REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: ASA-01

Product name(s): **VIARES**

Chemical active substance:

Acetamiprid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: XXXX

Submission date: March 2024, update 2025-03-24

Evaluation date: May 2025

MS Finalisation date: July 2025

Version history

When	What
2025-03-24	Update on evaluator request
May 2025	Version evaluated by zRMS PL

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

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

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

Comments of zRMS:	Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. The parts of the text amended or added by the zRMS evaluator are highlighted in grey and the parts struck off are visibly marked with the grey front.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

The overall assessment was performed according to the uniform principles. ZRMS considers that the data provided support the following uses: 1, 2, 3 presented in the GAP table. The application of 0,08 l/ha in use no. 1 (protection of oilseed rape against MELIAE) is proposed to be limited to lower pest pressure. What is more, product may control CARPO on apple medium effectively in the first week after application of the product. It is proposed to include this information on the label.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safen-er/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter-val between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter rape (BRSNW)	F	pollen beetle *Brassicogethes aeneus* (MELIAE)	Spraying	Spring BBCH 50-60	a) 1 b) 1	-	a) 0.08-0.1 L/ha b) 0.08-0.1 L/ha	a) 24-30 g a.s./ha b) 24-30 g a.s./ha	200-400 L/ha	-	-	The dose 0,08 l/ha limited for low pest pressure
2	PL	Apple (MABSD)	F	Aphids *Aphidae* (APXXSP)	spraying	Spring BBCH 56-75	a) 1 b) 1	-	a) 0.03-0.05 L/10000 m^2 LWA b) 0.03-0.05 L/10000 m^2 LWA	a) 9-15 g a.s./10000 m^2 LWA b) 9-15 g a.s. /10000 m^2 LWA	500-900 L/ha	14 days	max. 0.075 L/ha max. 22.5 g as/ha	
3	PL	Apple (MABSD)	F	codling moth *Cydia pomonella* (CARPPO)	spraying	Spring BBCH ~~57~~ 72-75	a) ~~1~~ 2 b) 2	~~7~~ 8-10 days	a) ~~0.07-0.09 L/10000 m^2 LWA~~ 0.14-0.18 L/ 10000 m^2 LWA b) 0.14-0.18 L/ 10000 m^2 LWA	a) ~~21-27 g a.s./10000 m^2 LWA~~ 42-54 g a.s. /10000 m^2 LWA b) 42-54 g a.s. /10000 m^2 LWA	500-750 L/ha	14 days	max. 2 x 0.09 L/ha max. 2 x 27 g as/ha	
Minor uses art. 51														
4	PL	Wild apple (MABSY) Pear (PYUCO) Chinese Pear (PYULI) Quince (CYDOB) Medlar (MSPGE)	F	Aphids *Aphidae* (APXXSP)	spraying	Spring BBCH 56-75	a) 1 b) 1	-	a) 0.03-0.05 L/10000 m^2 LWA b) 0.03-0.05 L/10000 m^2 LWA	a) 9-15 g a.s./10000 m^2 LWA b) 9-15 g a.s. /10000 m^2 LWA	500-900 L/ha	14 days	max. 0.075 L/ha max. 22.5 g as/ha	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safen-er/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter-val between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
5	PL	Wild apple (MABSY) Pear (PYUCO) Chinese Pear (PYULI) Quince (CYDOB) Medlar (MSPGE)	F	codling moth *Cydia pomonella* (CARPPO)	spraying	Spring BBCH 57-75	a) 1 b) 2	7-10 days	a) 0.07-0.09 L/10000 m^2 LWA b) 0.14-0.18 L/ 10000 m^2 LWA	a) 21-27 g a.s./10000 m^2 LWA b) 42-54 g a.s. /10000 m^2 LWA	500-750 L/ha	14 days	max. 0.09 L/ha max. 27 g as/ha	

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

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

Column 15: zRMS conclusion.

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

3.2 Efficacy data (KCP 6)

Introduction

This is the application for registration plant protection product ASA-01 according to Article 33 of Regulation 1107/2009. ASA-01 is a soluble concentrate (SC) containing 300 g/L of acetamiprid to be used as an insecticide to protect winter oilseed rape and apple. This is a core dossier in order to allow the approval of product ASA-01 in Poland (RMS).

Description of active substance

Acetamiprid was first introduced in 1995 for the control of aphids in pome fruit orchards and pollen beetles in oilseed rape, among other uses. Acetamiprid is neonicotinoid insecticide composed from a synthetic organic compound. Neonicotinoid insecticides were discovered in the 1980's and are used throughout the world. Acetamiprid is generally used to protect plants against sucking insects such as aphids, but it has also become common in household pest control to combat bed bugs. It is a broad-spectrum pesticide that can be used on plants ranging from leafy vegetables and fruit trees to ornamental plants. Today, acetamiprid is registered and commercialised in several formulations around the world.

Mode of action

Acetamiprid is an insecticide belonging to the neonicotinoid group and it is a systemic active substance with translaminar activity and with contact and stomach action belonging to the group of neonicotinoids. It is used to control *Hemiptera, Lepidoptera, Thysanoptera* and *Coleoptera*. It is an agonist of the nicotinic acetylcholine receptor, affecting the synapses in the insect central nervous system.

Active substance	**acetamiprid**
Concentration	300 g/L
Chemical group	neonicotinoids
Mode of action	Nicotinic acetylcholine receptor (nAChR) competitive modulators
Biological action	Post-emergence insecticide

Description of the plant protection product

ASA-01 is a suspension concentrate (SC) containing 300 g/L of acetamiprid. The plant protection product is intended to be registered in apple and winter oilseed rape.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

Uses		**Member State**	**Requested rate(s)**	**Comments / Other relevant details on GAPs**
Crop(s)	**Target(s)**			
Winter oilseed rape	pollen beetle	PL	0.08-0.1 L/ha	-
Apple	aphids	PL	0.03-0.05 L/10000 m^2 LWA (max. 0.075 L/ha)	-

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Apple	codling moth	PL	0.07-0.09 L/10000 m^2 LWA (max. 0.09 L/ha)	-

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

Description of the target pests

Table 3.2-2: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
CARPPO	*Cydia pomonella*	codling moth
APHIPO	*Aphis pomi*	green apple aphid
MELIAE	*Brassicogethes aeneus*	pollen beetle

Agricultural crop production has been the main branch of plant production in Poland for years. Taking into consideration season 2022, following numbers were presented by Statistics Poland.
In 2022, total sown area amounted to 10 977 000 ha. The sown area of industrial crops amounted to 1 390 thousand ha, of which 1 158 thousand ha were oilseeds. Yield of rape and turnip rape in 2022 was 33.8 dt/ha.
Cultivated area of fruit trees in 2022 was 215.5 thousand ha, of which 151.9 thousand ha was area of apple tree orchards. Fruit production in orchards was 4 763 400 tons, of which apples production was 4 264 700 tons.

According to Statistics Poland sales of plant protection products in the farming year 2022 (in commodity mass) was 71608 tonnes, out of which insecticides were sold in the amount of 3633 tons.

Table 3.2-3: Major / minor status of intended uses (for all cMS and zRMS).

The crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Apple	PL	-	green apple aphid	PL	-
			codling moth	PL	-
Winter oilseed rape	PL	-	pollen beetle	PL	-

Compliance with the Uniform Principles

The overall assessment was performed according to the uniform principles. All trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organizations.

Information on trials submitted (3.1 Efficacy data)

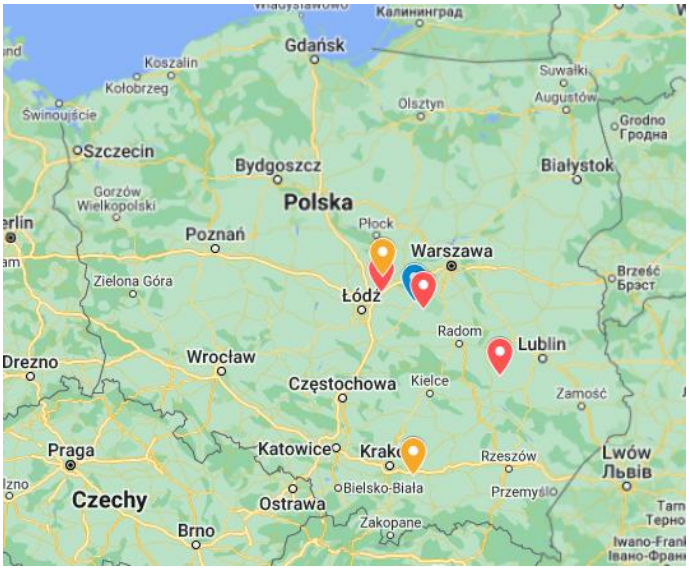
Table 3.2-4: Presentation of trials (efficacy trials, preliminary trials...)

Crops *	Targets*	Country	Years	Type of trial**	Number of trials (number of valid trials)	GEP, non-GEP, official***	Comments (any other relevant information)
					North-East zone		
Apple	Codling moth	Poland	2019	MED+E	1	GEP	
			2020	MED+E	3	GEP	
			2021	MED+E	3	GEP	
	TOTAL	-	-	-	7	-	
Apple	Green apple aphid	Poland	2019	MED+E	3	GEP	
			2020	MED+E	2	GEP	
			2021	MED+E	1	GEP	
			2023	MED+E	2		
	TOTAL	-	-	-	8	-	
Winter oilseed rape	Pollen beetle	Poland	2020	MED+E	4	GEP	
			2021	MED+E	2	GEP	
			2023	MED+E	2	GEP	
	TOTAL	-	-	-	8	-	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-emergence vs post-emergence, spring vs autumn).
** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.
*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Efficacy trials of ASA-01 were carried out in years 2019-2023 in different regions of Poland. Three following maps present locations of the trials, separately for apple: aphids and codling moth and winter oilseed rape- pollen beetle. Trials conducted in 2019 season are marked with blue tag, trials conducted in 2020 season are marked with red tag, trials conducted in 2021 are marked with orange tag, trials conducted in 2023 are marked with yellow tag.

