REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: Salaman 510

Product name(s): **FOSIKA**

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

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) Nº 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	*EFSA Journal 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 (Fosika) 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 (Fosika) does not require classification or labelling for health hazards.

The product SALAMAN 510 (FOSIKA) 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 (FOSIKA) 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 (FOSIKA) 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 (Fosika) was submitted.

Section 9. Ecotoxicology:

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

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of Salaman 510 (Fosika) 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	Formulation type:	SL [a, b]
Active substance:	potassium phosphonate	Conc. of a.s.:	510 g/L (as phosphorous acid) [c]
Safener:	--	Conc. of safener:	-- [c]
Synergist:	--	Conc. of synergist:	-- [c]
Applicant:	Lainco, S.A. / Exclusivas Sarabia S.A. / Biovert S.L.	Professional use:	☒
Zone(s):	Central EU zone [d]	Non-professional use:	☐
Verified by MS:	yes		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				**Application rate**				
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)	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	**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha [f]
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Pome fruits (apple, pear)	F	*Venturia inaequalis* *Venturia pyrina*	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.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high-volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions