

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: MEZ-HER 100 SC

Product name: MECORN 100 SC

Chemical active substance:

mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o. o.

Submission date: October 2023

MS Finalisation date: May 2024, August 2024

Version history

When	What
May 2024	zRMS assessment of dRR
August 2024	The final Registration Report after 1 st commenting period

Table of Contents

1	Section 1: Identity of the plant protection product.....	4
1.1	Applicant (KCP 1.1).....	4
1.2	Poland 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	Mesotrione	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).....	6
1.5	Type and code of the plant protection product (KCP 1.5).....	6
1.6	Function (KCP 1.6)	6
2	Section 2: Physical, chemical and technical properties of the plant protection product.....	7
3	Section 3 is presented as a separate document	20
4	Section 4: Further information on the plant protection product	21
4.1	Packaging and Compatibility with the Preparation (KCP 4.4).....	21
Appendix 1	Lists of data considered in support of the evaluation	24

No data gaps.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Pestila Spółka z ograniczoną odpowiedzialnością
Address: Studzianki 24a
97-320 Wolbórz

1.2 Poland 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 920 g/kg
(according to Regulation (EU) No 2017/725)

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

Company code number: MEZ-HER 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)

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 g/L	Not available 90 – 110 g/L	CONFIDENTIAL information is provided separately (Part C). 108.7 g/L	10.5

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

** Based on the density of the formulation = X.XX 1.033 g/mL (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)
NR	NR	NR	NR	NR

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

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

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
R287432	0.4600 ± 0.0212 g/Kg 0.22 g/L
1,2-Dichloroethane	below LOQ 0.11 g/L
R287431	0.8549 ± 0.0062 mg/Kg 0.22 mg/L

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	Variant
CAS No.	104206-82-8	not relevant
EC No.	609-064-00	not relevant
CIPAC No.	625	not relevant
ELINCS	609-064-00	not relevant
Salt, ester anion or cation present	not applicable	not relevant

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

Not relevant. Product does not contain safeners and synergists.

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Suspension concentrate

[Code: SC]

1.6 Function (KCP 1.6)

Herbicide

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that homogenous sand colour suspension liquid. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 443 °C. In aqueous solution, it has a pH value around 3.46 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 as well as relevant impurities 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 SC formulation. The intended concentration of use is 0.33% to 0.5%.

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

Neither classification nor labelling are relevant for this section.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not relevant.

Compliance with FAO specifications:

~~The product MEZ-HER 100 SC complies with FAO specifications.~~

At the time of the evaluation, there is no FAO specification for formulations containing mesotrione.

Formulation used for tests

Product used in the test has the same composition as the one cited in Part C.

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

Not relevant for new registration according art. 34 of Reg. 1107/2009 based on data which protection period has expired.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Organoleptic	MEZ-HER 100 SC Batch No. MEZ/01/23	MEZ-HER 100 SC is a sand colour suspension liquid, no separation phase, homogeneous, plastic colour odour.	Y	23214-02C	Accepted.
Explosive properties (KCP 2.2.1)	A.14	MEZ-HER 100 SC Batch No. MEZ/01/23	MEZ-HER 100 SC does not have explosive properties.	Y	2304703	In the thermal sensitivity test, no explosion occurred. In the mechanical sensitivity test (shock) no ignition, explosion, or decomposition occurred. The formulation is not explosive. Accepted.
Oxidizing properties (KCP 2.2.2)	A.21	MEZ-HER 100 SC Batch No. MEZ/01/23	MEZ-HER 100 SC does not have oxidizing properties.	Y	23214-02C	During the test no spontaneous ignition was noted; the mean pressure rise time was higher than the reference substance. The formulation is not oxidising. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
Flash point (KCP 2.3.1)	A.9	MEZ-HER 100 SC Batch No. MEZ/01/23	MEZ-HER 100 SC does not have flammable properties. Not applicable. MEZ-HER 100 SC is solid and does not contain flammable solvents.	Y	23214-02C	The flash point was determined using a closed cup apparatus according to ASTM D 56. No flash point was detected up to 190°C. The formulation is not flammable. Accepted.									
Flammability (KCP 2.3.2)	A.9	MEZ-HER 100 SC Batch No. MEZ/01/23	MEZ-HER 100 SC does not have flammable properties.	Y	23214-02C										
Self-heating/Auto ignition (KCP 2.3.3)	A.15	MEZ-HER 100 SC Batch No. MEZ/01/23	MEZ-HER 100 SC has got the auto-ignition temperature: 443 °C.	Y	23214-02C	The test was performed with a Koehler Instrument. Accepted.									
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191 CIPAC MT 75.3	MEZ-HER 100 SC Batch No. MEZ/01/23	<table><tr><td></td><td>Before storage:</td><td>After accelerated storage</td></tr><tr><td>Acidity/Alkalinity</td><td>1.48 % w/w</td><td>1.50 % w/w</td></tr><tr><td>pH</td><td>4.04</td><td>3.94</td></tr></table>		Before storage:	After accelerated storage	Acidity/Alkalinity	1.48 % w/w	1.50 % w/w	pH	4.04	3.94	Y	23214-02C	Accepted.
	Before storage:	After accelerated storage													
Acidity/Alkalinity	1.48 % w/w	1.50 % w/w													
pH	4.04	3.94													
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	MEZ-HER 100 SC Batch No. MEZ/01/23	Before storage: pH = 3.46 After accelerated storage: pH = 3.55	Y	23214-02C	Accepted.									

