REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: A23282A

Product name: **KAYAK ERA**

Chemical active substances:

Cyprodinil, 225 g/L
Prothioconazole, 115 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New product authorization)

Applicant: XXXX

Submission date: July 2022

Evaluation date: March 2023

MS Finalisation date: dd/mm/yyyy

Version history

When	What
July 2022	Submitted RR version
March 2023	Version evaluated by zRMS PL

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10 Relevance of metabolites in groundwater

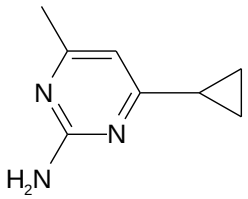
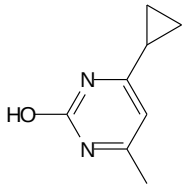
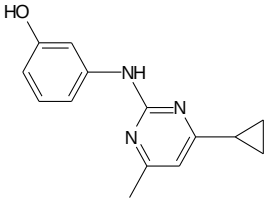
zRMS Comments:	The submitted justification was accepted. Based on PECgw assessment for metabolites of both active substances, the concentration in groundwater were below the trigger value of 0.1 µg/L for all relevant metabolites. Since all metabolite do not exceed in the ground water the concentration of 0.1 µg/L, the 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. None of the metabolites are considered as relevant.

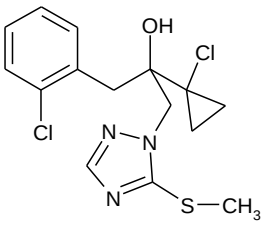
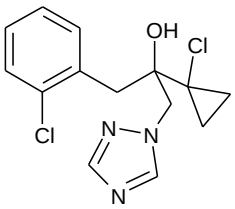
10.1 General information

The cyprodinil metabolites CGA249287, CGA321915 and CGA275535 and prothioconazole metabolites JAU 6476-S-methyl and JAU 6476-desthio are predicted to occur in groundwater at concentrations below 0.1 µg/L (see A23282A, dRR Part B, Section 8.8).

General information on the metabolites are provided in Table 10.1-1 below. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in the dRR Part B, Section 8 (Environmental fate and behaviour).

Table 10.1-1: General information on the metabolite(s)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Cyprodinil	CGA249287		Max PEC_{gw} Based on:	<0.001 µg/L All models/ All scenarios
	CGA321915		Max PEC_{gw} Based on:	<0.001 µg/L All models/ All scenarios
	CGA275535		Max PEC_{gw} Based on:	<0.001 µg/L All models/ All scenarios

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Prothioconazole	JAU 6476-S-methyl		Max PEC_{gw} Based on:	<0.001 µg/L All models/ All scenarios
	JAU 6476-desthio		Max PEC_{gw} Based on:	<0.001 µg/L All models/ All scenarios

10.2 Relevance assessment of the cyprodinil metabolite CGA249287

Summary:

The groundwater metabolite CGA249287 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. Studies supporting PEC_{gw} data are evaluated in A23282A, dRR Part B, Section 8.8.

10.2.1 STEP 1: Exclusion of degradation products of no concern

CGA249287 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.2.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for CGA249287 were performed. No uses for which concentrations of CGA249287 were considered to exceed 0.1 µg/L were identified. Details are given in A23282A, dRR Part B, Section 8.8.

10.3 Relevance assessment of the cyprodinil metabolite CGA275535

Summary:

The groundwater metabolite CGA275535 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. Studies supporting PEC_{gw} data are evaluated in A23282A, dRR Part B, Section 8.8.

10.3.1 STEP 1: Exclusion of degradation products of no concern

CGA275535 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.3.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for CGA275535 were performed. No uses for which concentrations of CGA275535 were considered to exceed 0.1 µg/L were identified. Details are given in A23282A, dRR Part B, Section 8.8.

10.4 Relevance assessment of the cyprodinil metabolite CGA321915

Summary:

The groundwater metabolite CGA321915 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. Studies supporting PEC_{gw} data are evaluated in A23282A, dRR Part B, Section 8.8.

10.4.1 STEP 1: Exclusion of degradation products of no concern

CGA321915 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.4.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for CGA321915 were performed. No uses for which concentrations of CGA321915 were considered to exceed 0.1 µg/L were identified. Details are given in A23282A, dRR Part B, Section 8.8.

10.5 Relevance assessment of the prothioconazole metabolite JAU 6476-S-methyl

Summary:

The groundwater metabolite JAU 6476-S-methyl is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. Studies supporting PEC_{gw} data are evaluated in A23282A, dRR Part B, Section 8.8.

10.5.1 STEP 1: Exclusion of degradation products of no concern

Phthalic acid does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.5.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for JAU 6476-S-methyl were performed. No uses for which concentrations of phthalic acid were considered to exceed 0.1 µg/L were identified. Details are given in A23282A, dRR Part B, Section 8.8.

10.6 Relevance assessment of the prothioconazole metabolite JAU 6476-desthio

Summary:

The groundwater metabolite JAU 6476-desthio is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. Studies supporting PEC_{gw} data are evaluated in A23282A, dRR Part B, Section 8.8.

10.6.1 STEP 1: Exclusion of degradation products of no concern

JAU 6476-desthio does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.6.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for JAU 6476-desthio were performed. No uses for which concentrations of JAU 6476-desthio were considered to exceed 0.1 µg/L were identified. Details are given in A23282A, dRR Part B, Section 8.8.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on (A23282A)

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
none					

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
none					

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	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

Appendix 2 Additional information

Please refer to A23282A, Part B, Section 8.