

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/H/PENDIF 599.5 SC

Product name(s): Cevino Trio 599.5 SC/ Trivino 599.5 SC

Chemical active substance(s):

Penoxsulam, 37.5 g/L

Diflufenican, 250 g/L

Flufenacet, 312 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: October 2021

MS Finalisation date: 24/08/2022

Version history

When	What
February 2022	Dossier sent for evaluation
April 2022	zRMS evaluation of dRR
August 2022	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 not available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- The two-year storage stability study is ongoing and has to be provided for evaluation when available
- ~~data gap 2~~
- ~~data gap 3~~

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Innvigo Sp. z o.o.

Address: Aleje 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 Penoxsulam

Penoxsulam min. 980 g/kg

Bis-CHYMP max. 0.1 g/kg

1.2.3.2 Diflufenican

Diflufenican min. 970 g/kg

1.2.3.3 Flufenacet

Flufenacet min. 950 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: Cevino Trio 599.5 SC
Trivino 599.5SC

Company code number: CHR/H/PENDIF 599.5 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 or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Penoxsulam	37.5	33.75 – 41.25		3.07%
Diflufenican	250	235 - 265		20.04%
Flufenacet	312	296.4 – 327.6		25.51%

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

** Based on the density of the formulation = 1.2233 (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/kg)
Bis-CHYMP	0.1

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

Table 1.4-3: Information on Penoxsulam

Type	Name/Code Number	
ISO common name	Penoxsulam	-
CAS No.	219714-96-2	-
EC No.	-	-
CIPAC No.	758	-

Table 1.4-4: Information on Diflufenican

Type	Name/Code Number	
ISO common name	Diflufenican	-
CAS No.	83164-33-4	-
EC No.	-	-
CIPAC No.	462	-

Table 1.4-5: Information on Flufenacet

Type	Name/Code Number	
ISO common name	Flufenacet	FOE 5043
CAS No.	142459-58-3	-
EC No.	-	-
CIPAC No.	588	-

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)

Herbicide

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of white liquid with a specific, delicate odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of 575 °C. In aqueous solution, it has a pH value around 4.40 at 4.77 °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 *SC* formulation.

The intended concentration of use is 0.1% to 0.2%.

Study of 2 years stability is ongoing.

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/H/PENDIF 599.5 SC complies with FAO specifications.

Formulation used for tests

CHR/H/PENDIF 599.5 SC

Date of production: 01.04.2020

Expiration period: 01.04.2022

Batch No: 042020

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)	OPPTS 830.6302, 830.6303 and 830.6304	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Initial: Colour (Munsell's notation) – N9.25/ (white) Physical state – liquid Odour – specific, delicate After accelerated storage: Colour (Munsell's notation) – N 9.5/ (white) Physical state – liquid Odour – specific, delicate After 1 year storage: Colour (Munsell's notation) – N 9.5/ (white) Physical state – liquid Odour – specific, delicate	Y	M. Patrzalek, Study code: ICB/115/2020 M. Patrzalek, Study code: ICB/29/2021 M. Patrzalek, Study code: ICB/116/2020	Accepted
Explosive properties (KCP 2.2.1)	EC A.14	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	CHR/H/PENDIF 599.5 SC does not have to explosive properties.		D. Buczkowski, Study code: BW-01/21	Accepted
Oxidizing properties (KCP 2.2.2)	EC A.21	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	CHR/H/PENDIF 599.5 SC has not got the oxidizing properties	Y	P. Flasińska, Study code: BC-03/21	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
Flash point (KCP 2.3.1)	EEC A.9	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Flash point was not observed. The test flame was extinguished by vapours of the test item at temperatures 68°C.	Y	M. Patrzalek, Study code: ICB/115/2020	Accepted
Flammability (KCP 2.3.2)	EEC A.9	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Flash point was not observed. The test flame was extinguished by vapours of the test item at temperatures 68°C.	Y	M. Patrzalek, Study code: ICB/115/2020	Accepted
Self-heating (KCP 2.3.3)	EC A.15	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	CHR/H/PENDIF 599.5 SC has got auto-ignition temperature: 575C		P. Flasińska, Study code: BC-03/21	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020	Initial: pH undiluted: 4.50 After accelerated storage:	Y	M. Patrzalek, Study code: ICB/115/2020	Accepted

