

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: **CHR/ZF/PROTI 100 FS**

Product name(s):

Gamelan 100 FS

Doraltes 100 FS

Chemical active substance:

Prothioconazole, 100 g/L

Central zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 05.2022

MS Finalisation date: 05/09/2022

Version history

When	What
October 2021	Dossier sent for evaluation
May 2022	Updates based on feedback from zRMS Poland
June 2022	zRMS evaluation of dRR
September 2022	Final version prepared by zRMS after Commenting period

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New and additional information were highlighted in yellow.

Evaluator comments:

The text highlighted in grey was provided by the evaluator.

Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are: The two years storage stability study is on-going.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Innvigo Sp. z o. o.

Address: Innvigo Sp. z o. o.
XXX

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 Prothioconazole

According to the *SANCO/3923 /07*

Prothioconazole	min. 970 g/kg
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Toluene	< 5 g/kg
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Prothioconazole-Desthio	< 0.5 g/kg
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1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Gamelan 100 FS/ Doraltes 100 FS

Company code number: CHR/ZF/PROTI 100 FS

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)
Prothioconazole	100.0 g/L	90.0 – 110.0	102.04	9.413

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

** Based on the density of the formulation = 1.088 g/ml (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Confidential information or data are provided separately (Part C).	

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

Table 1.4-3: Information on Prothioconazole

Type	Prothioconazole
ISO common name	Prothioconazole N/A
Chemical name	IUPAC: 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1H-1,2,4-triazole-3-thione
CAS No.	178928-70-6
EC No.	N/A-604-841-2
CIPAC No.	745

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

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

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

Type: Seed treatment in the form of flowable concentrate [Code: FS]

1.6 Function (KCP 1.6)

Fungicide seed treatment

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogenous intensive red liquid of characteristic odour. It is not explosive, has no oxidising properties. The product is flammable and has a flash point of 38.5 °C. It has a self-ignition temperature of 480 °C. In aqueous solution, it has a pH value around 7.5 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 2 weeks at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 1 year at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a *FS* formulation.

The intended concentration of use is 15.54 %.

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

H226: Flammable liquid and vapour

Notifier Proposals for Risk and Safety Phrases (KCP 12)

P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

P233: Keep away from any possible contact with water, because of violent reaction and possible flash fire.

P240: Ground/bond container and receiving equipment

P241: Use explosion-proof electrical/ventilating/lighting/.../equipment.

P242: Use only non-sparking tools.

P243: Take precautionary measures against static discharge

Compliance with FAO specifications:

The product CHR/ZF/PROTI 100 FS complies with FAO specifications.

Formulation used for tests

Material: CHR/ZF/PROTI 100 FS

Active Substances: Prothioconazole, 100 g/L

Producer: XXX

Batch number: 202003

Production date: 1.04.2020

Specification of the product

No.	Quality parameters	Method	Required
1.	Appearance	Visual	Homogenous intensive red liquid of characteristic odour
2.	Prothioconazole content g/l	HPLC	100 ± 10
3	Density in 20°C, g/ml	CIPAC MT 3	$1.085 \pm 0,02$
4.	pH of 1% (m/v) suspension in distilled water, 20°C	CIPAC MT 75.3	6.5 – 8,5
5	Suspensibility of 0.2, 12.5, 33.3% (m/v) suspension in CIPAC D water in 25±5°C after 30 minutes, min., %	CIPAC MT 184.1	90%
6	Particle size Dv(50), µm	CIPAC MT 187	2.0 – 2.5
7	Wet sieve test 75 µm, max., %	CIPAC MT 185	2.0
8	Foaming of 0.2, 12.5, 33.3% (m/v) suspension in CIPAC D water after 1 minute, max., ml	CIPAC MT 47.3	20

During the production of CHR/ZF/PROTI 100 FS, please pay attention to maximum particle size of 2.0 – 2.5 µm and proper conditions during milling process: maximum grinding temperature of 35°C. For further details see the technological process of the CHR/ZF/PROTI 100 FS product.

