

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/I/ADEL 280 SC

Product name(s): ADEL 280 SC/ PYRIFOS ADE 280 SC

Chemical active substances:

Deltamethrin, 30 g/L

Acetamiprid, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: July 2021

MS Finalisation date: 24/10/2024

Version history

When	What
September 2021	Dossier sent for evaluation
February 2023	Updated by Applicant
February 2023	zRMS finalised evaluation
October 2024	Final version prepared by zRMS after Commenting period

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zRMS comments:

The text highlighted in grey was provided by the evaluator.

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:

- none

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. Al. Jerozolimskie 178, 02-486 Warsaw, Poland

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

1.2.1 Producer(s) of the preparation

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 Deltamethrin

According to Deltamethrin 6504/VI/99-final 17 October 2002

Deltamethrin min. 980 g/kg

1.2.3.2 Acetamiprid

According to Acetamiprid SANTE/10502/2017 Rev 4 13 December 2017

Acetamiprid min. 990 g/kg

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

(KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)
 Trade name: ADEL 280 SC
 PYRIFOS ADE 280 SC
 Company code number: CHR/I/ADEL 280 SC

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Deltamethrin	30	27 - 33	27.6 - 33.7	2.5 - 3.1
Acetamiprid	250	235 - 265	239.8 - 270.4 (237.4-267.7)***	22.1 - 24.9 (21.9-24.7)***

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

** Based on the density of the formulation = 1.085 g/ml (Note: only applies if a liquid formulation – delete this comment if not needed)

***. Updated due to the minimal purity of acetamiprid source at 990 g/kg

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

Table 1.4-2: Information on deltamethrin

Type	Name/Code Number	
ISO common name	Deltamethrin	
CAS No.	52918-63-5	
EC No.	-	
CIPAC No.	333	

Table 1.4-3: Information on acetamiprid

Type	Name/Code Number	
ISO common name	Acetamiprid	
CAS No.	135410-20-7	
EC No.	-	
CIPAC No.	649	

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

CONFIDENTIAL information is provided separately (Part C).

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

Type: Suspension concentrate

[Code: SC]

1.6 Function (KCP 1.6)

The CHR/I/ADEL 280 is an insecticide in the form of suspension concentrate.

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 white liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has no self ignition temperature. In aqueous solution, it has a pH value around 6.93 in 1% water suspension and around 6.19 when undiluted at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient 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*. Its technical characteristics are acceptable for a suspension concentrate formulation.

The intended concentration of use is 0.02% to 0.08% (according to the final GAP table intended tank mix is from 0.05 to 0.08% 0.026 to 0.04% v/v).

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

NA

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not required

Compliance with FAO specifications:

The product CHR/I/ADEL 280 SC complies with FAO specifications.

Formulation used for tests

Test item:	CHR/I/ADEL 280 SC
Production date:	1.04.2020
Expiration date:	1.04.2022
Batch number:	CHR/20

The following table presents technical specifications as listed in the “Manual on development and use of FAO and WHO specifications for pesticides”, Third Revision, November 2016. The product CHR/I/ADEL 280 SC containing 250 g/L acetmiprid and 30 g/L deltamethrin. Studies on the physicochemical properties of the preparation were conducted and are presented in full in this section of the draft Registration Report.

No.	Quality parameters	Method	Required
1.	Appearance	Visual method	Homogenous white liquid with a characteristic odour
2.	Acetamiprid content, g/l	HPLC	250 ± 15
3.	Deltamethrin content, g/l	HPLC	30 ± 3
4.	Density at 20°C, g/ml	CIPAC MT 3	1.085 ± 0,02
5.	pH of 1% (w/v) suspension in distilled water, 20°C	CIPAC MT 75.3	6.0 – 8.0
6.	Suspensibility of 0.02, 0.08, 0.2% (w/v) suspension in water CIPAC D at 25±5 °C after 0,5 h, chemical method, min., %	CIPAC MT 184.1	Acetamiprid 70
			Deltamethrin 70
7.	Particle size Dv(50), µm	CIPAC MT 187	1.0 – 1.5
8.	Wet sieve test 75 µm, max., %	CIPAC MT 185	0.1
9.	Foaming of 0.02, 0.08, 0.2% (v/v) suspension in water CIPAC D after 1 minute, max., ml	CIPAC MT 47.3	20

