

# 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: Protiokonazol 300 EC

Product name(s): HERA 300 EC

Chemical active substance:

prothioconazole, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(authorization)

Applicant: Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023

MS Finalisation date: March 2024; July 2024

## Version history

When	What
March 2024	zRMS assessment of dRR
July 2024	The final Registration Report

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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:

- 2-years ambient stability test
- emulsion stability test with CIPAC Water A (results can be provided with 2-years stability results)

## 1 Section 1: Identity of the plant protection product

### 1.1 Applicant (KCP 1.1)

Name: Pestila Spółka z ograniczoną odpowiedzialnością  
Address: Studzianki 24a  
97-320 Wolbórz  
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

Name: Pestila Spółka z ograniczoną odpowiedzialnością  
Address: Studzianki 24a  
97-320 Wolbórz  
Poland

#### 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  $\geq 970$  g/kg

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 (LOD)

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

Trade name: Please refer to cover letter

Company code number: Protiokonazol 300 EC

## 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	300 g/L	285 – 315 g/L	306.1 g/L 290.8 – 321.4 g/L	29.63 28.2 – 31.1

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

\*\* Based on the density of the formulation = 1.033 g/mL

**Table 1.4-2: Safener and synergists**

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content (g/L or g/kg)	Technical content (%w/w)
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

**Table 1.4-3: Relevant impurities**

Relevant impurity	Maximum content (g/L or g/kg)
Toluene	0.22 1.53 g/L (0.15%)
Prothioconazole-desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol)	0.08 0.15 g/L (0.015%)

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

**Table 1.4-4: Information on prothioconazole**

Type	Name/Code Number	
ISO common name	prothioconazole	Variant
CAS No.	178928-70-6	not relevant
EC No.	not available	not relevant
CIPAC No.	745	not relevant

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

Not relevant. Product does not contain safeners and synergists.

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

Type: Emulsifiable concentrate

[Code: EC]

## **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 clear homogenous straw yellow to light brown liquid of characteristic odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 355 °C. In aqueous solution, it has a pH value around 6.14 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 year at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a EC formulation.

The intended concentration of use is ~~0.075% to 0.325%~~ 0.13% v/v to 0.65% v/v.

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

Study	Result	Classification acc. to Reg. 1272/2008	Labelling acc. to Reg. 1272/2008
Explosive properties (A.14)	Product does not have explosive properties.	Not classified.	None.
Oxidizing properties (A.21)	Product does not have oxidizing properties.	Not classified.	None.
Flammability – not relevant for liquids.	Product is not flammable.	Not classified.	None.
Flash point	135.5 °C	Not classified.	None.

No classification or labelling for physical chemical properties is proposed.

### Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not relevant.

### Compliance with FAO specifications:

~~The product Protiokonazol 300 EC complies with FAO specifications.~~

At the time of evaluation, no FAO specification was allocated for formulations containing prothioconazole.

### Formulation used for tests

Product used in the test has the same composition as the one cited in Part C.

**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)	Polish Pharmacopoeia VI Edition (2002) & EPA Product Properties Test Guidelines OPPTS 830.6302 to 04	Protiokonazol 300 EC Batch no. 01/PRO/2022	Protiokonazol 300 EC is a clear homogenous straw yellow liquid of characteristic odour.	Y	BF – 25/22	Accepted.
Explosive properties (KCP 2.2.1)	A.14	Protiokonazol 300 EC Batch no. 01/PRO/2022	Protiokonazol 300 EC does not have explosive properties.	Y	BW-13/22	In thermal sensitivity (Koenen) test no explosion occurred. In the mechanical sensitivity test (BAM Fall Hammer apparatus) no explosion occurred. The formulation is not classified as explosive. Accepted.
Oxidizing properties (KCP 2.2.2)	A.21	Protiokonazol 300 EC Batch no. 01/PRO/2022	Protiokonazol 300 EC does not have oxidizing properties.	Y	BC-45/22	The mean pressure rise time for formulation did not reach the critical value 690 kPa. The formulation is not classified as oxidising. Accepted.
Flash point (KCP 2.3.1)	A.9	Protiokonazol 300 EC Batch no. 01/PRO/2022	Protiokonazol 300 EC has got the flash point: 135.5 °C.	Y	BC-45/22	The test was performed with the Pensky-Martens closed cup apparatus. No flash was observed in



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						preliminary test. The formulation is not flammable. Accepted.
Flammability (KCP 2.3.2)	-	-	Not relevant. Protiokonazol 300 EC is liquid form.	-	-	
Self-heating (KCP 2.3.3)	A.15	Protiokonazol 300 EC Batch no. 01/PRO/2022	Auto-ignition temperature of Protiokonazol 300 EC is 355 °C.	Y	BC-45/22	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	Protiokonazol 300 EC Batch no. 01/PRO/2022	<u>Before storage:</u> pH = 5.88; <u>After accelerated storage:</u> pH = 6.45.	Y	BF – 25/22	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Protiokonazol 300 EC Batch no. 01/PRO/2022	<u>Before storage:</u> pH = 6.14; <u>After accelerated storage:</u> pH = 7.00.	Y	BF – 25/22	Accepted.
Viscosity (KCP 2.5.1)	OECD 114	Protiokonazol 300 EC Batch no. 01/PRO/2022	<u>At 20 °C</u> dynamic – 110 mPa·s at shear rates of 5, 10, 25, 50 s <sup>-1</sup> <u>At 40 °C</u> dynamic – 38 mPa·s at shear rates of 5, 10, 25, 50 s <sup>-1</sup> .	Y	BF – 25/22	The dynamic viscosity was determined with Brookfield rotational viscometer. The formulation is a Newtonian liquid. The formulation does not pose an aspiration hazard (it does not contain substances classified as a Category 1 aspiration hazard). Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																
Surface tension (KCP 2.5.2)	A.5	Protiokonazol 300 EC Batch no. 01/PRO/2022	<u>Concentrate</u> : 30.67 mN/m; <u>Highest concentration of usable liquid</u> : 33.96 mN/m.	Y	BF – 25/22	The surface tension of the formulation was tested using ring method. The concentration tested was 0.325% v/v and neat formulation. The formulation is classified as surface-active. Accepted.																																
Relative density (KCP 2.6.1)	A.3	Protiokonazol 300 EC Batch no. 01/PRO/2022	1.033 g/mL. Relative density: 1.033	Y	BF – 25/22	Gay-Lussac pycnometer was used. Accepted.																																
Bulk density (KCP 2.6.2)	-	-	Not relevant. Protiokonazol 300 EC is liquid form.	-	-																																	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.4 OPPTS 830.6302-04 CIPAC MT 75.3 A.3 OECD 114 CIPAC MT 47.3 A.5 CIPAC MT 36.3 CropLife International Technical Monograph	Protiokonazol 300 EC Batch no. 01/PRO/2022	Storage stability after 14 days at 54 °C. <table><tr><th colspan="2">Parameter</th><th>Initial</th><th>After storage for 14 days at 54 °C</th></tr><tr><td colspan="2">Appearance</td><td>clear homogenous straw yellow liquid of characteristic odour</td><td>clear homogenous light brown liquid of characteristic odour</td></tr><tr><td rowspan="2">pH</td><td>undiluted</td><td>5.88</td><td>6.45</td></tr><tr><td>1%</td><td>6.14</td><td>7.00</td></tr><tr><td colspan="2">Density</td><td>Absolute 1.033 g/ml Relative 1.033</td><td>Absolute 1.032 g/ml Relative 1.032</td></tr><tr><td rowspan="2">Viscosity</td><td>At 20°C</td><td>dynamic – 110 mPa·s</td><td rowspan="2">-</td></tr><tr><td>At 40°C</td><td>dynamic – 38 mPa·s</td></tr><tr><td rowspan="2">Persistent foam</td><td>0.075%</td><td>9 ml after 1 min 5.5 ml after 12 min</td><td>5.0 ml after 1 min 2.0 ml after 12 min</td></tr><tr><td>0.325%</td><td>6.5 ml after 1 min</td><td>5.0 ml after 1 min</td></tr></table>	Parameter		Initial	After storage for 14 days at 54 °C	Appearance		clear homogenous straw yellow liquid of characteristic odour	clear homogenous light brown liquid of characteristic odour	pH	undiluted	5.88	6.45	1%	6.14	7.00	Density		Absolute 1.033 g/ml Relative 1.033	Absolute 1.032 g/ml Relative 1.032	Viscosity	At 20°C	dynamic – 110 mPa·s	-	At 40°C	dynamic – 38 mPa·s	Persistent foam	0.075%	9 ml after 1 min 5.5 ml after 12 min	5.0 ml after 1 min 2.0 ml after 12 min	0.325%	6.5 ml after 1 min	5.0 ml after 1 min	Y	BF – 25/22	The test item was stored in the original package (1L HDPE bottle). The test temperature varied between 53.6°C and 54.2°C. The change of a.s. content was 0.1%. The content of relevant impurities was below the limits set in Regulation No 540/2011. The analytical methods for the determination of a.s. content and relevant impurities in the test item were validated
Parameter		Initial	After storage for 14 days at 54 °C																																			
Appearance		clear homogenous straw yellow liquid of characteristic odour	clear homogenous light brown liquid of characteristic odour																																			
pH	undiluted	5.88	6.45																																			
	1%	6.14	7.00																																			
Density		Absolute 1.033 g/ml Relative 1.033	Absolute 1.032 g/ml Relative 1.032																																			
Viscosity	At 20°C	dynamic – 110 mPa·s	-																																			
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Persistent foam	0.075%	9 ml after 1 min 5.5 ml after 12 min	5.0 ml after 1 min 2.0 ml after 12 min																																			
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Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
	No. 17 EPPO PP 1/292(1) MT/BA-43/22 MT/BA-46/22 MT/BA-40/22				5.0 ml after 12 min	0.0 ml after 12 min			under Study No. BF-25/22 (see dRR B5). See KCP 2.8.2 for comment on the persistence of foaming. See KCP 2.8.6.2 for comment on the emulsion stability. After accelerated storage, the colour of the package remained stable the weight change was 0.04%, there was no perforation, no leaking, the packaging was concave on one side. Accepted.
			Surface tension	0.325%	33.96 mN/m	-			
				concentrate	30.67 mN/m				
			Emulsion stability	0.075%	1) After one rotation and 30 s – homogenous 2) After ten rotations and 30 min – homogenous 3) After ten rotations and 2 h – homogenous 4) After ten rotations and 24 h – homogenous 5) Re-emulsification	1) After one rotation and 30 s – homogenous 2) After ten rotations and 30 min – homogenous 3) After ten rotations and 2 h – homogenous 4) After ten rotations and 24 h – homogenous 5) Re-emulsification			
				0.325%	• after ten rotations and 30 s – homogenous • after ten rotations and 30 min – homogenous	• after ten rotations and 30 s – homogenous • after ten rotations and 30 min – homogenous			
			Package stability		1 litre HDPE bottle	The colour of the 1 litre HDPE package were stable. Negligible mass change.  The package was concave on one side			
			Application equipment cleaning effectiveness		99.95%	-			
			Prothioconazole content		28.15% (290.80 g/L)	28.18% (291.12 g/L)			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments						
			<table><tr><td>Prothioconazole-Desthio content</td><td>0.0076%</td><td>0.0032%</td></tr><tr><td>Toluene content</td><td>0.0213%</td><td>0.0208%</td></tr></table>			Prothioconazole-Desthio content	0.0076%	0.0032%	Toluene content	0.0213%	0.0208%			
Prothioconazole-Desthio content	0.0076%	0.0032%												
Toluene content	0.0213%	0.0208%												
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant. Protiokonazol 300 EC was stable after 14 days at 54°C.			-	-							
Minimum content after heat stability testing (KCP 2.7.3)	CIPAC MT 47.3 MT/BA-43/22	Protiokonazol 300 EC Batch no. 01/PRO/2022	Prothioconazole - <del>288.13 g/L (27.89 %)</del> 291.12 (28.18).			Y	BF – 25/22	Accepted.						

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 OPPTS 830.6302-04 CIPAC MT 75.3 A.3 OECD 114 CIPAC MT 47.3 A.5 CIPAC MT 36.3 MT/BA-43/22	Protiokonazol 300 EC  Batch no. 01/PRO/2022	Storage stability after 7 days at 0°C.			Y	BF – 25/22	The formulation was stored in a transparent graduated glass cylinder. The recorded temperatures were between -0.8°C and 1.0°C. The sample was observed for transparency, homogeneity and colour change immediately after storage at, after reaching room temperature and after 24 hours at room temperature and single inversion. 1.4% change in a.s. content. See KCP 2.8.2 for comment on persistence of foaming. See KCP 2.8.6.2 for comment on the emulsion stability. Accepted.
			Parameter	Initial	After storage for 7 days at 0 °C			
			Appearance	clear homogenous straw yellow liquid of characteristic odour	clear homogenous straw yellow liquid of characteristic odour			
			pH	undiluted	5.88			
				1%	6.14			
			Density		Absolute 1.033 g/ml Relative 1.033			
			Viscosity	At 20°C	dynamic – 110 mPa·s			
				At 40°C	dynamic – 38 mPa·s			
			Persistent foam	0.075%	9 ml after 1 min 5.5 ml after 12 min			
				0.325%	6.5 ml after 1 min 5.0 ml after 12 min			
			Surface tension	0.325%	33.96 mN/m			
				concentrate	30.67 mN/m			
			Emulsion stability	0.075%	1) After one rotation and 30 s – homogenous 2) After ten rotations and 30 min – homogenous 3) After ten rotations and 2 h – homogenous 4) After ten rotations and 24 h – homogenous			
				0.325%	1) After one rotation and 30 s – homogenous 2) After ten rotations and 30 min – homogenous 3) After ten rotations and 2 h – homogenous 4) After ten rotations and 24 h – homogenous 5) Re-emulsification			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
					5) Re-emulsification <ul style="list-style-type: none"> <li>after ten rotations and 30 s – homogenous</li> <li>after ten rotations and 30 min – homogenous</li> </ul>	<ul style="list-style-type: none"> <li>after ten rotations and 30 s – homogenous</li> <li>after ten rotations and 30 min – homogenous</li> </ul>			
			Application equipment cleaning effectiveness		99.95%	-			
			Prothioconazole content		28.15% (290.80 g/L)	28.56% (294.98 g/L)			
Ambient temperature shelf life (KCP 2.7.5)	-	-	Study on-going. Expected date of completing the study November 2024.				-	-	
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Study on-going. Expected date of completing the study November 2023.				-	-	
Wettability (KCP 2.8.1)	-	-	Not relevant. Protiokonazol 300 EC is liquid form.				-	-	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Protiokonazol 300 EC Batch no.	<u>At concentration 0.075% v/v:</u> after 1 min. 9 ml <u>At concentration 0.325% v/v:</u> after 1 min. 6.5 ml				Y	BF – 25/22	The recommended use conc. are from 0.13% v/v to 0.65% v/v. The study was performed with a

