REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: SAP2101F

Product name(s): ZELORA START

Chemical active substance(s):

Prothioconazole, 120 g/L
Folpet, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Selectis Produtos para a Agricultura, S.A.

Submission date: December 2023

MS Finalisation date: June 2024 (initial Core Assessment)

August 2024 (final Core Assessment)

Version history

When	What
December 2023	V0 - Initial version submitted by the Selectis Produtos para a Agricultura, S.A. for submission to Poland in the frame of new PPP registration (Acording Art. 33 of Regulation EC No 1107/2009)
June 2024	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
August 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is made for registration of the ASCENZA S.A. new product SAP2101F containing 120 g/L of prothioconazole and 300 g/L of folpet as suspension concentrate (SC).
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.

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)
Central zone	Poland, ZELORA START New registration

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) 2019/707 of 07 May 2019
RMS	PL (original RMS was UK)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.08.2008
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline (Step 2)	
Current expiration of approval	15.08.2025 ~~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:

- 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 – 10/12/2007, updated 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 01/08/2007.

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 The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material: - Toluene: < 5 g/kg - Prothioconazole-desthio (2-(1-chlorocycloproyl)1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol): < 0.5 g/kg (LOD)	980 g/kg Equivalence report available: Y RMS: FR and NE

* 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*

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

0.1.3.2 Folpet

Table 0.1-4: Summary of regulatory history of CAS No: 133-07-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2007/5/EC of 7 February 2007 Commission implementing regulation (EU) 2019/707 of 07 May 2019
RMS	AT (original RMS was IT)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.10.2007
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline (Step 2)	
Current expiration of approval	15.02.2025 ~~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:

– the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment;

– the dietary exposure of consumers in view of future revisions of Maximum Residue Levels;
– the protection of birds, mammals, aquatic and soil organisms. Conditions of authorisation should include risk mitigation measures.

The SANCO report for folpet (SANCO/10032/2006 - rev.5 – 11/07/2008) 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 date 29.09.2006 and reviewed.

Table 0.1-5: 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 *, **
Minimum purity 940 g/kg	960 g/kg Equivalence report available: Y RMS: FR and UK

* 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	Endpoint used*

* 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:

See column 15 of the GAP table presented in Appendix 1 of this document.

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

See column 15 of the GAP table presented in Appendix 1 of this document.

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:

See column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 2 ~~1~~ date: May 2024

PP (product name/ code):	SAP2101F/~~MELVAR~~ ZELORA STAR	Formulation:	SC [a,b]
Active substance 1:	prothioconazole	Concentration of as 1:	120 g/L [c]
Active substance 2:	folpet	Concentration of as 2:	300 g/L [c]
Safener:	/	Concentration of safener:	/
Synergist:	/	Concentration of synergist:	/
Applicant:	Selectis Produtos para a Agricultura, S.A.	Professional use:	☒
Zone (s):	Central [d]	Non professional use:	☐
Verified by MS:	~~yes~~/no		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15								
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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]	**zRMS Conclusion**								
					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			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																						
1	PL	Soft wheat (spring) (TRZAS); Soft wheat (winter) (TRZAW); Durum wheat (spring) (TRZDS); Durum wheat (winter) (TRZDW)	F	*Septoria* (*Zymoseptoria tritici*, SEPTTR)	Tractor mounted spray	BBCH 32-**59** ~~61~~	a) 2 b) 2	14 days	a) 1.5 L/ha b) 3 L/ha	a) 180 g ai/ha + 450 g ai/ha b) 360 g ai/ha + 900 g ai/ha	150-400	**42**	Range: 1 L/ha - 1,5 L/ha	A	A	A	A	A	R Aquatic (R1 scenario) A Remained species	A	A TRZAW N TRZAS N TRZDW TRZDS (possible registration on the grounds of article 51)
2	PL	Barley (spring) (HORVS); Barley (winter) (HORVW)	F	*Helminthosporium* (*Pyrenophora teres*, PYRNTE)	Tractor mounted spray	BBCH 30-**61**	a) 2 b) 2	14 days	a) 1.5 L/ha b) 3 L/ha	a) 180 g ai/ha + 450 g ai/ha b) 360 g ai/ha + 900 g ai/ha	150-400	**42**	Range: 1 L/ha - 1,5 L/ha	A	A	A	A	A	R Aquatic (R1 scenario) A Remained species	A	N

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
15 Overall conclusions - explanation for the column 15 is below *

* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible