

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SAP09I

Product name(s): VOLKETE MAX

Chemical active substance:

Spinosad, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New product authorization according to article 33 and 34 of
Regulation (EC) 1107/2009)

Applicant: Albaugh TKI d.o.o.

Submission date: January 2025

MS Finalisation date: 12/2025

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Version history

When	What
January 2025	V0 – Original dRR version from applicant Albaugh TKI d.o.o. for submission to zRMS Poland in the frame of a new authorization according to Article 33/34 of Regulation (EC) No. 1107/2009.
April 2025	Dossier sent for evaluation
October 2025	zRMS evaluation of dRR
November 2025	RR update with additional risk assessment for worker
December 2025	Final RR

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zRMS comments:

The text highlighted in grey was provided by the zRMS.

6 Mammalian Toxicology (KCP 7)

General zRMS's comment	From a toxicological point of view, in accordance with the SANCO 12638/2011 rev.2 guidance document, it can be considered that the product VOLKETE MAX (SAP09I/Spinosad 480 SC) has a formulation composition sufficiently comparable to the composition of the product SpinTor 480 SC already registered in Poland, therefore the unprotected studies conducted for SpinTor 480 SC can be used to support the registration of VOLKETE MAX in Poland (see Composition's Comparison document).
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6.1 Summary

Table 6.1-1: Information on SAP09I / Spinosad 480 SC *

Product name and code	VOLKETE MAX (SAP09I / Spinosad 480 SC)
Formulation type	SC
Active substance(s) (incl. content)	Spinosad (480 g/L)
Function	Insecticide
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	No

* Information on the detailed composition SAP09I / Spinosad 480 SC 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:

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Table 6.1-2: Justified proposals for classification and labelling for SAP09I / Spinosad 480 SC 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)	P102: Keep out of reach of children. P270: Do not eat, drink or smoke when using this product. P501: Dispose of contents and/or their container according to the separated collection system used in your municipality.
Additional labelling phrases	EUH210: Safety Data Sheet available on request. EUH401: To avoid risks to man -human health and the environment, comply with the instructions for use.
	EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SAP09I / Spinosad 480 SC

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Low vegetables (Vehicle-mounted), Orchards (Manual hand held and Manual knapsack): - M/L: Workwear - App: Workwear Orchards (Vehicle-mounted): - M/L: Workwear + Protected hands - App: Workwear
Workers	Acceptable	Low vegetables (Reaching, picking (all except Brassica)), Orchards (Inspection, irrigation): - Workwear Low vegetables (Inspection, irrigation (All)) - None Low vegetables Harvest and Maintenance (Brassica only), Orchards (Maintenance/thinning) and Orchards (Searching, reaching, picking): - Workwear and gloves Orchards (Maintenance/thinning): - Workwear, gloves and re-entry period of 11 days Orchards (Maintenance/thinning): Workwear/gloves or worker/gloves/re-entry period of 11 days
Residents	Acceptable	Low vegetables: 2-3 m buffer zone Orchards: 5-m buffer zone
Bystanders	Acceptable	Low vegetables: 2-3 m buffer zone Orchards: 5-m buffer zone

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

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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, resident or bystander 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 as/ha Spinosad a) per use b) per crop/ season	Water L/ha min / max			Operator	Worker	Residents	Bystander
3	Onion (BBCH 10-49)	F	Spraying, LCTM	a) 3 b) 3 (10 days)	a) 0.096 b) 0.288	200 - 600	7	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032	A	R	A	A
5	Apple (BBCH >70)	F	Spraying, HCTM HCHH HCMK	a) 2 b) 2 (10 days)	a) 0.144 b) 0.288	300-1500	14		R TM	R	A	A
									N HH MK			

* 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, MK: manual-knapsack

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).

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

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

	Spinosad
Common Name	SPINOSAD a mixture of 50-95% spinosyn A and 5-50% spinosyn D
CAS-No.	Spinosad (mixture): 168316-95-8 Spinosyn A: 131929-60-7

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	Spinosad
	Spinosyn D: 131929-63-0
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories:- Code(s) for hazard pictogram(s):- Signal word:- Hazard statement(s):- Precautionary statement(s):-
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.012 mg/kg bw/d (corrected for 50% oral absorption)
AAOEL systemic	0.024 mg/kg bw/d (corrected for 50% oral absorption)
Reference	SANCO/1428/2001 – rev. final of 14 July 2006
Conditions to take into account/critical areas of concern with regard to toxicology	
According to SANCO/1428/2001 for spinosad	<i>“The review has identified acceptable exposure scenarios for operators, workers and bystanders, which require, however, confirmation for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.”</i>

6.3 Toxicological Evaluation of Plant Protection Product

zRMS's comment	The toxicological assessment of SAP09I/Spinosad 480 SC was carried out by a calculation method in accordance with the principles of Regulation 1272/2008. The calculation results were accepted. As it results from the calculations, SAP09I/Spinosad 480 SC does not have to be classified for human health, only the phrase EUH208 should be added on the label: <i>Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.</i> Details in Doc. C.
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The assessment has been conducted according to Regulation EC 1272/2008 requirements. The theoretical toxicological classification of the formulated product SAP09I (Spinosad 480 SC) is available on “Toxicological Classification” Document Part C. The available toxicological data are reported in the MSDS.

Table 6.3-1: Additional toxicological information relevant for classification/labelling of SAP09I / Spinosad 480 SC

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Spinosad (44.04% (w/w))	Aquatic Acute 1: H400 Aquatic Chronic 1: H410	Regulation 1272/2008 MSDS	None

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	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of non- active substance(s) (relevant for classification of product)	Coformulant (please refer to Part C)		Regulation 1272/2008 MSDS	EUH208: Contains 1,2- benzothiazol-3(2H)-one. May produce an allergic reaction
Further toxicological information	No data – not required	-	-	-

6.4 Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

zRMS's comment	Accepted. The composition of VOLKETE MAX (SAP09I/Spinosad 480 SC) is considered comparable to the composition of the product SpinTor 480 SC already registered in Poland, therefore the unprotected dermal absorption studies conducted for SpinTor 480 SC can be used for VOLKETE MAX.
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A summary of the dermal absorption rates for the active substances in SAP09I / Spinosad 480 SC are presented in the following table.

Products SAP09I / Spinosad 480 SC and SPINTOR 480 SC of Dow AgroScience Limited are identical, hence unprotected data for dermal absorption of product SpinTor 480 SC, for which 10-years protection period has expired, can be used to support this application.

Table 6.5-1: Dermal absorption rates for active substances in SAP09I / Spinosad 480 SC

Spinosad		
	Value	Reference
Concentrate	0.1%	Registration Report of SpinTor 480 SC (DOCUMENT M-III, GF-976 (SPINOSAD , 480 G/L SUSPENSION CONCENTRATE) ANNEX III, TIER 2 – SUMMARY, SECTION 3: TOXICOLOGY)
Dilution	2%	

6.5.1 Justification for proposed values - Spinosad

Proposed dermal absorption rates for spinosad are based on dermal absorption studies performed for a formulation identical to SAP09I / Spinosad 480 SC. The results are summarised in the table above.

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6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	SAP09I / Spinosad 480 SC
Formulation type	SC
Category	Insecticide
Active substance(s) (incl. content)	Spinosad 480 g/L (pure content)
AOEL systemic	0.012 mg/kg bw/d
AAOEL systemic	0.024 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	50 %
Dermal absorption	Concentrate: 0.1% Dilution: 2% (0.32 g/L) (Based on reference product (SpinTor 480 SC))

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 EU is given in Part B, Section 0.

