FINAL REGISTRATION REPORT
Part A
Risk Management

Product code: SHA5500A

Product name(s): ASSET (~~ZUXION~~)

Chemical active substance:

Acetamiprid, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

Applicant: Sharda Cropchem España S.L.

Submission date: April 2020

MS Finalisation date: 12/2020; 07/2021 ; 03/2023

Version history

When	What
12/2020	Finalisation of the assessment by ZRMS
07/2021	ZRMS made changes according to commenting period.
12/2022	Applicant update
03/2023	Assessment in relation to updated Section B7

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by SHARDA CROPCHEM ESPAÑA S.L..

The application is for approval of Acetamiprid 20% SG, a water soluble granules formulation containing 200 g/kg of Acetamiprid, for use on oilseed rape and pome fruits as an insecticide.

zRMS: Poland

1.2 Letters of Access

Not applicable. Letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relies on tests and studies providing data and information specific to the formulation Acetamiprid 20% SG as required by the EU regulation.

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	SHA5500A
Product name in MS	ASSET
Authorization number	-
Function	Insecticide
Applicant	Sharda Cropchem España S.L.
Active substance(s) (incl. content)	Acetamiprid 200 g/kg
Formulation type	Water soluble granules [Code: SG]
Packaging	60ml, 100 ml, 250 ml, 500 ml, 1 l, 5 l, 10 l (COEX) 20 L (fluorinated)
Coformulants of concern for	-

national authorizations	
Restrictions related to identiy	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

Metabolism and Residues:

Use on apples is accepted. Registration in the protection of oil seed rape will be possible after completing the equivalent studies to the following protected studies (see Data matching, The Netherlands, 2018):

Raufer, B., 2013, 2014 and Hobbs, G., Inns, L., 2012

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Alternative studies have been provided. The Applicant has fulfilled the requirements.

According to the current requirements (SANTE/11956/2016 rev. 9), information on residues in honey is required. Such information can be provided after authorization is obtained.

Ecotoxicology Section:

The evaluation of the application for Asset resulted in the decision to grant the authorization for oilseed rape (1 x40 g a.s./ha) and for late application in orchards: 1 x 36 g a.s./ha and 2 x 36 g a.s./ha according to submitted by the applicant the new updated GAP. (~~The evaluation of the application for **Asset** resulted in the decision to refuse the authorization for orchards for max application rate of 2 x 50 g a.s./ha. The reason for the refusal is not accepted the long – term risk for mammals (vole) and needs for further refinement for aquatic organism~~.

2.3 Substances of concern for national monitoring

Not relevant.

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 Aquatic Acute 1

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:	**GHS07, GHS09**
Signal word:	**Warning**

Hazard statement(s):	**H302,H361d, H410**
Precautionary statement(s):	**P264, P270, P273,** P280**, P301+P312, P308+P313,P330, P391, P501**
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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).
SPe3	***To protect aquatic organism respect for accepted uses in the* GAP *:*** Pome/stone fruits (early application, 1-2 x 36 g a.s./ha • 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip Pome/stone fruits (late application,1- 2 x 36 g a.s./ha) • 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip. ~~***To protect non-target arthropods respect for accepted uses in the GAP :***~~ ~~***Pome/stone fruits (early application, 1-2 x 36 g a.s./ha) - Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 50 m to non-agricultural land OR an unsprayed buffer zone of 40 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 30m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 90% of nozzles reduction.*~~ ~~***Pome/stone fruits (late application, 1-2 x 36 g a.s./ha) - Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 40 m to non-agricultural land OR an unsprayed buffer zone of 30 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction.*~~ ***Spe3: Pome/stone fruits (late application, 1-2 x 36 g a.s./ha):*** To protect non-target arthropods respect an unsprayed buffer zone of 30 m to non-agricultural land OR an unsprayed buffer zone of 20 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 15m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction. ***Spe3: Oilseed rape (application dose 1 x 40 g a.s./ha)****: To protect non-target arthropods respect an unsprayed buffer zone of 10 m to non-agricultural land OR an unsprayed buffer zone of 5 m to non-agricultural land with 50% of nozzles reduction OR no buffer zone to non-agricultural land with 90% of nozzles reduction.*

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

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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:	
-	Work wear (arms, body and legs covered) M/L and A
Worker protection:	
P280	Work wear (arms, body and legs covered) : Oilseed rape Work wear (arms, body and legs covered) + gloves - time period of 4 days after application : Pome fruits
–	Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
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 3	Pome/stone fruits (early application, 1-2 x 36 g a.s./ha • 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip Pome/stone fruits (late application,1- 2 x 36 g a.s./ha) • 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip. ~~***To protect non-target arthropods respect for accepted uses in the GAP :***~~ ~~***Pome/stone fruits (early application, 1-2 x 36 g a.s./ha) - Spe3**: To protect non-target arthropods respect an unsprayed buffer zone of 50 m to non-agricultural land OR an unsprayed buffer zone of 40 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 30m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 90% of nozzles reduction.***~~ ~~***Pome/stone fruits (late application, 1-2 x 36 g a.s./ha) - Spe3**: To protect non-target arthropods respect an unsprayed buffer zone of 40 m to non-agricultural land OR an unsprayed buffer zone of 30 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction***~~ ***Spe3: Pome/stone fruits (late application, 1-2 x 36 g a.s./ha):*** To protect non-target arthropods respect an unsprayed buffer zone of 30 m to non-agricultural land OR an unsprayed

	buffer zone of 20 m to non-agricultural land with 50% of nozzles reduction OR an un-sprayed buffer zone of 15m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction. ***Spe3: Oilseed rape (application dose 1 x 40 g a.s./ha)****: To protect non-target arthropods respect an unsprayed buffer zone of 10 m to non-agricultural land OR an unsprayed buffer zone of 5 m to non-agricultural land with 50% of nozzles reduction OR no buffer zone to non-agricultural land with 90% of nozzles reduction.*
Other specific restrictions	
-	-

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

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Not relevant.

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 0, date: 2020-April-6th

PPP (product name/code):	ASSET/SHA 5500 A	Formulation type:	SG (Water Soluble Granules)
Active substance 1:	Acetamiprid	Conc. of as 1:	200 g/kg
Active substance 2:	-	Conc. of as 2:	-
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Sharda Cropchem España S.L	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	yes/~~no~~		
Field of use:	Insecticide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					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		e.g. g safener/synergist per ha [f]

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	**Oilseed Rape**	F	Pollen Beetle (*Meligethes aeneus)*	Foliar spray	At pest presence. Before BBCH 69	a) 1 b) 1	NA	a) 0.2 b) 0.2	a) 0.04 b) 0.04	200-600	28	Metabolism and Residues Use is accepted
2	CEU	**Pome fruits**	F	Aphids	Foliar spray	~~At pest presence, Before BBCH 59 and~~ from BBCH 69	a) 1-2 b) 1-2	14	a) 0.18***- ~~0.25~~ b) 0.36***-~~0.5~~	a)0.036-~~0.05~~ b) 0.072***-~~0.10~~	900-1000	14	Section Ecotoxicology: 1-2 x 36 g a.s./ha is max acceptable rate. ~~For max application dose 2 x 50 g a.s./ha further refinement of long-term risk for mammals (vole) and further refinement for Chironomus riparius is required.~~

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of light blue solid granules odourless. It is not explosive, has no oxidising properties. The product is not flammable and is not self-ignition. In aqueous solution, it has a pH value around 8.33. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature. It's technical characteristics are acceptable for a water soluble granules formulation.
The intended concentration of use is 0.25 g/l to 1 g/l.

3.2 Efficacy (Part B, Section 3)

The Applicant applied for Zuxion, so dRR is with the name Zuxion. But since there is already a complex plant protection product with this name (Zuxion) he had to change the name of product. So, the new one is Asset.

Acetamiprid 20% SG is an insecticide for the control of pollen beetles in oilseed rape and aphids in pome fruit crops. Acetamiprid 20% SG is Water Soluble Granular (SG) formulation containing 200 g/kg acetamiprid.

In compliance with the GAP the following dose rates are applied for registration:

- One application in oilseed rape to control pollen beetle, target rate: 200 g/ha
- One or two applications in pome fruits to control aphids, target rate: 250 g/ha per application [= 125 g/ha per meter crown height]; max 500 g/ha per season

This document serves the registration of Acetamiprid 20% SG in the Central zone of the EU. The objective of this biological assessment dossier is to prove and support the label claims of the insecticidal efficacy and crop safety of Acetamiprid 20% SG in the label claimed crops.

Comprehensive field trials were conducted in England, Germany, Holland, France, Poland, Latvia, Lithuania, Hungary, Romania, Spain, Portugal and Italy in 2015 and 2019. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

3.3 Efficacy data

Preliminary tests

The activity of acetamiprid is well known, as it has been marketed since 1995 to control of *Hemiptera*, especially aphids, *Thysanoptera* and *Lepidoptera* in a wide range of crops. Based on the knowledge about the active substance (+21 years) and the experiences with using Acetamiprid in the label claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

Acetamiprid 20% SG was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Acetamiprid 20% SG applied at different dose rates was evaluated in 14 winter oilseed rape trials and 20 pome fruit trials (18 apple and 2 pear). In 13 oilseed rape trials, acetamiprid was applied at BBCH 32-62 at 20, 30 and 40 g acetamiprid/ha for the control of pollen beetle. In 18 pome fruit trials, acetamiprid was applied at BBCH 69-91 at 25, 36 and 50 g acetamiprid/ha to assess the minimum effective dose rate against aphids. These ranges reflects 50% to 100% of the full recommended rate of acetamiprid, in accordance with the EPPO guideline PP 1/225(1) "Minimum effective dose". The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product. Data is presented from trials conducted across the Maritime EPPO zone (i.e. from Germany, N-France, the Netherlands and the United Kingdom), the North-east (i.e. from Poland, Latvia and Lithuania), the South-east EPPO zone (i.e. from Hungary and Romania) and the Mediterranean EPPO zone (i.e. from S-France, Italy, Spain and Portugal). Data from each zone has been summarized separately.

Control of pollen beetle in oilseed rape: To prove and to support the requested dose rates of 200 g/ha Acetamiprid 20% SG [40 g acetamiprid per hectare] for the control of pollen beetle (*Meligethes aeneus* (MELIAE)) in winter oilseed rape (BRSNW), the assessment results of fourteen efficacy trials performed in the Maritime (6) EPPO zone, the North-east (6) EPPO zone and the South-east (2) EPPO zone in 2015 and 2019 are reported. Acetamiprid 20% SG was included in these trials at 200 g/ha to demonstrate the recommended dose rate as well as at two lower dose rates (100 g/ha and 150 g/ha [20 and 30 g acetamiprid per hectare]). In the trials specifically targeted for pollen beetle, acetamiprid was applied once in the spring, at growth stages ranging from BBCH 32 to BBCH 62.

The data from fourteen trials proves that the minimum effective dose rate of Acetamiprid 20% SG to control pollen beetles in oilseed rape is 200 g/ha (40 g ai/ha). Furthermore, the data demonstrated that if the application rate is reduced below this, a clear decrease in control as well as in persistence is observed.

Control of aphids in apple: To prove and to support the requested dose rates of 250 g/ha Acetamiprid 20% SG [50 g acetamiprid per hectare] for the control of aphids in apple orchards (MABSD), the assessment results of eighteen efficacy trials performed in the Maritime (4) EPPO zone, the North-east (6) EPPO zone, the South-east (2) EPPO zone and the Mediterranean (6) EPPO zone are reported. Acetamiprid 20% SG was included in these trials at 250 g/ha to demonstrate the recommended dose rate as well as at two lower dose rates (125 g/ha and 180 g/ha [25 and 36 g acetamiprid per hectare]). In the trials specifically targeted for aphids, acetamiprid was applied once (3) or twice (15) in the summer/autumn, at growth stages ranging from BBCH 69 to BBCH 91.

The data from eighteen trials proves that the minimum effective dose rate of Acetamiprid 20% SG to control aphids in apple orchards is 250 g/ha (50 g ai/ha). Furthermore, the data demonstrated that if the application rate is reduced below this, a clear decrease in control as well as in persistence is observed.

Control of aphids in pear: To prove and to support the requested dose rates of 250 g/ha Acetamiprid 20% SG [50 g acetamiprid per hectare] for the control of aphids in pear orchards (PYUCO), the assessment results of two efficacy trials performed in the Mediterranean (2) EPPO zone are reported. Acetamiprid 20% SG was included in these trials at 250 g/ha to demonstrate the recommended dose rate as well as at two lower dose rates (125 g/ha and 180 g/ha [25 and 36 g acetamiprid per hectare]). In the trials specifically targeted for aphids, acetamiprid was applied twice in the late autumn, at growth stage BBCH 91.

The data from two trials proves that the minimum effective dose rate of Acetamiprid 20% SG to control aphids in pear orchards is 250 g/ha (50 g ai/ha). Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Conclusion: In summary, reducing the application rate of Acetamiprid 20% SG from the proposed dose rate results in decreased efficacy against aphids in apple (*Aphis pomi* and *Dysaphis plantaginea*) and in pear (*Dysaphis pyri*) as well as pollen beetles (*Meligethes aeneus*) in oilseed rape.

According to the presented results, the dose of 40 g ai/ha of acetamiprid for pollen beetles in oilseed rape and 50 g ai/ha of acetamiprid for aphids in pome fruit crops provided the optimum overall control and should be considered as effective against the insect pests, for which activity of Acetamiprid 20% SG is claimed. **However, on the basis of evaluation performed by section of Ecotox, only dose 0,18 kg/ha once or twice a season in pome fruits can be accepted. As a result, we believe that a dose of 0.18 kg/ha should be appropriate (observed sufficient effectiveness during MED trials) and at the same time capable of being acceptable.**

The submitted documentation can be observed as acceptable in the opinion of Evaluator for winter oilseed rape in N-E and Maritime; apple in MED and N-E EPPO zone and pear in MED EPPO zone. cMS from MED should decide if lack of trials for winter oilseed rape and results from other EPPO zone can be accepted. cMS from S-E should decide if limited number of trials for winter oilseed rape (only 2) can be accepted. cMS from Maritime and S-E EPPPO zone should decide if limited number of trials for apple can be accepted.

Also, cMS should decide if pear can be accepted on the basis on efficacy trials carried out in one zone – MED. For registration pear in PL at least 1-2 efficacy trials are required carried out on pear in PL or neighbouring country. Only according to Article 51 pear without trials can be accepted in Poland as a minor crop.

Regarding the use on pome fruits against aphids applicant would like to refer to EPPO extrapolation tables PP 1/257 IEET 3 (2) Extrapolation table for effectiveness of insecticides, Pest on pome fruit where on the use against aphids is presented Apple as Indicator crop and extrapolation to the whole group of pome fruits is permitted. According to this, applicant would like to request evaluator to consider extrapolation from apple to the whole group of pome fruits as acceptable. Possibility of extrapolation should be consider by each cMS, in the opinion of Evaluator.

Concerned Member States should consider the current authorization of a reference product (a.s. acetamiprid) in their own Member State when they setting a minimum effective dose.

Efficacy tests and conclusions regarding authorization of intended uses

Efficacy data are presented from 34 efficacy trials where the level of infestation was sufficient high for the trial to be claimed valid, to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone. The trials were carried out from spring 2015 to autumn 2019 in Germany, France, the Netherlands, the United Kingdom, Poland, Latvia, Lithuania, Hungary, Romania, Spain, Italy and Portugal. Efficacy was assessed on blossom beetle (MELIAE), green apple aphid (APHIPO), rosy apple aphid (DYSAPL) and pear aphid (DYSAPY).

Control of pollen beetle in oilseed rape: When applied at 200 g/ha, the individual trial results clearly show that Acetamiprid 20% SG gave moderate to high levels of control of pollen beetle in oilseed rape, equivalent to that achieved by the reference product. At all assessments, Acetamiprid 20% SG performed statistically similar to the acetamiprid reference product included in the trials.

Control of aphids in apple: When applied at 250 g/ha, the individual trial results clearly show that Acetamiprid 20% SG gave high levels of control of aphids in apple, equivalent to that achieved by the reference product. At all assessments, Acetamiprid 20% SG performed statistically similar to the acetamiprid reference product included in the trials.

Control of aphids in pear: When applied at 250 g/ha, the individual trial results clearly show that Acetamiprid 20% SG gave high levels of control of aphids in pear, equivalent to that achieved by the reference product. At the clear majority of the assessments, Acetamiprid 20% SG performed statistically like the acetamiprid reference product included in the trials.

Conclusion: As the data obtained from trials conducted in oilseed rape and pome fruits show, the level of control of pollen beetles and aphids from Acetamiprid 20% SG is equivalent to that of the acetamiprid reference product used in the trials.

The number of trials is sufficient and fulfil EPPO requirements for winter oilseed rape in Maritime EPPO zone (6 trials: FR-2, DE-2, UK-2) and N-E EPPO zone (6 trials: PL-3, LT-3). cMS from S-E EPPO zone should decide if limited number of trials (2) can be accepted. cMS from MED EPPO zone should decide if lack of trials and consider results from other climatic zones are acceptable.

The number of trials is sufficient and fulfil EPPO requirements for apple in MED EPPO zone (6 trials: SP-1, IT-3, PT-1, FR-1) and N-E EPPO zone (6 trials: PL-1, LV-4, LT-1). cMS from Maritime EPPO zone should decide if limited number of trials (4) can be accepted. cMS from S-E EPPO zone should decide if limited number of trials (2) can be accepted.