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual inspection, nasal inhalation EPA OPPTS 830.6302 EPA OPPTS 830.6303 EPA OPPTS 830.6304 Polish Pharmacopoeia VI Edition (2002)	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemrol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	Initial preparation: Homogenous intensive red liquid of characteristic odour. After accelerated storage: Homogenous intensive red liquid of characteristic odour. After low temperature storage: Homogenous intensive red liquid of characteristic odour. After one year of production: Homogenous intensive red liquid of characteristic odour. After one year of storage: Homogenous intensive red liquid of characteristic odour.	Y	KCP 2.1/01 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21</i> KCP 2.1/02 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation. BF-10/21</i> KCP 2.1/03 Sądej, M., 2022, <i>CHR/ZF/PROTI 100 FS Stage III: Determination of physicochemical</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					<i>properties of the preparation after one year of storage. BF-10/21</i>	
Explosive properties (KCP 2.2.1)	EEC A.14	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	CHR/ZF/PROTI 100 FS does not have explosive properties according to the criteria of EEC A.14 method.	Y	KCP 2.2.1 Buczowski, D., 2021, <i>CHR/ZF/PROTI 100 FS</i> <i>Determination of explosive properties. BW-16/21</i>	Acceptable
Oxidizing properties (KCP 2.2.2)	EEC A.21	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch	CHR/ZF/PROTI 100 FS does not have oxidizing properties in accordance with the A.21 criteria.	Y	KCP 2.2.2 Flasińska, P., 2021, <i>CHR/ZF/PROTI 100 FS</i> <i>Determination of flash point, auto-ignition temperature and oxidizing properties.</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		number: 202003 Production date: 1.04.2020				
Flash point (KCP 2.3.1)	EEC A.9	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	Flash point: 38.5 °C The study was carried out in accordance with the recommended closed-cup method (PN-ISO 13736:2013-06 standard - presently 13736:2021-07). This method is not applicable only to unstable decomposing or explosive samples and the presence of the halogenated compound in the mixture had no effect on the test result.	Y	KCP 2.3.1 Flasińska, P, 2021, <i>CHR/ZF/PROTI 100 FS</i> Determination of flash point, auto-ignition temperature and oxidizing properties.	Acceptable
Flammability (KCP 2.3.2)	EEC A.9	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch	The preparation is classified as H226:Flammable liquid 3 where the flashpoint is $\geq 23^{\circ}\text{C}$ but $\leq 60^{\circ}\text{C}$		KCP 2.3.2 Flasińska, P, 2021, <i>CHR/ZF/PROTI 100 FS</i> Determination of flash point, auto-ignition temperature and oxidizing properties.	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		number: 202003 Production date: 1.04.2020				
Self-heating (KCP 2.3.3)	EEC A.15	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	Auto-ignition temperature of CHR/ZF/PROTI 100 FS is 480 °C.	Y	KCP 2.3.3 Flasińska, P, 2021, <i>CHR/ZF/PROTI 100 FS</i> <i>Determination of flash point, auto-ignition temperature and oxidizing properties.</i>	Acceptable
Acidity or alkalinity and pH (KCP 2.4.1)	N/A	N/A	N/A The pH of the mixture is about 8.0.	N/A	N/A	N/A
pH of a 1% aqueous dilution, emulsion or	MT 75.3	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L	Initial preparation: 1% (w/v) emulsion – 7.53 at 20 °C After accelerated storage: 1% (w/v) emulsion – 7.44 at 20 °C	Y	KCP 2.4.2/01 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
dispersion (KCP 2.4.2)		PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	<p>After one year of production: 1% (w/v) emulsion – 7.58 at 20 °C</p> <p>After one year of storage: 1% (w/v) emulsion – 6.94 at 20 °C</p>		<p><i>physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21</i></p> <p>KCP 2.4.2/02 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation. BF-10/21</i></p> <p>KCP 2.4.2/03 Sadej, M., 2022, <i>CHR/ZF/PROTI 100 FS Stage III: Determination of physicochemical properties of the preparation after one year of storage. BF-10/21</i></p>	
Viscosity (KCP 2.5.1)	OECD 114	CHR/ZF/PROTI 100	<p>shear rate at 20°C : at 40°C: 5.0 s⁻¹ 798mPa·s 668 mPa·s,</p>	Y	KCP 2.5.1 Arevalo, E.,	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
1)		FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	10.0 s ⁻¹ 473 mPa·s 395 mPa·s 25.0 s ⁻¹ 245 mPa·s 203 mPa·s 50.0 s ⁻¹ 153 mPa·s 125 mPa·s		2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21</i>	
Surface tension (KCP 2.5.2)	OECD 115	CHR/ZF/PROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	0.2% (v/v) – 42.39 [mN/m] 12.5% (v/v) – 28.46 [mN/m] 33.0% (v/v) – 27.83 [mN/m]	Y	KCP 2.5.2 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21</i>	Acceptable
Relative density	A.3 CIPAC	CHR/ZF/PROTI 100	Absolute density: 1.088 g/ml at 20 °C, Relative density: 1.088 g/ml at 20 °C	Y	KCP 2.6.1 Arevalo, E.,	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.6.1)	MT 3.2	FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	The pycnometer method used instead of EC A.3 is also used for liquid plant protection products. The method EC A.3 cites the ISO 758 standard for this type of studies, which is analogous to the pycnometer method.		2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21</i>	
Bulk density (KCP 2.6.2)	N/A	N/A	N/A. CHR/ZF/PROTI 100 FS is a liquid.	N/A	N/A	N/A

