REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: Salaman 510

Product name(s): **FOSIKA**

Chemical active substance:

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

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

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

Submission date: October 2021

MS Evaluation date: July 2022

MS Finalisation date: dd/mm/yyyy

Version history

When	What
October 2021	Application for the first approval of the product's code SALAMAN 510 in Poland.
July 2022	Version evaluated by zRMS Poland

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SALAMAN 510 *

Product name and code	Code name: SALAMAN 510
Formulation type	Soluble concentrate liquid [Code: SL]
Active substance(s) (incl. content)	Potassium phosphonate (510 g/L expressed as phosphonic acid)
Function	Fungicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	Yes

* Information on the detailed composition of SALAMAN 510 can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for SALAMAN 510 according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	None
Hazard pictograms or Code(s) for hazard pictogram(s):	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	None
Additional labelling phrases:	EUH401 (To avoid risks to man and the environment, comply with the instructions for use).

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders, and residents for SALAMAN 510

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Operator must wear adequate work clothing.
Workers	Acceptable	Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried. In case entering the treated area, long trousers and long-sleeved shirt should be worn.
Bystanders	Acceptable	None.
Residents	Acceptable	None.

No unacceptable risk for operators, workers, bystanders, and residents was identified when the product is used as intended. No specific PPE is necessary.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use-No. *	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, bystander or resident exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique ***	Max. number (min. interval between applications) a) per use b) per crop/ season	Max. application rate kg a.s./ha a) per use b) per crop/ season	Water L/ha min / max			Operator	Worker	Bystander	Residents
1	Pome fruits (BBCH 53-81)	F	Spraying, HCTM HCHH	3 (5)	a) 1.275 b) 3.825	500-1000	35	Operator EFSA (AOEM) Worker EFSA (AOEM) Resident & Bystander EFSA model (AOEM)	A	A	A	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application.
*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held.

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are: None

6.2 Toxicological Information on Active Substance(s)

The active substance was evaluated under directive No 94/414/EEC (as amended) or regulation (EC) No 1107/2009 (as amended). Information regarding classification of the active substance and on EU endpoints identified during the EU review is given in the following table(s). Further information on active substance is included in the reports on the results of the peer review process and in the respective background documents.

Table 6.2-1: Information on active substance(s)

	Potassium phosphonates
Common Name	Potassium phosphonates
CAS No.	13977-65-6 (for potassium hydrogen phosphonate) 13492-26-7 (for dipotasium phosphonate)
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes, categories: None Codes for hazard pictograms: None Signal word: None Hazard statement: None
Additional C&L proposal	None
Agreed EU endpoints	
AOEL systemic	5.00 mg/kg bw/d (Oral absorption: 100%)
Reference	*EFSA Journal* 2012;10(12):2963

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for Salaman 510 is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Salaman 510

Type of test, species, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral, rat (OECD 423)	> 2000 mg/kg bw	Yes	None	…
LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	…)
LC_{50} inhalation, rat (OECD 403)	> 2.01 mg/L air	Yes	None	…
Skin irritation, rabbit (OECD 404	Non-irritant	Yes	None	….
Eye irritation, rabbit (OECD 405)	Non-irritant	Yes	None	…
Skin sensitisation, guinea pig (OECD 406)	Non-sensitising	Yes	None	…
Supplementary studies for combinations of plant protection products	No data – not required	--	N/A	N/A

Table 6.3-2: Additional toxicological information relevant for classification/labelling of SALAMAN 510

	Substance (Concentration in product, % w/w)	**Classification and labelling of product (acc. to the criteria in Reg. 1272/2008)**
Toxicological properties of active substance(s) (relevant for classification of product)	Potassium phosphonates (54.5) [mixture of potassium hydrogen phosphonate (CAS nº.: 13977-65-6) and dipotassium phosphonate (CAS no.: 13492-26-7)]	Potassium hydrogen phosphonate: • Annex IV of RG (EC) 1272/2008: not included so far. • ECHA Substance Information: "According to the classification provided by companies to ECHA in REACH registrations this substance causes serious eye irritation (H319)". Dipotassium phosphonate: • Annex IV of RG (EC) 1272/2008): not included so far. • ECHA Substance Information: "According to the classification provided by companies to ECHA in REACH registrations this substance is harmful if swallowed (H302), causes serious eye irritation (H319) and causes skin irritation (H315)".
Toxicological properties of non-active substance(s) (relevant for classification of product)	None	None

6.4 Toxicological Evaluation of Groundwater Metabolites

For the applied uses the predicted groundwater concentrations of phosphonic acid (to which potassium phosphonates dissociates in water) are <0.1 µg/L. No toxicological evaluation of groundwater metabolites is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substance in Salaman 510 is presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SALAMAN 510

