

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: BAS 762 02 F

Product name(s): Revydas

Chemical active substance(s):

Mefentrifluconazole, 100 g/L

Boscalid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: March 2021

MS Finalisation date: November 2021 (initial Core Assessment)

April 2022 (final Core Assessment)

Version history

When	What
03/2021	Applicant Initial dRR – BASF DocID 2021/2003414
November 2021	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 .
April 2022	Final report (Core Assessment after 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 BAS 762 02 F/Revydas 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. The information on PEC_{GW} for metabolite has been corrected to comply with data agreed in area of Section 8.

10 Relevance of metabolites in groundwater

10.1 General information

Mefentrifluconazole

No metabolites of mefentrifluconazole were considered relevant for the groundwater assessment (chapter 8.8.2 in Part B, Section 8).

Only the following two metabolites were observed in laboratory studies conducted to investigate the metabolism of BAS 750 F in soil:

- M750F001 (1,2,4-triazole): with a maximum occurrence of 5.2% TAR
(one sampling in one soil out of four soils, decreasing towards study end)
- M750F003: with a maximum occurrence < 2% TAR

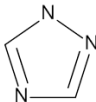
Field studies showed no substantial formation of either of the metabolites.

Thus, based on lab and field data it is not expected that 1,2,4-triazole nor M750F003 will be substantially produced from BAS 750 F field conditions. Considering the obtained information no groundwater assessment is required.

In spite of this, M750F001, a potential metabolite of azole fungicides, is included in the residue definition for risk assessment to address potential regulatory interest related to this compound because of its well-known toxicological properties.

Results of the ground water risk assessment indicate no risk of leaching of unacceptable amounts of 1,2,4-triazole into groundwater (see table below). Thus, assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 was therefore not 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	
Mefentrifluconazole	1,2,4-triazole (M750F001)		Max PEC _{gw} Based on:	0.032 µg L ⁻¹ 0.026 µg L ⁻¹ Crop: sunflower (2 x 100 g ha ⁻¹) (maize used as surrogate crop for Central Zone scenarios not defined for sunflower)

				FOCUS _{gw} scenario: Hamburg Piacenza, model: FOCUS-PEARL 4.4.4 PELMO 5.5.3, Tier 4
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Boscalid

No metabolites of boscalid were considered relevant for the groundwater assessment (chapter 8.8.2 in Part B, Section 8). Assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000–rev.10 was therefore not required.