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

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual inspection, nasal inhalation	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch: CHR/20 number:	Initial preparation: Homogenous white liquid with a characteristic odour. After accelerated storage: Homogenous white liquid with a characteristic odour. After Low temperature storage: Homogenous white liquid with a characteristic odour. After one year storage:	Y	Study code no. BF- 55/20; E. Arévalo; 2021, PART I Study code	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
			Homogenous white liquid with a characteristic odour.		no. BF- 55/20; E. Arévalo; January 2021, PART II	
Explosive properties (KCP 2.2.1)	EEC A.14	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022	CHR/I/ADEL 280 SC does not have explosive properties.	Y	Study code no. BW- 09/20; D. Buczkowski; 2020	Accepted
Oxidizing properties (KCP 2.2.2)	EEC A.21	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch number: CHR/20	CHR/I/ADEL 280 SC has no oxidizing properties.	Y	Study code no. BC- 24/20; P.; December 2020	Accepted
Flash point (KCP 2.3.1)	EEC A.9	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch number: CHR/20	CHR/I/ADEL 280 SC has no the flash point up to boiling point.	Y	Study code no. BC- 24/20; P.; December 2020	Accepted
Flammability (KCP 2.3.2)	EEC A.15	Test item: CHR/I/ADEL 280 SC	CHR/I/ADEL 280 SC has no auto-ignition temperature up to 650 °C.	Y	Study code no.	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
		Production date: 1.04.2020 Expiration date: 1.04.2022 Batch number: CHR/20			BC- 24/20; P. Flasińska; 2020	
Self-heating (KCP 2.3.3)	-	-	-	-	-	
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch number: CHR/20	Initial preparation: Undiluted: pH 6.19 Accelerated storage: Undiluted: pH 6.22 After one year storage: Undiluted: pH 6.34	Y	Study code no. BF- 55/20; E. Arévalo; 2021, PART I Study code no. BF- 55/20; E. Arévalo; January 2021, PART II	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch number: CHR/20	Initial preparation: 1% water suspension: pH 6.93 Accelerated storage: 1% water suspension: pH 6.94 After one year: 1% water suspension: pH 7.05	Y	Study code no. BF- 55/20; E. Arévalo; 2021, PART I Study code	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
					no. BF- 55/20; E. Arévalo; January 2021, PART II	
Viscosity (KCP 2.5.1)	PN-EN ISO 3219: 2000 [OECD 114]	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch: CHR/20 number:	shear rate at 20°C: at 40°C: 5.0 s-1 568mPa·s 476 mPa·s, 10.0 s-1 352 mPa·s 295 mPa·s 25.0 s-1 192 mPa·s 159 mPa·s 50.0 s-1 126 mPa·s 102 mPa·s	Y	Study code no. BF- 55/20; E. Arévalo; January 2021	Accepted
Surface tension (KCP 2.5.2)	OECD 115	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch: CHR/20 number:	Surface tension in 0.2% water suspension: 37.60 mN/m	Y	Study code no. BF- 55/20; E. Arévalo; January 2021	Accepted It's considered a surface active
Relative density (KCP 2.6.1)	CIPAC MT 3.2	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch: CHR/20 number:	The absolute density is 1.085 g/ml, relative density is 1.085	Y	Study code no. BF- 55/20; E. Arévalo; January 2021	Accepted
Bulk density	-	-	-	-	-	