Picture 1. A map with efficacy trial locations of ASA-01 against codling moth in apple



In 2019 one efficacy trial of ASA-01 against codling moth in apple was conducted in:

1) Wólka Babska (łódzkie) on variety: Szampion Reno 2, sandy loam pH 6.5

In 2020 three trials were conducted in:

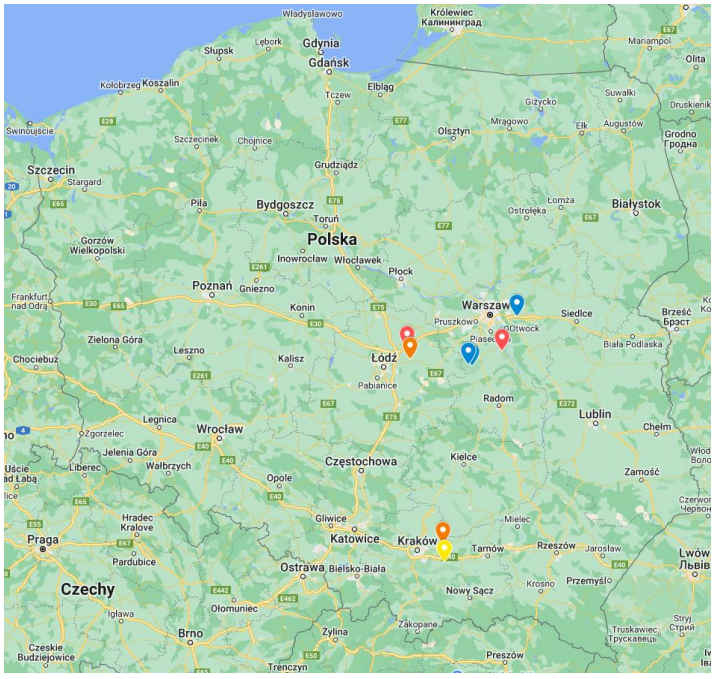
2) Nowe Szwejki (łódzkie) on variety: Idared, clay., pH 6.0
3) Józefów nad Wisłą (lubelskie) on variety Lobo, sandy clay pH 6.4
4) Kałęczew (łódzkie) on variety: Gloster, sandy loam, pH 6.2

In 2021, 3 efficacy trials were conducted in:

5) Kałeczew (łódzkie) on variety: Najdared, sandy loam pH 6.2
6) Kałeczew (łódzkie) on variety: Szampion, sandy loam pH 5.9
7) Gierczyce (małopolskie) on variety Szampion, silty clay pH 6.5

All trials were conducted in randomized complete block design in four replicates at crop stage BBCH 71-78 in line with EPPO PP 1/7(3).

Picture 2. A map with efficacy trial locations of ASA-01 against aphids in apple



In 2019 three efficacy trials of ASA-01 against aphids in apple were conducted in three different locations:

1) Aleksandrówka (mazowieckie) on variety: Idared, sandy loam
2) Wola Łęczeszycka (mazowieckie) on variety: Red Jonaprince, sandy loam
3) Błędów (mazowieckie) on variety: Ligol, sandy loam pH 6.4

In 2020 two efficacy trials were conducted in two different locations:

4) Kałęczew (łódzkie) on variety: Gala Schniga Schnico
5) Rososzka (mazowieckie) on two variety: Gloster, sandy loam pH 6.2

In 2021 one efficacy trial was conducted in:

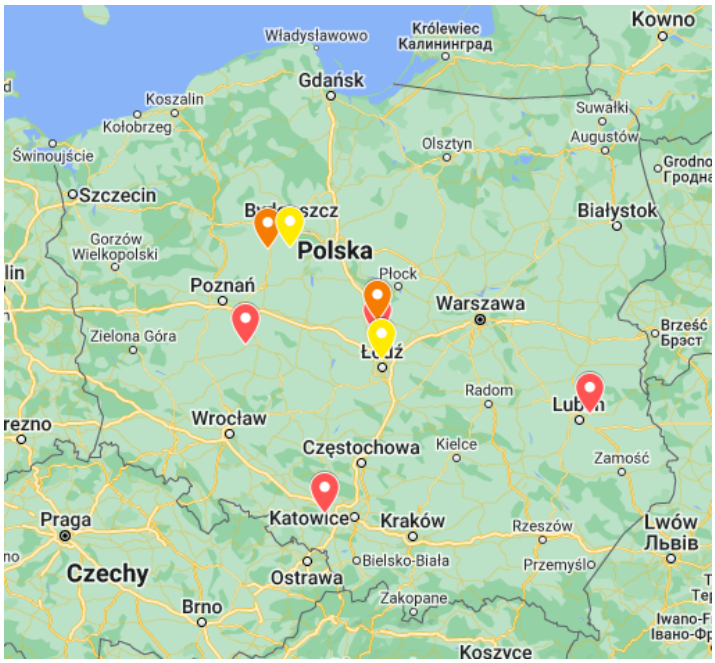
6) Gierczyce (małopolskie) on variety Elshof, sandy loam pH 6.5

In 2023 two efficacy trials were conducted in two locations:

7) Olsza (łódzkie) on variety: Ligol, pH 5.7
8) Gierczyce (małopolskie) on variety Idared, pH 6.5

All trials were conducted in randomized complete block design in four replicates at crop stage BBCH 55-76 in line with EPPO PP 1/258(2).

Picture 3. A map with efficacy trial locations of ASA-01 against pollen beetle in winter oilseed rape



In 2020 four efficacy trials in winter oilseed rape were carried out in four different locations:

1) Łany Wielkie (śląskie), on variety LG Architect, loam pH 6.2
2) Jaraczewo (wielkopolskie) on variety Monolit, sandy clay pH 7.1
3) Moraków (łódzkie) on variety Sergio, sandy loam pH 6.4
4) Łuszczów Drugi (lubelskie) on variety KWS Roberto, sandy loam pH 7.1

In 2021 2 efficacy trials were conducted in winter oilseed rape in:

5) Moraków (łódzkie) on variety Monolit, sandy loam pH 6.8
6) Brzyskorzystew (kujawsko-pomorskie) on variety Absolut, loamy sand pH6.3

In 2023, two efficacy trials were performed in two different locations:

7) Moraków (łódzkie) on variety: Condor F1, loamy sand pH 6.9
8) Gulczewo (kujawsko-pomorskie) on variety Chrobry.

All trials were conducted in randomized complete block design in four replicates at crop stage BBCH 52-60 in line with EPPO PP 1/178 (3).

Table 3.2-5: Presentation of reference standards used in trials (efficacy trials, preliminary trials)

Crop(s)/target	Reference standard	Country where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type(2)	Concentration of a.s.			
Apple, codling moth	Mospilan 20 SP	PL	R - 37/2008 R-228/2022d	Acetamiprid	SP	200	0.2 kg/ha (40 g a.s./ha)	0.2 kg/ha (40 g a.s./ha)	2 applications, 7-14 d interval
Apple, green apple aphid							0.125 kg/ha (25 g a.s./ha)	0.125 kg/ha (25 g a.s./ha)	1 application
Winter oilseed rape, pollen beetle							0.08-0.12 kg/ha (16-24 g a.s./ha)	0.12 kg/ha (24 g a.s./ha)	1 application

(1) only on use(s) applied for (with the test product).
(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country.
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

3.2.1 Preliminary tests (KCP 6.1)

No results of the preliminary range-finding tests are presented since no screening trials were carried out. However, the active substance of ASA-01- acetamiprid, has been commonly used in agricultural practice for many years.

Comments of zRMS:	Preliminary tests are not reported. The active substance acetamiprid has well been known and used in many authorised products with a known range of action.

3.2.2 Minimum effective dose tests (KCP 6.2)

Minimum effective dose tests were not carried out. However, several doses of ASA-01 were tested during efficacy studies and the lowest effective dose was selected. The tests were concluded in line with EPPO standard PP 1/225 (2) '*Minimum effective dose',* which advises on the minimum requirements necessary to ensure consistency of decision making.

Apple and codling moth

7 efficacy trials were conducted in years 2019-2021 in Poland to present the control of codling moth in apple. ASA-01 was tested at rates: 0.03 L/10000m^2 LWA (6 trials), 0.05 L/10000m^2 LWA (7 trials), 0.07 L/10000m^2 LWA (7 trials) and 0.09 L/10000m^2 LWA (7 trials) in order to determine the minimum effective dose in apple for the control of codling moth. The rates reflect the proposed label rates and 43% and 71% of the lowest recommended rate of ASA-01.

A summary of the dose response results is provided in Table 3.2-6.

Table 3.2-6: Minimum effective dose. Efficacy of ASA-01 at proposed label rates and at 43 %, 71% of the lowest recommended rate at BBCH 74-76 (22-37 DA-T) against codling moth in apple

Target	Number of trials	Infestation of the untreated control (% of damaged, fallen fruits)		% control with ASA-01							
				0.03L /10000m² LWA* (43% of the lowest recommended rate)		0.05 L/10000m² LWA (71% of the lowest recommended rate)		0.07 L/10000m2 LWA (the lowest recommended rate)		0.09 L/10000m2 LWA (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
	6	27.4	4.3-72.9	77.5	0-100	**88.5**	66.0-100	**100**	100	**100**	100
Codling moth	7	26.9	4.3-72.9	-	-	**88.1**	66.0-100	**98.9**	92.5-100	**100**	100

*6 trials with dose rate 0.03 L/10000m2 LWA were conducted

For the assessment conducted at 22-37 DA-T (BBCH 74-76), the recommended doses 0.07 L/10000m² LWA and 0.09 L/10000m² LWA of ASA-01 provided a superior control codling moth to dose 0.05 L/10000m² LWA of tested product in 2 out of 7 conducted trials and provided a superior control codling moth to dose 0.03 L/10000m² LWA in 3 out of 6 trials. In remaining trials, doses 0.07 L/10000m² LWA and 0.09 L/10000m² LWA of ASA-01 provided similar control to doses 0.03 and 0.05 L/10000m² LWA.

Apple and green apple aphid

8 efficacy trials were conducted in years 2019-2023 in Poland to present the control of green apple aphids in apple. ASA-01 was tested at rates: 0.01 L/10000m² (3 trials), 0.02 L/10000m² LWA (5 trials), 0.03 L/10000m² LWA (8 trials), 0.05 L/10000m² LWA (8 trials) and 0.06 L/10000m² LWA (3 trials) in order to determine the minimum effective dose in apple for the control of aphids. The rates reflect the proposed label rates and 33.3 %, 66.7% and 150% of the lowest recommended rate of ASA-01.

A summary of the dose response results is provided in Table 3.2-7.

Table 3.2-7: Minimum effective dose. Efficacy of ASA-01 at proposed label rates and at 33.3%, 66.7% and 150% of the lowest recommended rate at BBCH 65-76 (7-8 DA-T) against green apple aphid in apple

Target	Number of trials	Infestation of the untreated control (pest no/shoot)		% control with ASA-01									
				0.01 L/ 10000m² LWA*		0.02 L/ 10000m² LWA**		0.03 L/ 10000m² LWA		0.05 L/ 10000m2 LWA		0.06 L/ 10000m2 LWA*	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Green apple aphid	3	19.0	6.0-33.7	73.6	34.0-95.4	**83.0**	56.5-97.5	**95.7**	88.5-100	**99.7**	99.4-100	-	-
	5	31.7	6.0-74.9	-	-	**85.2**	56.5-99.6	**94.4**	84.8-100	**97.9**	90.2-100	-	-
	5	50.5	22.4-80.7	-	-	-	-	**94.8**	84.8-100	**97.0**	90.2-100	**97.7**	93.6-100
	8	38.8	6.0-80.7	-	-	-	-	**95.1**	84.8-100	**98.0**	90.2-100	-	-

*3 trials with dose rate 0.01 L/10000m^2 LWA were conducted
**5 trials with dose rate 0.02 and 0.06 L/10000m^2 LWA were conducted

For the assessment conducted at 7-8 DA-T (BBCH 65-76), the recommended doses 0.03 L/10000m^2 LWA and 0.05 L/10000m^2 LWA of ASA-01 provided a superior control green apple aphid to dose 0.01 L/10000m^2 LWA of tested product in 3 out of 3 conducted trials. Dose 0.02 L/10000m^2 LWA of ASA-01 provided an inferior control to the recommended doses 0.03 L/10000m^2 LWA and 0.05 L/10000m^2 LWA in 4 out of 5 conducted trials. In one out of 5 trials, dose 0.02 L/10000m^2 LWA provided similar control green apple aphids to recommended doses: 0.03 L/10000m^2 LWA and 0.05 L/10000m^2 LWA of ASA-01. Dose 0.06 L/10000m^2 LWA of ASA-01 provided similar control green apple aphids to dose 0.05 L/10000m^2 LWA in 5 out of 5 trials. Dose 0.06 L/10000m^2 LWA of ASA-01 provided similar control green apple aphids to dose 0.03 L/10000m^2 LWA in 2 out of 5 trials and provided superior control aphids in 3 out of 5 trials.

Winter oilseed rape and pollen beetle

8 efficacy trials were established in order to present the control of pollen beetle in winter oilseed rape. Trials were conducted in 2020-2023 in Poland. ASA-01 was tested at 0.03 to 0.12 L/ha (18 – 36 g of acetamiprid per hectare) in order to determine the minimum effective dose in winter oilseed rape for control of pollen beetle. The rates reflect the proposed label rates, 37.5 % (0.03 L/ha, 6 trials) and 75% of the lowest recommended rate (0.06 L/ha) of ASA-01 and 0.12 L/ha (150 % of the lowest recommended rate), in accordance with the EPPO standard PP 1/225 (2) '*Minimum effective dose'*.

A summary of the dose response results is provided in Table 3.2-8.

Table 3.2-8: Minimum effective dose. Efficacy of ASA-01 at proposed label rates, 37.5 % and at 75% and 150 % of the lowest recommended rate at BBCH 57-64 (7-9 DA-T) against pollen beetle in winter oilseed rape

Target	Number of trials	**Infestation of the untreated control before treatment (no of pest/plant)**		**% control with ASA-01**									
				0.03 L/ha* (37.5% of the lowest recommended rate)		**0.06 L/ha (75% of the lowest recommended rate)**		**0.08 L/ha (the lowest recommended rate)**		**0.1 L/ha (Full rate)**		**0.12 L/ha (150% of the lowest recommended rate)**	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Pollen beetle	6	3.6	1.1-6.8	54.3	25.8-72.1	69.3	40.1-83.3	**81.9**	71.0-91.7	**90.1**	81.3-94.4	**92.9**	84.2-96.5
	8	4.1	1.0-9.7	-	-	65.3	39.2-83.3	**80.2**	64.7-91.7	**88.2**	79.6-94.4	**92.7**	84.2-96.5

*6 efficacy trials with this dose rate were conducted

For the assessment conducted at 7-9 DA-T (BBCH 57-64), the higher recommended dose 0.1 L/ha of ASA-01 provided a superior control to dose 0.03 L/ha in 6 out of 6 trials and superior control to dose 0.06 L/ha in 7 out of 8 trials. In one trial, efficacy after application of dose rate 0.1 L/ha was similar to efficacy after 0.06 L/ha application. The lower recommended rate- 0.08 L/ha provides a superior control to dose 0.03 L/ha in 5 out of 6 trials and provided a superior control to dose 0.06 L/ha in 5 out of 8 trials. In the rest of trials, efficacies were similar.

Summary and conclusions on the minimum effective dose

According to the presented results, the doses 0.03 L/10000m2 LWA and 0.05 L/10000m2 LWA of ASA-01 applied once provided the optimum overall control and should be considered as effective against green apple aphids in apple. The higher, recommended dose is to be used in conditions of increased risk of infestation.

The dose rates 0.07 L/10000m2 LWA and 0.09 L/10000m2 LWA of ASA-01applied twice provided the optimum overall control and should be considered as effective against codling moth in apple. The higher, recommended dose is to be used in conditions of increased risk of infestation.
The dose rates 0.08 L/ha and 0.1 L/ha of ASA-01 applied once provided the optimum overall control and should be considered as effective against pollen beetle in winter oilseed rape. The higher, recommended dose is to be used in conditions of increased risk of infestation.

dRR point 3.2.2

Minimum effective dose tests

The claimed dose rates are:

- 0,03-0,05 L/10000 m^2 LWA in protection of apple against APHIPO
- 0,07-0,09 L/10000 m^2 LWA in protection of apple against CARPRO
- 0,08-0,1 L/ha in protection of winter oilseed rape against MELIAE

The doses justification of ASA-01 are supported by data from 23 efficacy trials on: apple against APHIPO (8 trials), on apple against CARPRO (7 trials), on winter oilseed rape against MELIAE (8 trials) for which efficacy of ASA-01 is claimed. Efficacy of the claimed doses was compared with the reduced doses:

- 0,01; 0,02; 0,03; 0,05; 0,06 L/10000 m^2 LWA in protection of apple against APHIPO
- 0,03; 0,05; 0,07; 0,09 L/10000 m^2 LWA in protection of apple against CARPRO
- 0,03; 0,06; 0,08; 0,1; 0,12 L/ha in protection of winter oilseed rape against MELIAE

Trials were conducted in PL, between 2019 and 2023.

Efficacy [%] against APHIPO on apple

Type of ASS	***0,01 L/10000 m^2 LWA**	****0,02 L/10000 m^2 LWA**	**0,03 L/10000 m^2 LWA**	**0,05 L/10000 m^2 LWA**	****0,06 L/10000 m^2 LWA**
1-4 DAA (8 trials)	41,9 (14,0-61,4)	53,7 (30,7-69,7)	75,4 (58,6-97,8)	84,2 (61,6-98,7)	86,2 (64,1-100)
7-8 DAA (4 trials)	73,6 (34-95,4)	85,2 (56,5-99,6)	95,1 (84,8-100)	98,0 (90,2-100)	97,7 (93,6-100)

*3 trials
**5 trials

ASA-01 at the dose rate of 0,03-0,05 L/10000 m2 LWA performed more consistent and gave higher level of efficacy in comparison to reduced dose rates. 0,06 L/10000 m^2 LWA performed comparable to the lower dose 0,05 L/10000 m^2. The dose rate 0,03 L/10000 m^2 LWA can be considered the minimum effective dose rate. The dose rate 0,05 L/10000 m^2 may be considered the minimum dose in case of higher density of the pest.

Efficacy [%] against CARPO on apple

Type of ASS	**0,03 L/10000 m^2 LWA**	**0,05 L/10000 m^2 LWA**	**0,07 L/10000 m^2 LWA**	**0,09L/10000 m^2 LWA**
8-10 DAA (2 trials)	31,5 (30,0-33,0)	60,0 (57,0-63,0)	69,5 (65,0-74,0)	78,0 (70,0-86,0)
14-18 DAA (4 trials)	39,3* (0,0-100)	69,4 (46,0-100)	85,0 (71,0-100)	82,1 (65,0-100)
22-26 DAA (5 trials)	**77,0 (0,0-100)	90,4 (66,0-100)	98,5 (92,5-100)	100
30-37 DAA (7 trials)	***74,4 (33,2-100)	83,4 (64,6-100)	94,9 (81,8-100)	97,3 (90,0-100)
76-115 DAA at harvest (7 trials)	***73,7 (48,9-100)	81,1 (62,5-100)	90,6 (68,9-100)	92,9 (76,3-100)

*3 trials
**4 trials

***6 trials

ASA-01 at the dose rate of 0,07-0,09 L/10000 m^2 LWA performed more consistent and gave higher level of efficacy in comparison to reduced dose rates. The dose rate 0,07 L/10000 m^2 LWA can be considered the minimum effective dose rate. The dose rate 0,09 L/10000 m^2 may be considered the minimal dose in case of higher density of the pest, because it gave a little bit more consistent results in comparison to the lower dose.

Efficacy [%] against MELIAE in winter oilseed rape

Type of ASS	*0,03 L/ha	0,06 L/ha	0,08 L/ha	0,1 L/ha	0,12 L/ha
1-2 DAA (8 trials)	41,9 (2,8-66,5)	55,7 (17,1-91,8)	68,2 (15,8-92,6)	75,7 (32,5-95,9)	82,1 (62,0-99,8)
4-6 DAA (8 trials)	55,1 (32,5-71,4)	65,9 (46,6-83,6)	76,8 (52,2-97,2)	84,7 (64,0-98,5)	87,5 (74,6-99,7)
7-9 DAA (8 trials)	54,3 (25,8-72,1)	65,3 (39,2-83,3)	80,2 (64,7-91,7)	88,2 79,6-93,7)	92,7 (84,2-96,5)

*6 trials

The dose rate of 0,1L/ha should be considered the minimum effective dose rate. Lower dose 0,08L/ha performed medium effectively, giving less consistent results (68,2%-76,8%) 1-6 DAA and achieved 80,2% 7-9 DAA. It may be considered sufficient in case of lower density of the pest.

3.2.3 Efficacy tests (KCP 6.2)

Table 3.2-9: Details on trial methodology- codling moth

Guidelines	General guidelines	EPPO PP 1/135(4), EPPO PP 1/152(4), EPPO PP 1/181(5), EPPO PP 1/225(2)
	Specific guidelines	EPPO PP 1/7 (3)
Experimental design	Plot design	RCBD
	Plot size	21-50 m²
	Number of replications	4
Crop	Trials per crop	Apple (7)
	Varieties per crop	Szampion Reno 2, Idared, Lobo, Gloster, Najdared, Szampion (2)
	Sowing period	NR
Application	Crop stage (BBCH)* at application	BBCH 71-74
	Pest stage at application	Mixed growth stages of codling moth
	Number of applications Intervals between applications	2/~~7~~8-10
	Spray volumes	500-750 L/ha
Assessment	Assessment types	- assessments at regular intervals the dropped fruits and determination of the percentage of fruits attacked by *C. pomonella* - assessment of % fruits attacked by the pest on at least 300 fruits per plot at harvest
	Efficacy calculation	Efficacy calculation according to Henderson-Tilton: Efficacy (%) = [1- (control before treatment * treatment after treatment/ control after treatment * treatment before treatment)]*100

		Efficacy calculation according to Abbott: = [1- (incidence treatment/ incidence control)]*100
	Assessment dates	3 DAT (1), 8-10 DAT (2), 14-18 DAT (4), 21-26 DAT (5), 28-34 DAT (6), 35-39 DAT (2), 42-45 DAT (1), 52-53 DAT (3), 62 DAT (2), 70-76 DAT (3), 88 DAT (3), 111 DAT (2), 76-88 DAT (2, at harvest), 109-120 DAT (5, at harvest)
	Field / Greenhouse	Field
	GEP	All trials were performed according to GEP

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-10: Details on trial methodology- aphid, apple

Guidelines	General guidelines	EPPO PP 1/135(4), EPPO PP 1/152(4), EPPO PP 1/181(5), EPPO PP 1/225(2)
	Specific guidelines	EPPO PP 1/258(2)
Experimental design	Plot design	RCBD
	Plot size	17.5-25.9 m²
	Number of replications	4
Crop	Trials per crop	Apple (8)
	Varieties per crop	Idared (2), Red Jonaprince, Ligol (2), Gala Schniga Schnico, Gloster, Elshof
	Sowing period	NR
Application	Crop stage (BBCH)* at application	BBCH 55-76
	Pest stage at application	Mixed growth stage of aphids
	Number of applications/ Intervals between applications	1/-
	Spray volumes	500-900 L/ha
Assessment	Assessment types	number of aphids per shoot based on 10 or 25 shoots per plot
	Efficacy calculation	Efficacy calculation according to Henderson-Tilton: Efficacy (%) = [1- (control before treatment * treatment after treatment/ control after treatment * treatment before treatment)]*100 Efficacy calculation according to Abbott: = [1- (incidence treatment/ incidence control)]*100
	Assessment dates	1-4 DAA (8), 7-8 DAA (8), 14 DAA (3), 21 DAA (2), 28 DAA (2)
	Field / Greenhouse	Field
	GEP	All trials were performed according to GEP

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-11: Details on trial methodology- pollen beetle, winter oilseed rape

Guidelines	General guidelines	EPPO PP 1/135(4), EPPO PP 1/152(4), EPPO PP 1/181(5), EPPO PP 1/225(2)
	Specific guidelines	EPPO PP 1/178(3)

Experimental design	Plot design	RCBD
	Plot size	25-49 m²
	Number of replications	4
Crop	Trials per crop	Winter oilseed rape (8)
	Varieties per crop	LG Architect, Sergio, KWS Roberto, Monolit (2), Absolut, Condor F1, Chrobry
	Sowing period	31.08.2019, 26.08.2019, 04.09.2019 (2), 25.08.2020, 28.08.2020, 23.08.2022, 02.08.2022
Application	Crop stage (BBCH)* at application	52-60
	Pest stage at application	Mixed
	Number of applications Intervals between applications	1/-
	Spray volumes	200 - 400 L/ha
Assessment	Assessment types	Visual assessment of number of pest at least 50 main shoots selected at random from the centre of each plot
	Efficacy calculation	Efficacy calculation according to Henderson-Tilton: Efficacy (%) = [1- (control before treatment * treatment after treatment/ control after treatment * treatment before treatment)]*100 Efficacy calculation according to Abbott: Efficacy (%) = [1- (incidence treatment/ incidence control)]*100
	Assessment dates	1-2 DAT(8), 4-6 DAT (8), 7-9DAT (6), 10-12 DAT (4), 14-15 DAT (4), 16-17 DAT (2)
	Field / Greenhouse	Field
	GEP	All trials were performed according to GEP

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Apple and codling moth

A total of 7 trials were carried out to evaluate the efficacy of ASA-01 for the control of codling moth in apple. All trials have been conducted between 2019-2021 in Poland.

Table 3.2-12: Efficacy of ASA-01 at BBCH 74- 76 at assessment timing 22-37 DA-B

Crop	Target	Number of trials	Infestation in the un-treated control (% of damaged, fallen fruits)		% control						No of trials where ASA-01 is >, <, = compared to stand-ard(s)
					ASA-01 at 0.07 L/10000m2 LWA		ASA-01 at 0.09 L/10000m2 LWA		Standard Mospi-lan 20 SP at 0.2 kg/ha		
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
Apple	Codling moth	7	26.9	4.3-72.9	**98.9**	92.5-100	**100**	100	**98.6**	90.5-100	7= (for both dose rates of product)

Data demonstrated that the efficacy of the product at the proposed rates of 0.07 L/10000 m2 LWA and 0.09 L/10000 m2 LWA 22-37 after last treatment were 98.9% and 100%, respectively. The efficacy of both dose rates was similar to the efficacy of standard-Mospilan 20 SP at rate 0.2 kg/ha against codling moth.

Table 3.2-13: Efficacy of ASA-01 at assessment timing 76-120 DA-B, after harvest

Crop	Target	Number of trials	Infestation in the un-treated control (% of damaged, fallen fruits)		% control						No of trials where ASA-01 is >, <, = compared to stand-ard(s)
					ASA-01 at 0.07 L/10000m2 LWA		ASA-01 at 0.09 L/10000m2 LWA		Standard Mospi-lan 20 SP at 0.2 kg/ha		
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
Apple	Codling moth	7	16.3	3.0-79.0	**90.6**	68.9-100	**93.0**	76.3-100	**89.4**	56.5-100	For 0.07 L/10000m2 LWA: 7= For 0.09 L/10000m2 LWA: 6=; 1>

Assessment of efficacy conducted on 300 harvested fruits showed that ASA-01 at both recommended doses and reference product provided high control codling moth in apple.

Apple / green apple aphid

A total of 8 trials were carried out to evaluate the efficacy of ASA-01 for the control of green apple aphids in apple. All trials have been conducted between 2019-2023 in Poland.

Table 3.2-14: Efficacy of ASA-01 at BBCH 65-76 at assessment timing 7-8 DA-A

Crop	Target	Number of trials	Infestation in the untreated control (pest no/shoot)		% control						No of trials where ASA-01 is >, <, = compared to stand-ard(s)
					ASA-01 at 0.03 L/10000m2 LWA		ASA-01 at 0.05 L/10000m2 LWA		Standard Mospilan 20 SP at 0.125 kg/ha		
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
Apple	Green apple aphid	7	38.8	6.0-80.7	**95.1**	84.8-100	**98.0**	90.0-100	**97.6**	90.5-100	Dose 0.03 L/10000m2 LWA: 5=, 2< Dose 0.05 L/10000m2 LWA: 7=

Data demonstrated that average efficacy of the product at the proposed rate of 0.03 L/10000 m^2 LWA was 95.1 % and average efficacy of the product at the proposed rate of 0.05 L/10000 m^2 LWA was 98.0%. Both dose rates provided similar control of green apple aphids to reference product Mospilan 20 SP at rate 0.2 kg/ha.

Winter oilseed rape / pollen beetle

8 efficacy trials were conducted in years 2020-2023 in Poland to present the control of pollen beetle in winter oilseed rape.

Table 3.2-15: Efficacy of ASA-01 at BBCH 74- 76 at assessment timing 7-9 DA-A

Target	Number of trials	Infestation of the untreated control before treatment (no of pests/plant)		% control with ASA-01						No of trials where ASA-01 is >, <, = compared to standard(s)
				0.08 L/ha (the lowest recommended rate)		0.1 L/ha (Full rate)		Mospilan 20 SP 0.2 kg/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min&Max	
Pollen beetle	8	4.1	1.0-9.7	**80.2**	64.7-91.7	**88.2**	79.6-94.4	**86.3**	79.2-90.6	For 0.08 L/ha: 5=, 2<; 1> For 0.1 L/ha 6=; 2>

Average efficacy of ASA-01 against *Brassicogethes aeneus* in winter oilseed rape for dose rate 0.08 L/ha was 80.2% (in range 64.7-91.7%), for dose rate 0.1 L/ha was 88.2 % (in range 79.6-94.4%) and was similar to efficacy of standard reference product Mospilan 20 SP.

dRR point 3.2.3

EN: Evaluator conclusion:
The applicant submitted 23 trials (apple 15 trials, oilseed rape 8 trials) carried out in different region of PL between 2019 and 2023:

- on apple against:

Aphis pomi (APHIPO) - 7 trials, applic. at BBCH 55-74
Cydia pomonella (CARPO) - 8 trials, applic. at BBCH 72-73

- on winter oilseed rape (BBCH 69) against:

Meligethes aeneus (MELAE) - 8 trials, at BBCH 55-60

Efficacy trials were carried out by organizations that are officially recognized as competent to carry out efficacy testing in accordance with Regulation (EC) 284/2013. All trials have been conducted according to GEP.
The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:
1. PP 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice.
3. PP 1/135 (4) Phytotoxicity assessment
4. PP 1/152 (4) Design and analysis of efficacy evaluation trials
5. PP 1/178 (3) *Meligethes aeneus* on rape
6. PP 1/7 (3) Cydia pomonella
7. PP 1/258 (2) Aphids on top fruit

Trials were conducted in Poland Trials were of randomized block design with a minimum of four replicates.
The tested insecticide ASA-01 was applied at the rates:
• 0,01; 0,02; 0,03; 0,05; 0,06 L/10000 m^2 LWA in protection of apple against APHIPO (one application, spray volume 500 – 900 l/ha)
• 0,03; 0,05; 0,07; 0,09 L/10000 m^2 LWA in protection of apple against CARPRO (two applications, spray volume 500 – 750 l/ha, interval between applications 8-10 days)
• 0,03; 0,06; 0,08; 0,1; 0,12 L/ha in protection of winter oilseed rape against MELIAE (one

application, spray volume 200 – 400 l/ha)

The minimum effective dose rates are:
- 0,03-0,05 L/10000 m^2 LWA in protection of apple against APHIPO
- 0,07-0,09 L/10000 m^2 LWA (two applications) in protection of apple against CARPRO
- 0,08 l/ha - 0,1 L/ha in protection of winter oilseed rape against MELIAE

The effectiveness of the product was describe according to the following scale:
≥ 80% – Effectively controlled **(E)**
60 – 80% – Medium effectively controlled **(ME)**
0 – 60% – Limiting the number of pest **(R)**

Efficacy [%] against APHIPO on apple

Type of ASS	0,03 L/10000 m^2 LWA	0,05 L/10000 m^2 LWA	Ref. Mospilan 20 SP
1-4 DAA (8 trials)	75,4 (58,6-97,8)	84,2 (61,6-98,7)	86,1 (62,6-99,5)
7-8 DAA (4 trials)	95,1 (84,8-100)	98,0 (90,2-100)	97,5 (9386-100)

ASA-01 at 0,03-0,05 L/10000 m^2 LWA effectively (**E**) protected the crop against APHIPO and performed comparable to the reference product. The higher dose rate is propose to be use in case of higher density of the pest.

Efficacy [%] against CARPO on apple

Type of ASS	0,07 L/10000 m^2 LWA	0,09L/10000 m^2 LWA	Ref. Mospilan 20 SP
8-10 DAA (2 trials)	69,5 (65,0-74,0)	78,0 (70,0-86,0)	87,5 (85,0-90,0)
14-18 DAA (4 trials)	85,0 (71,0-100)	82,1 (65,0-100)	88,8 (75,0-100)
22-26 DAA (5 trials)	98,5 (92,5-100)	100	98,1 (90,5-100)
30-37 DAA (7 trials)	94,9 (81,8-100)	97,3 (90,0-100)	97,5 (88,3-100)
76-115 DAA at harvest (7 trials)	90,6 (68,9-100)	92,9 (76,3-100)	89,5 (56,5-100)

ASA-01 at 0,07-0,09 L/10000 m^2 LWA effectively (**E**) protected the crop against CARPO from the second week after two applications of the product until the harvest time and performed comparable to the reference product. The higher dose rate is propose to be use in case of higher density of the pest.
In a first week after the product application, efficacy was medium and statistically lower than for the reference product. The number of trials for that time is limited, but the efficacy of the product in the first week after application is clearly lower in comparison to the reference product – **ME**. This information should be incorporated in the label.

Efficacy [%] against MELIAE in winter oilseed rape

Type of ASS	0,08 L/ha	0,1 L/ha	Ref. Mospilan 20 SP
1-2 DAA (8 trials)	68,2 (15,8-92,6)	75,7 (32,5-95,9)	74,1 (34,9-93,4)
4-6 DAA (8 trials)	76,8 (52,2-97,2)	84,7 (64,0-98,5)	81,2 (63,3-97,2)
7-9 DAA (8 trials)	80,2 (64,7-91,7)	88,2 79,6-93,7)	86,3 (78,2-90,6)

ASA-01 at 0,1 L/ha, applied one time in winter oilseed rape, controlled MELIAE effectively (**E**)

and performed comparable to the reference product. Lower dose 0,08L/ha performed medium effectively, giving less consistent results (68,2%-76,8%) 1-6 DAA and achieved 80,2% 7-9 DAA. It may be considered sufficient in case of lower density of the pest.

To sum up, it might be concluded that one application of ASA-01 at provides benefit and controls pest:

- APHIPO on apple – **E**;
- CARPO on apple - **E**
- MELIAE in winter oilseed rape – **E**

The label should inform that product may control CARPO on apple medium effectively in the first week after application of the product. What is more additional information on limitation of dose 0,08 l/ha in protection of oilseed rape against MELIAE for lower pest pressure should be placed on the label.

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

A summary of the yield and quality traits data from efficacy trials in winter oilseed rape is presented in Table 3.2-16 and Table 3.2-17. Summary of the yield and quality traits data from efficacy trials in apple is presented in Table 3.2-18 and Table 3.2-19.

Winter oilseed rape

A total 8 of trials were carried out in winter oilseed rape between 2020 and 2023 in countries. The objective was to confirm the yield and quality traits response of ASA-01 in the presence of pest.

In all efficacy trials conducted in winter oilseed rape yield was assessed. Thousand grain weight was assessed in 7 trials. Moisture content was assessed in 6 trials. Oil content was assessed in 8 trials. Protein content was assessed in 2 trials while fiber and neutral detergent content were assessed in one trial.

Table 3.2-16: Yield (quality) effect of product in efficacy trials, winter oilseed rape

Crop	Number of trials	Untreated control Absolute figures (tonnes/ha)		Yield (tonnes/ha)						No of trials where ASA-01 is >, <, = compared to standard(s)*
				ASA-01 at rate 0.08 L/ha		ASA-01 at rate 0.1 L/ha		Mospilan 20 SP at rate 0.12 kg/ha		
		Mean	Min & Max	Mean	Mean	Mean	Min & Max	Mean	Min & Max	
Winter oilseed rape	8	3.05	2.16-3.77	3.32	2.51-4.13	3.33	2.58-4.34	3.32	2.64-4.16	For 0.08 L/ha: 7=, 1< For 0.1 L/ha: 8=

* Optional.

In winter oilseed rape, in 3 from 8 conducted efficacy trials the application of ASA-01 regardless of the rate had no significant effect on yield. In 4 form 8 trials, significant positive effect of ASA-01 regardless of the rate was observed. In one efficacy trial, significant positive effect of ASA-01 application on yield was observed in case of higher rate and in case of reference product. A mean increase in yield over the untreated for dose rate 0.08 L/ha was 108.2% (range 98.9-116.2%) and a mean increase in yield over the untreated for dose rate 0.1 L/ha was 110.7 % (range 99.2-119.9%). Reference product showed similar impact on yield in winter oilseed rape.

Table 3.2-17: Quality traits effect of product in efficacy trials, winter oilseed rape

Grouping	Number of trials	Untreated control		ASA-01 at rate 0.08 L/ha		ASA-01 at rate 0.1 L/ha		Mospilan 20 SP at rate 0.12 kg/ha		No of trials where ASA-01 is >, <, = compared to standard(s)*
		Mean	Min & Max	Mean	Mean	Mean	Min & Max	Mean	Min & Max	
Moisture content (%)	6	8.56	7.10-9.83	8.45	7.10-9.73	8.41	7.10-9.17	8.45	7.0-10.03	For 0.08 L/ha: 6= For 0.1 L/ha: 6=
Oil content (%)	8	44.50	40.05-50.05	44.98	39.75-47.10	45.19	40.23-51.0	44.05	39.90-50.30	For 0.08 L/ha: 7=, 1> For 0.1 L/ha: 8=
Protein content (%)	2	21.35	19.9-22.8	21.44	19.48-23.40	21.27	20.13-22.40	21.23	19.55-22.90	For 0.08 L/ha: 2= For 0.1 L/ha: 2=
TGW (g)	7	4.95	3.69-6.10	4.97	3.73-6.17	5.01	3.71-6.08	5.09	3.74-6.54	For 0.08 L/ha: 6=, 1< For 0.1 L/ha: 7=
HLW (kg)	5	70.65	68.0-73.2	70.91	68.40-72.60	71.60	68.20-76.0	70.99	68.40-73.20	For 0.08 L/ha: 5= For 0.1 L/ha: 4=, 1>
Fiber content (%)	1	21.63	21.63	21.58	21.58	21.45	21.45	21.43	21.43	For 0.08 L/ha: 1= For 0.1 L/ha: 1=
NDR (%)*	1	29.03	29.03	29.03	29.03	28.70	28.7	29.03	29.03	For 0.08 L/ha: 1= For 0.1 L/ha: 1=

*neutral detergent fiber

In one efficacy trial significant differences were observed in case of yield quality traits: thousand grain weight and oil content. TGW values from plots treated with 0.1 L/ha of ASA-01 and with reference were statistically higher than values from untreated control and from plots treated with 0.8 L/ha of ASA-01. Oil content was statistically higher from plots treated with 0.8 L/ha than from untreated control and plots treated with 1 L/ha of ASA-01 and with reference. In other trial, hectolitre weight values from plots treated with 0.1 L/ha of ASA-01 was statistically higher than from untreated control and plots treated with 0.08 L/ha of ASA-01 and from plots treated with reference. In other cases, there was no significant difference in quality traits between untreated plots and plots treated with tested and reference products.

