

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/F/PROTAZO 375 SC

Product name(s): CLARO 375 SC, KAJMAN 375 SC

Chemical active substance(s):

Prothioconazole, 175 g/L

Azoxystrobin, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: May 2020

MS Finalisation date: 28/04/2022

Version history

When	What
May 2021	Dossier sent for evaluation
December 2021	Applicant updated data on the zRMS request
January 2022	zRMS finalised evaluation
April 2022	Final version prepared by zRMS after Commenting period

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Evaluator 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**

- ~~data gap 1~~
- ~~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 Jerozolismkie 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 Prothioconazole

Prothioconazole	min. 970 g/kg
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Toluene	max. 5 g/kg
Prothioconazole-desthio (2-(1-chlorocyclopropyl)- (2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2- ol)	max. 0.5 g/kg

1.2.3.2 Azoxystrobin

Azoxystrobin	min. 930 g/kg
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Toluene	max. 2 g/kg
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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: CLARO 375 SC
KAJMAN 375 SC

Company code number: CHR/F/PROTAZO 375 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)
Prothioconazole	175	235-265	178	15.87%
Azoxystrobin	200	188-212	204.5	18.24%

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

** Based on the density of the formulation = 1.121 (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Toluene	5 g/kg
Prothioconazole-desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol)	0.5 g/kg

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

Table 1.4-3: Information on Prothioconazole

Type	Name/Code Number
ISO common name	Prothioconazole
CAS No.	178928-70-6
EC No.	-
CIPAC No.	745

Table 1.4-4: Information on Azoxystrobin

Type	Name/Code Number
ISO common name	Azoxystrobin
CAS No.	131860-33-8
EC No.	-
CIPAC No.	571

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: Suspensible Concentration

[Code: SC]

1.6 Function (KCP 1.6)

Fungicide

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 creamy liquid with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable..In aqueous solution, it has a pH value around 7.2 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 1~~ **2** years at ambient temperature when stored in *HDPE*. Its technical characteristics are acceptable for a *SC* formulation. The intended concentration of use is ~~0.0937% to 0.375%~~ **0.25 -0.50%** v/v per an application.

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

No Classification is necessary

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not required

Compliance with FAO specifications:

The product CHR/F/PROTAZO 375 SC complies with FAO specifications.

Formulation used for tests

Protiokonazol + Azoxystrobin (175 + 200) SC
Batch No.: 03
Prod. Date: 13.06.2019
Expiry date: 13.06.2021