The number of trials carried out on perry is sufficient and fulfil EPPO requirements only for MED EPPO zone (2 trials). cMS from N-E, Maritime and S-E EPPO zone should decide if extrapolation results from another climatic zone (MED) can be accepted. For Poland is not possible. At least 1-2 efficacy trials carried out on perry against aphids in Poland or neighbouring country is needed. Only according to Article 51 pear without trials can be accepted in Poland as a minor crop.
Regarding the use on pome fruits against aphids applicant would like to refer to EPPO extrapolation tables PP 1/257 IEET 3 (2) Extrapolation table for effectiveness of insecticides, Pest on pome fruit where on the use against aphids is presented Apple as Indicator crop and extrapolation to the whole group of pome fruits is permitted. According to this, applicant would like to request evaluator to consider extrapolation from apple to the whole group of pome fruits as acceptable. Possibility of extrapolation should be consider by each cMS, in the opinion of Evaluator.

To demonstrate the effectiveness of the tested plant protection product at the recommended dose rate against pollen beetle and aphid's application in studied crops is compare to the reference product included in the trials.

Asset (SHA 5500 A) applied at the proposed dose rate of 0,2 kg/ha against pollen beetle and dose 0,25 kg/ha against aphids provides a very high level of control. Compared to the acetamiprid reference product, the efficacy obtained with SHA 550 A (Asset) is comparable against all pest species. **However, on the basis of evaluation performed by section of Ecotox, only dose 0,18 kg/ha in pome fruits can be accepted. As a result, we believe that a dose of 0.18 kg/ha should be appropriate (observed sufficient effectiveness) and at the same time capable of being acceptable.** Although its effectiveness at a dose of 0.18 kg/ha was lower than the reference standard, it is worth emphasizing that the standard was set at a dose twice as high (0,25 kg/ha). On the Polish market, there are registered plant protection products with acetamiprid in doses lower than 0.25 kg/ha - such as 0.125 l/ha or 0.2 kg/ha. In the opinion of Evaluator, ASSET at dose 0,18 kg/ha provides moderately effective control of aphids in pome fruits and could be register. Although its effectiveness at a dose of 0.18 kg/ha was lower than the reference standard, it is worth emphasizing that the standard was set at a dose twice as high (0,25 kg/ha). On the Polish market, there are registered plant protection products with acetamiprid in doses lower than 0.25 kg/ha - such as 0.125 l/ha or 0.2 kg/ha.

Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product (a.s. acetamiprid) in their own Member State.

It is recommended to authorize the product Asset (SHA 5500 A) in the extent of the authorization of the reference product (a.s. acetamiprid) at the equivalent dose rate.

EFFECTIVENESS ACCORDING TO LWA APPROACH:
According to EPPO PP 1/239, the application rate should be calculated per treated leaf wall area unit (LWA) and results of the test product should be presented and interpreted according to LWA by the applicant. From efficacy`s point of view, the reference to ha ground area is not sufficient any more (EPPO PP 1/239). Therefore, the Evaluator calculated the LWA for ASSET, using the treated canopy height as

well as the row distance between the rows from the single trial reports (where these parameters were available).
Conversion of the application dose in l/ha LWA
According to the EPPO guideline PP 1/239(2) "great efforts are being made to obtain optimum efficacy from the applied product and to avoid unnecessary emission of products into the environment and residues in feed and food" and "the best watt to achieves this is to adapt dose rate to the area where the treatment is needed (e.g. crop canopy) and its structure.
An easy way to establish correct application dose in three-dimensional crops is to use dose per treated leaf area unit (LWA).
To calculate LWA is needed to know distance between rows and treated foliage height.
Calculation of LWA:

$$\text{Leaf Wall Area (LWA)} = \frac{2 \times \text{tree height [m]}}{\text{Distance between rows [m]}} \times 10\,000 \text{ m2/ha}$$

LWA was calculated for each EPPO zone: for calculation the dose 10000 m^2 LWA was used 0,18 kg/ha per ground.

- Maritime EPPO zone: range of LWA vary between 12500 and 16250. If we consider the average of LWA's (14259) noted in all trials then the proposed dose should be: 0,13 kg ASSET/10000 m^2 LWA**.**
- North-East EPPO zone: range of LWA vary between 14667 and 20000. If we consider the average of LWA's (16556) noted in all trials then the proposed dose should be: 0,11 kg ASSET/10000 m^2 LWA**.**
- South-East EPPO zone: LWA vary between 12500 and 14667. If we consider the average of LWA's (13584) noted in all trials then the proposed dose should be: 0,13 kg ASSET/10000 m^2 LWA.
- MED EPPO zone: LWA vary between 12500 and 16667. If we consider the average of LWA's (14873) noted in all trials then the proposed dose should be: 0,12 kg ASSET/10000 m^2 LWA. For pear it is not possible to present dose LWA due to not enough data (height pear and distance between row is needed).

The final decision to accept this approach and to accept the data is left to cMS. The dose of LWA depends to a large extent on the height of the seedlings, therefore it should be individualized by each cMS based on the average height of crops, row spacing, etc. The field tests presented by the Applicant are characterized by very different testing conditions, e.g. large differences in the number of crops, height or row spacing which directly translates into the proposed dose of LWA. ZRMs present only the obtained results, and he expect their detailed interpretation by each cMS, accordingly to agro-climatic conditions and average LWA of apple trees crops.

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

Acetamiprid is an insecticide that belongs to the pyrethroid group. Acetamiprid act on the nervous system of insects and is characterised as an Acetylcholine receptor (nACHr) agonist. Acetamiprid shows a strong knock-down effect and also repellent and anti-feeding properties which help to protect the treated plants or part of plants.

Despite two decades of steadily increasing use of neonicotinoids, the aphids have proved remarkably resilient to the development of resistance and have remained highly effective against *M. persicae* as well as other aphids in pome- and stone fruits. However, recent studies of the peach aphid (*Myzus persicae*) in

southern Europe have revealed the presence of neonicotinoid resistant aphids in an increasing number of areas. No neonicotinoid resistance has yet been report from other aphid species affecting pome- and stone fruits. Furthermore, in oilseed rape, there are no evidence of resistance in pollen beetle (*Meligethes aeneus*) towards neonicotinoids.

To aid the reduction of selection pressure within insect pest populations, the label recommends alternating the use of acetamiprid with an insecticide with a different mode of action to avoid build-up of populations resistant towards neonicotinoid insecticides.

The resistance management strategy consists of:

- Use in alternation with insecticides with a different mode of action
- Use as recommended on the label. Do not use reduced doses.
- Acetamiprid 20% SG should only be applied when the pest population reaches the recommended threshold in the region/crop.
- Use other measures such as crop rotation, good agronomic practice

The Registration of Acetamiprid 20% SG is endorsed.

Good agricultural practices should be applied alongside physical and biological pest control methods. Monitor problematic pest populations in order to detect first shifts in sensitivity. The use of non-specific mode of action products helps to prevent the development of resistance. Plant protection products such as oils and soaps which have a non-specific mode of action are good resistance management tools which should be recommended for use in rotation or combination with Group 4 insecticides, provided that they effectively control both susceptible and resistant target pest populations.

The proposed resistance risk management strategy is acceptable. Final asassessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member States.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

Phytotoxicity was assessed in 34 efficacy trials, which were conducted in the Maritime EPPO zone (Northern part of France, Germany, the Netherlands and the UK), the North-east EPPO zone (Poland, Latvia and Lithuania), the South-east EPPO zone (Hungary and Romania) and the Mediterranean EPPO zone (Southern part of France, Italy, Spain and Portugal) in 2015 and 2019 to evaluate the selectivity of Acetamiprid 20% SG in oilseed rape and pome fruits.

Acetamiprid 20% SG applied at the recommended dose rate was perfectly crop safe and did not cause phytotoxicity in any of the trials conducted on winter oilseed rape and pome fruits (apple and pear).

Effects on yield and quality

The control of insects feeding from leaves, seeds and other plant parts is expected to positively impact the quality of plants and plant products.

No trials were harvested to demonstrate the impact of Acetamiprid 20% SG on the quality of plants and plant products.

Effect on transformation processes

There are no indications that the use of acetamiprid will have influence on possible transformation processes. It is therefore expected that Acetamiprid 20% SG, when applied in accordance with good agricultural practices will not cause any unacceptable adverse effects on transformation processes.

Furthermore, the residue data (see Part B Section 7) clearly demonstrate that, at the proposed application rates, no acetamiprid nor its metabolites above the LOQ (= limit of quantification) are found in any of the tested crops. In case of undetectable residues, no special studies are required according to the EPPO guideline PP 1/243(1).

Finally, it should be noted that acetamiprid has been used for a long time as an insecticide in the GAP claimed crops. Since the market introduction no effects on transformation processes have been recorded for any of these products, nor do acetamiprid containing products have any label restrictions concerning their use on crops destined for processing.

Impact on treated plants or plant products to be used for propagations

Special tests to investigate this purpose are not required.

Not applicable.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

Effects on succeeding crops are not to be expected, since the active acetamiprid is degraded within the timeframe of a normal cropping season. Furthermore, acetamiprid is not phytotoxic.