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																																																						
Storage Stability after 14 days at 54° C (KCP 2.7.1)	Visual inspection at nasal inhalation EPA OPPTS 830.6302 EPA OPPTS 830.6303 EPA OPPTS 830.6304 Polish Pharmacopoeia VI Edition CIPAC MT 75.3 CIPAC MT 3.2 OECD 114 CIPAC MT 47.3 CIPAC MT 184.1 CIPAC MT 185 CIPAC MT 175	CHR/ZF/PROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	<table><thead><tr><th rowspan="2">Test Type</th><th rowspan="2">Methods</th><th colspan="3">Findings</th></tr><tr><th>Initial preparation</th><th>After accelerated storage</th><th>After low temperature storage</th></tr></thead><tbody><tr><td>Physical state colour and odour</td><td>Visual inspection, nasal inhalation</td><td>Homogenous intensive red liquid of characteristic odour</td><td>Homogenous intensive red liquid of characteristic odour</td><td>Homogenous intensive red liquid of characteristic odour</td></tr><tr><td rowspan="2">pH</td><td>undiluted</td><td>7.93</td><td>7.78</td><td rowspan="2">-</td></tr><tr><td>1 %</td><td>7.53</td><td>7.44</td></tr><tr><td>Determination of density</td><td>CIPAC MT 3.2</td><td>Absolute density 1.088 g/ml, relative density 1.088</td><td>-</td><td>-</td></tr><tr><td>Determination of viscosity</td><td>OECD 114</td><td>shear rate at 20°C: at 40°C: 5.0 s⁻¹ 798mPa·s 668 mPa·s, 10.0 s⁻¹ 473 mPa·s 395 mPa·s 25.0 s⁻¹ 245 mPa·s 204 mPa·s 50.0 s⁻¹ 153 mPa·s 125 mPa·s</td><td>-</td><td>-</td></tr><tr><td rowspan="3">Foam</td><td>0.2%</td><td rowspan="3">CIPAC MT 47.3</td><td>0 ml after 1 and 12 min</td><td rowspan="3">-</td></tr><tr><td>12.5%</td><td>0 ml after 1 and 12 min</td></tr><tr><td>33%</td><td>0 ml after 1 and 12 min</td></tr><tr><td rowspan="3">Suspension stability</td><td>0.2%</td><td rowspan="3">CIPAC MT 184.1</td><td>101.66%</td><td>100.96%</td><td rowspan="3">-</td></tr><tr><td>12.5%</td><td>100.14%</td><td>100.18%</td></tr><tr><td>33%</td><td>99.52%</td><td>99.28%</td></tr><tr><td>Wet sieve test</td><td>CPAC MT 185</td><td>0.00%</td><td>0.00%</td><td>0.00%</td></tr><tr><td>Distribution uniformity</td><td>CIPAC MT 175</td><td colspan="3">Homogenous</td></tr><tr><td>Adherence</td><td>CIPAC MT 194</td><td>-</td><td>100 %</td><td>-</td></tr></tbody></table> <table><tbody><tr><td rowspan="3">Surface tension</td><td>0.2%</td><td rowspan="3">OECD 115</td><td>42.39 mN/m</td><td rowspan="3">-</td><td rowspan="3">-</td></tr><tr><td>12.5%</td><td>28.46 mN/m</td></tr><tr><td>33%</td><td>27.83 mN/m</td></tr><tr><td>Pourability</td><td>CIPAC MT 148.1</td><td>R = 2.16%, R' = 0.17%</td><td>R = 1.99 %, R' = 0.16%</td><td>-</td></tr><tr><td>Package stability</td><td>CropLife International Technical Monograph No. 17</td><td>1 litre HDPE</td><td>The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.</td><td>-</td></tr><tr><td>Particle size</td><td>CIPAC MT 187 / ISO 13320-1</td><td>Average d₁₀ = 0.242 µm Average d₅₀ = 1.028 µm Average d₉₀ = 4.797 µm Average d₁₃ = 1.833 µm, SD = 0.3 µm, RSD 1.50%</td><td>Average d₁₀ = 0.272 µm Average d₅₀ = 1.228 µm Average d₉₀ = 5.154 µm Average d₁₃ = 2.052 µm, SD = 0.12 µm, RSD 5.76%</td><td>-</td></tr><tr><td>Active ingredient content</td><td>HPLC</td><td>Prothioconazole 9.61%</td><td>Prothioconazole 9.63%</td><td>-</td></tr><tr><td>Relevant impurities</td><td>HPLC/GC</td><td>Prothioconazole-desthio 0.003% Toluene 0.006%</td><td>Prothioconazole-desthio 0.003% Toluene 0.005%</td><td>-</td></tr></tbody></table>	Test Type	Methods	Findings			Initial preparation	After accelerated storage	After low temperature storage	Physical state colour and odour	Visual inspection, nasal inhalation	Homogenous intensive red liquid of characteristic odour	Homogenous intensive red liquid of characteristic odour	Homogenous intensive red liquid of characteristic odour	pH	undiluted	7.93	7.78	-	1 %	7.53	7.44	Determination of density	CIPAC MT 3.2	Absolute density 1.088 g/ml, relative density 1.088	-	-	Determination of viscosity	OECD 114	shear rate at 20°C: at 40°C: 5.0 s ⁻¹ 798mPa·s 668 mPa·s, 10.0 s ⁻¹ 473 mPa·s 395 mPa·s 25.0 s ⁻¹ 245 mPa·s 204 mPa·s 50.0 s ⁻¹ 153 mPa·s 125 mPa·s	-	-	Foam	0.2%	CIPAC MT 47.3	0 ml after 1 and 12 min	-	12.5%	0 ml after 1 and 12 min	33%	0 ml after 1 and 12 min	Suspension stability	0.2%	CIPAC MT 184.1	101.66%	100.96%	-	12.5%	100.14%	100.18%	33%	99.52%	99.28%	Wet sieve test	CPAC MT 185	0.00%	0.00%	0.00%	Distribution uniformity	CIPAC MT 175	Homogenous			Adherence	CIPAC MT 194	-	100 %	-	Surface tension	0.2%	OECD 115	42.39 mN/m	-	-	12.5%	28.46 mN/m	33%	27.83 mN/m	Pourability	CIPAC MT 148.1	R = 2.16%, R' = 0.17%	R = 1.99 %, R' = 0.16%	-	Package stability	CropLife International Technical Monograph No. 17	1 litre HDPE	The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.	-	Particle size	CIPAC MT 187 / ISO 13320-1	Average d ₁₀ = 0.242 µm Average d ₅₀ = 1.028 µm Average d ₉₀ = 4.797 µm Average d ₁₃ = 1.833 µm, SD = 0.3 µm, RSD 1.50%	Average d ₁₀ = 0.272 µm Average d ₅₀ = 1.228 µm Average d ₉₀ = 5.154 µm Average d ₁₃ = 2.052 µm, SD = 0.12 µm, RSD 5.76%	-	Active ingredient content	HPLC	Prothioconazole 9.61%	Prothioconazole 9.63%	-	Relevant impurities	HPLC/GC	Prothioconazole-desthio 0.003% Toluene 0.006%	Prothioconazole-desthio 0.003% Toluene 0.005%	-	Y	KCP 2.7.1 Arevalo, E., 2021, CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21	Acceptable All physicochemical properties are accepted. The HDPE pack remained intact after storage
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Particle size	CIPAC MT 187 / ISO 13320-1	Average d ₁₀ = 0.242 µm Average d ₅₀ = 1.028 µm Average d ₉₀ = 4.797 µm Average d ₁₃ = 1.833 µm, SD = 0.3 µm, RSD 1.50%	Average d ₁₀ = 0.272 µm Average d ₅₀ = 1.228 µm Average d ₉₀ = 5.154 µm Average d ₁₃ = 2.052 µm, SD = 0.12 µm, RSD 5.76%	-																																																																																																								
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 194 OECD 115 CIPAC MT 148.1 CropLife International Technical Monograph No. 17 CIPAC MT 18/ISO 13320-1 HPLC HPLC/GC					
Storage Stability after storage for other periods and/or temperatures (KCP 2.7.2)	N/A EPA OPPTS 830.6302 EPA OPPTS 830.6303 EPA OPPTS 830.6304 Polish Pharmacopoeia VI Edition	N/A CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemrol” Sp. z o.o. Batch number: 202003	N/A One year after production date	N/A Y	N/A KCP 2.7.2/01 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature</i>	N/A Acceptable All tested parameter are accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																																						
	CIPAC MT 75.3 CIPAC MT 3.2 OECD 114 CIPAC MT 47.3 CIPAC MT 184.1 CIPAC MT 185 CIPAC MT 175 CIPAC MT 194 OECD 115 CIPAC MT 148.1 CropLife International Technical Monograph No. 17 CIPAC MT 18/ISO 13320-1/SPO/BF/24/b HPLC	Production date: 1.04.2020	<table><tr><th rowspan="2">Test Type</th><th rowspan="2">Methods</th><th colspan="2">Findings</th></tr><tr><th>Initial preparation</th><th>One year after production date</th></tr><tr><td>Physical state colour and odour</td><td>Visual inspection, nasal inhalation</td><td>Homogenous intensive red liquid of characteristic odour</td><td>Homogenous intensive red liquid of characteristic odour</td></tr><tr><td rowspan="2">pH</td><td>undiluted</td><td>7.93</td><td>7.99</td></tr><tr><td>1 %</td><td>7.53</td><td>7.58</td></tr><tr><td>Determination of density</td><td>CIPAC MT 3.2</td><td>Absolute density 1.088 g/ml, relative density 1.088</td><td>-</td></tr><tr><td>Determination of viscosity</td><td>OECD 114</td><td>shear rate at 20°C; at 40°C: 5.0 s⁻¹ 798mPa·s 668 mPa·s, 10.0 s⁻¹ 473 mPa·s 395 mPa·s 25.0 s⁻¹ 245 mPa·s 203 mPa·s 50.0 s⁻¹ 153 mPa·s 125 mPa·s</td><td>-</td></tr><tr><td rowspan="3">Foam</td><td>0.2%</td><td>0 ml after 1 and 12 min</td><td rowspan="3">-</td></tr><tr><td>12.5%</td><td>0 ml after 1 and 12 min</td></tr><tr><td>33%</td><td>0 ml after 1 and 12 min</td></tr><tr><td rowspan="3">Suspension stability</td><td>0.2%</td><td>101.66%</td><td>100.31%</td></tr><tr><td>12.5%</td><td>100.14%</td><td>99.72%</td></tr><tr><td>33%</td><td>99.52%</td><td>100.45%</td></tr><tr><td>Wet sieve test</td><td>CPAC MT 185</td><td>0.00%</td><td>0.00%</td></tr><tr><td>Distribution uniformity</td><td>CIPAC MT 175</td><td colspan="2">Homogeneous</td></tr><tr><td>Adherence</td><td>CIPAC MT 194</td><td>-</td><td>100 %</td></tr><tr><td></td><td>0.2%</td><td>OECD 115</td><td>42.39 mN/m</td><td>-</td></tr></table> <table><tr><td rowspan="2">Surface tension</td><td>12.5%</td><td>28.46 mN/m</td><td rowspan="2"></td></tr><tr><td>33%</td><td>27.83 mN/m</td></tr><tr><td>Pourability</td><td>CIPAC MT 148.1</td><td>R = 2.16%, R' = 0.17%</td><td>R =2.07 %, R' = 0.17%</td></tr><tr><td>Package stability</td><td>CropLife International Technical Monograph No. 17</td><td>1 litre HDPE</td><td>The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.</td></tr><tr><td>Particle size</td><td>CIPAC MT 187 / ISO 13320-1/ SPO/BF/24/b</td><td>Average d₁₀ = 0.242 µm Average d₅₀ = 1.028 µm Average d₉₀ = 4.797 µm Average d_{4,3} = 1.833 µm, SD = 0.03 µm, RSD 1.50%</td><td>Average d₁₀ = 0.222 µm Average d₅₀ = 1.261 µm Average d₉₀ = 8.294 µm Average d_{4,3} = 3.049 µm, SD = 0.48 µm, RSD 15.90%</td></tr><tr><td>Active ingredient content</td><td>HPLC</td><td>Prothioconazole 9.61%</td><td>Prothioconazole 9.61%</td></tr><tr><td>Relevant impurities</td><td>HPLC/GC</td><td>Prothioconazole-desthio 0.003% Toluene 0.006%</td><td>Prothioconazole-desthio <LOQ Toluene 0.006%</td></tr></table>	Test Type	Methods	Findings		Initial preparation	One year after production date	Physical state colour and odour	Visual inspection, nasal inhalation	Homogenous intensive red liquid of characteristic odour	Homogenous intensive red liquid of characteristic odour	pH	undiluted	7.93	7.99	1 %	7.53	7.58	Determination of density	CIPAC MT 3.2	Absolute density 1.088 g/ml, relative density 1.088	-	Determination of viscosity	OECD 114	shear rate at 20°C; at 40°C: 5.0 s ⁻¹ 798mPa·s 668 mPa·s, 10.0 s ⁻¹ 473 mPa·s 395 mPa·s 25.0 s ⁻¹ 245 mPa·s 203 mPa·s 50.0 s ⁻¹ 153 mPa·s 125 mPa·s	-	Foam	0.2%	0 ml after 1 and 12 min	-	12.5%	0 ml after 1 and 12 min	33%	0 ml after 1 and 12 min	Suspension stability	0.2%	101.66%	100.31%	12.5%	100.14%	99.72%	33%	99.52%	100.45%	Wet sieve test	CPAC MT 185	0.00%	0.00%	Distribution uniformity	CIPAC MT 175	Homogeneous		Adherence	CIPAC MT 194	-	100 %		0.2%	OECD 115	42.39 mN/m	-	Surface tension	12.5%	28.46 mN/m		33%	27.83 mN/m	Pourability	CIPAC MT 148.1	R = 2.16%, R' = 0.17%	R =2.07 %, R' = 0.17%	Package stability	CropLife International Technical Monograph No. 17	1 litre HDPE	The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.	Particle size	CIPAC MT 187 / ISO 13320-1/ SPO/BF/24/b	Average d ₁₀ = 0.242 µm Average d ₅₀ = 1.028 µm Average d ₉₀ = 4.797 µm Average d _{4,3} = 1.833 µm, SD = 0.03 µm, RSD 1.50%	Average d ₁₀ = 0.222 µm Average d ₅₀ = 1.261 µm Average d ₉₀ = 8.294 µm Average d _{4,3} = 3.049 µm, SD = 0.48 µm, RSD 15.90%	Active ingredient content	HPLC	Prothioconazole 9.61%	Prothioconazole 9.61%	Relevant impurities	HPLC/GC	Prothioconazole-desthio 0.003% Toluene 0.006%	Prothioconazole-desthio <LOQ Toluene 0.006%		storage. BF-10/21 KCP 2.7.2/02 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation. BF-10/21</i>	
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Minimum content after heat stability testing (KCP 2.7.3)	HPLC HPLC/GC	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	<table><tr><td>Active ingredient content</td><td>HPLC</td><td>Prothioconazole 9.63%</td></tr><tr><td>Relevant impurities</td><td>HPLC/GC</td><td>Prothioconazole-desthio 0.003% Toluene 0.005%</td></tr></table>	Active ingredient content	HPLC	Prothioconazole 9.63%	Relevant impurities	HPLC/GC	Prothioconazole-desthio 0.003% Toluene 0.005%			Y	KCP 2.7.3 Arevalo, E., 2021, CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21	Acceptable
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Effect of low temperatures on stability (KCP 2.7.4)	MT 39.3	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z	Physical state Homogenous intensive red liquid of characteristic odour. Wet sieve test 0.00%			Y	KCP 2.7.4 Arevalo, E., 2021, CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial	Acceptable						

