

REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information
Concise summary

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: October 2022

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
October 2022	Final RR

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

This is the version of dRR from October 2021, submitted by applicant in the framework of Article 33 of Regulation (EC) 1107/2009. The original text provided by applicant has been retained for transparency. The applicant's text is commented by zRMS and the comments and conclusions are placed in commenting boxes shaded in grey at the end of each chapter. Amendments in the text are highlighted in yellow.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

This evaluation concerns the registration of Salaman 510, containing inorganic active substance potassium phosphonates (510 g/L, expressed as phosphorous acid) for the control of apple scab (*Venturia inaequalis* – VENTIN) on apple trees and pear scab (*Venturia pyrina* – VENTPI) on pear trees, in Central Zone (Poland). Apple and pear trees are the major crops and both diseases *Venturia inaequalis* and *Venturia pyrina* are the major pests, also.

Potassium phosphonates belong to the class of phosphonate fungicides (FRAC group P07 (2021), earlier group 33 (2015)). Salaman 510 is a preventive fungicide with systemic and translocating properties against fungus infection with preventive fungicide action and activator of the self-defence mechanism of the plant. In the evaluation process Poland acts as zRMS.

Currently, fungicides containing potassium phosphonates (Alginure - 342 g/L; Soriale - 755 g/L) are registered in Poland as well as the products composed of the mixtures of 2 active substances: Merplus 800 SC (potassium phosphonates - 657 g/L + captan - 360 g/L) and Delan Pro (dipotassium phosphonates - 561 g/L + dithianon - 125 g/L).

ZRMS confirms that all trials submitted in this dossier were carried out by contractor companies recognized for efficacy testing of plant protection products, in accordance with the principles of Good Experimental Practice (GEP) and EPPO general and specific guidelines. No major deviation from the EPPO guidelines was observed. The assessment was made in accordance with Uniform Principles.

The efficacy and crop safety data supporting the registration of Salaman 510 were obtained in the trials carried out in the years of 2019-2020. In apple trees 6 trials were carried out in Poland and 4 trials in Germany, while in pear trees 4 trials were conducted in Germany. On apple trees Salaman 510 was used at the rate of 1.5 and 2.5 L/ha, in 3-5 applications in Poland, at the growth stages of BBCH 69-74 and in Germany in 6 applications, at the growth stages of BBCH 69-77, while on pears was used in 6 applications, at growth stages of BBCH 69-78.

Venturia inaequalis control

The level of apple trees infestation by *Venturia inaequalis* was considered as acceptable to validate the trials. The incidence and severity of *Venturia inaequalis* on the apple leaves sprayed with Salaman 510 in most cases was higher in comparison to reference product and in some trials were affected close to reference product. The count of leaves and fruits affected by *Venturia inaequalis* (with no attack, with 1-3 spots and with >3 spots) in the trials in Poland and in Germany was at the same level or a little higher than from reference product. A little better results were achieved in the trials carried out Germany.

The data demonstrate a good efficacy of Salaman 510 in controlling of *Venturia inaequalis* (VENTIN) on apple trees **when using at the rate of 2.5 L/ha and varying effectiveness at the rate of 1.5 L/ha**. The results

show that Salaman 510 applied at the rate of 1.5-2.5 L/ha under different growing conditions, achieves almost as good control of VENTIN as to existing registered dithianon + potassium phosphonate and potassium hydrogen carbonate standards.

In the trials conducted in Poland *Venturia inaequalis* control was variable, ranging from 29.29 to 100% on incidence on leaves and from 46.29 to 100% on severity on leaves, after Salaman 510 application at the rate of 1.5 L/ha, while after application at the rate of 2.5 L/ha ranging from 43.81 to 98.07% on incidence on leaves and from 67.23 to 98.39% on severity on leaves.

The level of *Venturia inaequalis* control by Salaman 510 in majority trials was similar to that achieved by the existing registered dithianon + potassium phosphonate standard (Delan Pro) applied at 2.5 L/ha, which ranged from 50.23 to 100 % on incidence on leaves and from 69.92 to 100 % on severity on leaves.

The results confirm a good **to satisfactory** efficacy (**depends on the rate**) of Salaman 510 against *Venturia inaequalis* on apple trees, when applied as preventive treatment. The number of trials for registration of this fungicide in apple trees is sufficient.

Venturia pyrina control

The results of trials carried out in Germany showed a good efficacy of Salaman 510 **at the rate of 2.5 L/ha** and **varying effectiveness at 1.5 L/ha**, in controlling *Venturia pyrina* on pear trees. In the trials with Salaman 510 use the count of affected leaves in UTC was higher than in reference product and the count of affected fruits (with no attack, with 1-3 spots and with >3 spots) was at the same level.

The applicant did not submit any data from Poland on *Venturia pyrina* control by Salaman 510 on pears, only 4 trial from Germany, which can support the registration of this product in Poland. Taking into account the lack of data from Poland, zRMS suggest the recognition of data from Germany and registration of Salaman 510 for *Venturia pyrina* control on pears under condition that applicant provides data of two trials to the end of 2023 or registration of this fungicide in pear trees as minor use. The extrapolation of data from Germany is possible but should be some data from Poland, also.

Conclusions. ZRMS confirms that presented data support the registration of Salaman 510 for apple scab (*Venturia inaequalis* – VENTIN) control on apple trees and pear scab (*Venturia pyrina* – VENTPI) control on pear tree but for pear tree it may be a minor use or the applicant will deliver the additional post registration data. For diseases control Salaman 510 can be recommended as a foliar application, at the rate of 1.5-2.5 L/ha, at maximum of 5 treatments between the growth stages of pome fruits BBCH 53-81, with water volume 500-1000 L/ha, with minimum 5 days intervals between applications.

Salaman 510 (Savial Forte) showed a good efficacy at the rate of 2.5 L/ha against *V. inaequalis* and *V. pyrina* on apple and pear trees and medium to good efficacy at the rate of 1.5 L/ha. Due to the satisfactory results the rate of 1.5 L/ha may be acceptable, mainly at the low diseases pressure and a good weather conditions. Under unfavorable weather conditions Salaman 510 may show a medium efficacy, therefore it should be recommended with another fungicide recommended for control of this pathogen. It can be also noted that Salaman 510 should be applied as an element of fungicides management program, in which the fungicides with different mode of action are included.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Mem- ber state	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn n or I**	Pests or Group of pests controlled (Additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclu- sion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applic. (days)	L product / 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	-	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** 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.

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

The following authorization for a new plant protection product (Salaman 510, based on potassium phosphonate 510 g/L, expr. as phosphorous acid) is proposed in this submission for Pome fruits: apple, against *Venturia inaequalis*, and pear, against *Venturia pyrina*.

Description of active substances

This section details the molecular structure, common name, code number and mode of action of the active substance potassium phosphonate contained in Salaman 510.

Potassium phosphonates (SANCO/10416/2013 rev 2 – 15/March/2013, EFSA Journal 2012;10(12):2963)

Endpoint	Active substance
<i>Common name (ISO)</i>	Potassium phosphonates (No ISO name)
<i>Chemical Name (IUPAC)</i>	Potassium hydrogen phosphonate Dipotassium phosphonate
<i>Chemical name (CA)</i>	Potassium hydrogen phosphonate Dipotassium phosphonate
<i>CIPAC No</i>	756 (for potassium phosphonates)
<i>CAS No</i>	13977-65-6 for potassium hydrogen phosphonate 13492-26-7 for dipotassium phosphonate Mixture: none
<i>EC No (EINECS or ELINCS)</i>	potassium hydrogen phosphonate: EC 604-162-9 dipotassium phosphonate: EC 236-809-2
<i>FAO SPECIFICATION</i>	None
<i>Minimum purity</i>	Specification for TK: 31.6 to 32.6 phosphonate ions (sum of hydrogen phosphonate and phosphonate ions) 17.8 to 20.0 potassium min. 990 g/kg on dry weight basis
<i>Molecular formula</i>	KH_2PO_3 [$\text{HPO}(\text{OH})(\text{O}-\text{K}^+)$] and K_2HPO_3 [$\text{HPO}(\text{O}-\text{K}^+)_2$]
<i>Molecular mass</i>	Monopotassium phosphonate: 120.1 g/mol Dipotassium phosphonate: 158.2 g/mol
<i>Structural formula</i>	$\begin{array}{c} \text{O}^- \text{K}^+ \\ \\ \text{HP}=\text{O} \\ \\ \text{OH} \end{array} \qquad \begin{array}{c} \text{O}^- \text{K}^+ \\ \\ \text{HP}=\text{O} \\ \\ \text{O}^- \text{K}^+ \end{array}$
<i>Appearance (state purity)</i>	Colourless liquid
<i>Solubility in water</i>	Miscible with water
<i>Dissociation constant</i>	Phosphonic acid: pK1 = 2.0, pK2 = 6.59
<i>UV/VIS absorption (max.)</i>	$\lambda_{\text{max}} = 198 \text{ nm}$ - absorbance = 1.7859 (TK solution) No absorption after 200 nm

FRAC group: Unknown mode of action, inorganic.

Formulation details: Salaman 510 is a soluble liquid (SL) containing a nominal content of Potassium phosphonate (as phosphorous acid) as reported in the following:

- Content of pure active substance: 510 g/L.
- Information with respect to formulants is included with all other confidential information in draft Registration Report Part C for Salaman 510.

Code Name: SALAMAN 510

Mode of action

Potassium phosphonate is an active ingredient belonging to the class of phosphonate fungicides. It has preventive and systemic action, and it is already authorised in several EU Member States to control a range of diseases.

Table 3.2-1: Details of the active substances

Active substance	Potassium phosphonate (as phosphorous acid)
Concentration (Unit: g/kg or g/L...)	510 g/L
Chemical group	Phosponates, FRAC group P07 (2021)
Mode of action	Preventive fungicide with systemic and translocating properties against fungus attacks with preventive fungicide action and activator of the self-defence mechanism of the plant.
Biological action	Fungicide

Description of the plant protection product

Salaman 510 is a soluble liquid (SL) containing 510 g potassium phosphonate (as phosphorous acid)/L.

Table 3.2-2: Simplified table of currently registered uses and requested uses for the product Salaman 510

Uses		Member State	Currently registered rate(s)		Requested rate(s)		Comments / Other relevant details on GAPs
Crop(s)	Target(s)		PPP	a.s.	PPP	a.s.	
Pome fruits (apple, pear)	<i>Venturia inaequalis</i> <i>Venturia pyrina</i>	PL	Not registered		1500-2500 mL/ha	0.765-1.275 kg/ha	Foliar spray Vol.: 500-1000 L/ha

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target pests

Table 3.2-3: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
VENTIN	<i>Venturia inaequalis</i>	Scab of apple
VENTPI	<i>Venturia pyrina</i>	Scab of pear

• Apple scab (*Venturia inaequalis*)

Apple scab occurs wherever Apples are grown and may be a very serious disease on susceptible varieties. The disease can also infect crab-apple and rowan. Scab diseases similar to apple scab occur on pear, fire-thorn, and hawthorn. The scab-like leaf spots and fruit spots, from which the name was developed, may cause defoliation and reduction in fruit quantity and quality.

Symptoms

The disease may affect leaves, petioles, pedicels, fruit and twigs. The symptomatic spots are most noticeable on leaves and fruit. Infections first appear as olive-green spots with indefinite borders. With age, these spots become more prominent and darken to greenish black with a velvety appearance. Severe spotting will cause leaves to senesce and fall off. Spots on young fruit result in deformation and cracking. If infection is severe, the fruit may drop off before ripening. Defoliation may result in a reduction of flower bud formation so that bloom or fruit yield the next year will be reduced.

Disease cycle

This disease, caused by the fungus *Venturia inaequalis* (anamorph *Spilocaea pomi*), may be quite severe when rainy, cool weather occurs in the spring. Fungal spores are produced in early spring on dead, fallen apple leaves about the time buds begin to develop. These spores are splashed by rain and blown by wind to land on developing plant tissue and initiate infections. After spots appear on the newly formed leaves, more spores are produced that spread infection to other parts of the tree. Again, rainy weather greatly encourages spore spread and infection during the secondary phase of spore production. The fungus overwinters on fallen leaves.

• **Pear scab (*Venturia pyrina*)**

European pear scabis common and economically important disease in commercial orchards in most of the pear (*Pyrus communis* L.) growing areas worldwide.

Symptoms

The disease may affect leaves, twigs, and fruits:

- On leaves: Patches of olive-green spots or blotches appear, which are initially velvety as they release airborne spores, and then darkening. Affected leaves often fall prematurely.
- On twigs: Infections cause blistering and cracking that can provide an entry point for the apple canker pathogen.
- On fruit: Brown or black scabby blotches develop. As the fruit enlarges, these can restrict expansion of the skin, leading to distortion and cracking. Light attacks only blemish the skin and eating quality is hardly affected (though the disease is commercially very serious, because growers cannot easily sell scabby fruit). However, if the fruits crack as a result of scab they become prone to fruit rots and will not store well.

Disease cycle

The life cycle begins in early spring when ascospores, the primary inoculum, are released from pseudothecia and germinate on the surface of leaves or pear fruits, penetrating the cuticle and establishing infection in the sub-cuticular space. During the growing season infections disrupt the cuticle to release asexual conidia that are dispersed by wind and rain, proliferating throughout spring and summer. In autumn, the fungus switches from its biotrophic lifestyle to a saprobic lifestyle, and fungal mating occurs on dead leaf litter between two isolates differing in mating type, prior to overwintering as developing pseudothecia. There are currently no commercial European pear cultivars available that are naturally resistant to the fungus and control measures involve multiple, timely applications of fungicide throughout spring through to summer and post-harvest. Asian pears such as Ya Li and Nashi are resistant to *V. pirina*.

Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS)

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Pome fruits (apple, pear)	PL	-	<i>Venturia inaequalis</i> <i>Venturia pyrina</i>	PL	-

Compliance with the Uniform Principles

Overall assessment has been performed according to the Uniform Principles.

Information on trials submitted (3.2 Efficacy data)

Table 3.2-5: Presentation of trials (efficacy trials, preliminary trials...)

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials		GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime climatic zone	North-East climatic zone		
Apple	<i>Venturia inaequalis</i>	Poland	2019-2020	E	-	6	GEP	Field
		Germany	2019-2020	E	4	-	GEP	Field
	TOTAL	-	2019-2020	-	4	6	-	-
Pear	<i>Venturia pyrina</i>	Germany	2019-2020	E	4	-	GEP	Field
	TOTAL	-	2019-2020	-	4	-	-	-
TOTAL		-	2019-2020	-	8	6	-	-

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial, S = selectivity trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

The authorization of the product Salaman 510 is sought for the North-East EPPO zone (Poland).

According to the EPPO guideline PP 1/226(2), to demonstrate the performance of a plant protection product it is necessary to conduct a range of 6-15 (for major pest on major crop), 2-6 (for minor uses) and 4-8 (for major pest in protected conditions) trials in different regions with distinct environmental conditions and normally in different years and growing seasons. The level of efficacy of the product Salaman 510 has been tested in 4-8 trials per use for two years distributed in EPPO North-East (Poland) and Maritime (Germany) climatic zones. Therefore, the number of trials performed has been considered appropriate.

The efficacy trials presented show a good level of efficacy of the product Salaman 510 for all uses intended. We should take into account that there is a large amount of supporting evidence from the use of the product, or of similar products, in the same pests and crops. Similar products with same concentration of active substance and same type of formulation have been used for many years.

Figure 3.2-1: Location of the Apple trials in Poland (North-east EPPO climatic zone) against *Venturia inaequalis*

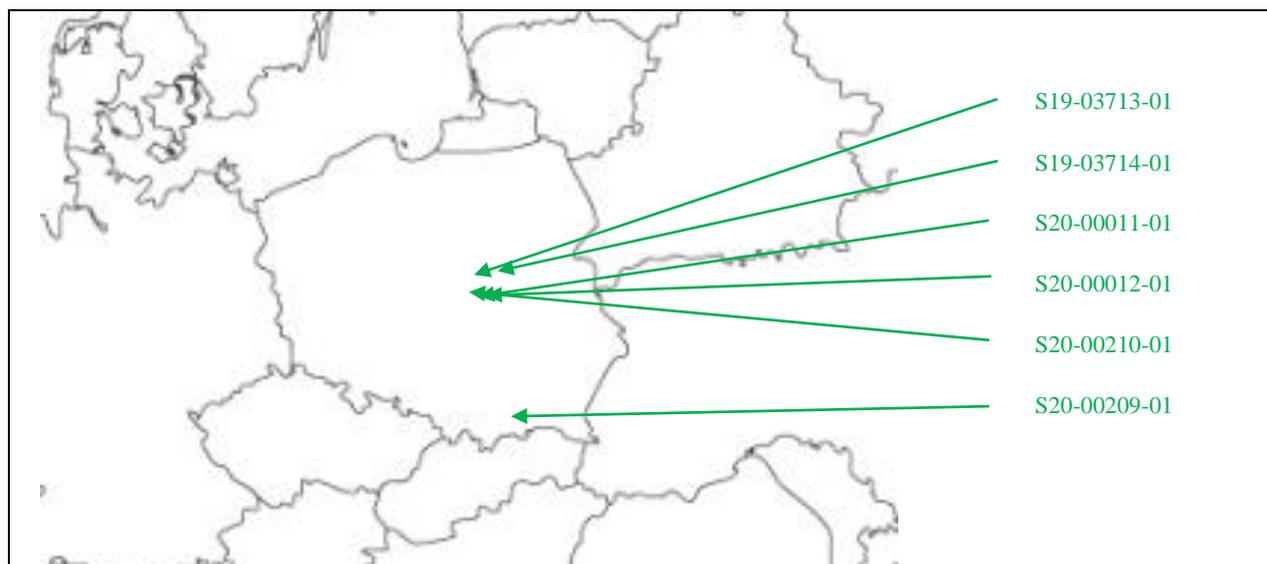


Figure 3.2-2: Location of the Apple trials in Germany (Maritime EPPO climatic zone) against *Venturia inaequalis*



Figure 3.2-3: Location of the Pear trials in Germany (Maritime EPPO climatic zone) against *Venturia pyrina*



Comments of zRMS:	ZRMS states that the active substance and its mode of action, the plant protection product, the target pests and the information on submitted trials are clearly described by applicant. The overall assessment has been performed in accordance with Uniform Principles.
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Table 3.2-6: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Crop(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Conc. of a.s. (%)			
Pome fruits	<i>Delan Pro</i>	Poland	100/2016	Potassium phosphonate + Dithianon	SC	56.12 + 12.5	2.5 L/ha	2.5 L/ha	-
	<i>Vitisan</i>	Germany	007593-00	Potassium hydrogen carbonate	SP	99.49	2.5 kg/ha	2.5 kg/ha	-
	<i>Funguran progress</i>	Germany	006896-00	Copper hydroxide	WG	53.70	0.6 kg/ha	1.2 kg/ha	

-(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetttable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g., uses, number of applications, spray volume, method of application, etc.).

3.2.1 Preliminary tests (KCP 6.1)

Preliminary range-finding tests are not included in this section. Potassium phosphonate (as phosphorous acid) has been used as a fungicide for many years in a wide range of applications. So, its potential biological activity is well known.

Comments of zRMS:	ZRMS agreed.
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3.2.2 Minimum effective dose tests (KCP 6.2)

As a result, the proposed rates of **1.50-2.50 L f.p./ha, with a water volume of 500-1000 L/ha** can be considered the minimum effective dose to deliver an effective control of *Venturia inaequalis* and *Venturia pyrina* under a wide range of environmental conditions.

The minimum effective dose is evaluated at the efficacy section (3.2.3).

Comments of zRMS:	<p>Minimum Effective Dose (MED)</p> <p>The Minimum Effective Dose (MED) of Salaman 510 for VENTIN and VENTPI control was determined in 14 efficacy trials in total, conducted in apple trees (Poland – 6, Germany – 4) and in pear trees (4 trials conducted in Germany).</p> <p>Presented data show a good efficacy of Salaman 510 applied at the rate of 2.5 L/ha and at lower rate the efficacy was various. This indicates that a dose of 2.5 L/ha can be considered as the MED. A lower dose (1.5 L/ha) at the low disease pressure and a good weather conditions may also show satisfactory effectiveness, therefore it can be included in the product label also. Entering a lower dose to the label is possible due to the record in the EPPO guideline PP 1/225 (2) “<i>the Minimum Effective Dose of a plant protection product is the dose that is the minimum necessary to achieve sufficient efficacy against a target pest across the broad range of situations in which the product will be applied</i>”. In some situations “<i>where the product is proposed for use under diverse conditions, there may be situations that warrant the use of different doses, for example, in situations with different cropping practices or crop structures, or variation in the inherent sensitivity of the target pest. Thus for a specific target, it may be possible to justify a number of specific ‘minimum effective doses’ under defined conditions, which should be established using the principles in this standard</i>”.</p>
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3.2.3 Efficacy tests (KCP 6.2)

3.2.3.1 Apple (against *Venturia inaequalis*)

Data and information to support the authorization of Salaman 510 for the control of *Venturia inaequalis* on pome fruits (apple) are provided from 10 efficacy trials conducted between 2019-2020 in Poland (6 trials) and Germany (4 trials).

Presentation of efficacy trials on pome fruits (apple) against *Venturia inaequalis*

Use Pest (Number of trials)	Trial number	Member State	Year	Testing facilities / Organisation	Guidelines	Trials status	Comments
Efficacy trials in Poland (North-east EPPO zone)							
Apple VENTIN (6 trials)	S19-03713-01	Poland	2019	Eurofins Agroscience Services, S.L.	PP 1/135 PP 1/152 PP 1/181 PP 1/5	GEP	-
	S19-03714-01	Poland	2019	Eurofins Agroscience Services, S.L.			-
	S20-00011-01	Poland	2020	EAS Spain			-
	S20-00012-01	Poland	2020	EAS Spain			-
	S20-00209-01	Poland	2020	EAS Spain			-
	S20-00210-01	Poland	2020	EAS Spain			-
Supportive efficacy trials in Germany (Maritime EPPO zone)							
Apple VENTIN (4 trials)	FRS118/20-V1	Germany	2020	Field Research Support	PP 1/135 PP 1/152 PP 1/181 PP 1/5	GEP	-
	FRS118/20-V2	Germany	2020	Field Research Support			-
	FRS161/19-V1	Germany	2019	Field Research Support			-
	FRS161/19-V2	Germany	2019	Field Research Support			-

Materials and methods

Test item and reference products

Preparation	Formulation Type	Composition	Dose of use	Dose of a.s.
SALAMAN 510	SL	Potassium phosphonate 510 g/L	1.50 L f.p./ha	765 g/ha
			2.50 L f.p./ha	1280 g/ha
SORIALE	SL	Potassium phosphonate 755 g/L	1.9 L f.p./ha	1430 g/ha
DELAN PRO	SC	Potassium phosphonate 561 g/L + Dithianon 125 g/L	2.5 L f.p./ha	1403 + 312.5 g/ha
VITISAN	SP	Potassium hydrogen carbonate 994.9 g/kg	2.5 kg f.p./ha	2488 g/ha

The tested dose expressed as LWA rate applied in each efficacy trial is presented in the following table:

Trial	Tested rate (L/ha)	Treated canopy height (m)	Row spacing (m)	Total LWA (m ² /ha)	Max. LWA rate conversion (L/10000 m ² LWA)
Poland					
S19-03713-01	1.50-2.50	3.20	3.60	17778	0.84-1.40
S19-03714-01		2.65-2.70	3.50	15143-15429	0.97-1.65
S20-00011		2.40	3.60	13333-14167	1.06-1.88
S20-00012		2.50	3.30	15152-15758	0.95-1.65
S20-00209		2.60	3.40	15294-15588	0.96-1.63
S20-00210		2.40	3.20	15000-15625	0.96-1.67
Germany					
FRS 118/20-V1	1.50-2.50	2.00	3.60	11111	1.35-2.25
FRS 118/20-V2		2.50	3.50	14286	1.05-1.75
FRS 161/19-V1		1.50	3.50	8571	1.75-2.92
FRS 161/19-V2		2.00	4.30	9302	1.61-2.68

¹⁾ Total LWA: ((Treated canopy height * 10000) / Row spacing) * 2.