Annex point	Method used / deviations	Test material	Findings				GL P Y/N	Reference	Acceptability / comments	
(KCP 2.6.2)										
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch number: CHR/20	Test type		Method	Findings		Y	Study code no. BF- 55/20; E. Arévalo; January 2021	Accepted. This dossier has been submitted in July 2021. So, the SANCO/10473/2003 –rev.5 is not relevant. FAO/WHO manual (2016) requirements on physicochemical test required for the storage stability study are taken into consideration.
						Initial preparation	After accelerated storage			
			Physical state colour and odour		Visual inspection, nasal inhalation	Homogenous white liquid with a characteristic odour	Homogenous white liquid with a characteristic odour			
			pH	1%	CIPAC MT 75.3	6.93	6.94			
				undiluted		6.19	6.22			
			Dispersion spontaneity		CIPAC MT 160	Deltamethrin: 104.22 %	Deltamethrin: 103.34%			
						Acetamidrid: 103.52 %	Acetamidrid: 103.04%			
			Suspension stability	0.08%	CIPAC MT 184.1	Deltamethrin: 100.91%	Deltamethrin: 100.75%			
						Acetamidrid:101.06%	Acetamidrid:101.23%			
						Deltamethrin: 98.23%	Deltamethrin: 98.23%			
						Acetamidrid:97.28%	Acetamidrid:96.66%			
						Deltamethrin: 74.46%	Deltamethrin: 70.28%			
						Acetamidrid:73.97%	Acetamidrid:70.00%			
			Wet sieve test		CPAC MT 185	0.00%	0.00%			
			Pourability		CIPAC MT 148.1	R = 1.80%, R' = 0.19%	R = 1.86%, R' = 0.19%			
Package stability		CropLife International Technical Monograph No. 17	1 L HDPE	Stable, 1L HDPE						
Active ingredient content		HPLC/DAD detector	Acetamidrid:24.08%(261.29 g/l).	Acetamidrid:24.16% (262.17 g/l).						
			Deltamethrin:3.04% (32.94 g/l).	Deltamethrin:3.04% (32.97 g/l).						
Stability after storage for other periods	-	-	-				-	-	Not required	

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
and/or temperatures (KCP 2.7.2)						
Minimum content after heat stability testing (KCP 2.7.3)		Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch number: CHR/20	Accelerated storage: Acetamiprid: 24.16% (262.17 g/l) Deltamethrin: 3.04% (32.97 g/l) After one year storage: Acetamiprid: 23.19% (251.66 g/L) Deltamethrin: 2.90% (31.46 g/L)	Y	Study code no. BF- 55/20; E. Arévalo; 2021, PART I Study code no. BF- 55/20; E. Arévalo; January 2021, PART II	Accepted

Annex point	Method used / deviations	Test material	Findings				GL P Y/N	Reference	Acceptability / comments	
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch number: CHR/20	Test type		Method	Findings		Y	Study code no. BF- 55/20; E. Arévalo; January 2021	Accepted
						After low temperature storage				
			Suspension stability	0.08%	CIPAC MT 184.1	Deltamethrin: 103.99%				
				0.02%		Acetamiprid:96.89%				
						Deltamethrin: 98.92%				
						Acetamiprid:98.79%				
						Deltamethrin: 77.74%				
			0.2%		Acetamiprid:79.46					
			Wet sieve test		CPAC MT 185	0.00%				
			Low temperature storage		CIPAC MT 39.3	Homogenous liquid				

