

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SAP09I

Product name(s): VOLKETE MAX

Chemical active substance:

Spinosad, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

Poland

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

Applicant: Albaugh TKI d.o.o.

Submission date: January 2025

MS Finalisation date: 02/2026

Version history

January 2025	V0 – Original dRR version from applicant Albaugh TKI d.o.o. for submission to zRMS Poland in the frame of a new authorization according to Article 33/34 of Regulation (EC) No. 1107/2009.
April 2025	Dossier sent for evaluation
October 2025	zRMS evaluation of dRR
November 2025	Applicant update: new GAP proposal according to the ecotox. risk assessment following different approaches after new suggested NOEC on <i>Folsomia</i> by evaluator under commenting phase
December 2025	RR
February 2026	Final RR

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PART A

RISK MANAGEMENT

1 Details of the application

The company Albaugh TKI d.o.o. has submitted a dRR to zRMS Poland in the frame of a new authorization according to Article 33/34 of Regulation (EC) No. 1107/2009 of the product SAP09I, a SC formulation containing 480 g/l Spinosad. The product is intended for use as an insecticide against various pests in vegetable crops:

- head cabbage to control cabbage caterpillar, imported cabbage worm and cabbage armyworm
- cauliflower and broccoli, to control imported cabbage worm and cabbage armyworm
- onion and leek to control onion thrips
- apple to control smaller tea tortrix

The requested uses also include minor uses (in accordance with Article 51 of Regulation 1107/2009):

- other *Allium* crops (garlic and shallot to control *Thrips* sp.)
- pome trees (pear, crab apple and quince for a control of smaller tea tortrix).

The applicant forms part of the Task Force “Spinosad 48% SC JDDA”, comprised of the following members:

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This document describes the specific conditions of use and labelling required for Poland for the authorisation of the generic plant protection product VOLKETE MAX (SAP09I), a suspension concentrate (SC) formulation containing 480 g/L Spinosad to be used as insecticide. The applicant details:
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This application is based on the data package and assessments of the reference product SPINTOR 480 SC registered in Poland since 2003 (Registration no. No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018, pursuant article 33/34 of Regulation (EC) 1107/2009 after the period for data protection for SPINTOR 480 SC data package has expired.

The formulation comparability has already been pre-screened by another Member State in the southern zone being considered to be comparable to that of Dow Agrosciences Ltd.. The composition of SAP09I and information of co-formulants is provided in order to assess the comparability to the existing authorised Dow AgroSciences Ltd. UK, (subsequently CORTEVA) product SPINTOR 480 SC. The conditions of use and GAP proposed for SPANNER 480 SC are the same as those authorised for SPINTOR 480 SC.

This document describes the specific conditions of use and labelling required for the registration of VOLKETE MAX.

This application was made to Poland as the zonal Rapporteur Member States (zRMS) without identified concerned Member States.

1.1 Application background

The application is for authorization of the plant protection product SAP09I, based on the authorised product SPINTOR 480 SC in Poland since 2003 (Registration no. No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018, pursuant article 33/34 of Regulation (EC) 1107/2009 after the period for data protection for SPINTOR 480 SC data package has expired.

1.2 Letters of Access

This application is based on out of protection data package and assessments of the reference product SPINTOR 480 SC in Poland (Registration no. No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

1.3 Justification for submission of tests and studies

Data submitted with the purpose of comparison with the reference product SPINTOR 480 SC in Poland (Registration no. R-47/2018wu of 19 October 2018).

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4. Studies provided in the application that have never been submitted to authority of Poland before and are deemed necessary for authorisation are protected for 10 years from the date of approval.

2 Details of the authorization decision

2.1 Product identity

Product code	SAP09I / Spinosad 480 SC
Product name in MS	VOLKETE / VOLKETE MAX
Authorization number	PL: not available (first registration)
Function	Insecticide
Applicant	Albaugh TKI d.o.o.
Active substance(s) (incl. content)	Spinosad (480 g/L)

Formulation type	Suspension concentrate [Code: SC]
Packaging	Bottle “PET” and “HDPE, HDPE/EVOH (Coex), HDPE/PA, HDPE/F”: 10 mL to 1 L Bottle HDPE, HDPE/EVOH, HDPE/F, HDPE/PA (Coex): 1 L Canister HDPE, HDPE/F, HDPE/EVOH, HDPE/PA: 2-10 L
Coformulants of concern for national authorizations	Contains: 1,2-benzisothiazol-3(2H)-one
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

Physicochemical Properties:

Volkete Max cannot be considered equivalent/ comparable to already registered SpinTor 480 SC in physicochemical area under Composition's comparison in accordance with Article 34 of Regulation 1107/2009. In summary, unprotected physicochemical data taken SpinTor 480 SC cannot be used to support Volkete Max registration in Poland.

Examples (amend as appropriate):

The evaluation of the application for product name resulted in the decision to grant the authorization.

All uses applied for were authorised except for use(s) on insert crop(s) due to insert reason(s) for refusal.
or

The evaluation of the application for product name resulted in the decision to refuse the authorization.
The reason(s) for the refusal is/are: insert reasons for refusal.

Residues:

All uses applied for were authorised except for use on broccoli. There is insufficient data to confirm that the applicable MRL for broccoli is not exceeded.

The new GAPs proposed by the applicant are less critical than those previously assessed. No additional assessment is required.

Ecotoxicology:

For *F. candida*, the risk assessment, based on laboratory study, indicated a potential for adverse effects of SAP09I proposed use pattern. Therefore, the refined PEC_{SOIL} or additional higher tier data are necessary to demonstrate the acceptable risk for soil organisms. Pending the submission of mentioned information, the risk is considered unacceptable for all proposed uses of SAP09I.

