REGISTRATION REPORT
Part A

Risk Management

Product code: **Alginure Bio Schutz**

Active Substance: **Potassium Phosphonates 342 g/L**

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: **TILCO BIOCHEMIE GmbH**

Date: **17 October 2017**

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PART A – Risk Management

This document describes the conditions required for the registration of Alginure Bio Schutz containing potassium phosphonates in Germany. This evaluation is required subsequent to the inclusion of potassium phosphonates on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Alginure Bio Schutz where that data has not been considered in the EU review. Otherwise assessments for the safe use of Alginure Bio Schutz have been made using endpoints agreed in the EU review of potassium phosphonates.

This document describes the specific conditions of use and labelling required for Germany for the registration of Alginure Bio Schutz.

Appendix 1: copy of the final product authorisation in Germany (see Appendix 4)

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3: Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4: copy of the final product authorisation in Germany

1 Details of the application

1.1 Application background

This application was submitted by GAB Consulting GmbH on behalf of Tilco Biochemie GmbH on 22. January 2013.

The application was for approval of Alginure Bioschutz, a soluble concentrate containing 342 g/L potassium phosphonate for use as a fungicide for control of downey mildew (*Plasmopara viticola*) in grapes.

1.2 Annex I inclusion

Potassium phosphonates was included on Annex I of Directive 91/414/EEC on 14. May 2013 under Commission Implementing Regulation (EU) No 369/2013.

The Commission Implementing Regulation (EU) No 369/2013 of 22 April 2013 for potassium phosphonates provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium phosphonates, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:
— the risk to birds and mammals,
— the risk of eutrophication of surface water, if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water. Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards the long-term risk to insectivorous birds. The applicant shall submit to the Commission, the Member States and the Authority that information by 30. September 2015

These concerns were all addressed in the submission.

1.3 Regulatory approach

To obtain approval the product Alginure Bio Schutz must meet the conditions of the Implementing Regulation (EC) No 396/2013 and be supported by dossiers satisfying the requirements of Uniform Principles Commission Regulation (EU) No 546/2011 and agreed end-points.

This application was submitted in order to allow the first approval of this product/use in Germany in accordance with the above.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of Minstrel, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1 - 7 and Part C.

1.5 Letters of Access

Data access has been proven. Tilco Biochemie GmbH. provided own data as well as a letter of access from Luxembourg Industries, Ltd. for the use of the Annex II dossier of the active ingredient potassium phosphonates.

2 Details of the authorisation

2.1 Product identity

Product Name	Alginure Bio Schutz
Authorization Number (for re-registration)	007839-00/00
Function	Fungicide

Applicant	Tilco Biochemie GmbH
Composition	342 g/L potassium phosphonates (equivalent to 228 g/L phosphonic acid)
Formulation type	Soluble concentrate [Code: SL]
Packaging	10 L canister, HDPE

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

The following labelling is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard classes and categories:	
None	
Hazard pictograms:	
None	
Signal word:	
None	
Hazard statements:	
None	
Precautionary statemtents:	
P501	Dispose of contents/container to ...
Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
12 percent of the mixture consist of an ingredient of unknown inhalation toxicity.	

2.2.3 Standard phrases under Regulation (EC) No 547/2011

None

2.3 Other phrases notified under Regulation (EC) No 547/2011

2.3.1 Restrictions linked to the PPP

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

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health

	damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.
SB166	Do not eat, drink or smoke when using this product.
SF194	When re-entering the treated bush and tree cultures on the day of application the protective suit for working with plant protection products and universal protective gloves (plant protection) must be worn. Successive work on/in the crops stated above may not be carried out until 24 hours after applying the product. During the first week, the standard protective suit for working with plant protection products and universal protective gloves (plant protection) must be worn.
SS206	Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.
Integrated pest management (IPM)/sustainable use	
WMFUN	Mode of action (FRAC-group): Unknown
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)
Ecosystem protection	
NW468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

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

Integrated pest management (IPM)/sustainable use	
NN1001	The product is classified as non-harmful for populations of relevant beneficial insects.
NN1002	The product is classified as non-harmful for populations of relevant beneficial predatory mites and spiders.

2.3.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.4 (Product uses)

Integrated pest management (IPM)/sustainable use	
NN134	The product is classified as harmless for populations of the species *Typhlodromus pyri* (predatory mite).
WW750	The maximum number of applications is limited due to active substance-specific reasons.

	Sufficient control is therefore not expected in all cases. If necessary, use products containing other active substances afterwards or alternately.
Ecosystem protection	
NW605-1	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*".Drift reduction by 90% * 75 % 5 50% 10 m
NW606	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. Buffer zone of 10 m

2.4 Product uses

GAP-Table of intended uses for Germany

GAP rev. (2), date: 2014-05-20

PPP (product name/code)	**Alginure Bio Schutz**	**Formulation type:**	**SL**
active substance	**Potassium phosphonates (formerly potassium phosphite)**	**Conc. of as :**	**342 g/L**
Applicant:	**Tilco Biochemie GmbH**	**professional use**	☒
Zone(s):	**central/EU**	**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	grape vine VITVI (utilisation as table and wine grape)	F	downy mildew of grapevine *Plasmopara viticola* PLASVI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 12 - 68	a) 6 b) 6 (min 7 days)	a) - base dose: 1.5 L/ha - BBCH 61: 3 L/ha - BBCH 68: 4.5 L/ha b) 27 L/ha	a) - base dose: 513 g as/ha - BBCH 61: 1026 g as/ha - BBCH 68: 1539 g as/ha b) 9234 g as/ha	max 400 L/ha max 800 L/ha max 1200 L/ha	14	NN134, WW750, NW605-1, NW606

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:

The appearance of the product Alginure Bio Schutz is that of a brown, non-viscous liquid with an organic and sweet odour containing suspended particles which settled down after a certain standing period of time. It is not explosive, has no oxidising properties. It has a self ignition temperature of 530°C. In aqueous solution, it has a pH value around 6 to 7. The storage stability for 14 days at 54°C showed good stability of the preparation in terms of active substance content and product characteristics. Alginure Bio Schutz cannot be stored under refrigerated conditions because after storage for 7 days at 0 °C phase separation occurred. The product label contains a warning against exposure to low temperatures.

Results of the technical tests (dilution stability, persistent foaming) showed that Alginure Bio Schutz is a preparation of acceptable quality which is compatible with several other products commonly used in plant protection.

Storage stability data demonstrates that the shelf life at ambient temperature is at least 2 years.

The technical characteristics are acceptable for a soluble concentrate formulation.

Experimental testing of a product sample was performed. Except for the surface tension no significant deviations from the data submitted by the applicant were detected. Regarding the surface tension a value of 46.6 mN/m were determined for a 0.1 % solution. In the study Birnschein, 2012b (report no. S12-02024) the determined values were between 64.7 and 71.5 mN/m. This discrepancy needs an explanation.

Implications for labelling: None

Compliance with FAO specifications:
The product Alginure Bio Schutz complies with FAO specifications.

Compliance with FAO guidelines:
The product Alginure Bio Schutz complies with FAO specifications, as far as could be assessed.

Compatibility of mixtures:
No tank mixture is foreseen.

Nature and characteristics of the packaging:
Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport and handling, resistance to and compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:
Information regarding the required protective clothing and equipment for the safe handling of Alginure Bio Schutz has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

Phosphonic acid can be quantified in Alginure Bio Schutz using the analytical IC method 12G05021-01-VMFO. The method was developed for quantifying phosphonic acid in Alginure Bio Schutz.
The active substance is diluted in demineralised water, chromatographed on an IC-system (Dionex IC 25) with Eluent Generator (Ion Pac AS17-C column) with conductivity detection and external calibration. The results are given in phosphonic acid and can be re-calculated to the content of phosphonate. The method can be used in soluble concentrates (SL).
Further information regarding accuracy and selectivity is needed.

Potassium can be quantified in Alginure Bio Schutz using the analytical method 12G05021-02-VMFO. The method was developed for quantifying potassium in Alginure Bio Schutz.
The active substance is diluted, solved by reflux heating and analysed with ICP-OES and external calibration. Due to the lack of blank formulation, the recovery experiments were done by fortification of the formulated product with reference items at two levels.
The method should be valid for determination of 10°% to 20°% potassium in soluble concentrates (SL).
Further information regarding accuracy is needed.

A CIPAC method is not available for the determination of potassium phosphonate in formulations.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

Analytical methods for food of plant origin are active substance data and were provided in the EU review of potassium phosphonates and were considered adequate. Methods for soil and water provided in the EU review involved the use of diazomethane which is considered to be an unacceptable derivatisation agent. However, this deficiencies of these methods were not withstanding the approval of potassium phosphonates.

An additional method for water without the use of diazomethane has been provided and is considered acceptable.

No residues in feeding stuff are expected from the intended use therefore methods for food of animal origin are not required. Methods for air and body fluids and tissues are not required because potassium phosphonates is not classified as toxic (T / T+) nor as Xi or Xn nor is it classified according to GHS as follows: Acute toxicity (cat. 1 -3), CMR (cat. 1) or STOT (cat. 1).

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

Alginure Bio Schutz, containing 342 g/L potassium phosphonate (equivalent to 228 g/L phosphonic acid) has a low toxicity in respect to oral and dermal toxicity. Its acute inhalation toxicity is not estimated (justification see Part B Section 3 annex 2). It has no sensitizing properties. It is not irritating to skin and to eyes.

3.1.3.2 Operator Exposure

Operator exposure to Alginure Bio Schutz was not evaluated as part of the EU review of potassium phosphonate. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

Operator exposure was assessed against the AOEL agreed in the EU review (5 mg/kg bw/d). Operator exposure was evaluated using UK POEM and German models.
According to the model calculations, it can be concluded that the risk for the operator using Alginure Bio Schutz on vine grapes is acceptable without the use of personal protective equipment (hand held and tractor amounted applications; German model).

3.1.3.3 Bystander Exposure

The bystander and/or resident exposure estimations indicated that the acceptable operator exposure level (AOEL) for potassium phosphonate will not be exceeded under conditions of intended uses.

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

The worker exposure was estimated using the model "German model". With the use of personal protective equipment the estimated consumption of AOEL was below 15 % for potassium phosphonate.

Implications for labelling resulting from operator, worker, bystander assessments:

See 2.2

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Fundamental residue data on potassium phosphonate like metabolism are already evaluated previously and is described in detail in the respective DARs.
The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 100 mg/kg as laid down in Reg. (EU) 396/2005 for fosetyl-A1 (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl), which covers also the active substance potassium phosphate, is not expected. An exceedence of the proposed MRL for potassium phosphonate of 90 mg/kg (EFSA, 2012) is also not expected.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

An estimation of dietary intake using EFSA PRIMo results in a maximum consumption of the ADI below 100 %.

ADI	**2.52 mg/kg bw** (recalculated for fosetyl)*
TMDI, EFSA PRIMo, German children, aged 2-4 years	73 % (MRLs for fosetyl-Al (sum of fosetyl and phosphorous acid, expressed as fosetyl) were used.
ARfD	Not necessary

*: Since according to the current residues definition in Regulation (EC) No 396/2005 the residues are expressed as fosetyl, the ADI derived for phosphonic acid needs to be corrected, applying the molecular weight correction factor of 1.12

The chronic and the short-term intake of potassium phosphonate residues are unlikely to present a public health concern.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

A full exposure assessment for the plant protection product Alginur Bio Schutz in its intended uses in vines is documented in detail in the core assessment of the plant protection product Alginur Bio Schutz performed by Germany.

The following chapters summarise specific exposure assessments for soil and surface water and the specific risk assessment for groundwater for the authorization of Alginur Bio Schutz in Germany according to its intended use in Vines (use No. 001).

Table: Critical use pattern of Alginure Bio Schutz for the risk assessment environment

Crop	Growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Max single aplication rate (g as/ha)	Max single soil effective application rate (g as/ha)
Vines	BBCH 12-68	Spray	6 applications 7 days interval BBCH 12 – 60: Interception: 40% Season:Spring BBCH 61-67: Interception: 70% Season: summer BBCH 68: Interception: 70% Season. summer	<u>Single application rates:</u> BBCH 12 – 60: 513 g a.s/ha (342 g/ha phosphonic acid eq.) BBCH 61-67: 1026 g a.s/ha (684 g/ha phosphonic acid eq.) BBCH 68: **1539 g a.s./ha (1026 g/ha phosphonic acid eq.)** <u>Cumulative max. application rate:</u> 9234 g a.s./ha (6156 g a.s./ha phosphonic acid)	<u>Single application rates:</u> BBCH 12 – 60: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 61-67: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 68: 461.7 g a.s./ha (307.8 g/ha phosphonic acid eq.) <u>Cumulative max. application rate:</u> 2770.2 g a.s./ha (1846.8 g a.s./ha phosphonic acid)

Potassium phosphonates
As described in the EFSA Conclusion (EFSA Journal 2012;10(12):2963) after applying the diluted product to soil, the chemical species in soil will be salts of potassium and predominantly hydrogen phosphonate and phosphonate (the possible salts of phosphonic acid). In soil laboratory incubations under aerobic conditions in the dark, the hydrogen phosphonate / phosphonate is oxidised (a microbially mediated oxidation) to phosphate ions.

In water/sediment systems phosphonic acid will be metabolized. A quick translocation into the sediment with a subsequent slow degradation towards phosphate ions is expected.

Metabolites:
For the active substance potassium phosphonates, the only potentially relevant metabolites are besides phosphinic acid phosphate and potassium ions. Based on the criteria laid down in the EFSA guidance

document Sanco/221/200-rev.10-final (2003) [1], phosphate and potassium ions are metabolites of no concern.
Phosphonic acid is biologically active and shows fungicidal properties.

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product Alginur Bio Schutz in Vines according to use no 001, PECsoil was calculated for phosphonic acid, representative for the active substance potassium phosphonates, considering a soil depth of 2.5 cm. Due to the slow degradation of the phosphonic acid in soil the accumulation potential of phosphonic acid was considered. Therefore PECsoil used for risk assessment comprises background concentration in soil (PECaccu) considering a tillage depth 5 cm (permanent crops) and the maximum annual soil concentration PECact considering the relevant soil depth of 2.5 cm, respectively.

Additional $PEC_{soil,act}$ was calculated for the formulation Alginur Bio Schutz for a soil depth of 2.5 cm.

Table: Overview of relevant PECsoil concentrations for risk assessment

active substance/ formulation	soil relevant application rate (g/ha)	soil depth$_{act}$ (cm)	PEC_{act} (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Phosphonic acid	5 x 205.2 + 1 x 307.8 g a.s./ha phosphonic acid equivalents	2.5	3.0453	20	0.2334	3.2786
Alginur Bio Schutz	7868 g/ha	2.5	11.6213	-	-	-

The results for PECsoil for the active substance and the formulation were used for the eco-toxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PECGW) (Part B, Section 5, Point 9.6)

Results of PECgw calculation of Phosphonic acid for the intended uses of Alginur Bio Schutz in Vines according to EU assessment using FOCUS PEARL 4.4.3 are given in the core assessment, part B, section 5, chapter 5.7.
For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.
Direct leaching after soil passage is generally assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Hold et al, 2011, endpoints for groundwater modelling are

[1]

derived with the program INPUT DECISION 3.1 and subsequent simulations are performed for the groundwater scenarios "Hamburg" or with the scenarios "Hamburg" and "Kremsmünster" of FOCUS PELMO 4.4.3.
In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.
Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance phosphonic acid is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended use of Alginure Bio Schutz in vine according to use No 001.

Consequences for authorization:
None.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance phosphonic acid due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PECsw) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product Alginur Bio Schutz in its intended uses in vines according to use no 001, PECsw was calculated for the active substance phosphonic acid, representative for the active substance potassium phosphonates, and for phosphate ions considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.

The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier. Since no vapour pressure was available for phosphonic acid and phosphate ions, exposure of surface water due to deposition following volatilization was calculated using a worst case default vapour pressure assuming very high volatility of phosphonic acid and phosphonic ions.

The concentrations of the active substance phosphonic acid and phosphate ions via spray drift and volatilization with subsequent deposition were calculated using the model EVA 3.0.

The concentration of the active substance phosphonic acid and phosphate ions in adjacent ditch due to surface run-off and drainage was calculated using the model EXPOSIT 3.01.

Table: Summary of PEC_{sw} values for the intended use in sugar beet used for German risk assessment

active substance/ formulation	PECsw Spray-Drift (incl. volatilisation) [µg/L] – with 1 m default buffer - scenario agriculture	PECsw run-off** [µg/L] – without buffer	PECsw drainage [µg/L] – scenario autum/winter/early spring	PECsw drainage [µg/L] – scenario spring/summer
Phosphonic acid	98.7	3.14	0.19	0.06
Phosphate ions	116.3	6.58	0.75	0.24
Preparation Alginure Bioschutz	160.4*	-	-	-

* single application

** total incl. dissolved particles

The results for PEC surface water for the active substance phosphonic acid and of phosphate ions were used for the eco-toxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 3.

