REGISTRATION REPORT

# Part B

# Section 10

# Assessment of the Relevance of Metabolites in Groundwater

Detailed summary of the risk assessment

Product code: GF-3307

Product name(s): Not yet defined

Chemical active substance(s):

Fenpicoxamid (XDE-777), 50 g/L

Prothioconazole, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Corteva Agriscience

Submission date: July 2021

MS Finalisation date: August 2022 (initial Core Assessment)

January 2023 (final Core Assessment)

# Version History

| When | What |
|---|---|
| July 2021 | New submission of GF-3307 in the Central Zone |
| August 2022 | Initial assessment by the zRMS<br><br>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~~. |
| January 2023 | Final report (Core Assessment updated following the commenting period).<br><br>No additional information or assessments after the commenting period. |

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**Reviewer summary:**

This part of dossier has been submitted to support registration of the plant protection product GF-3307 (an a SC formulation containing 50 g/L fenpicoxamid (XDE-777) and 100 g/L prothioconazole) 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.

# 10 Relevance of metabolites in groundwater

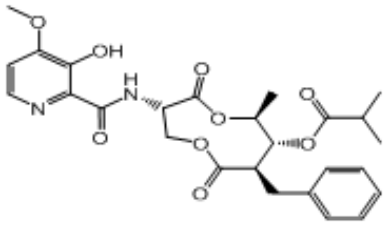
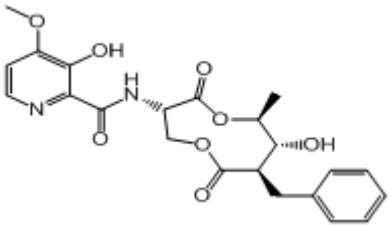
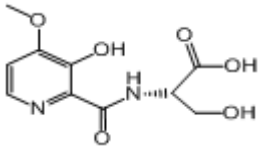
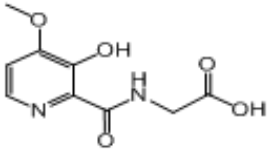
## 10.1 General information

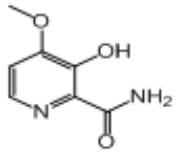
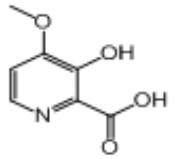
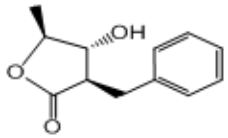
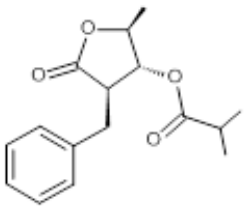
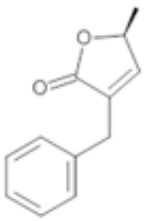
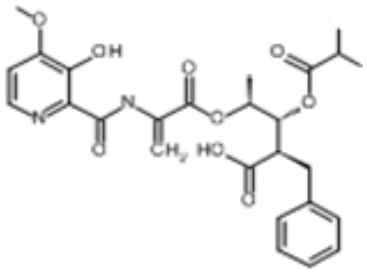
**Fenpicoxamid**

**Note that the risk envelope GAP of 2 x 130 g as/ha from BBCH 25 (20% and 80% interception) used for the PECgw calculations is protective of the GAP of 1 x 75 as/ha from BBCH 30 (80% interception) specific to the use of GF-3307 in cereals.**

There are no metabolites of fenpicoxamid predicted to occur in groundwater at concentrations above 0.1 µg/L from the risk envelope GAP (2 x 130 g as/ha; from BBCH 25; spring application, covering critical GAP for GF-3307 in CZ) (see Part B, point 8.8). Therefore, assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is not required. General information on the metabolites is provided in Table 10.1-1.

**Table 10.1-1: General information on the fenpicoxamid metabolites**

| Metabolite name and code | Structural/molecular formula | Trigger for relevance assessment | |
|---|---|---|---|
| X642188 |  | Max PECgw:<br>Based on: | **<0.001 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |
| X696872 |  | Max PECgw:<br>Based on: | **<0.001 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |
| X12264475 |  | Max PECgw:<br>Based on: | **0.083 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |
| X763024 |  | Max PECgw:<br>Based on: | **0.020 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |

| Metabolite name and code | Structural/molecular formula | Trigger for relevance assessment | |
|---|---|---|---|
| X12313581 |  | Max PECgw:<br>Based on: | **0.028 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |
| X696476 |  | Max PECgw:<br>Based on: | **0.003 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |
| X11963422 |  | Max PECgw:<br>Based on: | **0.025 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |
| X12314005 |  | Max PECgw:<br>Based on: | **<0.001 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |
| X12019520 |  | Max PECgw:<br>Based on: | **<0.001 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |
| X12255349 |  | Max PECgw:<br>Based on: | **<0.001 µg/L**<br>Worst case from FOCUSPELMO 5.5.3/ FOCUSPEARL 4.4.4 for winter or spring cereals |

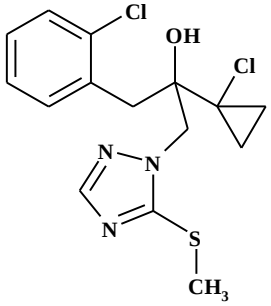
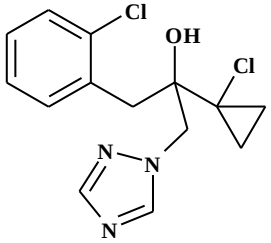
Refer to the core data, where the maximum PECgw values shown for each metabolite are greater than those derived using national modelling.

**Prothioconazole**

**Note that the risk envelope GAP of 2 x 187.5 g as/ha from BBCH 25 used for the PECgw calculations is protective of the GAP of 1 x 150 as/ha from BBCH 30 specific to the use of GF-3307 in cereals.**

There are no metabolites of prothioconazole predicted to occur in groundwater at concentrations above 0.1 µg/L from the risk envelope GAP (2 x 187.5 g as/ha with 50% interception; spring application, covering critical GAP for GF-3307 in CZ) (see Part B, point 8.8). Therefore, assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is not required. General information on the metabolites is provided in Table 10.1-2.

**Table 10.1-2: General information on the prothioconazole metabolites**

| Metabolite name and code | Structural/molecular formula | Trigger for relevance assessment | |
|---|---|---|---|
| JAU 6476-S-methyl (M01) |  | Max PECgw:<br>Based on: | **<0.001 µg/L**<br>Worst case from FOCUSPELMO/ FOCUSPEARL for winter or spring cereals |
| JAU 6476-desthio (M04) |  | Max PECgw:<br>Based on: | **<0.001 µg/L**<br>Worst case from FOCUSPELMO/ FOCUSPEARL for winter or spring cereals |

**Austria, Czech Republic, Poland, Romania, Slovakia**

Refer to the core data.

## 10.2 Relevance assessment of metabolites

Not required.

# Appendix 1 Lists of data considered in support of the evaluation

Not required.

# Appendix 2 Additional information

Not required.