

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: JMD-HER 387 OD

Product name(s): Jockey 387 OD

Chemical active substances:

2,4-D 2EHE 377 g/L (2,4-D, 250 g/L)

Iodosulfuron-methyl-sodium 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: December 2022

MS Finalisation date: December 2023; March 2024

Version history

When	What
12.2022	Submission date
12.2023	zRMS evaluation
03.2024	Final version of RR 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	Iodosulfuron	4
1.2.3.2	2,4-D	4
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3)	5
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).....	6
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	22
4	Section 4: Further information on the plant protection product	23
4.1	Packaging and Compatibility with the Preparation (KCP 4.4)	23
Appendix 1	Lists of data considered in support of the evaluation	26

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

Data gaps: None

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
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

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

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

Iodosulfuron (expressed as iodosulfuron-methyl- min 910 g/kg sodium)

No relevant impurities

1.2.3.2 2,4-D

2,4-D ≥ 960 g/kg
2,4-D (expressed as 2,4-D 2EHE) min. 960 g/kg

Relevant impurities	Maximum content (g/L or g/kg)
Free phenols (expressed as 2,4-DCP)	max. 3 g/kg (according to Regulation 2015/2033)
Sum of dioxins and furans	max. 0.01 mg/kg (according to Regulation 2015/2033)

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 and/or cover letter

Company code number: JMD-HER 387 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 (expressed as iodosulfuron-methyl-sodium)	10 g/L	8.5 g/L – 11.5 g/L	10.99 (9.34 g/L – 12.64 g/L)	1.05 (0.89 – 1.21)
2,4-D (expressed as 2,4-D acid)	250 g/L	235 – 265 237.5 g/L – 262.5 g/L	260.42 (244.8 – 276.05) 247.4 g/L – 273.4 g/L	24.91 (23.42 – 26.4) 23.7 – 26.2
2,4-D (expressed as 2,4-D 2EHE)	377 g/L	358.2 g/L – 395.9 g/L	392.7 373.1 g/L – 412.4 g/L	37.57 35.7 – 39.5

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

** Based on the density of the formulation = 1.0453 g/mL

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)
NA	NA	NA	NA	NA

* 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)
Free phenols (calculated as 2,4-D)	0.0306 g/L 0.78 g/L
Sum of dioxins and furans	not detected 0.003 mg/L

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

Table 1.4-4: Information on iodosulfuron

Type	Name/Code Number	
ISO common name	iodosulfuron	Variant
CAS No.	145701-23-1	not relevant
EC No.	604-422-1	not relevant
CIPAC No.	634	not relevant

Table 1.4-5: Information on 2,4-D/2,4-D 2EHE

Type	Name/Code Number	
ISO common name	2,4-D	acid
	2,4-D 2EHE (ethylexyl ethylexyl ester)	ester
CAS No.	94-75-7	acid
	1928-43-4	ester
EC No.	202-361-1	acid
	217-673-3	ester
CIPAC No.	1	acid
	1.3	ester

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: 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 of white to beige liquid, with a specific odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 370 °C. In aqueous solution, it has a pH value around 7.4 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 8 weeks at 40 °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/PA (COEX). Its technical characteristics are acceptable for a OD formulation.

The intended concentration of use is 0.33% to 0.5%.

No tank-mixing recommended

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

Study	Result	Classification acc. to Reg. 1272/2008	Labelling acc. to Reg. 1272/2008
Explosive properties (A.14)	Product does not have explosive properties.	Not classified.	None.
Oxidizing properties (A.21)	Product does not have oxidizing properties.	Not classified.	None.
Flammability – not relevant for liquids.	Product is not flammable.	Not classified.	None.
Flash point	Product is not flammable.	Not classified.	None.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not relevant.

Compliance with FAO specifications:

The product JMD-HER 387 OD complies with FAO specifications.

There is no FAO specification for 2,4-D and iodosulfuron both in the OD formulation.