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	OECD 114 CIPAC MT 192	MEZ-HER 100 SC Batch No. MEZ/01/23	Spindle	Speed	Viscosity at 20 °C	Viscosity at 40 °C	Y	23214-02C	The viscosity was determined by Brookfield rotational viscometer. The formulation is a non-Newtonian liquid. The formulation does not contain substances classified as a Category 1 aspiration hazard therefore it does not have to be considered for classification as an aspiration hazard. Accepted.
			n°	[rpm]	[mPa s]				
			RH7	3	4000.0	5333.0			
				10	1658.0	2073.0			
				31	643.0	771.6			
				100	279.9	319.9			
			RH6	3	3000.0	3333.0			
				10	1244.0	1347.0			
				31	514.4	514.4			
				100	229.9	219.9			
			RH5	3	2667.0	2533.0			
				10	1161.0	1078.0			
				31	475.8	450.1			
				100	207.9	191.9			
			RH4	3	2667.0	2333.0			
				10	1098.0	994.8			
				31	463.0	418.0			
				100	197.9	179.9			
			RH3	3	2500.0	2167.0			
				10	1047.0	922.3			
				31	430.8	389.0			
				100	182.9	166.9			
Surface tension (KCP 2.5.2)	A.5 OECD 115	MEZ-HER 100 SC Batch No. MEZ/01/23	Concentrate: 27.43 mN/m; Highest concentration of usable liquid: 36.33 mN/m				Y	23214-02C	The surface tension of the formulation (concentration of 0.5% w/w and neat formulation) was

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						tested using the Du-Noüy ring method. The formulation is surface-active. Accepted.
Relative density (KCP 2.6.1)	CIPAC MT 3.1 A.3	MEZ-HER 100 SC Batch No. MEZ/01/23	Range: 1.05 1.033 ± 0.05 g/mL (0.9830 – 1,083 g/mL) Relative density: 1.033 Density: 1.033 g/mL	Y	23214-02C	The Applicant provided a statement regarding the density range. Based on the results of density tests performed in Applicant's laboratory (GLP) for quality control purposes, the range ±0.05 g/mL is typically observed range for different batches of formulation. Accepted.
Bulk density (KCP 2.6.2)	-	-	Not relevant. Not required for SC formulation.	-	-	

