

REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: CHR/H/MEZO/30 OD

Product name(s): Vidal 30 OD, Pacyfik 30 OD

Chemical active substance:

Mesosulfuron-methyl, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

authorization

Applicant: Innvigo Sp. z o.o.

Submission date: December 2023

zRMS Assessment: 26/07/2024

MS Finalisation date: 19/11/2024

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Version history

When	What
July 2024	zRMS assessment
November 2024	Following commenting period

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State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

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).

Noticed data gaps are:

- Missing storage stability study at ambient temperature – study is ongoing. It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Innvigo Sp. z o.o.
Address: 178 Al. Jerozolimskie Street , 02-486 Warszawa

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

1.2.1 Producer(s) of the preparation

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

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

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

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

1.2.3.1 Mesosulfluron-methyl

Mesosulfuron min. 930 g/kg

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

Trade name: Vidal 30 OD

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Pacyfik 30 OD

Company code number: CHR/H/MEZO 30 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 and variant of the active substance

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)
Mesosulfuron-methyl	30 g/L	27 g/L-33g/L	30.77g/L	3,15%

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

** Based on the density of the formulation = 0.9526 g/ml (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Safener and synergists

Safener	Declared content of the safener (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Mefenpyr-diethyl	90 g/L	81g/L-99g/L	95.74g/L	9.45%

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

** Based on the density of the formulation = 0.9526 g/ml (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)
None	

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

Table 1.4-4: Information on Mesosulfuron-methyl

Type	Mesosulfuron	
ISO common name	Mesosulfuron	Mesosulfuron-methyl
CAS No.		208465-21-8
EC No.		No allocated
CIPAC No.	663 (mesosulfuron)	663.201 (mesosulfuron-methyl)

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

Table 1.4-5: Information on safener

Type	Mefenpyr-diethyl	
Safener /synergist		Safener
ISO common name	Mefenpyr	Mefenpyr-diethyl
CAS No.	193636-29-2	135590-91-9
EC No.		603-923-2

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 yellow liquid, with a characteristic, medium intensive odour. It is not explosive, has no oxidising properties. The product has a flash point of 116,7 °C. It has a self-ignition temperature of 255°C. In aqueous solution, it has a pH value around 3,69 at 20 °C. There is no effect of low temperature on the stability of the formulation, since after 7 days at 0 °C, neither the active ingredient content nor the technical properties were changed. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA packaging material. Its technical characteristics are acceptable for a oil dispersion formulation.

The intended concentration of use is 0.125% to 0.5%.

Studies of physical, chemical and technical properties of the plant protection product after ~~1 year and~~ 2 years of the storage are ongoing.

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

Not required.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No necessary.

Compliance with FAO specifications:

The product CHR/H/MEZO 30 OD complies with FAO specifications.

Formulation used for tests.

Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD)

Date of production: 04.03.2022

Batch No: 040322

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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)	OPPTS 830.6302, 830.6303 and 830.6304	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. Initial storage: Colour (Munsell's notation) – 5Y 8.5/6 (yellow), Physical state – liquid, Odour – medium intensive, characteristic, 2. Accelerated test storage: Colour (Munsell's notation) – 2.5Y 7/8 (yellow), Physical state – liquid, Odour – medium intensive characteristic, 3. After 1 year: Colour (Munsell's notation) – 5Y 8/6 (yellow), Physical state – liquid Odour – medium intensive, characteristic 4. After 2 years: study is ongoing	Y Y	Knapik I., ICB/80/2022 Knapik I., ICB/81/2022	Accepted
Explosive properties (KCP 2.2.1)	EC A.14	Test item name: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. : No explosive properties	Y	Ołowski G., BW-01/23	Accepted Based on the result of impact sensitivity and thermal sensitivity the product does not have explosive properties.
Oxidizing properties (KCP 2.2.2)	EC A.21	Test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. No oxidizing properties.	Y	Flasińska P., BC-07/23	Accepted Based on the results of test EC A.21 the product does not have oxidising properties. (for test item the pressure did not reach the critical value 2070 kPa).
Flash point	EEC A.9	Name of test item:	1. 116.7°C	Y	Knapik I.,	Accepted

