FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: Protiokonazol 300 EC

Product name(s): HERA 300 EC

Chemical active substance:

prothioconazole, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023

MS Finalisation date: April 2024; July 2024 December 2024

Version history

When	What
April 2024	zRMS assessmento of dRR.
July 2024	The final Registration Report.
December 2024	Efficacy section made correctiions in the final registration report.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. This application is according to the Article 33 of Regulation 1107/2009.

In case of active substances data out of protection are used. In addition to the submission of studies as listed in particular sections, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	Poland	Not relevant.

0.1.3 Regulatory history of the active(s)

0.1.3.1 Prothioconazole

Table 0.1-2: Summary of regulatory history of CAS No: 178928-70-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION DIRECTIVE 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, Paecilomyces lilacinus and prothioconazole as active substances https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0044&from=EN COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&from=EN COMMISSION IMPLEMENTING REGULATION (EU)

Status	
	2020/869 of 24 June 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and S-metolachlor https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0869&from=EN COMMISSION IMPLEMENTING REGULATION (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distilation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0745&from=EN COMMISSION IMPLEMENTING REGULATION (EU) 2022/708 of 5 May 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aclonifen, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, beflubutamid, benthiavalicarb, boscalid, calcium carbide, captan, cymoxanil, dimethomorph, dodemorph, ethephon, ethylene, extract from tea tree, fat distilation residues, fatty acids C7 to C20, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, magnesium phosphide, metam, metamitron, metazachlor, metribuzin, milbemectin, phenmedipham, pirimiphos-methyl, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, propamocarb, proquinazid, prothioconazole, pyrethrins, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, sulcotrione, tebuconazole and urea https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0708&from=EN
RMS	PL
Date of Approval (or most recent renewal) of Active Substance	01/08/2008

Status	
(date of Regulation to be applied)	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/01/2009
Date of final Commission (re-registration) deadline (Step 2)	31/01/2010
Current expiration of approval	~~31/07/2023~~ 15.08.2025
Low risk substance or Candidate for Substitution?	Not relevant

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:
- the operator safety in spray applications. Conditions of use shall include adequate protective measures,
- the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate,
- the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate.

The SANCO report for Prothioconazole (SANCO/3923 /07 - final 10 December 2007) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 12 July 2007.

Table 0.1-3: Information on minimum purity of prothioconazole

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ** **
≥ 970 g/kg	minimum purity of active substance – confidential information reffered in Part C of dRR Equivalence report available: Y RMS: ~~please refer to the Letter of Access~~ Malta (soruce 1) and Czech Republic (source 2)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	**Active Substance**	
	EU agreed endpoint from EFSA scientific report	**Endpoint used***
Not relevant.	Not relevant.	Not relevant.

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

Efficacy section: all Residues section: 1-7 Environmental fate and behavior section: all Ecotoxicology section: all

Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: none Residues section: 8-10 Environmental fate and behavior section: none Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

Conclusions

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 used claimed by Applicant in the GAP table were accepted by ZRMs (use against ERYSYGR in winter wheat is accepted only conditionally). Within 24 months after authorization PPP, Applicant should present at least one eff. trial (optimally two trials) carried out on winter wheat against ERYSYGR in N-E EPPO zone or neighboring country. For winter oilseed rape (autumn and spring application) – recommended dose should be only 0.6 L/ha. Against ALTEBA – two applications ~~schemes were recommended~~ in spring or one in autumn is recommended. Detailed assessment is presented in B3.

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..

Environmental fate and behavior section:

No risk for ground water is expected after application Protiokonazol 300 EC.

Ecotoxicology section:

Uses are accepted.

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

Appendix 1 ALL intended uses

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

PPP (product name/code):	Protiokonazol 300 EC	Formulation type:	EC [a, b]
Active substance 1:	prothioconazole	Conc. of as 1:	300 [c]
Safener:	n.a.	Conc. of safener:	n.a. [c]
Synergist:	n.a.	Conc. of synergist:	n.a. [c]
Applicant:	Pestila Sp. z o. o.	Professional use:	☒
Zone(s):	Central Zone [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / 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 applications (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		
1	PL	Winter wheat	F	Controlled diseases (0.5 – 0.65 L/ha): **Septoria leaf blotch** (*Zymoseptoria tritici)* SEPTTR **Powdery mildew of cereals** (*Blumeria graminis)* 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 **Eff. section**: use against ERYSYGR is accepted only conditionally.
2	PL	Spring wheat	F	Controlled diseases (0.5 – 0.65 L/ha): **Septoria leaf blotch** (*Zymoseptoria tritici)* 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	Controlled diseases (0.5 – 0.65 L/ha): **Septoria leaf blotch** (*Zymoseptoria tritici)* SEPTTR **Powdery mildew of cereals** (*Blumeria graminis)* 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
4	PL	Spring triticale	F	Controlled diseases (0.5 – 0.65 L/ha): **Septoria leaf blotch** (*Zymoseptoria tritici)* SEPTTR **Powdery mildew of cereals** (*Blumeria graminis)* 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	Controlled diseases (0.5 – 0.65 L/ha): **Net blotch of barley** (*Pyrenophora teres)* 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	Controlled diseases (0.5 – 0.65 L/ha): **Net blotch of barley** (*Pyrenophora teres)* 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	Winter Rye	F	Controlled diseases (0.5 – 0.65 L/ha): **Powdery mildew of cereals** (*Blumeria graminis)* 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~~	~~Controlled diseases (0.5 – 0.6 L/ha):~~ ~~***Dark spot of crucifers** (*Alternaria brassicae)*~~ ~~ALTEBA~~ ~~**Dry rot of crucifers** (*Plenodomus lingam)*~~ ~~LEPTMA~~ ~~**Downy mildew of rape** (*Hyaloperonospora brassicae)*~~ 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~~	~~not relevant~~ **Eff section:** recommended dose should be 0.6 L/ha ~~* against ALTEBA the scheme application with spring treatment is recommended~~. **LEPTMA, ALTEBA and HIPERBR – accepted one treatment in autumn** **Metabolism and residues** Not accepted Data gap: magnitude of residues of triazole derivative metabolites (TDMs) in oilseed rape

9	PL	Winter oilseed rape	F	Controlled diseases (0.5 – 0.6 L/ha): ***Dark spot of crucifers** (*Alternaria brassicae)* ALTEBA **Cottony rot** (*Sclerotinia sclerotiorum)* 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	not relevant **Eff section:** recommended dose should be 0.6 L/ha. Use in the following application scheme against ALTEBA: a) 1 appl. at BBCH 13-19 at autumn and 1 appl. at BBCH 61-72 at spring. Interval between treatments: at least 90 days. or b) use twice a season in spring application at BBCH 61-72. Interval between treatments: at least 21 days **Against SCLESC and ALTEBA two spring application are accepted.** **Metabolism and residues** Not accepted Data gap: magnitude of residues of triazole derivative metabolites (TDMs) in oilseed rape
Minor uses according to Article 51 (Zonal uses)													
10	PL	Spring oilseed rape	F	Controlled diseases (0.5 – 0.6 L/ha): **Dry rot of crucifers** (*Plenodomus lingam)* LEPTMA **Cottony rot** (*Sclerotinia sclerotiorum)* SCLESC	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	not relevant **Eff section:** recommended dose should be 0.6

				~~**Dark spot of crucifers** (*Alternaria brassicae*) ALTEBA~~									L/ha **Metabolism and residues** Not accepted Data gap: magnitude of residues of triazole derivative metabolites (TDMs) in oilseed rape

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.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
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)
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
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.
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.
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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
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