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments																																																	
Ambient temperature shelf life (KCP 2.7.5)	CIPAC MT 46.3 HPLC/DAD detector	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch number: CHR/20	<table><tr><th rowspan="2">Test type</th><th rowspan="2">Method</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 white liquid with a characteristic odour</td><td>Homogenous white liquid with a characteristic odour</td></tr><tr><td rowspan="2">pH</td><td>1%</td><td>6.93</td><td>7.05</td></tr><tr><td>undiluted</td><td>6.19</td><td>6.34</td></tr><tr><td colspan="2">Viscosity determination</td><td>shear rate at 20°C: at 40°C: 5.0 s⁻¹ 568mPa·s 476 mPa·s, 10.0 s⁻¹ 352 mPa·s 295 mPa·s, 25.0 s⁻¹ 192 mPa·s 159 mPa·s, 50.0 s⁻¹ 126 mPa·s 102 mPa·s</td><td>-</td></tr><tr><td colspan="2">Density determination</td><td>CIPAC MT 3.2 1.085 g/ml, relative density 1.085</td><td>-</td></tr><tr><td rowspan="3">Foaming</td><td>0.02%</td><td>2 ml after 1min and 0 ml after 12 min</td><td rowspan="3">-</td></tr><tr><td>0.08%</td><td>0 ml after 1min and 0 ml after 12 min</td></tr><tr><td>0.2%</td><td>0 ml after 1min and 0 ml after 12 min</td></tr><tr><td colspan="2">Dispersion spontaneity</td><td>CIPAC MT 160 Deltamethrin: 104.22 % Acetamiprid: 103.52 % Deltamethrin: 100.91% Acetamiprid:101.06% Deltamethrin: 98.23% Acetamiprid:97.28% Deltamethrin: 74.46% Acetamiprid:73.97%</td><td>Deltamethrin: 101.48 % Acetamiprid: 102.57 % Deltamethrin: 100.26% Acetamiprid:100.04% Deltamethrin: 97.54% Acetamiprid:100.59% Deltamethrin: 100.46% Acetamiprid:100.64%</td></tr><tr><td colspan="2">Suspension stability</td><td>CIPAC MT 184.1 0.08% 0.02% 0.2%</td><td></td></tr><tr><td colspan="2">Wet sieve test</td><td>CPAC MT 185 0.00%</td><td>0.00%</td></tr><tr><td colspan="2">Pourability</td><td>CIPAC MT 148.1 R = 1.80%, R' = 0.19%</td><td>-</td></tr></table>	Test type	Method	Findings		Initial preparation	One year after production date	Physical state colour and odour	Visual inspection, nasal inhalation	Homogenous white liquid with a characteristic odour	Homogenous white liquid with a characteristic odour	pH	1%	6.93	7.05	undiluted	6.19	6.34	Viscosity determination		shear rate at 20°C: at 40°C: 5.0 s ⁻¹ 568mPa·s 476 mPa·s, 10.0 s ⁻¹ 352 mPa·s 295 mPa·s, 25.0 s ⁻¹ 192 mPa·s 159 mPa·s, 50.0 s ⁻¹ 126 mPa·s 102 mPa·s	-	Density determination		CIPAC MT 3.2 1.085 g/ml, relative density 1.085	-	Foaming	0.02%	2 ml after 1min and 0 ml after 12 min	-	0.08%	0 ml after 1min and 0 ml after 12 min	0.2%	0 ml after 1min and 0 ml after 12 min	Dispersion spontaneity		CIPAC MT 160 Deltamethrin: 104.22 % Acetamiprid: 103.52 % Deltamethrin: 100.91% Acetamiprid:101.06% Deltamethrin: 98.23% Acetamiprid:97.28% Deltamethrin: 74.46% Acetamiprid:73.97%	Deltamethrin: 101.48 % Acetamiprid: 102.57 % Deltamethrin: 100.26% Acetamiprid:100.04% Deltamethrin: 97.54% Acetamiprid:100.59% Deltamethrin: 100.46% Acetamiprid:100.64%	Suspension stability		CIPAC MT 184.1 0.08% 0.02% 0.2%		Wet sieve test		CPAC MT 185 0.00%	0.00%	Pourability		CIPAC MT 148.1 R = 1.80%, R' = 0.19%	-	Y	Study code no. BF- 55/20; E. Arévalo; 2021, PART I Study code no. BF- 55/20; E. Arévalo; January 2021, PART II Study code no. BF- 55/20; E. Arévalo; July 2021, PART II, Annex No. 1	Accepted All physicochemical parameters before and after storage are accepted. Applicant has provided a two-year storage stability study. Summarising, the HDPE packaging remained intact after the two years. Therefore, the two-year shelf life can be granted for the PPP.
			Test type			Method	Findings																																																
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			<table><tr><td colspan="2">Package stability</td><td>Crop Life International Technical Monograph No. 17</td><td>1 L HDPE</td><td colspan="2">Stabe, 1 L HDPE</td></tr><tr><td>Surface tension</td><td>0.2%</td><td>OECD 115</td><td>37.60 mN/m</td><td colspan="2">-</td></tr><tr><td colspan="2">Low temperature storage</td><td>CIPAC MT 39.3</td><td colspan="3">Homogenous liquid</td></tr><tr><td colspan="2">Package cleaning effectiveness</td><td>Efficacy Guideline 305: 2004</td><td><u>Cleaning effectiveness:</u> Average for Deltamethrin: 100% Average for Acetamiprid: 99.91%</td><td colspan="2">-</td></tr><tr><td colspan="2" rowspan="2">Active ingredient content</td><td rowspan="2">HPLC/DAD detector</td><td colspan="2">Acetamiprid:24.08%(261.29 g/l).</td><td>Acetamiprid: 23.19% (251.66 g/l).</td></tr><tr><td colspan="2">Deltamethrin:3.04% (32.94 g/l).</td><td>Deltamethrin: 2.90% (31.46 g/l).</td></tr></table>				Package stability		Crop Life International Technical Monograph No. 17	1 L HDPE	Stabe, 1 L HDPE		Surface tension	0.2%	OECD 115	37.60 mN/m	-		Low temperature storage		CIPAC MT 39.3	Homogenous liquid			Package cleaning effectiveness		Efficacy Guideline 305: 2004	<u>Cleaning effectiveness:</u> Average for Deltamethrin: 100% Average for Acetamiprid: 99.91%	-		Active ingredient content		HPLC/DAD detector	Acetamiprid:24.08%(261.29 g/l).		Acetamiprid: 23.19% (251.66 g/l).	Deltamethrin:3.04% (32.94 g/l).		Deltamethrin: 2.90% (31.46 g/l).			
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Pourability after one year storage: R= 1.75%, R’= 0.18%																																										