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54°C (KCP 2.7.1)	CIPAC MT 46.4, CIPAC MT 75.3, CIPAC MT 191 CIPAC MT 3.1 EC A.3 A.14, CIPAC 47.3 CIPAC 160 CIPAC 184 CIPAC 185 CIPAC 148.1 CIPAC MT 187 HPLC-DAD HPLC-TOF GC-MS	MEZ-HER 100 SC Batch No. MEZ/01/23	Storage stability after 14 days at 54 °C.			Y	23214-02C	The test item was stored in the original containers (1L HDPE white plastic bottle). The temperature was measured continuously by a data logger. The change in a.s. content during storage was 0.9%. Min (0.33% v/v) and max (0.5% v/v) use rates were used for determination of persistent foam and suspensibility. No significant changes in the physical, chemical, and technical properties of the formulation were observed following storage. For the determination of the a.s. and
			Test	Before Storage	After Accelerated Storage			
			Appearance, colour and odour	Sand colour suspension liquid, no separation phase, homogeneous, plastic colour	Unchanged			
			Stability of packaging	1L HDPE white plastic bottle, intact, no leaks	Unchanged			
			Weight loss or an increase in the weight of the bottle	Accelerated storage Initial: 1158.46 g	1157.72 g Weight change: -0.74 g			
			pH of formulation and pH of 1% dilution	Neat: 4.04 1%: 3.46	Neat: 3.94 1%: 3.55			
			Acidity/Alkalinity ⁽¹⁾	1.48 % w/w	1.50 % w/w			
			Relative density	Relative density at 20°C: 1.033 20°C: 1.033 g/mL 40°C: 1.026 g/mL	20°C: 1.037 g/mL 40°C: 1.027 g/mL			
			Persistent Foam (Min and Max rate of use)	0.33%: 0 mL 0.50%: 0 mL	0.33%: 0 mL 0.50%: 0 mL			
			Spontaneity of Dispersion (CIPAC water D)	101 %	100 %			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments		
			Suspensibility (Min and Max rate of use) (CIPAC water D)	0.33%: 100 % 0.50%: 100 %	0.33%: 99 % 0.50%: 100 %			relevant impurities content, the methods validated according to SANCO/3030/99 rev.5 were used ; (see Part B5 of the dRR). During storage, the packaging material proved to be resistant to its content (intact, no leaks). Accepted.		
			Wet Sieve (0.75 um)	No residues	No residues					
			Pourability	R: 2.1 %	R: 2.0 %					
			Particle size distribution	D[4][3]: 2.753µm	D[4][3]: 2.794µm					
			Active ingredient and impurities determination	Mesotrione: 10.1 ± 0.04 %w/w 104 ± 0.46 g/L	Mesotrione: 9.9 ± 0.05 %w/w 102 ± 0.53 g/L					
				R287432: 0.0040 ± 0.0001 %w/w 0.3728 ± 0.0061 g/Kg ⁽⁴⁾ 0.0418 ± 0.0007 g/L	R287432: 0.0050 ± 0.0002 %w/w 0.4600 ± 0.0212 g/Kg ⁽⁴⁾ 0.0508 ± 0.0023 g/L					
				1,2-Dichloroethane: below LOQ ⁽⁵⁾	1,2-Dichloroethane: below LOQ ⁽⁵⁾					
				R287431: 0.0000088 ± 0.0000001% w/w 0.8063 ± 0.0100 mg/Kg ⁽⁶⁾ 0.0905 ± 0.0011 mg/L	R287431: 0.0000093 ± 0.0000001% w/w 0.8549 ± 0.0062 mg/Kg ⁽⁶⁾ 0.0959 ± 0.0007 mg/L					
			⁽²⁾ Determined in study 23214-01C;							
			⁽³⁾ Density of test item of 1.033 g/mL;							
⁽⁴⁾ g/Kg referred to technical material based on nominal test item solution concentration of 35.0 mg/mL, Content of AI % of 10.1 %										

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments		
			⁽⁵⁾ LOQ = 0.5671 g/kg of technical material; ⁽⁶⁾ g/Kg referred to technical material based on nominal test item solution concentration of 65.0 mg/mL, Content of AI % of 10.1 %;					
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant. The product was stable after 14 days at 54°C.	-	-			
Minimum content after heat stability testing (KCP 2.7.3)	HPLC-DAD	MEZ-HER 100 SC Batch No. MEZ/01/23	9.9 ± 0.05 % w/w 102 ± 0.53 g/L	Y	23214-02C	Accepted.		
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3, CIPAC MT 75.3, CIPAC MT 191 CIPAC MT 3.1 EC A.3 A.14, CIPAC 47.3 CIPAC 160 CIPAC 184 CIPAC 185	MEZ-HER 100 SC Batch No. MEZ/01/23	Low temperature storage stability after 14 days at 54 °C.	Y	23214-02C	The test item was stored in the original containers (1L HDPE white plastic bottle). The temperature was measured continuously by a data logger. The change in a.s. content during storage was 1%.		
			Test				Before Storage	Low temperature storage
			Appearance, colour and odour				Sand colour suspension liquid, no separation phase, homogeneous, plastic colour	Unchanged
			Stability of packaging				1L HDPE wthite plastic bottle, intact, no leaks	Unchanged