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
Colour and physical state (KCP 2.1)	OPPTS 830.6302, 830.6303 and 830.6304 guidelines.	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	<div>Initial preparation:</div> <table><tr><td>Appearance</td><td>OPPTS 830.6302, 830.6303 and 830.6304</td><td>Colour (Munsell's notation) – N9.25 (white creamy) Physical state – liquid Odour - specific</td></tr></table> <div>After accelerated storage:</div> <table><tr><td>Appearance</td><td>OPPTS 830.6302, 830.6303 and 830.6304</td><td>Colour (Munsell's notation)–N9.25 (white creamy) Physical state – liquid Odour - specific</td></tr></table>	Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N9.25 (white creamy) Physical state – liquid Odour - specific	Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation)–N9.25 (white creamy) Physical state – liquid Odour - specific	Y	I. Knapik, Study code: ICB/93/2019	Accepted
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N9.25 (white creamy) Physical state – liquid Odour - specific										
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation)–N9.25 (white creamy) Physical state – liquid Odour - specific										
Explosive properties (KCP 2.2.1)	EEC A.14	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Protiokonazol + Azoxystrobina (175+200) SC does not have explosive properties according to the criteria of EEC a.14 method.	Y	P. Śliwa, Study code: BW-07/19	Accepted						
Oxidizing properties (KCP 2.2.2)	EEC A.21	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Protiokonazol + Azoxystrobina (175+200) SC has not got the oxidixing propeties according to A.21 method	Y	P. Flasińska, Study code: BC-19/19	Accepted						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flash point (KCP 2.3.1)	EEC A.9	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Protiokonazol + Azoxystrobin (175+200) SC does not have explosive properties according to the criteria of EEC a.14 method.	Y	P. Śliwa, Study code: BW-07/19	Accepted
Flammability (KCP 2.3.2)		Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Protiokonazol + Azoxystrobin (175+200) SC has not got the auto-ignition temperature up to 650 °C according to A.15 method.	Y	P. Flasińska, Study code: BC-19/19	Accepted
Self-heating (KCP 2.3.3)		Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Protiokonazol + Azoxystrobin (175+200) SC has not got the auto-ignition temperature up to 650 °C according to A.15 method.	Y	P. Flasińska, Study code: BC-19/19	Accepted
Acidity or alkalinity and pH	-	-	-	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
(KCP 2.4.1)															
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	<p>pH in initial preparation:</p> <table><tr><td>pH</td><td>CIPAC MT 75.3</td><td>1% (w/v) suspension – 7.23 Undiluted – 7.56</td></tr></table> <p>pH after accelerate storage:</p> <table><tr><td>pH</td><td>CIPAC MT 75.3</td><td>1% (w/v) suspension – 7.35 Undiluted – 7.23</td></tr></table>	pH	CIPAC MT 75.3	1% (w/v) suspension – 7.23 Undiluted – 7.56	pH	CIPAC MT 75.3	1% (w/v) suspension – 7.35 Undiluted – 7.23	Y	I. Knapik, Study code: ICB/93/2019	Accepted			
pH	CIPAC MT 75.3	1% (w/v) suspension – 7.23 Undiluted – 7.56													
pH	CIPAC MT 75.3	1% (w/v) suspension – 7.35 Undiluted – 7.23													
Viscosity (KCP 2.5.1)	OECD 114		<p>Initial preparation:</p> <table><tr><th>Test type</th><th>Methods</th><th>Results</th></tr><tr><td>Determination of viscosity at 20°C</td><td>OECD 114</td><td>5 s⁻¹ – 420 mPa·s 10 s⁻¹ – 222 mPa·s 25 s⁻¹ – 157 mPa·s. 50 s⁻¹ – 105 mPa·s.</td></tr><tr><td>Determination of viscosity at 40°C</td><td>OECD 114</td><td>5 s⁻¹ – 322 mPa·s 10 s⁻¹ – 212 mPa·s. 25 s⁻¹ – 122 mPa·s. 50 s⁻¹ – 81 mPa·s.</td></tr></table>	Test type	Methods	Results	Determination of viscosity at 20°C	OECD 114	5 s ⁻¹ – 420 mPa·s 10 s ⁻¹ – 222 mPa·s 25 s ⁻¹ – 157 mPa·s. 50 s ⁻¹ – 105 mPa·s.	Determination of viscosity at 40°C	OECD 114	5 s ⁻¹ – 322 mPa·s 10 s ⁻¹ – 212 mPa·s. 25 s ⁻¹ – 122 mPa·s. 50 s ⁻¹ – 81 mPa·s.	Y	E. Arevalo, Study code: BF-32/19	Accepted
Test type	Methods	Results													
Determination of viscosity at 20°C	OECD 114	5 s ⁻¹ – 420 mPa·s 10 s ⁻¹ – 222 mPa·s 25 s ⁻¹ – 157 mPa·s. 50 s ⁻¹ – 105 mPa·s.													
Determination of viscosity at 40°C	OECD 114	5 s ⁻¹ – 322 mPa·s 10 s ⁻¹ – 212 mPa·s. 25 s ⁻¹ – 122 mPa·s. 50 s ⁻¹ – 81 mPa·s.													
Surface tension (KCP 2.5.2)	EEC A.5	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019	<p>Surface tension for initial preprataion:</p> <table><tr><td>Surface tension</td><td>EEC A.5</td><td>0.0937% (w/v) – 37.85 [mN/m] 0.375% (w/v) – 32.70 [mN/m]</td></tr></table> <p>Surface tension for concentration 0.2%: 31.89 [mN/m]</p>	Surface tension	EEC A.5	0.0937% (w/v) – 37.85 [mN/m] 0.375% (w/v) – 32.70 [mN/m]	Y	I. Knapik, Study code: ICB/93/2019	Accepted						
Surface tension	EEC A.5	0.0937% (w/v) – 37.85 [mN/m] 0.375% (w/v) – 32.70 [mN/m]													