During the commenting process, the Applicant introduced modifications to the proposed use pattern of SAP09I (Volkete Max). Additional risk assessment was performed for mammals and soil organisms. Acceptable risk for non-target organisms was demonstrated for following uses:

- Use no. 1, 2 (cabbage, broccoli, cauliflower) application rate:
 - 3 x 0.1 L/ha (3 x 48 g a.s./ha), interval: 10d, BBCH 10-49
 - 2 x 0.16 L/ha (2 x 76.8 g a.s./ha), interval: 10d, BBCH 20-49
- Uses no. 3, 4, 7 (onion, leek, garlic) application rate:
 - 1 x 0.15-0.16 L/ha (1 x 72-76.8g a.s./ha), BBCH 40-49
- Uses no. 5, 6 (pear, wild apple, quince) application rate:
 - 1 x 0.3 L/ha (1x 144 g a.s./ha) BBCH >70
 - 2 x 0.225 L/ha (2 x 108 g a.s./ha) BBCH >70, interval: 10d
 - 2 x 0.225 L/ha (2 x 108 g a.s./ha) BBCH 40-59 (1st appl.) / BBCH >70 (2nd appl.), interval: 10d

2.3 Substances of concern for national monitoring

Not applicable.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aquatic Acute 1 Aquatic Chronic 1
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P102: Keep out of reach of children. P270: Do not eat, drink or smoke when using this product. P391: Collect spillage. P501: Dispose of contents and/or their container according to the separated collection system used in your municipality.
Additional labelling phrases:	EUH210: Safety Data Sheet available on request.
	EUH401: To avoid risks to man-human health and the environment, comply with the instructions for use.
	EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPo2	All clothing should be washed after use.
SPe3	To protect aquatic organisms, respect an unsprayed buffer zone of 10m with vegetated buffer of 5m to surface water bodies in applications to leafy vegetables (uses no. 1, 2) and bulb and onion like vegetables (uses no. 3, 4, 7).
SPe3	To protect aquatic organisms, respect an unsprayed buffer zone of 40m or 20 m with 95% DRN to surface water bodies in early applications to orchards (uses no. 5, 6). To protect aquatic organisms, respect an unsprayed buffer zone of 30m or 10 m with 90% DRN or 20 m with 50% DRN to surface water bodies in late applications to orchards (uses no. 5, 6).
SPe8	Dangerous to bees. To protect bees and other pollinating insects do not apply on flowering crops. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.
SPe3	To protect non-target arthropods, respect an unsprayed buffer zone of 5m or 1m with 75% DRN to non-agricultural land in applications to vegetables.
SPe3	To protect non-target arthropods, respect an unsprayed buffer zone of 40m or 30m with 50% DRN or 15m with 90 % DRN to non-agricultural land in applications to orchards.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

Not relevant.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection	
Low vegetables (Vehicle-mounted)	M/L: Workwear App: Workwear
Orchards (Vehicle-mounted)	M/L: Workwear + Protected hands App: Workwear
Worker protection	
Low vegetables (Reaching, picking (all except Brassica)), Orchards (Inspection, irrigation)	Workwear
Low vegetables (Inspection, irrigation (All))	None
Low vegetables Harvest and Maintenance (Brassica only), Orchards (Searching, reaching, picking)	Workwear and gloves
Orchards (Maintenance/thinning)	Workwear, gloves and re-entry period of 11 days Workwear/gloves or worker/gloves/re entry period of 11 days
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe3	To protect aquatic organisms, respect an unsprayed buffer zone of 10m with vegetated buffer of 5m to surface water bodies in applications to leafy vegetables (uses no. 1, 2) and bulb and onion like vegetables (uses no. 3, 4, 7).
SPe3	To protect aquatic organisms, respect an unsprayed buffer zone of 40m or 20 m with 95% DRN to surface water bodies in early applications to orchards (uses no. 5, 6). To protect aquatic organisms, respect an unsprayed buffer zone of 30m or 10 m with 90% DRN or 20 m with 50% DRN to surface water bodies in late applications to orchards (uses no. 5, 6).
SPe8	Dangerous to bees. To protect bees and other pollinating insects do not apply on flowering crops. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.
SPe3	To protect non-target arthropods, respect an unsprayed buffer zone of 5m or 1m with 75% DRN to non-agricultural land in applications to vegetables.
SPe3	To protect non-target arthropods, respect an unsprayed buffer zone of 40m or 30m with 50% DRN or 15m with 90 % DRN to non-agricultural land in applications to orchards.
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
Respective code if available	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1 date: January 2025

PPP (product name/code): VOKETE MAX / (SAP09I /Spinosad 480 SC)
Active substance 1: Spinosad
Safener: --
Synergist: --
Applicant: Albaugh TKI d.o.o.
Zone(s): central ^(d)
Verified by MS: yes

Formulation type: SC ^(a, b)
Conc. of as 1: 480 g/kg ^(c)
Conc. of safener: - ^(c)
Conc. of synergist: - ^(c)
Professional use: ☒
Non professional use: ☐

Field of use: insecticide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					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		
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 BBCH 10-49	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 Residues: The intervals between applications — should correspond to the one in the residue studies, i.e. 10 days.
2	PL	Broccoli [BRSOK] Cauliflower [BRSOB]	F	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young — caterpillars / first damages BBCH 10-49	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 There is insufficient data to confirm that the applicable MRL for broccoli is not exceeded. Cauliflower: The ——— intervals between applications should correspond to

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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)	Application				Application rate			PHI (days)	Remarks: e.g.-g safener/synergist per ha (4)
					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		
													the one in the residue studies, i.e. 10 days.
3	PL	Onion [ALLCE]	F	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 10-39	a) 3 b) 3	10	a) 0.2 b) 0.6	a) 96 b) 288	2300- 600	7	Dose rate 0.15-02 L/ha Mammals: BBCH ≥ 40 — non safe
4	PL	Leek [ALLPO]	F	<i>Thrips tabaci</i> [THRITB]	Spraying	Young caterpillars / first damages BBCH 10-39	a) 3 b) 3	10	a) 0.2 b) 0.6	a) 96 b) 288	200- 600	7	Dose rate 0.15-02 L/ha Mammals: BBCH ≥ 40 — non safe
5	PL	Apple [MABSD]	F	<i>Adoxophyes orana</i> [CAPURE]	Spraying	<BBCH 569 (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	Max. 2 uses in season 0.23 L/1000 m ² of LWA Mammals: BBCH < 40 — non safe
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	Max. 2 uses in season 0.23 L/1000 m ² of LWA Mammals: BBCH < 40 — non safe
7	PL	Garlic [ALLSA] Shallot [ALLAS]	F	<i>Thrips</i> sp. [THRISP]	Spraying	Notice of the pest / first damages BBCH 10-39	a) 3 b) 3	10	a) 0.2 b) 0.6	a) 96 b) 288	200- 600	7	Dose rate 0.15-02 L/ha Mammals: BBCH ≥ 40 — non safe