No label restrictions on succeeding crops following application of Acetamiprid 20% SG are proposed, in accordance with current labelling of existing acetamiprid containing products.

Impact on other plants including adjacent crops

During the conduct of efficacy trials, no observations about negative or positive effects on other plants or neighbouring crops were reported. Furthermore, acetamiprid is not phytotoxic.

The data presented within this Annex Point justifies the recommendation of no restrictions on adjacent crops regarding the application of Acetamiprid 20% SG.

Effects on beneficial and other non-target organisms
There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy and crop safety trials conducted.

3.3.4 Analytical method for the formulation

An analytical method for the determination of Acetamiprid in Acetamiprid 20% SG has been developed.

According to the SANCO/3030/99 rev.4 guidance document, the analytical method for the determination of Acetamiprid in the Acetamiprid 20% SG was validated.

	Acetamiprid
Author(s), year	Jose Angel Escudero, 2016
Principle of method	Liquid chromatography (HPLC) and UV detection
Linearity (linear between mg/L / % range of the declared content)	Linear between 91.75 mg/L and 458.74 mg/L R^2: 0.99981

	Acetamiprid
(correlation coefficient, expressed as r^2)	
Precision – Repeatability Mean n = 5 (%RSD)	RSD% = 0.36
Accuracy n = 6 (% Recovery)	100.5 ± 0.6 %
Interference/ Specificity	No interferences
Comment	The analytical method meets the criteria of specificity, linearity, precision and accuracy. The method is acceptable and is suitable for determination of Acetamiprid in plant protection product SHA 5500 (Asset).

3.3.5 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.
Noticed data gaps are:

- None

Commodity/crop	Supported/ Not supported
High oil content (Oilseed rape)	Supported
High water content (Pome fruits)	Supported

3.4 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for ASSET were not evaluated as part of the EU review of acetamiprid. All relevant data were provided and are considered adequate. The assessment of all acute toxicological properties of ASSET was derived from the calculation method based on the classification of the active compound and co-formulants.

Classification: **H302** Harmful if swallowed
H361d Suspected of damaging the unborn child

3.4.1 Operator exposure

Operator exposure to ASSET was not evaluated as part of the EU review of acetamiprid e for this submitted rate/crop. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.
Estimations of potential operator exposure have been undertaken for both acetamiprid using the EFSA AOEM model.

Conclusion

Oilseed rape use:
According to the AOEM model calculations it can be concluded that the risk for the operator using ASSET is acceptable without use of personal protective equipment.

Pome fruits uses:
According to the AOEM model calculations is acceptable with the use working clothing (long sleeved shirt and trousers) during mix/loading and application

Implication for labelling: P280

3.4.2 Worker exposure

Worker exposure to ASSET was not evaluated as part of the EU review of acetamiprid. Therefore, all relevant data and risk assessments have been provided and are considered adequate.
It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated Oilseed rape even without gloves.
It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves) for maintenance activities when for re-entering cotton treated pome fruits with ASSET when a time period of 4days after application is respected.4 days is below PHI and therefore is acceptable.
As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

Implication for labelling: P280: Wear protective gloves

3.4.3 Bystander and resident exposure

Bystander and resident exposures to ASSET was not evaluated as part of the EU review of Acetamiprid. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the AOEM.
It can be concluded that there is no undue risk to any resident and bystander after accidental short-term exposure to ASSET

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

Toxicological reference values for the dietary risk assessment of acetamiprid

Reference value	Source	Year	Value	Study relied upon	Safety factor
Acetamiprid					
ADI	EFSA 2016	2016	0.025 mg/kg bw/day	rat developmental neurotoxicity study	100
ARfD	EFSA 2016	2016	0.025 mg/kg bw/day	rat developmental neurotoxicity study	100

3.5.1 Residues

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Storage stability

Acetamiprid is stable in crops containing high water content, and high oil content matrices when stored under freezer conditions not exceeding 12 months;

The stability tests (on high water content, and high oil content matrices) described in the EFSA document (EFSA Journal 2016;14(11):4610) were accepted during reevaluation of active substance and they are not protected.

New stability study of acetamiprid residues in apple during 2 years of storage have been submitted by the applicant in the framework of this application (see Appendix 2). The results of this study showed that Acetamiprid is stable in apple (fruits) when stored at ≤ -18°C for a period of up to 24 months.

Metabolism in plants and animals

The metabolism in plants and livestock for the active substance Acetamiprid was reviewed during the Annex I inclusion and renewal process. No additional studies are available in the framework of this application.

Metabolism in primary crops was investigated in the fruit, leafy, root and oilseeds/pulses crop groups.

Metabolism in rotational crops was investigated in the root/tuber crops, leafy crops and cereal (small grain)

Plant residue definition for monitoring and risk assessment: acetamiprid

Animal residue definition for monitoring: acetamiprid except honey: the sum of acetamiprid and IM-2-1, expressed as acetamiprid (Reg (EU) 219/88)

Based on animal metabolism studies, the residue definition was proposed by EFSA 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 (EFSA Journal 2016;14(11):4610).

Note:

Study Hobbs, G., Inns, L., 2012 (metabolism in rotational crops) is protected. Equivalent study should be provided (see Data matching, The Netherlands, 2018). Reference to protected data cannot be accepted.

However, data gap indicated in the data matching cannot be a reason for refusal to renew the PPP in Poland.

This study is important for the evaluation of acetamiprid as an active substance, taking into account the possible presence of the metabolite IM-1-5 in succeeding crops grown on calcareous soils. Metabolism in rotational crops is not required for uses of plant protection products in permanent crops (e.g. orchards and nuts) or semi-permanent crops. Given this we find that for ASSET, this requirement only applies to the cultivation of oilseed rape.

In addition, 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. The evaluator wants to emphasize that in Poland only 9% of soils are alkaline and the registration applies only to Poland. Despite this from a formal point of view this study is required for rape seed uses.

Consequently, the evaluator disagreed with the use of this PPP in oilseed rape. Registration will be possible after completing the equivalent study to the protected study (Hobbs, G., Inns, L., 2012 (metabolism in rotational crops)).

New metabolism study has been submitted by the Applicant in the framework of this application. The study was accepted by The Netherlands (2021) as an alternative study in the Matching Active Substance

Data check document.

NL conclusion: "The applicant provided an alternative metabolism study in rotational crops (Report no. S19-02432). The study is GLP- and guideline-compliant, and results in approximately the same endpoints at the study by Hobbs, G. and Inns, L. (2012). Acceptable"

A detailed assessment of the study should be carried out at the EU level.

The Applicant has fulfilled the requirements.

Magnitude of residues in plants

Oilseed rape

Proposed GAP:

BBCH: before-69, 1 application, Application rate per treatment: 0.04 kg as/ha, PHI: 28 days;

Critical GAP in NEU (EFSA Journal 2010; 8(11):1898, EFSA Journal 2011;9(7):2328):

BBCH 75-81 (PHI: 28 days); 1 application, Application rate per treatment: 0.05 kg as/ha.

2 applications were made in some of trials used for the active substance assessment instead of one.

New acceptable studies on the magnitude of residue have been submitted by the applicant in the frame-work of this application (see Appendix 2).

New acceptable studies GAP: 1 application, BBCH: 69, 0.04 kg as/ha, PHI: 28 days

Results: 2 x <0.01; 0.014, 2 x 0.016, 0.018, 2 x 0.022 mg/kg

Sufficient trials on oilseed rape are available to support the proposed uses. The residue data are valid with regard to storage stability data. Samples were stored to 195 days until analyses.

The validated analytical methods used for determination of acetamiprid in oil seed rape fulfil criteria of acceptance. described in SANCO/825/00 rev.8.1 document.

LOQ = 0.01 mg/kg

The residues arising from the proposed uses will not exceed the MRLs for acetamiprid established for oilseed rape (0.4 mg/kg ; Reg. (EU) 2019/88).

Pome fruits

Proposed GAP:

Apple: before BBCH 59 and from BBCH 69; 2 applications, Application rate per treatment: 0.05 kg as/ha, Interval between applications: 14 days, PHI: 14 days

EU GAP: 2 x 0.075 kg as/ha, BBCH 77-87 (List of Endpoints, Acetamiprid, The Netherlands, 2016)

The residue trials in pome fruit were already evaluated in the original DAR and in renewal process.

Below is the conclusion from the re-evaluation (Acetamiprid, Volume 3, B7 Residue, The Netherlands, 2016):

The GAP for pome fruit includes an interval of at least 14 days between the two applications. When evaluating the trials in more detail after the peer review within the renewal, it appears that the trials (which have already been used for the initial inclusion of acetamiprid) are performed with at least a 1-month interval up to an interval of 49 days between the two applications. From the trials it can be concluded that at a PHI of 14 days still residues are present on pome fruit. Higher residues might be present when an interval of 14 days is applied in the trials instead of at least 1 month. Therefore, the trials are not conducted according to the cGAP, and are not acceptable.

According to EU data GAP with 30 – 40 days interval between the two applications is acceptable for pome fruits.

New studies on the magnitude of residue have been submitted by the applicant with interval between treatments of 14 days in the framework of this application.

Trials GAP: 2x0.05 kg as/ha, interval between treatments 14 days, PHI: 14 days, outdoor.

Results: 0.016, 0.017, 0.019, 0.022, 0.026, 0.026, 0.029 mg/kg

The studies were performed according to proposed GAP with 14 days of interval.

The package of EU and the new trials allows to accept the use in pome fruits with 14 days interval between the two applications.

The residues from field trials are below MRL of 0.4 mg/kg (Reg (EU) 219/88).

According to the SANCO 7525/VI/95 rev.10.3 of 13 June 2017 extrapolation from apple to the whole group of pome fruit is possible.

Feeding studies

Data/information on livestock feeding studies were reviewed during the Annex I inclusion process and was considered to be acceptable and no further data have been generated.

The requested uses (and the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded after application of product according to the intended GAP uses.

Supplementary Studies on Industrial Processing and/or Household Preparation

Data on processing studies were evaluated at EU level.

Information given by the Applicant is sufficient. No further data are required.

Residues in Succeeding Crops

Acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops.

No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

Note:

Studies Raufer, B., 2013, 2014 are protected. Equivalent study should be provided (see Data matching, The Netherlands, 2018). Reference to protected data cannot be accepted.

See note for metabolism.

Evaluator disagreed with the use of this PPP in oilseed rape. Registration will be possible after completing the equivalent study to the protected studies.

New studies for residues in succeeding crops have been submitted by the Applicant in the framework of this application. Studies are acceptable.

New data:

Representative succeeding crops of carrots, spinach and barley were planted at plant back intervals of 30, 63, 130 and 348 days. No residues of Acetamiprid or metabolite IM-1-5 above the LOQ (0.01 mg/kg) were found in any of the samples taken from all the PBIs.

Conclusion:

Registration in the protection of oil seed rape will be possible after completing the equivalent studies to

the following protected studies (see Data matching, The Netherlands, 2018):

Study Hobbs, G., Inns, L., 2012 (metabolism in rotational crops).

Raufer, B., 2013, 2014 studies (field rotational crop studies).

Reference to protected data cannot be accepted.

Alternative studies have been provided.
According to the current requirements (SANTE/11956/2016 rev. 9), information on residues in honey is required. Such information can be provided after authorization is obtained.

3.5.2 Consumer exposure

Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	122.3% NL toddler
IEDI (% ADI) according to EFSA PRIMo	98.2% NL toddler
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 221.58% Pears 172.45% Apples 78.70% Quinces 44.27% Medlar 2.21% Rapeseeds/canola seeds Results for adults 48.87% Pears 48.67% Quinces 44.92% Apples 21.91% Medlar 0.84% Rapeseeds/canola seeds Processed commodities Results for children 86.6% Apples / juice 52.1% Pears / juice 9.7% Quinces / jam 0.9% Rapeseeds / oils Results for adults 53.3% Apples / juice 4.00% Quinces / jam
IESTI (% ARfD) according to EFSA PRIMo* Refined calculation	Unprocessed commodities Results for children 39.33% Pears 30.61% Apples 6.98% Quinces 3.93% Medlar 0.08% Rapeseeds/canola seeds Results for adults 8.67% Pears 7.97% Apples 4.32% Quinces 1.94% Medlar 0.03% Rapeseeds/canola seeds Processed commodities Results for children 5.6% Apples / juice 3.4% Pears / juice

	0.3% Quinces / jam 0.0% Rapeseeds / oils Results for adults 3.5% Apples / juice 0.13% Quinces / jam

The accepted use of acetamiprid in the formulation SHA5500A do not represent unacceptable acute and chronic risks for the consumer.

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

Concentrations of Acetamiprid in various environmental compartments are predicted following the proposed uses pattern.

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

The PEC_S of Acetamiprid and its metabolites in soil has been assessed with the CRD Excel spread sheet model using the following input data:

Use No.	1	**2***
Crop	Oilseed Rape	**Pome fruits**
Application rate (g as/ha)	40	**50**
Number of applications/interval	1	**2/14**
Crop interception (%)	80	**60/60**
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm	**5 cm**

*__In bold__: scenario considered as a representative worst case, and thus considered for the assessment.

Maximum PEC_{soil} values are:

- 0.039 mg/kg for Acetamiprid
- 0.032 mg/kg for the metabolite IM-1-4
- 0.042 mg/kg for the metabolite IM-1-5
- 0.016 mg/kg for the metabolite IM-1-2
- 0.003 mg/kg for the metabolite IC-0
- 0.267 mg/kg for formulation ASSET

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

The PEC_{GW} of ASSET in groundwater has been assessed with the models FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and FOCUS MACRO v5.5.4 (only for metabolite IM-1-5 in apple crop), and the DT_{50} and the soil sorption values established in the EU review.

It should be noted that as recommended in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (FOCUS 2011), a corrected application rate is calculated taking into account the interception by the crop canopy. Therefore, the substance is applied directly to the ground in the models, thus avoiding the internal interception routines in the models. The corrected application rates are 20 g as/ha for pome fruits applications and 8 g as/ha for oilseed rape applications.

PEC_{gw} for Acetamiprid and its metabolites were calculated accordingly.

According to the models Acetamiprid and its non-relevant metabolites IM-1-2, IM-1-4 and IC-0 showed PECgw values far below 0.1 µg/L for all uses and models. Only the metabolite IM-1-5 showed PECgw

values greater than trigger of 0.1 µg/L in several scenarios for apple in PELMO and PEARL models. However in MACRO model the PECgw was below 0.1 µg/L. The PECgw maximum was 0.205 µg/L in PELMO Hamburg scenario.

Considerations must be taken since IM-1-5 metabolite only appears in calcareous soils with pH (water) > 8 and none of the FOCUS scenarios has pH greater than 8, only Châteaudun has pH = 8. Therefore, the FOCUS models are not suitable to assess the ground water concentration of this metabolite. Furthermore, the metabolite IM-1-5 was found only in the top 10 cm in the field studies and not detected in the leaching studies.

Based on FOCUS PEARL and PELMO and MACRO simulations values of PECgw for acetamiprid and its metabolites are far below the threshold concentration of 0.1 µg/L for all scenarios and crops. Only the PECgw of metabolite IM-1-5 exceeded 0.1 µg/L in some scenarios and some crops, however they all were <0.75 µg/L. However, modeling MACRO for metabolite IM-1-5 showed PECgw < 0.1 µg/L.
A modelling performed for metabolite IM-1-5 together with evaluation of toxicological and ecotoxicological relevance is sufficient.
In opinion zRMS no unacceptable risk for groundwater was identified.

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

The $PEC_{sw/sed}$ of Acetamiprid and its relevant metabolites have been assessed with the models FOCUS Steps 1, 2, 3 and 4 using the DT_{50} and the soil sorption values established in the EU review for the Acetamiprid and its metabolites (EFSA Journal 2016;14(11): 4610). Please refer to Part B, Section 8, point 8.10 for more details about the results obtained.

Since the aquatic organisms risk assessments using FOCUS STEPS 1-2 v3.2 PEC_{sw} values still show unacceptable risks for the active substance Acetamiprid, further calculations were conducted at Step 3 using the models FOCUS SWASH v5.3, FOCUS PRZM v 4.3.1, FOCUS MACRO v5.5.4 and FOCUS TOXWA v5.5.3. However, Step 3 refinements were not sufficient to show acceptable risk. Therefore, in order to refine the aquatic risk assessment, further calculations were conducted at Step 4 to quantify the risk mitigation measures such as no spray buffer zones and drift reduction nozzles. The simulations were performed using the SWAN 5.0.0 model.

The results for PEC surface water (Step 1 to 4) for the active substance were used for the ecotoxicological risk assessment.

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

The vapour pressure at 20 °C of the active substance Acetamiprid is < 10^{-6} Pa. Hence the active substance Acetamiprid is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Acetamiprid due to volatilization with subsequent deposition should not be considered.

3.7 Ecotoxicology (Part B, Section 9)

According to the risk assessment performed on aquatic organisms:

3.7.1 Effects on terrestrial vertebrates

The risk assessment for birds has been done. The TER_A values are greater than the Annex VI trigger of 10, indicating low acute risk to birds from Acetamiprid following application of Asset at all proposed label rates. The TER_{LT} values are greater than the Annex VI trigger of 5, indicating low long-term risk to

birds from Acetamiprid following application of Asset at all proposed label rates. The risk for drinking water exposure is acceptable and effect of secondary poisoning is not expected.

The risk assessment for mammals has been done. The TER_A values are greater than the Annex VI trigger of 10, indicating low acute risk to mammals from Acetamiprid following application of Asset at all proposed label rates. The TER_{LT} values were below than the Annex VI trigger of 5, indicating a long-term risk to mammals from Acetamiprid following application of Asset at all proposed label rates. After the ftwa, MAF and DF refinement, the risk was considered acceptable expect use in orchards. Therefore, further refinement is required .
The risk for drinking water exposure is acceptable and effect of secondary poisoning is not expected.