	Potassium phosphonates	
	Value	**Reference**
Concentrate	10 %	Default value (concentrate) according to the EFSA Guidance on Dermal Absorption (*EFSA Journal 2017*:15 (6):4873) in the absence of any experimental data
Dilution	50 %	Default value (in-use field dilutions) according to the EFSA Guidance on Dermal Absorption (*EFSA Journal 2017*:15 (6):4873) in the absence of any experimental data

6.5.1 Justification for proposed values

No data on dermal absorption for potassium phosphonate in SALAMAN 510 is available. According to the EFSA Guidance on Dermal Absorption *(EFSA Journal 2017*:15 (6) :4873) default dermal absorption values of 10% (concentrate) and 50% (in-use field dilutions) should apply to a SL formulation in the absence of any experimental data.

Table 6.5-2: Default dermal absorption rates for potassium phosphonate

	Value	Justification for value	Acceptability of justification
Concentrate	10 %	Default value (concentrate) according to the EFSA Guidance on Dermal Absorption (*EFSA Journal 2017*:15 (6) :4873) in the absence of any experimental data	Justification acceptable
Dilution	50 %	Default value (in-use field dilutions) according to the EFSA Guidance on Dermal Absorption (*EFSA Journal 2017*:15 (6) :4873) in the absence of any experimental data	Justification acceptable

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Estimation of operator, worker, bystander and resident has been calculated considering the specific requirements of each southern country where this dossier will be presented.

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	Code name: SALAMAN 510
Formulation type	SL
Category	Fungicide
Container size(s), short description	HDPE or COEX Bottles of 100 mL, 250 mL, 500 mL and 1 L HDPE carafes of 5 L, 10 L, 20 L and 50 L COEX carafes of 5 L
Active substance(s) (incl. content)	Potassium phosphonate (510 g/L expressed as phosphonic acid)
AOEL systemic	5.00 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 10 % Dilution: 50 % (default)

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the Central EU zone is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of SALAMAN 510 according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in Table 6.6-3. Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use	Pome fruits ..... max. 1.275 kg a.s./ha; 500-1000 L water/ha
Model	Professional use EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products [*EFSA Journal 2014*;12(10):3874 [55 pp.]

Table 6.6-3: Estimated operator exposure

Model data	**Level of PPE**	**Total absorbed dose** (mg/kg bw/day)	**% of systemic AOEL** (5 mg/kg bw/day)
Max. application rate: 2.5 L product/ha (1.275 kg a.s./ha) *Water volume: 500-1000 L/ha*			
EFSA model (Vehicle-mounted) High crop	Work wear (arms, body and legs covered)	0.3997644	8.00 % (Table A3.1-1)
EFSA model (Manual-Hand held) High crop	Work wear (arms, body and legs covered)	0.1335987	2.67 % (Table A3.1-2)
EFSA model (Manual-Knapsack) High crop	Work wear (arms, body and legs covered)	0.0556993	1.11 % (Table A3.1-3)

An acceptable risk has been identified according to the EFSA Calculator (2015), even without PPE, assuming only adequate work clothing. The following phrase should be included in the product label: *"Operator must wear adequate work clothing.*

zRMS:
The exposure to Potassium phosphonate, an active substance of the product SALAMAN 510 (FOSIKA), of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying SALAMAN 510 on pome fruits, at maximal dose of 2.5 L product/ha (1.275 kg a.s./ha) using tractor-mounted/trailed sprayer, upward spraying, or manual hand held sprayer or manual knapsack sprayer calculated with the EFSA AOEM amounted respectively to 8.00 %, 2.67% and 1.11% of AOEL. The potential exposure without wearing work clothing covering arms, legs and body amounted respectively to 27.18%, 16.09% and 11.61% of AOEL .

Summing up the application of product SALAMAN 510 does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice even if operator is not wearing work wear covering arms, body and legs during mixing/loading and application but wearing a work clothing (long sleeved shirt, long trousers), but no PPE, is considerably reducing exposure and health risk.

6.6.3 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses even without the use of personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Salaman 510 according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use	Pome fruits ..... max. 1.275 kg a.s./ha; 500-1000 L water/ha
Model	Professional uses EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products [*EFSA Journal 2014*;12(10):3874 [55 pp.]

Table 6.6-5: Estimated worker exposure

Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL (5 mg/kg bw/day)
EFSA Model *Application rate: 1.275 kg a.s./ha* *Number of applications: 3 (5 days)* *Working hours: 8 hours*	Work wear (arms, body and legs covered)	3.0805776	61.61 % (Table A3.2-1)

An acceptable risk has been identified for workers according to the EFSA Calculator (2015), assuming only adequate work clothing**.** The following phrase should be included in the product label: *"Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried. In case a worker enters the field, long trousers and long-sleeved shirt should be worn*".

