FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: BAS 765 00 F

Product name(s): Daxur

Chemical active substance(s):

Mefentrifluconazole, 100 g/L
Kresoxim-methyl, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: December 2020

Finalisation date: 03/11/2021

Version history

When	What
12/2020	Initial dRR – BASF DocID 2020/2032158
02/2021	Dossier sent for evaluation to Merit Mark (PL)
08/2021	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR

Table of Contents

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

10 Relevance of metabolites in groundwater

Based on submitted PECgw assessment (see Section 8: Fate and Behaviour), the PECgw values for all relevant metabolites is below the trigger value of 0.1 µg/L.

Comments of zRMS:	**Mefentrifluconazole** The harmonised classification of 1,2,4-triazole is as follows: Acute Tox 4, H302; Eye Irrit 2, H19; Repr 2, H361d. Taking into account the guidelines (SANCO/221/2000-rev. 10-final), metabolites which are qualified for classification in any category of reproductive toxicity **are considered to be relevant and their concentration in in drinking water must not exceed 0.1 µg/L.** If the product BAS 765 00 F is used in accordance with the list of intended uses presented in the GAP Table the maximal estimated PECgw of the metabolite amounts to 0.056 µg/L, i.e. acceptable concentration. **Kresoxim-methyl** Acc. to Regulation 1272/2008, the parent substance is classified as carcinogen (Carc. 2, H351). Acc. to SANCO/221/2000-rev. 10-final, the metabolites are considered to be toxicological relevant. The maximal PECgw for metabolites: BF 490-1 (acid of kresoxim-methyl) and BF 490-5 (diacid of kresoxim-methyl) amounts to 0.016 and 0.012 µg/L, respectively, what is below the acceptable concentration for drinking water.

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

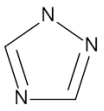
Field studies showed no substantial formation of either of the metabolites.

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.

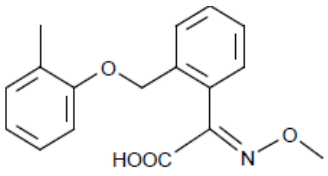
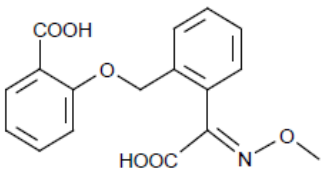
Table 10.1-1: General information on the metabolite(s)

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:	0.056 µg L^{-1} Crop: spring cereals, $FOCUS_{gw}$ scenario: Hamburg, model: FOCUS-PEARL 4.4.4, Tier 2

Kresoxim-methyl

Metabolites BF 490-1 and BF 490-5 of Kresoxim-methyl were not predicted to occur in groundwater at concentrations exceeding 0.1 µg/L (chapter 8.8.2 in Part B, Section 8). An assessment of the relevance of these metabolites was therefore not required.

Table 10.1-2: General information on the metabolite(s)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Kresoxim-methyl	BF 490-1 acid of kresoxim-methyl		Max PEC_{gw} Based on:	0.016 µg L^{-1} Crop: winter cereals, $FOCUS_{gw}$ scenario: Okehampton, model: FOCUS-PELMO 5.5.3
	BF 490-5 diacid of kresoxim-methyl		Max PEC_{gw} Based on:	0.012µg L^{-1} Crop: spring cereals, $FOCUS_{gw}$ scenario: Jokioinen, model: FOCUS-PELMO 5.5.3

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 in this Section

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

There are no already evaluated studies available