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| REGISTRATION REPORT  Part B  Section 10  Assessment of the relevance of metabolites in  groundwater  Detailed summary of the risk assessment |
| Product code: BAS 743 03 F  Product name(s): **DIVEXO**  Chemical active substance(s):  Ametoctradin 120 g/L  Propamocarb hydrochloride 451 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT (authorization of product) |
| Applicant: XXXX  Submission date: October 2023 (update September 2024)  Evaluation date: May 2024  MS Finalisation date: November 2024 |

Version history

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| When | What |
| October 2023 | Initial dRR – XXXX Doc ID 2022/2025094 |
| May 2024 | zRMS-PL evaluation |
| September 2024 | Updates following the Commenting phase XXXX Doc ID 2024/2031545:   * 10.2.3.2 Genotoxicity screening on M650F03 – A reference to the *in-vitro* MN test has been added in the text * 10.2.3.3 Toxicity screening on M650F03 – A reference to the 90-day oral rat study has been added into the text * 10.3.3.2 Genotoxicity screening on M650F04 – Typological error corrected * 10.3.3.3 Toxicity screening on M650F04 – A reference to the 90-day oral rat study has been added into the text * 10.4 Cumulative risk assessment to M650F03 and M650F04 |
| November 2024 | Updated dRR – after MSs consultation |

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# Relevance of metabolites in groundwater

## General information

The ametoctradin metabolites M650F03 and M650F04 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR part B, section 8, Chapter 8.8.2). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 (EC, 2021)[[1]](#footnote-1) is therefore required.

General information on the ametoctradin metabolites is provided in Table 10.1‑1. 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 chapter 8.1 of the dRR Part B, Section 8 (Environmental fate and behaviour).

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| **Review Comments:**  The leaching simulation run with FOCUS PELMO, FOCUS PEARL and FOCUS MACRO resulted in PECGW values below 0.1 µg/L for ametoctradin, metabolites M650F01, M650F02 and for M650F03, M650F04 for applications to acidic soil, for all FOCUS scenarios. Under alkaline soil condition, metabolites M650F03 and M650F04 exceed the threshold of 0.1 µg/L, but below 10 µg/L for all application uses and all simulated models  The submitted data are accepted.  The ametoctradin metabolites M650F03 and M650F04 are non-relevant from the toxicological point of view based on the criteria identified in guidance document on the assessment of groundwater metabolites SANCO/221/2000 –rev.11. |

Table 10.1‑1: General information on the metabolites

| Name of active substance | Metabolite name and code | Structural/molecular formula | Trigger for relevance assessment | |
| --- | --- | --- | --- | --- |
| Ametoctradin  BAS 650 F | **M650F03** | C9H11N5O2 | Max PECGW  Based on: | ~~4.493~~ 4.307 µg/L  Modelling results using PEARL 5.5.5 ~~/ salad crops, BBCH 10-19, 1×240 g a.s./ha, every year~~ /onion (BBCH 49) 2 x 240 g a.s./ha (5-d intervals), every 2nd year; Hamburg scenario |
| Ametoctradin  BAS 650 F | **M650F04** | C8H9N5O2 | Max PECGW  Based on: | 8.650 µg/L  Modelling results using PEARL 5.5.5 / onion, BBCH 14, 2×240 g a.s./ha (5-d intervals), every 2nd year / Hamburg scenario |

## Relevance assessment of M650F03

Summary:

The relevance of the groundwater metabolite M650F03 has already been assessed and the assessment agreed at EU level (see DAR of October 2011[[2]](#footnote-2) and EFSA conclusion 2012[[3]](#footnote-3)), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (*i.e.,* the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PECGW calculated for the GAP and groundwater scenarios considered in this dRR). M650F03 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11. A summary of the relevance assessment is given in Table 10.2‑1 and the corresponding studies are listed in the corresponding sections.