²⁾ Max. LWA rate conversion: (Tested rate / Total LWA) * 10000.

- Summary of relevant EPPO guidelines forming basis of trials design and methodology

All field trials were carried out by officially recognized testing organisations in accordance with EPPO standards PP 1/5 (*Venturia inaequalis* and *V. pyrina*), PP 1/152 (Design and analysis of efficacy evaluation trials) and PP 1/181 (Conduct and reporting of efficacy evaluation trials including good experimental practice). All trials were also conducted to evaluate crop selectivity and the EPPO standard PP 1/135 (Phytotoxicity assessment) was followed too.

- Application methods

In the efficacy trials carried out in Poland, the formulated products were sprayed 3 or 5 times at BBCH 69-74, with a sprayer. In the supportive trials (Germany), the formulated products were sprayed 6 times at BBCH 69-77, with a sprayer.

Trials were designed in Randomized Complete Blocks with 4 replicates. Plot size ranged from 18.5 to 33.25 m². The spray volume of application was 750 L/ha (4 trials) and 1000 L/ha (6 trials).

Specific comparisons are provided below in side-by-side trials *i.e.*, the trials where the same modalities were tested at the same time.

Further details of the individual trials conducted are provided in Table 3.2-7, Appendix 2 (Summary of data on trials site and application details per use) and Appendix 3 (Summary of data on effectiveness trials per use (crop/harmful organism); (EPPO code)) of BAD.

Table 3.2-7: Details on trial methodology – Pome fruits (apple) against *Venturia inaequalis*

		North-east and Maritime EPPO zones
Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/135 (4), PP 1/181 (4)
	Specific guidelines	EPPO PP 1/5 (3) (<i>Venturia inaequalis</i> and <i>Venturia pyrina</i>)
Experimental design	Plot design	RCB (10)
	Plot size	18.5 – 33.25 m ²
	Number of repl.	4
Crop	Trials per crop	Apple (10)
	Varieties per crop	• Poland (North-east EPPO zone): <i>Gloster</i> (2), <i>Idared</i> (2), <i>Jonaprince</i> , <i>Ligol</i> • Germany (Maritime EPPO zone): <i>Jonagold</i> , <i>Elstar</i> , <i>Gala</i> , <i>Shamplon</i>
	Sowing period	Not relevant
Application	Crop stage (BBCH) at application	• Poland (North-east EPPO zone): BBCH 69-74 • Germany (Maritime EPPO zone): BBCH 69-77
	Timing Pest stage at application (1)	Pre-infection / Mixed
	Number of applications Intervals between applications	• Poland (North-east EPPO zone): 3-5 applications (interval of 6-11 days) • Germany (Maritime EPPO zone): 6 applications (interval of 7-15 days)
	Spray volumes	• Poland (North-east EPPO zone): 750-1000 L water/ha • Germany (Maritime EPPO zone): 1000 L water/ha
Assessment	Assessment types	% Pest incidence/severity on leaves. Count of affected fruits (no attack / 1-3 spots/fruit / >3 spots/fruit). Count of affected leaves (no attack / 1-3 spots/fruit / >3 spots/fruit).
	Assessment dates	Please, refer to data tables below.
Other relevant information	e.g., Soil type, pH (in case of soil active substance ...)	• Poland (North-east EPPO zone): n.a. (2), sandy loam (2), loamy clay (1), silt loam (1). • Germany (Maritime EPPO zone): sandy loam (1), clay loam (1), silt loam (1), loam (1).
	e.g., Natural / artificial inoculation...	Natural
	e.g., Field / Greenhouse...	Field

• Results

A summary of the efficacy results is provided in:

- Poland (North-East EPPO zone): Table 3.2-8 (% incidence on leaves), Table 3.2-9 (% severity on leaves), Table 3.2-10 (count of affected fruits (no attack)), Table 3.2-11 (count of affected fruits (1-3 spots/fruit)), Table 3.2-12 (count of affected fruits (>3 spots/fruit)).
- Germany (Maritime EPPO zone): Table 3.2-13 (count of affected leaves), Table 3.2-14 (count of affected fruits (no attack)), Table 3.2-15 (count of affected fruits (1-3 spots/fruit)), Table 3.2-16 (count of affected fruits (>3 spots/fruit)).

Comments of zRMS:	<p><u>Efficacy tests</u></p> <p>This evaluation concerns the registration of Salaman 510 fungicide, containing inorganic active substance potassium phosphonates (510 g/L, expressed as phosphorous acid) for the control of apple scab (<i>Venturia inaequalis</i> – VENTIN) on apple trees and pear scab (<i>Venturia pyrina</i> – VENTPI) on pear trees, in Central Zone (Poland). Apple and pear trees are the major crops and both diseases <i>Venturia inaequalis</i> and <i>Venturia pyrina</i> are the major pests, also.</p> <p>Potassium phosphonates belong to the class of phosphonate fungicides (FRAC group P07 (2021), earlier group 33 (2015)). It is a preventive fungicide with systemic and translocating properties against fungus infection with preventive fungicide action and activator of the self-defence mechanism of the plant. In the evaluation process Poland acts as zRMS.</p> <p>Currently, fungicides containing potassium phosphonates (Alginure - 342 g/L; Soriale - 755 g/L) are registered in Poland as well as the products composed of mixtures of 2 active substances: Merplus 800 SC (potassium phosphonates - 657 g/L + captan - 360 g /L) and Delan Pro (dipotassium phosphonates - 561 g/L + dithianon - 125 g/L). Alginure is intended for control of downy mildew on grapevines, and Soriale, Merplus 800 SC and Delan Pro for control of apple and pear scab.</p> <p>ZRMS confirms that all trials submitted in this dossier were carried out by contractor companies recognized for efficacy testing of plant protection products, in accordance with the principles of Good Experimental Practice (GEP) and EPPO general guidelines: 1/152 (4), PP 1/135 (4), PP 1/181 (4) and specific EPPO guideline PP 1/5 (3) (<i>Venturia inaequalis</i> and <i>Venturia pyrina</i>). No major deviation from the EPPO guidelines was observed.</p> <p>The efficacy and crop safety data supporting the registration of Salaman 510 were obtained in the trials carried out in the years of 2019-2020. In apple trees 6 trials were carried out in Poland and 4 trials in Germany, while in pear trees 4 trials were conducted in Germany. On apple trees Salaman 510 was used at the rate of 1.5 and 2.5 L/ha, in 3-5 applications in Poland, at the growth stages of BBCH 69-74 and in 6 applications, at the growth stages of BBCH 69-77 in Germany, while on pears was used in 6 applications, at growth stages of BBCH 69-78.</p>
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Table 3.2-8: Dose effect of SALAMAN 510 against VENTIN on Apple (% incidence on leaves) - POLAND (North-East EPPO climatic zone)

Trial code	Location	Crop (Variety)	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY					No of trials where SAL-AMAN 510 is significant >, <, = compared to standard(s)		
						% incidence on leaves in UTC	% control						
							SALAMAN 510 1.50 L/ha (equivalent to 0.84-1.06 L/10000 m ² LWA)		SALAMAN 510 2.50 L/ha (equivalent to 1.40-1.88 L/10000 m ² LWA)			Reference product	
		Identity	% control										
S19-03713-01	Woła Łęczeszycza	Apple	<i>Gloster</i>	14 DA-C	0 (all treatments)	52.88	42.99	a	43.81	a	Delan Pro 2.50 L/ha*		
S19-03714-01	Miedzechów	Apple	<i>Idared</i>	14 DA-C	0 (all treatments)	50.88	29.29	b	47.61	ab			
S20-00011	Jajkowice	Apple	<i>Idared</i>	11 DA-C	0 (all treatments)	7.13	79.17	a	79.76	a			
				10 DA-D		10.63	85.52	a	64.76	a			
				14 DA-E		26.00	93.44	a	94.89	a			
S20-00012	Cesinów Las	Apple	<i>Red Jonaprince</i>	11 DA-C	0 (all treatments)	11.13	75.00	a	93.75	a			
				10 DA-D		11.63	79.81	a	93.75	a			
				14 DA-E		21.88	98.81	a	98.07	a			
S20-00209	Piekielko	Apple	<i>Gloster</i>	11 DA-C	0 (all treatments)	31.25	72.02	b	81.15	a			
				10 DA-D		26.75	64.15	c	86.55	a			
				14 DA-E		39.25	82.06	a	82.90	a			
S20-00210	Kussy	Apple	<i>Ligol</i>	11 DA-C	0 (all treatments)	10.63	100.00	a	83.89	b			
				10 DA-D		15.13	100.00	a	87.93	b			
				14 DA-E		33.50	94.22	c	96.76	b			
10-14 DA-T				Mean	n=14	24.91	78.32		81.11				
				<i>Min</i>		7.13	29.29		43.81		-	85.19	>1, =2, <3
				<i>Max</i>		52.88	100		98.07			100	
S20-00011	Jajkowice	Apple	<i>Idared</i>	42 DA-E	0 (all treatments)	23.00	75.99	b	81.35	b	Delan Pro 2.50 L/ha*	91.91 a	
S20-00012	Cesinów Las	Apple	<i>Red Jonaprince</i>	42 DA-E	0 (all treatments)	15.38	73.81	a	65.77	a		94.87 a	
S20-00209	Piekielko	Apple	<i>Gloster</i>	42 DA-E	0 (all treatments)	36.63	52.60	b	74.14	a		81.62 a	
S20-00210	Kussy	Apple	<i>Ligol</i>	42 DA-E	0 (all treatments)	24.13	94.28	c	97.60	b		100.00 a	
42 DA-T				Mean	n=4	24.79	74.17		79.72			92.10	>0, =2, <2
				<i>Min</i>		15.38	52.60		65.77		-	81.62	
				<i>Max</i>		36.63	94.28		97.60			100	

* Dithianon + Potassium phosphonate 686 g/L, SC.

Table 3.2-9: Dose effect of SALAMAN 510 against VENTIN on Apple (% severity on leaves) - POLAND (North-East Eppo climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY						No of trials where SAL- AMAN 510 is significant >, <, = compared to standard(s)	
						% severity on leaves in UTC	% control				Reference product		
							SALAMAN 510 1.50 L/ha (equivalent to 0.84-1.06 L/10000 m ² LWA)		SALAMAN 510 2.50 L/ha (equivalent to 1.40-1.88 L/10000 m ² LWA)		Identity		% con- trol
S19-03713-01	Wola Łęczeszycza	Apple	<i>Gloster</i>	14 DA-C	0 (all treatments)	7.97	51.42	b	55.95	b	Delan Pro 2.50 L/ha*	69.92 a	
S19-03714-01	Miedzechów	Apple	<i>Idared</i>	14 DA-C	0 (all treatments)	7.68	46.29	b	66.38	ab		75.09 a	
S20-00011	Jajkowice	Apple	<i>Idared</i>	11 DA-C	0 (all treatments)	0.31	79.17	a	80.91	a		93.41 a	
				10 DA-D		0.64	92.05	a	74.80	a		90.52 a	
				14 DA-E		2.72	94.73	a	97.16	a		97.70 a	
S20-00012	Cesinów Las	Apple	<i>Red Jonaprince</i>	11 DA-C	0 (all treatments)	0.67	80.95	a	94.64	a		77.83 a	
				10 DA-D		0.72	81.60	a	94.64	a		93.94 a	
				14 DA-E		1.68	99.00	a	98.39	a		95.91 b	
S20-00209	Piekielko	Apple	<i>Gloster</i>	11 DA-C	0 (all treatments)	2.03	81.33	a	83.17	a		88.50 a	
				10 DA-D		2.48	78.29	c	92.33	a		86.79 b	
				14 DA-E		7.73	92.04	a	93.06	a		95.94 a	
S20-00210	Kussy	Apple	<i>Ligol</i>	11 DA-C	0 (all treatments)	0.69	100.00	a	87.93	b		97.97 a	
				10 DA-D		1.43	88.62	a	89.45	a		90.63 a	
				14 DA-E		3.76	95.99	b	97.76	ab		100.00 a	
10-14 DA-T				Mean	n=14	2.89	82.96		86.18		-	89.58	>0, =3, <3
				<i>Min</i>		0.31	46.29		55.95			69.92	
				<i>Max</i>		7.97	100		98.39			100	
S20-00011	Jajkowice	Apple	<i>Idared</i>	42 DA-E	0 (all treatments)	3.14	86.61	c	91.60	b	Delan Pro 2.50 L/ha*	97.03 a	
S20-00012	Cesinów Las	Apple	<i>Red Jonaprince</i>	42 DA-E	0 (all treatments)	1.13	74.07	a	67.23	a		96.43 a	
S20-00209	Piekielko	Apple	<i>Gloster</i>	42 DA-E	0 (all treatments)	7.99	75.43	b	85.89	a		92.68 a	
S20-00210	Kussy	Apple	<i>Ligol</i>	42 DA-E	0 (all treatments)	2.79	87.55	b	96.71	a		95.69 a	
42 DA-T				Mean	n=4	3.76	80.92		85.36		-	95.41	>0, =3, <1
				<i>Min</i>		1.13	74.07		67.23			92.48	
				<i>Max</i>		7.99	87.55		96.71			97.03	

* Dithianon + Potassium phosphonate 686 g/L, SC.

Table 3.2-10: Dose effect of SALAMAN 510 against VENTIN on Apple (Count of affected fruits (no attack)) - POLAND (North-East EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY					No of trials where SAL- AMAN 510 is significant >, <, = compared to standard(s)		
						Count of affect- ed fruits (no attack) in UTC	Count		Reference product				
							SALAMAN 510 1.50 L/ha (equivalent to 0.96 L/10000 m² LWA)	SALAMAN 510 2.50 L/ha (equivalent to 1.63-1.67 L/10000 m² LWA)	Identity	Count			
S20-00209	Piekietko	Apple	<i>Gloster</i>	11 DA-C	0 (all treatments)	98.75	100	a	100	a	Delan Pro 2.50 L/ha*	100.00 a	
				10 DA-D		95.75	100	a	100	a		100.00 a	
				14 DA-E		91.00	100	a	100	a		100.00 a	
S20-00210	Kussy	Apple	<i>Ligol</i>	11 DA-C	0 (all treatments)	93.50	100	a	100	a	100.00 a		
				10 DA-D		94.75	100	a	100	a	100.00 a		
				14 DA-E		78.50	100	a	100	a	100.00 a		
10-14 DA-T				Mean	n=6	92.04	100		100		100	>0, =2, <0	
				<i>Min</i>		78.50	100		100		100		
				<i>Max</i>		98.75	100		100		100		
S20-00209	Piekietko	Apple	<i>Gloster</i>	42 DA-E	0 (all treatments)	54.00	83.00	ab	84.50	ab	Delan Pro 2.50 L/ha*	87.50 a	
S20-00210	Kussy	Apple	<i>Ligol</i>	42 DA-E	0 (all treatments)	62.75	93.75	a	96.50	a		94.75 a	
42 DA-T				Mean	n=2	58.38	88.38		90.50			91.13	>0, =2, <0
				<i>Min</i>		54.00	83.00		84.50		-	87.50	
				<i>Max</i>		62.75	93.75		96.50		-	94.75	

* Dithianon + Potassium phosphonate 686 g/L, SC.

Table 3.2-11: Dose effect of SALAMAN 510 against VENTIN on Apple (Count of affected fruits (1-3 spots/fruit)) - POLAND (North-East EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY					No of trials where SAL- AMAN 510 is significant >, <, = compared to standard(s)	
						Count of affect- ed fruits (1-3 spots/fruit) in UTC	Count			Reference product		
							SALAMAN 510 1.50 L/ha (equivalent to 0.97-1.06 L/10000 m ² LWA)	SALAMAN 510 2.50 L/ha (equivalent to 1.63-1.88 L/10000 m ² LWA)	Identity	Count		
S19-03714-01	Miedzechów	Apple	<i>Idared</i>	14 DA-C	0 (all treatments)	1.25	7.00	a	8.25	a	Delan Pro 2.50 L/ha*	6.00 a
S20-00011	Jajkowice	Apple	<i>Idared</i>	11 DA-C	0 (all treatments)	3.75	0.00	a	0.00	a		0.00 a
				10 DA-D		4.25	0.00	a	0.00	a		0.00 a
				14 DA-E		4.50	1.00	a	0.00	a		1.25 a
S20-00012	Cesinów Las	Apple	<i>Red Jonaprince</i>	11 DA-C	0 (all treatments)	2.75	0.00	a	0.00	a		0.00 a
				10 DA-D		2.75	0.00	a	0.00	a		0.00 a
				14 DA-E		4.50	2.19	a	0.00	a		1.25 a
S20-00209	Piekielko	Apple	<i>Gloster</i>	11 DA-C	0 (all treatments)	1.00	0.00	b	0.00	b		0.00 b
				10 DA-D		3.75	0.00	b	0.00	b		0.00 b
				14 DA-E		6.75	0.00	b	0.00	b		0.00 b
S20-00210	Kussy	Apple	<i>Ligol</i>	11 DA-C	0 (all treatments)	6.25	0.00	b	0.00	b		0.00 b
				10 DA-D		4.50	0.00	b	0.00	b		0.00 b
				14 DA-E		2.50	0.00	a	0.00	a		0.00 a
10-14 DA-T				Mean	n=13	3.73	0.78		0.63		-	0.65
				Min		1.00	0.00		0.00			0.00
				Max		6.75	7.00		8.25			6.00
S20-00011	Jajkowice	Apple	<i>Idared</i>	42 DA-E	0 (all treatments)	9.50	8.00	a	5.04	a	Delan Pro 2.50 L/ha*	5.50 a
S20-00012	Cesinów Las	Apple	<i>Red Jonaprince</i>	42 DA-E	0 (all treatments)	3.00	2.88	a	0.50	a		5.00 a
S20-00209	Piekielko	Apple	<i>Gloster</i>	42 DA-E	0 (all treatments)	14.25	14.25	a	9.00	a		10.54 a
S20-00210	Kussy	Apple	<i>Ligol</i>	42 DA-E	0 (all treatments)	16.00	5.75	b	3.25	b		5.00 b
42 DA-T				Mean	n=4	10.69	7.72		4.45		-	6.51
				Min		3.00	2.88		0.50			5.00
				Max		16.00	14.25		9.00			10.54

* Dithianon + Potassium phosphonate 686 g/L, SC.

Table 3.2-12: Dose effect of SALAMAN 510 against VENTIN on Apple (Count of affected fruits (>3 spots/fruit)) - POLAND (North-East EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY					No of trials where SAL- AMAN 510 is significant >, <, = compared to standard(s)	
						Count of affect- ed fruits (> 3 spots/fruit) in UTC	Count					Reference product
							SALAMAN 510 1.50 L/ha (equivalent to 0.97-1.06 L/10000 m ² LWA)	SALAMAN 510 2.50 L/ha (equivalent to 1.63-1.88 L/10000 m ² LWA)		Identity		
S19-03714-01	Miedzechów	Apple	<i>Idared</i>	14 DA-C	0 (all treatments)	28.00	16.50	b	13.25	b	Delan Pro 2.50 L/ha*	15.75 b
S20-00011	Jajkowice	Apple	<i>Idared</i>	11 DA-C	0 (all treatments)	0.25	0.00	a	0.00	a		0.00 a
				14 DA-E		1.25	0.25	a	0.00	a		0.00 a
S20-00012	Cesinów Las	Apple	<i>Red Jonaprince</i>	10 DA-D	0 (all treatments)	0.75	0.00	a	0.00	a		0.00 a
				14 DA-E		1.25	1.50	a	0.00	a		0.75 a
S20-00209	Piekielko	Apple	<i>Gloster</i>	11 DA-C	0 (all treatments)	0.25	0.00	a	0.00	a		0.00 a
				10 DA-D		0.50	0.00	a	0.00	a		0.00 a
				14 DA-E		2.25	0.00	b	0.00	b		0.00 b
S20-00210	Kussy	Apple	<i>Ligol</i>	11 DA-C	0 (all treatments)	0.25	0.00	a	0.00	a		0.00 a
				10 DA-D		0.75	0.00	a	0.00	a		0.00 a
				14 DA-E		17.50	0.00	a	0.00	a		0.00 a
10-14 DA-T				Mean	n=11	4.82	1.66	1.20	-	1.43	>0, =5, <0	
				Min		0.25	0.00	0.00		0.00		
				Max		28.00	16.50	13.25		15.75		
S20-00011	Jajkowice	Apple	<i>Idared</i>	42 DA-E	0 (all treatments)	9.25	1.75	a	0.00	a	Delan Pro 2.50 L/ha*	1.50 a
S20-00012	Cesinów Las	Apple	<i>Red Jonaprince</i>	42 DA-E	0 (all treatments)	1.50	0.81	a	0.00	a		0.75 a
S20-00209	Piekielko	Apple	<i>Gloster</i>	42 DA-E	0 (all treatments)	22.25	15.50	a	2.75	a		4.52 a
S20-00210	Kussy	Apple	<i>Ligol</i>	42 DA-E	0 (all treatments)	21.25	0.50	b	0.25	b		0.25 b
42 DA-T				Mean	n=4	13.56	4.64	0.75	-	1.76	>0, =4, <0	
				Min		1.50	0.50	0.00		0.25		
				Max		22.25	15.50	2.75		4.52		

* Dithianon + Potassium phosphonate 686 g/L, SC.