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments																																																																																																										
			<table><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>After two years of storage</th></tr><tr><td colspan="2">Appearance</td><td>OPPTS 830.6302-04</td><td>Homogenous white liquid with a characteristic odour</td><td>Before mixing - at the top ~ 10% v/v surfactants solution, after mixing - homogenous white liquid of characteristic odour</td></tr><tr><td rowspan="2">pH</td><td>1 %</td><td rowspan="2">CIPAC MT 75.3</td><td>6.93</td><td>7.71</td></tr><tr><td>undiluted</td><td>6.19</td><td>6.21</td></tr><tr><td colspan="2">Density</td><td>CIPAC MT 3.2</td><td>Absolute density 1.085 g/ml, relative density 1.085</td><td>-</td></tr><tr><td colspan="2">Viscosity</td><td>OECD 114</td><td>shear rate at 20°C : at 40°C: 5.0 s⁻¹ 568 mPa·s 476 mPa·s, 10.0 s⁻¹ 352 mPa·s 295 mPa·s, 25.0 s⁻¹ 192 mPa·s 159 mPa·s, 50.0 s⁻¹ 126 mPa·s 102 mPa·s</td><td>-</td></tr><tr><td rowspan="3">Persistent foam</td><td>0.02%</td><td rowspan="3">CIPAC MT 47.3</td><td>2 ml after 1 min and 0 ml after 12 min</td><td rowspan="3">-</td></tr><tr><td>0.08%</td><td>0 ml after 1 and 12 min</td></tr><tr><td>0.2%</td><td>0 ml after 1 and 12 min</td></tr><tr><td rowspan="5">Suspension stability</td><td>0.02%</td><td rowspan="5">CIPAC MT 184.1</td><td>Acetamiprid: 97.28%</td><td>Acetamiprid: 100.17%</td></tr><tr><td></td><td>Deltamethrin: 98.23%</td><td>Deltamethrin: 98.31%</td></tr><tr><td>0.08%</td><td>Acetamiprid: 101.06%</td><td>Acetamiprid: 100.44%</td></tr><tr><td></td><td>Deltamethrin: 100.91%</td><td>Deltamethrin: 100.08%</td></tr><tr><td>0.2%</td><td>Acetamiprid: 73.97%</td><td>Acetamiprid: 100.56%</td></tr><tr><td></td><td></td><td></td><td>Deltamethrin: 74.46%</td><td>Deltamethrin: 100.48%</td></tr><tr><td rowspan="2">Dispersion spontaneity</td><td></td><td rowspan="2">CIPAC MT 160</td><td>Acetamiprid: 103.52%</td><td>Acetamiprid: 98.70%</td></tr><tr><td></td><td>Deltamethrin: 104.22%</td><td>Deltamethrin: 99.33%</td></tr><tr><td colspan="2">Wet sieve test</td><td>CPAC MT 185</td><td>0.00 %</td><td>0.00 %</td></tr><tr><td colspan="2">Surface tension</td><td>OECD 115</td><td>37.60 mN/m</td><td>-</td></tr><tr><td colspan="2">Pourability</td><td>CIPAC MT 148</td><td>R = 1.80 %, R' = 0.19 %</td><td>R = 1.80 %, R' = 0.20 %</td></tr><tr><td colspan="2">Particle size analysis</td><td>CIPAC MT 187</td><td>-</td><td>Average d₁₀ = 0.407 µm Average d₅₀ = 1.143µm Average d₉₀ = 3.681µm Average d_{4,5} = 1.625 µm SD = 0.009 µm RSD = 0.554 %</td></tr><tr><td colspan="2">Package stability</td><td>Crop Life International Technical Monograph No. 17</td><td>1 L HDPE</td><td>The shape and colour of the 1 litre HDPE package were stable, negligible mass change</td></tr><tr><td colspan="2">Package cleaning effectiveness</td><td>Efficacy Guideline 305:2004</td><td>Cleaning effectiveness: Average for acetamiprid = 99.91% Average for deltamethrin = 100%</td><td>-</td></tr><tr><td rowspan="2">Active ingredient content</td><td rowspan="2"></td><td rowspan="2">HPLC</td><td>Acetamiprid: 24.08% (261.29 g/l)</td><td>Acetamiprid: 24.55% (266.38 g/L)</td></tr><tr><td>Deltamethrin: 3.04% (32.94 g/l)</td><td>Deltamethrin: 2.96% (32.07 g/L)</td></tr></table>	Test type		Methods	Findings		Initial preparation	After two years of storage	Appearance		OPPTS 830.6302-04	Homogenous white liquid with a characteristic odour	Before mixing - at the top ~ 10% v/v surfactants solution, after mixing - homogenous white liquid of characteristic odour	pH	1 %	CIPAC MT 75.3	6.93	7.71	undiluted	6.19	6.21	Density		CIPAC MT 3.2	Absolute density 1.085 g/ml, relative density 1.085	-	Viscosity		OECD 114	shear rate at 20°C : at 40°C: 5.0 s ⁻¹ 568 mPa·s 476 mPa·s, 10.0 s ⁻¹ 352 mPa·s 295 mPa·s, 25.0 s ⁻¹ 192 mPa·s 159 mPa·s, 50.0 s ⁻¹ 126 mPa·s 102 mPa·s	-	Persistent foam	0.02%	CIPAC MT 47.3	2 ml after 1 min and 0 ml after 12 min	-	0.08%	0 ml after 1 and 12 min	0.2%	0 ml after 1 and 12 min	Suspension stability	0.02%	CIPAC MT 184.1	Acetamiprid: 97.28%	Acetamiprid: 100.17%		Deltamethrin: 98.23%	Deltamethrin: 98.31%	0.08%	Acetamiprid: 101.06%	Acetamiprid: 100.44%		Deltamethrin: 100.91%	Deltamethrin: 100.08%	0.2%	Acetamiprid: 73.97%	Acetamiprid: 100.56%				Deltamethrin: 74.46%	Deltamethrin: 100.48%	Dispersion spontaneity		CIPAC MT 160	Acetamiprid: 103.52%	Acetamiprid: 98.70%		Deltamethrin: 104.22%	Deltamethrin: 99.33%	Wet sieve test		CPAC MT 185	0.00 %	0.00 %	Surface tension		OECD 115	37.60 mN/m	-	Pourability		CIPAC MT 148	R = 1.80 %, R' = 0.19 %	R = 1.80 %, R' = 0.20 %	Particle size analysis		CIPAC MT 187	-	Average d ₁₀ = 0.407 µm Average d ₅₀ = 1.143µm Average d ₉₀ = 3.681µm Average d _{4,5} = 1.625 µm SD = 0.009 µm RSD = 0.554 %	Package stability		Crop Life International Technical Monograph No. 17	1 L HDPE	The shape and colour of the 1 litre HDPE package were stable, negligible mass change	Package cleaning effectiveness		Efficacy Guideline 305:2004	Cleaning effectiveness: Average for acetamiprid = 99.91% Average for deltamethrin = 100%	-	Active ingredient content		HPLC	Acetamiprid: 24.08% (261.29 g/l)	Acetamiprid: 24.55% (266.38 g/L)	Deltamethrin: 3.04% (32.94 g/l)	Deltamethrin: 2.96% (32.07 g/L)	Y	Study code no. BF- 55/20; J. Kupiec; January 2023, STAGE IV	
Test type		Methods	Findings																																																																																																													
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Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	-	-	-	
Wettability (KCP 2.8.1)	-	-	-	-	-	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch: CHR/20 number:	Initial preparation: 0.02%: 2 ml after 1 minute and 0 ml after 2 min. 0.08%: 0 ml after 1 minute and 0 ml after 2 min. 0.2%: 0 ml after 1 minute and 0 ml after 2 min.	Y	Study code no. BF- 55/20; E. Arévalo; January 2021	Accepted
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch: CHR/20 number:	Initial preparation: 0.08%: Deltamethrin: 100.91 % Acetamiprid: 101.06 % 0.02%: Deltamethrin: 98.23 % Acetamiprid: 97.28 % 0.2%: Deltamethrin: 74.46 % Acetamiprid: 73.97 % Accelerated storage: 0.08%: Deltamethrin: 100.75 % Acetamiprid: 101.23 % 0.02%: Deltamethrin: 98.23 % Acetamiprid: 96.66 % 0.2%: Deltamethrin: 70.28 %	Y	Study code no. BF- 55/20; E. Arévalo; 2021, PART I Study code no. BF- 55/20; E. Arévalo; January 2021, PART II	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