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments															
		Expiry date: 13.06.2021																					
Relative density (KCP 2.6.1)	CIPAC 75.3	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Relative density	EEC A.3	1.1210	Y	I. Knapik, Study code: ICB/93/2019	Accepted															
Bulk density (KCP 2.6.2)	-	-	-			-	-																
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	<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 creamy) Physical state – liquid Odour - specific</td></tr><tr><td>pH</td><td>CIPAC MT 75.3</td><td>1% (w/v) suspension – 7.35 Undiluted – 7.23</td></tr><tr><td>Relative density</td><td>EEC A.3</td><td>1.1230</td></tr><tr><td>Suspensibility</td><td>CIPAC MT 184</td><td>0.0937% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): -azoxystrobin 98%</td></tr></table>			Study	Method	Results	Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation)-N9.25 (white creamy) Physical state – liquid Odour - specific	pH	CIPAC MT 75.3	1% (w/v) suspension – 7.35 Undiluted – 7.23	Relative density	EEC A.3	1.1230	Suspensibility	CIPAC MT 184	0.0937% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): -azoxystrobin 98%	Y	I. Knapik, Study code: ICB/93/2019, M. Wołoszynowska, Study code: BA-19/19	Accepted This story was done using HDPE bottle. All initial physicochemical parameter sare shown in the Table 2-2 and Table 2-3 below. According to GAP table the highest concentration is 0.5% v/v per each application. So,
Study	Method	Results																					
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation)-N9.25 (white creamy) Physical state – liquid Odour - specific																					
pH	CIPAC MT 75.3	1% (w/v) suspension – 7.35 Undiluted – 7.23																					
Relative density	EEC A.3	1.1230																					
Suspensibility	CIPAC MT 184	0.0937% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): -azoxystrobin 98%																					

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments																								
			<table><tr><td></td><td></td><td>- prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97%</td></tr><tr><td>Wet sieve</td><td>CIPAC MT 185</td><td>Residue (sieve 75 µm)– 0%</td></tr><tr><td>Spontaneity of dispersion</td><td>CIPAC MT 160</td><td>Standard Water C (30±2°C): -azoxystrobin 99% - prothioconazole 99%</td></tr><tr><td>Pourability</td><td>CIPAC MT 148.1</td><td>Residue - 1.53%</td></tr><tr><td>Stability of package</td><td>Standard Operational Procedure SPB/38</td><td>Change in packaging weight – 0.25 [%] Change in gross weight – 0.026[%]</td></tr><tr><td>Content of azoxystrobin and prothioconazole</td><td>Standard Operational Procedure SPB/139</td><td>Azoxystrobin – 204.61 g/L Prothioconazole - 180.96 g/L</td></tr><tr><td>Content of Z-azoxystrobin as impurity</td><td>Standard Operational Procedure SPB/144</td><td>Z-azoxystrobin - <1.759 µg/mL (<0.35 g/kg)</td></tr><tr><td>Content of toluene as impurity</td><td>Standard Operational Procedure SPB/134</td><td>Toluene - <1.16 µg/mL (<0.13 g/kg)</td></tr></table>			- prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97%	Wet sieve	CIPAC MT 185	Residue (sieve 75 µm)– 0%	Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): -azoxystrobin 99% - prothioconazole 99%	Pourability	CIPAC MT 148.1	Residue - 1.53%	Stability of package	Standard Operational Procedure SPB/38	Change in packaging weight – 0.25 [%] Change in gross weight – 0.026[%]	Content of azoxystrobin and prothioconazole	Standard Operational Procedure SPB/139	Azoxystrobin – 204.61 g/L Prothioconazole - 180.96 g/L	Content of Z-azoxystrobin as impurity	Standard Operational Procedure SPB/144	Z-azoxystrobin - <1.759 µg/mL (<0.35 g/kg)	Content of toluene as impurity	Standard Operational Procedure SPB/134	Toluene - <1.16 µg/mL (<0.13 g/kg)					the range above 0.375% w/v is uncovered. Nevertheless, it covers the highest Polish Gap anyway. So, each memberstate should reconsider possibility of thetesting the Parameter in post registration
		- prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97%																														
Wet sieve	CIPAC MT 185	Residue (sieve 75 µm)– 0%																														
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Pourability	CIPAC MT 148.1	Residue - 1.53%																														
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Content of toluene as impurity	Standard Operational Procedure SPB/134	Toluene - <1.16 µg/mL (<0.13 g/kg)																														
			Content of prothioconazole-desthio: 0.000164% after accelerated storage - 0.000148 ± 0.00003%,																													
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	-			-	-																									

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)		Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	After accelerated storage:			Y	I. Knapik, Study code: ICB/93/2019, M. Wołoszynowska, Study code: BA-19/19	Accepted
			Content of azoxystrobin and prothioconazole	Standard Operational Procedure SPB/139	Azoxystrobin – 204.61 g/L Prothioconazole – 180.96 g/L			
			Content of Z-azoxystrobin as impurity	Standard Operational Procedure SPB/144	Z-azoxystrobin - <1.759 µg/mL (<0.35 g/kg)			
			Content of toluene as impurity	Standard Operational Procedure SPB/134	Toluene - <1.16 µg/mL (<0.13 g/kg)			
			Content of prothioconazole-desthio: 0.000164%					
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	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 solid sediment at the bottom. After 24 h in room temperature and one invert– 0.05 mL solid sediment at the bottom. Residue on the wet sieve – 0%	Y	I. Knapik, Study code: ICB/93/2019	Accepted
Ambient temperature shelf life (KCP 2.7.5)	GIFAP	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	The two-year storage stability study was provided by applicant. For full details please refer to the Table 2-2 and Table 2-4 below.			Y	I. Knapik, Study code: ICB/93/2019, I. Knapik, Study code: ICB/94/2019 Wołoszańska BA-09/21	Accepted The two-year storage stability study in the HDPE bottle was accepted. All physicochemical parameters are accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments			
						Suspensibility at 0.5% v/v was tested after two-year of storage only. Being pragmatic RMS accepted lack of initial suspensibility at 0.5% v/v Summarizing, The two-year shelf life can be granted for the PPP.			
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	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Initial preparation: <table><tr><td>Persistent foam</td><td>CIPAC MT 47.3</td><td>0.0937% (w/v): -after 1 minute – 2 mL - after 12 minutes – 0 mL 0.375% (w/v): -after 1 minute – 4 mL - after 12 minutes – 0 mL</td></tr></table>	Persistent foam	CIPAC MT 47.3	0.0937% (w/v): -after 1 minute – 2 mL - after 12 minutes – 0 mL 0.375% (w/v): -after 1 minute – 4 mL - after 12 minutes – 0 mL	Y	I. Knapik, Study code: ICB/93/2019	Accepted It meets the Polish requirements. Yet , the highest GAP level is not tested (0.5% v/v). Each memberstae should
Persistent foam	CIPAC MT 47.3	0.0937% (w/v): -after 1 minute – 2 mL - after 12 minutes – 0 mL 0.375% (w/v): -after 1 minute – 4 mL - after 12 minutes – 0 mL							

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
						reconsider if it may be tested in post registration						
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	<div>Initial preparation:</div> <table><tr><td>Suspensibility</td><td>CIPAC MT 184</td><td>0.0937% (w/v) in Standard Water D (30±2°C): - azoxystrobin 98% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): - azoxystrobin 98% - prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): - azoxystrobin 99% - prothioconazole 97%</td></tr></table> <div>After accelerated storage:</div> <table><tr><td>Suspensibility</td><td>CIPAC MT 184</td><td>0.0937% (w/v) in Standard Water D (30±2°C): - azoxystrobin 99% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): - azoxystrobin 98% - prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): - azoxystrobin 99% - prothioconazole 97%</td></tr></table>	Suspensibility	CIPAC MT 184	0.0937% (w/v) in Standard Water D (30±2°C): - azoxystrobin 98% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): - azoxystrobin 98% - prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): - azoxystrobin 99% - prothioconazole 97%	Suspensibility	CIPAC MT 184	0.0937% (w/v) in Standard Water D (30±2°C): - azoxystrobin 99% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): - azoxystrobin 98% - prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): - azoxystrobin 99% - prothioconazole 97%	Y	I. Knapik, Study code: ICB/93/2019	Accepted
Suspensibility	CIPAC MT 184	0.0937% (w/v) in Standard Water D (30±2°C): - azoxystrobin 98% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): - azoxystrobin 98% - prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): - azoxystrobin 99% - prothioconazole 97%										
Suspensibility	CIPAC MT 184	0.0937% (w/v) in Standard Water D (30±2°C): - azoxystrobin 99% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): - azoxystrobin 98% - prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): - azoxystrobin 99% - prothioconazole 97%										
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	<div>Initial preparation:</div> <table><tr><td>Spontaneity of dispersion</td><td>CIPAC MT 160</td><td>Standard Water C (30±2°C): - azoxystrobin 99% - prothioconazole 98%</td></tr></table> <div>After accelerated storage:</div> <table><tr><td>Spontaneity of dispersion</td><td>CIPAC MT 160</td><td>Standard Water C (30±2°C): - azoxystrobin 99% - prothioconazole 99%</td></tr></table>	Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - azoxystrobin 99% - prothioconazole 98%	Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - azoxystrobin 99% - prothioconazole 99%	Y	I. Knapik, Study code: ICB/93/2019	Accepted
Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - azoxystrobin 99% - prothioconazole 98%										
Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - azoxystrobin 99% - prothioconazole 99%										
Dispersion	-	-	-	-	-							

