

# **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: JME-HER 12 OD

Product name(s): -

Chemical active substance:

iodosulfuron-methyl-sodium, 2 g/L

mesosulfuron methyl, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## **CORE ASSESSMENT**

(authorization)

Applicant: Pestila Sp. z o.o.

Submission date: December 2023

**MS Finalisation date: 03/10/2024**

## Version history

When	What
January 2024	Dossier sent for evaluation
July 2024	zRMS finalised evaluation
October 2024	Final version prepared by zRMS after Commenting period

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zRMS comments:

The text highlighted in grey was provided by the evaluator.

## **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 Iodosulfuron-methyl-sodium**

Iodosulfuron-methyl-sodium	min. 910 g/kg
There is no relevant impurity	as indicated in SANCO/10166/2003-Final and the EFSA Journal 2016; 14 (4): 4453

#### **1.2.3.2 Mesosulfuron-methyl**

Mesosulfuron-methyl	min. 930 g/kg,
There is no relevant impurity	according with newest Reg (EU) 2017/755 EFSA Journal 2016;14(10):4584

#### **1.2.3.3 Mefenpyr-diethyl (safener)**

Mefenpyr-diethyl	min. 960 g/kg (new purity in EU)
There is no relevant impurity	FAO specification min. 940 g/kg [FAO Specification 651.229/TC (May 2011)]

### **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: JME-HER 12 OD

## 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)
Iodosulfuron-methyl sodium	2	1.7 - 2.3	CONFIDENTIAL information is provided separately (Part C).	
Mesosulfuron-methyl-sodium (eq. in mesosulfuron-methyl)	10.4 (10)	8.84 - 11.96 (8.5 - 11.5)	CONFIDENTIAL information is provided separately (Part C).	

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

\*\* Based on the density of the formulation = 1.00

**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)
Mefenpyr-diethyl	30	27 - 33	31.3	3.13

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

\*\* Based on the density of the formulation = 1.00

**Table 1.4-3: Relevant impurities**

Relevant impurity	Maximum content (g/L or g/kg)
none	

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

**Table 1.4-4: Information on Iodosulfuron-methyl-sodium**

Type	Name/Code Number	
ISO common name	iodosulfuron	Variant : iodosulfuron-methyl-sodium
CAS No.	185119-76-0	144550-36-7
EC No.	not allocated	not allocated
CIPAC No.	634	634.501

**Table 1.4-5 Information on Mesosulfuron-methyl**

Type	Name/Code Number		
ISO common name	mesosulfuron	mesosulfuron-methyl	variant: mesosulfuron-methyl-sodium
CAS No.	not allocated	208465-21-8	208465-19-4
EC No.	not allocated	not allocated	not allocated
CIPAC No.	663	663.201	663.501

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

**Table 1.4-6: Information on safener: Mefenpyr-diethyl**

Type	Name/Code Number	
Safener /synergist	Safener	
ISO common name	mefenpyr	Variant : mefenpyr-diethyl
CAS No.	135591-00-3	135590-91-9
EC No.	not allocated	not allocated

CONFIDENTIAL information is provided separately (Part C).

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

Type: Oil dispersion

[Code: OD]

### 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, beige liquid of typical, weak smell. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 305 °C. In aqueous solution, it has a pH value around 10.1 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C, neither the active ingredients 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/PA (COEX). Its technical characteristics are acceptable for an OD formulation. The intended concentration of use is from 0.15 % to 0.6 %.

### **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 JME-HER 12 OD complies with FAO specifications.

### **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.

**RMS comment on use of the art. 34 of the 1107/2009 to support JME-HER 12 OD registration in Poland**  
From physicochemical perspective JME-HER 12 OD is considered equivalent/ comparable to already registered Atlantis 12 OD in Poland. So, unprotected physicochemical data taken from Atlantis 12 OD can be used to support JME-HER 12 OD registration in Poland.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
<b>Colour and physical state (KCP 2.1)</b>	Organoleptic	JME-HER 12 OD  Batch No. JME/01/2023	JME-HER 12 OD is a homogenous, beige liquid of typical, weak smell.	Y	Ciach J. 001/DPL/2023	Accepted
<b>Explosive properties (KCP 2.2.1)</b>	Expert judgment	-	JME-HER 12 OD does not have explosive the individual components of the preparation are not classified as explosive.	-	-Okrasa, 2024	Accepted
<b>Oxidizing properties (KCP 2.2.2)</b>	A.21	JME-HER 12 OD  Batch No. JME/01/2023	JME-HER 12 OD does not have oxidizing properties.	Y	23517-01C	Accepted
<b>Flash point (KCP 2.3.1)</b>	-	-	Not applicable. JME-HER 12 OD does not contain flammable solvents.	-	-	
<b>Flammability (KCP 2.3.2)</b>	A.9	JME-HER 12 OD  Batch No. JME/01/2023	JME-HER 12 OD does not have flammable properties.	Y	23517-01C	Accepted
<b>Self-heating/Auto ignition</b>	A.15	JME-HER 12 OD	JME-HER 12 OD has got the auto-ignition temperature: 305 °C.	Y	23517-01C	Accepted



Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
(KCP 2.3.3)		Batch No. JME/01/2023						
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	JME-HER 12 OD	Initial preparation	After 7 days at 0±2°C	After 8 weeks at 40±2°C	Y	Ciach J. 001/DPL/2023	Accepted
	CIPAC MT 75.3	Batch No. JME/01/2023	7.8	8.4	8.4			
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	JME-HER 12 OD	Initial preparation	After 7 days at 0±2°C	After 8 weeks at 40±2°C	Y	Ciach J. 001/DPL/2023	Accepted
		Batch No. JME/01/2023	10	10	10			
Viscosity (KCP 2.5.1)	OECD 114 CIPAC MT 192	JME-HER 12 OD		Dynamic viscosity at 20°C		Y	Ciach J. 001/DPL/2023	Accepted
		Batch No. JME/01/2023	30 RPM	44.63 mPa·s				
			55 RPM	43.76 mPa·s				
				Dynamic viscosity at 40°C				
			30 RPM	25.37 mPa·s				
			55 RPM	24.01 mPa·s				
Surface tension (KCP 2.5.2)	A.5 OECD 115		JME-HER 12 OD	0.6% (w/v)	25.7 mN/m		Y	Ciach J. 001/DPL/2023
		Batch No. JME/01/2023	concentrate	23.4 mN/m				

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments
Relative density (KCP 2.6.1)	CIPAC MT 3.1 A.3	JME-HER 12 OD  Batch No. JME/01/2023	Range: 1.0165 ± 0.05 g/mL						Y	Ciach J. 001/DPL/2023	Accepted
Bulk density (KCP 2.6.2)	-	-	Not relevant. Not required for OD formulation.						-	-	
Storage Stability after 14 days at 54°C (KCP 2.7.1)	-	-	Please refer to point 2.7.2						-	-	
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	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	JME-HER 12 OD  Batch No. JME/01/2023	Storage stability after 8 weeks at 40 °C.						Y	Ciach J. 001/DPL/2023	Accepted
			Test		Before Storage		After Accelerated Storage				
			Appearance, colour and odour		Homogenous, beige liquid of typical, weak smell		Homogenous, beige liquid of typical, weak smell				
			Stability of packaging		1L HDPE/PA (COEX)		The weight change between the bottle before and after stability test is -0.16 g.				
			pH of formulation and pH of 1% dilution		7.8 10.1		8.4 10.1				
			Relative density		1.0184 (1.0165 g/ml)		1.0179 (1.0160 g/ml)				
			Persistent foam	0.15% w/v	4 ml after 1 min.	0 ml after 12 min.	4 ml after 1 min.	0 ml after 12 min.			
				0.6% w/v	0 ml after 1 min.	0 ml after 12 min.	0 ml after 1 min.	0 ml after 12 min.			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
	HPLC-TOF GC-MS		Dispersion stability		<b>0.15% w/v</b>				
					Water A	Water D	Water A	Water D	
				0 h	Initial dispersion complete				
				0.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	
				24 h	Re-dispersion complete				
				24.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	
					<b>0.6% w/v</b>				
					Water A	Water D	Water A	Water D	
				0 h	Initial dispersion complete				
				0.5 h	Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.05 ml Free oil: traces Sediment: 0 ml	Cream: 0.20 ml Free oil: traces Sediment: 0 ml	
				24 h	Re-dispersion complete				
				24.5 h	Cream: 0.05 ml Free oil: traces Sediment: 0 ml	Cream: 0.10 ml Free oil: traces Sediment: 0 ml	Cream: 0.05 ml Free oil: traces Sediment: 0 ml	Cream: 0.20 ml Free oil: traces Sediment: 0 ml	