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(a)	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 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 ^(b)
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 BBCH 10-49	a) 2-3 b) 2-3	10	a) 0.2 b) 0.6	a) 96 b) 288	200- 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 Unacceptable risk for soil organisms
1a	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 BBCH 20-49	a) 2 b) 2	10	a) 0.16 b) 0.32	a) 76.8 b) 153.6	200- 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	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [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	2400- 600	3	Intended Use just in case higher tier assessment in Folsomia is not accepted
2	PL	Broccoli [BRSOK] Cauliflower [BRSOB]	F	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [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- 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 Unacceptable risk for soil organisms
2a	PL	Broccoli [BRSOK] Cauliflower [BRSOB]	F	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 20-49	a) 2 b) 2	10	a) 0.16 b) 0.32	a) 96-76.8 b) 288-153.6	200- 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	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [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	2400- 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
Use- No. (a)	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	Application Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	Application rate 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 (a)
3	PL	Onion [ALLCE]	F	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 10-49	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 risk for soil organisms
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 0.15 b) 0.16 0.15	a) 76.8 72 b) 76.8 72	2300- 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 10-49	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. 4a Unacceptable risk for soil organisms
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 0.15 b) 0.16 0.15	a) 76.8 72 b) 76.8 72	2300- 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 (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,e Unacceptable risk for soil organisms
5a	PL	Apple [MABSD]	F	<i>Adoxophyes orana</i> [CAPURE]	Spraying	>BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	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,e Unacceptable risk for soil organisms

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (a)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F. Fn. Fpn 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 (0)
5a	PL	Apple [MABSD]	F	<i>Adoxophyes orana</i> [CAPURE]	Spray	BBCH >70	a) 1 b) 1	NR	a) 0.3 b) 0.3	a) 144 b) 144	300- 1500	14	Dose range 0.18-0.3 L/ha Intended Use just in case high- er 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 0.18-0.225 Intended Use just in case high- er tier assessment in Folsomia is not accepted
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 0.18-0.225 Intended Use just 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
Use- No. ^(a)	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 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 (^(f))
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 1 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,e Unacceptable risk for soil organisms
6 ^c	PL	Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	F	<i>Adoxophyes orana</i> [CAPURE]	Spraying	>BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	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,e Unacceptable risk for soil organisms
6a	PL	Pear [PYUCO] Crab apple [MABSY] Quince [CYDOB]	F	<i>Adoxophyes orana</i> [CAPURE]	Spray	BBCH >70	a) 1 b) 1	NR	a) 0.3 b) 0.3	a) 144 b) 144	300- 1500	14	Dose range 0.18-0.3 L/ha Intended Use just in case high- er 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 0.18-0.225 Intended Use just 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 0.18-0.225 Intended Use just 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
Use- No. ^(a)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, 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 ^(f)
7	PL	Garlic [ALLSA] Shallot [ALLAS]	F	Thrips sp. [THRISP]	Spraying	Notice of the pest / first damages BBCH 10-49	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. 7a Unacceptable risk for soil organisms
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) 0.16	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

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of off-white liquid suspension concentrate, with a characteristic odour. It is not explosive, has no oxidising properties. No flash point was observed. It has an auto-ignition temperature of 400 °C. In aqueous solution, it has a pH value around 7.0 at 20.0 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 2 weeks at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 3 years at ambient temperature when stored in HDPE containers. According to GD SANCO/10473/2003–rev.5 for water-based formulations extrapolation is acceptable to all rigid packaging types, apart from metal with no further data (please refer to section 4). Its technical characteristics are acceptable for a suspension concentrate formulation.

Acceptable packaging material: HDPE, PET, Fluorinated HDPE, HDPE/PA and HDPE/EVOH.

The minimum and maximum intended concentration of use are respectively 0.0125% to 0.1%.

No tank mixes are recommended.

3.2 Efficacy (Part B, Section 3)

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 (please see the GAP table under point 2.6).

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 authorisation number: R-18/2003 of September 12th, 2003), 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 refers 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 between 2024 and 2025** 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, quince, garlic and shallo.

3.3 Efficacy data

Minimum effective dose tests

A total **4316** 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 in 2 to 3 applications, depending on the use. The target dose rates for each crop were aligned with the national authorisation of the standard reference product SpinTor 480 SC.

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”:

- 1 - head cabbage/PIERBR
- 2 - broccoli, cauliflower/PIERRA, BARABR
- 3 - onion/THRITB
- 4 – leek/THRITB

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 – *Brassica*. 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 than against PIERRA. Therefore efficacy mean efficacy data 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

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

Efficacy tests

In total 1316 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.

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 (MRiW 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. Effect of SAP09I and SPINTOR 480 SC should be comparable on the three pests, provided that the two products contain the same active, at the same concentration, share the same formulation type and are applied at the same doses. Particularly, when the products demonstrated in all the evaluated cases, full biological comparability. This reasoning supports the conclusion of possible extrapolation, according the EPPO guideline PP 1/257 (2) Efficacy and crop safety extrapolations for minor uses.

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 (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 data for both pest species can not be evaluated together.

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.

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.

Efficacy data for head cabbage (brassica vegetable) was carried out in one season, that is why it is proposed to accept the protection of cabbage against PIERRA conditionally with obligation to confirm efficacy in two trials carried out in the second season.

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.

Efficacy data for head cabbage and cauliflower was carried out in one season, that is why it is proposed to accept the protection of cauliflower against PIERRA conditionally with obligation to confirm efficacy in two trials carried out in the second season.

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.

Efficacy data for head cabbage and cauliflower was carried out in one season, that is why it is proposed to accept the protection of cauliflower against PIERRA conditionally with obligation to confirm efficacy in two trials carried out in the second season.

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. However, 2 efficacy trials on onion carried out in one season can be accepted conditionally. It is proposed to accept the protection of onion against THRITB conditionally with obligation to confirm efficacy in one or two trials carried out in the second season. 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. However, 2 efficacy trials on leek carried out in one season can be accepted conditionally. It is proposed to accept the protection of leek against THRITB conditionally with obligation to confirm efficacy in one or two trials carried out in the second season. 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..

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

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.

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)

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.

3.3.2 Adverse effects on treated crops

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 are only required if any adverse phytotoxic effects occur at target dose in any of the efficacy trials.

No adverse effect was observed in any of the 13 efficacy trials presented in this dossier, therefore no specific selective trials were performed.

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 tests.

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.

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 tests.

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.

Five efficacy trials were performed in 2024 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 five efficacy tests.

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.

3.3.3 Observations on other undesirable or unintended side-effects

Please refer to the data used in support of the registration for SpinTor 480 SC (first authorisation number: R-18/2003 of September 12th, 2003), which is now unprotected.

3.4 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substance(s) and relevant impurities in the plant protection product.

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions. Please refer to data submitted for SPINTOR 480 SC.

Noticed data gaps are:

- None.

Commodity/crop	Supported/ Not supported
Head cabbage	Supported
Broccoli, cauliflower	Supported
Onion, garlic, shallot	Supported
Leek	Supported
Apple, pear, crab apple, quince	Supported

3.4.1 Analytical method for the formulation

An analytical method has been developed for the determination of the active substance Spinosad in SAP09I. The HPLC-DAD method used for the determination of spinosad in the formulation SAP09I has been validated according to SANCO/3030/99-rev.5 and is considered acceptable.

3.4.2 Analytical methods for residues

Please see above 3.4.

Please refer to data submitted for SPINTOR 480 SC.

3.5 Mammalian toxicology (Part B, Section 6)

No experimental data on the toxicity of the formulation are available for VOLKETE MAX as the

submission is based on read across to unprotected data supporting the product SPINTOR 480 SC which has a full supporting vertebrate study set that is without data protection. SPINTOR 480 SC has been re-authorized according to Uniform Principles under Regulation (EC) 1107/2009. Furthermore, reference is made to the toxicity studies for the active substance which are also unprotected.

3.5.1 Acute toxicity

The assessment has been conducted according to Regulation EC 1272/2008 requirements. The theoretical toxicological classification of the formulated product SAP09I (Spinosad 480 SC) is available on “Toxicological Classification” Document Part C. The available toxicological data are reported in the MSDS.

3.5.2 Operator exposure

The operator exposure was assessed against the AOEL and AAOEL for spinosad (SANCO/1428/2001 – rev. final of 14 July 2006). Proposed dermal absorption rates used for the calculations are based on unprotected dermal absorption study of reference product.

The operator exposure was modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032).

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

Low vegetables (Vehicle-mounted):

- M/L: Workwear
- App: Workwear

Orchards (Vehicle-mounted):

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

3.5.3 Worker exposure

The worker exposure was assessed against the AOEL and AAOEL for spinosad (SANCO/1428/2001 – rev. final of 14 July 2006). Proposed dermal absorption rates used for the calculations are based on unprotected dermal absorption study of reference product.

The worker exposure was modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) and EUROPOEM II model.

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

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

- Workwear

Low vegetables (Inspection, irrigation (All))

- None

Low vegetables Harvest and Maintenance (Brassica only) and Orchards (Searching, reaching, picking):

- Workwear and gloves

Orchards (Maintenance/thinning):

- Workwear, gloves and re-entry period of 11 days.

Field:

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

Orchards:

Re-entry period of 11 days for maintenance/thinning.

~~Additional risk assessment for worker was performed using DFR studies submitted by the Applicant.~~

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

~~**Orchards (Maintenance/thinning):**~~

~~— Workwear and gloves.~~

3.5.4 Bystander and resident exposure

The bystander and resident exposure were assessed against the AOEL and AAOEL for spinosad (SANCO/1428/2001 – rev. final of 14 July 2006). Proposed dermal absorption rates used for the calculations are based on unprotected dermal absorption study of reference product.

The bystander and resident exposure were modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032).

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

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

The available residue information is sufficient to perform an adequate assessment. Residues that are expected from the intended use of the plant protection product will not exceed the MRLs for spinosad set in Regulation (EU) No. 396/2005.

The application is for authorization of the plant protection product SAP09I, based on the authorised product SPINTOR 480 SC in Poland since 2003 (Registration no. No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018, pursuant article 33/34 of Regulation (EC) 1107/2009 after the period for data protection for SPINTOR 480 SC data pack-age has expired.

Head Cabbage

The data submitted shows that no exceedance of the MRL of 2 mg/kg for cabbage (STMR 0.015 mg/kg, HR 0.17 mg/kg) will occur.

The intervals between applications should correspond to the one in the residue studies, i.e. 10 days.

Cauliflower, broccoli

The data submitted shows that no exceedance of the MRL of 2 mg/kg for cauliflower (STMR 0.01 mg/kg, HR 0.02 mg/kg) will occur.

The intervals between applications should correspond to the one in the residue studies, i.e. 10 days

According to the guideline SANTE/2019/12752 Rev.02, the extrapolation from cauliflower to broccoli is not possible. It is possible to extrapolate from 4 trials on cauliflower + 4 trials on broccoli to whole subgroup of flowering brassica. However, the applicant did not provide any residue studies for broccoli.

There is insufficient data to confirm that the applicable MRL for broccoli is not exceeded.

Onion, garlic, shallots

The data submitted shows that no exceedance of the MRL of 0.07 mg/kg for onion (STMR 0.002 mg/kg, HR 0.05 mg/kg) will occur.

The calculated using the OECD calculator indicates a higher value than the current MRL. However, the MRL in force was calculated for MRL setting, based on the same data as that provided by the applicant (EFSA Journal 2012;10(3):2630). Additionally, it should be noted that residue studies were performed with 4 applications at a dose of approximately 0.096 kg as/ha and the intended GAP applies to a max. 3 applications at this dose.

According to the guideline SANTE/2019/12752 Rev.02, the extrapolation from onion to garlic and shallots is possible. The data submitted show that no exceedance of the MRL of 0.07 mg/kg for garlic and shallots will occur.

Leek

The data submitted shows that no exceedance of the MRL of 0.2 mg/kg for leek (STMR 0.065 mg/kg, HR 0.17 mg/kg) will occur.

The calculated using the OECD calculator indicates a higher value than the current MRL. However, the MRL in force was calculated for MRL setting, based on the same data as that provided by the applicant (EFSA Journal 2012;10(3):2630). Additionally, it should be noted that residue studies were performed with 4 applications at a dose of approximately 0.096 kg as/ha and the intended GAP applies to a max. 3 applications at this dose.

Apple, pear, wild apple, quince

The data submitted shows that no exceedance of the MRL of 0.3 mg/kg for apple (STMR 0.04 mg/kg, HR 0.12 mg/kg) will occur.

According to the guideline SANTE/2019/12752 Rev.02, the extrapolation from apple to pear, wild apple, quince is possible. The data submitted show that no exceedance of the MRL of 0.3 mg/kg for pear, wild apple and quince will occur.

Honey

Studies indicating residue levels in crops with melliferous capacity are currently required. For the intended GAP for SAP09I this applies to apples, pears, crab apples and quinces. However, the pro-posed uses exclude the flowering phase (BBCH limited to: before BBCH 59 and after BBCH 70). It can therefore be concluded that for the uses proposed in the intended GAP, residue studies in honey are not required.

3.6.2 Consumer exposure

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1; calculation version 06/01/2021) provided on the internet homepage of EFSA (<https://www.efsa.europa.eu/>). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

The results of the consumer calculations with the PRIMo rev. 3.1 model are summarized in Part B Section 7, Point 7.2.8.

The results of the TMDI calculations show that there is no chronic risk for consumer for the active substance spinosad. The TMDI estimations resulted in 95% of the ADI based on NL toddler diet.

The results of the IESTI calculations show no acute risk for consumer either. The highest IESTI estimate for children was 17% of the ARfD in pears (unprocessed commodities) and 10% of the ARfD in leeks/boiled (processed commodities).

