

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/IMA 40 SL

Product name(s):

Mazzam 40 SL

Zemax 40 SL

Chemical active substance(s):

Imazamox, 40 g/L

Central Zone

Zonal Rapporteur Member State: Poland

Co-Rapporteur Member State: Hungary, Romania

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 09.2022

MS Finalisation date: 12/07/2024

Version history

When	What
January 2023	Dossier sent for evaluation
April 2024	zRMS evaluation of dRR
July 2024	Final version prepared by zRMS after Commenting period

Table of Contents

1	Section 1: Identity of the plant protection product.....	4
1.1	Applicant (KCP 1.1)	4
1.2	Producer of the plant protection product and of the active substances (KCP 1.2)	4
1.2.1	Producer(s) of the preparation	4
1.2.2	Producer(s) of the active substance(s)	4
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s)	4
1.2.3.1	Imazamox.....	4
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3)	4
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)	5
1.4.1	Composition of the plant protection product (KCP 1.4.1)	5
1.4.2	Information on the active substance(s) (KCP 1.4.2)	5
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3)	5
1.5	Type and code of the plant protection product (KCP 1.5)	5
1.6	Function (KCP 1.6)	5
2	Section 2: Physical, chemical and technical properties of the plant protection product	6
3	Section 3 is presented as a separate document.....	24
4	Section 4: Further information on the plant protection product	25
4.1	Packaging and Compatibility with the Preparation (KCP 4.4)	25
Appendix 1	Lists of data considered in support of the evaluation	50
Appendix 2	Additional data on the physical, chemical and technical properties of the active substance.....	56

zRMS comments:

The text highlighted in grey was provided by the zRMS.

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

Noticed data gaps are:

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, 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 Imazamox

Imazamox min. 950 g/kg

There are no relevant impurities in formulation CHR/H/IMA 40 SL.

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

Trade name: Zemax 40 SL
Mazzam 40 SL
Company code number: CHR/H/IMA 40 SL

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)
Imazamox	40 g/L	36 – 44 g/L	40 g/L	3.72 % (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 = 1.075 g/mL (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

There are no relevant impurities in formulation CHR/H/IMA 40 SL.

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

Table 1.4-3: Information on imazamox

Type	Name/Code number
ISO common name	Imazamox
CAS No.	114311-329
EC No.	Not allocated
CIPAC No.	619

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: Soluble concentrate

[Code: SL]

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 homogenous bright brown liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of 440 °C. In aqueous solution, it has a pH value around 6.4 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 3 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a formulation.

The intended concentration of use is 0.13% to 0.65%.

zRMS comments

The product was stable after three years of storage at ambient temperature (20±2°C) in HDPE package.

The analytical method which was used to determined active ingredient (Imazamox) content was validated in GLP laboratory (analytical method BA - 85/18). High performance liquid chromatography (HPLC) method using reverse phase column, UV/DAD detection (wavelength 244 nm) and external standard was used to determine the content of active substance. The initial concentration of Imazamox was 41.07 g/l, the concentration of Imazamox after 3 years of storage at ambient temperature was 39.71 g/l. It is recognized that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation.

Technical properties are acceptable for SL product.

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

Not required

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not required

Compliance with FAO specifications:

The product CHR/H/IMA 40 SL complies with FAO specifications.