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																																																			
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Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments					
Wettability (KCP 2.8.1)	N/A	N/A	N/A. CHR/ZF/PROTI 100 FS is a liquid.			N/A	N/A	Acceptable					
Persistence of foaming (KCP 2.8.2)	MT 47.3	CHR/ZF/PROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirrol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	<table><tr><td>0.2%</td><td rowspan="3">CIPAC MT 47.3</td><td>0 ml after 1 and 12 min</td></tr><tr><td>12.5%</td><td>0 ml after 1 and 12 min</td></tr><tr><td>33%</td><td>0 ml after 1 and 12 min</td></tr></table>	0.2%	CIPAC MT 47.3	0 ml after 1 and 12 min	12.5%	0 ml after 1 and 12 min	33%	0 ml after 1 and 12 min	Y	KCP 2.8.2 Arevalo, E., 2021, CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21	Acceptable
0.2%	CIPAC MT 47.3	0 ml after 1 and 12 min											
12.5%		0 ml after 1 and 12 min											
33%		0 ml after 1 and 12 min											
Suspensibility (KCP 2.8.3.1)	MT 184.1	CHR/ZF/PROTI 100 FS Prothioconazole,	After accelerated storage: 0.2% - 100.96% 12.5% - 100.18%			Y	KCP 2.8.3.1/01 Arevalo, E., 2021, CHR/ZF/PROTI 100 FS Stage I:	Acceptable					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																												
		100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	<div>33.0% - 99.28%</div> <table><thead><tr><th colspan="2" rowspan="2">Test Type</th><th rowspan="2">Methods</th><th colspan="2">Findings</th></tr><tr><th>Initial preparation</th><th>One year after production date</th></tr></thead><tbody><tr><td rowspan="3">Suspension stability</td><td>0.2%</td><td rowspan="3">CIPAC MT 184.1</td><td>101.66%</td><td>100.31%</td></tr><tr><td>12.5%</td><td>100.14%</td><td>99.72%</td></tr><tr><td>33%</td><td>99.52%</td><td>100.45%</td></tr></tbody></table> <div><table><thead><tr><th colspan="2">Test Type</th><th>After one year of storage</th></tr></thead><tbody><tr><td rowspan="3">Suspension stability</td><td>0.2%</td><td>99.23%</td></tr><tr><td>12.5%</td><td>99.49%</td></tr><tr><td>33%</td><td>98.36%</td></tr></tbody></table><div></div></div>	Test Type		Methods	Findings		Initial preparation	One year after production date	Suspension stability	0.2%	CIPAC MT 184.1	101.66%	100.31%	12.5%	100.14%	99.72%	33%	99.52%	100.45%	Test Type		After one year of storage	Suspension stability	0.2%	99.23%	12.5%	99.49%	33%	98.36%		<div>Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21</div> <div>KCP 2.8.3.1/02 Arevalo, E., 2021, CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation. BF-10/21</div> <div>KCP 2.8.3.1/03 Sadej, M., 2022, CHR/ZF/PROTI 100 FS Stage III: Determination of physicochemical properties of the preparation after one year of storage. BF-10/21</div>	
Test Type		Methods	Findings																															
			Initial preparation	One year after production date																														
Suspension stability	0.2%	CIPAC MT 184.1	101.66%	100.31%																														
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Test Type		After one year of storage																																
Suspension stability	0.2%	99.23%																																
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (KCP 2.8.3.2)	N/A	N/A	N/A	N/A	N/A	Acceptable
Dispersion stability (KCP 2.8.3.3)	N/A	N/A	N/A	N/A	N/A	Acceptable
Degree of dissolution and dilution stability (KCP 2.8.4)	N/A	N/A	N/A	N/A	N/A	Acceptable
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	N/A	N/A	N/A	N/A	N/A	Acceptable
Wet sieve test (KCP 2.8.5.1.2)	MT 185	CHR/ZF/P ROTI 100 FS Prothioconazole,	Initial preparation: 1% (w/v) solution – 0.00 After accelerated storage:	Y	KCP 2.8.5.1.2/01 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage I:</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		100 g/L PUH „Chemi-rol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	1% (w/v) solution – 0.00 After one year of production: 1% (w/v) solution – 0.00 After one year of storage: 1% (w/v) solution – 0.25		<i>Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21</i> KCP 2.8.5.1.2/02 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation. BF-10/21</i> KCP 2.8.5.1.2/03 Sadej, M., 2022, <i>CHR/ZF/PROTI 100 FS Stage III: Determination of physicochemical properties of the preparation after one year of storage. BF-10/21</i>	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dust content (KCP 2.8. 5.2.1)	N/A	N/A	N/A	N/A	N/A	N/A
Particle size of dust (KCP 2.8. 5.2.2)	N/A	N/A	N/A	N/A	N/A	N/A
Attrition (KCP 2.8. 5.3)	N/A	N/A	N/A	N/A	N/A	N/A
Hardness and integrity (KCP 2.8. 5.4)	N/A	N/A	N/A	N/A	N/A	N/A
Emulsifiability (KCP 2.8. 6.1)	N/A	N/A	N/A	N/A	N/A	N/A
Emulsion stability (KCP 2.8. 6.2)	N/A	N/A	N/A	N/A	N/A	N/A
Re-emulsifiability (KCP 2.8. 6.3)	N/A	N/A	N/A	N/A	N/A	N/A

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flowability (KCP 2.8.7.1)	N/A	N/A	N/A	N/A	N/A	N/A
Pourability (KCP 2.8.7.2)	MT 148.1	CHR/ZF/P ROTI 100 FS Prothio- conazole, 100 g/L PUH „Chemi- rol” Sp. z o.o. Batch number: 202003 Produc- tion date: 1.04.2020	Initial preparation: R = 2.16%, R' = 0.17% After accelerated storage: R = 1.99 %, R' = 0.16% After one year of production: R = 2.07 %, R' = 0.17% After one year of storage: R = 1.89 %, R' = 0.16%	Y	KCP 2.8.7.2/01 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF- 10/21</i> KCP 2.8.7.2/02 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation. BF-10/21</i> KCP 2.8.7.2/03 Sądej, M., 2022,	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					CHR/ZF/PROTI 100 FS Stage III: Determination of physicochemical properties of the preparation after one year of storage. BF-10/21	
Dustability following accelerated storage (KCP 2.8.7.3)	N/A	N/A	N/A	N/A	N/A	N/A
Physical compatibility of tank mixes (KCP 2.9.1)	N/A	N/A	N/A	N/A	N/A	N/A
Chemical compatibility of tank mixes (KCP 2.9.2)	N/A	N/A	N/A	N/A	N/A	N/A

