REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: ASA-01

Product name(s): **VIARES**

Chemical active substance:

Acetamiprid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: XXXX

Submission date: March 2024

Evaluation date: May 2025

PL Evaluation date: October 2025

Version history

When	What
May 2025	Version evaluated by zRMS PL
October 2025	RR amendment driven by MRL changing
February 2026	Update due to change in PUF value for metabolite IM-I-5 by zRMS PL

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is submitted for the authorization of the product ASA-01, formulated as a suspension concentrate (SC) containing 300 g/L acetamiprid, for the use as an insecticide for oilseed rape and apple. This application is submitted to Poland.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Northern zone	Poland: ASA-01	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Acetamiprid

Table 0.1-2: Summary of regulatory history of CAS No: 135410-20-7

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX%3A02011R0540-20231216 Commission Implementing Regulation (EU) 2018/113 of 24 January 2018 renewing the approval of the active substance acetamiprid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520336385887&uri=CELEX:32018R0113
RMS, Co-RMS	NL, ES

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.03.2018
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	28.02.2030
Date of final Commission (re-registration) deadline (Step 2)	28.05.2033
Current expiration of approval	28.02.2033
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the risk to aquatic organisms, bees and other non-target arthropods,
- the risk to birds and mammals,
- the risk to consumers,
- the risk to operators.

The SANCO report for Acetamiprid (SANTE/10502/2017 rev. 4 - 13 December 2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 11.11.2016.

Table 0.1-3: Information on minimum purity of acetamiprid

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ** **
minimum purity of active substance: 990 g/kg	minimum purity of active substance - confidential information reffered in Part C of dRR Equivalence report available: Y RMS: please refer to the Letter of Access

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Identity, physical and chemical properties:

Sufficient data on identity, physical and chemical properties are available for the plant protection product ASA-01.

The data provided by the applicant confirm the stability of the formulation ASA-01 with regard to

physicochemical properties, technical characteristics, as well as content of active substance when stored at least 2 years at ambient temperature in HDPE packaging material.

Efficacy:

Uses no. 1-3 in the GAP table are considered safe for PL. Sufficient data have been presented to confirmed efficacy oft he product.

Toxicology:

The application of product Viares (formulation ASA-01) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs during mixing/loading and application.

The application of product Viares (formulation ASA-01) does not pose an unacceptable risk to the health of worker for its intended use within good agricultural practice. No unacceptable risk for residents and bystanders is identified when the product is used as intended.

Residues:

The chronic and the short-term intakes of acetamiprid residues are unlikely to present a public health concern. As far as consumer health protection is concerned, PL agrees with the authorization of the intended uses except of apples, wild apples, pears, Chinese pears (MRL exceedance) consistently with the intended GAP (Appendix 1).

~~The residue data for rapeseed and apples are currently sufficient (see the table of MRLs in the B7) to grant the approval for these uses. However, the honey data presented indicate the possibility of exceeding the current MRL in honey. Thus PL agrees with the authorization of the intended uses only after the flowering period with the complete exclusion of rapeseed.~~

Fate and behaviour:

The submitted exposure assessment in soil, groundwater and surface water was sufficient. Predicted environmental concentration in particular compartments were performed in accordance with EU requirements and FOCUS guidance.

Ecotoxicology:

All relevant data and risk assessment are considered as adequate and sufficient. The risk assessment for all groups of organisms was performed in accordance with relevant guidance. An acceptable risk is expected if product is used in accordance with proposed pattern use in winter OSR and pome fruits (apple, wild apple, pear, Chinese pear, quince and medlar).

To protect the aquatic organisms the risk mitigations are required, (for details, please refer to B9).

To protect arthropods and non-target terrestrial plants a 1 or 3 m non-sprayed strip for winter OSR and pome fruits, respectively.

Uses to be considered safe on the basis of EU methodology:

Efficacy: uses 1 - 3 are considered to be safe for PL
Residues: 1, 4, 5

Others: uses 1 - 5

Uses to be considered non-safe on the basis of EU methodology:

Residues: 2, 3

Others: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

PL. In accordance with national requirements (PUF = 0) the additional PECgw assessment was provided.
The safe use of Viares can be concluded if:

- formulation is used every 2 years in Use No 3 and 5
- formulation is used every year in Use No 1, 2 and 4.

The following text is to be shortened or to be amended as necessary.

All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Appendix 1 ALL intended uses

GAP rev. 1.0, date: 2023-06-12

PPP (product name/code):	ASA-01	Formulation type:	SC [a, b]
Active substance 1:	acetamiprid	Conc. of as 1:	300 g/L [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	XXXX	Professional use:	☒
Zone(s):	central [d]	Non professional use:	☐
Verified by MS:	no		

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, Fpn 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)	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	NR	Dose 0,08 l/ha limited for low pest pressure.
~~2~~	~~PL~~	~~Apple (MABSD)~~	~~F~~	~~Aphids *Aphididae* (APYXSP)~~	~~spraying~~	~~Spring BBCH 56-75 BBCH 70-75~~	~~a) 1 b) 1~~	~~-~~	~~a) 0.03-0.05 L/10000 m² LWA b) 0.03-0.05 L/10000 m² LWA~~	~~a) 9-15 g a.s./10000 m² LWA b) 9-15 g a.s./10000 m² 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 56-75 BBCH 72-75~~	~~a) 1-2 b) 2~~	~~7-8-10 days~~	~~a) 0.07-0.09 L/10000 m² LWA 0.14-0.18 L/ 10000 m² LWA b) 0.14-0.18 L/ 10000 m² LWA~~	~~a) 21-27 g a.s./10000 m² LWA 42-54 g a.s. /10000 m² LWA b) 42-54 g a.s. /10000 m² 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 *Aphdidae* (APXXSP)	spraying	Spring BBCH 56-75 BBCH 70-75	a) 1 b) 1	-	a) 0.03-0.05 L/10000 m² LWA b) 0.03-0.05 L/10000 m² LWA	a) 9-15 g a.s./10000 m² LWA b) 9-15 g a.s. /10000 m² LWA	500-900 L/ha	14 days	max. 0.075 L/ha max. 22.5 g as/ha
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 BBCH 70-75	a) 1 b) 2	7-10 days	a) 0.07-0.09 L/10000 m² LWA b) 0.14-0.18 L/ 10000 m² LWA	a) 21-27 g a.s./10000 m² LWA b) 42-54 g a.s. /10000 m² LWA	500-750 L/ha	14 days	max. 0.09 L/ha max. 27 g as/ha

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