The proposed uses of Spinosad in the formulation SAP09I do not represent unacceptable chronic and acute risks for the consumer.

Estimation of the chronic and acute exposure provided in EFSA Journal 2021;19(2):6404 covers residue results adequate for this dossier.

During the first peer-review and approval of the active substance an ARfD was not deemed necessary. However, in the framework of the renewal of the approval of spinosad an ARfD of 0.1 mg/kg bw was proposed (EFSA Journal 2018;16(5):5252). It is noted that this value has not yet been formally adopted by the European Commission. Nevertheless, the proposed ARfD of 0.1 mg/kg bw was used in the estimation of the exposure. Chronic and acute exposure calculations were per-formed using revision 3.1 of the EFSA PRIMo. Based on these calculations, EFSA concludes that no risk to consumers was identified. Nonetheless, EFSA underlines that these conclusions were reached while considering residues of only spinosyn A and D, and it may need to be reconsidered pending revision of the residue definition for risk assessment as proposed by the peer review in the framework of the renewal.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The Predicted Environmental Concentrations in soil (PEC_{soil}) of the active substance spinosad and associated metabolites were based on the excel spreadsheet modelling approach. A soil depth of 5 cm and a bulk density of 1.5 g/cm³ were assumed. Application rates and crop interception (EFSA Journal 2014; 12(5):3662) were selected in concordance with the GAP.

Spinosad is a mixture of two components: spinosyn A and spinosyn D. Exposure assessments were done separately for the two components, using application rates calculated by correcting for the occurrence of each component considering only a ratio of 85:15 in the technical material. Overall, PEC_{soil} values for Spinosad were derived summing PEC values from the individual spinosyn components. The PEC values relevant for the ecotoxicological assessment are given in the ecotoxicology section.

During the commenting period, the Applicant has submitted a new proposed application scheme for formulation SAP09I (Volkete Max). Additional PECs assessment is provided in Part B8. The LWA approach presented by the Applicant was not considered and not accepted.

A detailed documentation of the PEC values is shown in Part B, Section 8 of this submission.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PEC of the active substance and its metabolites in groundwater (PEC_{gw}) have been assessed with FOCUS PELMO v6.6.4 and FOCUS PEARL v5.5.5. Additionally, the application dates according to AppDate software v3.06 were used. The calculated PEC_{gw} values are lower than the regulatory threshold of 0.1 µg/L for the active substance spinosad and its metabolites spinosyn B and N-demethylated spinosyn D, demonstrating a negligible risk of contamination of groundwater after application of SAP09I. A summary of PEC_{gw} modelling details is given in dRR Part B8 of this submission.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PEC of the active substance and its metabolites in surface water and sediment (PEC_{sw} and PEC_{sed}) have been assessed with FOCUS Step 1+2 (FOCUS Step 1-2, v3.2), Step 3 (FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3) and Step 4 (SWAN 5.0.1). The mitigation measures were proposed in Step 4 (in accordance with Landscape & Mitigation Guidance). The results for PEC_{sw} for the active substance and its metabolites were used for the ecotoxicological risk assessment. A summary of PEC_{sw} and PEC_{sed} modelling details is given in dRR Part B8 of this submission.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Spinosyn A and D are regarded as non-volatiles. Therefore, exposure of adjacent surface waters and terrestrial ecosystems due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

In accordance with the request of the Polish Ministry of Agriculture and Rural Development DHR.rs1.8208.1.5.2025, dated 09 April 2025, only SpinTor 480 SC (GF-976/NAF-85) studies included in document M-III: GF-976 (SPINOSAD, 480 G/L SUSPENSION CONCENTRATE) Section 6: Ecotoxicology, dated January 2004, may be used for the purposes of current evaluation of SAP09I. SpinTor 480 SC (GF-976/NAF-85) is a representative formulation. Consequently, the tests used to determine the endpoints provided in the document SANCO/1428/2001- rev. final dated 14 July 2006 were not reassessed.

3.8.1 Effects on terrestrial vertebrates

An acceptable risk was obtained for SAP09I at the screening phase for acute and long-term exposure. The risk assessment for drinking water is also acceptable as well as for the secondary poisoning scenarios. Overall, birds present an acceptable risk towards SAP09I when used according to the proposed application patterns.

An acceptable risk to mammals was obtained for SAP09I at the screening phase for acute exposure. The chronic risk assessment for mammals demonstrates acceptable risk for following uses of SAP09I:

- Leafy vegetables (use no. 1, 2) – BBCH 10-49, 3 x 96 g a.s./ha with min. interval of 10 days;
- Bulbs and onion like crops (use no. 3, 4, 7) – BBCH 10-39, 3 x 96 g a.s./ha with min. interval of 10 days;
- Bulbs and onion like crops (use no. 3, 4, 7) – BBCH $\geq$ 40, 1 x 76.8 g a.s./ha with min. interval of 10 days;
- Orchards (uses no. 5, 6) – BBCH $\geq$ 40, 1-2 x 144 g a.s./ha with min. interval of 21 days
- Orchards (uses no. 5, 6) – BBCH $\geq$ 40, 1-2 x 108 g a.s./ha with min. interval of 10 days
- ~~Orchards (uses no. 5, 6) – BBCH $\geq$ 70, 1-2 x 144 g a.s./ha with min. interval of 10 days~~

An unacceptable chronic risk to mammals (voles) has been identified for the following uses:

- Leafy vegetables (use no. 1, 2) – BBCH 10-49, 3 x 96 g a.s./ha with min. interval of 7 days;
- Bulbs and onion like crops (use no. 3, 4, 7) – BBCH $\geq$ 40, 3 x 96 g a.s./ha with min. interval of 10 days;
- Orchards (uses no. 5, 6) – BBCH $<$ 40, 1-2 x 144 g a.s./ha with min. interval of 10 days
- Orchards (uses no. 5, 6) – BBCH $\geq$ 70, 2 x 144 g a.s./ha with min. interval of 10 days
- Orchards – BBCH $<$ 40, 2 x 108 g a.s./ha with min. interval of 10 days

Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is acceptable.

3.8.2 Effects on aquatic species

The risk assessment to aquatic organisms was conducted according to EFSA Journal 2013; 11(7):3290. An acceptable risk is obtained for SPA09I application according to the intended uses when the following mitigation measures are implemented:

SPe3: To protect aquatic organisms, respect an unsprayed buffer zone of 10m with vegetated buffer of 5m to surface water bodies in applications to leafy vegetables (uses no. 1, 2) and bulb and onion like vegetables (uses no. 3, 4, 7).

SPe3: To protect aquatic organisms, respect an unsprayed buffer zone of 40m or 20 m with 95% DRN to surface water bodies in early applications to orchards (uses no. 5, 6).

SPe3: To protect aquatic organisms, respect an unsprayed buffer zone of 30m or 10 m with 90% DRN or 20 m with 50% DRN to surface water bodies in late applications to orchards (uses no. 5, 6).

3.8.3 Effects on bees

The risk assessment for bees was conducted according to SANCO/10329/2002 rev 2 final. An unacceptable risk is found for bees exposure to SAP09I. Therefore, a restriction must be imposed in the application of this product according to the proposed application patterns:

SPe8: Dangerous to bees. To protect bees and other pollinating insects do not apply on flowering crops. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering

3.8.4 Effects on other arthropod species other than bees

The risk assessment for non-target arthropods was conducted according to SANCO/10329/2002 rev 2 final and ESCORT 2. No unacceptable risk is expected when SAP09I is applied according to the proposed application patterns when the following mitigation measures are in place:

SPe3: To protect non-target arthropods, respect an unsprayed buffer zone of 5m or 1m with 75% DRN to non-agricultural land in applications to vegetables.

SPe3: To protect non-target arthropods, respect an unsprayed buffer zone of 40m or 30m with 50% DRN or 15m with 90 % DRN to non-agricultural land in applications to orchards.

3.8.5 Effects on soil organisms

The chronic TER values for earthworms and *H. aculeifer* exposed to spinosad and its relevant metabolites were greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that the risk to earthworms and *H. aculeifer* is acceptable following use of SAP09I according to the proposed use pattern.

For *F. candida* the chronic TER value are lower than 5, therefore further assessment is required. The refined PEC_{SOIL} or additional higher tier data should be provided.

~~Currently, available data are considered as not sufficient and the unacceptable risk assessment for soil organisms is identified.~~

~~In accordance with risk assessment for soil organisms acceptable risk is identified when endpoints from Tier I (NOEC_{corr} *Folsomia* = 0.35 mg/kg) and additional PECs modelling are considered for:~~

- ~~— Use no. 1, 2 (cabbage, broccoli, cauliflower) application rate 2 x 0.1 L/ha (2 x 48 g a.s./ha), interval: 10d, BBCH 10-49, application rate 2 x 0.16 L/ha (2 x 76.8 g a.s./ha), interval: 10d, BBCH 20-49,~~
- ~~— Uses no. 3, 4, 7 (onion, leek, garlic) application rate 1 x 0.15-0.16 L/ha (1 x 72-76.8g a.s./ha), BBCH 40-49~~
- ~~— Uses no. 5, 6 (pear, wild apple, quince) application rate 1 x 0.3 L/ha (1x 144 g a.s./ha) BBCH >70, application rate 2 x 0.225 L/ha (2x 108 g a.s./ha) BBCH >40, BBCH >70, interval: 10d,~~

~~However additional recalculated risk assessment from Tier 2 has been conducted to demonstrate the safe use on other non target soil organisms (*Folsomia candida*) due to the use of SAP09I in all intended uses according the refined endpoint EC_{10corrected} as recommended by *Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology – EFSA Supporting publication 2019* and *CZ Evaluation Manual Ecotoxicology version 3.0 December 2024* resulting in acceptance for uses according to the proposed applications patterns:~~

- ~~— Use no. 1, 2 (cabbage, broccoli, cauliflower) application rate 3 x 0.2 L/ha (3 x 96 g a.s./ha), interval: 7d, BBCH 10-49~~
- ~~— Uses no. 3, 4, 7 (onion, leek, garlic) application rate 1 x 0.15 L/ha (1 x 72 g a.s./ha), BBCH 10-49~~
- ~~— Uses no. 5, 6 (pear, wild apple, quince) application rate 2 x 0.3 L/ha (2 x 144 g a.s./ha), interval: 10d, BBCH 10-59 / BBCH >70~~

During the commenting process, the Applicant introduced modifications to the proposed use pattern of SAP09I (Volkete Max). Additional risk assessment was performed. Based on it, the acceptable risk was demonstrated for following uses:

- Use no. 1, 2 (cabbage, broccoli, cauliflower) application rate:
 - 3 x 0.1 L/ha (3 x 48 g a.s./ha), interval: 10d, BBCH 10-49
 - 2 x 0.16 L/ha (2 x 76.8 g a.s./ha), interval: 10d, BBCH 20-49
- Uses no. 3, 4, 7 (onion, leek, garlic) application rate:
 - 1 x 0.15-0.16 L/ha (1 x 72-76.8g a.s./ha), BBCH 40-49
- Uses no. 5, 6 (pear, wild apple, quince) application rate:
 - 1 x 0.3 L/ha (1x 144 g a.s./ha) BBCH >70
 - 2 x 0.225 L/ha (2 x 108 g a.s./ha) BBCH >70, interval: 10d
 - 2 x 0.225 L/ha (2 x 108 g a.s./ha) BBCH 40-59 (1st appl.) / BBCH >70 (2nd appl.), interval: 10d

The risk assessment for microorganisms was conducted according to SANCO/10329/2002 rev 2 final. An acceptable risk is proven for microorganisms when exposed to the active substance and its metabolites and consequently to the formulated product according to the proposed application patterns.

3.8.6 Effects on non-target terrestrial plants

The risk assessment for non-target terrestrial plants was conducted according to SANCO/10329/2002 rev 2 final. Since spinosad is an insecticide, a Tier 1 risk assessment was conducted, and an acceptable risk is proven when SAP09I is applied at the proposed application rates.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No available data

3.9 Relevance of metabolites (Part B, Section 10)

Not relevant.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Uwagi do etykiety:

Fizykochemia – podwyższono okres ważności środka do 3 lat. Wnioskodawca zaproponował w etykiecie dwuletni okres ważności. Na podstawie badania trwałości w temperaturze otoczenia możliwe jest zaakceptowanie trzech lat ważności.

Toksykologia – przekreślono możliwość stosowania środka przy użyciu opryskiwaczy ręcznych. Zmieniono treść etykiety w zakresie: ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH.

Pozostałości – do etykiety wprowadzono zmiany dotyczące odstępu między zabiegami na kapuście głowiastej i kalafiorze. 7-10 dni zamieniono na 10 dni co jest zgodne z dokumentacją dla środka referencyjnego. Z etykiety usunięto brokuł. Zgodnie z obowiązującym przewodnikiem do ekstrapolacji nie ma możliwości ekstrapolowania wyników z kalafiora na brokuł.

Los i zachowanie w środowisku – brak uwag do etykiety.

