

REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: Salaman 510

Product name(s): **PHYTOSARCAN**

Chemical active substance:

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

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Exclusivas Sarabia, S.A.

Submission date: ~~October 2021~~ July 2022

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	dRR Updated
July 2022	MS-PL evaluation

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zRMS's comments or conclusions are highlighted in grey colour.

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product Salaman 510 and the contained technical active substance potassium phosphonate.

Noticed data gaps are:

- the pH value of the neat plant protection product shall be determined and reported (according to requirements of Regulation (EU) No 284/2013, (KCP 2.4.1)
- dilution stability study (MT 41.1) was not conducted after 2y storage of formulation at ambient temperature (Romo, 2015). However 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. The results of dilution stability test in accelerated storage study (Romo, 2012) support shelf life of 2 years of the formulation, (KCP 2.7.5).

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Exclusivas Sarabia, S.A.
Address: Pol. Ind. "Fondo de Litera", Autovía A-2 km 441.6
22520 Fraga (Huesca) - SPAIN

Telephone: +34 973 737377
Fax: +34 973 736690
Contact: ...

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Manufacturer of the preparation

Name: Exclusivas Sarabia, S.A.
Address: ~~Pol. Ind. "Fondo de Litera", Autovía A-2 km 441.6~~
~~22520 Fraga (Huesca) - SPAIN~~
Cami de l'Albi Rec nou s/n
25110 Alpocat (Lleida) ; SPAIN

Telephone: +34 973 737377
Fax: +34 973 736690
Contact: ...

Plant location

Confidential information or data are provided separately (Part C of the first authorisation).

1.2.2 Producer(s) of the active substance(s)

Name: ~~Lainco, S.A.~~
Address: ~~Avda Bizet 8-12 (Polígono Industrial Can Jardí)~~
~~08191 Rubí (Barcelona) - SPAIN~~
Telephone: +34 93 5862015
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Contact: ...

Name: Exclusivas Sarabia, S.A.
Address: Cami de l'Albi Rec nou s/n
25110 Alpocat (Lleida) ; SPAIN

Telephone: +34 973 737377
Fax: +34 973 736690
Contact: ...

Plant location

Confidential information or data are provided separately (Part C of the first authorisation).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

Potassium phosphonates	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 [based on EFSA Journal 2012; 10(12):2963 Regulation (EU) No 369/2013]
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zRMS:

Based on EFSA, 2012, Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonates (EFSA Journal 2012;10(12):2963) and Regulation (EU) No 369/2013, *the active substance is manufactured only as a technical concentrate (TK) with the concentration range of the active substance of 31.6 to 32.6 % phosphonate ions and 17.8 to 20.0 % potassium. The minimum purity of the active substance on a dry weight basis is 990 g/kg. No FAO specification exists.*

Therefore Exclusivas Sarabia, S.A. source of potassium phosphonates TK (specification see Part C section 1.1.3) comply with above specification.

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trademark	Manufacturer's code
PHYTOSARCAN	SALAMAN 510

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

This formulation was not the representative formulation during the Annex I inclusion of the active substance potassium phosphonate.

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content (%w/w)
Potassium phosphonate (expressed as phosphorous acid)	510 g/L 35.0 (% w/w) 35.1 (% w/w)**	485 – 535 g/L 33.5 – 36.5 (% w/w) 33.4 – 36.8 (% w/w)**	1450 g/L (1425–1475 g/L)	100%

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (34% as TK).

** Based on the density of the formulation = 1.4524 g/ml

content of pure active substance: potassium phosphonates	782.1 g/L	53.955 (% w/w)
limits: (\pm 25 g/L as given by FAO specifications Nov 2010 and third revision 2016):	757.1 – 807 g/L	52.2 – 55.6 (% w/w)

content of technical active substance: potassium phosphonates TC	790 g/L	54.5 (% w/w)
limits: (\pm 25 g/L as given by FAO specifications Nov 2010 and third revision 2016):	765 – 815 g/L	52.7 – 56.2 (% w/w)

at a minimum purity of the technical active substance (as TC) of 99.0 % w/w

This formulation was not the representative formulation during the Annex I inclusion of the active substance potassium phosphonate.