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		01/PRO/2022				conc. 0.075% v/v which is lower than the min. recommended conc. and with a conc. 0.325% v/v which is lower than the max. recommended conc. As the results are well within limit it can be accepted. Accepted.
Suspensibility (KCP 2.8.3.1)	-	-	Not required for EC formulation.	-	-	
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required for EC formulation.	-	-	
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for EC formulation.	-	-	
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant. Protiokonazol 300 EC is liquid form.	-	-	
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required for EC formulation.	-	-	
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not required for EC formulation.	-	-	
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant. Protiokonazol 300 EC is liquid form.	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant. Protiokonazol 300 EC is liquid form.	-	-	

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Attrition (KCP 2.8.5.3)	-	-	Not relevant. Protiokonazol 300 EC is liquid form.			-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant. Protiokonazol 300 EC is liquid form.			-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for EC formulation.			-	-	See KCP 2.8.6.2 and KCP 2.8.6.3
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	Protiokonazol 300 EC  Batch no. 01/PRO/2022	<b>Concentration</b>	<b>Time</b>	<b>Result</b>	Y	BF – 25/22	The recommended use conc. are from 0.13% v/v to 0.65% v/v. The study was performed with a conc. 0.075% v/v which is lower than the min. recommended conc. and with a conc. 0.325% v/v which is lower than the max. recommended conc.  According to SANCO/10473/2003 – rev.5 both CIPAC standard Waters A and D should be used. In the test, only CIPAC Water D was used. As the results are well within limit it can be accepted provisionally accepted, provide that in the 2-years stability study, emulsion stability will be tested with both CIPAC Waters A and C.  Accepted
			0.075%	30 s	homogenous			
				30 min	homogenous			
				2 h	homogenous			
				24 h	homogenous			
			0.325%	30 s	homogenous			
				30 min	homogenous			
				2 h	homogenous			
				24 h	homogenous			



Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	Protiokonazol 300 EC  Batch no. 01/PRO/2022	Concentration	Time	Result	Y	BF – 25/22	See commnet in KCP 2.8.6.2. Accepted.
			0.075%	30 s	homogenous			
				30 min	homogenous			
			0.325%	30 s	homogenous			
				30 min	homogenous			
Flowability (KCP 2.8.7.1)	-	-	Not required for EC formulation.			-	-	
Pourability (KCP 2.8.7.2)	-	-	Not required for EC formulation.			-	-	
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant. Protiokonazol 300 EC is liquid form.			-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant. Protiokonazol 300 EC is not recommended for tank-mixes usage.			-	-	
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant. Protiokonazol 300 EC is not recommended for tank-mixes usage.			-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant. Protiokonazol 300 EC is not a seedtreatment.			-	-	
Distribution to seed (KCP 2.10.2)	-	-	Not relevant. Protiokonazol 300 EC is not a seedtreatment.			-	-	
Other/special studies (KCP 2.11)	EPPO PP 1/292(1)	Protiokonazol 300 EC  Batch no. 01/PRO/2022	Application equipment cleaning effectiveness – 99.95 %.			Y	BF – 25/22	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)

zRMS comment:	In the accelerated storage study, the formulation was stored in commercial packaging (1 L HDPE bottle) and the packaging remained stable during the storage (), therefore, the proposed commercial HDPE packs are considered acceptable. Since the formulation is EC formulation, according to SANCO/10473/2003 – rev.5 (21.10.2021) extrapolation from HDPE to HDPE co-extruded with any of the following; EVOH, fluorinated HDPE and polyamide is acceptable. Therefore, proposed HDPE/PA (COEX) and fHDPE (fluorinated HDPE) packs would all be supported without further data.
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Taking into account extrapolation rules of *Polish guideline on the general principles for approval of packaging of plant protection products* (actualization 18.10.2021), we are applying for additional packaging made of HDPE/PA (COEX) and fHDPE (fluorinated HDPE) for professional users. According to this guideline extrapolation from HDPE to HDPE/PA (COEX) and fHDPE (fluorinated HDPE) is possible for EC formulations.

**Table 4.1-1: Packaging information for 250 ml bottle**

Type	Description		
<b>Material:</b>	HDPE	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	126mm x Ø63,5mm	126mm x Ø63,5mm	126mm x Ø63,5mm
<b>Opening:</b>	50mmTE	50mmBE	50mmTE
<b>Closure:</b>	50mmTE	50mmBE	50mmTE
<b>Seal:</b>	HIS or PE	IHS	IHS or PET/ALU
<b>Manner of construction</b>	Blow moulded extrusion	Blow moulded coextrusion	Blow moulded extrusion
<b>UN/ADR</b>	Y 1,5/120	Y 1,9/120	Y 1,5/120

**Table 4.1-2: Packaging information for 0.5 L bottle**

Type	Description		
<b>Material:</b>	HDPE	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cylindrical / approx. 77,6 mm diameter x 160,6 mm	cylindrical / approx. 77,6 mm diameter x 160,6 mm	cylindrical / approx. 69 mm diameter x 186,2 mm
<b>Opening:</b>	31,3 mm diameter	31,3 mm diameter	45 mm inner diameter
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	31,3 mm inner diameter
<b>Seal:</b>	HF-seal	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	not relevant	not relevant	UN certified

**Table 4.1-3: Packaging information for 1L bottle**

Type	Description		
<b>Material:</b>	HDPE	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cylindrical / approx. 84 mm diameter x 230,1 mm	cylindrical / approx. 88 mm diameter x 236,5 mm	cylindrical / approx. 88,5 mm diameter x 233,2 mm
<b>Opening:</b>	31,3 mm diameter	48 mm inner diameter	45 mm inner diameter
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
<b>Seal:</b>	HF-seal	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	not relevant	not relevant	UN certified

**Table 4.1-4: Packaging information for 5L canister**

Type	Description		
<b>Material:</b>	HDPE	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cuboid / approx. 186 x 140 mm, H <sub>max</sub> =300 mm	cuboid / approx. 187 x 135 mm, H <sub>max</sub> =305 mm	cuboid / approx. 193 x 142 mm, H <sub>max</sub> =305 mm
<b>Opening:</b>	54 mm diameter	53 mm inner diameter	54 mm inner diameter
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
<b>Seal:</b>	HF-seal	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	not relevant	not relevant	UN certified

