FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: **CHR/ZF/PROTI 100 FS**

Product name(s):

Gamelan 100 FS

Doraltes 100 FS

Chemical active substance(s):

Prothioconazole, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 07.2021

MS Finalisation date: 05/09/2022

Version history

When	What
October 2021	Dossier sent for evaluation
June 2022	zRMS evaluation of dRR
September 2022	Final version prepared by zRMS after Commenting period

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zRMS comments:
The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for zonal registration of CHR/ZF/PROTI 100 FS (Gamelan 100 FS/ Doraltes 100 FS) containing prothioconazole in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to CHR/ZF/PROTI 100 FS where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/ZF/PROTI 100 FS have been made using endpoints agreed in the EU review of prothioconazole.

This document describes the specific conditions of use and labelling required for the registration of (Gamelan 100 FS/ Doraltes 100 FS), product code CHR/ZF/PROTI 100 FS.

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

In addition to the submission of studies as listed in section(s) ~~XXX~~ Appendix 4, 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 CHR/ZF/PROTI 100 FS Gamelan 100 FS/ Doraltes 100 FS	

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 Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011 Commission Implementing Regulation (EU) No. 2021/745 of 6 May 2021
RMS	PL
Date of Approval (or most recent renewal) of Active Substance	01.08.2009~~8~~

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)	31.07.2020
Date of final Commission (re-registration) deadline (Step 2)	31.07.2020
Current expiration of approval	31.07.2022
Low risk substance or Candidate for Substitution?	N/A

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:

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:
- The operator safety in spray applications. Conditions of use should include adequate protective measures.
- The protection of aquatic organisms. Risk mitigation measures such as buffer zones should be applied, where appropriate.
- The protection of birds and small mammals. Risk mitigation measures should be applied, where appropriate

The SANCO report for Prothioconazole (SANCO/3923 /07 – final 26 January 2021) 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 2007 - EFSA Scientific Report (2007) 106.

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	980 g/kg

* 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.

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
The two years storage stability study is on-going.

Section 3. Efficacy
The CHR/ZF/PROTI 100 FS is effective in controlling a *Fusarium spp.:* in winter wheat 73%(72 % lab.) and triticale 79% (75% lab.) - medium level of control and rye 79% (81% lab.)-effective control, *Mysphaerella nivalis/Microdochium nivale* in winter wheat 83%, triticale 85%, rye 92%-effective control, *Tilletia caries* in winter wheat 100% and *Urocistis occulta* in rye 100 % full effective control.*Ustilago tritici* (3 trials)100% full effective control. The presented number of studies for *Ustilago tritici* does not meet the registration requirements in Poland. It may be conditionally present on the label until the number of tests is completed.

The results of the field experiments were confirmed by the results of laboratory experiments. The test

product performed at a similar level of efficacy as the reference products.The data obtained in the experiments confirm the proposed uses.

The effectiveness of the studied product obtained in the experiments confirms the correctness of the information in the label. The Applicant has presented in the label appropriate elements of the anti-immune policy. CHR/ZF/PROTI 100 FS shows high selectivity towards cereals. No adverse plant symptoms or negative effects of the tested seed treatment on cereal yield were observed. The data obtained in the experiments confirm these features. Currently, there is no risk of pathogens resistance to prothioconazole, but with such frequent use this phenomenon may occur (Tab.3). Adequate policy should be followed and prothioconazole should not be applied more than twice per season on one crop e.g. seed treatment and one foliar(ear) application.

The results obtained in the experiments justify the needed for registration of the studied agent for pathogens control in winter cereals in Poland. The data provided in dRR confirm the above applications and authorize the registration of CHR/ZF/PROTI 100 FS in Poland.

Section 5. Analytical Methods
The analytical method used for analysing the prothioconazole and relevant impurities in the PPP is accepted.

Section 6. Mammalian Toxicology
Based on the calculation method taking into consideration valid data available on each of the components in the mixture, CHR/ZF/PROTI 100 FS is classified as Skin Sens. 1A (H317 May cause an allergic skin reaction).
Due to the exposure assessment CHR/ZF/PROTI 100 FS is safe for operator wearing coverall and gloves during mixing/loading, calibration and cleaning. Due to the hazard characterisation – gloves also during bagging.
Workers – coverall. No unacceptable risk for residents and bystanders.

Section 7. Metabolism and Residues
The intended GAP was accepted. The relevant MRLs exceedance is not expected. The chronic and acute intakes of prothioconazole and TDMs residues are unlikely to present a public health concern.
The approval can be granted.

Section 8. Environmental Fate
In accordance with proposed pattern use of CHR/ZF/PROTI 100 FS, all relevant information was submitted. No mitigation measure was proposed.

Section 9. Ecotoxicology
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of CHR/ZF/PROTI 100 FS – Gamelan 100 FS/Doraltes 100 FS in winter cereals poses acceptable risk to non-target organisms, if applied according to the recommended use pattern.

Section 10. Assessment of the relevance of metabolites in groundwater
The maximum PECGW values for metabolites are below the trigger value of 0.1 µg/L.
Therefore, the relevance assessment of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is not required.

Appendix 1 ALL intended uses

GAP rev. , date: 2020-09-23

PPP (product name/code)	CHR/ZF/PROTI	Formulation type:	FS
Active substance 1:	prothioconazole	Conc. of as 1:	100,0 g/l
Active substance 2:	n/a	Conc. of as 2:	n/a
Active substance….:	n/a	Conc. of as ….:	n/a
Safener:	-	Conc. of safener:	conc. (c)
Synergist:	-	Conc. of synergist:	conc. (c)
Applicant:	Innvigo	Professional use:	☒
Zone(s):	central	Non professional use:	☐
Verified by MS:	yes/~~no~~		

Field of use: Seed treatment

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate per treatment**			**PHI** (days)	**Remarks:** e.g. g safen-er/synergist per ha (f)
					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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1													
2													
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3	PL	Winter wheat (TRZAW)	F	*Tilletia caries, Fusarium sp., Microdochium majus,*	winter seed treat-	n/a	a)1 b)1	n/a	a) Max. 1.0 l /t seed	a) 0.018-0.025 kg a.s/ha	max. 0.7 L/100 kg	n/a	Sowing rate: 180-250 kg/ha

				Ustilago tritici	ment				b) Max. 1.0 l /t seed	b) 0.018-0.025 kg a.s/ha	seed		
4	PL	Winter triticale (TTLWI)	F	*Fusarium sp., Microdochium majus*	winter seed treatment	n/a	a)1 b)1	n/a	a) Max. 1.0 l /t seed b) Max. 1.0 l /t seed	a) 0.015-0.025 kg a.s/ha b) 0.015-0.025 kg a.s/ha	max. 0.7 L/100 kg seed	n/a	Sowing rate: 150-250 kg/ha
5	PL	Winter rye (SECCW)	F	*Fusarium sp., Microdochium majus, Urocystis occulta*	winter seed treatment	n/a	a)1 b)1	n/a	a) Max. 1.0 l /t seed b) Max. 1.0 l /t seed	a) 0.0095-0.025 kg a.s/ha b) 0.0095-0.025 kg a.s/ha	max. 0.7 L/100 kg seed	n/a	Sowing rate: 95-250 kg/ha
Minor uses according to Article 51 (zonal uses)													
6													
7													
Minor uses according to Article 51 (interzonal uses)													
8													
9													

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