Justification

The critical GAP was selected on a worst-case assumption

6.6.2 Operator exposure (KCP 7.2.1)

zRMS's comment	The Applicant performed operator exposure calculations using the EFSA OPEX calculator version 1.0.2 in accordance with the EFSA guidance (2022). The calculation results revealed that operator exposure is acceptable if the product is used for low vegetables (vehicle mounted) and the operator is wearing a workwear. In orchards, only normal use is acceptable, both for vehicle mounted and manual use (Hand-held and Knapsack), if the operator is wearing a workwear and additional gloves during the mixing/loading step. However, the Applicant did not calculate exposure for the dense option for manual use in orchards. Therefore, zRMS provided the calculation report in Appendix 3, generated from OPEX version 1.1.2 including the dense option in orchards. The calculation results revealed that there is no safe use for manual use in dense orchards. Therefore, finally, <u>operator exposure is acceptable only for vehicle mounted application and not acceptable for manual application in orchards (both Hand-held and Knapsack).</u>
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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 SAP09I / Spinosad 480 SC according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (acute exposure) and Table 6.6-3: (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical uses	Onion (max. 0.2 L product/ha) Apple (max. 0.3 L product/ha)
Model	AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032)

Table 6.6-3: Estimated operator exposure (acute exposure)

Spinosad			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		3x 0.096 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure	0.01	41.4
	M/L: Workwear App: Workwear	0.007	27.9
Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		2x 0.144 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure	0.1	446
	M/L: Workwear App: Workwear	0.02	102
	M/L: Workwear + Protected hands App: Workwear	0.02	99.9
Orchards/Outdoor/Upward spraying/Manual-hand held/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		2x 0.144 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure	0.2	861
	M/L: Workwear App: Workwear	0.01	49.2
Orchards/Outdoor/Upward spraying/Manual-hand held/Drift reduction: 0 %/95th percentile Crop density: Dense			

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Application rate		2x 0.144 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure		9977
	M/L: Workwear App: Workwear	0.2	904
	M/L: Workwear, gloves App: Workwear	0.2	904
	M/L: Workwear, gloves, mask App: Workwear, gloves, mask	0.2	869 (no safe use)
Orchards/Outdoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		2x 0.144 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure	0.2	827
	M/L: Workwear App: Workwear	0.007	28.1
Orchards/Outdoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/95th percentile Crop density: Dense			
Application rate		2x 0.144 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure		9980
	M/L: Workwear App: Workwear	0.2	908
	M/L: Workwear, gloves App: Workwear	0.2	906
	M/L: Workwear, gloves, mask App: Workwear, gloves, mask	0.2	870 (no safe use)

Table 6.6-4: Estimated operator exposure (long short term exposure)

Spinosad			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		3x 0.096 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.001	12.1
	M/L: Workwear App: Workwear	0.001	8.4
Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		2x 0.144 kg a.s./ha	

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Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.02	180
	M/L: Workwear App: Workwear	0.007	62
Orchards/Outdoor/Upward spraying/Manual-hand held/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		2x 0.144 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.07	548
	M/L: Workwear App: Workwear	0.004	34.6
Orchards/Outdoor/Upward spraying/Manual-hand held/Drift reduction: 0 %/75th percentile Crop density: Dense			
Application rate		2x 0.144 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure		8211
	M/L: Workwear App: Workwear	0.06	461
	M/L: Workwear, gloves, mask App: Workwear, gloves, mask	0.05	422 (no safe use)
Orchards/Outdoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		2x 0.144 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.05	433
	M/L: Workwear App: Workwear	0.003	23.6
Orchards/Outdoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Dense			
Application rate		2x 0.144 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure		8217
	M/L: Workwear App: Workwear	0.06	466
	M/L: Workwear, gloves, mask App: Workwear, gloves, mask	0.05	422 (no safe use)

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Conclusion

According to the model calculations, it can be concluded that no unacceptable risk for operators was identified when the product SAP09I is used as intended and provided that the below PPE/ risk mitigation measures are applied:

Low vegetables (Vehicle-mounted), ~~Orchards (Manual hand held and Manual knapsack):~~

- M/L: Workwear
- App: Workwear

Orchards (Vehicle-mounted):

- M/L: Workwear + Protected hands
- App: Workwear

6.6.2.2 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 and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

Comments of zRMS:	Acceptable. The Applicant performed worker exposure calculations using the EFSA OPEX calculator version 1.0.2 in accordance with the EFSA guidance (2022). <u>Results for <i>Low vegetable</i> scenario:</u> The calculation results revealed that worker exposure is acceptable for inspection/irrigation and reaching/picking activities when the worker is wearing a workwear. The EFSA calculator provides for harvest and maintenance activities only data for worker exposure when wearing workwear. In these cases, the AOEL value was exceeded (155% of AOEL), so further refinement was performed using the EUROPOEM II model. The calculation results revealed that worker exposure is acceptable when worker is wearing gloves during harvest and maintenance activities (31% of the AOEL). <u>Results for <i>Orchards</i> scenario:</u> The calculation results revealed that worker exposure is acceptable for inspection/irrigation and reaching/picking activities when the worker is wearing a workwear and gloves (17.9% and 71.6% of the AOEL, respectively). For maintenance/thinning activity, the AOEL is exceeded even when the worker is wearing gloves (129% of AOEL) and according to the calculation results, re-entry is restricted to 11 days. The EFSA calculator provides data on worker exposure when using gloves, therefore additional calculations using the EUROPOEM II model are unnecessary. As it was concluded, the composition of VOLKETE MAX (SAP09I/Spinosad 480 SC) is considered comparable to the composition of the product SpinTor 480 SC already registered in Poland, but <u>only unprotected studies</u> conducted for SpinTor 480 SC can be used for VOLKETE MAX. For this reason, the approach to the refined DFR used for SpinTor 480 SC was not accepted here.
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6.6.3.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SAP09I / Spinosad 480 SC according to the critical uses. Outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Onion (max. 0.2 L product/ha) Apple (max. 0.3 L product/ha)
Models	AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) EUROPOEM II model (Hemmen et al (2002) Post-application exposure of workers to pesticides in agriculture. Report of the re-entry working group. EUROPOEM II project. FAIR3 CT96-1406.)

Table 6.6-6: Estimated worker exposure (longer term exposure)

Spinosad				
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Re-entry restriction (days)
Low vegetables Reaching, picking (all except Brassica) / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 5800 cm ² /h TC (workwear (arms, body and legs covered)): 2500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 580 cm ² /h TC (gloves): NA cm ² /h DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days				
Application rate		3 x 0.096 kg a.s./ha		
Body weight: 60 kg	Potential	0.02	180	26
	Workwear	0.009	77.4	0
	Workwear and gloves	0.002	18	0
Low vegetables Inspection, irrigation (All) / Outdoor Work rate: 2 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days				
Application rate		3 x 0.096 kg a.s./ha		

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Body weight: 60 kg	Potential	0.01	96.8	0
	Workwear	0.001	10.8	0
	Workwear and gloves	0.001	9.7	0
Low vegetables Harvest (Brassica only) / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (potential): NA cm ² /h TC (workwear (arms, body and legs covered)): 5000 cm ² /h TC (workwear (arms, body and legs covered) and gloves): NA cm ² /h TC (gloves): NA cm ² /h DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days				
Application rate		3 x 0.096 kg a.s./ha		
Body weight: 60 kg	Potential	-	-	-
	Workwear	0.02	155	19
	Workwear and gloves	-	-	-
Low vegetables Maintenance (Brassica only) / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (potential): NA cm ² /h TC (workwear (arms, body and legs covered)): 5000 cm ² /h TC (workwear (arms, body and legs covered) and gloves): NA cm ² /h TC (gloves): NA cm ² /h DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days				
Application rate		3 x 0.096 kg a.s./ha		
Body weight: 60 kg	Potential	-	-	-
	Workwear	0.02	155	19
	Workwear and gloves	-	-	-
Orchards Maintenance/thinning / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 22500 cm ² /h TC (workwear (arms, body and legs covered)): 4500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 2250 cm ² /h TC (gloves): NA cm ² /h DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days				
Application rate		2 x 0.144 kg a.s./ha		
Body weight: 60 kg	Potential	0.2	1289	111
	Workwear	0.03	258	41

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	Workwear and gloves	0.02	129	11
Orchards Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days				
Application rate		2 x 0.144 kg a.s./ha		
Body weight: 60 kg	Potential	0.02	179	26
	Workwear	0.002	20	0
	Workwear and gloves	0.002	17.9	0
Orchards Searching, reaching, picking / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 3500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days				
Application rate		2 x 0.144 kg a.s./ha		
Body weight: 60 kg	Potential	0.09	716	86
	Workwear	0.02	200	31
	Workwear and gloves	0.009	71.6	0

Conclusion

According to the model calculations, it can be concluded that no unacceptable risk for workers was identified when the product SAP09I is used as intended and provided that the below PPE/ risk mitigation measures are applied:

Low vegetables (Reaching, picking (all except Brassica)), Orchards (Inspection, irrigation):

- Workwear (gloves are recommended)

Low vegetables (Inspection, irrigation (All))

- None

Low vegetables Harvest and Maintenance (Brassica only):

- Workwear + 19 days re-entry restriction

Orchards (Maintenance/thinning):

- Workwear and gloves + 11 days re-entry restriction

Orchards (Searching, reaching, picking):

- Workwear and gloves

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

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Refined calculations for Low vegetables Harvest and Maintenance (Brassica only) and Orchards (Maintenance/thinning) using EUROPOEM II model

Table 6.6-7: Estimated worker exposure (longer term exposure) – refined with EUROPOEM II model

Spinosad			
Model data	Level of PPE	Total absorbed dose (mg a.s./day)	% of systemic AOEL
Low vegetables Harvest (Brassica only) / Outdoor Maintenance (Brassica only) / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (workwear (arms, body and legs covered)): 5000 cm ² /h DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days MAF: 2.42			
Application rate		3 x 0.096 kg a.s./ha	
Body weight: 60 kg EUROPOEM II model	Potential	-	-
	Workwear	1.115	155
	Workwear and gloves	0.223	31
Orchards Maintenance/thinning / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (workwear (arms, body and legs covered)): 4500 cm ² /h DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days MAF: 1.79			
Application rate		2 x 0.144 kg a.s./ha	
Body weight: 60 kg	Potential	-	-
	Workwear	1.865	259
	Workwear and gloves	0.373	52

Conclusion

According to the model calculations, it can be concluded that no unacceptable risk for workers was identified when the product SAP09I is used as intended and provided that the below PPE/ risk mitigation measures are applied:

Low vegetables Harvest and Maintenance (Brassica only) and Orchards (Maintenance/thinning):

- Workwear and gloves

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Refined calculations for Low vegetables Harvest and Maintenance (Brassica only) and Orchards (Maintenance/thinning) using DFR data from RR SPINTOR 480 SC

Table 6.6-8: Estimated worker exposure (longer term exposure) – refined with updated DFR values

Spinosad				
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Re-entry restriction (days)
Low vegetables Harvest (Brassica only) / Outdoor Maintenance (Brassica only) / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (potential): NA cm ² /h TC (workwear (arms, body and legs covered)): 5000 cm ² /h TC (workwear (arms, body and legs covered) and gloves): NA cm ² /h TC (gloves): NA cm ² /h DFR: 0.16 µg/cm² foliage per kg a.s./ha DT50: 30 days				
Application rate		3 x 0.096 kg a.s./ha		
Body weight: 60 kg	Potential	-	-	-
	Workwear	0.001	8.3	0
	Workwear and gloves	-	-	-
Orchards Maintenance/thinning / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 22500 cm ² /h TC (workwear (arms, body and legs covered)): 4500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 2250 cm ² /h TC (gloves): NA cm ² /h DFR: 0.96 µg/cm² foliage per kg a.s./ha DT50: 30 days				
Application rate		2 x 0.144 kg a.s./ha		
Body weight: 60 kg	Potential	0.05	412	62
	Workwear	0.01	82.5	0
	Workwear and gloves	0.005	41.2	0

Conclusion

According to the model calculations, it can be concluded that no unacceptable risk for workers was identified when the product SAP09I is used as intended and provided that the below PPE/ risk mitigation measures are applied:

Low vegetables Harvest and Maintenance (Brassica only) and Orchards (Maintenance/thinning):

- Workwear (gloves are recommended)

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Comments of zRMS:	The refined calculations for Orchards were not accepted. According to GAP, the critical application for Orchards is 2 x 0.3 L/ha (0.144 kg a.s./ha. The worker exposure calculations with the default DFR of 3 µg/cm² are acceptable, while the refined DFR value was not accepted (see zRMS comment in A 2.11).
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Refined calculations Orchards (Maintenance/thinning) using DFR data from formulation VOLKETE MAX (SAP09I/Spinosad 480 SC)

Table 6.6-9: Estimated worker exposure (longer term exposure) – refined with updated DFR values of SAP09I

Spinosad				
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Re-entry restriction (days)
Orchards Maintenance/thinning / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg DFR: 1.19 µg/cm² foliage per kg a.s./ha DT50: 30 days				
Application rate		2 x 0.144 kg a.s./ha		
Body weight: 60 kg	Potential TC: 22500 cm²/h/person	0.06	511	71
	Workwear TC: 4500 cm²/h/person	0.01	102	1
	Workwear and gloves TC: 2250 cm²/h/person	0.006	51.1	0

Table 6.6-10: Estimated worker exposure (longer term exposure) – refined for application rate 1x 0.2 L/ha

Spinosad				
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Re-entry restriction (days)
Orchards Maintenance/thinning / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days				
Application rate		1 x 0.144 kg a.s./ha		
Body weight: 60 kg	Potential TC: 22500 cm²/h/person	0.09	720	86

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	Workwear TC: 4500 cm ² /h/person	0.02	144	16
	Workwear and gloves TC: 2250 cm ² /h/person	0.009	72	0

Conclusion

According to the model calculations, it can be concluded that no unacceptable risk for workers was identified when the product SAP09I is used as intended and provided that the below PPE/ risk mitigation measures are applied:

Orchards (Maintenance/thinning):

- Workwear and gloves.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Refinement of generic DFR value was based on unprotected data from Registration Report of SPINTOR 480 SC of Dow AgroScience Limited:

DOCUMENT M-III, GF-976 (SPINOSAD, 480 G/L SUSPENSION CONCENTRATE)

ANNEX III

TIER 2 – SUMMARY

SECTION 3: TOXICOLOGY

Exposure from contact with the crop

In order to estimate the amount of dermal exposure from contact with crops (brassicac/onions) and pome fruit it is necessary to determine the potential foliar deposit (mg as/cm²) for each crop. Foliar deposit can be estimated using the Leaf Area Index (LAI m²/m²) of the crop which applies to one side of the leaf, the application rate (AR, g as/ha).

$$\text{Foliar deposit} = \text{AR} / \text{LAI}$$

Table 7.2.3.1-1: Foliar deposit (based on Leaf Area Index)

Crop	Leaf area index	Max. Dose Rate g as /ha	Dislodgeable Foliar Residue mg as/cm ²
Pome	1.5	120	0.0008
Cauliflowers	5.9#	96	0.00016

Value based on data for potatoes
(note: 1 hectare = 10,000 m² or 10⁸ cm²)

DFR values for SAP09I:

Crop	Leaf area index m ² /m ²	Max. Dose Rate g as /ha	Dislodgeable Foliar Residue mg as/cm ²	Dislodgeable Foliar Residue µg as/cm ²
Orchards	1.5	144	0.00096	0.96
Brassica	5.9#	96	0.00016	0.16

Value based on data for potatoes
(note: 1 hectare = 10,000 m² or 10⁸ cm²)

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Refinement used on Orchards

Report No. 512SRES21X02 (Torres, M., 2022)

The objective of this study was to determine the decline of Spinosad (Spinosad as sum of spinosyn A and spinosyn D) in dislodgeable foliar residues (DFR) from apple and pear following one application of the formulated product SAP09I containing Spinosad 48% w/v (=480 g/L) rate of 0.2 L f.p./ha (=96 g Spinosad/ha) onto the crop in open field conditions.