Ekotoksykologia – ~~wykreślono wszystkie zastosowania ze względu na nieakceptowalne ryzyko dla makroorganizmów glebowych. Usunięto zwrot P273. Korygowano zarządzanie ryzykiem dla środowiska naturalnego.~~ wprowadzono ograniczenia we wszystkich zastosowaniach ze względu na nieakceptowalne ryzyko dla ssaków lub/i makroorganizmów glebowych. Usunięto zwrot P273. Skorygowano zarządzanie ryzykiem dla środowiska naturalnego.

Skuteczność działania – ~~zmieniono treść etykiety w zakresach: STOSOWANIE ŚRODKA oraz ŚRODKI OSTROŻNOŚCI ORAZ SZCZEGÓLNE WARUNKI STOSOWANIA.~~ wprowadzono zmiany w zakresie upraw chronionych, dawek skutecznych, zalecanej ilości wody, organizmów zwalczanych i ich wrażliwości na stosowane dawki produktu; uzupełniono zalecenia do strategii zarządzania odpornością.

Posiadacz zezwolenia:

Albaugh TKI d.o.o., Grajski trg 21, 2327 Rače, Republika Słowenii, tel.: xxxxxxxxxx
wskazówki dla użytkowników: tel.: xxxxxxxxxxxxxxxx, www.albaugh.eu

Volkete® Max

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

Spinosad: Spinozyn A, Spinozyn D (substancja z grupy makrocyclicznych laktonów) – 480 g/l (44.04%)

Zezwolenie MRiRW nr R- / z dnia . . . r.

	
UWAGA	
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
EUH208	Zawiera. 1,2-benzoizotiazolin-3-on (nr CAS: 2634-33-5). Może powodować

	wystąpienie reakcji alergicznej.
P102	Chronić przed dziećmi.
P270	Nie jeść, nie pić ani nie palić podczas używania produktu.
P273	Unikać uwolnienia do środowiska.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać zgodnie krajowymi przepisami.

OPIS DZIAŁANIA

Volkete® Max jest insektycydem otrzymywanym naturalnie w wyniku fermentacji bakterii *Saccharopolyspora spinosa*. Zawierają substancję czynną spinosad, należącą do rodziny chemicznej spinozyn. Jest to insektycyd o działaniu kontaktowym i żołądkowym, translaminarnym, działający na układ nerwowy owadów, jako aktywator nikotynowego receptora acetylocholino, IRAC MoA grupy 5.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy sadowniczych lub polowych ~~lub opryskiwaczy ręcznych~~.

Kapusta głowiasta biała uprawiana w gruncie

~~Bielinek kapustnik~~, ~~bielinek rzepnik~~, ~~piętnówka kapustnica~~

Maksymalna dawka dla jednorazowego zastosowania: 0,1 ~~0,2~~ 0,16 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,1 – ~~0,2~~ 0,16 l/ha.

~~Wyższą z zalecanych dawek stosować w przypadku dużej liczebności szkodnika lub na starsze stadia rozwojowe gąsienic.~~

Termin stosowania środka: Zabieg wykonać na najmłodsze stadia rozwojowe gąsienic lub po zauważeniu pierwszych uszkodzeń. W razie konieczności zabieg powtórzyć.

Zalecana ilość wody: 2400 - 600 l/ha.

Zalecane opryskiwanie: średniokropliste.

Odstęp między zabiegami: 10 dni.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3 x 0,1 L/ha (BBCH 10-49) ~~lub 2 x 0,16 L/ha (BBCH 20-49).~~

~~Brokuł uprawiany w gruncie~~, ~~kalafior uprawiany w gruncie~~

~~Bielinek rzepnik~~, ~~piętnówka kapustnica~~

Maksymalna dawka dla jednorazowego zastosowania: 0,1 ~~0,2~~ 0,16 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,1 – ~~0,2~~ 0,16 l/ha.

~~Wyższą z zalecanych dawek stosować w przypadku dużej liczebności szkodnika lub na starsze stadia rozwojowe gąsienic.~~

Termin stosowania środka: Zabieg wykonać na najmłodsze stadia rozwojowe gąsienic lub po zauważeniu pierwszych uszkodzeń. W razie konieczności zabieg powtórzyć.

Zalecana ilość wody: 2400 - 600 l/ha.

Zalecane opryskiwanie: średniokropliste.

Odstęp między zabiegami: 10 dni.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3 x 0,1 L/ha (BBCH 10-49) ~~lub 2 x 0,16 L/ha (BBCH 20-49).~~

Cebula

Wciornastek tytoniowiec

Maksymalna dawka dla jednorazowego zastosowania: 0,15 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,15 l/ha.

Wyższą z zalecanych dawek stosować w przypadku dużej liczebności szkodnika lub gdy występuje niska wilgotność powietrza oraz wysoka temperatura.

Termin stosowania środka: zabieg wykonać, gdy pojawią się pierwsze larwy i postacie dorosłe wciornastków, lub po zauważeniu pierwszych uszkodzeń (BBCH 40-49).

Zalecana ilość wody: 2300 - 600 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Środek we wskazanej dawce zwalcza wciornastka tytoniowca w uprawie cebuli na średnio skutecznym poziomie.

Por

Wciornastek tytoniowiec

Maksymalna dawka dla jednorazowego zastosowania: 0,15 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,15 l/ha.

Wyższą z zalecanych dawek stosować w przypadku dużej liczebności szkodnika lub gdy występuje niska wilgotność powietrza oraz wysoka temperatura.

Termin stosowania środka: zabieg wykonać, gdy pojawią się pierwsze larwy i postacie dorosłe wciornastków, lub po zauważeniu pierwszych uszkodzeń (BBCH 40-49).

Zalecana ilość wody: 2300 - 600 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Środek we wskazanej dawce zwalcza wciornastka tytoniowca w uprawie pora na średnio skutecznym poziomie.

Jabłoń

Zwójka siatkoweczka

Maksymalna dawka dla jednorazowego zastosowania: 0,3 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,18 – 0,3 l/ha.

Termin stosowania: BBCH 40-59 (1 zastosowanie) >BBCH 70 (2 zastosowanie)

Liczba zabiegów: 2 x 0,18-0,225 l/ha (BBCH 40-59 / BBCH > 70) lub 1 x 0,3 l/ha (BBCH > 70).

Odstęp między zabiegami: 10–21 dni.

Maksymalna dawka dla jednorazowego zastosowania: 0,3 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,18 – 0,3 l/ha.

Termin stosowania: >BBCH 70

Liczba zabiegów: 2 x 0,18-0,225 l/ha lub 1 x 0,3 l/ha.

Odstęp między zabiegami: 10

Zalecana ilość wody: 300-1500 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2 x 0,18-0,225 l/ha (BBCH 40-59 / BBCH > 70) lub 1 x 0,3 l/ha (BBCH > 70).