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	CIPAC 148.1 CIPAC MT 187 HPLC-DAD HPLC-TOF GC-MS		Weight loss or an increase in the weight of the bottle	Accelerated storage: 1158.46 g Low temperature storage: 1158.14 g	Weight change: +0.02 g			Min (0.33% v/v) and max (0.5% v/v) use rates were used for determination of persistent foam and suspensibility. No significant changes in the physical, chemical, and technical properties of the formulation were observed following storage. For the determination of the a.s. and relevant impurities content, the methods validated according to SANCO/3030/99 rev.5 were used ; (see Part B5 of the dRR). During storage, the packaging material proved to be resistant to
			pH of formulation and pH of 1% dilution	Neat: 4.04 1%: 3.46	Neat: 4.02 1%: 3.47			
			Acidity/Alkalinity	1.48 % w/w	1.49 % w/w			
			Relative density	Relative density at 20°C: 1.033 20°C: 1.033 g/mL 40°C: 1.026 g/mL	20°C: 1.035 g/mL 40°C: 1.026 g/mL			
			Persistent Foam (Min and Max rate of use)	0.33%: 0 mL 0.50%: 0 mL	0.33%: 0 mL 0.50%: 0 mL			
			Spontaneity of Dispersion	101 %	100%			
			Suspensibility (Min and Max rate of use)	0.33%: 100 % 0.50%: 100 %	0.33%: 99 % 0.50%: 100 %			
			Wet Sieve (0.75 um)	No residues	No residues			
			Pourability	R: 2.1 %	R: 2.0 %			
			Particle size distribution	D[4][3]: 2.753µm	D[4][3]: 2.750µm			
			Active ingredient and impurities determination	Mesotrione ⁽²⁾ : 10.1 ± 0.04 %w/w 104 ± 0.46 g/L ⁽³⁾	Mesotrione: 10.1±0.03 %w/w 105 ± 0.27 g/L ⁽³⁾			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				<p>R287432⁽²⁾: 0.0040 ± 0.0001 %w/w 0.3728 ± 0.0061 g/Kg⁽⁴⁾ 0.0418 ± 0.0007 g/L⁽³⁾</p>	<p>R287432: 0.0044 ± 0.0003 %w/w 0.4021 ± 0.0234 g/Kg⁽⁴⁾ 0.0444 ± 0.0034 g/L⁽³⁾</p>			its content (intact, no leaks). Accepted.
				<p>1,2-Dichloroethane⁽²⁾: below LOQ⁽⁵⁾</p>	<p>1,2-Dichloroethane: below LOQ⁽⁵⁾</p>			
				<p>R287431⁽²⁾: $0.0000088 \pm$ 0.0000001% w/w 0.8063 ± 0.0100 mg/Kg⁽⁶⁾ 0.0905 ± 0.0011 mg/L⁽³⁾</p>	<p>R287431: $0.0000090 \pm$ 0.0000003% w/w 0.8273 ± 0.0290 mg/Kg⁽⁶⁾ 0.0928 ± 0.0032 mg/L⁽³⁾</p>			
			<p>⁽²⁾ Determined in study 23214-01C; ⁽³⁾ Density of test item of 1.033 g/mL; ⁽⁴⁾ g/Kg referred to technical material based on nominal test item solution concentration of 35.0 mg/mL, Content of AI % of 10.1 % ⁽⁵⁾ LOQ = 0.5671 g/kg of technical material; ⁽⁶⁾ g/Kg referred to technical material based on nominal test item solution concentration of 65.0 mg/mL, Content of AI % of 10.1 %;</p>					
Ambient temperature shelf life (KCP 2.7.5)	-	-	Not relevant for new registration according art. 34 of Reg. 1107/2009 based on data which protection period has expired.			-	-	
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant for new registration according art. 34 of Reg. 1107/2009 based on data which protection period has expired.			-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Wettability (KCP 2.8.1)	-	-	Not relevant. MEZ-HER 100 SC is liquid form.	-	-	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	MEZ-HER 100 SC Batch No. MEZ/01/23	<u>At concentration 0.33%:</u> 0 mL <u>At concentration 0.5%:</u> 0 mL	Y	23214-02C	Min (0.33% v/v) and max (0.5% v/v) use rates were used for the determination of persistent foam. Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	MEZ-HER 100 SC Batch No. MEZ/01/23	<u>At concentration 0.33%:</u> 100 % <u>At concentration 0.5%:</u> 100 %	Y	23214-02C	Min (0.33% v/v) and max (0.5% v/v) use rates were used for determination of suspensibility. Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC 160	MEZ-HER 100 SC Batch No. MEZ/01/23	101 %	Y	23214-02C	Accepted.
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant. Not required for SC formulation.	-	-	
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant. Not required for SC formulation.	-	-	
Particle size distribution / nominal size range of granules	CIPAC MT 187	MEZ-HER 100 SC Batch No. MEZ/01/23	D[4][3]: 2.753µm	Y	23214-02C	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.1.1)						
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	MEZ-HER 100 SC Batch No. MEZ/01/23	Initial preparation and after accelerated storage – residue in 75 µm sieve 0.00 %	Y	23214-02C	Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant. MEZ-HER 100 SC is liquid form.	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant. MEZ-HER 100 SC is liquid form.	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not relevant. MEZ-HER 100 SC is liquid form.	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant. MEZ-HER 100 SC is liquid form.	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant. Not required for SC formulation.	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant. Not required for SC formulation.	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant. Not required for SC formulation.	-	-	
Flowability (KCP 2.8.7.1)	-	-	Not relevant. Not required for SC formulation.	-	-	
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	MEZ-HER 100 SC Batch No.	R: 2.1 %	Y	23214-02C	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																							
		MEZ/01/23																											
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant. Not required for SC formulation.	-	-																								
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant. MEZ-HER 100 SC is not recommended for tank-mixes usage.	-	-																								
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant. MEZ-HER 100 SC is not recommended for tank-mixes usage.	-	-																								
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant. MEZ-HER 100 SC is not a seedtreatment.	-	-																								
Distribution to seed (KCP 2.10.2)	-	-	Not relevant. MEZ-HER 100 SC is not a seedtreatment.	-	-																								
Other/special studies (KCP 2.11)	PSD 305 EPPO PP 1/292	MEZ-HER 100 SC Batch No. MEZ/01/23	<table><tr><td colspan="3">Cleaning procedure</td></tr><tr><td rowspan="2">Wash No.</td><td colspan="2">Residue</td></tr><tr><td>[mg]</td><td>[%]</td></tr><tr><td>Initial</td><td>158.15</td><td>100.00</td></tr><tr><td>first wash</td><td>1.09</td><td>2.06</td></tr><tr><td>second wash</td><td>0.10</td><td>0.20</td></tr><tr><td>third wash</td><td>0.06</td><td>0.12</td></tr><tr><td>last wash</td><td>0.06</td><td>0.11</td></tr></table>	Cleaning procedure			Wash No.	Residue		[mg]	[%]	Initial	158.15	100.00	first wash	1.09	2.06	second wash	0.10	0.20	third wash	0.06	0.12	last wash	0.06	0.11	Y	23214-02C	Accepted.
Cleaning procedure																													
Wash No.	Residue																												
	[mg]	[%]																											
Initial	158.15	100.00																											
first wash	1.09	2.06																											
second wash	0.10	0.20																											
third wash	0.06	0.12																											
last wash	0.06	0.11																											

