REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

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: Lainco, S.A. / Exclusivas Sarabia S.A / Biovert S.L.

Submission date: October 2021

MS Evaluation date: July 2022

MS Finalisation date: dd/mm/yyyy

Version history

When	What
October 2021	Application for the first approval of the product’s code SALAMAN 510 in Poland.
July 2022	MS-PL evaluation

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

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation SALAMAN 510 are presented in **Błąd! Nieprawidłowy odsyłacz do zakładki: wskazuje na nią samą.**. They have been selected from the individual GAPs in the central zone for pome fruits (apple, pear). A list of all intended uses within the central zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 150 mg/kg for Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)[1] as laid down in Reg. (EU) 396/2005 (recently amended with Reg. (EU) 2022/93) is not expected.

The chronic and the short-term intakes of potassium phosphonates residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS-PL agrees with the authorization of the intended uses.

According to available data, no specific mitigation measures should apply.

Data gaps: none

[1] The EU pesticides peer review of potassium phosphonates (EFSA Journal 2012;10(12):296) and the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA Journal 2021;19(8):6782) proposed the following residue definitions (for both risk assessment and for enforcement) for plant commodities: Phosphonic acid and its salts, expressed as phosphonic acid. The residue definitions apply to primary crops, rotational crops and processed products. The proposed residue definition for enforcement has not yet been implemented in Regulation (EC)No 396/2005; the current MRLs established in this regulation refer to the residue definition: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl).

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate**			**PHI** (days)	**Conclusion**
						Type	**Conc. of a.s. (g/L)**	**method kind**	**growth stage & season**	**number min max**	**interval between applic. (min) (days)**	**kg a.s./hL min max**	**water (L/ha) min max**	**kg a.s./ha min max**		
Zonal uses (field or outdoor uses, certain types of protected crops)																
1	Pome fruits	PL	Salaman 510	F	*Venturia inaequalis* *Venturia pyrina*	SL	510	Foliar spray	BBCH 10-61 BBCH 69-81	3	5	0.152-0.1275	500-1000	0.76-1.275	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.
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005.
*** 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.

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The plant protection product Salaman 510 (a soluble concentrate [SL]) is composed of 510 g/L of potassium phosphonate (as phosphorous acid).

Table 7.1-2: Toxicological reference values for the dietary risk assessment of potassium phosphonate

Reference value	Source	Year	Value	Study relied upon	Safety factor
Potassium phosphonate					
ADI	*EFSA Journal* 2012;10(12):2963	2012	2.25 mg/kg bw/day	2-year rat; with hydrated monosodium phosphonate, expressed as phosphonic acid	100
ARfD	*EFSA Journal* 2012;10(12):2963	2012	Not relevant	--	--

7.1.2.1 Summary for potassium phosphonate

Table 7.1-3: Summary for potassium phosphonate

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Pome fruits	Yes	Yes (8 N-EU trials)	Yes	Yes	Yes	No	No

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

Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

7.1.2.2 Summary for Salaman 510

Table 7.1-4: Information on Salaman 510 (KCA 6.8)

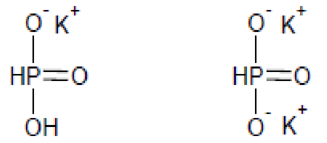
Crop	PHI for Salaman 510 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Salaman 510 proposed by zRMS	zRMS Comments (if different PHI proposed)
Pome fruits	35 days	Yes	35 days	-

* Purpose of withholding period to be specified.

7.2 Potassium phosphonate

General data on potassium phosphonate are summarized in the table below.

Table 7.2-1: General information on potassium phosphonate

Active substance (ISO Common Name)	Potassium phosphonates (No ISO name)
IUPAC	potassium hydrogen phosphonate dipotassium phosphonate
Chemical structure	KH_2PO_3 [HPO(OH)(O-K+)] and K_2HPO_3 [HPO(O-K+)$_2$]
Molecular formula	
Molar mass	monopotassium phosphonate: 120.1 g/mol dipotassium phosphonate: 158.2 g/mol
Chemical group	phosphonates
Mode of action (if available)	Once applied over the crops it slows down the growth of plant fungal pathogens and inhibits sporulation and after it inhibits the proliferation of the fungus by induction of plant natural resistance responses.
Systemic	Yes
Company (ies)	Luxembourg Industries (Pamol) Ltd (reference source) * The new sources from the task force (Lainco, S.A.; Biovert, S.L. and Exclusivas Sarabia, S.A.) were considered chemically equivalent to the reference source (Spain, April 2015).
Rapporteur Member State (RMS)	France
Approval status	Approved on 01st October 2013, under Commission Implementing Regulation (EU) No. 369/2013.
Restriction (e.g., is restricted to use as “...”)	None
Review Report	SANCO/10416/2013 rev 2, 15 March 2013
Current MRL regulation	Commission Regulation (EU) 2021/1807
Peer review of MRLs according to Article 12 of Reg. No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes; EFSA Journal 2012;10(12):2963
EFSA Journal: conclusion on article 12	Yes; EFSA Journal 2021;19(8):6782

* Notifier in the EU process to whom the a.s. belong(s).

7.2.1 Stability of residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Storage stability of phosphorous acid residues in frozen conditions was demonstrated up to 12 months for grapes in the context of the active substance inclusion (Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonates, *EFSA Journal 2012;10(12):2963*).

In the framework of the peer review, storage stability of the sum of phosphonic acid and fosetyl was demonstrated for a period of 12 months at -18°C in commodities with high water content (cucumber, potato and lettuce), high acid content (grapes) and high starch content (potato).

Table 7.2-2: Summary of stability data achieved at ≤ - 20°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Grapes	High acid content	12 months	DAR of Fosetyl-Al (2005)
Cucumber and lettuce	High water content	12 months	DAR of Fosetyl-Al (2005)
Potato	High starch content	12 months	DAR of Fosetyl-Al (2005)

Sufficient stability has been demonstrated to support the residue data presented in the current submission.

Furthermore based on reasoned opinion: Modification of the existing maximum residue levels forpotassium phosphonates in various crops (EFSA Journal 2020;18(9):6240) *the storage stability of phosphonic acid under frozen conditions was investigated in the framework of the peer review of potassium phosphonates (FSA Journal 2012;10(11):2961), the peer review of fosetyl (FSA Journal 2018;16(7):5307) and in a previous MRL application (FSA Journal 2019;17(5):5703). Phosphonic acid is stable under frozen conditions for up to 25 months in commodities with high water, high oil, high protein, dry/high starch and high acid contents*.

Conclusion on stability of residues during storage

zRMS:
Storage stability of phosphonic acid residues in frozen conditions (-18°C) was demonstrated up to 12 months for apples (according to table B.1.1.2 of EFSA Journal 2020;18(9):6240).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Storage stability of residues in sample extracts have not been tested, since all samples were analysed within 24 hours after extraction.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

The metabolism of Potassium phosphonates in plants was already addressed during the EU Review process. Scientific publications on the uptake and distribution of phosphonates (phosphonic acid) in plants as well as information from research on fertiliser properties of phosphonates versus phosphate have been submitted to address the metabolism of Potassium phosphonates in plants.

No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

From the data evaluated during the EU review, it was concluded that phosphonates are translocated through the entire plant after soil or foliar application and that phosphonates are not significantly oxidised to phosphate in plants. This suggests that phosphonates do not act as a phosphorus source in plants. The experts of the PRAPeR 09 expert meeting assumed that given the elementary nature of this active substance only transformation of the Potassium phosphonate salts into phosphonic acid is expected in plants and agreed that the available data from the public literature were sufficient to address the uptake and metabolism of Potassium phosphonates in plants.

The meeting of experts also discussed the possibility of another route of exposure to phosphonic acid residues resulting from the use of soil fertilisers and of fosetyl and disodium phosphonate. However, for fertilising purposes, only phosphorous(V) and not phosphorous (III) is relevant and therefore the contribution of phosphonic acid in plants resulting from the use of soil fertilisers does not have to be considered.

The intended uses are thus covered by the data evaluated during the EU review and no further data is required.

Conclusion on metabolism in primary crops

Given the elementary nature of the active substance, no additional metabolism studies are required for this dossier. The metabolism of the intended crops is covered by the DAR data.

Based on the available information the residue definition was proposed as phosphonic acid and its salts for both, monitoring and risk assessment. It is thus covered by the current residue definition of the active substance Fosetyl-Al (see also EFSA 2014), which is the sum of fosetyl and phosphonic acid and their salts, expressed as fosetyl.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Not required as pome fruits are perennial crops.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Potassium phosphonate is an inorganic substance that can be transformed in phosphonic acid and phosphate. Therefore, the studies submitted in the following points consider only the residues in phosphonic acid, since the phosphate is a natural substance.

EFSA 2012

In processed commodities, fosetyl and phosphonic acid were found to be hydrolytically stable during pasteurisation, cooking, boiling/brewing/baking and sterilisation and no formation of toxicologically relevant metabolites occurred.

EFSA 2013

The PRAPeR 09 expert meeting also agreed that phosphonic acid remained hydrolytically stable under conditions representative of pasteurisation and sterilisation.

Table 7.2-3: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)		Identified compound(s) (%)		Reference
EU data		Fosetyl-Al	Phosphonic acid	
Pasteurisation (30 minutes, 90°C, pH 4)		99.8%	101.8%	EFSA, 2006
Baking, boiling, brewing (60 minutes, 100°C, pH 5)		101.3%	102.6%	
Sterilisation (20 minutes, 120°C, pH 6)		99.5%	101.9%	
Other conditions	**Identified compound(s) (%)**			
Winemaking …	-			-

The available data are sufficient to support the uses of potassium phosphonates in the product SALAMAN 510. The residue pattern is similar in processed and raw commodities, therefore a specific residue definition for processed commodities is not required.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-4: Summary of the nature of residues in commodities of plant origin

Endpoints (*EFSA Journal* 2012;10(12): 2963)	
Plant groups covered	No study performed due to the simple nature of residue.
Rotational crops covered	Not required in this case.
Metabolism in rotational crops similar to metabolism in primary crops?	NA
Processed commodities	Not required. The chemistry of phosphonic acid is well understood. Apart from acid-base conversion, no further modification of the residue has to be expected.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) Reg. (EU) 2021/1807
Plant residue definition for risk assessment	Phosphonic acid and its salts expressed as phosphonic acid (EFSA Journal 2012;10(12): 2963)
Conversion factor from enforcement to RA	A conversions factor of 1.34, based on molecular weights of the active substances, is necessary to express phosphonic acid as equivalent fosetyl.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

Data on the nature of the residue of Potassium phosphonates in livestock can be drawn from the EU Review of fosetyl. Reported metabolism studies include three studies in lactating goats using 14C labelled fosetyl. Studies are summarised in Table 7.2-5 below.

Table 7.2-5: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat study 1	Ethyl group	2	0.41	7	Milk	twice daily	France, 2005; EFSA 2012b
						Urine and faeces	daily	
						Tissues	After sacrifice (24 h after the last dose)	
	Goat study 2	Ethyl group	1	0.51	7	Milk	twice daily	France, 2005; EFSA 2012b
						Urine and faeces	daily	
						Tissues	After sacrifice (24 h after the last dose)	
	Goat study 3	Ethyl group	2	1.49	7	Milk	twice daily	France, 2005; EFSA 2012b
						Urine and faeces	daily	
						Tissues	After sacrifice (24 h after the last dose)	

Summary of animal metabolism studies reported in the EU

Lactating goats were dosed with 0.41-1.49 mg/kg bw per d of fosetyl, corresponding to approximately 0.4-1.4 times the exposure of dairy ruminants and 0.1-0.5 times the exposure of meat ruminants. Highest TRR levels were found in liver (goat study 3; 2.37 mg eq/kg), kidney (goat study 3; 1.24 mg eq/kg), and milk (goat study 3; 1.38 mg eq/kg).

The metabolism studies in ruminants show that fosetyl is rapidly and extensively metabolised in animal tissues and products. This occurs via breakdown to ethanol and phosphonic acid; the ethanol is then excreted or oxidised to acetate and incorporated into fats, proteins and carbohydrates. The metabolism is such that in the ruminant studies fosetyl-Al, phosphonic acid and O-ethyl phosphate were only found in urine and stomach contents and in all other tissues and milk all radioactive residues were found incorporated into natural products.

In the peer review of fosetyl (EFSA, 2005) it was concluded that because of the similarity between ruminant and rat metabolism a metabolism study in pigs is not necessary. Based on the simple nature of the molecule and the extensive metabolism shown in the ruminant study, a study investigating metabolism in poultry is also not considered necessary (EFSA, 2012b).

Based on the above finding, EFSA concludes that the residue definition for enforcement and risk assessment is defined as phosphonic acid only. It is noted by EFSA that a different residue definition was previously derived in the framework of the peer review (EFSA, 2005). However, the residue definition previously derived by EFSA, which includes fosetyl, is no longer considered appropriate because fosetyl was not found in the goat metabolism study at significant levels in products of animal origin. In addition, in products of plant origin the majority of the residue is present as phosphonic acid; suggesting that exposure of livestock to fosetyl will be minimal.

In the framework of the peer review of Potassium phosphonates, the proposed residue was not considered to be fat soluble (EFSA, 2012a). Therefore, a metabolism study on fish is not required.

Conclusion on metabolism in livestock

Based on the above findings, (EFSA, 2012b) concluded that the residue definition for enforcement and risk assessment was defined as phosphonic acid. The same residue definitions are considered appropriate to reflect the use of Potassium phosphonates on feed items.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-6: Summary on the nature of residues in commodities of animal origin

Endpoints (*EFSA Journal* 2012;10(12): 2963)	
Animals covered	No toxicologically significant residues of phosphorous (=phosphonic) acid and its salts are anticipated in livestock feed and therefore studies with livestock were not performed (in compliance also with the Animal Protection Act). Lactating goats (fosetyl)
Time needed to reach a plateau concentration	Not applicable
Animal residue definition for monitoring	Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) Reg. (EU) 2021/1807
Animal residue definition for risk assessment	Phosphonic acid (EFSA Journal 2018;16(7):5307)
Conversion factor	A conversions factor of 1.34, based on molecular weights of the active substances, is necessary to express phosphonic acid as equivalent fosetyl.
Metabolism in rat and ruminant similar	Not applicable.
Fat soluble residue	No.

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

A summary of the magnitude of residues of Potassium phosphonates is given in the following table. For the detailed evaluation of new/additional studies on the magnitude of residues it is referred to Appendix 2. The residue definitions for risk assessment and enforcement are different. The current residue definition for enforcement is the one set for fosetyl (also covering phosphonates): sum of fosetyl, phosphonic acid and their salts expressed as fosetyl while the residue definition for risk assessment is defined as the sum of phosphonic acid and its salts expressed as phosphonic acid. To express residues of phosphonic acid as fosetyl, a molecular weight conversion factor of 1.34 was applied.

Table 7.2-7: Summary of EU reported and new data supporting the intended use of Salaman 510 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Pome fruits apples	New trials (8 trials)	N-EU	Trials GAP: 3 x 1215-1308 g a.s./ha, 762.5-821.3 L water/ha PHI 35 days, **outdoor** <u>Residue levels</u> (fruit) E (expressed as Phosphonic acid): 10.1, 10.4, 11.8, 24.6, 15.0, 4.91, 8.25, 8.25 ***E (expressed as fosetyl): 13.53, 13.93, 15.8, 32.93, 20.8, 6.57, 11.04, 11.04***	*RA: 10.25* *Mo: 13.73*	*24.60* *32.93*	*50.00*	*150*	*Yes*

* MRL based on: Commission Regulation (EU) 2021/1807 of 13 October 2021.

7.2.3.2 Conclusion on the magnitude of residues in plants

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.

All trials were carried out according to proposed GAP of 3x1.275kg a.s./ha, BBCH 53-81 (3 trials with last treatment at BBCH 83-87 – considered as more critical, thus acceptable) 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 uses on apples and 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).

The maximum storage period of deep-frozen samples in the supervised residue trials is covered by the storage stability studies (see section 7.2.1.1).

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

A dietary burden calculation was performed by EFSA in the framework of the review of the existing MRLs for fosetyl, article 12 (R.O, 2012). Inputs values reported correspond to the residue definitions (phosphonic acid and fosetyl separate) proposed by EFSA. In order to perform the dietary burden calculation, taking account value for apple pomace from residue trials submitted in the framework of this dossier, other input values from the draft reasoned opinion of article 12 were considered in the table below, corresponding to the right residue definition. As observed in the EFSA journal 2012, the default process factor of 2.5 was used for apple and citrus pomaces.

Table 7.2-8: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: phosphonic acid				
Cabbage	0.20	Median residue (EFSA, 2021)	1.30	Highest residue (EFSA, 2021)
Kale	4.90	Median residue (EFSA, 2021)	9.90	Highest residue (EFSA, 2021)
Triticale straw	19.8	Median residue-(EFSA, 2021)	81.4	Highest residue (EFSA, 2021)
Wheat straw	19.8	Median residue-(EFSA, 2021)	81.4	Highest residue (EFSA, 2021)
Potato	26.9	Median residue-(EFSA, 2021)	88.6	Highest residue (EFSA, 2021)
Wheat grain	23.13	Median residue (EFSA, 2021)	23.13	Median residue (EFSA, 2021)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Triticale grain	23.13	Median residue (EFSA, 2021)	23.13	Median residue (EFSA, 2021)
Apple pomace wet	10.25	STMR (Table 7.2-7) x 1.1 PF	11.28	STMR (Table 7.2-7) x 1.1 PF
Citrus dried pulp	74.76	STMR × 3.2 PF (EFSA, 2021)	74.76	STMR× 3.2 PF (EFSA, 2021)
Distiller's grain dried	76.33	STMR × 3.3 PF (EFSA, 2021)	76.33	STMR× 3.3 PF (EFSA, 2021)
Potato process waste	59.18	26.9 STMR × 2.2 PF (EFSA, 2021)	59.18	26.9 STMR × 2.2 PF (EFSA, 2021)
Potato dried pulp	129 .12	26.9 STMR × 4.8 PF (EFSA, 2021)	129.12	26.9 STMR × 4.8 PF (EFSA, 2021)
Wheat gluten meal	41.63	STMR × 0.2 PF (EFSA, 2021)	41.63	STMR × 0.2 PF (EFSA, 2021)
Wheat milled by-products	161.91	STMR × 1.1 PF (EFSA, 2021)	161.91	STMR × 1.1 PF (EFSA, 2021)

Results derived from the revised animal burden calculations are given in Table 7.2-9.

Table 7.2-9: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet	Most critical commodity		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.10
	Median	Maximum	Median	Maximum				mg/kg DM
Cattle (all diets)	7.694	11.713	246.75	351.26	Dairy cattle	Potato	Process wate	Yes
Cattle (dairy only)	7.694	11.713	200.03	304.55	Dairy cattle	Potato	Process wate	Yes
Sheep (all diets)	8.180	11.930	245.41	357.91	Lamb	Potato	Process wate	Yes
Sheep (ewe only)	8.180	11.930	245.41	357.91	Ram/Ewe	Potato	Process wate	Yes
Swine (all diets)	4.777	9.405	174.35	331.93	Swine (finishing)	Potato	culls	Yes
Poultry (all diets)	5.478	9.885	76.69	138.39	Turkey	Potato	culls	Yes
Poultry (layer only)	4.683	7.249	68.44	105.94	Poultry layer	Potato	culls	Yes

Considering that potatoes were the main contributor of the livestock exposure and the processing factors for potatoes process waste and dried pulp used to calculate the dietary burdens were not fully supported by data, the derived MRLs for livestock should be considered tentative only.

zRMS: Due to high water solubility of residues of phosphonic acid no accumulation in apple pomace or potential feeding stuff is expected, therefore MRLs in animal commodities for phosphonic acid will not be exceeded.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

No new data were submitted in the framework of this application.

Table 7.2-10: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose level (mg/kg bw/d) [(a)]	No	Result for enforcement		Result for RA					
					mean (mg/kg)	max. (mg/kg)	mean (mg/kg)	max. (mg/kg)				
EU data (EFSA, 2012)												
Enforcement and risk assessment residue definition: *phosphonic acid*												
			0.327	3	<0.5	<0.5	<0.5	<0.5				
Pig meat			0.982	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
			3.273	3	<0.5	<0.5	<0.5	<0.5				
			0.327	3	<0.5	<0.5	<0.5	<0.5				
Pig fat			0.982	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
			3.273	3	<0.5	<0.5	<0.5	<0.5				
	1.2139	1.7577	0.327	3	<0.5	<0.5	<0.5	<0.5				
Pig liver			0.982	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
			3.273	3	<0.5	<0.5	<0.5	<0.5				
			0.327	3	<0.5	<0.5	<0.5	<0.5				
Pig kidney			0.982	3	<0.5	<0.5	<0.5	<0.5	0.50	0.52	0.60	1
			3.273	3	0.55	0.60	0.55	0.6				
			0.327	3	<0.5	<0.5	<0.5	<0.5				
Ruminant meat			0.982	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
			3.273	3	<0.5	<0.5	<0.5	<0.5				
	2.8770	3.3913	0.327	3	<0.5	<0.5	<0.5	<0.5				
Ruminant fat			0.982	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
			3.273	3	<0.5	<0.5	<0.5	<0.5				
Ruminant liver			0.327	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1

			0.982	3	<0.5	<0.5	<0.5	<0.5				
			3.273	3	<0.5	<0.5	<0.5	<0.5				
Ruminant kidney			0.327	3	<0.5	<0.5	<0.5	<0.5	0.54	0.62	0.7	1
Ruminant kidney			0.982	3	<0.5	<0.5	<0.5	<0.5	0.54	0.62	0.7	1
Ruminant kidney			3.273	3	0.55	0.60	0.55	0.6	0.54	0.62	0.7	1
Milk	0.9834	1.2016	0.327	3	<0.1	n.a.	<0.1	n.a.	0.1	0.1	0.1*	1
Milk	0.9834	1.2016	0.982	3	<0.1	n.a.	<0.1	n.a.	0.1	0.1	0.1*	1
Milk	0.9834	1.2016	3.273	3	<0.1	n.a.	<0.1	n.a.	0.1	0.1	0.1*	1
Poultry meat	0.6389	0.9251	1.226	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Poultry meat	0.6389	0.9251	3.678	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Poultry meat	0.6389	0.9251	12.255	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Poultry fat	0.6389	0.9251	1.226	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Poultry fat	0.6389	0.9251	3.678	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Poultry fat	0.6389	0.9251	12.255	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Poultry liver	0.6389	0.9251	1.226	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Poultry liver	0.6389	0.9251	3.678	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Poultry liver	0.6389	0.9251	12.255	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Eggs	0.6389	0.9251	1.226	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Eggs	0.6389	0.9251	3.678	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1
Eggs	0.6389	0.9251	12.255	3	<0.5	<0.5	<0.5	<0.5	0.5	0.5	0.5*	1

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk; n.r.: Not reported
(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Ruminant study: based on a 550-kg animal consuming 20 kg feed DM/day. Poultry study: based on a 1.9 kg animal consuming 120 g feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.2.5.1 Available data for all crops under consideration

Processing studies in processed apples have been submitted in the framework of this application. Conclusion of the studies are submitted in point 7.2.5.2 and more detailed information in Appendix 2; KCP 6.5.2/01 (report number: S20-04337).

7.2.5.2 Conclusion on processing studies

Specimens of crop from the untreated and treated plots from trial S20-04337 (S20-04337-01, carried out in Spain, and S20-04337-02, carried out in Germany) were taken by hand and processed.

Treated plots were sprayed at a dose rate of 2.5 L f.p./ha, equivalent to 1275 g a.s./ha.

The objective of the processing phase was to produce specimens of processed apple. The processes described in the report were done following industrial procedures on a laboratory scale.

After processing, the processed specimens were collected and immediately placed in a freezer where they were stored deep frozen (≤ -18 °C) at the processing test site until shipment to the analytical laboratory.

The following residues were detected in the treated apple processing specimens.

Process - Sample Type	**Residue of Phosphonic Acid (mg/kg)**	
	S20-04337-01 (Spain)	**S20-04337-02 (Germany)**
Apple processed fractions from the samples of the untreated plots		
All processed fractions	Not detected	Not detected
Apple processed fractions from the samples of the treated plots		
Washing - fruits prior to processing	5.70	9.50
Washing - fruits prior to processing	9.10	8.44
Washing - washing water	0.51	n.d.
Washing - washed fruits	1.18	8.83
Canning - wastes	2.38	7.07
Canning - blanched fruits	2.62	8.12
Canning - blanching water	0.29	0.55
Canning - canned fruits	2.03	5.92
Canning - canned fruits after separation	2.16	5.75
Canning - syrup after separation	1.87	5.63
Drying - wastes	2.03	7.50
Drying - apple slices	2.58	7.85
Drying - dried fruits	14.05	46.10
Juice - crushed fruits	2.42	8.03
Juice - must	7.16	14.35
Juice - wet pomace	3.99	7.65
Juice - raw juice	3.98	9.12
Juice - deposits	4.95	9.82
Juice - apple juice	4.11	9.23
Applesauce - blanched fruits	3.48	13.56
Applesauce - blanching water	0.12	0.51
Applesauce - crushed fruits	4.59	7.91
Applesauce - wastes	2.88	7.82
Applesauce - raw puree	2.98	6.83

Process - Sample Type	Residue of Phosphonic Acid (mg/kg)	
	S20-04337-01 (Spain)	S20-04337-02 (Germany)
Applesauce - pasteurized applesauce	4.46	10.42

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.

7.2.6 Magnitude of residues in representative succeeding crops

Not applicable. Pome fruits are not rotational crops.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the potassium phosphonates sufficiently address aspects of the residue situation that might arise from the use of SALAMAN 510. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

The calculation of the TMDI was performed using the EFSA PRIMo revision 3.1 considering all commodities for which EU-MRLs have been proposed up to now for fosetyl by EFSA (see EFSA Reasoned opinions EFSA, 2012b; EFSA, 2012c; EFSA, 2015a; EFSA 2017; EFSA, 2018a; EFSA 2018b; EFSA, 2019; EFSA, 2021).

Combined data from the current submission (STMR from proposed uses), from MRLs according to the Regulation (EC) 2021/1807 and JMPR values, have been used to calculate TMDI. For all other commodities, MRLs established for fosetyl in Regulation (EC) No. 2021/1807 were recalculated to phosphonic acid. The molecular weight conversion factor of 0.745 was used to express residue values as phosphonic acid. In accordance with EFSA, 2021 crops with MRL set at the LOQ were disregarded.

Since no ARfD has been set, the calculation of the IESTI is not required.

Table 7.2-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Calculations refined with data derived from residue trials and published risk assessment values by EFSA and the JMPR	
	Input value phosphonic acid equiv. [mg/kg]	Comment
Grapefruits	55.875	MRL (RG (EU) 2021/1807)
Oranges	55.875	MRL (RG (EU) 2021/1807)
Lemons	55.875	MRL (RG (EU) 2021/1807)
Limes	55.875	MRL (RG (EU) 2021/1807)
Mandarins	55.875	MRL (RG (EU) 2021/1807)
Other citrus fruit	55.875	MRL (RG (EU) 2021/1807)
Almonds	1117.5	MRL (RG (EU) 2021/1807)
Brazil nuts	372.5	MRL (RG (EU) 2021/1807)
Cashew nuts	372.5	MRL (RG (EU) 2021/1807)
Chestnuts	1117.5	MRL (RG (EU) 2021/1807)
Coconuts	372.5	MRL (RG (EU) 2021/1807)
Hazelnuts/cobnuts	1117.5	MRL (RG (EU) 2021/1807)
Macadamia	372.5	MRL (RG (EU) 2021/1807)
Pecans	372.5	MRL (RG (EU) 2021/1807)
Pine nut kernels	372.5	MRL (RG (EU) 2021/1807)
Pistachios	1117.5	MRL (RG (EU) 2021/1807)
Walnuts	1117.5	MRL (RG (EU) 2021/1807)
Other tree nuts	372.5	MRL (RG (EU) 2021/1807)
Apples	10.25	STMR (Table 7.2-7)
Pears	10.25	STMR (Table 7.2-7)
Quinces	10.25	STMR (Table 7.2-7)
Medlar	10.25	STMR (Table 7.2-7)
Loquats/Japanese medlars	10.25	STMR (Table 7.2-7)
Other pome fruit	10.25	STMR (Table 7.2-7)
Apricots	9.55	STMR (EFSA, 2021)
Cherry	1.49	MRL (RG (EU) 2021/1807)
Peaches	9.55	STMR (EFSA, 2021)
Plum	1.49	MRL (RG (EU) 2021/1807)
Table grapes	19.00	STMR (EFSA 2021)
Wine grapes	19.00	STMR (EFSA 2021)
Strawberries	74.50	MRL (RG (EU) 2021/1807)
Blackberries	223.50	MRL (RG (EU) 2021/1807)
Raspberries (red and yellow)	223.50	MRL (RG (EU) 2021/1807)
Blueberries	149	MRL (RG (EU) 2021/1807)
Currants (red, black and white)	149	MRL (RG (EU) 2021/1807)
Gooseberries (green, red and yellow)	149	MRL (RG (EU) 2021/1807)
Azarole/Mediterranean medlar	37.25	MRL (RG (EU) 2021/1807)
Elderberries	59.6	MRL (RG (EU) 2021/1807)
Table olives	74.50	MRL (RG (EU) 2021/1807)
Kaki/Japanese persimmons	37.25	MRL (RG (EU) 2021/1807)
Kiwi fruits (green, red, yellow)	23.500	STMR (EFSA, 2012c)
Avocados	52.15	MRL (RG (EU) 2021/1807)
Pineapples	37.25	MRL (RG (EU) 2021/1807)
Potatoes	149	MRL (RG (EU) 2021/1807)
Celeriacs/turnip rooted celeries	0.150	STMR (EFSA, 2021)
Radishes	18.625	MRL (RG (EU) 2021/1807)
Onions	37.250	MRL (RG (EU) 2021/1807)
Spring onions/green onions and Welsh onions	22.350	MRL (RG (EU) 2021/1807)

Commodity	Chronic risk assessment	
	Calculations refined with data derived from residue trials and published risk assessment values by EFSA and the JMPR	
	Input value phosphonic acid equiv. [mg/kg]	Comment
Tomatoes	74.50	MRL (RG (EU) 2021/1807)
Sweet peppers/bell peppers	96.85	MRL (RG (EU) 2021/1807)
Aubergines/egg plants	74.500	MRL (RG (EU) 2021/1807)
Cucumbers	14.000	STMR (FAO, 2017)
Gherkins	55.875	MRL (RG (EU) 2021/1807)
Courgettes	25.500	STMR (FAO, 2017)
Other cucurbits - edible peel	55.875	MRL (RG (EU) 2021/1807)
Melons	14.000	STMR (FAO, 2017)
Pumpkins	55.875	MRL (RG (EU) 2021/1807)
Watermelons	55.875	MRL (RG (EU) 2021/1807)
Other cucurbits - inedible peel	55.875	MRL (RG (EU) 2021/1807)
Sweet corn	3.725	MRL (RG (EU) 2021/1807)
Other fruiting vegetables	3.725	MRL (RG (EU) 2021/1807)
Broccoli	52.15	MRL (RG (EU) 2021/1807)
Cauliflowers	52.15	MRL (RG (EU) 2021/1807)
Other flowering brassica	52.15	MRL (RG (EU) 2021/1807)
Brussels sprouts	7.450	MRL (RG (EU) 2021/1807)
Head cabbages	7.450	MRL (RG (EU) 2021/1807)
Other head brassica	7.450	MRL (RG (EU) 2021/1807)
Chinese cabbages/pe-tsai	7.450	MRL (RG (EU) 2021/1807)
Kales	22.35	MRL (RG (EU) 2021/1807)
Other leafy brassica	22.35	MRL (RG (EU) 2021/1807)
Kohlrabies	7.450	MRL (RG (EU) 2021/1807)
Lamb's lettuce/corn salads	55.875	MRL (RG (EU) 2021/1807)
Lettuces	223.50	MRL (RG (EU) 2021/1807)
Escaroles/broad-leaved endives	55.875	MRL (RG (EU) 2021/1807)
Cress and other sprouts and shoots	55.875	MRL (RG (EU) 2021/1807)
Land cress	55.875	MRL (RG (EU) 2021/1807)
Roman rocket/rucola	55.875	MRL (RG (EU) 2021/1807)
Red mustards	55.875	MRL (RG (EU) 2021/1807)
Baby leaf crops (including brassica species)	55.875	MRL (RG (EU) 2021/1807)
Other lettuce and other salad plants	55.875	MRL (RG (EU) 2021/1807)
Spinaches	223.50	MRL (RG (EU) 2021/1807)
Chards/beet leaves	11.175	MRL (RG (EU) 2021/1807)
Witloofs/Belgian endives	55.875	MRL (RG (EU) 2021/1807)
Herbs and edible flowers	298	MRL (RG (EU) 2021/1807)
Chervil	298	MRL (RG (EU) 2021/1807)
Chives	298	MRL (RG (EU) 2021/1807)
Celery leaves	298	MRL (RG (EU) 2021/1807)
Parsley	298	MRL (RG (EU) 2021/1807)
Sage	298	MRL (RG (EU) 2021/1807)
Rosemary	298	MRL (RG (EU) 2021/1807)
Thyme	298	MRL (RG (EU) 2021/1807)
Basil and edible flowers	298	MRL (RG (EU) 2021/1807)
Laurel/bay leaves	298	MRL (RG (EU) 2021/1807)
Tarragon	298	MRL (RG (EU) 2021/1807)
Other herbs	298	MRL (RG (EU) 2021/1807)
Globe artichokes	37.250	MRL (RG (EU) 2021/1807)
Leeks	22.350	MRL (RG (EU) 2021/1807)
Olives for oil production	74.50	MRL (RG (EU) 2021/1807)

Commodity	Chronic risk assessment	
	Calculations refined with data derived from residue trials and published risk assessment values by EFSA and the JMPR	
	Input value phosphonic acid equiv. [mg/kg]	**Comment**
Wheat	23.130	STMR (EFSA, 2021)
Chamomile	372.500	MRL (RG (EU) 2021/1807)
Hybiscus/roselle	372.500	MRL (RG (EU) 2021/1807)
Rose	372.500	MRL (RG (EU) 2021/1807)
Jasmine	372.500	MRL (RG (EU) 2021/1807)
Lime/linden	372.500	MRL (RG (EU) 2021/1807)
Other herbal infusions (dried flowers)	372.500	MRL (RG (EU) 2021/1807)
Strawberry leaves	372.500	MRL (RG (EU) 2021/1807)
Rooibos	372.500	MRL (RG (EU) 2021/1807)
Mate/maté	372.500	MRL (RG (EU) 2021/1807)
Other herbal infusions (dried leaves)	372.500	MRL (RG (EU) 2021/1807)
Valerian root	372.500	MRL (RG (EU) 2021/1807)
Ginseng root	372.500	MRL (RG (EU) 2021/1807)
Other herbal infusions (dried roots)	372.500	MRL (RG (EU) 2021/1807)
Herbal infusions - (any other parts of the plant) (other herbal infusions)	372.500	MRL (RG (EU) 2021/1807)
HOPS *(dried)*	350.000	STMR (FAO, 2017)
Anise/aniseed	74.000	STMR (EFSA, 2012c)
Black caraway/black cumin	74.000	STMR (EFSA, 2012c)
Celery seed	74.000	STMR (EFSA, 2012c)
Coriander seed	74.000	STMR (EFSA, 2012c)
Cumin seed	74.000	STMR (EFSA, 2012c)
Dill seed	74.000	STMR (EFSA, 2012c)
Fennel seed	74.000	STMR (EFSA, 2012c)
Fenugreek	74.000	STMR (EFSA, 2012c)
Nutmeg	74.000	STMR (EFSA, 2012c)
Other spices (seeds)	74.000	STMR (EFSA, 2012c)
Allspice/pimento	74.000	STMR (EFSA, 2012c)
Sichuan pepper	74.000	STMR (EFSA, 2012c)
Caraway	74.000	STMR (EFSA, 2012c)
Cardamom	74.000	STMR (EFSA, 2012c)
Juniper berry	74.000	STMR (EFSA, 2012c)
Peppercorn (black, green and white)	74.000	STMR (EFSA, 2012c)
Vanilla pods	74.000	STMR (EFSA, 2012c)
Tamarind	74.000	STMR (EFSA, 2012c)
Other spices (fruits)	74.000	STMR (EFSA, 2012c)
Cinnamon	74.000	STMR (EFSA, 2012c)
Other spices (bark)	74.000	STMR (EFSA, 2012c)
Liquorice	74.000	STMR (EFSA, 2012c)
Ginger	74.000	STMR (EFSA, 2012c)
Turmeric/curcuma	74.000	STMR (EFSA, 2012c)
Horseradish	74.000	STMR (EFSA, 2012c)
Other spices (roots)	74.000	STMR (EFSA, 2012c)
Cloves	74.000	STMR (EFSA, 2012c)
Capers	74.000	STMR (EFSA, 2012c)
Other spices (buds)	74.000	STMR (EFSA, 2012c)
Saffron	74.000	STMR (EFSA, 2012c)
Other spices (flower stigma)	74.000	STMR (EFSA, 2012c)
Mace	74.000	STMR (EFSA, 2012c)
Other spices (aril)	74.000	STMR (EFSA, 2012c)
Chicory roots	55.875	MRL (RG (EU) 2021/1807)

Commodity	Chronic risk assessment	
	Calculations refined with data derived from residue trials and published risk assessment values by EFSA and the JMPR	
	Input value phosphonic acid equiv. [mg/kg]	Comment
Swine: Muscle/meat	0.500	STMR (EFSA, 2021)
Swine: Fat tissue	0.500	STMR (EFSA, 2021)
Swine: Liver	0.500	STMR (EFSA, 2021)
Swine: Kidney	1.380	STMR (EFSA, 2021)
Swine: Edible offals (other than liver and kidney)	4.47	MRL (RG (EU) 2021/1807)
Bovine: Muscle/meat	0.500	STMR (EFSA, 2021)
Bovine: Fat tissue	0.610	STMR (EFSA, 2021)
Bovine: Liver	0.500	STMR (EFSA, 2021)
Bovine: Kidney	2.640	STMR (EFSA, 2021)
Bovine: Edible offals (other than liver and kidney)	5.96	MRL (RG (EU) 2021/1807)
Sheep: Muscle/meat	0.500	STMR (EFSA, 2021)
Sheep: Fat tissue	0.650	STMR (EFSA, 2021)
Sheep: Liver	0.500	STMR (EFSA, 2021)
Sheep: Kidney	2.810	STMR (EFSA, 2021)
Sheep: Edible offals (other than liver and kidney)	5.96	MRL (RG (EU) 2021/1807)
Goat: Muscle/meat	0.500	STMR (EFSA, 2021)
Goat: Fat tissue	0.610	STMR (EFSA, 2021)
Goat: Liver	0.500	STMR (EFSA, 2021)
Goat: Kidney	2.640	STMR (EFSA, 2021)
Goat: Edible offals (other than liver and kindey)	5.96	MRL (RG (EU) 2021/1807)
Equine: Liver	0.370	MRL (RG (EU) 2021/1807)
Equine: Kidney	0.370	MRL (RG (EU) 2021/1807)
Equine: Edible offals (other than liver and kidney)	0.370	MRL (RG (EU) 2021/1807)
Poultry: Muscle/meat	0.500	STMR (EFSA, 2021)
Poultry: Fat tissue	0.500	STMR (EFSA, 2021)
Poultry: Liver	0.500	STMR (EFSA, 2021)
Other farmed animals: Liver	0.370	MRL (RG (EU) 2021/1807)
Other farmed animals: Kidney	0.370	MRL (RG (EU) 2021/1807)
Other farmed animals: Edible offals (other than liver and kidney)	0.370	MRL (RG (EU) 2021/1807)
Milk: Cattle	0.150	STMR (EFSA, 2021)
Milk: Sheep	0.372	MRL (RG (EU) 2021/1807)
Milk: Goat	0.372	MRL (RG (EU) 2021/1807)
Milk: Horse	0.372	MRL (RG (EU) 2021/1807)
Milk: Others	0.372	MRL (RG (EU) 2021/1807)
Eggs: Chicken	0.500	STMR (EFSA, 2021)
Eggs: Duck	0.500	STMR (EFSA, 2021)
Eggs: Goose	0.500	STMR (EFSA, 2021)
Eggs: Quail	0.500	STMR (EFSA, 2021)
Eggs: Others	0.500	STMR (EFSA, 2021)

Moreover, it has also been considered the risk assessment with values used during the joint review of existing MRLs for fosetyl and phosphonates (EFSA Journal 2021;19(8):6782). Refer to Appendix D.2 (*Consumer risk assessment considering all sources of phosphonic acid and including the existing CXLs*) of EFSA Journal 2021;19(8):6782 for input data used for this additional calculation.

