

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SAP09I

Product name: Volkete Max

Chemical active substance:

Spinosad, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization art. 33 & art. 34)

Applicant: Albaugh TKI d.o.o.

Submission date: January 2025

MS Finalisation date: 02/2026

Version history

When	What
January 2025	Applicant's first version
April 2025	Dossier sent for evaluation
October 2025	zRMS evaluation of dRR
November 2025	Applicant update: new GAP proposal according to the ecotox. risk assessment following two different approaches and additional trials on apple 2025.
December 2025	Final RR
January 2026	Applicant's update according the zRMSs comment on apples (uses 5a, 5b and 5c of the GAP table).
February 2026	Final RR

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. The parts of the text amended or added by the zRMS evaluator are highlighted in grey and the parts struck off are visibly marked with the grey front.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

dRR point 3.1	ZRMS conclusion
The overall assessment was performed according to the uniform principles. ZRMS considers that the data provided support the following uses no.: 1, 1b, 2, 2b, 5 presented in the corrected GAP table. Uses no.: 3, 3a, 4, 4a are accepted with reservation/ further restriction. Uses no.: 1a, 2a, 5a, 5b, 5c are not supported by the presented data in the dossier.	

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Head cabbage [BRSOL]	F	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages	a) 3-2 b) 3-2	7-10	a) 0.2 b) 0.6-0,4	a) 96 b) 288-192	2400- 600	3	Dose rate 0.1-0.2 L/ha	
2	PL	Broccoli [BRSOK] Cauliflower [BRSOB]	F	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages	a) 3-2 b) 3-2	7-10	a) 0.2 b) 0.6-0,4	a) 96 b) 288-192	2400- 600	3	Dose rate 0.1-0.2 L/ha	
3	PL	Onion [ALLCE]	F	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages	a) 3 b) 3	10	a) 0.2 b) 0.6	a) 96 b) 288	2300- 600	7	Dose rate 0.15-0.2 L/ha	
4	PL	Leek [ALLPO]	F	<i>Thrips tabaci</i> [THRITB]	Spraying	Young caterpillars / first damages	a) 3 b) 3	10	a) 0.2 b) 0.6	a) 96 b) 288	200- 600	7	Dose rate 0.15-0.2 L/ha	
5	PL	Apple [MABSD]	F	<i>Adoxophyes orana</i> [CAPURE]	Spraying	<first application: BBCH 59-6 (up to 1 treatment) >BBCH 70 second application: in sum- mer, during incuba- tion of subsequent generations caterpil- lars (up to 2 treatments) If necessary, the application can be repeated.	a) 1-2 b) 2-3	7-10	a) 0.3-0,6 b) 0.6-0,9	a) 144-288 b) 288-432	300- 500- 1500- 750	14	Max. 3 uses in season 0.23 L/1000 m² of LWA Dose rate: 0,3-0,42 l/ha	
Minor uses according to Article 51 (field uses)														
6	PL	Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	F	<i>Adoxophyes orana</i> [CAPURE]	Spraying	<BBCH 59 (up to 1 treatment) >BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.3 b) 0.6	a) 144 b) 288	300- 1500	14	Max. 2 uses in season 0.23 L/1000 m² of LWA	
7	PL	Garlic [ALLSA] Shallot [ALLAS]	F	<i>Thrips</i> sp. [THRISP]	Spraying	Notice of the pest / first damages	a) 3 b) 3	10	a) 0.2 b) 0.6	a) 96 b) 288	200- 600	7	Dose rate 0.15-0.2 L/ha	

** F: professional field use, Fn: non-professional field use, Fnp: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gnp: professional and non-professional greenhouse use, I: indoor application

New proposal according to the ecotox. risk assessment following two different approaches.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks: e.g. g safener/synergist per ha (6)	zRMS Conclusion (efficacy)
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Head cabbage [BRSOL]	F	Pieris brassicae [PIERBR] Artogeia rapae [PIERRA] Mamestra brassicae [BARABR]	Spraying	Young caterpillars / first damages BBCH 10-49	a) 2-3 b) 2-3	10	a) 0.2 b) 0.6	a) 96 b) 288	200 400- 600	3	Dose range 0.1-0.2 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 1a,b	Three applications (BBCH 19-49) unacceptable because of the ecotox. risk assessment
1a	PL	Head cabbage [BRSOL]	F	Pieris brassicae [PIERBR] Artogeia rapae [PIERRA] Mamestra brassicae [BARABR]	Spraying	Young caterpillars / first damages BBCH 20-49	a) 2 b) 2	10	a) 0.16 b) 0.32	a) 76.8 b) 153.6	200 400- 600	3	Dose range 0.1-0.16 L/ha Intended Use just in case higher tier assessment in Folsomia is not accepted	
1b	PL	Head cabbage [BRSOL]	F	Pieris brassicae [PIERBR] Artogeia rapae [PIERRA] Mamestra brassicae [BARABR]	Spraying	Young caterpillars / first damages BBCH 10-49	a) 2-3 b) 2-3	10	a) 0.1 b) 0.3	a) 48 b) 144	200 400- 600	3	Intended Use just in case higher tier assessment in Folsomia is not accepted	
2	PL	Broccoli [BRSOK] Cauliflower [BRSOB]	F	Artogeia rapae [PIERRA] Mamestra brassicae [BARABR]	Spraying	Young caterpillars / first damages BBCH 10-49	a) 2-3 b) 2-3	10	a) 0.2 b) 0.6	a) 96 b) 288	200 400- 600	3	Dose range 0.1-0.2 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 2a	Three applications (BBCH 19-49) unacceptable because of the ecotox. risk assessment
2a	PL	Broccoli [BRSOK] Cauliflower [BRSOB]	F	Artogeia rapae [PIERRA] Mamestra brassicae [BARABR]	Spraying	Young caterpillars / first damages BBCH 20-49	a) 2 b) 2	10	a) 0.16 b) 0.32	a) 96 b) 288	200 400- 600	3	Dose range 0.1-0.16 L/ha Intended Use just in case higher tier assessment in Folsomia is not accepted	
2b	PL	Broccoli [BRSOK] Cauliflower [BRSOB]	F	Artogeia rapae [PIERRA] Mamestra brassicae [BARABR]	Spraying	Young caterpillars / first damages BBCH 20-49	a) 2-3 b) 2-3	10	a) 0.1 b) 0.3	a) 48 b) 144	200 400- 600	3	Intended Use just in case higher tier assessment in Folsomia is not accepted	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Member state(s)	Crop and/ situation (crop destination / purpose of crop)	F, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks: e.g. g safener/synergist per ha (%)	zRMS Conclusion (efficacy)
3	PL	Onion [ALLCE]	F	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 40-49	a) 1 b) 1	na	a) 0.15 b) 0.15	a) 72 b) 72	200- 600	7	If higher tier assessment in Folsomia is not accepted please refer to Use No. 3a	unacceptable because of the ecotox. risk assessment
3a	PL	Onion [ALLCE]	F	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 40-49	a) 1 b) 1	na	a) 0.16-15 b) 0.16-15	a) 76.8 b) 76.8	200- 600	7	Dose range 0.15-0.16 L/ha Intended Use just in case high-er tier assessment in Folsomia is not accepted	
4	PL	Leek [ALLPO]	F	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 40-49	a) 1 b) 1	na	a) 0.15 b) 15	a) 72 b) 72	200- 600	7	If higher tier assessment in Folsomia is not accepted please refer to Use No. 4a	unacceptable because of the ecotox. risk assessment
4a	PL	Leek [ALLPO]	F	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 40-49	a) 1 b) 1	na	a) 0.16-15 b) 0.16-15	a) 76.8 b) 76.8	200- 600	7	Dose range 0.15-0.16 L/ha Intended Use just in case high-er tier assessment in Folsomia is not accepted	
5	PL	Apple [MABSD]	F	<i>Adoxophyes orana</i> [CAPURE]	Spraying	BBCH 40-59 56 (up to 1 treatment) >BBCH 70 (up to 2 treatments)	a) 2 b) 2	10-21	a) 0.3 b) 0.6	a) 144 b) 288	300- 1500	14	Dose range 0.18-0.3 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 5a,b,c	unacceptable because of the ecotox. risk assessment
5a	PL	Apple [MABSD]	F	<i>Adoxophyes orana</i> [CAPURE]	Spray	BBCH >70	a) 1 b) 1	na	a) 0.3 b) 0.3	a) 144 b) 144	300- 1500	14	Dose range 0.14-0.23 L/10000 m2 LWA, equivalent to 0.18- 0.3 L/ha Intended Use in case higher tier assessment in Folsomia is not accepted	
5b	PL	Apple [MABSD]	F	<i>Adoxophyes orana</i> [CAPURE]	Spraying	>BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.225 b) 0.450	a) 108 b) 216	300- 1500	14	Dose range 0.14-0.17 L/10000 m2 LWA, equivalent to 0.18- 0.225 L/ha Intended Use in case high- er tier assessment in Folsomia is not accepted	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Member state(s)	Crop and/ situation (crop destination purpose of crop)	F, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks: e.g. g safener/synergist per ha (n)	zRMS Conclusion (efficacy)
5c	PL	Apple [MABSD]	F	<i>Adoxophyes orana</i> [CAPURE]	Spraying	BBCH 40-59 (up to 1 treatment) >BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.225 b) 0.450	a) 108 b) 216	300- 1500	14	Dose range 0.14-0.17 L/10000 m2 LWA, equivalent to 0.18- 0.225 L/ha Intended Use in case high- er tier assessment in Folsomia is not accepted	
Minor uses according to Article 51 (zonal uses)														
6	PL	Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	F	<i>Adoxophyes orana</i> [CAPURE]	Spraying	BBCH 40-59 (up to 1 treatment) >BBCH 70 (up to 2 treatments)	a) 2 b) 2	10-21	a) 0.3 b) 0.6	a) 144 b) 288	300- 1500	14	Dose range 0.18-0.3 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 6a,b,c	
6a	PL	Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	F	<i>Adoxophyes orana</i> [CAPURE]	Spray	BBCH >70	a) 1 b) 1	na	a) 0.3 b) 0.3	a) 144 b) 144	300- 1500	14	Dose range 0.14-0.23 L/10000 m2 LWA, equivalent to 0.18- 0.3 L/ha Intended Use in case higher tier assessment in Folsomia is not accepted	
6b	PL	Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	F	<i>Adoxophyes orana</i> [CAPURE]	Spray	>BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.225 b) 0.450	a) 108 b) 216	300- 1500	14	Dose range 0.14-0.17 L/10000 m2 LWA, equivalent to 0.18- 0.225 L/ha Intended Use in case high- er tier assessment in Folsomia is not accepted	
6c	PL	Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	F	<i>Adoxophyes orana</i> [CAPURE]	Spray	BBCH 40-59 (up to 1 treatment) >BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.225 b) 0.450	a) 108 b) 216	300- 1500	14	Dose range 0.14-0.17 L/10000 m2 LWA, equivalent to 0.18- 0.225 L/ha Intended Use in case high- er tier assessment in Folsomia is not accepted	
7	PL	Garlic [ALLSA] Shallot	F	<i>Thrips</i> sp. [THRISP]	Spraying	Notice of the pest / first damages BBCH 10-49	a) 1 b) 1	na	a) 0.15 b) 0.3	a) 72 b) 144	200- 600	7	If higher tier assessment in Folsomia is not accepted please refer to Use No. 7a	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha g as/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks: e.g. g safener/synergist per ha (n)	zRMS Conclusion (efficacy)
		[ALLAS]												
7a	PL	Garlic [ALLSA] Shallot [ALLAS]	F	Thrips sp. [THRISP]	Spraying	Notice of the pest / first damages BBCH 40-49	a) 1 b) 1	na	a) 0.16 b) 0.32	a) 72 b) 144	200- 600	7	Dose range 0.15-0.16 L/ha Intended Use just in case high-er tier assessment in Folsomia is not accepted	

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document is a concise summary of the Biological Assessment Dossier submitted to support the registration of the plant protection product SAP09I in Poland acting as a zRMS and cMS for this submission. This document summarizes the information related to the efficacy.

SAP09I contains the active substance spinosad (480 g/L) and it is a SC (suspension concentrate) formulation. The product is intended for use as an insecticide against various pests in vegetable crops (head cabbage, cauliflower, broccoli, onion and leek) and in apple.

SAP09I contains the same active ingredient and is the same formulation type as the reference product – SpinTor 480 SC. SpinTor 480 SC has been authorised in Poland since 2003 (first approval number R-18/2003 of September 12th, 2003; ~~current approval number R-47/2018wu of October 19th, 2018~~), which is where the registration of SAP09I is intended.

To determine the efficacy of SAP09I in vegetable crops, a bridging strategy was used, by which it is demonstrated that the product has comparable effectiveness and crop safety properties as SpinTor 480 SC. The number of trials per crop/target is in accordance with the provisions of EPPO PP 1/307(2) and the ‘Guideline for the preparation of assessments or comments on plant protection products by authorized entities in Poland’ (version of 13 August 2024). Therefore, to have a complete data package, applicant makes reference to the efficacy data of the reference product SpinTor 480 SC, for which data protection has expired.

In the case of apple, the applicant has provided the full number of registration trials carried out in one growing season and refers to unprotected data of the reference formulation SpinTor 480 SC.

For the requested minor uses applied for, in accordance with Article 51 of Regulation (EC) No 1107/2009 there is no requirement to submit information on efficacy or adverse effects. Therefore, no efficacy studies are submitted for the requested uses in pear, crab apple and in quince garlic and shallot.

For Spintor 480 SC, the data that is not subject to protection is that used for the initial registration of the product in 2003 (MRIRW authorisation no. 18/2003 of September 12, 2003).
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Description of active substances

The active substance as part of the composition of SAP09I is:

Spinosad	Existing active substance
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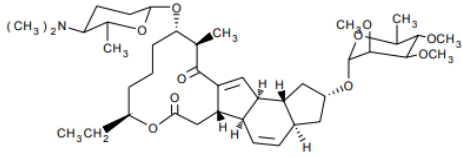
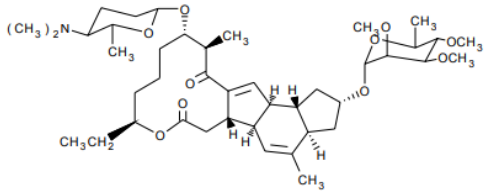
The active ingredient spinosad is known from the several commercial products present in the market. It was included into Annex I to the Council Directive 91/414/EEC in accordance with 2007/6/EC. Subsequently, the active substance has been included in the Annex to Commission Implementing Regulation (EU) No 540/2011 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

Mode of action

Spinosad belongs to the chemical group of the nicotinic acetylcholine receptor (nAChR) allosteric modulators – site I (Group 5 IRAC). Spinosad causes excitation of the insect nervous system, leading to

involuntary muscle contractions, prostration with tremors, and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors by a mechanism. It is effective against a wide range of pests (sucking and chewing pests) in a wide range of crops.

Table 3.2-1: Details of the active substances

Active substance	Spinosad (ISO) (a mixture of spinosyn A and spinosyn D)
Concentration	480 g/L
Chemical group	Spinosyns
Mode of action	Nicotinic acetylcholine receptor (nAChR) allosteric modulator – site I (Group 5 IRAC)
Biological action	Insecticide. Excitation of the insect nervous system. Contact, ingestion and translaminar activity.
Molecular structure	Spinosyn A  Spinosyn D 

Description of the plant protection product

SAP09I is a suspension concentrate (SC) containing spinosad (480 g/L).

SAP09I is intended for use as an insecticide against various insecticides in vegetable crops (head cabbage, cauliflower, broccoli, onion, leek) and in apple. The maximum single application rate for vegetable crops is 0.2 L/ha and for apple 0.3 L/ha. In vegetable crops, SAP09I can be applied a maximum of 3 times per growing season, with 7-10 days between applications for *Brassica* crops and for *Allium* crops with at least a 10-day interval. For apple crops, the product may be applied a maximum of two times per season, with a minimum interval of 10 days.

The requested uses also include minor uses (in accordance with Article 51 of Regulation 1107/2009): other *Allium* crops (garlic and shallot – up to 3 applications per season with a maximum dose rate of 0.2 L/h) and pome trees (pear, crab apple and quince – up to 2 applications per season with a maximum dose rate of 0.3 L/h).

SAP09I is not currently registered in Poland. In

Table 3.2-2 details concerning the crops, dose rates and other relevant comments for the requested uses can be found.

Table 3.2-2: Simplified table of requested uses for SAP09I

First option, if higher tier assessment in *Folsomia* is accepted.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAP
Crop(s)	Target(s)			
Head cabbage [BRSOL]	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1-0.2 L/ha	Max. 3 applic./ season
Broccoli [BRSOK] Cauliflower [BRSOB]	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1-0.2 L/ha	Max. 3 applic./ season
Onion [ALLCE]	<i>Thrips tabaci</i> [THRITB]	PL	0.15-0.2 L/ha	Max. 3 1 applic./ season
Leek [ALLPO]	<i>Thrips tabaci</i> [THRITB]	PL	0.15-0.2 L/ha	Max. 3 1 applic./ season
Apple [MABSD]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.18-0.3 L/ha (0.14-0.23 L/10000 m ² of LWA)	Max. 2 applic./ season
Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.18-0.3 L/ha (0.14-0.23 L/10000 m ² of LWA)	Art. 51 (minor use) Max. 2 applic./ season
Garlic [ALLSA] Shallot [ALLAS]	<i>Thrips</i> sp. [THRISP]	PL	0.15-0.2 L/ha	Art. 51 (minor use) Max. 3 1 applic./ season

Second option, if higher tier assessment in *Folsomia* is not accepted.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAP
Crop(s)	Target(s)			
Head cabbage [BRSOL]	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1 L/ha	Max. 3 applic./ season
Head cabbage [BRSOL]	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1-0.16 L/ha	Max. 2 applic./ season
Broccoli [BRSOK] Cauliflower [BRSOB]	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1 L/ha	Max. 3 applic./ season
Broccoli [BRSOK] Cauliflower [BRSOB]	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]		0.1-0.16 L/ha	Max. 2 applic./ season
Onion [ALLCE]	<i>Thrips tabaci</i> [THRITB]	PL	0.15-0.16 L/ha	Max. 1 applic./ season
Leek [ALLPO]	<i>Thrips tabaci</i> [THRITB]	PL	0.15-0.16 L/ha	Max. 1 applic./ season
Apple [MABSD]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.21-0.25 L/10000m ² LWA (0.23 L/10000m ² LWA, in average), equivalent to 0.3 L/ha	Max. 1 applic./ season
Apple [MABSD]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.14-0.171 L/10000 m ² of LWA, equivalent to 0.18-0.225 L/ha	Max. 2 applic./ season
Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.21-0.25 L/10000m ² LWA (0.23 L/10000m ² LWA, in average), equivalent to 0.3 L/ha	Art. 51 (minor use) Max. 1 applic./ season

Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.14-0.171 L/10000 m ² of LWA, equivalent to 0.18- 0.225 L/ha	Art. 51 (minor use) Max. 2 applic./ season
Garlic [ALLSA] Shallot [ALLAS]	<i>Thrips</i> sp. [THRISP]	PL	0.15-0.16 L/ha	Art. 51 (minor use) Max. 1 applic./ season

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target crops

Head cabbage

Of the brassica crops, mainly head cabbage is grown in Poland. After Romania, Poland is the second-largest country in the European Union for the cultivation of this crop. Further information on cabbage production in Poland is available from the Eurostat¹ website, with an extract provided in Table 3.2-3 below.

Table 3.2-3: Area of cabbage in Poland, where approval for SAP09I is requested

Country	Area ('000 ha)								
	2015	2016	2017	2018	2019	2020	2021	2022	2023
PL	24.9	20.9	21.4	22.1	21.8	13.7	14.6	14.0	13.7

Cauliflower & Broccoli

After cabbage, cauliflower, and broccoli are the next most important brassica vegetables grown in Poland. In the European Union, Poland ranks fourth in terms of cultivated area, after Spain, France, and Italy. Further information on the crop production in the country is available from the Eurostat¹ website, with an extract provided below in Table 3.2-4.

Table 3.2-4: Area of cauliflower and broccoli crops in Poland, where approval for SAP09I is requested

Country	Area ('000 ha)								
	2015	2016	2017	2018	2019	2020	2021	2022	2023
PL	15.5	14.86	15.18	15.18	15.8	10.3	10.7	10.8	10.1

Onion

Poland has the third highest onion acreage in the European Union, behind the Netherlands and Spain. Further information on the crop production in the country is available from the Eurostat² website, with an extract provided below in Table 3.2-5.