Apple

A total 7 trials were carried out in apple against codling moth between 2019 and 2021 in Poland. The objective was to confirm the yield and quality traits response of ASA-01 in the presence of pest.

In all efficacy trials against codling moth conducted in apple yield was assessed. Colour of fruits and % of russeting were assessed in two trials. BRIX degree and firmness of fruits were assessed in one trial. Effect of ASA-01 on yield gradation was assessed in 4 conducted trials.

Table 3.2-18: Yield (quality) effect of product in efficacy trials, apple

Crop	Number of trials	Untreated control Absolute figures (tonnes/ha)		Yield (tonnes/ha)								No of trials where ASA-01 is >, <, = compared to stand-ard(s)*
				ASA-01 at rate 0.05 L/10000m2 LWA		ASA-01 at rate 0.07 L/10000m2 LWA		ASA-01 at rate 0.09 L/ 10000m2 LWA		Mospilan 20 SP at rate 0.2 kg/ha		
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
Apple	7	36.05	10.6-72.66	38.9	12.0-77.74	39.03	12.2-76.35	39.65	13.5-78.97	39.03	12.0-78.29	For 0.07 L/ha: 7= For 0.09 L/ha: 7=

In efficacy trials against codling moth conducted in apple, in 2 of 7 trials no statistical differences were observed in case of marketable yield between protected and unprotected plots after application of ASA-01 with all dose rates of tested product and reference product. In 2 of 7 conducted efficacy trials in apple, significant positive effect of ASA-01 regardless of the rate was observed. In 2 trials significantly higher level of yield was observed for ASA-01 in dose rates 0.07 and 0.09 L/10000m^2 LWA in comparison to unprotected plot. In one trial, significant higher yield was observed only from plot treated with 0.07 10000m^2 LWA of ASA-01 in comparison with untreated control. A mean increase in yield over the untreated for dose rate 0.07 L/10000m^2 LWA was 109.9% (range 105.1-115.1%) and a mean increase in yield over the untreated for dose rate 0.09 L/10000m^2 LWA was 112.4% (range 102.9-127.4%). Reference product showed similar impact on yield of apple.

Table 3.2-19: Quality traits effect of product in efficacy trials, apple

Group-ing	Num ber of trials	Untreated control		ASA-01 at rate 0.05 L/10000 m^2 LWA		ASA-01 at rate 0.07 L/10000 m^2 LWA		ASA-01 at rate 0.09 L/10000 m^2 LWA		Mospilan 20 SP at rate 0.2 kg/ha		No of trials where ASA-01 is >, <, = compared to stand-ard(s)*
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
FRM kg/cm^2 (side A/B)	1	6.78/ 6.74	6.78/ 6.74	6.85/ 6.83	6.85/ 6.83	6.80/ 6.77	6.80/ 6.77	6.79/ 6.76	6.79/ 6.76	6.78/ 6.81	6.78/6. 81	1= (for all tested doses)
BRIX	1	12.86	12.86	12.84	12.84	12.86	12.86	12.81	12.81	12.88	12.88	1= (for all tested doses)
RUS (%)	2	1.77	0-3.53	2.08	0-4.15	1.88	0-3.75	2.08	0-4.15	1.92	0-3.83	2= (for all tested doses)
COL (%)	2	66.5	55.9-77.1	66.2	54.6-77.8	66.5	55.3-77.7	67.0	55.9-78.2	66.7	55.5-77.9	2= (for all tested doses)

FRM - firmness (side A and B), **BRX** – brix content (brix degree), **RUS** – russet (%), **COL** – color

No negative impact of ASA-01 was observed on quality traits of apple, such as: color of fruits, % of russeting, BRIX degree and firmness of fruits.

Summary and conclusion

During efficacy trials against codling moth in apple was proved that dose rates 0.07-0.09 L/10000 m^2 LWA of ASA-01 was equally effective as dose 0.2 kg/ha of reference Mospilan 20 SP and provided high control *Cydia pomonella* in apple. Therefore it was decided to recommend for registration ASA-01 in rates 0.07-0.09 L/10000 m^2 LWA in protection of apple against codling moth. The higher of the recommended rates use in case of increased pest occurrence.

During efficacy trials against green apple aphids in apple was proved that dose rates 0.03 L/10000 m^2 LWA and 0.05 L/10000 m^2 LWA of ASA-01 was equally effective as dose 0.125 kg/ha of reference product Mospilan 20 SP and provided high control *Aphis pomi*. Therefore, it was decided to recommend for registration ASA-01 in these doses in protection of apple against green apple aphids. The higher of the recommended doses use in case of increased pest occurrence.

During efficacy trials against pollen beetle in winter oilseed was proved that dose rates 0.8-0.1 g/ha of ASA-01 was equally effective as dose 0.2 kg/ha of reference product Mospilan 20 SP and provided high control *Brassicogethes aeneus*. Therefore, it was decided to recommend for registration ASA-01 in rates 0.8-0.1 g/ha in protection of winter oilseed rape against pollen beettle. The higher of the recommended doses use in case of increased pest occurrence.

A mean increase in yield of apple after double application of 0.07 L/10000m^2 LWA of ASA-01over untreated was 109.9% and a mean increase in yield of apple after double application of 0.09 L/10000m^2 LWA of ASA-01 over the untreated was 112.4%. In winter oilseed rape, a mean increase in yield over the untreated for dose rate 0.08 L/ha was 108.2% and a mean increase in yield over the untreated for dose rate 0.1 L/ha was 110.7 %. ASA-01 in recommended doses showed similar impact on yield and quality traits of apple and winter oilseed rape in comparison to reference product.

Comments of zRMS:	Yield of winter oilseed rape was tested in 8 efficacy trials and yield of apple was tested in 7 efficacy trials. No negative effects on the yield are expected after the application of ASA-01.

Comments of zRMS:	No negative effects on the quality of plants or plant products are expected after the application of ASA-01.

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

Acetamiprid is a broad-spectrum insecticide with both contact systemic. It belongs to nicotinic acetocholine receptor (NACHR) competitive modulators, chemical family- neonicotinoids (IRAC group 4A). Neonicotinoids mimic the agonist action of acetylcholine at nAChRs (Nicotinic acetylcholine receptor), causing hyperexcitation. Acetyl choline is the major excitatory neurotransmitter in the insect central nervous system. Neonicotinoids such as acetamiprid bind to the same site as acetylcholine at the nAChRs and causing a range of symptoms from hyper-excitation to lethargy and paralysis. Desensitized nAChR-neonicotinoid complexes no longer conduct ions and are essentially inhibited. It is used to control *Hemiptera*, *Lepidoptera*, *Thysanoptera* and *Coleoptera*.

The Arthropod Pesticide Resistance Database (https://www.pesticideresistance.org) reports worldwide 1189 cases of resistance to the group 4A insecticides. Resistance cases were reported particularly for *Bemisia tabaci*, *Aphis gossypii*, *Phenacoccus solenopsis*, *Diaphoria citri* and *Cydia pomonella*. Among 132 resistance cases reported for the active ingredient -acetamiprid, 16 of them pertaining to *Cydia pomonella* (CARPPO; 2 cases in USA- lab selected after field-evolved resistance and 14 cases in Argentina- field evolved resistance). So far, no resistance cases of CARPPO against acetamiprid were reported in European countries. No resistances of *Aphis pomi* and *Brassicogethes aeneus* against acetamiprid are known so far.

For neonicotinoids metabolic resistance as well as target-site resistance has been observed. According to the Arthropod Pesticide Resistance Database (APRD), in case of acetamiprid the metabolism resistance was more frequent than the target-site resistance.

Resistance management

- Recommended label rates

It is recommended to use product on the basis of label recommendations and GAP (Good Agricultural Practices). Insecticides used at rates lower or higher than recommended on the label can results in resistance or/and unwanted effects on non-target organism and the environment.

- Rotation of insecticide groups

Mode of action alternation is recommended and provides the best option for minimalizing resistance development. Despite the current scale of resistance, neonicotinoids remain a major component of many pest control programs and resistance management strategies, based on mode of action rotation, are of crucial importance in preventing resistance becoming more widespread. In control of multiple-generation pest, it is important to limit Group 4 treatments onto one generation of the target pest and to switch to other modes of action in the subsequence generation.

- Insecticide mixtures

The use of mixtures containing two effective components with different mode of action increase the spectrum of controlled insects and prevent the development of resistance. Two insecticides from the same Group should not be tank-mixed or co-formulated as a means to manage resistance.

- Rotation of subgroups 4A, 4C and 4 D

Successive generations of a pest should not be treated with compounds from the same MOA Group. In case of lack other option, there is possibility to rotate compounds between sub-groups if it is clear that cross-resistance mechanisms do not exist in the target population.

- Using Group 4 insecticides against different pests in the same crop

It is feasible but the pest population dynamics, overlapping of various species, they relative importance and each species' potential risk for developing resistance should be taken into account.

- Using Group 4 insecticides for follow up treatments where resistance has already reduced their effectiveness

The use of follow up treatments after a product failure more often than not necessitating higher rates than recommended, whether as solo treatments or in mixtures, may continue to promote and contribute to escalating resistance levels and thus should be avoided.

- The use of non-specific mode of action products

Product such as oils and soaps with non-specific mode of action are recommended for use in rotation or combination with Group 4 insecticides, provided that they effectively control both susceptible and resistant target pest populations.

- Good agricultural practices

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 crop rotation can help to slow down and even prevent resistance development.

- An integrated pest management (IPM) program

Insecticide use should be based on IPM program that includes scouting, record keeping and considers cultural, biological and other chemical control practices

- Monitor treated pest populations for resistance development.

For the uses in agricultural crops and orchards for which approval is sought- winter oilseed rape and apple, cultural and mechanical control measures as well as alternative mode of actions are available. According to Polish pesticide register following alternatives to the group 4A are available: in apple cultures for the control of APHIPO-groups 1A, 3A, 29 and UN, in apple cultures for the control of CARPPO-groups 3A, 5, 6, 11A, 28, 29 and 31, in oilseed rape groups 3A and 4D. Furthermore, in case of winter oilseed rape full or limited rotational cropping systems are implemented. Thus, when the product is

applied according to the proposed use and principles of good agricultural practice and resistance management are considered, the development of resistances in insects is assessed to be unlikely to occur.

dRR point 3.3	Strategy is acceptable.
EN: Evaluator conclusion: The active substance acetamiprid belongs to the 4 main group - Nicotinic acetylcholine receptor (nA-ChR) competitive modulators and 4 A sub-group – Neonicotinoids in accordance with IRAC classification. The following of found pests strains included as target pest in this dossier are resistant to acetamipryd*: Cydia pomonella* (16 cases worldwide, non in PL) to acetamiprid. The application of the product maintaining recommendations of IRAC resistance management strategy should prevent from development resistance to the insecticide. The applicant proposed resistance management strategy in order not to develop resistance to the insecticide which which corresponds to the IRAC recommendations.	

3.4 Adverse effects on treated crops (KCP 6.4)

Phytotoxicity symptoms were assessed during all performed efficacy trials. Details of trails methodology are summarized in Table 3.2-9,Table 3.2-10 and Table 3.2-11. Evaluation of the phytotoxic effects of ASA-01 on apple and winter oilseed rape was conducted visually by comparing the condition of the plants on plots with untreated plots (non-insecticides). A percentage scale 0%-100% (0% without phytotoxic, 100% total plant damage) was used. Phytotoxicity of ASA-01 was compared to phytotoxicity of reference product Mospilan 20 SP. For further assessment details including timing, number and BBCH stage of the crop, please refer to the Biological Assessment Dossier.

Table 3.4-1: Presentation of trials (same as table 3.2.4)

Crops *	Targets*	Country	Years	Type of trial**	Number of trials (number of valid trials)	GEP, non-GEP, official***	Comments (any other relevant information)
					North-East zone		
Apple	Codling moth	Poland	2019	MED+E	1	GEP	
			2020	MED+E	3	GEP	
			2021	MED+E	3	GEP	
	TOTAL	-	-	-	7	-	
Apple	Green apple aphid	Poland	2019	MED+E	3	GEP	
			2020	MED+E	2	GEP	
			2021	MED+E	1	GEP	
			2023	MED+E	2		
	TOTAL	-	-	-	8	-	
Winter oilseed rape	Pollen beetle	Poland	2020	MED+E	4	GEP	
			2021	MED+E	2	GEP	
			2023	MED+E	2	GEP	
	TOTAL	-	-	-	8	-	

* According to the GAP table

** S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation

*** Official: carried out by a national official organisation

Table 3.4-2: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Crop(s)/target	Reference standard	Country where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type(2)	Concentration of a.s.			
Apple, codling moth	Mospilan 20 SP	PL	R - 37/2008 R-228/2022d	Acetamiprid	SP	200	0.2 kg/ha (40 g a.s./ha)	0.2 kg/ha (40 g a.s./ha)	2 applications, 7-14 d interval
Apple, green apple aphid							0.125 kg/ha (25 g a.s./ha)	0.125 kg/ha (25 g a.s./ha)	1 application
Winter oilseed rape, pollen beetle							0.08-0.12 kg/ha (16-24 g a.s./ha)	0.12 kg/ha (24 g a.s./ha)	1 application

(1) only on use(s) applied for (with the test product)
(2) e.g.WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) Dose / dose range authorized in the country
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application…)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Table 3.4-3: Phytotoxicity of product

Number of trials with…		Selectivity trials (0 trials)				Efficacy trials (23 trials)	
		Test product		Standard 1		Test product	Mospilan 20 SP
		N	2N (or other)	N	2N (or other)	N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	-	-	-	-	23	23
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	-	-	-	-	23	23
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-

Phytotoxicity effect on apple was evaluated in 8 efficacy trials against green apple aphid where tested product was applied once in BBCH 55-76 and in 7 efficacy trials against codling moth where tested product was applied twice with interval 7-10 days in BBCH 71-74.

Phytotoxicity effect on winter oilseed rape was evaluated in 8 efficacy trials against pollen beetle where ASA-01 was used in one application in BBCH 52-60. All trials were carried out by officially recognized organizations in accordance with the Principles of *Good Experimental Practice* (GEP).

No phytotoxicity symptoms caused by ASA-01 at all tested dose rates were observed in all trials conducted in winter oilseed rape and in apple.

Comments of zRMS:	The applicant submitted 23 efficacy reports (apple and winter oilseed rape) where phytotoxicity of the product was carried out at the proposed maximum use rate of: - 0,06 L/10000 m^2 LWA in apple, at BBCH 55-74 - 0,09 L/10000 m^2 LWA (two applications) in apple, at BBCH 72-73 - 0,12 L/ha in winter oilseed rape, at BBCH 55-60 No symptoms of phytotoxicity were observed in efficacy trials.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

According to EPPO PP 1/135, 'for fungicides and insecticides…observations of phytotoxic effects should be made in the direct efficacy (effectiveness) trials. If any adverse effects occur in any of the effectiveness…trials at N dose, then…specific crop safety trials should be conducted.' As no phytotoxic effects were observed in any effectiveness trial, no specific crop safety trials were conducted.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

According to EPPO PP 1/135, 'for fungicides and insecticides…observations of phytotoxic effects should be made in the direct efficacy (effectiveness) trials. If any adverse effects occur in any of the effectiveness…trials at N dose, then…specific crop safety trials should be conducted.' As no phytotoxic effects were observed in any effectiveness trial, no specific crop safety trials were conducted.

dRR points 3.4.2 and 3.4.3	Yield and quality of plants or plants product were tested in efficacy trials (apple and winter oilseed rape) where no phytotoxicity and negative effect on yield were observed. Presented data and explanations are acceptable.

3.4.4 Effects on transformation processes (KCP 6.4.4)

As residues of acetamiprid do not exceed the trigger values defined in Regulation (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

dRR point 3.4.4	No negative effects on transformation processes are expected. The product has no fungicidal properties.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Submission of data on propagation material is not required for insecticides according to EPPO PP 1/135(4) 'Phytotoxicity assessment'.

Comments of zRMS:	No negative effects on treated plants or plant products to be used for propagation are expected. The product has had no negative influence on yield of treated crops.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Acetamiprid has been applied for many years not only in Poland but also in other countries of Europe. So far, any negative impact of acetamiprid on succeeding crops is not known. Acetamiprid decomposes in soil rapidly and does not pose risk for succeeding plants. ASA-01 is an insecticide without any herbicidal action and therefore it is not expected to be harmful for any succeeding crop.

Comments of zRMS:	The risk of adverse impact of ASA-01on succeeding crops is not expected.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

~~Studies of impact of ASA-01 on adjacent plants are not required. Any negative side effects on target or adjacent crops have not been reported in the efficacy trials. In order to avoid any adverse impact on adjacent crops, drift of working solution to adjacent crops should not be allowed~~.

The risk to adjacent crops was determined according to EPPO PP 1/256. According to this guideline, non-target plant data such as seedling emergence and vegetative vigour tests are useful to determine the effect on adjacent crops. For this the ED_{50} endpoint should be used. The sensitivity of possible adjacent crops can be derived from the toxicity data for non-target plants. In Table 3.5-1 below the endpoints for non-target terrestrial plants are given. For more information on toxicity of non-target plants is referred to Part B9 (Ecotoxicology) of this dossier.

Table 3.5-1: ED_{50}-values (mg/ha) of different test plants

Test plant		**EPPO Code**	**ED_{50} *test product* (mg/ha)**	**Reference**
Common name	**Scientific name (lat.)**			
Seedling-emergence-test				
Sunflower Cabbage Pea Carrot Perrenial ryegrass Oats	*Helianthus annuus* *Brassica oleracea var. capitata* *Pisum sativum* *Daucus carota* *Lolium perenne* *Avena sativa*	HELAN BRSOL PIBSX DAUCA LOLPE AVESA	Plant number at the end of the experiment ER_{50} > 405 ml/ha Shoot length (plants without roots) ER_{50} > 405 ml/ha Plant dry weight (plants without roots) ER_{50} > 405 ml/ha	Pieczka P/2020/Study code: G/59/19 KCP 6.5.2/01
Vegetative-vigour-test				
Sunflower Cabbage Pea Carrot Perrenial ryegrass Oats	*Helianthus annuus* *Brassica oleracea var. capitata* *Pisum sativum* *Daucus carota* *Lolium perenne* *Avena sativa*	HELAN BRSOL PIBSX DAUCA LOLPE AVESA	Plant number at the end of the experiment ER_{50} > 405 ml/ha Shoot length (plants without roots) ER_{50} > 405 ml/ha Plant dry weight (plants without roots) ER_{50} > 405 ml/ha	Wołany M/2020/Study code: G/58/19 KCP 6.5.2/02

The assessment for the double use in orchards also covers the off-field risk for non-target terrestrial plants from all other intended uses.

Table 3.5-2: PERoff-field (L product/ha) values for double application (drift) in fruit crops with maximum use rate 2 x 90 mL product/ha

Single application rate (mL/ha)	% drift	MAF	$PER_{off\text{-}field}$ (mL product/ha)
90	25.53	1.7	39.21

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1]MAF and drift rate from ESCORT 2 Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods

Table 3.5-3: Risk analysis for adjacent crops. TER values for Viares

Application rate (mL product/ha)	Drift mitigation	PERoff field (mL product/ha)	ER_{50} (mL product/ha)	TER
90	none	39.21	> 405 ml/ha	10.33

An acceptable risk is indicated for terrestrial non-target plants, at minimum distance. The respective TER values are >1, as requested in EPPO guideline PP 1/256. No further testing is required.

Comments of zRMS:	The risk of impact on other plants including adjacent crops of ASA-01280 SC is not expected with applying buffer zone of 1m mitigation measures.

Tank cleaning

An insufficient tank cleaning after use of Viares can cause negative effects on the next crops. Therefore, an appropriate tank cleaning might have to be performed after application of the product.
According to Appendix 4 of EPPO guideline PP 1/292(1), up to 2.6% of the spray solution will remain in the PAE following application (according to ISO 16119).
The following evaluation is presented for the worst – case scenario from the GAP table - assuming dose of 0.1 L product/ha in 200 L of water/ha and 300 g ai/ L of the product:

Table 3.5-4: Calculation of washout according to Appendix 4 of EPPO PP 1/292(1)

Calculations	
Amount of a.i. in 1000 L spray-er (assuming 200 L ha-1 water)	1000/200 = 5 5 x 0.1 L product (appl. dose in 1 ha) = 0.5 L product in 1000 L sprayer = 150 g ai in 1000 L sprayer
Amount left in sprayer after spraying (2.6%)	150 g ai x 2.6% = 3.9 g ai
Situation A (without washing)	
Dose applied (at 200 L/ha) to 2.5 ha (without washing)	3.9 g ai / 2.5 ha = 1.56 g ai /ha
Situation B (one washout - procedure)	
Amount of product left in sprayer after 1st stage of wash-out procedure (washing tank with 1000 L water and then empty it)	3.9 g ai x 2.6% = 0.1014 g ai
Dose applied (at 200 L/ha) to 2.5 ha after first washout procedure	0.1014 g ai / 2.5 ha = 0.04056 g ai/ha

The studies for non-target plants showed (please refer to respective chapter in section 9 of the dRR) that ER50 for all tested species was > 405 mL/ha (> 121.5 g ai /ha). Assuming a leftover of 2.6% of the spray solution, which results in 1.56 g ai/ha, the TER value without washing (situation A of the table above) is 77.9 which is above the trigger value of 1 and indicate no unacceptable risk risk. No special instruction for cleaning procedures are required.

Comments of zRMS:	ZRMS agrees with the presented data concerning tank cleaning procedure.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

An adverse impact on beneficial organisms was not observed in the course of efficacy experiments. Detailed discussion is included in Section 9 -Ecotoxicology.
Application of ASA-01 according to recommendations included in the label-instruction poses no unacceptable threat to beneficial organisms and no threat to earthworms.

3.6 Other/special studies

Not relevant.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
ANADIAG POLSKA	ul. Sadowa 16/22, 95-100 Zgierz, Poland	Yes
Fertico Sp. z o.o.	Goliany 43, 05-620 Błędów, Poland	Yes
Eurofins Agroscience Services Sp. z o.o.	ul. Parkowa 6, 64-530 Kaźmierz, Poland	Yes
Institute of Plant Protection (IPP) - National Research Institute (NRI), Pesticide Efficacy Testing Department	ul. Gliwicka 29, 44-153 Sośnicowice, Poland	Yes

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/1 KCP 6.4/1	Ogrodniczek A.	2019	Efficacy of ASA-01 in control of codling moth *Cydia pomonella* on apple, Poland 2019. Fertico Sp. z o.o. Report No: 231_01_F19_381 GEP: YES Published: No	N	XXXX
KCP 6.2/2 KCP 6.4/2	Kopeć J.	2020	Efficacy of ASA-01 against codling moth in apple orchard, Poland 2020. Fertico Sp. z o.o. Report No: 7_01_F20_10 GEP: YES Published: No	N	XXXX
KCP 6.2/3 KCP 6.4/3	Kopeć J.	2020	Efficacy of ASA-01 against codling moth in apple orchard, Poland 2020. Fertico Sp. z o.o. Report No: 7_02_F20_11 GEP: YES Published: No	N	XXXX
KCP 6.2/4 KCP 6.4/4	Jatczak J.	2020	Evaluation of the efficacy of insecticide ASA-01 applied against *Cydia pomonella* in apple. ANADIAG POLSKA,	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No: PL 20 022 PL1 GEP: YES Published: No		
KCP 6.2/5 KCP 6.4/5	Jatczak J.	2021	Evaluation of the efficacy of insecticide ASA-01 applied against *Cydia pomonella* in apple. ANADIAG POLSKA, Report No: PL 21 064 PL1 GEP: YES Published: No	N	XXXX
KCP 6.2/6 KCP 6.4/6	Jatczak J.	2021	Evaluation of the efficacy of insecticide ASA-01 applied against *Cydia pomonella* in apple. ANADIAG POLSKA, Report No: PL 21 064 PL2 GEP: YES Published: No	N	XXXX
KCP 6.2/7 KCP 6.4/7	Jatczak J.	2021	Evaluation of the efficacy of insecticide ASA-01 applied against *Cydia pomonella* in apple. ANADIAG POLSKA, Report No: PL PL 21 064 PL3 GEP: YES Published: No	N	XXXX
KCP 6.2/8 KCP 6.4/8	Pławuszewski M., Biniszewski K.	2019	Determination of efficacy of ASA-01 against Green apple aphid (*Aphis pomi*) in pome fruit, 1 site in Poland 2019. Eurofins Agroscience Services Sp. z o.o. Report No: S19-05192-01 GEP: YES Published: No	N	XXXX
KCP 6.2/9 KCP 6.4/9	Pławuszewski M., Biniszewski K.	2019	Determination of efficacy of ASA-01 against Green apple aphid (*Aphis pomi*) in pome fruit, 1 site in Poland 2019. Eurofins Agroscience Services Sp. z o.o. Report No: S19-05192-02 GEP: YES Published: No	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/10 KCP 6.4/10	Ogrodniczek A.	2019	Efficacy of ASA-01 in control of aphids on apple, Poland 2019. Fertico Sp. z o.o. Report No: 230_01_F19_380 GEP: YES Published: No	N	XXXX
KCP 6.2/11 KCP 6.4/11	Jatczak J.	2020	Evaluation of the efficacy of insecticide ASA-01 applied against Aphids in apple. ANADIAG POLSKA Report No: PL 20 023 PL1 GEP: YES Published: No	N	XXXX
KCP 6.2/12 KCP 6.4/12	Kopeć J.	2020	Efficacy of ASA-01 against aphids in apple orchard, Poland 2020. Fertico Sp. z o.o. Report No: 6_01_F20_09 GEP: YES Published: No	N	XXXX
KCP 6.2/13 KCP 6.4/13	Jatczak J.	2021	Evaluation of the efficacy of insecticide ASA-01 applied against Aphids in apple. ANADIAG POLSKA Report No: PL 21 065 PL1 GEP: YES Published: No	N	XXXX
KCP 6.2/14 KCP 6.4/14	Jatczak J.	2023	Evaluation of the efficacy of insecticide ASA-01 applied against Aphids in apple. ANADIAG POLSKA Report No: PL 23 026 PL1 GEP: YES Published: No	N	XXXX
KCP 6.2/15 KCP 6.4/15	Jatczak J.	2023	Evaluation of the efficacy of insecticide ASA-01 applied against Aphids in apple. ANADIAG POLSKA Report No: PL 23 026 PL2 GEP: YES Published: No	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/16 KCP 6.4/16	Drzewiecki S.	2020	Biological efficacy expertis of insecticide ASA-01 for *Brassicogethes aeneus* control in winter oilseed rape. Institute of Plant Protection (IPP) - National Research Institute (NRI), Pesticide Efficacy Testing Department Report No: 5 I/2020 GEP: YES Published: No	N	XXXX
KCP 6.2/17 KCP 6.4/17	Szemendera A.	2020	Efficacy of ASA-01 in control of Pollen beetle (*Brassicogethes aeneus)* in winter oilseed rape, Poland 2020. Fertico Sp. z o.o. Report No: 8_01_F20_12 GEP: YES Published: No	N	XXXX
KCP 6.2/18 KCP 6.4/18	Szemendera A.	2020	Efficacy of ASA-01 in control of Pollen beetle (*Brassicogethes aeneus)* in winter oilseed rape, Poland 2020. Fertico Sp. z o.o. Report No: 8_02_F20_13 GEP: YES Published: No	N	XXXX
KCP 6.2/19 KCP 6.4/19	Jatczak J.	2020	Evaluation of the efficacy of insecticide ASA-01 applied against *Brassicogethes aeneus* in winter oilseed rape. 2020. ANADIAG POLSKA Report No: PL 20 024 PL1 GEP: YES Published: No	N	XXXX
KCP 6.2/20 KCP 6.4/20	Jatczak J.	2021	Evaluation of the efficacy of insecticide ASA-01 applied against *Brassicogethes aeneus* in winter oilseed rape. 2021. ANADIAG POLSKA Report No: PL 21 066 PL1 GEP: YES Published: No	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/21 KCP 6.4/21	Jatczak J.	2021	Evaluation of the efficacy of insecticide ASA-01 applied against *Brassicogethes aeneus* in winter oilseed rape. 2021. ANADIAG POLSKA Report No: PL 21 066 PL2 GEP: YES Published: No	N	XXXX
KCP 6.2/22 KCP 6.4/22	Jatczak J.	2023	Evaluation of the efficacy of insecticide ASA-01 applied against *Brassicogethes aeneus* in winter oilseed rape. 2023. ANADIAG POLSKA Report No: PL 23 028 PL1 GEP: YES Published: No	N	XXXX
KCP 6.2/23 KCP 6.4/23	Jatczak J.	2023	Evaluation of the efficacy of insecticide ASA-01 applied against *Brassicogethes aeneus* in winter oilseed rape. 2023. ANADIAG POLSKA Report No: PL 23 028 PL2 GEP: YES Published: No	N	XXXX
KCP 6.5.2/01 filled as KCP 10.6.2/01	Pieczka P	2020	ASA-01 Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G/59/19 GLP: Y Published: N	N	XXXX
	Pieczka P	2021	AMENDMENT NO. 1 TO THE FINAL REPORT ASA-01 Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G/59/19 GLP: Y Published: N	N	XXXX
KCP 6.5.2/02	Wołany M	2020	ASA-01 Terrestrial Plant Test: Vegetative Vigour Test	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
filled as KCP KCP 10.6.2/02			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G/58/19 GLP: Y Published: N		
	Czarnynoga M	2021	AMENDMENT NO. 1 TO THE FINAL REPORT ASA-01 Terrestrial Plant Test: Vegetative Vigour Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G/58/19 GLP: Y Published: N	N	XXXX

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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