FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: CHR/I/ADEL 280 SC

Product name(s): ADEL 280 SC, PYRIFOS ADE 280 SC

Chemical active substance(s):

Acetamiprid, 250 g/L

Deltamethrin, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: December 2021

MS Finalisation date: 24/10/2024, 14/03/2025, evaluation of additional data 02/06/2025 update September 2025, update January 2026

Version history

When	What
September 2021	Dossier sent for evaluation
2022 - 2024	zRMS finalised evaluation
October 2024	Final version prepared by zRMS after Commenting period
March 2025	zRMS update - Efficacy
July 2025	Evaluation of additional data by zRMS – Resides and Analytical methods
September 2025	Update due to change in MRL values for acetamiprid in honey and conditional authorisation
January 2026	Update due to change in PUF value for metabolite IM-I-5

Table of Contents

PART A
RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for zonal registration of CHR/I/ADEL 280 SC (ADEL 280 SC, PYRIFOS ADE 280 SC) containing acetamiprid and deltamethrin in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to CHR/I/ADEL 280 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/I/ADEL 280 SC have been made using endpoints agreed in the EU review of acetamiprid and deltamethrin

This document describes the specific conditions of use and labelling required for the registration of (ADEL 280 SC/ PYRIFOS ADE 280 SC) product code CHR/I/ADEL 280 SC.

1.1 Application background

This application was finalized by Innvigo Sp. z o.o. in April 2019. Innvigo Sp. z o.o. is a company located at Aleje Jerozolimskie 178, 02-486, Warsaw, Poland, and registered in the Polish National Court Registry of entrepreneurs (KRS), with the number 0000540684.

The application is for the approval of CHR/I/ADEL 280 SC a suspension concentrate (SC) containing 250 g/L acetamiprid and 30 g/L deltamethrin for use as a insecticide for controls a broad-spectrum of insects in winter oilseed rape, sugarbeet and winter cereals. It is a applied by spray at BBCH 10 to 21 for winter oilseed rape, at BBCH 37-75 for winter cereals and at BBCH 12 to 19 for sugarbeets.

To obtain authorisation the product CHR/I/ADEL 280 SC must meet the conditions of renewal and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using renewal agreed endpoints.

This application was submitted in order to allow the renewal of authorisation of this product in Poland, in accordance with the above.

1.2 Letters of Access

Not relevant.

1.3 Justification for submission of tests and studies

In accordance with Art. 33 (3), the submitted studies and presented in Appendix 4, are relevant and necessary to obtain the first authorisation the product CHR/I/ADEL 280 SC in Poland and other countries.

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.

2 Details of the authorization decision

2.1 Product identity

Product code	CHR/I/ADEL 280 SC
Product name in MS	ADEL 280 SC, PYRIFOS ADE 280 SC

Authorization number	N/A
Function	insecticide
Applicant	Innvigo Sp. z o.o.
Active substance(s) (incl. content)	Acetamiprid 250 g/L Deltamethrin 30 g/L
Formulation type	Suspension concentrate [SC]
Packaging	HDPE: 188 ml HDPE bottles 250 ml HDPE bottles 500 ml HDPE bottles 510 ml HDPE bottles 600 ml HDPE bottles 800 ml HDPE bottles 1000 ml HDPE bottles 2000 ml HDPE bottles 3000 ml HDPE bottles 4000 ml HDPE bottles 5000 ml HDPE bottles 10000 ml HDPE container 20000 ml HDPE container HDPE/EvOH 100 ml HDPE/EvOH bottles 250 ml HDPE/EvOH bottles 500ml in HDPE/EvOH bottles 1000ml in HDPE/EvOH bottles 5000ml in HDPE/EvOH containers 10000ml in HDPE/EvOH containers 20000ml in HDPE/EvOH containers HDPE/PA: 120 ml HDPE/PA bottles 275 ml HDPE/PA bottles 323 ml HDPE/PA bottles 500 ml HDPE/PA bottles 550 ml HDPE/PA bottles 574 ml HDPE/PA bottles 1000 ml HDPE/PA bottles 1100 ml HDPE/PA bottles 5000 ml HDPE/PA bottles 5000 ml HDPE/PA cannister 5500 ml HDPE/PA bottles 5850 ml HDPE/PA container 10000 ml HDPE/PA container HDPE/F: 120 ml HDPE/F/bottles 312 ml HDPE/F bottles 318 ml HDPE/F bottles 570 ml HDPE/F bottles 575 ml HDPE/F bottles 580 ml HDPE/F bottles 585 ml HDPE/F bottles 1150 ml HDPE/F bottles 1160 ml HDPE/F bottles 1170 ml HDPE/F bottles 1185 ml HDPe/F bottles

	1200 ml HD{E/F bottles 5880 ml HDPE/F cannister 5950 ml HDPE/F bottles 5950 ml HDPE/F cannister 10000 ml HDPE/F cannister
Coformulants of concern for national authorizations	N/A
Restrictions related to identiy	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

2.2 Conclusion

Residues:
Uses to be considered safe on the basis of EU methodology:
Residues: sugar beet (roots), winter wheat and triticale, oilseed rape

Uses to be considered non-safe on the basis of EU methodology:
Residues: ~~oilseed rape~~

The Applicant did not provide a metabolism study taking into account alkaline soils. However, it should be noted that the residue definition covers only active substances and does not include any metabolites. It is the same for main and rotational crops. The results obtained from the Hobbs, G., Inns, L. (2012) study did not change the end points in this area. In addition in Poland only 9% of soils are alkaline. Therefore**, it seems that registration of CHR/I/ADEL 280 SC is possible in Poland with the reservation in the label that the product cannot be used on alkaline soils. However, the final decision should be made by risk managers.**
The Applicant provided additional explanations include comparison that demonstrate equivalence of the mentioned studies. zRMS accepts explanations. In the opinion of zRMS, the restriction previously indicated on the label is not required. However, the study presented by the Applicant should first be assessed in "Data matching studies for acetamiprid" to indicate that the studies are equivalent, so the final decision rests the risk managers.

The Applicant should indicate access to the study Netzband, D. J. 2003.
The Applicant provided a stability study for acetamiprid in cereal grain and whole plant. Stability has been demonstrated for spring cereal plant and spring cereal grain to cover up to 157 and 149 days freezer storage, respectively. **The presented stability studies do not cover the storage time of sample collection to analysis shown in the residue studies.**
The Applicant provided additional stability study (No DPL/01/2021) of acetamiprid in cereal grain. The study was evaluated and accepted in dRR Part B7 for CHR/I/ACE 200 SE. Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg. Stability has been demonstrated for cereal grain to cover up to 200 days so cover the storage time of sample collection to analysis shown in the residue studies.

For oilseed rape the data submitted show that no exceedance of the MRL will occur. However, it should be noted that the Applicant did not provide field studies with SC formulation. Taking into account that the STMR values from the studies presented for the SE formulation are very close to the results from studies assessed at EU level for the SG and SL formulations and that the residue results are much lower (HR 0.093 mg/kg) than the applicable MRL value (0.4 mg/kg, Reg. (EU) 2019/88), the MRL in force should not be expected to be exceeded also for SC formulation. In the opinion of zRMS, authorisation based on the data provided is therefore possible, but the final decision should be made by risk managers. Please indicate PHI equal to 45 days (according to

study).
Honey
Based on the study provided by the Applicant, it can be concluded that residues in honey would lead to a calculated MRL of 0.2 mg/kg by using the new EU MRL calculator of 2015. One of the results exceeds the currently applicable MRL value, i.e. 0.05 mg/kg.
In accordance with Article 6 of Regulation (EC) No 396/2005, the Nufarm Europe Gmbh submitted a request to the competent national authority in Austria to modify the existing maximum residue levels (MRLs) for acetamiprid in honey.
According to the EFSA Journal 2022;20(8):7535: EFSA proposes to amend the existing MRL for honey. Risk Managers are given the options to either set an MRL for honey of 2 mg/kg based on the four residue trials provided with the current application (despite the deviation of not having control samples for two trials) or merge two data sets to derive an MRL of 0.3 mg/kg based on six residue trials performed in accordance with the requirements of the honey guidelines. Risk for consumers unlikely for both MRLs proposed.
Based on EFSA opinion, a draft regulation (SANTE/11278/2021) amending the MRL value for honey is now available.
In line with EFSA Journal, 22(5), e8759 which proposed lowering toxicological reference values (ADI and ARfD): For honey, it was concluded that risk for consumers was still unlikely for the new MRLs (0.3 mg/kg), proposed in SANTE/11278/2021. Risk managers can therefore implement the MRLs proposed in SANTE/11278/2021.
Until the MRL value for acetamiprid in honey is raised, uses on oilseed rape are not supported.
According to the Reg. (EU) 2025/1212 (applicable from 20/08/2025), the MRL value for acetamiprid in honey has been raised to 0.3 mg/kg.

According to the decision of the Ministry of Agriculture and Rural Development in Poland in situation where the Applicant has submitted studies which show that the value of 0.3 mg/kg in honey is not exceeded, a conditional acceptance is possible with an indication of the need for re-verification after the publication of the new MRL value.

Analytical methods
Noticed data gaps are:

- confirmatory methods for deltamethrin in soil, body fluids and tissues (data gap for active substance, have to be fulfilled after renewal of active substance);
- primary analytical method for deltamethrin in body tissues (data gap for active substance, have to be fulfilled after renewal of active substance);
- a fully validated method for acetamiprid in body fluids with LOQ 0.01 mg/L is required (data gap for active substance, have to be fulfilled after renewal of active substance);
- extraction efficiency for deltamethrin in plant and animal matrices (data gap for active substance, have to be fulfilled after renewal of active substance)

In the context of the authorisation no data gaps were found.

Fate and behaviour
Based on submitted assessment it can be concluded that the safe use for annual application of Adel 280 SC in winter OSR and winter cereals was confirmed.
For sugar beets – every other year application of Adel 280 SC is required.

2.3 Substances of concern for national monitoring

This point is not relevant for authorisation of CHR/I/ADEL 280 SC..

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:	Acute Tox. 4, H302 Repr. 2, H361d Aquatic Acute, H400 Aquatic Chronic, H410

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	
Signal word:	Warning
Hazard statement(s):	H302 – Harmful if swallowed. H361d – Suspected of damaging the unborn child. H410 – Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	WARNING SECTION OF THE LABEL (first page) P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P280 - Wear protective gloves, protective clothing, eye/face protection. P301 + P312 – IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. P308 + P313 – IF exposed or concerned: Get medical advice/ attention. P391 – Collect spillage. P501 – Dispose of contents/container in accordance with applicable regulations
Additional labelling phrases:	Contains 1,2-Benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH208]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	

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).
SPe 2	To protect groundwater, apply formulation every other year in sugar beets.
e.g.SPe3	SPe3 - Aquatic species: a) 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for sugar beet and winter cereals in Poland, b) 20 meters vegetative buffer zone and 20 meters no-spray buffer zone and 50% nozzles reduction for winter oilseed rape in BBCH 10-21 c) 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for winter oilseed rape in BBCH 30-70 SPe3 - NTA:

	Application rate of 0.16 L/ha - 75 meters buffer zone - 40 meter buffer zone with 50% nozzles reduction - 20 meters buffer zone with 75% nozzles reduction - 10 meters buffer zone with 90% nozzles reduction Application rate of 0.08 L/ha - 40 meters buffer zone - 20 meter buffer zone with 50% nozzles reduction - 10 meters buffer zone with 75% nozzles reduction - 5 meters buffer zone with 90% nozzles reduction

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

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:	
	Gloves and workwear at mixing and loading and workwear during application. ~~Drift reduction during application.~~ Due to product classification: Protective gloves, protective clothing, eye/face protection at M&L.
Worker protection:	Workwear Gloves during removing bolting sugar beets.
	-
Integrated pest management (IPM)/sustainable use:	
N/A	e.g. The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
SPe 2	To protect groundwater, apply formulation every other year in sugar beets.
N/A	Aquatic species: a) 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for sugar beet and winter cereals in Poland, b) 20 meters vegetative buffer zone and 20 meters no-spray buffer zone and 50% nozzles reduction for winter oilseed rape in BBCH 10-21 c) 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for winter oilseed rape in BBCH 30-70 NTA: Application rate of 0.16 L/ha - 75 meters buffer zone - 40 meter buffer zone with 50% nozzles reduction - 20 meters buffer zone with 75% nozzles reduction - 10 meters buffer zone with 90% nozzles reduction Application rate of 0.08 L/ha - 40 meters buffer zone - 20 meter buffer zone with 50% nozzles reduction

	- 10 meters buffer zone with 75% nozzles reduction - 5 meters buffer zone with 90% nozzles reduction
Other specific restrictions	
N/A	-

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

Integrated pest management (IPM)/sustainable use:	
N/A	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.