Table 3.2-5: Area of onion crop in Poland, where approval for SAP09I is requested

Country	Area ('000 ha)								
	2015	2016	2017	2018	2019	2020	2021	2022	2023
PL	25.6	26.98	26.65	25.45	25.2	23.1	23.4	22.7	22.1

¹ Eurostat Data Browser, November 2024, Crop production in EU standard humidity (available at: https://doi.org/10.2908/APRO_CPSH1)

² Eurostat Data Browser, November 2024, Crop production in EU standard humidity (available at: https://doi.org/10.2908/APRO_CPSH1)

Leek

Although the overall acreage under leek seems small, in the European Union Poland is the 6th largest producer of this vegetable in terms of acreage cultivated. Further information on the crop production in the country is available from the Eurostat² website, with an extract provided below in Table 3.2-6.

Table 3.2-6: Area of leek crop in Poland, where approval for SAP09I is requested

Country	Area ('000 ha)								
	2015	2016	2017	2018	2019	2020	2021	2022	2023
PL	4.2	4.7	4.6	4.5	4.5	2.2	2.2	2.0	1.9

Apple

Poland's most economically important fruit crop. Three out of ten apples produced in the European Union in 2022 (34.0%) were harvested in Poland. Also, in terms of acreage, Poland is the largest producer of apples in the European Union. Further information on the crop production in the country is available from the Eurostat² website, with an extract provided below in Table 3.2-7.

Table 3.2-7: Area of apple crop in Poland, where approval for SAP09I is requested

Country	Area ('000 ha)									
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
PL	180.4	164.8	162.5	166.2	155.6	152.6	161.9	151.9	150.0	148.0

Description of the target pests

Table 3.2-8 below lists the target pests that are considered within this application. The first column includes the EPPO code of the pest that will be used along the dossier to refer. The scientific Latin name can be found in the third and the common name in the fourth column.

Table 3.2-8: Glossary of pests mentioned in the dossier

EPPO code	Scientific name	Common name
PIERRA	<i>Artogeia rapae</i>	Imported cabbage worm
PIERBR	<i>Pieris brassicae</i>	Cabbage caterpillar
THRITB	<i>Thrips tabaci</i>	Onion thrips
CAPURE	<i>Adoxophyes orana</i>	Smaller tea tortrix

The relative importance of the crops in Poland can be found in Table 3.2-9. All pests included in the dossier are considered major in the crops considering the damage they can make on the crop and the general presence in Poland.

Table 3.2-9: Major / minor status of intended uses in Poland

Crop	Crop Status		Target	Pest status	
	Major	Minor		Major	Minor
Head cabbage [BRSOL]		x	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PIERBR PIERRA BARABR	
Broccoli [BRSOK] Cauliflower [BRSOB]		x	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PIERRA BARABR	
Onion [ALLCE]		x	<i>Thrips tabaci</i> [THRITB]	THRITB	
Leek [ALLPO]		x	<i>Thrips tabaci</i> [THRITB]	THRITB	
Apple [MABSD]	x		<i>Adoxophyes orana</i> [CAPURE]	CAPURE	
Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]		x	<i>Adoxophyes orana</i> [CAPURE]	CAPURE	
Garlic [ALLSA] Shallot [ALLAS]		x	<i>Thrips</i> sp. [THRISP]	THRISP	

Master Label

A master draft label is prepared here to facilitate the understanding on the product and help in the construction of the label that is submitted into Part A.

First option, if higher tier assessment in *Folsomia* is accepted.

SAP09I

SC (suspension concentrate) formulation containing 480 g/L of spinosad

CROPS & TARGETS

Head cabbage: *Pieris brassicae*, *Artogeia rapae* and *Mamestra brassicae*

Broccoli and cauliflower: *Artogeia rapae* and *Mamestra brassicae*

Onion and leek: *Thrips tabaci*

Apple tree: *Adoxophyes orana*

Minor uses – registration according to art. 51:

Pear, crab apple and quince: *Adoxophyes orana*

Garlic and shallot: *Thrips* sp.

APPLICATION TIMING

Head cabbage, cauliflower and broccoli: treatment on the youngest stages of caterpillars or when the first damage is noticed.

Onion and leek: when the first larvae and adults of thrips appear or when the first damage is noticed.

Apple: <BBCH 59 (1 treatment) and/or >BBCH 70 (up to 2 treatments). In total 2 treatments in the season are allowed.

Minor uses – registration according to art. 51:

Pear, crab apple and quince: <BBCH 59 (1 treatment) and/or >BBCH 70 (up to 2 treatments). In total 2 treatments in the season are allowed.

Garlic and shallot: when the first larvae and adults of thrips appear or when the first damage is noticed.

NUMBER OF APPLICATIONS

Head cabbage, broccoli and cauliflower: max. 3 (7-10-day interval between treatments).

Onion and leek: max. 3-1 (at least 10-day interval between treatments).

Apple tree: max. 2 (at least 10-21-days interval between treatments).

Minor uses – registration according to art. 51:

Pear, crab apple and quince: max. 2 (at least 10-21-days interval between treatments).

Garlic and shallot: max. 3-1 (at least 10-day interval between treatments).

RATE & WATER VOLUME

Head cabbage, broccoli and cauliflower: 0.1-0.2 L/ha in 200-600 L/ha of spray volume.

Onion and leek: 0.15-0.2 L/ha in 200-600 L/ha of spray volume.

Apple tree: 0.18 - 0.3 L/ha in 300-1500 L/ha of spray volume.

Minor uses – registration according to art. 51:

Pear, crab apple and quince: 0.18 - 0.3 L/ha in 300-1500 L/ha of spray volume.

Garlic and shallot: 0.15-0.2 L/ha in 200-600 L/ha of spray volume.

APPLICATION DETAILS

Foliar spray

Second option, if higher tier assessment in *Folsomia* is not accepted.

SAP09I

SC (suspension concentrate) formulation containing 480 g/L of spinosad

CROPS & TARGETS

Head cabbage: *Pieris brassicae*, *Artogeia rapae* and *Mamestra brassicae*

Broccoli and cauliflower: *Artogeia rapae* and *Mamestra brassicae*

Onion and leek: *Thrips tabaci*

Apple tree: *Adoxophyes orana*

Minor uses – registration according to art. 51:

Pear, crab apple and quince: *Adoxophyes orana*

Garlic and shallot: *Thrips* sp.

APPLICATION TIMING

Head cabbage, cauliflower and broccoli: treatment on the youngest stages of caterpillars or when the first damage is noticed.

Onion and leek: when the first larvae and adults of thrips appear or when the first damage is noticed.

Apple: <BBCH 59 (1 treatment) and/or >BBCH 70 (1 or 2 treatments). In total 2 treatments in the season are allowed.

Minor uses – registration according to art. 51:

Pear, crab apple and quince: <BBCH 59 (1 treatment) and/or >BBCH 70 (up to 2 treatments). In total 2 treatments in the season are allowed.

Garlic and shallot: when the first larvae and adults of thrips appear or when the first damage is noticed.

NUMBER OF APPLICATIONS & RATES

Head cabbage, broccoli and cauliflower:

- max. 2 applications (10-day interval between treatments) at 0,1-0.16 L/ha, OR

- max. 3 applications (10-day interval between treatments) at 0.1 L/ha

Onion and leek: max. 1 application at 0.16 L/ha

Apple tree:

- max. 1 application from at 0.14-0.23 L/10000 m² LWA 0.3 L/ha, OR

- max. 2 applications, in post-flowering (at least 10-day interval between treatments) at 0.14-0.17 L/10000 m² LWA 0.18-0.225 L/ha, OR,

- max. 2 applications, one before and one after flowering (at least 10-day interval between treatments) at 0.14-0.17 L/10000 m² LWA 0.18-0.225 L/ha

Minor uses – registration according to art. 51:

Pear, crab apple and quince:

- max. 1 application from at 0.14-0.23 L/10000 m² LWA 0.3 L/ha, OR

- max. 2 applications, in post-flowering (at least 10-day interval between treatments) at 0.14-0.17 L/10000 m² LWA 0.18-0.225 L/ha, OR,

- max. 2 applications, one before and one after flowering (at least 10-day interval between treatments) at 0.14-0.17 L/10000 m² LWA 0.18-0.225 L/ha

Garlic and shallot: max. 1 application at 0.16 L/ha

WATER VOLUME

Head cabbage, broccoli and cauliflower: 200-600 L/ha of spray volume.

Onion and leek: 200-600 L/ha of spray volume.

Apple tree: 300-1500 L/ha of spray volume.

Minor uses – registration according to art. 51:

Pear, crab apple and quince 300-1500 L/ha of spray volume.

Garlic and shallot: 200-600 L/ha of spray volume.

APPLICATION DETAILS

Foliar spray

Compliance with the Uniform Principles

The key studies summarised in this document are consistent with the Uniform Principles, being carried out following the EPPO standards and in accordance with GEP, by officially recognised testing organisations.

Glossary

In order to make simple, some codes will be used in the report.
Decode can be found in Table 3.2-10.

Table 3.2-10: Glossary of the main codes used in the dossier

Item	Code	Decode
Countries	PL	ISO 3166 code for Poland
Crops	ALLAS	Shallot
	ALLCE	Onion
	ALLPO	Leek
	ALLSA	Garlic
	BRSOB	Cauliflower
	BRSOK	Broccoli
	BRSOL	Head cabbage
	CYDOB	Quince
	MABSD	Apple
	MABSY	Crab apple
EPPO climatic zones	PYUCO	Pear
	EPPONE	North-East EPPO climatic zone
	DA-A	Days after application A
	DA-B	Days after application B
Other codes	DA-B	Days after application C
	cMS	Concerned member state
	EPPO	European and Mediterranean Plant Protection Organisation
	GEP	Good experimental practice
	IRAC	Insecticide Resistance Action Committee
	LWA	Leaf wall area
	na	Not applicable
	n.r.	Not reported
	Trial ID	Trial identification
	UTC	Untreated Check
Pests	zRMS	Zonal rapporteur member state
	BARABR	<i>Mamestra brassicae</i>
	CAPURE	<i>Adoxophyes orana</i>
	PIERBR	<i>Pieris brassicae</i>
	PIERRA	<i>Artogeia rapae</i>
	THRITB	<i>Thrips tabaci</i>
	THRISP	<i>Thrips</i> sp.

Information on trials submitted (3.1 Efficacy data)

Efficacy test information is covered in the following Chapter, which includes: testing organisations, locations of trials, methodologies and result summaries.

In Between 2024 and 2025, a total of 13-16 field trials were conducted in vegetable crops (head cabbage, cauliflower, broccoli, onion, and leek) and in apple in Poland (the North-East EPPO zone) in order to evaluate the efficacy and comparability of SAP09I with SpinTor 480 SC against various pests.

In order to provide a complete data package to the authorities for evaluation of the test product SAP09I, trials for each intended use (crop/target) were performed to demonstrate that the test product has the same biological behaviour as the reference product SpinTor480 SC (according to EPPO PP 1/307(2)).

As both products have a comparable efficacy against the intended field uses and comparable crop safety, a reference to the unprotected data of SpinTor 480 SC is made to have a full data set demonstrating the efficacy of the test product. The trials also include lower dose rates as the proposed rate to support the 'minimum effective dose'.

All trials were carried out under GEP (Good Experimental Practices) conditions by certified Contract Research Organisation. The competent authority officially recognizes the organization to carry out field registration trials in accordance with the principles of Good Experimental Practices (GEP).

All efficacy trials are listed in Table 3.2-11.

Table 3.2-11: Presentation of efficacy trials

Crop	Target	Country	Years	Type of trial*	Number of trials EPPONE (valid trials)	GEP, non-GEP, official**
Head cabbage [BRSOL]	PIERRA	PL	2024	MED, E	2 (2)	GEP
Cauliflower [BRSOB]	PIERBR	PL	2024	MED, E	1 (1)	GEP
	PIERRA				1 (1)	
Onion [ALLCE]	THRITB	PL	2024	MED, E	2 (2)	GEP
Leek [ALLPO]	THRITB	PL	2024	MED, E	2 (2)	GEP
Apple [MABSD]	CAPURE	PL	2024	MED, E	5 (5)	GEP
Apple [MABSD]	CAPURE	PL	2025	MED, E	3 (3)	GEP
Total number of trials (valid trials)					13 (13)-16 (16)	

*MED = minimum effective dose, E = efficacy trial with phytotoxicity assessment.

** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In Figure 3.2-1 to Figure 3.2-5 the distribution of efficacy trials performed in Poland is shown.

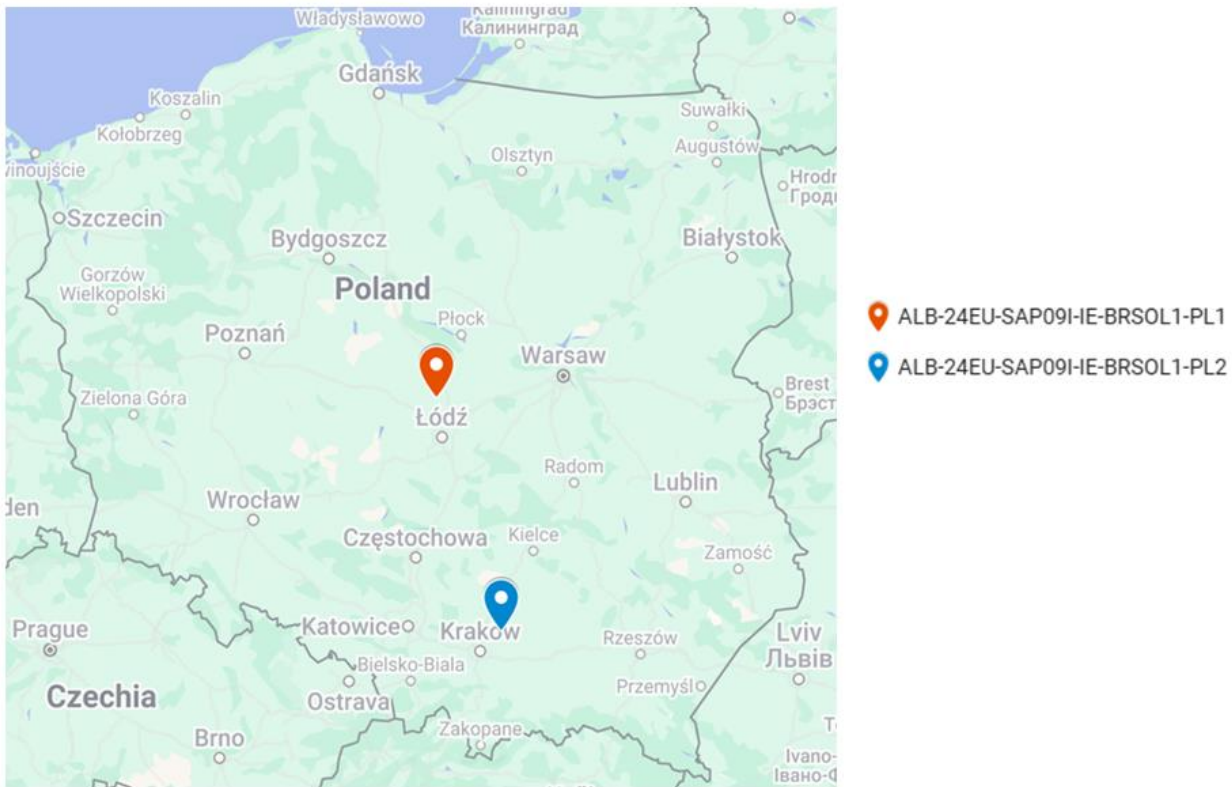


Figure 3.2-1: Distribution of efficacy trials performed in head cabbage

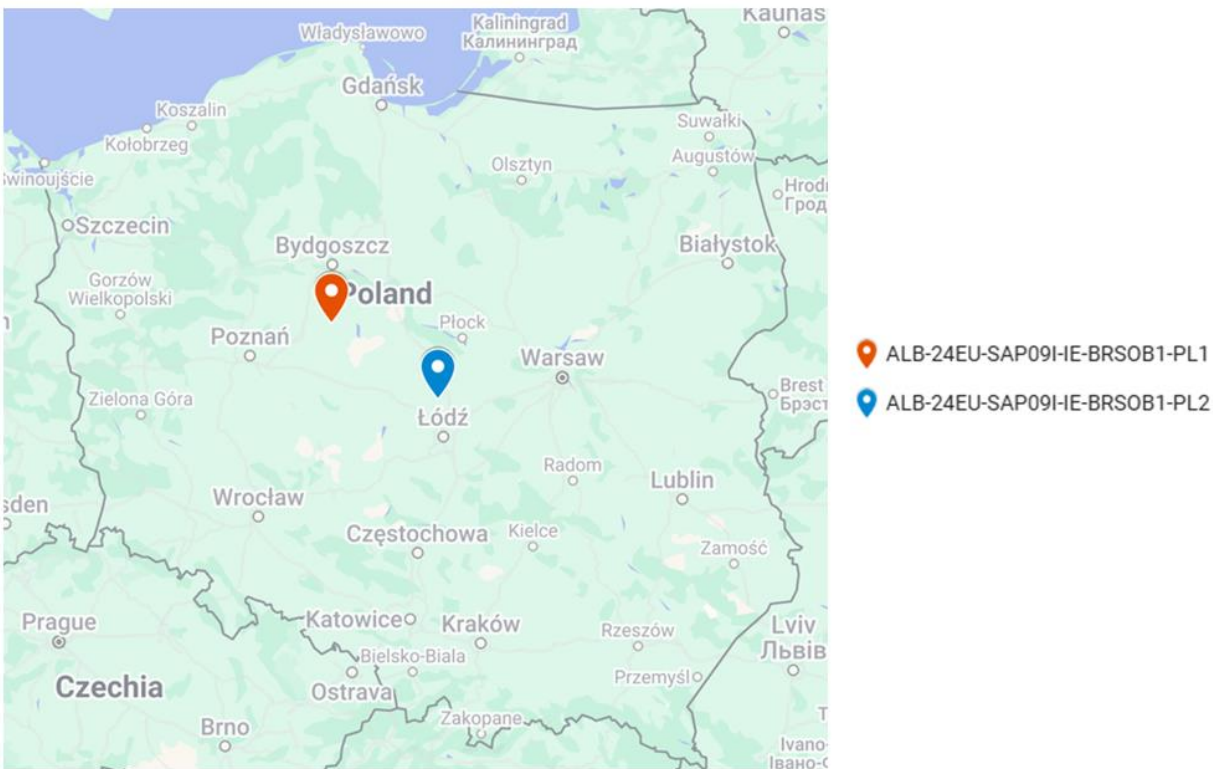


Figure 3.2-2: Distribution of efficacy trials performed in cauliflower

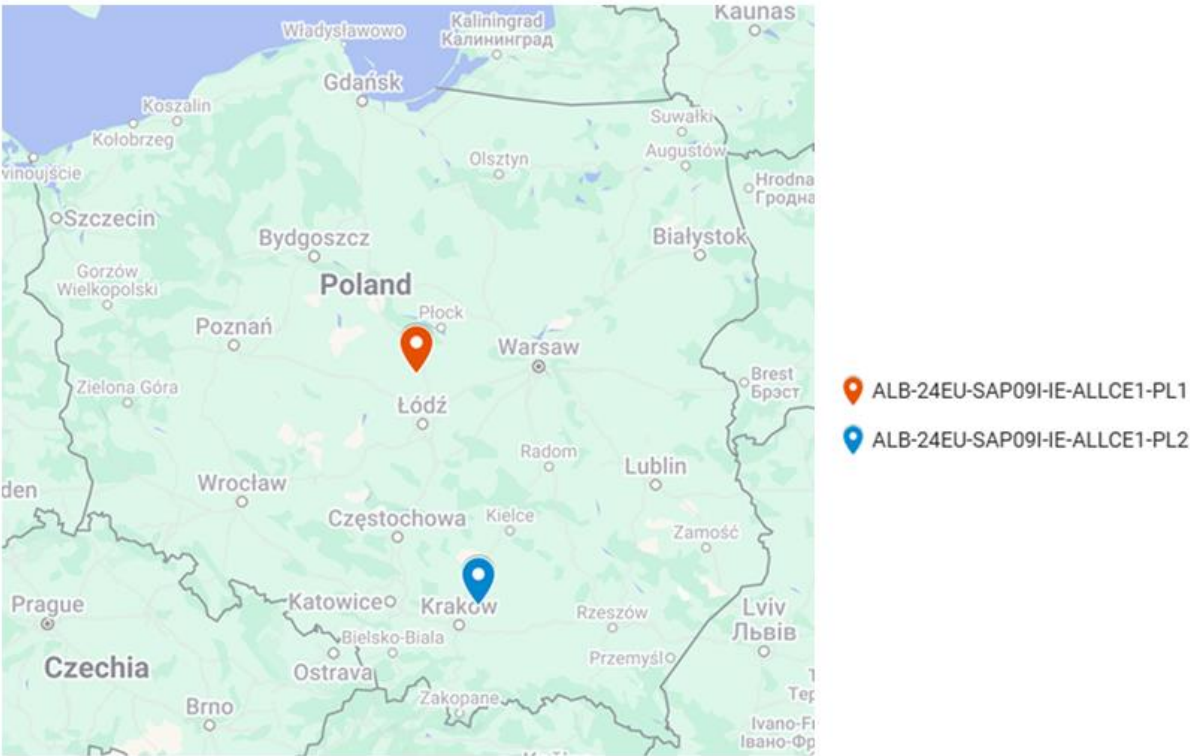


Figure 3.2-3: Distribution of efficacy trials performed in onion

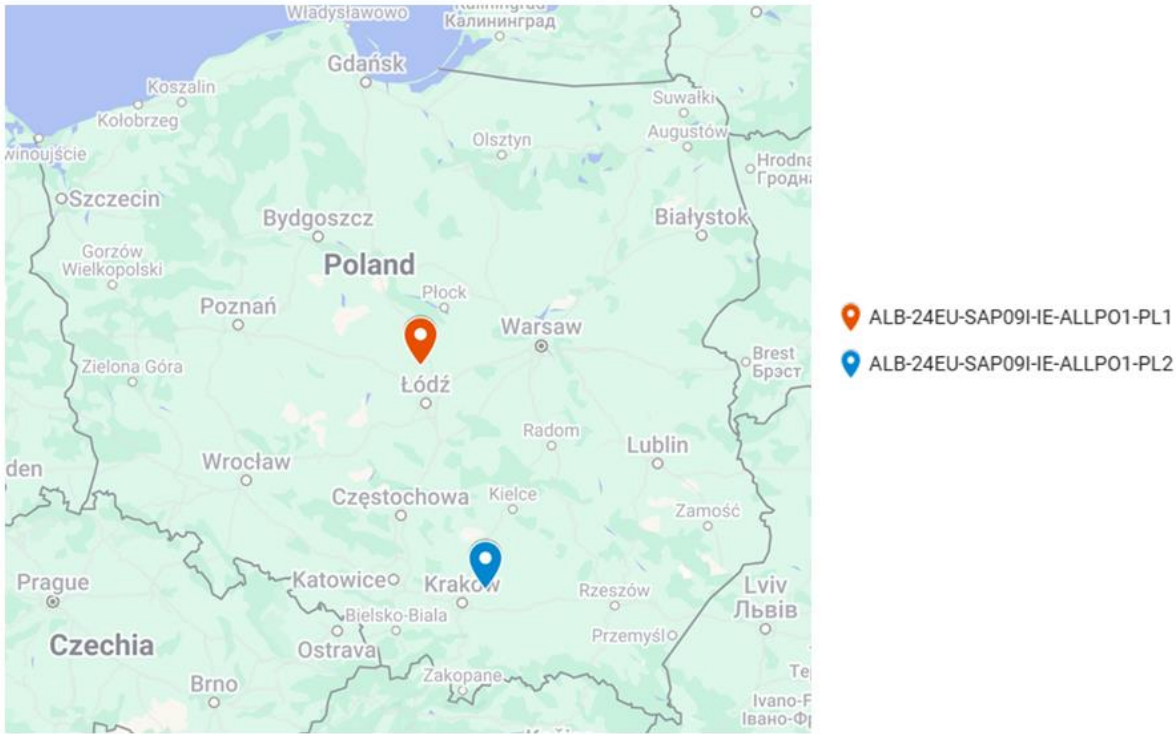


Figure 3.2-4: Distribution of efficacy trials performed in leek

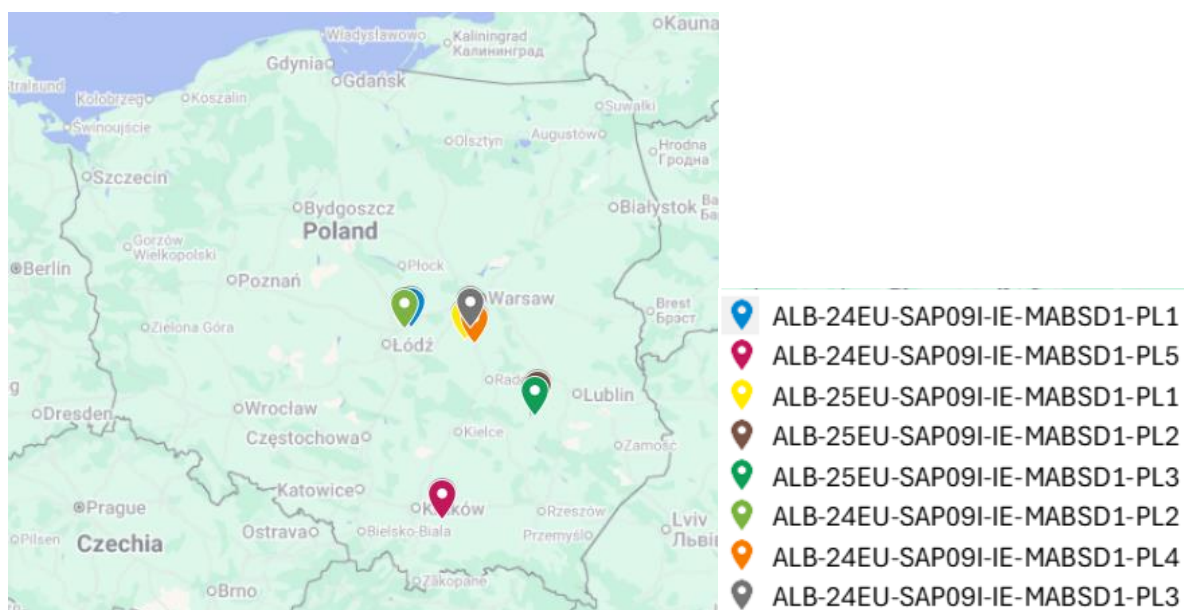


Figure 3.2-5: Distribution of efficacy trials performed in apple

Reference standards

Reference standard used for the experimentations are presented in Table 3.2-12 below.

Table 3.2-12: Presentation of reference standards used in trials

Active substance	Formulation		Registered application rate L/ha	Registered Crops	Reference standard / commercial name	Country where the product is registered	Authorization number	Application rate in trials per treatment
	Type	Concentration of a.s.						
Spinosad	SC	480 g/L	0.1-0.2	Head cabbage [BRSOL]	SpinTor 480 SC	PL	R-47/2018	0.06 L/ha 0.1 L/ha 0.2 L/ha
				Cauliflower [BR SOB]				
			0.15-0.2	Onion [ALLCE]				0.09 L/ha 0.15 L/ha 0.2 L/ha
			0.15-0.2	Leek [ALLPO]				
			0.3	Apple* [MABSD]				0.18 L/ha 0.3 L/ha

* In Poland SpinTor 480 SC is registered on crab tree and another pome fruit – pear

3.2.1 Preliminary tests (KCP 6.1)

For SAP09I there are no preliminary trials available on the formulation development. SAP09I is a generic product based on practical experiences with the registered, well-known spinosad product of Corteva

Agriscience – SpinTor 480 SC. The application rates selected for SAP09I fully reflect the registered rates of the Corteva product.

Comments of zRMS:	Preliminary tests are not reported. The active substance spinosad has well been known and used in many authorised products with a known range of action.
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3.2.2 Minimum effective dose tests (KCP 6.2)

In total 13 field trials were conducted in the North-East EPPO zone in order to confirm the minimum effective dose of SAP09I for the control of different pest species in a range of vegetable and horticultural crops. All trials were carried out according to GEP by certified test facilities; experimental details per crop group are summarized in Table 3.2-21, Table 3.2-22 and in Table 3.2-24. Further details on trials methodology are presented in Chapter 3.2.3, in the section ‘Methodology’.

SAP09I was tested at 0.06 to 0.3 L/ha:

- 0.06-0.2 L/ha for *Brassica* crops (head cabbage and cauliflower), against imported cabbage worm in head cabbage;
- 0.09-0.2 L/ha for *Allium* crops (onion and leek), against onion thrips;
- 0.14-0.23 L/10000 m² LWA (equivalent to 0.18-0.3 L/ha) for apple, to control smaller tea tortrix.

The intended dose rate depends on the authorized dose rate of the standard reference product SpinTor 480 SC. The rates reflect the proposed label rates as well as lower doses of SAP09I in accordance with the EPPO standard PP 1/225 ‘Minimum effective dose’.

A summary of the dose response results is provided in Table 3.2-13 to Table 3.2-20.

3.2.2.1 Use 1: Control of *Pieris brassicae* [PIERBR], *Artogeia rapae* [PIERRA], *Mamestra brassicae* [BARABR] in head cabbage

Two trials from the North-East EPPO zone (Poland) are submitted to demonstrate the minimum effective dose of SAP09I against imported cabbage worm in head cabbage.

The efficacy against PIERRA increased continuously with higher dose rate and number of treatments of SAP09I. The highest efficacy was noted at a dose rate of 0.2 L/ha SAP09I after 3 applications. Nevertheless, good results were also achieved after 3 treatments at a dose rate of 0.1 L/ha. The efficacy against PIERRA after three treatments at 0.06 L/ha was insufficient.

Considering the results of both trials, it can be concluded that a minimum effective dose rate of 0.1-0.2 L/ha for this use is justified.

A summary of the dose response results is provided in Table 3.2-13.

Table 3.2-13: Minimum effective dose of SAP09I for control of PIERRA in head cabbage (summary results)

No. of trials	Crop	Target	Assessment timing	Infestation (number of larvae / 25 plants)												% Control								
				UTC			SAP09I 0.06 L/ha			SAP09I 0.1 L/ha			SAP09I 0.2 L/ha			SAP09I 0.06 L/ha			SAP09I 0.1 L/ha			SAP09I 0.2 L/ha		
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.
2	BRSOL	PIERRA (larvae)	2-3 DA-A	32.8	14.0	51.5	18.5	9.5	27.5	14.1	6.8	21.3	9.0	4.0	14.0	32.8	29.9	43.5	53.4	48.4	58.4	70.5	66.0	75.0
			6-7 DA-A	35.2	13.3	57.0	17.3	9.5	25.0	9.9	6.3	13.5	5.5	3.5	7.5	39.5	25.9	53.2	62.3	48.9	75.8	77.9	67.9	87.9
			3 DA-B	34.7	11.8	57.5	13.3	5.5	21.0	6.9	4.3	9.5	3.2	2.0	4.3	56.1	51.5	60.7	71.3	59.7	82.9	86.7	80.2	93.3
			7 DA-B	35.4	12.3	58.5	13.3	5.0	21.5	6.0	3.0	9.0	2.3	1.8	2.8	58.5	56.8	60.2	78.6	73.2	84.0	89.8	83.8	95.8
			3 DA-C	33.8	8.3	59.3	12.7	3.3	22.0	4.3	1.8	6.8	1.2	0.8	1.5	56.8	53.5	60.2	81.6	75.0	88.1	94.2	90.7	97.7
			6-10 DA-C	33.9	6.0	61.8	11.2	1.8	20.5	3.6	0.8	6.3	0.4	0.3	0.5	66.9	63.9	69.9	87.0	84.3	89.7	95.6	91.7	99.6

3.2.2.2 Use 2: Control of *Artogeia rapae* [PIERRA] and *Mamestra brassicae* [BARABR] in cauliflower and in broccoli

The results for both pests will be presented together due to their similar biology.

Two trials from the North-East EPPO zone (Poland) are submitted to demonstrate the minimum effective dose of SAP09I against imported cabbage worm and cabbage caterpillar in cauliflower.

The average efficacy against PIERBR/PIERRA increased continuously with higher dose rate and number of treatments of SAP09I. The highest efficacy was noted at a dose rate of 0.2 L/ha after 3 applications. Nevertheless, good results were also achieved after 3 treatments at a dose rate of 0.1 L/ha. Although the average efficacy against PIERBR/PIERRA after three treatments at 0.06 L/ha was at 83.6%, the control of PIERRA after three treatments at 0.06 L/ha was insufficient. Therefore, this rate was considered ineffective. Considering the results of both trials, it can be concluded that a minimum effective dose rate of 0.1-0.2 L/ha for this use is justified.

A summary of the dose response results is provided in Table 3.2-14.

Table 3.2-14: Minimum effective dose of SAP09I for control of PIERBR/PIERRA in cauliflower (summary results)

No. of trials	Crop	Target	Assessment timing	Infestation (number of larvae / 25 plants)												% Control								
				UTC			SAP09I 0.06 L/ha			SAP09I 0.1 L/ha			SAP09I 0.2 L/ha			SAP09I 0.06 L/ha			SAP09I 0.1 L/ha			SAP09I 0.2 L/ha		
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.
2	BRSOL	PIERBR/PIERRA (larvae)	2-3 DA-A	49.8	48.5	51.0	28.7	7.8	49.5	26.9	1.8	52.0	25.2	0.3	50.0	43.7	5.4	81.9	54.1	12.4	95.8	57.6	15.5	99.6
			7 DA-A	47.4	40.5	54.3	22.4	2.0	42.8	19.0	0.0	38.0	12.2	0.0	24.3	58.7	23.1	94.2	70.1	40.1	100.0	80.9	61.8	100.0
			2-3 DA-B	46.5	36.5	56.5	17.2	0.0	34.3	12.3	0.0	24.5	8.4	0.0	16.8	70.7	41.3	100.0	81.5	63.0	100.0	87.4	74.7	100.0
			7 DA-B	46.0	35.0	57.0	14.3	0.0	28.5	9.5	0.0	19.0	5.5	0.0	11.0	76.1	52.1	100.0	85.9	71.7	100.0	91.7	83.4	100.0
			2-3 DA-C	45.2	34.0	56.3	12.0	0.0	24.0	7.2	0.0	14.3	3.4	0.0	6.8	49.8	59.0	100.0	89.3	78.5	100.0	95.0	90.0	100.0
			6-10 DA-C	38.2	17.5	58.8	10.0	0.0	20.0	6.2	0.0	12.3	2.4	0.0	4.8	83.6	67.1	100.0	91.1	82.1	100.0	96.6	93.2	100.0

3.2.2.3 Use 3: Control of *Thrips tabaci* [THRITB] in onion

Two trials from the North-East EPPO zone (Poland) are submitted to demonstrate the minimum effective dose of SAP09I against onion thrips in onion.

The efficacy against THRITB increased continuously with higher dose rate and number of treatments of SAP09I. The highest efficacy was noted at a dose rate of 0.2 L/ha after 3 applications. Nevertheless, good results were also achieved after 3 treatments at a dose rate of 0.15 L/ha. The efficacy against THRITB after three treatments at 0.09 L/ha was insufficient.

When analysing the level of plant damage, the last assessment was considered. During the earlier evaluations, the percentage damage area was too low for conclusive results. The results of the plant damage control also indicated a high efficacy of the 0.15 L/ha and 0.2 L/ha doses. The plant damage control at 0.09 L/ha dose was insufficient after a large infestation of the pest.

Considering the results of both trials, it can be concluded that a minimum effective dose rate of 0.15-0.2 L/ha for this use is justified.

A summary of the dose response results is provided in Table 3.2-15 and in Table 3.2-16.

Table 3.2-15: Minimum effective dose of SAP09I for control of THRITB in onion (summary results)

No. of trials	Crop	Target	Assessment timing	Infestation (number of larvae / 20 plants)												% Control								
				UTC			SAP09I 0.09 L/ha			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha			SAP09I 0.09 L/ha			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha		
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.
2	ALLCE	THRITB (larvae)	1 DA-A	186.3	86.3	286.3	128.3	54.0	202.5	105.3	36.8	173.8	70.7	41.5	99.8	31.0	28.9	33.1	47.8	39.8	55.8	60.1	55.5	64.7
			3 DA-A	189.6	89.3	289.8	117.9	41.3	194.5	95.3	21.0	169.5	59.2	21.0	97.3	41.7	32.5	50.9	58.9	42.0	75.8	72.1	66.0	78.2
			7 DA-A	189.2	89.3	289.0	114.0	37.5	190.5	93.2	18.5	167.8	57.9	19.3	96.5	44.5	33.7	55.2	60.6	42.5	78.7	73.1	66.2	80.0
			1 DA-B	182.3	77.8	286.8	65.4	21.0	109.8	45.7	14.3	77.0	19.1	13.3	24.8	66.2	61.3	71.1	77.2	73.4	81.1	87.7	84.1	91.2
			3 DA-B	178.7	67.0	290.3	60.1	15.8	104.3	43.3	11.0	75.5	16.9	10.5	23.3	69.3	63.7	74.8	78.5	74.2	82.8	88.6	85.4	91.8
			7 DA-B	169.9	56.5	283.3	54.5	13.0	96.0	41.7	9.3	74.0	15.4	8.5	22.3	70.5	65.8	75.2	78.4	74.0	82.9	89.0	86.0	92.0
			1 DA-C	167.8	45.3	290.3	33.8	11.0	56.5	10.5	7.0	14.0	6.4	5.8	7.0	77.0	73.7	80.3	89.7	84.1	95.2	92.8	88.0	97.5
			3 DA-C	159.9	32.0	290.3	29.6	9.8	49.3	9.6	6.8	12.3	4.4	4.0	4.8	65.5	63.7	67.2	87.2	78.6	95.8	92.4	86.2	98.6
			7 DA-C	152.4	15.0	287.8	25.4	5.0	45.8	7.2	2.3	12.0	0.9	0.0	1.8	73.8	63.6	84.1	91.4	86.9	95.9	99.7	99.4	100.0

Table 3.2-16: Minimum effective dose of SAP09I for control of THRITB in onion – plant damage (summary results)

No. of trials	Crop	Assessment type	Assessment timing	% Control											
				UTC Plant damage (% area from 20 plants)			SAP09I 0.09 L/ha			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha		
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.
1	ALLCE	Plant damage (% area from 20 plants)	7 DA-A	2.0			100.0			100.0			100.0		
1			7 DA-B	5.0			85.0			100.0			100.0		
2			7 DA-C	5.7	1.3	10.0	82.5	65.0	100.0	97.5	95.0	100.0	100.0	100.0	100.0

3.2.2.4 Use 4: Control of *Thrips tabaci* [THRITB] in leek

Two trials from the North-East EPPO zone (Poland) are submitted to demonstrate the minimum effective dose of SAP09I against onion thrips in leek.

The efficacy against THRITB increased continuously with higher dose rate and number of treatments of SAP09I. The highest efficacy was noted at a dose rate of 0.2 L/ha SAP09I after 3 applications. Nevertheless, good results were also achieved after 3 treatments at a dose rate of 0.15 L/ha. The efficacy against THRITB after three treatments at 0.09 L/ha was insufficient.

When analysing the level of plant damage also indicated a high efficacy of the 0.2 L/ha dose, a moderate efficacy of 0.15 L/ha dose and a low control at 0.09 L/ha.

Considering the results of both trials, it can be concluded that a minimum effective dose rate of 0.15-0.2 L/ha for this use is justified.

A summary of the dose response results is provided in Table 3.2-17 and in Table 3.2-18.