7.2.8.2 Conclusion on consumer risk assessment

Table 7.2-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	80 % (based on ~~DE child~~ NL toddler) * / 36 % (based on NL toddler) **
IEDI (% ADI) according to EFSA PRIMo	Not relevant
IESTI (% ARfD) according to EFSA PRIMo***	Not relevant

* Calculations refined with data derived from residue trials and published risk assessment values by EFSA and the JMPR.
** Calculations used data of existing MRLs for fosetyl and phosphonates (EFSA Journal 2021;19(8):6782).
*** Include raw and processed commodities if both values are required for PRIMo.

The estimated long-term (chronic) dietary intake for the phosphonic acid, using data derived from residue trials and published risk assessment values by EFSA and the JMPR accounted for a maximum 80% of the ADI (NL toddler).

The proposed uses of potassium phosphonates in the formulation Salaman 510 do not represent unacceptable chronic risks for the consumer.

Extensive calculation sheets are presented in Appendix 3.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

Commission Implementing Regulation (EU) No 369/2013 of 22 April 2013 approving the active substance potassium phosphonates, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 Text with EEA relevance.

Commission Regulation (EU) 2019/552 of 04 April 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products (Text with EEA relevance).

Commission Regulation (EU) 2021/1807 of 13 October 2021 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, aqueous extract from the germinated seeds of sweet Lupinus albus, azoxystrobin, clopyralid, cyflufenamid, fludioxonil, fluopyram, fosetyl, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole in or on certain products (Text with EEA relevance).

France, 2003. Draft assessment report (DAR) on the active substance fosetyl prepared by the Rapporteur Member State France in the framework of Council Directive 91/414/EEC, December 2003.

France, 2005. Final addendum of the draft assessment report on the active substance fosetyl prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, September 2005.

EFSA, 2006. Conclusion on the peer review of the pesticide risk assessment of the active substance fosetyl. EFSA Scientific Report (2005) 54, 1-79

SANCO/10416/2013 rev 2, 15 March 2013

EFSA Journal 2012a;10(12):2963. Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonates.

EFSA (European Food Safety Authority), 2012b. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fosetyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012; 10(11): 2961

EFSA (European Food Safety Authority), 2012c. Reasoned opinion on the modification of the existing MRLs for fosetyl in potato, kiwi and certain spices. EFSA Journal 2012; 10(12): 3019.

EFSA (European Food Safety Authority), 2015. Modification of the existing MRL for fosetyl in blackberry, celeriac and Florence fennel. EFSA Journal 2015; 13(12): 4327

EFSA (European Food Safety Authority), 2018a. Reasoned Opinion on the modification of the existing maximum residue levels for fosetyl-Al in tree nuts, pome fruit, peach and potato. EFSA Journal 2018;16(2):5161, 36 pp.

EFSA (European Food Safety Authority), 2018b. Reasoned opinion on the modification of the existing maximum residue levels for potassium phosphonates in certain small berries and fruits. EFSA Journal 2018;16(9):5411, 32 pp.

EFSA (European Food Safety Authority), 2018c. Peer review of the pesticide risk assessment of the active substance fosetyl. EFSA Journal 2018;16(7):5307

EFSA (European Food Safety Authority), 2019. Modification of the existing maximum residue level for fosetyl/phosphonic acid for potatoes and wheat. EFSA Journal 2019;17(5):5703

EFSA (European Food Safety Authority), 2020a. Modification of the existing maximum residue levels for fosetyl/phosphonic acid in various crops. EFSA Journal 2020;18(1):5964

EFSA (European Food Safety Authority), 2020b. Modification of the existing maximum residue levels for potassium phosphonates in flowering brassica, Chinese cabbages, kales and spinaches. EFSA Journal 2020;18(5):6122

EFSA (European Food Safety Authority), 2021. Reasoned opinion on the joint review of maximum residue levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(8):6782

FAO (Food and Agriculture Organization of the United Nations), 2017. Fosetyl. In: Pesticide residues in food – 2017. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 232.

Appendix 1 Lists of data considered in support of the evaluation

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
KCP 6.3.1 - Residue trials					
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	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	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 6.5.2 - Magnitude of residues in processed commodities					
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	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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 6.1/01	Kieken and Diot.	2001	"Storage stability at about - 20°C in grape, cucumber, potato and lettuce." R&D/CRLD/AN/mr/0115206; Report CO13256 GLP: yes. Unpublished report	N	--

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 Detailed evaluation of the additional studies relied upon

A 2.1 Potassium phosphonate

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No studies submitted.

A 2.1.1.1.2 Storage stability of residues in animal products

No studies submitted.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No studies submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No studies submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No studies submitted.

A 2.1.2.2 Nature of residues in livestock

No studies submitted.

A 2.1.3 Magnitude of residues in plants

Comments of zRMS:	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 both studies (Blanco, J., 2020, report no. S19-03964 and no. S20-00013). All trials were carried out according to proposed GAP of 3x1.275kg a.s./ha, BBCH 53-81 (3 trials with last treatment at BBCH 83-87 – considered as more critical, thus acceptable) and PHI of 35 days. No residue levels above the current MRL occurred. Therefore, all trials were considered for the assessment. 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)

Reference:	KCP 6.3.1/01
Report	"Determination of residues of potassium phosphonate (as phosphorous acid) after three applications of SALAMAN 510 in apple (outdoor) at 3 sites in Poland, 2019" Blanco, J. (2020) Eurofins Agroscience Services, S.L. Report: S19-03964 (trials S19-03964-02 and S19-03964-03)
Guideline(s):	✓ EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials. ✓ European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs. ✓ EU Guidance Document SANCO/3029/99 rev. 4 for generating and reporting methods of analysis in support of pre-registration data requirements.
Deviations:	Deviation nº 1 (at Trial S19-03964-03 dated on 15/11/2019): samples S1 NCH were collected not 35 DAA3 but 37 days after application 3. The farm was closed and not operating due to celebration of the national Independence Day on November 11th in Poland and the threat of possible demonstrations and road blockades. No impact in the study
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine residue levels of potassium phosphonate (as phosphorous acid) in the raw agricultural commodity apple.

Two residue trials were conducted on apple during 2019 in Poland.

Three applications of SALAMAN 510 (510 g a.s./L) were applied at 1.275 kg a.s./ha, diluted with water immediately prior to application to a spray volume of 800 L/ha.

<u>Analytical method</u>

Samples of apple from the untreated and treated plots were taken by hand and 0 days before and 0, 7, 14, 28 and 35 days after the final application for trial S19-03964-02 and 37 days after the final application for trial S19-03964-03.

Quantification was performed by use of LC-MS/MS detection.

The limit of quantification (LOQ) of the analytical method was 0.1 mg/kg with a limit of detection (LOD) set at 0.03 mg/kg (30 % of the LOQ).

<u>Method validation</u>

The analytical method followed in this analytical phase was previously validated according to SANCO/3029/99, rev. 4 for the determination of Phosphonic Acid in apple with an LOQ of 0.1 mg/kg in Study No. S19-03963 (please, refer to KCP 6.3.7.1/01, above).

All mean recovery values at fortification levels of 0.1 mg/kg (LOQ) and 1.0 mg/kg (10x LOQ) comply with the standard acceptance criteria of the guidance document SANCO/3029/99 rev. 4. with evaluation of one (1) mass transition.

The coefficients of determination (R^2) of linear regression of the calibration plots were ≥ 0.999 and thus demonstrated linearity of the detection system over the working range of no more than 30 % of the LOQ to at least + 20 % of the highest analyte concentration level in a (diluted) sample.

Matrix effects on LC-MS/MS detection were investigated and found to be insignificant.

For each analytical set of sample analysis, the method's applicability in terms of accuracy and repeatability was assessed by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the analytical method(s).

Fortifications were performed at the level of 0.1 mg/kg and 1.0 mg/kg and were thus in the range of the level or higher than the level of the highest residues found in (diluted) sample.

The following recoveries were obtained.

Matrix	Fortification level (mg/kg)	Recovery (%)	Mean Recovery (%)	Rel. Std. Dev. (%)	Replicates	Overall Mean recovery (%)	Overall Rel. Std. Dev. (%)
Ion Mass transition *m/z* 81 → 79 (quantification)							
Apple (fruits)	0.1	92.9, 98.1, 97.6	96.2	3.0	3	92.4	5.1
	1.0	90.9, 88.4, 86.5	88.6	2.5	3		
Ion Mass transition *m/z* 81 → 63 (quantification)							
Apple (fruits)	0.1	96, 98.4, 93.7	96.0	2.5	3	92.5	4.7
	1.0	91.2, 88.3, 87.5	89.0	2.0	3		

No observable peak was detected in any control sample extract.
Recoveries are without any blank correction.

No residues above 30 % of the LOQ were detected in the control (untreated) test portions used for recovery determinations.

The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120 % and the mean recoveries at each fortification level were in the range of 70 – 110 % with relative standard deviation(s) below 20 %.

Individual trial results are summarised in the tables below.

Active substance (common name):	Potassium phosphonate (as phosphorous acid)	Commercial Product (name):	SALAMAN 510
Crop/crop group:	**Apple**	Producer of commercial product:	Task Force Coordinator
Responsible body for reporting (Name, address):	LAINCO S.A., Pol. Ind. Can Jardi, Avda Bizet nº 8-12, 08191-RUBI (Barcelona), Spain		
Country:	Poland (North EU zone)	Indoor/ Outdoor:	**Outdoor**
Content of active substance nominal:	510 g/L	Other active substance in the formulation (common name and content):	none
Formulation (e.g., WP):	SL	Residues calculated as:	phosphorous acid (mg/kg)

1 Report No. Location (region)	2 Commodity/*Variety* (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e)	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: (g)
				g a.s./hL	Water (L/ha)	kg a.s./ha						
S19-03964-02 64-560 Zapust, Wielkopolskie (Poland)	Apple (EPPO code: MABSD) / *Idared*	1) 19 Nov 1993 2) 27 Apr 2019 to 05 May 2019 3) 13 Nov 2019	Foliar applic. with motorized knapsack sprayer	159.4 159.4 159.4	762.5 811.3 821.3	1.215 1.293 1.308	27 Sep 2019 03 Oct 2019 09 Oct 2019	BBCH 81 BBCH 81 BBCH 81	Fruits Fruits Fruits Fruits Fruits	2.90 4.04 5.86 6.72 10.1	0 DAA3 7 DAA3 14 DAA3 28 DAA3 35 DAA3 (NCH)	Residues above the LOQ were found in any of the untreated specimens S19-03964-02-006A
S19-03964-03 05-622 Belsk Duzy, Mazowieckie (Poland)	Apple (EPPO code: MABSD) / *Idared*	1) 10 Feb 2010 2) 29 Apr 2019 to 07 May 2019 3) 13 Nov 2019	Foliar applic. with motorized knapsack sprayer	159.4 159.4 159.4	766.1 775.0 782.1	1.221 1.235 1.246	27 Sep 2019 01 Oct 2019 07 Oct 2019	BBCH 81 BBCH 81 BBCH 81	Fruits	10.4	35 DAA3 (NCH)	Residues above the LOQ were found in any of the untreated specimens S19-03964-03-001A

(a) According to EPPO codes.
(b) Only if relevant.
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application.
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date.
(*) Limit of quantification = 0,1 mg/kg.

Reference:	KCP 6.3.1/02
Report	"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." Blanco, J. (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)
Guideline(s):	✓ EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials. ✓ European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs. ✓ EU Guidance Document SANCO/3029/99 rev. 4 for generating and reporting methods of analysis in support of pre-registration data requirements.
Deviations:	• Deviation at Trial S20-00013-02 (dated on 24/11/2020): The distance between trials S20-0013-02 and S20-00013-03 is 9.5 km. No impact in the study. • Deviation at Trial S20-00013-03 (dated on 24/11/2020): The distance between trials S20-0013-02 and S20-00013-03 is 9.5 km. No impact in the study. • Deviation at Trial S20-00013-04 (dated on 01/08/2020): Spray tolerance above 10%. No impact in the study.
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine residue levels of potassium phosphonate (as phosphorous acid) in the raw agricultural commodity apple.

Six residue trials were conducted on apple during 2020, three in Poland (S20-00013-01, S20-00013-02 and S20-00013-03), two in Austria (S20-00013-04 and S20-00013-05) and one in Germany (S20-00013-06).

Three applications of SALAMAN 510 (510 g a.s./L) were applied at 1275 g a.s./ha, diluted with water immediately prior to application to a spray volume of 800 L/ha for trial S20-00013-01, S20-00013-02, S20-00013-03 and S20-00013-06 and with a spray volume of 500 for trial S20-00013-04 and S20-00013-05.

Analytical method

Samples of apple from the untreated and treated plots were taken by hand and 0 days before and 0, 7, 14, 28 and 35 days after the final application for trial S20-00013-01, S20-00013-02 and S20-00013-03 and 35 days after the final application for trials S20-00013-04, S20-00013-05 and S20-00013-06.

Quantification was performed by use of LC-MS/MS detection.

The limit of quantification (LOQ) of the analytical method was 0.1 mg/kg for potassium phosphonate (as phosphorous acid) in apple with a limit of detection (LOD) set at 0.03 mg/kg (30% of the LOQ).

Method validation

The analytical method for the determination of phosphorous acid in apple with an LOQ of 0.1 mg/kg was validated in the current study.

For each analytical set of specimen analysis, the method's applicability in terms of accuracy and repeatability was assessed by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Fortifications were performed at the level of 0.1 mg/kg, 1.0 mg/kg and 80 mg/kg in this analytical phase.

No residues above 30% of the LOQ were detected in the control (untreated) test portions used for recovery determinations.

The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120 % and the mean recoveries were in the range of 70 – 110 % with relative standard deviation(s) below 20 %.

Individual trial results are summarised in the tables below.

Active substance (common name):	Potassium phosphonate (as phosphorous acid)	Commercial Product (name):	SALAMAN 510
Crop/crop group:	**Apple**	Producer of commercial product:	Task Force Coordinator
Responsible body for reporting (name, address):	LAINCO S.A., Pol. Ind. Can Jardi, Avda Bizet nº 8-12, 08191-RUBI (Barcelona), Spain		
Country:	Poland (North EU zone)	Indoor/ Outdoor:	**Outdoor**
Content of active substance nominal:	510 g/L	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	SL	Residues calculated as:	phosphorous acid (mg/kg)

1 Report No. Location (region)	2 Commodity/*Variety* (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment g a.s./hL	 Water (L/ha)	 kg a.s./ha	6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e)	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: (g)
S20-00013-01 62-080 Tarnowo Podgórne, Wielkopolskie (Poland)	Apple (EPPO code: MABSD) / *Cortland*	1) 01 Mar 1998 2) 05 May 2020 to 22 May 2020 3) 06 Oct 2020	Foliar applic. with motorized knapsack sprayer	159.4 159.4 159.4	741.4 781.3 775.0	1.1816 1.2452 1.2352	24 Aug 2020 28 Aug 2020 01 Sep 2020	BBCH 79 BBCH 79 BBCH 79	Fruits Fruits Fruits Fruits Fruits	5.70 7.45 14.3 11.8 11.8	0 DAA3 7 DAA3 14 DAA3 28 DAA3 35 DAA3 (NCH)	No residues above the LOQ were found in any of the untreated specimens
S20-00013-02 05-622 Belsk Duzy, Mazowieckie (Poland)	Apple (EPPO code: MABSD) / *Red Prince*	1) 05 Mar 2015 2) 27 Apr 2020 to 05 May 2020 3) 31 Oct 2020	Foliar applic. with motorized knapsack sprayer	159.4 159.4 159.4	812.5 811.3 808.2	1.2949 1.2930 1.2881	07 Sep 2020 11 Sep 2020 16 Sep 2020	BBCH 79 BBCH 81 BBCH 81	Fruits Fruits Fruits Fruits Fruits	10.7 15.9 16.9 23.8 24.6	0 DAA3 7 DAA3 14 DAA3 28 DAA3 35 DAA3 (NCH)	No residues above the LOQ were found in any of the untreated specimens
S20-00013-03 05-622 Belsk Duzy, Mazowieckie (Poland)	Apple (EPPO code: MABSD) / *Idared*	1) 10 Mar 2014 2) 29 Apr 2020 to 08 May 2020 3) 21 Oct 2020	Foliar applic. with motorized knapsack sprayer	159.4 159.4 159.4	803.9 867.2 809.3	1.2812 1.3821 1.2898	07 Sep 2020 11 Sep 2020 16 Sep 2020	BBCH 79 BBCH 81 BBCH 81	Fruits Fruits Fruits Fruits Fruits	7.95 10.6 12.2 15.2 15.0	0 DAA3 7 DAA3 14 DAA3 28 DAA3 35 DAA3 (NCH)	No residues above the LOQ were found in any of the untreated specimens

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0,1 mg/kg

Active substance (common name):	Potassium phosphonate (as phosphorous acid)	Commercial Product (name):	SALAMAN 510
Crop/crop group:	**Apple**	Producer of commercial product:	Task Force Coordinator
Responsible body for reporting (name, address):	LAINCO S.A., Pol. Ind. Can Jardi, Avda Bizet nº 8-12, 08191-RUBI (Barcelona), Spain		
Country:	Austria (North EU zone)	Indoor/ Outdoor:	**Outdoor**
Content of active substance nominal:	510 g/L	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	SL	Residues calculated as:	phosphorous acid (mg/kg)

1 Report No. Location (region)	2 Commodity/*Variety* (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment g a.s./hL	 Water (L/ha)	 kg a.s./ha	6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e)	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: (g)
S20-00013-04 8223 Freienberg, Styria (Austria)	Apple (EPPO code: MABSD) / *Golden Delicious*	1) 04 Mar 2007 2) 04 Apr 2020 to 04 May 2020 3) 12 Oct 2020	Foliar applic. with motorized knapsack sprayer	255.0 255.0 255.0	540.9 568.8 455.8	1.3793 1.4504 1.1623	26 Aug 2020 01 Sep 2020 07 Sep 2020	BBCH 85 BBCH 85 BBCH 85-87	Fruits	4.91	35 DAA3 (NCH)	No residues above the LOQ were found in any of the untreated specimens
S20-00013-05 8461 Ottenberg, Styria (Austria)	Apple (EPPO code: MABSD) / *Idared*	1) 09 May 2010 2) 04 Apr 2020 to 04 May 2020 3) 12 Oct 2020	Foliar applic. with motorized knapsack sprayer	255.0 255.0 255.0	480.2 484.5 483.6	1.2245 1.2355 1.2332	27 Aug 2020 01 Sep 2020 07 Sep 2020	BBCH 81-83 BBCH 83 BBCH 83-85	Fruits	8.25	35 DAA3 (NCH)	No residues above the LOQ were found in any of the untreated specimens

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0,1 mg/kg

Active substance (common name):	Potassium phosphonate (as phosphorous acid)	Commercial Product (name):	SALAMAN 510
Crop/crop group:	**Apple**	Producer of commercial product:	Task Force Coordinator
Responsible body for reporting (name, address):	LAINCO S.A., Pol. Ind. Can Jardi, Avda Bizet nº 8-12, 08191-RUBI (Barcelona), Spain		
Country:	Germany (North EU zone)	Indoor/ Outdoor:	**Outdoor**
Content of active substance nominal:	510 g/L	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	SL	Residues calculated as:	phosphorous acid (mg/kg)

1 Report No. Location (region)	2 Commodity/*Variety* (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e)	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: (g)
				g a.s./hL	Water (L/ha)	kg a.s./ha						
S20-00013-06 21683 Bützflether, Lower Saxony (Germany)	Apple (EPPO code: MABSD) / *Braebum*	1) 2015 2) 28 Apr 2020 to 15 May 2020 3) 30 Oct 2020	Foliar applic. with motorized knapsack sprayer	159.4 159.4 159.4	782.4 849.3 824.7	1.2470 1.3536 1.3144	16 Sep 2020 21 Sep 2020 25 Sep 2020	BBCH 85 BBCH 85 BBCH 85	Fruits	8.25	35 DAA3 (NCH)	No residues above the LOQ were found in any of the untreated specimens

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0,1 mg/kg

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No study submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No study submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

Comments of zRMS:	Study is acceptable. The analytical method is adequately validated for the determination of phosphonic acid in Apple (RAC and processed fractions) with LOQ=0.5mg/kg, according to SANCO/3029/99, rev. 4 and SANCO/825/00, rev. 8.1 In the treated samples, residues of phosphonic acid were ranging from not detected to 46 mg/kg. No residue levels above the current MRL occurred.

The following processing study in apple has been submitted in the framework of this application.

Reference:	KCP 6.5.2/01	
Report	"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." Vera, F. (2020) Eurofins Agroscience Services S.L. Report: S20-04337	
Guideline(s):	✓ Guideline 7029/VI/95 (rev. 5) ✓ Guideline 7525/VI/95 (rev. 10.2) ✓ OECD Test Guideline 508 ✓ OECD (2008) Guidance Document on magnitude of pesticide residues in processed commodities (Series on Testing and Assessment No. 96) ✓ SANCO/3029/99, rev. 4 ✓ SANCO/825/00, rev. 8.1	
Deviations:	At A2 we sprayed +12.8% while the Study Plan stated a spray tolerance of ± 10%. The machine did not work OK.	No impact in the study
	Samples sent in shipment chilled 20-1155 were more than 9 hours above 10 ºC. The samples were loaded at 17:00 to temperature of 23ºC (initial temperature). Temperature was decreased until 10 ºC (destination temperature). Average temperature during shipment: 14 ºC.	No impact in the study
	A1 was 46 DBNCH instead of 45 DBNCH. A3 was 6 DAA2 instead of 5 DAA2. To meet the 35 DAA3 timing.	No impact in the study
GLP:	Yes	

Acceptability:	Yes

Study objective

The study objective was to determine the residue levels and behaviour of the potassium phosphonate in the RAC and processed fractions of apple treated with SALAMAN 510.

Material and methods

Test item

Name: SALAMAN 510
Batch number: 9569
Formulation type: SL
Active substance: potassium phosphonate
Content of a.s. (nominal): 510 g/L potassium phosphonate, as phosphorous acid
Content of a.s. (analysed): 52.5% (w/v)

Field Site(s) and Plot Design

The residue trials were carried out at two locations, one in Spain (S20-04337-01) and one in Germany (S20-04337-02). Region, variety and cultivation were typical for apple. The trials comprised two plots (one untreated and one treated with SALAMAN 510).

Application

The proposed application schedule is given in the table below.

Proposed Application Schedule

Appl' code	Plot	Timing	Application rate (priority to product)		Water volume
-	U1	-	-	-	-
A1	2	45 DBNCH	2.5 L product/ha	1275 g a.s./ha*	500-1000 L/ha
A2	2	5 DAA1	2.5 L product/ha	1275 g a.s./ha*	500-1000 L/ha
A3	2	5 DAA2	2.5 L product/ha	1275 g a.s./ha*	500-1000 L/ha

DBNCH = Days Before Normal Commercial Harvest; DAA = days after application
* based on nominal content of a.s.

Sampling method

All samples were taken from at least 4 separate trees distributed over the plot to give at least 45 kg of fruit. Samples were taken from all parts of the tree, top and bottom, exposed and covered by foliage. Control samples were taken before treated samples.

Storage and shipment

Treated and untreated samples were shipped the same day of the sampling to the processing test site at chilled conditions for trial S20-04337-01 (except for the time registered in deviation No 2) and at ambient conditions for trial S20-04337-02, adequately separated during the shipment. Processed fractions were maintained in a deep-frozen conditions and adequately separated during storage and shipment. The final destination of the samples was the analytical test site.

Processing phase

The objective of the processing phase was to produce specimens of washing water, washed apples, wastes, blanched fruits, blanching water, whole canned fruits, canned fruits after separation, syrup after separation, apple slices, dried apples, crushed apples, must, pomace, raw juice, deposits, pasteurized fruit juice, raw puree, pasteurized applesauce from raw agricultural commodity to be then analysed at the analytical laboratory.

Field specimens of apple were transferred after harvest to the processing site and received in good conditions at chilled temperature for trial 01 and ambient temperature for trial 02. They were stored at a target temperature of 7°C and processed within 1-7 days after reception starting with the untreated samples. The processes were done following industrial procedures at a laboratory scale.

Analysis of residues

In the analytical phase of this study, samples of Apple (RAC and processed fractions) were analysed for residues of phosphonic acid.

Analytical method

Due to their similarity, the validation results generated for some matrices are considered to be representative for other matrices as described in the table below:

Matrix type	Representative of
Apple (whole fruit)	RAC apple (washing process), Washed apple (washing process), Apple slices (drying process), Crushed apple (juicing process}
Water	Washing water (washing process), Blanching water (canning & applesauce process)
Apple (canned fruit)	Blanched fruits (canning & applesauce process), Whole canned fruits Scanning process), Canned fruit after separation (canning process), Crushed fruits (applesauce process)
Apple (syrup)	Syrup after separation (canning process)
Apple (waste)	Apple wastes (canning process & applesauce process)
Apple (dried fruit)	Dried apples (drying process)
Apple (must)	Apple must (juicing process)
Apple (pomace)	Apple pomace (after pressing)
Apple (juice)	Apple raw juice (juicing process), Apple pasteurized fruit juice (juicing process)
Apple (deposits)	Apple deposit (juicing process)
Apple (applesauce)	Raw puree (applesauce process). Pasteurized applesauce (applesauce process)

Quantification was performed by addition of internal standard(s) and by use of LC-MS/MS detection.

The limit of quantification (LOQ) of the analytical method was 0.5 mg/kg for each matrix with a limit of detection (LOD) set at 0.15 mg/mg (30% of the LOQ).

Method Validation

The analytical method was validated for the determination of phosphonic acid in apple (RAC and processed fractions) according to SANCO/3029/99, rev. 4 and SANCO/825/00, rev. 8.1 within the analytical phase by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the recoveries. Five (5) fortifications of untreated control samples at the level of LOQ (0.5 mg/kg) and five (5) fortifications at the level of tenfold LOQ (5 mg/kg) were performed.

No residues above 30% of the LOQ were detected in the control (untreated) test portions used for recovery determinations.

All mean recovery values at fortification levels of 0.5 mg/kg (LOQ) and 5 mg/kg (10x LOQ) comply with the standard acceptance criteria of the guidance document SANCO/3029/9g rev. 4 and SANCO/825/00 rev 8.1, with evaluation of two (2) mass transitions.

The coefficients of determination (R^2) of linear regression of the calibration plots were ≥ 0.99 and thus demonstrated linearity of the detection system over the working range of no more than 30% of the LOQ to at least + 20 % of the highest analyte concentration level in a sample.

Results

Results in mg/kg are reported without correction for the obtained procedural recoveries, i.e. no adjustments to hypothetical procedural recoveries of 100 % were made. Refer Tables below.

Conclusions

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.

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Potassium phosphonate	Commercial Product (name):	Salaman 510
Crop/crop group:	Apple	Producer of commercial product:	POTASSIUM PHOSPHONATE TASK FORCE
Responsible body for reporting (name, address)	**LAINCO S.A.** Avda. Bizet 8-12 Pol. Ind. Can Jardí 08191 – Rubí – Barcelona (Spain) **BIOVERT S.L.** Ctra. C – 12 Km 150.5 25137 Corbins - Lleida (Spain) **EXCLUSIVAS SARABIA, S.A** Camí de l'Albí – Ptda. Rec Nou s/n Apdo. Correos nº 9 25110 Alpicat, Lleida (Spain)		
Country (of trial sites):	Spain	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal:	510 g/L	Other active substance in the formulation (common name and content):	none
Formulation:	SL	Residues calculated as:	Potassium phosphonate (as phosphorous acid)

1 Report No. Location (region)	2 Commodity/*Variety* (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment g as/hL	 Water (L/ha)	 g as/ha	6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
S20-04337-01 50297 Bárboles, Aragón, Spain	Apple, MABSD, *Golden Delicious*	1) 14 Feb 2006 2) N/A 3) 16 Sep 2020	Foliar application with mistblower	141.67 141.67 141.67	913.9 1015.3 927.8	1294.7 1438.3 1314.4	02 Aug 2020 07 Aug 2020 12 Aug 2020	75 75-76 76	Washing – fruits prior to processing (-025A) Washing – fruits prior to processing (-025B) Washing – washing water Washing – washed fruits Canning - wastes Canning – blanched fruits Canning – blanching water Canning – canned fruits Canning – canned fruits after separation Canning – syrup after separation	5.70 9.10 0.51 1.18 2.38 2.62 0.29 2.03 2.16 1.87	35 DAA3 (NCH)	No residues above the LOQ were found in any of the untreated samples

Continued…

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g as/ha						
									Drying - wastes	2.03		
									Drying – apple slices	2.58		
									Drying – dried fruits	14.05		
									Juice – crushed fruits	2.42		
									Juice - must	7.16		
									Juice – wet pomace	3.99		
									Juice – raw juice	3.98		
									Juice - deposits	4.95		
									Juice – apple juice	4.11		
									Applesauce – blanched fruits	3.48		
									Applesauce – blanching water	0.12		
									Applesauce – crushed fruits	4.59		
									Applesauce – wastes	2.88		
									Applesauce – raw puree	2.98		
									Applesauce – pasteurized applesauce	4.46		

(a) According to EPPO codes
(b) Only if relevant
c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.5 mg/kg; limit of detection = 0.15 mg/kg; n.d = not detectable

Active substance (common name):	Potassium phosphonate	Commercial Product (name):	Salaman 510
Crop/crop group:	Apple	Producer of commercial product:	POTASSIUM PHOSPHONATE TASK FORCE
Responsible body for reporting (name, address)	**LAINCO S.A.** Avda. Bizet 8-12 Pol. Ind. Can Jardí 08191 – Rubí – Barcelona (Spain) **BIOVERT S.L.** Ctra. C – 12 Km 150.5 25137 Corbins - Lleida (Spain) **EXCLUSIVAS SARABIA, S.A** Camí de l'Albí – Ptda. Rec Nou s/n Apdo. Correos nº 9 25110 Alpicat, Lleida (Spain)		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal:	510 g/L	Other active substance in the formulation (common name and content):	none
Formulation:	SL	Residues calculated as:	Potassium phosphonate (as phosphorous acid)

1 Report No. Location (region)	2 Commodity/*Variety* (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment g as/hL	 Water (L/ha)	 g as/ha	6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
S20-04337-02 21755 Hechthausen, Niedersachsen, Germany	Apple, MABSD, *Junami*	1) 2012 2) 20 Apr 2020 to 14 May 2020 1) 12 Oct 2020	Foliar application with motorized knapsack sprayer	182.14 182.14 182.14	686.1 665.3 705.9	1249.7 1211.8 1285.7	27 Aug 2020 01 Sep 2020 07 Sep 2020	N/D 83 85	Washing – fruits prior to processing (-073A) Washing – fruits prior to processing (-073B) Washing – washing water Washing – washed fruits Canning - wastes Canning – blanched fruits Canning – blanching water Canning – canned fruits Canning – canned fruits after separation Canning – syrup after separation	9.50 8.44 n.d 8.83 7.07 8.12 0.55 5.92 5.75 5.63	35 DAA3 (NCH)	No residues above the LOQ were found in any of the untreated samples

Continued…

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g as/ha						
									Drying - wastes	7.50		
									Drying – apple slices	7.85		
									Drying – dried fruits	46.10		
									Juice – crushed fruits	8.03		
									Juice - must	14.35		
									Juice – wet pomace	7.65		
									Juice – raw juice	9.12		
									Juice - deposits	9.82		
									Juice – apple juice	9.23		
									Applesauce – blanched fruits	13.56		
									Applesauce – blanching water	0.51		
									Applesauce – crushed fruits	7.91		
									Applesauce – wastes	7.82		
									Applesauce – raw puree	6.83		
									Applesauce – pasteurized applesauce	10.42		

(a) According to EPPO codes
(b) Only if relevant
c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.5 mg/kg; limit of detection = 0.15 mg/kg; n.d = not detectable

A 2.1.6 Magnitude of residues in representative succeeding crops

No study submitted.

A 2.1.7 Other/Special Studies

No other/special studies submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Calculations refined with data derived from residue trials and published risk assessment values by EFSA and the JMPR

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Phosphonic acid

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**2.25**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
80%	NL toddler	1796.43	28%	Potatoes	8%	Coconuts	7%	Spinaches		
66%	DE child	1480.28	17%	Potatoes	10%	Oranges	6%	Apples		
60%	NL child	1352.06	23%	Potatoes	8%	Coconuts	4%	Wheat		
57%	GEMS/Food G06	1288.96	13%	Potatoes	12%	Tomatoes	7%	Wheat		
55%	GEMS/Food G08	1240.66	26%	Potatoes	4%	Wheat	4%	Tomatoes		
53%	GEMS/Food G11	1197.72	26%	Potatoes	4%	Wheat	3%	Tomatoes		
52%	GEMS/Food G07	1165.49	25%	Potatoes	4%	Wheat	4%	Tomatoes		
51%	PT general	1155.76	35%	Potatoes	4%	Wheat	3%	Tomatoes		
49%	GEMS/Food G10	1103.55	20%	Potatoes	5%	Tomatoes	4%	Wheat		
49%	GEMS/Food G15	1101.52	24%	Potatoes	5%	Wheat	4%	Tomatoes		
48%	SE general	1081.73	28%	Potatoes	4%	Lettuces	3%	Wheat		
48%	RO general	1070.67	25%	Potatoes	6%	Tomatoes	5%	Wheat		
48%	IE adult	1068.98	15%	Potatoes	3%	Oranges	2%	Walnuts		
45%	FI 3 yr	1004.24	31%	Potatoes	2%	Tomatoes	2%	Raspberries (red and yellow)		
41%	UK toddler	933.24	23%	Potatoes	5%	Oranges	4%	Wheat		
41%	FR child 3 15 yr	911.72	10%	Potatoes	8%	Oranges	5%	Wheat		
38%	ES child	858.28	12%	Potatoes	5%	Oranges	5%	Wheat		
37%	FI 6 yr	830.34	26%	Potatoes	1%	Tomatoes	1%	Raspberries (red and yellow)		
36%	NL general	819.13	16%	Potatoes	5%	Coconuts	3%	Oranges		
33%	UK infant	739.40	22%	Potatoes	3%	Oranges	3%	Wheat		
33%	FR toddler 2 3 yr	736.38	12%	Potatoes	4%	Oranges	3%	Wheat		
31%	PL general	700.44	23%	Potatoes	3%	Tomatoes	2%	Walnuts		
31%	DK child	689.14	16%	Potatoes	5%	Wheat	2%	Tomatoes		
29%	DE women 14-50 yr	653.96	7%	Potatoes	5%	Oranges	2%	Tomatoes		
28%	ES adult	622.47	6%	Potatoes	5%	Lettuces	3%	Oranges		
28%	IT toddler	621.38	7%	Wheat	6%	Potatoes	5%	Tomatoes		
27%	LT adult	615.06	21%	Potatoes	2%	Tomatoes	1%	Wheat		
27%	DE general	612.09	8%	Potatoes	4%	Oranges	2%	Tomatoes		
23%	IT adult	516.44	4%	Wheat	4%	Potatoes	4%	Tomatoes		
23%	FR infant	510.53	13%	Potatoes	3%	Spinaches	0.8%	Wheat		
22%	UK vegetarian	505.96	9%	Potatoes	2%	Oranges	2%	Wheat		
19%	UK adult	428.18	9%	Potatoes	2%	Wheat	1%	Tomatoes		
18%	FR adult	414.51	5%	Potatoes	2%	Wheat	2%	Wine grapes		
17%	DK adult	375.30	8%	Potatoes	2%	Tomatoes	1%	Wheat		
16%	FI adult	368.70	8%	Potatoes	2%	Tomatoes	1%	Lettuces		
7%	IE child	155.53	4%	Potatoes	1%	Wheat	0.2%	Currants (red, black and white)		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Phosphonic acid is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Calculations considering risk assessment values from joint MRL review (EFSA Journal 2021;19(8):6782)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Phosphonic acid

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**2.25**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
36%	NL toddler	805.39	10%	Apples	5%	Potatoes	4%	Wheat		
33%	DE child	742.75	11%	Apples	4%	Wheat	3%	Potatoes		
24%	NL child	534.70	5%	Apples	4%	Wheat	4%	Potatoes		
22%	GEMS/Food G06	502.90	7%	Wheat	2%	Potatoes	2%	Tomatoes		
19%	GEMS/Food G08	429.69	5%	Potatoes	4%	Wheat	2%	Wine grapes		
19%	GEMS/Food G11	425.94	5%	Potatoes	4%	Wheat	2%	Wine grapes		
19%	GEMS/Food G07	416.61	4%	Potatoes	4%	Wheat	2%	Wine grapes		
18%	PT general	410.40	6%	Potatoes	4%	Wheat	4%	Wine grapes		
18%	RO general	397.86	5%	Wheat	4%	Potatoes	3%	Wine grapes		
17%	GEMS/Food G15	383.67	5%	Wheat	4%	Potatoes	2%	Wine grapes		
17%	IE adult	379.51	3%	Potatoes	2%	Wheat	2%	Wine grapes		
17%	FR child 3 15 yr	373.70	5%	Wheat	2%	Oranges	2%	Potatoes		
16%	GEMS/Food G10	367.29	4%	Wheat	4%	Potatoes	0.9%	Tomatoes		
14%	DK child	321.79	5%	Wheat	3%	Potatoes	2%	Apples		
14%	SE general	320.20	5%	Potatoes	3%	Wheat	0.9%	Apples		
14%	UK toddler	316.43	4%	Potatoes	4%	Wheat	2%	Apples		
14%	ES child	310.57	5%	Wheat	2%	Potatoes	1%	Oranges		
13%	FR toddler 2 3 yr	302.49	3%	Wheat	3%	Apples	2%	Potatoes		
13%	DE women 14-50 yr	285.33	2%	Apples	2%	Wheat	1%	Wine grapes		
13%	IT toddler	284.60	7%	Wheat	1%	Potatoes	0.9%	Tomatoes		
12%	FI 3 yr	273.78	6%	Potatoes	1%	Wheat	1%	Cucumbers		
12%	NL general	268.82	3%	Potatoes	2%	Wheat	1%	Apples		
12%	DE general	264.21	2%	Apples	2%	Wheat	1%	Potatoes		
11%	UK infant	238.68	4%	Potatoes	3%	Wheat	1%	Apples		
10%	FR adult	234.32	4%	Wine grapes	2%	Wheat	0.9%	Potatoes		
10%	ES adult	224.15	2%	Wheat	1%	Potatoes	1.0%	Lettuces		
10%	FI 6 yr	218.20	5%	Potatoes	1.0%	Wheat	0.8%	Cucumbers		
9%	IT adult	213.59	4%	Wheat	0.7%	Tomatoes	0.7%	Potatoes		
8%	UK vegetarian	190.01	2%	Wheat	2%	Potatoes	1%	Wine grapes		
8%	PL general	189.82	4%	Potatoes	2%	Apples	0.6%	Tomatoes		
8%	LT adult	182.00	4%	Potatoes	2%	Apples	1%	Wheat		
7%	UK adult	167.39	2%	Wheat	2%	Wine grapes	2%	Potatoes		
7%	FR infant	165.04	2%	Potatoes	2%	Apples	0.8%	Wheat		
7%	DK adult	162.35	2%	Potatoes	2%	Wine grapes	1%	Wheat		
5%	FI adult	115.39	1%	Potatoes	0.5%	Apples	0.5%	Wine grapes		
3%	IE child	62.10	1%	Wheat	0.7%	Potatoes	0.3%	Apples		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Phosphonic acid is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

Not relevant.

A 3.3 IESTI calculations - Raw commodities

Not relevant.

A 3.4 IESTI calculations - Processed commodities

Not relevant.

Appendix 4 Additional information provided by the applicant

No additional information provided.