

**FINAL REGISTRATION REPORT**

**Part B**

**Section 10**

**Assessment of the relevance of metabolites in  
groundwater**

Detailed summary of the risk assessment

Product code: **FLUDIO 025 GF**

Product names: **FLUDIO ŻEL 025 FS /**

**FUNABEN<sup>®</sup> ŻEL 025 FS**

Chemical active substance:

Fludioxonil, 25 g/L

Central Zone

Zonal Rapporteur Member State: **Poland**

**CORE ASSESSMENT**

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: **01/2023**

MS Finalisation date: **06/2023; 10/2023**

## Version history

| When    | What                      |
|---------|---------------------------|
| 01/2023 | Initial dRR               |
| 06/2023 | Initial zRMS assessment   |
| 10/2023 | Final Registration Report |
|         |                           |

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## 10 Relevance of metabolites in groundwater

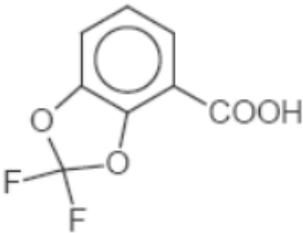
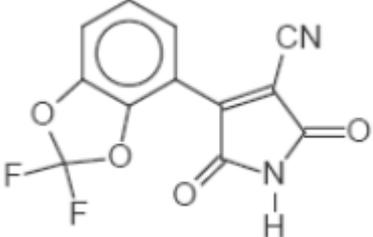
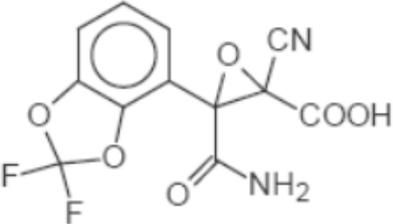
### 10.1 General information

The metabolites of fludioxonil (i.e. CGA 192155, CGA 265378 and CGA 339833) are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B section 8).

Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

General information on the metabolites are provided in Table 10.1-1.

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

| Name of active substance | Metabolite name and code | Structural/molecular formula  | Trigger for relevance assessment |   |
|--------------------------|--------------------------|---|----------------------------------|---|
| Fludioxonil              | CGA 192155               |   | Max PEC <sub>gw</sub>            | < 0.1 µg/L  |
| Fludioxonil              | CGA265378                |  | Max PEC <sub>gw</sub>            | < 0.1 µg/L  |
| Fludioxonil              | CGA 339833               |  | Max PEC <sub>gw</sub>            | < 0.1 µg/L  |
|                          |                          |   | Based on:                        | each scenario; calculated with PEARL 5.5.5<br>PELMO 6.6.4 |

### 10.2 Relevance assessment of metabolites

#### Summary:

The groundwater metabolites CGA 192155, CGA 265378 and CGA 339833 are considered as non-relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10 (*Step 2 – Quantification of potential groundwater contamination*), since their predicted concentration in the groundwater do not exceed the concentration of 0.1 µg/L. Studies supporting PEC<sub>gw</sub> data are evaluated in Section 8 (Environmental fate and behaviour).

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

### List of data submitted by the applicant and relied on

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title</b><br><b>Company Report No.</b><br><b>Source (where different from company)</b><br><b>GLP or GEP status</b><br><b>Published or not</b> | <b>Vertebrate study</b><br><b>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|---------------------------------------|--------------|
|                   |                  |             |  |                                       |              |
|                   |                  |             |  |                                       |              |

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

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title</b><br><b>Company Report No.</b><br><b>Source (where different from company)</b><br><b>GLP or GEP status</b><br><b>Published or not</b> | <b>Vertebrate study</b><br><b>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|---------------------------------------|--------------|
|                   |                  |             |  |                                       |              |
|                   |                  |             |  |                                       |              |

**List of data submitted by the applicant and not relied on**

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title<br/>Company Report No.<br/>Source (where different from company)<br/>GLP or GEP status<br/>Published or not</b> | <b>Vertebrate<br/>study<br/>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
|                   |                  |             |  |                                     |              |
|                   |                  |             |  |                                     |              |

**List of data relied on not submitted by the applicant but necessary for evaluation**

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title<br/>Company Report No.<br/>Source (where different from company)<br/>GLP or GEP status<br/>Published or not</b> | <b>Vertebrate<br/>study<br/>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
|                   |                  |             |  |                                     |              |
|                   |                  |             |  |                                     |              |

## Appendix 2 Additional information

|                   |  |
|-------------------|--|
| Comments of zRMS: |  |
|-------------------|--|