**Table 4.1-5: Packaging information for 10L canister**

Type	Description		
<b>Material:</b>	HDPE	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cuboid / approx. 228 x 192 mm, H <sub>max</sub> =306,6 mm	cuboid / approx. 230 x 166 mm, H <sub>max</sub> =375 mm	cuboid / approx. 240 x 179 mm, H <sub>max</sub> =377,5 mm
<b>Opening:</b>	46,8 mm diameter	53 mm inner diameter	54 mm inner diameter
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
<b>Seal:</b>	HF-seal	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	compliant	compliant	UN certified

**Table 4.1-6: Packaging information for 20L canister**

Type	Description		
<b>Material:</b>	HDPE	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cuboid / approx. 259 x 237 mm, H <sub>max</sub> =415±3 mm	cuboid / approx. 292 x 256 mm, H <sub>max</sub> =345,4 mm	cuboid / approx. 294 x 245 mm, H <sub>max</sub> =400 mm
<b>Opening:</b>	63,4 mm diameter	46,8 mm diameter	53 mm diameter

Type	Description		
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
<b>Seal:</b>	HF-seal	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	compliant	compliant	compliant

**Table 4.1-7: Packaging information for 220L barrel**

Type	Description	
<b>Material:</b>	HDPE	HDPE
<b>Shape/size:</b>	935 (± 5)mm x Ø581 (± 5)mm	973mm x Ø590mm
<b>Opening:</b>	Ø581 (±5)	Ø590mm
<b>Closure:</b>	Cap types: 2 layer high-density polyethylene - HBCS 70x6 (Ø80 ± 0,5mm, height 23 ±1 mm) or 2 caps high-density polyethylene - BCS 56x4 (Ø71,8 ±0,3 mm, height 21,4 ±1 mm)	Lid injection moulded out of HDPE with lever action clamping ring, made from galvanised steel.
<b>Seal:</b>	EPDM foam rubber or PE	PUR foamed or EPDM foam rubber
<b>Manner of construction</b>	Blow moulded in one operation together with top and bottom out and integrated L - ring in top.	Blow moulded out of high molecular HDPE in a one-step process.
<b>UN/ADR</b>	UN 1H1	UN 1H2

**Table 4.1-8: Packaging information for 1000 L container**

Type	Description		
<b>Material:</b>	HDPE container in steel cage on plastic pallet	HDPE container in steel cage on wooden pallet	HDPE container in steel cage on hybrid pallet
<b>Shape/size:</b>	1000mm x 1200mm x 1180mm	1000mm x 1200mm x 1174 mm	1000 mm x 1200mm x 1151mm (± 5mm)
<b>Opening:</b>	NW150	NW150	NW150
<b>Closure:</b>	DN 50	DN 50	DN 50
<b>Seal:</b>	ETFE/PE	EPDM	ETFE/PE
<b>Manner of construction</b>	Blow-molded from high-density UV-stabilized PE, galvanized steel cage, plastic pallet.	Blow-molded from high-density UV-stabilized PE, galvanized steel cage, wooden pallet.	Blow-molded from high-density UV-stabilized PE, galvanized steel cage, palette made of steel corners are filled with plastic.
<b>UN/ADR</b>	UN 31HA1	UN 31HA1	UN 31HA1

## 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 2.7.4 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.1/01 KCP 2.7.3 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.6.2 KCP 2.8.6.3 KCP 2.8.7.2	Łysik A.	2022	Protiokonazol 300 EC. Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Report No BF – 25/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 2.2.1	Ołowski G.	2022	Protiokonazol 300 EC. Determination of explosive properties. Report No BW-13/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 2.2.2 KCP 2.3.1 KCP 2.3.3	Flasińska P.	2022	Protiokonazol 300 EC. Determination of flash point, auto-ignition temperature and oxidizing properties. Report No BC-45/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**

\*Pestila Spółka z ograniczoną odpowiedzialnością (short name Pestila Sp. z o. o.)

\*\*ProAgri International Spółka z ograniczoną odpowiedzialnością (short name ProAgri International Sp. z o.o.)

Please note that Pestila Sp. z o. o. and ProAgri International Sp. z o.o. are co-sponsors of the studies for Prothioconazole 300 EC and have the same rights for using data in registration processes without Letter of access issuing.

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>



The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>

**List of data relied on and not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>

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

### **A 2.1            Prothioconazole**

No further data available.