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content (%w/w)
No safener/synergists declared				

* Based on the minimum purity of the safener/synergist declared for registration.

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
No relevant impurities declared.	

zRMS:

Based on Peer Review of the pesticide risk assessment of the active substance potassium phosphonates (EFSA Journal 2012;10(12):2963) no relevant impurities of toxicological, ecotoxicological and/or environmental concern were identified in the active substance as manufactured

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on potassium phosphonates

Type	Name/Code Number
ISO common name	Potassium phosphonates (No ISO name)
CAS No.	13977-65-6 for potassium hydrogen phosphonate 13492-26-7 for dipotassium phosphonate Mixture: none
EC No.	--
CIPAC No.	756 (for potassium phosphonates)
Salt, ester anion or cation present	Potassium phosphonate is a salt containing phosphonate ions and potassium ions

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Soluble (liquid) concentrate [SL]

1.6 Function (KCP 1.6)

Fungicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

The product Salaman 510 is not the representative formulation assessed for the registration of potassium phosphonates. Therefore, physical-chemical properties have been provided for this preparation.

The product Salaman 510 is a soluble concentrate liquid (SL) formulation containing 510 g/L of potassium phosphite (as phosphonic acid, H_3PO_3). All studies have been performed in accordance with the current requirements, the critical GAP 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 409°C. 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. (UN Recommendations on the Transport of Dangerous Goods. Manual of test Criteria). Therefore, it has no labelling implications.

In aqueous solution, Salaman 510 has a pH value around 5.8 (at 1 % dilution and at 20°C). The kinematic viscosity is $5.33 \times 10^{-6} \text{ m}^2/\text{s}$ at 20°C and $3.19 \times 10^{-6} \text{ m}^2/\text{s}$ 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.

Accelerated stability test at 54°C for 14 days was performed, showing that the product does not degrade, and its physical properties does not change. Further, stability report at 20°C for 2 years shows that the product does not change in its concentration 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.

Therefore, its technical characteristics are acceptable for a SL 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 54°C and 2-y at ambient temperature. For aqueous based formulation type, like SL, extrapolation between any plastic material types is acceptable¹. Therefore HDPE, HDPE (COEX) and polyethylene – High Molecular Weight packs (listed in section 4.1 of this document) are supported based on data for plastic container.

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

No tank mixtures were proposed for this formulation.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

No implications for classification and labelling resulting from the physical and chemical properties.

¹ All rigid packaging types, apart from metal are supported with no further data based on the rules for Extrapolation of packaging types (in Final Draft Guidance Document For The Generation And Evaluation Of Data On The Physical, Chemical And Technical Properties Of Plant Protection Products Under Regulation (Ec) No. 1107/2009 Of The Eu Parliament And Council On Placing Plant Protection Products On The Market)

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No Risk and safety Phrases proposed.

Compliance with FAO specifications:

The product Salaman 510 complies with FAO specifications.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual/organoleptic assessment	Salaman 510 Batch N°: 20120806	<u>Storage at 20°C for 14 days:</u> Clear liquid with strong odour	Y	Cambium Study Nr.- E12079 Romo (2012)	Acceptable
Explosive properties (KCP 2.2.1)	Predicted from composition- al information using Method A 14 of commission Directive 92/69/EEC	Salaman 510 (potassium phosphonate 510 g/L SL)	Not explosive. There are no chemical groups associated with explosive properties in the components of the mixture. (UN Recommendations on the Transport of Dangerous Goods. Manual of test Criteria)	N	Cambium Study Nr.- 17/060- EF Alvarez-Cuevas, N. (2017)	Acceptable
Oxidizing properties (KCP 2.2.2)	Predicted from composition- al information using Method A 21 of commission Directive 2004/73/EC	Salaman 510 (potassium phosphonate 510 g/L SL)	Not oxidizing. There are no chemical groups associated with oxidizing properties in the components of the mixture. (UN Recommendations on the Transport of Dangerous Goods. Manual of test Criteria)	N	Cambium Study Nr.- 17/060- EF Alvarez-Cuevas, N. (2017)	Acceptable
Flash point (KCP 2.3.1)	EEC A9 (Regulation (CE) 440/2008) ASTM D93	Salaman 510 Batch N°: 20120806	Not-flammable. Flash point temperature in higher than 100°C. (=111.0°C)	Y	Cambium Study Nr.- E12078 Romo (2012)	Acceptable As no flash point <60°C the product should not be classified as flammable liquid according to requirements of CLP regulation.
Flammability (KCP 2.3.2)	-	-	Not required. Salaman 510 is a soluble liquid formulation.	-	-	-
Self-heating (KCP 2.3.3)	EEC 15 (Regulation (CE) 440/2008) ASTM E 659 – 78 (2005)	Salaman 510 Batch N°: 20120806	Auto-ignition temperature is 409°C ±8°C at 751.8 mmHg	Y	Cambium Study Nr.- E12078 Romo (2012)	Acceptable The formulation is not considered as self-heating.
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Not required. The pH 1% of the formulation is between 4.0 and 10	-	-	In the case of aqueous plant protection products, the pH value of the neat plant protection product shall be determined and reported (according to Regulation (EU) No 284/2013, annex, section 2.4)-
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Salaman 510 Batch N°: 20120806	<u>Storage at 20°C for 14 days:</u> 5.8 at 19.8°C <u>Storage at 54°C for 14 days:</u> 5.8 at 20.0°C	Y	Cambium Study Nr.- E12079 Romo (2012)	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Kinematic viscosity (KCP 2.5.1)	OECD 114, ISO 3105 and 3104 using a glass capillary viscometer	Salaman 510 Batch N°: 20120806	at 20 °C: $5.33 \times 10^{-6} \text{ m}^2/\text{s}$ at 40 °C: $3.19 \times 10^{-6} \text{ m}^2/\text{s}$	Y	Cambium Study Nr.- E12078 Romo (2012)	The product does not contain hydrocarbons thus is not considered as hazardous after aspiration.
Surface tension (KCP 2.5.2)	EEC A5 (Regulation (CE) 440/2008) OCDE 115	Salaman 510 Batch N°: 20120806	concentration tested: 1% of formulation 70.6 mN/m at 20.2°C	Y	Cambium Study Nr.- E12078 Romo (2012)	Acceptable The formulation is not considered as surface active (surface tension >60 mN/m) Highest in use concentration of the product is covered within concentration tested.
Relative density (KCP 2.6.1)	EEC A3 (Regulation (CE) 440/2008) ISO 758-1987, CIPAC MT 3 and OECD 109	Salaman 510 Batch N°: 20120806	1.4524 ± 0.0002	Y	Cambium Study Nr.- E12078 Romo (2012)	Acceptable
Bulk density (KCP 2.6.2)	-	-	Not required. Salaman 510 is a liquid formulation.	-	-	-
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	Salaman 510 Batch N°: 20120806	Weight variation < 1%	Y	Cambium Study Nr.- E12079 Romo (2012)	Acceptable The formulation is stable upon the heat stability test. No significant changes in content active substance and technical properties observed upon accelerated storage at 54°C for 2 weeks. The analytical method for the determination of the active substance phosphonic acid is available and validated according to the guideline SANCO/3030/99 rev. 4 (see section B5 of this dossier). The test item does not change significantly after the accelerated storage procedure, only the smell of test item stored at 54°C for 14 days is slightly stronger than the smell of test item stored at 20°C for 14 days. The highest in use dilution - 0.5% v/v is covered within concentration tested – 0.8% w/v The samples were stored, in their commercial packaging described as a plastic container (study report by Romo, 2012). No change in packaging was observed after the accelerated storage of the product. There was no significant reduction in weight of container, less than 1%.
	Appearance description		<u>Initial:</u> Clear liquid with strong odour <u>Storage at 54°C for 14 days:</u> Clear liquid with very strong odour	Y		
	Phosphonic acid content (%) HPLC-IC		<u>Initial:</u> 518.4 g/L <u>Storage at 54°C for 14 days:</u> 517.8 g/L	Y		
	pH 1% CIPAC MT 75.3		<u>Initial:</u> pH 1%: 5.8 (at 19.8°C) <u>Storage at 54°C for 14 days:</u> pH 1%: 5.8 (at 20.0°C)	Y		
	CIPAC MT41 Stability of diluted solutions		The formulation was diluted in standard water D at 0.8 % w/v. <u>Initial:</u> The diluted solution is stable 18h after dilution <u>Storage at 54°C for 14 days:</u> The diluted solution is stable 18h after dilution	Y		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required. Salaman 510 is stable after 14 days at 54°C.	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 Low temperature stability at 0°C	Salaman 510 Batch N°: 20120806	The volume of solid separated on the bottom is 0.0 mL	-	Cambium Study Nr.- E12078 Romo (2012)	Acceptable No separation or crystallisation occurs. The product is stable when stored at low temperature.
	CIPAC MT 75.3 pH at 1%w/v at 0°C		<u>Initial:</u> pH 1%: 5.8 (19.8°C) <u>Storage at 0°C for 7 days:</u> pH 1%: 5.8 (20.8°C)			
Ambient temperature shelf life (KCP 2.7.5)	CIPAC 46.3	Salaman 510 Batch N°: 20120806	Weight variation < 1%	Y	Cambium Study Nr.- E12080 Romo (2015)	Acceptable However dilution stability study (MT 41.1) was not conducted after 2y storage of formulation at ambient temperature. The formulation can be considered stable upon the 2 years stability test based on no significant changes in content active substance and technical properties (pH 1% and appearance) observed upon storage at ambient temperature. The results of dilution stability test in accelerated storage study (above) support shelf life of 2 years of the formulation. The analytical method for the determination of the active substance phosphonic acid is available and validated according to the guideline SANCO/3030/99 rev. 4 (see section B5 of this dossier). The samples were stored, in their commercial packaging described as a plastic container (study report by Romo, 2015). No change in packaging was observed after 2-y storage of the product. There was no significant reduction in weight of container, less than 1%.
	Appearance description		<u>Initial:</u> Clear liquid with strong odour <u>1 year at 20°C:</u> Clear liquid with mild odour No change in the packaging <u>2 years at 20°C:</u> Clear liquid with mild odour No change in the packaging	Y		
	Phosphonic acid content (%) HPLC-IC		<u>Initial:</u> 518.4 g/L <u>1 year at 20°C:</u> 518 g/L <u>2 years at 20°C:</u> 517 g/L	Y		
	pH 1% CIPAC MT 75.3		<u>Initial:</u> pH 1%: 5.8 (19.8°C) <u>1 year at 20°C:</u> pH 1%: 5.8 (20.8°C) <u>2 years at 20°C:</u> pH 1%: 5.8 (20.9°C)	Y		
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	-	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Wettability (KCP 2.8.1)			Not required. Salaman 510 is a liquid formulation.	-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.1	Salaman 510 Batch N°: 20120806	Maximum 0.0 ml after 1 minute at 0.8% w/v in standard water D	Y	Cambium Study Nr.- E12078 Romo (2012)	Acceptable No foam is expected at the lowest in use concentration which was not tested.
Suspensibility (KCP 2.8.3.1)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Dispersion stability (KCP 2.8.3.3)	-	-	-	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41	Salaman 510 Batch N°: 20120806	The formulation was diluted in standard water D at 0.8 % w/v. <u>After storage at 20 °C 14 days:</u> The dilute solution is stable <u>After storage at 54 °C 14 days:</u> The dilute solution is stable	Y	Cambium Study Nr.- E12079 Romo (2012)	Acceptable The diluted solution is stable 18h after dilution.
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required. Salaman 510 is a liquid formulation.	-	-	-
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Dust content (KCP 2.8.5.2.1)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsifiability (KCP 2.8.6.1)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	-	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Pourability (KCP 2.8.7.2)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required. Salaman 510 is a soluble liquid formulation (SL)	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	-	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	-	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	Not required. Salaman 510 is not used in seed treatments.	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not required. Salaman 510 is not used in seed treatments.	-	-	-
Other/special studies (KCP 2.11)	-	-	-	-	-	-

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Details of packaging types used for Salaman 510 product are described in the table below.

Package	Material	Package Weight	Color	Dimensions	Closure
100 mL bottle	HDPE/COEX *	18 ± 1 g	White	Height: 78 ± 0.5mm Diameter: 57 ± 0.5mm	Cap: Induction term, aluminium, polyester Neck diameter: 42 ± 1 mm
250 mL bottle	HDPE/COEX *	30 ± 2 g	White	Height: 133± 1 mm Diameter: 63.5± 0.5 mm	Cap: Induction term, aluminium, polyester Neck diameter: 42 ± 1 mm
500 mL	HDPE	45± 2 g	White	Height: 189± 1 mm Diameter: 69± 0.5 mm	Cap: Induction term, aluminium, polyester Neck diameter: 47 ± 1 mm
1 L bottle	HDPE/COEX *	100 ± 5 g	White	Height: 240 ± 1.5 mm Diameter: 88.5 ± 0.5 mm	Cap: Induction term, aluminium, polyester Neck diameter: 41.5 ± 0.5 mm
5 L bottle	HDPE/COEX *	250 ± 6.25 g	White	Height: 280 ± 3 mm Width: 192 ± 3 mm	Cap: Induction term, aluminium, polyester Neck diameter: 54.4 ± 0.6 mm
10 L bottle	Polyethylene – High Molecular Weight	450 ± 15 g	White	Height: 310 ± 3 mm Width: 194 ± 2 mm	Cap: Induction term, aluminium, polyester Neck diameter: 47 ± 2 mm
20 L bottle	HDPE	900 ± 6 g	White	Height: 382 ± 5 mm Width: 295 ± 5 mm	Cap: PEAD Neck diameter: 48.5 ± 2 mm
50 L bottle	Polyethylene – High Molecular Weight	2000± 6 g	White	Height: 550 ± 5 mm Width: 335 ± 5 mm	Cap: PEAD Neck diameter: 47 ± 2 mm

* the inner layer of COEX bottles packaging declared is of HDPE.

zRMS:

For aqueous based formulation type, like SL, extrapolation between any plastic material types is acceptable². Therefore HDPE, HDPE (COEX) and polyethylene – High Molecular Weight packs are supported based on data for plastic container (for details see findings of storage stability tests (KCP 2.7.1; KCP 2.7.5).

² All rigid packaging types, apart from metal are supported with no further data based on the rules for Extrapolation of packaging types (in Final Draft Guidance Document For The Generation And Evaluation Of Data On The Physical, Chemical And Technical Properties Of Plant Protection Products Under Regulation (Ec) No. 1107/2009 Of The Eu Parliament And Council On Placing Plant Protection Products On The Market)

Appendix 1 Lists of data considered in support of the evaluation

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	Vertebrate study Y/N	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	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	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	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 2.7.5	Romo, S.	2015	Salaman 510. Two years stability at 20°C Cambium Study Code - E12080 GLP Yes Unpublished	N	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

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 and 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

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

No additional data submitted.