

# FINAL REGISTRATION REPORT

## Part A

### Risk Management

Product code: Protiokonazol 300 EC

Product name(s): HERA 300 EC

Chemical active substance:

prothioconazole, 300 g/L

NATIONAL ASSESSMENT Poland

(authorization)

CORE ASSESSMENT

(authorization)

Applicant: Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023

MS Finalisation date: April 2024; July 2024 December 2024

February 2025

## Version history

When	What
April 2024	zRMS assessment of dRR.
July 2024	The final Registration Report
December 2024	Efficacy section made corrections in final Registration Report.
February 2025	Updated version

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# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

This document describes the acceptable used conditions required for the registration of Protiokonazol 300 EC, containing active substance prothioconazole, 300 g/L in Poland. This evaluation is required since the product is a new formulation and has not yet been authorised in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in the Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Protiokonazol 300 EC where that data has not been considered in the EU review. Otherwise, assessments for the safe use of Protiokonazol 300 EC have been made using endpoints agreed in the EU review of prothioconazole.

This document describes the specific conditions of use and labelling required for Poland for the registration of Protiokonazol 300 EC.

#### **1.1 Application background**

This application was submitted by Pestila Spółka z ograniczoną odpowiedzialnością.

This is the application for registration plant protection product under working name of Protiokonazol 300 EC according to Article 33 of Regulation 1107/2009. Protiokonazol 300 EC is an emulsifiable concentrate (EC), containing 300 g/L of prothioconazole to be used as a fungicide to protect winter and spring cereals as well as winter oilseed rape and as a minor uses in Poland in spring oilseed rape.

#### **1.2 Letters of Access**

Letter of Access is submitted. See Appendix 3.

#### **1.3 Justification for submission of tests and studies**

The study reports submitted within this application are in agreement with the data requirements of the Regulation 284/2013. No vertebrate studies are included within the present application. Justification for submission of the test and studies is provided in the list of references in Appendix 4.

#### **1.4 Data protection claims**

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

### **2 Details of the authorization decision**

## 2.1 Product identity

Product code	Protiokonazol 300 EC
Product name in MS	Please refer to the cover letter.
Authorization number	Not applicable.
Function	Fungicide
Applicant	Pestila Spółka z ograniczoną odpowiedzialnością
Active substance(s) (incl. content)	Prothioconazole 300 g/L
Formulation type	Emulsifiable concentrate [EC]
Packaging	Bottles (HDPE, HDPE/PA (COEX), fHDPE): 250mL, 0.5L, 1L, Canisters (HDPE, HDPE/PA (COEX), fHDPE): 5L, 10L, 20L Barrels (HDPE): 220L, Containers (HDPE): 1000L professional
Coformulants of concern for national authorizations	Not applicable.
Restrictions related to identity	Not applicable.
Mandatory tank mixtures	Not applicable.
Recommended tank mixtures	Not applicable.

## 2.2 Conclusion

### The evaluation of the application for Protiokonazol 300 EC resulted in the decision to grant the authorization.

#### Physical-chemical properties section:

2-years ambient stability test is on-going (expected date of completing the study November 2024); the emulsion stability test with CIPAC Water A should be performed (the results can be provided with 2-years stability test results).

#### Efficacy section:

All uses claimed in GAP table were accepted for registration (against ERYSYGR in winter wheat – conditionally). ~~ZRM's proposed application scheme for use against ALTEBA in winter oilseed rape (included in GAP and label project).~~ For winter oilseed rape (autumn and spring application) – only dose 0.6 L/ha should be recommended. Recommended use against ALTEBA – once in autumn or twice in spring.

#### Mammalian toxicology:

According toxicological properties PROTHOCONAZOLE 300 EC is classified as Skin Irrit. 2/ H315; Eye Dam. 1/ H318; STOT SE 3/ H335.

According to the model calculations, it can be concluded that the risk for the operator, worker using Protiokonazol 300 EC on intended uses presented in GAP table is acceptable. Regarding calculations bystander and resident safety, additional risk mitigation measures should be applied as below: During spraying, a buffer zone of at least 5 m away from residential buildings/habitats and bystanders with 50% drift reduction should be used.

#### Ecotoxicology section:

Uses are accepted. On the basis of conducted risk assessment it was concluded that HERA 300 EC does not pose unacceptable risk provided following risk mitigations are applied for the following scenarios:

Winter cereals and spring cereals, application rate: 2x195 g a.s./ha, interval 14d  
To protect aquatic organisms respect an unsprayed buffer zone of 5m to surface water bodies.  
Winter oilseed rape, application rate: 2x180 g a.s./ha, interval 21d  
To protect aquatic organisms respect an unsprayed buffer zone of 5m to surface water bodies.  
Spring oilseed rape, application rate: 2x180 g a.s./ha, interval 14-21d  
To protect aquatic organisms respect an unsprayed buffer zone of 5m to surface water bodies.  
**Metabolism and residues:**  
Uses No. 8-10 (oilseed rape) are not acceptable.  
Data gap: magnitude of residues of triazole derivative metabolites (TDMs) in oilseed rape

## 2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.




## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Chronic 1, H410
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	   <b>GHS05      GHS07      GHS09</b>
Signal word:	<b>Danger</b>
Hazard statement(s):	<b>H315 - Causes skin irritation.</b> <b>H318 - Causes serious eye damage.</b> <b>H335 - May cause respiratory irritation.</b> <b>H410 - Very toxic to aquatic life with long lasting effects.</b>
Precautionary statement(s):	<b>P261 - Avoid breathing dust/vapours/ spray.</b> <b>P264 - Wash hands thoroughly after handling.</b> <b>P280 - Wear protective gloves/protective clothing/eye protection/face protection.</b> <b>P302 + P352 - IF ON SKIN: Wash with plenty of water with soap.</b> <b>P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.</b> <b>P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several</b>

	<b>minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor. P332 + P313 - If skin irritation occurs: Get medical advice/ attention. P391 - Collect spillage. P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.</b>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

See Part C for justifications of the classification and labelling proposals.

## 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	<p>Winter cereals and spring cereals, application rate: 2x195 g a.s./ha, interval 14d To protect aquatic organisms respect an unsprayed buffer zone of 5m to <b>non-agricultural land</b>/surface water bodies.</p> <p>Winter oilseed rape, application rate: 2x180 g a.s./ha, interval 21d To protect aquatic organisms respect an unsprayed buffer zone of 5m to <b>non-agricultural land</b>/surface water bodies.</p> <p>Spring oilseed rape, application rate: 2x180 g a.s./ha, interval 14-21d To protect aquatic organisms respect an unsprayed buffer zone of 5m to <b>non-agricultural land</b>/surface water bodies.</p>

## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	Workwear (arms, body and legs covered) and gloves during mixing/loading and during application.
Worker protection:	
-	Workwear (arms, body and legs covered) and gloves when inspecting the treated crops.
Integrated pest management (IPM)/sustainable use:	



-	-
Environmental protection	
SPe3	<p>Winter cereals and spring cereals, application rate: 2x195 g a.s./ha, interval 14d To protect aquatic organisms respect an unsprayed buffer zone of 5m to <b>non-agricultural land</b>/surface water bodies.</p> <p>Winter oilseed rape, application rate: 2x180 g a.s./ha, interval 21d To protect aquatic organisms respect an unsprayed buffer zone of 5m to <b>non-agricultural land</b>/surface water bodies.</p> <p>Spring oilseed rape, application rate: 2x180 g a.s./ha, interval 14-21d To protect aquatic organisms respect an unsprayed buffer zone of 5m to <b>non-agricultural land</b>/surface water bodies</p>
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
SPe3	<p>Winter cereals and spring cereals, application rate: 2x195 g a.s./ha, interval 14d To protect aquatic organisms respect an unsprayed buffer zone of 5m to <b>non-agricultural land</b>/surface water bodies.</p> <p>Winter oilseed rape, application rate: 2x180 g a.s./ha, interval 21d To protect aquatic organisms respect an unsprayed buffer zone of 5m to <b>non-agricultural land</b>/surface water bodies.</p> <p>Spring oilseed rape, application rate: 2x180 g a.s./ha, interval 14-21d To protect aquatic organisms respect an unsprayed buffer zone of 5m to <b>non-agricultural land</b>/surface water bodies.</p>	1-6, 8,9

## 2.6 Intended uses (only NATIONAL GAP)

GAP rev.1, date: 2023-10-01

PPP (product name/code): Protiokonazol 300 EC  
Active substance 1: prothioconazole  
Safener: n.a.  
Synergist: n.a.  
Applicant: Pestila Spółka z ograniczoną odpowiedzialnością  
Zone(s): Central Zone <sup>(d)</sup>  
Verified by MS: no

Formulation type: EC <sup>(a, b)</sup>  
Conc. of as 1: 300 <sup>(c)</sup>  
Conc. of safener: n.a. <sup>(c)</sup>  
Conc. of synergist: n.a. <sup>(c)</sup>  
Professional use: ☒  
Non professional use: ☐

Field of use: Fungicide

	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Mem- ber state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I**	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Winter wheat	F	<u>Controlled diseases (0.5 – 0.65 L/ha):</u> <b>Septoria leaf blotch</b> ( <i>Zymoseptoria tritici</i> ) SEPTTR <b>Powdery mildew of cereals</b> ( <i>Blumeria graminis</i> ) ERYSGR	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant <b>Eff. section: use against ERY- SYGR is accepted conditionally.</b>
2	PL	Spring wheat	F	<u>Controlled diseases (0.5 – 0.65 L/ha):</u> <b>Septoria leaf blotch</b> ( <i>Zymoseptoria tritici</i> ) SEPTTR	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant
3	PL	Winter triticale	F	<u>Controlled diseases (0.5 – 0.65 L/ha):</u>	broadcast	BBCH 29-65	1	14	0.5 – 0.65 L/ha	150-195 g	100-400	35	not relevant

				<b>Septoria leaf blotch</b> ( <i>Zymoseptoria tritici</i> ) SEPTTR <b>Powdery mildew of cereals</b> ( <i>Blumeria graminis</i> ) ERYSGR	spraying	Spring, post emergence	a) 1 b) 2		a) 0.65 L/ha b) 1.3 L/ha	a) 195 g b) 390 g			
4	PL	Spring tritcale	F	<u>Controlled diseases (0.5 – 0.65 L/ha):</u> <b>Septoria leaf blotch</b> ( <i>Zymoseptoria tritici</i> ) SEPTTR <b>Powdery mildew of cereals</b> ( <i>Blumeria graminis</i> ) ERYSGR	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant
5	PL	Spring barley	F	<u>Controlled diseases (0.5 – 0.65 L/ha):</u> <b>Net blotch of barley</b> ( <i>Pyrenophora teres</i> ) PYRNTE	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant
6	PL	Winter barley	F	<u>Controlled diseases (0.5 – 0.65 L/ha):</u> <b>Net blotch of barley</b> ( <i>Pyrenophora teres</i> ) PYRNTE	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant
7	PL	Rye	F	<u>Controlled diseases (0.5 – 0.65 L/ha):</u> <b>Powdery mildew of cereals</b> ( <i>Blumeria graminis</i> ) ERYSGR	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g a) 195 g b) 390 g	100-400	35	not relevant
8	PL	Winter oilseed rape	F	<u>Controlled diseases (0.5 – 0.6 L/ha):</u> <b>Dark spot of crucifers</b> ( <i>Alternaria brassicae</i> ) ALTEBA <b>Dry rot of crucifers</b> ( <i>Plenodomus lingam</i> ) LEPTMA <b>Downy mildew of rape</b> ( <i>Hyaloperonospora brassicae</i> ) HPERBR	broadcast spraying	BBCH 13-19 Autumn, post emergence	1 a) 1 b) 1	NA	0.5 – 0.6 L/ha a) 0.6 L/ha b) 0.6 L/ha	150-180 g a) 180 g b) 180 g	100-400	56	<b>not relevant</b> EHL section: against ALTEBA the scheme application with spring treatment is recommended <b>LEPTMA, ALTEBA and HPERBR</b> – accepted one treatment in autumn Recommended dose 0.6 L/ha. <b>Metabolism and residues</b> Not accepted Data gap: magnitude of residues of triazole derivative metabolites (TDMs) in oilseed rape
9	PL	Winter oilseed rape	F	<u>Controlled diseases (0.5 – 0.6 L/ha):</u> <b>Dark spot of crucifers</b> ( <i>Alternaria brassicae</i> ) ALTEBA <b>Cottony rot</b> ( <i>Sclerotinia sclerotiorum</i> ) SCLESC	broadcast spraying	BBCH 61-72 Spring, post emergence	1 a) 1 b) 2	21	0.5 – 0.6 L/ha a) 0.6 L/ha b) 1.2 L/ha	150-180 g a) 180 g b) 360 g	100-400	56	<b>not relevant</b> EHL section: use in the following scheme against ALTEBA "1 appl at BBCH 13-19 at autumn and 1 appl at BBCH 61-72 at spring. Interval between treatments"

													<p>at least 90 days</p> <p>or 2 use twice a season at spring application at BBCH 61-73. Interval between treatments at least 21 days</p> <p>Against SCLESC and ALTEBA only two spring applications are recommended. Recommended dose should be 0.6 L/ha.</p> <p><b>Metabolism and residues</b></p> <p>Not accepted</p> <p>Data gap: magnitude of residues of triazole derivative metabolites (TDMs) in oilseed rape</p>
Minor uses according to Article 51 (Zonal uses)													
10	PL	Spring oilseed rape	F	<p>Controlled diseases (0.5—0.6 L/ha):</p> <p><b>Dry rot of crucifers</b> (<i>Plenodomus lingam</i>) LEPTMA</p> <p><b>Cottony rot</b> (<i>Sclerotinia sclerotiorum</i>) SCLESC</p> <p><b>Dark spot of crucifers</b> (<i>Alternaria brassicae</i>) ALTEBA</p>	broadcast spraying	BBCH 16-69 Spring Post-emergence	a)1 b)2	14-21	0.5—0.6 L/ha a) 0.6 L/ha b) 1.2 L/ha	150-180 g a) 180 g b) 360 g	100-400	56	<p>not relevant</p> <p><b>Eff. section:</b></p> <p>Recommended dose should be 0.6 L/ha.</p> <p><b>Metabolism and residues</b></p> <p>Not accepted</p> <p>Data gap: magnitude of residues of triazole derivative metabolites (TDMs) in oilseed rape</p>

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

### **3 Background of authorization decision and risk management**

#### **3.1 Physical and chemical properties (Part B, Section 2)**

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 an EC formulation.

The intended concentration of use 0.13% v/v to 0.65% v/v.

#### **3.2 Efficacy (Part B, Section 3)**

#### **3.3 Efficacy data**

This dRR was prepared by Applicant for registration of HERA 300 EC (product code: Protiokonazol 300 EC) against SEPTTR and ERYSYGR on winter wheat, winter triticale and spring triticale and against SEPTTR on spring wheat, against PYRNTE on winter and spring barley and ERYSYGR on rye for spring post-emergence use and against ALTEBA, LEPTMA and HIPERBR on winter oilseed rape for autumn post-emergence use and against ALTEBA and SCLESC for spring post-emergence use. Also, in line to Article 51 Applicant would like to register spring post-emergence use against LEPTMA and ALTEBA on spring oilseed rape (as a minor use).

HERA 300 EC (product code: Protiokonazol 300 EC) is an emulsifiable concentrate (EC) containing 300 g/L of prothioconazole.

Prothioconazole is a fungicide belonging to the group of SBI-Class I: Demethylation-Inhibitors (DMI) a subgroup of the Sterol Biosynthesis Inhibitors (SBI)-triazoles. Triazoles are the largest class of fungicides commonly used in medical and agriculture. They were first introduced for crop protection in 1973 by Bayer (triadimefon) [Morton and Staub 2008]. In the following years, the following substances were commercialized further substances from this group, including: tebuconazole [1986], epoxi-conazole [1990] and prothioconazole [2002], which are currently the most widely used [Parker et al. 2014]. The active ingredient is classified after the target site and code FRAC to inhibition of biosynthesis in membrane G1 (group 3): C14-demethylase in sterol biosynthesis. The active ingredient has systemic properties, is very rapidly absorbed into the plant and acropetally distributed in the transpiration stream. This results in both a protective and curative action. The result of the effect of prothioconazole is the abnormal formation of fungal infection structures and a strong inhibition of mycelial growth and spore germination. A penetration of the plant or the seed is thus prevented. The active ingredient is selective on a wide range of dicotyledonous and monocotyledonous crops species. Prothioconazole is used for foliar application and seed treatment.

For now, mentioned active substance (prothioconazole) is on the list of approved active substances. What is important, a large-scale efficacy trials are available to evaluate the effectiveness of products containing this active compound.

All necessary information's about tested PPP, active substance, studied fungal diseases, reference products, etc. are correctly presented in this dRR by Applicant.

In Poland 126 PPPs containing prothioconazole as an active substance are already registered (on the basis on Registry of Plant Protection Products, dated 14.02.2024).

Poland is a ZRMS. The PPP – HERA 300 EC (product code: Protiokonazol 300 EC) by Pestila Spółka z ograniczoną odpowiedzialnością has not been previously evaluated in any county according to Uni-form Principles.

**Preliminary studies:** The active substance of HERA 300 EC (product code: Protiokonazol 300 EC) – prothioconazole is registered and have been commonly used in agricultural practice for many years. Large scale efficacy trials are available to evaluate the effectiveness of products containing this active compound. ZRMs agree with Applicant that preliminary tests are not described and not required in this case.

**MED (minimum effective dose):**

To provide information to establish the minimum effective dose (MED), some of the trials conducted to demonstrate efficacy should include at least two lower dose (s) than recommended one. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in line with EPPO 1/225 (2). Applicant submitted in total 59 trials carried out in 2023 (cereal: winter rye, autumn application in winter oilseed rape), 2022 (cereals: winter wheat, spring wheat, winter triticale, spring triticale, winter barley, spring barley and winter oilseed rape – spring application) and 2021 (winter oilseed rape – autumn application).

Below, ZRMs presented MED assessment for those trials:

- on **winter wheat** against ERYSYGR (5 trials), SEPTTR (8 trials), PUCCSI (3) and PYRNTR (3) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest recommended) and 0.65 L/ha (full N rate). Those trials were performed in PL (N-E EPPO zone) in 2022.
- on **spring wheat** against SEPTTR (2 trials), PUCCSI (1) and PYNTR (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (full N rate). Those trials were performed in PL (N-E EPPO zone) in 2022.
- on **winter triticale** against ERYSYGR (1), SEPTTR (1) and PYRNTR (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (full N rate). Those trials were carried out in PL (N-E EPPO zone) in 2022.
- on **spring triticale** against ERYSYGR (1), SEPTTR (1), PUCCSI (1) and RHYNSE (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (full N rate). Those trials were performed in PL (N-E EPPO zone) in 2022.
- on **winter barley** against PYRNTE (3 trials) and ERYSYGR (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (full N rate). Those trials were performed in PL (N-E EPPO zone) and CZ (Maritime EPPO zone – 1 trial) in 2022. In line to Polish rules, CZ and PL trials were assessed together.
- on **spring barley** against PYRNTE (8 trials), ERYSYGR (1) and PUCCRE (1) three different doses were studied: 0.4 L/ha (0.6N), 0.5 L/ha (the lowest N recommended) and 0.65 L/ha (the full N rate). Those trials were carried out in PL (N-E EPPO zone) in 2022. Also, in 2 trials PUCCRE was studied – due to limited number of trials it was not claimed in GAP, also extrapolating results is not possible.
- on **winter rye** against ERYSYGR (1 trial), SEPTTR (2), PYRNTR (1), RHYNSE (2) and PUCCSI (1) – five different doses were studied: 0,25 L/ha (0.5N), 0.33 L/ha (0.66N), 0.4 L/ha (0.6N), 0.5 L/ha (the lowers N recommended) and 0.65 L/ha (N full rate recommended). Those trials were carried out in PL (N-E EPPO zone) in 2023.
- **spring application on winter oilseed rape** against ALTEBA (7 trials) and SCLESC (9 trials) three different doses were studied: 0.35 L/ha (0.6N), 0.5 L/ha and 0.6 L/ha (full N rate recommended). Those trials were carried out in Poland (N-E EPPO zone) and Czech Republic from Maritime EPPO zone (1 trial) in 2022. In line to Polish rules, CZ and PL trials were assessed together.
- **autumn application on winter oilseed rape** against ALTEBA (6 trials) and LEPTMA (7 trials) three different doses were studied: 0.2 L/ha (0.33N), 0.3 L/ha (0.5N), 0.5 (L/ha) and 0.6 L/ha full N rate recommended). HIPERBR (8 trials) was studied in the following doses: 0.35 L/ha (0.58N), 0.5 L/ha (0.83N) and 0.6 L/ha (N full recommended dose). Those trials were carried out in PL (N-E EPPO

zone) in 2021 and 2023 (against HIPERBR).

### Results for MED (Minimum Effective Dose):

#### – against SEPTTR

Cereal	No. trials	Infestation	Eff. at dose 0.4 L/ha	Eff. at dose 0.5 l/ha	Eff. at dose 0.65 L/ha
winter wheat	8	16.9%	67.6%	82.2%	88.89%
spring wheat	2	23.6%	65.4%	82.7%	90.75%
winter triticale	1	42.4%	58.6%	74.1%	80.8%
spring triticale	1	35.3%	67.4%	81.1%	83.4%

#### – against ERYSYGR

Cereal	No. trials	Infestation	Eff. at dose 0.25 L/ha	Eff. at dose 0.33 L/ha	Eff. at dose 0.4 L/ha	Eff. at dose 0.5 l/ha	Eff. at dose 0.65 L/ha
winter wheat	5	10.82%	n.a.	n.a.	69.78%	82.76%	87.06%
spring wheat	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
winter triticale	1	30.1%	n.a.	n.a.	91.0%	97.0%	100%
spring triticale	1	12.7%	n.a.	n.a.	80.2%	82.9%	89.4%
winter rye	1	6.0%	62.9%	82.5%	n.a.	n.a.	84.5%

#### – against PYRNTE

Cereal	No. trials	Infestation	Eff. at dose 0.4 L/ha	Eff. at dose 0.5 l/ha	Eff. at dose 0.65 L/ha
winter barley	3	6.46%	69.06%	80.1%	87.6%
spring barley	8	18.04%	67.76%	82.59%	90.41%

#### – spring application on winter oilseed rape

Cereal	No. trials	Infestation	Eff. at dose 0.35 L/ha	Eff. at dose 0.5 l/ha	Eff. at dose 0.6 L/ha
ALTEBA	7	6.35%	60.43%	72.47%	83.46%
SCLESC	9	12.7%	61.1%	80.54%	90.32%

#### – autumn application on winter oilseed rape

Cereal	No. trials	Infestation	Eff. at dose 0.2 L/ha	Eff. at dose 0.3 l/ha	Eff. at dose 0.35 L/ha	Eff. at dose 0.5 L/ha	Eff. at dose 0.6 L/ha
ALTEBA	5	9.66%	62.56%	76.12%	n.a.	n.a.	91.02%
	1	6.80%	n.a.	79.0%	n.a.	89.0%	
LEPTMA	6	14.72%	20.88%	57.66%	n.a.	n.a.	86.32%
	1	6.90%	n.a.	70.0%	n.a.	94.0%	
HIPERBR	8	7.65%	n.a.	n.a.	66.6%	79.67%	87.39%

<60% eff.

60-80% eff

>80% eff.

Results reveal a positive dose response to increasing amounts of the test products. In many cases HERA 300 EC (product code: Protiokonazol 300 EC) was significantly more effective at full dose (0.65 L/ha for cereals and 0.6 L/ha for winter oilseed rate) than at the reduced rates (60% for cereals or 33% and 50% in winter oilseed rape). However dose 0.5 L/ha in cereal against fungal diseases was characterized also by good efficiency. So, both doses in cereals (0.5 and 0.65 L/ha ) should be recommended for use. Dose 0.5 L/ha used in winter oilseed rape (at spring and autumn application) was characterized by lower efficiency than dose 0.6 L/ha. In the opinion of ZRMs dose 0.5 L/ha should not been recommended for winter oilseed due to lower efficacy at autumn application against HIPERBR (ME-0.5 L/ha and E at 0.6 L/ha) and ALTEBA in spring application (0.5 L/ha-ME, 0.6 L/ha –E). Against ALTEBA and LEPTMA at autumn application – dose 0.5 L/ha was studied only in one trial so it is very difficult to make right conclusions. Only against SCLESC the efficacy between dose 0.5 L/ha and 0.6 L/ha was comparable.

**It can be concluded that the dose rate of 0.5 -0.65 L/ha should be recommended for cereals against SEPTTR (winter and spring wheat, winter and spring triticale), ERYSYGR (winter wheat, winter and spring triticale) and PYRNTE (winter and spring barley). It can be concluded that dose 0.6 L/ha should be recommended for winter oilseed rape for spring application against ALTEBA and SCLESC and autumn application against ALTEBA, HIPERBR and LEPTMA.**

### **Efficacy:**

Justification for the use of biological efficacy data included in this dossier is made in line to EPPO



1/241(2) "Guidance on comparable climates". All trials carried out in the respective EPPO zones can be extrapolated to each country belonging to this agro-climatic EPPO zone. Moreover, trials conducted at the border of one country are relevant for the neighbouring country. All presented trials can be therefore relevant for a submission in the Central Regulatory Zone. However, in the opinion of ZRMs for extrapolating results always should be presented weather and agro-technical conditions. For example, Poland can use results from neighbouring countries (ex. CZ) but results from other countries and other EPPO zones are not acceptable. Each country can have its own rules, so in the opinion of ZRMs decision about use results or extrapolating results should be made on cMS level.

Trials were conducted according to EPPO guidelines, for example with: 1/135 (4), 1/152 (4), 1/26 (4) and 1/78 (3). The GEP certificates of the official testing organizations were provided. EPPO standard PP 1/226 *Number of efficacy trials* provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization zone (PP 1/278 *Principles of zonal data production and evaluation*), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

Details of experiment are presented above by Applicant. All used methodology is in line with GEP rules, except for EPPO 1/181 (4). Spring cereals: wheat, barley, triticale (2022) and winter cereals: wheat, barley, triticale (2022) and spring application on winter oilseed rape (2022) were studied only in one growing season. Winter rye was characterized by studies conducting in two growing seasons (2022 and 2023) and autumn application on winter oilseed rape (2021 and 2023). In the opinion of ZRMs, this extension (for spring cereals and winter wheat, winter barley, winter triticale and spring application on winter oilseed rape) can be acceptable. Especially when prothioconazole is known as a fungicide for many years and commonly used. Applicant presented explanation as (accepted by ZRMS) for conducting field trials only in one growing season.

**Cereals:** The level of plant infestation in the studied area was recorded directly before the first application of the product by % severity or % incidence. As in most trials % of severity was assessed this parameter was used in the tables presented by Applicant above. The design of the trial was a randomized complete block (with 4 replicates) with included untreated plots. Disease control % - estimate the mean % area of specified leaves (separately for individual leaves, e.g. L-1 flag leaf, L-2 – flag leaf minus 1; L-3 – flag leaf minus 3; etc.) affected by individual diseases, on a minimum of 20 tillers per plot selected at random and recorded separately to allow for calculation of disease incidence/severity. So, mean percentage (%) control based on diseases incidence/severity on leaves compared to untreated plots. Two full efficacy assessments were done: at application B and 14-21 days after application B. Green leaf index % was also assessed - Estimate the mean % green leaf area on 20 randomly selected plants per plot on leaf L-1 (flagleaf). In the opinion of ZRMs, this methodology is in line to EPPO 1/26. Efficacy after first application was not noted.

**Winter oilseed rape:** Disease control % - leaf infection: Estimate the mean % area of plant, from the leaf layer with average infection, affected by individual diseases, derived from a minimum of 25 plants per plot, on an overall plot basis. Disease control % - stem infection Estimate the mean % area of stem, affected by individual diseases, derived from a minimum of 25 plants per plot, on an overall plot basis. Disease control % - pod infection Estimate the mean % area of pod, affected by individual diseases, derived from a minimum of 25 plants per plot, on an overall plot basis. For autumn application against ALTEBA (6 trials), HIPERB (8 trials) and LEPTMA (7 trials) only one application was studied. For spring application two application were studied against ALTEBA (7 trials), LEPTMA (2 trials) and SCLESC (9 trials). Efficacy after one spring application was assessed only in 2 trials against ALTEBA (020GPSE202201 and 020GPSE202202), 2 trials against LEPTMA (020GP202201 and 020GP202202) and one trial against SCLESC (020GP202202). Assessed after two spring application was made in all trials.

Applicant submitted in total 59 efficacy trials showing the results in research into product efficacy: 10 trials were carried out on winter wheat, 2 trials – spring wheat, 2 trials – winter triticale, 2 trials – spring triticale, 9 trials – spring barley, 3 trials – winter barley, 5 trials – rye and 16 trials – winter oilseed rape. Major crops should be represented by sufficient number of trials. Only for winter wheat (10), spring barley (9) and winter oilseed rape (16) – Applicant presented enough number of trials. Rest of crops claimed

in the GAP table can be accepted on the basis on extrapolating results from winter wheat to spring wheat (2), winter triticale (2) and spring triticale (2). Also, winter barley (2 trials) can be accepted in line to extrapolate results from spring barley and winter rye (5 trials) on the basis on extrapolated results from winter wheat.

Following varieties were studied during trials: **winter wheat** – Formacja (1), Linus (1), Euforia (1), Arkadia (4), Astoria (2), Hondia (1); **spring wheat**: Harenda (1), Arabella (1); **spring triticale** – Milewo (1), Mamut (1); **winter triticale**: Grenado (1), Lombardo (1); **spring barley** – Radek (1), Melius (1), Ela (1), Etoile (2), Penguin (1), Pilote (1), Saldo (1), Ella (1); **winter barley**: Zenek (1), KWS Kosmos (1), Sonnegold (1); **winter rye**: KWS VI Netto F1 (1), KWS Serafino (1), KWS Delaro (1), Stanko (1), Antonińskie (1) and **winter oilseed rape (autumn application)** – ES Imperio (1), Derrick (1), Kuga F1(1), KWS Marcopolo (1), Duke F1 (1), Absolut (1), Anabella (1), Arganos (1), Sienna (1), Hevelius (1), Nelson (1), Factor KWS F1 (1), Uniwersum (1), Kadore (1), Chopin (1), SY Ilona (1) and **winter oilseed rape (spring application)** – LG Ambassador F1 (1), Derrick (1), Anabella (1), Architekt (1), Kepler (1), Duke F1 (1), KWS Marcopolo (1), Ilona (1) and Kadore (1).

Following BBCH window were studied during trials: **autumn application on winter oilseed rape** – BBCH 13-17; **spring application on winter oilseed rape** – BBCH 61-72; **winter wheat** – BBCH 16-65; **spring wheat**: BBCH 31-47; **winter triticale** – BBCH 39-49; **spring triticale** – BBCH 32-61; **winter barley** – BBCH 37-61; **spring barley** – BBCH 29-65, **winter rye** – BBCH 33-61. **In the opinion of ZRMS proposed by Applicant application window for cereals: BBCH 29-65, spring application in winter oilseed rape (BBCH 61-72) and autumn application in winter oilseed rape (BBCH 13-19) can be accepted on the basis on submitted documentation.**

Following water volume were studied during trials: **autumn application on winter oilseed rape** –100-400 L/ha; **spring application on winter oilseed rape** – 200-300 L/ha; **winter wheat** – 200-300 L/ha; **spring wheat**: 200-300 L/ha; **winter triticale** – 200-300 L/ha; **spring triticale** – 200-300 L/ha; **winter barley** – 200-300 L/ha; **spring barley** – 200-300 L/ha; **winter rye** – 300 L/ha. **In the opinion of ZRMs, proposed by Application window can be accepted on the basis on submitted documentation and plant protection programs.**

Following plot size were studied during trials: **autumn application on winter oilseed rape** – 19,5 – 30 m<sup>2</sup>; **spring application on winter oilseed rape** – 19,5-30m<sup>2</sup>; **winter wheat** – 19,5-30m<sup>2</sup>; **spring wheat** – 30 m<sup>2</sup>; **winter triticale** –30 m<sup>2</sup>; **spring triticale** – 24m<sup>2</sup>; **winter barley** –24.3-27m<sup>2</sup>; **spring barley** – 24-30m<sup>2</sup>; **winter rye** – 19.5-30m<sup>2</sup>. **Plot size used during trials was accepted as in line to appropriate EPPO standards (1/78 and 1/26).**

We are dealing with the active substance commonly used for many years in many countries. We must emphasize that each pest should be represented by sufficient number of field efficacy trials (at least 6 for major pest and at least 3 for minor pest). All fungal diseases claimed in GAP table are major for cereals and winter oilseed rape.

Against SEPTTR (8 trials) on winter wheat Applicant submitted enough number of trials. Also use against SEPTTR can be accepted on winter triticale (1 trial), spring triticale (1 trial) and spring wheat (2 trials) by extrapolating results from winter wheat (8). SEPTTR was also studied in 2 trials carried out on winter rye. However, in line to Polish extrapolating tables it is not allowed to extrapolate results from winter wheat to rye. So, this use was correctly not included in the GAP by Applicant.

