FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: BAS 768 00 F

Product name(s): Revytur

Chemical active substance(s):

Mefentrifluconazole, 25 g/L
Sulfur, 600 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: March 2023

MS Finalisation date: 11/12/2023

Version history

When	What
03/2023	Initial dRR – BASF DocID 2022/2030239
04/2023	Dossier sent for evaluation
08/2023	zRMS evaluation of dRR
12/2023	Final version prepared by zRMS after Commenting period

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Evaluator comments:
The text highlighted in grey was provided by the Evaluator.

10 Relevance of metabolites in groundwater

zRMS Comments:	The submitted information was accepted. The maximum PECgw values for metabolite 1,2,4-triazole are below the trigger value of 0.1 µg/L in all tested scenarios and at all Tiers with the maximum PECgw of 0.066 µg L^{-1}. For details, please refer to Section 8. The relevance assessment of metabolites of mefentrifluconazole according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is not required. Sulfur and sulfates are of no toxicological relevance and as sulfur is a mineral, the consideration of metabolites is not applicable.

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

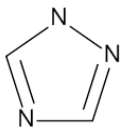
Field studies showed no substantial formation of either of the metabolites.

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 (1,2,4-triazole), 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 10.1-1 below). Thus, assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 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:	0.066 µg L^{-1} Crop: Spring cereals (2× 100 g a.s./ha; BBCH 30) $FOCUS_{gw}$ scenario: Hamburg, model: FOCUS-PEARL 5.5.5, Tier 1

Sulfur

According to the EFSA Scientific Report (2008) for sulfur, no metabolites are considered to be relevant for exposure and risk assessment in soil. Sulfur transformation in soil is governed by oxidation. Main transformation products are sulfates which are part of Sulfur cycle. Furthermore, as sulfur is a mineral the consideration of metabolites is not applicable.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

There are no studies submitted with this section.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

BAS 768 00 F is a new product; no product data have been evaluated previously.

Appendix 2 Additional information

Not applicable