3.7.2 Effects on aquatic species

After Step 3 calculations, for the intended uses, calculated PEC/RAC ratios did indicate an unacceptable risk for the most sensitive group of aquatic organisms (risk for sediment dwelling organism as characterised by an NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} (for application doses: 1 x 36 g a.s./ha and 2x 36 g.a./ha in orchards) considering reduced exposure of surface water bodies
Based on the results of the risk assessment at step 4 and calculation for accepted uses including in the GAP for Poland the following conclusions regarding buffer zones and nozzles reduction may be drawn:

P**ome/stone fruits (early application, 1-2 x 36 g a.s./ha)**

- 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip

Pome/stone fruits (late application, 1-2 x 36 g a.s./ha)

- 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.

3.7.3 Effects on bees

The risk assessment for bees has been done. All the hazard quotients are considerably less than 50, indicating that the active substances pose a low risk to bees. Therefore a low risk to bees is expected from the application of Asset at all proposed label rates.
According to Commission regulation (EU) No 284/2013, point 10.3.1. the Applicant provided the chronic test on bees and chronic test for larvae for acetamiprid. According to Harmonization Meeting in Polish Ministry on area of Ecotoxicology these studies should be taken into account in the risk assessment when GD for Bees, 2013 will be implemented.

3.7.4 Effects on other arthropod species other than bees

The results of the risk assessment for non-target arthropods showed an acceptable in-field and off-field risk after the application of Acetamiprid 20% SG. A potential of recovery of the in-field area have been demonstrate in a short period of time. In addition, an acceptable off-field risk was obtained with the application , of the following risk mitigation measures for accepted uses included in GAP table for Poland:

Pome/stone fruits (early application, 1-2 x 36 g a.s./ha) - Spe3: *To protect non-target arthropods respect*

~~*an unsprayed buffer zone of 50 m to non-agricultural land OR an unsprayed buffer zone of 40 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 30m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 90% of nozzles reduction.*~~

~~***Pome/stone fruits (late application, 1-2 x 36 g a.s./ha) - Spe3**: To protect non-target arthropods respect an unsprayed buffer zone of 40 m to non-agricultural land OR an unsprayed buffer zone of 30 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction.*~~
~~*The risk mitigation measures for two applications covers the risk for one application at 36 g a.s./ha.*~~

***Pome/stone fruits (late application, 1-2 x 36 g a.s./ha)–Spe3**: To protect non-target arthropods respect an unsprayed buffer zone of 30 m to non-agricultural land OR an unsprayed buffer zone of 20 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 15m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction.*

***Oilseed rape – Spe3 (1x 40 g a.s./ha)**: To protect non-target arthropods respect an unsprayed buffer zone of 10 m to non-agricultural land OR an unsprayed buffer zone of 5 m to non-agricultural land with 50% of nozzles reduction OR no buffer zone to non-agricultural land with 90% of nozzles reduction.*

It should be noted that only for acceptable uses the risk mitigation measures are included in the label for Poland.

3.7.5 Effects on soil organisms

The risk assessment for earthworms has been done. All the chronic TER values are much higher than the Annex VI long-term trigger value of 5, indicating that Asset poses low chronic risk to earthworms when applied according to the proposed use rates.

The risk assessment for earthworms has been done. The risk to soil microbial processes from the proposed uses of Asset is considered to be acceptable when applied according to the proposed use rates.

3.7.6 Effects on non-target terrestrial plants

The risk assessment for non-target plants has been done. The risk to non-target plants for Asset is considered to be acceptable when applied according to the proposed use rates.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not required.

3.8 Relevance of metabolites (Part B, Section 10)

Only metabolite IM-1-5 was predicted to occur in groundwater at concentrations above 0.1 µg/L. it was considered as toxicologically relevant in the EFSA Journal 2016;14(11): 4610. However, considerations must be taken since IM-1-5 metabolite only appears in calcareous soils with pH (water) > 8 and none of the FOCUS scenarios has pH greater than 8, only Châteaudun has pH = 8. Therefore, the FOCUS models are not suitable to assess the ground water concentration of this metabolite. Furthermore, the metabolite IM-1-5 was found only in the top 10 cm in the field studies and not detected in the leaching studies.

Therefore no assessment according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 was done.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant.

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

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Sekcja pozostałości:
~~Brak zgody na ochronę upraw rzepaku do czasu uzupełnienia badań równoważnych do badań chronionych~~ Proponowane zastosowania są zaakceptowane.
~~**Sekcja Ekotox:**~~ ~~Brak zgody na max. dawkę 2 x 50 g a.s./ha (0.25 kg/ha) w sadach (wczesne i późne zastosowanie) z uwagi na brak akceptowalnego ryzyka długoterminowego dla ssaków i konieczność dalszego uściślenia ryzyka dla organizmów wodnych.~~

Załącznik do zezwolenia MRiRW nr R - …../…… z dnia ……2020

Posiadacz zezwolenia:
Sharda Cropchem España S.L., Edifico Atalayas Business Center Carril Condomina n°3, 12th Floor, 30006 Murcia, Hiszpania tel. +34868127589, e-mail: eu.sales@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: +48 17 240 13 07, e-mail: eu.sales@shardaintl.com.

ASSET ~~(ZUXION)~~

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
Acetamipryd (związek z grupy pochodnych neonikotynoidów) – **200 g/kg (20.37 %).**

Zezwolenie MRiRW nr R- /2020 z dnia . .2020 r.

UWAGA	
H302	Działa szkodliwie po połknięciu.
H361d	Podejrzewa się, że działa szkodliwie 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.

P264	Dokładnie umyć ręce po użyciu.
P270	Nie jeść, nie pić i nie palić podczas używania produktu.
~~P273~~	~~Unikać uwolnienia do środowiska..~~
P301+P312	W PRZYPADKU POŁKNIĘCIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.
P308+P313	W przypadku narażenia lub styczności: Zasięgnąć porady/ zgłosić się pod opiekę lekarza
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do specjalnego punkt zbioru niebezpiecznych lub specjalnych odpadów, zgodnie z przepisami miejscowymi, regionalnymi, krajowymi i/lub międzynarodowymi

OPIS DZIAŁANIA

ASSET ~~(ZUXION)~~ jest środkiem owadobójczym w formie granul rozpuszczalnych w wodzie, o działaniu kontaktowym i żołądkowym, przeznaczony do zwalczania szkodników ssących i gryzących w uprawie rzepaku ozimego i roślin sadowniczych. Na roślinie działa powierzchniowo, wgłębnie i systemicznie.

Środek ASSET (~~ZUXION~~) przeznaczony jest do stosowania przy użyciu opryskiwaczy polowych i sadowniczych.

STOSOWANIE ŚRODKA

Rzepak

Słodyszek rzepakowiec

Maksymalna dawka dla jednorazowego zastosowania: 0,2 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 0,2 kg/ha

Liczba zabiegów: 1

Termin stosowania środka: Opryskiwać w momencie nalotu szkodnika na plantację, do końca fazy kwitnienia rzepaku (BBCH 69).

Zalecana ilość wody: **200-600 l/ha**.

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Owoce ziarnkowe

Mszyce

Maksymalna dawka dla jednorazowego zastosowania: ~~0,25 kg/ha (0,15 kg/ 10000 m2 ściany owoconośnej liści)~~, 0.18 kg/ha (0,11 kg/ 10000 m^2 ściany owoconośnej liści)

Zalecana dawka dla jednorazowego zastosowania: 0,~~25 kg/ha 0,15 kg/ 10000 m2 ściany owoconośnej liści)~~, 0.18 kg/ha (0,11 kg/ 10000 m^2 ściany owoconośnej liści)

Liczba zabiegów: 1-2

Odstęp między zabiegami: 14 dni

Termin stosowania środka: Opryskiwać ~~w momencie pojawienia się pierwszych kolonii mszyc, przed rozpoczęciem fazy kwitnienia (BBCH 59) lub~~ po zakończeniu kwitnienia (BBCH 69).

Zalecana ilość wody: **900-1000 l/ha**.

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe.

NASTĘPSTWO ROŚLIN
W przypadku konieczności wcześniejszej likwidacji plantacji opryskanej środkiem ASSET (~~ZUXION~~), roślin następczych (przesiewów) nie należy chronić środkiem owadobójczym zawierającym substancję czynną acetamipryd.
ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ
1. W ramach strategii zarzadzania odpornością:
   – środek stosować przemiennie ze środkami owadobójczymi zawierającymi substancje czynne należące do innych grup chemicznych i o innych mechanizmach działania,
   – nie należy stosować środka w dawkach niższych od zalecanych,
   – w przypadku konieczności powtórzenia zabiegu zamiast środka ASSET (~~ZUXION~~) zaleca się zastosować środek owadobójczy zawierający substancję czynną z innej grupy chemicznej, o odmiennym mechanizmie działania.
2. Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiadujące plantacje roślin uprawnych.
3. Opryskiwanie przeciwko szkodnikom (zwłaszcza ssącym) wykonać dokładnie, pokrywając wszystkie części roślin cieczą użytkową

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego do połowy 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 nie wyposażonego 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

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:
– po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe 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.
Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

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

Środki ostrożności dla osób stosujących środek: (pracowników oraz osób postronnych)

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

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

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.

~~**Owoce ziarnkowe (wczesna aplikacja, 1-2x 180 g/ha)**~~

~~**SPe3**~~

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej w odległości:~~

- ~~20 m zadarnionej strefy ochronnej od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 95% od zbiorników i cieków wodnych lub~~
- ~~30 m strefy ochronnej w tym 20 metrowej zadarnionej z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% od zbiorników i cieków wodnych lub~~
- ~~40 m strefy ochronnej w tym 20 metrowej zadarnionej z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% od zbiorników i cieków wodnych lub~~
- ~~50 m strefy ochronnej w tym 20 metrowej zadarnionej od zbiorników i cieków wodnych~~

~~**SPe3**~~

~~W celu ochrony stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej w odległości:~~

- ~~50 m od terenów nieużytkowanych rolniczo lub~~
- ~~40 m od terenów nieużytkowanych rolniczo z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% lub~~
- ~~30 m od terenów nieużytkowanych rolniczo z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub~~
- ~~20 m terenów nieużytkowanych rolniczo z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%~~

Owoce ziarnkowe (późna aplikacja, 1-2 x 36 g a.s./ha))

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej w odległości:

~~**Pome/stone fruits (late application, 1-2 x 36 g a.s./ha)**~~

- 10 metrowej zadarnionej strefy ochronnej z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 95% od zbiorników i cieków wodnych lub
- 20 metrowej zadarnionej strefy ochronnej z jednoczesnym zastosowaniem rozpylaczy redukują-

cych znoszenie cieczy użytkowej podczas zabiegu o 90% od zbiorników i cieków wodnych lub
- 30 m strefy ochronnej w tym 20 metrowej zadarnionej z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% od zbiorników i cieków wodnych lub
- 40 m strefy ochronnej w tym 20 metrowej zadarnionej z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% od zbiorników i cieków wodnych lub
- 50 m strefy ochronnej w tym 20 metrowej zadarnionej od zbiorników i cieków wodnych

SPe3

W celu ochrony stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej od terenów nieużytkowanych rolniczo w odległości:

- ~~40 m od terenów nieużytkowanych rolniczo lub~~
- 30 m od terenów nieużytkowanych rolniczo z ~~jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%~~ lub
- 20 m od terenów nieużytkowanych rolniczo z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o ~~7~~50% lub
- 15 m od terenów nieużytkowanych rolniczo z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub
- 10 m od terenów nieużytkowanych rolniczo z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.