Applicant submitted only 5 trials against ERYSYGR on winter wheat. In the opinion of ZRMs, limited number of trials against ERYSYGR can be accepted **conditionally**. Prothioconazole is a quite old active substance used commonly in PPPs used on cereals. So, its efficacy is already known against ERYSYGR. **In order to reduce the number of trials, it is necessary to conduct research over two growing seasons. Unfortunately, the Applicant has only submitted results for one season and therefore only a conditional registration is possible against ERYSYGR on winter wheat. Within 24 months of receiving the registration, the Applicant should submit the missing study, which should be conducted either in the North-Eastern Zone or in a neighbouring country.** Use against ERYSYGR should be accepted also on winter triticale (1 trial), spring triticale (1 trial) by extrapolating results from winter wheat (5). ERYSYGR was also studied in 1 trial carried out on spring barley and 1 trial on winter barley. However, in line to Polish extrapolating tables it is not allowed to extrapolated results from winter wheat to winter barley and spring barley. So,

this use was correctly not included in the GAP by Applicant.

PUCCSI (winter wheat: 3 trials, spring wheat: 1 trial, spring triticale: 1 trial, winter rye: 1 trial), PYRNTR (winter wheat: 3 trials, spring wheat: 1 trial, winter triticale: 1 trial, winter rye: 1 trial), PUCCRE (spring barley: 1 trial) and RHYNSE (spring triticale: 1 trial, winter rye: 2 trials) were not represented by enough number of trials. So, those uses were correctly not included in the GAP table by Applicant.

Applicant submitted enough number of trials for spring application on winter oilseed rape against ~~LEPTMA~~ ALTEBA (7 trials) and SCLESC (9 trials). LEPTMA should be excluded due to not enough number of trials (only 2 were presented, whilst at least 6 should be assessed).

Applicant submitted sufficient number of trials against PYRNTE on spring barley (8 trials). Use against PYRNTE can be also accepted on spring barley (3 trials) by extrapolating results between those crops.

Applicant submitted accepted number of trials against LEPTMA (7 trials), ALTEBA (6 trials) and HIPERBR (8 trials) for autumn application.

Lack of trials against LEPTMA, SCLESC and ALTEBA on spring oilseed rape for spring application. However, spring oilseed rape is a minor use, so it can be accepted in line to Article 51 as already Applicant claimed.

The following efficacy scale was used:

- L – limiting (0-60% efficacy) <60% eff.
- ME – moderately efficiency (60-80%) 60-80% eff
- E – effectively (80%) >80% eff.

All trials were characterized by sufficient level of infestation (at least 5%).

Below, ZRMs presented results for studied fungal diseases in cereals and winter oilseed rape:

– against SEPTTR

Cereal	No. trials	Infestation	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	8	16.9%	67.6%	82.2%	88.89%	86.70%
spring wheat	2	23.6%	65.4%	82.7%	90.75%	89.85%
winter triticale	1	42.4%	58.6%	74.1%	80.8%	77.80%
spring triticale	1	35.3%	67.4%	81.1%	83.4%	83.10%

All trials were characterized by sufficient level of infestation. In the opinion of ZRMs use against SEPTTR can be accepted on winter wheat (enough number of trials), spring wheat (by extrapolating results from ww), winter triticale (by extrapolating results from ww) and spring triticale (by extrapolating results from ww). HERA 300 EC effectively control SEPTTR on winter cereals (wheat, triticale) and spring cereals (wheat, triticale) at dose 0.5 L/ha and 0.65 L/ha. Higher dose should be used only in case of high fungal disease pressure. Results of tested HERA 300 EC were comparable to st. ref. product (Poleposition 300 EC) or even higher (in winter triticale).

– against ERYSYGR

Cereal	No. trials	Infestation	Hera 300 EC at dose 0.25 L/ha	HERA 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	Hera 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha	Protendo 300 EC at dose 0.65 L/ha
winter wheat	5	10.82%	n.a.	n.a.	69.78%	82.76%	87.06%	85.56%	n.a.
spring wheat	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
winter triticale	1	30.1%	n.a.	n.a.	91.0%	97.0%	100%	100%	n.a.
spring triticale	1	12.7%	n.a.	n.a.	80.2%	82.9%	89.4%	90.40%	n.a.
winter rye	1		62.9%	82.5%				84.5%	80.5%

All trials were characterized by sufficient level of infestation. In the opinion of ZRMs use against ERY-SYGR can be accepted **conditionally** on winter wheat (accepted limited number of trials **if Applicant present missing one trial (optimally two trials) within 24 months after authorisation the product**), winter triticale (by extrapolating results from ww), spring triticale (by extrapolating results from ww) and winter rye (by extrapolating results from ww). HERA 300 EC effectively control ERYSYGR on winter cereals (wheat, triticale, rye ) and spring cereals (triticale) at dose 0.5 L/ha and 0.65 L/ha. Higher dose should be used only in case of high fungal disease pressure. Results of tested HERA 300 EC were comparable to st. ref. product (Poleposition 300 EC). Use on spring wheat against ERYSYG is not accepted due to lack of trials.

– **against PYRNTE**

Cereal	No. trials	Infestation	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter barley	3	6.46%	69.06%	80.1%	87.6%	89.13%
spring barley	8	18.04%	67.76%	82.59%	90.41%	88.81%

All trials were characterized by sufficient level of infestation. In the opinion of ZRMs use against PYRNTE can be accepted on spring barley (enough number of trials) and winter barley (by extrapolating results from spring barley). HERA 300 EC effectively control PYRNTE on winter barley and spring barley at dose 0.5 L/ha and 0.65 L/ha. Higher dose should be used only in case of high fungal disease pressure. Results of tested HERA 300 EC were comparable to st. ref. product (Poleposition 300 EC).

– **spring application on winter oilseed rape**

Cereal	No. trials	Infestation	HERA 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Poleposition 300 EC at dose 0.6 L/ha
ALTEBA	7	6.35%	60.43%	72.47%	83.46%	81.27%
SCLESC	9	12.7%	61.1%	80.54%	90.32%	88.56%

All trials were characterized by sufficient level of infestation. In the opinion of ZRMs use against ALTEBA and SCLESC can be accepted for spring application on winter oilseed rape. HERA 300 EC effectively control ALTEBA and SCLESC on winter oilseed rape at dose 0.6 L/ha. Results of tested HERA 300 EC were comparable to st. ref. product (Poleposition 300 EC at dose 0.6 L/ha).

– **autumn application on winter oilseed rape**

Cereal	No. trials	Infestation	HERA 300 EC at dose 0.2 L/ha	HERA 300 EC at dose 0.3 l/ha	Hera 300 EC at dose 0.35 L/ha	Hera 300 EC at dose 0.5 L/ha	HERA 300 EC at dose 0.6 L/ha	Promino 300 EC at dose 0.6 L/ha	Tauron 240 EC at dose 0.75 L/ha
ALTEBA	5	9.66%	62.56%	76.12%	n.a	n.a	91.02%	87.88%	n.a
	1	6.80%	n.a.	79.0%	n.a	89.0%	97.0%	99.0%	n.a
LEPTMA	6	14.72%	20.88%	57.66%	n.a	n.a	86.32%	84.03%	n.a
	1	6.90%	n.a	70.0%	n.a	94.0%	100%	100%	n.a
HIPERBR	8	7.65%	n.a.	n.a.	66.6%	79.67%	87.39%	n.a.	85.5%

All trials were characterized by sufficient level of infestation. For HIPERBR, ALTEBA and LEPTMA – Applicant submitted enough number of trials. HERA 300 EC effectively control ALTEBA, LEPTMA and HIPERBR on winter oilseed rape at dose 0.6 L/ha. Results of tested HERA 300 EC were comparable to st. ref. product (Promino 300 EC at dose 0.6 L/ha against LEPTMA and ALTEBA and Tauron 240 EC at dose 0.75 L/ha against HIBERBR). Dose 0.5 L/ha should not been recommended – HIBERBR at 0.5 L/ha was ME and efficacy against ALTEBA and LEPTMA is difficult to concluded only on the basis on 1 trial with studied dose 0.5 L/ha.

**Summary:** It can be concluded that the dose rate of 0.5 -0.65 L/ha should be recommended for cereals against SEPTTR (winter and spring wheat, winter and spring triticale), ERYSYGR (winter wheat, winter and spring triticale, winter rye) and PYRNTE (winter and spring barley). It can be concluded that dose 0.6 L/ha should be recommended for winter oilseed rape for spring application against ALTEBA and SCLESC and autumn application against ALTEBA, HIPERBR and LEPTMA. Use on spring oilseed rape against LEPTMA, SCELSC and ALTEBA can be accepted in line to Article 51 without any submitted trials. HERA 300 EC applied twice a season effectively controlled studied fungal diseases **on cereals and**



winter oilseed rape in spring against ALTEBA and SCLESC. Hera 300 SC applied once a season in autumn effectively control ALTEBA, HIPERBR and LEPTMA on winter oilseed rape. What is important, use against ALTEBA can be done only in autumn (once) or in spring (twice application).

HERA 300 EC contain only one active substance (prothioconazole) so risk of developing resistance is high in the case of multiple application (even only two per season). Applicant would like to register HERA 300 EC (product code: Protiokonazol 300 EC) for applied max 2 times per season for cereals and spring application on winter oilseed rape and for use once a season in case of autumn application on winter oilseed rape.

The products registered in Poland for the protection of winter oilseed rape based exclusively on prothioconazole, which are intended for use in autumn and spring, are recommended for two treatments only: one treatment in autumn and one treatment in spring or two treatments in spring [early spring and full spring], and, taking this into account the currently evaluated study package (not enough number of trials with evaluated efficacy from one spring application), it would be appropriate to consider recommending the use of the product in question either only in autumn (one treatment) or only in spring (two treatments).

We should remember that repeated application for cereals of DMI or amine fungicides alone should not be used on the same crop in one season against risky pathogens (e.g. cereal powdery mildews, barley net blotch, scald) in areas of high disease pressure for that particular pathogen. Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen in winter oilseed crops. **So, in line to resistance strategy Applicant proposed to included following entry in the label at point PRECAUTIONS AND SPECIFIC CONDITIONS OF USE:**

*<sup>1)</sup> With recommendations of resistance strategy in mind, it would be reasonable to limit the use of the product to one treatment on cereals per season against powdery mildew and barley net blotch[or the second treatment should already be carried out with a product containing a fungicide from another FRAC group – with a different mechanism of action.*

*<sup>2)</sup> If only one treatment is planned in the adopted protection programme HERA 300 EC, in order to achieve satisfactory efficacy this treatment should be carried out as a preventative measure.*

Also it is important to not use HERA 300 EC more than twice a season on the winter oilseed rape. So, ZRMs proposed application scheme for HERA 300 EC against ALTEBA:

Apply the product according to one of the two application schedules given below.

**1) use once at autumn application at BBCH 13-19 ~~and use once for spring application at BBCH 61-72.~~**

Timing of application of the product:

- ✓ ~~Apply~~ **one treatment (autumn):** carry out treatment from the third leaf stage to the nine leaf stage or more (BBCH 13-19). Apply the product as a preventative measure or as soon as the first signs of disease are observed.

- ~~✓ **second treatment (spring):** carry out treatment from the beginning of flowering (open 10% of flowers on main inflorescence) to fruit development (Approximately 10% of the canes have reached typical size) as a preventative measure or as soon as the first symptoms of the disease are observed.~~

or

**2) use twice per season for spring application at BBCH 61-72. Use as a preventive measure or as soon as the first signs of disease are visible, from the stage of 61 to 72 BBCH.**

HERA 300 EC is recommended for a single autumn application against HIPERBR and LEPTMA at BBCH 13-19. HERA 300 EC against ALTEBA should be applied once in autumn at BBCH 13-19 or ~~and double~~ **twice in spring application against SCLESC at BBCH 61-72 on winter oilseed rape. Control against SCLESC can be done only by twice applications of HERA300 EC in spring.**

### 3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Applicant did not present the information on the occurrence or possible occurrence of the development of resistance in line to appropriate EPPO standard. So, for this reason ZRMs presented below widely characteristic of resistance against prothioconazole in cereals and rapeseed crops.

The risk of resistance to fungicides containing prothioconazole depends on various factors, including the type of pathogens, environmental conditions, agricultural practices, and the frequency of fungicide application. Prothioconazole is used against fungal diseases in agricultural crops such as wheat, corn, rapeseed, and fruits.

To minimize the risk of resistance development, it is recommended to implement diversified strategies for managing fungal diseases.

Here are some general recommendations:

- **Fungicide Rotation:** Avoid using the same fungicides from the same chemical group too frequently. Rotating different active substances can reduce pressure on pathogens and decrease the risk resistance.
- **Use of Mixtures:** Choose fungicides that contain combinations of different active substances. Mixtures may have a broader spectrum of action and can be more effective in preventing resistance.
- **Integrated Pest Management (IPM):** Implement strategies for managing fungal diseases within an overall IPM program, which may include field monitoring, use of resistant varieties, improvement of air circulation, proper fertilization, and other cultivation practices.
- **Education and Monitoring:** Regularly monitor fields for the presence of pathogens and assess the effectiveness of applied fungicides. Educate farmers and sustainable management practices.

It is also important for farmers to consult with local plant protection specialists and adhere to fungicide label recommendations and guidelines for resistance management.

The mode of action of prothioconazole is stated to be demethylation inhibition (DMI). Resistance to DMI fungicides has been found for several pathogens including *Erysiphe graminis tritici*. The ZRMs considers the risk of resistance developing is high for powdery mildew of cereals (*Blumeria graminis*) and net blotch of barley (*Pyrenophora teres*) and is a moderate for septoria leaf blotch (*Zymoseptoria tritici*) for DMI fungicides including prothioconazole. A series of sensitivity studies have been carried throughout Europe to establish the baseline sensitivity of cereal mildew, net blotch leaf spot. In addition, a study was conducted to demonstrate cross-resistance between prothioconazole and a DMI fungicide for a range of cereal diseases.

Prothioconazole could be applied as a seed treatment and as a foliar spray to the same crop. However, the dose of prothioconazole applied in the seed treatment is low and would not be expected to produce significant selection of less sensitive strains of leaf, stem and ear diseases of cereals proposed for the spray formulation.

Prothioconazole is well known [cf. The Pesticide Manual, Fifteenth Edition, C.D.S. Tomlin (Ed.), 2009, BCPC Publications] as fungicide. Triazole fungicides including the fungicide Prothioconazole are well known as sterol biosynthesis inhibitors, see FRAC classification (FRAC website <http://www.frac.info/>), in particular subgroup 3 (legacy G1). It is in particular known that triazoles fungicides including the fungicide Prothioconazole are inhibitors of fungal sterol C14 demethylase cyp51, which is a cytochrome P450 monooxygenase. However, so far the use of triazoles fungicides and in particular of the fungicide Prothioconazole as host defence inducer has never been reported before. The effect that Prothioconazole induces host defence responses and accumulation of salicylic acid is the more surprising since other triazole fungicides known as sterol biosynthesis inhibitors show a less substantial host defence response inducement and SA accumulation inducement.

**Specific Recommendations by Crop / Pathogen for DMIs, Amines and KRIs**  
**(<https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi>):**

✓ **Cereals – DMIs and Amines:**

- The recommendations for the use of DMI and amine fungicides in mixture or alternation programmes with different mode of action fungicides remain unchanged. It needs to be emphasized that it is essential for resistance management purposes to follow strictly the manufacturer's and FRAC recommendations.
- Repeated application of DMI or amine fungicides alone should not be used on the same crop in one season against risky pathogens (e.g. cereal powdery mildews, barley net blotch, scald) in areas of high disease pressure for that particular pathogen.
- Reduced rates of DMIs can contribute to accelerate the shift to less sensitive populations. It is critical to use effective rates of DMIs in order to ensure robust disease control and effective resistance management. DMIs must provide effective disease control and be used at manufacturers' recommended rates.
- When used in mixture, recommended effective rates of the SBI must be maintained.
- Split and reduced rate programmes, using multiple repeated applications at dose rates below manufacturer's recommendations, provide continuous selection pressure and accelerate the development of resistant populations, and therefore must not be used.
- To ensure good performance and particularly resistance management in situations of even low disease pressure, it is essential to adhere to dosages and spray timings as recommended by manufacturers. Curative applications should be avoided. Application timing has to be appropriate to all mix partners' characteristics. Mixing with a non-cross resistant fungicide at effective dose rates contributes to a more effective disease control and resistance management.
- The amine fungicides are effective non-cross-resistant partner fungicides for DMIs on cereals for the control of pathogens included in the label recommendation of each respective product.
- Ramularia leaf spot (*Ramularia collo-cygni*) in barley: Given that there already exist populations of *Ramularia collo-cygni* in Europe resistant to all main site-specific modes of actions it is recommended to add precautionary a multi-site to ensure robust disease control and an effective resistance management in barley

✓ **Oilseed rape (general recommendations)**

- The SBI fungicides represent one of the most potent classes of fungicides available to the grower for the control of many economically important pathogens. It is in the best interest of all those involved in recommending and using these fungicides that they are utilised in such a way that their effectiveness is maintained
- The working group concentrates its resources on the major crop/pathogen targets from the point of view of resistance risk. Inevitably many, still important pathogens are omitted. To help in making recommendations for crops and pathogens not directly covered, the following general recommendations can be made:
- Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- For crop/pathogen situations where repeated spray applications (e.g. orchard crops/powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non cross-resistant fungicide are recommended (see FRAC Code List on Download Page).
- Where alternation or the use of mixtures is not feasible because of a lack of effective or compatible non cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.
- If the performance of SBIs should decline and sensitivity testing has confirmed the presence of less sensitive isolates, SBIs should only be used in mixture or alternation with effective non cross-resistant partner fungicides.
- The introduction of new classes of chemistry offers opportunities for more effective resistance management. The use of different modes of action should be maximized for the most effective resistance management strategies.

- Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended use rates, or to poorly timed applications.
- Fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation, etc.
- Exclusive frequency measurements of single cyp51 mutations are not sufficient to describe the sensitivity situation towards DMIs but can help to better understand the background of sensitivity shifts.

SBI fungicides have been characterized by FRAC (<http://www.frac.info>) as medium risk resistance but as pathogens have different risk levels, combination of both fungicide and pathogen resistance risk should also be investigated.

Diseases vary in their sensitivity towards fungicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. DMI fungicides have been tested and used worldwide for up to 30 years (or more), it is therefore difficult to find unexposed fungal populations. No true base line sensitivity data can therefore be established. FRAC has been monitoring the development in sensitivity in the most important diseases for a number of years.

In terms of agronomic practice, the selection pressure on the intended disease target for HERA 300 EC (product code: Protiokonazol 300 EC) may be medium to high in annual cereal crops like wheat (depending on whether a successful crop rotation system is applied or mono-cropping is carried out in the crop, respectively). The agronomic risk for HERA 300 EC is estimated as medium for prothioconazole.

The resistance management is coordinated by FRAC recommendation. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

As part of a resistance management strategy, it is recommended to:

- Do not apply the product at rates lower than dose recommended in the label;
- Use the product interchangeably with fungicides containing active ingredients from other chemical groups with a different mode of action;
- Apply the product a maximum of 2 times per growing season, in rotation with other fungicides containing active substances belonging to other groups according to the FRAC classification, with different mechanism of action FRAC classification, with a different mechanism of action;
- Adjust the dosage according to the level of disease severity or their predicted severity on the protected crop;
- Monitor the effects of the treatments performed.

**In line to resistance strategy against powdery mildew and barley net blotch, ZRMs proposed following entry to label in the point of PRECAUTIONS AND SPECIFIC CONDITIONS OF USE:**

*<sup>1)</sup> With recommendations of resistance strategy in mind, it would be reasonable to limit the use of the product to one treatment on cereals per season against powdery mildew in cereals and barley net blotch[or the second treatment should already be carried out with a product containing a fungicide from another FRAC group – with a different mechanism of action.*

*<sup>2)</sup> If only one treatment is planned in the adopted protection programme HERA 300 EC, in order to achieve satisfactory efficacy this treatment should be carried out as a preventative measure.*

### **3.3.2 Adverse effects on treated crops**

Both EY Directive 9EU, 1991) and EPPO PP 1/226 – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 – Phytotoxicity assessment states: "EPPO Standards on fungicides, insecticides and plant growth regulators, on the other hand, include only a relatively simple special section on phytotoxicity as-assessment, because, for these



types of plant protection products, phytotoxic effects will be less frequent'. Selectivity trials were not required, which is in accordance with EPPO 1/135 (3)."

The crop safety of applying HERA 300 EC (product code: Protiokonazol 300 EC) at recommended dose of 0.5-0.65 L/ha for cereals and 0.6 L/ha for winter oilseed rape (spring and autumn application).

Applicant presented efficacy trials in which phytotoxic effect was assessed and an assessment of the impact on the yield and its quality has been carried out. Trials for winter wheat, spring wheat, winter triticale, spring triticale, spring barley, winter rye, winter oilseed rape (autumn and spring application) were carried out in Poland (N-E EPPO zone). Trials from winter barley were performed in CZ (1 trial) and PL (2 trials) and for winter oilseed rape for spring application in CZ (1 trial) and PL (9 trials).

- ✓ **Winter wheat:** 10 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ✓ **Spring wheat:** 2 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ✓ **Winter triticale:** 2 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ✓ **Spring triticale :** 2 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ✓ **Winter barley:** 3 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ✓ **Spring barley:** 9 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.5-0.65 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ✓ **Winter rye:** 5 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates and st. ref. product (at dose 0.6 L/ha). Dose 0.5-0.65 L/ha was studied in 2 trials. During 2 trials doses: 0.25 L/ha; 0.33 L/ha and 0.65 L/ha was studied.
- ✓ **Winter oilseed rape (autumn application):** 16 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.6 L/ha) and st. ref. product (at dose 0.6 L/ha).
- ✓ **Winter oilseed rape (spring application):** 10 trials. No symptoms of phytotoxicity were observed on the plots treated with the tested product: HERA 300 EC at the recommended rates (0.6 L/ha) and st. ref. product (at dose 0.6 L/ha).

**Summary:** No phytotoxicity symptoms assessed in terms of general injury (PHYGEN) caused by HERA 300 EC (product code: Protiokonazol 300 EC) at the proposed rate (0.5-0.65 L/ha for cereals and 0.6 L/ha for winter oilseed rape) in efficacy trials were recorded in all trials (59). Those results were comparable to standard reference products.

For Poland, documentation is sufficient for registration HERA 300 EC for use on winter cereals (wheat, triticale, barley, rye) and spring cereals (wheat, triticale, barley) and winter oilseed rape. Lack of trials for spring oilseed rape is accepted as its registration is on the basis on the Article 51 (as a minor crop).

**In conclusion, no negative influence of the product HERA 300 EC (product code: Protiokonazol 300 EC) is to be expected when at the intended rate and used according to the label recommendations.**

**Effect on the yield:**

- ✓ **Cereals:** Yield was studied during efficacy trials (59). Below, ZRMs presented results for each crop and each dose studied. The yield must be specified or, if it is not specified, it is necessary to provide justification. The fresh weight content and moisture content of the harvested grain. The yield should be calculated in t/ha or dt/ha according to the established level of moisture content (specified national standard or international) and is compared to the yield obtained for the control object or preparation comparison in line to EPPO 1/26.

*Yield (t/ha) noted in efficacy trials on fungal diseases on winter and spring cereals*

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.25 L/ha	Hera 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	10	6.63	n.a	n.a	6.80	6.97	7.05	6.95
spring wheat	2	4.89	n.a	n.a	5.29	5.01	5.08	5.14
winter triticale	2	6.72	n.a	n.a	6.89	6.77	6.89	7.02
spring triticale	2	4.89	n.a	n.a	5.29	5.01	5.08	5.14
winter rye	2	6.52	n.a	n.a	7.20	7.00	7.25	7.06
	3	5.88	6.07	6.16	n.a	n.a	6.22	6.23
winter barley	3	7.73	n.a	n.a	8.16	8.13	8.26	8.26
spring barley	9	4.58	n.a	n.a	4.89	5.00	5.23	5.06

Hera 300 EC at the proposed label rate had positive effect on the yield on the studied cereals. Hera 300 EC is assumed to have no negative effects on the yield of treated plants. Results were compared to untreated control and st. reference product.

- ✓ **Winter oilseed rape:** Recording yields can be useful. For make it easier to harvest the crop and reduce losses, you should divide the rows before the 71-78 developmental stage on the BBCH. The yield should be calculated in kg ha<sup>-1</sup> according to the established moisture level (according to national or international standards), and in relative to a control plot or preparation comparison. Useful information can also be obtained by measuring the weight of 1,000 grains (g) and measuring oil content. In line to EPPO 1/78.

*Yield (t/ha) noted in efficacy trials on fungal diseases on winter oilseed rape (spring application)*

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (spring application)	10	3.15	3.38	3.47	3.57	3.49

Hera 300 EC at the proposed label rate had positive effect on the yield on the studied winter oilseed rape (spring application). Hera 300 EC is assumed to have no negative effects on the yield of treated plants. Results were compared to untreated control and st. reference product.

*Yield (t/ha) noted in efficacy trials on fungal diseases on winter oilseed rape (autumn application)*

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.2 L/ha	HERA 300 EC at dose 0.3 l/ha	HERA 300 EC at dose 0.6 L/ha	Promino 300 EC at dose 0.6 L/ha
winter oilseed rape (autumn application)	6	3.63	3.66	3.63	3.63	3.65

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.3 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Poleposition 300 EC at dose 0.6 L/ha
winter oilseed rape (autumn application)	2	3.54	3.52	3.67	3.82	3.79

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Tauron 240 EC at dose 0.75 L/ha
winter oilseed rape (autumn application)	8	3.77	3.94	3.88	3.97	3.95

Hera 300 EC at the proposed label rate had positive effect on the yield on the studied winter oilseed rape (autumn application). Hera 300 EC is assumed to have no negative effects on the yield of treated plants. Results were compared to untreated control and st. reference product.

**In conclusion, no negative impact of the product – Hera 300 EC (product code: Protiokonazol 300 EC) on the yield is to be expected when applied at the intended rate and used according to the label recommendation's.**

#### **Effect on quality of yield:**

Quality of yield was assessed during 59 efficacy trials. Below, ZRMs presented results for each crop and each dose studied for quality of yield.

#### **✓ Cereals:**

#### ***Moisture (%) noted in efficacy trials on fungal diseases on winter and spring cereals***

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.25 L/ha	Hera 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	10	13.025	n.a.	n.a.	13.013	13.073	13.098	13.043
spring wheat	2	12.35	n.a.	n.a.	12.35	12.35	12.30	12.20
winter triticale	2	11.55	n.a.	n.a.	11.65	11.55	11.60	11.55
spring triticale	2	12.25	n.a.	n.a.	12.35	12.40	12.35	12.20
winter rye	2	14.70	n.a.	n.a.	14.80	14.80	14.85	14.80
	3	13.01	13.1	13.11	n.a.	n.a.	13.22	13.03
winter barley	3	12.67	n.a.	n.a.	12.20	12.10	12.20	12.20
spring barley	9	12.31	n.a.	n.a.	12.32	12.34	12.38	12.30

Hera 300 EC at the proposed label rate had positive effect on the moisture content (%) on the studied cereals. Hera 300 EC is assumed to have no negative effects on the quality of yield (moisture) of treated plants. Results were compared to untreated control and st. reference product.

#### ***Weight of 1000 grains (g) noted in efficacy trials on fungal diseases on winter and spring cereals***

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.25 L/ha	Hera 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	10	42.614	n.a.	n.a.	43.019	43.049	43.099	43.241
spring wheat	2	36.385	n.a.	n.a.	36.74	37.295	36.32	36.44
winter triticale	2	39.205	n.a.	n.a.	39.26	37.87	39.305	39.23
spring triticale	2	34.67	n.a.	n.a.	34.84	35.255	35.065	34.285
winter rye	2	32.79	n.a.	n.a.	32.58	32.27	32.80	32.68
	3	31.29	31.59	31.42	n.a.	n.a.	31.53	31.27
winter barley	3	46.63	n.a.	n.a.	47.40	47.70	47.69	47.92
spring barley	9	45.27	n.a.	n.a.	45.26	45.26	45.70	45.49

Hera 300 EC at the proposed label rate had positive effect on the weight of 1000 grains (g) on the studied cereals. Hera 300 EC is assumed to have no negative effects on the quality of yield (weight of 1000 grains) of treated plants. Results were compared to untreated control and st. reference product.

#### ***Test weight (kg/hl) noted in efficacy trials on fungal diseases on winter and spring cereals***

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.25 L/ha	Hera 300 EC at dose 0.33 L/ha	HERA 300 EC at dose 0.4 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.65 L/ha	Poleposition 300 EC at dose 0.65 L/ha
winter wheat	10	77.932	n.a.	n.a.	78.159	78.079	77.916	78.122
spring wheat	2	73.335	n.a.	n.a.	73.51	73.67	73.675	73.67
winter triticale	2	73.95	n.a.	n.a.	73.97	74.56	74.255	74.28
spring triticale	2	58.68	n.a.	n.a.	58.69	58.55	58.77	58.74
winter rye	2	74.25	n.a.	n.a.	74.5	74.03	75.0	74.74
	3	68.75	69.43	69.03	n.a.	n.a.	68.78	69.14

winter barley	3	67.99	n.a.	n.a.	68.27	68.14	68.73	68.40
spring barley	9	68.65	n.a.	n.a.	68.46	68.25	68.64	68.8

Hera 300 EC at the proposed label rate had positive effect on the test weight (kg/hl) on the studied cereals. Hera 300 EC is assumed to have no negative effects on the quality of yield (test weight) of treated plants. Results were compared to untreated control and st. reference product.

✓ **Winter oilseed rape:**

Recording yields can be useful. For make it easier to harvest the crop and reduce losses, you should divide the rows before the 71-78 developmental stage on the BBCH. The yield should be calculated in kg ha<sup>-1</sup> according to the established moisture level (according to national or international standards), and in relative to a control plot or preparation comparison. Useful information can also be obtained by measuring the weight of 1,000 grains (g) and measuring oil content in line to EPPO 1/78.

**Moisture (%) noted in efficacy trials on fungal diseases on winter oilseed rape (spring application)**

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (spring application)	10	3.15	3.38	3.47	3.57	3.49

**Weight of 1000 grains (g) noted in efficacy trials on fungal diseases on winter oilseed rape (spring application)**

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (spring application)	10	4.35	4.39	4.40	4.67	4.42

**Oil content (%) noted in efficacy trials on fungal diseases on winter oilseed rape (spring application)**

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (spring application)	10	42.05	42.10	42.24	42.16	42.37

Hera 300 EC at the proposed label rate had positive effect on the quality of yield on the studied winter oilseed rape (spring application). Hera 300 EC is assumed to have no negative effects on the quality of yield (moisture, weight of 1000 grains, oil content) of treated plants. Results were compared to untreated control and st. reference product.

**Moisture (%) noted in efficacy trials on fungal diseases on winter oilseed rape (autumn application)**

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.2 L/ha	HERA 300 EC at dose 0.3 l/ha	HERA 300 EC at dose 0.6 L/ha	Promino 300 EC at dose 0.6 L/ha
winter oilseed rape (autumn application)	6	7.30	7.28	7.33	7.32	7.40

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.3 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Poleposition 300 EC at dose 0.6 L/ha
winter oilseed rape (autumn application)	2	6.10	6.25	6.15	6.15	6.20

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Tauron 240 EC at dose 0.75 L/ha
winter oilseed rape (autumn application)	8	8.10	8.12	8.17	8.13	8.13

**Oil content (%) noted in efficacy trials on fungal diseases on winter oilseed rape (autumn application)**

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.20 L/ha	HERA 300 EC at dose 0.3 l/ha	HERA 300 EC at dose 0.60 L/ha	Promino 300 EC at dose 0.60 L/ha
winter oilseed rape (autumn application)	6	42.07	42.45	42.78	41.85	42.13

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.3 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Poleposition 300 EC at dose 0.6 L/ha
winter oilseed rape (autumn application)	2	43.38	44.01	44.88	45.09	44.73

Cereal	No. trials	Untreated control	Hera 300 EC at dose 0.35 L/ha	HERA 300 EC at dose 0.5 l/ha	HERA 300 EC at dose 0.6 L/ha	Tauron 240 EC at dose 0.75 L/ha
winter oilseed rape (autumn application)	8	41.74	41.95	42.07	41.96	41,64

Hera 300 EC at the proposed label rate had positive effect on the quality of yield on the studied winter oilseed rape (autumn application). Hera 300 EC is assumed to have no negative effects on the quality of yield (moisture and oil content) of treated plants. Results were compared to untreated control and st. reference product.

**In conclusion, no negative impact of the product – Hera 300 EC (product code: Protiokonazol 300 EC) on the quality of yield is to be expected when applied at the intended rate and used according to the label recommendation's.**

### 3.3.3 Observations on other undesirable or unintended side-effects

**Effect on the succeeding crops:** Applicant did not provide a sufficient level of information to address the impact on succeeding crops in accordance with EPPO PP 1/207. Normally, no special data for fungicides are prepared and submitted for that point if no persistence of the product is known or in discussion. Some data can be described at other parts of this section or in other sections (persistence situation of the applied substance). However, problems from authorisations of prothioconazole products at cereals and rape seed have not been reported.

Lack of phytotoxicity symptoms recorded during the field trials suggested that product (HERA 300 EC) application in accordance with label recommendations shall not adversely impact on succeeding crops.

The half-life of prothioconazole in soils was lower than it metabolites, with the DT<sub>50</sub> of ranging from 16.6 to 99.6 days, 15.8 and 50.7 days for M01 and M04 under aerobic condition, respectively.