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.
N/A	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.	use number from GAP table in 2.6
Environmental protection:		Relevant for use no.
N/A	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed.	use number from GAP table in 2.6
SPe 2	To protect groundwater, apply formulation every other year	use number 5 from GAP table in 2.6

2.6 Intended uses (only NATIONAL GAP)

PPP product name:		Formulation type:	SC [a, b]
product code:	CHR/I/ADEL 280 SC		
Active substance 1:	acetamiprid	Conc. of as 1:	250g/l [c]
Active substance 2:	deltamethrin	Conc. of as 2:	30 g/L[c]
Active substance 3:	-	Conc. of as 3:	-
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	yes		

Field of use: Insecticide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
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]	ZRMs Conclusion
					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			
1	PL	Winter Oilseed rape (BRSNW) (0401060)	F	*Aphids: Brevicoryne brassicae, ~~Myzus persicae, Athalia rosae~~*	Spray, medium sprayer	Autumn BBCH 10-21	a)1 b)1	n/a	a) 0.08 - ~~0.16~~ L/ha b) 0.08 - ~~0.16~~ L/ha	a) (0.02 kg as/ha A + 0.0024 kg as/ha D) - ~~(0.04 kg a.s/ha A+0.0048~~	200-300	45		**Efficacy:** dose rate of 0,08 l/ha: not recommended for *Myzus persicae, Athalia rosae*

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
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)	ZRMs Conclusion
					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			
										~~kg a.s/ha D)~~ b) (0.02 kg as/ha A + 0.0024 kg as/ha D) - ~~(0.04 kg a.s/ha A+0.0048 kg a.s/ha D)~~				• conditionally accepted for *Brevicoryne brassicae* (6 efficacy trials submitted post-authorised are needed)
~~2~~	~~PL~~	~~Winter Oilseed rape (BRSNW) (0401060)~~	~~F~~	~~*Ceutorhynchus quadridens*, syn. *C. pallidactylus*, *Ceutorhynchus napi*, *Brassicogethes aeneus* syn. *Meligethes aeneus*, *Ceutorhynchus assimilis*, *Dasineura brassicae*~~	~~Spray, medium sprayer~~	~~Spring BBCH 30-70~~	~~a)1 b)1~~	~~n/a~~	~~a) 0.08 - 0.16 L/ha b) 0.08 - 0.16 L/ha~~	~~a) (0.02 kg as/ha A + 0.0024 kg as/ha D) - (0.04 kg a.s/ha A+0.0048 kg a.s/ha D) b) (0.02 kg as/ha A + 0.0024 kg as/ha D) - (0.04 kg a.s/ha A+0.0048 kg a.s/ha D)~~	~~200 - 300~~	~~45~~		Efficacy: dose rate of 0,08 l/ha not recomended

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
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)	ZRMs Conclusion
					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			
~~3~~	~~PL~~	~~Winter wheat (TRZAW) (0500090)~~	~~F~~	~~*Sitobion avenae, Thrips* sp.~~	~~Spray, medium sprayer~~	~~Spring BBCH 65-75~~	~~a)1 b)1~~	~~n/a~~	~~a) 0.08 L/ha b) 0.08 L/ha~~	~~a) (0.02 kg as/ha A + 0.0024 kg as/ha D) b) (0.02 kg as/ha A + 0.0024 kg as/ha D~~	~~200-300~~	~~35~~		Efficacy: dose rate of 0,08 l/ha not recommended
~~4~~	~~PL~~	~~Winter triticale (TTLWI) (0500090)~~	~~F~~	~~*Sitobion avenae, Thrips* sp.~~	~~Spray, medium sprayer~~	~~Spring BBCH 49-75~~	~~a)1 b)1~~	~~n/a~~	~~a) 0.08 L/ha b) 0.08 L/ha~~	~~a) (0.02 kg as/ha A + 0.0024 kg as/ha D) b) (0.02 kg as/ha A + 0.0024 kg as/ha D~~	~~200-300~~	~~35~~		Efficacy: dose rate of 0,08 l/ha not recommended
5	PL	Sugar beet (BEAVA) (900010)	F	~~*Aphis fabae,*~~ *Pegomya hyoscyami*	Spray, medium sprayer	Spring BBCH 12-19	a)1 b)1	n/a	a) 0.08 L/ha b) 0.08 - L/ha	a) (0.02 kg as/ha A + 0.0024 kg as/ha D) b) (0.02 kg as/ha A + 0.0024 kg as/ha D	200-300	n/a		Efficacy: dose rate of 0,08 l/ha not recommended against APHIFA F&B. Apply every other year

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
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)	ZRMs Conclusion
					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			
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
7														
8														
Minor uses according to Article 51 (zonal uses)														
9														
10														
Minor uses according to Article 51 (interzonal uses)														
11														
12														

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 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 homogenous white liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has no a self ignition temperature. In aqueous solution, it has a pH value around 6.93 in 1% water suspension and around 6.19 when undiluted at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of 2 years at ambient temperature when stored in *HDPE*. Its technical characteristics are acceptable for a suspension concentrate formulation.
The intended concentration of use is 0.02% to 0.08%.

3.2 Efficacy (Part B, Section 3)

The 91 trials in total (winter oilseed rape 50 trails, winter wheat 10 trials, winter triticale 15 trials, sugar beet 16 trials) were carried out in 2019, 2020 and 2021 (in winter oilseed rape – autumn application in 2019 and 2020, in winter oilseed rape – spring application, winter wheat, winter triticale and sugar beet in 2020 and 2021) in Poland in the North-East EPPO zone within the Central registration zone to evaluate the efficacy of applied at the maximum rate of 0.04 g a.s./ha acetamiprid and 0.0048 g a.s./ha delthametrin per application for the control of insects in winter oilseed rape, winter wheat, winter triticale and sugar beet. Trials were conducted in the main winter oilseed rape, winter wheat, winter triticale and sugar beet growing areas in the North-East EPPO zone in Poland.

Details are provided in dRR Part B section 3 in KCP 6 point 3.2 and KCP 6.2 point 3.2.3.

3.3 Efficacy data

The submitted efficacy/selectivity data (reports from field trials) and additional information fulfill requirements and conditions determined in the following EPPO guidelines:
- PP 1/135 (3) Phytotoxicity assessment
- PP 1/152 (3) Design and analysis of efficacy evaluation trials
- PP 1/181 (3) Conduct and reporting of efficacy evaluation trials including good experimental practice.

They were carried out on the field in the conditions of natural agrofag infestation. The efficacy trials were concluded according to the EPPO standards:
- PP 1/233(1) Athalia r, Plutella x. and Autographa g. on arable Brassicaceae
- PP 1/228(2) Aphids on beet
- PP 1/229(1) Aphids on leguminous crops
- PP 1/230(1) Aphids on potato
- PP 1/20(3) Aphids on cereals
- PP 1/85(3) Thrips on outdoor crops
- PP 1/209(2) Pegomya spp. on beet and spinach
- PP 1/24(2) Aphids on potato, sugar beet, pea, broad bean and other vegetables
- PP 1/107(3) Ceutorhynchus assimilis
- PP 1/220(1) Dasineura brassicae
- PP 1/178(3) Meligethes aeneus on rape
- PP 1/219(1) Ceutorhynchus napi and C. pallidactylus (quadridens) in OSR
- PP1/237(1) Thrips on cereals

The studies fulfill also requirements of the Commission Implementing Regulation (EU) 2020/1511 of 16 October 2020 amending 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 data requirements for plant protection products.

CHR/I/ADEL 280 SC containing 250 g/L of acetamiprid and 30 g/L of deltamethrin as active substances is prepared for the use in agricultural practice as an insecticide in the form SC – suspension concentrate.

The product constitutes a new mixture on the Polish market and according to the EPPO standard PP 1/306 (1) General principles for the development of co-formulated mixtures of plant protection products, requires justification for using mixtures from the point of view of efficacy.
Two substances contained in the product, have different mode of action (no overlapping activity), belong to the different IRAC groups and present different modes of action against pests. Acetamiprid is neonicotinoid systemic insecticide, has translaminar activity with contact and stomach action on insect pests. It is an agonist of the nicotinic acetylcholine receptor, affecting the synapses in the insect central nervous system. Acetamiprid belongs to the neonicotinoid insecticides and is classified under IRAC group 4A. On the other hand, Deltamethrin is a non-systemic insecticide which acts on the insect by contact and ingestion. Deltamethrin affect both the peripheral and central nervous systems of pest insects. Upon binding to voltage-gated sodium channels they initially stimulate nerve cells to produce repetitive discharges and eventually cause paralysis. Deltamethrin is classified as group 3A by the IRAC. Both actives are generally fast acting what is key point in the resistance management strategy. Effective insecticide resistance management (IRM) strategies have to include major points to minimize the selection of resistance to any one type of insecticide. In practice it is realized by alternations, sequences or rotations of compounds from different mode of action groups provide sustainable and effective insecticide resistance management.
Taking into account above, it might be concluded that the mixture contained two active substances with different mode of action might be a good alternative to insecticide resistance management in cereals, oilseed rape and sugar beet compared to insecticides containing one or two actives already registered.
What is more, another advantage of the mixture is that dose rates of both actives have been reduced in the product in comparison to solo registered products giving excellent efficacy results. There is a need to direct focus that the initially evaluated in the dossier dose rate 0,16 L/ha, which constituted the minimum effective dose rate and provided excellent benefit and controled pest on the high level against:
- ATALCO (E), BRVCBR (E), MYZUPE (E), CEUTQU (M), CEUTNA (M), MELIAE (E), CEUTPL (E larvae and eggs), DASYBR (E) on winter oil seed rape com-parable or better with standard products: Los Ovados 200 SE + Asystent, Decis Mega 50 EW, Inazuma 130 WG;
- MACSAV (E), METODOR (E), RHOPPA (E), THRISP (E) on winter wheat comparable or better with standard products: Decis Mega 50 EW and Fastac Active 50 ME;
- MACSAV (E), RHOPPA (E), THRISP (E) on winter triticale comparable or bet-ter with standard product Decis Mega 50 EW;
- AFIFA (E), PEGOHY (E - for larvae stadium and L - limitatig control level of 60% for egss stadium of insect) on sugar beet comparable or better with standard product Decis Mega 50 EW.

It is possible to assume that excellent performance of two actives substances in the mixture, against more presented pests, demonstrate lack of antagonism of these two active substances in the product.
The undeniable advantage of this mixture is also the fact that the mixture with 2 active substances means also less packaging and reducing number of operations for operators.
To sum up, it might be concluded that advantages of the new mixture, mentioned above might be enough justification to place CHR/I/ADEL 280 SC on the market.

No specific minimum effective dose tests are not reported. In the assessment of efficacy and phytotoxicity trials the following dose rates were tested: 0,06; 0,08; 0,1; 0,12; 0,14; 0,16 L/ha and 0,08 + Asystent + 0,1 L/ha. In the section 3.2.3, efficacy all doses were tested and the dose rate of 0,16 L/ha applied once a season in winter oilseed rape, winter wheat, winter triticale and sugar beet has demonstrated a good pest control and were considered as the minimum effective doses.

However, during the evaluation, the applicant changed the maximum effective dose in the GAP table from 0,16 L/ha to 0,08 L/ha, explaining this change by the risk of in ecotoxicology section and asking for re-evaluation of the efficacy of the product at a maximum dose of 0,08 L/ha. It has to be underlined that the dose rate 0,08 L/ha does not constitute the minimum effective dose rate in the light of EPPO standard PP 1/225 (2) Minimum effective dose.

The applicant submitted 91 reports (in total) showing the results in research into product efficacy carried out in 2019 in winter oilseed rape (autumn application - 4 trials), in 2020 in winter oilseed rape (spring application - 7 trails, autumn application – 12 trials), winter wheat (4 trails), winter triticale (3 trials) and in sugar beet (4 trials) and in 2021 in winter oilseed rape (spring application - 27 trails), winter wheat (6 trails), winter triticale (12 trials) and in sugar beet (12 trials).Trials were conducted in different regions in Poland where winter oilseed rape, winter wheat, winter triticale and sugar beet are grown commercially.

During the evaluation, the applicant changed the effective dose in the GAP table from 0,16 L/ha to 0,08 L/ha, explaining this change by the risk of in ecotoxicology section and asking for re-evaluation of the efficacy of the product at a maximum dose of 0,08 L/ha. It has to be underlined that the dose rate 0,08 L/ha does not constitute the minimum effective dose rate in the light of EPPO standard PP 1/225 (2) Minimum effective dose.

~~Due to risk in ecotoxicology section, the Applicant requested for modification in dose from 0,16 L/ha to 0,08 L/ha. The dossier was evaluated for a dose of 0,08 L/ha of CHR/I/ADEL 280 SC.~~

The obtained data in performed trials show that CHR/I/ADEL 280 SC controls the most important insects in winter oilseed rape, winter wheat, winter triticale and sugar beet.

The following table describes the effectiveness of insects control

E	at least 80 % - effectively protect
M	60 % - 80% - medium effectively protect
L	less than or 40 % - 60 % - limiting the number of pest

The obtained data in performed trials show CHR/I/ADEL 280 SC provides benefits against the most important insects in winter oilseed rape, winter wheat, winter triticale and sugar beet.

It might be concluded that the post-emergence application of CHR/I/ADEL 280 SC provides benefit and controls pest on the medium level or limited the number of pest, at 0,08 l/ha dose rate against:

- ATALCO (ME), BRVCBR (E), MYZUPE (ME), CEUTQU (L), CEUTNA (L), MELIAE (ME), CEUTPL (ME), DASYBR (ME) on winter oil seed rape;
- MACSAV (ME), THRISP (ME) on winter wheat;
- MACSAV (ME), THRISP (ME) on winter triticale;
- AFIFA (ME), PEGOHY (**E** - for larvae stadium and L - limiting control level of 46,6% for egss stadium of insect) on sugar beet

The product controlled PEGONY larvae efficiently (**E**). In 6 trials, efficacy of the product was statistically comparable to the efficacy of the reference product and into two trials product performed much more better than the reference product. It should be noted that the dose of 0,16 l/ha gave numerically better results, at around 90% and above. Nevertheless, the dose rate 0,08 l/ha seems to ensure benefit in controlling PEGONY in sugar beet.

The number of trials presented for METODR, RHOPPA in winter wheat and for RHOPPA in winter triticale is insufficient to conclude on efficacy of the product.
To confirm presented efficacy of the product in oilseed rape ~~it is proposed to~~ submission post-authorised of 2-3 efficacy trials against BRVCBR and 2-3 efficacy trials against MYZUPE would be needed.
To confirm presented efficacy of the product in oilseed rape ~~it is proposed to~~ submission post-authorised of 1-2 effi-cacy trials against CEUTNA would be needed.

Reducing the product dose by half (from 0,16 L/ha to 0,08 L/ha) significantly reduced the efficacy of the product against the pests tested. Satisfactory efficacy of 96% was only achieved by the product against BRVCBR in oilseed rape.

The risk owner has decided on the possibility of conditional authorisation of the product for this use. In view of the above, the evaluator proposes to submit at least six post-authorisation efficacy trials (optimal number of trials for a new mixture: 10 trials) confirming the mean efficacy of the product above 90%, at a dose of 0,08 l/ha.

~~However, in the opinion of ZRMS, insufficient number of trials was presented by the applicant.~~

Furthermore for pest control, the product at 0,08 l/ha showed much lower efficacy against all pests, than the reference products with one active substance. Compared to some of the reference products used in the trials, CHR/I/ADEL 280 SC showed a similar efficacy (against CEUTQU, CEUTNA, MELIAE, CEUTPL, ATALCO, MYZUPE). However, it should be noted that in both cases the efficacy was not satisfactory. Both products were moderately effective or limiting the number of pests. It is therefore worth returning to the assumption made when marketing a mixture of 2 substances, which should, in principle, give at least similar efficacy results to the reference product containing a single substance, and in the optimum solution this efficacy should be more satisfactory than for solo active substance product. This optimum solution was only provided by the dose of 0,16 l/ha.

Reducing the product dose by half (from 0,16 L/ha to 0,08 L/ha) induces yet another problem.

Using the optimum dose of plant protection products for maximum reduction of pests is a key point in a resistance management strategy. This is one of the elements that is strongly emphasised in IRAC recommendations. Reduced pesticide doses that do not provide high efficacy against pests can encourage the emergence of pest resistance. Surviving pests, over time, develop different types of resistance mechanisms that cause rapid detoxification of the active substances and further control of pests requires higher doses of insecticides or, in the worst case, the active substances become ineffective. This kind of resistace is resistance-inducing operational factors, namely the resistance arises from operational factors (Georghiou G. P., Taylor C. E. (1986). Factors influencing the evolution of resistance. Pestic. Resist. Strateg. tactics Manag. 157–619. Washington, DC: National Academies Press). In ZRMS opinion, reducing the product dose by half, not giving satisfactory efficacy, will have impact on pest resisntace development.

Reduced dose of the product (0,08 l/ha) ensured satistactory efficacy only against PEGONY in sugar beet. Therefore, dose rate of 0,08 l/ha may be recomended for protection of sugar beet against PEGONY.

Taking the above into account, a positive recommendation for registration of a dose of 0,08 L/ha in oilseed rape, cereals and sugar beet against APHIFA cannot be issued.

Insecticide CHR/I/ADEL 280 SC has demonstrated good crop tolerance to winter oilseed rape, winter wheat, winter triticale and sugar beet. Therefore concluded that CHR/I/ADEL 280 SC is safe usage at proposed rate and this support the label claim for the use in winter oilseed rape, winter wheat, winter triticale and sugar beet.

Undesirable effects are not expected on succeeding crops, adjacent crop, part of plants used for propagating purposes and beneficial organisms.

According to the above, the plant protection product CHR/I/ADEL 280 SC can be approved to the market and use in Poland according to proposed range of use – GAP
Based on submitted data the following regulation on the label is proposed:
Poland
~~Winter oilseed rape, winter wheat, winter triticale,~~ sugar beet:
Recommended dose at:
CHR/I/ADEL 280 SC 0,08 L/ha

The product CHR/I/ADEL 280 SC should be use once per season post – emergence~~ in autumn or in~~

~~spring in winter oilseed rape, in autumn in winter wheat and winter triticale, and~~ in spring in sugar beet. To avoid resistance, products contain active substance with the same group shouldn't be used year after year on the same field.

CHR/I/ADEL 280 EC is to be applied ~~in autumn:~~
~~**winter oilseed rape**~~
~~BBCH 10-21 in winter oilseed rape,~~
~~and~~ in spring:
~~**winter oilseed rape, winter wheat, winter triticale,**~~ **sugar beet against PEGONY:**
~~BBCH 30-70 in winter oilseed rape,~~
~~BBCH 65-76 in winter wheat,~~
~~BBCH 49-77 in winter triticale,~~
BBCH 12-19 in sugar beet.
Recommended volume of water 200-300 L/ha (winter oilseed rape, winter wheat, winter triticale, sugar beet)
Recommended medium droplet spraying

Use of CHR/I/ADEL 280 SC according to the proposed GAP does not represent a hazard to rotational crops and does not justify a specific labelling. CHR/I/ADEL 280 SC is not persistent in soil nor is it taken up by succeeding crops.

Details will be provided in dRR Part B section 3 in KCP 6 point 3.2 and KCP 6.2 point 3.2.3.

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

According to Acetamiprid_RAR_05_Volume 3CA B-3_2015-11-27.pdf
Acetamiprid belongs to the chemical family of neonicotinoids which are nicotinic acetylcholine receptor (nAChR) agonists. Acetamiprid belongs to the neonicotinoid insecticides and is classified under IRAC group 4A. Acetamiprid is a possible candidate for resistance development due to its single site mode of action at the nicotinic acetylcholine receptor and its persistence of action. The Insecticide Resistance Action Committee (IRAC) continuously monitors globally for cases of resistance and according to the database, some cases of resistance have been noted in the literature.

Table 3.3-1: Cases of acetamiprid resistance indicated on the IRAC database (http://www.pesticideresistance.com/search.php)

Genus Species	Taxonomy (family-order)	Common Name(s)	Cases	Group
Acarus siro	acaridae acari	grain mite	1	AG
Aphis gossypii	aphididae homoptera	melon and cotton aphid	13	AG
Bemisia tabaci	aleyrodidae homoptera	sweetpotato whitefly	44	AG
Brevicoryne brassicae	aphididae hemiptera	cabbage aphid	3	AG
Cimex lectularius	cimicidae hemiptera	bed bug	11	MED
Cydia pomonella	tortricidae lepidoptera	codling moth	16	AG
Deraeocoris brevis	miridae hemiptera		2	AG
Diaphorina citri	psilidae hemiptera	Asian Citrus Psyllid	12	AG
Dysdercus koenigii	pyrrhocoridae hemiptera	red cotton bug	9	AG
Frankliniella occidentalis	thripidae thysanoptera	western flower thrips	1	AG
Leptinotarsa decemlineata	chrysomelidae coleoptera	colorado potato beetle	1	AG
Musca domestica	muscidae diptera	house fly	2	MED

Nilaparvata lugens	delphacidae homoptera	brown planthopper	3	AG
Phenacoccus solenopsis	pseudococcidae homoptera	cotton mealybug	16	AG
Plutella xylostella	plutellidae lepidoptera	diamond-back moth	1	AG
Sitobion avenae	aphididae hemiptera	English Grain Aphid	1	AG
Spodoptera litura	noctuidae lepidoptera	mediterranean climbing cutworm	1	AG
Trialeurodes vaporariorum	aleyrodidae homoptera	greenhouse whitefly	1	AG

Table 3.3-2 List of established target site mutations associated with published cases of a nicotinic acetylcholine receptors resistance.

IRAC MoA Group	Target Site	Affected Organisms	Mutation	Literature References
4	Nicotinic acetylch-oline receptor	*Myzus persicae*	R81T	Bass et al, (2011) BMC Neuroscience, 12:51
				Beckingham et al, (2013) Pest Biochem Phys, 107:293
				Panini et al, (2014) Pest Manag Sci, 70:931
				Puinean et al, (2013) Pest Manag Sci, 69:195
		Aphis gossypii	R81T	Koo et al, (2014) Crop Protection, 55:91
				Kim et al, (2015) J Asia-Pacific Entom, 18:291
		Nilaparvata lugens	Y151S	Liu et al, (2005) PNAS, 102:8420

Cross resistance

In terms of cross resistance, IRAC classifies acetamiprid as a Subgroup 4A active and categorised as low risk of metabolic cross-resistance between other Subgroup 4 Nicotinic acetylcholine receptor (nAChR) agonists which include nicotine (Subgroup 4B), sulfoxaflor (Subgroup 4C) and butenolides (Subgroup 4D).

Agronomic risk

The risk of resistance inherent in the plant protection product and the pest can be increased by certain conditions of use. This agronomic risk affects selection pressure on the development of resistance and is influenced by the particular characteristics of the crop, the geographic area in which the product is applied and the use pattern.
Agronomic risk can be enhanced by monoculture in particular regions. Together with agronomic risk, it can be concluded, that the risk for the development of acetamiprid resistant pests biotypes is considered low to medium.
Besides generally recommended measures to avoid resistance, no special restrictions on the label are deemed necessary. However, in order to further prevent any resistance risk, non-chemical measures of pests control should be considered. In chemical pests control, alternation of insecticides is highly recommended. Nevertheless, integrated pests management measures should be considered, since these are most effective in the prevention of insecticide resistance in pests.
For resistance risk management purposes, a number of anti-resistance management recommendations are available.

- Follow good IPM practices such as scouting, utilizing economic thresholds and preservation of beneficials.
- Utilize alternation of insecticides with different mode of action corresponding to the life cycle of pests, to ensure that consecutive generations are not treated with insecticides with the same mode of action.
- Follow the maximum number of applications per season and the full effective dose rates and intervals recommended on labels.
- If it appears that the neonicotinoids are not working, discontinue usage of this class of chemistry and assay the population for susceptibility to this class of chemistry. See also the General Principles of Insecticide Resistance Management from IRAC[1].

According to Deltamethrin_RAR_05_Volume_3CA_B-3_2018-02-20.pdf
Deltamethrin is a pyrethroid (Insecticide Resistance Action Committee (IRAC) mode of action group 3a, sodium channel modulators. There are a number of global cases of resistance to pyrethroids, with both metabolic (involving elevated levels of detoxifying enzymes, including esterase and monooxygenase), and target site knock down resistance (kdr or super-kdr, varioius mutations at the voltage gated sodium channel). A wide range of insect species, across various orders, have developed resistance, although field rates may stil have a degree of effectiveness. Resistance in one pyrethroid usually confers cross-resistance across the group. Key European examples include Colorado beetle (L. decemlineata), peach potato aphid (M. persicae), Cotton aphid (A. gossypii), and Cotton bollworm (H. armigera), pollen beetle (Meligethes aeneus) and more recently the grain aphid (S. avenae) in UK cereals. In the case of the latter, a target site mode of action has been identified, and only in heterozygote indivividuals. Currently field approved rates remain effective.
In fact since the applicant's submission, further cases of resistance have been identified. Most important has been cabbage stem flea beetle (Psylliodes chrysocephala). In most of Europe currently only target site mechanism has been identified, and generally field rate remains effective, however in the UK there is a further metabolic mechanism as well as target site, resulting in lack of control. In 2015 resistance was identified in the UK in pea and bean weevil (Sitona lineatus). The applicant has argued that the risks of resistance are considered overall judged as moderate, due to the properties of the compound, mode of action, persistence and metabolism. Although it is acknowledged that crop, pest and environmental factors result in complex case by case risks. In the rapporteur assessment, the risk should always be considered as high, given the regular occurrence of new cases.