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

Nie dotyczy

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

Rzepak – 28 dni

Owoce ziarnkowe – 14 dni

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,
- w temperaturze 0^{o}C - 30^{o}C, z dala od źródeł ciepła.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.2 KCP 2.3 KCP 2.4 KCP 2.6 KCP 2.7.1 KCP 2.8.1 KCP 2.8.2 KCP 2.8.4 KCP 2.8.5.1 KCP 2.8.5.2 KCP 2.8.5.3 KCP 2.8.7	Jose Angel Escudero	2016	Physico-Cheùical Characterization of ACETAMIPRID 20% SG Laboratorios Munuera Report No 15-4150-03 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.7.5	Jose Angel Escudero	2018	Storage stability for two years at 25 ± 2 ºC of ACETAMIPRID 20% SG Laboratorios Munuera Report No 15-4150-04 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.11	Jose Angel Escudero	2016	Cleaning application equipment – Small scale jar test protocol for ACETAMIPRID 20% SG Laboratorios Munuera Report No 15-4150-27	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 5.1.1	J. A. Escudero	2016	Physico-Chemical Characterization of ACETAMIPRID 20% SG. Laboratorios Munuera, Report No. 15-4150-03 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Acetamiprid 20% SG (200 g/kg Acetamiprid) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 7.1.5	xxx	2017	Acetamiprid 20% SG:Acute Eye Irritation / Corrosion Study in Rabbit xxx, Report No.15366 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 7.6.2	Brufau Donés, G	2018	In vitro percutaneous absorption of Acetamiprid, formulated as Acetamiprid 20 % SG, through human skin Triskelion B.V , Report No.21130/26 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.2.1	S. Tobias	2021	Metabolism of [Pyridil^{14}C]-IM-1-5 metabolite in Rotational Crops Eurofins Agroscience Services EcoChem GmbH Report No.: S19-02432 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1-01	Rump, K.	2017	Determination of residues at harvest of Acetamprid in oilseed rape, followring one broadcast applciation of Acetamiprid 20% SG, under open field conditions, Central Europe – Season 2017. Field Research Support Report no. FRS 003/17 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1-02	Sikorski, P.	2018	Determination of acetamiprid residues in oilseed rape after application of "Acetamiprid 20% SG" in one trial (1HS), Germany – 2017. Food Safety Laboratory Report no. ZBBZ-2016/14/DPL/1DE GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1-03	Rump, K.	2017	Determination of residues at harvest and decline of Acetamprid in oilseed rape, followring one broadcast applciation of Acetamiprid 20% SG, under open field conditions, Central Europe – Season 2016. Field Research Support Report no. FRS 058/16-V2 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1-04	Sikorski, P.	2017	Determination of acetamiprid residues in oilseed rape after application of "Acetamiprid 20% SG". Food Safety Laboratory Report no. ZBBZ-2016/14/DPL/1DE GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1-05	Kull, S.	2018	Residue study (Harvest and Decline) in oilseed rape following one application with Acetamiprdi 20% SG in Germany 2017 – field part. CropTrials GmbH Report no. CT17-1-35 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1-06	Sikorski, P.	2018	Magniture of residues of acetamprid in oilseed rape raw agricutlural commodity after one application of acetamprid 20% SG under field conditions – 1 harvest trial and 1 decline trial – Germany – 2017 Food Safety Laboratory Report no. ZBBZ-2017/25/DPL/1DE	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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			GLP Unpublished				
KCP 8.3.1-07	Romero, S.	2018	Magnitude of residue of Acetamiprid in oilseed rape Raw Agricultural Commodity after one application of Acetamiprid 20% SG under field conditions – 1 harevesttrial and 1 decline trial – Poland – 2017. BIOTEK Agriculture España SL Report no. BPL17-013 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1-08	Gábor Wágner	2020	Determination of the residues of acetamiprid in/on oilseed rape after one application of acetamiprid 20% SG in Northern Europe – Hungary in 2019. SynTech Research Hungary Study number 034SRHU19R32 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1-09	A. Markowicz	2019	Determination of the residues of acetamiprid in/on oilseed rape after one application of acetamiprid 20% SG in Northern Europe – Hungary in 2019. Food Safety Laboratory Study number ZBBZ-2017/25/DPL/1HU GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.2-01	H. Zoellner	2019	Determination of residues at harvest of acetamiprid in apple, following two applications of acetamiprid 20% SG, under open field conditions. Germany - season 2018. Field Research Support. Study number FRS 055/18 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.2-02	Z. Hordyjewicz-Baran	2019	Determination of residues at harvest of acetamiprid in apple, following two applications of acetamiprid 20% SG, under open field conditions Germany – Season 2018 Analytical	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			part. Łukasiewicz Research Network – Institute of Heavy Organic Synthesis "Blachownia" Study number 206/2019 GLP Unpublished				
KCP 8.3.2-03	R. Figurski	2019	Magnitude of the residue of acetamiprid in pome fruits (raw agricultural commodity - rac) grown in open field conditions after two applications of formulated product acetamiprid 20% SG - two decline curve trials in Poland – 2018. Fertico Sp. z o.o. Study number PB-2018-02 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.2-04	M. Zarębska	2019	Magnitude of the residue of acetamiprid in pome fruits (raw agricultural commodity - rac) grown in open field conditions after two applications of formulated product acetamiprid 20% SG - two decline curve trials in Poland – 2018. Łukasiewicz Research Network – Institute of Heavy Organic Synthesis "Blachownia" Study number 197/2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.2-05	Gábor Szilágyi	2019	Determination of the residues of acetamiprid in/on apple after two applications of acetamiprid 20% SG in Northern Europe - Hungary in 2019. SynTech Research Hungary Study number 034SRHU19R22 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.2-06	M. Zarębska	2019	Determination of the residues of acetamiprid in/on apple after two applications of acetamiprid 20% SG in Northern Europe - Hungary in 2019. Łukasiewicz Research Network – Institute of Heavy Organic	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Synthesis “Blachownia” Study number 205/2019 GLP Unpublished				
KCP 8.3.2-07	Z. Hordyjewicz-Baran	2020	Magnitude of the residue of acetamiprid in pome fruits (Raw Agricultural Commodity) after two applications of Acetamiprid 20% SG – one harvest and two decline curbe trials in Poland – 2018. Łukasiewicz Research Network – Institute of Heavy Organic Synthesis “Blachownia” Study number 18SGS01. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.3-01	Gábor Wágner	2022	Determination of the residues of acetamiprid in/on crop rotation crops after one application of Acetamiprid 20% SG in Northern Europe - Hungary in 2019, CPR Europe Kft. Report No.: 034SRHU19R21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.3-02	Charlotte Marteau	2022	Determination of the residues of Acetamiprid in/on crop rotation crops after one application of Acetamiprid 20% SG in Hungary in 2019, Eurofins Agroscience Services Chem SAS Report No.: S22-01946 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-01	xxxx	2017	Acetamiprid 20% SG Rainbow trout Acute toxicity test xxx, W/12/17 GLP Unpublished	Y	N	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-02	xxxx	2017	Acetamiprid 20% SG *Daphnia magna*, acute immobilization test xxx, W/14/17	N	N	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 10.2.1-03	xxx	2017	Acetamiprid 20% SG *Pseudokirchneriella subcapitata* SAG 61.81 Growth inhibition test xxx, W/13/17 GLP Unpublished	N	N	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-04	xxx	2017	Acetamiprid 20% SG. *Lemna gibba* CPCC 310, Growth inhibition test xxx, W/15/17 GLP Unpublished	N	N	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-05	Angayarkanni, V.	2018	Acute Immobilization Effect of Acetamiprid 20% SG on *Chironomus riparius* BIOSCIENCE RESEARCH FOUNDATION, Study nº 4343/2018 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.1.1	Elzbieta Kulec-Ploszczyca	2016	Acetamiprid 20% SG, Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Institute of Industrial Organic Chemistry, B/100/15 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.1.2	Elzbieta Kulec-Ploszczyca	2016	Acetamiprid 20% SG, Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Institute of Industrial Organic Chemistry, B/101/15 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.2	Gimeno, I.	2019	Acetamiprid 20 % SG – Chronic Oral Toxicity Test (10-Day Feeding) to the Honey Bee, *Apis mellifera* L. under Laboratory Conditions Trialcamp S.L.U, TRC17-065BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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KCP 10.3.1.3	Gimeno, I.	2019	Acetamiprid Technical – Honey Bee (*Apis mellifera* L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions Trialcamp S.L.U, S18-05066 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.2-01	Elzbieta Kulec-Ploszczyca	2016	An extended laboratory test for evaluating the effects of Acetamiprid 20% SG on the predatory mite, *Typhlodromus pyri* (Sch.) Institute of Industrial Organic Chemistry, B/98/15 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.2-02	Elzbieta Kulec-Ploszczyca	2016	An extended laboratory test for evaluating the effects of Acetamiprid 20% SG on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez) Institute of Industrial Organic Chemistry, B/99/15 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.2-03	Luna, F.	2018	Aged residue test with the formulation “Acetamiprid 20 % SG” on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) Trialcamp S.L.U, TRC17-087BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.2-04	Varela, S.	2017	Aged residue test with the formulation “Acetamiprid 20% SG” on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) Trialcamp S.L.U, TRC17-086BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.2-05	Luna, F.	2018	Aged residue test with the formulation “Acetamiprid 20% SG” on *Chrysoperla carnea* (Neuroptera: Chrysopidae) Trialcamp S.L.U, TRC17-088BA GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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			Unpublished				
KCP 10.3.2.2-06	Luna, F.	2018	Aged residue test with the formulation "Acetamiprid 20% SG" on *Coccinella septempunctata* L. (Coleoptera: Coccinellidae) Trialcamp S.L.U, TRC17-089BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.4.1.1	Aneta Gierbuszewska	2017	ACETAMIPRID 20% SG Earthworm Reproduction Test *(Eisenia fetida)* Institute of Industrial Organic Chemistry, G/187/15 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.4.2.1-01	Angayarkanni, V.	2019	Effect of Acetamiprid 20% SG on the reproduction of the collembolans (*Folsomia candida*) in artificial soil 4344/2018 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.4.2.1-02	Josep Lozano Garcia	2017	ACETAMIPRID 20% SG Effects on the Reproductive Out-put of the Predatory Soil Mite *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari: Laelapidae) in Artificial Soil Trialcamp S.L.U, TRC17-096BA GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.5.1	Aneta Gierbuszewska	2016	ACETAMIPRID 20% SG Soil Microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry, G/186/15 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.5.2	Aneta Gierbuszewska	2016	ACETAMIPRID 20% SG Soil Microorganisms: Carbon Transformation Test Institute of Industrial Organic Chemistry, G/185/15 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.6.2-01	Aneta Gierbuszewska	2016	ACETAMIPRID 20% SG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Institute of Industrial Organic Chemistry, G/190/15 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.6.2-02	Aneta Gierbuszewska	2016	ACETAMIPRID 20% SG Terrestrial Plant Test: Vegetative Vigour Test Institute of Industrial Organic Chemistry, G/191/15 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	T. Schwarz	2008	Acetamiprid: Validation of an enforcement method for plant materials, PTRL Europe, Report No. RD-01937 GLP Published	N	N	Data/study already evaluated at EU peer review.	Nippon Soda
	A. Giesau, H. Weber	2012	Independent laboratory validation of an enforcement method (QuEChERS) for the Determination of Residues of Acetamiprid in Crops using LC-MS/MS, Eurofins Agroscience Services, Study No. RD-02454 GLP Published	N	N	Data/study already evaluated at EU peer review.	Nippon Soda
	K. Miya	2010	Validation Study of the Analytical Method for the Determination of the Residues of Acetamiprid and Its Metabolite (IM-2-1) in Animal Commodities, Nisso Chemical Analysis Service Co., Japan, Report No. NCAS 10-144, Document ID RD-02080	N	N	Data/study already evaluated at EU peer review.	Nippon Soda

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			GLP Published				
	E. Knoch	2010	Independent Laboratory Validation: Analytical Method for the Determination of the Residues of Acetamiprid and its Metabolite (IM-2-1) in Animal Commodities, SGS Institut Fresenius GmbH, Report No. IF -10/01687868, Document ID RD-02156 GLP Published	N	N	Data/study already evaluated at EU peer review.	Nippon Soda
	A. Täufer, H. Weber	2010	Validation of an Analytical Method for the Determination of Residues of Acetamiprid and Acetamiprid Soil Metabolite IM-1-5 in Calcareous Soil using LC-MS/MS, Eurofins Dr. Specht, Germany, Report No. S09-03287, Document ID RD- 02062N GLP Published	N	N	Data/study already evaluated at EU peer review.	Nippon Soda
	K. Miya	2007	Validation Study of the Confirmatory Method for the Determination of Acetamiprid in Water, Nisso Chemical Analysis Service Co., Japan, Report No. NCAS 06-209, Document ID RD-01204 GLP Published	N	N	Data/study already evaluated at EU peer review.	Nippon Soda
	M. Scenciuc	2014a	Independent Laboratory Validation (ILV) of a Residues Analytical Method for the Determination of Acetamiprid in Drinking Water, PTRL Europe GmbH, Germany, Report No. P 3244 G, Document ID RD-02951 GLP Published	N	N	Data/study already evaluated at EU peer review.	Nippon Soda
	A. Giesau, H. Weber	2012	Validation of an Analytical Method for the Determination of Residues of Acetamiprid Metabolite IM-1-5 in Water using LC-MS/MS, Eurofins Agroscience Services, Germany, Report No. S12-02719, Document ID RD-02604 GLP	N	N	Data/study already evaluated at EU peer review.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Published				
	M. Senciuc	2014b	Independent Laboratory Validation (ILV) of a Residues Analytical Method for the Determination of Acetamiprid Metabolite IM-1-5 in Drinking Water, PTRL Europe GmbH, Germany, Report No. P 3245 G, Document ID RD-02952 GLP Published	N	N	Data/study already evaluated at EU peer review.	Nippon Soda
	I. Beck, T. Class	2009	Acetamiprid: Development and Validation of an Analytical Method(s) for the Determination of Residues on Operator Exposure Dosimeters from Field Studies, PTRL Europe, Germany, Report No. P/B 1603 G, Document ID RD-01863 GLP Published	N	N	Data/study already evaluated at EU peer review.	Nippon Soda
	M. Senciuc	2014c	Development and Validation of an Analytical Method for the Determination of Acetamiprid in Blood, PTRL Europe, Germany, Report No. P3208 G, Document ID RD-02943 GLP Published	N	N	Data/study already evaluated at EU peer review.	Nippon Soda

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in **this** MS:	Owner

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Published/Unpublished			Data protection started with: <insert authorization number of first authorization>	

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

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KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in **this** MS: Data protection started with: <insert authorization number of first authorization>	Owner