Formulation used for tests

CHR/H/IMA 40 SL

Date of production: 08/2018

Batch No.: 2018.08.21

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual inspection Nasal inhalation	CHR/H/IMA 40 SL	<p>Initial: Transparent and homogenous bright brown liquid of characteristic odour</p> <p>After accelerated storage test: Transparent and homogenous bright brown liquid of characteristic odour</p> <p>After low temperature storage test: Transparent and homogenous bright brown liquid of characteristic odour</p> <p>After 1 year shelf-life test: Transparent and homogenous bright brown liquid of characteristic odour</p> <p>After 2 years shelf-life test: Transparent and homogenous bright brown liquid of characteristic odour</p> <p>After 3 years shelf-life test: Transparent and homogenous bright brown liquid of characteristic odour</p>	Y	Al Amin I. 2018 BF-62/18 Arévalo E. 2020 BF – 62/18 Arévalo E. 2021 BF – 62/18	<p>Acceptable</p> <p>The preparation after three years of storage was a homogenous and transparent bright brown liquid of characteristic odor.</p>
Explosive properties (KCP 2.2.1)	EEC A.14 method	CHR/H/IMA 40 SL	CHR/H/IMA has not got explosive properties according to the criteria of EEC A.14 method.	Y	Śliwa P. BW-36/18	<p>Acceptable</p> <p>Impact sensitivity and thermal sensitivity were carried out.</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						No explosion reaction of studied material.
Oxidizing properties (KCP 2.2.2)	N/R		Active substance and co-formulants of CHR/H/IMA 40 SL have not been classified as oxidizing. Therefore, this formulation has not got oxidizing properties.			Acceptable Theoretical assessment based on the information of ingredients of plant protection product and the classification of ingredients. Active substance and co-formulants are not classified, according to CLP regulation, as oxidising. The plant protection product CHR/H/IMA 40 SL is not classified as oxidising (has not oxidising properties).
Flash point (KCP 2.3.1)	Standard Operating Procedure SPO/BC/09/b	CHR/H/IMA 40 SL	CHR/H/IMA has not got the flash point up to the boiling point according to A.9 method.	Y	Flasińska P. BC-111/18	Acceptable A closed cup method was used to

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						determined the flash point of CHR/H/IMA 40 SL. CHR/H/IMA 40 SL does not have the flash point up to the boiling point.
Flammability (KCP 2.3.2)	SPO/BC/06/b	CHR/H/IMA 40 SL	Auto-ignition temperature: 440°C	Y	Flasińska P. BC-111/18	Acceptable
Self-heating (KCP 2.3.3)	SPO/BC/06/b	CHR/H/IMA 40 SL	Auto-ignition temperature: 440°C	Y	Flasińska P. BC-111/18	Acceptable
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	CHR/H/IMA 40 SL	Initial pH: 6.37 pH after accelerated storage test: 6.20 pH after storage at 0°C: 6.41 pH after 1 year of storage: 6.24 pH after 2 years of storage: 5.84 pH after 3 years of storage: 5.67	Y	Al Amin I. 2018 BF-62/18 Arévalo E. 2020 BF – 62/18 Arévalo E. 2021 BF – 62/18	Acceptable
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	CHR/H/IMA 40 SL	Initial pH: 6.06 pH after accelerated storage test: 5.60 pH after storage at 0°C: 5.57 pH after 1 year of storage: 6.41 pH after 2 years of storage: 4.98 pH after 3 years of storage: 4.88	Y	Al Amin I., 2018 BF-62/18 Arévalo E. 2020 BF – 62/18 Arévalo E. 2021 BF – 62/18	Acceptable
Viscosity (KCP 2.5.1)	OECD 114	CHR/H/IMA 40 SL	At 20°C: Kinematic 94.0 mm ² /s At 40°C: Kinematic 34.3 mm ² /s	Y	Al Amin I. BF – 62/18	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Surface tension (KCP 2.5.2)	EEC A. 5	CHR/H/IMA 40 SL	0.65% concentration 36.29 mN/m	Y	Al Amin I. BF – 62/18	Acceptable The surface tension was determined at the highest in use concentration (0.65%) at 20°C.
Relative density (KCP 2.6.1)	CIPAC MT 3.2	CHR/H/IMA 40 SL	1.075	Y	Al Amin I. BF – 62/18	Acceptable The density determination of the tested material, using the Gay-Lussac pycnometer in accordance with EEC Method A3 (CIPAC MT 3.2) was based on measuring the mass of the tested material contained by the pycnometer and defining its volume. The test was performed at 20°C temperature.
Bulk density (KCP 2.6.2)	N/R		N/R			N/R

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)	CIPAC MT 46.3.1	CHR/H/IMA 40 SL	Test type	Results	Y	Al Amin I. BF – 62/18	Acceptable The accelerated storage test was carried out according to a CIPAC MT 46.3.1. A 1L HDPE bottle containing the tested material was placed in a thermostated oven at (54 ±2)°C temperature for 14 days. The registered accelerated storage test temperature varied between 53.8°C and 54.6°C. The content of active ingredient was determined in accordance with the analytical method no. BA - 85/18, developed and validated in the
			Physical state colour and odour	Transparent and homogenous bright brown liquid of characteristic odour			
			pH	Undiluted			
				1% solution			
			Diltion stability	Homogenous and transparent			
			Active ingredients	Imazamox 3.7 % (39.78 g/L)			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>Analytical Department of the Institute of Industrial Organic Chemistry (GLP test facility). High performance liquid chromatography (HPLC) method using reverse phase column, UV/DAD detection (wavelength 244 nm) and external standard was used to determine the content of active substance. The determined content of the active ingredient imazamox in the preparation after accelerated storage was 3.70% (39.78 g/l). The content of the active ingredient</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						imazamox in the preparation after accelerated storage meets FAO Limits (min – max) 36 – 44 g/L.
t after storage for other periods and/or temperatures (KCP 2.7.2)	N/R	-	N/R	-	-	N/R
Minimum content after heat stability testing (KCP 2.7.3)	HPLC	CHR/H/IMA 40 SL	Content of imazamox: Initial: 3.82% (41.07 g/L) After accelerated storage test: 3.70% (39.78 g/L) After 1 year of storage: 3.81% (40.91 g/l) After 2 years of storage: 3.74% (40.21 g/l) After 3 years of storage: 3.69% (39.71 g/l)	Y	Al Amin I. 2018 BF-62/18 Arévalo E. 2020 BF – 62/18 Arévalo E. 2021 BF – 62/18	Acceptable The content of active ingredient was determined in accordance with the analytical method no. BA - 85/18, developed and validated in the Analytical Department of the Institute of Industrial Organic Chemistry (GLP test facility). High performance liquid

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						chromatography (HPLC) method using reverse phase column, UV/DAD detection (wavelength 244 nm) and external standard was used to determined the content of active substance. The determined content of the active ingredient imazamox in the preparation after accelerated storage test and after 3 years storage at ambient temperature meets FAO Limits (min – max) 36 – 44 g/L.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	CHR/H/IMA 40 SL	Test type	Y	Al Amin I. BF-62/18	Acceptable Two transparent graduated glass cylinders were loaded
			Physical state colour and odour			
			pH Undiluted			
			Results			
			Transparent and homogenous bright brown liquid of characteristic odour			
			6.41			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				1% solution	5.57			with one hundred milliliters of the initial preparation. The cylinders with the tested material were stored at (0±2)°C for 7 days. After the test period elapsed the samples were observed for their transparency, homogeneity and if any color change took place immediately after storage at 0°C, at room temperature and after 24 hours at room temperature and one inversion. The recorded temperatures were between – 0.2 and 0.2°C. The preparation immediately
			Dilution stability		Homogenous and transparent			
			Effect of low temperature		Homogenous and transparent liquid			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
									after storage at 0°C, at room temperature and after 24 hours at room temperature was transparent and homogenous liquid.
Ambient temperature shelf life (KCP 2.7.5)	Elaborated standard procedure no. SPO/BF/07/b (ed.4)	CHR/H/IMA 40 SL	Test type	Results			Y	Arévalo E. 2020 BF – 62/18 Arévalo E. 2021 BF – 62/18	Acceptable The stability data indicate a shelf life of at least 3 years at ambient temperature when stored in HDPE package. The content of active ingredient was determined in accordance with the analytical method no. BA - 85/18, developed and validated in the Analytical Department (GLP test facility). The content of active substance was
				After one year	After two years	Afer three years			
			Physical state colour and odour	Transparent and homogenous bright brown liquid of characteristic odour	Transparent and homogenous bright brown liquid of characteristic odour	Transparent and homogenous bright brown liquid of characteristic odour			
			pH	Undil.	6.24	5.84	5.67		
				1% sol.	6.41	4.98	4.88		
			Dilution stability (0.13%, 0.2%, 0.65%)		Homogenous and transparent	Homogenous and transparent	Homogenous and transparent		
			Persistent foam	0.13%	2 ml of foam after 1 min and 2 after 12 minutes	2 ml of foam after 1 min and 2 after 12 minutes	7 ml of foam after 1 min and 4 after 12 minutes		
				0.65%	0 ml of foam after 1 and 12 minutes	4 ml of foam after 1 min and 2 after 12 minutes	0 ml of foam after 1 min and 0 after 12 minutes		

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
			Package stability	Stable, 1 litre HDPE	Stable, 1 litre HDPE	Stable, 1 litre HDPE			analyze by high performance liquid chromatography (HPLC) method using reverse phase column, DAD detection (wavelength 244 nm) and external standard. The determined content of the active ingredient imazamox in the preparation after 3 years storage was 3.69% (39.71 g/l). The content of the active ingredient imazamox in the preparation after 3 years storage meets FAO Limits (min – max) 36 – 44 g/L. After 3 years storage at ambient temperature the technical properties of the
			Active ingredients	Imazamox 3.81% (40.91 g/l)	Imazamox 3.74% (40.21 g/l)	Imazamox 3.69% (39.71 g/l)			

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
										plant protection product were not changed.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	N/R	-	N/R					-	-	N/R
Wettability (KCP 2.8.1)	N/R	-	N/R					-	-	N/R
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	CHR/H/IMA 40 SL						Y	Al Amin I. 2018 BF – 62/18 Arévalo E. 2020 BF – 62/18 Arévalo E. 2021 BF – 62/18	Acceptable Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation. Acceptable Limits: Max 60 mL foam after 1 minute. The acceptable limit was met.
				Initial	After 1 year	After 2 years	After 3 years			
			Concentration 0.13%	2 ml of foam after 1 min and 0 after 12 minutes	2 ml of foam after 1 min and 2 after 12 minutes	2 ml of foam after 1 min and 2 after 12 minutes	7 ml of foam after 1 min and 4 after 12 minutes			
			Concentration 0.65%	0 ml of foam after 1 and 12 minutes	0 ml of foam after 1 and 12 minutes	4 ml of foam after 1 and 2 after 12 minutes	0 ml of foam after 1 and 12 minutes			
Suspensibility (KCP 2.8.3.1)	N/R	-	N/R					-	-	N/R

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (KCP 2.8.3.2)	N/R	-	N/R	-	-	N/R
Dispersion stability (KCP 2.8.3.3)	N/R	-	N/R	-	-	N/R
Degree of dissolution and dilution stability (KCP 2.8.4)	CPAC MT 41.1	CHR/H/IMA 40 SL	Initial: homogenous and transparent After accelerated storage test: homogenous and transparent After storage at 0°C: homogenous and transparent After 1 year: homogenous and transparent After 2 years: homogenous and transparent After 3 years: homogenous and transparent	Y	Al Amin I. 2018 BF – 62/18 Arévalo E. 2020 BF – 62/18 Arévalo E. 2021 BF – 62/18	Acceptable The dilution stability is determined to ensure that water-soluble preparations dissolve readily and/or, when diluted, produce stable solutions without precipitation, flocculation, etc. The results submitted should fully describe the appearance and amount of any separation or sediment. Acceptable limits:- MT 41.1 'trace' of sediment after

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						30 minutes – the amount and appearance of any sediment should be fully described. The criteria of method were met – after 3 years of storage the product was transparent and homogenous liquid.
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	N/R	-	N/R	-	-	N/R
Wet sieve test (KCP 2.8.5.1.2)	N/R	-	N/R	-	-	N/R
Dust content (KCP 2.8.5.2.1)	N/R	-	N/R	-	-	N/R
Particle size of dust (KCP 2.8.5.2.2)	N/R	-	N/R	-	-	N/R
Attrition (KCP 2.8.5.3)	N/R	-	N/R	-	-	N/R
Hardness and integrity (KCP 2.8.5.4)	N/R	-	N/R	-	-	N/R

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsifiability (KCP 2.8.6.1)	N/R	-	N/R	-	-	N/R
Emulsion stability (KCP 2.8.6.2)	N/R	-	N/R	-	-	N/R
Re-emulsifiability (KCP 2.8.6.3)	N/R	-	N/R	-	-	N/R
Flowability (KCP 2.8.7.1)	N/R	-	N/R	-	-	N/R
Pourability (KCP 2.8.7.2)	N/R	-	N/R	-	-	N/R
Dustability following accelerated storage (KCP 2.8.7.3)	N/R	-	N/R	-	-	N/R
Physical compatibility of tank mixes (KCP 2.9.1)	N/R	-	N/R	-	-	N/R
Chemical compatibility of tank mixes (KCP 2.9.2)	N/R	-	N/R	-	-	N/R
Adhesion to seeds (KCP 2.10.1)	N/R	-	N/R	-	-	N/R

