

# 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® 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

## Table of Contents

<b>10</b>	<b>Relevance of metabolites in groundwater.....</b>	<b>4</b>
10.1	General information .....	4
10.2	Relevance assessment of metabolites .....	4
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation.....</b>	<b>5</b>
<b>Appendix 2</b>	<b>Additional information .....</b>	<b>7</b>

## 10 Relevance of metabolites in groundwater

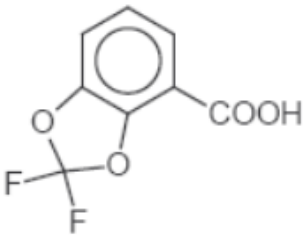
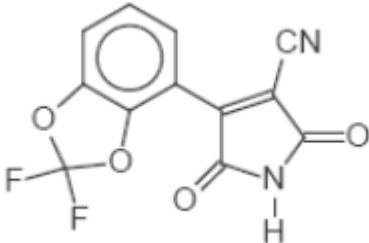
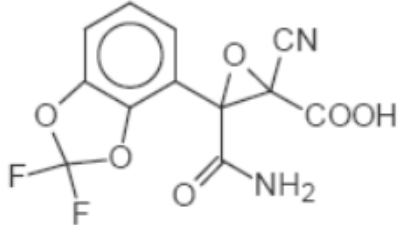
### 10.1 General information

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> Based on:	< 0.1 µg/L each scenario; calculated with PEARL 5.5.5 PELMO 6.6.4
Fludioxonil	CGA265378		Max PEC <sub>gw</sub> Based on:	< 0.1 µg/L each scenario; calculated with PEARL 5.5.5 PELMO 6.6.4
Fludioxonil	CGA 339833		Max PEC <sub>gw</sub> Based on:	< 0.1 µg/L each scenario; calculated with PEARL 5.5.5 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

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

### 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

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

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

## Appendix 2 Additional information

Comments of zRMS:	
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