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Not refinement required.

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

6.6.4.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable worker exposure level (AOEL) will not be exceeded under conditions of intended uses even without the use of personal protective equipment (PPE), a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

Table 6.6-6 shows the exposure model(s) used for estimation of bystander and resident exposure to potassium phosphonates. Outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Model
Resident & Bystander Pome fruits Dose: max. 3 applications x 1.275 kg a.s./ha Water volume: 500-1000 L/ha	EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products [*EFSA Journal 2014;12(10):3874* [55 pp.]

Table 6.6-7: Estimated bystander and resident exposure

Model data		**Total absorbed dose** (mg/kg bw/day)	**% of systemic AOEL** (5 mg/kg bw/day)
Resident (child) EFSA Model Body weight: 10 kg Buffer strip: 5 m	Spray drift	0.1770040	3.54 %
	Vapour	0.0010700	0.02 %
	Surface deposits	0.0780979	1.56 %
	Re-entry into treated crops	0.2888042	5.78 %
	SUM....	0.4055521	8.11 % (Table A3.3-1)
Resident (adult) EFSA Model Body weight: 60 kg Buffer strip: 5 m	Drift	0.0981920	1.96 %
	Vapour	0.0002300	0.00 %
	Deposits	0.0328786	0.66 %
	Re-entry	0.1604468	3.21 %
	SUM....	0.2166972	4.33 % (Table A3.3-1)

In the absence of acute AOEL value for potassium phosphonates, the bystander exposure cannot be calculated with the EFSA Calculator, but it is covered by the estimation of resident exposure, which is a worst-case scenario.

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

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

6.6.5.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable bystander and/or resident exposure level (AOEL) for potassium phosphonates will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

6.6.6 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted or referred to by the applicant and relied on, but already evaluated for the approval of the product

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 7.1.1/01	.	2012	Potassium phosphite 510g/L. Evaluation of acute oral toxicity in Rats – Acute toxic class method PBD Study Number: . GLP Unpublished	Y	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.2/01	..	2012	Potassium phosphite 510 g/L. Evaluation of acute dermal toxicity in rats PBD Study Number: . GLP Unpublished	Y	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.3/01		2012	Salaman 510 (potassium phosphite 510g/L): Acute inhalation toxicity study in Wistar rat IIBAT Study . GLP Unpublished	Y	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.4/01	.	2012	Assessment of acute dermal irritation with the item: Potassium Phosphite 510g/L Phycher Study Number: . GLP Unpublished	Y	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.5/01	.	2012	Assessment of acute eye irritation with the item: Potassium phosphite 510 g/L Phycher Study Number: . GLP Unpublished	Y	Lainco S.A. Exc.Sarabia S.A. Biovert S.L.
KCP 7.1.6/01	…	2012	Potassium phosphite 510 g/L. Assessment of sensitising properties on albino guinea pigs. Maximisation test according to Magnusson and Kligman Phycher Study Nr. . GLP Unpublished	Y	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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

No bridging was necessary for the toxicological assessment of Salaman 510.

Comments of zRMS:	No bridging statement is required since the acute toxicity studies were performed on formulation being evaluated in this registration report .

A 2.2 Acute oral toxicity (KCP 7.1.1)

Reference:	KCP 7.1.1/01
Report:	"Potassium phosphite 510g/L. Evaluation of acute oral toxicity in Rats – Acute toxic class method". …. Report No. ……
Guideline(s):	OECD Guidelines for Testing of Chemicals N° 423 "Acute Oral Toxicity- Acute Toxic Class Method", adopted by the Council on 17th December, 2001. Test method B.1tris Council Regulation N0. 440/2008
Deviations:	No
GLP:	Yes

Material and Methods:

Salaman 510 (batch No. 1132015) is a colourless liquid containing potassium phosphite (nominal concentration: 510g/L. The test item was administered to a group of 3 females Sprague Dawley rats at the single dose of 2000 mg/Kg bw (step 1) and then to a 3 females Sprague Dawley rats at the single dose of 2000 mg/Kg bw three rats, step 2). The administration volume for the first step one and two was 1.36 mL/kg bw (corresponding to 2g/kg, according to the calculated density).

Table 7.1.1-1: Acute oral toxicity in rats of potassium phosphite

Dose (mg/kg)	Toxicological results*	Duration of signs	Time of death	LD_{50} (mg/kg) (14 days)
6 Females Sprague Dawkey Rats				
2000 mg/kg	1/2/6	1 day	9 days	>2000 mg/kg

* Number of animals which died/number of animals with clinical signs/number of animals used

Findings:

It was noted the death of one rat treated at 2000 mg/kg bw (1/6), on day 9. The mortality was preceded by a decrease in spontaneous activity, partial ptosis, piloerection and hollow flanks.

A decrease in body weight was noted on the day of the death compared to day 0 (-45%).

A marked lysis, preventing the macroscopic examinations was noted in this animal.

In the survival animals treated at 2000 mg/kg bw (5/6), a decrease in spontaneous activity (2/5) was noted from the first hours of the test. The animals recovered a normal behaviour on day 1.

The body weight gain of these five animals was lower on day 2 compared to historical control (-36%). Then, the body weight evolution recovered a normal evolution.

The macroscopic examination of the animal at the end of the study did not reveal treatment related changes.

Conclusion/endpoint:

The LD_{50} of the test item SALAMAN 510 is higher than 2000 mg/kg body weight by oral route in the rat.

In accordance with the OECD guideline No. 423, the LD_{50} cut-off of the test item may be considered as 2500 mg/kg body weight by oral route in the rat.

The test submitted has been performed with technical potassium phosphonate with a concentration of 564.1 g/L in phosphorous acid (batch Nr. - 1132015) and it can be applied as a worst case to Salaman 510.

The Salaman 510 is prepared from the technical potassium phosphonate with the only addition of water to adjust the concentration at 510 g/L in phosphorous acid. Therefore, the toxicological tests submitted with the technical product can be applied to the formulated Salaman 510.

According to the criteria for classification, packaging and labelling of dangerous substances and preparations in accordance with Regulation EC No. 1272/2008, Salaman 510 **must not be classified.** No symbol or risk phrase is required.

In accordance with the Regulation EC No. 1272/2008 on classification, labelling and packaging of substances and mixtures, Salaman 510 **must not be classified**. No signal word or hazard statement is required.

Comments of zRMS:	The study performed according to relevant OECD guidelines and in GLP conditions is acceptable. Product Salman 510 does not require classification according to criteria given in the Regulation EC No. 1272/2008 for acute oral toxicity since LD50 is above 2000 mg/kg bw.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Reference:	KCP 7.1.2/01
Report:	"Potassium phosphite 510 g/L. Evaluation of acute dermal toxicity in rats". …..
Guideline(s):	OECD Guidelines for Testing of Chemicals N° 402 "Acute Dermal Toxicity", adopted by the Council on 24th February, 1987. Test method B.3 Council Regulation N0. 440/2008
Deviations:	No
GLP:	Yes

Material and Methods:

The test item Potassium Phosphite 510 g/L was applied onto the intact skin of 10 Sprague Dawley rats (5 males and 5 females) at the single dose of 2000 mg/kg body weight.

Table 7.1.2-1: Acute dermal toxicity in rats of potassium phosphite

Dose (mg/kg)	Toxicological results*	Duration of signs	Time of death	LD_{50} (mg/kg) (14 days)
10 Sprague Dawley rats				
2000 mg/Kg	0/0/10	-	-	>2000

* Number of animals which died/number of animals with clinical signs/number of animals used.

Findings:

No mortality occurred during the study.

Neither cutaneous reactions nor systemic clinical signs related to the administration of the test item were observed.

The body weight evolution of the animals remained normal throughout the study.

The macroscopic examination of the animals at the end of the study did not reveal treatment-related changes.

Conclusion/endpoint:

The LD_{50} of the test item potassium phosphite is higher than 2000 mg/kg body weight by dermal route in the rat.

The test submitted has been performed with technical potassium phosphonate with a concentration of 564.1 g/L in phosphorous acid (batch Nr. - 1132015) and it can be applied as a worst case to Salaman 510.

The Salaman 510 is prepared from the technical potassium phosphonate with the only addition of water to adjust the concentration at 510 g/L in phosphorous acid. Therefore, the toxicological tests submitted with the technical product can be applied to the formulated Salaman 510.

According to the criteria for classification, packaging and labelling of dangerous substances and preparations in accordance with Regulation EC No. 1272/2008, Salaman 510 **must not be classified**. No symbol or risk phrase is required.

In accordance with the Regulation EC No. 1272/2008, the test item **must not be classified**. No signal word or hazard statement is required.

Comments of zRMS:	The study performed according to relevant OECD guidelines and in GLP conditions is acceptable. Product Salman 510 does not require classification according to criteria given in the Regulation EC No. 1272/2008 for acute dermal toxicity since LD50 is above 2000 mg/kg bw.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Reference:	KCP 7.1.3/01
Report:	"Salaman 510 (potassium phosphite 510g/L): Acute inhalation toxicity study in Wistar rat". …
Guideline(s):	OECD Guidelines for Testing of Chemicals (2009) N° 403, section 4 "Acute Inhalation Toxicity – Acute Toxic Class method"
Deviations:	No
GLP:	Yes

Material and Methods:

An acute inhalation toxicity study of Potassium phosphite was carried out in Wistar rats. Prior to the sighting study, a pilot study was conducted to determine the maximum attainable concentration. Parameter such as collection efficiency, oxygen concentration, temperature, relative humidity, air flow rate, particle size distribution was assessed to determine the dynamic nature of the exposure system. In the sighting study, a single group containing three males and three female rats were exposed to a mean actual concentration of 2.03 mg/L continuously for four hours and observed further for 5 days for clinical signs of toxicity, if any.

As no mortality was observed in the sighting study, a limit test was conducted: a single group containing six animals (3 males and 3 females) were exposed through nose only 2.01 mg/L (mean actual concentration) of Potassium phosphite for 4 hours. The rats were observed for mortality and clinical signs of toxicity during the exposure and daily for 14 subsequent days. Body weight was recorded on days 0,1,3,7 and 14.

Table 7.1.3-1: Acute inhalation toxicity in rats of Potassium phosphite

Dose (mg/L air)	Toxicological results*	Duration of signs	Time of death	LC_{50} (mg/L air) (4 hours)
Treatment group - Females				
2.01 mg/L	0/3	-	-	> 2.01
Treatment group – Males				
2.01 mg/L	0/3	-	-	> 2.01

* Number of animals which died/number of animals used.

Findings:

None of the animals show any clinical signs of toxicity during the observation period. Normal body weight was observed on days 1, 3, 7 and 14. No gross lesions were observed in a gross pathology examination conducted on day 14.

Conclusion/endpoint:

The actual inhalation LC_{50} of Potassium phosphite was determined to be greater than 2.01 mg/L (mean actual concentration) in Wistar rats under the present experimental conditions.

The test submitted has been performed with technical potassium phosphonate with a concentration of 510 g/L in phosphorous acid (batch Nr. - 131132015) and it can be applied.

The Salaman 510 is prepared from the technical potassium phosphonate with the only addition of water to adjust the concentration at 510 g/L in phosphorous acid. Therefore, the toxicological tests submitted with the technical product can be applied to the formulated Salaman 510.

According to the criteria for classification, packaging and labelling of dangerous substances and preparations in accordance with the Regulation EC No. 1272/2008, the test item SALAMAN 510 **must not be classified**. No symbol or risk phrase is required.

In accordance with the Regulation EC No. 1272/2008, the test item **must not be classified**. No signal word or hazard statement is required.

Comments of zRMS:	The study performed according to relevant OECD guidelines and in GLP conditions is acceptable. The exposure of rats to aerosol of Salman 510 at nominal concentration of 19.21 mg/L and actual measured concentration of 2.01 mg/L, considered as the highest technically attainable concentration, for four hours in the acute inhalation toxicity limit test did not cause mortality of rats, thus a LC_{50} of the Salman 510 is above 2.01 mg/L. The product does not require classification according to criteria given in the Regulation EC No. 1272/2008 for acute inhalation toxicity.

A 2.5 Skin irritation (KCP 7.1.4)

Reference:	KCP 7.1.4/01
Report:	"Assessment of acute dermal irritation with the item: Potassium Phosphite 510g/L". ….
Guideline(s):	OECD Guidelines for Testing of Chemicals N° 404 "Acute dermal irritation/corrosion", adopted on 24th April, 2002 Test method B.4 of the Council Regulation No. 440/2008 of 30 May 2008
Deviations:	No
GLP:	Yes

Material and Methods:

The test item Potassium phosphite 510g/L was applied, as supplied, at the dose of 0.5 mL, under semi-occlusive dressing during 4 hours on an undamaged skin area of three New Zealand rabbits. The experi-

mental protocol was established from the OECD guideline N. 404 and the test method B.4 of the Council Regulation No. 440/2008.

Findings:

A very slight erythema was noted on the treated area of all animals, 1 hour after the patch removal, and was totally reversible between days 1 and 2.

The individual and mean scores obtained during the study are given in the table below.

Table 7.1.4-1: Skin irritation of Potassium phosphite 510 g/L

Animal No.	Skin reactions	Scores after treatment				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
A2318	Erythema Oedema	1 0	1 0	0 0	0 0	0.33 0	- -
A2322	Erythema Oedema	1 0	0 0	0 0	0 0	0 0	- -
A2323	Erythema Oedema	1 0	0 0	0 0	0 0	0 0	- -

Conclusion/endpoint:

The test submitted has been performed with technical potassium phosphonate with a concentration of 564.1 g/L in phosphorous acid (batch Nr. - 1132015) and it can be applied as a worst case to Salaman 510.

The Salaman 510 is prepared from the technical potassium phosphonate with the only addition of water to adjust the concentration at 510 g/L in phosphorous acid. Therefore, the toxicological tests submitted with the technical product can be applied to the formulated Salaman 510.

The result obtained, under these experimental conditions, enable to conclude that Salaman 510 **must not be classified**, according to the criteria for classification, packaging and labelling of dangerous substances and preparations in compliance with the Regulation (EC) No.1272/2008. **No symbol or risk phrase is required**.

In accordance with the Regulation (EC) No.1272/2008, Salaman 510 **must not be classified**. No signal word or hazard statement is required.

Comments of zRMS:	The study performed according to relevant OECD guidelines and in GLP conditions is acceptable. Since the observed dermal effects were well below the criteria given in the Regulation EC No. 1272/2008 for classification into category Skin Irrit. 2, the product Salman 510 does not require classification for skin irritation.

A 2.6 Eye irritation (KCP 7.1.5)

Reference:	KCP 7.1.5/01
Report:	"Assessment of acute eye irritation with the item: Potassium phosphite 510 g/L". …..
Guideline(s):	OECD Guidelines for Testing of Chemicals N° 405 "Acute Eye Irritation/ Corrosion", adopted by the Council on 24th April, 2002 Test method B.5 of the Council Regulation No. 440/2008.
Deviations:	No
GLP:	Yes

Material and Methods:

The test item Potassium phosphite 510 g/L was instilled as supplied, into the eye of three New Zealand rabbits at the dose of 0.1 mL. The experimental protocol was established from the OECD guideline N. 405 and the test method B.5 of the Council Regulation No. 440/2008.

Findings:

The conjunctivae reactions observed during the study have been moderate and totally reversible: a moderate redness noted 1 hour after the test item instillation and totally reversible between days 1 and 3 associated to a moderate chemosis noted 1 hours after the test item instillation and totally reversible between days 1 and 2.

Table 7.1.5-1: Eye irritation of Potassium phosphite 510 g/L

Animal No.	Eye reactions	Scores after treatment *			Mean scores (24h-72h)	Reversible (day)
		24 h	48 h	72 h		
A2293	Corneal opacity	0	0	0	0	-
	Iritis	0	0	0	0	-
	Redness conjunctivae	2	1	0	1	-
	Chemosis conjunctivae	1	0	0	0.33	-
A2336	Corneal opacity	0	0	0	0	-
	Iritis	0	0	0	0	-
	Redness conjunctivae	2	1	0	1	-
	Chemosis conjunctivae	1	0	0	0.33	-
A2337	Corneal opacity	0	0	0	0	-
	Iritis	0	0	0	0	-
	Redness conjunctivae	0	0	0	0	-
	Chemosis conjunctivae	0	0	0	0	-

* scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis.

Conclusion/endpoint:

The test submitted has been performed with technical potassium phosphonate with a concentration of 564.1 g/L in phosphorous acid (batch Nr. 1132015) and it can be applied as a worst case to Salaman 510.

The Salaman 510 is prepared from the technical potassium phosphonate with the only addition of water to adjust the concentration at 510 g/L in phosphorous acid. Therefore, the toxicological tests submitted with the technical product can be applied to the formulated Salaman 510.

In accordance with the Regulation (EC) No. 1272/2008, Salaman 510 **must not be classified**. No signal word or hazard statement is required.

Comments of zRMS:	The study performed according to relevant OECD guidelines and in GLP conditions is acceptable. Since the observed intensity effects in eye were well below the criteria given in the Regulation EC No. 1272/2008 for classification into category Eye Irrit. 2, the product Salman 510 does not require classification for eye irritation.

A 2.7 Skin sensitisation (KCP 7.1.6)

Reference:	KCP 7.1.6/01
Report:	"Potassium phosphite 510 g/L. Assessment of sensitising properties on albino guinea pigs. Maximisation test according to Magnusson and Klingman". …..
Guideline(s):	OECD Guideline No. 406 dated on 17 July 1992 and the test method B.6 of the Council Regulation No. 440/2008
Deviations:	No
GLP:	Yes

Material and Methods:

Preliminary studies

Determination by intradermal injection of the Maximal Non-Necrotizing Concentration (MNNC)

Two animals received on both sides of the spine, a volume of 0.1 mL of the test item, at 4 concentrations: diluted at 50%, 20%, 10% and 5% in isotonic sodium chloride in view to determine the MNNC. Due to necrosis observed at all concentrations, the same animals received on both sides of the spine, a volume of 0.1 mL of the test item, at 3 concentrations: diluted at 2%, 1% and 0.5% in isotonic sodium chloride in view to determine the MNNC.

No necrosis has been observed since the concentration of 2%. The first induction of the treated group has been carried out by intradermal injection at the maximal non-necrotizing concentration of 2%.

Determination by topical application of the Pre-Maximal Non-Irritant Concentration (Pre-MNIC)

The test item was applied on the dorso-lumbar zone of two guinea pigs shorn beforehand, with occlusive dressing for 24 hours, at 4 different concentrations: 100%, diluted at 50%, 20% and 10% in distilled water.

24 hours after the removal of the occlusive dressings, no macroscopic cutaneous reaction was recorded on the treated areas. In view of these results, the concentration selected was 100% for the 2nd induction of the treated group and the MNIC determination began at the concentration of 100%.

Determination by topical application of the Maximal Non-Irritant Concentration (MNIC)

Three guinea pigs were treated according to the same treatment as animals from the negative control group for the induction phase (*i.e.* isotonic sodium chloride and distilled water). During the challenge phase, the animals were treated with the test item placed onto the selected treatment sites and covered with an occlusive dressing for a period of 24 hours at 4 different concentrations: 100%, diluted at 50%, 20% and 10% in distilled water.

24 and 48 hours after the removal of the occlusive dressings, no macroscopic cutaneous reaction was recorded on the treated areas. In view of this result, the concentrations selected were 100% (MNIC) and 50% (1/2 MNIC) for the challenge phase.

Main study

After induction (intradermal injection at 2% and topical application at 100%) of 10 Guinea Pigs of treated group with the test item Potassium Phosphite 510g/L and a 10-day rest phase, the challenge phase, under occlusive dressing for 24 hours, consisted to a single topical application of the test item undiluted (100%) and diluted at 50% in distilled water. The experimental protocol was established according to the OECD guideline No. 406 dated July 17th, 1992 and the test method B.6 of the council regulation No. 440/2008.

Findings:

No cutaneous reaction attributable to allergy was recorded in animals from the treated group after the challenge phase, on the treated area at 100% and 50%.

No cutaneous intolerance reaction was recorded in animals from the negative control group after the challenge phase, on the treated area with the test item at 100% and 50%.

Conclusion/endpoint:

The test submitted has been performed with technical potassium phosphonate with a concentration of 564.1 g/L in phosphorous acid (batch Nr. 1132015) and it can be applied as a worst case to Salaman 510.

The Salaman 510 is prepared from the technical potassium phosphonate with the only addition of water to adjust the concentration at 510 g/L in phosphorous acid. Therefore, the toxicological tests submitted with the technical product can be applied to the formulated Salaman 510.

In accordance with the Regulation EC No. 1272/2008 on classification, labelling and packaging of substances and mixtures, Salaman 510 **must not be classified**. No hazard statement or signal word is required.

Comments of zRMS	The study performed according to relevant OECD guidelines and in GLP conditions is acceptable. Since no positive skin responses were observed in the challenge test the criteria given in the Regulation EC No. 1272/2008 for classification into category Skin Sens. 1 are not met and the product Salman 510 does not require classification for skin sensitisation

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies have been conducted with Salaman 510.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co- formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

No data on dermal absorption for potassium phosphonate in Salaman 510 is available.

A 2.11 Other/Special Studies

No other/special studies submitted.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

Table A3.1-1 Operator exposure calculations. Vehicle-mounted sprayer. AOEM model.

Operator exposure for Salaman 510 outdoor spray applications

Application rate of active substance	1.275	kg a.s./ha	*i_AppRate*
Assumed area treated	10	ha/day	*d_AreaTreated*
Amount of active substance applied	12.75	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

Outdoor|Soluble concentrates, emulsifiable concentrate, etc.|Upward spraying|Vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	34468	129164	AOEM	
	Body	21351	150889	AOEM	
	Head	662	3628	AOEM	
	Protected hands (gloves)	181	2525	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	227	1865	AOEM	
	Protected head (hood and face shield)	11	205	AOEM	
	Inhalation	8	31	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	24116	79519	AOEM	No data available for a drift reduction scenario
	Body	112349	655557	AOEM	
	Head	14765	90617	AOEM	
	Protected hands (gloves)	449	11723	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1466	2865	AOEM	
	Inhalation	269	1054	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	81.5400299	23.9858660	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	1.3590005	0.3997644	
% of RVNAS	27.18%	8.00%	

Operator exposure for Salman 510 outdoor spray applications

Application rate of active substance	1,275	kg a.s./ha	*i_AppRate*
Assumed area treated	10	ha/day	*d_AreaTreated*
Amount of active substance applied	12,75	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Upward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	34468	129164	AOEM	
	Body	21351	150889	AOEM	
	Head	662	3628	AOEM	
	Protected hands (gloves)	181	2525	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	227	1865	AOEM	
	Protected head (hood and face shield)	11	205	AOEM	
	Inhalation	8	31	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	24116	79519	AOEM	No data available for a drift reduction scenario
	Body	112349	655557	AOEM	
	Head	14765	90617	AOEM	
	Protected hands (gloves)	449	11723	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1466	2865	AOEM	
	Inhalation	269	1054	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	81,5400299	81,5400299
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	1,3590005	1,3590005
% of RVNAS	27,18%	27,18%

Table A3.1-2 Operator exposure calculations. Manual-Hand held sprayer. AOEM model.