Table 3.2-13: Dose effect of SALAMAN 510 against VENTIN on Apple (Count of affected leaves) - GERMANY (Maritime EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY					No of trials where SAL- AMAN 510 is significant >, <, = compared to standard(s)		
						Count of affect- ed leaves in UTC	% control						
							SALAMAN 510 1.50 L/ha (equivalent to 1.05-1.75 L/10000 m ² LWA)	SALAMAN 510 2.50 L/ha (equivalent to 1.75-2.92 L/10000 m ² LWA)	Reference product				
Identity	% con- trol												
FRS161/19-V1	Seboldshausen	Apple	Gala	8 DA-D	0 (all treatments)	1.5	33.3	a	83.3	a	Vitisan 2.50 kg/ha*	50.0 a	>1, =1, <0
				8 DA-E		6.0	83.3	b	70.8	b		54.2 b	
FRS161/19-V2	Goseck	Apple	Shamplon	7 DA-D	0 (all treatments)	40.8	55.8	b	58.3	b	34.4 ab		
7-8 DA-T				Mean	n=3	16.10	57.47		70.80		46.20		
				<i>Min</i>		<i>1.50</i>	<i>33.30</i>		<i>58.30</i>		<i>34.40</i>		
				<i>Max</i>		<i>40.80</i>	<i>83.30</i>		<i>83.30</i>		<i>54.20</i>		
FRS118/20-V1	Bad Holzhausen	Apple	Jonagold	14 DA-C	0 (all treatments)	16.8	50.7	b	56.7	b	Vitisan 2.50 kg/ha*	76.1 b	
				14 DA-D		17.3	52.2	b	59.4	b		71.0 b	
				14 DA-E		18.3	54.8	b	65.8	b		65.8 b	
				13 DA-F		22.5	45.6	b	60.0	b		63.3 b	
FRS118/20-V2	Seesen	Apple	Elstar	15 DA-D	0 (all treatments)	2.8	90.9	b	100.0	b	Vitisan 2.50 kg/ha*	81.8 b	
				13 DA-E		3.8	100.0	b	100.0	b		86.7 b	
				15 DA-F		5.3	76.2	b	76.2	b		66.7 b	
FRS161/19-V1	Seboldshausen	Apple	Gala	10 DA-F	0 (all treatments)	37.0	80.4	b	91.2	b	75.0 b		
FRS161/19-V2	Goseck	Apple	Shamplon	10 DA-C	0 (all treatments)	41.3	61.8	b	73.3	b	Vitisan 2.50 kg/ha*	52.7 b	
				11 DA-E		45.8	62.8	b	56.8	b		38.3 ab	
				10 DA-F		27.0	49.1	a	46.3	a		27.8 a	
10-15 DA-T				Mean	n=11	21.63	65.86		71.43		64.11		
				<i>Min</i>		<i>2.80</i>	<i>45.60</i>		<i>46.30</i>		<i>27.80</i>		
				<i>Max</i>		<i>45.80</i>	<i>100</i>		<i>100</i>		<i>86.70</i>		
FRS118/20-V1	Bad Holzhausen	Apple	Jonagold	28 DA-F	0 (all treatments)	30.3	47.9	b	68.6	b	Vitisan 2.50 kg/ha*	68.6 b	
FRS118/20-V2	Seesen	Apple	Elstar	27 DA-F	0 (all treatments)	9.8	71.8	b	84.6	b	76.9 b		
27-28 DA-T				Mean	n=2	20.05	59.85		76.60		72.75		
				<i>Min</i>		<i>9.80</i>	<i>47.90</i>		<i>68.60</i>		<i>68.60</i>		
				<i>Max</i>		<i>30.30</i>	<i>71.80</i>		<i>84.60</i>		<i>76.90</i>		

* Potassium hydrogen carbonate 994.9 g/kg, SP.

Table 3.2-14: Dose effect of SALAMAN 510 against VENTIN on Apple (Count of affected fruits (no attack)) - GERMANY (Maritime EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY						No of trials where SAL- AMAN 510 is significant >, <, = compared to standard(s)	
						Count of affect- ed fruits (no attack) in UTC	Count				Reference product		
							SALAMAN 510 1.50 L/ha (equivalent to 1.05-1.75 L/10000 m ² LWA)		SALAMAN 510 2.50 L/ha (equivalent to 1.75-2.92 L/10000 m ² LWA)		Identity		Count
FRS161/19-V1	Seboldshausen	Apple	<i>Gala</i>	8 DA-E	0 (all treatments)	93.5	98.0	a	96.8	a	Vitisan 2.50 kg/ha*	95.5 a	
8 DA-T				Mean	n=1	93.5	98.0		96.8		-	95.5	>0, =1, <0
FRS118/20-V2	Seesen	Apple	<i>Elstar</i>	13 DA-E	0 (all treatments)	99.8	100.0	a	100.0	a	Vitisan 2.50 kg/ha*	100.0 a	
				15 DA-F		99.3	100.0	a	100.0	a		100.0 a	
FRS161/19-V1	Seboldshausen	Apple	<i>Gala</i>	10 DA-F	0 (all treatments)	80.5	92.0	a	95.5	a		91.3 a	
FRS161/19-V2	Goseck	Apple	<i>Shamplon</i>	11 DA-E	0 (all treatments)	98.8	100.0	-	100.0	-		100.0 -	
				10 DA-F		93.3	96.8	-	96.5	-	96.5 -		
10-15 DA-T				Mean	n=5	94.34	97.76		98.40		-	97.56	>0, =3, <0
				<i>Min</i>		80.50	92.00		95.50		91.30		
				<i>Max</i>		99.80	100		100		100		
FRS118/20-V1	Bad Holzhausen	Apple	<i>Jonagold</i>	28 DA-F	0 (all treatments)	99.3	98.3	a	99.8	a	Vitisan	99.8 a	
FRS118/20-V2	Seesen	Apple	<i>Elstar</i>	27 DA-F	0 (all treatments)	99.0	100.0	a	100.0	a	2.50 kg/ha*	100.0 a	
27-28 DA-T				Mean	n=2	99.15	99.15		99.90		-	99.90	>0, =2, <0
				<i>Min</i>		99.00	98.30		99.80		99.80		
				<i>Max</i>		93.30	100		100		100		

* Potassium hydrogen carbonate 994.9 g/kg, SP.

Table 3.2-15: Dose effect of SALAMAN 510 against VENTIN on Apple (Count of affected fruits (1-3 spots)) - GERMANY (Maritime EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY						No of trials where SAL- AMAN 510 is significant >, <, = compared to standard(s)	
						Count of affect- ed fruits (1-3 spots) in UTC	Count				Reference product		
							SALAMAN 510 1.50 L/ha (equivalent to 1.05-1.75 L/10000 m ² LWA)		SALAMAN 510 2.50 L/ha (equivalent to 1.75-2.92 L/10000 m ² LWA)		Identity		Count
FRS161/19-V1	Seboldshausen	Apple	<i>Gala</i>	8 DA-E	0 (all treatments)	4.5	1.8	a	1.8	a	Vitisan 2.50 kg/ha*	3.0 a	
8 DA-T				Mean	n=1	4.50	1.80		1.80		-	3.00	>0, =1, <0
FRS118/20-V2	Seesen	Apple	<i>Elstar</i>	13 DA-E	0 (all treatments)	0.3	0.0	a	0.0	a	Vitisan 2.50 kg/ha*	0.0 a	
				15 DA-F		0.8	0.0	a	0.0	a		0.0 a	
FRS161/19-V1	Seboldshausen	Apple	<i>Gala</i>	10 DA-F	0 (all treatments)	11.8	5.5	b	3.5	b		6.0 b	
FRS161/19-V2	Goseck	Apple	<i>Shamplon</i>	11 DA-E	0 (all treatments)	1.3	0.0	-	0.0	-		0.0 -	
				10 DA-F		6.3	3.0	-	2.3	-	3.0 -		
10-15 DA-T				Mean	n=5	4.10	1.70		1.16		-	1.80	>0, =3, <0
				<i>Min</i>		<i>0.30</i>	<i>0.00</i>		<i>0.00</i>		<i>0.00</i>		
				<i>Max</i>		<i>11.80</i>	<i>5.50</i>		<i>3.50</i>		<i>6.00</i>		
FRS118/20-V1	Bad Holzhausen	Apple	<i>Jonagold</i>	28 DA-F	0 (all treatments)	0.8	0.5	a	0.3	a	Vitisan 2.50 kg/ha*	0.0 a	
FRS118/20-V2	Seesen	Apple	<i>Elstar</i>	27 DA-F	0 (all treatments)	1.0	0.0	a	0.0	a	0.0 a		
27-28 DA-T				Mean	n=2	0.9	0.25		0.15		-	0.00	>0, =2, <0
				<i>Min</i>		<i>0.8</i>	<i>0.00</i>		<i>0.00</i>		<i>0.00</i>		
				<i>Max</i>		<i>1.0</i>	<i>0.50</i>		<i>0.30</i>		<i>0.00</i>		

* Potassium hydrogen carbonate 994.9 g/kg, SP.

Table 3.2-16: Dose effect of SALAMAN 510 against VENTIN on Apple (Count of affected fruits (> 3 spots)) - GERMANY (Maritime EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	Count of affected fruits (> 3 spots) in UTC	EFFICACY				No of trials where SAL- AMAN 510 is significant >, <, = compared to standard(s)		
							SALAMAN 510		Reference product				
							Count		Identity	Count			
FRS161/19-V1	Seboldshausen	Apple	<i>Gala</i>	8 DA-E	0 (all treatments)	2.0	SALAMAN 510 1.50 L/ha (equivalent to 1.32-1.75 L/10000 m ² LWA)		SALAMAN 510 2.50 L/ha (equivalent to 2.25-2.92 L/10000 m ² LWA)		Vitisan 2.50 kg/ha*	1.5 a	
8 DA-T				Mean	n=1	2.00	1.50	0.30	-	1.50		>0, =1, <0	
FRS161/19-V1	Seboldshausen	Apple	<i>Gala</i>	10 DA-F	0 (all treatments)	7.8	2.8 ab		1.0 b		Vitisan	2.8 ab	
FRS161/19-V2	Goseck	Apple	<i>Shamplon</i>	10 DA-F	0 (all treatments)	0.5	0.3 -		1.3 -		2.50 kg/ha*	0.5 -	
10 DA-T				Mean	n=2	4.15	1.55	1.15	-	1.65		>1, =1, <0	
				<i>Min</i>		0.50	0.30	1.00		0.50			
				<i>Max</i>		7.80	2.80	1.30		2.80			
FRS118/20-V1	Bad Holzhausen	Apple	<i>Jonagold</i>	28 DA-F	0 (all treatments)	0.1	0.0 a		1.3 a		Vitisan 2.50 kg/ha*	0.0 a	
28 DA-T				Mean	n=1	0.10	0.00	1.30	-	0.00		>0, =1, <0	

* Potassium hydrogen carbonate 994.9 g/kg, SP.

Conclusion

A total of 10 trials (6) Poland and (4) Germany) in the Central Registration zone, developed sufficient levels of *V. inaequalis* to demonstrate the efficacy of SALAMAN 510 on apple. All trials developed adequate levels of leaves disease, ranging from 7.13 to 52.88 % incidence on leaves and from 0.31 to 7.99 % severity on leaves.

- *Minimum Effective Dose (MED)*

Regarding the MED, Salaman 510 applied at 2.5 L/ha reached numerically the highest control of the pathogen among the treatments. A dose response among the different doses of the product was recorded. In detail, in 2 out of the trials conducted in Poland Salaman 510 applied at 2.5 L/ha showed statistically superior compared to Salaman 510 applied at 1.5 L/ha. However, in 1 trial conducted also in Poland, Salaman 510 applied at 1.5 L/ha showed statistically superior over Salaman at 2.5 L/ha. No statistically significant control was observed **between** the dose rates of 1.5 L/ha and 2.5 L/ha in the trials conducted in Germany. Overall, we consider the doses 1.5–2.5 L/ha as the justified dose range.

- *Efficacy*

Trials conducted in POLAND (North-East EPPO climatic zone)

For summary purposes, several assessments (10-14 DA-T; 42 DA-T) have been used. All trials achieved a significant level of control from SALAMAN 510 applied at 1.5-2.5 L/ha and the dithianon + potassium phosphonate reference standard. The results are summarized in Table 3.2-8 (% incidence on leaves), Table 3.2-9 (% severity on leaves), Table 3.2-10 (Count of affected fruits (no attack)), Table 3.2-11 (Count of affected fruits (1-3 spots/fruit)) and Table 3.2-12 (Count of affected fruits (>3 spots/fruit)) for the rates recommended for use. Full data for the assessments used and the individual trial data are presented in Appendix 3 of BAD.