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments
					2% w/v						
					Water A	Water D	Water A	Water D			
				0 h	Initial dispersion complete						
				0.5 h	Cream: 0.35 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.35 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.43 ml Free oil: traces Sediment: 0 ml	Cream: 0.55 ml Free oil: traces Sediment: 0 ml			
				24 h	Re-dispersion complete						
				24.5 h	Cream: 0.35 ml Free oil: traces Sediment: 0 ml	Cream: 0.35 ml Free oil: traces Sediment: 0 ml	Cream: 0.50 ml Free oil: traces Sediment: 0 ml	Cream: 0.50 ml Free oil: traces Sediment: 0 ml			
				Wet Sieve		No residues		No residues			
			Pourability		R: 0.79 %		R: 0.77 %				
			Particle size distribution	Dx 10 (µm)	0.93		1.11				
				Dx 50 (µm)	2.63		3.74				
				Dx 90 (µm)	15.3		25.5				
				Dx 99 (µm)	25.15		45.4				
				D [3;2] (µm)	2.04		2.61				
				D [4;3] (µm)	5.55		9.03				
			Content of active substances		Mesosulfuron methyl						
					0.99% (10.06 g/L)		0.95% (9.66 g/L)				
					Iodosulfuron-methyl-sodium						

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments
				0.20% (2.03 g/L)		0.20% (2.03 g/L)					
Minimum content after heat stability testing (KCP 2.7.3)	HPLC-DAD	JME-HER 12 OD  Batch No. JME/01/2023	Mesosulfuron methyl 0.949 % Iodosulfuron-methyl-sodium 0.195 %						Y	Ciach J. 001/DPL/2023	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 CIPAC 148.1 CIPAC MT 187 HPLC-DAD HPLC-TOF GC-MS	JME-HER 12 OD  Batch No. JME/01/2023	Low temperature storage stability after 7 days at 0 °C.						Y	Ciach J. 001/DPL/2023	Accepted
			Test		Before Storage		After Accelerated Storage				
			Appearance, colour and odour		Homogenous, beige liquid of typical, weak smell		Homogenous, beige liquid of typical, weak smell				
			Stability of packaging		1L HDPE/PA (COEX)						
			pH of formulation and pH of 1% dilution		7.8 10.1		8.4 10.0				
			Relative density		1.0184 (1.0165 g/ml)		1.0181 (1.0162g/ml)				
			Persistent foam	0.15% w/v	4 ml after 1 min.	0 ml after 12 min.	8 ml after 1 min.	4 ml after 12 min.			
				0.6% w/v	0 ml after 1 min.	0 ml after 12 min.	0 ml after 1 min.	0 ml after 12 min.			
			Dispersion stability		0.15% w/v						
					Water A	Water D	Water A	Water D			
				0 h	Initial dispersion complete						

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments
				0.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
				24 h	Re-dispersion complete						
				24.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
					0.6% w/v						
					Water A	Water D	Water A	Water D			
				0 h	Initial dispersion complete						
				0.5 h	Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml			
				24 h	Re-dispersion complete						
				24.5 h	Cream: 0.05 ml Free oil: traces Sediment: 0 ml	Cream: 0.10 ml Free oil: traces Sediment: 0 ml	Cream: 0.05 ml Free oil: traces Sediment: 0 ml	Cream: 0.05 ml Free oil: traces Sediment: 0 ml			
					2% w/v						
					Water A	Water D	Water A	Water D			
				0 h	Initial dispersion complete						