Phosphonic acid is treated as semi-volatile substance with a vapour pressure at 20 °C (Pa) of 1×10^{-02} (worst case default value).

Implications for labelling resulting from environmental fate assessment: (

For the authorization of the plant protection product Alginure Bio Schutz following labeling and conditions of use are mandatory:

Classification and labelling
Based on the data on the active substance potassium phosphonates the plant protection product Alginur Bio Schutz is considered to be not readily degradable in the sense of the CLP regulation.

R and S phrases under Directive 2003/82/EC (Annex IV and V)
none
Other labels /conditions for use

Labelling

none

Conditions of use:

None

Further data requirements:

None

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

A full risk assessment according to Uniform Principles for the plant protection product Alginure Bio Schutz in its intended uses in vines is documented in detail in the core assessment of the plant protection product Alginure Bio Schutz dated from July 2014 performed by Germany. The intended use of Alginure Bio Schutz in Germany is generally covered by the uses evaluated in the course of the core assessment by Germany.
The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of Alginure Bio Schutz in Germany according to its intended use in vines (use No. 001).

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Table: Endpoints used for risk assessment for birds and mammals

Test system	Species	Results
Photassium Phosphonates		
Acute toxicity	*Colinus virginianus* (Bobwhite quail)	LD_{50} > 2250 mg a.s./kg bw/d
Acute toxicity	rat	LD_{50} = 5000 mg/kg bw (equivalent to 1736 mg phosphonic acid/kg bw)
Fosetyl-Al [EU-LoEP: bridging data from fosetyl-Al]		
Reproductive toxicity	*Colinus virginianus* (Bobwhite quail)	NOEC = 216 mg /kg bw equivalent to 149.04 mg phosphonic acid/ kg bw
Reproductive toxicity	rat	NOEL = 439 mg/kg bw (equivalent to 302.9 mg phosphonic acid/kg bw)⁾
Alginure Bio Schutz		
Acute toxicity	rat	LD_{50} > 2000 mg product/kg bw (equivalent to 343.4 mg phosphonic acid/kg bw)

The study on formulation toxicity showed no increased toxicity.

Based on the presumptions of the screening step and Tier 1, the calculated TER values for the acute and long-term risk resulting from an exposure of birds and mammals to the active substance Potassium Phosphonates according to the intended use of the formulation Alginure Bio Schutz in vines achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds and mammals.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Results of aquatic risk assessment for the intended for uses of Alginure Bio Schutz in vines based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.

Relevant toxicity endpoint for aquatic risk assessment is an E_bC_{50} = 19410 µg Phosphonic acid equivalents./L (*Desmodesmus subspicatus*) with a relevant TER of 10. Resulting in a regulatory acceptable concentration (RAC) for phosphonic acid of 1941 µg/l .
For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

1. Exposure by spraydrift and deposition following volatilization

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressures at 20 °C of the active substance Potassium Phosphonates is > 10^{-4} Pa. Therefore, exposure of surface water by the active substance Potassium Phosphonate due to deposition following volatilization was considered.

The aquatic risk assessment of spray drift entries in surface water by the use of Alginure Bio Schutz in vines according to use No. 00-001 is based on the effects of Alginure Bio Schutz to algae.

Based on the relevant toxicity of the active substance, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to Alginure Bio Schutz according to the use No 00-001 achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. However, risk mitigation measures need to be applied in order to address the potential risk of eutrophication.

According to the water framework directive (2000/60/EC) and the implementation law in Germany, the regulation for the protection of surface waters (Oberflächengewässerverordnung), the environmental quality standard representing a good ecological status of surface water bodies is 20 µg *ortho*-Phosphates/L or 50 µg total P/L. Based on the EVA 3 calculations these limits are exceeded in case no risk mitigation measures are implemented. In addition to that the present algae and *Lemna* studies indicate a potential risk of eutrophication. The inclusion directive for Potassium Phosphonates states that member states shall pay particular attention to the risk or eutriphication of surface water. Since no definition for an acceptable limit of eutrophication exists, the environmental quality standard representing a good ecological status of surface water bodies for *ortho*-phosphates is taken as limit value for setting risk mitigation measures.

2. Exposure by surface run-off and drainage

The concentration of the active substance Potassium Phosphonates in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.01.

The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by the active substance Potassium Phosphonates due to run-off and drainage according to the use No 00-001 achieve the acceptability criteria of TER ≥ 100 or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Consequences for authorization:

For the authorization of the plant protection product Alginure Bio Schutz the following labelling and conditions of use are mandatory:

<u>Conditions for use</u>

All uses	NW468
use No. 00-001	NW605-1/NW606 (90%: *m, 75%: 5 m, 50% and common: 10 m)

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

Effects on bees for Alginure Bio Schutz were not evaluated as part of the EU review of potassium phosphonates or phosphonic acid. Therefore, all relevant data and assessments are provided here and are considered adequate.

Due to the results of laboratory tests Alginure Bio Schutz is considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field. It is concluded that Alginure Bio Schutz will not adversely affect bees or bee colonies when used as recommended.

The product is classified as non-hazardous to bees up to the maximum intended application rate.

Other non-target arthropods

For the results of study with T. pyri exposed to Alginure Bio Schutz (LR50 = 55900 g prep./ha - equivalent to 12.5 kg a.s./ha), a vegetation distribution factor has to be considered (study conducted in 2D environment).

Based on the calculated rates of Alginure Bio Schutz in off-field areas, the calculated TER values for the risk resulting from an exposure of non-target arthropods to Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of Alginure Bio Schutz in vines according to the label.

3.1.6.4 Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)

Table Relevant endpoints for earthworms and other soil macro- and mesofauna (Tier-1)

Species	Test item	Time scale	Endpoint [mg/kg soil dw]
Eisenia fetida	Potassium Phosphonates	Acute	> 500
	Potassium Phosphonates	Chronic	31.3
	Alginure Bio Schutz	Acute	> 5000
	Alginure Bio Schutz	Chronic	360
	Alginure Bio Schutz	Chronic	1983

Based on the predicted concentrations of Potassium Phosphonates/Alginure Bio Schutz in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to Potassium Phosphonates /Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Alginure Bio Schutz in vines according to the label.

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

Since no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of Alginure Bio Schutz in vines, data on the effects on organic matter breakdown (litterbag) is not required.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

Based on the predicted concentrations of Potassium Phosphonates and Alginure Bio Schutz in soils, the risk to soil microbial processes following exposure to Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz is considered to be acceptable/ not acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Terrestrial plants

The observed toxicity towards terrestrial plants is low with an ER_{50} of > 36 l product/ha.

Based on the predicted rates of Alginure Bio Schutz in off-field areas, the TER values describing the risk for non-target plants following exposure to Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an unacceptable risk for non-target terrestrial plants due to the intended use of Alginure Bio Schutz in vines according to the label.

Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product Alginure Bio Schutz the following labelling and conditions of use are mandatory:

Classification and labelling of the formulation

Relevant toxicity	Active substance: Potassium Phosphonates (content 34 %) E_bC_{50} = 19.4 mg/L (*Desmodesmus subspicatus*)
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	none
Signal word	No signal word used
Hazard statement	-

R and S phrases under Directive 2003/82/EC (Annex IV and V)

None

Other labels /conditions for use

Conditions of use:

All uses:

NW468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

Use No. 00-001:

NW605-1	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". Drift reduction by 90% * 75 % 5 m 50% 10 m
NW606	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. Buffer zone: 10 m without drift reducing technique

3.1.7 Efficacy

Public available data and own experimental data of the applicant were presented in a BAD and in related studies. GEP requirements were fulfilled and EPPO-Guidelines considered. The assessment is valid for the Maritime EPPO Zone in the Central zone. The application modalities were outlined appropriately and the biology of the host has been considered appropriately.

3.1.7.1 Efficacy Data

Preliminary range finding tests were not documented and are not deemed to be necessary; the product was already on the market as plant strengthener in Germany. The minimum effective dose was not approved by experiments. Explicit experiments should be elaborated until a potential renewal of the product. Sufficient efficacy has been approved. Due to the application modalities the disease cannot be controlled with the product alone.
Alginure Bio Schutz has been on the market as a plant strengthener for many years and no adverse effects on yield and quality of plants or plant products have been reported. No adverse effects are expected concerning the processing procedure.

3.1.7.2 Adverse Effects

Phytotoxicity to target plants has not been observed. Alginure Bio Schutz is classified as not harmful for populations of relevant predatory mites and spiders as well as for populations of relevant beneficial insect species. There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality when Alginure Bio Schutz is used according to the recommended use pattern.
The risk of development of resistance or cross-resistance is low. Due to the application characteristics the product will be used alternating with other products.

3.1.7.3 Economics and Benefits

In general, the number of pesticides which can be used in organic farming is very limited. In organic vine growing only products based on the active substance copper are currently available against *Plasmopara viticola*. Therefore, Alginure Bio Schutz can be used as an important alternative and complement in organic wine growing.

3.2 Conclusions

With respect to efficacy, an authorisation can be granted
Regarding identity, physical, chemical and technical properties, packaging and further information as well as analytical methods (formulation and residues) an authorisation can be granted.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

An authorisation is recommended.

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

The following information is required in order to obtain (a prolongation of) the authorisation: none

Appendix 1 – Copy of the product authorisation (see Appendix 4)

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 – Letter of Access

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4 – Copy of the product authorisation

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

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Referentin

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.007839-00/00.77966
(bitte bei Antwort angeben)

DATUM 17. Oktober 2017

ZV1 007839-00/00

Alginure Bio Schutz

Zulassungsverfahren für Pflanzenschutzmittel

Widerspruchsbescheid

Auf Ihren Widerspruch vom 10. Oktober 2016 wird das o.g. Pflanzenschutzmittel

mit dem Wirkstoff:	342 g/l	Kaliumphosphonat (Kaliumphosphit)
Zulassungsnummer:	007839-00	
Versuchsbezeichnungen:	TIL-11111-F-0-SL	
Antrag vom:	22. Januar 2013	

unter Aufhebung meines Bescheides vom 23. September 2016 auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

BVL_FO_05_2437_200_V1.8

Zulassungsende

Die Zulassung endet am 30. September 2024.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007839-00/00-001	Falscher Mehltau (Plasmopara viticola)	Weinrebe	Nutzung als Tafel- und Keltertraube

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666), festgesetzt:

(NW468)
Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.
Begründung:
Der im o.g. Pflanzenschutzmittel enthaltene Wirkstoff Kaliumphosphonat weist aufgrund seiner Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis übersteigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Kanister	HDPE	1		10,00		l

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung nur durch berufliche Anwender zulässig.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Kennzeichnungsauflagen:

(SB001)
Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB005)
Ist ärztlicher Rat erforderlich, Verpackung oder Etikett des Produktes bereithalten.

(SB010)
Für Kinder unzugänglich aufbewahren.

(SB110)
Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

(SB166)
Beim Umgang mit dem Produkt nicht essen, trinken oder rauchen.

(SF194)
Beim Wiederbetreten der behandelten Raumkulturen sind am Tage der Applikation der Schutzanzug gegen Pflanzenschutzmittel und Universal-Schutzhandschuhe (Pflanzenschutz) zu tragen. Nachfolgearbeiten auf/in den oben genannten Kulturen dürfen grundsätzlich erst 24 Stunden nach der Ausbringung des Mittels durchgeführt werden. Innerhalb von einer Woche sind dabei der Schutzanzug gegen Pflanzenschutzmittel und Universal-Schutzhandschuhe (Pflanzenschutz) zu tragen.

(SS206)
Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

(WMFUN)
Wirkungsmechanismus (FRAC-Gruppe): unbekannt

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 2.

BVL_FO_05_2437_200_V1.8

Sonstige Auflagen:

(WH952)

Auf der Verpackung und in der Gebrauchsanleitung ist die Angabe zur Kennzeichnung des Wirkungsmechanismus als zusätzliche Information direkt jedem entsprechenden Wirk-stoff-namen zuzuordnen.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

- keine -

Gefahrenpiktogramme:

- keine -

Gefahrenhinweise (H-Sätze):

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

Sicherheitshinweise (P-Sätze):

(P501)

Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

- keine -

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:

(NB6641)

Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienen-gefährlich eingestuft (B4).

BVL_FO_05_2437_200_V1.8

(NN1001)
Das Mittel wird als nicht schädigend für Populationen relevanter Nutzinsekten eingestuft.

(NN1002)
Das Mittel wird als nicht schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

Weitere Hinweise und Bemerkungen
Zum Etikett:
Auf dem Etikett ist zusätzlich zum Wirkstoffgehalt anzugeben:
"Enthält ca. 370 g/L Algenextrakt als Netzmittel"

Gemäß Verordnung (EG) Nr. 1272/2008 ist das Gemisch mit folgendem Hinweis zu kennzeichnen:
"12 Prozent des Gemisches bestehen aus einem oder mehreren Bestandteilen von unbekannter inhalativer Toxizität."

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen meinen Bescheid vom 23. September 2016 in der Gestalt, die er durch den vorliegenden Widerspruchsbescheid gefunden hat, kann innerhalb eines Monats nach Zustellung Klage bei dem Verwaltungsgericht Braunschweig, Wilhelmstraße 55, 38100 Braunschweig, erhoben werden.

Die Klage muss den Kläger, den Beklagten und den Gegenstand des Klagebegehrens bezeichnen. Sie soll einen bestimmten Antrag enthalten. Die zur Begründung dienenden Tatsachen und Beweismittel sollen angegeben werden.

Der Klage nebst Anlagen sollen so viele Abschriften beigefügt werden, dass alle Beteiligten eine Ausfertigung erhalten können.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

BVL_FO_05_2437_200_V1.8

Anlage 1 zugelassene Anwendung: 007839-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Falscher Mehltau (Plasmopara viticola)
Pflanzen/-erzeugnisse/Objekte:	Weinrebe
Verwendungszweck:	Nutzung als Tafel- und Keltertraube

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Weinbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	12 bis 68
Anwendungszeitpunkt:	Bei Infektionsgefahr bzw. ab Warndiensthinweis
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	6
- für die Kultur bzw. je Jahr:	6
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 7 Tage
Anwendungstechnik:	spritzen oder sprühen
Aufwand:	
- Basisaufwand:	1,5 l/ha in maximal 400 l Wasser/ha
- ES 61:	3 l/ha in maximal 800 l Wasser/ha
- ES 68:	4,5 l/ha in maximal 1200 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(NN134)
Das Mittel wird als nichtschädigend für Populationen der Art Typhlodromus pyri (Raubmilbe) eingestuft.

(WW750)
Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

14 Tage	Freiland: Weinrebe (Tafel- und Keltertrauben)

BVL_FO_05_2437_200_V1.8

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 10 m, 75% 5 m, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Alginure Bio Schutz bzw. der darin enthaltene Wirkstoff Kaliumphosphonat kann in Gewässern zu Eutrophierung führen. Da ein es keine abgestimmten Konzepte zur Bewertung von Eutrophierung gibt, wird hilfsweise die Umweltqualitätsnorm (UQN) als die Konzentration eines Schadstoffs oder einer Schadstoffgruppe, die in Wasser, Sedimenten oder Biota aus Gründen des Gesundheits- und Umweltschutzes nicht überschritten werden darf, herangezogen. In Deutschland werden die UQN für die Beurteilung des ökologischen Zustands in der Oberflächengewässerverordnung festgelegt und liegen für ortho-Phosphat bei 20 µg/L und gesamt-Phosphor bei 50 µg/L. Ohne die erteilten Anwendungsbestimmungen wird die UQN überschritten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
<u>Begründung:</u>
Siehe Anwendungsbestimmung NW605-1

REGISTRATION REPORT
Part B

Section 1: Identity, physical and chemical properties, other information
Detailed summary of the risk assessment

Product Name: Alginure Bio Schutz

Active Substance: Potassium phosphonates 342 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: TILCO BIOCHEMIE GmbH

Date: 19-09-2016

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Introduction

This document summarises the information related to the identity, the physical, chemical and technical properties, the data on application, further information and the classification for the product Alginure Bio Schutz containing Potassium Phosphonates as active substance which is to be included in the Annex to Regulation (EC) No 1107/2009.

A full risk assessment according to Uniform Principles is provided to demonstrate that the product is safe for operators, workers and bystanders.
Alginure Bio Schutz (Frutogard) was up to now registered as a plant strengthener in Germany (list number 5075-00). According to Regulation (EC) No. 1107/2009, § 2, it will have to be considered as a plant protection product in future. Tilco Biochemie therefore applied for the further use of this product as a plant protection product.
Where appropriate this document refers to the conclusions of the EU review of the active substance Potassium Phosphonates. The active substance data is relied upon in the risk assessment of Alginure Bio Schutz.
The product was not already evaluated as the 'representative formulation' during the Annex I inclusion or re-inclusion. The product has not been previously evaluated according to Uniform Principles.
For the active substance Potassium Phosphonates, the DAR (2005) and the EFSA conclusions (2012)[1] are considered to provide the relevant review information or a reference to where such information can be found.
Information on the detailed composition of Alginure Bio Schutz can be found in the confidential dossier of this submission (Registration Report - Part C).

The following table provides the EU endpoints to be used in the evaluation.

Agreed EU End-points

End-Point	**Potassium phosphonates** (Reg. (EU) No 369/2013)
Purity of active substance	min 990 g/kg on dry weight basis

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

[1] EFSA Journal 2012; 10(12): 2963: Conclusion on the peer review of the pesticide risk assessment of the active substance Potassium Phosphonates

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

IIIA 1.1 Applicant

Tilco Biochemie GmbH

Holländerkoppel 1a

23858 Reinfeld

Germany

Contact person:	Dr. Iradj Scharafat
Tel.No.:	+49 (0) 17171 80023
e-mail:	dr.scharafat@tilco-biochemie.de

IIIA 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)

IIIA 1.2.1 Manufacturer(s) of the preparation

Confidential information - data provided separately (Part C).

IIIA 1.2.2 Manufacturer(s) of the active substance(s)

Confidential information - data provided separately (Part C).

IIIA 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

Potassium phosphonates: min. 990 g/kg

Further information/justification is provided in Part C.

IIIA 1.3 Trade Names and Manufacturer's Code Numbers for the Preparation

Trade name:	Alginure Bio Schutz
Company code number:	None

IIIA 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation

IIIA 1.4.1 Content of active substance and formulants

The pure active substance is deposited as equivalent to a theoretical mixture of mono- and di-potassium salts of phosphonic acid (KH_2PO_3 + K_2HPO_3) resulting in a pH 5.9 to 6.4 after dissolution in water. This mixture does not exist as a homogenous crystalline solid structure.

The tables below summarise the content of the pure and technical active substance.

Pure active substance:

content of pure potassium phosphonates (calculated an a dry weight basis, only theoretical):	342 g/L
limits potassium phosphonates*:	329 – 355 g/L

For a content of 661 g/L technical material the acceptable variation is ± 25 g/L, calculated only on the content of potassium phosphonate gives a variation of ± 13 g/L.
The content is equivalent to 228 g/L phosphonic acid.

Technical active substance:

content of technical potassium phosphonates at minimum purity (50.0 %):	661.3 g/L	49.2 % w/w

The active substance in the formulation is not present in the form of a salt, ester, anion or cation.

Further information on the active substances and on the certified limits of formulants is considered confidential and is provided separately (Part C).

IIIA 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by regulation (EU) 2011/545.

IIIA 1.4.3 Common names and code numbers for the active substance(s)

Data Point	Type	Name/Code Number
1.4.3.1	ISO common name	Potassium phosphonates (no ISO name)
1.4.3.2	CAS No.	13977-65-6 for potassium hydrogen phosphonate 13492-26-7 for dipotassium phosphonate Mixture: none
1.4.3.2	EINECS No.	236-809-2 for dipotassium phosphonate
1.4.3.2	CIPAC No.	756 for potassium phosphonates
1.4.3.2	ELINCS	–
1.4.3.3	Salt, ester anion or cation present	Potassium phosphonates

IIIA 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function.

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

This is not an EC data requirement/ not required regulation (EU) 2011/545.

IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern

Potassium Phosphonates does not contain any impurities of toxicological or ecotoxicological concern.

IIIA 1.5 Type of Preparation and Code

Type : Soluble concentrate Code : SL

IIIA 1.6 Function

The product will be used as fungicide.

IIIA 1.7 Other/Special Studies

None.

IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product Alginure Bio Schutz is that of a brown, non-viscous liquid with an organic and sweet odour containing suspended particles which settled down after a certain standing period of time. It is not explosive, has no oxidising properties. It has a self ignition temperature of 530°C. In aqueous solution, it has a pH value around 6 to 7. The storage stability for 14 days at 54°C showed good stability of the preparation in terms of active substance content and product characteristics. Alginure Bio Schutz cannot be stored under refrigerated conditions because after storage for 7 days at 0°C phase separation occurred. The product should be labelled with a warning against exposure to low temperatures. Results of the technical tests (dilution stability, persistent foaming) showed that Alginure Bio Schutz is a preparation of a high technical quality which is compatible with several other products commonly used in plant protection. Storage stability data regarding a shelf life of at least 2 years at ambient temperature are missing. Its technical characteristics are acceptable for a soluble concentrate formulation.

The product is applied in concentrations between 0.1 % and 0.67 % (main application and applications for further uses).

Compositon of batch no. 32104: 332.0 g/L Potassium Phosphonates (221.3 g/L Phosphonic acid equivalents)

Tabelle 1: Summary of the physical, chemical and technical properties of the plant protection product

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Colour, odour and physical state (IIIA 2.1)	Visual assessment and organoleptic determination	Alginure Bio Schutz Batch no.: 32104	The preparation is brown, non-viscous liquid with an organic, sweet odour containing suspended particles which settled down after a certain standing period of time.	Y	Birnschein, K., 2013, S12-02027	Acceptable.
Explosive properties (IIIA 2.2.1)	EEC A 14 (DSC)	Alginure Bio Schutz Batch no.: 32104	Formulation has no explosive properties.	Y	Möller, M., 2012a, CSL-12-0338.02	Acceptable.
Oxidizing properties (IIIA 2.2.2)	EEC A 21	Alginure Bio Schutz Batch no.: 32104	Formulation has no oxidising properti es.	Y	Möller, M., 2012b, CSL-12-0338.04	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Flash point (IIIA 2.3.1)	EEC A 9	Alginure Bio Schutz Batch no.: 32104	No flash point up to 100 °C.	Y	Möller, M., 2012c, CSL-12-0338.01	Acceptable.
Flammability (IIIA 2.3.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Auto-flammability (IIIA 2.3.3)	EEC A 15	Alginure Bio Schutz Batch no.: 32104	Auto-ignition at 530 °C.	Y	Möller, M., 2012d, CSL-12-0338.03	Acceptable.
Acidity or alkalinity and pH (IIIA 2.4.1)			The test was not conducted, because the pH value of the neat product was between 4 and 10.			Acceptable.
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75.3	Alginure Bio Schutz Batch no.: 32104	Before storage: deionised water: 6.36 Neat formulation: 6.13 After 2 weeks, 54 °C: deionised water: 6.38 Neat formulation: 6.14	Y	Birnschein, K., 2013, S12-02027	Acceptable.
Kinematic viscosity (IIIA 2.5.1)	OECD 114		Not required by regulation (EU) 2011/545.			Acceptable.
Dynamic viscosity (IIIA 2.5.2)	OECD 114 CIPAC MT 192	Alginure Bio Schutz Batch no.: 32104	20 °C, sheer rate between 5 and 100 s^{-1}: 4.90 - 5.34 mPa s 40 °C, sheer rate between 5 and	Y	Birnschein, K., 2012a, S12-02023	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			100 s^{-1}: 3.03 – 3.40 mPa s Newtonian liquid.			
Surface tension (IIIA 2.5.3)	EEC A 5	Alginure Bio Schutz Batch no.: 32104	0.1 %, deionised water, 20 °C: 64.7 - 71.5 mN/m Tendency to decreasing values, maybe caused by sedimentation.	Y	Birnschein, K., 2012b, S12-02024	Acceptable. Should be tested at minimum and maximum use rate.
Relative density (IIIA 2.6.1)	EEC A.3	Alginure Bio Schutz Batch no.: 32104	Before storage: d_4^{20} = 1.3445	Y	Birnschein, K., 2012c, S12-02025	Acceptable.
Bulk or tap density (IIIA 2.6.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Storage Stability after 14 days at 54º C (IIIA 2.7.1)	CIPAC MT 46	Alginure Bio Schutz Batch no.: 32104	Storage material: 5 L polyethylene container The content of the active substance does not decrease > 5 %. The changes of the physical and chemical properties are negligible. Content of: potassium phosphonates Before storage: 332.0 g/L corresponding to phosphonic acid 221.3 g/L After storage: 329.7 g/L corresponding to	Y	Birnschein, K., 2013, S12-02027	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			phosphonic acid 219.8 g/L			
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Minimum content after heat stability testing (IIIA 2.7.3)			Please refer to IIIA 2.7.1.			Acceptable.
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.3	Alginure Bio Schutz Batch no.: 32104	Directly after storage: 0.7 mL fine sediment, 8 mL coarse sediment 70 – 75 mL dark brown phase 15 mL bright brown phase after 24 h to reach room temperature: 0.8 mL fine sediment, 90 mL dark brown phase 5 mL bright brown phase A wet sieve test according to CIPAC M T 185 was performed with the sediment: 0 % on 75 µm sieve	Y	Birnschein, K., 2012d, S12-02026	Acceptable. The poduct should be labelled with a warning against storage at low temperatures.
Ambient temperature shelf life		Alginure Bio Schutz Batch no.: 32104	storage in HDPE Content of phosphonic acid:	Y	Birnschein, K, 2015 S12-02028	Acceptable Study submitted after

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.7.5)			initial: 221.3 g/L after 2 a at 20 °C: 214.6 g/L (- 3.0 %) The change in the physical parameter appearance, pH, dilution stability, persistent foaming and packaging was neclectable. After 18 h up to 1 cm of sediment could be observed, but this passed a 45 µm sieve after rinsing.			request
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	-		Please refer to 2.7.5			Acceptable.
Wettability (IIIA 2.8.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	Alginure Bio Schutz Batch no.: 32104	CIPAC water D, 1.35 %: Before storage 10s: 0 mL 1 min: 0 mL 3 min: 0 mL 12 min: 0 mL 2 weeks, 54 °C 10s: 2 mL 1 min: 0 mL 3 min: 0 mL 10 min: 0 mL	Y	Birnschein, K., 2013, S12-02027	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility (IIIA 2.8.3.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Spontaneity of dispersion (IIIA 2.8.3.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Dilution stability (IIIA 2.8.4)	CIPAC MT 41	Alginure Bio Schutz Batch no.: 32104	CIPAC water D, 1.0°%: Before and after storage for 2 weeks, 54 °C: 30 min: suspended particles in the dilution, about 0.5 cm sediment 18 h: few suspended particles in the dilution, about 0.7 to 0.8 cm sediment. Sediment could pass a 45 µm sieve after rinsing with 50 mL water.	Y	Birnschein, K., 2013, S12-02027	Acceptable.
Dry sieve test (IIIA 2.8.5.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Wet sieve test (IIIA 2.8.5.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Particle size distribution (IIIA 2.8.6.1)			Not required by regulation (EU) 2011/545.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Nominal size range of granules (IIIA 2.8.6.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Dust content (IIIA 2.8.6.3)			Not required by regulation (EU) 2011/545.			Acceptable.
Particle size of dust (IIIA 2.8.6.4)			Not required by regulation (EU) 2011/545.			Acceptable.
Friability and attrition (IIIA 2.8.6.5)			Not required by regulation (EU) 2011/545.			Acceptable.
Emulsifiability (IIIA 2.8.7.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Dispersibility (IIIA 2.8.7.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Flowability (IIIA 2.8.8.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Pourability (including rinsed residue) (IIIA 2.8.8.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Dustability following accelerated storage (IIIA 2.8.8.3)			Not required by regulation (EU) 2011/545.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Physical compatibility of tank mixes (IIIA 2.9.1)			No tank mixtures foreseen.			Acceptable.
Chemical compatibility of tank mixes (IIIA 2.9.2)			No tank mixtures foreseen.			Acceptable.
Distribution to seed (IIIA 2.10.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Adhesion to seeds (IIIA 2.10.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Miscibility (IIIA 2.11)			Not required by regulation (EU) 2011/545.			Acceptable.
Dielectric breakdown (IIIA 2.12)			Not required by regulation (EU) 2011/545.			Acceptable.
Corrosion characteristics (IIIA 2.13)			Not required by regulation (EU) 2011/545.			Acceptable.
Container material (IIIA 2.14)			Not required by regulation (EU) 2011/545.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Other/special studies (IIIA 2.15)			Not required by regulation (EU) 2011/545.			Acceptable.

IIIA 2.16 Summary and Evaluation of Data Presented Under Points 2.1 to 2.15

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product Alginure Bio Schutz is that of a brown, non-viscous liquid with an organic and sweet odour containing suspended particles which settled down after a certain standing period of time. It is not explosive, has no oxidising properties. It has a self ignition temperature of 530°C. In aqueous solution, it has a pH value around 6 to 7. The storage stability for 14 days at 54°C showed good stability of the preparation in terms of active substance content and product characteristics. Alginure Bio Schutz cannot be stored under refrigerated conditions because after storage for 7 days at 0°C phase separation occurred. The product should be labelled with a warning against exposure to low temperatures. Results of the technical tests (dilution stability, persistent foaming) showed that Alginure Bio Schutz is a preparation of a high technical quality which is compatible with several other products commonly used in plant protection. Storage stability data indicate a shelf life of at least 2 years at ambient temperature.

The technical characteristics are acceptable for a soluble concentrate formulation.

Experimental testing of the product's physico-chemical and technical characteristics:

See Appendix 3

Implications for labelling:

No labelling necessary due to physical or chemical properties described above.

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

Alginure Bio-Schutz is a fungicide against Downy mildew (Plasmopara viticola) in vine grapes.

IIIA 3.2 Nature of the Effects on Harmful Organisms

The product enhances the natural defence system of the plant and can cause an inhibition of mycelial growth in different fungi, especially in oomycetes.

IIIA 3.3 Details of Intended Use

IIIA 3.3.1 Details of existing and intended uses

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.3 Effects achieved

Alginure Bio-Schutz is a fungicide against Downy mildew (Plasmopara viticola) in vine grapes.

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.5 Concentration of the Active Substance in the Material Used

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.6 Method of Application, Type of Equipment Used and Volume of Diluent

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7 Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection

IIIA 3.7.1 Maximum number of applications and their timings

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.2 Growth stages of crops or plants to be protected

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.3 Development stages of the harmful organism concerned

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.4 Duration of protection afforded by each application

Please refer to Part B Section 7.

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications

Please refer to Part B Section 7.

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.2 Limitations on choice of succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.3 Description of damage to rotational crops

Please refer to Part B Section 7.

IIIA 3.9 Proposed Instructions for Use as Printed on Labels

Please refer to Registration Report – Part A, Appendix 2 for the relevant country.

IIIA 3.10 Other/Special Studies

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

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

IIIA 4.1 Packaging and Compatibility with the Preparation

Packaging Summary

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport and handling, resistance to and compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

IIIA 4.1.1 Description and specification of the packaging

Alginure Bio Schutz is to be marketed in high-density polyethylene containers. They are sealed by foil seals, protected by a non removable screw cap.

10 litre canister:	material:	HDPE
	shape/size:	321 mm x 228 mmx 187 mm
	opening:	44 mm inner diameter
	closure:	Non removable screw cap
	seal:	-

IIIA 4.1.2 Suitability of the packaging and closures

Report:	Baumann, H., Loidl, D., 2004
Title:	Zulassungsschein Kanister 10L (380g)
Document No:	302.097
Guidelines:	UN/IATA/IMDG/ICAO-TI/ADR/RID
GLP	No

Report:	Anonymous, 2005
Title:	SABIC HDPE B5205 Produkt info
Document No:	None
Guidelines:	
GLP	No

Report:	Anonymous, 2005
Title:	SABIC HDPE B5210 Produkt info
Document No:	None
Guidelines:	
GLP	No

ADR-test 3552 was performed for drop resistance, ADR 3553 for leak testing, ADR 3554 for hydrostatic test. Permeation testing was performed according to ADR 3556. The tightness of the containers was successfully tested. They resist against drop and internal pressure. The permeation rate is less than 0.008 g/L h. They are labelled individually with all the use instructions.

The results of the tests indicate that the HDPE container complies with the above mentioned requirements.

IIIA 4.1.3 Resistance of the packaging material to its contents

HDPE containers are used in the storage stability study (see Point IIIA 2.7.5) that is still ongoing.
And reveales that resistance of the packaging material is acceptable.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

Application equipment should be washed three times with water or with water and detergent if necessary. The addition of detergent enhances the cleaning process. For cleaning efficiency see Point IIIA 4.2.2 below.

It is recommended that the drain sprayer will be sprayed out completely after each washing. After cleaning procedure drain pump and sprayer should stay open.

Protective clothing should be washed with water and detergent before re-use.

Collected spills should be put into appropriated container and disposed safely to special waste collection point.

IIIA 4.2.2 Effectiveness of the cleaning procedures

Due to its good solubility in water and to the low percentage of rinsed residue, the effectiveness of the cleaning procedure of contaminated equipment (tanks) is considered to be very high.

IIIA 4.3 Re-entry Periods to Protect Man, Livestock and the Environment

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop

See section 4.

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

See section 4.

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated

See section 4.

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs

See section 4.

IIIA 4.3.5 Waiting period (in days) between application and handling of treated products

See section 4.

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

See section 4.

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used

See section 4.

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

IIIA 4.4.1 Warehouse storage

Precautions for safe handling: Keep away from excessive heat, open flames and from strong oxidizing agents. When using do not eat, drink or smoke.

Storage: Keep in original containers. Keep away from food, drink and animal feedingstuffs. Store in dry, well-ventilated area. Store away from direct sunlight.

Precautions in handling and storage: Handle in accordance with good industrial hygiene and safety procedures.

Please refer to the safety data sheet Section 7.

IIIA 4.4.2 User level storage

Storage: Keep in original containers. Keep away from food, drink and animal feedingstuffs. Store in dry, well-ventilated area. Store away from direct sunlight.

Precautions in handling and storage: Handle in accordance with good industrial hygiene and safety procedures.

Please refer to the safety data sheet Section 7.

IIIA 4.4.3 Transport

UN number: Not regulated

UN proper shipping name: Not regulated

Transport hazards class(es): Not applicable

Packing group: Not applicable

Environment hazards: Not applicable

Special precautions for users: Not applicable

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable

Please refer to the safety data sheet Section 14.

IIIA 4.4.4 Fire

Extinguishing media:

Suitable extinguishing media: use appropriate extinguishing media for surrounding fire.

Special hazards arising from the substance or mixture:

Hazardous combustion products: Phosphorus oxide

Advices for fire-fighters:

Protection against fire: Self-confident breathing apparatus and total protection required in enclosed areas

Please refer to the safety data sheet Section 5 (KIIIA 4.4/01).

IIIA 4.4.5 Nature of protective clothing proposed

Personal Protective Equipment:

Eye/Face protection: Safety glasses. Consult manufacturer specifications for further information

Skin protection (Hand, Body): Wear impervious gloves. Wear a long-sleeved shirt and long pants. Consult manufacturer specifications for further information.

Respiratory protection: Not normally required. In case of inadequate ventilation wear respiratory protection.

Please refer to the safety data sheet Section 8 (KIIIA 4.4/01).

IIIA 4.4.6 Characteristics of protective clothing proposed

No information is provided on the suitability and effectiveness of protective clothing and equipment because its use is recommended on the basis of general advice / standards. Accordingly, protective clothing and equipment should meet respective DIN standards.

Please refer to the safety data sheet Section 8 (KIIIA 4.4/01).

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

Please refer to Point IIIA 4.4.6.

IIIA 4.4.8 Procedures to minimise the generation of waste

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. Do not reuse empty containers. Wash empty containers three times with water and pour the washing water into the tank sprayer. Do not reuse empty containers. Make holes in the bottom of the empty packages and bury them in the soil far away from water sources.

Please refer to the safety data sheet Section 13 (KIIIA 4.4/01).

IIIA 4.4.9 Combustion products likely to be generated in the event of fire

Reactivity: Will react will strong oxidizers

Chemical stability: Stable at room temperature and under recommended storage and handling conditions

Possibility of hazardous reactions: None-know

Conditions to avoid: Avoid exposure to incompatible materials. Exposure to excessive heat or open flame.

Incompatible materials: Strong oxidizers.

Hazardous decompositions products: None-known

Please refer to the safety data sheet Section 10 (KIIIA 4.4/01).

IIIA 4.5 Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use

IIIA 4.5.1 Containment of spillages

Please refer to item "Detailed instructions for safe disposal of product and its packaging" and for personal protection refer to point "Nature of protective clothing proposed", "Characteristics of protective clothing proposed" and "Suitability and effectiveness of protective clothing and equipment" and as well to Section 6 of the safety data sheet (KIIIA 4.4/01).

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Methods for containment: Contain spill. Reclaim material if possible

Methods for clean-up: Stop leak if possible. Contain product with an inert diking material. Vacuum up as much as possible. Place reclaimed product in a closed and properly labelled waste drum. Store drum in separate area until proper disposal. Flush residue with water. Wash thoroughly after handling.

Please refer to the safety data sheet Section 6 (KIIIA 4.4/01).

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. Do not reuse empty containers. Wash empty containers three times with water and pour the washing water into the tank sprayer. Do not reuse empty containers. Make holes in the bottom of the empty packages and bury them in the soil far away from water sources.

Please refer to the safety data sheet Section 13 (KIIIA 4.4/01).

IIIA 4.5.4 Protection of emergency workers and bystanders

Precautions for safe handling: Keep away from excessive heat, open flames and from strong oxidizing agents. When using do not eat, drink or smoke.

Storage: Keep in original containers. Keep away from food, drink and animal feedingstuffs. Store in dry, well-ventilated area. Store away from direct sunlight.

Precautions in handling and storage: Handle in accordance with good industrial hygiene and safety procedures.

Please refer to the safety data sheet Section 7 (KIIIA 4.4/01).

IIIA 4.5.5 First aid measures

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

Skin contact: Wash with plenty of soap and water. If skin irritation occurs, get medical advice/attention. Take off contaminated clothing and wash before reuse.

Inhalation: Remove victim to fresh air. If signs/symptoms persist, get medical attention.

Ingestion: Wash out mouth with plenty of water. Seek medical advice immediately and show this contained or label. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Note to physician: No specific antidote known. Treat symptomatically and give supportive therapy.

Please refer to the safety data sheet Section 4 (KIIIA 4.4/01).

IIIA 4.6 Neutralisation Procedure for Use in the Event of Accidental Spillage

IIIA 4.6.1 Details of proposed procedures for small quantities

A neutralization procedure cannot be proposed. Refer to general recommendations in the SDS and, if required, consult a specialist for disposal of recovered product and ensure compliance with local regulations.

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

See above.

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

See above.

IIIA 4.6.4 Details of proposed procedures for large quantities

See above.

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

See above.

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

See above.

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

Due to halogen content in the active ingredient and the formulants of less than 60 %, combustion of Alginure Bio Schutz in a waste incinerator plant does not raise concern about the formation of halogenated dibenzodioxins/-furans.

IIIA 4.8 Disposal Procedures for the Plant Protection Product

IIIA 4.8.1 Detailed instructions for safe disposal of product and its packaging

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. Do not reuse empty containers. Wash empty containers three times with water and pour the washing water into the tank sprayer. Do not reuse empty containers. Make holes in the bottom of the empty packages and bury them in the soil far away from water sources.

Please refer to the safety data sheet Section 13 (KIIIA 4.4/01).

IIIA 4.8.2 Methods other than controlled incineration for disposal

There are no methods other than controlled incineration proposed.

IIIA 4.9 Other/Special Studies

No additional studies were performed.

IIIA 11 FURTHER INFORMATION

IIIA 11.1 Information of Authorisations in Other Countries

see EU pesticide data base (http://ec.europa.eu/sanco_pesticides/public/)

IIIA 11.2 Information on Established Maximum Residue Limits (MRL) in Other Countries

MRLs are set at European level, see Regulation (EC) No. 396/2005.

IIIA 11.3 Justified Proposals for Classification and Labelling

Proposals for classification and labelling of Alginure Bio Schutz in accordance with the EC Directive on dangerous preparations 1999/45/EC and Directive 2001/59/EC (as amended) are presented below:

Physico-chemical properties

Table 11.3-1 Physico-chemical properties

Study Type	Findings (triggered risk phrase)	Reference
Explosivity	Not explosive (-)	Möller, M., 2012a, CSL-12-0338.02
Oxidizing properties	Not oxidizing (-)	Möller, M., 2012b, CSL-12-0338.04
Flammability	Auto-ignition temperature is 530°C.	Möller, M., 2012d, CSL-12-0338.03

Table 11.3-1 Physico-chemical properties

Study Type	Findings (triggered risk phrase)	Reference
Viscosity (dynamic)	20 °C, sheer rate = 100 s^{-1}: 5.15 - 5.34 mPa s 40 °C, sheer rate = 100 s^{-1}: 3.28 – 3.31 mPa s Nwetonian liquid	Birnschein, K., 2012a, S12-02023
Surface tension	1.0 %, deionised water, 20 °C: 64.7 - 71.5 mN/m	Birnschein, K., 2012b, S12-02024

Toxicology

see section 3.

Ecotoxicology/Environment

see section 6.

IIIA 11.4 Proposals for Risk and Safety Phrases

Please refer to Registration Report – Part A.

IIIA 11.5 Proposed Label

Please refer to Registration Report – Part A.

IIIA 11.6 Specimens of Proposed Packaging

Specimens of the packaging were not provided as there was no request.

Appendix 1: List of data used in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 2.1, KIIIA1 2.4.2, KIIIA1 2.7.1, KIIIA1 2.8.2, KIIIA1 2.8.4	Birnschein, K.	2013	Physico-chemical Properties of Alginure Bio Schutz before and after Accelerated Storage at 54°C for 2 weeks, S12-02027, GLP, not published	Y	TIL	1
KIIIA1 2.2.1	Möller, M.	2012a	Alginure Bio Schutz Determination of physico-chemical properties. Explosive Properties (EC A.14.), CSL-12-0338.02, GLP, not published	Y	TIL	1
KIIIA1 2.2.2	Möller, M.	2012b	Alginure Bio Schutz Determination of physico-chemical properties. Oxidizing Properties of Liquids (EC A.21.), CSL-12-0338.04, GLP, not published	Y	TIL	1
KIIIA1 2.3.1	Möller, M.	2012c	Alginure Bio Schutz Determination of physico-chemical properties Flash Point (EC A.9.), CSL-12-0338.01, GLP, not published	Y	TIL	1
KIIIA1 2.3.3	Möller, M.	2012d	Alginure Bio Schutz Determination of physico-chemical properties. Auto-Ignition Temperature (EC A.15.) (Liquids and Gases), CSL-12-0338.03, GLP, not published	Y	TIL	1
KIIIA1 2.5.2	Birnschein, K.	2012a	Viscosity of Alginure Bio Schutz, S12-02023, GLP, not published	Y	TIL	1
KIIIA1 2.5.3	Birnschein, K.	2012b	Surface Tension of Alginure Bio Schutz, S12-02024, GLP, not published	Y	TIL	1

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 2.6.1	Birnschein, K.	2012c	Relative density of Alginure Bio Schutz, S12-02025, GLP, not published	Y	TIL	1
KIIIA1 2.7.4	Birnschein, K.	2012d	Storage Stability of the Formulation Alginure Bio Schutz for 7 Days at 0°C, S12-02026, GLP, not published	Y	TIL	1
KIIIA1 2.7.5	Birnschein, K.	2015	Physico-chemical Properties of Alginure Bio Schutz over 2 Years at 20°C, S12-02028 GLP, not published	Y	TIL	1
KIIIA1 4.1.1, KIIIA1 4.1.2	Baumann, H., Loidl, D.	2004a	UN-Zulassungsschein: Kanisterbauart 10 L, 302.097, Not GLP, not published	Y	TIL	1
KIIIA1 4.1.1, KIIIA1 4.1.2	Baumann, H., Loidl, D.	2004b	Zulassungsschein Kanister 10l (380g), 302.097, Not GLP, not published	Y	TIL	1
KIIIA1 4.1.1	Anonymous	2011	Produktinformation PE-Kanister 10 L, P6820, Not GLP, not published	Y	TIL	1
KIIIA1 4.1.2	Anonymous	2005	SABIC HDPE B5205 Produkt info, Not GLP, not published	Y	TIL	1
KIIIA1 4.1.2	Anonymous	2005	SABIC HDPE B5210 Produkt info, Not GLP, not published	Y	TIL	1

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2: Critical Uses – Justification and GAP tables

GAP-Table of intended uses for Germany (no cMS applied for)

GAP rev. (2), date: 2014-05-20

PPP (product name/code)	**Alginure Bio Schutz**	**Formulation type:**	**SL**
active substance	**Kaliumphosphit (Kaliumphosphonate)**	**Conc. of as :**	**342 g/L**
Applicant:	**Applicant Tilco Biochemie GmbH**	**professional use**	☒
Zone(s): central/EU		**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	grape vine VITVI (utilisation as table and wine grape)	F	downy mildew of grapevine *Plasmopara viticola* PLASVI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 12 - 68	a) 6 b) 6 (min 7 days)	a) - base dose: 1.5 L/ha - BBCH 61: 3 L/ha - BBCH 68: 4.5 L/ha b) 27 L/ha	a) - base dose: 513 g as/ha - BBCH 61: 1026 g as/ha - BBCH 68: 1539 g as/ha b) 9234 g as/ha	max 400 L/ha max 800 L/ha max 1200 L/ha	15	

Appendix 3: Experimental testing of the product's physico-chemical and technical characteristics:

The following physical, chemical and technical properties of the plant protection product were experimentally tested:

density, colour, pH, surface tension, storage stability at high temperatures (14 d at 54 °C), low temperature stability (7 d at 0 °C), persistent foaming and dilution stability.

Except for the surface tension no significant deviations from the data submitted by the applicant were detected. Regarding the surface tension a value of 46.6 mN/m were determined for a 0.1 % solution. In the study Birnschein, 2012b (report no. S12-02024) the determined values were between 64.7 and 71.5 mN/m. This discrepancy needs an explanation.

The formulation complies with the chemical, physical and technical criteria which are stated for this type of formulation in the FAO/WHO manual (2010).

REGISTRATION REPORT
Part B

Section 2: Analytical Methods
Detailed summary of the risk assessment

Product Name: Alginure Bio Schutz
Active Substance: Potassium phosphonates 342 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: TILCO BIOCHEMIE GmbH
Date: 19-09-2016

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IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the product Alginure Bio Schutz containing the active substance potassium phosphonates which is to be included in the Annex I of Commission Implementing Regulation (EU) No 540/2011.

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

Information on the detailed composition of Alginure Bio Schutz can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 5.1 Analytical Standards and Samples

IIIA 5.1.1 Samples of the preparation

A sample of the preparation was provided by the applicant but no analysis of the contents of the active substance was performed.

IIIA 5.1.2 Analytical standards for the pure active substance

Analytical standards were not provided because there was no request.

IIIA 5.1.3 Samples of the active substance as manufactured

No samples were provided because there was no request.

IIIA 5.1.4 Analytical standards for relevant metabolites and all other components included in the residue definition

No samples were provided because there was no request.

IIIA 5.1.5 Samples of reference substances for relevant impurities

No samples were provided because there was no request.

IIIA 5.2 Methods for the Analysis of the Plant Protection Product

Analytical methods for the determination of potassium and phosphonate and their impurities and relevance of CIPAC methods in Alginure Bio Schutz were not evaluated as part of the EU review of potassium and phosphonate. Therefore all relevant data are provided and are considered adequate.

IIIA 5.2.1 Description of the analytical methods for the determination of the active substance in the plant protection product

The following analytical method for the determination of the active substances in the plant protection product performed on Alginure Bio Schutz has not previously been reviewed.

Report:	5.2.1/01 Schott, C., 2012a
Title:	Determination of Phosphonate in Alginure Bio Schutz Formulation and Validation of the Analytical Method
Document No:	12G05021-01-VMFO
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description

The analyte is determined by Ion Chromatography (IC) (Ion Pac AS17-C column) with conductivity detection at approximately 30°°C column temperature.
Injection volume is 25°µL. The separation is achieved by using gradient flow conditions for the detection and quantification of the actives at 1.0°mL/min.
The eluent is generator cartidge potassium hydroxide 5.0°% to 40.0°% concentration in demineralised water. Quatification was performed by using the external standard calibration.
Due to the fact, that Phosphonic acid was used as reference item for calibration, fortification and control, all values refer directly to Phosphonic acid.

Method validation

The validation data of method 12G05021-01-VMFO was determined for the formulation Alginure Bio Schutz.

Table containing the validation of the methods (formulation Alginure Bio Schutz)

Analyte	Linearity n = 10	Accuracy n = 5 Mean [%]	Repeatability n = 5 [%RSD]	Specificity/Inteferences
Phosphonic acid	10 to 100 mg/L; (20 to 200 % of nominal concentration) $r^2 = 0.9999$	101 (at a concentration of 245 g/L and 293 g/L)	0.34 (mean content:. 235.6 g/L)	For checking the specificity the retention time of phosphonate in the test item, the solutions were compared with the retention time of phosphonate in the calibration standard solutions. The retention times were corresponding. The solution of the test item was spiked with a Multi-Element Standard solution, which contained the anions Chloride, Fluoride, Nitrite, Bromide, Nitrate, Phosphate and Sulfate. All these anions were clearly separated from the Phosphonate peak. Chromatograms of formulation without active substance present were not submitted.

The accuracy was determined by stocking a batch of Alginure Bio Schutz which already contained the active substance. The fortification level were plus 5 % and plus 25 %. No fortification with blank formulation was done.

Summary
Phosphonic acid can be quantified in Alginure Bio Schutz using the analytical IC method 12G05021-01-VMFO. The method was developed for quantifying phosphonic acid in Alginure Bio Schutz.
The active substance is diluted in demineralised water, chromatographed on an IC (Dionex IC 25) with Eluent Generator (Ion Pac AS17-C column) with conductivity detection and external calibration. The results are given in phosphonic acid and can be re-calculated to the content of phosphonate. The method can be used in soluble concentrates (SL).
Further information regarding accuracy and selectivity is needed.

Report:	5.2.1/02 Schott, C., 2012b
Title:	Determination of potassium in Alginure Bio Schutz formulation and validation of the analytical method
Document No:	12G05021-02-VMFO
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description
The content of potassium is determined by ICP-OES at two independent wavelengths highly specific for Potassium), using external calibration.
The detection and quantification is achieved by using argon gas at 1.0 L/min and nebulising at a rate of 0.60 L/min. Detection is performed at 766.490 nm for quantification and 769.896 nm for confirmation.
Solutions for calibration and for samples were prepared by pipetting the respective volume into a 50 mL volumetric flask. After adding 2.5 mL Nitric acid 65 % the flask was filled up to the mark with demineralized water and shaken well. For sample preparation the solution was digested by heating under reflux. The analytes are quantified by comparing the specific response ratios of the samples with those of standards of known quality.

Method validation
The validation data of method 12G05021-02-VMFO was determined for the formulation Alginure Bio Schutz.

Table containing the methods and validation of the methods (formulation Alginure Bio Schutz**)**

Analyte	**Linearity** **n = 6**	**Accuracy** **n = 5** **Mean [%]**	**Repeatability** **n = 5** **[%RSD]**	**Specificity/Inteferences**
Potassium	1.0 mg/L to 50.0 mg/L; r^2 = 0.9999	199 / 100 (at a concentration of 15.5 % and 20.5 %)	0.51 (mean content 14.95 %)	Significant interferences were not observed. The method is highly specific for the analysis of potassium Typical ICP-OES scans for potassium determination at 766.490°nm, representing analysis of sample, recovery samples, calibration standard and digestion blank were submitted.

The accuracy of the method was determined by fortification experiments. As no blank formulation was available, recoveries were determined by fortification of the formulated product Alginure Bio Schutz with reference item at 0.5 % and 5 % respectively of the nominal concentration. No fortification with blank formulation was done.

Summary
Potassium can be quantified in Alginure Bio Schutz using the analytical method 12G05021-02-VMFO. The method was developed for quantifying potassium in Alginure Bio Schutz.
The active substance is diluted, solved by reflux heating and analysed with ICP-OES and external calibration. Due to the lack of blank formulation, the recovery experiments were done by fortification of the formulated product with reference items at two levels.
The method should be valid for determination of 10 % to 20 % potassium in soluble concentrates (SL).
Further information regarding accuracy is needed.

IIIA 5.2.2 For preparations containing more than one active substance, description of method for determining each in the presence of the other

Please refer to chapter 5.2.1 as Alginure Bio Schutz F contains only one active substance.

IIIA 5.2.3 Applicability of existing CIPAC methods

A CIPAC method is not available for the determination of potassium phosphonate in formulations.

IIIA 5.2.4 Description of analytical methods for the determination of relevant impurities

Not required since no relevant impurities were defined for potassium phosphonate.

IIIA 5.2.5 Description of analytical methods for the determination of formulants

No formulants with toxicological or ecotoxicological relevant compounds are present in the formulation. Therefore, no analytical methods for the determination of formulants are necessary.

IIIA 5.3 Description of Analytical Methods for the Determination of Residues

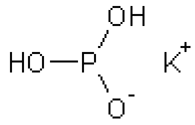
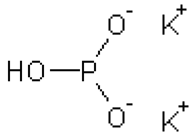
The applicant has access to methods evaluated in the DAR by a Letter of Access provided by Luxembourg Industries.

IIIA 5.3.1 Evaluation of potassium phosphonate

The conclusions regarding the peer review of the analytical methods for residues of potassium phosphonate are summarized in EFSA’s Journal 2012;10(12):2963

Table 5.3-1: Information on the active substance potassium phosphonate

Name of component of residue definition substance code IUPAC name formula	Structural formula

monopotassium phosphonate CAS N°: 13977-65-6 KH_2PO_3	
dipotassium phosphonate CAS N°: 13492-26-7 K_2HPO_3	

IIIA 5.3.1.1 Overview of residue definitions and levels for which compliance is required

The current legal residue definition for food of plant and animal origin differs from the one proposed in the respective EFSA conclusion, because the current definition considers phosphonic acid as a metabolite of fosetyl-Al.

Table 5.3-2: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
plant material	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Regulation (EU) No 459/2010, annex III part A
plant material	Phosphonic acid and its salts expressed as phosphonic acid	EFSA conclusion, EFSA Journal 2012;10(12):2963, ASB2012-16090
foodstuff of animal origin	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Regulation (EU) No 459/2010, annex III part A
foodstuff of animal origin	not required	EFSA conclusion, EFSA Journal 2012;10(12):2963, ASB2012-16090
soil	Phosphonic acid and its salts expressed as phosphonic acid	EFSA conclusion, EFSA Journal 2012;10(12):2963, ASB2012-16090
surface water	Phosphonic acid and its salts expressed as phosphonic acid	EFSA conclusion, EFSA Journal 2012;10(12):2963, ASB2012-16090
drinking/ground water	Phosphonic acid and its salts expressed as phosphonic acid	EFSA conclusion, EFSA Journal 2012;10(12):2963, ASB2012-16090
air	not residue relevant	not classified as T / T+ / Xi / Xn
body fluids/tissue	not residue relevant	not classified as T / T+

Table 5.3-3: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
plant, high water content	2 mg/kg	Regulation (EC) No 459/2010, annex III part A
plant, acidic commodities	2 mg/kg	
plant, dry commodities	2 mg/kg	
plant, high oil content	2 mg/kg	
plant, difficult matrices (hops,	not required	

Matrix	MRL	Reference for MRL/level Remarks
spices, tea)		
meat	0.5 mg/kg	Regulation (EC) No 459/2010, annex III part A
milk	0.1 mg/kg	
eggs	0.1 mg/kg	
fat	0.5 mg/kg	
liver, kidney	0.5 mg/kg	
meat	not required	EFSA conclusion, EFSA Journal 2012;10(12):2963, ASB2012-16090
milk		
eggs		
fat		
liver, kidney		
soil	0.05 mg/kg	common limit
drinking water	0.1 µg/L	general limit for drinking water
surface water	>118,000 µg/L	LC_{50} *O. mykiss* (96h) EC_{50} *Daphnia magna* (48h) EFSA conclusion, EFSA Journal 2012;10(12):2963, ASB2012-16090
air	not required	not classified as T / T+ / Xi / Xn
tissue (meat or liver)	not required	not classified as T / T+
body fluids	not required	not classified as T / T+

IIIA 5.3.1.2 Description of Analytical Methods for the Determination of Residues of potassium phosphonates in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of potassium phosphonate in plant matrices is given in the following tables. New studies were not provided.

Table 5.3-4: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
high water content	Toledo, 2011*	Mende, 2011*	Toledo, 2011*
acidic	Toledo, 2010*	Mende, 2011*	Toledo, 2010*
fatty	Toledo, 2011*	not required	Toledo, 2011*
dry	Toledo, 2011*	not required	Toledo, 2011*
difficult	not required	not required	not required

*EU agreed method (see Draft Assessment Report, revised Volume 3, Annex B-5, June 2012)

Table 5.3-5: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Not available
Not required, because:	Typical metabolism studies with extraction of radio-labbelled phosphonate are not described in DAR. Phosphonates are sufficiently stable and highly mobile in plants (DAR Vol. 3, B.7.1). Therefore, extraction with solvents containing water seems adequate.

Table 5.3-6: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in
Toledo, 2010, ASB2012-507	acidic	0.5 mg/kg	LC-MS/MS, graphitized carbon, ESI-, m/z 81→79, 81→63	confirmation included	Draft Assessment Report, revised Volume 3, Annex B-5, June 2012
Toledo, 2011, ASB2012-508	high water content, dry, fatty	0.5 mg/kg	LC-MS/MS, graphitized carbon, ESI-, m/z 81→79, 81→63	confirmation included	Draft Assessment Report, revised Volume 3, Annex B-5, June 2012
Mende, 2011, ASB2012-509	high water content, acidic	0.5 mg/kg	LC-MS/MS, graphitized carbon, ESI-, m/z 81→79, 81→63	confirmation included, ILV of Toledo, 2010 and Toledo, 2011	Draft Assessment Report, revised Volume 3, Annex B-5, June 2012

IIIA 5.3.1.3 Description of Analytical Methods for the Determination of Residues of potassium phosphonates in Animal Matrices (OECD KIII A 5.3.1)

It is expected that the intended use (grapes) will not result in residues in feeding stuffs. Therefore analytical methods for residues of potassium phosphonate in animal matrices are not required.

IIIA 5.3.1.4 Description of Methods for the Analysis of potassium phosphonates in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of potassium phosphonate in soil is given in the following tables. New studies were not provided.

Table 5.3-7: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
Phosphorous acid	Hamberger, 2006*	missing

* Accepted method in the Draft Assessment Report (revised Volume 3, Annex B-5, June 2012). However, due to the use of diazomethane not accepted in the "Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonate" (EFSA Journal 2012;10(12):2963, ASB2012-16090)

Table 5.3-8: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Hamberger, 2006* ASB2010-1093	0.05 mg/kg	GC-NPD, stabil-wax column	Not suitable according to SANCO/825/00 rev .8.1 because methylation with diazomethane	Draft Assessment Report, revised Volume 3, Annex B-5, June 2012

IIIA 5.3.1.5 Description of Methods for the Analysis of potassium phosphonates in Water (OECD KIII A 5.6)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of potassium phosphonate in surface and drinking water is given in the following table. For the detailed evaluation of new/additional studies it is referred to Appendix 2.

Table 5.3-9: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Phosphorous acid	drinking water	Bannwarth, 2012	Bannwarth, 2012
Phosphorous acid	surface water	Bannwarth, 2012	Bannwarth, 2012

Table 5.3-10: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in Appendix 2
Bannwarth, 2012	drinking water: 0.1 µg/L surface water: 100 µg/L	LC-MS/MS, hypercarb column, ESI-, m/z 81→79, m/z 81→63	confirmation included; applicable for surface water after 1000-fold dilution	Appendix 2

IIIA 5.3.1.6 Description of Methods for the Analysis of potassium phosphonates in Air (OECD KIII A 5.7)

Methods for air are not required, because potassium phosphonates is not considered to be toxic or very toxic (T / T+) nor is it classified as Xi or Xn.

IIIA 5.3.1.7 Description of Methods for the Analysis of potassium phosphonates in Body Fluids and Tissues (OECD KIII A 5.8)

Methods for body fluids and tissues are not required, because potassium phosphonates is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

IIIA 5.3.1.8 Other Studies/ Information

Other studies are not provided

IIIA 5.4 Conclusion on the availability of analytical methods for the determination of residues

Sufficiently sensitive and selective analytical methods are available for food of plant origin and water. For residues in food of animal origin no methods are available and none required.

The following minor data gaps were noticed:

- A primary analytical method for the determination of residues of potassium phosphonate in soil is missing.
- A confirmatory analytical method for the determination of residues of potassium phosphonate in soil is missing.

Appendix 1 – List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 5.2.1/01	Schott, C.	2012a	Determination of Phosphonate in Alginure Bio Schutz Formulation and Validation of the Analytical Methods, 12G02021-01-VMFO, GLP, not published	Y	TIL	1
KIIIA 5.2.1/02	Schott, C.	2012b	Determination of Potassium in Alginure Bio Schutz and Validation of the Analytical Method, 12G05021-02-VMFO, GLP, not published	Y	TIL	1

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance Potassium phosphonates EFSA Journal 2012;10(12):2963 ! EFSA-Q-2009-00317 EFSA Journal 2012;10(12):2963 ASB2012-16090			Add
KIIA 4.3	Fenn, M. E.; Coffey, M. D.	1989	Quantification of Phosphonate and Ethyl phosphonate in tobacco and tomato tissues and significande for the mode of action of two Phosphonate fungicides A2AS02P040201_03 ASB2010-1080	No	LIT	N
KIIA 4.3	Glenn, T. J.; Biggins, M. R.; Magarey, P. A.	1990	Rapid, quantitative detection of Phosphonate by simple ion- exchange chromatography using postseparation suppression A2AS02P040201_05 ASB2010-1081	No	LIT	N
KIIA 4.3	Hargreaves, P. A.; Ruddle, L. J.	1990	Potassium phosphite: Analysis of residues of Phosphonate in plant material A2AS02P040201_04 ASB2010-1082	No	LIT	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3	Mende, P.	2011	Independent laboratory validation (ILV) of an analytical method for dertermination of residues of Phosphonic acid in food of plant origin S11-03203 ASB2012-509	Yes	LBG	Y
KIIA 4.3	Pollmann, B.	2002	Determination of residues of Stamina after 6 applications in vines - 2 sites in Northern Italy, 2 sites in Southern France, 2 sites in Northern France and 2 sites in Southern Germany, 2001 20011174/E1-FPVI ASB2010-1087	Yes	LBG	N
KIIA 4.3	Roos, G. H.; Loane, C.; Dell, B.; Hardy, G. E. St. J.	1999	Facile high performance ion chromatographic analysis of Phosphite and Phosphate in plant samples A2AS02P040201_07 ! 238 ASB2010-1088	No	LIT	N
KIIA 4.3	Smillie, R. H.; Grant, B. R.; Cribbes, R. L.	1988	Determination of Phosphate and Phosphite in plant material by gas chromatography-mass spectrometry and ion chromatography A2AS02P040201_06 ASB2010-1089	No	LBG	N
KIIA 4.3	Toledo, F.	2010	Determination of Phosphonic acid in grapes and grape-processed fractions - Validation of the method IF-09/01419440 ASB2012-507	Yes	LBG	Y
KIIA 4.3	Toledo, F.	2011	Determination of phosphonic acid in plant matrices: Lettuce, rape seed and cereal grain - Validation of the method IF-10/01711965 ASB2012-508	Yes	LBG	Y
KIIA 4.3, KIIA 4.4	Ouimette, D. G.; Coffey, M. D.	1988	Quantitative analysis of organic Phosphonates, Phosphonate and other inorganic anions in plants and soil by using high-performance ion chromatography A2AS02P040201_02 ! 120 ASB2010-1086	No	LBG	N
KIIA 4.3, KIIA 4.5	Bertrand, A.; Müller, M. A.; Nolting, H.-G.; Blancha-Puller, M.; Siebers, J.	1989	Fosetyl: Gas-chromatographic determination in grapes, hop cones, lettuce, strawberries, wine, water A2AS02P040201_08 ASB2010-1091	No	LIT	N
KIIA 4.4	Hamberger, R.	2006	Validation of an analytical method for the determination of Phosphorous acid in soil 20061235/01-RVS ASB2010-1093	Yes	LBG	Y
KIIA 4.5	Hamberger, R.	2006	Validation of an analytical method for the determination of Phosphorous acid in water 20061235/01-RVW ASB2010-1122	Yes	LBG	N
KIIA 4.5	Kendall, T. Z.; Nixon, W. B.	1999	Analytical Method verification for the determination of Potassium phosphite in freshwater (incl. amended report dated 28.12.1999) A2AS02P040203_02 ! 286C-104 ASB2010-1097	Yes	LBG	N
KIIIA1 5.6	Bannwarth, M.	2012	Validation of an analytical method for determination of residues of Phosphonic acid in drinking water S12-01523 GLP: Yes Published: No BVL-2566141, ASB2014-2063	Yes	LBG	Y

* Y Yes , relied on

N	No, not relied on
Add:	Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Analytical methods for potassium phosphonate

A 2.1.1 Description of Methods for the Analysis of Water
A 2.1.1.1 Analytical method 1

Reference: OECD KIIIA1 5.6

Report: Validation of an analytical method for determination of residues of Phosphonic acid in drinking water, Bannwarth, M., 2012, report no. S12-01523; ASB2014-2063

Guideline(s): Yes, SANCO/825/00 rev. 8.1

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Drinking water is filtered through a protonated cation exchange resin (type: AG50W-X8). The filtrate and the eluate from a washing with demineralized water is collected. After evaporation to dryness, the dry reminder of the filtrate is dissolved in a small volume of demineralized water. The sample concentration in the final extract is 25 mL/mL.
Residues in the final extract are quantified by LC-MS/MS with negative electrospray ionization using a porous graphitic carbon column (Thermo Hypercarb) and SRM transitions m/z 81→79 and 81→63.