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Adhesion to seeds (KCP 2.1 0.1)	MT 194	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	Adherence to seeds: 100 %	Y	KCP 2.10.1 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21</i>	Acceptable
Distribution to seed (KCP 2.1 0.2)	MT 175	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH „Chemirol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020	Initial preparation: Homogenous. After accelerated storage: Homogenous. After one year of production: Homogenous. After one year of storage: Homogenous.	Y	KCP 2.10.2/01 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. BF-10/21</i> KCP 2.10.2/02	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation.</i> BF-10/21 KCP 2.10.2/03 Sadej, M., 2022, <i>CHR/ZF/PROTI 100 FS Stage III: Determination of physicochemical properties of the preparation after one year of storage.</i> BF-10/21	
Stability of packaging (KCP 2.11)	CropLife International Technical Monograph No. 17	CHR/ZF/PROTI 100 FS Prothioconazole, 100 g/L PUH „Chemrol” Sp. z o.o. Batch number: 202003	After accelerated storage: The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change. After one year of production: The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change. After one year of storage: The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.	Y	KCP 2.11/01 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																												
		Production date: 1.04.2020			<i>storage. BF-10/21</i> KCP 2.11/02 Arevalo, E., 2021, <i>CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation. BF-10/21</i> KCP 2.11/03 Sądej, M..., 2022, <i>CHR/ZF/PROTI 100 FS Stage III: Determination of physicochemical properties of the preparation after one year of storage. BF-10/21</i>																													
Effectiveness of cleaning (KCP 2.12)	Efficacy Guideline 305: 2004	CHR/ZF/P ROTI 100 FS Prothioconazole, 100 g/L PUH	<table><tr><th colspan="5">Findings</th></tr><tr><th>Water used</th><th>Initial Prothioconazole content</th><th>Prothioconazole content after rinsing</th><th>Cleaning effectiveness</th><th>Average</th></tr><tr><th>[mL]</th><th>[mg]</th><th>[mg]</th><th>[%]</th><th>[%]</th></tr><tr><td>10</td><td>3171.3</td><td>0.5115</td><td>99.98</td><td rowspan="3">99.99</td></tr><tr><td>2 × 10</td><td>3171.3</td><td>0.0349</td><td>100.00</td></tr><tr><td>3 × 10</td><td>3171.3</td><td>0.0116</td><td>100.00</td></tr></table>	Findings					Water used	Initial Prothioconazole content	Prothioconazole content after rinsing	Cleaning effectiveness	Average	[mL]	[mg]	[mg]	[%]	[%]	10	3171.3	0.5115	99.98	99.99	2 × 10	3171.3	0.0349	100.00	3 × 10	3171.3	0.0116	100.00	Y	KCP 2.12 Arevalo, E., 2021, Annex No. 1 to Final report: <i>CHR/ZF/PROTI 100 FS Stage II:</i>	Acceptable
Findings																																		
Water used	Initial Prothioconazole content	Prothioconazole content after rinsing	Cleaning effectiveness	Average																														
[mL]	[mg]	[mg]	[%]	[%]																														
10	3171.3	0.5115	99.98	99.99																														
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		„Chemi-rol” Sp. z o.o. Batch number: 202003 Production date: 1.04.2020			<i>Determination of physicochemical properties of the preparation. BF-10/21</i>	

