

# REGISTRATION REPORT

## Part B

### Section 10

#### **Assessment of the relevance of metabolites in groundwater**

Detailed summary of the risk assessment

Product code: FHO04

Product name(s): Prothioconazole/Sulphur (50+625) SC,  
/ Patton Supra

Chemical active substance(s): Prothioconazole 50 g/L,  
Sulphur 625 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: 31/05/2024

MS Finalisation date: November 2024 (initial Core Assessment)

February 2025 (final Core Assessment)

### Version history

When	What
31 May 2024	Applicant version.
November 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 <del>struck through</del> and shaded for transparency.
February 2025	Final report (Core Assessment updated following the commenting period)  No additional information or assessments after the commenting period.

## Table of Contents

<b>10</b>	<b>Relevance of metabolites in groundwater.....</b>	<b>4</b>
10.1	General information.....	4
10.2	Relevance assessment of prothioconazole metabolites .....	5
10.3	Relevance assessment of sulfate.....	5
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation.....</b>	<b>7</b>
<b>Appendix 2</b>	<b>Additional information.....</b>	<b>8</b>

### Reviewer comments:

This part of dossier has been submitted to support registration of the plant protection product/Patton Supra (product code FHO04) 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

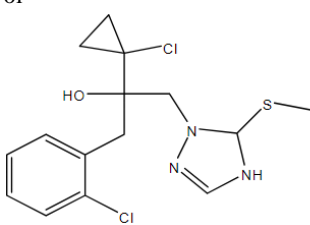
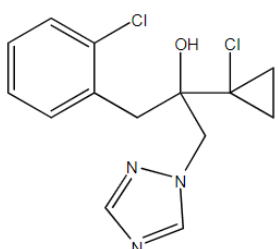
### 10.1 General information

Prothioconazole and its soil metabolites are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B Section 8.8.2.1). All  $PEC_{gw}$  values are <0.001 µg/L for all FOCUS groundwater scenarios for the requested GAP. Assessment of the relevance of these metabolites according to the step-wise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

Sulfate, the transformation product of sulfur, is predicted to occur in groundwater at concentrations above 0.1 µg/L (see Section 8.8.2.2). However, according to Annex 1, Part C of the Drinking Water Directive (Council Directive 98/83(EC)) an indicator parameter of 250 mg/L applies for sulfate. The groundwater relevance of sulfate is warranted by the residue definitions for exposure and risk assessments given under CA 7.4.1 in document M-CA, Section 7 of the DAR (2007).

General information on the prothioconazole soil metabolites and sulfate is provided in **Błąd! Nie można odnaleźć źródła odwołania..** 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 Section 8.8 of 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	Result of assessment	
Prothioconazole	Prothioconazole S-methyl (M01)	2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(4,5-dihydro-5-methylthio-1,2,4-triazolyl-1)-propan-2-ol 	Max $PEC_{gw}$ Based on:	<0.001 µg/L PEARL v5.5.5 /PELMO v6.6.4, all scenarios, winter and spring cereals
Prothioconazole	Prothioconazole desthio (M04)	2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol 	Max $PEC_{gw}$ Based on:	<0.001 µg/L PEARL v5.5.5 /PELMO v6.6.4, all scenarios, winter and spring cereals
Sulfur	Sulfate	$SO_4^{2-}$	Max $PEC_{gw}$ Based on:	11.097 mg/L Winter cereals

Name of active substance	Metabolite name and code	Structural/molecular formula	Result of assessment
			(Châteaudun, PELMO v6.6.4)

## 10.2 Relevance assessment of prothioconazole metabolites

The  $PEC_{gw}$  values for the prothioconazole metabolites JAU 6476-S-methyl (M01) and JAU 6476-desthio (M04) are by far below 0.1 µg/L, therefore no further assessment of their relevance is necessary.

## 10.3 Relevance assessment of sulfate

The relevance of the groundwater transformation product sulfate has already been assessed and the assessment agreed at EU level (see EFSA, 2008), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the  $PEC_{gw}$  calculated for the GAP and groundwater scenarios considered in this dRR). Sulfate is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. Sulfate is an inorganic compound (not containing a heavy metal) and is considered a transformation product of no concern and additional data are not required.

Furthermore, tier 1  $PEC_{gw}$  of sulfate at 1 m depth from all relevant FOCUS PELMO, PEARL and MACRO groundwater scenarios as provided in Section 8.8 of the dRR Part B, Section 8 (Environmental fate and behaviour) are considerably less than the drinking water indicator parameter of 250 mg/L for each GAP use of the formulation on winter and spring cereals. Therefore, it can be concluded that the transformation product sulfate does not pose an unacceptable risk to groundwater if the products are used in compliance with the label recommendations. A summary of the relevance assessment is given in **Błąd! Nie można odnaleźć źródła odwołania..**

**Table 10.3-1: Summary of the relevance assessment for sulfate**

		Assessment step		Result of assessment	
		STEP 1		Metabolite of no concern?	Yes, inorganic compound, not containing a heavy metal
Quantification of ground water contamination		STEP 2		Max PEC <sub>gw</sub>	11.097 mg/L*
				Based on	Winter cereals (Châteaudun, PELMO v6.6.4)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	N/R	
		Stage 2	Genotoxic properties of metabolite	N/R	
		Stage 3	Toxic properties of metabolite;	N/R	
			Classification of parent	N/R	
			Classification of metabolite	N/R	
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	N/R	
	STEP 5		Refined risk assessment	N/R	

		Predicted exposure (% of ADI)	N/R
		ADI based on	N/R

\* According to Annex 1, Part C of the Drinking Water Directive (Council Directive 98/83(EC)) an indicator parameter of 250 mg/L applies for sulfate.

N/R: not required. The transformation product sulfate potentially of concern meets at least one of the criteria for products of no concern defined in Step 1 of the guideline, i.e. it is an inorganic compound, not containing a heavy metal. No further non-relevance assessment is required according to the principles of SANCO/221/2000, rev. 10-final

## 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
-	-	-	-	-	-

### 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
-	-	-	-	-	-

## **Appendix 2    Additional information**

None.