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.3.1)		Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322			ICB/80/2022	The product is not classified, according to CLP Regulation, as flammable.
Flammability (KCP 2.3.2)	Not required for this formulation.					Accepted
Self-heating (KCP 2.3.3)	EEC A.15	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. 255°C	Y	Flasińska P., BC-07/23	Accepted The test item has got auto-ignition temperature 255°C according to EC A.15 method.
Acidity (KCP 2.4.1)	CIPAC MT 191	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. Initial storage: 0.60% 2. Accelerated test storage: 0.51% 3. After 1 year: 0.57% 4. After 2 years: study is ongoing	Y Y	Knapik I., ICB/80/2022 Knapik I., ICB/81/2022	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD)	1. Initial storage: 3.69 2. Accelerated test storage: 3.73 3. After 1 year: 3.73 4. After 2 years: study is ongoing	Y Y	Knapik I., ICB/80/2022 Knapik I., ICB/81/2022	Accepted The pH was determined at 20°C. Due to pH less

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.4.2)		Batch No: 040322				than 4, the acidity was tested.
Viscosity (KCP 2.5.1)	OECD 114	Test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. Initial storage: <div style="display: flex; justify-content: space-around;"> <div>20°C</div> <div>40°C</div> </div> 2.5 s-1: 2037 mPa·s; 1419 mPa·s; 5.0 s-1: 1272 mPa·s; 861 mPa·s; 10.0 s-1: 823 mPa·s; 545 mPa·s; 25.0 s-1: 487 mPa·s; 315 mPa·s.	Y	Łysik A., BF-04/23	Accepted The results demonstrate that test item is a non-Newtonian liquid.
Surface tension (KCP 2.5.2)	EEC A.5	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. 0.5% (w/v) – 34.58 [mN/m]	Y	Knapik I., ICB/80/2022	Accepted The surface tension is below 60 mN/m, the product is surface active.
Relative density (KCP 2.6.1)	EEC A.3	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. 0.9526	Y	Knapik I., ICB/80/2022	Accepted The relative density of the test item was calculated from the obtained value of absolute density at 20°C divided by the absolute density value of the pure water at 4°C.

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Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments		
Bulk density (KCP 2.6.2)	Not required for this formulation										
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 OPPTS 830.6302, 830.6303 and 830.6304 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 180 CIPAC MT 148.1 CIPAC MT 185 Standard Operational Procedure SPB/38 Standard Operational Procedure SPB/263	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	Study	Method	Results		Y	Knapik I., ICB/80/2022	Accepted Concentrations of the a.s. and safener before and after accelerated storage (14 days at temperature 14°C) are in the FAO/WHO tolerance. All other parameters meet requirements for OD formulation, Analytical methods used for analysing a.s. and safener in the PPP are validated in accordance with SANCO/3030/99 rev.5.		
			Accelerated storage test	CIPAC MT 46.3	Accelerated storage test (14 days at 54±2°C)						
			Appearance	OPPTS 830.630 2, 830.630 3 and 830.630 4	Colour (Munsell’s notation) – 2.5Y 7/8 (yellow) Physical state – liquid Odour – medium intensive, characteristic						
			pH	CIPAC MT 75.3	1% (w/v) dispersion – 3.73						
			Acidity	CIPAC MT 191	0.51%						
			Dispersion stability	CIPAC MT 180	Water A		Water D				
					Initial dispersion	complete	complete				
					Dispersion after 30 min	trace of cream	trace of cream				
		Re-dispersion	complete	complete							
		Re-dispersion after 30 min	trace of cream	complete							
		Concentration 0.5% (w/v):									

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Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
					<i>Water A</i> Initial dispersion complete <i>Water D</i> complete Dispersion after 30 min 0.16 mL of cream trace of cream Re-dispersion complete complete Re-dispersion after 30 min 0.12 mL of cream trace of cream			
			Pourability	CIPAC MT 148.1	Residue – 3.31%			
			Wet sieve	CIPAC MT 185	Residue (sieve 75 µm) – 0%			
			Stability of package	Standard Operational Procedure SPB/38	Change in packaging weight – 0.32 [%] Change in gross weight – 0.025 [%]			
			Content of mesosulfuron-methyl and mefenpyr-diethyl	Standard Operational Procedure SPB/26 3	mesosulfuron-methyl – 28.88 g/L mefenpyr-diethyl – 87.68 g/L			
Stability								

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
after storage for other periods and/or temperatures (KCP 2.7.2)						
Minimum content after heat stability testing (KCP 2.7.3)	Standard Operational Procedure SPB/263	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. Initial storage: mesosulfuron-methyl – 29.69 g/L, mefenpyr-diethyl – 90.96 g/L 2. Accelerated test storage: mesosulfuron-methyl – 28.88 g/L, mefenpyr-diethyl – 87.68 g/L 3. After 1 year: mesosulfuron-methyl – 30.19 g/L, mefenpyr-diethyl – 88.35 g/L 4. After 2 years: study is ongoing	Y Y	Knapik I., ICB/80/2022 Knapik I., ICB/81/2022	Accepted The analytical method which was used to determined active ingredient (mesosulfuron-methyl) and safener (mefenpyr-diethyl) content was validated in GLP laboratory (in-house methodology. Analytical method used for analysing a.s. and safener in the PPP was validated in accordance with SANCO/3030/99 rev.5). Content of mesosulfuron-

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>methyl at a level of 30 g/L and mefenpyr-diethyl at a level of 90 g/L in the test item was determined accordingly by liquid chromatography with diode array detection (HPLC-DAD).</p> <p>Concentrations of the a.s. and safener before and after storage (accelerated storage – 14 days at 54°C and after 1 year at ambient temperature) are in the FAO/WHO tolerance.</p> <p>It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the</p>

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Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								preparation. The criteria were met.
Effect of low temperatures on stability (KCP 2.7.4)	Standard Operational Procedure SPB/157 CIPAC MT 180	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322				Y	Knapik I., ICB/80/2022	Accepted
			Study	Method	Results			
			Storage test under low temperature conditions	Standard Operational Procedure SPB/157	Storage test under low temperature conditions (7 days at 0±2°C)			
			Dispersion stability	CIPAC MT 180	Concentration 0.125% (w/v): <div>Water A</div> <div>Water D</div> <div>Initial dispersion</div> <div>complete</div> <div>complete</div> <div>Dispersion after 30 min</div> <div>complete</div> <div>complete</div> <div>Re-dispersion</div> <div>complete</div> <div>complete</div> <div>Re-dispersion after 30 min</div> <div>trace of cream</div> <div>trace of cream</div>			
					Concentration 0.5% (w/v): <div>Water A</div> <div>Water D</div> <div>Initial dispersion</div> <div>complete</div> <div>complete</div> <div>Dispersion after 30 min</div> <div>0.12 mL of cream</div> <div>complete</div>			

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments										
			<table><tr><td></td><td></td><td>Re-dispersion</td><td>complete</td><td>complete</td></tr><tr><td></td><td></td><td>Re-dispersion after 30 min</td><td>0.08 mL of cream</td><td>trace of cream</td></tr></table> <p>After low temperature stability 0°C for 7 days – trace of oil at the top After 24 h in room temperature and one invert – no phase separation, no sediment. Residue (sieve 75 µm) – 0%</p>			Re-dispersion	complete	complete			Re-dispersion after 30 min	0.08 mL of cream	trace of cream			
		Re-dispersion	complete	complete												
		Re-dispersion after 30 min	0.08 mL of cream	trace of cream												
Ambient temperature shelf life (KCP 2.7.5)			<u>After 2 years:</u> study is ongoing			Data gap Missing storage stability study at ambient temperature (2 years storage stability study) - study is ongoing. It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level.										
Shelf life in months (if less than 2 years) (KCP 2.7.6)	CIPAC MT 46.3 OPPTS 830.6302, 830.6303 and 830.6304	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	<u>After 1 year:</u>	Y	Knapik I., ICB/81/2022	Accepted Concentrations of the a.s. and safener before and after 1 year storage at ambient temperature are										