A review of available literature as well as the lack of phytotoxicity symptoms recorded during the field trials suggest that product application in line to label, shall not adversely impact on succeeding crops. Also, based on the absence of any adverse effects in typical cropping situations, it was concluded that the fungicide – HERA 300 EC (product code: Protiokonazol 300 EC) poses no risk to succeeding crops.

**Impact on adjacent crops:** The Applicant initially did not provide any data for the impact on adjacent crops. Fungicides containing prothioconazole are used to protect cultivated plants, especially cereals from fungal diseases. However, they can also affect neighbouring plants, referred to as companion plants.

Below, ZRMs presented several potential impacts on these plants (adjacent):

- **drift:** During fungicide application, the phenomenon of drift, where active substance particles are carried by the wind, can occur. This may lead to the unintentional delivery of fungicides to neighbouring plants. Therefore, it is important to exercise caution during application and use appropriate techniques to minimize the risk of drift. Such information should be added to label: “*During the application of the substance, prevent the drift of the spray onto neighbouring crops*”.
- **allergic reactions and toxicity:** Companion plants may be exposed to the active substances in fungicides, leading to allergic reactions or toxicity, especially if these substances come into contact with the leaves or roots of neighbouring plants.
- **changes in soil microflora:** Fungicides can influence soil microflora, disrupting the balance of microorganism at both the soil level and in the rhizosphere, the area around plant roots. This can impact the health and functions of neighbouring plants.
- **effects on soil fauna:** Fungicides can also affect organisms living in the soil, such as bacteria, fungi,

or small animals. Disturbances in the soil ecosystem can influence neighbouring plants.

- **disease protection:** On the other hand, fungicides used to protect cultivated plants can also provide benefits to companion plants by shielding them from potential pathogens transmitted by wind or soil.

It is crucial for farmers to apply fungicides in line with the label's recommendations and local regulations. Adhering to pesticide application standards, employing suitable application techniques, and considering environmental factors can help minimize potential adverse effects on neighbouring plants.

The following provision on the label should be done:

- When applying the product, do not allow spray to drift onto neighbouring crops

**Tank cleaning procedure:** ZRMs accepted the procedure proposed by Applicant and included in the label project. So, normal procedure tank cleaning should be made.

**Effects on transformation processes:** In general, fungicides containing prothioconazole are used to protect cereals from fungal diseases. They are also used on rape seed and other crops. Thus active substance can impact grain processing, especially if used in excessive amounts or not in accordance with the label's recommendations.

Below, ZRMs presented general pieces of information regarding the influence of these fungicides on cereal processing:

- **grain quality:** The use of fungicide can help maintain better grain quality by controlling fungal diseases. However, if used excessively, it may potentially affect the physical and chemical characteristics of the grain.
- **mycotoxin content:** Fungicides can assist in reducing the occurrence of mycotoxins produced by certain fungal species, thereby affecting the food safety. Nevertheless, in the case of excessive fungicide use, there is a risk that some mycotoxins may still be present in the grain.
- **processing efficiency:** If fungicides application is appropriately balanced and in line with recommendations, it can contribute to maintaining the efficiency of cereal processing. They protect plants from diseases, which can impact the quantity and quality of yields.
- **compliance with regulations:** It is crucial to adhere to local and international regulations regarding pesticide residue levels in food. Non-compliance with these regulations may result in rejection of product batches.

The impact of fungicides on cereal processing will depend on various factors such as the applied dosage, grain type, growing conditions, and protection period. It is always recommended to strictly follow the label's recommendations and consult with experts in plant protection and food processing to minimize potential adverse effects.

No indication from agricultural practice is known that fungicides with the active substance – prothioconazole have affected cereals or oilseed rape for propagation purposes. No negative of the product – HERA 300 EC on the yield, quality and processing procedure is expected. So, no negative impact of the product HERA 300 EC (product code: Protiokonazol 300 EC) is to be expected when applied at the intended dose rate and used according to the label recommendations. Furthermore, the test product is intended for application in BBCH 29-65 of cereals and, for oilseed rape, BBCH 13-19 and 61-72. With plenty of time to commercial harvest and very short period of prothioconazole dissipation in plant matrix, product is considered as having no effects on transformation processes. According to DAR for prothioconazole (Section 6, December 2017) under conditions designed to mimic pasteurisation, baking, brewing, boiling and sterilization there was no significant hydrolysis of prothioconazole following incubation at different pH values and temperatures. Prothioconazole is stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation, and no additional metabolites are formed in processed commodities as compared to raw agricultural commodities.

**Since the market introduction no effects on transformation processes have been recorded for any of**

**these products, nor prothioconazole containing products have any label restriction concerning their use on crops destined for processing. In the opinion of ZRMs, no undesirable effects are expected on the transformation processes.**

**Impact on propagation purposes:** Prothioconazole is a fungicide used to protect cereals from fungal diseases. The impact of this substance on reproductive goals in cereals may depend on several factors, such as the applied dosage, application period, type of cereals, environmental conditions, and other agricultural practices.

**Below, ZRMs presented some general aspects to consider:**

- ***disease protection:*** Prothioconazole are effective in combating various fungal diseases, such as rust, fusarium and powdery mildew. Protecting plants from these diseases can contribute to better plant health, influencing their ability to reproduce.
- ***impact on yield:*** Protecting plants from diseases using fungicides can improve yield as healthier plants are less susceptible to losses caused by diseases. Increased yield can affect the availability of seed for the reproduction processes.
- ***effect on seed quality:*** Proper use of fungicide can influence the quality of cereal seeds, which, in turn, is essential for reproductive processes. Preventing fungal diseases can contribute to obtaining healthy seeds.
- ***sustainable application:*** It is important to use fungicides in accordance with the label's recommendations and adopt a sustainable approach to their use. Excessive use or failure to adhere to recommendations may lead to potential side effects.
- ***protection against environmental stress:*** Fungicides can assist plants in overcoming environmental stresses, such as attacks by pathogenic fungi. Protection against stress can support reproductive processes by maintaining healthy plants.

**In conclusion, no negative impact of the product – HERA 300 EC on the yield, quality and processing procedure is to be expected. No indication from agricultural practice is known that fungicides with the active substance – prothioconazole have affected cereals or oilseed rape used for propagating purposes. No negative impact of the product – HERA 300 EC is to be expected when applied at the intended dose rate and used according to the label recommendations.**

No phytotoxicity symptoms occurring during the field trials suggested that product application in accordance with label recommendations has no negative impact on parts of plant used for propagating purposes. Also, the fungicides containing prothioconazole have been allowed to use for many years. Based on the expert knowledge about prothioconazole, it can be concluded to accept the information's provided by Applicant. According to the above statement, additional studies are not required in this range, in the opinion of ZRMs

**Effects on beneficial and other non-target organisms:** Data and information on the safety of HERA 300 SC (product code: Protiokonazol 300 EC) to beneficial and other non-target organisms can be found in the Ecotoxicology section..

### **3.4 Methods of analysis (Part B, Section 5)**

#### **3.4.1 Analytical method for the formulation**

Analytical methods for determination of prothioconazole in Protiokonazol 300 EC was not evaluated as part of the EU review of prothioconazole. Therefore, all relevant data are provided and are considered adequate.

#### **Prothioconazole**

The method for determination of prothioconazole in Protiokonazol 300 EC formulation is based reversed phase high performance liquid chromatography (RP-HPLC) with UV-Vis detection at wavelength 206 nm and external standard. In order to confirm method specificity, chromatograms of acetonitrile, placebo, standard and analysed sample were superimposed and compared.

There were no peaks interfering with the prothioconazole peak. The correlation coefficient was  $R^2 = 0.994$  (the criterion of acceptability is  $R^2 \geq 0.99$ ). The relative standard deviation of instrument precision for the determined active substance was  $RSD = 0.48$  (criterion of acceptability is  $H_r \leq 1$ ). Acceptable relative standard deviation of repeatability for the determined active substance is  $\leq 1.62\%$ . The obtained results of  $0.78\%$  is acceptable. The accuracy of active ingredient determination was estimated by the recovery measurement. The recovery value for the main component should be  $97\% \div 103\%$ . The obtained result  $99.72\%$  is acceptable.

The method for determination of prothioconazole in Protiokonazol 300 EC fulfils acceptability criteria contained in SANCO/3030/99 rev.5, 22 March 2019 guidance and assure appropriate active substance determination in the formulation.

#### **Relevant impurities - Prothioconazole-desthio**

There were no peaks interfering with the impurity peak. The correlation coefficient was  $R^2 = 0.9990$  (the criterion of acceptability is  $R^2 \geq 0.99$ ). The relative standard deviation of instrument precision was  $0.81\%$  (criterion of acceptability is  $H_r \leq 1$ ). Acceptable relative standard deviation of repeatability is  $\leq 5.69\%$ . The obtained results of  $4.60\%$  is acceptable. The accuracy was estimated by the recovery measurement. The recovery value for the main component should be  $70\% \div 130\%$ . The obtained result  $101.3\%$  is acceptable.

The method for determination of relevant impurity – Prothioconazole-desthio in Protiokonazol 300 EC fulfils acceptability criteria contained in SANCO/3030/99 rev.5, 22 March 2019 guidance and assure its appropriate determination in the formulation.

#### **Relevant impurities - toluene**

There were no peaks interfering with the impurity peak. The correlation coefficient was  $R^2 > 0.9992$  (the criterion of acceptability is  $R^2 \geq 0.99$ ). The relative standard deviation of instrument precision was  $0.41\%$  (criterion of acceptability is  $H_r \leq 1$ ). Acceptable relative standard deviation of repeatability is  $RSD \leq 4.75\%$ . The obtained results of  $RSD = 1.93\%$  is acceptable. The accuracy was estimated by the recovery measurement. The recovery value for the main component should be  $75\% \div 125\%$ . The obtained result  $101.9\%$  is acceptable.

The method for determination of relevant impurity - toluene in Protiokonazol 300 EC fulfils acceptability criteria contained in SANCO/3030/99 rev.5, 22 March 2019 guidance and assure its appropriate determination in the formulation.

### **3.4.2 Analytical methods for residues**



Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Commodity/crop	Supported/ Not supported
Winter wheat	Supported
Spring wheat	Supported
Winter triticale	Supported
Spring triticale	Supported
Spring barley	Supported
Winter barley	Supported
Rye	Supported
Winter oilseed rape	Supported

### 3.5 Mammalian toxicology (Part B, Section 6)

#### 3.5.1 Acute toxicity

No acute toxicity studies were performed for Protiokonazol 300 EC. The classification of Protiokonazol 300 EC was based on the composition of the product and was performed according to the Regulation (EC) of the European Parliament and of the Council No. 1272/2008 of December 16<sup>th</sup>, 2008 *on classification, labelling and packaging of substances and mixtures*. Details on composition and classification of formulants are provided in dRR Part C.

Taking into account the composition of the product and the provisions of the Regulation EC No. 1272/2008, the formulation Protiokonazol 300 EC containing 300 g/L of prothioconazole does not require classification with regard to oral, dermal and inhalation acute toxicity. Protiokonazol 300 EC requires classification with regards to eye irritation, skin irritation and specific target organ toxicity.

According to Regulation (EC) 1272/2008, the proposed toxicological classification of Protiokonazol 300 EC is:

- Skin Irrit. 2, H315 - Causes skin irritation.
- Eye Dam. 1, H318 - Causes serious eye damage.
- STOT SE 3, H335 - May cause respiratory irritation.

#### 3.5.2 Operator exposure

Operator exposure to Protiokonazol 300 EC was not evaluated as part of the EU review of prothioconazole. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The operator exposure was assessed against the AOEL agreed in the EU review of prothioconazole and its metabolite prothioconazole-desthio. Operator exposure calculations were performed using the EFSA model AOEM (*Agricultural Operator Exposure Model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015)*). **EFSA model AOEM (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1**

According to the model calculations, it can be concluded that the risk for the operator using Protiokonazol 300 EC on intended uses presented in GAP table is acceptable if operator is equipped with work wear (arms, body and legs covered) and protective gloves during mixing/loading and during application.

### 3.5.3 Worker exposure

Worker exposure to Protiokonazol 300 EC was not evaluated as part of the EU review of prothioconazole. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The worker exposure was assessed against the AOEL agreed in the EU review of prothioconazole and its metabolite prothioconazole-desthio. Worker exposure calculations were performed using the EFSA model AOEM (*Agricultural Operator Exposure Model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015)*). EFSA model AOEM (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

The results of the exposure estimations show that the use of Protiokonazol 300 EC according to the list of intended uses presented in GAP Table, causes no health risk for the worker if the workwear (arms, body and legs covered) is used.

Taking into account hygienic rules, it is recommended that a worker inspecting treated area was dressed properly (long trousers, long-sleeve shirt) and equipped with protective gloves.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

### 3.5.4 Bystander and resident exposure

Bystander and resident exposure to Protiokonazol 300 EC was not evaluated as part of the EU review of prothioconazole. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The bystander and resident exposure was assessed against the AOEL agreed in the EU review of prothioconazole and its metabolite prothioconazole-desthio. Bystander and resident exposure calculations were performed using the EFSA model AOEM (*Agricultural Operator Exposure Model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015)*). EFSA model AOEM (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

The reference value acutely toxic active substance (RVAAS, AAOEL) for prothioconazole and its metabolite, prothioconazole-desthio is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards this active substance.

Regarding above calculations and bystander and resident safety, additional risk mitigation measures should be applied as below:

During spraying, a buffer zone of at least 5 m away from residential buildings/habitats and bystanders with 50% drift reduction should be used.

### 3.6 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.1 mg/kg (wheat incl. triticale), 0.2 mg/kg (barley) and 0.15 mg/kg (oilseed rape) for as laid down in Reg. (EU) 396/2005 (last amendment - Reg. (EU) 2019/552) is not expected.

The chronic and the short-term intakes of prothioconazole residues are unlikely to present a public health concern.

#### 3.6.1 Residues

##### Storage stability

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in high water content matrices (wheat green matter), cereal grain and straw and for 24 months in high oil content.

Storage stability data for TDMs are presented in EFSA Journal 2018;16(7):5376.

Residues are stable in wheat and barley grain for 12 month - 1,2,4-Triazole, for 26 month – TA, for 26 month – TAA and for 48 month – TLA.

Residues are stable in cereal straw for 12 month - 1,2,4-Triazole, for 53 month – TA, for 40 month – TAA and there is no data for TLA. However, storage stability for TLA in cereal straw is covered by acceptable storage stabilities in 5 different group matrices - 48 months covered

Residues of 1,2,4-Triazole and TA are not stable in oilseed rape (seed). Residues of TAA are stable for 53 month and TLA are stable for 48 month in oilseed rape (seed).

Applicant has LoA from Indofil Industries (Netherlands) B.V. to following study:

Longhi, D., 2022. *Storage stability of Triazole Derivative Metabolites (TDM) in wheat forage, wheat grain, rapeseed seeds, wheat straw, apple, tomato, carrot. Final Report No. GLP-STUDY-21-124.*

The applicant does not have access to a copy of the study. Therefore, the study was not summarized. The study was accepted by zRMS (PL) in *Prothioconazole\_fRR Part B7\_INDIFIL Prothio 250 EC\_Indofil Industries\_PL\_rev 02.2024.*

Part of the study for which the access is granted:

Storage stability of TDM (TRZ, TA, TLA, TAA) in matrices:

- high water (green forage wheat)
- high starch (wheat grain)
- dry (wheat straw)

The study demonstrated the stability of all tested metabolites in all tested matrices for 7 months.

The study was found to be acceptable.

##### Metabolism in plants and animals

Plant residue definition for monitoring (RD-Mo):

Prothioconazole: Prothioconazole-desthio (sum of isomers)

Plant residue definition for risk assessment (RD-RA):

a) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)

b)TDMs (EFSA, 2018, SANCO/3923 /07 – final 10 December 2007, 26 January 2021), with separate assessment of:

- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T)

### Magnitude of residues in plants

Winter and spring: wheat, triticale and barley; rye

Proposed GAPs cereals: 1-2 Applications (14 days interval), BBCH 29-65, 150-195 g as/ha, PHI: 35 days  
EU GAPs:

Wheat, rye, triticale: 3 x 0.2 kg a.s./ha, BBCH 69, PHI 35 d, int. 14-21 days

Barley: 2 x 0.2 kg a.s./ha, BBCH 69, PHI 35 d, int. 14-21 days

Prothioconazole

No new data are submitted in the framework of this application. The residue data on cereals were evaluated during the EU review of prothioconazole. Sufficient EU trials on wheat, barley are available to support the proposed uses. The residue data are valid with regard to storage stability. The residues arising from the proposed uses will not exceed the MRLs for Prothioconazole established for cereals (0.1 (wheat, triticale, durum, spelt), 0.2 (barley) mg/kg, 0.05 (oat, rye); Reg. (EU) 2019/552). Residues were measured according to the current enforcement residue definition - prothioconazole-desthio (sum of isomers).