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOObszarowych

Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik.

Grusza, jabłoń dzika, pigwa

Zwójka siatkoweczka

Maksymalna dawka dla jednorazowego zastosowania: 0,3 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0.18-0.3 L/ha.

Termin stosowania środka: BBCH 40-59 (1 zastosowanie) >BBCH 70 (2 zastosowanie)

Liczba zabiegów: 2 x 0,18-0,225 l/ha (BBCH 40-59 / BBCH > 70) lub 1 x 0,3 l/ha (BBCH > 70)

Odstęp między zabiegami: 10 -21 dni.

Zalecana ilość wody: 300-1500 l/ha.

Grusza, jabłoń dzika, pigwa

Zwójka siatkoweczka

Maksymalna dawka dla jednorazowego zastosowania: 0,3 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0.18-0.3 L/ha.

Termin stosowania: Środek stosować po kwitnieniu drzew (>BBCH 70).

Liczba zabiegów: 2 x 0,18-0,225 l/ha lub 1 x 0,3 l/ha.

Odstęp między zabiegami: co najmniej 10 dni

Zalecana ilość wody: 300-1500 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Czosnek, czosnek askaloński uprawiane w gruncie

Wciornastki

Maksymalna dawka dla jednorazowego zastosowania: 0,15 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,15

Termin stosowania środka: zabieg wykonać, gdy pojawią się pierwsze larwy i postacie dorosłe wciornastków, lub po zauważeniu pierwszych uszkodzeń; BBCH 10 40-49

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 200-600 l/ha.

Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI ORAZ SZCZEGÓLNE WARUNKI STOSOWANIA

1. Aby opóźnić rozwój oporności zaleca się:

- w każdej uprawie produkt nie może być stosowany w ilości przekraczającej zalecaną maksymalną liczbę zabiegów w sezonie wegetacyjnym;
- naprzemienne traktowanie produktami należącymi do innych grup chemicznych o innym mechanizmie działania;
- unikać stosowania produktu na kolejne pokolenia szkodnika, produkt może być stosowany kilkakrotnie na tę samą generację;
- jeśli nie można dokładnie zidentyfikować następnego pokolenia, nie należy stosować go więcej niż 2-3 razy z rzędu i nie dłużej niż 30 dni (liczba aplikacji zgodnie z instrukcją stosowania środka).

2. Środek działa najskuteczniej w temperaturze od 8° do 25°C.
3. Opryskiwać całe rośliny, zwracając uwagę na dokładne pokrycie cieczą użytkową również dolnej strony liści.
4. Zabieg wykonać co najmniej na 4 godziny przed spodziewanym deszczem i co najmniej 12 godzin przed planowanym deszczowaniem plantacji.
5. Efekt działania środka jest widoczny po kilku dniach od momentu wykonania zabiegu.

OKRESY KARENCJI

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

- grusza, jabłoń, jabłoń dzika, pigwa - 14 dni
- cebula, por, czosnek, czosnek askaloński uprawiane w gruncie - 7 dni
- kapusta głowiasta biała, kalafior, brokuł uprawiane w gruncie - 3 dni.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Przed użyciem wstrząsnąć zawartością opakowania. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika z cieczą użytkową. Następnie zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości. Opryskiwać z włączonym mieszadłem. Po wleciu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne ciecz mechanicznie wymieszać.

Po przerwie w wykonywaniu zabiegu i przed ponownym przystąpieniem do zabiegu ciecz dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Stosować rękawice ochronne przy pracach przy uprawach kapustnych i przy pracach w sadach.

Całą odzież należy wyprać po użyciu produktu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji): **Uprawy polowe:** nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

Sady: Nie wchodzić przed upływem 11 dni od zastosowania produktu.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych.

Niebezpieczne dla pszczoł. W celu ochrony pszczoł i innych owadów zapylających nie stosować na rośliny uprawne w czasie kwitnienia. Nie używać w miejscach, gdzie pszczoły mają pożytek. Nie stosować, kiedy występują kwitnące chwasty. Unikać znoszenia cieczy użytkowej na sąsiadujące tereny.

W przypadku uprawy kapusty głowiastej białej, kalafiora, **brokuła**, cebuli, pora, czosnku i czosnku askalońskiego:

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 10 metrów od zbiorników i cieków wodnych.~~

W celu ochrony organizmów wodnych konieczne jest wyznaczenie nieopryskiwanej strefy ochronnej o szerokości 10 metrów w tym 5m strefy zadarnionej od zbiorników i cieków wodnych.

W celu ochrony stawonogów niebędących przedmiotem zwalczania należy przestrzegać strefy buforowej o długości:

~~- 20 m;~~

~~- 10 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50 %;~~

- 5 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 %

w odniesieniu do przyległych upraw/gruntów nierolnych w przypadku zastosowań w warzywach.

W przypadku uprawy gruszy, **jabłoni**, jabłoni dzikiej, pigwy - **późne fazy**:

W celu ochrony organizmów wodnych należy przestrzegać strefy buforowej o długości:

- 30 m;

- 10 m przy zastosowaniu technik redukujących znoszenie cieczy użytkowej o 90%;

- 20 m przy zastosowaniu technik redukujących znoszenie cieczy użytkowej o 50%

od zbiorników i cieków wodnych:

W przypadku uprawy gruszy, **jabłoni**, jabłoni dzikiej, pigwy- **wczesne fazy**:

W celu ochrony organizmów wodnych należy przestrzegać strefy buforowej o długości:

- 40 m;

- 20 m przy zastosowaniu technik redukujących znoszenie cieczy użytkowej o 95%;
od zbiorników i cieków wodnych

W celu ochrony stawonogów niebędących przedmiotem zwalczania należy przestrzegać strefy buforowej o długości:

~~- 20 m~~ 40 m;

- ~~10-30~~ m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%;

- ~~5~~ 15 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o przy ~~90% 75 %~~

w odniesieniu do przyległych upraw/gruntów nierolnych w przypadku zastosowań w sadach.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

w miejscu suchym i dobrze wietrzonym, z dala od źródeł ciepła i bezpośrednich promieni słonecznych;
w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
w temperaturze 5 °C – 25 °C,

Środek należy utrzymywać z dala od źródeł palnych, czynników utleniających i materiałów silnie kwaśnych lub alkalicznych.

Nie palić.

Po otwarciu pojemnika, należy zamknąć ostrożnie i umieścić pinowo, aby uniknąć wylania.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.
Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę

Okres ważności – 2-3 lat

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not applicable.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Please refer to the reference list.

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

Please refer to the reference list.

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

Please refer to the reference list.