTTLE
Material:	PE-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

Packaging information for 1000 ml BOTTLE	
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

Packaging information for 1000 ml BOTTLE	
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

Packaging information for 1000 ml BOTTLE	
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

Packaging information for 5000 ml CONTAINER	
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

Packaging information for 5000 ml BOTTLE	
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

Packaging information for 5000 ml BOTTLE	
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

Packaging information for 5000 ml CANNISTER	
Type	CANNISTER
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

Packaging information for 10000 ml CONTAINER	
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
Packaging information for 10000 ml CONTAINER	
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 (*Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin*) storage stability study can be extrapolated to new packaging material HDPE/F and HDPE/EvOH from provided and evaluated storage stability studies of packing HDPE/PA. Therefore, no further studies are required for the additional packaging materials.

Comment: The packaging material HDPE/PA was tested during the accelerated storage stability studies. The packaging material was found to be stable. Extrapolation of the data conducted with HDPE/PA packaging material to HDPE/F or HDPE/EvOH is possible according to SAN-CO/10473/2003 –rev.5 21.10.2021 when provided that stability is demonstrated in an accelerated test (seepage data). We propose consent to expand it to include HDPE/EvOH and HDPE/F packaging that seepage data will be provided.

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

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

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

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

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

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

Type	BOTTLE
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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

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

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

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

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

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

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

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

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

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

Type	CANNISTER
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

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

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

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

Packaging information for 250ml BOT-TLE	
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

Packaging information for 250ml BOT-TLE	
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

Packaging information for 500 ml BOT-TLE	
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

Packaging information for 500 ml BOT-	
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TLE	
Type	BOTTLE
Material:	HDPE/EvOH
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

Packaging information for 500 ml BOT-TLE	
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

Packaging information for 1000 ml BOT-TLE	
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

Packaging information for 1000 ml BOT-TLE	
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
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Packaging information for 1000 ml BOT-TLE	
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

Packaging information for 5000 ml CONTAINER	
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

Packaging information for 1000 ml BOT-TLE	
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

Packaging information for 10000 ml CONTAINER	
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

Packaging information for 20000 ml CONTAINER	
Type	CONTAINER
Material:	HDPE/EvOH
size:	375 mm \pm 2 mm/290mm \pm 2 mm/245mm \pm 2 mm
Opening:	85mm \pm 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

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 KCP 2.3.1 KCP 2.3.2 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.1 KCP 2.8.6.2 KCP 2.8.6.3 KCP 2.11	Knapik, I.	2022	<i>Determination of physicochemical properties of CHR/H/FETEC-PART B-PARTB 110 EC before and after accelerated storage test</i> ICB/91/2021 GLP Unpublished	N	Chemirol
KCP 2.1 KCP 2.4.2 KCP 2.7.5 KCP 2.7.6 KCP 2.8.2 KCP 2.8.6.2 KCP 2.11	Knapik, I.	2023	<i>Determination of physicochemical properties of CHR/H/FETEC-PARTB 110 EC after 12 months shelf-life test</i> ICB/92/2021 GLP Unpublished	N	Chemirol
KCP 2.5.1	Kupiec, J.	2022	<i>CHR/H/FETEC-PART B-PART b 110 EC Viscosity determination</i> BF-64/21 GLP Unpublished	N	Chemirol

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 2.2.2	Flasińska, P.	2022	CHR-H-FETEC-Part B 110 EC Determination of auto-ignition temperature and oxidizing properties. Study code: BC-01/22 GLP Unpublished	N	Chemiroł
KCP 2.2.1	Buczowski, D.	2022	CHR/H/FETEC-Part B 110 EC Determination of explosive properties Study code: BW-36/21 GLP Unpublished	N	Chemiroł
KCP 2.6.1	I. Knapik	2023	Determination of physicochemical properties of CHR/H/FETEC-PART B-PARTB 110 EC ICB/84/2023 GLP Unpublished	N	Chemiroł
KCP 2.9.1	I. Knapik	2023	Determination of physical compatibility of TRIBEN SUPER 50 SG (CHR/H/ITR 50 SG) with CHR/H/FETEC-PARTB 110 EC ICB/71/2023 GLP Unpublished	N	Chemiroł
KCP 2.9.1	I. Knapik	2023	Determination of physical compatibility of CHR/H/FETEC-PARTB 110 EC with GALAPER 200 EC ICB/72/2021 GLP Unpublished	N	Chemiroł
KCP 2.7.4 KCP 2.8.6.1 KCP 2.8.6.2	I. Knapik	2023	Determination of physicochemical properties of CHR/H/FETEC-PARTB 110 EC after storage test under low temperature conditions ICB/38/2023 GLP Unpublished	N	Chemiroł
KCP 2.9.2	Knapik	2023	Determination of chemical compatibility of CHR/H/FETEC-PARTB 110 EC with GALAPER 200 EC Company Report No ICB/86/2023	N	Chemiroł

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
			ICB Pharma Jaworzno Poland GLP Unpublished		
KCP 2.9.2	Knapik	2023	Determination of chemical compatibility of TRIBEN SUPER 50 SG (CHR/H/1TR 50 SG) with CHR/H/FETEC-PARTB 110 EC Company Report No ICB/85/2023 ICB Pharma, 10 Lema Street, 43-600 Jaworzno Poland GLP Unpublished	N	Chemirol

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

Not relevant.