			<p>Acetamiprid: 70.00 %</p> <p>Low temperature storage: 0.08%: Deltamethrin: 103.99 % Acetamiprid: 96.89 %</p> <p>0.02%: Deltamethrin: 98.92 % Acetamiprid: 98.79 %</p> <p>0.2%: Deltamethrin: 77.74 % Acetamiprid: 79.46 %</p> <p>After one year storage: 0.08%: Deltamethrin: 100.26 % Acetamiprid: 100.04 %</p> <p>0.02%: Deltamethrin: 97.54 % Acetamiprid: 100.59 %</p> <p>0.2%: Deltamethrin: 100.46 % Acetamiprid: 100.64 %</p>			
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	<p>Test item: CHR/I/ADEL 280 SC</p> <p>Production date: 1.04.2020</p> <p>Expiration date: 1.04.2022</p> <p>Batch number: CHR/20</p>	<p>Initial preparation: Deltamethrin: 104.22 % Acetamiprid: 103.52 %</p> <p>Accelerated storage: Deltamethrin: 103.34% Acetamiprid: 103.04%</p> <p>After one year storage: Deltamethrin: 101.48%</p>	Y	<p>Study code no. BF- 55/20; E. Arévalo; 2021, PART I</p> <p>Study code no.</p>	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
			Acetamiprid: 102.57%		BF- 55/20; E. Arévalo; January 2021, PART II	
Dispersion stability (KCP 2.8.3.3)	-	-	-	-	-	
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	-	-	-	
Particle size distribution / nominal size range of granules (KCP 2.8.5.1. 1)	-	-	-	-	-	
Wet sieve test (KCP 2.8.5.1. 2)	CIPAC MT 185	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch: CHR/20 number:	Initial preparation: sieve size = 75 µm 0.00% Accelerated storage: sieve size = 75 µm 0.00% Low temperature storage: sieve size = 75 µm 0.00%	Y	Study code no. BF- 55/20; E. Arévalo; 2021, PART I Study code no. BF- 55/20;	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
			After one year storage: sieve size = 75 µm 0.00%		E. Arévalo; January 2021, PART II	
Dust content (KCP 2.8.5.2.1)	-	-	-	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	-	-	-	
Attrition (KCP 2.8.5.3)	-	-	-	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	-	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	-	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	-	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	-	-	-	
Flowability (KCP 2.8.7.1)	-	-	-	-	-	
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Test item: CHR/I/ADEL 280 SC	Initial preparation: The residue (R) = 1.80%; the rinsed residue (R') = 0.19%	Y	Study code no.	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
		Produc- tion date: 1.04.2020 Expira- tion date: 1.04.2022 Batch number: CHR/20	After accelerated storage: The residue (R) = 1.86%; the rinsed residue (R') = 0.19% After one year storage: The residue (R) = 1.75%; the rinsed residue (R') = 0.18%		BF- 55/20; E. Arévalo; January 2021 Study code no. BF- 55/20; E. Arévalo; July 2021, PART II, Annex No. 1	
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	-	-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	-	-	-	
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	-	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	-	-	-	
Distribution to	-	-	-	-	-	