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments		
				0.5 h	Cream: 0.35 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.35 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.50 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.50 ml Free oil: 0 ml Sediment: 0 ml					
				24 h	Re-dispersion complete								
				24.5 h	Cream: 0.35 ml Free oil: traces Sediment: 0 ml	Cream: 0.35 ml Free oil: traces Sediment: 0 ml	Cream: 0.50 ml Free oil: traces Sediment: 0 ml	Cream: 0.50 ml Free oil: traces Sediment: 0 ml					
			Wet Sieve		No residues		No residues						
			Pourability		R: 0.79 %		R: 0.80 %						
			Particle size distribution	Dx 10 (µm)		0.93		1.03					
				Dx 50 (µm)		2.63		3.92					
				Dx 90 (µm)		15.3		16.3					
				Dx 99 (µm)		25.15		24.3					
				D [3;2] (µm)		2.04		2.46					
				D [4;3] (µm)		5.55		6.80					
			Content of active substances		Mesosulfuron methyl								
					0.99% (10.06 g/L)		0.99% (10.06 g/L)						
					Iodosulfuron-methyl-sodium								
					0.20% (2.03 g/L)		0.20% (2.03 g/L)						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
<b>Ambient temperature shelf life (KCP 2.7.5)</b>	-	-	Not relevant for new registration according art. 33 and art. 34 of Reg. 1107/2009 based on data which protection period has expired.	-	-	Accepted  Please refer to Atlantis 12 OD dossier in Poland  Considering physicochemical properties, all unprotected physicochemical data taken from Atlantis 12 OD can be used to support JME-HER 12 OD registration in Poland under art.34 of Reg. 1107/2009  In summary, based on Atlantis 12 OD dossier, the two-year shelf life is acceptable for this PPP in Poland
<b>Shelf life in months (if less than 2 years) (KCP 2.7.6)</b>	-	-	Not relevant for new registration according art. 33 and art. 34 of Reg. 1107/2009 based on data which protection period has expired.	-	-	Considering physicochemical properties, all unprotected physicochemical



Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
									data taken from Atlantis 12 OD can be used to support JME-HER 12 OD registration in Poland under art.34 of Reg. 1107/2009
Wettability (KCP 2.8.1)	-	-	Not relevant. JME-HER 12 OD is liquid form.				-	-	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	JME-HER 12 OD  Batch No. JME/01/2023	0.15% w/v				Y	Ciach J. 001/DPL/2023	Accepted
			after 1 min.	4 ml					
			after 12 min.	0 ml					
			0.6% w/v						
			after 1 min.	0 ml					
			after 12 min.	0 ml					
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	JME-HER 12 OD  Batch No. JME/01/2023	Not relevant. Not required for OD formulation.				-	-	
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC 160	JME-HER 12 OD  Batch No. JME/01/2023	Not relevant. Not required forOD formulation.				-	-	
Dispersion stability (KCP 2.8.3.3)	CIPAC 180	JME-HER 12 OD  Batch No.	Dispersion stability		0.15% w/v		Y	Ciach J. 001/DPL/2023	Accepted
					Water A	Water D			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
		JME/01/2023		0 h	Initial dispersion complete			
				0.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml		
				24 h	Re-dispersion complete			
				24.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml		
					0.6% w/v			
					Water A	Water D		
				0 h	Initial dispersion complete			
				0.5 h	Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml		
				24 h	Re-dispersion complete			
				24.5 h	Cream: 0.05 ml Free oil: traces Sediment: 0 ml	Cream: 0.10 ml Free oil: traces Sediment: 0 ml		
					2% w/v			
					Water A	Water D		
				0 h	Initial dispersion complete			
				0.5 h	Cream: 0.35 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0.35 ml Free oil: 0 ml Sediment: 0 ml		
				24 h	Re-dispersion complete			
				24.5 h	Cream: 0.35 ml Free oil: traces Sediment: 0 ml	Cream: 0.35 ml Free oil: traces Sediment: 0 ml		

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant. Not required for OD formulation.		-	-	
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	JME-HER 12 OD  Batch No. JME/01/2023	Dx 10 (µm)	0.93	Y	Ciach J. 001/DPL/2023	Accepted
			Dx 50 (µm)	2.63			
			Dx 90 (µm)	15.3			
			Dx 99 (µm)	25.15			
			D [3;2] (µm)	2.04			
			D [4;3] (µm)	5.55			
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	JME-HER 12 OD  Batch No. JME/01/2023	Initial preparation and after accelerated storage – residue in 75 µm sieve 0.00 %		Y	Ciach J. 001/DPL/2023	Accepted
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant. JME-HER 12 OD is liquid form.		-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant. JME-HER 12 OD is liquid form.		-	-	
Attrition (KCP 2.8.5.3)	-	-	Not relevant. JME-HER 12 OD is liquid form.		-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant. JME-HER 12 OD is liquid form.		-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
<b>Emulsifiability (KCP 2.8.6.1)</b>	-	-	Not relevant. Not required for OD formulation.	-	-	
<b>Emulsion stability (KCP 2.8.6.2)</b>	-	-	Not relevant. Not required for OD formulation.	-	-	
<b>Re-emulsifiability (KCP 2.8.6.3)</b>	-	-	Not relevant. Not required for OD formulation.	-	-	
<b>Flowability (KCP 2.8.7.1)</b>	-	-	Not relevant. Not required for OD formulation.	-	-	
<b>Pourability (KCP 2.8.7.2)</b>	CIPAC MT 148.1	JME-HER 12 OD  Batch No. JME/01/2023	R = 0.79 %	Y	Ciach J. 001/DPL/2023	Accepted
<b>Dustability following accelerated storage (KCP 2.8.7.3)</b>	-	-	Not relevant. Not required for OD formulation.	-	-	
<b>Physical compatibility of tank mixes (KCP 2.9.1)</b>	-	-	Not relevant. JME-HER 12 OD is not recommended for tank-mixes usage.	-	-	
<b>Chemical compatibility of tank mixes (KCP 2.9.2)</b>	-	-	Not relevant. JME-HER 12 OD is not recommended for tank-mixes usage.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
<b>Adhesion to seeds (KCP 2.10.1)</b>	-	-	Not relevant. JME-HER 12 OD is not a seedtreatment.	-	-	
<b>Distribution to seed (KCP 2.10.2)</b>	-	-	Not relevant. JME-HER 12 OD is not a seedtreatment.	-	-	
<b>Other/special studies (KCP 2.11)</b>	-	-	Not relevant for new registration according art. 33 and art. 34 of Reg. 1107/2009 based on data which protection period has expired.	-	-	Considering physicochemical properties, all unprotected physicochemical data taken from Atlantis 12 OD can be used to support JME-HER 12 OD registration in Poland under art.34 of Reg. 1107/2009

### 3 Section 3 is presented as a separate document

Not relevant for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. For the purpose of evaluation of JME-HER 12 OD please refer to Renewal RR for Atlantis 12 OD.

## 4 Section 4: Further information on the plant protection product

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

#### RMS comment

Based on the accelerated study done in HDPE/PA (COEX) the proposed packaging is approved. Furthermore, considering physicochemical properties, all unprotected physicochemical data (e.g. the ambient storage stability study) taken from Atlantis 12 OD can be used to support JME-HER 12 OD registration in Poland under art.34 of Reg. 1107/2009.

**Table 4.1-1: Packaging information for 250 ml bottle**

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

**Table 4.1-2: Packaging information for 0,5L bottle**

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

**Table 4.1-3: Packaging information for 1L bottle**

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

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

**Table 4.1-4: Packaging information for 5L canister**

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

**Table 4.1-5: Packaging information for 10L canister**

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

**Table 4.1-6: Packaging information for 20L**

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

**Table 4.1-7: Packaging information for 220 L drum**

Type	Description	
<b>Material:</b>	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	935 (± 5)mm x Ø581 (± 5)mm	973mm x Ø590mm
<b>Opening:</b>	Ø581 ( ±5)	Ø590mm
<b>Closure:</b>	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.
<b>Seal:</b>	EPDM foam rubber or PE	PUR foamed or EPDM foam rubber
<b>Manner of construction</b>	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.
<b>UN/ADR</b>	compliant	UN certified

**Table 4.1-8: Packaging information for 1000 L container**

Type	Description		
<b>Material:</b>	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
<b>Shape/size:</b>	1000mm x 1200mm x 1180mm	1000mm x 1200mm x 1174 mm	1000 mm x 1200mm x 1151mm (± 5mm)
<b>Opening:</b>	NW150	NW150	NW150
<b>Closure:</b>	DN 50	DN 50	DN 50
<b>Seal:</b>	ETFE/PE	EPDM	ETFE/PE
<b>Manner of construction</b>	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.
<b>UN/ADR</b>	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

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.3.3 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	Ciach J.	2023	JME-HER 12 OD. Determination of physicochemical properties of the preparation in a COEX bottle. Report No: 001/DPL/2023 Source: Pestila Sp. z o. o. GLP: Yes Published: No	N	Pestila*
KCP 2.2.2 KCP 2.3.1 KCP 2.3.2	Condorelli A.	2023	Determination of the Physical-Chemical properties of JME-HER 12 OD product Report No: 23517-01C Renolab S.r.l. GLP: Yes Published: No	N	Pestila*
	Okrasa A.	2024	Oświadczenie dotyczące badań wybuchowości i właściwości utleniających	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**

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

**List of data submitted by the applicant and not relied on**

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

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

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