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CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 180 CIPAC MT 148.1 CIPAC MT 185 Standard Operational Procedure SPB/38 Standard Operational Procedure SPB/263	Study	Method	Results		
	Appearance, physical state, odour	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – 5Y 8/6 (yellow) Physical state – liquid Odour – medium intensive, characteristic		
	pH	CIPAC MT 75.3	1% (w/v) dispersion – 3.73		
	Acidity	CIPAC MT 191	0.57%		
	Pourability	CIPAC MT 148.1	Residue – 3.87%		
	Wet sieve	CIPAC MT 185	Residue (sieve 75 µm) – 0.10%		
	Dispersion stability	CIPAC MT 180	Concentration 0.125% (w/v):		
			Water A	Water D	
			Initial dispersion	complete	complete
			Dispersion after 30 min	trace of cream	trace of cream
		Concentration 0.5% (w/v):			
		Water A	Water D		
		Initial dispersion	complete	complete	
		Dispersion after 30 min	0.16 mL of cream	trace of cream	
Stability of package (HDPE/PA)	Standard Operational Procedure SPB/38	Change in packaging weight – 0.21% Change in gross weight – 0.009%			
		mesosulfuron-methyl – 30.19 g/L mefenpyr-diethyl – 88.35 g/L			

in the FAO/WHO tolerance. All other parameters meet requirements for OD formulation.
Analytical methods used for analysing a.s. and safener in the PPP are validated in accordance with SANCO/3030/99 rev.5.

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Wettability (KCP 2.8.1)	Not required for this formulation					Accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	<ul style="list-style-type: none"> 0.125% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL 0.5% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL 	Y	Knapik I., ICB/80/2022	Accepted Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation. Acceptable limits : max 60 mL foam after 1 minute. The above mentioned criteria were met.
Suspensibility (KCP 2.8.3.1)	Not required for this formulation					Accepted
Spontaneity of dispersion (KCP 2.8.3.2)	Not required for this formulation					Accepted

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Dispersion stability (KCP 2.8.3.3)	CIPAC MT 180	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. Initial storage: Concentration 0.125% (w/v): <div> <div></div> <div>Water A</div> <div>Water D</div> </div> <div> <div>Initial dispersion</div> <div>complete</div> <div>complete</div> </div> <div> <div>Dispersion after 30 min</div> <div>complete</div> <div>complete</div> </div> <div> <div>Re-dispersion</div> <div>complete</div> <div>complete</div> </div> <div> <div>Re-dispersion after 30 min</div> <div>complete</div> <div>complete</div> </div> Concentration 0.5% (w/v): <div> <div></div> <div>Water A</div> <div>Water D</div> </div> <div> <div>Initial dispersion</div> <div>complete</div> <div>complete</div> </div> <div> <div>Dispersion after 30 min</div> <div>0.12 mL of cream</div> <div>complete</div> </div> <div> <div>Re-dispersion</div> <div>complete</div> <div>complete</div> </div> <div> <div>Re-dispersion after 30 min</div> <div>0.12 mL of cream</div> <div>complete</div> </div> 2. Accelerated storage: Concentration 0.125% (w/v): <div> <div></div> <div>Water A</div> <div>Water D</div> </div> <div> <div>Initial dispersion</div> <div>complete</div> <div>complete</div> </div> <div> <div>Dispersion after 30 min</div> <div>complete</div> <div>complete</div> </div>	Y	Knapik I., ICB/80/2022	Accepted Dispersion stability is determined to demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying.