Annex point	Method used / deviations	Test material	Findings				GL P Y/N	Reference	Acceptability / comments
seed (KCP 2.10.2)									
Other/special studies (KCP 2.11)	CropLife International Technical Monograph No. 17	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch: CHR/20 number:	Test type	Method	Findings		Y	Study code no. BF- 55/20; E. Arévalo; 2021, PART I Study code no. BF- 55/20; E. Arévalo; January 2021, PART II	Accepted
					Initial preparation	After accelerated storage			
			Package stability	CropLife International Technical Monograph No. 17	1 L HDPE	Stable, 1L HDPE			
			After one year:						
			Package stability	Crop Life International Technical Monograph No. 17	1 L HDPE	Stabe, 1 L HDPE			
	Efficacy Guideline 305:2004	Test item: CHR/I/ADEL 280 SC Production date: 1.04.2020 Expiration date: 1.04.2022 Batch: CHR/20 number:	Test type	Method	Findings		Y	Study code no. BF- 55/20; E. Arévalo; January 2021	Accepted
					Initial preparation				
			Package cleaning effectiveness	Efficacy Guideline 305: 2004	<u>Cleaning effectiveness:</u> Average for Deltamethrin: 100% Average for Acetamiprid: 99.91%				

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)

RMS comment

Based on the two-year storage stability study in HDPE packaging all the presented below rigid packaging are acceptable for this aqueous SC formulation in Poland

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

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
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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

Table 4.1-27: Packaging information

Type	CONTAINER
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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
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Material:	HDPE
size:	127±2 mm/192±2 mm/285±5 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	5000 ml
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 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.

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 ± 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 ± 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 4.1-43: 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 4.1-44: 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 4.1-45: 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 ml
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 ml±150 ml
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 ml
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 ml
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 ml
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 \pm 5 mm
Opening:	63 mm minimum \pm 5 mm
Closure:	screw cap with seal
Capacity	10000 ml \pm 150 ml
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 \pm 5 mm
Opening:	54 mm min \pm 5 mm
Closure:	screw cap with seal
Capacity	10000 ml \pm 150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-1: Packaging information

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

Table 4.1-2: Packaging information

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

Table 4.1-3: 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 4.1-4: 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 4.1-5: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	575 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: 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 4.1-7: 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 4.1-8: 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	1160 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: 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 4.1-10: 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 4.1-11: 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 4.1-12: Packaging information

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: 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 4.1-14: 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 4.1-15: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 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 4.1-16: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
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 4.1-17: 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 4.1-18: 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 4.1-19: 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 4.1-20: Packaging information

Type	Cannister
Material:	HDPE/F
size:	240 \pm 2 mm/179 \pm 2mm/375 \pm 3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	10 000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-62: Packaging information for 500 ml bottle

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

Table 4.1-63: Packaging information for 500ml bottle

Type	Description
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 4.1-64: Packaging information for 1000ml bottle

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 for 1000 ml bottle

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 for 1000 ml bottle

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 for 5000 ml container

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 for 10000 ml container

Type	Description
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 4.1-69: Packaging information for 20000 ml container

Type	Description
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 seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-24: Packaging information

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

Table 4.1-9: Packaging information for HDPE/EOH 0.1 liter bottle

Packaging information for 100 ml Bottle	
Type	BOTTLE
Material:	HDPE / EVOH
Body diameter / total height:	48,50mm +- 1 ,00mm / 95,50mm +- 1,00mm
External thread diameter:	27,3mm +- 0,15mm
Closure:	screw cap with seal
Capacity	100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

Table 4.1-10: Packaging information for HDPE/EOH 0.25 liter bottle

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.2 KCP 2.7.3 KCP 2.7.4 KCP 2.7.5 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	E. Arévalo	2021	CHR/I/ADEL 280 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature BF- 55/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., Warsaw, Poland GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 2.2.1	D. Buczkowski	2020	CHR/I/ADEL 280 SC Determination of explosive properties BW- 09/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., Warsaw, Poland GLP	N	PUH Chemirol Sp. z o.o.

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
			Unpublished		
KCP 2.1.2 KCP 2.3.1 KCP 2.3.2	P. Flasińska	2020	CHR/I/ADEL 280 SC Determination of flash point, auto-ignition temperature and oxidizing properties BC- 24/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., Warsaw, Poland GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.7.1 KCP 2.7.3 KCP 2.7.5 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.11	E. Arévalo	2021	CHR/I/ADEL 280 SC Part II: Determination of physicochemical properties of the preparation BF- 55/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., Warsaw, Poland GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 2.7.5 KCP 2.8.7.2	E. Arevalo	2021	Annex No 1 to Final Report “CHR/I/ADEL 280 SC Part II: Determination of physicochemical properties of the preparation Study code: BF-55/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., Warsaw, Poland GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 2.7.5	J. Kupiec	2023	Report CHR/I/ADEL 280 SC Stage IV: Determination of physicochemical properties of the preparation after two years of storage Study code: BF-55/20	N	PUH Chemirol Sp. z o.o.

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, 6 Annopol St., Warsaw, Poland GLP Unpublished		