| Table 10.2‑1: Summary of the relevance assessment for M650F03 | | | | |
| --- | --- | --- | --- | --- |
|  | **Assessment step** | | **Result of assessment** | |
|  | STEP 1 | | Metabolite of no concern? | no |
| **Quantification of groundwater contamination** | STEP 2 | | Max PECGW | ~~4.493~~ 4.307 µg/L |
| Based on | PEARL 5.5.5 ~~/ salad crops, BBCH 10-19, 1×240 g a.s./ha, every year~~ /onion (BBCH 49) 2 x 240 g a.s./ha (5-d intervals), every 2nd year; Hamburg scenario |
| **Hazard assessment** | STEP 3 | Stage 1 | Biological activity comparable to the parent? | no |
| Stage 2 | Genotoxic properties of metabolite | non-genotoxic |
| Stage 3 | Toxic properties of metabolite |  |
| Classification of parent | not classified as acutely or chronically toxic; not classified as reprotoxic; not classified as carcinogen |
| Classification of metabolite | not classified as acutely or chronically toxic; not classified as reprotoxic; not classified as carcinogen |
| **Consumer health risk assessment** | STEP 4 | | Estimated consumer exposure via drinking water and other sources; threshold of concern approach | not acceptable (> 0.75 µg/L) |
| STEP 5 | | Refined risk assessment | acceptable |
| Predicted exposure (% of ADI) | < 0.01% of ADI (=10 mg/kg bw/day, EFSA Conclusion 2012) |
|  | | ADI based on | all considered consumer groups |

### STEP 1: Exclusion of degradation products of no concern

Metabolite M650F03 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

### STEP 2: Quantification of potential groundwater contamination

PECGW calculations after leaching from soil for M650F03 were performed (see Part B, Section 8, chapter 8.8.2). The uses for which concentrations of M650F03 were considered to exceed 0.1 µg/L are listed in Table 8.1-1 (GAP table)*.* Details are given in Part B, Section 8, chapter 8.8.

~~The maximum PEC~~~~GW~~ ~~calculated for M650F03 (Salad crops, BBCH 10-19, 1×240 g a.s./ha, every year application) was above 0.75 µg/L, but <10 µg/L.~~

### STEP 3: Hazard assessment – identification of relevant metabolites

#### STEP 3, Stage 1: screening for biological activity

Fungicidal efficacy of Ametoctradin metabolites was evaluated in glasshouse trials with 2 major fungal pathogens representing the fungicide profile of Ametoctradin (*Phytophthora infestans* and *Plasmopara viticola*). None of the tested metabolites did provide significant efficacy against any of the fungal pathogens, while the parent compound Ametoctradin provided very good control [see former EU dossier Aug. 2008, chapter MII, 3.5.2; XXXX DocID 2008/1021354 Merk & Scherer, 2008].

#### STEP 3, Stage 2: screening for genotoxicity

M650F03 was screened for genotoxic activity by the following data package of *in vitro* and *in vivo* genotoxicity studies: Ames test, *in vitro* gene mutation test with mammalian cells, and an *in vitro* chromosome aberration test and *in vitro* and *in vivo* micronucleus test. M650F03 was non-genotoxic as shown by a negative Ames test, negative gene mutation test with mammalian cells, negative chromosome aberration test *in vitro* and negative micronucleus test *in vivo*. M650F03 is considered not relevant and is further evaluated in Stage 3. The genotoxicity studies are evaluated in Part B, Section 6, studies referenced in DAR (Volume 3, Annex B.6.8).

Full summary of *in vitro* MNT study (Naumann, 2019) on metabolite M650F03 that has not previously been considered within an EU peer review process is described in detail in Appendix 2 of fRR B6 (A 2.11 Other/Special Studies). M650F03 is considered to be non-mutagenic in this *in vitro* micronucleus test in human lymphocytes when tested up to the highest concentration evaluated (2395 µg/mL).

Based on DE comment received during commenting period for this dossier: *ametoctradin is currently under re-assessment and according to the current RAR (April 2024) there are some deviations in some of the genotoxicity studies which justify a downgrade to supplementary (i.e. only 200 metaphases analysed instead of 300 in the chromosome aberration studies and no evidence of bone marrow exposure + only 2000 cells scored instead of 4000 in the in vivo MN study)*.

#### STEP 3, Stage 3: screening for toxicity

Ametoctradin is not classified as acutely or chronically toxic or very toxic (Acute Tox. Cat. 1 or 2, STOT Re 1 or STOT SE according to the CLP regulation 1272/2008). Ametoctradin is also not classified for reproductive toxicity (Repr. Cat 1 or 2). Also it is not classified in any category for carcinogens. In addition, semi chronic testing of M650F03 for 13 weeks (90-day oral study, Kaspers, U. et al.., 2008a) in rats yielded no toxicological relevant effects up to the limit dose. According to the most recent assessment at EU level (RAR April 2024) no relevant adverse findings were observed 90-d oral study in rat. The NOAELs were 942.6 mg/kg bw/d (male) and 1093.6 mg/kg bw/d (female) [based on DE comment received during commenting period for this dossier].