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Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Re-dispersion	complete	complete			
			Re-dispersion after 30 min	trace of cream	trace of cream			
			Concentration 0.5% (w/v): Water A Water D					
			Initial dispersion	complete	complete			
			Dispersion after 30 min	0.12 mL of cream	complete			
			Re-dispersion	complete	complete			
			Re-dispersion after 30 min	0.08 mL of cream	trace of cream			
			3. After 1 year:					
			Concentration 0.125% (w/v): Water A Water D					
			Initial dispersion		complete			
			Dispersion after 30 min		trace of cream			
			Re-dispersion		complete			
			Re-dispersion after 30 min of cream		0.04 mL of cream			
			Concentration 0.5% (w/v): Water A Water D					
			Initial dispersion		complete			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>Dispersion after 30 min 0.16mL of cream trace of cream</p> <p>Re-dispersion complete complete</p> <p>Re-dispersion after 30 min 0.12 mL 0.04 mL of cream of cream</p> <p>4. <u>After 2 years:</u> study is ongoing</p>			
Degree of dissolution and dilution stability (KCP 2.8.4)	Not required for this formulation					Accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1 .1)	Not required for this formulation					Accepted
Wet sieve test (KCP 2.8.5.1 .2)	CIPAC MT 185	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. <u>Initial storage:</u> Residue (sieve 75 µm) – 0% 2. <u>Accelerated storage:</u> Residue (sieve 75 µm) – 0% 3. <u>After 1 year:</u> Residue (sieve 75 µm) – 0.10% 4. <u>After 2 years:</u> study is ongoing	Y Y	Knapik I., ICB/80/2022 Knapik I., ICB/81/2022	Accepted Wet sieve test is required for water dispersible products. The residue remaining on a sieve is

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on application equipment. Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The criteria were met.
Dust content (KCP 2.8.5.2 .1)	Not required for this formulation					Accepted
Particle size of dust (KCP 2.8.5.2 .2)	Not required for this formulation					Accepted
Attrition (KCP 2.8.5.3)	Not required for this formulation					Accepted
Hardness and integrity (KCP 2.8.5.4	Not required for this formulation					Accepted

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
)						
Emulsifiability (KCP 2.8.6.1)			Not required for this formulation			Accepted
Emulsion stability (KCP 2.8.6.2)			Not required for this formulation			Accepted
Re-emulsifiability (KCP 2.8.6.3)			Not required for this formulation			Accepted
Flowability (KCP 2.8.7.1)			Not required for this formulation			Accepted
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	1. Initial storage: Residue – 4.19% 2. Accelerated storage: Residue – 3.31% 3. After 1 year: Residue – 3.87% 4. After 2 years: study is ongoing	Y Y	Knapik I., ICB/80/2022 Knapik I., ICB/81/2022	Accepted The data are required to demonstrate that the user can make use of the maximum amount of the preparation and that an excessive amount of the material does not remain in the

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						container. Acceptable limits : Maximum 5 % residue. The criteria were met.
Dustability following accelerated storage (KCP 2.8.7.3)	Not required for this formulation					Accepted
Physical compatibility of tank mixes (KCP 2.9.1)	Not required.					Accepted
Chemical compatibility of tank mixes (KCP 2.9.2)	Not required.					Accepted
Adhesion to seeds (KCP 2.10.1)	Not required for this formulation					Accepted
Distribution to seed (KCP 2.10.2)	Not required for this formulation					Accepted

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
)						
Other/special studies (KCP 2.11)	Efficacy Guideline 305	Name of test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Batch No: 040322	Effectiveness of cleaning: Single rinse procedure: 99.84 [%] mesosulfuron-methyl removed from the bottle 99.69 [%] mefenpyr-diethyl removed from the bottle Double rinse procedure: 99.92 [%] mesosulfuron-methyl removed from the bottle 99.88 [%] mefenpyr-diethyl removed from the bottle Triple rinse procedure: 99.93 [%] mesosulfuron-methyl removed from the bottle 99.92 [%] mefenpyr-diethyl removed from the bottle	Y	Knapik I ., ICB/80/2022	Accepted The study was conducted according to Efficacy Guideline 305. The mixture of test item was prepared at a concentration of 0.5% (w/v), then was poured into 3 polyethylene bottles and allowed to stand at temperature (18-28°C) to next day, but not longer than 24 h. After that, the bottles was rinsed by the tap water. Then the bottles was rinsed with acetonitrile which was analysed for active ingredient and safener content. HPLC analysis was conducted to

[illegible]

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Change in gross weight – 0.009%			

3 Section 3 is presented as a separate document

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

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.1-1: Packaging information

Type	BOTTLE
Material:	HDPE/PA
Size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information

Type	BOTTLE
Material:	HDPE/PA
Size:	62.5±1 mm/131.3±1 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	323 ± 5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	65 mm/234.8 mm ± 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal

Table 4.1-4: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	74± 1 mm/177 ± 1 mm/

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Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information

Type	BOTTLE
Material:	HDPE/PA
Size:	69 mm ± 2 mm/186.5 mm ± 2 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	574 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	88 mm ± 2 mm/238 mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	248.5±3 mm/84±1.5mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8 Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	248.5±3 mm/84±1.5mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information

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

Table 4.1-10: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	84± 1.5 mm/248.5 ± 3 mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1.-11: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	238± 1 mm/88 ± 1 mm/
Opening:	41.7±0,7 mm
Closure:	screw cap with seal
Capacity	1100 ml

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

Table 4.1-12: Packaging information

Type	BOTTLE
Material:	HDPE/PA
Size:	233.5± 1.5 mm/88.5 ± 1 mm/
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information

Type	BOTTLE
Material:	HDPE/PA
Size:	195 ± 3/ 130 ± 5 mm/310,5 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-19: Packaging information

Type	CANNISTER
Material:	HDPE/PA
size:	313± 5mm/190±3/140±5mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-14: Packaging information

Type	BOTTLE
Material:	HDPE/PA
Size:	193 ± 3/ 142 ± 5 mm/320 mm± 5 mm

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Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-15: Packaging information

Type	CONTAINER
Material:	HDPE/PA
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ±5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-16: Packaging information

Type	CONTAINER
Material:	HDPE/PA
size:	305mm/193 mm/142 mm ± 5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-17: Packaging information

Type	CONTAINER
Material:	HDPE/PA
size:	377,7mm/178 mm/239,5 mm ± 5 mm
Opening:	54 mm min ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

According to guideline from Ministry of Agriculture and Rural Development (*Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin*) data of stability in the material HDPE/PA are extrapolable to the all materials (HDPE/F and HDPE/EOH). Therefore, no further studies are required for the additional packaging materials.

Table 4.1-18: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	63.5±1 mm/126±1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	312 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-19: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	63.5±1 mm/126±1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	318 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-20 Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	570 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-21: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	69±1 mm/186±1.6 mm
Opening:	50 mm

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Closure:	screw cap with seal
Capacity	575 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-22: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	580 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-23: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	585 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-24: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1150 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-25: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	88.5±1 mm/233.2±1.6 mm

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Opening:	50 mm
Closure:	screw cap with seal
Capacity	1160 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-26: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1170 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-27: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1185 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-28: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1200 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-29: Packaging information

Type	Cannister
Material:	HDPE/F
Size:	193±2 mm/142±2mm/305±3mm

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Opening:	50 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-30: Packaging information

Type	Cannister
Material:	HDPE/F
Size:	193±2 mm/142±2mm/305±3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-31: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	54,2 mm ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-32 Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	63.4 mm min ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-33: Packaging information

Type	BOTTLE
Material:	HDPE/F
Size:	297,3mm/193 mm/142 mm ± 2 mm

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Opening:	67,5 mm \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34: Packaging information

Type	CANNISTER
Material:	HDPE/F
Size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	54,2 mm min \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35: Packaging information

Type	CANNISTER
Material:	HDPE/F
Size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	63,4 mm min \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-36: Packaging information

Type	CANNISTER
Material:	HDPE/F
Size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	67,5 mm min \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-37: Packaging information

Type	Cannister
Material:	HDPE/F

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size:	240±2 mm/179±2mm/375±3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	10 000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-38: Packaging information

Type	BOTTLE
Material:	HDPE/ EVOH
Body diameter / total height:	62,50 +- 0,50 / 126,50 +- 1,50
External thread diameter:	49,65 +- 0,35
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

Table 4.1-39: Packaging information

Type	BOTTLE
Material:	HDPE / EVOH
Body diameter / total height:	59 +- 1 mm / 143 +- 1 mm
External thread diameter:	41.7 +- 0,4 mm
Closure:	screw cap with seal
Capacity	310 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