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments						
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)	CIPAC MT 187	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Particle size	CIPAC MT 187 and Standard Operational Procedure SPB/32	d ₁₀ -0.346 [µm] d ₂₀ -0.476 [µm] d ₃₀ -0.830 [µm] d ₄₀ -1.180 [µm] d ₅₀ -1.572 [µm] d ₆₀ -2.023 [µm] d ₇₀ -2.562 [µm] d ₈₀ -3.269 [µm] d ₉₀ -4.371 [µm] d ₉₉ -12.067 [µm]	Y	I. Knapik, Study code: ICB/93/2019	Accepted						
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Initial preparation: <table><tr><td>Wet sieve</td><td>CIPAC MT 185</td><td>Residue (sieve 75 µm)– 0%</td></tr></table> After accelerated storage: <table><tr><td>Wet sieve</td><td>CIPAC MT 185</td><td>Residue (sieve 75 µm)– 0%</td></tr></table>			Wet sieve	CIPAC MT 185	Residue (sieve 75 µm)– 0%	Wet sieve	CIPAC MT 185	Residue (sieve 75 µm)– 0%	Y	I. Knapik, Study code: ICB/93/2019	Accepted
Wet sieve	CIPAC MT 185	Residue (sieve 75 µm)– 0%												
Wet sieve	CIPAC MT 185	Residue (sieve 75 µm)– 0%												
Dust content (KCP 2.8.5.2.1)	-	-				-	-							
Particle size of dust (KCP 2.8.5.2.2)	-	-				-	-							

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
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	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	<div>Initial preparation:</div> <table><tr><td>Pourability</td><td>CIPAC MT 148.1</td><td>Residue - 1.57%</td></tr></table> <div>After accelerated storage:</div> <table><tr><td>Pourability</td><td>CIPAC MT 148.1</td><td>Residue - 1.53%</td></tr></table>	Pourability	CIPAC MT 148.1	Residue - 1.57%	Pourability	CIPAC MT 148.1	Residue - 1.53%	Y	I. Knapik, Study code: ICB/93/2019	Accepted
Pourability	CIPAC MT 148.1	Residue - 1.57%										
Pourability	CIPAC MT 148.1	Residue - 1.53%										
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	-	-	-							

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
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	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019 Expiry date: 13.06.2021	Effectiveness of cleaning	Efficacy Guideline 305	<p>Single rinse procedure:</p> <ul style="list-style-type: none"> - 99.92 [%] azoxystrobin removed - the bottle - 99.78 [%] prothioconazole removed - the bottle <p>Double rinse procedure:</p> <ul style="list-style-type: none"> - 99.96 [%] azoxystrobin removed - the bottle - 99.80 [%] prothioconazole removed - the bottle <p>Triple rinse procedure:</p> <ul style="list-style-type: none"> - 99.98 [%] azoxystrobin removed - the bottle - 99.88 [%] prothioconazole removed - the bottle 	Y	I. Knapik, Study code: ICB/93/2019	Accepted
	Standard Operational Procedure SPB/38	Protiokonazol + Azoxystrobin (175 + 200) SC Batch No.: 03 Prod. Date: 13.06.2019	Stability of package	Standard Operational Procedure SPB/38	<p>Change in packaging weight – 0.25 [%] Change in gross weight – 0.026[%]</p>	Y	I. Knapik, Study code: ICB/93/2019	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Expiry date: 13.06.2021				