Annex point	Method used / deviations	Test material	Findings			GL P Y/N	Reference	Acceptability / comments
		Expiration period: 01.04.2022 Batch No: 042020	pH undiluted: 4.77 After 1 year storage: pH undiluted: 4.63				M. Patrzalek, Study code: ICB/29/2021 M. Patrzalek, Study code: ICB/116/2020	
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Initial: pH 1% (w/v) suspension – 4.43 After accelerated storage: pH 1% (w/v) suspension – 4.63 After 1 year storage: pH 1% (w/v) suspension – 4.60			Y	M. Patrzalek, Study code: ICB/115/2020 M. Patrzalek, Study code: ICB/29/2021 M. Patrzalek, Study code: ICB/116/2020	Accepted
Viscosity (KCP 2.5.1)	OECD 114	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020					E. Arevalo, Study code: BF-02/21	Accepted
			Test type	Methods	Results			
			Determination of viscosity at 20°C	OECD 114	2.5 s ⁻¹ – 1507 mPa·s 5.0 s ⁻¹ – 1007 mPa·s 10.0 s ⁻¹ – 693 mPa·s. 25.0 s ⁻¹ – 451mPa·s.			
Determination of viscosity at 40°C	OECD 114	2.5 s ⁻¹ – 1067 mPa·s 5.0 s ⁻¹ – 708 mPa·s. 10.0 s ⁻¹ – 479 mPa·s. 25.0 s ⁻¹ – 302 mPa·s.						
Surface tension	EEC A.5	CHR/H/PENDIF	0.1% (w/v) – 39.28 [mN/m]			Y	M. Patrzalek,	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments			
(KCP 2.5.2)		F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	0.2% (w/v) – 38.34 [mN/m]		Study code: ICB/115/2020				
Relative density (KCP 2.6.1)	EEC A.3	CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	1.2233 g/ml	Y	M. Patrzalek, Study code: ICB/115/2020	Accepted			
Bulk density (KCP 2.6.2)			N/R						
Storage Stability after 14 days at 54° C (KCP 2.7.1)		CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Initial: <table><tr><td>Content of penoxulam, flufenacet and diflufenican</td><td>Standard Operational Procedure SPB/199</td><td>Penoxulam – 38.75 g/L Flufenacet – 314.75 g/L Diflufenican – 254.16 g/L</td></tr></table>	Content of penoxulam, flufenacet and diflufenican	Standard Operational Procedure SPB/199	Penoxulam – 38.75 g/L Flufenacet – 314.75 g/L Diflufenican – 254.16 g/L		M. Patrzalek, Study code: ICB/115/2020 M. Patrzalek, Study code: ICB/29/2021 S. Lobstein, Study code: C1028 B. Lebek,	Accepted The HDPE bottle remained intact after storage . All the physicochemical parameter before and after storage are accepted
Content of penoxulam, flufenacet and diflufenican	Standard Operational Procedure SPB/199	Penoxulam – 38.75 g/L Flufenacet – 314.75 g/L Diflufenican – 254.16 g/L							