M650F03 is not considered relevant and is further evaluated in Step 4.

### STEP 4: Exposure assessment – threshold of concern approach

The potential exposure to M650F03 is > 0.75 µg/L but <10 µg/L. A further assessment in Step 5 is required.

### STEP 5: Refined risk assessment

M650F03 has a PECGW between 0.75 µg/L and 10 µg/L. A refined assessment of the potential toxicological significance based on the ametoctradin ADI of 10 mg/kg bw/day (as stated in the EFSA Conclusion 2012) is presented below and demonstrates an acceptable risk.

The acceptable daily intake (ADI) of ametoctradin apply to the metabolite M650F04 (according to EFSA Conclusion 2012).

Based on NL comment received during commenting period for this dossier, parent equivalent concentration should be used to account for the differences in molecular weight between parent and metabolite.

Parent equivalent concentration is calculated as follows:

predicted max. conc metabolite / mol. weight parent x mol. weight metabolite

For metabolite M650F03 this would lead to a parent equivalent concentration of 4.307/220.87 x 275.39 = 5.4 µg/L

**Calculation of risk (% ADI) for 5-kg bottle-fed infant (consuming 0.75 l/day):**

The predicted maximum level of M650F03 in groundwater is ~~4.493~~ 5.4 µg/L. Therefore, the potential intake of M650F03 is ~~0.67~~ 0.81 µg/kg bw (~~4.493~~ 5.4 x 0.75 / 5). This represents ~~0.0067~~ 0.0081% of the ametoctradin ADI (10 mg/kg bw/day) and will have a negligible impact on the TMDI of ametoctradin and its metabolites.

**Calculation of risk (% ADI) for 10-kg child (consuming 1.0 l/day):**

The predicted maximum level of M650F03 in groundwater is ~~4.493~~ 5.4 µg/L. Therefore, the potential intake of M650F03 is ~~0.45~~ 0.54 µg/kg bw (~~4.493~~ 5.4 x 1 / 10). This represents ~~0.0045~~ 0.0054% of the ametoctradin ADI (10 mg/kg bw/day) and will have a negligible impact on the TMDI of ametoctradin and its metabolites.

**Calculation of risk (% ADI) for 60-kg adult (consuming 2.0 l/day):**

The predicted maximum level of M650F03 in groundwater is ~~4.493~~ 5.4 µg/L. Therefore, the potential intake of M650F03 is ~~0.15~~ 0.18 µg/kg bw (~~4.493~~ 5.4 x 2 / 60). This represents ~~0.0015~~ 0.0018% of the ametoctradin ADI (10 mg/kg bw/day) and will have a negligible impact on the TMDI of ametoctradin and its metabolites.

Based on DE comment received during commenting period for this dossier: *the current assessment at EU level (RAR April 2024) resulted in a lower ADI for ametoctradin of 0.7 mg/kg bw/d, which could be considered here*.

Considering the ADI of 0.7 mg/kg bw/d the consumer risk assessment still demonstrates an acceptable risk, when the potential intake of metabolite M650F03 is 0.12 % of ADI (infant), 0.08 % of ADI (child), 0.03 % of ADI (adult).

## Relevance assessment of M650F04

Summary:

The relevance of the groundwater metabolite M650F04 has already been assessed and the assessment agreed at EU level (see DAR of December 2010 and EFSA conclusion 2012), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (*i.e*., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PECGW calculated for the GAP and groundwater scenarios considered in this dRR). M650F04 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.3‑1 and the corresponding studies are listed in the corresponding sections.

| Table 10.3‑1: Summary of the relevance assessment for M650F04 | | | | |
| --- | --- | --- | --- | --- |
|  | **Assessment step** | | **Result of assessment** | |
|  | STEP 1 | | Metabolite of no concern? | no |
| **Quantification of groundwater contamination** | STEP 2 | | Max PECGW | 8.650 µg/L |
| Based on | PEARL 5.5.5 / onion, BBCH 14, 2×240 g a.s./ha (5-d intervals), every 2nd year / Hamburg scenario |
| **Hazard assessment** | STEP 3 | Stage 1 | Biological activity comparable to the parent? | no |
| Stage 2 | Genotoxic properties of metabolite | non-genotoxic |
| Stage 3 | Toxic properties of metabolite; |  |
| Classification of parent | no classification |
| Classification of metabolite | no classification |
| **Consumer health risk assessment** | STEP 4 | | Estimated consumer exposure via drinking water and other sources; threshold of concern approach | not acceptable (> 0.75 µg/L) |
| STEP 5 | | Refined risk assessment | acceptable |
| Predicted exposure (% of ADI) | < 0.02% of ADI (=10 mg/kg bw/day, EFSA Conclusion 2012) |
|  | | ADI based on | all considered consumer groups |