3 Section 3 is presented as a separate document

Not relevant for new registration according art. 34 of Reg. 1107/2009 based on data which protection period has expired.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

zRMS comment:	Based on the accelerated storage results, HDPE packaging is an appropriate and acceptable packaging type for Mecorn 100 SC. According to the guidelines of the Polish Ministry of Agriculture and Rural Development, extrapolation to HDPE/PA (COEX) and fHDPE packaging is acceptable. All packaging types are acceptable.
---------------	---

Table 4.1-1: Packaging information for 250 ml bottle

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	126mm x Ø63,5mm	126mm x Ø63,5mm	126mm x Ø63,5mm
Opening:	50mmTE	50mmBE	50mmTE
Closure:	50mmTE	50mmBE	50mmTE
Seal:	HIS or PE	IHS	IHS or PET/ALU
Manner of construction	Blow moulded extrusion	Blow moulded coextrusion	Blow moulded extrusion
UN/ADR	Y 1,5/120	Y 1,9/120	Y 1,5/120

Table 4.1-2: Packaging information for 0.5 L bottle

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cylindrical / approx. 77,6 mm diameter x 160,6 mm	cylindrical / approx. 77,6 mm diameter x 160,6 mm	cylindrical / approx. 69 mm diameter x 186,2 mm
Opening:	31,3 mm inner diameter	31,3 mm inner diameter	45 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	31,3 mm inner diameter
Seal:	HF-seal	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	not relevant	not relevant	UN certified