Samples were generated in 3 trials, 2 in Spain (Trial SRES21-600-512IX in apple and trial SRES21-601-512IX in pear) and 1 in Portugal (Trial SRPT21-076-512IX in pear).

Moreover, the quantification of Spinosyn A and Spinosyn D in the samples was performed using a linear regression analytical calibration with matrix matched calibration standards. Procedural recovery tests in control specimens were injected concurrently with the analytical specimens.

The results were in accordance with the requirements on SANTE/2020/12830, Rev 1. On the table below the relevant values for the DFR refinement were highlighted, the results for all the samples are compiled on point A 2.11.

Trial	Days	Spinosad (µg/cm ²)	Mean Spinosad (µg/cm ²)	Application rate	New DFR (µg/cm ² kg as/ha)
SRPT21-076-512IX	0DAA	0.089	0.114	0.2 L p.f./ha (= 0.096 kg as/ha)	1.1875
SRES21-600-512IX		0.088			
SRES21-601-512IX		0.165			

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

Comments of zRMS:	Acceptable. The Applicant performed resident and bystander exposure calculations using the EFSA OPEX calculator version 1.0.2 in accordance with the EFSA guidance (2022). The calculation results revealed that resident and bystander exposure (both for child and adult) is acceptable (below the AOEL) considering all pathways of exposure – drift, vapour, deposit and re-entry when a 2-3 m buffer zone is used in the <i>Low vegetable</i> scenario and a 5 m buffer zone is used in the <i>Orchards</i> scenario (early and late season).
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6.6.4.1 Estimation of resident and bystander exposure

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

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Table 6.6-11 shows the exposure model used for estimation of resident and bystander exposure to Spinosad. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term resident exposure) and Table 6.6-12: Estimated bystander exposure (acute)

Spinosad			
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Low vegetables Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 200 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Application rate		3 x 0.096 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.001	5.1
	Vapour (95 th perc.)	0.0008	3.3
	Deposits (95 th perc.)	0.0007	2.7
	Re-entry (95 th perc.)	0.002	6.5
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.0003	1.3
	Vapour (95 th perc.)	0.0003	1.1
	Deposits (95 th perc.)	0.0002	0.8
	Re-entry (95 th perc.)	0.0009	3.6
Orchards Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 300 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Application rate		2x 0.144 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.01	43
	Vapour (95 th perc.)	0.0008	3.3
	Deposits (95 th perc.)	0.002	10.1
	Re-entry (95 th perc.)	0.003	12.1
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.006	23.7
	Vapour (95 th perc.)	0.0003	1.1
	Deposits (95 th perc.)	0.0008	3.4

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	Re-entry (95 th perc.)	0.002	6.7
Orchards Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 300 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Application rate		2x 0.144 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.01	43
	Vapour (95 th perc.)	0.0008	3.3
	Deposits (95 th perc.)	0.001	4.3
	Re-entry (95 th perc.)	0.003	12.1
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.006	23.7
	Vapour (95 th perc.)	0.0003	1.1
	Deposits (95 th perc.)	0.0003	1.5
	Re-entry (95 th perc.)	0.002	6.7

Table 6.6-13: Estimated resident exposure (long term exposure)

Spinosad			
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Low vegetables Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 200 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Number of applications and application rate		3 x 0.096 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0005	4.4
	Vapour (75 th perc.)	0.0008	6.7
	Deposits (75 th perc.)	0.0002	1.9
	Re-entry (75 th perc.)	0.002	13.1
	Sum (mean)	0.003	20.9
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0001	1
	Vapour (75 th perc.)	0.0003	2.3
	Deposits (75 th perc.)	6e-0.5	0.5
	Re-entry (75 th perc.)	0.0009	7.3
	Sum (mean)	0.001	8.9
Orchards			

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Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 300 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Number of applications and application rate		2x 0.144 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.004	37.3
	Vapour (75th perc.)	0.0008	6.7
	Deposits (75th perc.)	0.001	8.3
	Re-entry (75th perc.)	0.003	24.2
	Sum (mean)	0.007	56.7
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	20.7
	Vapour (75th perc.)	0.0003	2.3
	Deposits (75th perc.)	0.0003	2.8
	Re-entry (75th perc.)	0.002	13.4
	Sum (mean)	0.003	28.5
Orchards Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 300 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.004	37.3
	Vapour (75th perc.)	0.0008	6.7
	Deposits (75th perc.)	0.0004	3.2
	Re-entry (75th perc.)	0.003	24.2
	Sum (mean)	0.067	52.5
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	20.7
	Vapour (75th perc.)	0.0003	2.3
	Deposits (75th perc.)	0.0001	1.1
	Re-entry (75th perc.)	0.002	13.4
	Sum (mean)	0.003	27.1

Conclusion

Regarding above calculations it is concluded that the use of SAP09I according to the GAP Table, causes no risk to human health if the product is used in accordance with the intended uses (acute bystander exposure). Detailed calculations are in Appendix 3.

Table 6.6-11: Exposure models for intended uses

Critical use	Onion (max. 0.2 L product/ha)
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	Apple Pear, wild apple, quince (max. 0.3 L product/ha)
Model	AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032)

Table 6.6-12: Estimated bystander exposure (acute)

Spinosad			
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Low vegetables Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 200 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Application rate		3 x 0.096 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.001	5.1
	Vapour (95 th perc.)	0.0008	3.3
	Deposits (95 th perc.)	0.0007	2.7
	Re-entry (95 th perc.)	0.002	6.5
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.0003	1.3
	Vapour (95 th perc.)	0.0003	1.1
	Deposits (95 th perc.)	0.0002	0.8
	Re-entry (95 th perc.)	0.0009	3.6
Orchards Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 300 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Application rate		2x 0.144 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.01	43
	Vapour (95 th perc.)	0.0008	3.3
	Deposits (95 th perc.)	0.002	10.1
	Re-entry (95 th perc.)	0.003	12.1

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Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.006	23.7
	Vapour (95 th perc.)	0.0003	1.1
	Deposits (95 th perc.)	0.0008	3.4
	Re-entry (95 th perc.)	0.002	6.7
Orchards Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 300 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Application rate		2x 0.144 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.01	43
	Vapour (95 th perc.)	0.0008	3.3
	Deposits (95 th perc.)	0.001	4.3
	Re-entry (95 th perc.)	0.003	12.1
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.006	23.7
	Vapour (95 th perc.)	0.0003	1.1
	Deposits (95 th perc.)	0.0003	1.5
	Re-entry (95 th perc.)	0.002	6.7

Table 6.6-13: Estimated resident exposure (long term exposure)

Spinosad			
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Low vegetables Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 200 L DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Number of applications and application rate		3 x 0.096 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0005	4.4
	Vapour (75 th perc.)	0.0008	6.7
	Deposits (75 th perc.)	0.0002	1.9
	Re-entry (75 th perc.)	0.002	13.1
	Sum (mean)	0.003	20.9
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0001	1
	Vapour (75 th perc.)	0.0003	2.3
	Deposits (75 th perc.)	6e-0.5	0.5

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	Re-entry (75th perc.)	0.0009	7.3
	Sum (mean)	0.001	8.9
Orchards Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 300 L DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			
Number of applications and application rate		2x 0.144 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.004	37.3
	Vapour (75th perc.)	0.0008	6.7
	Deposits (75th perc.)	0.001	8.3
	Re-entry (75th perc.)	0.003	24.2
	Sum (mean)	0.007	56.7
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	20.7
	Vapour (75th perc.)	0.0003	2.3
	Deposits (75th perc.)	0.0003	2.8
	Re-entry (75th perc.)	0.002	13.4
	Sum (mean)	0.003	28.5
Orchards Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 300 L DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.004	37.3
	Vapour (75th perc.)	0.0008	6.7
	Deposits (75th perc.)	0.0004	3.2
	Re-entry (75th perc.)	0.003	24.2
	Sum (mean)	0.067	52.5
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	20.7
	Vapour (75th perc.)	0.0003	2.3
	Deposits (75th perc.)	0.0001	1.1
	Re-entry (75th perc.)	0.002	13.4
	Sum (mean)	0.003	27.1

Conclusion

Regarding above calculations it is concluded that the use of SAP09I according to the GAP Table, causes no risk to human health if the product is used in accordance with the intended uses.

6.6.4.2 Measurement of resident and/or bystander exposure

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

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

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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 7.2/03	Torres, M.	2022	SAP09I (Spinosad 480 g/L) – DISLodgeABLE FOLIAR RESIDUE DECLINE STUDY ON POMEFRUIT (APPLE OR PEAR) IN SOUTHERN EUROPE IN 2021 Syntech Research Group Report No. 512SRES21X02 GEP Unpublished	N	Task force “Spinosad 48% SC JDDA”
KCP 7.2/04	Gaffney, V.	2022	Determination of the Decline of Spinosad (Spinosyn A and Spinosyn D) Dislodgeable Foliar Residues on Pomefruit (Apple and Pear) in Southern Europe in 2021 after Application of SAP09I (Spinosad 480 g/L). 2022 Ascenza Agro S.A. Reprot No.:DFR13/21 GLP Unpublished	N	Task force “Spinosad 48% SC JDDA”

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

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 7.3	-	2002	Dermal absorption study in rats with [¹⁴ C]-Spinosyn, formulated as a suspension concentrate and as a spray dilution xxxxxxxxxxxxxxxxxx Report V4356 (Ref. H12) GLP unpublished	Y	Unprotected (originally DAS)
KCP 7.3	-	2002	In vitro percutaneous absorption study with [¹⁴ C]Spinosyn through rat and human skin xxxxxxxxxxxxxxxxxxxxxxxxxx Report V3474 (Ref. H13) GLP unpublished	Y	Unprotected (originally DAS)

DAS: Dow AgroScience Limited

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

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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

Comments of zRMS:	Accepted. The toxicological assessment of SAP09I/Spinosad 480 SC was carried out by a calculation method in accordance with the principles of Regulation 1272/2008. Details in Doc. C.
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Not required.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Accepted. Details in Doc. C.
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The classification and labelling of SAP09I for human health effects, based on existing data for all formulation components is provided in Part C section, Toxicological Classification of this registration report.

Conclusion

Following the assessment of the formulants properties, SAP09I should **not be classified** for acute oral toxicity, according to Regulation (EC) 1272/2008.

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

Comments of zRMS:	Accepted. Details in Doc. C.
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The classification and labelling of SAP09I for human health effects, based on existing data for all formulation components is provided in Part C section, Toxicological Classification of this registration report.

Conclusion

Following the assessment of the formulants properties, SAP09I should **not be classified** for acute dermal toxicity according to Regulation EC 1272/2008.

A 2.4 Acute (EC) toxicity (KCP 7.1.3)

Comments of zRMS:	Accepted. Details in Doc. C.
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The classification and labelling of SAP09I for human health effects, based on existing data for all formulation components is provided in Part C section, Toxicological Classification of this registration report.

Conclusion

Following the assessment of the formulants properties, SAP09I should **not be classified** for acute inhalation toxicity, according to Regulation (EC) 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Accepted. Details in Doc. C.
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The classification and labelling of SAP09I for human health effects, based on existing data for all formulation components is provided in Part C section, Toxicological Classification of this registration report.

Conclusion

Following the assessment of the formulants properties, SAP09I should **not be classified** for skin irritation according to Regulation (EC) 1272/2008.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Accepted. Details in Doc. C.
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The classification and labelling of SAP09I for human health effects, based on existing data for all formulation components is provided in Part C section, Toxicological Classification of this registration report.

Conclusion

Following the assessment of the formulants properties, SAP09I should **not be classified** for eye irritation according to Regulation (EC) 1272/2008.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Accepted with the phrase EUH208 on the label: <i>Contains 1,2-benzizothiazol-3(2H)-one. May produce an allergic reaction.</i> Details in Doc. C.
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The classification and labelling of SAP09I for human health effects, based on existing data for all formulation components is provided in Part C section, Toxicological Classification of this registration report.

Conclusion

Following the assessment of the formulants properties, it is proposed that SAP09I should **not be classified** for skin sensitization, according to Regulation (EC) 1272/2008. Only the phrase EUH208 should be added on the label: *Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.*

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

Not required.

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)

Products SAP SAP09I / Spinosad 480 SC and SPINTOR 480 SC of Dow AgroScience Limited are identical, hence unprotected data for dermal absorption of product SPINTOR 480 SC, for which 10-years protection period has expired, can be used to support this registration.

Comments of zRMS:	Accepted. The composition of VOLKETE MAX (SAP09I/Spinosad 480 SC) is considered comparable to the composition of the product SpinTor 480 SC already registered in Poland, therefore the unprotected dermal absorption studies conducted for SpinTor 480 SC can be used for VOLKETE MAX. The values of dermal absorption of 0.1% (concentration) and 2% (dilution) was also accepted in document SANCO/1428/2001 – rev. final of 14 July 2006.
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Registration Report of SPINTOR 480 SC of Dow AgroScience Limited:
DOCUMENT M-III, GF-976 (SPINOSAD , 480 G/L SUSPENSION CONCENTRATE)
ANNEX III
TIER 2 – SUMMARY
SECTION 3: TOXICOLOGY

Overall conclusion, Point 7.3, Dermal absorption

Dermal absorption of spinosad from undiluted NAF-85 and the most dilute spray was investigated in vivo in the rat and in vitro in rat and human skin in compliance with OECD test guidelines 427 and 428.

In rats, total in vivo absorption over 120 hours was 11% and 0.5% of applied radioactivity at the low and high dose, respectively. The maximum daily absorption was ca. 4% and 0.3% at these concentrations. For risk assessment purposes dermal absorption should be calculated as a maximum daily rate so that the maximum daily exposure can be calculated for comparison with the relevant AOEL, which has units of mg/kg bw/day.

In excised rat skin, total in vitro absorption over 72 hours was 4.6% and 0.08% of applied radioactivity at the low and high dose, respectively. The maximum daily absorption was ca. 2% and 0.04% at these concentrations.

In excised human skin, total in vitro absorption over 72 hours was 2.3% and 0.02% of applied radioactivity at the low and high dose, respectively. The maximum daily absorption was ca. 1% and 0.01% at these concentrations.

Based on a comparison of either total absorption or maximum absorption over 24 hours, in vitro absorption of spinosad from a spray dilution and undiluted GF-976 (NAF-85) was ca. 2- and 4-fold lower in human versus rat skin, respectively. This is consistent with published data which show that absorption in rats is typically 2-10 times higher than in humans (ECETOC No. 20, 1993; Ross, J.H., et al., (2000) Regulatory Toxicology and Pharmacology, 31(1), 53-58).

These in vivo and in vitro data can be applied to the following equation cited in the EU Guidance Document on Dermal Absorption (Sanco/222/2000 rev. 6, 27 November 2002):

$$\text{In vivo human absorption} = \text{in vivo rat absorption} \times \frac{\text{in vitro human absorption}}{\text{in vitro rat absorption}}$$

$$\text{GF-976: in vivo human absorption} = 0.3\% \times \frac{0.01\%}{0.04} = 0.075\%$$

$$\text{Spray: in vivo human absorption} = 4\% \times \frac{1\%}{2} = 2\%$$

Based on these data, dermal absorption values of 0.1% and 2% were used in the operator, bystander and re-entry worker risk assessments in IIIA7.2.

Dermal absorption rat in vivo (IIIA 7.3/01)

Report: **Dermal absorption study in rats with [¹⁴C]-Spinosyn, formulated as a suspension concentrate and as a spray dilution**
 xxxx (2002)
 xxxxxxxxxxxxxxxxxxxxxxxxx. Report V4356

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	(Ref. H12)
Guidelines:	OECD 427, draft December 2000 Deviations from guideline: None
GLP	Yes. Certified laboratory.
Methodology:	The absorption of [14C]-Spinosyn A was assessed in vivo in female Fischer 344 rats, 9-10 weeks of age following a single topical application of either undiluted NAF-85 (480 g /L) or a spray dilution (0.32 g/L), chosen to represent the most dilute concentration that will be applied to crops. Both test preparations were applied to a 10 cm² area at a rate of 10 µl/cm² to the clipped dorsal skin of the rats. Nominal doses equated to 0.0032 mg/cm² and 4.8 mg/cm²; actual doses administered were 0.0018 mg/cm² and 5.8 mg/cm². The dose remained in contact with the skin for 8 hours then the application site was washed with soap solution to aid removal of residual dose remaining on the skin. Each test preparation was administered to a group of 12 animals. Four animals per group were killed at 24, 72 and 120 hours after dosing. Radioactivity was determined in the skin washes, urine and faeces each 24-hour period, cage wash, application site, untreated (control) skin, wash solution of cover and 'O'-ring, and at termination, blood, plasma and residual carcass.
Findings:	The overall average total recoveries were between 93 and 108% for all six groups of animals. A summary of systemic absorption is presented in Table 7.3/01-I. Removal of the dose after 8 hours was relatively efficient for the high dose (ca. 90-94%) compared with the low dose (72-74%). In both situations, absorption of the dose is mainly complete after 24-72 hours. Continual elimination of radioactivity through 120 hours was considered to reflect loss from the carcass. The maximum average absorption was ca. 4% per day and 0.3% per day at the low and high dose, respectively.

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Table 7.3/01-1: Percentage of applied dose following a single topical application

Group	Low dose			High dose		
Time	24	72	120	24	72	120
Urine	0.70	1.16	1.32	< 0.01	0.01	0.02
Faeces	0.49	1.16	2.44	0.02	0.04	0.25
Cage wash	1.67	1.18	1.23	0.01	< 0.01	0.01
Control skin/blood	0.02	0.05	0.09	0.01	< 0.01	0.01
Carcass	1.27	5.95	5.39	0.023	0.04	0.16
Total absorbed	4.15	9.52	10.48	0.28	0.09	0.45

Conclusion: *In rats, total absorption in vivo was 11% and 0.5% of applied radioactivity at the low and high dose, respectively. The maximum daily absorption was 4.15% and 0.28% at these concentrations.*

Dermal absorption rat: human in vitro (IIIA 7.3/02)

Report: *In vitro percutaneous absorption study with [¹⁴C]Spinosyn through rat and human skin
xxxx (2002)
xx. Report V3474 (Ref. H13)*

Guidelines: *OECD 428, draft December 2000
Deviations from guideline:
None*

GLP *No*

Methodology: *The study design comprised six experiments combining a range of test preparations, doses and skins types, as summarised in Table 7.3/02-1.*

Table 7.3/02-1: Summary of study design

Group	Species	Test Preparation	Radiolabelled Test Substance	Concentration (mg/ml)
A	Rat	Spinosyn A in Dowanol DPM	Spinosyn A	100
B	Rat	Spinosyn D in Dowanol DPM	Spinosyn D	100*
C	Rat	NAF-85 formulation	Spinosyn A	480
D	Human	NAF-85 formulation	Spinosyn A	480

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<i>E</i>	<i>Rat</i>	<i>NAF-85 Spray Solution</i>	<i>Spinosyn A</i>	<i>0.32</i>
<i>F</i>	<i>Human</i>	<i>NAF-85 Spray Solution</i>	<i>Spinosyn A</i>	<i>0.32</i>

** Achieved concentration was only 14.4 mg/ml due to limited solubility of spinosyn D in vehicle*

Methodology:

Each test preparation was applied topically to an area of 0.64 cm² of rat or human skin. The rat skin was obtained from freshly sacrificed female Fischer 344 rats. The human skin was freshly thawed, dermatomed and trimmed of subcutaneous fat so that the thickness was comparable to that of the rat skin.

The test preparation (10 µL/cm²) remained in contact with the skin membrane for 72 hours. Samples of the receptor fluid were taken at 6, 24, 48 and 72 hours. At the cessation of the study, the skin was washed and wiped in an attempt to remove any test preparation remaining on the skin surface. The receptor fluid, washings/wipings, the skin and cell washes were analyzed for residual radioactivity using Liquid Scintillation Counting. Dermal absorption was calculated based on the radioactivity found in the receptor fluid.

Results:

Recoveries ranged from 82-97%. Analysis of the test preparations showed the actual doses applied to the skin were as presented in Table 7.3/02-2. The dermal absorption values resulting from each application are summarised in Table 7.3/02-2/3. Absorption of Spinosyn D was about 4-fold higher than Spinosyn A but as Spinosyn A is present at 7-fold higher levels (spinosad is typically 85% A, 15% D) the difference is not significant. Over a 72-hour period, absorption of spinosyn A from NAF-85 was 0.08% and 0.02% in rat and human skin, respectively. Absorption of spinosyn A from the spray solution tested was 2.3% through human skin compared to 4.58% through rat skin.

Table 7.3/02-2: Applied Dose

<i>Group</i>	<i>Target applied mg</i>	<i>Actual applied mg</i>	<i>Percentage of target</i>
<i>A</i>	<i>0.599</i>	<i>0.740</i>	<i>123</i>
<i>B</i>	<i>0.086</i>	<i>0.086</i>	<i>100</i>
<i>C</i>	<i>2.882</i>	<i>3.36</i>	<i>117</i>
<i>D</i>	<i>2.882</i>	<i>3.36</i>	<i>117</i>
<i>E</i>	<i>0.002</i>	<i>0.0007</i>	<i>35</i>
<i>F</i>	<i>0.002</i>	<i>0.0007</i>	<i>35</i>

The test concentration in Groups E and F was lower than target because the spinosyn A could not be efficiently resuspended.

Table 7.3/02-3: Mean Percentage Dermal Absorption of Spinosyn from Various Test Preparations

<i>Group</i>	<i>A</i>	<i>B</i>
	<i>Spinosyn A</i>	<i>Spinosyn D</i>
	<i>Rat</i>	<i>Rat</i>

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<i>Duration (hrs)</i>	<i>Mean Percentage Absorption</i>	
6	0.01	0.03
24	0.06	0.19
48	0.23	0.90
72	0.49	1.85

<i>Group</i>	<i>C</i>	<i>D</i>
	<i>NAF-85</i>	<i>NAF-85</i>
	<i>Rat</i>	<i>Human</i>
<i>Duration (hrs)</i>	<i>Mean Percentage Absorption</i>	
6	0.00	0.00
24	0.01	0.00
48	0.04	0.01
72	0.08	0.02

<i>Group</i>	<i>E</i>	<i>F</i>
	<i>Spray Dilution</i>	<i>Spray Dilution</i>
	<i>Rat</i>	<i>Human</i>
<i>Duration (hrs)</i>	<i>Mean Percentage Absorption</i>	
6	0.24	0.23
24	0.83	0.65
48	2.51	1.35
72	4.58	2.30

Conclusion:

In rats, total absorption in vitro was 4.6% and 0.08% of applied radioactivity at the low and high dose, respectively. The maximum daily absorption was ca. 2% and 0.04% at these concentrations.

In humans, total absorption in vitro was 2.3% and 0.02% of applied radioactivity at the low and high dose, respectively. The maximum daily absorption was ca. 1% and 0.01% at these concentrations.

Based on a comparison of either total absorption at 72 hours or maximum absorption over 24 hours, absorption of spinosyn A from a spray dilution and undiluted NAF-85 was 2- and 4-fold lower in human versus rat skin, respectively.

A 2.11 Other/Special Studies

Comments of zRMS: Study not accepted.

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	The DRF decline study on apple and pear was performed in Southern (not Central) Europe in two provinces in Spain (Alicante and Castellon) and one district in Portugal (Leiria). Furthermore, the application rate in the study was lower than in GAP (1 x 0.2 L/ha vs 2 x 0.3 L/ha). The test conditions do not fully reflect those in the Central zone, therefore the study was not accepted.
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Not relevant.

Dislodgeable Foliar Residues Studies

FIELD PHASE

Reference	KCP 7.2/01
Report	SAP09I (Spinosad 480 g/L) – DISLodgeable Foliar Residue Decline Study on Pomefruit (Apple or Pear) in Southern Europe in 2021 Torres, M., 2022, Report No. 512SRES21X02
Guideline(s)	- Regulation (EC) No 1107/2009; Concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, 21/10/2009. - Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament. "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997. - OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009). - OECD Series on Testing and Assessment No. 9 "Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application", Paris 1997. OCDE/GD(97)148. - U.S. EPA Series 875.2100 Occupational and Residential Exposure Test Guidelines, Foliar Dislodgeable Residue Dissipation.
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

SUMMARY

SAP09I (Spinosad 480 g/L) is an insecticide based on chemical compounds (Spinosyn A & Spinosyn D) found in the bacterial species *Saccharopolyspora spinosa* developed by Task force "Spinosad 48% SC JDDA". Spinosad is highly active, by both contact and ingestion for the control of a broad range of insect pests, including Lepidoptera, Diptera, Thysanoptera, Coleoptera, Orthoptera, and Hymenoptera.

The objective of this study was to generate specimens on decline of Spinosad (Spinosad, sum of spinosyn A and spinosyn D) in dislodgeable foliar residues (DFR) from apple and/or pear in order to support the

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registration of market value of plant protection products applied according good agricultural practice (GAP).

Three decline curve trials coded as SRES21-600-512IX, SRES21-601-512IX and SRPT21-076-512IX were conducted in Agres (Alicante - Spain), Castellnovo (Castellon– Spain) and Alcobaça (Leiria - Portugal) during 2021, respectively, and the dislodging and storage areas were done at Test Facility for Spanish trials and for the Portuguese trial at the Field Test Site SynTech Research Portugal.

One foliar application of the formulated product SAP09I containing a nominal concentration of Spinosad 48% w/v (=480 g/L) was applied at a target rate of 0.2 L f.p./ha (=96 g Spinosad/ha) onto the crop in open field conditions between BBCH 87-89 and 7 days before normal commercial harvest (=DBNCH) for both trials.

The formulation was applied using appropriate application equipment at the proposed normal use rates and timings.

Untreated samples (leave discs) were collected at 0 days before application (=DBA) and 7 days after application (=DAA), while treated samples were collected, at 0 DBA, 0 DAA, 24 hours after application (=HAA), 3 DAA, 5 DAA, and 7 DAA.

Untreated samples were also collected for field fortifications purposes at 0 DBA, 3DAA and 7 DAA.

The specimens (untreated & treated) were stored separated and deep frozen [max: -18°C, min: -29.5°C] until their shipment to the Test Facility Laboratorio de Resíduos ASCENZA AGRO S.A., Portugal to be analysed in a different GLP study coded as DFR13/21 being the Study Director Vanessa Gaffney. Shipment was done in insulated boxes with dry ice and samples were received in perfect conditions with dry ice presence.

There were no unusual events that affected this study.

ANALYTICAL PHASE

Reference	KCP 7.2/02
Report	Determination of the Decline of Spinosad (Spinosyn A and Spinosyn D) Dislodgeable Foliar Residues on Pomefruit (Apple and Pear) in Southern Europe in 2021 after Application of SAP09I (Spinosad 480 g/L), 2022. Gaffney, V., 2022, Report No. DFR13/21
Guideline(s)	▪ Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17). ▪ Directive 2004/10/EC (codified version) from European Parliament and Council of 11 February 2004. ▪ Decreto-Lei nº 99/2000 of 30 May 2000 (Portuguese decree on OECD Principles of GLP). ▪ Regulation (EC) nº 1107/2009 of the European Parliament and of Council of 21 October 2009. ▪ Commission Regulation (EU) Nº 283/2013 of the Commission of 1 March 2013; ▪ Commission Regulation (EU) Nº 284/2013 of the Commission of 1 March 2013.

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Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

OBJECTIVE

The objective of this study was to determine the decline of Spinosad (Spinosad as sum of spinosyn A and spinosyn D) in dislodgeable foliar residues (DFR) from apple and pear following one application of the formulated product SAP09I containing Spinosad 48% w/v (=480 g/L) rate of 0.2 L f.p./ha (=96 g Spinosad/ha) onto the crop in open field conditions.

Leaf disc wash solutions and leaf disc wash field fortified solutions were analysed for residues of spinosyn A and spinosyn D. The analytical method was developed and validated within the scope of this study.

Samples were generated in 3 trials, 2 in Spain (Trial SRES21-600-512IX in apple and trial SRES21-601-512IX in pear) and 1 in Portugal (Trial SRPT21-076-512IX in pear), during the field phase of study 512SRES21X02 from SynTech Research Spain S.L. which is directed by Manuel Torres.

This analytical phase was conducted by an independent study from the field phase.

SUMMARY

Leaf disc wash solutions and leaf disc wash field fortified solutions were sent frozen to Laboratório de Resíduos de Pesticidas (LabRP) in order to analyse the magnitude of spinosyn A and spinosyn D in dislodgeable foliar residues from apple and pear, generated under three field trials, 2 in Spain and 1 trial in Portugal by SynTech Research Spain S.L., under the direction of Manuel Torres.

The solutions were obtained by washing leaf discs from apple or pear leaves with an aqueous solution of a surfactant after one applications of the formulated product SAP09I.

According to the field information, sampling has been taken at 0 DBA (DBA – days before application), 0 DAA (DAA – days after application), 24 HAA (HAA – hours after application), 3 DAA, 5 DAA and 7 DAA.

Untreated modality and control samples have been performed at 0 DBA and 7 DAA. Field recovery tests has been performed at 0 DBA, 3 DAA and 7 DAA. Regarding treated modalities sampling has been performed at 0 DBA, 0 DAA, 24 HAA, 3 DAA, 5 DAA and 7 DAA.

To assess the stability of spinosyn A and Spinosyn D residues under field, storage and transport conditions, leaf disc wash field fortified solutions were also delivered together with the samples.

Although the untreated specimens's fortifications in the dislodgeable solution have been performed by the field unit, the fortification solutions were prepared by Laboratório de Resíduos de Pesticidas and shipped chilled at the attention of the field phase principal investigators of study 512SRES21X02. Field Fortification tests were performed the 2000 µg/L and 2 µg/L levels.

After reception all samples were stored at $\leq -18^{\circ}\text{C}$ until analysis.

The validation assays were performed under the current study.
Specimens were analysed by direct injection into LC-MS/MS.

Moreover, the quantification of Spinosyn A and Spinosyn D in the samples was performed using a linear regression analytical calibration with matrix matched calibration standards.

Procedural recovery tests in control specimens were injected concurrently with the analytical specimens.

The results were in accordance with the requirements on SANTE/2020/12830, Rev 1.

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Final results are compiled in the tables below.

