

FINAL REGISTRATION REPORT

Part B

Section 10

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

Detailed summary of the risk assessment

Product code: GLOB2021dF

Product name: Pirlanko

Chemical active substances:

Boscalid: 156 g/L

Prothioconazole: 156 g/L

Central

Zonal Rapporteur Member State:

Poland

CORE ASSESSMENT

(authorization)

Applicant: GLOBACHEM NV

Submission date: November 2023

zRMS Assessment : 31/01/2025

Following commenting period: 15/05/2025

Final Report : 26/06/2026

Version history

When	What
January 2025	zRMS evaluation
May 2025	Following commenting period
June 2026	Final Report

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10 Relevance of metabolites in groundwater

zRMS comment: None of the metabolites of boscalid and prothioconazole exceeded the threshold value of 0.1 µg/L in groundwater. The assessment of toxicological relevance of the metabolites is not required according to SANCO/221/2000 – rev.11, 21 October 2021.

10.1 General information

The metabolites M510F47, M510F49 and M510F64 of boscalid and the metabolites M04, M01, M13 and M12 of Prothioconazole are predicted to occur in groundwater at concentrations below 0.1 µg/L (see 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 is therefore not required.

General information on the metabolites is provided in Table 10.1-1 and Table 10.1-2. 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 metabolites of boscalid

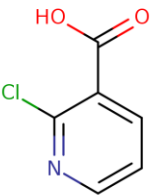
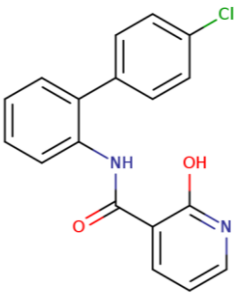
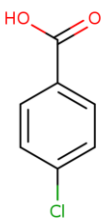
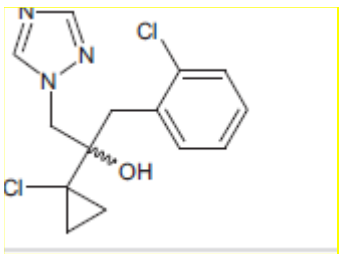
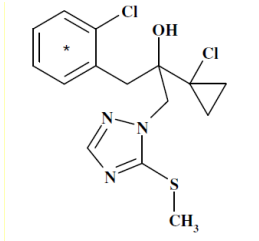
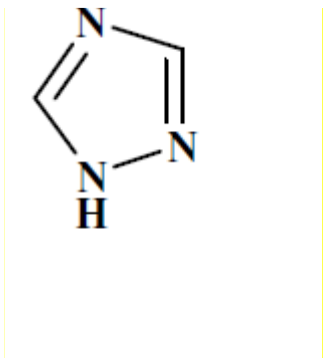
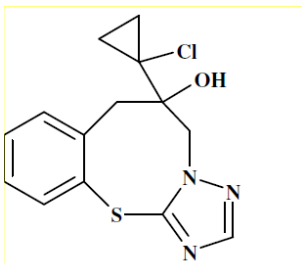
Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Boscalid	M510F47 (M47)		Max PEC _{gw} Based on	< 0.001 PELMO 5.5.3
	M510F49 (M49)		Max PEC _{gw} Based on	< 0.001 PELMO 5.5.3
	M510F64 (M64)		Max PEC _{gw} Based on	< 0.001 PELMO 5.5.3

Table 10.1-2: General information on the metabolites of prothioconazole
None of the metabolites exceeds the threshold value of 0.1 µg/L in groundwater

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Prothioconazole-desthio (M04)	312.2 g/mol		Soil: 49.4% Water/sediment systems: - sediment: 26.9%, - water: 32.3%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk for soil organisms PEC _{sw/sed} : risk for aquatic organisms PEC _{air}
Prothioconazole-S-methyl (M01)	358.3 g/mol		Soil: 14.6 % Water/sediment systems: - sediment: 9.6%, - water: 3.1%.	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk for soil organisms PEC _{sw/sed} : risk for aquatic organisms
1,2,4-triazole (M13)	69.1 g/mol		Water/sediment systems: - sediment: 6.1% - water: 37.2%	PEC _{sw/sed} : risk for aquatic organisms
Prothioconazole-thiazocine (M12)	307.8 g/mol		- aqu. photolysis: 14.1%	In the EFSA 106 (2007) it is concluded that under environmental conditions M12 is unlikely to be formed at > 10% in natural surface water systems based on in-

				formation from the photolysis and water-sediment studies. Therefore, no PEC _{sw} calculations were performed.
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Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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
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
KCP	Author	YYYY	Title	Y/N	Owner

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
XX			Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished		

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner