

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

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

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

Table of Contents

| | | |
|-------------------|---|----------|
| 0 | Product background, regulatory context and GAP information | 4 |
| 0.1 | Introduction..... | 4 |
| 0.1.1 | Reason for application | 4 |
| 0.1.2 | Details of zRMS(s) and concerned MS | 4 |
| 0.1.3 | Regulatory history of the active(s)..... | 4 |
| 0.1.4 | Regulatory history of the product (if relevant) | 5 |
| 0.2 | zRMS conclusion | 5 |
| Appendix 1 | ALL intended uses | 8 |

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

In addition to the submission of studies as listed in the separate sections of this application, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

| | zRMS, product name and authorization no. (if relevant) | (If relevant) Concerned MS, MS' product name and authorization number (if applicable) |
|----------------------|---|--|
| Northern zone | Not relevant | Not relevant |
| Central zone | Poland | Not applicable |
| Southern zone | Not relevant | Not relevant |
| Inter-zonal | Not relevant | Not relevant |

0.1.3 Regulatory history of the active(s)

Table 0.1-2: Summary of regulatory history of CAS No: 13977-65-6 (potassium hydrogen phosphonate); of CAS No: 13492-26-7 (dipotassium phosphonate)

| | |
|---|---|
| Status | |
| Approved in EU | Y |
| Commission Implementing Regulation | Commission Implementing Regulation (EU) No. 369/2013 of 22 April 2013 |
| RMS | France |
| Date of Approval of active substance | 01/10/2013 (Reg. (EU) N° 369/2013) |
| Current expiration of approval of active substance | 31/12/2026 |
| Date of deadline for renewal of authorization (renewal) | 31/03/2027 |
| Low risk substance or Candidate for Substitution? | N/A |

Issues that need to be considered as part of the EU approval are listed below.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium phosphonates, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account.

In this overall assessment, “Member States must pay particular attention to:

- the risk to birds and mammals;
- the risk of eutrophication of surface water if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water.

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards the long-term risk to insectivorous birds.

The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.

The SANCO report for potassium phosphonates (SANCO/10416/2013 rev 2 – 15/March/2013) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 2012 (*EFSA Journal* 2012; 10(12):2963).

Table 0.1-3: Information on minimum purity of potassium phosphonate

| EU agreed minimum purity from Inclusion Directive or Implementing regulation | (if different) Minimum purity of active substance used in the product / information on available equivalency report *, ** |
|---|---|
| minimum purity of active substance: 990 g/kg according to regulation 369/213 no relevant impurities | Minimum purity of active substance: 990g/kg (as TC) Equivalence report available: Y RMS: Spain (2015) |

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval, then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

| Endpoint | Potassium phosphonates | |
|--------------------|---|----------------------|
| | EU agreed endpoint from EFSA scientific report | Endpoint used* |
| Environmental fate | <i>EFSA Journal</i> 2012;10(12):2963 – Potassium phosphonates | Refer to dRR Part B8 |
| Ecotoxicology | | Refer to dRR Part B9 |

* Since EU approval new studies on the active substance have been performed (e.g., new manufacturing site, new specification, confirmatory data).

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised in Poland.

The product coded Salaman 510 is already authorized in South EU countries.

0.2 zRMS conclusion

Section 1,2,4 & 5: Identity, physicochemical properties and analytical methods:

Sufficient data on identity, physical and chemical properties are available for the plant protection product Salaman 510.

An acceptable, analytical method for the determination of potassium phosphonates (expressed as phosphonic acid in the formulation) has been provided and considered acceptable.

Section 3. Efficacy:

ZRMS considers that data provided by applicant are supporting the registration of Salaman 510 (Savial Forte) for apple scab (*Venturia inaequalis* – VENTIN) control on apple trees and pear scab (*Venturia pyrina* – VENTPI) control on pear trees but in case of pear trees the data from Germany should be recognized for Salaman 510 registration and applicant should provide the post-registration data of two efficacy and selectivity trials to the end of 2023 or this product can be registered as a minor use.

Section 6. Toxicology and health risk:

Based on all available data the product Salaman 510 (Savial Forte) does not require classification or labelling for health hazards.

The product SALAMAN 510 (SAVIAL FORTE) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice even if operator is not wearing work wear covering arms, body and legs during mixing/loading and application, however the wearing a work clothing (long sleeved shirt, long trousers) is considerably reducing exposure and health risk.

The application of a product SALAMAN 510 (SAVIAL FORTE) on pome fruits (BBCH 53-81), at maximal dose of 2.5 L product/ha (1.275 kg a.s./ha) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice

The application of a product SALAMAN 510 (SAVIAL FORTE) on pome fruits (BBCH 53-81), at maximal dose of 2.5 L product/ha (1.275 kg a.s./ha), in line with GAP does not pose an unacceptable health risk for adult and child residents and bystanders.

Section 7. Residues:

The evaluation of the application for Salaman 510 resulted in the decision to grant the authorization consistently with the evaluation of the residues and the relevant analytical methods. The use no. 1 (pome fruits) submitted were accepted.

Section 8. Fate and behaviour:

In accordance with proposed pattern use, an exposure assessment for the formulation of Salaman 510 (Savial forte) was submitted.

Section 9. Ecotoxicology:

In accordance with proposed pattern use, risk assessment to non-target organisms for the formulation Salaman 510 (Savial forte) was submitted.

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of Salaman 510 (Savial forte) as fungicide in orchards poses an acceptable risk to non-target organisms. To protect the aquatic organisms, it is proposed to apply a mitigation measure of 3 m non-sprayed buffer strip.

Uses to be considered safe on the basis of EU methodology:

Use number 1 in GAP table in Appendix 1.

Ecotoxicology: Use No 1 at application rates 2.5 L/ha.

Uses to be considered non-safe on the basis of EU methodology:

None

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

None

The following text is to be shortened or to be amended as necessary.

Use no. 1 (pome fruits: apple, pear) is covered by established MRLs.

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Appendix 1 ALL intended uses

GAP rev. 0, date: 2024-05-10

PPP (product name/code): Salaman 510
Active substance: potassium phosphonate
Safener: --
Synergist: --
Applicant: Lainco, S.A. / Exclusivas Sarabia S.A. / Biovert S.L.
Zone(s): Central EU zone ^(d)
Verified by MS: yes
Field of use: fungicide

Formulation type: SL ^(a, b)
Conc. of a.s.: 510 g/L (as phosphorous acid) ^(c)
Conc. of safener: -- ^(c)
Conc. of synergist: -- ^(c)
Professional use:
Non-professional use:

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|--------------------|--|---|---|------------------|---|--|--|---|---|--------------------------------|---------------|--|
| Use- No. (e) | Member state(s) | Crop and/ or situation (crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I | Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/ synergist per ha (f) |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Min- Max. number a) per use b) per crop/ season | Min. interval between applic. (days) | L f.p./ha a) min-max. rate per appl. b) min-max. total rate per crop/season | kg a.s./ha a) min-max. rate per appl. b) min-max. total rate per crop/season | Water L/ha min / max | | |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | |
| 1 | PL | Pome fruits (apple, pear) | F | <i>Venturia inaequalis</i> <i>Venturia pyrina</i> | Foliar spray | BBCH 53-81 | a) 3 b) 3 | 5 | a) 1.50-2.50 b) 4.50-7.50 | a) 0.765-1.275 b) 2.295-3.825 | 500-1000 | 35 | - |

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/L

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