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments																																				
			<table><tr><th>Study</th><th>Method</th><th>Results</th></tr><tr><td>Appearance</td><td>OPPTS 830.6302, 830.6303 and 830.6304</td><td>Colour (Munsell's notation) – N9.25/ (white) Physical state – liquid Odour – specific, delicate</td></tr><tr><td>pH</td><td>CIPAC MT 75.3</td><td>1% (w/v) suspension – 4.43 Undiluted – 4.50</td></tr><tr><td>Relative density</td><td>EEC A.3</td><td>1.2233</td></tr><tr><td>Flash point</td><td>EEC A.9</td><td>Flash point was not observed. The test flame was extinguished by vapours of the test item at temperatures 68°C.</td></tr><tr><td>Suspensibility</td><td>CIPAC MT 184</td><td>0.1% (w/v) in Standard Water D (30±2°C): - penoxulam 97% - flufenacet 92% - diflufenican 93% 0.2% (w/v) in Standard Water D (30±2°C): - penoxulam 95% - flufenacet 89% - diflufenican 91%</td></tr><tr><td>Spontaneity of dispersion</td><td>CIPAC MT 160</td><td>Standard Water C (30±2°C): - penoxulam 89% - flufenacet 87% - diflufenican 88%</td></tr><tr><td>Wet sieve</td><td>CIPAC MT 185</td><td>Residue (sieve 75 µm) – 0.00%</td></tr><tr><td>Surface tension</td><td>EEC A.5</td><td>0.1% (w/v) – 39.28 [mN/m] 0.2% (w/v) – 38.34 [mN/m]</td></tr><tr><td>Persistent foaming</td><td>CIPAC MT 47.3</td><td>0.1% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL 0.2% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL</td></tr><tr><td>Low temperature stability of liquid formulations</td><td>CIPAC MT 39.3 CIPAC MT 185</td><td>After low temperature stability 0°C for 7 days – 0.05 mL sediment After 24 h in room temperature and one invert – 0.05 mL sediment Residue on the wet sieve – 0.016%</td></tr><tr><td>Pourability</td><td>CIPAC MT 148.1</td><td>Residue – 3.74%</td></tr></table>	Study	Method	Results	Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N9.25/ (white) Physical state – liquid Odour – specific, delicate	pH	CIPAC MT 75.3	1% (w/v) suspension – 4.43 Undiluted – 4.50	Relative density	EEC A.3	1.2233	Flash point	EEC A.9	Flash point was not observed. The test flame was extinguished by vapours of the test item at temperatures 68°C.	Suspensibility	CIPAC MT 184	0.1% (w/v) in Standard Water D (30±2°C): - penoxulam 97% - flufenacet 92% - diflufenican 93% 0.2% (w/v) in Standard Water D (30±2°C): - penoxulam 95% - flufenacet 89% - diflufenican 91%	Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - penoxulam 89% - flufenacet 87% - diflufenican 88%	Wet sieve	CIPAC MT 185	Residue (sieve 75 µm) – 0.00%	Surface tension	EEC A.5	0.1% (w/v) – 39.28 [mN/m] 0.2% (w/v) – 38.34 [mN/m]	Persistent foaming	CIPAC MT 47.3	0.1% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL 0.2% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL	Low temperature stability of liquid formulations	CIPAC MT 39.3 CIPAC MT 185	After low temperature stability 0°C for 7 days – 0.05 mL sediment After 24 h in room temperature and one invert – 0.05 mL sediment Residue on the wet sieve – 0.016%	Pourability	CIPAC MT 148.1	Residue – 3.74%		Study code: ICB/87/2021	
Study	Method	Results																																								
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N9.25/ (white) Physical state – liquid Odour – specific, delicate																																								
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Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments																											
			<p>After accelerated sotrage:</p> <p>Table 2: Physicochemical properties of the test item after accelerated storage test.</p> <table><tr><th>Study</th><th>Method</th><th>Results</th></tr><tr><td>Appearance</td><td>OPPTS 830.6302, 830.6303 and 830.6304</td><td>Colour (Munsell's notation) – N 9.5/ (white) Physical state – liquid Odour – specific, delicate</td></tr><tr><td>pH</td><td>CIPAC MT 75.3</td><td>1% (w/v) suspension – 4.63 Undiluted – 4.77</td></tr><tr><td>Relative density</td><td>EEC A.3</td><td>1.2234</td></tr><tr><td>Spontaneity of dispersion</td><td>CIPAC MT 160</td><td>Standard Water C (30±2°C): - penoxulam 97% - flufenacet 85% - diflufenican 95%</td></tr><tr><td>Wet sieve</td><td>CIPAC MT 185</td><td>Residue (sieve 75 µm) – 0.1%</td></tr><tr><td>Pourability</td><td>CIPAC MT 148.1</td><td>Residue – 3.04%</td></tr><tr><td>Stability of package</td><td>Standard Operational Procedure SPB/38</td><td>Change in packaging weight – 0.15 [%] Change in gross weight – 0.006 [%]</td></tr><tr><td>Content of penoxulam, flufenacet and diflufenican</td><td>Standard Operational Procedure SPB/199</td><td>Penoxulam – 37.32 g/L Flufenacet – 303.24 g/L Diflufenican – 246.79 g/L</td></tr></table> <p>Suspensibility: 0.1% (w/v) in Standard Water D (30±2°C): - penoxulam 99% - flufenacet 69% - diflufenican 95%</p>	Study	Method	Results	Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N 9.5/ (white) Physical state – liquid Odour – specific, delicate	pH	CIPAC MT 75.3	1% (w/v) suspension – 4.63 Undiluted – 4.77	Relative density	EEC A.3	1.2234	Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - penoxulam 97% - flufenacet 85% - diflufenican 95%	Wet sieve	CIPAC MT 185	Residue (sieve 75 µm) – 0.1%	Pourability	CIPAC MT 148.1	Residue – 3.04%	Stability of package	Standard Operational Procedure SPB/38	Change in packaging weight – 0.15 [%] Change in gross weight – 0.006 [%]	Content of penoxulam, flufenacet and diflufenican	Standard Operational Procedure SPB/199	Penoxulam – 37.32 g/L Flufenacet – 303.24 g/L Diflufenican – 246.79 g/L			
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Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments						
			0.2% (w/v) in Standard Water D (30±2°C): - penoxulam 99% - flufenacet 63% - diflufenican 96% Impurities before and after accelerated storage: <table><tr><th>Test</th><th>Results for un-aged test item</th><th>Results after accelerated storage stability</th></tr><tr><td>Relevant Impurity: Bis-CHYMP content</td><td>nd* (5 determinations)</td><td>nd* (3 determinations)</td></tr></table>	Test	Results for un-aged test item	Results after accelerated storage stability	Relevant Impurity: Bis-CHYMP content	nd* (5 determinations)	nd* (3 determinations)			
Test	Results for un-aged test item	Results after accelerated storage stability										
Relevant Impurity: Bis-CHYMP content	nd* (5 determinations)	nd* (3 determinations)										
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			N/R									
Minimum content after heat stability testing (KCP 2.7.3)		CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Initial: Penoxulam – 38.75 g/L Flufenacet – 314.75 g/L Diflufenican – 254.16 g/L Bis-CHYMP – not detected After accelerated storage: Penoxulam – 37.32 g/L Flufenacet – 303.24 g/L Diflufenican – 246.79 g/L Bis-CHYMP – not detected After 1 year storage: Penoxulam – 37.25 g/L Flufenacet – 304.47 g/L		M. Patrzalek, Study code: ICB/115/2020 M. Patrzalek, Study code: ICB/29/2021 M. Patrzalek, Study code: ICB/116/2020 S. Lobstein,	Accepted						

Annex point	Method used / deviations	Test material	Findings			GL P Y/N	Reference	Acceptability / comments
			Diflufenican – 248.78 g/L Bis-CHYMP – not detected				Study code: C1028 S. Lobstein, Study code: C1029	
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 CIPAC MT 185 CIPAC MT 184	CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	<div>Low temperature stability of liquid formulations</div>	<div>CIPAC MT 39.3 CIPAC MT 185</div>	<div>After low temperature stability 0°C for 7 days – 0.05 mL sediment After 24 h in room temperature and one invert – 0.05 mL sediment Residue on the wet sieve – 0.016%</div>	Y	M. Patrzalek, Study code: ICB/115/2020	Accepted
			Study	Method	Results			
			Suspensibility	CIPAC MT 184	<div>0.1% (w/v) in Standard Water D (30±2°C): - penoxulam 96% - flufenacet 91% - diflufenican 92%</div> <div>0.2% (w/v) in Standard Water D (30±2°C): - penoxulam 96% - flufenacet 90% - diflufenican 92%</div>			
Ambient temperature shelf life (KCP 2.7.5)		CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Initial: <div><div>Content of penoxulam, flufenacet and diflufenican</div><div>Standard Operational Procedure SPB/199</div><div>Penoxulam – 38.75 g/L Flufenacet – 314.75 g/L Diflufenican – 254.16 g/L</div></div>				M. Patrzalek, Study code: ICB/115/2020 M. Patrzalek, Study code: ICB/116/2020 S.Lobstein,	Ongoing Applicant has provided the year storage stability study in HDPE at ambient temperature up to now. The study meets the

