REGISTRATION REPORT

Part A

Risk Management

Product code: Salaman 510

Product name(s): **PHYTOSARCAN**

Chemical active substance:

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

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT - Poland

(authorization)

Applicant: Exclusivas Sarabia S.A.

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

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application is submitted by Exclusivas Sarabia, S.A.

The application is for the authorization of the plant protection code product Salaman 510 in the field crops of pome fruits (apple, pear), against *Venturia inaequalis* and *Venturia pyrina*.

1.2 Letters of Access

Not applicable. All the data submitted is owned by the applicant.

1.3 Justification for submission of tests and studies

It is considered that all studies carried out regarding physico-chemical properties, analytical methods, toxicology, residues and ecotoxicology, submitted in this application, are necessary and enough to support the authorization/uses applied for.

1.4 Data protection claims

Studies for which data protection is claimed are identified in the list of data submitted in support of the evaluation in Appendix 1 of each Part B Section of the core assessment.

Exclusivas Sarabia, S.A. claims protection of plant protection product data supporting the application for authorization of Salaman 510 according to the provisions set in Articles 33.4, 59, 80.2 and 80.5 (b) of Regulation EC No. 1107/2009 as applicable.

2 Details of the authorization decision

2.1 Product identity

Product Name	*Phytosarcan*
Product Code	Salaman 510
Authorization Number (for re-registration)	n.a. (product not authorised yet in Poland)
Function	Fungicide
Applicant	Exclusivas Sarabia, S.A. Pol. Ind. "Fondo de Litera", Autovía A-2 km 441.6 22520 Fraga (Huesca) - SPAIN
Composition	Potassium phosphonate (510 g/L) (expressed as phosphorous acid)
Formulation type	Soluble (liquid) concentrate [SL]
Packaging	- 100 mL, 250 mL, 500 mL and 1 L bottles HDPE/COEX - 5 L, 10 L, 20 L and 50 L jerrycans HDPE - 5 L jerrycans HDPE/COEX, - 10L, 50L containers PE – High Molecular Weight

2.2 Conclusion

The evaluation of the application for product Phytosarcan (Salaman 510) resulted in the decision to grant the authorization.

All uses applied for were authorised.

2.3 Substances of concern for national monitoring

Not applicable. The plant protection product code Salaman 510 does not contain any substance of concern for national monitoring.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Not classified.

The following labelling information is derived from the classification and to be mentioned in the safety data sheet and label.

Hazard pictograms:	None
Signal word:	--
Hazard statement(s):	None
Precautionary statement(s):	None
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401].
	Do not contaminate water with the product or its container. Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads. [SP1]
	To protect aquatic organisms, respect an unsprayed buffer zone of 3 m to surface water bodies [SPe3]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

The Regulation (EU) 547/2011 as of 14 June 2011, has been replaced by the Regulation (EU) No. 284/2103.

Hazard Statement	Text	Triggered by	Justification
SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads)	Standard phrase for plant protection product	Commission Regulation (EU) No 547/2011
SPe3	To protect aquatic organisms, respect an unsprayed buffer zone of 3 m to surface water bodies	Environmental effects.	--

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
	Operator must wear adequate work clothing.
Worker protection:	
	Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried. In case a worker enters the field, long trousers and long-sleeved shirt should be worn.
Integrated pest management (IPM)/sustainable use:	
	None.
Environmental protection	
	1.- Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). 2.- To protect aquatic organisms, respect an unsprayed buffer zone of 3 m to surface water bodies.
Other specific restrictions	
	It is recommended to alternate with fungicides that do not belong to this group in order to avoid the development of resistance.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
	None.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
	None	
Environmental protection:		Relevant for use no.
	None	

2.6 Intended uses (only NATIONAL GAP)

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:	Exclusivas Sarabia, S.A.	Professional use:	☒
Zone(s):	Central EU zone [d]	Non-professional use:	☐
Verified by MS:	yes/no		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Min-Max. number a) per use b) per crop/ season	Min. interval between applic. (days)	L f.p./ha a) min-max. rate per appl. b) min-max. total rate per crop/season	kg a.s./ha a) min-max. rate per appl. b) min-max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Pome fruits (apple, pear)	F	*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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

Overall Summary: The product Salaman 510 is a soluble concentrate liquid (SL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a liquid. The colour is clear with strong odour. It is not flammable, has a flash point above 60°C and the self-ignition temperature above 409ºC. According to the structure, the formulation is not explosive nor oxidizing, since there are no chemical groups associated with explosive properties in the components of the mixture. In aqueous solution, Salaman 510 present, after 14 days, a pH value around 5.8 (at 1% dilution and 20°C and 54°C). The kinematic viscosity is 5.33 x 10^{-6} m^2/s at 20 °C and 3.19 x 10^{-6} m^2/s at 40 °C, and the surface tension of the dilution at 0.1% is 70.6 mN/m at 20.2°C. Therefore, the product is not considered as surface active and since the product does not contain hydrocarbons is not considered as hazardous after aspiration.

The relative density of Salaman 510 is 1.4524. The persistent foaming at 0.8% w/v has a maximum of 0.0 mL after 1 minute.

An accelerated stability test at 54ºC for 14 days was performed, showing that the product does not degrade, and its physical properties does not change. Further, the stability report at 20ºC for 2 years shows that the product does not show any change in its concentration of active substance and its physical properties.

However dilution stability study (MT 41.1) was not conducted after 2 years storage of formulation at ambient temperature. The formulation can be considered stable upon the 2 years stability test based on no changes in content active substance and technical properties (pH 1% and appearance) observed upon storage at ambient temperature. Furthermore, the results of dilution stability test in accelerated storage study (Romo, 2012) support shelf life of 2 years of the formulation.

Its technical characteristics are acceptable for a soluble concentrate liquid formulation.

The samples were stored, in their commercial packaging described as a plastic container (study report by Romo, 2012 and 2015). No change in packaging was observed after storage 14 days at 54ºC and 2-y at ambient temperature. For aqueous based formulation type, like SL, extrapolation between any plastic material types is acceptable. Therefore HDPE, HDPE (COEX) and polyethylene – High Molecular Weight packs (listed in section 4.1 of dRR) are supported based on data for plastic container.

The intended concentration of use is 0.15 % (v/v) product to 0.25 % (v/v) product.

Implications for labelling: None

Compliance with FAO specifications: The product Salaman 510 complies with FAO specifications.

Compatibility of mixtures: No tank mixes are foreseen for the product Salaman 510.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling of Salaman 510 has been provided and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

All the data regarding the efficacy of the product have been submitted in Part B3. These data demonstrate that Salaman 510 fulfils all criteria for the authorization of plant protection products. No phytotoxicity or effects on neighbouring crops were observed.

Salaman 510 is a preventive and systemic fungicide for use on pome fruits (apple, pear). It is a soluble concentrate liquid formulation (SL) containing the active substance potassium phosphonate (510 g/L).

3.3 Efficacy data

Summary and conclusions of the efficacy trials

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

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

Efficacy trials conducted on apple and pear showed that Salaman 510 applied at 1.5-2.5 L/ha under different growing conditions, achieves good control of *V. inaequalis* and *Venturia inaequalis* at least equivalent to existing registered standards.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

No resistance effects have been shown during the trials. The product contains phosphonic acid as active ingredient, which is an inorganic multi-site fungicide. As described very often in public literature, the development of resistance effects when using multi-site inorganic active ingredients is very unlikely to occur.

3.3.2 Adverse effects on treated crops

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

Salaman 510 applied according to the label recommendations and following the good practices doesn’t have any negative effect on the yield of treated plants or plants products.

No adverse effect on qualitative features of the harvested product is expected after application of the product according to the recommendations of the GAP table.

3.3.3 Observations on other undesirable or unintended side-effects

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

No unacceptable effects on non-target arthropods are expected from the application of the product. To be noted that results from effects on non-target arthropods in the Ecotoxicological Section should also be considered.

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.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The content of the active ingredient phosphonic acid (H_3PO_3) in Salaman 510 formulation is determined by dilution of the test item in acidic water and determination by chromatography HPLC with ionic detection.

The method was successfully validated according to SANCO/3030/99 rev. 4. The method demonstrates adequate specificity, linearity, accuracy and precision. The method requires equipment and instrumentation which are commonly available in many well-equipped laboratories.

3.4.2 Analytical methods for residues

Analytical methods for the determination of residues of phosphonic acid (H_3PO_3) in high water matrices were submitted for citrus (Gimeno Martos, C., 2014a) and grapes (Gimeno Martos, C., 2014b). The analytical methods have been performed and validated in accordance to SANCO/3030/99 rev.4 and they are acceptable for pre-registration. These methods are also accepted for monitoring purposes. ILV method was provided.

Analytical method for the determination of residues of potassium phosphonate (as phosphorous acid) in the raw agricultural commodity apple is submitted (Blanco, J., 2020). This LC-MS/MS analytical method has been performed and validated in accordance to SANCO/3030/99 rev.4 with LOQ=0.1 mg/kg and it is acceptable for pre-registration.

An analytical method (Guillet & Simonin, 1998) and its ILV (Wais, 1999), using GC/FPD for the determination of fosetyl-Al residues in plants have already been provided by the notifier (Bayer) in the DAR/Monograph and were considered as validated with LOQ = 0.5 mg/kg for phosphonic acid (H_3PO_3) in acidic commodities and in high water content commodities.

A confirmatory method (Mende, 2011) using GC/NPD was presented and validated in the Addendum 1 of the DAR (2005) with LOQ = 0.2 mg/kg for phosphonic acid separately in high water content commodities. As the extraction is performed at controlled pH, the method is also suitable for acidic crops.

The analytical methods proposed for the determination of residues of phosphonic acid (H_3PO_3) in soil and in water are the same methods considered for Annex I inclusion of fosetyl-Al and were considered acceptable.

The analytical methods for determination of phosphonic acid in water have been submitted for eco-toxicological studies in aquatic organisms. The analytical methods are validated and considered acceptable for pre-registration.

Analytical method for the determination of residues of potassium phosphonate in body fluids and tissues is not required as the active substance is not classified as “toxic” or “highly toxic”. Furthermore, Potassium phosphonate has no metabolites classified as toxic or highly toxic. Therefore, an analytical method is not required.

The analytical method for determination of potassium phosphonate (expressed as phosphonate acid) in samples from ecotoxicological studies on honeybees was submitted and fully validated according to the requirements of guideline SANCO/3029/99 rev.4 for pre-registration and also according to SANCO/825/00 rev.8.1.

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for Salaman 510 were evaluated for the registration of the product under Principle Uniforms. Taking into account all submitted data, the product was classified according to Regulation (EC) No. 1272/2008 as follows:

Hazard class(es), categories:	Not classified
Hazard pictograms or Code(s) for hazard pictogram(s):	None
Signal word:	--
Hazard statement(s):	None

zRMS:
The product Salaman 510 (Phytosacran) does not require classification for health hazards.

3.5.1 Acute toxicity

A summary of the toxicological evaluation for Salaman 510 is given in the following table.

Type of test, species, model system (guideline)	Result	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 423)	> 2000 mg/kg bw	None	… (2012)
LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	None	…. (2012)
LC_{50} inhalation, rat (OECD 403)	> 2.01 mg/L air	None	…. (2012)
Skin irritation, rabbit (OECD 404	Non-irritant	None	…. (2012)
Eye irritation, rabbit (OECD 405)	Non-irritant	None	… (2012)
Skin sensitisation, guinea pig (OECD 406)	Non-sensitising	None	…. (2012)

3.5.2 Operator exposure

Operator exposure was assessed considering the AOEL level agreed in the Review Report for potassium phosphonate (5.00 mg/kg bw/day; *EFSA Journal 2012*;10(12):2963).

An acceptable risk has been identified for operators, even without PPE, assuming only adequate work clothing.

The following phrase should be included in the product label:

"*Operator must wear adequate work clothing*"

zRMS:
The exposure to Potassium phosphonate, an active substance of the product SALAMAN 510 (PHYTO-SARCAN), of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying SALAMAN 510 on pome fruits, at maximal dose of 2.5 L product/ha (1.275 kg a.s./ha) using tractor-mounted/trailed sprayer, upward spraying, or manual hand held sprayer or manual knapsack sprayer cal-

culated with the EFSA AOEM amounted respectively to 8.00 %, 2.67% and 1.11% of AOEL. The potential exposure without wearing work clothing covering arms, legs and body amounted respectively to 27.18%, 16.09% and 11.61% of AOEL .

Summing up the application of product SALAMAN 510 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 but wearing a work clothing (long sleeved shirt, long trousers), but no PPE, is considerably reducing exposure and health risk.

3.5.3 Worker exposure

Worker exposure was assessed considering the AOEL level agreed in the Review Report for potassium phosphonate (5.00 mg/kg bw/day; *EFSA Journal 2012*;10(12):2963).

An acceptable risk has been identified for workers, according to the EFSA Calculator (2015), assuming that only adequate work clothing is used**.**

The following sentence should be included in the product label:

"Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried. In case a worker enters the field, long trousers and long-sleeved shirt should be worn".

zRMS:
The exposure to Potassium phosphonate, an active substance of the product SALAMAN 510 (PHYTOSARCAN), of worker not wearing PPE(gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 8 hours for handling a crop a field treated with Salaman 510 at maximal dose of 2.5 L product/ha (1.275 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 61.6 % of respective AOEL. In case a worker is also wearing protective gloves the exposure is reduced to 30.8% of AOEL.
Thus, it is concluded that the application of product SALAMAN 510 (PHYTOSARCAN) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice.

3.5.4 Bystander and resident exposure

Bystander and resident exposure were assessed considering the AOEL level agreed in the Review Report for potassium phosphonate (5.00 mg/kg bw/day; *EFSA Journal 2012*;10(12):2963).

There is no undue risk to bystanders and residents after exposure to Salaman 510, when the product is applied as intended.

zRMS:
The exposure of resident (adult and child) to Potassium phosphonate, an active substance of the product SALAMAN 510 (PHYTOSARCAN) applied on pome fruits, at maximal dose of 2.5 L product/ha (1.275 kg a.s./ha) using tractor-mounted/trailed sprayer, upward spraying calculated with the EFSA AOEM amounted for child resident to 8.11 % of AOEL and for adult resident to 4.33% of AOEL. Therefore the application of product SALAMAN 510 (PHYTOSARCAN) in line with its intended use within good agricultural practice does not pose an unacceptable risk to the health of adult and child resident.

No bystander acute exposure estimation for Potassium phosphonate is required since no acute acceptable operator exposure value (AAOEL) has be set for this active substance. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Potassium phosphonate as a result of application of SALAMAN 510 (PHYTOSARCAN) with accordance with intended use within good agricultural practice.

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

According to the available data, the intended use on pome fruits is considered as sufficiently supported. It is not expected to have residues of potassium phosphonates above the EU MRLs (=150 mg/kg) when the product is applied according to the GAPs proposed by the applicant.

The current MRLs established for potassium phosphonates in this regulation (EU) 396/2005 (recently amended with Reg. (EU) 2022/93) refer to the residue definition: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl).

It was concluded that the following use is supported and acceptable:

Crop and/ or situation	**Application**			**Application rate**		**PHI** (days)
	Timing / Growth stage of crop & season	Max. No. of applications	Min. interval between applic. (days)	L f.p./ha	Water (L/ha)	
Pome fruits (apple, pear)	BBCH 53-81	3	5	1.50-2.50	500-1000	35

A total of eight residue trials were conducted on apple at NEU in Poland (5 trials), Austria (2 trials) and Germany (1 trial) and reported in two studies (Blanco, J., 2020, report no. S19-03964 and no. S20-00013), and all considered acceptable for support proposed GAPs.

All trials were carried out according to proposed GAP of 3x1.275kg a.s./ha, BBCH 53-81 and PHI of 35 days.

No residue levels above the current MRL (150mg/kg, Reg. (EU) 2022/93) were occurred. Therefore, all trials were considered for the assessment.

According to SANCO 7525/VI/95 Rev. 10.3 if eight trials for major crop -apple are available then an extrapolation is possible to the whole group of pome fruits. Therefore according to the available data, the intended use on pears are considered acceptable.

The analytical method applied to determine phosphonic acid residues is deemed adequately validated and fit for purpose of magnitude of residue potassium phosphonate (as phosphorous acid).

3.6.2 Consumer exposure

A summary of the toxicological reference values relevant for dietary risk assessment were reported in the summary of the evaluation. As ARfD was not deemed necessary, acute risk assessment was not relevant. For the chronic risk assessment, STMR values derived in previous EFSA assessments (expressed as phosphonic acid) and the MRLs established for fosetyl-Al in EFSA Journal 2021;19(8):6782, recalculated to phosphonic acid, were used as input values. The molecular weight CF of 0.74 was used to express residue levels as phosphonic acid.

Calculation results are presented in the table below.

TMDI (% ADI) according to EFSA PRIMo	Based on legally established toxicological reference value of ADI= 2.25 mg/kg bw/d: 80 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not relevant
IESTI (% ARfD) according to EFSA PRIMo*	Not relevant

It was concluded that the proposed use (pome fruit trees) of potassium phosphonate (as phosphorous acid) in the formulation Salaman 510 does not represent unacceptable acute and chronic risks for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

Accumulated PEC_{SOIL} are calculated with the ESCAPE model by considering background concentration in soil for tillage depths of 5 cm and 20 cm and initial concentrations.

Following the use of Salaman 510 according to the GAP, the maximum PEC accumulation in soil of the active substance phosphonic acid was 6.912 mg a.s./kg soil.

The results for PEC_{soil} for the active substance were used for the ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PECs of active substance and its metabolites in groundwater have been assessed with FOCUS (FOCUS, 2009) scenarios and the models PEARL 4.4.4 and PELMO 5.5.3, for phosphonic acid (in practice the species in the environment will be salts of phosphonic acid). As the standard FOCUS model parameterizations are not designed for the simulation of the leaching of inorganic compounds, the parametrization was adapted.

The standard substance transformation rate factor reductions with depth down the soil profile and routines for adjusting substance transformation rate with changing soil moisture content and temperature were maintained.

As soil adsorption is not expected to be well correlated with organic carbon content down the soil profile the parameterisation for adsorption was modified. Adsorption in that topsoil layer was implemented based on the Kd.

According to PELMO and PEARL modelling, the PEC_{GW} of phosphonic acid in leachate did not exceed the groundwater threshold value of 0.1 µg/L in all simulations.

Despite, as an inorganic fungicide, the parametric drinking water limit of 0.1 µg/L does not apply to potassium phosphonates / phosphonic acid. According to EFSA 2012, a maximum acceptable concentration (MAC) in drinking water of 3 mg/L for phosphonic acid was calculated following the WHO 2009 guideline, using 20% of the phosphonic acid ADI (2.25 mg/kg bw/day), an infant bodyweight of 5 kg and daily water consumption value of 0.75 L. The PEC_{GW} calculated for the intended crop is below the MAC for phosphonic acid.

Therefore, no unacceptable risk of groundwater contamination is expected from the intended use.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The predicted environmental concentrations of phosphonic acid in surface water (PEC_{SW}) and sediment (PEC_{SED}) in applications of Salaman 510 were assessed with the FOCUS models STEPS 1-2.

The derived PEC_{SW} and PEC_{SED} were used for aquatic risk assessment of SALAMAN 510 in its intended use.

The use of potassium phosphonates leads to addition of phosphorous in the environment, high phosphorous content in surface waters causes eutrophication at moderate to higher temperatures that means exaggerate algae growth accompanied with a decline of dissolved oxygen. Therefore, an evaluation of the potential risk of eutrophication of surface water (OECD, 1982) should by performed.

The potential risk of eutrophication following the use of SALAMAN 510 (potassium phosphonates) was evaluated.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Phosphonic acid is an inorganic substance with a very low vapour pressure due to its ionic properties. Therefore, no significant volatilization is to be expected. Therefore, the investigation of the route and rate of degradation is deemed not necessary.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The calculated TER_A and TER_{LT} values are above the triggers of 10 and 5 respectively, indicating no unacceptable risk to birds and mammals following application of Salaman 510 according to the proposed use pattern.

No unacceptable effects to birds and mammals through drinking water are expected following application of Salaman 510 according to the proposed use pattern.

No unacceptable effects to fish-eating and earthworm-eating birds and mammals are expected following application of Salaman 510 according to the proposed use pattern.

3.8.2 Effects on aquatic species

According to the risk assessment submitted the PEC/RAC values for the active substance phosphonic acid and phosphates are below 1. Therefore, the risk is acceptable for aquatic organisms.

However, to manage the risk for eutrophication it is proposed to respect an unsprayed buffer zone of 3 m to surface water bodies.

3.8.3 Effects on bees

Based on the risk assessment for honeybees according to SANCO/10329/2002 and EFSA guideline, an acceptable risk to bees can be concluded.

No unacceptable risk is expected for bees for the intended uses of Salaman 510.

3.8.4 Effects on other arthropod species other than bees

The risk to non-target arthropods is assessed using the approach recommended in the published *ESCORT 2 document* (Candolfi *et al.* 2001) and the *EC Guidance Document on Terrestrial Ecotoxicology.*

No unacceptable risk is expected for arthropods other than bees for the intended uses of Salaman 510.

3.8.5 Effects on soil organisms

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The chronic TER values for earthworms and other non-target soil organisms (meso- and macrofauna) exposed to potassium phosphonates (as phosphorous acid) resulted greater than the trigger value of 5, indicating that the risk to earthworms and other non-target soil organisms (meso- and macrofauna) is acceptable following use of Salaman 510 according to the proposed use pattern.

3.8.6 Effects on non-target terrestrial plants

Limit tests at rates up to 23.63 L/ha were conducted with formulation and effects were below the critical threshold as defined by the "Guidance Document on Terrestrial Ecotoxicology" (SANCO/10329/2002 rev.2 final. 2002). The limit test rates exceed the highest field application rate in intended uses and are thus considered an indicator for an acceptable risk.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further testing on, or assessment of risk to, other organisms is considered necessary.

3.9 Relevance of metabolites (Part B, Section 10)

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

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Salaman 510 contains potassium phosphonate which is not a candidate for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label (draft)

Appendix 3 Letter of Access

Appendix 4 Lists of data considered for national authorization

PART B SECTION 1, 2 and 4

List of data submitted or referred to 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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.1 2.2.2	Álvarez-Cuevas, N.	2017	Theoretical Determination: Explosive properties. Oxidizing properties. SALAMAN 510 (potassium phosphonate 510 g/L SL) Cambium Study Code - 17060-F GLP No Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 2.3.1 2.3.3 2.5.1 2.5.2 2.6.1 2.8.2	Romo, S,	2012	Salaman 510. Study of Physical-chemical properties Cambium Study Code - E12078 GLP Yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 2.1 2.4.2 2.7.1 2.8.4	Romo, S.	2012	Salaman 510. Content analysis and stability in accelerated storage conditions Cambium Study Code - E12079 GLP Yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 2.7.5	Romo, S.	2015	Salaman 510. Two years stability at 20ºC Cambium Study Code - E12080 GLP Yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

PART B SECTION 3

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Point 6.0	Duran, P	2021	Biological assessment dossier GEP: Not applicable Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
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 *Venturia inaequalis* in apple. Poland. OUTDOOR 2019. Report No.: S19-03713-01 Eurofins Agroscience Services, S.L. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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 *Venturia inaequalis* in apple. Poland. OUTDOOR 2019. Report No.: S19-03714-01 Eurofins Agroscience Services, S.L. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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 *Venturia inaequalis* in apple. Poland. OUTDOOR 2020. Report No.: S20-00011-01 EAS Spain (Eurofins Agroscience Services) GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
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 *Venturia inaequalis* in apple. Poland. OUTDOOR 2020. Report No.: S20-00012-01 EAS Spain (Eurofins Agroscience Services) GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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 *Venturia inaequalis* in apple. Poland. OUTDOOR 2020. Report No.: S20-00209-01 EAS Spain (Eurofins Agroscience Services) GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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 *Venturia inaequalis* in apple. Poland. OUTDOOR 2020. Report No.: S20-00210-01 EAS Spain (Eurofins Agroscience Services) GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 3.2.3.1/07	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 *Venturia inaequalis* on apple trees in Germany. Open Field Efficacy and Selectivity Study 2020. Report No.: FRS118/20-V1 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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 phosponate 51%, expressed as phosphorus acid) on control of *Venturia inaequalis* on apple trees in Germany. Open Field Efficacy and Selectivity Study 2020. Report No.: FRS118/20-V2 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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	Data protection claimed Y/N	Justification if data protection is claimed	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 *Venturia inaequalis* on apple trees in Germany. Open Field Efficacy and Selectivity Study 2019. Report No.: FRS161/19-V1 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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 *Venturia inaequalis* on apple trees in Germany. Open Field Efficacy and Selectivity Study 2019. Report No.: FRS161/19-V2 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
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 *Venturia pyrina* on pear trees in Germany. Open Field Efficacy and Selectivity Study 2020. Report No.: FRS119/20-V1 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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 *Venturia pyrina* on pear trees in Germany. Open Field Efficacy and Selectivity Study 2020. Report No.: FRS119/20-V2 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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	Data protection claimed Y/N	Justification if data protection is claimed	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 *Venturia pyrina* on pear trees in Germany. Open Field Efficacy and Selectivity Study 2019. Report No.: FRS162/19-V1 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	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 *Venturia pyrina* on pear trees in Germany. Open Field Efficacy and Selectivity Study 2019. Report No.: FRS162/19-V2 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

PART B SECTION 5

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1/01	Romo, S.	2012	"Salaman 510. Content analysis and stability in accelerated storage conditions." Report No. E12079 Cambium GLP: yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 5.2/01	Sahvorost, N	2014b	ANALYTICAL REPORT.- Magnitude of residues in Grapevine following three applications with the formulated product SALA-MAN 510 (Potassium Phosphite 510 g/L SL) PTRL Europe ID P2744 G (Analytical part of the study TRC12-244) GLP: Yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 5.2/02	Martinez, S.	2017	"Determination of phosphonate residues in plant matrices (citrus, grapes, olives and apples). Independent laboratory validation." Report No. E15011 Cambium, S.L. GLP: yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 5.2/03	Blanco, J.	2020	Analytical phase report of study: "Determination of residues of potassium phosphonate (as phosphorous acid) after three applications of SALAMAN 510 in apple (outdoor) at 3 sites in Poland, 2019." Report No. S19-03964 Eurofins AgroSciences Services GLP: yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 5.2/04	…	2012a	"Acute Toxicity of Salaman 510 (510 g/L phosphorous acid) to Rainbow Trout (*Oncorhynchus mykiss*) in a 96-hour Static Limit Test." Analytical phase of the study Nr.- … GLP: Yes Published	N	N	Data/study report never submitted before to Poland.	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/05	Pupp and Wydra	2012b	"Acute Toxicity of Salaman 510 (510 g/L phosphorous acid) to Daphnia magna in a Static 48-hour Immobilisation Limit-Test." Analytical phase of the study Nr.- IBACON 65672220 GLP: Yes Published	N	N	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 5.2/06	Pupp and Wydra	2012c	"Toxicity of Salaman 510 (510 g/L phosphorus acid) to Pseudo-kirchneriella subcapitata in an Algal Growth Inhibition Test." Analytical phase of the study Nr.- IBACON 65671210 GLP: Yes Published	N	N	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 5.2/07	….	2013	"Toxicity of Salaman 510 (510 g/L phosphorous acid) to Rainbow Trout (*Oncorhynchus mykiss*) in a Prolonged Semi Static Test over 28 Days." Analytical phase of the study …. GLP: Yes Published	N	N	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 5.2/08	Hernández, S.	2017	"Determination of potassium phosphonate (expressed as phospho-nate acid) in samples from ecotoxicological studies on honeybees." Report No. E16145 Cambium, S.L. GLP: yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

PART B SECTION 6

List of data submitted or referred to 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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.1/01	…	2012	Potassium phosphite 510g/L. Evaluation of acute oral toxicity in Rats – Acute toxic class method PBD Study Number: … GLP Unpublished	Y	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.2/01	…	2012	Potassium phosphite 510 g/L. Evaluation of acute dermal toxicity in rats PBD Study Number: … GLP Unpublished	Y	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.3/01	…	2012	Salaman 510 (potassium phosphite 510g/L): Acute inhalation toxicity study in Wistar rat IIBAT Study Number: … GLP Unpublished	Y	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.4/01	…	2012	Assessment of acute dermal irritation with the item: Potassium Phosphite 510g/L Phycher Study Number: … GLP Unpublished	Y	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.5/01	…	2012	Assessment of acute eye irritation with the item: Potassium phosphite 510 g/L Phycher Study Number: … GLP Unpublished	Y	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.6/01	…	2012	Potassium phosphite 510 g/L. Assessment of sensitising properties on albino guinea pigs. Maximisation test according to Magnusson and Kligman Phycher Study Nr. … GLP Unpublished	Y	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L

PART B SECTION 7

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.3.1/01	Blanco, J.	2020	"Determination of residues of potassium phosphonate (as phosphorous acid) after three applications of SALAMAN 510 in apple (outdoor) at 3 sites in Poland, 2019." Eurofins Agroscience Services, S.L. Report: S19-03964 (trials S19-03964-02 and S19-03964-03) GLP: yes. Unpublished report	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 6.3.1/02	Blanco, J.	2020	"Determination of residues of potassium phosphonate (as phosphorous acid) after three applications of SALAMAN 510 in apple (outdoor) at 3 sites in Poland, 2 sites in Austria and 1 site in Germany, 2020." Eurofins Agroscience Services, S.L. Report: S20-00013 (trials S20-00013-01, S20-00013-02, S20-00013-03, S20-00013-04, S20-00013-05, and S20-00013-06) GLP: yes. Unpublished report	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 6.5.2/01	Vera, F.	2020	"Determination of residues of Potassium phosphonate (as phosphorous acid) after three applications of SALAMAN 510 in the RAC and processed fractions of Apple at 2 sites in Europe, 2020." Eurofins Agroscience Services, S.L. Report: S20-04337 GLP: yes. Unpublished report	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

PART B SECTION 9

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protec-tion is claimed	Owner
KCP 10.2.1/01	…	2012a	Acute Toxicity of Salaman 510 (510 g/L phosphorous acid) to Rainbow Trout (*Oncorhynchus mykiss*) in a 96-hour Static Limit test … GLP Unpublished	Y	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.2.1/02	Pupp, A. and Wydra V.	2012b	Acute Toxicity of Salaman 510 (510 g/L phosphorous acid) to *Daphnia magna* in a Static 48-hour Immobilization Limit test IBACON Final Report Nr.- 65672220 GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.2.1/03	Pupp, A. and Wydra V.	2013a	Toxicity of Salaman 510 (510 g/L phosphorus acid) to *Pseudo-kirchneriella subcapitata* in an Algal Growth Inhibition Test IBACON Final Report Nr.- 65671210 GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.2.2/01		2013b	Toxicity of Salaman 510 (510 g/L phosphorous acid) to Rainbow Trout (*Oncorhynchus mykiss*) in a Prolonged Semi Static Test over 28 Days GLP Unpublished	Y	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.2.2/03	Zawadsky	2014	Toxicity to the Water Flea *Daphnia magna* Straus under Laborato-ry Conditions (Reproduction Test) EUROFINS Final Report Nr.- S14-00233 GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.2.2/04	Pupp, A. and Wydra V.	2013c	Effects of Salaman 510 (510 g/L phosphorous acid) on the Devel-opment of Sediment Dwelling Larvae of *Chironomus riparius* in a Sediment-Water System – exposed via spiked Water IBACON Final Report Nr.- 65676250 GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protec-tion is claimed	Owner
KCP 10.3.1.1.1/01	Ansaloni, T.	2012	Acute oral and contact toxicity of "SALAMAN 510" (Potassium phosphite 510g/L, as Phosphorous acid) on honeybees (*Apis mellifera* L.) TRIALCAMP Study Nr.- TRC12-018BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.3.1.2/01	Ansaloni. T.	2016	Chronic toxicity of "SALAMAN 510" (Potassium phosphite 510 g/L. as phosphorous acid) on honeybees (*Apis mellifera* L.) Trial report no.: TRC16-088BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.3.1.2/02	Ansaloni. T.	2021	SALAMAN 510: Chronic Oral Toxicity Test (10-Day Feeding) to the Honey Bee (*Apis mellifera* L.) under Laboratory Conditions). Trial report no.: S20-08782 Trialcamp S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L
KCP 10.3.1.3/01	Ansaloni. T.	2016	Toxicity of "SALAMAN 510" (Potassium phosphite 510g/L. as Phosphorous acid). SL on honeybee larvae (*Apis mellifera* L.) after repeated exposure under laboratory conditions Trial report no.: TRC16-202BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.3.1.3/02	Ansaloni. T.	2021	SALAMAN 510: Honey Bee (*Apis mellifera* L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions. Trial report no.: S20-08783 TrialCamp S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.3.1.6/01	Gimeno, I	2021	SALAMAN 510 (Potassium Phosphonate 510 g/L, as Phosphorous Acid): A Semi-Field Study to Evaluate Side Effects on the Brood of Honey Bees (*Apis mellifera* L.) in Rapeseed (*Brassica napus* L.) in Spain in 2021. Trial report no.: S21-00857 TrialCamp S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2/01	Luna, F.	2013a	Side-effects of the product "SALAMAN 510" (Potassium phosphite 510 g/L, as Phosphorous acid) on *Chrysoperla carnea* (Neuroptera: Chrysopidae) under laboratory conditions. TRIALCAMP Study Nr.- TRC12-286BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.3.2/02	Luna, F.	2013c	An extended laboratory test to determine the LR_{50} of the product "SALAMAN 510" (Potassium phosphite 510g/L, as Phosphorous acid) on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) TRIALCAMP Study Nr.- TRC12-015BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.3.2/03	Luna, F.	2013b	An extended laboratory test to determine the LR_{50} of the product "SALAMAN 510" (Potassium phosphite 510 g/L, as Phosphorous acid) on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) TRIALCAMP Study Nr.- TRC12-014BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L
KCP 10.3.2/04	Luna, F.	2013e	Side-effects of the formulated product "SALAMAN 510" (Potassium phosphite 510 g/L, SL) on the predatory mite, *Euseius stipulatus* (Athias-Henriot) (Acari: Phytoseiidae) in citrus under field conditions. TRIALCAMP Study Nr.- TRC12-283BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.3.2/05	Luna, F.	2013d	Side-effects of the product "SALAMAN 510" (Potassium phosphite 510g/L, as Phosphorous acid) on *Chrysoperla carnea* (Neuroptera: Chrysopidae) under extended laboratory conditions. TRIALCAMP Study Nr.- TRC12-156BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protec-tion is claimed	Owner
CP 10.4.1.1/01	Ansaloni, T.	2012	A laboratory test to determine the chronic (sub-lethal) effects of "SALAMAN 510" (Potassium phosphite 510g/L, as Phosphorous acid) to the earthworm *Eisenia foetida foetida* (Oligochaeta: Lum-bricidae) TRIALCAMP Study Nr.- TRC 11-295BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.4.2.1/01	Luna. F.	2015	Effects of the formulation "SALAMAN 510" (Potassium phos-phite 510 g/L. as Phosphorous acid) on the non-target soil arthro-pod. *Folsomia candida* (Collembola. Isotomidae) Trial report no.: TRC13-297BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L
KCP 10.4.2.1/02	Ansaloni. T.	2016	Side-effects of "SALAMAN 510" (POTASSIUM PHOSPHITE 510G/L. AS PHOSPHOROUS ACID) on the predatory mite. *Hypoaspis* (*Geolaelaps*) aculeifer Canestrini (Acari: Laelapidae) under laboratory conditions. Trial report no.: TRC13-298BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.5/01	Hammesfahr, U.	2013	Effects of SALAMAN 510 (510 g/l Phosphorus acid) on the Ac-tivity of the Soil Microflora in the Laboratory IBACON Project Nr.- 65677080 GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L
10.6.2/01	Gimeno C.	2013a	Effects of the formulated product "SALAMAN 510" (Potassium phosphite 510 g/L SL) on Vegetative Vigour of terrestrial non-target plants TRIALCAMP Study Nr.- TRC12-012BP GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 10.6.2/02	Gimeno C.	2013b	Effects of the formulated product "SALAMAN 510" (Potassium phosphite 510 g/L SL) on Seedling Emergence and Seedling growth TRIALCAMP Study Nr.- TRC12-011BP GLP Unpublished	N	Y	Data/study report never submitted before to Poland.	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.