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
Distribution to seed (KCP 2.10.2)	N/R	-	N/R					-	-	N/R
Other/special studies (KCP 2.11)	Application equipment cleaning: Efficacy Guideline 305: 2004	CHR/H/IMA 40 SL	Water used	Initial imazamox content	Imazamox content after rinsing	Cleaning effectiveness	Average[mL]	Y	Al Amin I. 2019 BF – 62/18	Acceptable The objective of the study was to evaluate the package cleaning effectiveness. The cleaning was performed in accordance with Efficacy Guideline 305: 2004 using small scale tests. Testes were performed in triplicate and the results averaged. The content of active ingredient in the acetonitrile solution was determined by high performance liquid
			[mL]	[mg]	[mg]	[%]	[%]			
			10	24.8	0.0052	99.98	99.99			
			2 x 10	24.8	0.0010	100.00				
			3 x 10	24.8	< LOQ	100.00				

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments								
									chromatography (HPLC) using reversed phase column with UV/DAD detection at wavelength measuring 244 nm. External standard method was used. The analytical method was validated.								
	Stability of package: Elaborated standard procedure no. SPO/BF/07/b (ed.4)	CHR/H/IMA 40 SL	<table><tr><th>Initial</th><th>After one year</th><th>After two years</th><th>After three years</th></tr><tr><td>1 litre HDPE</td><td>Stable, 1 litre HDPE</td><td>Stable, 1 litre HDPE</td><td>Stable, 1 litre HDPE</td></tr></table>	Initial	After one year	After two years	After three years	1 litre HDPE	Stable, 1 litre HDPE	Stable, 1 litre HDPE	Stable, 1 litre HDPE				Y	Al Amin I. 2018 BF – 62/18 Arévalo E. 2020 BF – 62/18 Arévalo E. 2021 BF – 62/18	Acceptable The packages of HDPE including the test item were stored at (20±2)°C temperature in a thermostated chamber. The mass of the initial packages containing the preparation and the mass of the stored packages after the third year of storage before emptying was determined. After the third
Initial	After one year	After two years	After three years														
1 litre HDPE	Stable, 1 litre HDPE	Stable, 1 litre HDPE	Stable, 1 litre HDPE														

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						year of storage at 20±2°C the shape and colour of the 1 litre HDPE package were stable. The minor mass change and shape of the packages has no effect in the physicochemical properties of the tested preparation.

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)

HDPE bottles/jars

Type	BOTTLE
Material:	HDPE
size:	64 mm± 2 mm/130 mm ± 3 mm
Opening:	40 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	72 mm± 2 mm/111,8 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	72±1 mm/111.8±2 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	45.65± 2 mm
Closure:	screw cap with seal
Capacity	564 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	90,5 mm± 2 mm/151 mm ± 3 mm
Opening:	40,6 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	77,6 mm± 2 mm/160,6 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	77.6 ±1 mm/160.6±2 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box
Material: HDPE
Type of construction: jar
Size: approximate diameter/height: 80 mm/138 mm
Capacity: 510 ml overflow
Type of closure: screw-cap with seal
Size of opening: 46 mm minimum
Accessories: one measuring device per each jar

Type	BOTTLE
Material:	HDPE

size:	145.5mm± 2 mm/78mm ± 2 mm
Opening:	56mm ± 2 mm
Closure:	screw cap with seal
Capacity	600 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	JAR
Material:	HDPE
size:	79/80 mm/ 201 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	80 mm± 2 mm/201 mm ± 2 mm
Opening:	64 mm
Closure:	screw cap with seal
Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	88.5 mm± 2 mm/283.5 mm ± 2 mm
Opening:	45.30 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	88 mm± 4 mm/242 mm ± 6 mm
Opening:	39mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	238 mm± 2 mm/90mm ± 2 mm
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

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

Type	BOTTLE
Material:	HDPE
size:	84 mm± 2 mm/248.2 mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	cap with seal
Capacity	1200 ± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE

size:	84 ± 1.5 mm/230.1 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	157,2 mm± 2 mm/101mm ± 2 mm
Opening:	72 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	JAR
Material:	HDPE
size:	108/110 mm/ 266 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	94 ± 1 mm/103 ± 1 mm/272.5 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Type	BOTTLE
Material:	HDPE
size:	224,1 mm± 2 mm/122mm ± 2 mm
Opening:	73 mm ± 2 mm
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