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Polish Pharmacopoeia VI Edition (2002) & EPA Product Properties Test Guidelines OPPTS 830.6302 to 04	JMD-HER 387 OD Batch No. JMD/01/2021	JMD-HER 387 OD is a homogenous, beige liquid of typical weak smell.	Y	002/DPL/2021 stage 1	Accepted
Explosive properties (KCP 2.2.1)	A.14	JMD-HER 387 OD Batch No. JMD/01/2021	JMD-HER 387 OD does not have explosive properties.	Y	BW-06/21	Accepted No reaction (explosion) reported Considered non-explosive
Oxidizing properties (KCP 2.2.2)	A.21	JMD-HER 387 OD Batch No. JMD/01/2021	JMD-HER 387 OD does not have oxidizing properties.	Y	BC-11/21	Accepted No oxidising properties
Flash point (KCP 2.3.1)	A.9	JMD-HER 387 OD Batch No. JMD/01/2021	Flash point temperature of JMD-HER 387 OD is 88 °C.	Y	BC-11/21	Accepted The test was performed with the Pensky-Martens closed cup apparatus. The formulation is not flammable.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flammability (KCP 2.3.2)	-	-	Not relevant. JMD-HER 387 OD is liquid form.	-	-	Not required
Self-heating (KCP 2.3.3)	A.15	JMD-HER 387 OD Batch No. FLD/01/2019	Auto-ignition temperature of JMD-HER 387 OD is 370°C.	Y	BC-11/21	Accepted Not auto-flammable.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	JMD-HER 387 OD Batch No. JMD/01/2021	Before storage: pH = 6.3 After accelerated storage: pH = 6.0	Y	002/DPL/2021 stage 1&3	Acidity/alkalinity test not required (see KCP 2.4.2)
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	JMD-HER 387 OD Batch No. JMD/01/2021	pH neat: 6.3 Before storage: pH (1% dilution) = 7.4 After accelerated storage: pH = 5.9	Y	002/DPL/2021 stage 1&3	Accepted
Viscosity (KCP 2.5.1)	OECD 114 CIPAC MT 192	JMD-HER 387 OD Batch No. JMD/01/2021	Dynamic viscosity in 20°C [mPa*s] 80 RPM 360.7 140 RPM 339.8 Dynamic viscosity in 40°C [mPa*s] 80 RPM 173.2 140 RPM 152.8	Y	001/DPL/2022	Accepted The formulation is non-Newtonian liquid. The formulation does not pose an aspiration hazard.
Surface tension (KCP 2.5.2)	A.5	JMD-HER 387 OD Batch No. JMD/01/2021	Concentrate: 22.9 mN/m Highest concentration of usable liquid (0.5% v/v): 29.6 mN/m	Y	001/DPL/2022	Accepted The product is surface active
Relative	CIPAC MT 3	JMD-HER	1.0453 g/ml at 20 °C	Y	002/DPL/	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments				
density (KCP 2.6.1)	A.3	387 OD Batch No. JMD/01/2021			2021 stage 1&3					
Bulk density (KCP 2.6.2)	-	-	Not relevant. JMD-HER 387 OD is liquid form.	-	-	Not required				
Storage Stability after 14 days at 54° C (KCP 2.7.1)	-	-	See point 2.7.2	-	-	See point 2.7.2				
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.3 IA/L/016 A3 CIPAC MT 47.3 CIPAC MT 180 CIPAC MT 185 CIPAC MT 187 CIPAC MT 148 CIPAC MT 184 CIPAC MT 160 IA/L/056 IA/L/058	JMD-HER 387 OD Batch No. JMD/01/2021	Storage stability after 8 weeks at 40 °C.			Y	001/DPL/2021 stage 1&3 002/DPL/2021 stage 1&3 K733/JP	Accepted A.s. decrease: - Iodosulfuron: 1.14% - 2,4-D (expressed as 2,4-D acid): 1.3%. Impurities content were below the limits. Packaging (COEX HDPE/PA): no loss of packaging weight, no deterioration, leakage etc. was reported.		
			Parameter	Initial	After storage for 8 weeks at 40 °C					
			Iodosulfuron content	9.62 g/L	9.51 g/L					
			2,4-D acid content	250.04 g/L	246.82 g/L					
			Physical state, colour and odour	Homogenous, beige liquid of typical, weak smell	Inhomogeneous liquid with separated layers, subjected to re-homogenization during intensive mixing, after which: Homogenous, beige liquid of typical, weak smell					
			pH directly	6.3	6.0					
			pH of 1% suspension	7.4	5.9					
			Relative density	1.0453 g/mL	1.0454 g/mL					
			Dispersion stability	0,33% (w/v)					0,33% (w/v)	
				CIPAC Water A	CIPAC Water D				CIPAC Water A	CIPAC Water D
0 h Initial dispersion complete Cream: 0 ml	Initial dispersion complete Cream: 0 ml	0 h Initial dispersion complete Cream: 0 ml		Initial dispersion complete Cream: 0 ml						
			0.5 Free oil: 0 ml	0.5 ml						

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments	
				h	ml	Free oil: 0 ml	h	Free oil: 0 ml	Free oil: 0 ml			
				24 h	ml	Sediment: 0 ml	24 h	Sediment: 0 ml	Sediment: 0 ml			
				24.5 h	Re-dispersion complete	Re-dispersion complete	24.5 h	Re-dispersion complete	Re-dispersion complete			
					Cream: 0 ml	Cream: 0 ml		Cream: 0 ml	Cream: 0 ml			
					Free oil: 0 ml	Free oil: 0 ml		Free oil: 0 ml	Free oil: 0 ml			
					Sediment: 0 ml	Sediment: 0 ml		Sediment: 0 ml	Sediment: 0 ml			
				0,5% (w/v)		0,5% (w/v)						
				CIPAC Water A		CIPAC Water D						
				0 h	Initial dispersion complete	Initial dispersion complete	0 h	Initial dispersion complete	Initial dispersion complete			
	Cream: 0 ml	Cream: 0 ml		Cream: 0 ml	Cream: 0 ml							
	Free oil: 0 ml	Free oil: 0 ml		Free oil: 0 ml	Free oil: 0 ml							
0.5 h	Sediment: 0 ml	Sediment: 0 ml	0.5 h	Sediment: 0 ml	Sediment: 0 ml							
24 h	Re-dispersion complete	Re-dispersion complete	24 h	Re-dispersion complete	Re-dispersion complete							
24.5 h	Cream: 0 ml	Cream: 0 ml	24.5 h	Cream: 0 ml	Cream: 0 ml							
	Free oil: 0 ml	Free oil: 0 ml		Free oil: 0 ml	Free oil: 0 ml							
	Sediment: 0 ml	Sediment: 0 ml		Sediment: 0 ml	Sediment: 0 ml							
2% (w/v)		2% (w/v)										
CIPAC Water A		CIPAC Water D										

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
				Initial dispersion complete 0 h Cream: 0 ml Free oil: 0 ml 0.5 h Sediment: 0 ml Re- 24 h dispersion complete 24.5 h Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Initial dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml Re- dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Initial dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml Re- dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
			Particle size analysis by laser diffraction	Dx 10 (µm) = 0.66 Dx 50 (µm) = 1.69 Dx 90 (µm) = 7.00 Dx 99 (µm) = 27.05 D [3;2] (µm) = 1.35 D [4;3] (µm) = 3.31	Dx 10 (µm) = 0.66 Dx 50 (µm) = 1.58 Dx 90 (µm) = 5.44 Dx 99 (µm) = 18.8 D [3;2] (µm) = 1.30 D [4;3] (µm) = 2.64				
			Wet sieve test	0.0%	0.0%				
			Pourability of suspension	R = 2.48% R' = 0.32%	R = 2.30% R' = 0.37%				
			Ability to form a suspension iodosulfuron-methyl-sodium	0.33% (w/v) 101% 0.5% (w/v) 101%	0.33% (w/v) 102% 0.5% (w/v) 101%				
			Ability to form a suspension 2,4-D	0.33% (w/v) 101% 0.5% (w/v) 101%	0.33% (w/v) 101% 0.5% (w/v) 100%				
			Spontaneity of dispersion iodosulfuron-methyl-sodium	0.33% (w/v) 97% 0.5% (w/v)	0.33% (w/v) 98% 0.5% (w/v)				

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				92%	92%			
			Spontaneity of dispersion 2,4-D	0.33% (w/v)	0.33% (w/v)			
				97%	96%			
				0.5% (w/v)	0.5% (w/v)			
				96%	92%			
			Persistent foam	0.33 % (v/v)	0.33 % (v/v)			
				after 1 min. 0 ml	after 1 min. 0 ml			
				after 12 min. 0 ml	after 12 min. 0 ml			
				0.5% (v/v)	0.5% (v/v)			
				after 1 min. 0 ml	after 1 min. 0 ml			
				after 12 min. 0 ml	after 12 min. 0 ml			
			Loss of bottle weight (COEX) after 40°C storage stability test	-	after 8 weeks (40±2°C): inhomogeneous liquid with separated layers, 35 ml upper oil phase and the remaining 15 ml lower solid phase (bottle weigh loss: 0.00 g). The preparation is subject to re-homogenization during intensive mixing.			
			Free phenols (calculated as 2,4-D)	0.0293 g/kg	0.0033 g/kg accelerated storage in 54°C for 14 days			
			Sum of dioxins and furans	not detected	8.5 x10 ⁻⁷ mg/kg accelerated storage in 54°C for 14 days			
Minimum content after heat stability testing (KCP 2.7.3)	IA/L/056 IA/L/058 CIPAC 46.3	JMD-HER 387 OD Batch No. JMD/01/2021	Iodosulfuron – 9.51 g/L (0.91 %). 2,4-D (expressed as acid) – 246.82 g/L (23.61 %).			Y	001/DPL/2021 stage 3	See KCP 2.7.2
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 CIPAC MT 59 IA/L/016 CIPAC MT 75.3 EEC A.3. CIPAC MT	JMD-HER 387 OD Batch No. JMD/01/2021	Storage stability after 7 days at 0°C.			Y	001/DPL/2021 stage 1&2 002/DPL/2021 stage 1&2	Accepted Not affected by low temperature
			Parameter	Initial	After storage for 7 days at 0 °C			
			Iodosulfuron content	9.62 g/L	9.72 g/L			
			2,4-D acid content	250.04 g/L	249.15 g/L			
			Physical state, colour and odour	Homogenous, beige liquid of typical, weak smell	Homogenous, beige liquid of typical, weak smell			