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments																																				
			<table><tr><th>Study</th><th>Method</th><th>Results</th></tr><tr><td>Appearance</td><td>OPPTS 830.6302, 830.6303 and 830.6304</td><td>Colour (Munsell's notation) – N9.25/ (white) Physical state – liquid Odour – specific, delicate</td></tr><tr><td>pH</td><td>CIPAC MT 75.3</td><td>1% (w/v) suspension – 4.43 Undiluted – 4.50</td></tr><tr><td>Relative density</td><td>EEC A.3</td><td>1.2233</td></tr><tr><td>Flash point</td><td>EEC A.9</td><td>Flash point was not observed. The test flame was extinguished by vapours of the test item at temperatures 68°C.</td></tr><tr><td>Suspensibility</td><td>CIPAC MT 184</td><td>0.1% (w/v) in Standard Water D (30±2°C): - penoxulam 97% - flufenacet 92% - diflufenican 93% 0.2% (w/v) in Standard Water D (30±2°C): - penoxulam 95% - flufenacet 89% - diflufenican 91%</td></tr><tr><td>Spontaneity of dispersion</td><td>CIPAC MT 160</td><td>Standard Water C (30±2°C): - penoxulam 89% - flufenacet 87% - diflufenican 88%</td></tr><tr><td>Wet sieve</td><td>CIPAC MT 185</td><td>Residue (sieve 75 µm) – 0.00%</td></tr><tr><td>Surface tension</td><td>EEC A.5</td><td>0.1% (w/v) – 39.28 [mN/m] 0.2% (w/v) – 38.34 [mN/m]</td></tr><tr><td>Persistent foaming</td><td>CIPAC MT 47.3</td><td>0.1% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL 0.2% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL</td></tr><tr><td>Low temperature stability of liquid formulations</td><td>CIPAC MT 39.3 CIPAC MT 185</td><td>After low temperature stability 0°C for 7 days – 0.05 mL sediment After 24 h in room temperature and one invert – 0.05 mL sediment Residue on the wet sieve – 0.016%</td></tr><tr><td>Pourability</td><td>CIPAC MT 148.1</td><td>Residue – 3.74%</td></tr></table>	Study	Method	Results	Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N9.25/ (white) Physical state – liquid Odour – specific, delicate	pH	CIPAC MT 75.3	1% (w/v) suspension – 4.43 Undiluted – 4.50	Relative density	EEC A.3	1.2233	Flash point	EEC A.9	Flash point was not observed. The test flame was extinguished by vapours of the test item at temperatures 68°C.	Suspensibility	CIPAC MT 184	0.1% (w/v) in Standard Water D (30±2°C): - penoxulam 97% - flufenacet 92% - diflufenican 93% 0.2% (w/v) in Standard Water D (30±2°C): - penoxulam 95% - flufenacet 89% - diflufenican 91%	Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - penoxulam 89% - flufenacet 87% - diflufenican 88%	Wet sieve	CIPAC MT 185	Residue (sieve 75 µm) – 0.00%	Surface tension	EEC A.5	0.1% (w/v) – 39.28 [mN/m] 0.2% (w/v) – 38.34 [mN/m]	Persistent foaming	CIPAC MT 47.3	0.1% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL 0.2% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL	Low temperature stability of liquid formulations	CIPAC MT 39.3 CIPAC MT 185	After low temperature stability 0°C for 7 days – 0.05 mL sediment After 24 h in room temperature and one invert – 0.05 mL sediment Residue on the wet sieve – 0.016%	Pourability	CIPAC MT 148.1	Residue – 3.74%		Study code: C1029	requirements. Conditional shelf-life of two year can be granted for the PPP. Nevetheles, the two-year study has to be given for evaluation in Poland when available.
Study	Method	Results																																								
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N9.25/ (white) Physical state – liquid Odour – specific, delicate																																								
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Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments																											
			<p>After one year:</p> <table><tr><th>Study</th><th>Method</th><th>Results</th></tr><tr><td>Appearance</td><td>OPPTS 830.6302, 830.6303 and 830.6304</td><td>Colour (Munsell's notation) – N 9.5/ (white) Physical state – liquid Odour – specific, delicate</td></tr><tr><td>pH</td><td>CIPAC MT 75.3</td><td>1% (w/v) suspension – 4.60 Undiluted – 4.63</td></tr><tr><td>Suspensibility</td><td>CIPAC MT 184</td><td>0.1% (w/v) in Standard Water D (30±2°C): - penoxulam 96% - flufenacet 92% - diflufenican 92% 0.2% (w/v) in Standard Water D (30±2°C): - penoxulam 95% - flufenacet 88% - diflufenican 90%</td></tr><tr><td>Spontaneity of dispersion</td><td>CIPAC MT 160</td><td>Standard Water C (30±2°C): - penoxulam 99% - flufenacet 97% - diflufenican 98%</td></tr><tr><td>Wet sieve</td><td>CIPAC MT 185</td><td>Residue (sieve 75 µm) – 0.00%</td></tr><tr><td>Pourability</td><td>CIPAC MT 148.1</td><td>Residue – 3.90%</td></tr><tr><td>Stability of package</td><td>Standard Operational Procedure SPB/38</td><td>Change in packaging weight – 0.22 [%] Change in gross weight – 0.002 [%]</td></tr><tr><td>Content of penoxulam, flufenacet and diflufenican</td><td>Standard Operational Procedure SPB/199</td><td>Penoxulam – 37.25 g/L Flufenacet – 304.47 g/L Diflufenican – 248.78 g/L</td></tr></table> <p>Impurities before and after 1 years storage:</p>	Study	Method	Results	Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N 9.5/ (white) Physical state – liquid Odour – specific, delicate	pH	CIPAC MT 75.3	1% (w/v) suspension – 4.60 Undiluted – 4.63	Suspensibility	CIPAC MT 184	0.1% (w/v) in Standard Water D (30±2°C): - penoxulam 96% - flufenacet 92% - diflufenican 92% 0.2% (w/v) in Standard Water D (30±2°C): - penoxulam 95% - flufenacet 88% - diflufenican 90%	Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - penoxulam 99% - flufenacet 97% - diflufenican 98%	Wet sieve	CIPAC MT 185	Residue (sieve 75 µm) – 0.00%	Pourability	CIPAC MT 148.1	Residue – 3.90%	Stability of package	Standard Operational Procedure SPB/38	Change in packaging weight – 0.22 [%] Change in gross weight – 0.002 [%]	Content of penoxulam, flufenacet and diflufenican	Standard Operational Procedure SPB/199	Penoxulam – 37.25 g/L Flufenacet – 304.47 g/L Diflufenican – 248.78 g/L			
Study	Method	Results																															
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Annex point	Method used / deviations	Test material	Findings			GL P Y/N	Reference	Acceptability / comments
			Test	Timing	Results			
			Relevant Impurity: Bis-CHYMP content	T ₀	nd* (5 determinations)			
				T ₁ year	nd* (5 determinations)			
Shelf life in months (if less than 2 years) (KCP 2.7.6)								
Wettability (KCP 2.8.1)			N/R					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Initial: 0.1% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL 0.2% (w/v): -after 1 minute – 0 mL - after 12 minutes – 0 mL			Y	M. Patrzalek, Study code: ICB/115/2020	Accepted
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Initial: 0.1% (w/v) in Standard Water D (30±2°C): - penoxulam 97% - flufenacet 92% - diflufenican 93% 0.2% (w/v) in Standard Water D (30±2°C): - penoxulam 95% - flufenacet 89% - diflufenican 91%			Y	M. Patrzalek, Study code: ICB/115/2020 M. Patrzalek, Study code: ICB/116/2020	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
			<p>After accelerated storage:</p> <p>0.1% (w/v) in Standard Water D (30±2°C):</p> <ul style="list-style-type: none"> - penoxulam 99% - flufenacet 69% - diflufenican 95% <p>0.2% (w/v) in Standard Water D (30±2°C):</p> <ul style="list-style-type: none"> - penoxulam 99% - flufenacet 63% - diflufenican 96% <p>After 1 year storage:</p> <p>0.1% (w/v) in Standard Water D (30±2°C):</p> <ul style="list-style-type: none"> - penoxulam 96% - flufenacet 92% - diflufenican 92% <p>0.2% (w/v) in Standard Water D (30±2°C):</p> <ul style="list-style-type: none"> - penoxulam 95% - flufenacet 88% - diflufenican 90% 		B. Lebek, Study code: ICB/87/2021	
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	<p>Initial:</p> <p>Standard Water C (30±2°C):</p> <ul style="list-style-type: none"> - penoxulam 89% - flufenacet 87% - diflufenican 88% <p>After accelerated storage:</p> <p>Standard Water C (30±2°C):</p> <ul style="list-style-type: none"> - penoxulam 97% - flufenacet 85% - diflufenican 95% <p>After 1 year storage:</p> <p>Standard Water C (30±2°C):</p> <ul style="list-style-type: none"> - penoxulam 99% 	Y	<p>M. Patrzalek, Study code: ICB/115/2020</p> <p>M. Patrzalek, Study code: ICB/29/2021</p> <p>M. Patrzalek, Study code: ICB/116/2020</p>	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
			- flufenacet 97% - diflufenican 98%			
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	CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Initial: Residue (sieve 75 µm) – 0.00% After accelerated storage: Residue (sieve 75 µm) – 0.1% After 1 year storage: Residue (sieve 75 µm) – 0.00%	Y	M. Patrzalek, Study code: ICB/115/2020 M. Patrzalek, Study code: ICB/29/2021 M. Patrzalek, Study code: ICB/116/2020	Accepted
Dust content						

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
(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	CHR/H/PENDI F 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Initial: Residue – 3.74% After accelerated storage: Residue – 3.04% After 1 year storage: Residue – 3.90%		M. Patrzalek, Study code: ICB/115/2020 M. Patrzalek, Study code: ICB/29/2021	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
					M. Patrzalek, Study code: ICB/116/2020	
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 seed (KCP 2.10.2)						
Other/special studies (KCP 2.11)	Efficacy Guideline 305	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Effectiveness of cleaning: Single rinse procedure: >99.84 [%] penoxulam 99.85 [%] flufenacet 99.92 [%] diflufenican - Double rinse procedure: >99.84 [%] penoxulam	Y	M. Patrzalek, Study code: ICB/115/2020	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
			99.91 [%] flufenacet 99.95 [%] diflufenican - Triple rinse procedure: >99.84 [%] penoxulam 99.91 [%] flufenacet 99.94 [%] diflufenican			
	Standard Operational Procedure SPB/38	CHR/H/PENDIF 599.5 SC Date of production: 01.04.2020 Expiration period: 01.04.2022 Batch No: 042020	Stability of package: After accelerated storage: Change in packaging weight – 0.15 [%] Change in gross weight – 0.006 [%] After 1 year storage: Change in packaging weight – 0.22 [%] Change in gross weight – 0.002 [%]	Y	M. Patrzalek, Study code: ICB/29/2021 M. Patrzalek, Study code: ICB/116/2020	Accepted

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 conclusion:

Based on the accelerated and the year storage stability studies, these packaging can be accepted for the PPP.

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
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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

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 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

Table 4.1-33:: Packaging information

Type	Description
Material:	HDPE
Size:	375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal

Type	Description
Capacity	11220±50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34:: Packaging information

Type	Description
Material:	HDPE
Size:	312 mm± 5 mm/225mm± 5 mm/185mm ± 5 mm
Opening:	40.8 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-31: Packaging information for 10L container

Type	Description
Material:	HDPE
Size:	375 mm± 5 mm/230± 5 mm/165 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35:: Packaging information

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

Table 4.1-36:: Packaging information

Type	Description
Material:	HDPE
Size:	192±3 mm/228±7/313±7 mm
Opening:	52 mm ± 2 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-37:: Packaging information

Type	Description
Material:	HDPE
Size:	185±2 mm/225±2/312±3 mm
Opening:	40.8 mm ± 0.3 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-38:: Packaging information

Type	Description
Material:	HDPE
Size:	443mm/288mm/230mm
Opening:	44mm (internal) 60mm (external)
Closure:	screw cap with seal
Capacity	22000ml ± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-39:: Packaging information

Type	Description
Material:	HDPE
Size:	376.3±3 mm/295±3mm/246±3mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal

Type	Description
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-40:: Packaging information

Type	Description
Material:	HDPE
Size:	378±5 mm/288±5/258±5 mm
Opening:	53.7±1.5 mm
Closure:	screw cap with seal
Capacity	22000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-41:: Packaging information

Type	Description
Material:	HDPE
Size:	376±8 mm/257,5±5/376±8 mm
Opening:	52 mm± 3
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-42:: Packaging information

Type	Description
Material:	HDPE
Size:	257.5±6 mm/292±8/376±8 mm ± 5 mm
Opening:	52 mm ± 2 mm
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-43:: Packaging information

Type	Description
Material:	HDPE
Size:	90000mm/59000mm ± 2 mm
Opening:	45mm ± 2 mm

Type	Description
Closure:	screw cap with seal
Capacity	200 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 4.1-44:: Packaging information

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	coextruded
UN/ADR	compliant

Table 4.1-45:: Packaging information

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	coextruded
UN/ADR	compliant

Table 4.1-46:: Packaging information

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 4.1-47:: Packaging information

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

Table 4.1-48:: Packaging information

Packaging information	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	74 \pm 1 mm/177 \pm 1 mm/
Opening:	41.7 \pm 0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-49:: Packaging information

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	coextruded
UN/ADR	compliant

Table 4.1-50:: Packaging information

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 4.1-51:: Packaging information

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

Table 4.1-52:: Packaging information

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	coextruded
UN/ADR	compliant

Table 4.1-53:: Packaging information

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	coextruded

UN/ADR	compliant
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Table 4.1-54:: Packaging information

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	coextruded
UN/ADR	compliant