Guidelines

- Long-term rotation act best against rapid selection of resistant populations. This means, the change of

active ingredient should take place when the next generation of the pest has to be treated to prevent a

selection with the other chemical group within the same generation of the pest.

- Control in alternation should not be carried out with products of just one chemical class.
- The use of non-specific products (e.g. oils) helps to prevent the development of resistance.
- All possible cultivation techniques should be used alongside physical and biological pest control methods.
- Crop protection products should be used in such a way as to reduce the risk to beneficial organisms.
- Preparations should be used at the recommended doses and spray intervals.
- Ensure that uniform spray coverage is achieved.
- If signs of diminished efficacy become evident, do not carry out a follow-up treatment with an active

ingredient of the same chemical class.

• Monitor the situation wherever possible so as to detect the first signs of resistance development.

Details will be provided in the dRR Part B Section 3 KCP 6.3 point 3.3.

3.3.2 Adverse effects on treated crops

91 trials in total (winter oilseed rape 50 trails, winter wheat 10 trials, winter triticale 15 trials and sugar beet 16 trials) were carried out in Poland in 2019, 2020 and 2021 on a wide range of commercially grown varieties. There were not observed any phytotoxicity symptoms on tested product and standard. In the course of studies carried out in Poland in the season of 2019, 2020 and 2021 on product CHR/I/ADEL 280 SC the insecticide has not been observed to have any significant influence on yield.
The product may be used in winter oilseed rape, winter wheat, winter triticale and sugar beet.

Details will be provided in the dRR Part B Section 3 KCP 6.4 point 3.4.

3.3.3 Observations on other undesirable or unintended side-effects

Acetamiprid residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here (Palau I., 2021, ACI19-002). It is very unlikely that residues will be present in succeeding crops.

Delthamethrin residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here (Krebs, Eickhoff, and Raquet, 1986). It is very unlikely that residues will be present in succeeding crops.

Details will be provided in the dRR Part B Section 3 KCP 6.5 point 3.5.

3.4 Methods of analysis (Part B, Section 5)

Analytical methods for determination of acetamiprid, deltamethrin and their relevant impurities and relevance of CIPAC methods in CHR/I/ADEL 280 SC were not evaluated as part of the EU review of acetamiprid and deltamethrin. Therefore all relevant data are provided and are considered adequate.

3.4.1 Analytical method for the formulation

The method for determination of active substances in CHR/I/ADEL 280 SC preparation is specific. The validation parameters for linearity, instrument precision, repeatability and accuracy are within the acceptance range. The determined average content of active substance in CHR/I/ADEL 280 SC is respectively:
Deltamethrin: 3.04% (32.94 g/l)
Acetamiprid: 24.08% (261.29 g/l)

3.4.2 Analytical methods for residues

Analytical methods for residues were not evaluated as part of the EU review of acetamiprid and deltamethrin. Therefore all relevant data are provided section B5.

Noticed data gaps are:

- confirmatory methods for deltamethrin in soil, body fluids and tissues (data gap for active substance, have to be fulfilled after renewal of active substance);
- primary analytical method for deltamethrin in body tissues (data gap for active substance, have to be fulfilled after renewal of active substance);
- a fully validated method for acetamiprid in body fluids with LOQ 0.01 mg/L is required (data gap for active substance, have to be fulfilled after renewal of active substance);
- extraction efficiency for deltamethrin in plant and animal matrices (data gap for active substance, have to be fulfilled after renewal of active substance)

In the context of the authorisation no data gaps were found.

3.5 Mammalian toxicology (Part B, Section 6)

Table 3.5-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for CHR/I/ADEL 280 SC

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (calculation method)	> 300 mg/kg bw	Yes	Acute Tox. 4, H302	M. Kolodziej, 2021
LD_{50} dermal, rat (calculation method)	> 2 000 mg/kg bw	Yes	None	M. Kolodziej, 2021
LC_{50} inhalation, rat (calculation method)	>20 mg/L air	Yes	None	M. Kolodziej, 2021
Skin irritation (calculation method)	Non-irritant	Yes	None	M. Kolodziej, 2021
Eye irritation, (calculation method)	Non-irritant	Yes	None	M. Kolodziej, 2021
Skin sensitisation, (calculation method)	Non-sensitising	Yes	None	M. Kolodziej, 2021
Supplementary studies for combinations of plant protection products	Suspected of damaging the unborn child.	Yes	Repr. 2, H361d	M. Kolodziej, 2021

3.5.1 Acute toxicity

Acute toxicity studies for CHR/I/ADEL 280 SC were not evaluated as part of the EU review of acetamiprid and deltamethrin. Therefore, all relevant data were provided and are considered adequate.

3.5.2 Operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) and acute acceptable operator exposure level (AAOEL for Acetamiprid) will not be exceeded under conditions of intended uses and considering above men-tioned personal protective equipment (PPE) ~~and a drift reduction technology~~, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Gloves and workwear at mixing and loading and workwear during application. ~~Drift reduction during application.~~ Due to product classification: Protective gloves, protective clothing, eye/face protection at M&L.

3.5.3 Worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses a study to provide measurements of worker exposure was not necessary and was there-fore not performed.

	Result	PPE / Risk mitigation measures
Workers	Acceptable	Workwear Gloves during removing bolting sugar beets.

3.5.4 Bystander and resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Acetamiprid and deltamethrin will not be exceeded under conditions of intended uses a study to pro-vide measurements of bystander/resident exposure was not necessary and was therefore not per-formed.

	Result	PPE / Risk mitigation measures
Bystanders	Acceptable	None
Residents	Acceptable	None

3.5.5 Residues

Noticed data gaps are:
Acetamiprid:

- The Applicant did not provide a metabolism study taking into account alkaline soils. However, it should be noted that the residue definition covers only active substances and does not include any metabolites. It is the same for main and rotational crops. The results obtained from the Hobbs, G., Inns, L. (2012) study did not change the end points in this area. In addition in Poland only 9% of soils are alkaline. Therefore, **it seems that registration of CHR/I/ADEL 280 SC is possible in Poland with the reservation in the label that the product cannot be used on alkaline soils. However, the final decision should be made by risk managers**.

The Applicant provided additional explanations include comparison that demonstrate equivalence of the mentioned studies. zRMS accepts explanations. In the opinion of zRMS, the restriction previously indicated on the label is not required. However, the study presented by the Applicant should first be assessed in "Data matching studies for acetamiprid" to indicate that the studies are equivalent, so **the final decision rests the risk managers.**

- Based on the study provided by the Applicant, it can be concluded that residues in honey would lead to a calculated MRL of 0.2 mg/kg by using the new EU MRL calculator of 2015. One of the results exceeds the currently applicable MRL value, i.e. 0.05 mg/kg.

Until the MRL value for acetamiprid in honey is raised, uses on oilseed rape are not supported.

According to the decision of the Ministry of Agriculture and Rural Development in Poland in situation where the Applicant has submitted studies which show that the value of 0.3 mg/kg in honey is not exceeded, a conditional acceptance is possible with an indication of the need for re-verification after the publication of the new MRL value.
According to the Reg. (EU) 2025/1212 (applicable from 20/08/2025), the MRL value for acetamiprid in honey has been raised to 0.3 mg/kg.

Acetamiprid
As of the assessment date, the applicable MRLs were included in the Regulation (EU) 2019/88. A new version of the regulation will soon come into force. However, SANTE 11278/2021 does not change the MRL values for sugar beet, wheat and rapeseed.

Please note that in May 2024, EFSA published Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites. EFSA Journal, 22(5), e875. It is recommended:

- To modify the residue definition for risk assessment in **leafy and fruit crops** as follows: 'sum of acetamiprid and N- desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid'.
- To require additional supervised residue trials analysing simultaneously for acetamiprid and N-desmethyl-acetamiprid (IM-2-1), supporting existing and any new intended uses on **leafy and fruit crops**.
- To derive robust conversion factors (CF) from enforcement to risk assessment. Robust CFs for each plant commodity should be derived based on supervised residue trials compliant with authorised or intended GAPs and analysing simultaneously for acetamiprid and N-desmethyl-acetamiprid

(IM-2-1).
A risk for consumer has been identified for 38 MRLs currently in place in the EU Regulation. Consequently, it is recommended to lower the existing MRLs for these commodities. This does not apply to crops under consideration for CHR/I/ADEL 280 SC.

The available monitoring data indicate that metabolite IM-2-1 may be a relevant component of the residues in some commodities belonging to the fruit and leafy crop groups and, **very unlikely in pulses and oilseeds crops**. No major differences were found between unprocessed and processed commodities.
Pulses/oilseeds:
The overall average for the metabolite IM-2-1 in pulses and oilseeds is below 0.01 mg/kg. Metabolite IM-2-1 is below the LOQ in 903 out of the 914 available samples available on pulses and oilseeds. The 11 samples in which metabolite IM-2-1 was quantified correspond to beans with pods (7), peas with pods (2) and peas without pods (2). Therefore, there are no pulses and oilseeds commodities in the short-listed commodities where metabolite IM-2-1 was quantified in more than 10 samples. The quantified values ranged between 0.001 and 0.012 mg/kg. In all samples, the calculated ratio was below the value of 1, meaning that the concentration of IM-2-1 was always lower than the one of acetamiprid. Overall, it is concluded that **the metabolite IM-2-1 is not a relevant component of the residues in pulses and oilseeds**, based to the available monitoring samples.
Regarding pulses/oilseeds, root crops and cereals, the collected monitoring data do not reveal a significant occurrence of IM-2-1 in commodities belonging to these categories. Therefore, **it is not proposed to modify the residue definition for risk assessment in pulses/oilseeds, root crops and cereals, which therefore remains acetamiprid**. Regarding the residue definition for enforcement, the available data do not indicate a need to modify the existing definition because acetamiprid is still a sufficient marker of the residues in all crop groups.
The existing toxicological reference values (ADI = 0.025 mg/kg bw per day; ARfD = 0.025 mg/kg bw) for acetamiprid were derived in the framework of the EU pesticides peer review (European Commission, 2018). However, in the framework of the present mandate, EFSA derived new toxicological reference values for acetamiprid. The newly derived toxicological reference values are lower than the existing ones: **ADI = 0.005 mg/kg bw per day; ARfD = 0.005 mg/kg bw.**
Furthermore, for honey (0.3 mg/kg), it was concluded that risk for consumers was still unlikely for the new MRLs proposed in SANTE/11278/2021. For these crops, risk managers can therefore implement the MRLs proposed in SANTE/11278/2021.

Metabolism in rotational crops
According to the EFSA Journal 2016;14(11):4610: Having regard to the low persistence of acetamiprid in soil (highest field period required for 90% dissipation (DT90) 43 days and 20°C lab DT90 54 days), confined rotational crop studies were not conducted with the active substance and the metabolism in rotational crops was investigated using the more persistent soil metabolite IM-1-5 (period required for 50% dissipation (DT50) 319–663 days) at a single plant back interval of 0 days. In the different rotational crops investigated (wheat, turnip, spinach), IM-1-5 was shown to remain the main component of the radioactive residues accounting in mature plant at harvest for 77–94% TRR. Additional field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha, confirmed that acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops.
However, the study: Hobbs, G., Inns, L., 2012: 14C]-IM-1-5: Uptake and Metabolism of Soil Residues in Confined Rotational Crops, Report no . RD-02391assessed in RAR is still protected.
A new study on the nature of residues in rotational crops was conducted for data matching purposes. Metabolism in succeeding crops was investigated with the IM-1-5. [14C]-IM-1-5 was applied on bare soil, supplied as [pyridyl-2,6-14C] decyano-acetamiprid hydrochloride, at a nominal rate of 0.266 kg/ha. The application rate of the study presented in the RAR (The Netherlands, 2015, 2016) was with the same dose 266 g a.s./ha. The seed used for this study was spring wheat, turnip and spinach. Minor uptake of IM-1-5 was observed for spinach and wheat grain. IM-1-5 residues within these sample types were below the 0.01 mg/kg. Some notable uptake of the test item was observed for wheat forage hay and straw. Residues were also detected in turnips above the 0.01 mg/kg. 24.68 % of the total radioactive residues

remained bound to wheat hay and 22.26 % bound to wheat straw. However, uptake into the wheat hay, 22.26 % only represented 0.005 mg/kg. Only limited metabolism of IM-1-5 is observed in the crops and therefore no metabolic pathway is proposed. However, the study used sandy loam soil and not calcareous soil. It should be noted that according to the EFSA Journal 2016;14(11):4610 formation of metabolite IM-1-5 occurred only in the soils stated to be calcareous.
The Applicant did not provide a metabolism study taking into account alkaline soils. However, it should be noted that the residue definition covers only active substances and does not include any metabolites. It is the same for main and rotational crops. The results obtained from the Hobbs, G., Inns, L. (2012) study did not change the end points in this area. In addition in Poland only 9% of soils are alkaline. Therefore, **it seems that registration of CHR/I/ADEL 280 SC is possible in Poland with the reservation in the label that the product cannot be used on alkaline soils. However, the final decision should be made by risk managers.**
The Applicant provided additional explanations include comparison that demonstrate equivalence of the mentioned studies. zRMS accepts explanations. In the opinion of zRMS, the restriction previously indicated on the label is not required. However, the study presented by the Applicant should first be assessed in "Data matching studies for acetamiprid" to indicate that the studies are equivalent, so the final decision rests the risk managers.

Metabolism in livestock
According to the EFSA Journal 2016;14(11):4610: Metabolism studies on livestock conducted on animals dosed with 14 C-acetamiprid at 10 mg/kg dry matter (DM) over 7 (goat) or 17 (poultry) consecutive days were submitted. Most of the radioactivity was excreted in urine and faeces and only 2% of the administrated radioactivity was recovered in organs, tissues, blood and milk or eggs. Acetamiprid was extensively metabolised and not detected in any animal matrices except in milk. The major component was identified as the N-desmethyl metabolite(IM-2-1) representing 50–89% TRR in all animal matrices, except goat muscle (10% TRR) where residues were mainly composed of the metabolite IM-2-2 accounting for 50% TRR (0.03 mg eq/kg).The metabolic profile was confirmed by the feeding studies on cow and poultry where IM-2-1 was detected as the most abundant component in all animal matrices. Acetamiprid was not present in poultry and only detected in significant levels in milk at all feeding levels and at the highest feeding level in the other matrices. Based on these studies, **the residue definition was proposed as 'IM-2-1 expressed as acetamiprid' for monitoring and as 'the sum of acetamiprid and IM-2-1, expressed as acetamiprid' for risk assessment.** Conversion factors (CF) of 1.3 and 1.1 were derived for milk and other mammalian products, respectively. CF values were concluded to be unnecessary for poultry products. It is highlighted that RMS expressed its disagreement on the livestock residue definition for risk assessment and proposes to include IM-2-1 compound only.
Animal residue definition for monitoring currently implemented in the EU legislation (Reg. (EU) 2019/88) is sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid.

Stability study
The Applicant should indicate access to the study Netzband, D. J. 2003.
The Applicant provided a stability study for acetamiprid in cereal grain and whole plant. Stability has been demonstrated for spring cereal plant and spring cereal grain to cover up to 157 and 149 days freezer storage, respectively. **The presented stability studies do not cover the storage time of sample collection to analysis shown in the residue studies.**
The Applicant provided additional stability study (No DPL/01/2021) of acetamiprid in cereal grain. The study was evaluated and accepted in dRR Part B7 for CHR/I/ACE 200 SE. Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg. Stability has been demonstrated for cereal grain to cover up to 200 days so cover the storage time of sample collection to analysis shown in the residue studies.

Magnitude of residues in plants
Wheat
EU GAP, EFSA Journal 2016;14(2):4385:
2 appl., interval 14 days, BBCH 51-79, max appl. rate per treatment 42 g a.s./ha, PHI-28 days, SL

formulation
Intended GAP: 1 appl., BBCH 37-75, max appl. rate 40 g a.s./ha, SC formulation

The Applicant provided 5 studies performed for the SE formulation and 4 for the SC formulation. Most of them (all but two studies for SE formulation) are not covered by stability studies for wheat grain. The storage period ranges from 155 to 192 days for wheat grain, while stability studies were performed for a maximum of 149 days in this matrices. Taking the above into account, the results of the presented studies cannot support the proposed use in wheat.
The proposed uses on wheat and triticale are not accepted.
The Applicant provided additional stability study (No DPL/01/2021) of acetamiprid in cereal grain. Stability of acetamiprid has been demonstrated in cereal grain to cover up to 200 days so cover the storage time of sample collection to analysis shown in the residue studies.
All studies showed no acetamiprid residues above LOQ in cereal grain.
The data submitted show that no exceedance of the MRL will occur.
Residues of acetamiprid in straw (SC formulation): 0.076, 0.086, 0.1, 0.26 mg/kg.
Residues of acetamiprid in straw (SE formulation): < 0.01, 0.047, 0.066, 0.29, 0.52 mg/kg
The use is considered acceptable.

Sugar beet
Intended GAP
1 appl., BBCH 12-19, max appl. rate 40 g a.s./ha, SC formulation

The Applicant provided 4 studies performed for the SE formulation and 4 for the SC formulation. All presented studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application. All studies showed no acetamiprid residues above LOD in both leaves and roots.
The data submitted show that no exceedance of the MRL will occur.
The use is considered acceptable.

Rapeseed
GAP assessed at EU level:
EFSA Journal 2011;9(7):2328: formulation SG,
1 appl., BBCH 75-81, max appl. rate 50 g a.s./ha, PHI-28,
Residues of acetamiprid in seeds harvested at the PHI: 3 x <0.01; 0.03; 0.04; 2 x 0.08; 0.1 (STMR 0.035 mg/kg)

EFSA Journal 2016;14(2):4385:
2 app., 1st appl. BBCH 59, 2nd appl. BBCH 80, max appl. rate per treatment 42 g a.s./ha, PHI- n.r.,
two different formulations were investigated (SL and SG) and the highest residue level from these two formulations was selected for MRL calculation.
Residues of acetamiprid in seeds harvested at the PHI ranging from 26 to 43 days: < 0.01; 2 x 0.02; 0.021; 0.036; 0.05; 0.11; 0.20 (STMR 0.036 mg/kg)

Intended cGAP: formulation SC, 1 appl., BBCH 30-70, max appl. rate 40 g a.s./ha
The Applicant provided 8 studies performed for the SE formulation. All presented studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application.
Residues of acetamiprid in seeds harvested at the PHI 39-45: 2 x <0.012; 0.014; 0.015; 0.045; 0.087; 0.089; 0.093 (STMR 0.03 mg/kg).

The data submitted show that no exceedance of the MRL will occur. However, it should be noted that the Applicant did not provide field studies with SC formulation. Taking into account that the STMR values from the studies presented for the SE formulation are very close to the results from studies assessed at EU level for the SG and SL formulations and that the residue results are much lower (HR 0.093 mg/kg) than the applicable MRL value (0.4 mg/kg, Reg. (EU) 2019/88), the MRL

in force should not be expected to be exceeded also for SC formulation. In the opinion of zRMS, authorisation based on the data provided is therefore possible, but the final decision should be made by risk managers. Please indicate PHI equal to 45 days.

Processing studies
According to the EFSA Journal 2016;14(2):4385: The effect of processing on the nature of acetamiprid residues was investigated and the results indicated that acetamiprid is hydrolytically stable under standard hydrolysis conditions (Greece, 2001; EFSA, 2011). Thus, residue definitions proposed for primary crops are also applicable for processed commodities.
Some residue trials on olives and gherkins were performed at exaggerated dose rates (10x and 5x, respectively) to generate samples for processing studies (Greece, 2015b). Olives were processed into canned olives or raw oil; the relevant intermediate products – cake and brine – were also analysed for residues. Gherkins were canned; in two trials, washed gherkins and brine were also analysed for residues. However, no details of the processing conditions were provided. A reduction of residues is observed in all processed edible commodities: canned olives, raw olive oil and canned gherkins.

According to Regulation (EU) 283/2013 processing studies are required if residues in plants to be processed are ≥0.1 mg/kg. If the level of residues is <0.1 mg/kg, processing studies shall be carried out if the contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is ≥10% of the ADI or if the estimated daily intake is ≥10% of the ARfD for any European consumer group diet.
Wheat
No residues above 0.1 mg/kg were found and TMDI is <10% of the ADI and IESTI is < 10% (6%)of ARfD. Therefore, processing studies are not required as they are not expected to affect the outcome of the risk assessment significantly.
Oilseed rape
No residues above 0.1 mg/kg (HR = 0.093 mg/kg) were found and TMDI is <10% of the ADI and IESTI is < 10% of ARfD. Therefore, processing studies are not required as they are not expected to affect the outcome of the risk assessment significantly.
Sugar beet
No residues above 0.1 mg/kg were found and TMDI is <10% (0.2%) of the ADI and IESTI is < 10% of ARfD. Therefore, processing studies are not required as they are not expected to affect the outcome of the risk assessment significantly.

Field rotational crop studies
According to the EFSA Journal 2018;16(5):5262: Field studies in NEU and SEU conducted at ca 300 g/ha on bare soil showed that no residues are expected in rotational crops.
Considering that the conditions of application of the representative uses assessed during the renewal and in the new provided by the Applicant study cover the intended use of acetamiprid in CHR/I/ADEL 280 SC, this conclusion is still relevant in the framework of the present assessment.

Honey
Based on the study provided by the Applicant, it can be concluded that residues in honey would lead to a calculated MRL of 0.2 mg/kg by using the new EU MRL calculator of 2015. One of the results exceeds the currently applicable MRL value, i.e. 0.05 mg/kg.
In accordance with Article 6 of Regulation (EC) No 396/2005, the Nufarm Europe Gmbh submitted a request to the competent national authority in Austria to modify the existing maximum residue levels (MRLs) for acetamiprid in honey.
According to the EFSA Journal 2022;20(8):7535: EFSA proposes to amend the existing MRL for honey. Risk Managers are given the options to either set an MRL for honey of 2 mg/kg based on the four residue trials provided with the current application (despite the deviation of not having control samples for two trials) or merge two data sets to derive an MRL of 0.3 mg/kg based on six residue trials performed in accordance with the requirements of the honey guidelines. Risk for consumers unlikely for both MRLs proposed.
Based on EFSA opinion, a draft regulation (SANTE/11278/2021) amending the MRL value for honey is

now available.
In line with EFSA Journal, 22(5), e8759 which proposed lowering toxicological reference values (ADI and ARfD): For honey, it was concluded that risk for consumers was still unlikely for the new MRLs (0.3 mg/kg), proposed in SANTE/11278/2021. Risk managers can therefore implement the MRLs proposed in SANTE/11278/2021.
Until the MRL value for acetamiprid in honey is raised, uses on oilseed rape are not supported.
According to the Reg. (EU) 2025/1212 (applicable from 20/08/2025), the MRL value for acetamiprid in honey has been raised to 0.3 mg/kg.

Deltamethrin
Stability study
Stability of residues in plants according to EFSA Journal 2015;13(11):4309:

Plant products	Category	Commodity	T (°C)	Stability (months)
	High water content	Lettuce	-20	26
		Cabbage	-20	34
		Tomato	-20	24
	High oil content	Cotton seed	-12	30
	Dry/High starch	Cereals grain	-12	9
	Studies cover also the stability of the isomers included in the residue definition. Result from the storage stability study on tomatoes (borderline between highwater and acidic commodity) are extrapolated to the acidic commodities. Sources: Sweden, 1998, 2002; FAO, 2002.			

Data are sufficient to cover the trials supporting intended GAPs of CHR/I/ADEL 280 SC.