Table 2-2. Initial physicochemical results for the PPP

Study	Method	Results
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N9.25 (white creamy) Physical state – liquid Odour - specific
pH	CIPAC MT 75.3	1% (w/v) suspension – 7.23 Undiluted – 7.56
Flash point	EEC A.9	Flash point was not observed. The test flame was extinguished by vapours of the test item at temperatures between 65-70°C.
Surface tension	EEC A.5	0.0937% (w/v) –37.85 [mN/m] 0.375% (w/v) – 32.70 [mN/m]
Relative density	EEC A.3	1.1210
Persistent foam	CIPAC MT 47.3	- 0.0937% (w/v): -after 1 minute – 2 mL after 12 minutes – 0 mL - 0.375% (w/v): -after 1 minute – 4 mL after 12 minutes – 0 mL
Suspensibility	CIPAC MT 184	0.0937% (w/v) in Standard Water D (30±2°C): -azoxystrobin 98% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): -azoxystrobin 98% - prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97% 0.5% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97%

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 solid sediment at the bottom. After 24 h in room temperature and one invert– 0.05 mL solid sediment at the bottom. Residue on the wet sieve – 0%
Particle size	CIPAC MT 187 and Standard Operational Procedure SPB/32	d10-0.346 [µm] d20-0.476 [µm] d30-0.830 [µm] d40-1.180 [µm] d50-1.572 [µm] d60-2.023 [µm] d70-2.562 [µm] d80-3.269 [µm] d90-4.371 [µm] d99-12.067 [µm]

Table 2-3. Results after an accelerated storage.

Study	Method	Results
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation)–N9.25 (white creamy) Physical state – liquid Odour - specific
pH	CIPAC MT 75.3	1% (w/v) suspension – 7.35 Undiluted – 7.23
Relative density	EEC A.3	1.1230
Suspensibility	CIPAC MT 184	0.0937% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): -azoxystrobin 98%

		- prothioconazole 96% 0.375% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97%
Wet sieve	CIPAC MT 185	Residue (sieve 75 µm)– 0%
Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): -azoxystrobin 99% - prothioconazole 99%
Pourability	CIPAC MT 148.1	Residue - 1.53%
Stability of package	Standard Operational Procedure SPB/38	Change in packaging weight – 0.25 [%] Change in gross weight – 0.026[%]
Content of azoxystrobin and prothioconazole	Standard Operational Procedure SPB/139	Azoxystrobin – 204.61 g/L Prothioconazole - 180.96 g/L
Content of Z- azoxystrobin as im- purity	Standard Operational Procedure SPB/144	Z-azoxystrobin - <1.759 µg/mL (<0.35 g/kg)
Content of toluene as impu- rity	Standard Operational Procedure SPB/134	Toluene - <1.16 µg/mL (<0.13 g/kg)

Based on BA-19/19 study the content of prothioconazole-desthio in PROTIOKONAZOL + AZOXYSTROBIN (175 + 200) SC determined by developed and validated method is: at initial time - $0.000164 \pm 0.00003\%$, after accelerated storage - $0.000148 \pm 0.00003\%$,

Table 2-4. Physicochemical properties of the test item after 24 months shelf-life test.

Study	Method	Results
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N9.25 (white creamy) Physical state – liquid Odour - specific
pH	CIPAC MT 75.3	1% (w/v) suspension – 7.48 Undiluted – 7.43
Relative density	EEC A.3	1.1181
Suspensibility	CIPAC MT 184	0.0937% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97% 0.2% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97% 0.375% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97% 0.50% (w/v) in Standard Water D (30±2°C): -azoxystrobin 99% - prothioconazole 97%
Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): -azoxystrobin 99% - prothioconazole 98%
Pourability	CIPAC MT 148.1	Residue - 1.43%
Wet sieve	CIPAC MT 185	Residue (sieve 75 µm)– 0%
Stability of package	Standard Operational Procedure SPB/38	Change in packaging weight – 0.47 [%] Change in gross weight – 0.04 [%]

Content of azoxystrobin and prothioconazole	Standard Operational Procedure SPB/139	Azoxystrobin – 208.52 g/L Prothioconazole – 183.54 g/L
Content of Z- azoxystrobin as impurity	Standard Operational Procedure SPB/144	Z-azoxystrobin - <1.759 µg/mL (<0.35 g/kg)
Content of toluene as impurity	Standard Operational Procedure SPB/134	Toluene - <1.16 µg/mL (<0.13 g/kg)

Based on BA-09/21 study the content of relevant impurity of prothioconazole (prothioconazole-desthio) in PROTIOKONAZOL + AZOXYSTROBI-NA (175 + 200) SC after 24 months of storage is below limit of quantification (LOQ), it means below (0.0001 %) 0.00108 g/kg of preparation.

