REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SAP2101F

Product name(s): ZELORA START

Chemical active substance(s):

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

Southern Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

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

Submission date: December 2023

MS Finalisation date: May 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).
May 2024	Initial assessment by the zRMS 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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Reviewer comments:

This part of dossier has been submitted to support registration of the plant protection product SAP2101F / Prothioconazole + Folpet (120+300) g/L SC according art. 33 of 1107/2009.
Document refers data related to the forming of metabolites in the environment (see dRR B8). dRR Part B10 has been reviewed for the purposes of ongoing registration and also checked its compliance with the current guidelines. Information has been considered as sufficient and appropriate for concluding.

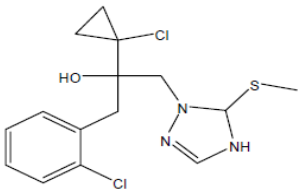
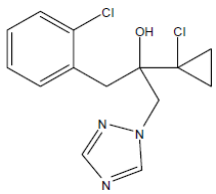
10 Relevance of metabolites in groundwater

10.1 General information

10.1.1 Prothioconazole and its metabolites

Both metabolites JAU 6476-S-methyl and JAU 6476-desthio predicted to occur in groundwater will occur at concentrations below 0.1 µg/L (see chapter 8.8.2.1 in dRR Part B, Section 8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.11 are therefore not required. General information on the metabolites is provided in Table 10.1.1 1.

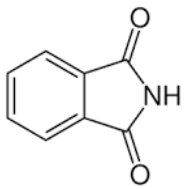
Table 10.1.1-1: General information on the prothioconazole metabolites

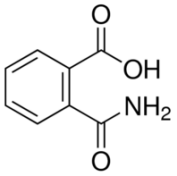
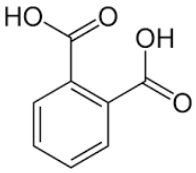
Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessmnent	
Prothioconazole	M01: JAU 6476-S methyl CAS 178928-71-7		Max PEC_{gw} Based on:	< 0.001 µg/L FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 in all scenarios
	M04: JAU 6476-desthio CAS 120983-64-4		Max PEC_{gw} Based on:	< 0.001 µg/L FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 in all scenarios

10.1.2 Folpet and its metabolites

The metabolites Phthalimide, Phthalamic acid and Phthalic acid predicted to occur in groundwater will occur at concentrations below 0.1 µg/L (see chapter 8.8.2.2 in dRR Part B, Section 8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.11 are therefore not required. General information on the metabolites is provided in Table 10.1.2 1.

Table 10.1.2-2: General information on the folpet metabolites

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessmnent	
Folpet	Phthalimide		Max PEC_{gw} Based on:	< 0.001 µg/L FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 in all scenarios

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessmnent	
	Phthalamic acid		Max PEC_{gw} Based on:	< 0.001 µg/L FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 in all scenarios
	Phthalic acid		Max PEC_{gw} Based on:	< 0.001 µg/L FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 in all scenarios

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4/01	Fernandes, V.	2021a	Predicted Environmental Concentrations of Prothioconazole and its metabolites in Groundwater (PEC_{gw}) based on FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4 for risk assessment of SAP2101F on Cereals ASC123-2021 non GLP Unpublished	N	Ascenza Agro SA
KCP 9.2.4/02	Fernandes, V.	2021b	Predicted Environmental Concentrations of Folpet and its metabolites in Groundwater (PEC_{gw}) based on FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4 for risk assessment of SAP2101F on Cereals ASC124-2021 non GLP Unpublished	N	Ascenza Agro SA

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	Owner
-	-	-	-	-	-

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	Owner
-	-	-	-	-	-

List of data relied on 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	Owner
-	-	-	-	-	-