### STEP 1: Exclusion of degradation products of no concerns

Metabolite M650F04 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

### STEP 2: Quantification of potential groundwater contamination

PECGW calculations after leaching from soil for M650F04 were performed (see Part B, Section 8, chapter 8.8.2). The uses for which concentrations of M650F04 were considered to exceed 0.1 µg/L are listed in Table 8.1-1 (GAP table). Details are given in Part B, Section 8, chapter 8.8.

The maximum PECGW calculated for M650F04 (onion, BBCH 14, 2×240 g a.s./ha (5-d intervals), every 2nd year application) was above 0.75 µg/L, but < 10 µg/L.

### STEP 3: Hazard assessment – identification of relevant metabolites

#### STEP 3, Stage 1: screening for biological activity

Fungicidal efficacy of Ametoctradin metabolites was evaluated in glasshouse trials with 2 major fungal pathogens representing the fungicide profile of Ametoctradin (*Phytophthora infestans* and *Plasmopara viticola*). None of the tested metabolites did provide significant efficacy against any of the fungal pathogens, while the parent compound Ametoctradin provided very good control [see former EU dossier Aug. 2008, chapter MII, 3.5.2; XXXX DocID 2008/1021354 Merk & Scherer, 2008].

#### STEP 3, Stage 2: screening for genotoxicity

M650F04 was screened for genotoxic activity by the following data package of *in vitro* and *in vivo* genotoxicity studies: Ames test, *in vitro* gene mutation test with mammalian cells, and an *in vitro* chromosome aberration test and an *in vitro* micronucleus test. M650F04 was non-genotoxic as shown by a negative Ames test, negative gene mutation test with mammalian cells, negative chromosome aberration test *in vitro* and negative micronucleus test *in ~~vivo~~ vitro*. M650F04 is considered not relevant and is further evaluated in Stage 3. The genotoxicity studies are evaluated in Part B, Section 6, studies referenced in DAR (Volume 3, Annex B.6.8).

Full summary of *in vitro* MNT study (Naumann, 2019) on metabolite M650F04 that has not previously been considered within an EU peer review process is described in detail in Appendix 2 of fRR B6 (A 2.11 Other/Special Studies). M650F04 is considered to be non-mutagenic in this *in vitro* micronucleus test in human lymphocytes when tested up to the highest concentration evaluated (2000 µg/mL).

#### STEP 3, Stage 3: screening for toxicity

Ametoctradin is not classified as acutely or chronically toxic or very toxic (Acute Tox. Cat. 1 or 2, STOT Re 1 or STOT SE according to the CLP regulation 1272/2008). Ametoctradin is also not classified for reproductive toxicity (Repr. Cat 1 or 2). Also it is not classified in any category for carcinogens. In addition, semi chronic testing of M650F04 for 13 weeks in rats yielded no toxicological relevant effects up to the limit dose.

According to the most recent assessment at EU level (RAR April 2024) no relevant adverse findings were observed in 90-d oral study in rat. The NOAELs were 1033.5 mg/kg bw/d (male) and 1161.4 mg/kg bw/d (female) [based on DE comment received during commenting period for this dossier].

M650F04 is not considered relevant and is further evaluated in Step 4.

### STEP 4: Exposure assessment – threshold of concern approach

The potential exposure to M650F04 is > 0.75 µg/L, but < 10 µg/L. A further assessment in Step 5 is required.

### STEP 5: Refined risk assessment

M650F04 has a PECGW >0.75 µg/L, but < 10 µg/L. A refined assessment of the potential toxicological significance based on the ametoctradin ADI of 10 mg/kg bw/day (as stated in the EFSA Conclusion 2012) is presented below and demonstrates an acceptable risk.

The acceptable daily intake (ADI) of ametoctradin apply to the metabolite M650F04 (according to EFSA Conclusion 2012).

Based on NL comment received during commenting period for this dossier, parent equivalent concentration should be used to account for the differences in molecular weight between parent and metabolite.

Parent equivalent concentration is calculated as follows:

predicted max. conc metabolite / mol. weight parent x mol. weight metabolite

For metabolite M650F04 this would lead to a parent equivalent concentration of 8.65/207.1 x 275.39 = 11.5 µg/L.

**Calculation of risk (% ADI) for 5-kg bottle-fed infant (consuming 0.75 l/day):**

The predicted maximum level of M650F04 in groundwater is ~~8.65~~ 11.5 µg/L. Therefore, the potential intake of M650F04 is ~~1.30~~ 1.73 µg/kg bw (~~8.65~~ 11.5 x 0.75 / 5). This represents ~~0.013~~ 0.0173% of the ametoctradin ADI (10 mg/kg bw/day) and will have a negligible impact on the TMDI of ametoctradin and its metabolites.

**Calculation of risk (% ADI) for 10-kg child (consuming 1.0 l/day):**

The predicted maximum level of M650F04 in groundwater is ~~8.65~~ 11.5 µg/L. Therefore, the potential intake of M650F04 is ~~0.87~~ 1.15 µg/kg bw (~~8.65~~ 11.5 x 1 / 10). This represents ~~0.0087~~ 0.0115% of the ametoctradin ADI (10 mg/kg bw/day) and will have a negligible impact on the TMDI of ametoctradin and its metabolites.

**Calculation of risk (% ADI) for 60-kg adult (consuming 2.0 l/day):**

The predicted maximum level of M650F04 in groundwater is ~~8.65~~ 11.5 µg/L. Therefore, the potential intake of M650F04 is ~~0.29~~ 0.38 µg/kg bw (~~8.65~~ 11.5 x 2 / 60). This represents ~~0.0029~~ 0.0038% of the ametoctradin ADI (10 mg/kg bw/day) and will have a negligible impact on the TMDI of ametoctradin and its metabolites.

Based on DE comment received during commenting period for this dossier: *the current assessment at EU level (RAR April 2024) resulted in a lower ADI for ametoctradin of 0.7 mg/kg bw/d, which could be considered here*.

Considering the ADI of 0.7mg/kg bw/d the consumer risk assessment still demonstrates an acceptable risk, when the potential intake of metabolite M650F04 is 0.25 % of ADI (infant), 0.16 % of ADI (child), 0.05 % of ADI (adult).

## Cumulative risk assessment to M650F03 and M650F04

A cumulative assessment for the potential exposure to M650F03 and M650F04 for all consumer groups are presented below and demonstrates acceptable risk.

|  |  |  |  |
| --- | --- | --- | --- |
| **Population group** | **Metabolite** | **Estimated exposure / ADI (%)**  ADI = 10 mg/kg bw/day (EFSA Conclusion 2012) | **Estimated exposure / ADI (%)**  ADI = 0,7 mg/kg bw/day (as proposed in the draft RAR April 2024, RMS: DE) |
| Toddler | M650F03 | ~~0.0067~~  0.0081 | 0.12 |
| M650F04 | ~~0.013~~  0.0173 | 0.25 |
| **Cumulative risk (%)** | **~~0.02~~**  **0.08** | **0.37** |
| Child | M650F03 | ~~0.0045~~  0.0054 | 0.08 |
| M650F04 | ~~0.0087~~  0.0115 | 0.16 |
| **Cumulative risk (%)** | **~~0.01~~**  **0.02** | **0.24** |
| Adult | M650F03 | ~~0.0015~~  0.0018 | 0.03 |
| M650F04 | ~~0.0029~~  0.0038 | 0.05 |
| **Cumulative risk (%)** | **~~0.004~~**  **0.006** | **0.08** |

1. Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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** |
| --- | --- | --- | --- | --- | --- |
| KCP 11 | Merk M.,  Scherer M. | 2008 | Fungicidal efficacy of BAS 650 F soil metabolites: M650F03, M650F04  2008/1021354  XXXX SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished | No | XXXX |

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

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 |

1. Additional information

Not relevant.

1. European Commission (2021): Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Regulation (EC) No 1107/2009. SANCO/221/2000-rev. 11, 21 October 2021 [↑](#footnote-ref-1)
2. DAR (2011): Draft assessment report (DAR), Initial risk assessment provided by the rapporteur Member State The Netherlands for the new active substance BAS 650F of the review programme referred to in Article 11(1) of Commission Regulation (EC) No 1107/2009, Volume 3 B8, October 2011. [↑](#footnote-ref-2)
3. EFSA (2012): Conclusion on the peer review of the pesticide risk assessment of the active substance ametoctradin (BAS 650 F). EFSA Journal 2012;10(11):2921. [↑](#footnote-ref-3)