Metabolism in crops
The metabolism of deltamethrin in primary crops belonging to the groups of fruits (apples and tomatoes), pulses and oilseeds (cotton seed) and cereals (maize) was investigated in the framework of the MRL review (EFSA, 2015). The metabolism studies after foliar and local treatment showed that the metabolic pathway is similar in all crop groups investigated. Deltamethrin was the main component of residues (up to 77% of the total radioactive residue (TRR)) with alpha-R-isomer and trans-isomer accounting for approximately 30–40% of the TRR.
For the intended uses on oilseed rape, wheat and sugar beet, the metabolic behaviour in primary crops is sufficiently addressed.
Deltamethrin is proposed to be used on wheat, oilseed rape and sugar beet which can be grown in rotation with other crops. A rotational crop metabolism study is available and was assessed in the framework of the MRL review (EFSA Journal 2015;13(11):4309). EFSA concluded that the metabolism in rotational crops was comparable to that in primary crops.
For the intended uses, the metabolic behaviour in rotational crops is sufficiently addressed and no further information is required.
The effect of processing on the nature of deltamethrin has been investigated in the framework of Directive 91/414/EEC (Sweden, 2002) and in the framework of the MRL review (EFSA Journal 2015;13(11):4309). It was concluded that deltamethrin is hydrolytically stable under conditions simulating pasteurisation and brewing, baking and boiling. Under sterilisation conditions, significant degradation of deltamethrin in two main metabolites was observed, which were considered during the peer review as well-known plant metabolites with no toxicological relevance, and therefore, this evidence base was accepted during the MRL review (EFSA Journal 2015;13(11):4309). In the MRL review, it was outlined that in the hydrolysis studies, residues were reported as deltamethrin however it was not clear whether the analytical method used analysed for the sum of all isomers.
Residue definition:
For enforcement: deltamethrin (cis-deltamethrin), Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342;
For risk assessment: sum of deltamethrin ant its alpha-R isomer and trans-isomer (tentative), EFSA Journal 2015;13(11):4309

Metabolism in livestock
According to the EFSA Journal 2015;13(11):4309: Metabolism of deltamethrin in ruminants and poultry was investigated in the framework of Directive 91/414/EEC (Sweden, 1998, 2002).
Cows were dosed for three consecutive days with 10 mg/kg body weight (bw) per day (labelled on both the benzyl- and dimethyl-rings, one cow for each label). Deltamethrin was the major compound in all tissues accounting for up to 90% of the TRR in fat. Metabolites Br2CA andPB acid were present at the same level as parent in liver and kidney (23 and 33% of the TRR, respectively).
Hens were dosed for three consecutive days with 5 mg/kg bw per day (also labelled on both rings). In poultry tissues and eggs, deltamethrin was the main compound found (19-65% of the TRR), except in kidney where, apart for deltamethrin (25-28% TRR), metabolites c-Br2CA and c/t-COOH-c-Br2CA (together 22% TRR), and c-CH2OH-c-Br2CA and t-COOH-c-CH2OH-c-Br2CA-lactone (together 15-22% TRR) were also identified.
As metabolic pathways are expected to be similar in ruminants and rodents, the results of the cow metabolism study could be extrapolated to pigs.
Residue definition:
For enforcement: deltamethrin (cis-deltamethrin), Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342;
For risk assessment: sum of deltamethrin ant its alpha-R isomer and trans-isomer, EFSA Journal 2015;13(11):4309

Magnitude of residues in plants
Wheat
EU GAP, EFSA Journal 2016;14(2):4385:
3 appl., interval 14 days, BBCH n.a., max appl. rate per treatment 7.5 g a.s./ha, PHI-30 days, EC formulation
Intended GAP: 1 appl., BBCH 37-75, max appl. rate 4.8 g a.s./ha, SC formulation

The Applicant provided 4 adequate independent studies performed for the SC formulation. All of them are covered by stability studies for wheat grain. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application. All studies showed no deltamethrin residues above LOQ in grain. Straw residue results were found in the range 0.1 mg/kg – 0.46 mg/kg (STMR – 0.155 mg/kg).
The data submitted show that no exceedance of the MRL (1 mg/kg, according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.
The proposed uses on wheat and triticale are accepted.

Oilseed rape
EU GAP, EFSA Journal 2015;13(11):4309:
4 appl., interval 14 days, BBCH n.a., max appl. rate per treatment 6.25 g a.s./ha, PHI-45 days, EC formulation
Intended cGAP: 1 appl., BBCH 30-70, max appl. rate 4.8 g a.s./ha, SC formulation
The Applicant provided 4 adequate independent studies performed for the SC formulation. All of them are covered by stability studies for wheat grain. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application. All studies showed no deltamethrin residues above LOQ in seeds.
The data submitted show that no exceedance of the MRL (0.2 mg/kg according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.
The proposed uses of deltamethrin on oilseed rape are accepted.

Sugar beets
EU GAP, EFSA Journal 2015;13(11):4309:
3 appl., BBCH n.a., max appl. rate per treatment 10 g a.s./ha, PHI-3 days, EC formulation
Intended cGAP: 1 appl., BBCH 12-19, max appl. rate 4.8 g a.s./ha, SC formulation
The Applicant provided 5 adequate independent studies performed for the SC formulation. All of them are covered by stability studies. The studies were performed in accordance with the proposed GAP in

terms of the number of applications, application rate and growth stage of crop during application.
All studies showed no deltamethrin residues above LOD in roots. One sample of leaves with tops contained deltamethrin at a level of 0.01 mg/kg. No residues above LOD were found in the remaining samples of leaves.
The data submitted show that no exceedance of the MRL (0.02 mg/kg according to Reg. (EU) 2018/832 and 0.01 mg/kg for sugar beet roots in not yet applicable Reg. (EU) 2024/1342) will occur.
The proposed use of deltamethrin on sugar beets is accepted.

Honey
Sugar beet, wheat and triticale have no melliferous capacity therefore magnitude of residues in honey are not necessary. For oilseed rape application new magnitude of residues in honey were provided.
The Applicant provided 4 adequate studies performed for the SC formulation. All of them are covered by stability studies. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage.
All studies showed no deltamethrin residues above LOD in honey.
Samples were analysed 15 days after sampling. Storage stability data are not normally required for samples extracted and analysed within 30 days from sampling.
The data submitted show that no exceedance of the MRL (0.05 mg/kg for honey according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.

Processing studies
According to the EFSA Journal 2015;13(11):4309: Studies investigating the magnitude of residues in processed commodities of apples, tomatoes, pulses, sunflower seeds, rape seeds, cotton seed, olive, barley, maize, rice (Sweden, 1998, 2002), potatoes (EFSA, 2010) and strawberries (Italy, 2015) were reported. In these studies, residues were always reported as 'deltamethrin' and it is not clear if an analytical method covering all the isomers has been used. Consequently, no robust processing factors for enforcement and risk assessment could be derived. The processing factors should therefore be considered as indicative only.

Residues in succeeding crops
According to the EFSA Journal 2015;13(11):4309: The results of the confined rotational crop study is confirmed by a field rotational crop study analysing residues in spinach, carrots and radishes planted in soil treated once at 0.12 kg a.s./ha. Considering that deltamethrin was applied to a bare soil (interception of active substance by the plants is expected in practice), it can be concluded that residue levels in rotational commodities are not expected to exceed 0.01 mg/kg provided that deltamethrin is used according to the GAPs assessed in the present review.
Studies evaluated at EU level represent a much worse scenario, the dose proposed in the intended GAP is significantly lower. Residue levels in rotational commodities are not expected to exceed 0.01 mg/kg provided that deltamethrin is used according to the intended GAPs.

3.5.6 Consumer exposure

Table 3.5-2: Consumer risk assessment for acetamiprid

ADI	0.025 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo	3 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	3% % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Wheat: 6 % (based on NL toddler) rapeseeds: 2 % (based on NL toddler) beet leaves 0.8% (based on NL toddler)
ARfD	0.025 mg/kg bw

* include raw and processed commodities if both values are required for PRIMo

In addition, TMDI calculation was performed taking into account the applicable EU MRLs (Reg. (EU) 2019/88) for the intended crops and all products of animal origin, except for honey, where the new proposed MRL have been considered. For IESTI calculation the current EU MRLs were used for the intended crops, except for honey, where the new proposed MRL have been considered.

TMDI (% ADI) according to EFSA PRIMo 3.1	56% for milk (based on NL toddler) 7% for wheat (based on GEMS/Food G06) 99% for milk cattle (based on children) 5% for wheat, milling (wholemeal) (based on children)
IESTI (% ARfD) according to EFSA PRIMo3.1	6% wheat 2% rapeseeds Processed commodities 5% whet/milling (flour) 4% sugar beets (root)/sugar 0.9% rapeseeds/oils

Calculations were also made taking into account the reduced ADI and ARfD values proposed in EFSA Journal, 22(5), e875.
The chronic risk assessment was performed taking into account the applicable EU MRLs (Reg. (EU) 2019/88) for the intended crops, except for honey, where the new proposed MRL have been considered and STMR values given in EFSA Journal 2018;16(5):5262 for products of animal origin. The acute risk assessment was performed taking into account the applicable EU MRLs (Reg. (EU) 2019/88) for the intended crops, except for honey, where the new proposed MRL have been considered.

ADI	0.005 mg/kg bw per day
ARfD	0.005 mg/kg bw
IEDI (% ADI) according to EFSA PRIMo 3.1	43% (based on NL toddler) 9% (based on FR child)
IESTI (% ARfD) according to EFSA PRIMo3.1	29% wheat 11% rapeseeds Processed commodities 25% whet/milling (flour) 22% sugar beets (root)/sugar 5% rapeseeds/oils

An ADI of 0.01 mg/kg bw/d and an ARfD of 0.01 mg/kg bw were used as toxicological reference values (EC, 2002; EFSA Journal 2015;13(11):4309).

TMDI (% ADI) according to EFSA PRIMo	Not conducted, please refer to IEDI
IEDI (% ADI) according to EFSA PRIMo Rev. 3.1	78 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo Rev. 3.1	Unprocessed commodities (based on children) Cattle milk: 25% Wheat: 1% Processed commodities (based on children) Sugar beets (root)/sugar: 11% Wheat/mailing/(flour): 1% Rapeseeds/oils: 0.1%

The proposed uses of acetamiprid and deltamethrin in the formulation CHR/I/ADEL 280 SC do not represent unacceptable acute and chronic risks for the consumer.

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

No new studies are presented; all data were reviewed in the EU review of acetamiprid and deltamethrin. Appropriate endpoints from the EU review were used to calculate PECs for CHR/I/ADEL 280 SC,

acetamiprid, deltamethrin, and metabolites of each active substance in soil, surface water, ground water and air for the intended use patterns.

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

The PEC_{SOIL} of acetamiprid, deltamethrin and their relevant metabolites in soil have been assessed with the DT50 values established in the EU review. Based on the recommended use rate of one application of 160 ml/ha formulation.

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

According to PECgw modelling with FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 a groundwater contamination of the acetamiprid and deltamethrin at a concentration of ≥ 0.1 µg/L is not expected in use on all intendend crops. For the metabolites in groundwater concentration of ≥ 0.1 µg/L can be excluded.

In accordance with national requirements the additional PECgw assessment updated with PUF=0 for metabolite MI-I-5 was provided and accepted. Based on submitted assessment it can be concluded that the safe use for annual application of Adel 280 SC in winter OSR and winter cereals was confirmed.
For sugar beets – every other year application of Adel 280 SC is required.

The risk assessment for metabolites was performed in B-10 section and concluded that there is no risk to consumer.

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

The PEC surface water of acetamiprid, deltamethrin and metabolites in surface water (PECsw and PECsed) have been assessed with the FOCUS SW and the DT50 water/sediment values established in the EU review. Based on the maximum recommended use rate of one application of 160 ml formulation per hectare. The maximum PEC values for surface water and sediment have been calculated according to FOCUS Steps 1-4 for the parent and FOCUS 1-2 for the metabolites.

The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

The acute and chronic risks of CHR/I/ADEL 280 SC to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredients, and maximum residues occurring on food items.

All TER values exceed the relevant triggers indicating that CHR/I/ADEL 280 SC F does not pose an unacceptable risk to birds following applications according to recommended use pattern.

Evaluation of exposing to birds through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is low.
The acute and chronic risks of CHR/I/ADEL 280 SC to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with active ingredients and maximum residues occurring on food items.
All TER values exceed the relevant triggers in the screening step risk assessment for deltamethrin (acute and chronic).

For acetamiprid an acceptable acute and chronic risk for mammals can be concluded for all intended uses of. The combined risk assessment demonstrated the acceptable acute and chronic risk for mammals for all intended uses of CHR/I/ADEL 280 SC except for use in cereals in BBCH ≥ 40 (chronic).

Based on the higher tier chronic risk assessment for CHR/I/ADEL 280 SC, where the PD values for voles were modified, the TERs exceed the trigger values set by Commission regulation (EU) 546/2011 for acceptability of effects.

Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk. The

potential risk of secondary poisoning is low.

3.7.2 Effects on aquatic species

The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). The initial risk assessment was based on the worst case PECsw values and the results of laboratory toxicity testing. The PEC_{sw} Step 1-2 (for active substances and their metabolites) and Step 3-4 (for active substances) were used.

Only for Daphnia magna was possible to performed mixture toxicity assessment, as for Chironomus riparius the acute endpoint of deltamethrin is not available. Based on toxic units, it is concluded that deltamethrin is driving the toxicity of the mixture (TU ≥ 90%) for Daphnia magna.

CHR/I/ADEL 280 SC applications close to surface water pose acceptable risk to aquatic organisms with appropriate risk mitigation measures.

a) 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for sugar beet and winter cereals,
b) Autumn: 20 meters vegetative buffer zone and 20 meters no-spray buffer zone and 50% nozzles reduction for winter oilseed rape (BBCH 10-21)
c) Spring: 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for winter oilseed rape (BBCH 30-70)

3.7.3 Effects on bees

The evaluation of the acute risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). The submitted risk assessment, based on laboratory studies, has been accepted. It can therefore be concluded that there will be negligible acute risk associated with the exposure of *Apis mellifera* to CHR/I/ADEL 280 SC.

The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled.

3.7.4 Effects on other arthropod species other than bees

For the application rate of 0.16 L/ha, based on currently available data, it was not possible to demonstrate an acceptable in-field risk for non-target arthropods. Therefore, the Applicant modified the product's application pattern by including a lower application rate of 0.08 L/ha.

For application rate of 0.08 L/ha, the in-field risk for non-target arthropods is acceptable. For higher application rate an unacceptable risk is considered.

Based on the results of the conducted risk assessment it can be concluded that no off-field risk for non-target arthropods is expected from use of CHR/I/ADEL 280 SC. Following mitigation measures are required:

Application rate of 0.16 L/ha

- 75 meters buffer zone
- 40 meter buffer zone with 50% nozzles reduction
- 20 meters buffer zone with 75% nozzles reduction
- 10 meters buffer zone with 90% nozzles reduction

Application rate of 0.08 L/ha

- 40 meters buffer zone
- 20 meter buffer zone with 50% nozzles reduction
- 10 meters buffer zone with 75% nozzles reduction
- 5 meters buffer zone with 90% nozzles reduction

3.7.5 Effects on soil organisms

CHR/I/ADEL 280 SC pose no unacceptable risk to non-target soil meso- and macrofauna and microbial

activity according to the label.

3.7.6 Effects on non-target terrestrial plants

CHR/I/ADEL 280 SC pose no unacceptable risk to non-target terrestrial plants.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not required.

3.8 Relevance of metabolites (Part B, Section 10)

The metabolites of acetamiprid and deltamethrin are predicted to occur in groundwater at concentrations lower than 0.1 µg/L (see PART B Section 8 of CHR/I/ADEL 280 SC). Assessment of the relevance of these metabolites is not required.

4 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 etykiet:
Fizykochemia – zaakceptowano 2-letni okres trwałości środka.
Toksykologia – dodano zwrot EUH208. Zmieniono treść etykiety w zakresie ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH.
Pozostałości – Wnioskodawca dostarczył dodatkowe wyjaśnienia, w tym porównanie, które wykazuje równoważność wspomnianych badań. zRMS akceptuje wyjaśnienia. Zdaniem zRMS ograniczenie wcześniej wskazane na etykiecie „NIE STOSOWAĆ NA GLEBACH ALKALICZNYCH" nie jest wymagane. Jednak badanie przedstawione przez Wnioskodawcę powinno zostać najpierw ocenione w „Data matching studies for acetamiprid", aby wskazać, że badania są równoważne, więc ostateczna decyzja należy do zarządzającego ryzykiem.
Przekroczenie NDP acetamiprydu w miodzie. Dopóki wartość NDP acetamiprydu w miodzie nie zostanie podniesiona, zastosowania w OSR nie są możliwe. W przypadku rzepaku Wnioskodawca przedstawił badania dotyczące preparatu SE zamiast SC. Ostateczną decyzję powinni podjąć zarządzający ryzykiem. Jeżeli stosowanie na rzepaku zostanie dopuszczone, należy podać PHI równe 45 dni do stosowania w BBCH 30-70.
Zgodnie z decyzją MRiRW, która zapadła trakcie spotkania harmonizacyjnego (14/05/2025) możliwe jest udzielenie warunkowej zgody na zastosowanie w rzepaku uwzględniając, że wnioskodawca dostarczył wyniki badań pozostałości wskazujące na brak przekroczeń pozostałości acetamiprydu powyżej 0.3 mg/kg.
Zgodnie z Rozporządzeniem (UE) 2025/1212 (obowiązuje od 20/08/2025), wartość NDP dla acetamiprydu w miodzie została podniesiona do 0.3 mg/kg.
Los i zachowanie w środowisku – ~~brak uwag do etykiety.~~
Zgodnie z krajowymi wymaganiami dotyczącymi oszacowania wartości PECgw (PUF = 0 dla substancji i jej wszystkich metabolitów) wprowadzono ograniczenie stosowania formulacji w uprawie buraka cukrowego: środek ochrony roślin zawierający acetamipiryd można stosować raz na dwa lata.
Ekotoksykologia – ze względu na niezakończenie oceny ryzyka „w polu" dla stawonogów dla dawki 0,16 L/ha, wszystkie zastosowania środka zostały ograniczone do dawki 0,08 L/ha, jak podano w zmodyfikowanej etykiecie. Dodano zwrot P501. Skorygowano zarządzenie ryzykiem dla organizmów wodnych oraz stawonogów.
Skuteczność działania – zmieniono treść etykiet w zakresie STOSOWANIE ŚRODKA.

Posiadacz zezwolenia:
Innvigo Sp. z o.o., Al. Jerozolimskie 178, 02-486 Warszawa, tel. xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Przedmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:….

ADEL 280 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

~~NIE STOSOWAĆ NA GLEBACH ALKALICZNYCH~~

Zawartość substancji czynnej:
acetamipryd (związek z grupy neonikotynoidów) - 250 g/l (23,0 %)
deltametryna (związek z grupy pyretroidów) - 30 g/l (2,8 %)

Zezwolenie MRiRW nr R - …../2021 z dnia …….2021 r.

Uwaga	
H302	Działa szkodliwie po połknięciu.
H361d	Podejrzewa się, że działa szkodliwie na dziecko w łonie matki.
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-benzoizotiazol-3(2H)-on. Może powodować wystąpienie reakcji alergicznej.
~~P261~~	~~Unikać wdychania rozpylonej cieczy.~~
P264	Dokładnie umyć ręce po użyciu.
P270	Nie jeść, nie pić i nie palić podczas używania produktu
~~P271~~	~~Stosować wyłącznie na zewnątrz.~~
P280	Stosować rękawice ochronne oraz odzież ochronną, ochronę oczu/twarzy.
P301 + P312	W PRZYPADKU POŁKNIĘCIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.
P308 + P313	W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
~~P362 + P364~~	~~Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.~~
P391	Zebrać wyciek.
P501	….

OPIS DZIAŁANIA
INSEKTYCYD w postaci koncentratu w formie stężonej zawiesiny przeznaczonym do rozcieńczania wodą przed zastosowaniem (SC), o działaniu kontaktowym i żołądkowym. Na roślinie działa powierzchniowo.

Zgodnie z klasyfikacją IRAC substancja czynna acetamipryd zaliczana jest do grupy 4A, a deltametryna zaliczana jest do grupy blokerów kanałów sodowych, IRAC 3A.

STOSOWANIE ŚRODKA
Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych lub sadowniczych.

Rzepak ozimy
~~*Mszyce: mszyca brzoswiniowo - ziemniaczana,*~~ *mszyca kapuściana*~~*, gnatarz rzepakowiec*~~

Termin stosowania: środek stosować jesienią, opryskiwać w momencie nalotu szkodnika na plantację od początku fazy rozwoju liści do fazy pierwszego pędu bocznego (BBCH 10-21).
Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.
Zalecana ilość wody: 200 – 300 l/ha
Ilość wody dostosować do wielkości roślin i ich zagęszczenia.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Odstęp między zabiegami: nie dotyczy

~~Środek średnioskutecznie chroni rzepak ozimy w zwalczaniu gnatarza rzepakowca oraz mszycy brzoskwiniowo - ziemniaczanej~~

~~*Chowacz czterozębny, chowacz brukwiaczek*~~

Termin stosowania: środek stosować wiosną, opryskiwać w momencie nalotu szkodnika na plantację od początku fazy wydłużania pędu, brak międzywęźli (‘rozeta’) do fazy rozwój pąków kwiatowych – pąki kwiatowe zamknięte w liściach (BBCH 30-50).
Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.
Zalecana ilość wody: 200 – 300 l/ha
Ilość wody dostosować do wielkości roślin i ich zagęszczenia.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Odstęp między zabiegami: nie dotyczy

Środek działa ogranicza liczbę szkodników: chowacza czterozębnego, chowacza brukwiaczka w uprawie rzepaku ozimego.

Słodyszek rzepakowy

Termin stosowania: środek stosować wiosną, opryskiwać w momencie nalotu szkodnika na plantację od początku fazy rozwój pąków kwiatowych pąki kwiatowe zamknięte do fazy widocznych pierwszych płatków, paki kwiatowe nadal zamknięte (żółty pąk) (BBCH 50-59).
Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.
Zalecana ilość wody: 200 – 300 l/ha
Ilość wody dostosować do wielkości roślin i ich zagęszczenia.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Odstęp między zabiegami: nie dotyczy

Środek średnioskutecznie chroni rzepak ozimy w zwalczaniu słodyszka rzepakowego.

Chowacz podobnik, pryszczarek kapustnik

Termin stosowania: środek stosować wiosną, opryskiwać w momencie nalotu szkodnika na plantację od początku fazy pełnego kwitnienia: 50% kwiatów na głównym kwiatostanie otwartych, starsze płatki opadają do początku fazy rozwoju łuszczyn (BBCH 65-70).
Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.
Zalecana ilość wody: 200 – 300 l/ha
Ilość wody dostosować do wielkości roślin i ich zagęszczenia.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Odstęp między zabiegami: nie dotyczy

Środek średnioskutecznie chroni rzepak ozimy w zwalczaniu chowacza podobnika oraz pryszczarka kapustnika.

Pszenica ozima
Mszyce: mszyca zbożowa, mszyca różano – zbożowa, mszyca czeremchowo - zbożowa, wciornastki

Termin stosowania: środek stosować wiosną w fazie BBCH 65-756.
Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.
Zalecana ilość wody: 200 – 300 l/ha
Ilość wody dostosować do wielkości roślin i ich zagęszczenia.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Odstęp między zabiegami: nie dotyczy

Środek średnioskutecznie chroni pszenicę ozimą w zwalczaniu mszycy zbożowej oraz wciornastków.

~~**Pszenżyto ozime**~~
~~*Mszyce: mszyca zbożowa, mszyca czeremchowo - zbożowa, wciornastki*~~

~~Termin stosowania: środek stosować wiosną w fazie BBCH 49-757.~~
~~Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.~~
~~Zalecana ilość wody: 200 – 300 l/ha~~
~~Ilość wody dostosować do wielkości roślin i ich zagęszczenia.~~
~~Zalecane opryskiwanie: średniokropliste.~~
~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~
~~Odstęp między zabiegami: nie dotyczy~~

~~Środek średnioskutecznie chroni pszenżyto ozime w zwalczaniu mszycy zbożowej oraz wciornastków.~~

Burak cukrowy

Po zastosowaniu tego środka, środki zawierające substancję acetamipiryd można zastosować na tym samym polu najwcześniej za 2 lata

~~*Mszyca trzmielinowo - burakowa*~~

~~Termin stosowania: środek stosować wiosną w fazie BBCH 12-19.~~
~~Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.~~
~~Zalecana ilość wody: 200 – 300 l/ha~~
~~Ilość wody dostosować do wielkości roślin i ich zagęszczenia.~~
~~Zalecane opryskiwanie: średniokropliste.~~
~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~
~~Odstęp między zabiegami: nie dotyczy~~

~~Środek średnioskutecznie chroni buraka cukrowego w zwalczaniu szycy trzmielinowo – burakowej.~~

śmietka ćwiklanka

Termin stosowania: środek stosować wiosną w fazie BBCH 12-16.
Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.
Zalecana ilość wody: 200 – 300 l/ha
Ilość wody dostosować do wielkości roślin i ich zagęszczenia.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Odstęp między zabiegami: nie dotyczy

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji~~): Pszenica, pszenżyto – 35 dni~~.rzepak minimum 45 dni

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz): nie dotyczy.

1. Środek zawiera substancję czynną acetamipryd – związek z grupy pochodnych neonikotynoidów (insektycydy współdziałające z nikotynowymi receptorami acetylocholiny (Ach) - grupa IRAC 4A). Celem zminimalizowania ryzyka uodpornienia się populacji zwalczanych szkodników zaleca się:
   - stosowanie środka tylko w zalecanych dawkach i terminach,
   - w przypadku konieczności wykonania kolejnych zabiegów zastosowanie środka zawierającego substancję czynną z innej grupy, o odmiennym mechanizmie działania.

2. Opryskiwanie przeciwko szkodnikom ~~(zwłaszcza ssącym)~~ wykonać dokładnie, pokrywając wszystkie części roślin cieczą użytkową.
3. Zaleca się stosować środek w temperaturze poniżej 20°C. W wyższej temperaturze zabieg wykonać pod koniec dnia.
4. Zabieg wykonać TYLKO po oblocie pszczół i innych zapylaczy.
5. Nie stosować na plantacjach z kwitnącymi chwastami.
6. Nie stosować w ciągu dnia na rośliny mokre.

NASTĘPSTWO ROŚLIN
W razie konieczności wcześniejszej likwidacji plantacji, nie stosować środków zawierających acetamipryd na rośliny uprawiane następczo w sezonie wegetacyjnym, w którym został uprzednio zastosowany środek ochrony roślin Adel 280 SC.

SPORZĄDZANIE CIECZY UŻYTKOWEJ
Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).
Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.
W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy, ciecz użytkową w zbiorniku opryskiwacza 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.

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 i odzież ochronną ~~roboczą~~ oraz ochronę oczu/twarzy w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.
~~W czasie oprysku należy zastosować techniki zmniejszające znos preparatu.~~
Pracownicy polowi – stosować odzież roboczą oraz rękawice podczas zbioru buraków cukrowych.
Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.
Stosować wyłącznie na zewnątrz.
Nie wprowadzać do oczu, na skórę lub na odzież.
Unikać wdychania rozpylonej cieczy.
Dokładnie umyć ręce po użyciu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji): 1 dzień.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO
Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.
Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.
W czasie kwitnienia roślin uprawnych zaleca się stosowanie środka poza okresami aktywności pszczół.

Burak cukrowy, zboża ozime, rzepak ozimy – zastosowanie wiosenne (BBCH 30-70)
W celu ochrony organizmów wodnych konieczne jest wyzanczenie 20 m nieopryskiwanej, zadarnionej strefy ochronnej od zbiorników i cieków wodnych.
W celu ochrony wód podziemnych po zastosowaniu tego środka, środki zawierające substancję acetamipiryd można zastosować na tym samym polu najwcześniej za 2 lata.

Rzepak ozimy – zastosowanie jesienne (BBCH 10-21)
W celu ochrony organizmów wodnych konieczne jest wyzanczenie 20 m nieopryskiwanej, zadarnionej strefy ochronnej od zbiorników i cieków wodnych oraz techenik redukujących znoszenie na poziomie 50%.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 40 m od terenów nieużytkowanych rolniczo, lub 20 m oraz techenik redukujących znoszenie na poziomie 50%, lub 10 m oraz techenik redukujących znoszenie na poziomie 75%, lub 5 m oraz techenik redukujących znoszenie na poziomie 90%.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA
Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- wyłącznie w oryginalnym opakowaniu w temperaturze 0°C - 30°C.

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 pojemnik lub etykietę.
W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.
W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Posiadacz zezwolenia:
Innvigo Sp. z o.o., Al. Jerozolimskie 178, 02-486 Warszawa, tel. xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Przedmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:….

PYRIFOS ADE 280 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

~~NIE STOSOWAĆ NA GLEBACH ALKALICZNYCH~~

Zawartość substancji czynnej:
acetamipryd (związek z grupy neonikotynoidów) - 250 g/l (23,0 %)
deltametryna (związek z grupy pyretroidów) - 30 g/l (2,8 %)

Zezwolenie MRiRW nr R - …../2021 z dnia …….2021 r.

Uwaga	
H302	Działa szkodliwie po połknięciu.
H361d	Podejrzewa się, że działa szkodliwie na dziecko w łonie matki.
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-benzoizotiazol-3(2H)-on. Może powodować wystąpienie reakcji alergicznej.
~~P261~~	~~Unikać wdychania rozpylonej cieczy.~~
P264	Dokładnie umyć ręce po użyciu.
P270	Nie jeść, nie pić i nie palić podczas używania produktu
~~P271~~	~~Stosować wyłącznie na zewnątrz.~~
P280	Stosować rękawice ochronne oraz odzież ochronną, ochronę oczu/twarzy.
P301 + P312	W PRZYPADKU POŁKNIĘCIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.
P308 + P313	W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
~~P362 + P364~~	~~Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.~~
P391	Zebrać wyciek.
P501	….

OPIS DZIAŁANIA
INSEKTYCYD w postaci koncentratu w formie stężonej zawiesiny przeznaczonym do rozcieńczania wodą przed zastosowaniem (SC), o działaniu kontaktowym i żołądkowym. Na roślinie działa powierzchniowo.

Zgodnie z klasyfikacją IRAC substancja czynna acetamipryd zaliczana jest do grupy 4A, a deltametryna zaliczana jest do grupy blokerów kanałów sodowych, IRAC 3A.

STOSOWANIE ŚRODKA

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

Rzepak ozimy

~~*Mszyce: mszyca brzoswiniowo - ziemniaczana,* *mszyca kapuściana*~~*~~, gnatarz rzepakowiec~~*

Termin stosowania: środek stosować jesienią, opryskiwać w momencie nalotu szkodnika na plantację od początku fazy rozwoju liści do fazy pierwszego pędu bocznego (BBCH 10-21).
Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.
Zalecana ilość wody: 200 – 300 l/ha
Ilość wody dostosować do wielkości roślin i ich zagęszczenia.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Odstęp między zabiegami: nie dotyczy

~~Środek średnioskutecznie chroni rzepak ozimy w zwalczaniu gnatarza rzepakowca oraz mszycy brzoskwiniowo - ziemniaczanej~~

~~*Chowacz czterozębny, chowacz brukwiaczek*~~

~~Termin stosowania: środek stosować wiosną, opryskiwać w momencie nalotu szkodnika na plantację od początku fazy wydłużania pędu, brak międzywęźli ('rozeta') do fazy rozwój pąków kwiatowych - pąki kwiatowe zamknięte w liściach (BBCH 30-50).~~
~~Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.~~
~~Zalecana ilość wody: 200 – 300 l/ha~~
~~Ilość wody dostosować do wielkości roślin i ich zagęszczenia.~~
~~Zalecane opryskiwanie: średniokropliste.~~
~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~
~~Odstęp między zabiegami: nie dotyczy~~

~~Środek działa ogranicza liczbę szkodników: chowacza czterozębnego, chowacza brukwiaczka w uprawie rzepaku ozimego.~~

~~*Słodyszek rzepakowy*~~

~~Termin stosowania: środek stosować wiosną, opryskiwać w momencie nalotu szkodnika na plantację od początku fazy rozwój pąków kwiatowych pąki kwiatowe zamknięte do fazy widocznych pierwszych płatków, paki kwiatowe nadal zamknięte (żółty pąk) (BBCH 50-59).~~
~~Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.~~
~~Zalecana ilość wody: 200 – 300 l/ha~~
~~Ilość wody dostosować do wielkości roślin i ich zagęszczenia.~~
~~Zalecane opryskiwanie: średniokropliste.~~
~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~
~~Odstęp między zabiegami: nie dotyczy~~

~~Środek średnioskutecznie chroni rzepak ozimy w zwalczaniu słodyszka rzepakowego.~~

~~*Chowacz podobnik, pryszczarek kapustnik*~~

~~Termin stosowania: środek stosować wiosną, opryskiwać w momencie nalotu szkodnika na plantację od początku fazy pełnego kwitnienia: 50% kwiatów na głównym kwiatostanie otwartych, starsze płatki opadają do początku fazy rozwoju łuszczyn (BBCH 65-70).~~
~~Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.~~

~~Zalecana ilość wody: 200 – 300 l/ha~~
~~Ilość wody dostosować do wielkości roślin i ich zagęszczenia.~~
~~Zalecane opryskiwanie: średniokropliste.~~
~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~
~~Odstęp między zabiegami: nie dotyczy~~

~~Środek średnioskutecznie chroni rzepak ozimy w zwalczaniu chowacza podobnika oraz pryszczarka kapustnika.~~

~~Pszenica ozima~~
~~Mszyce: mszyca zbożowa, mszyca różano – zbożowa, mszyca czeremchowo - zbożowa, wciornastki~~

~~Termin stosowania: środek stosować wiosną w fazie BBCH 65-756.~~
~~Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.~~
~~Zalecana ilość wody: 200 – 300 l/ha~~
~~Ilość wody dostosować do wielkości roślin i ich zagęszczenia.~~
~~Zalecane opryskiwanie: średniokropliste.~~
~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~
~~Odstęp między zabiegami: nie dotyczy~~

~~Środek średnioskutecznie chroni pszenicę ozimą w zwalczaniu mszycy zbożowej oraz wciornastków.~~

~~Pszenżyto ozime~~
~~Mszyce: mszyca zbożowa, mszyca czeremchowo - zbożowa, wciornastki~~

~~Termin stosowania: środek stosować wiosną w fazie BBCH 49-757.~~
~~Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.~~
~~Zalecana ilość wody: 200 – 300 l/ha~~
~~Ilość wody dostosować do wielkości roślin i ich zagęszczenia.~~
~~Zalecane opryskiwanie: średniokropliste.~~
~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~
~~Odstęp między zabiegami: nie dotyczy~~

~~Środek średnioskutecznie chroni pszenżyto ozime w zwalczaniu mszycy zbożowej oraz wciornastków.~~

Burak cukrowy

Po zastosowaniu tego środka, środki zawierające substancję acetamipiryd można zastosować na tym samym polu najwcześniej za 2 lata

~~Mszyca trzmielinowo – burakowa~~

~~Termin stosowania: środek stosować wiosną w fazie BBCH 12-19.~~
~~Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.~~
~~Zalecana ilość wody: 200 – 300 l/ha~~
~~Ilość wody dostosować do wielkości roślin i ich zagęszczenia.~~
~~Zalecane opryskiwanie: średniokropliste.~~
~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~
~~Odstęp między zabiegami: nie dotyczy~~

~~Środek średnioskutecznie chroni buraka cukrowego w zwalczaniu szycy trzmielinowo – burakowej.~~

śmietka ćwiklanka

Termin stosowania: środek stosować wiosną w fazie BBCH 12-16.

Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,08 l/ha.
Zalecana ilość wody: 200 – 300 l/ha
Ilość wody dostosować do wielkości roślin i ich zagęszczenia.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Odstęp między zabiegami: nie dotyczy

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji~~): Pszenica, pszenżyto – 35 dni.~~rzepak minimum 45 dni

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz): nie dotyczy.

7. Środek zawiera substancję czynną acetamipryd – związek z grupy pochodnych neonikotynoidów (insektycydy współdziałające z nikotynowymi receptorami acetylocholiny (Ach) - grupa IRAC 4A). Celem zminimalizowania ryzyka uodpornienia się populacji zwalczanych szkodników zaleca się:
   - stosowanie środka tylko w zalecanych dawkach i terminach,
   - w przypadku konieczności wykonania kolejnych zabiegów zastosowanie środka zawierającego substancję czynną z innej grupy, o odmiennym mechanizmie działania.
8. Opryskiwanie przeciwko szkodnikom ~~(zwłaszcza ssącym)~~ wykonać dokładnie, pokrywając wszystkie części roślin cieczą użytkową.
9. Zaleca się stosować środek w temperaturze poniżej 20°C. W wyższej temperaturze zabieg wykonać pod koniec dnia.
10. Zabieg wykonać TYLKO po oblocie pszczół i innych zapylaczy.
11. Nie stosować na plantacjach z kwitnącymi chwastami.
12. Nie stosować w ciągu dnia na rośliny mokre.

NASTĘPSTWO ROŚLIN

W razie konieczności wcześniejszej likwidacji plantacji, nie stosować środków zawierających acetamipryd na rośliny uprawiane następczo w sezonie wegetacyjnym, w którym został uprzednio zastosowany środek ochrony roślin Adel 280 SC.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).
Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.
W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy, ciecz użytkową w zbiorniku opryskiwacza 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.

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 i odzież ochronną ~~roboczą~~ oraz ochronę oczu/twarzy w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.
~~W czasie oprysku należy zastosować techniki zmniejszające znos preparatu.~~
Pracownicy polowi – stosować odzież roboczą oraz rękawice podczas zbioru buraków cukrowych.
Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.
Stosować wyłącznie na zewnątrz.
Nie wprowadzać do oczu, na skórę lub na odzież.
Unikać wdychania rozpylonej cieczy.
Dokładnie umyć ręce po użyciu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji): 1 dzień.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.
Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.
W czasie kwitnienia roślin uprawnych zaleca się stosowanie środka poza okresami aktywności pszczół.

Burak cukrowy, zboża ozime, rzepak ozimy – zastosowanie wiosenne (BBCH 30-70)
W celu ochrony organizmów wodnych konieczne jest wyzanczenie 20 m nieopryskiwanej, zadarnionej strefy ochronnej od zbiorników i cieków wodnych.
W celu ochrony wód podziemnych po zastosowaniu tego środka, środki zawierające substancję acetamipiryd można zastosować na tym samym polu najwcześniej za 2 lata.

Rzepak ozimy – zastosowanie jesienne (BBCH 10-21)
W celu ochrony organizmów wodnych konieczne jest wyzanczenie 20 m nieopryskiwanej, zadarnionej strefy ochronnej od zbiorników i cieków wodnych oraz techenik redukujących znoszenie na poziomie 50%.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 40 m od terenów nieużytkowanych rolniczo, lub 20 m oraz techenik redukujących znoszenie na poziomie 50%, lub 10 m oraz techenik redukujących znoszenie na poziomie 75%, lub 5 m oraz techenik redukujących znoszenie na poziomie 90%.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- wyłącznie w oryginalnym opakowaniu w temperaturze 0°C - 30°C.

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 pojemnik lub etykietę.
W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.
W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

Appendix 4 Lists of data considered for national authorization

Please refer to the reference list.