HDPE containers/cannisters

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	CANNISTER
Material:	HDPE
size:	96 ± 3 mm/195 ± 3.5 mm/297.2 ± 4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	4000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	CONTAINER
Material:	HDPE
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm
Opening:	59.20 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	CONTAINER
------	-----------

Material:	HDPE
size:	336 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

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

Type	CANNISTER
Material:	HDPE
size:	190 mm± 5 mm /140 mm± 5 mm/ 314 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	CANNISTER
Material:	HDPE
size:	127±2 mm/192±2 mm/285±5 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	CANNISTER
Material:	HDPE
size:	145±2 mm/190.8±3/294±4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	6000 ml

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

Type	Description
Material:	HDPE
Size:	375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	11220±50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	312 mm± 5 mm/225mm± 5 mm/185mm ± 5 mm
Opening:	40.8 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	375 mm± 5 mm/230± 5 mm/165 mm ± 5 mm
Opening:	54.5 mm ± 5 mm

Type	Description
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	377,7 mm \pm 5 mm/239,5 \pm 5 mm/178 mm \pm 5 mm
Opening:	54 mm \pm 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	192 \pm 3 mm/228 \pm 7/313 \pm 7 mm
Opening:	52 mm \pm 2 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	185 \pm 2 mm/225 \pm 2/312 \pm 3 mm

Type	Description
Opening:	40.8 mm \pm 0.3 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	443mm/288mm/230mm
Opening:	44mm (internal) 60mm (external)
Closure:	screw cap with seal
Capacity	22000ml \pm 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	376.3 \pm 3 mm/295 \pm 3mm/246 \pm 3mm
Opening:	50 mm \pm 5 mm
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	378 \pm 5 mm/288 \pm 5/258 \pm 5 mm
Opening:	53.7 \pm 1.5 mm
Closure:	screw cap with

Type	Description
	seal
Capacity	22000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	376±8 mm/257,5±5/376±8 mm
Opening:	52 mm± 3
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	257.5±6 mm/292±8/376±8 mm ± 5 mm
Opening:	52 mm ± 2 mm
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Type	Description
Material:	HDPE
Size:	90000mm/59000mm ± 2 mm
Opening:	45mm ± 2 mm
Closure:	screw cap with seal
Capacity	200 ml

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

HDPE/PA bottles

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/PA and HDPE/PA COEX from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP to HDPE. Therefore, no further studies are required for the additional packaging materials.

Acceptable

According to Guidelines for specifying and managing shelf life and expiry date of crop protection products (Technical Monograph N°17, 3rd edition, CropLife) guideline from Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin) for water based formulation (e.g. SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of others. Storage stability study can be extrapolated to new packaging material HDPE/PA and HDPE/PA COEX from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP in HDPE.

Packaging information	
Type	BOTTLE
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

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

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

Packaging information	
Type	BOTTLE
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

Packaging information	
Type	BOTTLE
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

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

Packaging information	
Type	BOTTLE
Material:	HDPE/PA
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Packaging information	
Type	BOTTLE
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

Packaging information	
Type	BOTTLE
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

Packaging information	
Type	BOTTLE
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

Packaging information	
Type	CONTAINER
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

Packaging information	
Type	BOTTLE
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

Packaging information	
Type	BOTTLE
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

Coextruded HDPE/PA containers/cannisters

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/PA and HDPE/PA COEX from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP to HDPE. Therefore, no further studies are required for the additional packaging materials.

Acceptable

According to Guidelines for specifying and managing shelf life and expiry date of crop protection products (Technical Monograph N°17, 3rd edition, CropLife) guideline from Ministry of Agriculture and Rural

Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin) for water based formulation (e.g. SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of others. Storage stability study can be extrapolated to new packaging material HDPE/PA and HDPE/PA COEX from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP in HDPE.

Packaging information	
Type	CANNISTER
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

Packaging information	
Type	CONTAINER
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

Packaging information	
Type	CONTAINER
Material:	HDPE/PA COEX
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	coextruded
UN/ADR	compliant

HDPE/F bottles

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 from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP to HDPE. Therefore, no further studies are required for the additional packaging materials.

Acceptable

According to Guidelines for specifying and managing shelf life and expiry date of crop protection products (Technical Monograph N°17, 3rd edition, CropLife) guideline from Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin) for water based formulation (e.g. SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of others. Storage stability study can be extrapolated to new packaging material HDPE/F from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP in HDPE.

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
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	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 ± 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

HDPE/F cannisters

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 from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP to HDPE. Therefore, no further studies are required for the additional packaging materials.

Acceptable

According to Guidelines for specifying and managing shelf life and expiry date of crop protection products (Technical Monograph N°17, 3rd edition, CropLife) guideline from Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin) for water based formulation (e.g. SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of others. Storage stability study can be extrapolated to new packaging material HDPE/F from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP in HDPE.

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

HDPE/EvOH bottles

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/EvOH from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP to HDPE. Therefore, no further studies are required for the additional packaging materials.

Acceptable

According to Guidelines for specifying and managing shelf life and expiry date of crop protection products (Technical Monograph N°17, 3rd edition, CropLife) guideline from Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin) for water based formulation (e.g. SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of others. Storage stability study can be extrapolated to new packaging material HDPE/EvOH from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP in HDPE.

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

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

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

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

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

Packaging information	
Type	BOTTLE
Material:	HDPE/EvOH
size:	234±3 mm/88.5±2mm
Opening:	50 mm ± 3 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

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

HDPE/EvOH containers/cannisters

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/EvOH from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP to HDPE. Therefore, no further studies are required for the additional packaging materials.

Acceptable

According to Guidelines for specifying and managing shelf life and expiry date of crop protection products (Technical Monograph N°17, 3rd edition, CropLife) guideline from Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin) for water based formulation (e.g. SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of others. Storage stability study can be extrapolated to new packaging material HDPE/EvOH from provided and evaluated storage stability studies of packing CHR/H/IZOXACYP in HDPE.

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

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

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

Packaging information	
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 2.1/1	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemrol
KCP 2.1/2	Arévalo E.	2020	Determination of physicochemical properties of the preparation after two years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemrol
KCP 2.1/3	Arévalo E.	2021	Determination of physicochemical properties of the preparation after three years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemrol
KCP 2.2.1	Śliwa P.	2018	Determination of explosive properties Study code: BF – 36/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemrol
KCP 2.3.1	Flasińska P.	2018	Determination of flash point and auto-ignition temperature Study code: BF – 118/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemrol

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 2.4.1/1	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
KCP 2.4.1/2	Arévalo E.	2020	Determination of physicochemical properties of the preparation after two years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
KCP 2.4.1/3	Arévalo E.	2021	Determination of physicochemical properties of the preparation after three years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
KCP 2.4.2/1	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
KCP 2.4.2/2	Arévalo E.	2020	Determination of physicochemical properties of the preparation after two years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
KCP 2.4.2/3	Arévalo E.	2021	Determination of physicochemical properties of the preparation after three years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	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
2.5.1	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.5.2	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.6.1	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.6.2	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.7.1	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.7.3/1	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	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
2.7.3/2	Arévalo E.	2020	Determination of physicochemical properties of the preparation after two years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.7.3/3	Arévalo E.	2021	Determination of physicochemical properties of the preparation after three years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.7.4	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.7.5/1	Arévalo E.	2020	Determination of physicochemical properties of the preparation after two years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.7.5/2	Arévalo E.	2021	Determination of physicochemical properties of the preparation after three years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.8.2/1	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	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
2.8.2/2	Arévalo E.	2020	Determination of physicochemical properties of the preparation after two years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.8.2/3	Arévalo E.	2021	Determination of physicochemical properties of the preparation after three years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.8.4/1	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.8.4/2	Arévalo E.	2020	Determination of physicochemical properties of the preparation after two years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.8.4/3	Arévalo E.	2021	Determination of physicochemical properties of the preparation after three years of storage Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes Unpublished	N	Chemiroł
2.11	Al Amin I.	2018	Determination of physicochemical properties of the initial, after accelerated and low temperature storage; Amendment No. 1: Application equipment cleaning effectiveness Study code: BF – 62/18 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP - yes	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
			Unpublished		

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

No additional data have been submitted because it is not necessary.