Table 3.2-17: Minimum effective dose of SAP09I for control of THRITB in leek (summary results)

No. of trials	Crop	Target	Assessment timing	Infestation (number of larvae / 20 plants)												% Control								
				UTC			SAP09I 0.09 L/ha			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha			SAP09I 0.09 L/ha			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha		
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.
2	ALLPO	THRITB (larvae)	1-2 DA-A	147.2	128.8	165.5	135.2	129.5	140.8	96.3	96.3	96.3	65.7	47.8	83.5	14.8	12.7	16.9	41.2	40.6	41.8	57.8	48.9	66.7
			3-4 DA-A	146.2	129.0	163.3	121.6	112.8	130.3	64.1	55.3	72.8	33.3	24.3	42.3	22.9	18.0	27.8	60.7	55.9	65.4	78.5	73.8	83.1
			7 DA-A	152.4	135.0	169.8	114.7	100.0	129.3	61.6	53.3	69.8	30.3	22.8	37.8	30.2	21.9	38.6	63.7	59.7	67.6	81.1	77.3	85.0
			1-2 DA-B	150.4	131.0	169.8	103.8	89.0	118.5	49.2	48.0	50.3	20.1	16.8	23.3	35.8	28.2	43.5	70.6	70.1	71.0	87.4	86.1	88.7
			3-4 DA-B	150.7	137.0	164.3	94.9	81.8	108.0	43.1	42.3	43.8	11.4	9.5	13.3	41.3	32.6	50.1	74.4	73.7	75.1	92.8	91.4	94.1
			7 DA-B	147.7	137.8	157.5	88.7	77.8	99.5	40.2	38.5	41.8	13.4	9.8	17.0	44.0	35.6	52.4	75.3	72.3	78.2	91.5	89.0	93.9
			1-2 DA-C	154.4	141.0	167.8	70.9	63.3	78.5	31.2	27.3	35.0	9.8	5.0	14.5	57.0	52.1	61.8	81.8	78.8	84.9	94.2	91.3	97.0
			3-4 DA-C	147.8	142.3	167.8	61.7	55.8	67.5	24.4	18.5	30.3	12.5	2.5	22.5	60.0	53.7	66.4	84.8	79.7	89.8	87.4	85.0	89.8
			7 DA-C	152.7	146.3	153.3	61.1	45.3	76.8	22.1	15.8	28.3	1.9	1.0	2.8	61.8	50.3	73.2	86.6	81.7	91.6	98.9	98.3	99.5

Table 3.2-18: Minimum effective dose of SAP09I for control of THRITB in leek – plant damage (summary results)

No. of trials	Crop	Assessment type	Assessment timing	% Control											
				UTC Plant damage (% area from 20 plants)			SAP09I 0.09L/ha			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha		
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.
2	ALLPO	Plant damage (% area from 20 plants)	7 DA-A	4.0	1.5	6.5	71.4	42.8	100.0	67.4	34.8	100.0	74.5	49.0	100.0
			7 DA-B	7.7	5.0	10.3	70.0	50.0	90.0	73.8	52.6	95.0	83.8	67.5	100.0
			7 DA-C	8.8	5.5	12.0	55.6	43.3	67.9	73.1	54.7	91.4	91.3	82.5	100.0

3.2.2.5 Use 5: Control of *Adoxophyes orana* [CAPURE] in apple

Five Eight trials from the North-East EPPO zone (Poland) are submitted to demonstrate the minimum effective dose of SAP09I against smaller tea tortrix in apple.

Due to the low infestation of the pest during the growing season, confirmation of the minimum dose was carried out based on fruit damage assessments. It was also decided to conduct a second season of trials to confirm the originally submitted results.

The dose rates (in L/ha) justified by the originally submitted risk assessment in the other sections of the dossier sections (residues, ecotoxicology...) were considered as the maximum possible rates for efficacy. Following the guidance of EPPO standard PP 1/239 (3) Dose expression for plant protection products, the treated LWA was calculated, and the doses were expressed both in L/ha and in L/10000 m² LWA.

The LWA treated in these 8 trials ranged from 11892m²/ha to 14286m²/ha.

Analysing the level of infested fruit, results on shoots and fruits, it is seen that there was very good effectiveness of the 0.21-0.25 L/10000m² LWA (0.3 L/ha) dose and insufficient lower but still sufficient level of control at 0.13-0.15 L/10000m² LWA (0.18 L/ha), when the product was applied twice. In addition, it is shown that only one application of SAP09I at 0.21-0.25 L/10000m² LWA (0.3 L/ha) gave similar results than two applications at 0.13-0.15 L/10000m² LWA (0.18 L/ha).

It could be hypothesised that a further reduction of the dose will display insufficient control. However, the applicant acknowledges that new trials to prove this are necessary and is willing to perform them and submit the summarised results as a post-approval requirement.

Therefore, it can be concluded that a minimum effective dose rate of 0.3-0.18 L/ha 0.13-0.15 L/10000m² LWA (0.14 L/10000m² LWA), for this use is justified, when the product is applied twice and of 0.3 L/ha 0.21-0.25 L/10000m² LWA (0.23 L/10000m² LWA, in average), when the product is applied only once.

A summary of the dose response results is provided in Table 3.2-19 and in Table 3.2-20.

Table 3.2-19: Minimum effective dose of SAP09I for control of CAPURE in apple (summary results) – after 1 or 2 applications

No. of trials	Crop	Target	Assessment timing	Infestation (no. of larvae / 100 shoots)									% Control					
				UTC			SAP09I 0.18 L/ha			SAP09I 0.3 L/ha			SAP09I 0.18 L/ha			SAP09I 0.3 L/ha		
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.
5	MABSD	CAPURE (larvae)	14-17 DA-B	1.8	0.8	3.0	0.1	0.0	0.3	0.1	0.0	0.3	85.0	75.0	100.0	93.3	75.0	100.0
			41-52 DA-B	6.2	2.3	12.8	0.4	0.0	1.0	0.2	0.0	0.5	94.4	81.7	100.0	98.2	92.3	100.0

Crop	Target	Infestation (no. of larvae / 100 shoots)				% Control (# larvae/100 shoots)											
		UTC				SAP09I				SAP09I				SAP09I			
						0.14 L/10000m2 LWA				0.23 L/10000m2 LWA				0.23 L/10000m2 LWA			
						0.18 L/ha				0.3 L/ha				0.3 L/ha			
						Applications A & B				Applications A & B				Application A			
		Assessment: 24-27 DA-A / 14-17 DA-B															
MABSD	CAPURE	Mean	Min.	Max.	#	Mean	Min.	Max.	#	Mean	Min.	Max.	#	Mean	Min.	Max.	#
		7.1	0.8	21.5	8	78.5	44.2	100.0	8.0	92.3	75.0	100.0	8.0	87.5	75.0	100.0	5.0

Table 3.2-20: Minimum effective dose of SAP09I for control of CAPURE in apple – attacked fruits (summary results) – after 1 or 2 applications

							% Control					
No. of tri- als	Crop	Assessment type	Assessment timing	UTC			SAP09I 0.18 L/ha			SAP09I 0.3 L/ha		
				Fruit attacked (%)			Mean	Min.	Max.	Mean	Min.	Max.
5	MARSD	% Fruit attacked (500 fruits)	51-52 DA-B	3.1	1.4	5.1	64.6	43.9	94.4	86.5	80.2	97.5

Crop	Target	Incidence = % Fruits attacked (500 fruits)				% Control (incidence on 500 fruits)											
		UTC				SAP09I				SAP09I				SAP09I			
						0.14 L/10000m2 LWA				0.23 L/10000m2 LWA				0.23 L/10000m2 LWA			
						0.18 L/ha				0.3 L/ha				0.3 L/ha			
						Applications A & B				Applications A & B				Application A			
		Assessment: 53-62 DA-A / 41-69 DA-B															
MABSD	CAPURE	Mean	Min.	Max.	#	Mean	Min.	Max.	#	Mean	Min.	Max.	#	Mean	Min.	Max.	#
		5.1	1.4	12.1	8	70.1	43.9	94.4	8	88.6	80.2	98.1	8	67.6	55.9	88.3	5

Summary and conclusion

A total 13 16 field trials were established in the North-East EPPO zone to determine the minimum effective dose of SAP09I for the control of different pest species in a range of vegetable and horticultural crops. The trials were conducted in 2024 and 2025, in Poland.

In the trials, SAP09I was tested at 0.06 to 0.2 L/ha after 2 to 3 applications, depending on the use. The target dose rates for each crop were aligned with the national authorization of the standard reference product SpinTor 480 SC.

The results of the trials confirmed the below minimum effective doses for the tested uses:

- 0.1-0.2 L/ha for *Brassica* crops (on head cabbage against imported cabbage worm [PIERRA]; on cauliflower against imported cabbage worm and cabbage caterpillar [PIERBR]);
- 0.15-0.2 L/ha for *Allium* crops (onion and leek), against onion thrips [THRITB];
- 0.14-0.23 L/10000 m² LWA (0.18-0.3 L/ha) for apple, against smaller tea tortrix [CAPURE].

In case the data package for SAP09I should be completed, a reference is made to non-protected data from the product SpinTor 480 SC.

Study Comments3.2.2 dRR point 3.2.2	Minimum effective dose tests
For the following uses in the GAP table, evaluation in accordance with the art. 33 rules is proposed by the evaluator, because of the fact that these uses were not subjects of the first authorization (unprotected data) and can not be evaluated considering “bridging concept”: • head cabbage/PIERBR • broccoli, cauliflower/PIERRA, BARABR • onion/THRITB • leek/THRITB That is why, minimum effective dose needs to be evaluated. The dose justification of SAP09I was supported by data from efficacy trials on: cauliflower against PIERBR (1 trial) and against PIERRA (1 trial on cauliflower and 2 trials on head cabbage); onion and leek against THRITB (2 trials for onion and two trials for leek) for which efficacy of SAP09I is claimed. In trials efficacy of reduced doses were compared: • 0,06; 0,1; 0,2 L/ha in protection of head cabbage and cauliflower against PIERRA (2 applications) • 0,06; 0,1; 0,2 L/ha in protection of cauliflower against PIERBR (3 applications) • 0,09; 0,15; 0,2 L/ha in protection of onion and leek against THRITB (3 applications) Trials were conducted in PL, in 2024. SAP09I at the dose rate of 0,2 l/ha against PIERRA gave higher level of efficacy in comparison to reduced dose rates. Data from head cabbage and cauliflower can be considered together as both minor crops belong to the same genus – <i>Brassica</i>. The dose rate 0,2 l/ha may be considered the minimum dose. In case of combination cauliflower/PIERBR, results showed that dose rate 0,06 l/ha can be acceptable to protect the brassica vegetables. Nevertheless, 1 trial can not be sufficient to confirm efficacy. What is more, the product showed much more better efficacy against PIERBR that against PIERRA. Therefore mean efficacy results for both pest species can not be presented together. Minimum effective dose against BARABR was not tested. SAP09I at the dose rate of 0,2 l/ha against THRITB on onion and leek gave higher level of efficacy in comparison to reduced dose rates. The dose rate 0,2 l/ha may be considered the minimum dose.	

The applicant changed the GAP table after commenting period, because of the ecotox. risk assessment and asked for re-evaluation according the changed GAP table. The lower doses were proposed for most uses, that is why for more information, please see the comment for point 3.2 Efficacy tests.

3.2.3 Efficacy tests (KCP 6.2)

In total 13-16 field trials were conducted to evaluate the efficacy and comparability of SAP09I with SpinTor480 SC against various pests in vegetable and horticultural crops:

- 2 trials were conducted in head cabbage against *Artogeia rapae* [PIERRA]
- 2 trials were conducted in cauliflower. One to investigate product efficacy against *Artogeia rapae* [PIERRA] and the second against *Pieris brassicae* [PIERBR]
- 2 trials were done in onion against *Thrips tabaci* [THRITB]
- 2 trials were performed in leek against *Thrips tabaci* [THRITB]
- 8 5 trials were conducted in apple against *Adoxophyes orana* [CAPURE]

Testing facilities and organisations

CRO (Contract Research Organisation) were in charge of the trials. The testing facilities responsible for conducting the trials are listed under the point 3.7. All are GEP approved and copies to the corresponding certificates are included under the same point.

Location of trials

All 13-16 field trials were conducted in Poland belonging to the North-East EPPO climatic zone in Europe as set out in the EPPO standard PP 1/241(2).

Methodology

Brassica crops

Trials were designed, conducted and reported in accordance with general EPPO standards PP 1/225(2), PP 1/135(4), PP 1/152(4) and PP 1/181(5) on design, analyses and reporting. Moreover, the specific EPPO standard PP 1/83(2) '*Caterpillars on leaf brassicas*' has been followed in the efficacy trials presented in this Chapter. The specific standard mainly recommends:

- a trial design with minimum 4 replicates;
- a plot size containing at least 25 plants (10 plant in the case of artificial infestation);
- the type, number and timing of application should be as specified for the intended use;
- for assessment, caterpillar number on 25 plants per plot (live and dead caterpillars from 10 plant in the case of artificial infestation).

To determine the efficacy of SAP09I, a bridging strategy was used, by which it is demonstrated that the product has comparable effectiveness as SpinTor 480 SC, following the provisions of EPPO PP 1/307(2) '*Efficacy considerations and data generation when making changes to the chemical composition or formulation type of plant protection products*'.

The number of trials per crop/target complied with the provisions of EPPO PP 1/307(2) and the '*Guideline for the preparation of assessments or comments on plant protection products by authorized entities in Poland*' (version of 13 August 2024).

As both products have a comparable efficacy against the intended field uses and comparable crop safety, a reference to the unprotected data of SpinTor 480 SC is made to have a full data set demonstrating the efficacy of the test product.

The main characteristics of field trials is presented in BAD. Additional information on trial sites, applications and data on effectiveness are given in the single trial reports.

Products tested

The product SAP09I was tested at 0.1 L/ha and 0.2 L/ha (48 and 96 g/ha of spinosad, respectively) reflecting the proposed label rates and the dose rates registered for the reference product SpinTor 480 SC.

Three applications with 7-day intervals were performed, according to the proposed GAP.

SAP09I was compared with the product containing spinosad 480 g/L that is registered in Poland. More information about reference standard can be found in Table 3.2-12.

Assessments

Assessments were performed at application (preliminary assessment), 2-3 and 7-14 days after each application, according to the EPPO standard PP 1/83(2) requirements. Results from all assessments will be presented. However, the results from the last evaluation after the last application are considered representative.

Presentation of efficacy & Data grouping

The control level is presented as % efficacy. The efficacy was calculated according to with the Henderson-Tilton formula as the population was non-uniform, to take the infestation before treatment into account.

In all trials, efficacy against target pests was calculated based on evaluation of target density.

All available data for the crop will be presented together. All trials were performed in Poland belonging to the North-East one EPPO zone and the Central Regulatory zone, so no additional grouping was considered necessary.

Statistical analysis

Data were subjected to analysis of variance (ANOVA) at the 95% confidence level. When significant differences were found a Student-Newman-Keuls (SNK) test was applied to separate the means. Treatment means with no letters in common are significantly different according to the SNK test.

A general overview of the methodology used in efficacy trials in *Brassica* crops is shown in Table 3.2-21.

Table 3.2-21: Details on trial methodology. *Brassica* crops

		North-East EPPO zone	
		Head cabbage	Cauliflower
Trials	Total number	2	2
Guidelines	General EPPO standards	EPPO PP 1/135(4) EPPO PP 1/152(4) EPPO PP 1/181(5)	EPPO PP 1/135(4) EPPO PP 1/152(4) EPPO PP 1/181(5)
	Specific EPPO standards	EPPO PP 1/83(2)	EPPO PP 1/83(2)
Experimental design	Plot design	Randomized Complete Blocks, untreated included (2)	Randomized Complete Blocks, untreated included (2)
	Plot size	12.5 m ² (1), 13.5 m ² (1)	7.4 m ² (1), 10.5 m ² (1)
	Number of replications	4 (2)	4 (2)
Crop	Trials per crop	Head cabbage [BRSOL] (2)	Cauliflower [BRSOB] (2)
	Varieties per crop	Kronos (1), Zoltan (1)	Claforsa (1), Whitex (1)
	Planting period	June (1), July (1)	July (1)
Application	Crop stage (min and max BBCH) at application	Application A: 19-44 (2) Application B: 19-44 (2) Application C: 41-45 (2)	Application A: 18-42 (2) Application B: 34-43 (2) Application C: 37-44 (2)
	Timing Pest stage at application	<i>Artogeia rapae</i> [PIERRA] (2) Application A: mixed (1), larvae (1) Application B: mixed, larvae (1) Application C: mixed, larvae (1)	<i>Pieris brassicae</i> [PIERBR] (1) Application A: larvae (1) Application B: larvae (1) Application C: larvae (1) <i>Artogeia rapae</i> [PIERRA] (1) Application A: mixed (1), larvae (1) Application B: mixed, larvae (1) Application C: mixed, larvae (1)
	Number of applications	3 (2)	3 (2)
	Intervals between applications	7 days	7 days
	Spray volumes	Application A: 400 L/ha (1), 500 L/ha (1) Application B: 400 L/ha (1), 500 L/ha (1) Application C: 400 L/ha (1), 500 L/ha (1)	Application A: 300 L/ha (1), 400 L/ha (1) Application B: 400 L/ha (2) Application C: 400 L/ha (1), 500 L/ha (1)
Assessment	Assessment types	Number of caterpillars / 25 plants per plot; Phytotoxicity	Number of caterpillars / 25 plants per plot; Phytotoxicity
	Assessment dates	0 DA-A, 2-3 DA-A, 7-14 DA-A; 2-3 DA-B, 7-14 DA-B; 2-3 DA-C, 7-14 DA-C	0 DA-A, 2-3 DA-A, 7-14 DA-A; 2-3 DA-B, 7-14 DA-B; 2-3 DA-C, 7-14 DA-C
Other relevant information	Infestation	Natural	Natural
	Site type	Field	Field

***Allium* crops**

Trials were designed, conducted and reported in accordance with general EPPO standards PP 1/225(2), PP 1/135(4), PP 1/152(4) and PP 1/181(5) on design, analyses and reporting. Moreover, the specific EPPO standard PP 1/267(1) '*Thrips in Allium crops*' has been followed in the efficacy trials presented in this Chapter. The specific standard mainly recommends:

- a trial design with minimum 4 replicates;
- a plot size at least 10 m²;
- the type, number and timing of application should be as specified for the intended use;
- for assessment, thrips number – particularly larvae (20 plants per plot); evaluation of damaged area (20 plants per plot).

To determine the efficacy of SAP09I, a bridging strategy was used, by which it is demonstrated that the product has comparable effectiveness as SpinTor 480 SC, following the provisions of EPPO PP 1/307(2) '*Efficacy considerations and data generation when making changes to the chemical composition or formulation type of plant protection products*'.

The number of trials per crop/target complied with the provisions of EPPO PP 1/307(2) and the '*Guideline for the preparation of assessments or comments on plant protection products by authorized entities in Poland*' (version of 13 August 2024).

As both products have a comparable efficacy against the intended field uses and comparable crop safety, a reference to the unprotected data of SpinTor 480 SC is made to have a full data set demonstrating the efficacy of the test product.

The main characteristics of field trials is presented in BAD. Additional information on trial sites, applications and data on effectiveness are given in the single trial reports.

Products tested

The product SAP09I was tested at 0.15 L/ha and 0.2 L/ha (72 and 96 g/ha of spinosad, respectively) reflecting the proposed label rates and the dose rates registered for the reference product SpinTor 480 SC. Three applications with 10-day intervals were performed, according to the proposed GAP.

SAP09I was compared with the product containing spinosad 480 g/L that is registered in Poland. More information about reference standard can be found in Table 3.2-12.

Assessments

Assessments were performed at application (preliminary assessment), 1-2, 3-5 and 7 days after each application, according to the EPPO standard PP 1/267(1) requirements.

Results from all assessments will be presented. However, the results from the last evaluation after the last application are considered representative.

Presentation of efficacy & Data grouping

The control level is presented as % efficacy. The efficacy on larvae was calculated according to with the Henderson-Tilton formula as the population was non-uniform, to take the infestation before treatment into account. In all trials, efficacy against target pest was calculated based on evaluation of target density. The plant damage control was calculated using the Abbott formula.

All available data for the crop will be presented together. All trials were performed in Poland belonging to the North-East one EPPO zone and the Central Regulatory zone, so no additional grouping was considered necessary.

Statistical analysis

Data were subjected to analysis of variance (ANOVA) at the 95% confidence level. When significant differences were found a Student-Newman-Keuls (SNK) test was applied to separate the means. Treatment means with no letters in common are significantly different according to the SNK test.

A general overview of the methodology used in efficacy trials in *Allium* crops is shown in Table 3.2-22.

Table 3.2-22: Details on trial methodology. *Allium* crops

		North-East EPPO zone	
		Onion	Leek
Trials	Total number	2	2
Guidelines	General EPPO standards	EPPO PP 1/135(4) EPPO PP 1/152(4) EPPO PP 1/181(5)	EPPO PP 1/135(4) EPPO PP 1/152(4) EPPO PP 1/181(5)
	Specific EPPO standards	EPPO PP 1/267(1)	EPPO PP 1/267(1)
Experimental design	Plot design	Randomized Complete Blocks, untreated included (2)	Randomized Complete Blocks, untreated included (2)
	Plot size	12.0 m ² (2)	12.0 m ² (1), 18.9 m ² (1)
	Number of replications	4 (2)	4 (2)
Crop	Trials per crop	Onion [ALLCE] (2)	Leek [ALLPO] (2)
	Varieties per crop	Majka (1), Rijnsburger S VS 114 (1)	Cherokee (1), Krypton (1)
	Planting period	March (1), April (1)	June (1), July (1)
Application	Crop stage (min and max BBCH) at application	Application A: 15-45 (2) Application B: 17-47 (2) Application C: 41-48 (2)	Application A: 15-17 (2) Application B: 15-41 (2) Application C: 16-43 (2)
	Timing Pest stage at application	<i>Thrips tabaci</i> [THRITB] (2) Application A: mixed (2) Application B: mixed (2) Application C: mixed (2)	<i>Thrips tabaci</i> [THRITB] (2) Application A: mixed (2) Application B: mixed (2) Application C: mixed (2)
	Number of applications	3 (2)	3 (2)
	Intervals between applications	10 days	10 days
	Spray volumes	Application A: 300 L/ha (1), 500 L/ha (1) Application B: 300 L/ha (1), 500 L/ha (1) Application C: 300 L/ha (1), 500 L/ha (1)	Application A: 200 L/ha (1), 500 L/ha (1) Application B: 200 L/ha (1), 500 L/ha (1) Application C: 300 L/ha (1), 500 L/ha (1)
Assessment	Assessment types	Number of thrips (20 plants per plot); Percentage of damaged plants (20 plants per plot); Phytotoxicity	Number of thrips (20 plants per plot); Percentage of damaged plants (20 plants per plot); Phytotoxicity
	Assessment dates	0 DA-A, 1-2 DA-A, 3-5 DA-A, 7 DA-A; 1-2 DA-B, 3-5 DA-B, 7 DA-B; 1-2 DA-C, 3-5 DA-C, 7 DA-C;	0 DA-A, 1-2 DA-A, 3-5 DA-A, 7 DA-A; 1-2 DA-B, 3-5 DA-B, 7 DA-B; 1-2 DA-C, 3-5 DA-C, 7 DA-C;
Other relevant information	Infestation	Natural	Natural
	Site type	Field	Field

Apple

Trials were designed, conducted and reported in accordance with general EPPO standards PP 1/225(2), PP 1/135(4), PP 1/152(4) and PP 1/181(5) on design, analyses and reporting. Moreover, the specific EPPO standard PP 1/6(3) 'Adoxophyes orana' has been followed in the efficacy trials presented in this Chapter. The specific standard mainly recommends:

- a trial design with minimum 4 replicates;
- a plot size at least 4 trees or sufficient to provide 100 extension shoots and 500 fruits;
- the type, number and timing of application should be as specified for the intended use;
- for assessment, larvae and pupae number (on at least 100 extension shoots per plot); at harvest evaluation of percentage of fruits attacked (at least 500 fruits per plot).

A full set of trials performed in one season has been provided to evaluate efficacy of SAP09I against Adoxophyes orana as set in the 'Guideline for the preparation of assessments or comments on plant protection products by authorized entities in Poland' (version of 13 August 2024).

Nevertheless, as both products SAP09I and the reference have a comparable efficacy against the intended field uses and comparable crop safety, a reference to the unprotected data of SpinTor 480 SC is made to have a complete data set demonstrating the efficacy of the test product.

The main characteristics of field trials is presented in BAD. Additional information on trial sites, applications and data on effectiveness are given in the single trial reports.

Products tested

The product SAP09I was tested at 0.21-0.25 L/10000m² LWA (0.3 L/ha = 144 g/ha of spinosad) reflecting the proposed label rate and the dose rate registered for the reference product SpinTor 480 SC. A lower rate 0.13-0.15 L/10000m² LWA (0.18 L/ha) was also tested.

One or two applications with 10-day interval were performed, according to the proposed GAP. SAP09I was compared with the product containing spinosad 480 g/L that is registered in Poland. More information about reference standard can be found in Table 3.2-12.

Dose rate expression – calculation of the leaf wall area (LWA)

Since 2020, the leaf wall area has to be considered for pome fruits, grapes and high growing vegetables in the Central Registration zone. The calculation of the leaf wall area (LWA) in apple had been performed according to the EPPO PP 1/239 (3).

A summary of tested doses and dose conversions is presented in Table 3.2-23.

Dose conversions along with the required parameters are given in BAD.

Following the guidance of EPPO standard PP 1/239 (3) Dose expression for plant protection products, the treated LWA was calculated, and the doses were expressed in L/10000 m² LWA, with maximum L/ha (originally 0.3 L/ha) according to the risk assessment in the other sections of the dossier.

During the evaluation of the dossier, the maximum supported dose for 2 applications of SAP09I had to be reduced from 0.3 L/ha to 0.225 L/ha, to solve some issues in the ecotoxicological risk assessment. Therefore, the maximum dose for 2 applications was set between the two evaluated doses. Since either 0.13-0.15 L/10000m² LWA (equivalent to 0.18 L/ha) and 0.21-0.25 L/10000m² LWA (equivalent to 0.3 L/ha), demonstrated to be effective against CAPURE when two applications were performed, this new intermediate dose is considered supported by the efficacy data summarised in this document. Taking in consideration the treated LWA, the new max. dose in L/1000m² LWA for two applications is shown in the following table.

Table 3.2-23: Tested and new maximum doses for two applications dose conversion in apple trials

Number of trials	Spray volume (L/ha)	Crop	Treated LWA (m ² /ha)	Tested rates of SAP09I		
				Ground Area Dose (L/ha)		
				0.18	0.225	0.3
				L/1000 m ² of LWA		
58	500-1000	Apple [MABSD]	11892-13514 14286	0.14	0.17	0.23

Assessments

Assessments were performed at application (preliminary assessment), 14 days after the first application, 14 and 30 days after the second application and after harvest (on fruits), according to the EPPO standard PP 1/6(3) requirements.

Results from all assessments will be presented. However, due to a low infestation on shoots, the efficacy results on fruit are considered representative. Results from the most representative assessments on shoots and fruits are presented.

Presentation of efficacy & Data grouping

The control level is presented as % efficacy. The efficacy (pest population and control on shoots and fruits of fruit damage) was calculated according to with the Abbott formula. In all trials, efficacy against target pest was calculated based on evaluation of target density.

All available data for the crop will be presented together. All trials were performed in Poland belonging to the North-East one EPPO zone and the Central Regulatory zone, so no additional grouping was considered necessary.

Statistical analysis

Data were subjected to analysis of variance (ANOVA) at the 95% confidence level. When significant differences were found a Student-Newman-Keuls (SNK) test was applied to separate the means. Treatment means with no letters in common are significantly different according to the SNK test.

A general overview of the methodology used in efficacy trials in apple is shown in Table 3.2-24.

Table 3.2-24: Details on trial methodology. Apple

		North-East EPPO zone
		Apple
Trials	Total number	58
Guidelines	General EPPO standards	EPPO PP 1/135(4) EPPO PP 1/152(4) EPPO PP 1/181(5) EPPO PP 1/239 (3)
	Specific EPPO standards	EPPO PP 1/6(3)
Experimental design	Plot design	Randomized Complete Blocks, untreated included (5)
	Plot size	18.5 m ² (2), 21 m ² (2) 24 m ² (1), 30.0 m ² (2), 30.4 m ² (1)

		North-East EPPO zone
		Apple
	Number of replications	4 (5)
Crop	Trials per crop	Apple [MABSD] (8)
	Varieties per crop	Eliza (1), Gloster (1), Golden Delicious (2), Szampion (2) Ligol (1), Jonaprince (1)
	Plant age	5 years (2), 7 years (2), 8 years (1), 10 years (1), 12 years (1), 17 years (1)
Application	Crop stage (min and max BBCH) at application	Application A: 73-81 (8) Application B: 75-83 (8)
	Timing Pest stage at application	<i>Adoxophyes orana</i> [CAPURE] (8) Application A: larvae (5), Mixed (3) Application B: larvae (5), Mixed (3)
	Number of applications	2 (8)
	Intervals between applications	10 days
	Spray volumes	Application A: 500 L/ha (3), 680 L/ha (1), 750 L/ha (1), 1000 L/ha (3) Application B: 500 L/ha (3), 680 L/ha (1), 750 L/ha (1), 1000 L/ha (3)
Assessment	Assessment types	Number of larvae & pupae (100 extension shoots); Percentage of attacked fruit (500 fruits per plot); Phytotoxicity
	Assessment dates	0 DA-A, 12-14 DA-A, 14-17 DA-B, 30 DA-B; At harvest
Other relevant information	Infestation	Natural
	Site type	Field

Trials results

3.2.3.1 Use 1: Control of *Pieris brassicae* [PIERBR], *Artogeia rapae* [PIERRA], *Mamestra brassicae* [BARABR] in head cabbage

In order to support the requested use, two trials from the North-East EPPO zone (Poland) were carried out to evaluate efficacy of SAP09I against imported cabbage worm in head cabbage.

According to ‘Guideline for the preparation of assessments or comments on plant protection products by authorized entities in Poland’ (version of 13 August 2024), tests must be carried out for representative uses, (i.e., crop-pest relationship). *Artogeia rapae* [PIERRA] is an important pest in *Brassica* crops and its biology corresponds to remaining requested pests. Therefore, the efficacy results against this pest are considered representative for the remaining requested Lepidoptera species: *Pieris brassicae* [PIERBR] and *Mamestra brassicae* [BARABR].

After the first application (assessment 6-7 DA-A) at 0.1 L/ha and 0.2 L/ha, SAP09I showed efficacy against PIERRA larvae of 62.3% and 77.9%, respectively.

After the second application (assessment 7 DA-B), the efficacy of product SAP09I at 0.1 L/ha and 0.2 L/ha increased. PIERRA larvae control was 78.6% and 89.8%, respectively.

After the third and the last application (assessment 6-10 DA-C), SAP09I reached its highest efficacy: 87.0% at 0.1 L/ha at 95.6% at 0.2 L/ha.

The control of PIERRA larvae by SAP09I was statistically equivalent to the reference product SpinTor 480 SC except for one assessment (3 DA-C) in one trial, where the efficacy of the 0.1 L/ha dose of SAP09I was inferior to the reference.

A summary of the results is provided in Table 3.2-25.

As both products have an equivalent efficacy against the intended uses, a reference to the unprotected data of SpinTor 480 SC is made to have a full data set demonstrating the efficacy of the test product.

Table 3.2-25: Efficacy of SAP09I against PIERRA in head cabbage at different assessment timings (summary results)

				Infestation (number of larvae / 25 plants)						% Control										% Control: number of trials where SAP09I is >, <, = vs. SpinTor 480 SC*		Infestation level: number of trials where SAP09I is >, <, = vs. UTC*	
No. of trials	Crop	Target	Assessment timing	UTC		SAP09I 0.1 L/ha		SAP09I 0.2 L/ha		SAP09I 0.1 L/ha		SAP09I 0.2 L/ha		SpinTor 480 SC 0.1 L/ha			SpinTor 480 SC 0.2 L/ha						
				Mean	Min. Max.	Mean	Min. Max.	Mean	Min. Max.	Mean	Min. Max.	Mean	Min. Max.	Mean	Min.	Max.	Mean	Min.	Max.	0.1 L/ha	0.2 L/ha	0.1 L/ha	0.2 L/ha
2	BRSOL	PIERRA (larvae)	2-3 DA-A	32.8	14.0 51.5	14.1	6.8 21.3	9.0	4.0 14.0	53.4	48.4 58.4	70.5	66.0 75.0	56.4	47.2 65.6	63.3	59.7 66.9	2 trials =	2 trials =	2 trials <	2 trials <		
			6-7 DA-A	35.2	13.3 57.0	9.9	6.3 13.5	5.5	3.5 7.5	62.3	48.9 75.8	77.9	67.9 87.9	62.9	46.6 79.2	71.2	61.0 81.4	2 trials =	2 trials =	2 trials <	2 trials <		
			3 DA-B	34.7	11.8 57.5	6.9	4.3 9.5	3.2	2.0 4.3	71.3	59.7 82.9	86.7	80.2 93.3	74.2	62.5 85.9	81.9	76.8 87.0	2 trials =	2 trials =	2 trials <	2 trials <		
			7 DA-B	35.4	12.3 58.5	6.0	3.0 9.0	2.3	1.8 2.8	78.6	73.2 84.0	89.8	83.8 95.8	82.8	74.5 91.2	89.1	85.3 92.9	2 trials =	2 trials =	2 trials <	2 trials <		
			3 DA-C	33.8	8.3 59.3	4.3	1.8 6.8	1.2	0.8 1.5	81.6	75.0 88.1	94.2	90.7 97.7	89.2	83.4 95.0	92.3	88.6 96.0	1 trial <; 1 trial =	2 trials =	2 trials <	2 trials <		
			6-10 DA-C	33.9	6.0 61.8	3.6	0.8 6.3	0.4	0.3 0.5	87.0	84.3 89.7	95.6	91.7 99.6	90.1	85.8 94.4	96.7	95.2 98.1	2 trials =	2 trials =	2 trials <	2 trials <		

* Based on Student-Newman-Keuls (SNK) test at p=0.05

3.2.3.2 Use 2: Control of *Artogeia rapae* [PIERRA] and *Mamestra brassicae* [BARABR] in cauliflower and in broccoli

The results for both pests will be presented together due to their similar biology.

Two trials from the North-East EPPO zone (Poland) were performed to assess efficacy of SAP09I against imported cabbage worm (*Artogeia rapae* [PIERRA]) and cabbage caterpillar (*Pieris brassicae* [PIERBR]) in cauliflower.

According to ‘Guideline for the preparation of assessments or comments on plant protection products by authorized entities in Poland’ (version of 13 August 2024), tests must be carried out for representative uses, (i.e., crop-pest relationship). *Artogeia rapae* [PIERRA] and *Pieris brassicae* [PIERBR] are important pests in *Brassica* crops and their biology corresponds to remaining requested pests. Therefore, the efficacy results against these pests are considered representative for the remaining requested Lepidoptera species: *Mamestra brassicae* [BARABR].

After the first application (assessment 7 DA-A) at 0.1 L/ha and 0.2 L/ha, SAP09I showed efficacy against PIERRA/PIERBR larvae of 70.1.% and 80.9%, respectively.

After the second application (assessment 7 DA-B), the average efficacy against both species was 85.9% at 0.1 L/ha and 91.7% at 0.2 L/ha.

After the third and the last application (assessment 8-10 DA-C), SAP09I reached its highest average efficacy against both pests: 91.1% at 0.1 L/ha and **96.6%** at 0.2 L/ha.

The control of PIERRA/PIERBR larvae by SAP09I was statistically equivalent to the reference product SpinTor 480 SC except for one assessment (7 DA-A) in one trial, where the efficacy of the 0.1 L/ha dose of SAP09I was inferior to the reference.

A summary of the results is provided in Table 3.2-26.

As both products have an equivalent efficacy against the intended uses, a reference to the unprotected data of SpinTor 480 SC is made to have a full data set demonstrating the efficacy of the test product.

According to EPPO standard PP 1/257(2), it is possible to extrapolate efficacy results among vegetable *Brassica* crops against *Artogeia rapae* and *Pieris brassicae*. As broccoli in Poland is a minor crop, the above extrapolation is applicable. Therefore, no additional studies are required for the proposed uses of SAP09I in broccoli.

Table 3.2-26: Efficacy of SAP09I against PIERBR/PIERRA in cauliflower at different assessment timings (summary results)

No. of trials	Crop	Target	Assessment timing	Infestation (number of larvae / 25 plants)						% Control								% Control: number of trials where SAP09I is >, <, = vs. SpinTor 480 SC*		Infestation level: number of trials where SAP09I is >, <, = vs. UTC*	
				UTC		SAP09I 0.1 L/ha		SAP09I 0.2 L/ha		SAP09I 0.1 L/ha		SAP09I 0.2 L/ha		SpinTor 480 SC 0.1 L/ha		SpinTor 480 SC 0.2 L/ha		0.1 L/ha	0.2 L/ha	0.1 L/ha	0.2 L/ha
				Mean	Min. Max.	Mean	Min. Max.	Mean	Min. Max.	Mean	Min. Max.	Mean	Min. Max.	Mean	Min. Max.	Mean	Min. Max.				
2	BRSOB	PIERBR/PIERRA (larvae)	2-3 DA-A	49.8	48.5 51.0	26.9	1.8 52.0	25.2	0.3 50.0	54.1	12.4 95.8	57.6	15.5 99.6	53.7	13.2 94.2	57.0	14.0 100.0	2 trials =	2 trials =	1 trial <; 1 trial =	1 trial <; 1 trial =
			7 DA-A	47.4	40.5 54.3	19.0	0.0 38.0	12.2	0.0 24.3	70.1	40.1 100.0	80.9	61.8 100.0	76.1	52.2 100.0	79.4	58.8 100.0	1 trial <; 1 trial =	2 trials =	2 trials <	2 trials <
			2-3 DA-B	46.5	36.5 56.5	12.3	0.0 24.5	8.4	0.0 16.8	81.5	63.0 100.0	87.4	74.7 100.0	84.3	68.6 100.0	86.3	72.5 100.0	2 trials =	2 trials =	2 trials <	2 trials <
			7 DA-B	46.0	35.0 57.0	9.5	0.0 19.0	5.5	0.0 11.0	85.9	71.7 100.0	91.7	83.4 100.0	88.6	77.1 100.0	91.0	81.9 100.0	2 trials =	2 trials =	2 trials <	2 trials <
			2-3 DA-C	45.2	34.0 56.3	7.2	0.0 14.3	3.4	0.0 6.8	89.3	78.5 100.0	95.0	90.0 100.0	89.9	79.8 100.0	94.0	88.0 100.0	2 trials =	2 trials =	2 trials <	2 trials <
			8-10 DA-C	38.2	17.5 58.8	6.2	0.0 12.3	2.4	0.0 4.8	91.1	82.1 100.0	96.6	93.2 100.0	91.8	83.5 100.0	96.0	92.0 100.0	2 trials =	2 trials =	2 trials <	2 trials <

* Based on Student-Newman-Keuls (SNK) test at p=0.05

3.2.3.3 Use 3: Control of *Thrips tabaci* [THRITB] in onion

Two trials from the North-East EPPO zone (Poland) were carried out to evaluate efficacy of SAP09I against onion thrips in onion.

After the first application (assessment 7 DA-A) at 0.15 L/ha and 0.2 L/ha, SAP09I controlled THRITB larvae at 60.6% and 73.1%, respectively.

After the second application (assessment 7 DA-B), the efficacy of SAP09I increased to 78.4% at 0.1 L/ha and 89.0% at 0.2 L/ha.

After the third and the last application of the product (assessment 7 DA-C), SAP09I reached its highest average efficacy: 91.4% at 0.15 L/ha and **99.7%** at 0.2 L/ha.

The control of onion thrips by SAP09I was statistically equivalent to the reference product SpinTor 480 SC after the third treatment (both trials).

When analysing the level of plant damage (sucking damage), the last assessment was considered. During the earlier evaluations, the percentage damage area was too low for conclusive results. The assessments on plant damage after the third treatment (3 DA-C) showed 97.5% efficacy of SAP09I at 0.15 L/ha and a full control (**100.0%**) at 0.2 L/ha. Statistical analysis confirmed the comparability of SAP09I to the reference product, regardless of the dose tested.

A summary of the results is provided in Table 3.2-27 (pest control) and in Table 3.2-28 (plant damage).

As both products have an equivalent efficacy against the intended uses, a reference to the unprotected data of SpinTor 480 SC is made to have a full data set demonstrating the efficacy of the test product.

Table 3.2-27: Efficacy of SAP09I against THRITB in onion at different assessment timings (summary results)

No. of trials	Crop	Target	Assessment timing	Infestation (number of larvae / 20 plants)									% Control												% Control: number of trials where SAP09I is >, <, = vs. SpinTor 480 SC*		Infestation level: number of trials where SAP09I is >, <, = vs. UTC*	
				UTC			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha			SpinTor 480 SC 0.15 L/ha			SpinTor 480 SC 0.2 L/ha			0.15 L/ha	0.2 L/ha	0.15 L/ha	0.2 L/ha
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.				
2	ALLCE	THRITB (larvae)	1 DA-A	186.3	86.3	286.3	105.3	36.8	173.8	70.7	41.5	99.8	47.8	39.8	55.8	60.1	55.5	64.7	51.7	50.4	53.1	61.4	55.4	67.5	1 trial <; 1 trial =	2 trials =	2 trials <	2 trials <
			3 DA-A	189.6	89.3	289.8	95.3	21.0	169.5	59.2	21.0	97.3	58.9	42.0	75.8	72.1	66.0	78.2	60.7	51.4	70.1	71.2	68.7	73.7	1 trial <; 1 trial =	2 trials =	2 trials <	2 trials <
			7 DA-A	189.2	89.3	289.0	93.2	18.5	167.8	57.9	19.3	96.5	60.6	42.5	78.7	73.1	66.2	80.0	62.1	51.4	72.9	72.8	69.3	76.3	1 trial <; 1 trial =	2 trials =	2 trials <	2 trials <
			1 DA-B	182.3	77.8	286.8	45.7	14.3	77.0	19.1	13.3	24.8	77.2	73.4	81.1	87.7	84.1	91.2	79.6	79.2	80.0	88.5	82.4	94.5	1 trial <; 1 trial =	1 trial <; 1 trial =	2 trials <	2 trials <
			3 DA-B	178.7	67.0	290.3	43.3	11.0	75.5	16.9	10.5	23.3	78.5	74.2	82.8	88.6	85.4	91.8	81.4	81.0	81.8	90.5	86.4	94.7	1 trial <; 1 trial =	1 trial <; 1 trial =	2 trials <	2 trials <
			7 DA-B	169.9	56.5	283.3	41.7	9.3	74.0	15.4	8.5	22.3	78.4	74.0	82.9	89.0	86.0	92.0	81.3	80.4	82.2	90.2	85.5	95.0	1 trial <; 1 trial =	1 trial <; 1 trial =	2 trials <	2 trials <
			1 DA-C	167.8	45.3	290.3	10.5	7.0	14.0	6.4	5.8	7.0	89.7	84.1	95.2	92.8	88.0	97.5	88.3	81.4	95.1	92.9	87.1	98.7	2 trials =	2 trials =	2 trials <	2 trials <
			3 DA-C	159.9	32.0	290.3	9.6	6.8	12.3	4.4	4.0	4.8	87.2	78.6	95.8	92.4	86.2	98.6	87.0	78.5	95.6	92.9	86.6	99.2	2 trials =	2 trials =	2 trials <	2 trials <
			7 DA-C	152.4	15.0	287.8	7.2	2.3	12.0	0.9	0.0	1.8	91.4	86.9	95.9	99.7	99.4	100.0	90.0	84.2	95.7	99.8	99.6	100.0	2 trials =	2 trials =	2 trials <	2 trials <

* Based on Student-Newman-Keuls (SNK) test at p=0.05

Table 3.2-28: Efficacy of SAP09I against THRITB in onion at different assessment timings – plant damage (summary results)

							% Control									% Control: number of trials where SAP09I is >, <, = vs. SpinTor 480 SC*	
No. of trials	Crop	Assessment type	Assessment timing	UTC Plant damage (% area from 20 plants)			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha			SpinTor 480 SC 0.2 L/ha				
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.		
1	ALLCE	Plant damage (% area from 20 plants)	7 DA-A	2.0			100.0			100.0			100.0			1 trial =	1 trial =
1			7 DA-B	5.0			100.0			100.0			100.0			1 trial =	1 trial =
2			7 DA-C	5.7	1.3	10.0	97.5	95.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	2 trials =	2 trials =

* Based on Student-Newman-Keuls (SNK) test at p=0.05

3.2.3.4 Use 4: Control of Thrips tabaci [THRITB] in leek

Two trials from the North-East EPPO zone (Poland) were carried out to evaluate efficacy of SAP09I against onion thrips in leek.

After the first application (assessment 7 DA-A) at 0.15 L/ha and 0.2 L/ha, SAP09I showed efficacy against THRITB of 63.7% and 81.1%, respectively.

After the second application (assessment 7 DA-B), the efficacy of product SAP09I at 0.15 L/ha and at 0.2 L/ha increased – the control was at 75.3% and 91.5% respectively.

After the third and the last application of the product (assessment 7 DA-C), SAP09I reached its highest average control: 86.6% at 0.15 L/ha and **98.9%** at 0.2 L/ha.

The control of onion thrips by SAP09I was statistically equivalent to the reference product SpinTor 480 SC at last assessment considered representative. During earlier assessments, at times SAP09I was statistically superior to the reference control (3-4 DA-A, 7 DA-A, 1-2 DA-B, 3-4 DA-B), in two trials (assessments 1-2 DA-A at 0.1 L/ha and 3-4 DA-C at 0.2 L/ha) it was statistically inferior to Spin Tor 480 SC. The differences found do not establish a lack of equivalence in the effectiveness of the products. The variability in statistical analysis is more related to the high infestation in one study and the frequent evaluations. In the last evaluation considered representative, both products were statistically equivalent, regardless of the dose tested.

The assessments on plant damage (sucking damage) after the first treatment (assessment 7 DA-A) showed 67.4% efficacy of SAP09I at 0.15 L/ha and 74.5% at 0.2 L/ha. At the second application (assessment 7 DA-B), SAP09I provided 73.8% control at 0.15 L/ha and 83.8% at 0.2 L/ha. After the third and the last application (assessment 7 DA-C), SAP09I reached 73.1% of control at 0.15 L/ha and **91.3%** at 0.2 L/ha. Statistical analysis confirmed the comparability of SAP09I to the reference product, regardless of the dose tested. Apart from one assessment in one study (7 DA-C), both products were equivalent.

A summary of the results is provided in Table 3.2-29 (pest control) and in Table 3.2-30 (plant damage).

As both products have an equivalent efficacy against the intended uses, a reference to the unprotected data of SpinTor 480 SC is made to have a full data set demonstrating the efficacy of the test product.

Table 3.2-29: Efficacy of SAP09I against THRITB in leek at different assessment timings (summary results)

No. of trials	Crop	Target	Assessment timing	Infestation (number of larvae / 20 plants)									% Control												% Control: number of trials where SAP09I is >, <, = vs. SpinTor 480 SC*		Infestation level: number of trials where SAP09I is >, <, = vs. UTC*	
				UTC			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha			SpinTor 480 SC 0.15 L/ha			SpinTor 480 SC 0.2 L/ha			% Control: number of trials where SAP09I is >, <, = vs. SpinTor 480 SC*		Infestation level: number of trials where SAP09I is >, <, = vs. UTC*	
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	0.15 L/ha	0.2 L/ha	0.15 L/ha	0.2 L/ha
2	ALLPO	THRITB (larvae)	1-2 DA-A	147.2	128.8	165.5	96.3	96.3	96.3	65.7	47.8	83.5	41.2	40.6	41.8	57.8	48.9	66.7	46.3	46.0	46.6	58.7	49.6	67.9	1 trial <; 1 trial =	2 trials =	2 trials <	2 trials <
			3-4 DA-A	146.2	129.0	163.3	64.1	55.3	72.8	33.3	24.3	42.3	60.7	55.9	65.4	78.5	73.8	83.1	59.1	54.1	64.2	72.4	70.5	74.4	2 trials =	1 trial >; 1 trial =	2 trials <	2 trials <
			7 DA-A	152.4	135.0	169.8	61.6	53.3	69.8	30.3	22.8	37.8	63.7	59.7	67.6	81.1	77.3	85.0	64.2	58.7	69.7	75.9	73.9	78.0	2 trials =	1 trial >; 1 trial =	2 trials <	2 trials <
			1-2 DA-B	150.4	131.0	169.8	49.2	48.0	50.3	20.1	16.8	23.3	70.6	70.1	71.0	87.4	86.1	88.7	66.6	60.9	72.3	81.9	80.2	83.5	1 trial >; 1 trial =	1 trial >; 1 trial =	2 trials <	2 trials <
			3-4 DA-B	150.7	137.0	164.3	43.1	42.3	43.8	11.4	9.5	13.3	74.4	73.7	75.1	92.8	91.4	94.1	70.7	67.6	73.8	87.7	85.7	89.6	1 trial >; 1 trial =	2 trials >	2 trials <	2 trials <
			7 DA-B	147.7	137.8	157.5	40.2	38.5	41.8	13.4	9.8	17.0	75.3	72.3	78.2	91.5	89.0	93.9	73.1	72.8	73.4	89.5	89.3	89.7	2 trials =	2 trials =	2 trials <	2 trials <
			1-2 DA-C	154.4	141.0	167.8	31.2	27.3	35.0	9.8	5.0	14.5	81.8	78.8	84.9	94.2	91.3	97.0	79.8	76.5	83.2	91.2	88.4	93.9	2 trials =	2 trials =	2 trials <	2 trials <
			3-4 DA-C	147.8	142.3	167.8	24.4	18.5	30.3	12.5	2.5	22.5	84.8	79.7	89.8	87.4	85.0	89.8	83.4	75.6	91.2	89.2	81.9	96.5	2 trials =	1 trial <; 1 trial =	2 trials <	2 trials <
			7 DA-C	152.7	146.3	153.3	22.1	15.8	28.3	1.9	1.0	2.8	86.6	81.7	91.6	98.9	98.3	99.5	85.0	76.2	93.9	97.5	97.2	97.8	2 trials =	2 trials =	2 trials <	2 trials <

* Based on Student-Newman-Keuls (SNK) test at p=0.05

Table 3.2-30: Efficacy of SAP09I against THRITB in leek at different assessment timings – plant damage (summary results)

							% Control									% Control: number of trials where SAP09I is >, <, = vs. SpinTor 480 SC*	
No. of trials	Crop	Assessment type	Assessment timing	UTC Plant damage (% area from 20 plants)			SAP09I 0.15 L/ha			SAP09I 0.2 L/ha			SpinTor 480 SC 0.2 L/ha			0.15 L/ha	0.2 L/ha
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.		
2	ALLPO	Plant damage (% area from 20 plants)	7 DA-A	4.0	1.5	6.5	67.4	34.8	100.0	74.5	49.0	100.0	71.7	43.5	100.0	2 trials =	2 trials =
			7 DA-B	7.7	5.0	10.3	73.8	52.6	95.0	83.8	67.5	100.0	82.8	70.7	95.0	2 trials =	2 trials =
			7 DA-C	8.8	5.5	12.0	73.1	54.7	91.4	91.3	82.5	100.0	89.6	87.7	91.4	1 trial <; 1 trial =	2 trials =

* Based on Student-Newman-Keuls (SNK) test at p=0.05

3.2.3.5 Use 5: Control of *Adoxophyes orana* [CAPURE] in apple

Five Eight trials from the North-East EPPO zone (Poland) are submitted to demonstrate the minimum effective dose of SAP09I against smaller tea tortrix in apple.

Although Since the infestation (number of pests per 100 extension shoots) among the trials conducted in 2024 was low, it was also decided to conduct a second season of trials to confirm the originally submitted results. ~~the percentage of fruit attacked during harvest was considered sufficient to draw reliable conclusions~~

Furthermore, due to the economic aspect, the evaluation of attacked fruits should be the primary measure of the product's effectiveness against smaller tea tortrix in apples. Therefore, the efficacy results from the fruit are considered representative. The assessments on the shoot extensions are presented just for information.

The evaluation done 24-27 DA-A (or 14-17 DA-B), the experimental and the reference products showed similar efficacies on shoots (measured as the # of larvae on 100 shoots), whenever the doses (g ai/ha) and the number of applications (A or A& B) were comparable.

In the evaluations during the harvest (41-52 69 DA-B), the average percentage of infested fruits was 5.1 3.1%.

The mean control rate of two applications of SAP09I at 0.18 and 0.3 L/ha 0.14 L/10000m² LWA and at 0.23 L/10000m² LWA was 70.1% and 88.6%, respectively. The effectiveness of two applications of the reference product at 0.3 L/ha was 86.9 85.1%.

One application of SAP09I and the reference product at their higher rates, obtained 67.6 and 72.7% efficacy, respectively on fruits.

86.5%, while the effectiveness of the reference product was 85.1%.

In all 5-8 trials, the efficacy of the two products, when applied at the same dose of spinosad per hectare, was statistically and/or numerically comparable, either with one or two applications.

These results clearly demonstrate the value of SAP09I in the control of CAPURE on MABSD as part of an integrated pest management, where the dose rate and/or the number of applications can vary depending upon the pest pressure.

In addition, as both products have an equivalent efficacy against the intended uses, a reference to the unprotected data of SpinTor 480 SC is made to have a full data set demonstrating the efficacy of the test product.

A summary of the results is provided in Table 3.2-31 (pest control on shoots) and in Table 3.2-32 (control on fruits).

Table 3.2-31: Efficacy of SAP09I against CAPURE on shoots in apple at different assessment timings (summary results) – after 1 or 2 applications

				Infestation (number of larvae / 100 shoots)						% Control						% Control: number of trials where	Infestation level: number of trials where
No. of trials	Crop	Target	Assessment timing	UTC				SAP09I 0.3 L/ha		SAP09I 0.3 L/ha			SpinTor 480 SC 0.3 L/ha			SAP09I is >, <, =	SAP09I is >, <, =
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	vs. SpinTor 480 SC*	vs. UTC*
5	MABSD	CAPURE (larvae)	14-17 DA-B	1.8	0.8	3.0	0.1	0.0	0.3	93.3	75.0	100.0	92.5	75.0	100.0	5 trials =	4 trials <; 1 trial =
			28-30 DA-B	6.2	2.3	12.8	0.2	0.0	0.5	98.2	92.3	100.0	96.9	88.7	100.0	5 trials =	5 trials <

* Based on Student-Newman-Keuls (SNK) test at p=0.05

Crop	Target	% Control (# larvae/100 shoots)																
		SAP09I									SpinTor 480 SC						number of trials where SAP09I is	number of trials where SAP09I is
		0.14 L/10000m2 LWA			0.23 L/10000m2 LWA			0.23 L/10000m2 LWA			0.23 L/10000m2 LWA			0.23 L/10000m2 LWA				
		0.18 L/ha			0.3 L/ha			0.3 L/ha			0.3 L/ha			0.3 L/ha			>, <, =	>, <, =
		Applications A & B			Applications A & B			Application A			Applications A & B			Application A			vs. SpinTor 480 SC*	vs. UTC*
		Assessment: 24-27 DA-A / 14-17 DA-B																
MABSD	CAPURE	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	% Control:	Infestation level:
		78.5	44.2	100.0	92.3	75.0	100.0	87.5	75.0	100.0	89.8	75.0	100.0	86.7	75.0	100.0	6 trials =	8 trials <
# trials		8			8			5			8			5			2 trials >	

* Based on Student-Newman-Keuls (SNK) test at p=0.05

Table 3.2-32: Efficacy of SAP09I against CAPURE in apple at different assessment timings – attacked fruits (summary results) – after 1 or 2 applications

No. of trials	Crop	Assessment type	Assessment timing	UTC			% Control						% Control: number of trials where SAP09I is >, <= vs. SpinTor 480 SC*
				% Fruit attacked (500 fruits)			SAP09I 0.3 L/ha			SpinTor 480 SC 0.3 L/ha			
				Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	
5	MABSD	% Fruit attacked (500 fruits)	41-52 DA-B	3.1	1.4	5.1	86.5	80.2	97.5	85.1	79.9	96.4	5 trials =

* Based on Student-Newman-Keuls (SNK) test at p=0.05

Crop	Target	% Control (incidence on 500 fruits)																		
		SAP09I									SpinTor 480 SC						number of trials where SAP09I is	number of trials where SAP09I is		
		0.14 L/10000m2 LWA			0.23 L/10000m2 LWA			0.23 L/10000m2 LWA			0.23 L/10000m2 LWA			0.23 L/10000m2 LWA						
		0.18 L/ha			0.3 L/ha			0.3 L/ha			0.3 L/ha			0.3 L/ha					>, <, =	>, <, =
		Applications A & B			Applications A & B			Application A			Applications A & B			Application A					vs. SpinTor 480 SC*	vs. UTC*
		Assessment: 53-62 DA-A / 41-69 DA-B																		
MABSD	CAPURE	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	Mean	Min.	Max.	% Control:	Infestation level:		
		70.1	43.9	94.4	88.6	80.2	98.1	67.6	55.9	88.3	86.9	79.9	96.4	72.7	55.1	94.4	7 trials =	8 trials <		
# trials		8			8			5			8			5			1 trials >			

* Based on Student-Newman-Keuls (SNK) test at p=0.05

3.2.3.6 Use 6 – Minor use, art. 51: Control of *Adoxophyes orana* [CAPURE] in pear, crab apple and in quince

According to Regulation of the Minister of Agriculture and Rural Development of 18 September 2023 amending the Regulation on minor uses of the plant protection product, pear, crab apple and quince are considered minor crops in Poland.

The provisions of Article 51 of Regulation (EC) No 1107/2009 do not require the submission of information on efficacy or adverse effects for minor uses. Therefore, no efficacy studies are submitted for the requested use in pear, crab apple and quince.

Given the decreasing number of approved insecticides for orchard crops, the requested uses are justified.

3.2.3.7 Use 7 – Minor use, art. 51: Control of *Thrips* sp. [THRISP] in garlic and shallot

According to Regulation of the Minister of Agriculture and Rural Development of 18 September 2023 amending the Regulation on minor uses of the plant protection product, garlic and shallot are considered minor crops in Poland.

The provisions of Article 51 of Regulation (EC) No 1107/2009 do not require the submission of information on efficacy or adverse effects for minor uses. Therefore, no efficacy studies are submitted for the requested uses in garlic and shallot.

Given the decreasing number of approved insecticides for *Allium* crops, the requested uses are justified.

Summary and conclusion

In total 13 16 trials were conducted in the North-East EPPO zone in Poland to evaluate the efficacy of SAP09I and its comparability to the reference product SpinTor 480 SC against various pests in vegetable crops and in apple.

As both products, SAP09I and the reference have an equivalent efficacy against the intended uses, a reference to the unprotected data of SpinTor 480 SC is made to have a full data set demonstrating the efficacy of the test product.

Use 1: Control of *Pieris brassicae* [PIERBR], *Artogeia rapae* [PIERRA], *Mamestra brassicae* [BARABR] in head cabbage

To justify the above use, two o trials were submitted against imported cabbage worm [PIERRA] in head cabbage.

After the last application, SAP09I reached 87.0% at 0.1 L/ha and 95.6% at 0.2 L/ha.

Statistical analysis confirmed the tested product at the proposed dose rates of 0.1-0.2 L/ha is equivalent to the efficacy achieved by the reference product SpinTor 480 SC.

It can therefore be concluded that the results obtained confirm the effectiveness of SAP09I in the proposed applications in head cabbage.

Use 2: Control of *Artogeia rapae* [PIERRA] and *Mamestra brassicae* [BARABR] in cauliflower and in broccoli

To support the above use, two o trials were submitted against imported cabbage worm [PIERRA] and cabbage caterpillar [PIERBR] in cauliflower.

Following the last application, the average efficacy of SAP09I in controlling larvae of both species was 91.1% at 0.1 L/ha and **96.6%** at 0.2 L/ha.

Statistical analysis confirmed the tested product at the proposed dose rates of 0.1-0.2 L/ha is equivalent to the efficacy achieved by the reference product SpinTor 480 SC.

No studies have been carried out in broccoli. The proposed use in broccoli is possible by extrapolating efficacy results from cauliflower.

It can therefore be concluded that the results obtained confirm the effectiveness of SAP09I in the proposed applications in cauliflower and in broccoli.

Use 3: Control of *Thrips tabaci* [THRITB] in onion

To justify the above use, two trials were submitted against onion thrips [THRITB] in onion.

After the last application, SAP09I controlled the pest with 91.4% at 0.15 L/ha and **99.7%** at the maximum dose of 0.2 L/ha. Following the last treatment, the control of plant damage by SAP09I at 0.15 L/ha was at 97.5% and **100.0%** at 0.2 L/ha.

Statistical analysis confirmed that SAP09I at the proposed dose rates of 0.15-0.2 L/ha is equivalent to the efficacy achieved by the reference product SpinTor 480 SC.

Therefore, the results obtained confirm the effectiveness of SAP09I for the proposed use in onion.

Use 4: Control of *Thrips tabaci* [THRITB] in leek

Two trials were submitted against onion thrips [THRITB] in leek.

Following the last application, SAP09I controlled the pest with 86.6% at 0.15 L/ha and **98.9%** at the maximum dose of 0.2 L/ha. After three applications, the control of plant damage by SAP09I at 0.15 L/ha was at 73.1% and **91.3%** at 0.2 L/ha.

Statistical analysis confirmed that SAP09I at the proposed dose rates of 0.15-0.2 L/ha is equivalent to the efficacy achieved by the reference product SpinTor 480 SC.

Therefore, the results obtained confirm the effectiveness of SAP09I for the proposed use in leek.

Use 5: Control of *Adoxophyes orana* [CAPURE] in apple

To justify the above use, five trials were submitted against smaller tea tortrix [CAPURE] in apple.

Due to low infestation on shoots and economic importance on direct pest damage, the efficacy results from the fruit were considered representative.

The mean control rate of SAP09I at **0.3 L/ha** the highest tested dose (21-0.25 L/10000m² LWA -equivalent to 0.3 L/ha-) was **86.5%**. Statistical analysis confirmed that SAP09I at the proposed dose rate is equivalent to the reference SpinTor 480 SC. A lower tested dose (0.13-0.15 L/10000m² LWA (equivalent to 0.18 L/ha)), applied twice, also demonstrated to be effective against CAPURE.

During the evaluation of the dossier, the maximum supported dose for 2 applications of SAP09I had to be reduced from 0.3 L/ha to 0.225 L/ha, to solve some issues in the ecotoxicological risk assessment. Therefore, the maximum dose for 2 applications was set between the two evaluated doses. Since either 0.13-0.15 L/10000m² LWA (equivalent to 0.18 L/ha) and 0.21-0.25 L/10000m² LWA (equivalent to 0.3 L/ha), demonstrated to be effective against CAPURE when two applications were performed, while there was a clear dose-rate response in most of the trials, this new intermediate dose is considered supported by the efficacy data summarised in this document. Taking in consideration the treated LWA, the new max. dose in L/1000m² LWA for two applications is shown in the following table.

In all **5-8** trials, the efficacy of the two products, **when applied at the same dose of spinosad per hectare LWA**, was statistically **and/or numerically** comparable, **either with one or two applications**.

Therefore, the results obtained confirm the effectiveness of SAP09I for the proposed use in apple.

Use 6 – Minor use, art. 51: Control of *Adoxophyes orana* [CAPURE] in pear, crab apple and in quince

The provisions of Article 51 of Regulation (EC) No 1107/2009 do not require the submission of information on efficacy or adverse effects for minor uses. Therefore, no efficacy studies are submitted for the requested use in the above-mentioned pome fruits.

Use 7 – Minor use, art. 51: Control of *Thrips* sp. [THRISP] in garlic and shallot

The provisions of Article 51 of Regulation (EC) No 1107/2009 do not require the submission of information on efficacy or adverse effects for minor uses. Therefore, no efficacy studies are submitted for the requested use in the above-mentioned *Allium* crops.

Study Comments: 3.2.3 dRR point 3.2.3	Efficacy tests
Evaluator conclusion To support authorization of the product SAP09I considering Art. 34 of the Regulation 1107/2009, the applicant submitted: • 2 bridging trials carried out on cabbage (at BBCH 19-45) in 2024, in Poland against PIERRA; spray volume used in trials – 400 – 500 l/ha; • 1 bridging trial carried out on cauliflower (at BBCH 35-43) in 2024, in Poland against PIERBR; spray volume used in trials – 300 – 500 l/ha; • 1 bridging trial carried out on cauliflower (at BBCH 35-43) in 2024, in Poland against PIERRA; spray volume used in trials – 300 – 500 l/ha; • 2 bridging trials carried out on onion (at BBCH 16-45) in 2024, in Poland against THRITB; spray volume used in trials – 300 – 500 l/ha; • 2 bridging trials carried out on leek (at BBCH 15-41) in 2024, in Poland against THRITB; spray volume used in trials – 200 – 500 l/ha; • 5 bridging trials carried out on apple against CAPURE in 2024 (at BBCH 75-81), in couple regions of Poland; spray volume used in trials – 500 – 1000 l/ha. The applicant changed the GAP table after the commenting period, because of the ecotox. risk assessment and asked for re-evaluation according the changed GAP table. The applicant presented 3 additional trials carried out on apple against CAPURE in 2025 (at BBCH 73-77), in couple regions of Poland. The applicant refers to the unprotected data of the reference product SpinTor 480 SC (MRiRW authorisation no. 18/2003 of 12 September 2003). SAP09I can be authorised in the same scope as the reference product in Poland, taking into account non-protected data concerning the reference product SpinTor 480 SC (crop/pest combinations) – assumption of a “bridging concept”. Based on the data provided by the Ministry of Agriculture and Rural Development, from among the data presented in the BAD/dRR, the following scope can be assessed using the “bridging concept”: • efficacy data on apple against CAPURE (2 applications) – use no 5 • efficacy data on cabbage against PIERRA (2 applications) – uses no 1, 1b; What is more any data against BARABR on head cabbage was not presented to compare efficacy of SAP09I with efficacy of the reference product assuming bridging concept. This use can not be acceptable.	

The GAP table has listed the following uses that are not subject to the procedure set out in Article 33/34 of the Regulation:

- head cabbage/PIERBR (uses no.: 1, 1a, 1b)
- head cabbage PIERRA (3 applications) (uses no.: 1, 1b)
- broccoli, cauliflower/PIERRA (2-3 applications), BARABR (uses no.: 2, 2a, 2b)
- onion/THRITB (uses no.: 3, 3a)
- leek/THRITB (uses no.: 4, 4a)
- apple (uses no.: 5a, 5b, 5c)

It is proposed to evaluate these uses in accordance with the art. 33 rules (taking into account also extrapolation rules for minor uses according to EPPO Database on PPP Data Extrapolation and extrapolation rules for PL). There is no confirming efficacy data for broccoli, that is why extrapolation is not possible. According to the national guidance 'Efficacy evaluation of Plant Protection Products', an authorisation of a plant protection product for minor uses under Article 33 of Regulation (EC) No 1107/2009 requires the submission of efficacy trials. A zero-trial data package is not acceptable for such authorisations. In cases where the number of trials is insufficient and/or doubts persist regarding the trial results, the possibility of registering the use under Article 51 may still be considered.

The applicant did not presented any data against BARABR on brassica vegetables, therefore this scope can not be acceptable. In case of combination head cabbage/PIERBR, 1 trial can not be sufficient to confirm efficacy. What is more, the product showed much more better efficacy against PIERBR that against PIERRA. Therefore mean efficacy results for both pest species can not be evaluated together.

Efficacy trials were carried out by organizations that are officially recognized as competent to carry out efficacy testing in accordance with Regulation (EC) 284/2013. All trials have been conducted according to GEP.

Trials were conducted in Poland. Trials were of randomized block design with a minimum of four replicates.

The effectiveness of the product was describe according to the following scale:

≥ 80% – Effectively controlled (**E**)

60 – 80% – Medium effectively controlled (**ME**)

0 – 60% – Limiting the number of pest (**R**)

1. **Uses: 1, 1b – 2 applications:** The efficacy of product on head cabbage against PIERRA was tested at 0,1 l/ha and 0,2 l/ha, applied three times. SAP09I controlled PIERRA at the same level as the reference product SpinTor 480 SC. Results after second application was taken into account, as unprotected data of the reference product assumed a double application. Both product controlled PIERRA at mean level of about 80% for dose 0,1 l/ha and about 90% for dose 0,2 l/ha, after two applications of the product. There were no statistical differences in any of the assessment results presented in 2 efficacy trials. What should be underlined is that in bringing trials the product was applied at different growth stages of PIERRA, whereas the label of the reference product pointed application at the earliest growth stages of PIERRA. That recommendation should be reflected in the product label. To conclude, efficacy comparability of both products can be considered.

Use no. 1 unacceptable because of the ecotox. risk assessment.

2. **Uses 1, 1b – 3 applications:** The efficacy of product on head cabbage against PIERRA was tested in two trials, at 0,1 l/ha and 0,2 l/ha, applied three times. SAP09I controlled PIERRA at the same level as the reference product SpinTor 480 SC. Both product controlled PIERRA at mean level of about 87% for dose 0,1 l/ha (**E**) and about 95,6% for dose 0,2 l/ha (**E**), after three applications of the product. Three applications (0,2 l/ha) should be limited for cabbage from BBCH 19 as the applicant did not present phytotoxicity data at earlier growth stage.

Use no. 1 unacceptable because of the ecotox. risk assessment.

3. Uses 1a, 2a – 2 applications: The applicant did not present efficacy results for dose 0,16 l/ha applied two times. Nevertheless, efficacy results presented for two applications of 0,1 l/ha can be applicable for dose rate 0,16 l/ha (please see point no. 1, 4), as higher dose rate should ensure better results than 0,1 l/ha. Since the ecotox. risk assessment allowed to accept doses 0,1 and 0,16 l/ha (uses: 1a, 1b, 2a, 2b), it is proposed to accept and place on the label dose 0,1 l/ha applied 2 or 3 times (use no. 1b, 1b), because the lower dose ensures a good level of protection.
4. Uses no.: 2, 2b – 2 applications: The efficacy of product on cauliflower against PIERRA was tested at 0,1 l/ha and 0,2 l/ha, applied three times. This use was not a subject of the first authorization, therefore there is no support of this use by the unprotected data of the reference product. It is proposed to extrapolate data against PIERRA obtained for head cabbage after two applications into cauliflower. SAP09I controlled PIERRA at the same level as the reference product SpinTor 480 SC. In the one trial on cauliflower both product controlled PIERRA at level of about 70% for dose 0,1 l/ha and about 80% for dose 0,2 l/ha, after two applications of the product.

Use no. 2 unacceptable because of the ecotox. risk assessment.

5. Uses 2, 2b – 3 applications: The efficacy of product on cauliflower against PIERRA was tested at 0,1 l/ha and 0,2 l/ha, applied three times. It is proposed to extrapolate data against PIERRA obtained for head cabbage after three applications into cauliflower. SAP09I controlled PIERRA at the same level as the reference product SpinTor 480 SC. In the one trial on cauliflower both product controlled PIERRA at level of about 91,1% for dose 0,1 l/ha (E) and about 96,6% for dose 0,2 l/ha (E), after three applications of the product. Three applications (0,2 l/ha) should be limited for brassica vegetable (cauliflower) from BBCH 19 as the applicant did not present phytotoxicity data at earlier growth stage.

Use no. 2 unacceptable because of the ecotox. risk assessment.

6. Uses no.: 3, 3a (one application): The efficacy of product on onion against THRITB was tested at 0,15 l/ha and 0,2 l/ha, applied ~~one to~~ three times. This uses were not a subject of the first authorization, therefore there is no support of this use by the unprotected data of the reference product. SAP09I controlled THRITB at the same level as the reference product SpinTor 480 SC and ~~performed at satisfied level~~ medium effectively controlled THRITB at dose ~~0,2 l/ha~~ 0,15 l/ha, after ~~two or three~~ one applications of the product (~~E 60,6 %~~, ME). Application of the product should be limited for allium vegetable (onion) from BBCH 15 as the applicant did not present phytotoxicity data at earlier growth stage. The applicant did not present efficacy results for dose 0,16 l/ha applied one time. It is proposed to accept and place on the label dose 0,15 l/ha applied one time at BBCH 40-49 (use no. 3a), because of the ecotox. risk assessment.

Use no. 3 unacceptable because of the ecotox. risk assessment.

7. Uses no.: 4, 4a (one application): The efficacy of product on leek against THRITB was tested at 0,15 l/ha and 0,2 l/ha, applied ~~one to~~ three times. This uses were not a subject of the first authorization, therefore there is no support of this use by the unprotected data of the reference product. SAP09I controlled THRITB at the same level as the reference product SpinTor 480 SC and ~~performed at satisfied level~~ medium effectively controlled THRITB at dose ~~0,2 l/ha~~ 0,15 l/ha, after ~~two or three~~ one applications of the product (~~E 63,7 %~~, ME). Application of the product should be limited for allium vegetable (leek) from BBCH 15 as the applicant did not present phytotoxicity data at earlier growth stage. The applicant did not present efficacy results for dose 0,16 l/ha applied one time. It is proposed to accept and

place on the label dose 0,15 l/ha applied one time at BBCH 40-49 (use no. 4a), because of the ecotox. risk assessment.

Use no. 4 unacceptable because of the ecotox. risk assessment.

8. **Use no. 5:** The efficacy of product on apple against CAPURE was tested at 0,3 l/ha, applied two times (8 trials). SAP09I controlled CAPURE at the same similar level as the reference product SpinTor 480 SC. ~~Both~~ The product controlled CAPURE at mean level of ~~above 90%~~ 92,3% after the second application. ~~There were no statistical differences in any of the assessment results presented in 5 efficacy trials.~~ To conclude, efficacy comparability of both products can be considered. The applications should be limited from BBCH 56 as the reference product is applied from BBCH 56 and the applicant did not present phytotoxicity data at earlier growth stage (BBCH 40-56).

Use no. 5 unacceptable because of the ecotox. risk assessment.

9. Uses no.: 5a, 5b, 5c - doses in the uses do not meet the requirements of Article 34 (lower doses), therefore a full set of data must be submitted (at least 6 trials) with doses expressed as L of the tested product /10 000 m² tLWA. Since the applicant did not submit efficacy results where dose rates expressed in L of the tested product /10 000 m² tLWA were tested, efficacy of product efficacy can not be concluded.

Uses 5a, 5b and 5c

For applications and dossiers of plant protection products recommended for the protection of tall crops (apple) with the requirement to express the dose per 10 000 m² tLWA, efficacy trials should be designed, conducted and presented in BAD and dRR, in which efficacy of a dose per 10 000 m² tLWA was conducted. This means that the applicant should define the dose ensuring sufficient efficacy (minimum effective dose - MED) as the dose per 10 000 m² tLWA, and ensure that this dose is used in registration trials on efficacy, including phytotoxicity. In the BAD and in the dRR, the summary of the parameters under which these trials were conducted and the results obtained should include the specific doses of the product per 10 000 m² tLWA, and not just their range. Efficacy data based on dose conversion from l/ha to 10 000 m² tLWA can be considered supportive rather than primary.

The applicant requested the doses of 0,3 l/ha applied 1x and 0,225 l/ha applied 2x which are lower doses than the dose being a subject of the first authorization (0,3 l/ha applied 2x). The applicant did not presented trials where the efficacy of dose per 10 000 m² tLWA was conducted. The dRR/BAD only shows the conversion of the dose from l/ha to 10,000 m² tLWA.

It should be noted that the dose of 0,225 l/ha applied 2x was not tested at all in efficacy trials. The dose of 0,3 l/ha applied one time was tested in only 5 trials in a single season 2024 (less than required). Furthermore, the lower doses referred to do not meet the requirements of Article 34 of the Regulation and therefore a full set of data (at least 6 trials, carried out in two seasons) in which efficacy were conducted at doses of 10 000 m² tLWA must be submitted to demonstrate efficacy.

Taking into account above, ZMRS cannot grant the applicant's request.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

Modes of action

Spinosad belongs to the chemical group of the nicotinic acetylcholine receptor (nAChR) allosteric modulators – site I (Group 5 IRAC). Spinosad causes excitation of the insect nervous system, leading to involuntary muscle contractions, prostration with tremors, and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors by a mechanism.

It is effective against a wide range of pests (sucking and chewing pests) in a wide range of crops.

Mechanism of resistance

Specific resistance mechanisms are not reported. According to EPPO Standard PP 1/213(4), a knowledge of the mode of action of a compound and, if known, the mechanism of resistance can be informative. For example, a mode of action involving a single biochemical site may indicate a potential higher risk, whereas ‘multisite’ action may indicate a lower risk. Similarly, any mode of action which involves an existing mechanism to which resistance has already occurred would, in the absence of contrary evidence, be considered to indicate a high risk of resistance.

Evidence of resistance

Resistance events have been reported in Europe (in Spain and in the United Kingdom) for SAP09I active ingredient (spinosad). However, cases of resistance in Europe have been reported for other species than those requested in this dossier. Table 3.3-1 summarizes these events (source: Mota-Sanchez, D. and J.C. Wise. 2024. The Arthropod Pesticide Resistance Database, Michigan State University. On-line at: <http://www.pesticideresistance.org>; December 2024). Insect species are listed alphabetically. Cases reported in Europe are indicated in the last column.

Table 3.3-1: Reported cases of resistance to spinosad

Scientific name [EPPO code]	Taxonomy		Common name	Number of reported cases	Number of cases outside of Europe	Number of cases in Europe
	Order	Family				
<i>Alabama argillacea</i> [ALABAR]	Lepidoptera	Noctuidae	Cotton leafworm	3	Brazil (3)	
<i>Bactrocera cucurbitae</i> [DACUCU]	Diptera	Tephritidae	Melon fly	15	China (11), USA (4)	
<i>Bactrocera dorsalis</i> [DACUDO]	Diptera	Tephritidae	Oriental fruit fly	4	Taiwan (4)	
<i>Bactrocera oleae</i> [DACUOL]	Diptera	Tephritidae	Olive fruit fly	3	USA (3)	
<i>Bactrocera zonata</i> [DACUZO]	Diptera	Tephritidae	Peach fruit fly	7	Pakistan (7)	
<i>Diaphorina citri</i> [DIAACI]	Hemiptera	Psilidae	Asian citrus psyllid	6	Mexico (6)	
<i>Drosophila suzukii</i> [DROSSU]	Diptera	Drosophilidae	Spotted-wing drosophila	14	USA (14)	
<i>Earias vittella</i> [EARIVI]	Lepidoptera	Noctuidae	Spotted bollworm	8	Pakistan (8)	
<i>Frankliniella occidentalis</i> [FRANOC]	Thysanoptera	Thripidae	Western flower thrips	26	China (2), Turkey (8)	Spain (16)
<i>Helicoverpa armigera</i> [HELIAR]	Lepidoptera	Noctuidae	Cotton bollworm	8	China (2), Pakistan (6)	
<i>Heliothis virescens</i> [HELIVI]	Lepidoptera	Noctuidae	Tobacco budworm	4	USA (4)	
<i>Leptinotarsa decemlineata</i> [LPTNDE]	Coleoptera	Chrysomelidae	Colorado potato beetle	8	USA (8)	
<i>Liriomyza trifolii</i> [LIRITR]	Diptera	Agromyzidae	American serpentine leaf miner	7	USA (7)	
<i>Oxycarenus hyalinipennis</i> [OXYAHY]	Hemiptera	Lygaeidae	Cotton seed bug	1	Pakistan (1)	
<i>Pectinophora gossypiella</i> [PECTGO]	Lepidoptera	Gelechiidae	Pink bollworm	1	Egypt	
<i>Phenacoccus solenopsis</i> [PHENSO]	Homoptera	Pseudococcidae	Cotton mealybug	2	Pakistan (2)	
<i>Plutella xylostella</i> [PLUTMA]	Lepidoptera	Plutellidae	Diamond-back moth	65	Benin(1), China (35), India (3), Malaysia (3), Pakistan (7), Taiwan (12), Thailand (1), USA (3)	
<i>Scirtothrips dorsalis</i> [SCITDO]	Thysanoptera	Thripidae	Cilli thrips / Yellow tea thrips	2	India (2)	
<i>Sesamia inferens</i> [SESAIN]	Lepidoptera	Noctuidae	Pink stem borer	1	Taiwan (1)	
<i>Spodoptera exigua</i> [LAPHEG]	Lepidoptera	Noctuidae	Beet armyworm	59	China (23), Mexico (4), Pakistan (31), Thailand (1)	

Scientific name [EPPO code]	Taxonomy		Common name	Number of reported cases	Number of cases outside of Europe	Number of cases in Europe
	Order	Family				
<i>Spodoptera frugiperda</i> [LAPHFR]	Lepidoptera	Noctuidae	Fall armyworm	5	Brazil (2), China (3)	
<i>Spodoptera littoralis</i> [SPODLI]	Lepidoptera	Noctuidae	Egyptian cotton leafworm	2	Egypt (2)	
<i>Spodoptera litura</i> [PRODLI]	Lepidoptera	Noctuidae	Tropical armyworm	39	Pakistan (39)	
<i>Thrips palmi</i> [THRIPL]	Thysanoptera	Thripidae	Melon thrips	2	Japan (2)	
<i>Thrips tabaci</i> [THRITB]	Thysanoptera	Thripidae	Onion thrips	2	Israel (2)	
<i>Tribolium castaneum</i> [TRIBCA]	Coleoptera	Tenebrionidae	Red flour beetle	2	Pakistan (2)	
<i>Tuta absoluta</i> [GNORAB]	Lepidoptera	Gelechiidae	Tomato leafminer	16	Brazil (8), Chile (5)	United Kingdom (3)

Cross-resistance

Spinosad has two modes of action: the first involves disrupting/inhibiting the binding of acetylcholine at the nicotinic acetylcholine receptors located at the post-synaptic cell junctions, which prolongs stimulation or activation of the nicotinic acetylcholine receptors. Consequently, this results in excitation of the insect central nervous system, paralysis and eventually death.