Table 4.1-40: Packaging information

Type	BOTTLE
Material:	HDPE/ EvOH
Size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	42±3 mm
Closure:	screw cap with cutter
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-41: Packaging information

Type	BOTTLE
------	--------

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Material:	HDPE/EvOH
Size:	65 mm/234.8 mm \pm 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-42: Packaging information

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

Table 4.1-43: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
Size:	234 \pm 3 mm/88.5 \pm 2mm
Opening:	42 mm \pm 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-44: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
Size:	234 \pm 3 mm/88.5 \pm 2mm
Opening:	42 mm \pm 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

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Table 4.1-45: Packaging information

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

Table 4.1-46: Packaging information

Type	BOTTLE
Material:	HDPE/EvOH
Size:	242±1.5 mm/88.5±1mm
Opening:	49.5 mm ± 0.3 mm
Closure:	screw cap with cutter
Capacity	1200± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-47: Packaging information

Type	CONTAINER
Material:	HDPE/EvOH
Size:	165 mm ± 2 mm/195 mm ± 2 mm/228mm± 2 mm
Opening:	48 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-48: Packaging information

Type	CANNISTER
Material:	HDPE/EvOH
Size:	142 mm ± 1.5 mm/193 mm ± 2 mm/307mm± 3 mm
Opening:	63.3 mm ± 0.3 mm
Closure:	screw cap with cutter
Capacity	5650 ml
Seal:	Induction seal

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Manner of construction	extruded
UN/ADR	compliant

Table 4.1-49: Packaging information

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

Table 4.1-50: Packaging information

Type	CONTAINER
Material:	HDPE/EvOH
Size:	375 mm \pm 2 mm/290mm \pm 2 mm/245mm \pm 2 mm
Opening:	85mm \pm 2 mm
Closure:	screw cap with cutter
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Appendix 1 Lists of data considered in support of the evaluation

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 2.3.1 KCP 2.4.1 KCP 2.4.2 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 2.8.3.3 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Knapik I.	2023	Determination of physicochemical properties of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) before and after accelerated storage test ICB/80/2022 ICB Pharma GLP Unpublished	N	PUH „Chemiroł” Sp. z o. o.
KCP 2.2.2 KCP 2.3.2 KCP 2.3.3	Flasińska P.	2023	MESOSULFURON 30 OD (CHR/H/MEZO 30 OD) Determination of auto-ignition temperature and oxidizing properties BC-07/23	N	PUH „Chemiroł” Sp. z o. o.

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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
			Łukasiewicz Research Network -Institute of Industrial Organic Chemistry GLP Unpublished		
KCP 2.2.1	Ołowski T.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Determination of explosive properties BW-01/23 Łukasiewicz Research Network -Institute of Industrial Organic Chemistry GLP Unpublished	N	PUH „Chemiroł” Sp. z o. o.
KCP 2.5.1	Łysik A.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Determination of viscosity BF-04/23 Łukasiewicz Research Network -Institute of Industrial Organic Chemistry GLP Unpublished	N	PUH „Chemiroł” Sp. z o. o.
KCP 2.1 KCP 2.3.1 KCP 2.3.3 KCP 2.4.1 KCP 2.4.2 KCP 2.6.1 KCP 2.7.3 KCP 2.7.6 KCP 2.8.3.3 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Knapik I.	2023	Determination of physicochemical properties of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) after 12 months shelf-life test. ICB/81/2022 ICB Pharma GLP Unpublished	N	PUH „Chemiroł” Sp. z o. o.

CHR/H/MEZO/30 OD / Vidal 30 OD, Pacyfik 30 OD
 Part B – Section 1, 2 and 4 - Core Assessment
 Applicant version

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	Verte- brate 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	Verte- brate study Y/N	Owner

CHR/H/MEZO/30 OD / Vidal 30 OD, Pacyfik 30 OD

Part B – Section 1, 2 and 4 - Core Assessment

Applicant version

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	Verte- brate study Y/N	Owner

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

Not required.