Residues:

Wheat grain – 10 x <0.01 mg/kg

Barley grain - 9 x <0.01 mg/kg

Extrapolations from wheat to rye and triticale are possible.

TDMs

Considering TDMs, the intended uses are covered by the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data (EFSA, 2018). Additional studies are not required.

Additionally the applicant has LoA from Indofil Industries (Netherlands) B.V. to following study:

Sala, A.2021. *Determination of difenoconazole and prothioconazole residues in winter or spring wheat raw and processed commodities (white flour and white bread) following two applications of IN233C1560 Northern and Southern Europe – 16 trials. GLP-STUDY-21-24.*

The applicant does not have access to a copy of the study. Therefore, the study was not summarized.

Part of the study for which the access is granted:

Determination of the residues level of the following analytes in wheat samples (whole plant, straw, grain) and processed commodities (white flour and white bread):

- prothioconazole-desthio
- triazole derivative metabolites (TDMs)
- Prothioconazole-desthio-3-hydroxy
- Prothioconazole-desthio-4-hydroxy
- Prothioconazole-desthio-5-hydroxy
- Prothioconazole-desthio-6-hydroxy

- Prothioconazole-desthio-alpha-hydroxy

The study was accepted by zRMS (PL) in *Prothioconazole\_fRR Part B7\_INDOFIL Prothio 250 EC\_Indofil Industries\_PL\_rev 02.2024*.

#### Oilseed Rape

Proposed GAPs:

1 Application (BBCH 13-19; Autumn, post emergence), 150 - 180 g as/ha, PHI: 56 days

2 Applications (interval 21 days, BBCH 61-72, Spring, post emergence), 150 - 180 g as/ha, PHI: 56 days

EU-GAP: 1-2 Applications (14 – 28 days interval), start BBCH 53, 0.175 kg as/ha, PHI: 56 days

Prothioconazole

No new data are submitted in the framework of this application. Applicant refers to the unprotected EU data.

Prothioconazole

Residues in Seed: 5 x <0.01, 0.01, 2 x 0.02 mg/kg.

Sufficient EU trials on oilseed Rape are available to support the proposed uses. The residue data are valid with regard to storage stability. The residues arising from the proposed uses will not exceed the MRLs for Prothioconazole established for oilseed Rape (0.15 mg/kg, Reg. (EU) 2019/552). Residues were measured according to the current enforcement residue definition - prothioconazole-desthio (sum of isomers).

TDMs

No data were provided (data gap).

Use is not accepted.

#### Livestock Feeding Studies

The calculated dietary burdens were found to be above the trigger value of 0.004 mg/kg bw (0.1 mg/kg dry matter (DM) for all types of livestock. Applicant refers to out of protection EU data. No exceedances of the existing EU MRLs for prothioconazole in animal commodities are anticipated as a result of the proposed uses.

TDMs

EFSA Journal 2018;16(7):5376:

The livestock exposure assessment cannot be finalised with regard to the outstanding data for acceptable residue trials in primary and rotational crops.

*Data gap: Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin (data gap at EU level).*

No further data is required.

#### Industrial Processing and/or Household Preparation

As quantifiable residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing.

The TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation (EFSA Journal 2018;16(7):5376).

No further data is required.

#### Residues in Representative Succeeding Crops

## Prothioconazole

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed

### TDMs

Data gap: Rotational crops field residue trials supported by acceptable storage stability data on TDMs.  
(data gap at EU level).

No further data is required.

## Other / special studies

Four new studies (2 NEU and 2 SEU trials) have been performed on phacelia crop to investigate the magnitude of prothioconazole residues in honey. These studies consider a “worst case” situation (the most critical scenario was used on a crop (phacelia) representing a worst case in terms of residues in honey). The intended GAP for oilseed rape is 2x 180 g as/ha, BBCH 61-72, outdoor. In four honey trials Protiokonazol 300 EC was applied at a rate 390 g as/ha at a flowering phase (BBCH 65). In these trials all residues of prothioconazole, prothioconazole-desthio and TDMs in honey were below LOD (<0.002 mg/kg).

All samples were analysed within 30 days from sampling (23 days), therefore there is no need to perform studies on the stability of residues during storage.

The residues will not exceed the MRL of 0.05 mg/kg established for honey (Regulation (EU) 2019/552).

No further data is required.

## 3.6.2 Consumer exposure

The proposed uses of prothioconazole in the formulation Protiokonazol 300 EC does not represent unacceptable chronic and acute risks for the consumer.

<b>ADI</b>	0.01 mg/kg bw/d (prothioconazole-desthio)
<b>TMDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	29 % (based on NL toddler diet)
<b>IEDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	Not relevant. TMDI< 100%
<b>ARfD</b>	0.01 mg/kg bw/d (prothioconazole-desthio)
<b>IESTI (% ARfD) according to EFSA PRIMo rev. 3.1</b>	<p><u>Unprocessed commodities - children</u> Wheat: 14 % (based on UK 4-6 years diet) Barley: 11 % (based on UK 7-10 years diet) Rapeseed/canola: 2 % (based on DE child diet)</p> <p><u>Unprocessed commodities - adult</u> Wheat: 10 % (based on UK 15-18 years diet) Barley: 8 % (based on DE general population diet) Rapeseed/canola: 0.8 % (based on DE women 14-50 diet)</p> <p><u>Processed commodities - children</u> Wheat / milling (flour): 12 % (based on DE child diet) Barley / cooked: 7 % (based on NL child diet) Wheat / milling (wholemeal)-baking: 6 % (based on NL child diet)</p>

	<p>Barley / milling (flour): 4 % (based on NL child diet) Rapeseeds / oils: 0.9 % (based on NL toddler diet)</p> <p><u>Processed commodities - adult</u> Barley / beer: 14 % (based on NL general population diet) Wheat / bread/pizza: 4 % (based on IT adult diet) Wheat / pasta: 4 % (based on NL general population diet) Wheat / bread (wholemeal): 3 % (based on NL general population diet)</p>
<b>NTMDI (% ADI)</b>	Not relevant.
<b>NEDI (% ADI)</b>	Not relevant.
<b>NESTI (% ARfD)</b>	Not relevant.

Consumer risk assessment – Triazole alanine (TA) and triazole lactic acid (TLA)

<b>ADI</b>	0.3 mg/kg bw/d
<b>TMDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	11 % (based on NL toddler diet)
<b>IEDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	Not relevant. TMDI < 100%
<b>ArfD</b>	0.3 mg/kg bw
<b>IESTI (% ArfD) according to EFSA PRIMo rev. 3.1</b>	<p><u>Unprocessed commodities – children</u> Wheat: 6% (based on UK 4-6 years diet) Barley: 2% (based on UK 7-10 years diet) Rapeseed/canola: 1% (based on DE child diet)</p> <p><u>Unprocessed commodities – adult</u> Wheat: 4% (based on UK 15-18 years diet) Barley: 2% (based on DE general population diet) Rapeseed/canola: 0.4% (based on DE women 14-50 diet)</p> <p><u>Processed commodities – children</u> Wheat / milling (flour): 5% (based on DE child diet) Wheat / milling (wholemeal)-baking: 2% (based on NL child diet) Barley / cooked: 2% (based on NL child diet) Barley / milling (flour): 0.8% (based on NL child diet) Rapeseeds / oils: 0.4% (based on NL toddler diet)</p> <p><u>Processed commodities – adult</u> Barley / beer: 3% (based on NL general population diet) Wheat / bread/pizza: 2% (based on IT adult diet) Wheat / pasta: 2% (based on NL general population diet) Wheat / bread (wholemeal): 1% (based on NL general population diet)</p>
<b>NTMDI (% ADI)</b>	Not relevant.
<b>NEDI (% ADI)</b>	Not relevant.
<b>NESTI (% ArfD)</b>	Not relevant.

Consumer risk assessment – Triazole acetic acid (TAA)

<b>ADI</b>	1 mg/kg bw/d
<b>TMDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	2% (based on NL toddler diet)
<b>IEDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	Not relevant. TMDI < 100%
<b>ArfD</b>	1 mg/kg bw

<b>IESTI (% ArfD) according to EFSA PRIMo rev. 3.1</b>	<p><u>Unprocessed commodities – children</u> Wheat: 2% (based on UK 4-6 years diet) Barley: 0.9% (based on UK 7-10 years diet) Rapeseed/canola: 0.03% (based on DE child diet)</p> <p><u>Unprocessed commodities – adult</u> Wheat: 1% (based on UK 15-18 years diet) Barley: 0.8% (based on DE general population diet) Rapeseed/canola: 0.01% (based on DE women 14-50 diet)</p> <p><u>Processed commodities – children</u> Wheat / milling (flour): 2% (based on DE child diet) Wheat / milling (wholemeal)-baking: 0.9% (based on NL child diet) Barley / cooked: 0.6% (based on NL child diet) Barley / milling (flour): 0.3% (based on NL child diet) Rapeseeds / oils: 0.0% (based on NL toddler diet)</p> <p><u>Processed commodities – adult</u> Barley / beer: 1% (based on NL general population diet) Wheat / bread/pizza: 0.7% (based on IT adult diet) Wheat / pasta: 0.6% (based on NL general population diet) Wheat / bread (wholemeal): 0.6% (based on NL general population diet)</p>
<b>NTMDI (% ADI)</b>	Not relevant.
<b>NEDI (% ADI)</b>	Not relevant.
<b>NESTI (% ArfD)</b>	Not relevant.
Consumer risk assessment – 1, 2, 4-triazole (1,2,4-T)	
<b>ADI</b>	0.023 mg/kg bw/d
<b>TMDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	91% (based on NL toddler diet)
<b>IEDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	Not relevant. TMDI < 100%
<b>ArfD</b>	0.1 mg/kg bw
<b>IESTI (% ArfD) according to EFSA PRIMo rev. 3.1</b>	<p><u>Unprocessed commodities – children</u> Wheat: 1% (based on UK 4-6 years diet) Barley: 0.6% (based on UK 7-10 years diet) Rapeseed/canola: 0.1% (based on DE child diet)</p> <p><u>Unprocessed commodities – adult</u> Wheat: 0.8% (based on UK 15-18 years diet) Barley: 0.5% (based on DE general population diet) Rapeseed/canola: 0.05% (based on DE women 14-50 diet)</p> <p><u>Processed commodities – children</u> Wheat / milling (flour): 1% (based on DE child diet) Wheat / milling (wholemeal)-baking: 0.6% (based on NL child diet) Barley / cooked: 0.4% (based on NL child diet) Barley / milling (flour): 0.2% (based on NL child diet) Rapeseeds / oils: 0.1% (based on NL toddler diet)</p> <p><u>Processed commodities – adult</u> Barley / beer: 0.7% (based on NL general population)</p>



	diet) Wheat / bread/pizza: 0.4% (based on IT adult diet) Wheat / pasta: 0.4% (based on NL general population diet) Wheat / bread (wholemeal): 0.3% (based on NL general population diet)
<b>NTMDI (% ADI)</b>	Not relevant.
<b>NEDI (% ADI)</b>	Not relevant.
<b>NESTI (% ArfD)</b>	Not relevant.

### 3.7 Environmental fate and behaviour (Part B, Section 8)

#### 3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

PECs modelling was performed with Excel calculator based on simple equations included in FOCUS soil persistence document issued in 1997. PECs for formulation was obtained from PECs for prothioconazole (worst case) taking into account content of active substance and density of the formulation. For further risk assessment worst case PECs values were used.

#### 3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

PEC<sub>gw</sub> for active substance- prothioconazole and its metabolites after application to winter cereals, spring cereals and winter oilseed rape, were calculated with PELMO 6.6.4 and PEARL 5.5.5. For all scenarios PEC<sub>gw</sub> values for prothioconazole and its metabolites are below the trigger value of 0.1 µg/L.

#### 3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

PEC<sub>sw</sub> for prothioconazole and its metabolites after application to winter cereals, spring cereals and winter oilseed rape were calculated with FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v.5.0.1. PEC<sub>sw</sub> values were used in aquatic risk assessment.

#### 3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)

The fate and behaviour of prothioconazole in air was evaluated during the EU review. The vapour pressure at 20 °C of the active substance prothioconazole is < 10<sup>-5</sup> Pa. Hence the active substance prothioconazole is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilization with subsequent deposition is not relevant.

### **3.8 Ecotoxicology (Part B, Section 9)**

#### **3.8.1 Effects on terrestrial vertebrates**

##### **Birds**

Effects on birds for Protiokonazol 300 EC were not evaluated as part of the EU review of prothioconazole. However further data on Protiokonazol 300 EC is not relevant as data on toxicity to birds for active substance are considered essential. It is possible to extrapolate from data for active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for Protiokonazol 300 EC with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of Protiokonazol 300 EC to birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substance and prothioconazole-desthio (JAU 6476-desthio) (M04), as well as  $SV_{90}$  and  $SV_m$ .

Drinking water exposure (leaf scenario) has not been estimated since Protiokonazol 300 EC is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures. Drinking water exposure (puddle scenario) has not been performed since the ratio of effective application rate to relevant endpoints does not exceed 3000 ( $Koc \geq 500$  L/kg).

Exposure for earthworm-eating birds and fish-eating birds via secondary poisoning has been estimated since  $\log P_{ow}$  of prothioconazole, prothioconazole-desthio (JAU 6476-desthio) (M04) and prothioconazole-S-methyl (M01) are above the trigger value of 3. The long term secondary poisoning risk of Protiokonazol 300 EC to birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substance and metabolites, as well as 21d PECs and PEC in worms and fishes.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to birds from the proposed use of Protiokonazol 300 EC. No risk management measures are required.

##### **Terrestrial vertebrates (other than birds)**

Effects on mammals for Protiokonazol 300 EC were not evaluated as part of the EU review of prothioconazole. However further data on Protiokonazol 300 EC is not relevant as toxicity data to mammals for active substance are considered essential. It is possible to extrapolate from data for active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for Protiokonazol 300 EC with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on terrestrial vertebrates other than birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of Protiokonazol 300 EC to mammals were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substance and prothioconazole-desthio (JAU 6476-desthio) (M04), as well as  $SV_{90}$  and  $SV_m$ .

Drinking water exposure (leaf scenario) has not been estimated since Protiokonazol 300 EC is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures. Drinking water exposure (puddle scenario) has not been performed since the ratio of effective application rate to relevant endpoints does not exceed 3000 ( $Koc \geq 500$  L/kg).

Exposure for earthworm-eating mammals and fish-eating mammals via secondary poisoning has been estimated since log  $P_{ow}$  of prothioconazole, prothioconazole-desthio (JAU 6476-desthio) (M04) and prothioconazole-S-methyl (M01) are above the trigger value of 3. The long term secondary poisoning risk of Protiokonazol 300 EC to mammals were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substance and metabolites, as well as 21d PECs and PEC in worms and fishes.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to mammals from the proposed use of Protiokonazol 300 EC. No risk management measures are required.

### **3.8.2 Effects on aquatic species**

Effects on aquatic organisms for Protiokonazol 300 EC were not evaluated as part of the EU review of prothioconazole. The studies on effects of Protiokonazol 300 EC on *Daphnia magna* and algae were submitted in this dossier and deemed acceptable for evaluation and authorisation of Protiokonazol 300 EC.

Risk assessments for Protiokonazol 300 EC with the proposed use pattern was carried out according to the latest guidance for risk assessment for aquatic organisms in edge-of-field surface water EFSA Journal 2013; 11(7):3290.

PEC/RAC values were calculated on the basis of PEC<sub>sw</sub> values as well as worst case toxicity end-points from studies for active substance, metabolites and formulation Protiokonazol 300 EC. PEC<sub>sw</sub> Step 1-3/RAC values were less than 1 for most scenarios indicating acceptable risk. In case of R1 scenario further evaluation with Step 4 PEC<sub>sw</sub> was performed.

On the basis of conducted risk assessment it was concluded that Protiokonazol 300 EC does not pose unacceptable risk provided following risk mitigations are applied for the following scenarios:

Winter cereals (max. application rate 2x195 g a.s./ha, interval 14d, BBCH 29-65):

- R1 stream – 5m buffer zone

Spring cereals (max. application rate 2x195 g a.s./ha, interval 14d, BBCH 29-65):

- R1 stream – 5m buffer zone.

Winter oilseed rape (max. application rate 2x180 g a.s./ha, interval 21d, BBCH 61-72):

- R1 stream – 5m buffer zone.

Spring oilseed rape (max. application rate 2x180 g a.s./ha, interval 14-21d, BBCH 16-69):

- R1 stream – 5m buffer zone.