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments	
	47.3 CIPAC MT 180 CIPAC MT 185 CIPAC MT 187 CIPAC MT 148 CIPAC MT 184 CIPAC MT 160 IA/L/056 IA/L/058		pH directly	6.3		5.8		Dispersion stability				
			pH of 1% suspension	7.4		5.7						
			Relative density	1.0453 g/mL		1.0451 g/mL						
				0.33% (w/v)		0.33% (w/v)						
				CIPAC Water A	CIPAC Water D	CIPAC Water A	CIPAC Water D					
				0 h	Initial dispersion complete	Initial dispersion complete	0 h				Initial dispersion complete	Initial dispersion complete
				0.5 h	Cream: 0 ml	Cream: 0 ml	0.5 h				Cream: 0 ml	Cream: 0 ml
					Free oil: 0 ml	Free oil: 0 ml					Free oil: 0 ml	Free oil: 0 ml
					Sediment: 0 ml	Sediment: 0 ml					Sediment: 0 ml	Sediment: 0 ml
				24 h	Re-dispersion complete	Re-dispersion complete	24 h				Re-dispersion complete	Re-dispersion complete
				24.5 h	Cream: 0 ml	Cream: 0 ml	24 h				Cream: 0 ml	Cream: 0 ml
					Free oil: 0 ml	Free oil: 0 ml	24.5 h				Free oil: 0 ml	Free oil: 0 ml
				0.5% (w/v)		0.5% (w/v)						
				CIPAC Water A	CIPAC Water D	CIPAC Water A	CIPAC Water D					
				0 h	Initial dispersion complete	Initial dispersion complete	0 h				Initial dispersion complete	Initial dispersion complete
				0.5 h	Cream: 0 ml	Cream: 0 ml	0.5 h				Cream: 0 ml	Cream: 0 ml
					Free oil: 0 ml	Free oil: 0 ml					Free oil: 0 ml	Free oil: 0 ml
					Sediment: 0 ml	Sediment: 0 ml					Sediment: 0 ml	Sediment: 0 ml
				24 h	Re-dispersion complete	Re-dispersion complete	24 h				Re-dispersion complete	Re-dispersion complete
				24.5 h	Cream: 0 ml	Cream: 0 ml	24.5 h				Cream: 0 ml	Cream: 0 ml
					Free oil: 0 ml	Free oil: 0 ml					Free oil: 0 ml	Free oil: 0 ml
	Sediment: 0 ml	Sediment: 0 ml		Sediment: 0 ml	Sediment: 0 ml							
2% (w/v)		2% (w/v)										
CIPAC Water A	CIPAC Water D	CIPAC Water A	CIPAC Water D									
0 h	Initial dispersion complete	Initial dispersion complete	0 h	Initial dispersion complete	Initial dispersion complete							
0.5 h	Cream: 0 ml	Cream: 0 ml	0.5 h	Cream: 0 ml	Cream: 0 ml							
	Free oil: 0 ml	Free oil: 0 ml		Free oil: 0 ml	Free oil: 0 ml							
	Sediment: 0 ml	Sediment: 0 ml		Sediment: 0 ml	Sediment: 0 ml							
24 h	Re-dispersion complete	Re-dispersion complete	24 h	Re-dispersion complete	Re-dispersion complete							
24.5 h	Cream: 0 ml	Cream: 0 ml	24.5 h	Cream: 0 ml	Cream: 0 ml							
	Free oil: 0 ml	Free oil: 0 ml		Free oil: 0 ml	Free oil: 0 ml							
	Sediment: 0 ml	Sediment: 0 ml		Sediment: 0 ml	Sediment: 0 ml							

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
			Particle size analysis by laser diffraction	Dx 10 (µm) = 0.66 Dx 50 (µm) = 1.69 Dx 90 (µm) = 7.00 Dx 99 (µm) = 27.05 D [3;2] = 1.35 D [4;3] = 3.31	Dx 10 (µm) = 0.67 Dx 50 (µm) = 1.75 Dx 90 (µm) = 6.88 Dx 99 (µm) = 27.1 D [3;2] = 1.38 D [4;3] = 3.26		
			Wet sieve test	0.0%	0.0%		
			Pourability of suspension	R = 2.48% R' = 0.32%	R = 2.62% R' = 0.32%		
			Ability to form a suspension	0.33% (w/v) 101%	0.33% (w/v) 101%		
			iodosulfon-methyl-sodium	0.5% (w/v) 101%	0.5% (w/v) 101%		
			Ability to form a suspension 2,4-D	0.33% (w/v) 101% 0.5% (w/v) 101%	0.33% (w/v) 101% 0.5% (w/v) 100%		
			Spontaneity of dispersion	0.33% (w/v) 97%	0.33% (w/v) 98%		
			iodosulfon-methyl-sodium	0.5% (w/v) 92%	0.5% (w/v) 95%		
			Spontaneity of dispersion 2,4-D	0.33% (w/v) 97% 0.5% (w/v) 96%	0.33% (w/v) 97% 0.5% (w/v) 96%		
			Persistent foam	0.33 % (v/v) after 1 min. 0 ml after 12 min. 0 ml 0.5% (v/v) after 1 min. 0 ml after 12 min. 0 ml	0.33 % (v/v) after 1 min. 0 ml after 12 min. 0 ml 0.5% (v/v) after 1 min. 0 ml after 12 min. 0 ml		
			Loss of bottle weight (CO-EX) after 0°C storage stability test	-	after 7 days (0±2°C): homogeneous liquid without separated layers after 7 days (0±2°C) and one turn after 24h (23±2°C): homogeneous liquid without separated layers (wet sieving test: 0.00%; bottle weigh loss: 0.00g).		
Ambient	GIFAP 17,	JMD-HER	Storage stability after 2 years at ambient temperature.		Y	001/DPL/	Accepted

