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: MEZOT 100 SC

Product name(s): Mezot 100 SC

Chemical active substance:

Mesotrione, 100 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 28/01/2021

Update: 02/2023, 07/2023

MS Finalisation date: 08/2023; 12/2023

Version history

When	What
01/2021	Submission date
02.02.2023	Table 2-1, Point 2.4.1 – Completion of data and information.
02.02.2023	Table 2-1, Point 2.7.5 – Completion of data and information.
02.02.2023	Table 2-1, Point 2.11 – Completion of data and information.
10.07.2023	Table 2-1, Point 2.7.1 – Completion of data and information.
10.07.2023	Point 4.1. – Completion of data and information.
08.2023	ZRMs evaluated dRR submitted by Applicant
12.2023	The final Registration Report

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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: none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Elvita Sp. z o.o.
Address: Różewo, 78-627 Różewo

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

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

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

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

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

1.2.3.1 Mesotrione

Mesotrione	min. 920 g/kg (Regulation (EU) 2017/725; SANTE/11654/2016, 23 March 2017)
	min. ~~930~~ 980 g/kg (Elvita's source)
Relevant impurities:	
R287431	max. 2 mg/kg
R287432	max. 2 g/kg
1,2-dichloroethane	max. 1 g/kg

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

Trade name:	Please refer to Registration Report Part A for the relevant country (or)
Trade name:	Mezot 100 SC
Company code number:	Mezot 100 SC

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)

The formulation SC like the product Mezot 100 SC was the representative formulation.

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

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Mesotrione	100	~~None~~ 90-110	~~107,5~~ 102.04	~~9,92~~ 9.41

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers
** Based on the density of the formulation = 1.084 g/L

Table 1.4-2: Safener and synergists

Neither safener nor synergists were used in the formulation.

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L) in PPP
R287431 R287432 1,2-dichloroethane	0.0002 0.2 0.1

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

Table 1.4-4: Information on Mesotrione

Type	Name/Code Number
ISO common name	Mesotrione
CAS No.	104206-82-8
EC No.	~~N/A~~ 600-533-4
CIPAC No.	625

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: SC (Suspension concentrate) [Code: (SC)]

1.6 Function (KCP 1.6)

Herbicide

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of Homogenous creamy liquid of characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable, has a self-ignition temperature of 410°C. In aqueous solution, it has a pH value around 2.97 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 2 years at ambient temperature when stored in HDPE packaging material. Its technical characteristics are acceptable for a *Suspension Concentrate* formulation.

The intended concentration of use is 0.5 – 0.75 % v/v

No tank mixes recommended

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

None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None

Compliance with FAO specifications:

~~The product Mezot 100 SC complies with FAO specifications.~~

At the time of the evaluation, there is no FAO specification for the formulation with mesotrione.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual inspection	Mezot 100 SC Batch No.: 190521	Homogenous creamy liquid of characteristic odour.	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted
Explosive properties (KCP 2.2.1)	Not applicable. Considering the composition of the formulation and the indiviuals components, the product is not expected to have explosive and oxidizing properties.					Accepted Not explosive
Oxidizing properties (KCP 2.2.2)						Accepted No oxidizing properties
Flash point (KCP 2.3.1)	EEC A.9	Mezot 100 SC Batch No.: 190521	Product not got the flash point up to the boiling point according to A.9 method.	Y	Paulina Flasińska, MSc; Institute of Industrial Organic Chemistry; BC-16/19; Warsaw; 2019	Accepted Not flammable
Flammability (KCP 2.3.2)	Not applicable. It is not a solid or gas plant protection product.					Not required
Self-heating (KCP 2.3.3)	EEC A.15	Mezot 100 SC Batch No.: 190521	Auto-ignition temperature of Mezot 100 SC is 410°C according to A.15 method.	Y	Paulina Flasińska, MSc; Institute of Industrial Organic Chemistry; BC-16/19; Warsaw; 2019	Accepted Not auto-flammable
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	Mezot 100 SC Batch No.: 190521	5.42 %	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
~~Acidity or alkalinity and pH~~ ~~(KCP 2.4.1)~~ pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Mezot 100 SC	pH at 20°C = 4.75 (Undiluted product)	Y	Inga Sowik MSc.; Institute of Industrial Organic Chemistry; BA-03/22; Warsaw; 2022	Accepted
	CIPAC MT 75.3	Mezot 100 SC Batch No.: 190521	pH of 1% at 20°C = 2.97	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted Beacause of pH < 4, the acidity was tested, see KCP 2.4.1
Viscosity (KCP 2.5.1)	OECD 114	Mezot 100 SC Batch No.: 190521	Dynamic viscosity: at 20ºC: at 40ºC: - at shear rate of 2,5 s^{-1} 1038 mPa·s, 589 mPa·s, - at shear rate of 5 s^{-1} 836 mPa·s, 431 mPa·s, - at shear rate of 10 s^{-1} 698 mPa·s, 336 mPa·s, - at shear rate of 25 s^{-1} 580 mPa·s, 255 mPa·s,	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted Non-Newtonian behaviour. Based on the results formulation is not considered an aspiration hazard
Surface tension (KCP 2.5.2)	EEC A.5	Mezot 100 SC Batch No.: 190521	29.23 mN/m at 20ºC	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted Concentration used – 0.8% (higher than the highest reccomended). The formulation is considered surface active.
Relative density (KCP 2.6.1)	CIPAC MT 3.2	Mezot 100 SC Batch No.: 190521	Density: 1.084 g/ml at 20°C Relative density: 1.084 at 20°C	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted
Bulk density (KCP 2.6.2)	Not applicable. It is not a plant protection product in the form of powder or granules.					Not required

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)	Physical state colour and odour	CIPAC MT 46.3	Organoleptic	Mezot 100 SC Batch No.: 190521	Homogenous creamy liquid of characteristic odor. Right after storage, an upper-layer (~2%) was present. The preparation became homogenous after shaking it.	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted Studies required for the SC formulation have been submitted and accepted; no significant change of physical-chemical properties after storage. According to the Applicant's statement, the test was performed in a commercial packaging (HDPE), which didn't present any deformation, loss of sample or corrosion. A.s. content after storage was stable (initial result: 9.52 %; 103.20 g/L). Data on R287431 was completed in additional study. All impurities within their limits.
	pH		CIPAC MT 75.3		2.96			
	Acidity		CIPAC MT 191		5.45 %			
	Suspension stability		CIPAC MT 184		1.5 ltr/400 ltr water – 94.18 % 1.5 ltr/200 ltr water – 93.27 %			
	Dispersion spontaneity		CIPAC MT 160		88.01 %			
	We sieve test		CIPAC MT 185		0.00 %			
	Pourability		CIPAC MT 148.1		R = 2.1 % and R' = 0.19 %			
	Particle size distribution		CIPAC MT 187		-			
	Mesotrione		HPLC / DAD		9.55 % (104.58 g/L)			
	R287432		HPLC / DAD		Initial: 0.00044% (0.0048 g/L in the formulation) After storage: 0.00077 % (0.0084 g/L in the formulation)			
	1,2-dichloroethane		HS-GC-FID		<LOQ (0.0067 g/kg), before and after storage			
	Packaging		-		As stated in storage stability reports after 1st and 2nd year of storage accelerated storage stability test was performed in original packagings HDPE.			
	R287431	CIPAC MT 46.4	UHPLC-MS/MS	Mezot 100 SC Batch No.: 01/22	<LOQ (0.00000105 g/kg of the preparation and 0.0000105 g/kg of mesotrione), before and after storage	Y	Inga Sowik MSc.; Institute of Industrial Organic Chemistry; BA-03/22; Warsaw; 2022	

Annex point	Method used / deviations	Test mate-rial	Findings	GLP Y/N	Reference	Acceptability / comments
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not applicable. The product is chemically and physically stable after storage for 14 days at 54 ^{0}C.					Not required
Minimum content after heat stability testing (KCP 2.7.3)	HPLC / DAD detector	Mezot 100 SC Batch No.: 190521	9.55 % (104.58 g/l)	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Mezot 100 SC Batch No.: 190521	Temperatures were between -1,0 ^{0}C to 0,1 ^{0}C. Observations: - immediately after storage - at room temperature - after 24 h at room temp. and one inversion. Result: Homogenous liquid.	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted Wet sieve test was not determined. Based on initial results and other results after cold stability testing, formulation is considered not sensitive to low temperature.
	Suspension stability: CIPAC MT 184		1.5 ltr/400 ltr water – 94.16 % 1.5 ltr/200 ltr water – 94.41 %			
	Particle size distribution: CIPAC MT 187		d_{10} = 0.668 µm d_{50} = 7.405 µm d_{90} = 23.48 µm $d_{4,3}$ = 11.17 µm SD = 0.11 µm; RSD = 0.98 %			
Ambient temperature shelf life (KCP 2.7.5)	Studies for Mezot 100 SC; Batch No.: 180216/3.					Accepted A.s. content stable after storage and there were no significant changes of PPP physical-chemical properties. Test was performed in a
			Results given after 1 year of storage.	Results given after 2 year of storage.		
	Physical state colour and odour	Mesotrione R287432	Homogenous creamy liquid of characteristic odor.	Homogenous creamy liquid of characteristic odor (on the surface a 5% layer of surfactants)	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19;

Annex point		Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
	pH Determination of 1%	CIPAC MT 75.3		2.98	2.65		Warsaw; 2020 Warsaw, 2021	commercial packaging (HDPE), which didn't present any deformation, corrosion etc. No information related to relevant impurities. As the content of the a.s. was stable during the storage and based on the results after accelerated testing it can be waived.
	Acidity	CIPAC MT 191		5.61 %	5.61 %			
	Viscosity	OECD 114		-	-			
	Density determination	CIPAC MT 3.2		-	-			
	Foaming	CIPAC MT 47.3		-	-			
	Dispersion spontaneity	CIPAC MT 160		88.12 %	85.65 %			
	Suspension stability	CIPAC MT 184		1.5 ltr/400 ltr water – 98.41 % 1.5 ltr/200 ltr water – 96.94 %	1.5 ltr/400 ltr water – 96.36 % 1.5 ltr/200 ltr water – 95.60 %			
	Wet sieve test	CIPAC MT 185		0,00	0,00			
	Pourability	CIPAC MT 148.1		R = 3.00 %; R´ = 0.25 %	R = 2.77 %; R´ = 0.56 %			
	Surface tension	EEC A.5		-	-			
	Package stability	GIFAP No. 17		Stable, 1 litre HDPE	Stable, 1 litre HDPE			
	Mesotrione	HPLC/ DAD		9.54 (103.41 g/L)	9.41 (103.20 g/L)			
Shelf life in months (if less than 2 years) (KCP 2.7.6)		Not applicable. Proposed shelf life isn't less than 2 years.						Not required
Wettability (KCP 2.8.1)		Not applicable. It is not a solid plant protection product, which is diluted for use.						Not required
Persistence of foaming		CIPAC MT 47.3	Mezot 100	For 1.5 ltr/200 ltr water CIPAC D:		Y	Enzo Arévalo, Ph.D.;	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.2)		SC Batch No.: 190521	11 ml of foam after 60 s. 2 ml of foam after 12 min.		Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Highest in-use conc. was tested (0.75%)
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Mezot 100 SC Batch No.: 190521	1.5 ltr/~~5~~ 400 ltr water – 95.10 % 1.5 ltr/200 ltr water – 94.71 %	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted Concentrations tested: - 0.375%, lower than recommended - 0.75%, the highest in-use conc.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Mezot 100 SC Batch No.: 190521	92.45 %	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	Accepted The test was performed with standard water D at 30 ±1 °C. Conc. tested: 5%
Dispersion stability (KCP 2.8.3.3)	Not applicable. Product isn't a SE (aqueous suspo-emulsion), OD (oil-based suspension concentrate) ~~oraz~~ nor EG (emulsifiable granule) formulation.					Not required
Degree of dissolution and dilution stability (KCP 2.8.4)	Not applicable for a SC formulation.					Not required
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	Mezot 100 SC Batch No.: 190521	-	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019	See KCP 2.7.4
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Mezot 100 SC Batch No.:	0.00 %	Y	Enzo Arévalo, Ph.D.; Institute of Industrial Organic Chemistry;	Accepted The procedure used was

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		190521			BF-21/19; Warsaw; 2019	different from the MT 185: - the amount of water used to dilute the material was 20 ml and no stirring was applied to the dilution, - the amount of water used to rinse the beaker and sieve was 150 ml. Still, there was no residue on a sieve.
Dust content (KCP 2.8.5.2.1)	Not applicable. It is not a granular plant protection product.					Not required
Particle size of dust (KCP 2.8.5.2.2)	Not applicable. It is not a granular plant protection product.					Not required
Attrition (KCP 2.8.5.3)	Not applicable. It is not a plant protection product in the form of granules or tablets.					Not required
Hardness and integrity (KCP 2.8.5.4)	Not applicable. It is not a plant protection product in the form of tablets.					Not required
Emulsifiability (KCP 2.8.6.1)	Not applicable. Product is not an EC (emulsifiable concentrate) formulation.					Not required
Emulsion stability (KCP 2.8.6.2)	Not applicable. Product is not an EC (emulsifiable concentrate) formulation.					Not required
Re-emulsifiability (KCP 2.8.6.3)	Not applicable. Product is not an EC (emulsifiable concentrate) formulation.					Not required
Flowability (KCP 2.8.7.1)	Not applicable. It is not a plant protection product in the form of granules.					Not required
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Mezot 100 SC	R = 2.93 %; R’ = 0.29 %	Y	Enzo Arévalo, Ph.D.; Institute of Industrial	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch No.: 190521			Organic Chemistry; BF-21/19; Warsaw; 2019	
Dustability following accelerated storage (KCP 2.8.7.3)	Not applicable. It is not a plant protection product in the form of dustable powder.					Not required
Physical compatibility of tank mixes (KCP 2.9.1)	Not applicable. No tank mixtures with this product are recommended.					Not applied for
Chemical compatibility of tank mixes (KCP 2.9.2)	Not applicable. No tank mixtures with this product are recommended.					Not applied for
Adhesion to seeds (KCP 2.10.1)	Not applicable. It is not a plant protection product for seed treatment.					Not required
Distribution to seed (KCP 2.10.2)	Not applicable. It is not a plant protection product for seed treatment.					Not required
Other/special studies (KCP 2.11)	Efficacy Guideline 305 HPLC- UV/Vis	Mezot 100 SC Batch No. 01/22	Cleaning effectiveness after triple rinsing: 99.96 %	Y	Grażyna Oleksa MSc,; Institute of Industrial Organic Chemistry; BA-22/22; Warsaw; 2022	Accepted

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

zRMS comment: In the accelerated storage and 2-years shelf-life stability study, the formulation was stored in commercial packaging (bottles made of HDPE) and the packaging remained stable during the storage. As packaging material proved to be resistant to its content, HDPE packs are considered acceptable.

The containers was used for technical properties determinations and the accelerate storage stability study and no problems have been reported. Such packaging and closures are used as standard and their suitability is known from experience.

The materials proposed for use are known from experience to be compatible with solvent based formulations and are resistant to the influences of chemicals. The resistance of packaging material to its contents has been tested in the accelerate storage stability studies and the results show that no detrimental effects were noted thus demonstrating the acceptability of the packaging material.

Table 4.1-1: Packaging information for 1 liter bottle

Type	Description
Trade name:	Romak – Butelka D7 z wlewem Φ 40
Material:	HDPE
Shape/size:	cylindrical / approx. 88.5 ± 1 mm diameter x 231 ± 2 mm; weight 78 ± 2 g
Opening:	40 ± 1 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal, HF-seal
Manner of construction:	extruded
UN/ADR:	compliant

Table 4.1-2: Packaging information for 1 liter bottle

Type	Description
Trade name:	Suwary – Butelka BO-1
Material:	HDPE
Shape/size:	cylindrical / approx. 84 ± 1.5 mm diameter x 230.1 ± 3 mm
Opening:	38 mm outer diameter
Closure:	polyethylene screw cap
Seal:	induction seal, HF-seal
Manner of construction:	extruded
UN/ADR:	compliant

Table 4.1-3: Packaging information for 1 liter bottle

Type	Description
Trade name:	Romak – Butelka D7 z wlewem Φ 55
Material:	HDPE
Shape/size:	cylindrical / approx. 88.5 mm diameter x 227 mm; weight 80 ± 2 g
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal, HF-seal
Manner of construction:	extruded
UN/ADR:	compliant

Table 4.1-4: Packaging information for 5 liter canister

Type	Description
Trade name:	Romak - Kanister “AGRO”
Material:	HDPE
Shape/size:	canister / approx. 195 mm x 139 mm x 305 mm; weight 230 g
Opening:	39 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal, HF-seal
Manner of construction:	extruded
UN/ADR:	compliant

Table 4.1-5: Packaging information for 10 liter canister

Type	Description
Trade name:	Suwary – Kanister K-10N
Material:	HDPE
Shape/size:	canister / approx. 228 ± 7 mm x 192 ± 3 mm x 313 ± 7 mm
Opening:	52 mm outer diameter
Closure:	polyethylene screw cap
Seal:	induction seal, HF-seal
Manner of construction:	extruded
UN/ADR:	compliant

Table 4.1-6: Packaging information for 20 liter canister

Type	Description
Trade name:	Suwary – K-20N
Material:	HDPE
Shape/size:	canister / approx. 292 ± 8 mm x 257.5 ± 6 mm x 376 ± 8 mm

Type	Description
Opening:	52 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal, HF-seal
Manner of construction:	extruded
UN/ADR:	compliant

Table 4.1-7: Packaging information for 120 ml bottle

Type	Description
Trade name:	Turnaire – 0L120 C40 Obturateur
Material:	HDPE
Shape/size:	bottle / 50 ± 1 mm x 93 ± 1 mm
Opening:	28.4 ± 0.3 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal, HF-seal
Manner of construction:	extruded
UN/ADR:	compliant

Table 4.1-8: Packaging information for 250 ml bottle

Type	Description
Trade name:	Chempak – Pojemnik P250/38
Material:	HDPE
Shape/size:	bottle / 110.7 ± 1 mm x 63 ± 1 mm
Opening:	30.5 ± 0.2 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal, HF-seal
Manner of construction:	extruded
UN/ADR:	compliant

Table 4.1-9: Packaging information for 500 ml bottle

Type	Description
Trade name:	Inter Chempak – Butelka B-28
Material:	HDPE
Shape/size:	bottle / 221 ± 0.5 % x 65 ± 1.5 %
Opening:	38 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal, HF-seal
Manner of construction:	extruded

Type	Description
Trade name:	Inter Chempak – Butelka B-28
UN/ADR:	compliant

Table 4.1-10: Packaging information for 220 liter drum

Type	Description
Trade name:	Schutz – 220l F1 tight drum / blue
Material:	HDPE
Shape/size:	drum / 935 ± 5 mm x 581 ± 3 mm
Opening:	Two closures with inner diameter 57,3 and 52,9 mm
Closure:	Polyethylene cover
Seal:	HF-seal
Manner of construction:	extruded
UN/ADR:	compliant

Table 4.1-11: Packaging information for 1000 liter container

Type	Description
Trade name:	Schutz – Ecobulk LX
Material:	HDPE
Shape/size:	IBC container / 1200 x 1000 x 1160 mm
Opening:	DN 150/225 with screw cap DN 50 – outlet valve
Closure:	Polyethylene cover
Seal:	HF-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	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.3.1	Paulina Flasińska, MSc.	2019	Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry; BC-16/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.3.3	Paulina Flasińska, MSc.	2019	Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry; BC-16/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.4.1/01	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP	N	Elvita Sp. z o.o.

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		
KCP 2.4.1/02	Inga Sowik, MSc.	2022	MEZOT 100 SC Determination of physicochemical properties. Institute of Industrial Organic Chemistry; BA-03/22; Warsaw; 2022 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.4.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.5.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.5.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.6.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C.	N	Elvita Sp. z o.o.

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**
			Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished		
KCP 2.7.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.7.3	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.7.5/01	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.7.5/02	Enzo Arévalo, Ph.D.	2020	Part II: Determination of physicochemical properties of the preparation after one year of storage. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2020	N	Elvita Sp. z o.o.

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
			GLP Unpublished		
KCP 2.7.5/02	Enzo Arévalo, Ph.D.	2021	Part III: Determination of physicochemical properties of the preparation after ~~one year~~ 2 years of storage. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2021 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.3.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.3.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.5.1.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage	N	Elvita Sp. z

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
			and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished		o.o.
KCP 2.8.5.1.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.7.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.11	Grażyna Oleksa, MSc	2022	Mezot 100 SC Cleaning of equipment. Institute of Industrial Organic Chemistry; BA-22/22; Warsaw; 2022 GLP Unpublished	N	Elvita Sp. z o.o.

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

A 2.1 Mesotrione.

No additional data.