### **3.8.3 Effects on bees**

Effects on bees for Protiokonazol 300 EC were not evaluated as part of the EU review of prothioconazole. The studies concerning effects of Protiokonazol 300 EC on bees were submitted in this dossier and deemed acceptable for evaluation and authorisation of Protiokonazol 300 EC.

Risk assessments for Protiokonazol 300 EC with the proposed use pattern was carried out according to the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002) and the latest Draft EFSA Guidance for risk assessment for bees EFSA Journal 2013; 11(7):3295.

The risk of Protiokonazol 300 EC to honeybees was assessed from HQ and ETR values between toxicity endpoints, estimated from acute and chronic studies with active ingredient and formulated product Protiokonazol 300 EC as well as the maximum single application rate of 195 g as/ha.

All the hazard quotients were considerably less than the respective triggers, indicating that Protiokonazol 300 EC in accordance with proposed GAP does not pose unacceptable risk to bees. No risk management measures are required.

### **3.8.4 Effects on other arthropod species other than bees**

Effects on non-target arthropods for Protiokonazol 300 EC were not evaluated as part of the EU review of prothioconazole. The studies on effects of Protiokonazol 300 EC on arthropods were submitted in this dossier and deemed acceptable for evaluation and authorisation of Protiokonazol 300 EC.

Risk assessments for Protiokonazol 300 EC with the proposed use pattern was carried out according to the guidance for risk assessment for arthropods “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and in consideration of the recommendations of the guidance document ESCORT 2.

The in-field and off-field risk of Protiokonazol 300 EC to non-target arthropods was assessed from Hazard Quotients (HQ) between toxicity endpoints estimated from studies with the formulated product Protiokonazol 300 EC as well as in-field and off-field predicted environmental rate. No risk was determined in-field and off-field after application of Protiokonazol 300 EC in accordance with proposed GAP. No risk management measures are required.

### **3.8.5 Effects on soil organisms**

Effects on earthworms and other soil micro-organisms for Protiokonazol 300 EC were not evaluated as part of the EU review of prothioconazole. The studies on effects of Protiokonazol 300 EC on earthworms and other micro and macro-organisms were submitted in this dossier and deemed acceptable for evaluation and authorisation of Protiokonazol 300 EC.

Risk assessments for Protiokonazol 300 EC with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

#### **Earthworms, collembola and *Hypoaspis***

The chronic risk of Protiokonazol 300 EC to earthworms, collembola and *Hypoaspis* was assessed from toxicity exposure ratios (TERs) between the selected toxicity endpoint for the active ingredient, metabolites and the formulated product Protiokonazol 300 EC as well as the maximum soil PECs.

The chronic TER values were greater than the trigger of 5 indicating an acceptable risk to earthworms, collembola and *Hypoaspis* following application of Protiokonazol 300 EC in accordance with proposed GAP. No risk management measures are required.

#### **Micro-organisms**

The risk of Protiokonazol 300 EC to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for active substance, metabolites and the formulated product Protiokonazol 300 EC with predicted application concentrations (PECs) obtained for active substances, metabolites and the formulation.

According to the performed risk assessment it was assessed that the application of Protiokonazol 300 EC in accordance with proposed GAP does not pose unacceptable risk to soil micro-organisms. No risk man-

agement measures are required.

### **3.8.6 Effects on non-target terrestrial plants**

Effects on non-target terrestrial plants for Protiokonazol 300 EC were not evaluated as part of the EU review of prothioconazole. The studies on seedling emergence and vegetative vigour for Protiokonazol 300 EC were submitted in this dossier and deemed acceptable for evaluation and authorisation of Protiokonazol 300 EC.

The risk of Protiokonazol 300 EC to non-target plants was assessed from toxicity exposure ratios between toxicity endpoints for the formulation Protiokonazol 300 EC and off-field predicted environmental rate.

According to the performed risk assessment it was assessed that the application of Protiokonazol 300 EC in accordance with proposed GAP does not pose unacceptable risk to non-terrestrial plants. No risk management measures are required.

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

Not relevant.

### **3.9 Relevance of metabolites (Part B, Section 10)**

Metabolites of prothioconazole are predicted to occur in groundwater at concentration below 0.1 µg/L (see dRR Part B8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 - rev.10 is therefore not required.

## **4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

Protiokonazol 300 EC contains active substance prothioconazole, which is not a candidate for substitution. A comparative assessment was therefore considered not necessary.

## **5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

2-years ambient stability test (test is on-going; expected date of completing the study November 2024)
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## **Appendix 1    Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.
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## Appendix 2 Copy of the product label

Sekcja Fiz-chem, Los i zachowanie w środowisku: brak uwag

Sekcja skuteczność: zgodnie z programami ochrony roślin, ocenioną dokumentacją oraz zapisami w tabeli GAP – rekomendowana dawka wody w przypadku wszystkich upraw powinna wynosić: 100-400 L/ha. Dla rzepaku ozimego – rekomendowana dawka to 0.6 L/ha. ~~Dla alternarij kapustnych zaproponowano dwa schematy stosowania: jesienny (1 aplikacja) i wiosenny (1 aplikacja) lub tylko wiosenny (2 aplikacje).~~ Zaakceptowano wszystkie jednostki chorobowe i uprawy. Przy czym, zastosowanie przeciwko mączniakowi prawdziwemu zbóż i traw w pszenicy ozimej jest akceptowane tylko warunkowo. Aplikant w ciągu 24 miesięcy od uzyskania rejestracji powinien przedstawić co najmniej jedno (optymalnie dwa) badania skuteczności wykonane na tej jednostce chorobowej w pszenicy ozimej w strefie płu.-wsch. lub kraju sąsiadującym z Polską. Zmodyfikowano zapisy dotyczące strategii przeciwdziałania rozwojowi odporności. Etykieta nie wymaga zamieszczenia wpisów dot. wpływu na rośliny następce i sąsiadujące. Zastosowanie przeciwko czerni krzyżowej (ALTEBA) na rzepaku ozimym – jedna aplikacja jesienią lub dwie aplikacje wiosenne.

Sekcja ekotoksykologii: dodano P501 oraz w celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych.

Sekcja pozostałości: Brak zgody na zastosowanie w ochronie rzepaku

Draft of label is provided in a separate appendix.

### Posiadacz zezwolenia:

Pestila Spółka z ograniczoną odpowiedzialnością, Studzianki 24a, 97-320 Wolbórz,  
tel./fax: +48 446164375, e-mail: info@pestila.pl.

## HERA 300 EC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

protiokonazol (związek z grupy triazoli) – 300 g/l (28,04 %)

Zezwolenie MRiRW nr R - /2023 z dnia .2023 r.



### Niebezpieczeństwo

- |         |   |  |
|---------|---|--|
| H315    | – | Działa drażniąco na skórę.   |
| H318    | – | Powoduje poważne uszkodzenie oczu.   |
| H335    | – | Może powodować podrażnienie dróg oddechowych.                              |
| H410    | – | Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki. |
| EUH 401 | – | W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy po-      |

- stępować zgodnie z instrukcją użycia.
- |                    |   |  |
|--------------------|---|--|
| P261               | – | Unikać wdychania rozpylonej cieczy.  |
| P264               | – | Dokładnie umyć ręce po użyciu.   |
| P280               | – | Stosować rękawice ochronne/odzież ochronną/ochronę twarzy.   |
| P302 + P352        | – | W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody z mydłem.  |
| P304 + P340        | – | W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania. |
| P305 + P351 + P338 | – | W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.   |
| P310               | – | Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem.  |
| P332 + P313        | – | W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.   |
| P391               | – | Zebrać wyciek.   |
| P403 + P233        | – | Przechowywać w dobrze wentylowanym miejscu. Przechowywać pojemnik szczelnie zamknięty.   |
| P501               | – | Zawartość/pojemnik usuwać zgodnie z przepisami miejscowymi/regionalnymi/ narodowymi / międzynarodowymi   |

## OPIS DZIAŁANIA

FUNGICYD w formie rozpuszczalnego koncentratu (EC) do sporządzania roztworu wodnego o działaniu układowym do stosowania zapobiegawczego, interwencyjnego oraz wyniszczającego. Zgodnie z klasyfikacją FRAC substancja czynna protiokonazol zaliczana jest do grupy 3 (fungicydy SBI-DMI).

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieźnego lub ciągnikowego opryskiwacza polowego.

### Pszenica ozima

*septorioza paskowana liści pszenicy, mączniak prawdziwy zbóż i traw*

Maksymalna dawka dla jednorazowego zastosowania: 0,65 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,5-0,65 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od końca fazy krzewienia do początku fazy kwitnienia (BBCH 29-65).

Liczba zabiegów: 2.

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami: co najmniej 14 dni.

### Pszenica jara

*septorioza paskowana liści pszenicy*

Maksymalna dawka dla jednorazowego zastosowania: 0,65 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,5-0,65 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od końca fazy krzewienia do początku fazy kwitnienia (BBCH 29-65).

Liczba zabiegów: 2.

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.



Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami: co najmniej 14 dni.

### **Żyto**

*mączniak prawdziwy zbóż i traw*

Maksymalna dawka dla jednorazowego zastosowania: 0,65 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,5-0,65 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od końca fazy krzewienia do początku fazy kwitnienia (BBCH 29-65).

Liczba zabiegów: 2.

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami: co najmniej 14 dni.

### **Pszenżyto ozime, pszenżyto jare**

*septorioza liści, mączniak prawdziwy zbóż i traw*

Maksymalna dawka dla jednorazowego zastosowania: 0,65 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,5-0,65 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów chorób, od końca fazy krzewienia do początku fazy kwitnienia (BBCH 29-65).

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami: co najmniej 14 dni.

### **Jęczmień ozimy, jęczmień jary**

*plamistość siatkowa jęczmienia*

Maksymalna dawka dla jednorazowego zastosowania: 0,65 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,5-0,65 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów choroby, od końca fazy krzewienia do początku fazy kwitnienia (BBCH 29-65).

Zalecana ilość wody: ~~200~~ 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 14 dni.

### **Rzepak ozimy**

**Jeden zabieg jesienny:** *alternarioza kapustnych\**, *czern krzyżowych*, *mączniak rzekomy kapustnych*

Maksymalna dawka dla jednorazowego zastosowania: 0,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,5-0,6 l/ha

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po wystąpieniu pierwszych objawów chorób, ~~jesienią~~: od fazy 3 liści do fazy 9 liści rzepaku (BBCH 13-19).

Zalecana ilość wody: 100—400 l/ha.

Zalecane opryskiwanie: drobnokropliste

Liczba zabiegów: 1.

**Dwa zabiegi wiosenne:** *alternarioza kapustnych\**, *zgnilizna twardzikowa*

Maksymalna dawka dla jednorazowego zastosowania: 0,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,3-0,6 l/ha

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po wystąpieniu pierwszych objawów chorób, wiosną: od początku fazy kwitnienia do fazy gdy 20% łuszczyń osiągnie typową wielkość (BBCH 61-72).

Liczba zabiegów: 2.

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami wiosennymi: co najmniej 21 dni.

\* alternarioza kapustnych należy przeprowadzić jeden zabieg jesienny lub dwa zabiegi wiosenne.

**Alternarioza kapustnych**

**Środek stosować według jednego z dwóch podanych poniżej schematów stosowania.**

**1. Schemat (dwa zabiegi – jesień i wiosna)** Termin stosowania środka: pierwszy zabieg (jesień): zabieg wykonać od fazy trzeciego liścia do fazy dziewięciu liści lub więcej (BBCH 13-19). Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób. Drugi zabieg (wiosna): zabieg wykonać od początku fazy kwitnienia do fazy gdy 20% łuszczyń osiągnie typową wielkość (BBCH 61-72). Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób.

Maksymalna dawka dla jednorazowego zastosowania: 0,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,6 l/ha

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Liczba zabiegów: 2

Odstęp między zabiegami: co najmniej 90 dni.

**2. Schemat (dwa wiosenne zabiegi)**

Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku fazy kwitnienia do fazy gdy 20% łuszczyń osiągnie typową wielkość (BBCH 61-72).

Maksymalna dawka dla jednorazowego zastosowania: 0,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,6 l/ha

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Liczba zabiegów: 2

Odstęp między zabiegami: co najmniej 21 dni.

## STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOObszarowych

Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik.

### Rzepak jary

*czerni krzyżowych, zgnilizna twardzikowa, alternarioza kapustnych*

Maksymalna dawka dla jednorazowego zastosowania: 0,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,5-0,6 l/ha

~~Termin stosowania środka: Środek należy stosować zapobiegawczo lub bezpośrednio po wystąpieniu pierwszych objawów chorób od fazy 6 liści rzepaku do końca fazy kwitnienia (BBCH 16-69). W przypadku zwalczania czerni krzyżowych i / lub zgnilizny twardzikowej środek stosować od początku fazy kwitnienia (BBCH 61).~~

~~Zalecana ilość wody: 200 100 400 l/ha.~~

~~Zalecane opryskiwanie: drobnokropliste~~

~~Odstęp między zabiegami: 14 21 dni~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2~~

## **ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA**

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

- zboża ozime i jare – 35 dni,
- ~~rzepak ozimy, rzepak jary – 56 dni.~~

1. Zabieg środkiem wykonać w temperaturze powietrza powyżej 12°C.
2. Środek zawiera substancję czynną protiokonazol z grupy triazoli (fungicydy inhibitory biosyntezy steroli - inhibitory demetylacji, SBI- DMI, wg FRAC grupa 3). W ramach strategii antyodpornościowej zaleca się m. in.:
  - stosowanie środka głównie do zabiegów zapobiegawczych,
  - niestosowanie środka w dawkach innych niż jest zalecana,
  - włączenie do przyjętego programu ochrony środków grzybobójczych, zawierających substancje czynne z innych grup, o odmiennych mechanizmach działania (stosowanie przemienne lub w mieszaniu zbiornikowej).
  - ~~stosować maksymalnie 2 razy w sezonie wegetacyjnym, w rotacji z innymi fungicydami zawierającymi substancje czynne należące do innych grup wg klasyfikacji FRAC, o innym mechanizmie działania wg klasyfikacji FRAC, o innym mechanizmie działania;~~
  - ~~monitorować efekty przeprowadzonych zabiegów.~~
3. ~~Mając na uwadze zalecenia strategii antyodpornościowej, zasadne byłoby ograniczenie stosowania środka do jednego zabiegu na zboża w sezonie przeciwko mączniakowi prawdziwemu zbóż i plamistości siatkowej jęczmienia[lub drugi zabieg powinien być już wykonany środkiem zawierającym fungicyd z innej grupy FRAC - o innym mechanizmie działania.~~
4. ~~Jeżeli w przyjętym programie ochrony planowany jest tylko jeden zabieg, w celu osiągnięcia zadowalającej skuteczności zabieg ten należy wykonać jako środek zapobiegawczy.~~

## **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

## **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub – unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

### **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne, odzież ochronną, ochronę oczu oraz ochronę twarzy zabezpieczające przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

W czasie oprysku należy zastosować co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

Zanieczyszczonej odzieży ochronnej nie wносить poza miejsce pracy.

Unikać zanieczyszczenia skóry i oczu.

Dokładnie umyć ręce i twarz po użyciu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

### **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W czasie kwitnienia roślin uprawnych zaleca się stosownie środek poza okresami aktywności pszczoł.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

### **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C,
- w dobrze wentylowanym pomieszczeniu.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych. Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku połknięcia: W przypadku złego samopoczucia skontaktować się z ośrodkiem zatruc lub z lekarzem. Wypłukać usta.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z ośrodkiem zatruc lub lekarzem.

W przypadku kontaktu ze skórą: Umyć dużą ilością wody z mydłem. W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza. Wskazówki dla lekarza: leczenie symptomatyczne (dekontaminacja, funkcje vitalne). Płukanie żołądka.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

### **Appendix 3 Letter of Access**

Letter of Access is provided in a separate appendix.

## Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<b>Section B1-B2 and B4: Identity, Physical and Chemical Properties, Further information</b>							
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	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	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	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	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	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance	Pestila Sp. z o.o.* ProAgri In-

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished			with GLP.	ternational Sp. z o.o.**
<b>Section B3: Efficacy Data and Information</b>							
KCP 3.2/01	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-01 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/02	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-02 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/03	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-03 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/04	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-04 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/05	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied	N	Y	New data for formulation, not pre-	Pestila Sp. z



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			against leaf diseases in winter wheat. Poland 2022. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S22-03727-05 GEP: Yes Published: No			viously submitted or evaluated. Study conducted in compliance with GEP.	o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/06	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter wheat for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 013GPSE202201 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/07	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter wheat for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 013GPSE202202 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/08	Ławiński K.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in Winter Wheat. Poland 2022. Green & Property Poland; Report No.: 013GPSE202203 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/09	Ławiński K.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in Winter Wheat. Poland 2022. Green & Property Poland; Report No.: 013GPSE202204 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.2/10	Čáp J.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in cereals. Czech Republic, 2022 Zkušební stanice Nechanice, Czech Republic; Report No.: CZOR-PSZ22-TRZAW-053NEC GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/11	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring wheat. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-06 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/12	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on spring wheat for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 014GPSE202201 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/13	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter triticale. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-07 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/14	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter triticale for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 015GPSE202201 GEP: Yes	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Published: No				
KCP 3.2/15	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring triticale. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-08 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/16	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on spring triticale for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 016GPSE202201 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/17	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-10 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/18	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-11 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/19	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-12	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP: Yes Published: No				
KCP 3.2/20	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S22-03727-13 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/21	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in spring barley. Poland 2022. Eurofins Agrosience Services Sp. z o.o., Poland; Report No.: S22-03727-14 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/22	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on spring barley for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 019GPSE202201 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/23	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on spring barley for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 019GPSE202202 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/24	Ławiński K.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in Spring Barley.	N	Y	New data for formulation, not previously submitted or evaluated.	Pestila Sp. z o.o.*

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			Poland 2022. Green & Property Poland; Report No.: 019GPSE202203 GEP: Yes Published: No			Study conducted in compliance with GEP.	ProAgri International Sp. z o.o.**
KCP 3.2/25	Ławiński K.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in Spring Barley. Poland 2022. Green & Property Poland; Report No.: 019GPSE202204 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/26	Čáp J.	2022	Determination of efficacy of Prothioconazole applied against leaf diseases in cereals. Czech Republic, 2022 Zkušební stanice Nechanice, Czech Republic; Report No.: CZOR-PSZ22-HORVW-057NEC GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/27	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter barley. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03727-15 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/28	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter barley for the control of fungal diseases, Poland 2022. Green & Property Poland; Report No.: 018GPSE202201 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**

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KCP 3.2/29	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-01 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/30	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-02 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/31	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-03 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/32	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-04 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/33	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-03740-05 GEP: Yes	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**

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KCP 3.2/34	Figurski R.	2022	Published: No Efficacy evaluation of Prothioconazole 300 EC after two applications on winter OSR for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 020GP202201 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/35	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter OSR for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 020GP202202 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/36	Ławiński K.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Green & Property Poland; Report No.: 020GPSE202203 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/37	Ławiński K.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Poland 2022. Green & Property Poland; Report No.: 020GPSE202203 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 3.2/38	Čáp J.	2022	Determination of efficacy of Protiokonazol 300 EC applied in winter rape against fungal diseases. Czech Republic 2022	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri International

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			Zkušební stanice Nechanice, Czech Republic; Report No.: CZOR-PSZ22-BRSNN-045NEC GEP: Yes Published: No				Sp. z o.o.**
KCP 3.2/39	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202101 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/40	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202102 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/41	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202103 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/42	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202104 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/43	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202105 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**



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KCP 3.2/44	Figurski R.	2022	Efficacy evaluation of F-01-2021 applied in autumn against fungal diseases of winter oilseed rape Green & Property Poland; Report No.: 004GP202106 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/45	Figurski R.	2022	Efficacy evaluation of Prothioconazole 300 EC after two applications on winter rye for the control of fungal diseases, Poland 2022 Green & Property Poland; Report No.: 017GPSE 202201 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/46	Głowacki G.	2022	Determination of efficacy of Protiokonazol 300 EC applied against leaf diseases in winter rye. Poland 2022. Eurofins Agroscience Services Sp. z o.o., Poland Report No.: S22-03727-09 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/47	Springer M.	2023	Efficacy evaluation of Protiokonazol 300 EC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 007GPSE202301 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/48	Huszcza-Podgórska A.	2023	Efficacy evaluation of Protiokonazol 300 EC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 007GPSE202302 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/49	Figurski R.	2023	Efficacy evaluation of Protiokonazol 300 EC against diseases in cereals in Poland 2023 Green & Property Poland;	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No.: 007GPSE202303 GEP: Yes Published: No				
KCP 3.2/50	Głowacki G.	2023	Determination of efficacy of Protiokonazol 300 EC applied in the autumn, in winter rape against fungal diseases. Poland 2022 Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-07447-01 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/51	Głowacki G.	2023	Determination of efficacy of Protiokonazol 300 EC applied in the autumn, in winter rape against fungal diseases. Poland 2022 Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S22-07447-02 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/52	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-01 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/53	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-02 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/54	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Green & Property Poland; Report No.: 006GPAE2022-03 GEP: Yes Published: No				
KCP 3.2/55	Figurski R.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-04 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/56	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-05 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/57	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-06 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/58	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-07 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 3.2/59	Ławiński K.	2023	Protiokonazol 300 EC - Evaluation of efficacy and selectivity against diseases in winter oilseed rape after autumn	N	Y	New data for formulation, not previously submitted or evaluated.	Pestila Sp. z o.o.*

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			application. Poland 2022 Green & Property Poland; Report No.: 006GPAE2022-08 GEP: Yes Published: No			Study conducted in compliance with GEP.	ProAgri Sp. z o.o.**
<b>Section B5: Analytical Methods</b>							
KCP 5.1.1/01 KCP 5.1.1/02	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	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri International Sp. z o.o.**
KCP 5.1.2/01	Peda T.	2022	Magnitude of residue of prothioconazole and metabolites prothioconazole-desthio, triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in honey after one application of Protiokonazol 300 EC on phacelia (Raw agricultural Commodity) – two harvest study trials in Poland. Study Code: 22SGS46; LBN-0044-2022 SGS Polska Sp. z o. o. GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 5.1.2/02	Mautino G.	2023	Earthworm Reproduction Test ( <i>Eisenia fetida</i> ) with PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) Analytical Phase: Validation of an analytical method and determination of content of PROTHIOCONAZOLE in soil samples (OECD 222) Study Code: 1139.1F.SAG22; Test Site Code: 22293-02R Renolab S.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 5.1.2/03	Mautino G.	2023	Effects of PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) on Honeybees ( <i>Apis mellifera</i> L.) in the laboratory – Larval Toxicity Test Following Repeated Exposure Analytical Phase: Validation of an analytical method and determination of the	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			content of PROTHIOCONAZOLE in the water stock solutions (OECD 239) Study Code: 1002.1F.SAG22; Test Site Code: 22293-03R Renolab S.r.l., Italy GLP Unpublished				
	Morsiani S.	2023	Amendment No. 1 Analytical Phase Report 22293-03R (1002.1F.SAG22) Effects of PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) on Honeybees ( <i>Apis mellifera</i> L.) in the laboratory – Larval Toxicity Test Following Repeated Exposure Analytical Phase: Validation of an analytical method and determination of the content of PROTHIOCONAZOLE in the water stock solutions (OECD 239)	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 5.1.2/04	Mautino G.	2023	Predatory mites <i>Hypoaspis (Geolaelaps) aculeifer</i> reproduction test in soil with PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) Analytical Phase: Determination of content of PROTHIOCONAZOLE in soil samples Study code: Study Code: 1142.1F.SAG22; Test Site Code: 22293-04R Renolab S.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 5.1.2/05	Mautino G.	2023	Effects of PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) on Honeybees ( <i>Apis mellifera</i> L.) in the laboratory – Chronic Oral Toxicity Test Analytical Phase: Validation of an Analytical method and determination of content of prothioconazole in the feeding solutions of honey bees new born workers and in the water stock solution (OECD 245) Study Code: 1001.1F.SAG22; Test Site Code: 22293-01R Renolab S.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 5.1.2/06	Mautino G.	2023	Collembolan <i>Folsomia candida</i> reproduction test in soil with PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) Analytical Phase: Determination of content of PROTHIOCONAZOLE in soil samples (OECD 232) Study Code: 1143.1F.SAG22; Test Site Code: 22293-05R	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Renolab S.r.l., Italy GLP Unpublished				
KCP 5.1.2/07	Artusio M.	2023	Daphnia sp. Acute Immobilization Test ( <i>Daphnia magna</i> ) with PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) Analytical Phase: Determination of the content of PROTHIOCONAZOLE in water medium samples (OECD 202) Study Code: 1136.1F.SAG22; Test Site Code: 22293-06R Renolab S.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 5.1.2/08	Mautino G.	2023	Effects of PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) on Bumblebee ( <i>Bombus terrestris</i> L.) in the laboratory – Acute Oral and Contact Toxicity Test Analytical Phase: Determination of content of prothioconazole in the feeding solutions and in the water contact solution for bumblebees (OECD 246 and 247) Study Code: 1138.1F.SAG22; Test Site Code: 22293-07R Renolab S.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 5.1.2/09	Mautino G.	2023	Effects of PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) on terrestrial Non-target plants – Seedling Emergence and Seedling growth Analytical Phase: Determination of the content of PROTHIOCONAZOLE in the water spray solutions (OECD 208) Study Code: 1140.1F.SAG22; Test Site Code: 22293-08R Renolab S.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 5.1.2/10	Mautino G.	2023	Effects of PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) on Terrestrial Plant Vegetative Vigour – OECD 227 Analytical Phase: Determination of the content of PROTHIOCONAZOLE in the water spray solution Study Code: 1141.1F.SAG22; Test Site Code: 22293-09R Renolab S.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 5.1.2/11	Tediosi E.	2023	Validation of the analytical method for the determination of prothioconazole content in aqueous solutions	N	Y	New data for formulation, not previously submitted or evaluated.	Pestila 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			coming from ecotoxicological tests with PROTIOKONAZOL 300 EC Study No. CH – 0912-2022 ChemService S.r.l. Controlli e Ricerche, Italy GLP Unpublished			Study conducted in compliance with GLP.	ProAgri Sp. z o.o.**
KCP 5.1.2/12	Tediosi E.	2023	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Prothioconazole, Prothioconazole-desthio and Triazole-derivative metabolites (TDMs) in Honey after application of Protiokonazol 300 EC Study No. CH – 0303 -2023 ChemService S.r.l. Controlli e Ricerche, Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
<b>Section B7: Metabolism and Residues</b>							
KCA 6.10/01a	Peda T.	2022	Magnitude of residue of prothioconazole and metabolites prothioconazole-desthio, triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in honey after one application of Protiokonazol 300 EC on phacelia (Raw agricultural Commodity) – two harvest study trials in Poland. Company Report No.: 22SGS46 SGS Polska Sp. z o. o. GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCA 6.10/01b	Peda T.	2022	ANALYTICAL PHASE REPORT: Magnitude of residue of prothioconazole and metabolites prothioconazole-desthio, triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in honey after one application of Protiokonazol 300 EC on phacelia (Raw agricultural Commodity) – two harvest study trials in Poland. Company Report No.: 22SGS46; LBN-0044-2022 SGS Polska Sp. z o. o.; LabAnalysis s.r.l. GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCA 6.10/02a	Rovetto I.	2023	Magnitude of the residue of prothioconazole,	N	Y	New data for formulation, not pre-	Pestila

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			prothioconazoledesthio and triazole-derivative metabolites (TDMs) in honey after one application of PROTIOKONAZOL 300 EC on Phacelia crop under semi field conditions in two trials in Southern Europe – 2022 Company Report No.: 1147.2F.SAG22 SAGEA Centro di Saggio s.r.l. GLP Unpublished			viously submitted or evaluated. Study conducted in compliance with GLP.	Sp. z o.o.* ProAgri Sp. z o.o.**
KCA 6.10/02b	Rovetto I.	2022	ANALYTICAL PHASE REPORT: Magnitude of the residue of prothioconazole, prothioconazole-desthio and triazole-derivative metabolites (TDMs) in honey after one application of PROTIOKONAZOL 300 EC on Phacelia crop under semi field conditions in two trials in Southern Europe – 2022 Company Report No.: 1147.2F.SAG22; LBN-0045-2022 SAGEA Centro di Saggio s.r.l.; LabAnalysis s.r.l. GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
<b>Section B8: Environmental Fate</b>							
KCP 9.2.4	Hara-Skrzypiec A.	2022	Protiokonazol 300 EC Calculation of predicted environmental concentrations of prothioconazole and its metabolites in groundwater using the FOCUS groundwater scenarios (FOCUS PEARL, FOCUS PELMO) Company Report No: EST/20/2022 ESTICON Sp. z o.o. GLP: No Published: No	N	N	-	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 9.2.5	Hara-Skrzypiec A.	2022	Protiokonazol 300 EC Calculation of Predicted Environmental Concentrations of prothioconazole and its metabolites in surface water using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/19/2022 ESTICON Sp. z o.o. GLP: No Published: No	N	N	-	Pestila Sp. z o.o.* ProAgri 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<b>Section B9: Ecotoxicology</b>							
KCP 10.2.1.2/01	Artusio M	2023	Daphnia sp. Acute Immobilization Test ( <i>Daphnia magna</i> ) with PROTIKONAZOL 300 EC (prothioconazole 300 g/L) Company Report No: 1136.1F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.2.1.3/01	Mautino G	2023	PROTIKONAZOL 300 EC: toxicity to green algae <i>Pseudo-kirchneriella subcapitata</i> in a growth inhibition study Company Report No: 4546.1F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.3.1.1.1/01 KCP 10.3.1.1.2/01	Mautino G	2023	Effects of PROTIKONAZOL 300 EC (prothioconazole 300 g/L) on Honeybees ( <i>Apis mellifera</i> L.) in the laboratory – Acute Oral and Contact Toxicity Test Company Report No: 1137.1F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.3.1.1.1/02 KCP 10.3.1.1.2/02	Mautino G	2023	Effects of PROTIKONAZOL 300 EC (prothioconazole 300 g/L) on Bumblebee ( <i>Bombus terrestris</i> L.) in the laboratory – Acute Oral and Contact Toxicity Test Company Report No: 1138.1F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.3.1.2/01	Mautino G	2023	Effects of PROTIKONAZOL 300 EC (prothioconazole 300 g/L) on Honeybees ( <i>Apis mellifera</i> L.) in the laboratory – Chronic Oral Toxicity Test Company Report No: 1001.1F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.3.1.4/01	Mautino G	2023	Effects of PROTIKONAZOL 300 g/L EC (prothioconazole 300 g/L) on Honeybees ( <i>Apis mellifera</i> L.) in the laboratory – Larval Toxicity Test Following Repeated Exposure	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance	Pestila Sp. z o.o.* & ProAgri

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Company Report No: 1002.1F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished			with GLP.	Sp. z o.o.**
KCP 10.3.2.1/01	Mautino G	2022	Effects of PROTIKONAZOL 300 EC (prothioconazole 300 g/L) on <i>Typhlodromus pyri</i> – Extended laboratory aged residue test – 2022 Company Report No: 1020.F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.3.2.1/02	Mautino G	2022	Effects of PROTIKONAZOL 300 EC (prothioconazole 300 g/L) on <i>Aphidius rhopalosiphi</i> – Extended laboratory aged residue test – 2022 Company Report No: 1019.F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.3.2.1/03	Mautino G	2022	Effects of PROTIKONAZOL 300 EC (prothioconazole 300 g/L) on <i>Coccinella septempunctata</i> – Extended laboratory aged residue test – 2022 Company Report No: 1018.F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.3.2.1/04	Mautino G	2022	Effects of PROTIKONAZOL 300 EC (prothioconazole 300 g/L) on <i>Chrysoperla carnea</i> – Extended laboratory aged residue test – 2022 Company Report No: 1021.F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.4.1.1/01	Mautino G	2022	Earthworm Reproduction Test ( <i>Eisenia fetida</i> ) with PROTIKONAZOL 300 EC (prothioconazole 300 g/L) Company Report No: 1139.1F.SAG22	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance	Pestila Sp. z o.o.* & ProAgri

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished			with GLP.	Sp. z o.o.**
KCP 10.4.2/01	Mautino G	2022	Predatory mite <i>Hypoaspis (Geolaelaps) aculeifer</i> reproduction test in soil with PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) Company Report No: 1142.1F.SA22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.4.2/02	Mautino G	2022	Collembolan <i>Folsomia candida</i> reproduction test in soil with PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) Company Report No: 1143.F.SA22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.5/01	Mautino G	2023	Soil Microorganisms: Nitrogen Transformation Test with PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) Company Report No: 4545.1F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.6.2/01	Mautino G	2023	Effects of PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) on terrestrial Non-target plants – Seedling Emergence and Seedling Growth Company Report No: 1140.1F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**
KCP 10.6.2/02	Mautino G	2023	Effects of PROTIOKONAZOL 300 EC (prothioconazole 300 g/L) on Terrestrial Plant Vegetative Vigour - OECD 227 Company Report No: 1141.1F.SAG22 Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila Sp. z o.o.* & ProAgri Sp. z o.o.**

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

\*\*ProAgri International Spółka z ograniczoną odpowiedzialnością / ProAgri Spółka z ograniczoną odpowiedzialnością (short names: ProAgri International Sp. z o.o. / ProAgri 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

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner

The following tables are to be completed by MS

### List of data submitted by the applicant and not 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner

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

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner