

FINAL REGISTRATION REPORT

**Part B**

**Section 10**

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

Detailed summary of the risk assessment

Product code: MIEDZIAN 50 WP

Product name(s): **MIEDZIAN 50 WP**,

Chemical active substance(s):

**Copper as a copper oxychloride, 500 g/kg**

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(re-authorization according art. 43 and art. 51, Reg. 1107/2009)

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

Submission date: **07/2020**

MS Finalisation date: **05/2021**, 08/2022

## Version history

| When    | What  |
|---------|---|
| 07/2020 | Renewal of registration of plant protection product according art. 43, Reg. 1107/2009 |
| 05/2021 | Assessment by expert  |
| 08/2022 | The Final RR  |
|         |   |

## Table of Contents

|                   |  |          |
|-------------------|--|----------|
| <b>10</b>         | <b>Relevance of metabolites in groundwater .....</b>               | <b>4</b> |
| 10.1              | General information .....  | 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>5</b> |

## **10 Relevance of metabolites in groundwater**

### **10.1 General information**

Copper in a form of an oxychloride, which is main and only active substance in MIEDZIAN 50 WP, has no relevant metabolites. Therefore, assessment according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is not required.

**Acceptable**

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

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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

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

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

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

## Appendix 2 Additional information

Comments of zRMS: Comment on statement; acceptable or not.