Pest control was variable ranging from 29.29 to 100 % on incidence on leaves and from 46.29 to 100 % on severity on leaves, for SALAMAN 510 at 1.5 L/ha. Pest control ranging from 43.81 to 98.07 % on incidence on leaves and from 67.23 to 98.39 % on severity on leaves, for SALAMAN 510 at 2.5 L/ha. The level of control achieved by SALAMAN 510 was broadly similar to that achieved by the existing registered dithianon + potassium phosphonate standard, Delan Pro applied at 2.5 L/ha, ranging from 50.23 to 100 % on incidence on leaves and from 69.92 to 100 % on severity on leaves.

Although SALAMAN 510 achieved a very good control with **respect** the % on incidence and severity on leaves, the existing registered dithianon + potassium phosphonate standard reached a higher level of control compared to SALAMAN 510 with statistically significant differences in some trials, mainly compared to the lower application rate of 1.5 L/ha.

Regarding the control on affected fruits, there were no statistically significant differences in the performance of the SALAMAN 510 at 1.5-2.5 L/ha and the reference standard.

Supportive trials conducted in GERMANY (Maritime EPPO climatic zone)

For summary purposes, several assessments (7-8 DA-T; 10-15 DA-T; 27-28 DA-T) have been used. All trials achieved a significant level of control from SALAMAN 510 applied at 1.5-2.5 L/ha and the potassium hydrogen carbonate reference standard. The results are summarized in Table 3.2-13 (Count of affected leaves), Table 3.2-14 (Count of affected fruits (no attack)), Table 3.2-15 (Count of affected fruits (1-3 spots/fruit)) and Table 3.2-16 (Count of affected fruits (>3 spots/fruit)) for the rates recommended for use. Full data for the assessments used and the individual trial data are presented in Appendix 3 of BAD.

Pest control was variable ranging from 33.30 to 100 % on affected leaves, for SALAMAN 510 at 1.5-2.5 L/ha. The level of control achieved by SALAMAN 510 was broadly similar to that achieved by the existing registered potassium hydrogen carbonate standard, Vitisan applied at 2.50 kg/ha, ranging from 27.80 to 86.70 % on affected leaves.

There were no statistically significant differences in the performance of the SALAMAN 510 at 1.5-2.5 L/ha and the reference standard, except in trial FRS161/19-V2 where SALAMAN 510 achieved a higher disease control.

SALAMAN 510 achieved a good control on fruits, similar to the reference product without statistically significant differences.

Overall conclusion

Efficacy trials conducted on apple showed that SALAMAN 510 applied at 1.5-2.5 L/ha under different growing conditions, achieves good control of *V. inaequalis* at least equivalent to existing registered dithianon + potassium phosphonate and potassium hydrogen carbonate standards.

Comments of zRMS:	<p><u>Venturia inaequalis control</u></p> <p>The level of apple trees infestation by <i>Venturia inaequalis</i> was considered as acceptable to validate the trials, e.g. in the trials carried out in Poland the mean apple scab incidence in untreated plots ranged from 7.13 to 50.88%. The mean severity from all the trials at 10-14 DAT after C-E treatments was 2.9% and the maximum severity in individual trial 7.9%. The low level of severity resulted from the preventive use of the product.</p> <p>The incidence and severity of <i>Venturia inaequalis</i> on the apple leaves sprayed with Salaman 510 in most cases was higher in comparison to reference product and in some trials were affected close to reference product. The count of leaves and fruits affected by <i>Venturia inaequalis</i> (with no attack, with 1-3 spots and with >3 spots) in the trials in Poland and in Germany was at the same level or a little higher than from reference product. A little better results were achieved in the trials carried out Germany.</p> <p>The data demonstrate a good efficacy of Salaman 510 in controlling of <i>Venturia inaequalis</i> (VENTIN) on apple trees when using at the rate of 2.5 L/ha and varying effectiveness at the rate of 1.5 L/ha. The results show that Salaman 510 applied at the rate of 1.5-2.5 L/ha under different growing conditions, achieves almost as good control of VENTIN as to existing registered dithianon + potassium phosphonate and potassium hydrogen carbonate standards.</p> <p>In the trials conducted in Poland <i>Venturia inaequalis</i> control was variable, ranging from 29.29 to 100% on incidence on leaves and from 46.29 to 100% on severity on leaves, after Salaman 510 application at the rate of 1.5 L/ha, while after application at the rate of 2.5 L/ha ranging from 43.81 to 98.07% on incidence on leaves and from 67.23 to 98.39% on severity on leaves. In the trials in Germany the count of leaves and fruits affected by <i>Venturia inaequalis</i> (with no attack, with 1-3 spots and with >3 spots) was at the same level or a little higher than from reference product.</p> <p>The level of <i>Venturia inaequalis</i> control by Salaman 510 in majority trials was similar to that achieved by the existing registered dithianon + potassium phosphonate standard (Delan Pro) applied at 2.5 L/ha, which ranged from 50.23 to 100 % on incidence on leaves and from 69.92 to 100 % on severity on leaves.</p> <p>ZRMS confirms a good efficacy of Salaman 510 at the rate of 2.5 L/ha against <i>Venturia inaequalis</i> on apple trees, when applied as preventive treatment. The efficacy of lower rate (1.5 L/ha) was varied and at the low disease pressure and a good weather conditions product gave a satisfactory results, so the lower dose may be acceptable for <i>V. inaequalis</i> control. Under unfavorable weather conditions Salaman 510 may show a medium efficacy, therefore it should be recommended with another fungicide recommended for control of this pathogen. In can be also noted that Salamon 510 should be applied as an element of weed control program, in which the fungicides with dyfferent mode of action are included. The number of trials for registration of Salaman 510 in apple trees is sufficient.</p>
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3.2.3.2 Pear (against *Venturia pyrina*)

Data and information to support the authorization of Salaman 510 for the control of *Venturia pyrina* on pome fruits (pear) are provided from 4 efficacy trials conducted between 2019-2020 in Germany (Maritime EPPO zone).

Moreover, according to the “EPPO extrapolation table for effectiveness of fungicides: diseases on pome fruit (n° 14/20152)”, trials against *Venturia* carried out in the indicator crop (apple) can be extrapolated to any pome fruit.

Presentation of efficacy trials on pome fruits (pear) against *Venturia pyrina*

Use (Number of trials)	Trial number	Member State (EPPO climatic zone)	Year	Testing facilities / Organisation	Guidelines	Trials status	Comments
Supportive efficacy trials in Germany (Maritime EPPO zone)							
Pear VENTPI (4)	FRS 119/20-V1	Germany	2020	Field Research Support	PP 1/135	GEP	-
	FRS 119/20-V2	Germany	2020	Field Research Support	PP 1/152		-
	FRS 162/19-V1	Germany	2019	Field Research Support	PP 1/181		-
	FRS 162/19-V2	Germany	2019	Field Research Support	PP 1/5		-

Materials and methods

Test item and reference products

Preparation	Formulation Type	Composition	Dose of use	Dose of a.s.
SALAMAN 510	SL	Potassium phosphonate 510 g/L	1.50 L f.p./ha	765 g/ha
			2.50 L f.p./ha	1280 g/ha
SORIALE	SL	Potassium phosphonate 755 g/L	1.9 L f.p./ha	1430 g/ha
VITISAN	SP	Potassium hydrogen carbonate 994.9 g/kg	2.5 kg f.p./ha	2488 g/ha

The tested dose expressed as LWA rate applied in each efficacy trial is presented in the following table:

Trial	Tested rate (L/ha)	Treated canopy height (m)	Row spacing (m)	Total LWA (m ² /ha)	Max. LWA rate conversion (L/10000 m ² LWA)
Germany					
FRS 162/19-V1	1.50-2.50	1.50	3.50	8571	1.75-2.92
FRS 162/19-V2		1.50	3.60	8333	1.80-3.00
FRS 119/20-V1		2.00	3.50	11429	1.31-2.18
FRS 119/20-V2		2.50	4.50	11111	1.20-2.00

- Summary of relevant EPPO guidelines forming basis of trials design and methodology

All field trials were carried out by officially recognized testing organisations in accordance with EPPO standards PP 1/5 (*Venturia inaequalis* and *V. pyrina*), PP 1/152 (Design and analysis of efficacy evaluation trials) and PP 1/181 (Conduct and reporting of efficacy evaluation trials including good experimental practice). All trials were also conducted to evaluate crop selectivity and the EPPO standard PP 1/135 (Phytotoxicity assessment) was followed too.

- Application methods

The preparations were sprayed 6-8 times at BBCH 69-78, with a sprayer.

Trials were designed in Randomized Complete Blocks with 4 replicates. Plot size ranged from 21.0 to 21.6 m². The spray volume of application was 1000 L/ha.

Specific comparisons are provided below in side-by-side trials *i.e.*, the trials where the same modalities were tested at the same time.

Further details of the individual trials conducted are provided in Table 3.2-17, Appendix 2 (Summary of data on trials site and application details per use) and Appendix 3 (Summary of data on effectiveness trials per use (crop/harmful organism); (EPPO code)) of BAD.

Table 3.2-17: Details on trial methodology – Pome fruits (pear) against *Venturia pyrina*

		Maritime EPPO Zone
Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/135 (4), PP 1/181 (4)
	Specific guidelines	EPPO PP 1/5 (3) (<i>Venturia inaequalis</i> and <i>Venturia pyrina</i>)
Experimental design	Plot design	RCB (4)
	Plot size	21.0 - 21.6 m ²
	Number of repl.	4
Crop	Trials per crop	Pear (4)
	Varieties per crop	<i>Conference</i> (2), <i>William Christ</i> , <i>Gellerts Butterbirne</i>
	Sowing period	Not relevant
Application	Crop stage (BBCH) at application	BBCH 69-78
	Timing Pest stage at application (1)	Pre-infection / Mixed
	Number of applications Intervals between applications	6-8 applications with intervals of 8-15 days
	Spray volumes	1000 L/ha
Assessment	Assessment types	Count of affected leaves Count of affected fruits (no attack / 1-3 spots/fruit / >3 spots/fr)
	Assessment dates	Please, refer to data tables below.
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Sandy loam (2), clay loam, loam
	e.g. Natural / artificial inoculation...	Natural
	e.g. Field / Greenhouse...	Field

- Results

A summary of the efficacy results is provided in:

- Germany (Maritime EPPO zone): Table 3.2-18 (count of affected leaves), Table 3.2-19 (count of affected fruits (no attack)), Table 3.2-20 (count of affected fruits (1-3 spots/fruit)), Table 3.2-21 (count of affected fruits (>3 spots/fruit)).