Trial	Syntech Sample Code	LabRP Sample Code	Specimen	Plot	Days	Mean Spinosyn A ^{**} (µg/cm ²)	Corrected Mean Spinosyn A [*] (µg/cm ²)	Mean Spinosyn D ^{**} (µg/cm ²)	Corrected Mean Spinosyn D [*] (µg/cm ²)	Spinosad ^{***} (µg/cm ²)
SRPT21-076-512IX - Portugal	SRPT21-076-512IX-01	1682/DFR13/21	Leaf disc wash	U	0 DBA	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-02	1683/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-03	1684/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-10	1691/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-11	1692/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-12	1693/DFR13/21		T	0 DAA	0.082	0.079	0.01	0.01	0.089
	SRPT21-076-512IX-13	1694/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-14	1695/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-15	1696/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-16	1697/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-17	1698/DFR13/21			24 HAA	0.009	0.009	0.002	0.002	0.011
	SRPT21-076-512IX-18	1699/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-25	1706/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-26	1707/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-27	1708/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-28	1709/DFR13/21			3 DAA	0.003	0.003	0.001	0.001	0.005
	SRPT21-076-512IX-29	1710/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-30	1711/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-31	1712/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-32	1713/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-33	1714/DFR13/21		U	7 DAA	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-40	1721/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-41	1722/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRPT21-076-512IX-42	1723/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ

T - treated plot; U - untreated plot; DBA - days before application; DAA - days after application; LOQ - limit of quantification 0.001 µg/cm² for Spinosyn A and Spinosyn D).

* Values corrected taking into account the overall recovery of the field fortification samples of this trial for each analyte (103.3 % for Spinosyn A and 98.3 % for Spinosyn D).

** When one replicate is < LOQ, the LOQ value is used as default value for calculating the mean.

*** Spinosad as the sum of Spinosyn A and Spinosyn D (LOQ 0.002 µg/cm²).

Table 1 - Summary of results from trial SRPT21-076-512IX - Portugal

Trial	Syntech Sample Code	LabRP Sample Code	Specimen	Plot	Days	Mean Spinosyn A ^{**} (µg/cm ²)	Corrected Mean Spinosyn A [*] (µg/cm ²)	Mean Spinosyn D ^{**} (µg/cm ²)	Corrected Mean Spinosyn D [*] (µg/cm ²)	Spinosad ^{***} (µg/cm ²)
SRES21-600-512IX - Spain	SRES21-600-512IX-01	1544/DFR13/21	Leaf disc wash	U	0 DBA	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-02	1545/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-03	1546/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-10	1553/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-11	1554/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-12	1555/DFR13/21		T	0 DAA	0.075	0.072	0.015	0.015	0.088
	SRES21-600-512IX-13	1556/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-14	1557/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-15	1558/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-16	1559/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-17	1560/DFR13/21			24 HAA	0.003	0.002	0.001	0.001	0.003
	SRES21-600-512IX-18	1561/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-25	1568/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-26	1569/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-27	1570/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-28	1571/DFR13/21			3 DAA	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-29	1572/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-30	1573/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-31	1574/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-32	1575/DFR13/21		U	7 DAA	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-33	1576/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-40	1583/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-41	1584/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-600-512IX-42	1585/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ

T - treated plot; U - untreated plot; DBA - days before application; DAA - days after application; LOQ - limit of quantification 0.001 µg/cm² for Spinosyn A and Spinosyn D).

* Values corrected taking into account the overall recovery of the field fortification samples of this trial for each analyte (103.3 % for Spinosyn A and 98.3 % for Spinosyn D).

** When one replicate is < LOQ, the LOQ value is used as default value for calculating the mean.

*** Spinosad as the sum of Spinosyn A and Spinosyn D (LOQ 0.002 µg/cm²).

Table 2 - Summary of results from trial SRES21-600-512IX - Spain

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Trial	Syntech Sample Code	LabRP Sample Code	Specimen	Plot	Days	Mean Spinosyn A ⁺⁺ (µg/cm ²)	Corrected Mean Spinosyn A [*] (µg/cm ²)	Mean Spinosyn D ^{***} (µg/cm ²)	Corrected Mean Spinosyn D [*] (µg/cm ²)	Spinosad ^{***} (µg/cm ²)
SRES21-601-512IX - Spain	SRES21-601-512IX-01	970/DFR13/21	Leaf disc wash	U	0 DBA	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-02	971/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-03	972/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-10	979/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-11	980/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-12	981/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-13	982/DFR13/21		0 DAA	0.154	0.149	0.015	0.015	0.165	
	SRES21-601-512IX-14	983/DFR13/21			0.154	0.149	0.015	0.015	0.165	
	SRES21-601-512IX-15	984/DFR13/21			24 HAA	0.011	0.010	0.001	0.001	0.012
	SRES21-601-512IX-16	985/DFR13/21				0.011	0.010	0.001	0.001	0.012
	SRES21-601-512IX-17	986/DFR13/21				0.011	0.010	0.001	0.001	0.012
	SRES21-601-512IX-18	987/DFR13/21				0.011	0.010	0.001	0.001	0.012
	SRES21-601-512IX-25	994/DFR13/21		3 DAA		0.070	0.068	0.001	0.001	0.069
	SRES21-601-512IX-26	995/DFR13/21				0.070	0.068	0.001	0.001	0.069
	SRES21-601-512IX-27	996/DFR13/21		5 DAA	0.031	0.030	0.001	0.001	0.031	
	SRES21-601-512IX-28	997/DFR13/21			0.031	0.030	0.001	0.001	0.031	
	SRES21-601-512IX-29	998/DFR13/21		U	7 DAA	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-30	999/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-31	1000/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-32	1001/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-33	1002/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-40	1009/DFR13/21				< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
	SRES21-601-512IX-41	1010/DFR13/21		T		0.006	0.005	0.001	0.001	0.007
	SRES21-601-512IX-42	1011/DFR13/21				0.006	0.005	0.001	0.001	0.007

T - treated plot; U - untreated plot; DBA - days before application; DAA - days after application; LOQ - limit of quantification 0.001 µg/cm² for Spinosyn A and Spinosyn D).

* Values corrected taking into account the overall recovery of the field fortification samples of this trial for each analyte (103.3 % for Spinosyn A and 98.3 % for Spinosyn D).

** When one replicate is < LOQ, the LOQ value is used as default value for calculating the mean.

*** Spinosad as the sum of Spinosyn A and Spinosyn D (LOQ 0.002 µg/cm²).

Table 3 - Summary of results from trial SRES21-601-512IX - Spain

CONCLUSIONS

An analytical method validated under the scope of this study was used to determine the magnitude of spinosyn A and spinosyn D in dislodgeable foliar residues in apple and pear leaves generated under SynTech Research study 512SRES21X02. For this purpose, leaf disc wash solutions and leaf disc wash field fortified solutions were analysed for residues of spinosyn A and spinosyn D.

The results of the field recovery tests demonstrated that the residues of spinosyn A and spinosyn D in apple and pear leaf disc wash solutions are stable under field, storage and transport conditions and also during the experimental work performed in this study.

The performance of the analytical method was demonstrated by recovery tests injected concurrently with the samples. The results achieved fulfill with the criteria set on SANTE/2020/12830, Rev 1.

All the analytical work has been conducted in accordance to GLP principles.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1), worker exposure calculations (KCP 7.2.3.1), resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.1.1 Calculations for Spinosad



SAP09I _ Spinosad 480 SC_20240927_09h56_opex1.0.2.zip



SAP09I _ Spinosad
480 SC_20240927.doc

Estimated worker exposure (longer term exposure) – refined with EUROPOEM II model



Low veg europoem
II worker.xls



Orchards
europoem II worker.

Estimated worker exposure (longer term exposure) – refined with updated DFR values



SAP09I _ Spinosad 480 SC_20240927_10h08_opex1.0.2 DFR.zip



SAP09I _ Spinosad
480 SC_20240927 DF

Calculations including the “dense” option for orchards



GENERAL_SAP09I_202 SAP09I_20250801_08h
50801.docx 15_opex1.1.2.zip

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Estimated worker exposure (longer term exposure) – refined with updated DFR values of SAP09I

	
GENERAL_SAP09I _ Spinosad 480 SC_20	SAP09I _ Spinosad 480 SC_20251104_07h25_opex1.1.3.zip

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A 3.2 Combined exposure calculations

Not required.

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Albaugh TKI d.o.o.

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)

Not relevant.

Please refer to point 6.6.3.1 and 6.6.3.2.