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	JAR
Material:	HDPE
size:	63/64 mm / 91.5 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	188 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information

Type	BOTTLE
Material:	HDPE
size:	64 mm± 2 mm/130 mm ± 3 mm
Opening:	40 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information

Type	BOTTLE
Material:	HDPE
size:	72 mm± 2 mm/111,8 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information

Type	BOTTLE
Material:	HDPE
size:	72±1 mm/111.8±2 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	250 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information

Type	BOTTLE
Material:	HDPE
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	45.65± 2 mm
Closure:	screw cap with seal
Capacity	564 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information

Type	BOTTLE
Material:	HDPE
size:	90,5 mm± 2 mm/151 mm ± 3 mm
Opening:	40,6 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information

Type	BOTTLE
Material:	HDPE
size:	77,6 mm± 2 mm/160,6 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 mL
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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Table 4.1-8: Packaging information

Type	BOTTLE
Material:	HDPE
size:	77.6 ±1 mm/160.6±2 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	500 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box
Material: HDPE
Type of construction: jar
Size: approximate diameter/height: 80 mm/138 mm
Capacity: 510 mL overflow
Type of closure: screw-cap with seal
Size of opening: 46 mm minimum
Accessories: one measuring device per each jar

Table 4.1-10: Packaging information

Type	BOTTLE
Material:	HDPE
size:	145.5mm± 2 mm/78mm ± 2 mm
Opening:	56mm ± 2 mm
Closure:	screw cap with seal
Capacity	600 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information

Type	JAR
Material:	HDPE
size:	79/80 mm/ 201 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	800 mL
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Table 4.1-12: Packaging information

Type	BOTTLE
Material:	HDPE
size:	80 mm± 2 mm/201 mm ± 2 mm
Opening:	64 mm
Closure:	screw cap with seal
Capacity	800 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information

Type	BOTTLE
Material:	HDPE
size:	88.5 mm± 2 mm/283.5 mm ± 2 mm
Opening:	45.30 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-14: Packaging information

Type	BOTTLE
Material:	HDPE
size:	88 mm± 4 mm/242 mm ± 6 mm
Opening:	39mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-15: Packaging information

Type	BOTTLE
Material:	HDPE
size:	238 mm± 2 mm/90mm ± 2 mm
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 mL

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

Table 4.1-16: Packaging information

Type	BOTTLE
Material:	HDPE
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 4.1-17: Packaging information

Type	BOTTLE
Material:	HDPE
size:	84 mm± 2 mm/248.2 mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-18: Packaging information

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	cap with seal
Capacity	1200 ± 50 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-19: Packaging information

Type	BOTTLE
Material:	HDPE
size:	84 ± 1.5 mm/230.1 ± 3 mm
Opening:	38 mm

Closure:	screw cap with seal
Capacity	1000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-20: Packaging information

Type	BOTTLE
Material:	HDPE
size:	157,2 mm± 2 mm/101mm ± 2 mm
Opening:	72 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-21: Packaging information

Type	JAR
Material:	HDPE
size:	108/110 mm/ 266 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	2000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-22: Packaging information

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-23: Packaging information

Type	BOTTLE
Material:	HDPE
size:	94 ± 1 mm/103 ± 1 mm/272.5 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	2000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-24: Packaging information

Type	BOTTLE
Material:	HDPE
size:	224,1 mm± 2 mm/122mm ± 2 mm
Opening:	73 mm ± 2 mm
Closure:	screw cap with seal
Capacity	2000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-25: Packaging information

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-26: Packaging information

Type	CANNISTER
Material:	HDPE
size:	96 ± 3 mm/195 ± 3.5 mm/297.2 ± 4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	4000 mL
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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Table 4.1-27: Packaging information

Type	CONTAINER
Material:	HDPE
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm
Opening:	59.20 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 4.1-28: Packaging information

Type	CONTAINER
Material:	HDPE
size:	336 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-29: Packaging information

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

Table 4.1-30: Packaging information

Type	CANNISTER
Material:	HDPE
size:	190 mm± 5 mm /140 mm± 5 mm/ 314 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-31: Packaging information

Type	CANNISTER
Material:	HDPE
size:	127±2 mm/192±2 mm/285±5 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	5000 m ³ L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-32: Packaging information

Type	CANNISTER
Material:	HDPE
size:	145±2 mm/190.8±3/294±4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	6000 m ³ L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-33: Packaging information

Type	Description
Material:	HDPE
Size:	745 mm x 493 mm
Opening:	BCS 70x6/ BCS 38x6
Closure:	Bung
Capacity	124 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34: Packaging information

Type	Description
Material:	HDPE
Size:	90000mm/59000mm ± 2 mm
Opening:	45mm ± 2 mm
Closure:	screw cap with seal
Capacity	22000 ml 220 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35: Packaging information

Type	Description
Material:	HDPE
Size:	935 mm x 581 mm
Opening:	BCS 70x6/ BCS 56x4
Closure:	Bung
Capacity	220 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-37: Packaging information

Type	Description
Material:	HDPE
Size:	942 mm ± 10 mm x 582 mm ± 10 mm
Opening:	70x6 / 56 x4
Closure:	Openings on top, 3 high, straight wrapped with cover on top Bungs 70x6 and 56 x 4 lose screw
Capacity	222 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-33: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	50 ± 1 mm/93 ± 1 mm
Opening:	28,4 ± 0,3 mm
Closure:	screw cap with seal
Capacity	120 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34: Packaging information

Packaging information for 120 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	50 ± 1 mm/93 ± 1 mm
Opening:	28,4 ± 0,3 mm
Closure:	screw cap with seal
Capacity	120 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
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 4.1-36: 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 4.1-37: 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 4.1-38: 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 4.1-39: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	74± 1 mm/177 ± 1 mm/
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 4.1-40: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	74± 1 mm/177 ± 1 mm/
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 4.1-41: Packaging information

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

Table 4.1-43: Packaging information

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

Table 4.1-44: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	248.5 \pm 3 mm/84 \pm 1.5mm
Opening:	50 mm \pm 5 mm
Closure:	screw cap with seal
Capacity	1000 mL

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

Table 4.1-45: Packaging information

Type	BOTTLE
Material:	PE-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 4.1-46: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	238± 1 mm/88 ± 1 mm/
Opening:	41.7±0,7 mm
Closure:	screw cap with seal
Capacity	1100 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-47: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
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 4.1-48: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
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 4.1-49: Packaging information

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

Table 4.1-50: Packaging information

Type	CONTAINER
Material:	HDPE/PA COEX
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 m ³ ±150 m ³ L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-51: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	193 ± 3/ 142 ± 5 mm/320 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5500 m ³ L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-52: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	195 ± 3/ 130 ± 5 mm/310,5 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal

Capacity	5000 m L ^L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-53: Packaging information

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

Table 4.1-54: Packaging information

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

Table 4.1-55: Packaging information

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

Table 4.1-56: 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 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-57: 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 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-58: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	67,5 mm ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-59: Packaging information

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

Table 4.1-60: Packaging information

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

Table 4.1-61: Packaging information

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

Table 4.1-62: Packaging information

Type	Description
Material:	HDPE/EvOH
Size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	45.30 mm ± 2 mm
Capacity	500 ml L
Closure:	screw cap with cutter
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-63: Packaging information

Type	Description
Material:	HDPE/EvOH
size:	65 mm/234.8 mm ± 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-64: Packaging information

Type	Description
Material:	HDPE/EvOH
size:	234±3 mm/88.5±2mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-65: Packaging information

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

Table 4.1-66: Packaging information

Type	Description
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 4.1-67: Packaging information

Type	Description
Material:	HDPE/EvOH
Size:	165 mm ± 2 mm/195 mm ± 2 mm/228mm± 2 mm
Opening:	48 mm ± 2 mm

Type	Description
Closure:	screw cap with cutter
Capacity	5000 mL
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-68: Packaging information

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

Table 4.1-69: Packaging information

Type	Description
Material:	HDPE/EvOH
Size:	375 mm ± 2 mm/290mm± 2 mm/245mm± 2 mm
Opening:	85mm ± 2 mm
Closure:	Screw cap with seal
Capacity	20000 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 are extrapolable to the all materials (HDPE/PA; HDPE/F; HDPE/EvOH). Therefore, no further studies are required for the additional packaging materials.

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 2.1/01 KCP 2.4.2/01 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 2.7.56/01 KCP 2.8.2 KCP 2.8.3/01 KCP 2.8.5.1.2/01 KCP 2.8.7.2/01 KCP 2.10.1 KCP 2.10.2/01 KCP 2.11/01	Arevalo, E.	2021	<i>CHR/ZF/PROTI 100 FS Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage.</i> BF-10/21 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Annopol St., Warsaw, Poland GLP Unpublished	N	Chemiroł
KCP 2.1/02 KCP 2.4.2/02 KCP 2.7. 56/02 KCP 2.8.3.1/02 KCP 2.8.5.1.2/02 KCP 2.8.7.2/02 KCP 2.10.2/02 KCP 2.11/02	Arevalo, E.	2021	<i>CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation.</i> BF-10/21 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Annopol St., Warsaw, Poland GLP Unpublished	N	Chemiroł
KCP 2.1/03 KCP 2.4.2/03	Sądej, M.	2022	<i>CHR/ZF/PROTI 100 FS Stage III: Determination of physicochemical properties of the preparation after one year of storage.</i>	N	Chemiroł

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 2.7.56/03 KCP 2.8.3.1/03 KCP 2.8.5.1.2/03 KCP 2.8.7.2/03 KCP 2.10.2/03 KCP 2.11/03			BF-10/21 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Annopol St., Warsaw, Poland GLP Unpublished		
KCP 2.2.1	Buczowski, D.	2021	CHR/ZF/PROTI 100 FS Determination of explosive properties BW-16/21 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Annopol St., Warsaw, Poland GLP Unpublished	N	Chemrol
KCP 2.2.2 KCP 2.2.3	Flasińska, P.	2021	CHR/ZF/PROTI 100 FS Determination of flash point, auto-ignition temperature and oxidizing properties. BC-17/21 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Annopol St., Warsaw, Poland GLP Unpublished	N	Chemrol
KCP 2.12	Arevalo, E.	2021	Annex No. 1 to Final Report CHR/ZF/PROTI 100 FS Stage II: Determination of physicochemical properties of the preparation. BF-10/21 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Annopol St., Warsaw, Poland GLP Unpublished	N	Chemrol

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