Table 3.2-18: Dose effect of SALAMAN 510 against VENTPI on Pear (Count of affected leaves) - GERMANY (Maritime EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY				No of trials where SAL- AMAN 510 is significant >, <, = compared to standard(s)		
						Count of affect- ed leaves in UTC	% control		Reference product			
							SALAMAN 510 1.50 L/ha (equivalent to 1.20-1.80 L/10000 m ² LWA)	SALAMAN 510 2.50 L/ha (equivalent to 2.00-3.00 L/10000 m ² LWA)	Identity		% con- trol	
FRS119/20-V1	Bad Holzhausen	Pear	<i>Conference</i>	11 DA-C	0 (all treatments)	7.3	58.6	b	75.9	b	Vitisan 2.50 kg/ha*	65.5 b
				14 DA-D		17.0	35.3	b	64.7	c		51.5 bc
				14 DA-E		20.8	32.5	b	53.0	c		44.6 bc
				14 DA-F		28.3	47.8	b	61.9	c		46.9 b
FRS119/20-V2	Bad Gandersheim	Pear	<i>William Christ</i>	14 DA-E	0 (all treatments)	9.0	47.2	b	66.7	b	Vitisan 2.50 kg/ha*	58.3 b
				10 DA-F		18.3	54.8	b	53.4	b		50.7 b
FRS162/19-V1	Einecke	Pear	<i>Gellerts Butterbirne</i>	14 DA-F	0 (all treatments)	2.5	70.0	bc	100.0	c	Appl. (ABCDE) Vitisan 2.50 kg/ha*	30.0 ab
				12 DA-G		4.5	55.6	b	66.7	b		66.7 b
				13 DA-H		9.5	63.2	b	78.9	b		68.4 b
FRS162/19-V2	Einecke	Pear	<i>Conference</i>	14 DA-F	0 (all treatments)	4.0	68.8	b	87.5	b	2.50 kg/ha* Appl. (GH) Fung. Progress 1.20 kg/ha**	50.0 b
				12 DA-G		6.0	66.7	b	75.0	b		58.3 b
				13 DA-H		10.5	59.5	b	81.0	b		69.0 b
10-15 DA-T				Mean	n=12	11.48	55.00		72.06		54.99	>1, =3, <0
				<i>Min</i>		2.50	32.50		53.00		30.00	
				<i>Max</i>		28.30	70.00		100		69.00	
FRS119/20-V1	Bad Holzhausen	Pear	<i>Conference</i>	27 DA-F	0 (all treatments)	28.0	45.5	b	59.8	c	Vitisan 2.50 kg/ha*	48.2 b
FRS119/20-V2	Bad Gandersheim	Pear	<i>William Christ</i>	25 DA-F	0 (all treatments)	23.5	57.4	b	56.4	b		53.2 b
25-28 DA-T				Mean	n=2	25.75	51.45		58.10		50.70	>1, =1, <0
				<i>Min</i>		23.50	45.50		56.40		48.20	
				<i>Max</i>		28.00	57.40		59.80		53.20	

* Potassium hydrogen carbonate 994.9 g/kg, SP.

** Copper hydroxide 537.0 g/kg, WG.

Table 3.2-19: Dose effect of SALAMAN 510 against VENTPI on Pear (Count of affected fruits (no attack)) - GERMANY (Maritime EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY						No of trials where SAL-AMAN 510 is significant >, <, = compared to standard(s)	
						Count of affected fruits (no attack) in UTC	Count				Reference product		
							SALAMAN 510 1.50 L/ha (equivalent to 1.80 L/10000 m ² LWA)		SALAMAN 510 2.50 L/ha (equivalent to 3.00 L/10000 m ² LWA)		Identity		Count
FRS162/19-V2	Einecke	Pear	Conference	14 DA-F	0 (all treatments)	99.5	100.0	-	100.0	-	Appl. (ABCDEF) Vitisan 2.50 kg/ha* Appl. (GH) Fung. Progress 1.20 kg/ha**	100.0 -	
				12 DA-G		99.5	100.0	-	100.0	-		100.0 -	
				13 DA-H		98.0	100.0	a	100.0	a		100.0 a	
12-14 DA-T				Mean	n=3	99.00	100	100	100	100	100	>0, =1, <0	
				<i>Min</i>		98.00	100	100	100	-	100		
				<i>Max</i>		99.50	100	100	100	-	100		

* Potassium hydrogen carbonate 994.9 g/kg, SP.

** Copper hydroxide 537.0 g/kg, WG.

Table 3.2-20: Dose effect of SALAMAN 510 against VENTPI on Pear (Count of affected fruits (no attack)) - GERMANY (Maritime EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	EFFICACY						No of trials where SAL-AMAN 510 is significant >, <, = compared to standard(s)	
						Count of affected fruits (1-3 spots) in UTC	Count				Reference product		
							SALAMAN 510 1.50 L/ha (equivalent to 1.80 L/10000 m ² LWA)		SALAMAN 510 2.50 L/ha (equivalent to 3.00 L/10000 m ² LWA)		Identity		Count
FRS162/19-V2	Einecke	Pear	Conference	14 DA-F	0 (all treatments)	0.5	0.0	-	0+0	-	Appl. (ABCDEF) Vitisan 2.50 kg/ha* Appl. (GH) Fung. Progress 1.20 kg/ha**	0.0 -	
				12 DA-G		0.5	0.0	-	0.0	-		0.0 -	
				13 DA-H		1.8	0.0	b	0.0	b		0.0 b	
12-14 DA-T				Mean	n=3	0.93	0.00	0.00	0.00	0.00	0.00	>0, =1, <0	
				<i>Min</i>		0.50	0.00	0.00	0.00	-	0.00		
				<i>Max</i>		1.80	0.00	0.00	0.00	-	0.00		

* Potassium hydrogen carbonate 994.9 g/kg, SP.

** Copper hydroxide 537.0 g/kg, WG.

Table 3.2-21: Dose effect of SALAMAN 510 against VENTPI on Pear (Count of affected fruits (> 3 spots)) - GERMANY (Maritime EPPO climatic zone)

Trial code	Location	Crop	Variety	DAT	SELECTIVITY (Phytotoxicity)	Count of affected fruits (> 3 spots) in UTC	EFFICACY				No of trials where SAL-AMAN 510 is significant >, <, = compared to standard(s)
							SALAMAN 510		Reference product		
							Count		Identity	Count	
							SALAMAN 510 1.50 L/ha (equivalent to 1.80 L/10000 m ² LWA)	SALAMAN 510 2.50 L/ha (equivalent to 3.00 L/10000 m ² LWA)			
FRS162/19-V2	Einecke	Pear	<i>Conference</i>	13 DA-H	0 (all treatments)	0.3	0.0 -	0.0 -	Fung. Progress 1.20 kg/ha*	0.0 -	
10-13 DA-T				Mean	n=1	0.30	0.00	0.00	-	0.00	>0, =1, <0

* Copper hydroxide 537.0 g/kg, WG.

Conclusion

A total of 4 trials conducted in the Central Registration zone, developed sufficient levels of *V. pyrina* to demonstrate the efficacy of SALAMAN 510 on pear. All trials developed adequate levels of leaves disease, ranging from 2.5 to 28.3 % on infected leaves.

- *Minimum Effective Dose (MED)*

Regarding the MED, no statistic difference was recorded between application rates of 150 mL fp/hL and 250 mL fp/hL. Nevertheless, the 250 mL fp/hL of Salaman 510 reached numerically the highest control of the pathogen among the treatments. Overall, we consider the doses 150 mL fp/hL - 250 mL fp/hL as the justified dose range.

- *Efficacy*

For summary purposes, several assessments (10-15 DA-T; 27-28 DA-T) have been used. All trials achieved a significant level of control from SALAMAN 510 applied at 1.5-2.5 L/ha and the potassium hydrogen carbonate and copper hydroxide reference standards. The results are summarized in Table 3.2-18 (count of affected leaves), Table 3.2-19 (count of affected fruits (no attack)), Table 3.2-20 (count of affected fruits (1-3 spots/fruit)) and Table 3.2-21 (count of affected fruits (>3 spots/fruit)) for the rates recommended for use. Full data for the assessments used and the individual trial data is presented in Appendix 3 of BAD.

Pest control was variable ranging from 32.50 to 100 % on affected leaves, for SALAMAN 510 at 1.5-2.5 L/ha. The level of control achieved by SALAMAN 510 was broadly similar to that achieved by the existing registered potassium hydrogen carbonate standard, Vitisan applied at 2.50 kg/ha (applications ABCDEF), and copper hydroxide standard, Fung. Progress applied at 1.20 kg/ha (applications GH) ranging from 30.00 to 69.00 % on affected leaves.

There were no statistically significant differences in the performance of the SALAMAN 510 and the reference standard, except in trial FRS119/19-V2 where SALAMAN 510 showed an efficacy with a clear dose rate response on leaves during the trial with higher efficacy for both dose rates until the end of the trial compared to Vitisan.

SALAMAN 510 achieved a good control on fruits, similar to the reference product without statistically significant differences.

Overall conclusion

Efficacy trials conducted on pear showed that SALAMAN 510 applied at 1.5-2.5 L/ha under different growing conditions, achieves good control of *V. pyrina* at least equivalent to existing registered potassium hydrogen carbonate and copper hydroxide standards.

Comments of zRMS:	<p><u>Venturia pyrina control</u></p> <p>The results of trials carried out in Germany showed a good efficacy of Salaman 510 at the rate of 2.5 L/ha and varying effectiveness at 1.5 L/ha, in controlling <i>Venturia pyrina</i> on pear trees. In the trials with Salaman 510 use the count of affected leaves in UTC was higher than in reference product and the count of affected fruits (with no attack, with 1-3 spots and with >3 spots) was at the same level.</p> <p>The applicant did not submit any data from Poland on <i>Venturia pyrina</i> control by Salaman 510 on pears, only 4 trial from Germany, which can support the registration of this product in Poland. Taking into account the lack of data from Poland, zRMS suggest the recognition of data from Germany and registration of Salaman 510 for <i>Venturia pyrina</i> control in pears under condition that applicant provides data of 2 trials to the end of 2023 or registration of this fungicide in pear trees as minor uses. The extrapolation of data from Germany is possible but should be some data from Poland, also.</p> <p>Conclusions. ZRMS confirms that presented data support the registration of Salaman 510 for apple scab (<i>Venturia inaequalis</i> – VENTIN) control on apple trees and pear scab</p>
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	<p>(<i>Venturia pyrina</i> – VENTPI) control on pear tree but for pear tree it may be a minor use or the applicant will deliver the additional post registration data. For diseases control Salaman 510 can be recommended as a foliar application, at the rate of 1.5-2.5 L/ha, at maximum of 5 treatments between the growth stages of pome fruits BBCH 53-81, with water volume 500-1000 L/ha, with minimum 5 days intervals between applications. Salaman 510 (Savial Forte) showed a good efficacy at the rate of 2.5 L/ha against <i>V. pyrina</i> on pear trees and medium to good efficacy at the rate of 1.5 L/ha. Due to the satisfactory results the rate of 1.5 L/ha may be acceptable, mainly at the low disease pressure and a good weather conditions. Under unfavorable weather conditions Salaman 510 may show a medium efficacy, therefore it should be recommended with another fungicide recommended for control of this pathogen. It can be also noted that Salamon 510 should be applied as an element of weed control program, in which the fungicides with different mode of action are included.</p>
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

Salaman 510 is a fungicide containing potassium phosphonate (510 g/L, expr. as phosphorous acid). Potassium phosphonate belongs to P07 (33) group of FRAC. This signifies that it causes host plant defence induction as its mode of action (P: host plant defence induction) and it was reclassified accordingly in 2018. Furthermore, phosphonates possess a low risk for the development of resistance and only a few cases of resistance have been reported in a few pathogens.

There are no confirmed reports of pathogen resistance to phosphonate fungicides in pome fruits. This is probably due to two major factors. The first risk-minimizing factor is the fungicide mode of action of phosphonates, which may involve several sites. The second parameter may involvement the stimulation of the host defences mechanisms. Both of these factors are very strong barriers for pathogens to overcome through resistance.

In addition, no specific resistance management guidelines are proposed by FRAC. The development of resistance is not expected.

Comments of zRMS:	ZRMS agree with the applicant`s explanation.
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3.4 Adverse effects on treated crops (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Phytotoxicity was recorded in all efficacy trials conducted both in North-east and Maritime EPPO zones.

Data and information to assess the safety of Salaman 510 in pome fruits are provided from 14 efficacy trials (10 in apple and 4 in pear) conducted between 2019-2020, in presence of disease.

11 different cultivars (8 in apple and 3 in pear) were tested in the efficacy trials on pome fruit trees and no pattern of phytotoxicity associated with any cultivar could be identified.

