

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 5500 A

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

Chemical active substance:

Acetamiprid, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April/2020

MS Finalisation date: 22/12/2020 07/2021

Version history

When	What
September 2020	Applicant updated document
December 2020	ZRMs evaluated version of dRR.
July 2021	ZRMS made changes according to commenting period.

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

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

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

Comments of zRMS:	Comments of zRMS are in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are in grey). In yellow were marked changes after commenting period.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. 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 (<i>Meligethes aeneus</i>)	Foliar spray	At pest pres- ence. Before BBCH 69	a) 1 b) 1	NA	a) 0.2 b) 0.2	a) 0.04 b) 0.04	200-600	28		To be con- firmed by cMS
2	CEU	Pome fruits	F	Aphids	Foliar spray	At pest pres- ence, Before BBCH 59 and from BBCH 69	a) 1-2 b) 1-2	14 NA	a) 0.25 0,18 b) 0.5 0,36	a) 0.05 0,036 b) 0.10 0,072	900-1000	14		To be con- firmed by cMS. Ecotox can accept only dose 0,18 kg/ha and BBCH from BBCH 69

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

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

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Acetamiprid 20% SG (ZUXION; Product code: SHA 5500 A)** containing the active substance acetamiprid, which was included into Annex I of Council Directive 91/414/EEC.

The SANCO report for Acetamiprid (SANCO/1392/2001-final) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Acetamiprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29th June 2004 shall be taken into account. Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of Acetamiprid relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	KCP 6.0/001 Biological Assessment Dossier Acetamiprid 20% SG, Central
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Description of active substance acetamiprid

Acetamiprid was first introduced in 1995 for the control of aphids in pome fruit orchards and pollen beetles in oilseed rape, among other uses.

Acetamiprid is an odourless, neonicotinoid insecticide composed from a synthetic organic compound. Neonicotinoid insecticides were discovered in the 1980's and are used throughout the world. Acetamiprid is generally used to protect plants against sucking insects such as aphids, but it has also become common in household pest control to combat bed bugs. It is a broad-spectrum pesticide that can be used on plants ranging from leafy vegetables and fruit trees to ornamental plants.

Today, acetamiprid is registered and commercialised in several formulations around the world.

Table 3.2-1: Current approvals of acetamiprid in the EU Central zone as well as connected EPPO zones where trials were conducted

Country	Product	Active ingredient	Approval number
Austria	Mospilan 20 SG	Acetamiprid 200 g/kg SG	2830
Czech Rep.	Gazelle Mospilan 20 SP	Acetamiprid 200 g/kg SG	4053-9
		Acetamiprid 200 g/kg SP	4053-7
Germany	Mospilan SG	Acetamiprid 200 g/kg SG	005665-00
Greece	Mospilan 20 SP	Acetamiprid 200 g/kg SP	1902
Hungary	Gazelle 20 SG Mospilan 20 SG	Acetamiprid 200 g/kg SG	04.2/2190/1/2012
		Acetamiprid 200 g/kg SG	04.2/2883/1/2011
Italy	Mospilan	Acetamiprid 200 g/L SP	12217
Latvia	Mospilan 20 SP	Acetamiprid 200 g/L SP	n.r.
Lithuania	Mospilan 20 SP	Acetamiprid 200 g/L SP	02671/06
Netherlands	Gazelle	Acetamiprid 200 g/kg SG	12809
Poland	Mospilan 20 SP	Acetamiprid 200 g/kg SP	R-37/2008
Portugal	Gazelle SG	Acetamiprid 200 g/kg SG	0079

Romania	Mospilan 20 SG	Acetamiprid 200 g/kg SG	2616/02.03.2006
Slovakia	Mospilan 20 SP	Acetamiprid 200 g/kg SP	96-05-1401
Spain	Gazel Plus SG	Acetamiprid 200 g/kg SG	25393
UK	Gazelle SG	Acetamiprid 200 g/kg SG	13725

Mode of action

Neonicotinoid insecticides target the nervous system of insects causing paralysation. Due to its primary target site and its chemical family, in the IRAC mode of action classification it is classified as group 4A insecticide.

Table 3.2-2: Details of the formulation and the active substance

Proposed trade name	Acetamiprid 20% SG
A.S. content:	Acetamiprid 200 g/kg
Formulation type:	SG
Synonyms:	-
Active substance	Acetamiprid
IUPAC name:	(E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine
Chemical group:	Neonicotinoid
Mode of action:	Systemic with translaminar activity having both contact and stomach action. Acetylcholine receptor (nAChR) agonist.

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Description of the plant protection product

Acetamiprid 20% SG is a Water Soluble Granular (SG) formulation containing 200 g/kg Acetamiprid for use in oilseed rape and pome fruits.

According to the GAP, the proposed application rate of Acetamiprid 20% SG is 200 grams per hectare (g/ha), with one application per season in oilseed rape, against pollen beetles (*Meligethes aeneus*). When targeting aphids in pome fruit crops, the proposed application rate is 250 g/ha, with up to two applications per season, when the threshold of the target pests has been reached. This will deliver 40 or 50 g Acetamiprid per hectare, depending on the crop and pest to control. In pome fruits and oilseed rape, the dose rates tested against registered dose rates of acetamiprid reference product was 20 to 50 g/ha.

The data presented in this dossier fully support the label claim for Acetamiprid 20% SG for the control of aphids in pome fruits and *Meligethes aeneus* in oilseed rape.

Table 3.2-3: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Oilseed rape	Pollen beetle <i>Meligethes aeneus</i>	CEU	1 x 200 g/ha	At pest presence. Before BBCH 69
Pome fruit	Aphids	CEU	2 x 250 g/ha	At pest presence, Before BBCH 59 and from BBCH 69

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

Description of the target pests

Key targets for this product are aphids in pome fruits and *Meligethes aeneus* in oilseed rape. All the listed pests are present throughout or in parts of the Central zone and in relevant EPPO zones. The key targets for this product are described in detail in the Biological Assessment dossier.

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
MELIAE	<i>Meligethes aeneus</i>	Pollen beetle
MYZUPE	<i>Myzus persicae</i>	Green peach aphid
DYSAPL	<i>Dysaphis plantaginea</i>	Rosy apple aphid
DYSAPY	<i>Dysaphis pyri</i>	Pear aphid
APHIPO	<i>Aphis pomi</i>	Green apple aphid

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Oilseed rape	CEU	-	Pollen beetle	CEU	-
Pome fruit	CEU	-	Aphids	CEU	-

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Germany, the Netherlands, France, the United Kingdom, 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.

Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application, 34 efficacy trials were conducted in the Maritime (10), the North-east (12), the South-east (4) and the Mediterranean (8) EPPO zone. In the 34 trials, the level of control obtained by Acetamiprid 20% SG applied in oilseed rape (14) and pome fruit (20) was assessed on pollen beetles or aphids, respectively, present in the trials.

Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Oilseed rape	Pollen beetle	France	2015	E + MED	2 (2)	-	-	-	GEP	
		Germany	2015	E + MED	2 (2)	-	-	-	GEP	
		UK	2015	E + MED	2 (2)	-	-	-	GEP	
		Poland	2015	E + MED	-	-	-	2 (2)	GEP	
		Poland	2019	E + MED	-	-	-	1 (1)	GEP	
		Lithuania	2015	E+MED	-	-	-	3 (3)	GEP	
		Romania	2015	E + MED	-	-	2 (2)	-	GEP	
		Total, Oilseed rape				6 (6)	-	2 (2)	6 (6)	-
Apple	Aphids	Germany	2015	E + MED	3 (3)	-	-	-	GEP	
		Netherlands	2015	E + MED	1 (1)	-	-	-	GEP	
		Latvia	2015	E + MED	-	-	-	2 (2)	GEP	
		Latvia	2019	E + MED	-	-	-	2 (2)	GEP	
		Lithuania	2015	E + MED	-	-	-	1 (1)	GEP	
		Hungary	2015	E + MED	-	-	2 (2)	-	GEP	
		Spain	2015	E + MED	-	1 (1)	-	-	GEP	
		Italy	2015	E + MED	-	3 (3)	-	-	GEP	
		Portugal	2015	E + MED	-	1 (1)	-	-	GEP	
		Poland	2019	E + MED	-	-	-	1 (1)	GEP	
		France	2015	E + MED	-	1 (1)	-	-	GEP	
		Total, Apple				4 (4)	6 (6)	2 (2)	6 (6)	-
Pear	Aphids	Spain	2015	E + MED	-	2 (2)	-	-	GEP	
		Total, Pear				-	2 (2)	-	-	-

Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country¹.

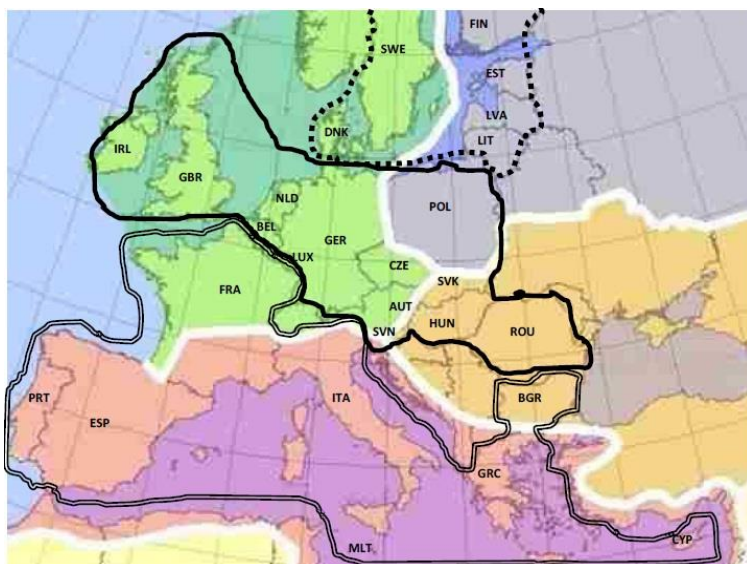
The United Kingdom, the Netherlands, Germany and N-France are located in the EPPO Maritime zone; Poland, Latvia and Lithuania are located in the North-east EPPO zone; Hungary and Romania are located in the South-east EPPO zone; and Spain, Portugal, Italy and S-France are located in the Mediterranean EPPO zone (Figure 3.2-1).

This BAD is prepared to support the submission of Acetamiprid 20% SG throughout the Central Registration zone, therefore data from the Maritime, the North-east as well as the South-East EPPO zones are

¹ Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

included. Data obtained in the Mediterranean EPPO zone has also been added as supporting information, however the data from each climatic zone is summarised separately.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



Agronomic conditions

Cultural conditions and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) differs slightly between the countries in the EU, but common is that aphids attack leaves and fruits of pome fruit crops and blossom beetles attack oilseed rape plant and - flowers from the South to the North, from East to West when the weather conditions are favourable for the pests to infest the crops.

Furthermore, the same acetamiprid products are also registered in the countries in which trials have been conducted to support the current registration. Please refer to Table 3.2-1 for the registration numbers in the different countries. In all countries, the products are registered for the same use. Acetamiprid-containing insecticides are used as insecticides throughout the EU, which should be applied when population levels in the different crops reaches the trigger level for the specific insect pests.

(i) Pest physiology

The physiology of individual pests presented is common throughout Europe. Although trials were performed in different countries and EPPO/EU zones, sites were selected to exert maximum control pressure and to exacerbate treatment differences. No difference in the level of control was apparent between the different countries or regions in which the trials were conducted. The level of control achieved from acetamiprid in the different countries was equivalent throughout the EU. Therefore, the efficacy results from one country should be valid in another country.

(iii) Agronomic practices

Agronomic practices for cultivating the tested crops are rather similar throughout the EU. The levels of inorganic fertilizers and other crop inputs are also generally similar between the countries.

(iv) Varieties

Although crop varieties tend to differ between countries, efficacy trials have not indicated any particular varietal sensitivity. Crop tolerance data generated in one country is therefore relevant in another Member state.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for agricultural production of the respective crops due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

It is not expected that an insecticide will be affected in any way by soil type and so this factor can be ignored for the purposes of this dossier.

On the basis that the above factors do not influence the overall performance of Acetamiprid 20% SG, it is the applicant's contention that data from Germany, the Netherlands, the UK, France, Poland, Hungary and Romania is equally valid in demonstrating the products performance throughout the Central EU zone and the data from Latvia and Lithuania as well as the Mediterranean zone is valid as supporting data.

Efficacy trials were carried out with Acetamiprid 20% SG in comparison to the Nisso Chemical reference Acetamiprid 200 g/kg product (Gazel Plus SG / Gazelle / Mospilan 20 SG / Mospilan 20 SP / Supreme 20 SG) in Germany, France, the Netherlands, the UK, Poland, Latvia, Lithuania, Hungary, Romania, Spain, Portugal and Italy. The trials were carried out on winter oilseed rape as well as pome fruit trees.

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates [kg/ha]	Indication	Country	N° of trials
Mospilan 20 SP	SP	200 g/kg Acetamiprid	0.20	Control of pollen beetle in oilseed rape	PL	3
Mospilan 20 SP	SP	200 g/kg Acetamiprid	0.25	Control of aphids in pome fruits	LV LT PL	2 4 1
Mospilan 20 SG Supreme 20 SG	SG	200 g/kg Acetamiprid	0.20	Control of pollen beetle in oilseed rape	FR DE UK RO LV	2 2 2 2 2
Gazel Plus SG Gazelle Mospilan 20 SG Supreme 20 SG	SG	200 g/kg Acetamiprid	0.25	Control of aphids in pome fruits	DE NL HU ES IT PT FR	3 1 2 3 3 1 1

Comments of zRMS:	<p>This document was prepared by Applicant for registration the Asset (product code: SHA 5500 A) containing acetamiprid (200 g/kg). 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.</p> <p>The formulation of this product is a water-soluble granules (SG).</p>
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	<p>All necessary information's about tested plant protection products, active substance, studied pests, reference products, etc. are correctly presented in this drr by Applicant.</p> <p>Acetamiprid is an odourless, neonicotinoid insecticide composed from a synthetic organic compound. Neonicotinoid insecticides were discovered in the 1980's and are used throughout the world. Acetamiprid is generally used to protect plants against sucking insects such as aphids, but it has also become common in household pest control to combat bed bugs. It is a broad-spectrum pesticide that can be used on plants ranging from leafy vegetables and fruit trees to ornamental plants.</p> <p>In Poland 32 plant protection product with acetamiprid as active compound are registered and use. 19 plant protection products with acetamiprid are registered for use on winter oilseed rape, and 18 for use on apple. Recommendations for the use of the Asset are in accordance with the insecticides already registered (e.g. number of applications per season, phases of development, dosage).</p> <p>The product – Asset (product code: SHA 5500 A) containing acetamiprid by Sharda Cropchem España S.L. has not been previously evaluated in any country according to Uniform Principles.</p> <p>Poland is a ZRMs.</p>
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3.2.1 Preliminary tests (KCP 6.1)

The activity of acetamiprid is well known, as it has been marketed since 1995 by e.g. Nisso Chemical 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.

Comments of zRMS:	Acetamiprid has been registered in a number of Member States for several years. It has been marketed since 1995. The ZRMs considers that preliminary data are not needed in this case for Asset (SHA 5500 A).
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3.2.2 Minimum effective dose tests (KCP 6.2)

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 14 oilseed rape trials, acetamiprid was applied at BBCH 53-62 at 20, 30 and 40 g acetamiprid/ha for the control of pollen beetle. In 20 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 reflect 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 (*Meligethes aeneus*) 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. The trials were conducted in N-France (2 trials), Germany (2 trials), the United Kingdom (2 trials), Poland (3 trials), Lithuania (3) and Romania (2 trials) in 2015 and 2019. 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 results obtained with Acetamiprid 20% SG applied for the control of pollen beetle in oilseed rape are presented in Table 3.2-8 for results obtained in the Maritime EPPO zone (six trials), the North-east EPPO zone (three trials) and the South-east EPPO zone (two trials).

The data from the eleven 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.

Table 3.2-8: Minimum effective dose – Maritime, North-east and South-east zone: Efficacy of Acetamiprid 20% SG at 50%, 75% and 100% of proposed label rate on pollen beetle in oilseed rape, at 1-3, 4-8 and 11-15 days after single application.

Target: Pollen beetle [MELIAE]	No. of trials	Untreated COUINS Mean Range		Mean % Control at a range of doses of acetamiprid Acetamiprid 20% SG					
				0.10 kg/ha = 20 g ai/ha		0.15 kg/ha = 30 g ai/ha		0.20 kg/ha = 40 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Maritime EPPO zone									
1-3 days after treatment	6	2.5	0.5-4.0	67.6	36.0-89.7	72.6	34.0-94.5	78.3	42.0-100
4-6 days after treatment	6	2.2	0.6-4.5	64.3	24.0-94.0	72.9	34.0-96.3	82.4	51.0-99.3
11-14 days after treatment	4	3.9	0.4-5.7	37.3	12.0-70.1	55.3	33.0-79.9	66.6	45.0-91.4
North-east EPPO zone									
1-2 days after treatment	6	4.78	1.2-19.4	58.3	18.4-92.4	66.0	37.1-97.2	67.7	40.3-93.7
3-8 days after treatment	6	5.07	0.4-20.7	44.9	0.0-95.9	52.9	2.1-97.7	62.7	15.1-98.4
14-15 days after treatment	2	13.6	1.4-25.8	86.8	76.1-97.5	91.9	85.6-98.2	92.2	85.6-98.8
South-east EPPO zone									
2 days after treatment	2	14.3	14.0-14.6	65.5	64.2-66.7	74.7	73.7-75.7	79.5	79.0-80.0
6 days after treatment	2	12.8	12.1-13.5	72.7	70.9-74.4	83.6	83.4-83.9	90.5	90.4-90.7
14 days after treatment	2	8.8	6.9-10.7	72.6	69.5-75.6	85.2	83.1-87.3	92.9	91.7-94.2

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. The trials were conducted in Germany (3 trials), the Netherlands (1 trial), Latvia (4 trials), Lithuania (1 trial), Poland (1 trial), Hungary (2 trials), Spain (1 trial), Portugal (1 trial), Italy (3 trials) and S-France (1 trial) in 2015 and 2019. 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 (5) or twice (13) in the summer/autumn, at growth stages ranging from BBCH 69 to BBCH 91.

In nine trials, the aphids were identified as green apple aphid (*Aphis pomi* – APHIPO) and in the remaining nine trials, the aphids treated were identified as rosy apple aphids (*Dysaphis plantaginea* – DYSAPL).

The results obtained with Acetamiprid 20% SG applied for the control of wingless and winged aphids in apple are presented in Table 3.2-9 and Table 3.2-10, respectively, for results obtained in the Maritime EPPO zone (four trials), the North-east EPPO zone (six trials), the South-east EPPO zone (two trials) and the Mediterranean EPPO zone (six trials).

The data from the 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.

Table 3.2-9: Minimum effective dose – Maritime, North-east, South-east and Mediterranean zone: Efficacy of Acetamiprid 20% SG at 50%, 75% and 100% of proposed label rate on wingless aphids in apple, at 2-4, 7-11 and 11-21 days after 1st application and 1-4, 7-12 and 15 days after 2nd application.

Target: Apple aphids [APHIPO/DYSAPL]	No. of trials	Untreated COUINS		Mean % Control at a range of doses of acetamiprid Acetamiprid 20% SG					
		Mean	Range	0.125 kg/ha = 25 g ai/ha		0.18 kg/ha = 36 g ai/ha		0.25 kg/ha = 50 g ai/ha	
				Mean	Range	Mean	Range	Mean	Range
Maritime EPPO zone									
2-4 days after 1 st appl.	4	110	43-213	57.3	7.1-90.6	67.0	41.2-81.4	74.0	30.4-93.8
7-11 days after 1 st appl.	4	115	30-204	76.8	58.8-90.7	84.0	72.2-92.5	90.7	84.9-96.5
19-21 days after 1 st appl.	4	41	28-71	81.2	54.8-100	83.6	60.7-100	94.4	91.5-99.8
1-3 days after 2 nd appl.	3	49	26-83	76.5	45.1-94.3	77.4	62.4-96.5	97.3	96.2-98.5
7-8 days after 2 nd appl.	3	82	2-132	86.2	64.7-98	99.3	98.9-100	98.8	98.1-99.6
North-east EPPO zone									
2-4 days after 1 st appl.	5	158.1	6-389	59.9	34.6-94.2	69.9	45.5-94.3	75.4	38.2-95.1
7-8 days after 1 st appl.	1	62.4	-	81.9	-	87.2	-	95.2	-
11-14 days after 1 st appl.	5	91.2	6-375	79.4	20.0-100	91.3	63.6-100	95.6	81.8-100
2-3 days after 2 nd appl.	2	40.7	17.1-64.3	81.9	51.5-96.9	87.2	59.8-98.2	95.2	98.2-98.7
7-8 days after 2 nd appl.	2	67.9	16.9-119	98.3	63.8-100	87.2	74.4-100	95.2	90.4-100
South-east EPPO zone									
2-3 days after 1 st appl.	2	58	53-61	91.5	90.5-92.6	94.9	92.5-97.4	92.9	88.3-97.5
7-10 days after 1 st appl.	2	88	79-98	93.9	89.6-98.1	94.0	89.2-98.7	93.0	86.2-99.8
13-14 days after 1 st appl.	2	84	81-88	84.3	84.1-84.4	91.5	85.9-97.1	91.0	83.1-99.0
2-3 days after 2 nd appl.	2	84	73-96	99.9	99.8-100	100.0	99.9-100	99.9	99.7-100
7-8 days after 2 nd appl.	2	100	88-112	99.9	99.7-100	100.0	99.9-100	100.0	100-100
Mediterranean EPPO zone									
2-3 days after 1 st appl.	6	595	18-2236	62.8	0-100	78.6	38.2-100	79.0	17.1-100
9-11 days after 1 st appl.	6	507	39-2241	76.9	47-100	90.7	82.5-100	95.9	87.9-100
14-21 days after 1 st appl.	4	611	50-1763	72.6	8.1-100	80.2	31.8-100	86.3	53.7-100
2-4 days after 2 nd appl.	6	284	18-935	90.1	70.1-100	95.9	89.4-100	98.5	95.3-100
7-12 days after 2 nd appl.	6	227	7-715	96.0	87.1-100	91.1	59.2-100	93.6	65.3-100
15 days after 2 nd appl.	1	3	-	100	-	100	-	100	-

Table 3.2-10: Minimum effective dose – Mediterranean and Maritime zone: Efficacy of Acetamiprid 20% SG at 50%, 75% and 100% of proposed label rate on winged (alate) aphids in apple, at 2-3, 7-10 and 20-21 days after 1st application and 2-3 and 7-10 days after 2nd application.

Target: Apple aphids [APHIPO/DYSAPL]	No. of trials	Untreated COUINS Mean Range		Mean % Control at a range of doses of acetamiprid Acetamiprid 20% SG					
				0.125 kg/ha = 25 g ai/ha		0.18 kg/ha = 36 g ai/ha		0.25 kg/ha = 50 g ai/ha	
				Mean	Range	Mean	Range	Mean	Range
Mediterranean EPPO zone									
3 days after 1 st appl.	2	36.4	27.0-45.8	94.6	93.5-95.6	94.2	88.9-99.5	96.1	92.6-99.5
10 days after 1 st appl.	2	36.0	12.5-59.5	91.8	89.5-94	98.6	97.1-100	97.8	97.5-98
20-21 days after 1 st appl.	2	28.0	13.5-42.5	90.4	88.9-91.8	92.2	91.8-92.6	96.1	94.1-98.1
2-3 days after 2 nd appl.	2	19.1	15.3-23	93.2	88-98.4	96.0	93.5-98.4	97.9	95.7-100
7-10 days after 2 nd appl.	2	14.8	12.8-16.8	88.4	80.6-96.1	97.8	95.5-100	99.3	98.5-100

Continued on the following page...

Maritime EPPO zone									
2 days after 1 st appl.	1	6.3	-	65.1	-	73.0	-	79.4	-
7 days after 1 st appl.	1	6.3	-	65.1	-	73.0	-	79.4	90.4-90.7
21 days after 1 st appl.	1	0.6	-	100	-	100	-	100	-
3 days after 2 nd appl.	1	1.0	-	95	-	97.5	-	100	-
7 days after 2 nd appl.	1	0.6	-	74.5	-	95.3	-	87.2	-

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 results obtained with Acetamiprid 20% SG applied for the control of wingless and winged aphids in pear are presented in Table 3.2-11 and Table 3.2-12, respectively, for results obtained in the Mediterranean EPPO zone (two trials).

The data from the 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.

Table 3.2-11: Minimum effective dose – Mediterranean zone: Efficacy of Acetamiprid 20% SG at 50%, 75% and 100% of proposed label rate on wingless aphids in pear, at 2, 9 and 20 days after 1st application and 2 and 9 days after 2nd application.

Target: Pear aphids [DYSAPY]	No. of trials	Untreated COUINS		Mean % Control at a range of doses of acetamiprid Acetamiprid 20% SG					
		Mean	Range	0.125 kg/ha = 25 g ai/ha		0.18 kg/ha = 36 g ai/ha		0.25 kg/ha = 50 g ai/ha	
				Mean	Range	Mean	Range	Mean	Range
Mediterranean EPPO zone									
2 days after 1 st appl.	2	229.9	176-284	91.6	91.5-91.6	94.0	92.3-95.6	95.8	95.0-96.6
9 days after 1 st appl.	2	231.9	151-313	91.1	91.0-91.1	95.5	93.7-97.2	96.7	95.1-98.2
20 days after 1 st appl.	2	198.4	123-274	93.6	91.2-95.9	95.8	93.5-98.0	96.9	94.5-99.2
2 days after 2 nd appl.	2	178.3	112-245	98.0	96.8-99.1	99.1	98.8-99.3	99.6	99.4-99.8
9 days after 2 nd appl.	2	152.5	75-230	98.9	98.3-99.5	99.6	99.3-99.8	99.6	99.3-99.9

Table 3.2-12: Minimum effective dose – Mediterranean zone: Efficacy of Acetamiprid 20% SG at 50%, 75% and 100% of proposed label rate on winged (alate) aphids in pear, at 2, 9 and 20 days after 1st application and 2 and 9 days after 2nd application.

Target: Pear aphids [DYSAPY]	No. of trials	Untreated COUINS		Mean % Control at a range of doses of acetamiprid Acetamiprid 20% SG					
		Mean	Range	0.125 kg/ha = 25 g ai/ha		0.18 kg/ha = 36 g ai/ha		0.25 kg/ha = 50 g ai/ha	
				Mean	Range	Mean	Range	Mean	Range
Mediterranean EPPO zone									
2 days after 1 st appl.	2	8.3	2.8-13.8	75.5	72.7-78.2	82.7	74.5-90.9	72.7	63.6-81.8
9 days after 1 st appl.	2	9.9	2.5-17.3	88.4	76.8-100	77.7	75.4-80	69.8	69.6-70
20 days after 1 st appl.	2	6.5	1.5-11.5	90.2	80.4-100	95.7	91.3-100	96.8	93.5-100
2 days after 2 nd appl.	2	4.4	1.3-7.5	90.0	80-100	96.7	93.3-100	100.0	-
9 days after 2 nd appl.	2	4.0	1.3-6.8	94.5	88.9-100	98.2	96.3-100	100	-

Summary and conclusions on the minimum effective dose

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.

As the efficacy data on oilseed rape and pome fruits show (as presented in Section 6.1.3), the efficacy of Acetamiprid 20% SG is equivalent to that of the acetamiprid reference product to which it was compared. For any claims on the draft Acetamiprid 20% SG label not adequately supported by the applicant's trials data, Sharda wishes to cite the original registrant's data on acetamiprid now out of protection and requests that Zonal Evaluators extrapolate from those data.

Comments of zRMS:	<p>In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).</p> <p>During field tests Applicant used different doses: 0,10 kg/ha (0,5N), 0,15 kg/ha (0,75N) and 0,20 kg/ha (N) on winter oilseed rape and 0,125 kg/ha (0,5N), 0,18 kg/ha (0,72N) and 0,25 kg/ha (N) on apple and pear of insecticide – Asset (product code: SHA 5500 A) containing acetamiprid (200 g/kg). So, in the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).</p> <p>In total, Applicant submitted 34 trials carried out on: winter oilseed rape (14 trials), apple (18 trials) and pear (2 trials). Trials were carried out in MED (apple, pear), Maritime (winter oilseed rape, apple), N-E EPPO zone (winter oilseed rape, apple) and S-E (winter oilseed rape, apple).</p> <ul style="list-style-type: none"> • winter oilseed rape: 6 trials from Maritime EPPO zone (FR-2; DE-2; UK-2); lack of trials for MED EPPO zone, 2 trials for S-E EPPO zone (RO) and 6 trials for N-E EPPO zone (PL-3; LT-3); • apple: 4 trials from Maritime EPPO zone (DE-3, NT-1); 6 trials for MED EPPO zone (SP-2; IT-3; PT-1, FR-1); 2 trials for S-E EPPO zone (HU) and 6 trials for N-E EPPO zone (LV-4; LT-1; PL-1). <p>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. According to EPPO, dose lower: 0,125 kg/ha and higher: 0,25 kg/ha than recommended was studied. Dose 0,18 kg/ha was characterized by much higher efficiency than dose 0,125 kg/ha. The highest dose recommended by the applicant (0,25 kg/ha) had the best efficacy, but due to environmental constraints it could not be recommended for use.</p> <p>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 EPPO zone should decide if limited number of trials for apple can be accepted.</p> <p>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. <u>Only according to Article 51 pear without trials can be accepted in Poland as a minor crop.</u></p> <p>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.</p>
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	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.
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3.2.3 Efficacy tests (KCP 6.2)

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 2015 and 2019 in the Maritime EPPO zone (10; i.e. N-France (2), Germany (5), the Netherlands (1) and the United Kingdom (2)), the North-east EPPO zone (10; i.e. Latvia (4), Poland (2) and Lithuania (4)) and the South-east EPPO zone (4; i.e. Hungary (2) and Romania (2)) and additionally, eight efficacy trials conducted in the Mediterranean EPPO zone (8; i.e. Italy (3), Spain (3), Portugal (1) and S-France (1)) have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone. Efficacy was assessed on blossom beetle (MELIAE), green apple aphid (APHIPO), rosy apple aphid (DYSAPL) and pear aphid (DYSAPY). Data from each zone has been summarized separately.

In the efficacy trials, the performance of Acetamiprid 20% SG was measured against a commercial standard formulation of Acetamiprid. In all trials, the Acetamiprid standard used was Gazelle / Gazel Plus SG / Mospilan 20 SG / Mospilan 20 SP / Supreme 20 SG (registered by Nisso Chemical). The trials were carried out on winter oilseed rape as well as pome fruit trees.

Data on each individual insect pest species is only included from trials in which a minimum of 0.3 insects per shoot were seen at the timing of the assessment.

Table 3.2-13: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152(4), PP 1/181(4), PP 1/135(4)
	Specific guidelines	Oilseed rape / pollen beetle: EPPO PP 1/178(3,4) Pome fruits / aphids: EPPO PP 1/258(1)
Experimental design	Plot design	RCBD (34)
	Plot size	10.4-72 m ²
	Number of replications	4 (34)
Crop	Trials per crop	Oilseed rape (14), apple (18), pear (2)
	Varieties per crop	<u>Oilseed rape</u> : Albatros, Arot, Columb, Expedio, DK Expower, DK Exprit, Falcon, Fleyer, SY Hamas, NK Technic, Visby, Troy, Fenja, Galileus <u>Apple</u> : Ariana, Fuji, Gala, Gloster, Golden, Golden Reinders, Aukis, Idared, Jonared Prince, Ligol, Rode Boskoop, Royal Gala, Sinap Orlovskij <u>Pear</u> : Blanquilla, Ercolini
	Sowing period	Oilseed rape: August 18 th to September 27 th , 2014 Pome fruits: n.a.
Application	Crop stage (BBCH)* at application	Oilseed rape: BBCH 32-62 Pome fruit: BBCH 69-91
	Timing Pest stage at appl. (1)	Oilseed rape: Adults Pome fruit: Mixed
	Number of appl. Intervals between appl.	1 (19 trials); 2 (15 trials) n.a.; 7-28 days (average: 18 days)
	Spray volumes	Oilseed rape: 200-500 L/ha Pome fruit: 800-1000 L/ha

Assessment	Assessment types	- Calculated, based on insect counts (COUINS) in a defined area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms.
	Assessment dates	1-21 DAT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field

Control of pollen beetle (*Meligethes aeneus*) in oilseed rape

The efficacy trials were conducted to prove the following label claims:

Crop	Oilseed rape
Use rate	200 g/ha acetamiprid 20% SG
Use frequency	1x
Application timing	At pest presence, before BBCH 69
Target pest	Pollen beetle (<i>Meligethes aeneus</i>)

The effectiveness of 200 g/ha Acetamiprid 20% SG against pollen beetle (*Meligethes aeneus* - MELIAE) in oilseed rape are listed in Table 3.2-14, Table 3.2-15 and Table 3.2-16 for results from all trials conducted in the Maritime (6), the North-east (6) and the South-east (2) EPPO zones, respectively. In the efficacy trials, the number of pollen beetles was counted at three different timings following application, i.e. 1-3, 4-7 and 11-15 days after treatment. The trials were conducted in 2015 in the Northern part of France (2x), Germany (2x), the United Kingdom (2x), Poland (3x), Lithuania (3x) and Romania (2x). The objective was to confirm the performance of acetamiprid at 40 g ai/ha. In the trials specifically targeted for pollen beetle, the application was applied in the spring, when the crop was at growth stages ranging from BBCH 32 to BBCH 62.

In all trials, Acetamiprid 20% SG was tested alongside a locally approved acetamiprid SG formulation, i.e. Mospilan 20 SG (DE), Mospilan 20 SP (PL, LT) and Supreme 20 SG (FR, UK and RO).

Table 3.2-14: Maritime zone: Efficacy of 200 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against pollen beetle in oilseed rape in the efficacy tests 2015 – 1-3, 4-6 and 11-14 DAT.

Product applied	Dose rate applied	Control obtained at different assessment timings						
		No. of trials	Mean % control, first assessment timing, at 1-3 DAT COUINS: 2.5 n=6		Mean % control, second assessment timing, at 4-6 DAT COUINS: 2.3 n=6		Mean % control, third assessment timing, at 11-14 DAT COUINS: 3.9 n=4	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.200 kg/ha	6	78.3	42-100	82.4	51-99	66.6	45-91
Acetamiprid reference product	0.200 kg/ha	6	77.9	34-100	77.8	29-99	55.1	21-90

Table 3.2-15: North-east zone: Efficacy of 200 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against pollen beetle in oilseed rape in the efficacy tests 2015 and 2019 – 2, 5-7 and 15 DAT.

Product applied	Dose rate applied	Control obtained at different assessment timings						
		No. of trials	Mean % control, first assessment timing, at 1-2 DAT <i>COUINS: 4.78</i> <i>n=6</i>		Mean % control, second assessment timing, at 3-8 DAT <i>COUINS: 5.07</i> <i>n=6</i>		Mean % control, third assessment timing, at 14-15 DAT <i>COUINS: 13.6</i> <i>n=2</i>	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.200 kg/ha	6	67.7	40-93.7	62.7	15-98.4	92.2	85.6-98.8
Acetamiprid reference product	0.200 kg/ha	6	63.2	31.8-95	62.0	0-97.9	95.1	91.6-98.6

Table 3.2-16: South-east zone: Efficacy of 200 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against pollen beetle in oilseed rape in the efficacy tests 2015 – 2, 6 and 14 DAT.

Product applied	Dose rate applied	Control obtained at different assessment timings						
		No. of trials	Mean % control, first assessment timing, at 2 DAT <i>COUINS: 14.3</i> <i>n=2</i>		Mean % control, second assessment timing, at 6 DAT <i>COUINS: 12.8</i> <i>n=2</i>		Mean % control, third assessment timing, at 14 DAT <i>COUINS: 8.8</i> <i>n=2</i>	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.200 kg/ha	2	79.5	79-80	90.5	90-91	92.9	92-94
Acetamiprid reference product	0.200 kg/ha	2	78.6	78-79	88.8	88-90	91.2	90-92

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.

No differences in the level of pest control or crop safety were seen from the trials conducted in the different EU Member States.

Control of aphids in apple

The efficacy trials were conducted to prove the following label claims:

Crop	Pome fruits
Use rate	250 g/ha Acetamiprid 20% SG [= 125 g/m crown height/ha]
Use frequency	2x
Application timing	At pest presence, before BBCH 59 and from BBCH 69
Target pest	Green apple aphid (<i>Aphis pomi</i>), rosy apple aphids (<i>Dysaphis plantaginea</i>) and other aphids affecting pome fruit crops

The effectiveness of 250 g/ha Acetamiprid 20% SG against aphids (green apple aphids (*Aphis pomi*) and rosy apple aphids (*Dysaphis plantaginea*) in apple crops are listed in Table 3.2-17, Table 3.2-18, Table 3.2-19 and Table 3.2-20 for results from all trials conducted in the Maritime (4), the North-east (6), the South-east (2) and the Mediterranean (6) EPPO zones, respectively. In the efficacy trials, the number of aphids was counted at three different timings following each application, i.e. 2-4, 7-11 and 11-21 days

after 1st application and 1-4, 7-12 and 15 days after 2nd application. The trials were conducted in 2015 and 2019 in the Netherlands (1x), Germany (3x), Poland (1x), Latvia (4x), Lithuania (1x), Hungary (2x), the Southern part of France (1x), Spain (1x), Italy (3x) and Portugal (1x). The objective was to confirm the performance of acetamiprid at 50 g ai/ha. In the trials specifically targeted for aphids, one (5x) and two (13x) applications were applied during the growing season, when the aphids were observed. When treated in the late spring (May to June), the crop was at growth stage ranging between BBCH 69 and BBCH 77 and when treated in the autumn (September and October), the crop was at growth stage BBCH 91.

In all trials, Acetamiprid 20% SG was tested alongside a locally approved acetamiprid SG formulation, i.e. Gazel Plus SG (ES and PT), Gazelle (NL), Mospilan 20 SG (DE, HU), Mospilan 20 SP (LV, PL, LT) and Supreme 20 SG (FR and IT).

Table 3.2-17: Maritime zone: Efficacy of 250 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against wingless aphids in apple in the efficacy tests 2015 – 2-4, 7-11 and 19-21 days after 1st application and 1-3 and 7-8 days after 2nd application.

Product applied	Dose rate applied	Mean % Control obtained at different assessment timings						
		No. of trials	First assessment timing, at 2-4 DAA <i>COUINS: 101.1</i> <i>n=4</i>		Second assessment timing, at 7-11 DAA <i>COUINS: 114.7</i> <i>n=4</i>		Third assessment timing, at 19-21 DAT <i>COUINS: 40.5</i> <i>n=4</i>	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	4	74.0	30-100	91.3	85-97	94.4	92-100
Acetamiprid reference product	0.250 kg/ha	4	80.1	60-100	95.4	95-97	93.5	90-100
Product applied	Dose rate applied	No. of trials	Fourth assessment timing, at 1-3 DAB <i>COUINS: 49.3</i> <i>n=3</i>		Fifth assessment timing, at 7-8 DAB <i>COUINS: 81.5</i> <i>n=3</i>			
			Mean	Range	Mean	Range		
Acetamiprid 20% SG	0.250 kg/ha	3	97.3	96-99	98.8	98-100		
Acetamiprid reference product	0.250 kg/ha	3	95.8	95-97	99.3	99-100		

Table 3.2-18: North-east zone: Efficacy of 250 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against wingless aphids in apple in the efficacy tests 2015 – 2-4, 7 and 11-14 days after 1st application and 3, 7 and 10 days after 2nd application.

Product applied	Dose rate applied	Mean % Control obtained at different assessment timings						
		No. of trials	First assessment timing, at 2-4 DAA <i>COUINS: 158.1</i> <i>n=5</i>		Second assessment timing, at 7-8 DAA <i>COUINS: 62.4</i> <i>n=1</i>		Third assessment timing, at 11-14 DAT <i>COUINS: 91.2</i> <i>n=5</i>	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	5	75.4	38-95	95.2	-	95.6	82-100
Acetamiprid reference product	0.250 kg/ha	5	71.8	33-96	98.3	-	93.5	77-100
Product applied	Dose rate applied	No. of trials	Fourth assessment timing, at 2-3 DAB <i>COUINS: 17.1</i> <i>n=2</i>		Fifth assessment timing, at 7-8 DAB <i>COUINS: 16.9</i> <i>n=2</i>		Sixth assessment timing, at 10 DAB <i>COUINS: 17.4</i> <i>n=1</i>	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	2	98.5	98-99.0	95.2	90-100	100.0	-
Acetamiprid reference product	0.250 kg/ha	2	96.9	95.6-98	98.3	97-100	100.0	-

Table 3.2-19: South-east zone: Efficacy of 250 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against wingless aphids in apple in the efficacy tests 2015 – 2-3, 7-10 and 19-21 days after 1st application and 2-3 and 7-8 days after 2nd application.

Product applied	Dose rate applied	Mean % Control obtained at different assessment timings						
		No. of trials	First assessment timing, at 2-3 DAA COUINS: 58.4 n=2		Second assessment timing, at 7-10 DAA COUINS: 88.4 n=2		Third assessment timing, at 19-21 DAT COUINS: 84.2 n=2	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	2	92.9	88-98	93.0	86-100	91.0	83-99
Acetamiprid reference product	0.250 kg/ha	2	98.2	97-99	98.9	98-100	98.3	97-100
Product applied	Dose rate applied	No. of trials	Fourth assessment timing, at 2-3 DAB COUINS: 84.2 n=2		Fifth assessment timing, at 7-8 DAB COUINS: 100.2 n=2			
			Mean	Range	Mean	Range		
Acetamiprid 20% SG	0.250 kg/ha	2	99.9	99-100	100.0	-		
Acetamiprid reference product	0.250 kg/ha	2	100.0	-	100.0	-		

Table 3.2-20: Mediterranean zone: Efficacy of 250 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against wingless aphids in apple in the efficacy tests 2015 – 2-3, 9-11 and 14-21 days after 1st application and 2-4, 7-12 and 15 days after 2nd application.

Product applied	Dose rate applied	Mean % Control obtained at different assessment timings						
		No. of trials	First assessment timing, at 2-3 DAA COUINS: 595.0 n=6		Second assessment timing, at 9-11 DAA COUINS: 506.8 n=6		Third assessment timing, at 14-21 DAT COUINS: 611.1 n=4	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	6	79.0	17-100	95.9	88-100	86.3	54-100
Acetamiprid reference product	0.250 kg/ha	6	89.3	74-100	95.0	88-100	82.6	40-100
Product applied	Dose rate applied	No. of trials	Fourth assessment timing, at 2-4 DAB COUINS: 284.3 n=6		Fifth assessment timing, at 7-12 DAB COUINS: 227.0 n=6		Sixth assessment timing, at 15 DAB COUINS: 3.1 n=1	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	6	98.5	95-100	93.6	65-100	100	-
Acetamiprid reference product	0.250 kg/ha	6	97.7	92-100	96.9	87-100	100	-

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.

In the trials where alate aphids were evaluated, the same trend was observed as when evaluating the wingless aphids, i.e. Acetamiprid 20% SG also achieved high level of control against winged 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.

Table 3.2-21: Maritime zone: Efficacy of 250 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against winged (alate) aphids in apple in the efficacy tests 2015 – 2, 7 and 20-21 days after 1st application and 1-3 and 7 days after 2nd application.

Product applied	Dose rate applied	Mean % Control obtained at different assessment timings						
		No. of trials	First assessment timing, at 2 DAA <i>COUINS: 2.3</i> <i>n=1</i>		Second assessment timing, at 7 DAA <i>COUINS: 6.3</i> <i>n=1</i>		Third assessment timing, at 20-21 DAT <i>COUINS: 0.9</i> <i>n=2</i>	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	3	30.4	-	79.4	-	50.0	0-100
Acetamiprid reference product	0.250 kg/ha	3	56.5	-	71.4	-	50.0	0-100
Product applied	Dose rate applied	No. of trials	Fourth assessment timing, at 1-3 DAB <i>COUINS: 0.7</i> <i>n=2</i>		Fifth assessment timing, at 7 DAB <i>COUINS: 0.6</i> <i>n=1</i>			
			Mean	Range	Mean	Range		
Acetamiprid 20% SG	0.250 kg/ha	2	50.0	0-100	87.2	-		
Acetamiprid reference product	0.250 kg/ha	2	50.0	0-100	81.9	-		

Table 3.2-22: Mediterranean zone: Efficacy of 250 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against winged (alate) aphids in apple in the efficacy tests 2015 –3, 10 and 20-21 days after 1st application and 2-3 and 7-10 days after 2nd application.

Product applied	Dose rate applied	Mean % Control obtained at different assessment timings						
		No. of trials	First assessment timing, at 3 DAA <i>COUINS: 36.4</i> <i>n=2</i>		Second assessment timing, at 10 DAA <i>COUINS: 36.0</i> <i>n=2</i>		Third assessment timing, at 20-21 DAT <i>COUINS: 28.0</i> <i>n=2</i>	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	2	96.1	93-100	97.8	97-98	96.1	94-98
Acetamiprid reference product	0.250 kg/ha	2	93.5	87-100	98.3	97-100	94.6	93-96
Product applied	Dose rate applied	No. of trials	Fourth assessment timing, at 2-3 DAB <i>COUINS: 19.1</i> <i>n=2</i>		Fifth assessment timing, at 7-10 DAB <i>COUINS: 14.8</i> <i>n=2</i>			
			Mean	Range	Mean	Range		
Acetamiprid 20% SG	0.250 kg/ha	2	97.9	96-100	99.3	99-100		
Acetamiprid reference product	0.250 kg/ha	2	97.3	95-100	99.3	99-100		

No differences in the level of pest control or crop safety were seen from the trials conducted in the different EU Member States.

Control of aphids in pear

The efficacy trials were conducted to prove the following label claims:

Crop	Pome fruits
Use rate	250 g/ha Acetamiprid 20% SG [= 125 g/m crown height/ha]
Use frequency	2x
Application timing	At pest presence, before BBCH 59 and from BBCH 69
Target pest	Pear aphid (<i>Dysaphis pyri</i>) and other aphids affecting pome fruit crops

The effectiveness of 250 g/ha Acetamiprid 20% SG against aphids (pear aphid (*Dysaphis pyri*)) in pear crops are listed in Table 3.2-23 and Table 3.2-24 for results on wingless and winged aphids, respectively from the two trials conducted in the Mediterranean EPPO zone. In the efficacy trials, the number of aphids was counted at three different timings following each application, i.e. 2, 9 and 20 days after 1st application and 2 and 9 days after 2nd application. The trials were conducted in 2015 in Spain. The objective was to confirm the performance of acetamiprid at 50 g ai/ha. In the trials specifically targeted for aphids, two applications were applied during the growing season, when the aphids were observed. When treated in the late autumn (November and December), the crop was at growth stage BBCH 91.

In all trials, Acetamiprid 20% SG was tested alongside a locally approved acetamiprid SG formulation, i.e. Gazel Plus SG.

Table 3.2-23: Mediterranean zone: Efficacy of 250 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against wingless aphids in pear in the efficacy tests 2015 – 3, 9 and 20 days after 1st application and 2 and 9 days after 2nd application.

Product applied	Dose rate applied	Mean % Control obtained at different assessment timings						
		No. of trials	First assessment timing, at 3 DAA <i>COUINS: 229.9</i> <i>n=2</i>		Second assessment timing, at 9 DAA <i>COUINS: 231.9</i> <i>n=2</i>		Third assessment timing, at 20 DAT <i>COUINS: 198.4</i> <i>n=2</i>	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	2	95.8	95-97	96.7	95-98	96.9	95-99
Acetamiprid reference product	0.250 kg/ha	2	97.6	97-98	98.5	98-99	98.1	97-99
Product applied	Dose rate applied	No. of trials	Fourth assessment timing, at 2 DAB <i>COUINS: 178.3</i> <i>n=2</i>		Fifth assessment timing, at 9 DAB <i>COUINS: 152.5</i> <i>n=2</i>			
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	2	99.6	99-100	99.6	99-100		
Acetamiprid reference product	0.250 kg/ha	2	99.7	99-100	99.7	99-100		

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.

In the two trials where alate aphids were evaluated, the same trend was observed as when evaluating the wingless aphids, i.e. Acetamiprid 20% SG also achieved high level of control against winged aphids in pear, 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.

Table 3.2-24: Mediterranean zone: Efficacy of 250 g/ha Acetamiprid 20% SG and reference product at equivalent dose rate applied against winged (alate) aphids in pear in the efficacy tests 2015 – 3, 9 and 20 days after 1st application and 2 and 9 days after 2nd application.

Product applied	Dose rate applied	Mean % Control obtained at different assessment timings						
		No. of trials	First assessment timing, at 3 DAA <i>COUINS: 8.3</i> <i>n=2</i>		Second assessment timing, at 9 DAA <i>COUINS: 9.9</i> <i>n=2</i>		Third assessment timing, at 20 DAT <i>COUINS: 6.5</i> <i>n=2</i>	
			Mean	Range	Mean	Range	Mean	Range
Acetamiprid 20% SG	0.250 kg/ha	2	72.7	64-82	69.8	69-70	96.8	94-100
Acetamiprid reference product	0.250 kg/ha	2	87.3	75-100	82.0	74-90	96.8	94-100
Product applied	Dose rate applied	No. of trials	Fourth assessment timing, at 2 DAB <i>COUINS: 4.4</i> <i>n=2</i>		Fifth assessment timing, at 9 DAB <i>COUINS: 4.0</i> <i>n=2</i>			
			Mean	Range	Mean	Range		
Acetamiprid 20% SG	0.250 kg/ha	2	100.0	-	100.0	-		
Acetamiprid reference product	0.250 kg/ha	2	100.0	-	100.0	-		

No differences in the level of pest control or crop safety were seen from the trials conducted in the different EU Member States.

Summary and 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.

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.

For crops and insect pest species claimed on the draft labels not adequately supported by the applicant's trials data, the applicant wishes to bridge to the trials conducted in pome fruits as well as oilseed rape where equivalence between the effectiveness of the acetamiprid formulation prepared by Sharda Cropchem España and the reference acetamiprid product was demonstrated. The applicant therefore wishes to cite the original registrant's data on acetamiprid now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Rapporteur extrapolate from those data.

Comments of zRMS:	<p>Details of experiment are presented above by Applicant. Methodology is in accordance to GEP rules.</p> <p>Applicant submitted in total 34 trials showing the results in research into product efficacy carried out during one growing season in perry (2 trials) and two growing seasons on apple and winter oilseed rape. Those efficacy trials were performed in MED (perry, apple), Maritime (winter oilseed rape, apple), S-E EPPO zone (winter oilseed rape, apple) and N-E EPPO zone (winter oilseed rape, apple).</p> <p>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</p>
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	<p>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 considering results from other climatic zones are acceptable.</p> <p>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.</p> <p>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.</p> <p>Only according to Article 51 pear without trials can be accepted in Poland as a minor crop.</p> <p>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 considered by each cMS, in the opinion of Evaluator.</p> <p>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.</p> <p>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/Zuxion) is comparable against all pest species. However, on the basis of evaluation performed by section of Ecotox, only dose 0,18 kg/ha (1-2 per 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) and at the same time capable of being acceptable. The efficacy results of dose 0,18 kg/ha are presented in MED (Minimum Effective Dose) chapter of dRR. 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.</p> <p>Accepted BBCH for pome fruits (apple) is from 69. Trials were carried out from BBCH 69 to 91.</p> <p>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.</p> <p>It is recommended to authorize the product Asset/Zuxion (SHA 5500 A) in the extent of the authorization of the reference product (a.s. acetamiprid) at the equivalent dose rate.</p> <p><u>EFFECTIVENESS ACCORDING TO LWA APPROACH:</u></p>
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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 in submitted trials).

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 way to achieve 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:

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

LWA was calculated for each EPPO zone: for calculation the dose 10000 m² LWA was used recommended dose: 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 of ASSET/10000 m² 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 of ASSET/10000 m² 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 of ASSET/10000 m² 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 of ASSET/10000 m² 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. 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 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The following dossier section follows EPPO standard PP 1/213(3) *Resistance risk analysis* in particular point 6. *Registration requirements* of the standard.

Introduction

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds, fungi and molluscs. It usually becomes evident after the repeated use of a particular pesticide which selects the naturally-occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The insect-resistant population develops because the sensitive population is suppressed and the rare insecticide-resistant individual can multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the infestation and use pattern of the insecticide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of insect control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, insecticide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential and/or possible resistance cases, the term resistance will be limited to situations where the conditions in both (a) and (b) below are met:

- (a) the development of resistance leads to failure of control under practical field conditions following application of an insecticide correctly and according to the label and
- (b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced insecticide sensitivity.

3.3.1 Active ingredient

Acetamiprid has a cyanoamidine structure, which contains a 6-chloro-3-pyridylmethyl moiety. The compound was invented in the search for nitromethylene derivatives by Nippon Soda Co., Ltd., in 1989 and was first introduced in 1995 in Japan. Acetamiprid is employed for the control of aphids in stone- and pome fruit orchards and pollen beetles in oilseed rape, among other uses.

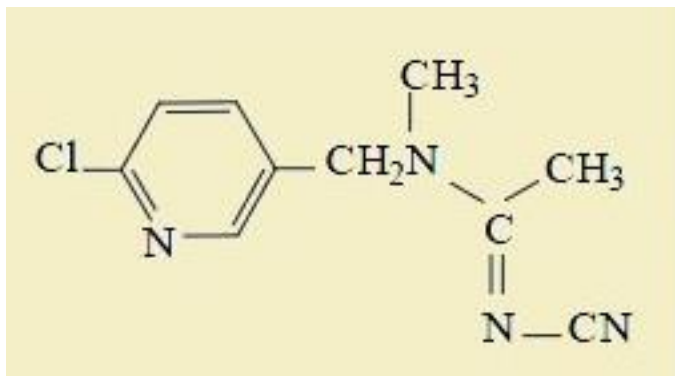
Acetamiprid is an odourless, neonicotinoid insecticide composed from a synthetic organic compound. Neonicotinoid insecticides target the nervous system of insects causing paralysation. Acetamiprid-treated insects show a fast knockdown and some symptoms of intoxication, such as excitation, convulsion and paralysis, followed by death, in that order. Neonicotinoid insecticides were discovered in the 1980's and are used throughout the world. Acetamiprid is generally used to protect plants against sucking insects such as aphids, but it has also become common in household pest control to combat bed bugs. It is a broad-spectrum pesticide that can be used on plants ranging from leafy vegetables and fruit trees to ornamental plants.

Due to its primary target site and its chemical family, in the IRAC mode of action classification it is classified as group 4A insecticide:

- Mode of Action: Acetylcholine receptor (nAChR) agonist.
- Chemical family: Neonicotinoid

The chemical structure of acetamiprid is shown in Figure 3.3-1.

Figure 3.3-1: **Structure of acetamiprid (Source: Pesticide Properties DataBase (PPDB), University of Hertfordshire. Online. Internet. Sunday, November 26, 2016. Available. <http://sitem.herts.ac.uk/aeru/ppdb/en/index.htm>)**



3.3.2 Mechanism- and evidence of resistance

Despite two decades of steadily increasing use of neonicotinoids have proved remarkably resilient to the development of resistance and have remained highly effective against aphids in pome fruits. However, recent studies of the peach aphid (*Myzus persicae*) in southern Europe have revealed the presence of neonicotinoid resistant aphids (IRAC, 2016).

IRAC has provided the following advice for the impacted stone fruits producers:

Where no loss of performance to neonicotinoids has been experienced, it is recommended to use a maximum of one neonicotinoid application per crop cycle against *Myzus persicae* to minimise the further spread and intensification of the resistance and maintain effectiveness of the neonicotinoids. Depending on crop and country and local guidelines, this single spray may be pre-flowering or post-flowering, but not during flowering, to fit with local IPM recommendations.

If a decline in neonicotinoid efficacy against *Myzus persicae* was observed during the previous seasons, it is recommended not to use this group of insecticides to prevent escalation or development of resistance. It is recommended to use insecticides with other modes of action, according to local registrations, such as products from groups 1A, 3A, 9, 23 and 29 as well as mineral oil to control *Myzus persicae*. IRAC supports the use of any other IPM measures locally recommended, and may assist with the characterisation of resistance mechanisms in local *Myzus* populations.

Figure 3.3-2: Map of the Southern region showing areas where target site resistance to neonicotinoids was detected in *Myzus persicae* collected from stone fruit orchards from 2010 to 2016 (Source: IRAC, 2016)



Bioassays, metabolism and gene expression studies implied the presence of two resistance mechanisms in the resistant clone, one based on enhanced detoxification by cytochrome P450 monooxygenases, and another unaffected by a synergist that inhibits detoxifying enzymes. Binding of radiolabelled imidacloprid (a neonicotinoid) to whole body membrane preparations showed that the high affinity [3H]-imidacloprid binding site present in susceptible *M. persicae* is lost in the resistant clone and the remaining lower affinity site is altered compared to susceptible clones. This confers a significant overall reduction in binding affinity to the neonicotinoid target: the nicotinic acetylcholine receptor (nAChR). Comparison of the nucleotide sequence of six nAChR subunit (Mpa1-5 and Mpβ1) genes from resistant and susceptible aphid clones revealed a single point mutation in the loop D region of the nAChR β1 subunit of the resistant clone, causing an arginine to threonine substitution (R81T).

Previous studies have shown that the amino acid at this position within loop D is a key determinant of neonicotinoid binding to nAChRs and this amino acid change confers a vertebrate-like character to the insect nAChR receptor and results in reduced sensitivity to neonicotinoids. The discovery of the mutation at this position and its association with the reduced affinity of the nAChR for imidacloprid is the first example of field-evolved target-site resistance to neonicotinoid insecticides and also provides further validation of existing models of neonicotinoid binding and selectivity for insect nAChRs.

No neonicotinoid resistance has yet been report from other aphid species affecting e.g. pome fruits.

Oilseed rape: Blossom beetle

No neonicotinoid resistance has yet been report from *Meligethes aeneus* in oilseed rape.

3.3.3 Cross-resistance

Many insect pests have recently developed resistance to most conventionally used insecticides. In aphids, three resistant strains from the peach-potato aphid, *Myzus persicae*, and one from the cotton aphid, *Aphis gossypii*, were assayed to investigate cross-resistance between conventional insecticides and acetamiprid.

One organophosphate-resistant strain of *M. persicae*, the Tokushima strain, showed a 19-fold higher LC₅₀ value for acetamiprid than that of the susceptible Odawara strain (Iwasa et al., 1993). The value for the Tokushima strain, 3.9 ppm, is however still lower than the values of acephate or pirimicarb for the susceptible strain. For the diamondback moth, *Plutella xylostella*, two insecticide-resistant strains were assayed (Mitsui et al., 1993). Acetamiprid was effective on both Mizobe and Haibara strains, which were acephate- and cypermethrin resistant, as well as the susceptible Hiratsuka strain. No obvious cross-resistance to acetamiprid in any pest species is known up to this point.

3.3.4 Sensitivity data

Aphids and pollen beetles vary in their sensitivity towards insecticides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. Acetamiprid has been tested and used worldwide for over 20 years and it is therefore difficult to find unexposed insect pest populations. No true base line sensitivity data can therefore be established.

3.3.5 Use pattern

In the EU Central zone, Acetamiprid 20% SG is proposed for use against aphids in pome fruits and pollen beetle in oilseed rape, as listed in the GAP table in Appendix 2. The insecticide is proposed applied once in oilseed rape and twice in pome fruit crops during the season at the recommended dose rates.

The application may be employed when the pest population in the crop has reached the threshold as recommended for the different crops in the different regions. Dependent on the crop and the pest to be controlled, this will deliver 40 or 50 g/ha acetamiprid per application.

Acetamiprid has been used as straight product as well as in mixtures for many years.

3.3.6 Resistance Risk Assessment of Unrestricted Use pattern

Agronomic practice

In terms of agronomic practice, the selection pressure on the intended targets for Sharda acetamiprid formulation is higher in some cropping systems compared to others. This can be due to the prevalence of continuous cropping of e.g. pome fruit crops or short rotation intervals between successive crops like oilseed rape where acetamiprid can be used. In contrast, other crops tend to be grown on a longer rotation cycle.

The plant protection product

For optimum insect control, acetamiprid is applied at the rates recommended on the proposed label. These have been shown to be the minimum effective dose for the major targets, i.e. aphids in pome fruits and pollen beetles in oilseed rape (CP 6.1.2).

Unrestricted Use pattern

In the absence of any potential resistance risk and in the absence of any other restrictions on the GAP (residues, toxicology etc.), the unrestricted use pattern for acetamiprid would be season long usage with an unrestricted number of applications.

Resistance risk assessment of unrestricted use pattern

Overall, it is clear that the unrestricted use of acetamiprid presents an unacceptable resistance risk and therefore modifiers as part of a Management Strategy are proposed.

3.3.7 Test methods

There are several methods recommended to monitor the resistance in the insect pests for which the use of Acetamiprid 20% SG is claimed. In the table below, a number of examples are listed.

Table 3.3-1: List of test methods recommended for resistance monitoring

Crop	Pest	Test Method
Stone fruit	<i>Myzus persicae</i>	IRAC susceptibility method 019
Pome fruit	<i>Aphis pomi</i>	Lowery, D.T., Smirle, M.J., et al., 2006
Pome fruit	<i>Dysaphis plantaginea</i>	Schaub, L, Alame, M. et al., 2001
Oilseed rape	<i>Meligethes aeneus</i>	IRAC susceptibility method 021

3.3.8 Acceptability of the Resistance risk

Without any precautions the resistance risk is unacceptable. However; taking the right precautions and following Good Agricultural Practise, the risk is acceptable. Should resistant populations arise, control could be achieved through use of alternative products.

3.3.9 Management Strategy

As the unmodified use pattern is considered unacceptable, a number of modifiers are proposed which are entirely in accordance with the general recommendations.

- 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

3.3.10 Implementation of the management strategy

Information on the management of resistance and the specific Resistance Management Strategy for acetamiprid is disseminated by a number of routes including, but not exclusively:

- Product label has a clear statement regarding resistance risk and the management strategy
- Pack inserts- for general information or to address a particular issue in a specific geographical area where it to occur.
- Leaflets available at, and distributed by distributors/wholesalers/merchants
- Information released by national and local advisory services re. monitoring
- Training for distributors/wholesalers/merchants and farmer groups
- Links from company web sites to local Resistance working groups for information and advice

3.3.11 Implementation of the Management Strategy

Monitoring of field performance

Where field performance is significantly less than expected and where no other explanation can be found for the reduced performance e.g. application errors, then samples may be taken for sensitivity testing. Where testing is carried out it will be conducted at laboratories experienced in carrying out such testing and using methods recommended by the authorities.

Analysis of performance-related complaints

Where no other reason for a failure in performance can be identified, samples may be taken for testing as described above

Where resistance is confirmed as the cause for loss of field performance this will be reported to the authorities on an annual basis or as required.

Containment plan

The above recommendations will be adjusted as needed depending on the success of the proposed strategy. In the event that practical field resistance should occur on any significant scale, Sharda's plan for containing the further development or spread of resistance includes a number of possible actions on a temporary or permanent basis, including but not exclusively:

- Recommendations to use only insecticides from alternative mode of action groups for the remainder of the growing season
- Recommendation to use only in a programme e.g. before or after an application of an insecticide from a different mode of action group.

Normally any action taken would be in consultation with the relevant authorities.

Comments of zRMS:	<p>Neonicotinoids have a novel mode of action thus classified as an advanced class of insecticides. These insecticides have made a key status in Integrated Pest Management (IPM) programs because of their high efficacy against a wide range of insect pests (Yamamoto and Casida 1999).</p> <p>Acetamiprid is a neonicotinoid to control sucking insect pests of plants. It has osmotic, systemic, and contact action (Takahashi 1998).</p> <p>Resistance to acetamiprid has been reported in different insect pests including <i>Plutella xylostella</i> (Linnaeus) (Sayyed and Crickmore 2007), <i>Bemisia tabaci</i> (Gennadius) (Basit et al. 2011), <i>Leptinotarsa decemlineata</i> (Say) (Mota-Sanchez et al. 2006), <i>Aphis gossypii</i> (Glover) (Herron and Wilson 2011), <i>Frankliniella occidentalis</i> (Pergande) (Minakuchi et al. 2013), and <i>Phenacoccus solenopsis</i> (Fernald) (Ijaz et al. 2016).</p> <p>An EPPO conform analysis of the resistance risk was carried out. Evaluator accepted strategy against resistance developing.</p> <p>The resistance management for acetamiprid is coordinated by IRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.</p> <p>Group 4 insecticides used at rates higher or lower than recommended on the label can result in resistance and/or unwanted effects on non-target organisms and the environment. Always make sure that all the spray equipment is in good condition and that there is no blocking of nozzles or filters as this results in incorrect rates.</p> <p>By diversifying the mode of action used in the crop cycle, the farmer is avoiding prolonged selection for one resistance mechanism. Carefully planned rotation of active ingredients from different mode of action groups provides the best option for minimizing resistance development. Sufficient intervals should be left between applications of active ingredients with the same modes of action. Avoid using Group 4 compounds for more than 50% of the total crop cycle.</p> <p>When using mixtures containing a Group 4 compound as one of the components, always use the full recommended rates of the individual active ingredients. The use of mixtures whether as a premix or tank mix, containing two effective active</p>
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	<p>ingredients with different modes of action is becoming very popular either to increase the spectrum of insect pests controlled or to prevent the development of resistance. More and more mixtures containing both a pyrethroid and a Group 4 insecticide are being used against difficult to control insect pests. The use of such mixtures in any form is not recommended if the target pest is already resistant to one of the modes of action in the mixture! Do not develop an over reliance for a specific mixture as this can result in selection for multi-resistant populations which are very difficult to control. When using mixtures always be sure to change the active ingredient combinations and not to repeatedly use only one mixture of the same active ingredients or modes of action within a single cropping cycle.</p> <p>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.</p> <p>The proposed resistance risk management strategy is acceptable. Final assessment 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.</p>
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3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

As Acetamiprid 20% SG is an insecticide, no specific studies are required as long as in the efficacy trials no negative effects are observed. The crop safety of applying Acetamiprid 20% SG at the recommended rates in oilseed rape and pome fruits was evaluated in 31 efficacy trials. The results obtained in these trials, where reported, are presented in Appendix 7.

The efficacy trials were conducted in the Maritime zone (10; Germany (5), the Netherlands (1), the United Kingdom (2) and N-France (2)), the North-east zone (12; Poland (4), Latvia (4) and Lithuania (4)), the South-east zone (4; Hungary (2) and Romania (2)) and the Mediterranean zone (8; Spain (3), Italy (3), Portugal (1) and S-France (1)) in 2015 and 2019 to evaluate the crop safety of Acetamiprid 20% SG in the GAP claimed crops.

3.4.1.1 Winter oilseed rape

Crop phytotoxicity was evaluated in 14 efficacy trials where Acetamiprid 20% SG was applied with one application in winter oilseed rape, when the crop was at growth stages ranging from BBCH 32 to BBCH 62, at the rate of 100 to 200 g/ha. The 200 g/ha dose rate corresponds to 100% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest.

Phytotoxicity in oilseed rape trials, Maritime EPPO zone

A total of six efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Acetamiprid 20% SG when applied as recommended in oilseed rape. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the six efficacy trials conducted in the Maritime EPPO zone.

Phytotoxicity in oilseed rape trials, North-east EPPO zone

A total of six efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Acetamiprid 20% SG when applied as recommended in oilseed rape. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity were observed in either of the six efficacy trials conducted in the North-east EPPO zone.

Phytotoxicity in oilseed rape trials, South-east EPPO zone

A total of two efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Acetamiprid 20% SG when applied as recommended in oilseed rape. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in either of the two efficacy trials conducted in the South-east EPPO zone.

3.4.1.2 Apple fruit trees

Crop phytotoxicity was evaluated in 18 efficacy trials where Acetamiprid 20% SG was applied with one (5x) or two (13x) applications in apple, when the crop was at growth stages ranging from BBCH 69 to BBCH 91, at the rate of 125 to 250 g/ha. The 250 g/ha dose rate corresponds to 100% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest.

Phytotoxicity in apple trials, Maritime EPPO zone

A total of four efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Acetamiprid 20% SG when applied as recommended in apple crops. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the four efficacy trials conducted in the Maritime EPPO zone.

Phytotoxicity in apple trials, North-east EPPO zone

A total of six efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Acetamiprid 20% SG when applied as recommended in apple crops. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the six efficacy trials conducted in the North-east EPPO zone.

Phytotoxicity in apple trials, South-east EPPO zone

A total of two efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Acetamiprid 20% SG when applied as recommended in apple crops. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in either of the two efficacy trials conducted in the South-east EPPO zone.

Phytotoxicity in apple trials, Mediterranean EPPO zone

A total of six efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Acetamiprid 20% SG when applied as recommended in apple crops. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the six efficacy trials conducted in the Mediterranean EPPO zone.

3.4.1.3 Pear fruit trees

Crop phytotoxicity was evaluated in two efficacy trials where Acetamiprid 20% SG was applied with two applications in pear, when the crop was at growth stage BBCH 91, at the rate of 125 to 250 g/ha. The 250 g/ha dose rate corresponds to 100% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest.

Phytotoxicity in pear trials, Mediterranean EPPO zone

Two efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Acetamiprid 20% SG when applied as recommended in pear crops. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity were observed in either of the two efficacy trials conducted in the Mediterranean EPPO zone.

3.4.1.4 Overall conclusion

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 pome fruit (pear and apple) and winter oilseed rape.

As the data on oilseed rape and pome fruits show, the crop safety and efficacy of Acetamiprid 20% SG is equivalent to that of the acetamiprid reference product. For recommendations claimed on the draft Acetamiprid 20% SG label not adequately supported by the applicant's trials data, Sharda wishes to cite the original registrant's data on acetamiprid now out of protection and requests that the evaluators extrapolate from those data.

Table 3.4-1: Phytotoxicity of product

Number of trials with...		Selectivity trials (0 trials)				Efficacy trials (34 trials)	
		Test product		Standard 1		Test product	Standard 1
		-	-	-	-	200-250 g/ha	200-250 g/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%					34	34
	>5% to 10%					0	0
	>10% to 15%					0	0
	>15 %					0	0
Level of symptoms at the last assessments	0% to 5%					34	34
	>5% to 10%					0	0
	>10% to 15%					0	0
	>15 %					0	0

Comments of zRMS:	The applicant's conclusion on crop safety can be agreed. No phytotoxic effects were observed in efficacy trials. In conclusion, the test product Asset (SHA 5500 A) is regarded safe for the treated plants when applied at the intended dose rate and used according to the label recommendations.
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

The control of insects feeding from leaves, seeds and other plant parts is expected to positively impact the harvested mass of treated crops.

No trials were harvested to demonstrate the impact of Acetamiprid 20% SG on the yield of treated crops.

Comments of zRMS:	The applicant's conclusion on crop safety can be agreed. The control of insects feeding from leaves, seeds and other plant parts is expected to positively impact the harvested mass of treated crops. So, no negative influence of the product Asset (SHA 5500 A) on the yield of treated plants or plant product is to be expected when applied at the proposed label rate.
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

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.

Comments of zRMS:	No assessments of yield quality data are available. The control of insects feeding from leaves, seeds and other plant parts is expected to positively impact the quality of plants and plant products. The zRMS considers that the adverse effects on the quality of plants or plant products are low when Asset (SHA 5500 A) is applied at the proposed label rate and used according to the label recommendations.
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3.4.4 Effects on transformation processes (KCP 6.4.4)

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.

Comments of zRMS:	The applicant demonstrated that residues are undetectable (Part B Section 7). It is not expected that Asset (SHA 5500 A) at the proposed label rate will have adverse effects on transformation processes.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Acetamiprid 20% SG is an insecticide without herbicidal activity. According to EPPO PP 1/135(4), no data are normally required for non-systemic insecticides such as Acetamiprid 20% SG. In addition, no phytotoxic or other adverse effects were recorded at the recommended rates on several crops targeted for this registration during efficacy trials reported in this biological assessment dossier.

Currently there are no label restrictions regarding the use of acetamiprid on crops destined for propagation and there seems no reason to suppose that Acetamiprid 20% SG will perform any differently to those products in this respect.

The product complies with the Uniform Principles.

Comments of zRMS:	Applicant's statement can be agreed. A detailed evaluation of the adverse effect on parts of plants used for propagating purposes can be waived.
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Not relevant.

As per the review report for Acetamiprid (SANCO/1392/2001 – Final), average DT₉₀ in the laboratory and in the field are 2.6 days (range 0.8-5.4 days, n=4) and 20.2 days (range 11.3-31.2 days, n=4), respectively, and therefore no studies are needed according to guidelines. No soil dissipation studies were required.

Hence, no significant residue levels are to be expected in rotational crops following application of Acetamiprid according to the proposed GAP.

Comments of zRMS:	No assessment following the EPPO Standard PP 1/207 'Effects on succeeding
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	crops' was carried out. This assessment can be waived, since acetamiprid has no herbicidal activity. Applicant's statement can be agreed. Asset (SHA 5500 A) did not cause any symptoms of phytotoxicity. It is not probable that this product would cause damage to succeeding crops at the recommended rate.
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

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.

In addition, acetamiprid has a low vapour pressure (1.73×10^{-4} Pa at 25°C), therefore volatilization from soil or water is not expected to be significant. For more details please refer to Registration Report Part B Section 5. For further information and guidance on the agronomic risk following an application of acetamiprid at the recommended dose rates, please refer to Registration Report Part B Section 9: Ecotoxicological studies.

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

Comments of zRMS:	No assessment following the EPPO Standard PP 1/256 'Effects on adjacent crops' was carried out. This assessment can be waived, since acetamiprid has no herbicidal activity. Applicant's statement can be agreed. There should not be any negative effect on adjacent crops when Asset (SHA 5500 A) is used as recommended.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Specific assessments of beneficial and non-crop organisms were taken in the efficacy trials and in these, no adverse effects were noted when visual observations were made within these field trial sites.

The impact of acetamiprid against non-target organisms is summarized in the document Part B, Section 6 (Ecotoxicological studies). Detailed studies on the potential adverse effects to beneficial organisms are submitted in Part B Section 9.

The product complies with the Uniform Principles.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	In efficacy trials no adverse effect on beneficial and other non-target organisms were seen. Reference should be made to Section 9 (Ecotoxicology). Applicant's statement can be agreed. Moreover, for details concerning adverse effects on beneficial and other non-target organisms see Part B9 of the dossier (eco-toxicological data).
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3.5.4 Tank cleaning

Please refer to section B1,2,4 for complete information

Comments of zRMS:	Complete information's are presented in section B1, 2, 4.
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3.6 Other/special studies

No other studies were conducted

Comments of zRMS:	Statement accepted.
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3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

Testing facility	Zone	Country	Year and trial type			
			2015		2019	
			Oilseed rape	Pome fruit	Oilseed rape	Pome fruit
			Efficacy	Efficacy	Efficacy	Efficacy
Biochem Agrar GmbH	MAR	DE	2			
Field Research Support	MAR	DE		3		
Bredelaar	MAR	NL		1		
Charles River Lab.	MAR	UK	2			
Promo-Vert	MAR	FR	2			
BioChem Agrar GmbH	N-E	PL	2			
Latvian Plant Protection Research Centre	N-E	LV		2		2
Lithuanian Research Centre for Agriculture and Forestry	N-E	LT	3	1		
Sharda Poland Sp. Z.o.o.	N-E	PL			1	
SGS Polska Sp. Zo.o.	N-E	LV				1
Eurofins AgroScience Services	S-E	HU		2		
Eurofins AgroScience Services	S-E	RO	2			
Promo-Vert	MED	ES		3		
Promo-Vert	MED	PT		1		
Promo-Vert	MED	IT		3		
Promo-Vert	MED	FR		1		
Total			13	17		

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Acetamiprid 20% SG (200 g/kg Acetamiprid) – EU Central zone Sharda Cropchem España -, - Unpublished	N	SHA