Operator exposure for Salaman 510 outdoor spray applications

Application rate of active substance	1.275	kg a.s./ha	*i_AppRate*
Assumed area treated	4	ha/day	*d_AreaTreated*
Amount of active substance applied	5.1	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Manual-Hand held		
Season	not relevant		

Mixing and loading

Exposure values	µg exposure/day mixed and loaded		Reference	Comment
	75th centile	95th centile		
Hands	17024	63283	AOEM	
Body	11212	115623	AOEM	
Head	265	1451	AOEM	
Protected hands (gloves)	99	1010	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	101	746	AOEM	
Protected head (hood and face shield)	4	82	AOEM	
Inhalation	6	30	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied		Reference	Comment
	75th centile	95th centile		
Hands	10627	30605	AOEM	No data available for a drift reduction scenario
Body	79316	181494	AOEM	
Head	257	1402	AOEM	
Protected hands (gloves)	122	633	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
Inhalation	312	482	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	48.2683889	8.0159229	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.8044731	0.1335987	
% of RVNAS	16.09%	2.67%	

Table A3.1-3 Operator exposure calculations. Manual-Knapsack sprayer. AOEM model.

Operator exposure for Salaman 510 outdoor spray applications

Application rate of active substance	1.275	kg a.s./ha	*i_AppRate*
Assumed area treated	1	ha/day	*d_AreaTreated*
Amount of active substance applied	1.275	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Manual-Knapsack		
Season	not relevant		

Mixing and loading

Exposure values	µg exposure/day mixed and loaded		Reference	Comment
	75th centile	95th centile		
Hands	9495	25482	AOEM	
Body	803	2787	AOEM	
Head	5	11	AOEM	
Protected hands (gloves)	18	164	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
Protected head (hood and face shield)	5	11	AOEM	
Inhalation	25	26	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied		Reference	Comment
	75th centile	95th centile		
Hands	3334	10597	AOEM	No data available for a drift reduction scenario
Body	63845	179154	AOEM	
Head	165	890	AOEM	
Protected hands (gloves)	30	158	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
Inhalation	99	211	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	34.8255419	3.3419564	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.5804257	0.0556993	
% of RVNAS	11.61%	1.11%	

A 3.2 Worker exposure calculations (KCP 7.2.1.2)

Table A3.2-1 Worker exposure calculations. AOEM model.

Worker exposure from residues on foliage for Salaman 510			
Crop type	Pome fruit		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Searching, reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1.275	kg a.s./ha	*i_AppRate*
Number of applications	3		*i_AppNo*
Interval between multiple applications	5	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	2.7		*d_MAF*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50.00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	3.825	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	924.1732898	184.8346580	92.4173290	
Total systemic exposure per kg body weight (mg/kg bw/day)	15.4028882	3.0805776	1.5402888	
% of RVNAS	308.06%	61.61%	30.81%	

A 3.3 Resident/Bystander exposure calculations (KCP 7.2.1.3)

Table A3.3-1 Resident exposure calculations. EFSA model.

Resident exposure for Salaman 510			
Croptype	Pome fruit		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	5	m	*i_Buffer*
Application rate of the product	1.275	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	2.55	g a.s./l	*d_ConcAS*
Dermal absorption of product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorpInuse*
Oral absorption	100.00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	3.825	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	5.63	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	1.689	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0.00210	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0.00164	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	3.68	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	1.11	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0.00170	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0.00133	ml spray dilution/person	
Exposure duration dermal	2	hours	*d_ReExpDur*
Exposure duration inhalation	24	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	15.79%		
Drift percentage on surface (mean)	11.69%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	9.5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h	*d_TcEntryCh*

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	1.7700404	0.0107000	0.7809795	2.8880415	4.0555213
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1770040	0.0010700	0.0780979	0.2888042	0.4055521
% of RVNAS	3.54%	0.02%	1.56%	5.78%	8.11%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	5.8915200	0.0138000	1.9727163	9.6268051	13.0018323
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0981920	0.0002300	0.0328786	0.1604468	0.2166972
% of RVNAS	1.96%	0.00%	0.66%	3.21%	4.33%

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

No data submitted.