

# REGISTRATION REPORT

## Part B

### Section 10

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

Detailed summary of the risk assessment

Product code: Salaman 510

Product name(s): **SAVIAL FORTE**

Chemical active substance:

potassium phosphonates (510 g/L, expr. as phosphorous acid)

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(authorization)

Applicant: Lainco, S.A. /Exclusivas Sarabia S.A / Biovert S.L.

Submission date: October 2021

MS Evaluation date: July 2022

MS Finalisation date: dd/mm/yyyy

## Version history

<b>When</b>	<b>What</b>
October 2021	Application for the first approval of the product's code SALAMAN 510 in Poland.
July 2022	Version evaluated by zRMS Poland

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

### **10.1 General information**

None metabolite is predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of the metabolites according to the stepwise procedure of the EC guidance document SAN-CO/221/2000 –rev.10 is therefore not required.

### **10.2 Relevance assessment of metabolites**

Not relevant.

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

#### **10.2.2 STEP 2: Quantification of potential groundwater contamination**

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

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

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

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

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

#### **10.2.5 STEP 5: Refined risk assessment**

## 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 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 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 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>

The following tables are to be completed by MS

**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:	The submitted information and justification were accepted. Since none metabolite is predicted to occur in groundwater at concentrations above 0.1 µg/L the assessment of the relevance of the metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore not required.
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