3 Section 3 is presented as a separate document

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

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

TABLE 4.1-1 Packaging information

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

Table 4.1-2: Packaging information

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

Table 4.1-3: Packaging information

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

Table 4.1-4: Packaging information

Type	BOTTLE
Material:	HDPE
size:	72±1 mm/111.8±2 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	250 ml

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

Table 4.1-5: Packaging information

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

Table 4.1-6: Packaging information

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

Table 4.1-7: Packaging information

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

Table 4.1-8: Packaging information

Type	BOTTLE
Material:	HDPE
size:	77.6 ±1 mm/160.6±2 mm
Opening:	38 mm
Closure:	screw cap with seal

Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information

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

Table 4.1-10: Packaging information

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

Table 4.1-11: Packaging information

Type	JAR
Material:	HDPE
size:	79/80 mm/ 201 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-12: Packaging information

Type	BOTTLE
Material:	HDPE
size:	80 mm± 2 mm/201 mm ± 2 mm
Opening:	64 mm

Closure:	screw cap with seal
Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information

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

Table 4.1-14: Packaging information

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

Table 4.1-15: Packaging information

Type	BOTTLE
Material:	HDPE
size:	238 mm± 2 mm/90mm ± 2 mm
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-16: Packaging information

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm

Opening:	42 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-17: Packaging information

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

Table 4.1-18: Packaging information

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

Table 4.1-19: Packaging information

Type	BOTTLE
Material:	HDPE
size:	84 ± 1.5 mm/230.1 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-20: Packaging information

Type	BOTTLE
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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

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
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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 ± 5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-55: 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 4.1-56: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	54,2 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 4.1-57: Packaging information

Type	BOTTLE
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 4.1-58: 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 4.1-59: 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 4.1-60: 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 4.1-61: 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 4.1-62: 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

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

Table 4.1-65: Packaging information for 1000 ml bottle

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

Table 4.1-66: 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
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 ± 2 mm/225mm± 2 mm/306mm± 2 mm
Opening:	48 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-69: Packaging information for 20000 ml container

Type	Description
Material:	HDPE/EvOH
Size:	375 mm ± 2 mm/290mm± 2 mm/245mm± 2 mm
Opening:	85mm ± 2 mm
Closure:	Screw cap with seal
Capacity	20000 ml

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

RMS conclusion

Based on the two-year storage stability study at ambient temperature all the HDPE packs are accepted for the PPP. Furthermore, for aqueous formulation like SC every extrapolation from HDPE on any other in this point proposed pack type and material is accepted as well.

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 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1. KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	I. Kanpik	2019	Determination of physicochemical properties Study code: ICB/93/2019 ICB Pharma, Lema 10, Street, 43-600, Jaworzno POLAND GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 2.5.1	E. Arevalo	2019	Prothioconazole + Azoxystrobin (I75 + 200) SC Viscosity determination Study code: BF-32/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 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 2.2.1 KCP 2.3.1	P. Śliwa	2019	Protiokonazol + Azoxystrobin (I75 + 200) SC Determination of explosive properties Study code: BW-07/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 2.2.2 KCP 2.3.2 KCP 2.3.3	P. Flasińska	2019	Protiokonazol + Azoxystrobin (I75 + 200) SC Determination of auto-ignition temperature and oxidizing properties Study code: BC-19/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 2.7.1 KCP 2.7.3 KCP 2.7.5	M. Wołoszynowska	2019	Protiokonazol + Azoxystrobin (I75 + 200) SC Determination of the relevant impurity of prothioconazole (prothioconazole-desthio) in the formulation at initial time and after accelerated storage Study code: BA-19/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 2.7.5	M. Wołoszynowska	2021	Protiokonazol + Azoxystrobin (I75 + 200) SC Determination of the relevant impurity of prothioconazole (prothioconazole-desthio) in the formulation after 24 months of storage Study code: BA-09/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236	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
			Warsaw, Poland GLP Unpublished		
KCP 2.7.5	I. Kanpik	2021	Determination of physicochemical properties Study code: ICB/94/2019 ICB Pharma, Lema 10, Street, 43-600, Jaworzno POLAND GLP Unpublished	N	PUH Chemirol Sp. z o.o.