Table 4.1-3: Packaging information for 1 L bottle

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cylindrical / approx. 84 mm diameter x 230,1 mm	cylindrical / approx. 88 mm diameter x 236,5 mm	cylindrical / approx. 88,5 mm diameter x 233,2 mm
Opening:	31,3 mm inner diameter	48 mm inner diameter	45 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
Seal:	HF-seal	HF-seal	HF-seal

Type	Description		
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	not relevant	not relevant	UN certified

Table 4.1-4: Packaging information for 5 L canister

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cuboid / approx. 186 x 140 mm, H _{max} =300 mm	cuboid / approx. 187 x 135 mm, H _{max} =305 mm	cuboid / approx. 193 x 142 mm, H _{max} =305 mm
Opening:	54 mm inner diameter	53 mm inner diameter	54 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
Seal:	HF-seal	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	not relevant	not relevant	UN certified

Table 4.1-5: Packaging information for 10 L canister

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cuboid / approx. 228 x 192 mm, H _{max} =306,6 mm	cuboid / approx. 230 x 166 mm, H _{max} =375 mm	cuboid / approx. 240 x 179 mm, H _{max} =377,5 mm
Opening:	46,8 mm inner diameter	53 mm inner diameter	54 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
Seal:	HF-seal	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	compliant	compliant	UN certified

Table 4.1-6: Packaging information for 20 L

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cuboid / approx. 292 x 256 mm, H _{max} =345,4 mm	cuboid / approx. 294 x 245 mm, H _{max} =400 mm	cuboid / approx. 293 x 245 mm, H _{max} =400 mm
Opening:	46,8 mm inner diameter	53 mm inner diameter	48,5 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
Seal:	HF-seal	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	compliant	compliant	UN certified

Table 4.1-7: Packaging information for 220 L drum

Type	Description	
Material:	HDPE/PA (COEX)	HDPE
Shape/size:	935 (± 5)mm x Ø581 (± 5)mm	973mm x Ø590mm
Opening:	Ø581 (±5)	Ø590mm
Closure:	Cap types: 2 layer high-density polyethylene - HBCS 70x6 (Ø80 ± 0,5mm, height 23 ±1 mm) or 2 caps high-density polyethylene - BCS 56x4 (Ø71,8 ±0,3 mm, height 21,4 ±1 mm)	Lid injection moulded out of HDPE with lever action clamping ring, made from galvanised steel.
Seal:	EPDM foam rubber or PE	PUR foamed or EPDM foam rubber
Manner of construction	Blow moulded in one operation together with top and bottom out and integrated L - ring in top.	Blow moulded out of high molecular HDPE in a one-step process.
UN/ADR	compliant	UN certified

Table 4.1-8: Packaging information for 1000 L container

Type	Description		
Material:	HDPE/PA (COEX) container in steel cage on plastic pallet	HDPE/PA (COEX) container in steel cage on wooden pallet	HDPE/PA (COEX) container in steel cage on hybrid pallet
Shape/size:	1000mm x 1200mm x 1180mm	1000mm x 1200mm x 1174 mm	1000 mm x 1200mm x 1151mm (± 5mm)
Opening:	NW150	NW150	NW150
Closure:	DN 50	DN 50	DN 50
Seal:	ETFE/PE	EPDM	ETFE/PE
Manner of construction	Blow-molded from high-density UV-stabilized PE, galvanized steel cage, plastic pallet.	Blow-molded from high-density UV-stabilized PE, galvanized steel cage, wooden pallet.	Blow-molded from high-density UV-stabilized PE, galvanized steel cage, palette made of steel corners are filled with plastic.
UN/ADR	UN 31HA1	UN 31HA1	UN 31HA1

Bottles and canisters (5-10 L) may be additionally packed in cardboard boxes.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.2.2 KCP 2.3.1 KCP 2.3.3 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 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 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Digrandi S.	2023	Determination of the Physical-Chemical properties of MEZ-HER 100 SC Product Before and after Accelerated Storage for 14 days at 54±2 °C and low temperature storage for 7 days at 0±2°C Report No 23214-02C Renolab S.r.l. GLP: Yes Unpublished	N	Pestila*

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 2.2.1	Mazzei A.	2023	Determination of Explosive Properties on the Sample MEZ-HER 100 SC Report No 2304703 Innovhub – Stazioni Sperimentali per l'Industria S.r.l. GLP: Yes Unpublished	N	Pestila*

* Pestila Spółka z ograniczoną odpowiedzialnością

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-