

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: GPF515 / FGE03

Product name(s): Boscalid / Prothioconazole 350 / 200 WG

Chemical active substance(s):

Boscalid, 350 g/kg

Prothioconazole, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Article 33 application for a new product registration)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024

MS Finalisation date: April 2025 (initial Core Assessment)

August 2025 (final Core Assessment)

Version history

When	What
November 2024	V01 – Version from applicant for submission to z-RMS Poland in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No 1107/2009.
April 2025	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 2025	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/Patton Boost (product code GPF515 / FGE03) according art. 33 of 1107/2009.

Document refers data related to the forming of metabolites in the environment (see dRR B8). Predicted Environmental Concentrations of boscalid, prothioconazole and their metabolites in groundwater (PEC_{gw}) are below the trigger of 0.1 µg/L indicating safe use for proposed GAP.

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.

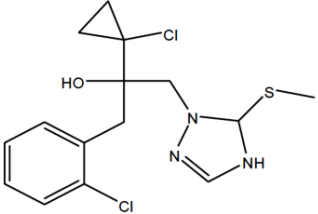
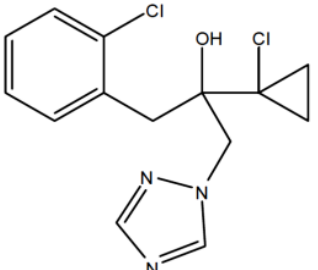
10 Relevance of metabolites in groundwater

10.1 General information

For boscalid, no major degradation products were found in aerobic soil metabolism studies or field dissipation studies. Therefore, there are no soil metabolites of boscalid triggering PEC_{GW} calculations and thus, assessment of the relevance of metabolites in groundwater is not applicable.

No metabolites of prothioconazole were considered relevant for the groundwater relevance assessment (refer to point 8.8.2 in dRR Part B, Section 8). The metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) are predicted to occur in groundwater at concentrations far below 0.1 µg/L (see table below). No assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

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	
Prothioconazole	Prothioconazole-S-methyl M01		Max PEC _{gw} Based on: 1 or 2 × 140 g a.s./ha, winter and spring oilseed rape	< 0.001 µg/L All FOCUS models and scenarios
Prothioconazole	Prothioconazole-desthio M04		Max PEC _{gw} Based on: 1 or 2 × 140 g a.s./ha, winter and spring oilseed rape	< 0.001 µg/L All FOCUS models and scenarios

10.2 Relevance assessment of metabolite

10.2.1 STEP 1: Exclusion of degradation products of no concern

Not required, please refer to 10.1.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not required, please refer to 10.1.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not required, please refer to 10.1.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not required, please refer to 10.1.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not required, please refer to 10.1.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not required, please refer to 10.1.

10.2.5 STEP 5: Refined risk assessment

Not required, please refer to 10.1.