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments	
temperature shelf life (KCP 2.7.5)	IA/L/020 CIPAC MT 18 IA/L/050 CIPAC MT 59 IA/L/016 CIPAC MT 75.3 EEC A.3. CIPAC MT 47.3 CIPAC MT 180 CIPAC MT 185 CIPAC MT 187 CIPAC MT 148 CIPAC MT 184 CIPAC MT 160 IA/L/056 IA/L/058	387 OD Batch No. JMD/01/2021	Parameter	Initial		After storage for 2 years at ambient temperature			2021 stage 1&5 002/DPL/2021 stage 1&5	A.s. content after storage: - Iodosulfuron-methyl-sodium: 4.37 % decrease - 2,4-D (expressed as 2,4-D acid): 0.12% increase. Relevant impurities were not determined. However, since the 2,4-D content was stable during the storage and the contents of the relevant impurities after accelerated storage were below the limits, it can be accepted. Packaging (COEX HDPE/PA): no deterioration, leakage etc. was reported.		
			Iodosulfuron content	9.62 g/L		9.20 g/L						
			2,4-D acid content	250.04 g/L		250.33 g/L						
			Physical state, colour and odour	Homogenous, beige liquid of typical, weak smell		Homogenous, beige liquid of typical, weak smell						
			pH directly	6.3		5.8						
			pH of 1% suspension	7.4		6.2						
			Relative density	1.0453 g/mL		1.0452 g/mL						
			Dispersion stability	0.33% (w/v)		0.33% (w/v)						
				CIPAC Water A CIPAC Water D		CIPAC Water A CIPAC Water D						
				0 h	Initial dispersion complete	Initial dispersion complete	0 h				Initial dispersion complete	Initial dispersion complete
					Cream: 0 ml	Cream: 0 ml					Cream: 0 ml	Cream: 0 ml
				0.5 h	Free oil: 0 ml	Free oil: 0 ml	0.5 h				Free oil: 0 ml	Free oil: 0 ml
					Sediment: 0 ml	Sediment: 0 ml					Sediment: 0 ml	Sediment: 0 ml
				24 h	Re-dispersion complete	Re-dispersion complete	24 h				Re-dispersion complete	Re-dispersion complete
					Cream: 0 ml	Cream: 0 ml					Cream: 0 ml	Cream: 0 ml
				24.5 h	Free oil: 0 ml	Free oil: 0 ml	24.5 h				Free oil: 0 ml	Free oil: 0 ml
					Sediment: 0 ml	Sediment: 0 ml					Sediment: 0 ml	Sediment: 0 ml
				0.5% (w/v)		0.5% (w/v)						
				CIPAC Water A CIPAC Water D		CIPAC Water A CIPAC Water D						
				0 h	Initial dispersion complete	Initial dispersion complete	0 h				Initial dispersion complete	Initial dispersion complete
					Cream: 0 ml	Cream: 0 ml					Cream: 0 ml	Cream: 0 ml
				0.5 h	Free oil: 0 ml	Free oil: 0 ml	0.5 h				Free oil: 0 ml	Free oil: 0 ml
					Sediment: 0 ml	Sediment: 0 ml					Sediment: 0 ml	Sediment: 0 ml
				24 h	Re-dispersion complete	Re-dispersion complete	24 h				Re-dispersion complete	Re-dispersion complete
					Cream: 0 ml	Cream: 0 ml					Cream: 0 ml	Cream: 0 ml
				24.5 h	Free oil: 0 ml	Free oil: 0 ml	24.5 h				Free oil: 0 ml	Free oil: 0 ml
					Sediment: 0 ml	Sediment: 0 ml					Sediment: 0 ml	Sediment: 0 ml
				2% (w/v)		2% (w/v)						