TOTAL NUMBER OF TRIALS				
Crop (EPPO zone)	VARIETIES	CONDUCTED (efficacy/selectivity trials)	NO SYMPTOMS	VISUAL SYMPTOMS
Apple (North-east)	<i>Gloster, Idared, Jonaprince, Ligol</i>	6	6	0
Apple (Maritime)	<i>Jonagold, Elstar, Gala, Shamplon</i>	4	4	0
Pear (Maritime)	<i>Conference, William Christ, Gellerts Butterbirne</i>	4	4	0

No phytotoxicity was observed on leaves and fruits of pome fruits' varieties performing up to 8 applications at dose rates up to 2.50 L product/ha with a water volume of 750-1000 L/ha.

No phytotoxic symptoms were recorded in the efficacy trials when the product was applied at the N dose.

Conclusion

No unacceptable phytotoxicity effects are normally expected after application of the product provided that the product is applied according to the proposed GAP.

Comments of zRMS:	Considering the lack of phytotoxicity on leaves and fruits, even after 8 applications of tested fungicide it should be concluded that Salaman 510 is safe for apple and pear trees.
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Not relevant. No additional data was provided.

Comments of zRMS:	Considering the mode of action of potassium phosphonates and the use of this active substance in other products for several years zRMS accept not providing additional data.
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Not relevant. No additional data was provided.

Comments of zRMS:	Considering the mode of action of potassium phosphonates and the use of this active substance in other products for several years zRMS accept not submitting the additional data for this section.
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3.4.4 Effects on transformation processes (KCP 6.4.4)

Potassium phosphonate, Phosphonates/Phosphites, as well as Fosetyl-Al, and their associated formulations, are well-known in Europe. Products containing Fosetyl-Al, Potassium Phosphonate, Disodium phosphonate and Phosphonates/Phosphites are authorized and used as PPPs and fertilizers in Europe since several years.

Despite this intensive use of these products on apple and pear since several years, negative effects on the quality of plants or plant products have never been shown nor suspected.

Two residue trials in apple (study number: S20-04337) were carried out (1 in **Spain** and another one in Germany) according to the OECD guideline 508 residues in processed commodities and following its recommendation. Please refer to Section B7.

In all cases, the residues found in processed apples were below the current EU MRL for apple (150.0 mg/kg). Therefore, the use of SALAMAN 510 in apple produce residues lower than MRL in the processed fractions.

Conclusion: no adverse effect on transformation processes of the harvested product is expected after application of the product according to the recommendations of the GAP table.

Comments of zRMS:	ZRMS agree with the applicant's explanation. The potassium phosphonates was used in another products for several years and no adverse effect on transformation processes of apples and pears was noted.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Not relevant. No additional data was provided.

Comments of zRMS:	Considering do not usage of apple and pear fruits for propagation zRMS agree with applicant
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Not relevant. No additional data was provided as the intended crops are perennial (pome fruits).

Comments of zRMS:	ZRMS agree with applicant. The impact on succeeding crops might have only a meaning after removing the orchard.
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Potassium phosphonates 510 g/L products are already registered in several EU Member States and, therefore, it is assumed that the risk of impact on other plants including adjacent crops is acceptable.

Salaman 510 is normally not expected to cause unacceptable effects on adjacent crops after application of the product according to the recommendations of the GAP table.

Comments of zRMS:	ZRMS accept the applicant`s explanation.
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Tank cleaning

Salaman 510 is a water-soluble formulation, therefore the product is perfectly soluble in water and the equipment can be cleaned by rinsing several times with water. The rinsing water can be sprayed on the field. Protective clothing can be washed with water and soap.

Comments of zRMS:	ZRMS agree with applicant, the three rinsing of equipment ensure proper cleaning.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

The fungicide SALAMAN 510 (510 g/L potassium phosphonate) has been proposed for application in apple and pear at a total maximum application rate of 7.5 L/ha and year (3 applications, max. rate per application: 2.5 L product/ha). Taking into account the potential disappearance of the active ingredient between the applications (using the maximum default value MAF of 2.3), this corresponds to 2.93 kg active substance/ha and year.

Throughout the field trials on effectiveness and selectivity there have been no reports or observations to suggest a detrimental impact of SALAMAN 510 on beneficial or non-target organisms.

Appropriate studies on the potential adverse effects on beneficial arthropods were available from Registration Report Part B, Section 9, Annex Point 9.7 (Effects on arthropods other than bees), Core Assessment.

The toxicity of SALAMAN 510 have been tested by carrying out:

- laboratory tests on *Aphidius rhopalosiphi*.
- extended laboratory tests on *Typhlodromus pyri*.

The results are presented in Table 3.5.3-1.

Table 3.5.3-1: Effects of SALAMAN 510 on beneficial arthropods in extended laboratory tests

Species	Substrate	Rate [g a.s./ha]	Corrected Mortality [%]	Reduction [%]	Reference
<i>Typhlodromus pyri</i> (Protonymphs)	bean leaves	13538 g H ₃ PO ₃ /ha	23.81	No significant effects	KCP 10.3.2/02 Luna (2013)
<i>Aphidius rhopalosiphi</i> (Adults)	bean leaves	13538 g H ₃ PO ₃ /ha	2.5	28.98 %	KCP 10.3.2/03 Luna (2013)

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i>	Potassium phosphonate	Extended laboratory test	LR ₅₀ >24 L SALAMAN/ha equivalent to > 13538 g H₃PO₃/ha	KCP 10.3.2/02 Luna (2013)
<i>Aphidius rhopalosiphi</i>			LR ₅₀ >24 L SALAMAN/ha equivalent to > 13538 g H₃PO₃/ha	KCP 10.3.2/03 Luna (2013)

Based on the presented results no effects > 30% for populations of *Aphidius rhopalosiphi* and no effects for populations of *Typhlodromus pyri* are expected when SALAMAN 510 is applied according to the recommended use pattern. The results indicate that the recommended application of SALAMAN 510 has no effects > 30% on populations of relevant beneficial insects when applied in the proposed crops.

Conclusion

No unacceptable effects on non-target organisms are expected from the application of the product.

Comments of zRMS:	No comments.
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3.6 Other/special studies

Not relevant. No additional data was provided.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
EAS Spain (Eurofins Agrosience Services)	Polígono de Malpica, Nave 68 50016, Zaragoza, Spain	Yes
Field Research Support	Max-Planck-Strasse 5 D-31515 Wunstorf, Germany	Yes

Appendix 1 Lists of data considered in support of the evaluation

Comments of zRMS:	All trials presented below were used for the evaluation.
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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
Point 6.0	Duran, P	2021	Biological assessment dossier GEP: Not applicable Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.1 - APPLE					
Poland (North-East Eppo climatic zone)					
KCP 3.2.3.1/01	Pérez Muriel, A.	2020	Determination of Efficacy and Crop Safety of SALAMAN 510 (Potassium phosphonate 51%, expressed as phosphorous acid) against <i>Venturia inaequalis</i> in apple. Poland. OUTDOOR 2019. Report No.: S19-03713-01 Eurofins Agroscience Services, S.L. GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.1/02	Pérez Muriel, A.	2020	Determination of Efficacy and Crop Safety of SALAMAN 510 (Potassium phosphonate 51%, expressed as phosphorous acid) against <i>Venturia inaequalis</i> in apple. Poland. OUTDOOR 2019. Report No.: S19-03714-01 Eurofins Agroscience Services, S.L. GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.1/03	Pérez Muriel, A.	2020	Determination of Efficacy and Crop Safety of SALAMAN 510 (Potassium phosphonate 51%, expressed as phosphorous acid) against <i>Venturia inaequalis</i> in apple. Poland. OUTDOOR 2020. Report No.: S20-00011-01 EAS Spain (Eurofins Agroscience Services) GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

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
KCP 3.2.3.1/04	Pérez Muriel, A.	2020	Determination of Efficacy and Crop Safety of SALAMAN 510 (Potassium phosphonate 51%, expressed as phosphorous acid) against <i>Venturia inaequalis</i> in apple. Poland. OUTDOOR 2020. Report No.: S20-00012-01 EAS Spain (Eurofins Agroscience Services) GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.1/05	Pérez Muriel, A.	2020	Determination of Efficacy and Crop Safety of SALAMAN 510 (Potassium phosphonate 51%, expressed as phosphorous acid) against <i>Venturia inaequalis</i> in apple. Poland. OUTDOOR 2020. Report No.: S20-00209-01 EAS Spain (Eurofins Agroscience Services) GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.1/06	Pérez Muriel, A.	2020	Determination of Efficacy and Crop Safety of SALAMAN 510 (Potassium phosphonate 51%, expressed as phosphorous acid) against <i>Venturia inaequalis</i> in apple. Poland. OUTDOOR 2020. Report No.: S20-00210-01 EAS Spain (Eurofins Agroscience Services) GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
Supportive efficacy trials - Germany (Maritime EPPO climatic zone)					
KCP 3.2.3.1/07	Zöllner, H.	2020	Field study to determinate the efficacy and crop safety of Salaman 510 (Potassium fosponate 51%, expressed as phosphorus acid) on control of <i>Venturia inaequalis</i> on apple trees in Germany. Open Field Efficacy and Selectivity Study 2020. Report No.: FRS118/20-V1 Field Research Support GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.1/08	Zöllner, H.	2020	Field study to determinate the efficacy and crop safety of Salaman 510 (Potassium fosponate 51%, expressed as phosphorus acid) on control of <i>Venturia inaequalis</i> on apple trees in Germany. Open Field Efficacy and Selectivity Study 2020. Report No.: FRS118/20-V2 Field Research Support GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

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
KCP 3.2.3.1/09	Zöllner, H.	2019	Field study to determinate the efficacy and crop safety of Salaman 510 (Potassium phosponate 51%, expressed as phosphorus acid) on control of <i>Venturia inaequalis</i> on apple trees in Germany. Open Field Efficacy and Selectivity Study 2019. Report No.: FRS161/19-V1 Field Research Support GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.1/10	Zöllner, H.	2019	Field study to determinate the efficacy and crop safety of Salaman 510 (Potassium phosponate 51%, expressed as phosphorus acid) on control of <i>Venturia inaequalis</i> on apple trees in Germany. Open Field Efficacy and Selectivity Study 2019. Report No.: FRS161/19-V2 Field Research Support GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.2 - PEAR					
Supportive efficacy trials - Germany (Maritime EPPO climatic zone)					
KCP 3.2.3.2/01	Zöllner, H.	2020	Field study to determinate the efficacy and crop safety of Salaman 510 (Potassium phosponate 51%, expressed as phosphorus acid) on control of <i>Venturia pyrina</i> on pear trees in Germany. Open Field Efficacy and Selectivity Study 2020. Report No.: FRS119/20-V1 Field Research Support GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.2/02	Zöllner, H.	2020	Field study to determinate the efficacy and crop safety of Salaman 510 (Potassium phosponate 51%, expressed as phosphorus acid) on control of <i>Venturia pyrina</i> on pear trees in Germany. Open Field Efficacy and Selectivity Study 2020. Report No.: FRS119/20-V2 Field Research Support GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

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
KCP 3.2.3.2/03	Zöllner, H.	2019	Field study to determinate the efficacy and crop safety of Salaman 510 (Potassium phosponate 51%, expressed as phosphorus acid) on control of <i>Venturia pyrina</i> on pear trees in Germany. Open Field Efficacy and Selectivity Study 2019. Report No.: FRS162/19-V1 Field Research Support GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.2/04	Zöllner, H.	2019	Field study to determinate the efficacy and crop safety of Salaman 510 (Potassium phosponate 51%, expressed as phosphorus acid) on control of <i>Venturia pyrina</i> on pear trees in Germany. Open Field Efficacy and Selectivity Study 2019. Report No.: FRS162/19-V2 Field Research Support GEP Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

* PPTF: Potassium Phosponates Task Force (Lainco, S.A., Biovert, S.L., Exclusivas Sarabia, S.A.).

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 Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

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

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