The second mode of action is affiliated with negatively affecting GABA-gated ion channels. The mode of action of spinosad is similar to the neonicotinoid insecticides (imidacloprid, dinotefuran, thiamethoxam and acetamiprid) in IRAC Group 4, as both groups target similar proteins on receptor sites. However, spinosad is active on different target sites on these proteins. Furthermore, whereas neonicotinoids directly bind to the receptors, spinosad binds partially to the receptor and changes the shape.

spinosad also has a similar mode of action as Group 6 by acting on the GABA-gated chloride channels, but at a different target site in the nervous system. Consequently, spinosad and abamectin should never be applied successively in rotation programs against western flower thrips (*Frankliniella occidentalis*). In fact, populations of western flower thrips have developed resistance to spinosad based on modification of the target site (nicotinic acetylcholine receptor), which reduces sensitivity, however, enhanced metabolic detoxification may also be involved.

Sensitivity data

According to EPPO guideline PP 1/213(4) (resistance risk analysis) this data not necessary for the performance of resistance risk analysis.

Use pattern

The intended uses of SAP09I are summarized in the table below:

First option, if higher tier assessment in *Folsomia* is accepted.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAP
Crop(s)	Target(s)			
Head cabbage [BRSOL]	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1-0.2 L/ha	Max. 3 applic./ season
Broccoli [BRSOK] Cauliflower [BRSOB]	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1-0.2 L/ha	Max. 3 applic./ season
Onion [ALLCE]	<i>Thrips tabaci</i> [THRITB]	PL	0.15-0.2 L/ha	Max. 3 1 applic./ season
Leek [ALLPO]	<i>Thrips tabaci</i> [THRITB]	PL	0.15-0.2 L/ha	Max. 3 1 applic./ season
Apple [MABSD]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.18-0.3 L/ha (0.14-0.23 L/10000 m ² of LWA)	Max. 2 applic./ season
Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.18-0.3 L/ha (0.14-0.23 L/10000 m ² of LWA)	Art. 51 (minor use) Max. 2 applic./ season
Garlic [ALLSA] Shallot [ALLAS]	<i>Thrips</i> sp. [THRISP]	PL	0.15-0.2 L/ha	Art. 51 (minor use) Max. 3 1 applic./ season

Second option, if higher tier assessment in *Folsomia* is not accepted.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAP
Crop(s)	Target(s)			
Head cabbage [BRSOL]	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1 L/ha	Max. 3 applic./ season
Head cabbage [BRSOL]	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1-0.16 L/ha	Max. 2 applic./ season
Broccoli [BRSOK] Cauliflower [BRSOB]	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	PL	0.1 L/ha	Max. 3 applic./ season
Broccoli [BRSOK] Cauliflower [BRSOB]	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]		0.1-0.16 L/ha	Max. 2 applic./ season
Onion [ALLCE]	<i>Thrips tabaci</i> [THRITB]	PL	0.15-0.16 L/ha	Max. 1 applic./ season
Leek [ALLPO]	<i>Thrips tabaci</i> [THRITB]	PL	0.15-0.16 L/ha	Max. 1 applic./ season
Apple [MABSD]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.21-0.25 L/10000m ² LWA (0.23 L/10000m ² LWA, in average), equivalent to 0.3 L/ha	Max. 1 applic./ season
Apple [MABSD]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.14-0.171 L/10000 m ² of LWA, equivalent to 0.18- 0.225 L/ha	Max. 2 applic./ season
Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.21-0.25 L/10000m ² LWA (0.23 L/10000m ² LWA, in average), equivalent to 0.3 L/ha	Art. 51 (minor use) Max. 1 applic./ season
Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	<i>Adoxophyes orana</i> [CAPURE]	PL	0.14-0.171 L/10000 m ² of LWA, equivalent to 0.18- 0.225 L/ha	Art. 51 (minor use) Max. 2 applic./ season
Garlic [ALLSA] Shallot [ALLAS]	<i>Thrips</i> sp. [THRISP]	PL	0.15-0.16 L/ha	Art. 51 (minor use) Max. 1 applic./ season

According to EPPO guideline PP 1/213(4) (resistance risk analysis), a use pattern should be suggested for optimum effect or pest control that would be used in the absence of resistance. This could be the unrestricted use pattern before any management strategy has been applied.

To obtain optimum effect or pest control on targeted species for SAP09I, several applications are likely to be required through a complete crop season at different intervals.

Resistance risk assessment of unrestricted use pattern

Resistance development depends on factors associated with the product, with the target, and agronomic factors. The use of the active substance spinosad has led to development of resistance in *Thrips tabaci*, nevertheless all cases were reported outside Europe. The inherent risk of resistance is therefore considered medium risk, management strategies are advised.

Acceptability of the risk

According to this assessment the use of SAP09I in an unmodified use pattern could lead to the development of resistance. To avoid/delay the development of resistance a resistance risk management strategy is proposed.

Management strategy

Resistance management begins with a good agricultural practice including crop rotation, utilization of resistant varieties, sanitation, healthy seeds, as well as pest monitoring and forecasting. For a successful resistance management, it needs to be an integrated approach.

To reduce selection pressure, apply insecticides only when pest control is warranted, based on insect presence or historical pest pressure. Where possible, minimize the number of generations exposed to the same active substance, ideally to one single generation.

Tank mixes: for resistance management, rotation between insecticides with different modes of action is considered a more sustainable practice than tank mixtures. However, for improved efficacy or a broader spectrum of pest control, it is often considered necessary to mix different active substances. When using tank mixtures, it is also important to mix labelled rates of each compound and use compounds that have different modes of action to maximize pest control. Where possible, compounds should persist for similar periods in order to expose insects to both modes of action for the same duration. Use of multiple products of the same mode of action in the spray tank could lead to increased selection pressure.

Good agricultural practices should be applied alongside physical and biological pest control methods: There are many ways today's farmer can help prevent resistance developing by simply complying with the concepts of integrated crop management. Monitoring and adhering to recommended pest and/or damage thresholds, respecting the usefulness of natural enemies, simple sanitation and removal of post-harvest residues in the fields, the use of resistant crop varieties and even by simply avoiding continuous year-round cultivation of a single crop can all help to slow down and even prevent resistance development.

Integrate escape crops into the cropping system: the use of escape crops not treated with Group 5 insecticides can form an important reservoir for susceptible pest populations. Neighbouring crops that are not treated at all, allow interbreeding between the treated and untreated insect populations, thus diluting the genes for resistance. This has proved to be one of the most successful strategies for insecticide resistance management and should be actively continued to maintain susceptibility to these products in the future.

Integrated Pest Management (IPM): applications of insecticides, including those containing spinosad, should be integrated into an overall integrated pest management program. Cultural practices known to reduce insect pest development should be followed. Consult your local extension specialist, certified crop advisor and/or manufacturer representative for additional IPM strategies established in your area.

Product performance: determine the efficacy of insecticides used in the pest management program against the target pest. If a Group 5 mode of action insecticide appears to be less effective against an insect that is previously controlled or suppressed, contact the manufacturer representative, local extension specialist or certified crop advisor for further investigation.

Implementation of the management strategy

To assist users in the selection of insecticides for use in Integrated Resistance Management strategies employing sequences, rotations or alternations of MoA groups, it is proposed to clearly indicate the IRAC MoA group and description on the product label. Additionally, specific guidelines how to prevent resistance development should be given to the operator. A proposal for such information is given below.

SAP09I label statements (Example)

SAP09I 480 g/L Spinosad IRAC MoA Group 5 Nicotinic acetylcholine receptor (nAChR) allosteric modulators – Site 1 (Spinosyns) Suspension Concentrate (SC)

For resistant management purposes, spinosad belongs to IRAC Mode of Action Group 5 insecticides (Nicotinic acetylcholine receptor (nAChR) allosteric modulators – Site 1). Any insect population may contain individuals naturally resistant to this active. If insecticides containing spinosad are used repeatedly, the resistant individuals may eventually dominate the pest insect population. These resistant insects may not be controlled by spinosad.

To delay the development of resistance:

- in each crop, the product must not be applied in excess of the prescribed maximum number of treatments per growing season;
- alternate treatment with products belonging to other chemical groups with a different mechanism of action;
- avoid applying the product to successive generations of the pest. The product may be applied several times on the same generation;
- if the next generation cannot be accurately identified, do not apply more than 3 times in succession and for no longer than 30 days.

For further information on resistant management and advice contact your local distributor.

Study Comments: 3.3 dRR point 3.3	EN: Strategy is acceptable.
EN: Evaluator conclusion: The active substance Spinosad belongs to the 5 main group - Nicotinic acetylcholine receptor (NACHR) allosteric modulators in accordance with IRAC classification. Allosterically activate nAChRs, causing hyperexcitation of the nervous system. Acetylcholine is the major excitatory neurotransmitter in the insect central nervous system. Insecticides that act on nerve and muscle are generally fast acting. The following of found pests strains included as target pest in this dossier are resistant to Spinosad: <i>Thrips tabaci</i> (2 cases worldwide, non in PL). The application of the product maintaining recommendations of IRAC resistance management strategy should prevent from development resistance to the insecticide. The applicant proposed resistance management strategy in order not to develop resistance to the insecticide which which corresponds to the IRAC recommendations.	

3.4 Adverse effects on treated crops (KCP 6.4)

Possible phytotoxic effects of SAP09I to different crops were determined in thirteen efficacy trials conducted in the North-East EPPO zone in Poland in vegetable and horticultural crops.

Phytotoxicity evaluations in efficacy trials were conducted in accordance with EPPO guideline PP 1/135(4) 'Phytotoxicity assessment'.

The following doses of SAP09I were tested in efficacy trials:

- 0.1 and 0.2 L/ha for *Brassica* crops (head cabbage and cauliflower);
- 0.15 and 0.2 L/ha for *Allium* crops (onion and leek);
- 0.21-0.25 L/10000m² LWA (0.23 L/10000m² LWA, in average), equivalent to 0.3 L/ha for apple.

All trials were conducted in 2024 on commercially grown varieties.

The distribution of trials is shown in Figure 3.2-1 to Figure 3.2-5.

Details on trials methodology per crop group are given in Chapter 3.2.3 – Table 3.2-21 (*Brassica* crops – head cabbage and cauliflower), Table 3.2-22 (*Allium* crops – onion and leek) and in Table 3.2-24 (apple).

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

According to EPPO guideline PP 1/135(4), in case of insecticides applications, observations for phytotoxic effects should be made in the direct efficacy (effectiveness) trials. Specific selectivity trials at N and 2N doses are only required if any adverse phytotoxic effects occur at 1N in any of the efficacy trials.

No adverse effect was observed on any of the 13 efficacy trials presented in this dossier.

Therefore, no specific selectivity trial is required to be presented.

Table 3.4-1: Explanation of the evaluation of the symptoms severity at phytotoxicity assessments

Evaluation of the symptoms severity at observation	% general phytotoxicity
No effect: no visible symptoms.	0
Very slight effect is noticeable, observed only after detailed comparison with Untreated check (the experimenter is not sure that the symptoms are due to the product).	1 to 5
Slight effect is visible: noticeable symptoms after comparison with Untreated check. However, it is not of practical importance in the field.	6 to 10
Obvious effect of the product, visible even without comparison with the Untreated check. Nevertheless, the symptoms are still acceptable in the field. Some users might complain.	11 to 15*
Very obvious effect of the product; symptoms are worrying. Users would certainly complain.	16 to 20
Damage considered as more and more serious: very worrying (21 to 23) to unacceptable (29 to 30). Users and the company would be involved in litigation.	21 to 30
Damage absolutely unacceptable, which brings into question the continuation of the experiments on the product (depending on the frequency of damage in the trials).	> 30
Total destruction of the crop.	100

*The 15% of visual damage is the maximum damage generally considered as acceptable.

Trials performed in head cabbage – BRSOL

Two efficacy trials were performed in 2024 in head cabbage in Poland belonging to the North-East EPPO zone. These trials were performed in 2 different varieties.

There were no symptoms of phytotoxicity for any of the doses tested in these two efficacy trials.

A summary of the mentioned results can be found in Table 3.4-2.

Table 3.4-2: Phytotoxicity of SAP09I in head cabbage. Efficacy trials

Number of trials with...		Efficacy trials (2 trials)			
		SAP09I N = 0.1 L/ha	SAP09I N = 0.2 L/ha	SpinTor 480 SC N = 0.1 L/ha	SpinTor 480 SC N = 0.2 L/ha
Maximum of Phytotoxicity recorded during the trials	0% to 5%	2	2	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15%	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	2	2	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15%	0	0	0	0

Trials performed in cauliflower – BRSOB

Two efficacy trials were performed in 2024 in cauliflower in Poland belonging to the North-East EPPO zone. These trials were performed in 2 different varieties.

There were no symptoms of phytotoxicity for any of the doses tested in these two efficacy trials.

A summary of the mentioned results can be found in Table 3.4-3.

Table 3.4-3: Phytotoxicity of SAP09I in cauliflower. Efficacy trials

Number of trials with...		Efficacy trials (2 trials)			
		SAP09I N = 0.1 L/ha	SAP09I N = 0.2 L/ha	SpinTor 480 SC N = 0.1 L/ha	SpinTor 480 SC N = 0.2 L/ha
Maximum of Phytotoxicity recorded during the trials	0% to 5%	2	2	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15%	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	2	2	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15%	0	0	0	0

Trials performed in onion – ALLCE

Two efficacy trials were performed in 2024 in onion in Poland belonging to the North-East EPPO zone. These trials were performed in 2 different varieties.

There were no symptoms of phytotoxicity for any of the doses tested in these two efficacy trials.

A summary of the mentioned results can be found in Table 3.4-4.

Table 3.4-4: Phytotoxicity of SAP09I in onion. Efficacy trials

Number of trials with...		Efficacy trials (2 trials)			
		SAP09I N = 0.15 L/ha	SAP09I N = 0.2 L/ha	SpinTor 480 SC N = 0.15 L/ha	SpinTor 480 SC N = 0.2 L/ha
Maximum of Phytotoxicity recorded during the trials	0% to 5%	2	2	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15%	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	2	2	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15%	0	0	0	0

Trials performed in leek – ALLPO

Two efficacy trials were performed in 2024 in leek in Poland belonging to the North-East EPPO zone. These trials were performed in 2 different varieties.

There were no symptoms of phytotoxicity for any of the doses tested in these two efficacy trials.

A summary of the mentioned results can be found in Table 3.4-5.

Table 3.4-5: Phytotoxicity of SAP09I in leek. Efficacy trials

Number of trials with...		Efficacy trials (2 trials)			
		SAP09I N = 0.15 L/ha	SAP09I N = 0.2 L/ha	SpinTor 480 SC N = 0.15 L/ha	SpinTor 480 SC N = 0.2 L/ha
Maximum of Phytotoxicity recorded during the trials	0% to 5%	2	2	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15%	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	2	2	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15%	0	0	0	0

Trials performed in apple – MABSD

Eight Five efficacy trials were performed in 2024 and 2025 in apple in Poland belonging to the North-East EPPO zone. These trials were performed in 4 different varieties.

There were no symptoms of phytotoxicity in these eight five efficacy trials.

A summary of the mentioned results can be found in Table 3.4-6.

Table 3.4-6: Phytotoxicity of SAP09I in apple. Efficacy trials

Number of trials with...		Efficacy trials (5 trials)	
		SAP09I N = 0.21-0.25 L/10000m ² LWA (0.23 L/10000m ² LWA, in average), equivalent to 0.3 L/ha	SpinTor 480 SC N = 0.21-0.25 L/10000m ² LWA (0.23 L/10000m ² LWA, in average), equivalent to 0.3 L/ha
Maximum of Phytotoxicity recorded during the trials	0% to 5%	≤ 8	≤ 8
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15%	0	0
Level of symptoms at the last assessments	0% to 5%	≤ 8	≤ 8
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15%	0	0

Overall conclusions on phytotoxicity

The product SAP09I and the reference SpinTor 480 SC were completely selective and therefore comparable in all trials regardless of the dose tested.

Therefore, it can be concluded that when SAP09I is applied according to the proposed GAP, no unacceptable phytotoxic effect is expected on none of the crops tested:

- head cabbage,
- cauliflower,
- onion,
- leek
- apple.

Comments of zRMS:	The applicant submitted 136 efficacy trials, where phytotoxicity of the product was carried out at the proposed use rates of: - 0,3 L/ha in apple (two applications); - 0,1 and 0,2 L/ha (three applications) in head cabbage and cauliflower; - 0,15 and 0,2 L/ha in onion and leek (three applications) No symptoms of phytotoxicity were observed in efficacy trials.
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

There is no indication of a negative influence of SAP09I on yield of different agricultural and horticultural crops from practical use.

According to the relevant EPPO guideline PP 1/135(4) no specific crop safety trials under pest-free conditions are required where yield is assessed.

Comments of zRMS:	Yield of protected crops was not tested in efficacy trials. No negative effects on the yield of head cabbage, cauliflower, onion, apple and leek are expected after the application of SAP09I, because no phytotoxicity symptoms were observed in efficacy trials.
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Please refer to the data used in support of the registration for SpinTor 480 SC (first approval number R-18/2003 of September 12th, 2003; ~~current approval number R-47/2018wu of October 19th, 2018~~), which is now unprotected.

Comments of zRMS:	No negative effects on the quality of plants or plant products are expected after the application of SAP09I.
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3.4.4 Effects on transformation processes (KCP 6.4.4)

Please refer to the data used in support of the registration for SpinTor 480 SC (first approval number R-18/2003 of September 12th, 2003; ~~current approval number R-47/2018wu of October 19th, 2018~~), which is now unprotected.

Comments of zRMS:	No negative effects on transformation processes are expected. The product has no fungicidal properties.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Please refer to the data used in support of the registration for SpinTor 480 SC (first approval number R-18/2003 of September 12th, 2003; ~~current approval number R-47/2018wu of October 19th, 2018~~), which is now unprotected.

Comments of zRMS:	No negative effects on treated plants or plant products to be used for propagation are expected. The product has had no systemic activity nor phytotoxic effect were observed on crops.
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Please refer to the data used in support of the registration for SpinTor 480 SC (first approval number R-18/2003 of September 12th, 2003; ~~current approval number R-47/2018wu of October 19th, 2018~~), which is now unprotected.

Comments of zRMS:	The risk of adverse impact of SAP09I on succeeding crops is not expected.
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Please refer to the data used in support of the registration for SpinTor 480 SC (first approval number R-18/2003 of September 12th, 2003; ~~current approval number R-47/2018wu of October 19th, 2018~~), which is now unprotected.

Comments of zRMS:	The risk of impact on other plants including adjacent crops of SAP09I is not expected with applying buffer zone of 1m mitigation measures.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Please refer to the data used in support of the registration for SpinTor 480 SC (first approval number R-18/2003 of September 12th, 2003; ~~current approval number R-47/2018wu of October 19th, 2018~~), which is now unprotected.

Also, new studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

3.6 Other/special studies

No other studies were provided.

3.7 List of test facilities including the corresponding certificates

The tests facilities involved in the trials can be found in Table 3.7-1 below.
The GEP certificates are provided in BAD.

Table 3.7-1: List of test facilities

Trial facility	Address	Certificate (Yes or No)
ANADIAG SAS Oddział w Polsce	Sadowa 16/22, Zgierz, 95-100 Poland	Yes
Agrineo Rafał Figurski	Stare Olszyny 4A, 09-142 Załuski Poland	Yes

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 -Source (where different) Report no GEP/ GLP Published or not	Vertebrate study (Y/N)	Data protection claim (Y/N)	Justification if data protection is claimed	Owner
KCP 6.0	Anonymous	2025	Biological Assessment Dossier, Product code/name: SAP09I/Volkete, 2025 Albaugh Europe Sàrl Unpublished	N	Y	Data/study report never submitted before to Poland	Albaugh Europe Sàrl

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