Annex point	Method used / deviations	Test materi- al	Findings						GLP Y/N	Reference	Acceptability / comments	
				0 h	CIPAC Water A Initial dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	CIPAC Water D Initial disper- sion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	0 h	CIPAC Water A Initial disper- sion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	CIPAC Water D Initial disper- sion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
				0.5 h	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	0.5 h	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
				24 h	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	24 h	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
				24.5 h	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	24.5 h	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
				Dx 10 (µm) = 0.66		Dx 10 (µm) = 0.61						
				Dx 50 (µm) = 1.69		Dx 50 (µm) = 1.57						
				Dx 90 (µm) = 7.00		Dx 90 (µm) = 4.74						
				Dx 99 (µm) = 27.05		Dx 99 (µm) = 11.90						
				D [3;2] = 1.35		D [3;2] = 1.21						
				D [4;3] = 3.31		D [4;3] = 2.92						
			Wet sieve test	0.0%		0.0%						
			Pourability of suspension	R = 2.48%		R = 2.70%						
				R' = 0.32%		R' = 0.39%						
			Ability to form a sus- pension iodosulfron- methyl- sodium	0.33% (w/v) 101%		0.33% (w/v) 100%						
				0.5% (w/v) 101%		0.5% (w/v) 101%						
			Ability to form a sus- pension 2,4-D	0.33% (w/v) 101%		0.33% (w/v) 100%						
				0.5% (w/v) 101%		0.5% (w/v) 99%						
				0.33% (w/v) 97%		0.33% (w/v) 97%						
			Spontaneity of dispersion iodosulfuron- methyl- sodium	0.33% (w/v) 97%		0.33% (w/v) 96%						
				0.5% (w/v) 96%		0.5% (w/v) 96%						
			Spontaneity of dispersion 2,4- D	0.33 % (v/v)		0.33 % (v/v)						
				after 1 min. 0 ml		after 1 min. 5 ml						
				after 12 min. 0 ml		after 12 min. 3 ml						

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				0.5% (v/v)	0.5% (v/v)			
				after 1 min. 0 ml	after 1 min. 5 ml			
				after 12 min. 0 ml	after 12 min. 3 ml			
			Loss of bottle weight (CO-EX) after 2 years storage stability test	-	after 2 years (20±2°C): weigh growth between the bottles before and after storage stability test: 0.10 g			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant. Product is stable for 2-years.			-	-	Not required
Wettability (KCP 2.8.1)	-	-	Not relevant. JMD-HER 387 OD is liquid form.			-	-	Not required
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	JMD-HER 387 OD Batch No. JMD/01/2021	<u>At concentration 0.33%:</u> after 1 min. 0 ml <u>At concentration 0.5%:</u> after 1 min. 0 ml			Y	002/DPL/2021 stage 1	Accepted
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	JMD-HER 387 OD Batch No. JMD/01/2021	Iodosulfuron <u>At concentration 0.33%:</u> 101% <u>At concentration 0.5%:</u> 101% 2,4-D <u>At concentration 0.33%:</u> 101% <u>At concentration 0.5%:</u> 101%			Y	002/DPL/2021 stage 1	Additional study, results acceptable
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	JMD-HER 387 OD Batch No. JMD/01/2021	Iodosulfuron <u>At concentration 0.33%:</u> 97% <u>At concentration 0.5%:</u> 92% 2,4-D <u>At concentration 0.33%:</u> 97% <u>At concentration 0.5%:</u> 96%			Y	002/DPL/2021 stage 1	Additional study, results acceptable
Dispersion	CIPAC MT	JMD-HER	Dispersion	0.33% (w/v)		Y	002/DPL/	Accepted

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments	
stability (KCP 2.8.3.3)	180	387 OD Batch No. JMD/01/ 2021	stability	CIPAC Water A		CIPAC Water D		2021 stage 1	Performed at the lowest (0.33%) and the highest (0.5%) conc. recommended
				0 h	Initial dispersion complete Cream: 0 ml Free oil: 0 ml	Initial dispersion complete Cream: 0 ml Free oil: 0 ml			
				0.5 h	Sediment: 0 ml	Sediment: 0 ml			
				24 h	Re-dispersion complete Cream: 0 ml Free oil: 0 ml	Re-dispersion complete Cream: 0 ml Free oil: 0 ml			
				24.5 h	Sediment: 0 ml	Sediment: 0 ml			
				0.5% (w/v)					
				CIPAC Water A		CIPAC Water D			
				0 h	Initial dispersion complete Cream: 0 ml Free oil: 0 ml	Initial dispersion complete Cream: 0 ml Free oil: 0 ml			
				0.5 h	Sediment: 0 ml	Sediment: 0 ml			
				24 h	Re-dispersion complete Cream: 0 ml Free oil: 0 ml	Re-dispersion complete Cream: 0 ml Free oil: 0 ml			
				24.5 h	Sediment: 0 ml	Sediment: 0 ml			
				2% (w/v)					
CIPAC Water A		CIPAC Water D							
0 h	Initial dispersion complete Cream: 0 ml Free oil: 0 ml	Initial dispersion complete Cream: 0 ml Free oil: 0 ml							
0.5 h	Sediment: 0 ml	Sediment: 0 ml							
24 h	Re-dispersion complete Cream: 0 ml Free oil: 0 ml	Re-dispersion complete Cream: 0 ml Free oil: 0 ml							
24.5 h	Sediment: 0 ml	Sediment: 0 ml							
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant. JMD-HER 387 OD is liquid form.			-	-	Not required	
Particle size distribution / nominal size range of granules	CIPAC MT 187	JMD-HER 387 OD Batch No. JMD/01/	Dx 10 (µm) = 0.66 Dx 50 (µm) = 1.69 Dx 90 (µm) = 7.00 Dx 99 (µm) = 27.05 D [3;2] = 1.35			Y	002/DPL/ 2021 stage 1	Additional study, results acceptable	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.1.1)		2021	D [4;3] = 3.31			
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	JMD-HER 387 OD Batch No. JMD/01/2021	Residue on 75 µm sieve 0%.	Y	002/DPL/2021 stage 1	Accepted
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant. JMD-HER 387 OD is liquid form.	-	-	Not required
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant. JMD-HER 387 OD is liquid form.	-	-	Not required
Attrition (KCP 2.8.5.3)	-	-	Not relevant. JMD-HER 387 OD is liquid form.	-	-	Not required
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant. JMD-HER 387 OD is liquid form.	-	-	Not required
Emulsifiability (KCP 2.8.6.1)	-	-	Not applicable. JMD-HER 387 OD is a concentrate to form water suspension.	-	-	Not required
Emulsion stability (KCP 2.8.6.2)	-	-	Not applicable. JMD-HER 387 OD is a concentrate to form water suspension.	-	-	Not required
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not applicable. JMD-HER 387 OD is a concentrate to form water suspension.	-	-	Not required
Flowability (KCP 2.8.7.1)	-	-	Not applicable. JMD-HER 387 OD is not a granulate.	-	-	Not required
Pourability (KCP 2.8.7.2)	CIPAC MT 148	JMD-HER 387 OD	R = 2.48% R' = 0.32%	Y	002/DPL/2021 stage 1	Accepted Residue < 5%

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
		Batch No. JMD/01/2021										
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant. JMD-HER 387 OD is liquid form.	-	-	Not required						
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant. JMD-HER 387 OD is not recommended for tank-mixes usage.	-	-	Not required						
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant JMD-HER 387 OD is not recommended for tank-mixes usage.	-	-	Not required						
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant. JMD-HER 387 OD is not a seedtreatment.	-	-	Not required						
Distribution to seed (KCP 2.10.2)	-	-	Not relevant. JMD-HER 387 OD is not a seedtreatment.	-	-	Not required						
Other/special studies (KCP 2.11)	Efficacy Guideline 305: 2004	JMD-HER 387 OD Batch No. JMD/01/2021	Application equipment cleaning effectiveness. <table><tr><th>Substance</th><th>Cleaning effectiveness [%]</th></tr><tr><td>2,4-D EHE</td><td>82.67</td></tr><tr><td>Iodosulfuron-methyl-sodium</td><td>99.99</td></tr></table>	Substance	Cleaning effectiveness [%]	2,4-D EHE	82.67	Iodosulfuron-methyl-sodium	99.99	Y	BA-05/21	Accepted It is proposed to add one more rinsing (total of 4 rinses) – information has been added to the label
Substance	Cleaning effectiveness [%]											
2,4-D EHE	82.67											
Iodosulfuron-methyl-sodium	99.99											

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

Taking into account extrapolation rules of *Polish guideline on the general principles for approval of packaging of plant protection products* (actualization 18.10.2021), we are applying for additional packaging made of fHDPE (fluorinated HDPE) for professional users. According to this guideline extrapolation from HDPE/PA (COEX) to fHDPE (fluorinated HDPE) is possible for OD formulations.

zRMS comment: According to the *Polish guideline on the general principles for approval of packaging of plant protection products*, 18.10.2021, extrapolation from HDPE/PA to fHDPE was possible for OD formulation. However, since the update on 5.09.2023¹, extrapolation in the above case can only be supported with acceptable seepage data from accelerated storage test (no leakage, no ballooning, no panelling of the packaging etc.).

As this application was submitted before 5.09.2023, it is proposed to accept the extrapolation from HDPE/PA (COEX) to fHDPE (fluorinated HDPE) for the formulation JMD-HER 387 OD.

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.1-1: Packaging information for 250ml bottle

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

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

Type	Description	
Material:	HDPE/PA (COEX)	fHDPE
Shape/size:	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	45 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	31,3 mm inner diameter
Seal:	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion
UN/ADR	not relevant	UN certified

¹ Właściwości fizyczne, chemiczne i techniczne środka ochrony roślin (aktualizacja 05.09.2023);
<https://www.gov.pl/web/rolnictwo/ustalenia-dotyczace-sporzadzania-oceny-lub-uwag-w-zakresie-srodkow-ochrony-roslin-przez-podmioty-upowaznione>

Table 4.1-3: Packaging information for 1L bottle

Type	Description	
Material:	HDPE/PA (COEX)	fHDPE
Shape/size:	cylindrical / approx. 88 mm diameter x 236,5 mm	cylindrical / approx. 88,5 mm diameter x 233,2 mm
Opening:	48 mm inner diameter	45 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
Seal:	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion
UN/ADR	not relevant	UN certified

Table 4.1-4: Packaging information for 5L canister

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

Table 4.1-5: Packaging information for 10L canister

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

Table 4.1-6: Packaging information for 20 L canister

Type	Description	
Material:	HDPE/PA (COEX)	fHDPE
Shape/size:	cuboid / approx. 294 x 245 mm, H _{max} =400	cuboid / approx. 293 x 245 mm,

Type	Description	
	mm	Hmax=400 mm
Opening:	53 mm inner diameter	48,5 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
Seal:	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion
UN/ADR	compliant	UN certified

Table 4.1-7: Packaging information for 220 L drum

Type	Description	
Material:	HDPE/PA (COEX)	fHDPE
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

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 2.4.1 KCP 2.4.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.6.2 KCP 2.8.6.3 KCP 2.8.7.2	Ciach J.	2021	JMD-HER 387 OD. Determination of physicochemical properties of preparation in an COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Report No 002/DPL/2021 Pestila Spółka z ograniczoną odpowiedzialnością. GLP Yes Unpublished	N	Pestila*
KCP 2.2.1	Buczowski D.	2021	JMD-HER 387 OD Determination of explosive properties Report No BW-06/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Pestila*
KCP 2.2.2 KCP 2.3.1 KCP 2.3.3	Flasińska P.	2021	JMD-HER 387 OD Determination of flash point, auto-ignition temperature and oxidizing properties. Report No BC-11/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry 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 2.4.1 KCP 2.4.2 KCP 2.6.1 KCP 2.7.1	Ciach J.	2021	JMD-HER 387 OD. Determination of physicochemical properties of preparation in an COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Stage 3: Determination of physicochemical properties of preparation stored at temperature 40±2°C for 8 weeks. Report No 002/DPL/2021 Pestila Spółka z ograniczoną odpowiedzialnością. GLP Yes Unpublished	N	Pestila*
KCP 2.5.1 KCP 2.5.2	Ciach J.	2022	JMD-HER 387 OD. Determination of the surface tension and viscosity of the preparation in a COEX bottle. Report No 001/DPL/2022 Pestila Spółka z ograniczoną odpowiedzialnością. GLP Yes Unpublished	N	Pestila*
KCP 2.7.1/01 KCP 2.7.3	Ciach J.	2021	JMD-HER 387 OD. Determination of active substances content of preparation in an COEX bottle. Stage 1: Determination of active substances content of initial preparation. Stage 2: Determination of physicochemical properties of the preparation stored at temperature 0±2°C for 7 days. Stage 3: Determination of active substances content of preparation stored at temperature 40±2°C for 8 weeks. Report No 001/DPL/2021 Pestila Spółka z ograniczoną odpowiedzialnością. 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 2.7.4	Ciach J.	2021	JMD-HER 387 OD. Determination of active substances content of preparation in an COEX bottle. Stage 1: Determination of active substances content of initial preparation. Stage 2: Determination of physicochemical properties of the preparation stored at temperature 0±2°C for 7 days. Report No 001/DPL/2021 Pestila Spółka z ograniczoną odpowiedzialnością. GLP Yes Unpublished		
KCP 2.7.1/02 KCP 2.7.1/03 KCP 2.11	Wołoszynowska M.	2021	JMD-HER 387 OD Determination of physicochemical properties. Report No BA-05/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Pestila*
KCP 2.7.1/04	Pstuś J.	2022	Analysis of JMD-HER 387 OD before and after ageing tests to determine content of dioxins and furans. Report No K733/JP Selvita Services Sp. z o.o. GLP Yes Unpublished.	N	Pestila*
KCP 2.7.5/01	Ciach J.	2023	JMD-HER 387 OD. Determination of physicochemical properties of preparation in an COEX bottle. Stage 5: Determination of physicochemical properties of the preparation stored at temperature 20±2°C for 2 years. Report No 002/DPL/2021 Pestila Spółka z ograniczoną odpowiedzialnością 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 2.7.5/02	Ciach J.	2023	JMD-HER 387 OD. Determination of active substances content of preparation in an COEX bottle. Stage 5: Determination of an active substance content in a preparation stored at temperature 20±2°C for 2 years. Report No 001/DPL/2021 Pestila Spółka z ograniczoną odpowiedzialnością. GLP Yes Unpublished	N	Pestila*

* Pestila Spółka z ograniczoną odpowiedzialnością.