Table 4.1-55:: Packaging information

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	coextruded
UN/ADR	compliant

Table 4.1-56:: Packaging information

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	coextruded
UN/ADR	compliant

Table 4.1-57:: Packaging information

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	coextruded
UN/ADR	compliant

Table 4.1-58:: Packaging information

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	coextruded
UN/ADR	compliant

Table 4.1-59:: Packaging information

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 ml±150 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-60:: Packaging information

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 ml±150 ml

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

Table 4.1-61:: Packaging information

Type	BOTTLE
Material:	HDPE/F
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 4.1-62:: Packaging information

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

Table 4.1-63:: Packaging information

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

Table 4.1-64:: 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 4.1-65:: 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 4.1-66:: 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 4.1-67:: 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 4.1-68:: 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 4.1-69:: 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 4.1-70:: 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 4.1-71:: 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 4.1-72:: 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 4.1-73:: 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 4.1-74:: 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 4.1-75:: Packaging information

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

Table 4.1-76:: 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
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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Table 4.1-77:: 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 4.1-78:: 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 4.1-79:: 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 4.1-80:: 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 4.1-81:: Packaging information

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

Table 4.1-82:: Packaging information

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

Table 4.1-83:: Packaging information

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

Table 4.1-84:: Packaging information

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

UN/ADR	compliant
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Table 4.1-85:: Packaging information

Packaging information	
Type	BOTTLE
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 4.1-86:: Packaging information

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

Table 4.1-87:: Packaging information

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

Table 4.1-88:: Packaging information

Packaging information	
Type	BOTTLE
Material:	HDPE/EvOH
size:	242 \pm 1.5 mm/88.5 \pm 1mm

Opening:	49.5 mm \pm 0.3 mm
Closure:	screw cap with cutter
Capacity	1200 \pm 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-89:: Packaging information

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

Table 4.1-90:: Packaging information

Packaging information	
Type	CANNISTER
Material:	HDPE/EvOH
size:	142 mm \pm 1.5 mm/193 mm \pm 2 mm/307mm \pm 3 mm
Opening:	63.3 mm \pm 0.3 mm
Closure:	screw cap with cutter
Capacity	5650 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-91:: Packaging information

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

Table 4.1-92:: Packaging information

Packaging information	
Type	CONTAINER

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.3.1 KCP 2.3.2 KCP 2.4.1 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.7.5 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	M. Patrzalek	2021	Determination of physicochemical properties Study code: ICB/115/2020 ICB Pharma, Lema 10, Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	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	M. Patrzalek	2021	Determination of physicochemical properties after accelerated storage test Study code: ICB/29/2021 ICB Pharma, Lema 10, Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	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
2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11					
KCP 2.1 KCP 2.4.1 KCP 2.4.2 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 2.8.7.2 KCP 2.11	M. Patrzalek	2021	Determination of physicochemical properties after shelf-life test Study code: ICB/116/2020 ICB Pharma, Lema 10, Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.7.1 KCP 2.8.3.1	B. Lebek	2021	Determination of physicochemical properties after shelf-life test Study code: ICB/87/2021 ICB Pharma, Lema 10, Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.7.1 KCP 2.7.3	S. Lobstaine	2021	Method validation and determination of a relevant impurity before and after and accelerated storage procedure for 14 days at 54°C on one batch of CHR/H/PENDIF 599.5 SC Study code: C1028 ANADIAG, 16 rue Ampere, 67500 HAGUENAU, FRANCE GLP Unpublished	N	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
KCP 2.7.3 KCP 2.7.5	S. Lobstaine	2021	Determination of a relevant impurity in one batch of CHR/H/PENDIF 599.5 SC after 1 year of storage Study code: C1029 ANADIAG, 16 rue Ampere, 67500 HAGUENAU, FRANCE GLP Unpublished	N	Chemirol sp. z o.o.
KCP 2.2.1	D. Buczkowski	2021	CHR/H/PENDIF 599.5 SC Determination of explosice properties Study code: BW-01/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 2.5.1	E. Arevalo	2021	CHR/H/PENDIF 599.5 SC Viscosity determination Study code: BF-02/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland GLP Unpublished	N	Chemirol sp. z o.o.
KCP 2.2.2 KCP 2.3.3	P. Flasińska	2021	CHR/H/PENDIF 599.5 SC Study code: BC-03/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland GLP Unpublished	N	Chemirol Sp. z o.o.

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