Results and discussions

Table A 1: Recovery results from method validation of drinking water using the analytical method. Standards were prepared in matrix

Matrix	Fortification level (µg/L	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
drinking water	0.1 1.0	5 5	90 83	6 4	m/z 81→79
drinking water	0.1 1.0	5 5	89 84	8 5	m/z 81→63

Table A 2: Characteristics for the analytical method used for the quantitation of potassium phosphonates residues in drinking water

	potassium phosphonate, m/z 81→79	potassium phosphonate, m/z 81→63
Calibration function	area = 56500 × c + 11100; c in ng/mL; r = 0.9994	Area=30100 x c + 7330, c in ng/mL, r=0.9989
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 25 ng/mL	0.5 – 25 ng/mL

Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.02 – 1.00 µg/L	0.02 – 1.00 µg/L
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)?	Yes (7 level)	Yes (7 level)
Assessment of matrix effects is presented (yes/no)	yes	yes
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is suitable according to the number of levels and the fortified samples per level, the recovery, the repeatability, the selectivity (blank value) and the calibration for the determination of residues in drinking water. Matrix enhancement of 19 % was observed. For compensation of matrix effects matrix-matched standards were used.
Due to the very low sensitivity needed for the determination of potassium phosphonate in surface water, this method is also applicable for surface water.

Comments of zRMS:	The method is acceptable as primary and confirmatory method for drinking and surface water.

REGISTRATION REPORT
Part B

Section 3: Mammalian Toxicology
Detailed summary of the risk assessment

Product Name: Alginure Bio Schutz
Active Substance: Potassium phosphonates (342 g/L)

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: TILCO BIOCHEMIE GmbH
Date: 19-09-2016

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3 Mammalian Toxicology (IIIA 7)

3.1 Summary

Table 3.1-1: Information on Alginure Bio Schutz *

Product name and code	Alginure Bio Schutz (TIL-11111-F-0-SL)
Formulation type	SL
Active substance(s) (incl. content)	Potassium phosphonates; 342 g/L
Function	Fungicide
Product already evaluated as the 'representative formulation' during the Annex I inclusion	No
Product previously evaluated in an other MS according to Uniform Principles	No

* Information on the detailed composition of Alginure Bio Schutz can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

In accordance with Directives 67/548/EEC and 1999/45/EC and according to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 3.1-2: Justified proposals for classification and labelling

C&L according to Directives 67/548/EEC and 1999/45/EC	
Hazard symbols:	None
Indications of danger:	None
Risk phrases:	None
Safety phrases:	None
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use.
C&L according to Regulation (EC) No 1272/2008	
Hazard classes, categories:	None
Signal word:	None
Hazard statements:	None
Precautionary statements:	None
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	'12 percent of the mixture consist of an ingredient of unknown inhalation toxicity.'

Table 3.1-3: Summary of risk assessment for operators, workers, bystanders and residents for Alginure Bio Schutz

	Result	**PPE / Risk mitigation measures**
Operators	Acceptable	- Avoid any unnecessary contact with the product. Misuse can lead to health damage. [SB001] - Keep out of the reach of children. [SB010] - The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed. [SB110]
Workers	Acceptable	- When re-entering the treated vineyards on the day of application the protective suit for working with plant protection products and universal protective gloves (plant protection) must be worn. Successive work on/in the crops stated above may not be carried out until 24 hours after applying the product. During the first week, the standard protective suit for working with plant protection products and universal protective gloves (plant protection) must be worn. [SF194]
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, bystanders and residents was identified when the product is used as intended. No specific PPE is necessary

No unacceptable risk for workers was identified when the product is used as intended and provided that the PPE stated in Table 3.1-3 are applied.

The risk assessment according to the German model has shown that the estimated exposure towards potassium phosphonates in Alginure Bio Schutz does exceed the particular systemic AOEL for workers. Worker exposure will be below the systemic AOEL only, if prescribed PPE is worn.

The risk assessment according to the UK-POEM has shown that the estimated exposure towards potassium phosphonates in Alginure Bio Schutz does exceed the particular systemic AOEL for operators. Operator exposure will be below the systemic AOEL only, if prescribed PPE is worn.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in Table 3.1-4.

Table 3.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8			
Crops 1) and situation (e.g. growth stage of crop)	**F/G or I 2)**	**Application**		**Application rate**		**Remarks: (e.g. surfactant (L /ha))**	**Acceptability of exposure assessment**			
		Method / Kind (incl. application technique 3))	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**	**critical gap for operator, worker, bystander or resident exposure based on [*Exposure model*]**	**Operator**	**Worker**	**Bystander**	**Residents**
Grape vine	F	spraying	a) 6 b) 6	a) 2.052 b) 12.312	1600	Critical gap for operator, worker, bystander or resident exposure based on German Model.				
						Critical gap for operator exposure based on UK-POEM				

	Exposure acceptable without PPE / risk mitigation measures
	Further refinement and/or risk mitigation measures required
	Exposure not acceptable/ Evaluation not possible

1) Pooled critical GAPS with the same max. application rate per application and using the same application technique
2) F: field or outdoor application, G: greenhouse application, I: indoor application
3) e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Max. application rate has been changed during assessment period (max. rate per appl. has been changed from 2.052 kg as/ha to 1.539 kg as/ha), however this has no impact on the outcome of the risk assessment - even if a multiple application factor of 4.2 instead of 6 is considered – therefore the calculations in this report were not adapted.

3.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 3.2-1.

Table 3.2-1: Information on active substance(s)

Reference doses		
	Value	Source
ADI	2.25 mg/kg bw	EFSA Journal 2012; 10(12):2963 (2012-11-19) ASB2012-16090
AOEL systemic	5.0 mg/kg bw/d	EFSA Journal 2012; 10(12):2963 (2012-11-19) ASB2012-16090
ARfD	Not allocated – not necessary	EFSA Journal 2012; 10(12):2963 (2012-11-19) ASB2012-16090

Classification and proposed labelling	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Regulation (EC) No 1272/2008 (Table 3.2): substance not listed up to and including 1st ATP Proposal BfR: none additional
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Regulation (EC) No 1272/2008 (Table 3.1): substance not listed up to and including 1st ATP Proposal BfR: none additional

3.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for Alginure Bio Schutz is given in Table 3.3-1. Full summaries of studies on the product are presented in Appendix 2. MSDS on Alginure Bio Schutz can be found in the confidential dRR Part C.

Table 3.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Alginure Bio Schutz

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Dir. 67/548/EEC)	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 423)	> 2000 mg/kg bw	Yes	None	None	[redacted]; 2001
LD_{50} dermal, rat (OECD 402)	> 4000 mg/kg bw	Yes	None	None	[redacted]; 2001
LC_{50} inhalation, rat (OECD 403)	Not submitted, not necessary. Justification presented in Annex 2				
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	None	[redacted]; 2001
Eye irritation, rabbit (OECD 405)	Non-irritant	Yes	None	None	[redacted]; 2001
Skin sensitisation, mouse (OECD 429, LLNA)	Non-sensitising	Yes	None	None	[redacted]; 2012
Supplementary studies for combinations of plant protection products	No data – not required				

Table 3.3-2: Additional toxicological information relevant for classification/labelling of Alginure Bio Schutz

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Dir. 67/548/EEC and/or in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Dir. 67/548/EEC, in Dir. 1999/45/EC and/or in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	None			
Toxicological properties of non-active substance(s) (relevant for classification of product)	None			
Further toxicological information	No data – not required			

[1]Material safety data sheet by the applicant

3.4 Toxicological evaluation of groundwater metabolites

The relevance of the groundwater metabolite phosphonic acid has already been assessed and accepted at EU level (see EFSA Journal 2012; 10(12):2963). Phosphonic acid is not considered as relevant in concentrations up to 0.75µg / L according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

3.5 Dermal Absorption (IIIA 7.6)

A summary of the dermal absorption endpoints for the active substances in Alginure Bio Schutz are presented in Table 3.5-1.

Table 3.5-1: Dermal absorption endpoints for active substances in Alginure Bio Schutz

	Potassium phosphonate	
	Value	Reference
Concentrate	25 %	Default-value
Dilution	75 %	Default-value

3.5.1 Justification for proposed values – potassium phosphonate

No data on dermal absorption for Potasssium phosphonate in Alginure Bio Schutz is available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table 3.5-2.

Table 3.5-2: Default dermal absorption endpoints for potassium phosphonate

	Value	Justification for value	Acceptability of justification
Concentrate	25 %	EFSA Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665)	yes
Dilution	75 %		yes

3.6 Exposure Assessment of Plant Protection Product

Table 3.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	Alginure Bio Schutz (TIL-11111-F-0-SL)
Formulation type	SL
Category	Fungicide
Container size, short description	10 L canister, Sabic HDPE B 5205
Active substance(s) (incl. content)	**Potassium phosphonates** 342 g/L
AOEL systemic	5.0 mg/kg bw/d
Inhalative absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 25 % Dilution: 75 % Default

3.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in see Table 3.1-4.

3.6.2 Operator exposure (IIIA 7.3)

3.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substance(s) during application of Alginure Bio Schutz according to the critical use(s) is presented in Table 3.6-2. Outcome of the estimation is presented in Table 3.6-3. Detailed calculations are in Appendix 3.

Table 3.6-2: Exposure models for intended uses

Critical use	Grapevine (max. 6 L product/ha)
Model	German model [Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection), Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft, Berlin-Dahlem, Heft 277, 1992]
Critical use	Grapevine (max. 6 L product/ha)

Model	Revised UK-POEM [Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical Association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992]

Table 3.6-3: Estimated operator exposure

		Potassium phosphonates	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Hand held outdoors to high crops (HCHH) Application rate: 6 kg a.s./ha 'worst case'			
German Model Body weight: 70 kg	no PPE[1)]	2..40	48.0
	with PPE (gloves m/l)	0.91	18.3
UK POEM Application volume: 6 L/ha Container: 10 L (45 mm closure) Body weight: 60 kg	no PPE[2)]	92.39	1847.8
	with PPE (gloves during m/l and gloves + impermeable coveralls during appl.)	4.83	96.5
Tractor mounted outdoors to high crops (HCTM) Application rate: 6 kg a.s./ha			
German Model Body weight: 70 kg	no PPE[1)]	2.17	43.4
	with PPE (gloves m/l)	2.03	40.6
UK POEM Application volume: 6 L/ha Container: 10 L (45 mm closure) Body weight: 60 kg	no PPE[2)]	3.23	64.6
	with PPE (gloves m/l and appl.)	1.436	28.7

1) no PPE: Operator wearing T-shirt and shorts
2) no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

3.6.2.2 Measurement of operator exposure

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

3.6.3 Worker exposure (IIIA 7.5)

3.6.3.1 Estimation of worker exposure

Table 3.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Alginure Bio Schutz according to the critical use(s). Outcome of the estimation is presented in Table 3.6-5. Detailed calculations are in Appendix 3.

Table 3.6-4: Exposure models for intended uses

Critical use	Grapevine (max. 6 x 6 L product/ha)
Model	German re-entry model, Krebs et al. (2000) [Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products, Nachrichtenbl. Deut. Pflanzenschutzdienst., 52(1), p. 5-9]

Table 3.6-5: Estimated worker exposure

		Potassium phosphonates	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate: 6 x 12.312 kg a.s./ha 'worst case' [1)]			
8 hours/day [2)], TC: 10000 cm^2/person/h [3)] Body weight: 60 kg	no PPE [4)]	12.31	246.2
	with PPE [5)]	0.62	12.3

[1)] 6 applications used as 'worst case', because there are no further degredation data available.
[2)] 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc.
[3)] US-EPA policy paper [EPA, Science Advisory Council for Exposure; 2000; Agricultural Default Transfer Coefficients, Policy # 003.1, May 7 1998 revised 7 August 2000].
[4)] no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
[5)] with PPE: see 'Instructions for use'

3.6.3.2 Measurement of worker exposure

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

3.6.4 Bystander and resident exposure (IIIA 7.4)

3.6.4.1 Estimation of bystander and resident exposure

Table 3.6-6 shows the exposure model(s) used for estimation of bystander and resident exposure to potassium phosphonates . Outcome of the estimation is presented in Table 3.6-7. Detailed calculations are in Appendix 3.

Table 3.6-6: Exposure models for intended uses

Critical use	Grapevine (max. 6 x 6 L product/ha)
Model	Martin, S. et al. (2008) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76

Table 3.6-7: Estimated bystander and resident exposure

	Potassium phosphonates	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Air assisted spray application outdoors to high crops (HCHH) 'worst case' Application rate: 6 x 2.052 kg a.s./ha		
Bystanders (adult) Drift rate: 8.02 % (3 m) Body weight: 60 kg	0.2059	4.12
Bystanders (children) Drift rate: 8.02 % (3 m) Body weight: 16.15 kg	0.1608	3.22
Residents (adult) Drift rate: 6.41 % (3 m) Body weight: 60 kg	0.0720	1.44
Residents (children) Drift rate: 6.41 % (3 m) Body weight: 16.15 kg	0.1075	2.15

3.6.4.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for potassium phosphonates will not be exceeded under conditions of intended uses, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

3.6.5 Statement on combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIIA 7.1.1	[redacted]	2001	Alginure Bio Schutz: Acute oral toxicity in the rat - Acute toxic class method 1495/001 GLP: Yes Published: No BVL-2435037, ASB2011-6861	Yes	TIL	Y
KIIIA 7.1.2	[redacted]	2001	Alginure Bio Schutz: Acute dermal toxicity (Limit test) in the rat 1495/002 GLP: Yes Published: No BVL-2435627, ASB2011-6859	Yes	TIL	Y
KIIIA 7.1.4	[redacted]	2001	Alginure Bio Schutz: Acute dermal irritation in the rabbit 1495/003 GLP: Yes Published: No BVL-2435638, ASB2011-6858	Yes	TIL	Y
KIIIA 7.1.5	[redacted]	2001	Alginure Bio Schutz: Acute eye irritation in the rabbit 1495/004 GLP: Yes Published: No BVL-2435640, ASB2011-6860	Yes	TIL	Y
KIIIA 7.1.6	[redacted]	2012	Alginure Bio Schutz - Skin sensitisation: Modified local lymph node assay in NMRI mice [redacted] 28209 GLP: Yes Published: No BVL-2435645, ASB2013-6165	Yes	TIL	Y

* Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

No bridging. Studies were performed on the formulation applied for.

A 2.2 Acute oral toxicity (IIIA1 7.1.1)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation.

Reference:	7.1.1
Report	Alginure Bio Schutz: Acute Oral Toxicity in the rat – acute Toxic Class Method, [redacted], 2001, 1495/001, ASB2011-6861
Guidelines:	OECD 423 (1996), 96/54/EC – method B.1 tris
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	Alginure Bio Schutz
Species	Rat, Sprague-Dawley CD (Crl: CD® (SD) BR)
No. of animals (group size)	3 rats/sex
Dose(s)	2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of Alginure Bio Schutz

Dose [mg/kg bw]	Toxicological results [1]	Duration of signs	Time of death	LD_{50} [mg/kg bw] (14 days)
Male rats				
2000	0/0/3	-	-	> 2000
Female rats				
2000	0/0/3	-	-	> 2000

[1] Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats of Alginure Bio Schutz

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the oral LD_{50} of Alginure Bio Schutz is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (IIIA1 7.1.2)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation.

Reference: 7.1.2
Report: Acute Dermal Toxicity (Limit Test) In The Rat, [redacted], 2001, 1495/002, ASB2011-6859
Guidelines: OECD 402 (1987)
EC 92/69/EEC - method B.3
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	Alginure Bio Schutz
Species	Rat, Sprague-Dawley CD (Crl: CD® (SD) IGS BR)
No. of animals (group size)	5 rats/sex
Dose(s)	4000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of Alginure Bio Schutz

Dose [mg/kg bw]	**Toxicological results [1)]**	**Duration of signs**	**Time of death**	**LD_{50} [mg/kg bw] (14 days)**
Male rats				
4000	0/0/5	-	-	> 4000
Female rats				
xxx	0/0/5	-	-	> 4000

[1)] Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats of Alginure Bio Schutz

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD_{50} of Alginure Bio Schutz is higher than 4000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (IIIA1 7.1.3)

Comments of zRMS:	Justification for waiving of the study acceptable.

An acute inhalation toxicity study of Alginure Bio Schutz containing Potassium Phosphonates as active ingredient was not conducted due to the low vapour pressure of the active substance and considering that the product is not a powder or granule formulation containing a significant proportion of particles of diameter < 50 µm. In addition, Alginure Bio Schutz is intended to be applied by spraying and normal spray application of plant protection products will not generate droplets of diameter < 50 µm (no confirmation).

Alginure Bio Schutz does not contain any formulant with classification regarding acute inhalation toxicity.

According to EC Regulation 1272/2008 Alginure Bio Schutz does not warrant classification as being toxic or harmful on the basis of its acute inhalation toxicity.

A 2.5 Skin irritation (IIIA1 7.1.4)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation.

Reference:	7.1.4
Report	Alginure Bio Schutz: Acute Dermal Irritation in the Rabbit, [redacted], 2001, 1495/003, ASB2011-6858
Guidelines:	OECD No. 404 (1992) 92/69/EEC B.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	Alginure Bio Schutz
Species	Rabbit, New Zealand White
No. of animals (group size)	3 males
Initial test using one animal	Yes
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Skin irritation of Alginure Bio Schutz

Animal No.		**Scores after treatment [1)]**				**Mean scores (24-72 h)**	**Reversible [day]**
		1 h	**24 h**	**48 h**	**72 h**		
1	Erythema Oedema	0 0	0 0	0 0	0 0	0.0 0.0	- -
2	Erythema Oedema	0 0	0 0	0 0	0 0	0.0 0.0	- -
3	Erythema Oedema	0 0	0 0	0 0	0 0	0.0 0.0	- -

[1)] scores in the range of 0 to 4

Clinical signs:	None

Conclusion

Under the experimental conditions, Alginure Bio Schutz is not a skin irritant. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (IIIA1 7.1.5)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation.

Reference: 7.1.5
Report: Alginure Bio Schutz: Acute Eye Irritation in the Rabbit, [redacted]., 2001, 1495/004, ASB2011-6860
Guidelines: OECD 405 (1987)
92/69/EEC - method B.5
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	Alginure Bio Schutz
Species	Rabbit, New Zealand White
No. of animals (group size)	3 males
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	No
Vehicle/Dilution	None
Post exposure observation period	3 days
Remarks	None

Results and discussions

Table A 6: Eye irritation of Alginure Bio Schutz

Animal No.		Scores after treatment 1)				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 1 1	0 0 0 0	0 0 0 0	0 0 0 0	0.0 0.0 0.0 0.0	- - - -
2	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 1 1	0 0 0 0	0 0 0 0	0 0 0 0	0.0 0.0 0.0 0.0	- - - -

3	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 1 1	0 0 0 0	0 0 0 0	0 0 0 0	0.0 0.0 0.0 0.0	- - - -

1) scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

Clinical signs:	None

Conclusion

Under the experimental conditions, Alginure Bio Schutz is not an eye irritant. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (IIIA1 7.1.6)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation.

Reference: 7.1.6
Report: Alginure Bio Schutz: Skin Sensitisation: Modified Local Lymph Node Assay in NMRI Mice, [redacted], 2012, 28209, ASB2013-6165
Guidelines: OECD 429 (modified)
EC method B.42
OPPTS guideline 870.2600
Deviations: Modified method (lymph node weight, lymph node cell count)
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	Alginure Bio Schutz (32111)
Species	Mouse, NMRI (Crl: NMRI) strain
No. of animals (group size)	Test substance group: 3 x 6 females Vehicle control goup: 6 females
Range finding:	Yes
Exposure (concentration(s), no. of applications)	25 %, 50 % and 100 %
Vehicle	dimethyl sulfoxide (DMSO)
Reliability check	α-hexyl cinnamic aldehyde (25 %)
Remarks	None

Results and discussions

Table A 7: Results of skin sensitisation study of Alginure Bio Schutz

	No. of animals	Concentration [%]	Stimulation index (SI)
Alginure Bio Schutz	6	25	1.109
	6	50	0.973
	6	100	0.973
Test Vehicle Control Group	6	0	1.000
Positive control	6	25	1.458*

* Values > 1.4 (lymph node cell count) are considered positive

Clinical signs:	None

Conclusion

Under the experimental conditions, Alginure Bio Schutz is not a skin sensitiser. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products (IIIA1 7.1.7)

No combination intended.

A 2.9 Data on co-formulants (III1 7.9)

A 2.9.1 Material safety data sheet for each co-formulant

Material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (IIIA1 7.3.1)

A 3.1.1 Calculations for Potassium phosphonates

Table A 8: Input parameters considered for the estimation of operator exposure (HCTM)

Formulation type:	SL		**Application technique:**	High Crop Tractor Mounted (HCTM)	
Application rate (AR):	2.052	kg a.s./ha			
Area treated per day (A):	8	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	25	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.7	mg/person/kg a.s.
	75	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	9.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	1.2	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	5	mg/kg bw/d	**Inhalation appl. (I_A):**	0.018	mg/person/kg a.s.

Table A 9: Estimation of operator exposure towards Potassium phosphonates using the German model (HCTM)

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in Grapevine					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE$ [1] $\times DA) / BW$		
(2.4 x 2.052 x 8 x 25%) / 70			(2.4 x 2.052 x 8 x 0.01 x 25%) / 70		
External dermal exposure	39.3984	mg/person	External dermal exposure	0.393984	mg/person
External dermal exposure	0.562834	mg/kg bw/d	External dermal exposure	0.005628	mg/kg bw/d
Systemic dermal exposure	**0.140709**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001407**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.7 x 2.052 x 8 x 75%) / 70			(0.7 x 2.052 x 8 x 1 x 75%) / 70		
External dermal exposure	11.4912	mg/person	External dermal exposure	11.4912	mg/person
External dermal exposure	0.16416	mg/kg bw/d	External dermal exposure	0.16416	mg/kg bw/d
Systemic dermal exposure	**0.12312**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.12312**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(9.6 x 2.052 x 8 x 75%) / 70			(9.6 x 2.052 x 8 x 1 x 75%) / 70		
External dermal exposure	157.5936	mg/person	External dermal exposure	157.5936	mg/person
External dermal exposure	2.251337	mg/kg bw/d	External dermal exposure	2.251337	mg/kg bw/d
Systemic dermal exposure	**1.688503**	**mg/kg bw/d**	**Systemic dermal exposure**	**1.688503**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(1.2 x 2.052 x 8 x 75%) / 70			(1.2 x 2.052 x 8 x 1 x 75%) / 70		
External dermal exposure	19.6992	mg/person	External dermal exposure	19.6992	mg/person
External dermal exposure	0.281417	mg/kg bw/d	External dermal exposure	0.281417	mg/kg bw/d
Systemic dermal exposure	**0.211063**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.211063**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	228.1824	mg/person	Total external dermal exposure	189.177984	mg/person
Total external dermal exposure	3.259749	mg/kg bw/d	Total external dermal exposure	2.702543	mg/kg bw/d
Total systemic dermal	**2.163394**	**mg/kg bw/d**	**Total systemic dermal**	**2.024093**	**mg/kg bw/d**

exposure			**exposure**		
Operators: Systemic inhalation exposure after application in Grapevine					
Inhalation exposure during mixing/loading					
SIE_{OM} = (I_M x AR x A x IA) / BW			SIE_{OM} = (I_M x AR x A x PPE x IA) / BW		
(0.0006 x 2.052 x 8 x 100%) / 70			(0.0006 x 2.052 x 8 x 1 x 100%) / 70		
External inhalation exposure	0.00985	mg/person	External inhalation exposure	0.00985	mg/person
External inhalation exposure	0.000141	mg/kg bw/d	External inhalation exposure	0.000141	mg/kg bw/d
Systemic inhalation exposure	**0.000141**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000141**	**mg/kg bw/d**
Inhalation exposure during application					
SIE_{OA} = (I_A x AR x A x IA) / BW			SIE_{OA} = (I_A x AR x A x PPE x IA) / BW		
(0.018 x 2.052 x 8 x 100%) / 70			(0.018 x 2.052 x 8 x 1 x 100%) / 70		
External inhalation exposure	0.295488	mg/person	External inhalation exposure	0.295488	mg/person
External inhalation exposure	0.004221	mg/kg bw/d	External inhalation exposure	0.004221	mg/kg bw/d
Systemic inhalation exposure	**0.004221**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.004221**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.305338	mg/person	Total external inhalation exposure	0.305338	mg/person
Total external inhalation exposure	0.004362	mg/kg bw/d	Total external inhalation exposure	0.004362	mg/kg bw/d
Total systemic inhalation exposure	**0.004362**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.004362**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	151.742938	mg/person	Total systemic exposure	141.991834	mg/person
Total systemic exposure	**2.167756**	**mg/kg bw/d**	**Total systemic exposure**	**2.028455**	**mg/kg bw/d**
% of AOEL	**43.4**	**%**	**% of AOEL**	**40.6**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)

Table A 10: Input parameters considered for the estimation of operator exposure (HCHH)

Formulation type:	SL		**Application technique:**	High Crop Hand Held (HCHH)	
Application rate (AR):	2.052	kg a.s./ha			
Area treated per day (A):	1	ha	**Dermal hands m/l ($D_{M(H)}$):**	205	mg/person/kg a.s.
Dermal absorption (DA):	25	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	10.6	mg/person/kg a.s.
	75	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	25	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	4.8	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.05	mg/person/kg a.s.
AOEL	5	mg/kg bw/d	**Inhalation appl. (I_A):**	0.3	mg/person/kg a.s.

Table A 11: Estimation of operator exposure towards Potassium phosphonates using the German model (HCHH)

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in Grapevine					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)}$ = ($D_{M(H)}$ x AR x A x DA) / BW			$SDE_{OM(H)}$ = ($D_{M(H)}$ x AR x A x PPE [1)] x DA) / BW		
(205 x 2.052 x 1 x 25%) / 70			(205 x 2.052 x 1 x 0.01 x 25%) / 70		
External dermal exposure	420.66	mg/person	External dermal exposure	4.2066	mg/person
External dermal exposure	6.009429	mg/kg bw/d	External dermal exposure	0.060094	mg/kg bw/d
Systemic dermal exposure	**1.502357**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.015024**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)}$ = ($D_{A(H)}$ x AR x A x DA) / BW			$SDE_{OA(H)}$ = ($D_{A(H)}$ x AR x A x PPE x DA) / BW		
(10.6 x 2.052 x 1 x 75%) / 70			(10.6 x 2.052 x 1 x 1 x 75%) / 70		
External dermal exposure	21.7512	mg/person	External dermal exposure	21.7512	mg/person
External dermal exposure	0.310731	mg/kg bw/d	External dermal exposure	0.310731	mg/kg bw/d
Systemic dermal exposure	**0.233049**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.233049**	**mg/kg bw/d**
Body			Body		

$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x DA) / BW			$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x PPE x DA) / BW		
(25 x 2.052 x 1 x 75%) / 70			(25 x 2.052 x 1 x 1 x 75%) / 70		
External dermal exposure	51.3	mg/person	External dermal exposure	51.3	mg/person
External dermal exposure	0.732857	mg/kg bw/d	External dermal exposure	0.732857	mg/kg bw/d
Systemic dermal exposure	**0.549643**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.549643**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x DA) / BW			$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x PPE x DA) / BW		
(4.8 x 2.052 x 1 x 75%) / 70			(4.8 x 2.052 x 1 x 1 x 75%) / 70		
External dermal exposure	9.8496	mg/person	External dermal exposure	9.8496	mg/person
External dermal exposure	0.140709	mg/kg bw/d	External dermal exposure	0.140709	mg/kg bw/d
Systemic dermal exposure	**0.105531**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.105531**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	503.5608	mg/person	Total external dermal exposure	87.1074	mg/person
Total external dermal exposure	7.193726	mg/kg bw/d	Total external dermal exposure	1.244391	mg/kg bw/d
Total systemic dermal exposure	**2.39058**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.903246**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in Grapevine					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M$ x AR x A x IA) / BW			$SIE_{OM} = (I_M$ x AR x A x PPE x IA) / BW		
(0.05 x 2.052 x 1 x 100%) / 70			(0.05 x 2.052 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.1026	mg/person	External inhalation exposure	0.1026	mg/person
External inhalation exposure	0.001466	mg/kg bw/d	External inhalation exposure	0.001466	mg/kg bw/d
Systemic inhalation exposure	**0.001466**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.001466**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A$ x AR x A x IA) / BW			$SIE_{OA} = (I_A$ x AR x A x PPE x IA) / BW		
(0.3 x 2.052 x 1 x 100%) / 70			(0.3 x 2.052 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.6156	mg/person	External inhalation exposure	0.6156	mg/person
External inhalation exposure	0.008794	mg/kg bw/d	External inhalation exposure	0.008794	mg/kg bw/d
Systemic inhalation exposure	**0.008794**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.008794**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.7182	mg/person	Total external inhalation exposure	0.7182	mg/person
Total external inhalation exposure	0.01026	mg/kg bw/d	Total external inhalation exposure	0.01026	mg/kg bw/d
Total systemic inhalation exposure	**0.01026**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.01026**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	168.0588	mg/person	Total systemic exposure	63.94545	mg/person
Total systemic exposure	**2.40084**	**mg/kg bw/d**	**Total systemic exposure**	**0.913506**	**mg/kg bw/d**
% of AOEL	**48**	**%**	**% of AOEL**	**18.3**	**%**
[1)] reduction factor for gloves is 0.01 (professional appl.)					

Table A 12: Estimation of operator exposure towards Potassium phosphonates using the UK-POEM (HCHH) without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Potassium phosphonates**		
Product	Alginure Bio Schutz		
Formulation type	water-based		
Concentration of a.s.	342	mg/mL	
Dose	6	L preparation/ha	(2.052 kg a.s./ha)
Application volume	1600	L/ha *	
Application method	Hand-held rotary atomiser equipment (2.5 L tank). Outdoor, high level target		
Container	10 litres 45 mm closure		
Work rate/day	1	ha	
Duration of spraying	6	h	
PPE during mix./loading	None		

PPE during application	None					
Dermal absorption from product	25	%				
Dermal absorption from spray	75	%				
EXPOSURE DURING MIXING AND LOADING						
Container size	10	Litres				
Hand contamination/operation	0.1	mL				
Application dose	6	Litres product/ha				
Work rate	1	ha/day				
Number of operations	640	/day				
Hand contamination	64	mL/day				
Protective clothing	None					
Transmission to skin	100	%				
Dermal exposure to formulation	64	mL/day				
DERMAL EXPOSURE DURING SPRAY APPLICATION						
Application technique	Hand-held rotary atomiser equipment (2.5 L tank). Outdoor, high level target					
Application volume	1600	spray/ha				
Volume of surface contamination	50	mL/h				
Distribution	Hands		Trunk		Legs	
	10%		65%		25%	
Clothing	None		Permeable		Permeable	
Penetration	100%		15%		20%	
Dermal exposure	5		4.875		2.5	mL/h
Duration of exposure	6	h				
Total dermal exposure to spray	74.25	mL/day				
ABSORBED DERMAL DOSE						
	Mix/load				Application	
Dermal exposure	64	mL/day			74.25	mL/day
Concen. of a.s. product or spray	342	mg/mL			1.283	mg/mL
Dermal exposure to a.s.	21888	mg/day			95.226	mg/day
Percent absorbed	25	%			75	%
Absorbed dose	5472	mg/day			71.419	mg/day
INHALATION EXPOSURE DURING SPRAYING						
Inhalation exposure	0.01	mL/h				
Duration of exposure	6	h				
Concentration of a.s. in spray	1.283	mg/mL				
Inhalation exposure to a.s.	0.077	mg/day				
Percent absorbed	100	%				
Absorbed dose	0.077	mg/day				
PREDICTED EXPOSURE						
Total absorbed dose	5543.496	mg/day				
Operator body weight	60	kg				
Operator exposure	92.392	mg/kg bw/day				
Amount of AOEL	**1847.8**	**%**				

*Only maximum value for application volume (=1600 L/ha) are available.

Table A 13: Estimation of operator exposure towards Potassium phosphonates using the UK-POEM (HCHH) with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Kaliumphosphit**		
Product	Alginure Bio Schutz		
Formulation type	water-based		
Concentration of a.s.	342	mg/mL	
Dose	6	L preparation/ha	(2.052 kg a.s./ha)
Application volume	1600	L/ha*	
Application method	Hand-held rotary atomiser equipment (2.5 L tank). Outdoor, high level		

	target						
Container	10 litres 45 mm closure						
Work rate/day	1	ha					
Duration of spraying	6	h					
PPE during mix./loading	Gloves						
PPE during application	Gloves and impermeable coveralls						
Dermal absorption from product	25	%					
Dermal absorption from spray	75	%					
EXPOSURE DURING MIXING AND LOADING							
Container size	10	Litres					
Hand contamination/operation	0,1	mL					
Application dose	6	Litres product/ha					
Work rate	1	ha/day					
Number of operations	640	/day					
Hand contamination	64	mL/day					
Protective clothing	Gloves						
Transmission to skin	5	%					
Dermal exposure to formulation	3.2	mL/day					
DERMAL EXPOSURE DURING SPRAY APPLICATION							
Application technique	Hand-held rotary atomiser equipment (2.5 L tank). Outdoor, high level target						
Application volume	1600	spray/ha					
Volume of surface contamination	50	mL/h					
Distribution	Hands		Trunk		Legs		
	10%		65%		25%		
Clothing	Gloves		Impermeable		Impermeable		
Penetration	10%		5%		5%		
Dermal exposure	0.5		1.625		0.625	mL/h	
Duration of exposure	6	h					
Total dermal exposure to spray	16.5	mL/day					
ABSORBED DERMAL DOSE							
	Mix/load				Application		
Dermal exposure	3.2	mL/day			16.5	mL/day	
Concen. of a.s. product or spray	342	mg/mL			1.283	mg/mL	
Dermal exposure to a.s.	1094.4	mg/day			21.161	mg/day	
Percent absorbed	25	%			75	%	
Absorbed dose	273.6	mg/day			15.871	mg/day	
INHALATION EXPOSURE DURING SPRAYING							
Inhalation exposure	0.01	mL/h					
Duration of exposure	6	h					
Concentration of a.s. in spray	1.283	mg/mL					
Inhalation exposure to a.s.	0.077	mg/day					
Percent absorbed	100	%					
Absorbed dose	0.077	mg/day					
PREDICTED EXPOSURE							
Total absorbed dose	289.548	mg/day					
Operator body weight	60	kg					
Operator exposure	4.826	mg/kg bw/day					
Amount of AOEL	**96.5**	**%**					

*Only maximum value for application volume (=1600 L/ha) are available.

Table A 14: Estimation of operator exposure towards Potassium phosphonates using the UK-POEM (HCTM) without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)						
Active substance	**Kaliumphosphit**					
Product	Alginure Bio Schutz					
Formulation type	water-based					
Concentration of a.s.	342	mg/mL				
Dose	6	L preparation/ha	(2.052 kg a.s./ha)			
Application volume	1600	L/ha*				
Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 L/ha					
Container	10 litres 45 mm closure					
Work rate/day	15	ha				
Duration of spraying	6	h				
PPE during mix./loading	None					
PPE during application	None					
Dermal absorption from product	25	%				
Dermal absorption from spray	75	%				
EXPOSURE DURING MIXING AND LOADING						
Container size	10	Litres				
Hand contamination/operation	0,1	mL				
Application dose	6	Litres product/ha				
Work rate	15	ha/day				
Number of operations	9	/day				
Hand contamination	0.9	mL/day				
Protective clothing	None					
Transmission to skin	100	%				
Dermal exposure to formulation	0.9	mL/day				
DERMAL EXPOSURE DURING SPRAY APPLICATION						
Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 L/ha					
Application volume	1600	spray/ha				
Volume of surface contamination	400	mL/h				
Distribution	Hands		Trunk		Legs	
	10%		65%		25%	
Clothing	None		Permeable		Permeable	
Penetration	100%		2%		5%	
Dermal exposure	10		5.2		5	mL/h
Duration of exposure	6	h				
Total dermal exposure to spray	121.2	mL/day				
ABSORBED DERMAL DOSE						
	Mix/load				Application	
Dermal exposure	0.9	mL/day			121.2	mL/day
Concen. of a.s. product or spray	342	mg/mL			1.283	mg/mL
Dermal exposure to a.s.	307.8	mg/day			155.439	mg/day
Percent absorbed	25	%			75	%
Absorbed dose	76.95	mg/day			116.579	mg/day
INHALATION EXPOSURE DURING SPRAYING						
Inhalation exposure	0.05	mL/h				
Duration of exposure	6	h				
Concentration of a.s. in spray	1.283	mg/mL				
Inhalation exposure to a.s.	0.385	mg/day				
Percent absorbed	100	%				
Absorbed dose	0.385	mg/day				
PREDICTED EXPOSURE						
Total absorbed dose	193.914	mg/day				

Operator body weight	60	kg
Operator exposure	3.232	mg/kg bw/day
Amount of AOEL	**64.6**	**%**

*Only maximum value for application volume (=1600 L/ha) are available.

Table A 15: Estimation of operator exposure towards Potassium phosphonates using the UK-POEM (HCTM) with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Kaliumphosphit**				
Product	Alginure Bio Schutz				
Formulation type	water-based				
Concentration of a.s.	342	mg/mL			
Dose	6	L preparation/ha	(2.052 kg a.s./ha)		
Application volume	1600	L/ha*			
Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 L/ha				
Container	10 litres 45 mm closure				
Work rate/day	15	ha			
Duration of spraying	6	h			
PPE during mix./loading	Gloves				
PPE during application	Gloves				
Dermal absorption from product	25	%			
Dermal absorption from spray	75	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	10	Litres			
Hand contamination/operation	0,1	mL			
Application dose	6	Litres product/ha			
Work rate	15	ha/day			
Number of operations	9	/day			
Hand contamination	0.9	mL/day			
Protective clothing	Gloves				
Transmission to skin	5	%			
Dermal exposure to formulation	0.045	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 L/ha				
Application volume	1600	spray/ha			
Volume of surface contamination	400	mL/h			
Distribution	Hands		Trunk	Legs	
	10%		65%	25%	
Clothing	Gloves		Permeable	Permeable	
Penetration	10%		2%	5%	
Dermal exposure	4		5.2	5	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	85.2	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.045	mL/day		85.2	mL/day
Concen. of a.s. product or spray	342	mg/mL		1.283	mg/mL
Dermal exposure to a.s.	15.39	mg/day		109.269	mg/day
Percent absorbed	25	%		75	%
Absorbed dose	3.848	mg/day		81.952	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.05	mL/h			
Duration of exposure	6	h			

Concentration of a.s. in spray	1.283	mg/mL
Inhalation exposure to a.s.	0.385	mg/day
Percent absorbed	100	%
Absorbed dose	0.385	mg/day
PREDICTED EXPOSURE		
Total absorbed dose	86.184	mg/day
Operator body weight	60	kg
Operator exposure	1.436	mg/kg bw/day
Amount of AOEL	**28.7**	**%**

*Only maximum value for application volume (=1600 L/ha) are available.

A 3.2 Worker exposure calculations (IIIA1 7.5.1)

A 3.2.1 Calculations for Potassium phosphonates

Table A 16: Input parameters considered for the estimation of worker exposure

Intended use(s):	Grapevine Grapevine		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	2.052	kg a.s./ha	**Transfer coefficient (TC):**	10000	cm²/person/h
Number of applications (NA):	6		**Work rate per day (WR):**	8	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	75	% ('worst case')			
AOEL	5	mg/kg bw/d			

Table A 17: Estimation of worker exposure towards Potassium phosphonates using the German re-entry model

Without PPE			**With PPE [1)]**		
Worker (re-entry): Systemic dermal exposure after application in Grapevine Grapevine					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 10000 x 8 x 2.052 x 6 x 75%) / 60			(1 x 10000 x 8 x 2.052 x 6 x 5% x 75%) / 60		
External dermal exposure	984.96	mg/person	External dermal exposure	49.248	mg/person
External dermal exposure	16.416	mg/kg bw/d	External dermal exposure	0.8208	mg/kg bw/d
Total systemic exposure	738.72	mg/person	Total systemic exposure	36.936	mg/person
Total systemic exposure	**12.312**	**mg/kg bw/d**	**Total systemic exposure**	**0.6156**	**mg/kg bw/d**
% of AOEL	**246.2**	**%**	**% of AOEL**	**12.3**	**%**

1) acceptable only with PPE: see 'Instructions for use'

A 3.3 Bystander and resident exposure calculations (IIIA1 7.4.1)

A 3.3.1 Calculations for Potassium phosphonates

Table A 18: Input parameters considered for the estimation of bystander exposure, (HCHH)

Intended use(s):	Grapevine		**Drift (D):**	8.02	% (HC, 3 m)
Application rate (AR):	2.052	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	205.2	mg/m²		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.3	mg/kg a.s. (6 hours, adults)

	16.15	kg/person (children)		0.172414	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75	% ('worst case')	**Area Treated (A):**	1	ha/d (based on HCHH)
Inhalation absorption (IA):	100	%			
AOEL:	5	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 19: Estimation of bystander exposure towards Potassium phosphonates

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(205.2 x 8.02% x 1 x 75%) / 60			(205.2 x 8.02% x 0.21 x 75%) / 16.15		
External dermal exposure	16.45704	mg/person	External dermal exposure	3.455978	mg/person
External dermal exposure	0.274284	mg/kg bw/d	External dermal exposure	0.213992	mg/kg bw/d
Systemic dermal exposure	**0.205713**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.160494**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in Grapevine Grapevine (via spray drift)					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0.3 / 360 x 2.052 x 1 x 5 x 100%) / 60			(0.172414 / 360 x 2.052 x 1 x 5 x 100%) / 16.15		
External inhalation exposure	0.00855	mg/person	External inhalation exposure	0.004914	mg/person
External inhalation exposure	0.000143	mg/kg bw/d	External inhalation exposure	0.000304	mg/kg bw/d
Systemic inhalation exposure	**0.000143**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000304**	**mg/kg bw/d**
Total systemic exposure: SE_B = SDE_B + SIE_B			Total systemic exposure: SE_B = SDE_B + SIE_B		
Total systemic exposure	12.35133	mg/person	Total systemic exposure	2.596898	mg/person
Total systemic exposure	**0.205856**	**mg/kg bw/d**	**Total systemic exposure**	**0.160799**	**mg/kg bw/d**
% of AOEL	**4.12**	**%**	**% of AOEL**	**3.22**	**%**

Table A 20: Input parameters considered for the estimation of resident exposure (HCHH)

Intended use(s):	Grapevine Grapevine		**Drift (D):**	6.41	% (HC, 3 m)
Application rate (AR):	2.052	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.02052	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	6		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m^3
Dermal absorption (DA):	75	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	5	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 21: Estimation of resident exposure towards Potassium phosphonates

Adults			**Children**		
Residents: Systemic dermal exposure after application in Grapevine Grapevine (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.02052 x 6 x 6.41% x 5% x 7300 x 2 x 75%) / 60			(0.02052 x 6 x 6.41% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	5.761154	mg/person	External dermal exposure	2.051918	mg/person
External dermal exposure	0.096019	mg/kg bw/d	External dermal exposure	0.127054	mg/kg bw/d
Systemic dermal exposure	**0.072014**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.09529**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in Grapevine Grapevine (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		

(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.02052 x 6 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.15784	mg/person
			External oral exposure	0.009773	mg/kg bw/d
			Systemic oral exposure	**0.009773**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.02052 x 6 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.03946	mg/person
			External oral exposure	0.002443	mg/kg bw/d
			Systemic oral exposure	**0.002443**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	4.320866	mg/person	Total systemic exposure	1.736238	mg/person
Total systemic exposure	**0.072014**	**mg/kg bw/d**	**Total systemic exposure**	**0.107507**	**mg/kg bw/d**
% of AOEL	**1.44**	**%**	**% of AOEL**	**2.15**	**%**

DRAFT REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product Name: Alginure Bio Schutz

Active Substance: Potassium phosphonates 342 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: TILCO BIOCHEMIE GmbH

Date: 19-09-2016

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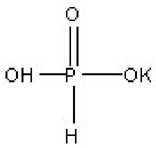
8 METABOLISM AND RESIDUES DATA

8.1 Evaluation of the active substances

8.1.1 Potassium (mono) phosphite

Table 8.1-1: Identity of the active substance

Structural formula	
Common Name	Potassium (mono) phosphite
CAS number	13977-65-6

8.1.1.1 Storage stability

A brief summary of the storage stability data on potassium phosphite is given in the following table. Data that has been previously evaluated at EU level is described in detail in the DAR (France, ASB2010-10598), the final addendum to the DAR (ASB2012-13621) and in EFSA´s Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonate (ASB2012-16090).

Table 8.1-2: Stability of residues (Annex IIA, point 6.1)

Stability of potassium phosphite	Grapes: >12 months at ≤ -22°C (ASB2010-1153)

8.1.1.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of potassium phosphite in plants is given in the following table. Data that has been previously evaluated at EU level is described in detail in the DAR (France, ASB2010-10598), the final addendum to the DAR (ASB2012-13621) and in EFSA´s Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonate (ASB2012-16090).

Table 8.1-3: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	The behaviour of potassium phosphite was described in several studies in open literature. The major conclusions drawn from these studies were: – Potassium phosphite readily penetrates both bark and cuticle of Betula pendula trees (ASB2010-1158). – Following trunk injection, phosphite is bipetally translocated in phloem and in xylem (ASB2010-1157). – Following foliar application, phosphite is detected in the plant roots, confirming the mobility of phosphite in the plant phloem (ASB2009-4287, ASB2009-4288). – Distribution of phosphite to both roots and leaves is more rapid after foliar application than after trunk injection (ASB2010-1156). – Phosphite can be actively taken up into the symplast of castor bean plants and sugar beet leaf discs, and transported through the phloem. The

	involvement of an active transport system is evidenced by the effect of metabolic inhibitors (ASB2009-4288). – Levels of phosphite residues are related to the total dose applied, and to the route of application (ASB2009-4287). – In aerial plant parts, residue levels increase rapidly after foliar application but decline within 4-6 weeks after treatment (ASB2009-4287). – Phosphite is not readily oxidised in the plant to phosphate, evidenced by the fact that phosphate levels in plant tissues are not raised upon phosphite applications, but sometimes even reduced (ASB2009-4284, ASB2010-1163). Thus, phosphite bound phosphorus does not serve as an immediate P source in plants.
Rotational crops	Not required, only uses on grapes applied for yet.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Not applicable.
Distribution of the residue in peel/ pulp	Not applicable
Processed commodities (nature of residue)	Not required. The chemistry of phophorous acid is well understood. Apart from acid-base conversion no further modification of the residue has to be expected.
Residue pattern in raw and processed commodities similar? (yes/no)	Not applicable
Plant residue definition for monitoring	Potassium phosphite forms phosphorous acid. Thus it is covered by the already existing residue definition “Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)” which is established in Reg. (EC) No 396/2005. Note: Currently discussions are ongoing if separate MRLs should be set for fosetyl-Al and for phosphorous acid and its salts. For the time being the current residue definition is kept.
Plant residue definition for risk assessment	Phosphorous (=Phosphonic) acid and its salts, expressed as phosphorous (=phosphonic) acid (EFSA, 2012, ASB2012-16090)
Conversion factor(s) (monitoring to risk assessment)	None

8.1.1.3 *Metabolism in livestock and animal residue definition(s)*

A brief summary of the metabolism of potassium phosphite in livestock is given in the following table. Data that has been previously evaluated at EU level is described in detail in the DAR (France, ASB2010-10598), the final addendum to the DAR (ASB2012-13621) and in EFSA´s Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonate (ASB2012-16090).

Table 8.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	No toxicologically significant residues of phosphorous (=phosphonic) acid and its salts are anticipated to occur in livestock feed and therefore studies with livestock were not performed considering the Animal Protection Act.
Time needed to reach a plateau concentration in milk and eggs	Not applicable
Animal residue definition for monitoring	Not required

Animal residue definition for risk assessment	Not required
Conversion factor(s) (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not applicable
Fat soluble residue: (yes/no)	No

8.1.1.4 Residues in rotational crops

No field rotational crop studies on potassium phosphite were required, because the active substance is used on grapes only (permanent crop).

8.1.1.5 Residues in livestock

Residues of potassium phosphite in commodities of animal origin were not assessed, since grapes are normally not fed to livestock.

Table 8.1-5: Conditions of requirement of livestock feeding studies on potassium phosphite

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	no	no	no
Potential for accumulation (yes/no):	No data	No data	No data
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	No data	No data	No data

Livestock feeding studies are not required and no residues are expected to occur in food commodities of animal origin.

8.2 Evaluation of the intended use(s)

8.2.1 Selection of critical use and justification

The only GAP reported for the Central zone is presented in Table 8.2-1. It has been used for consumer intake and risk assessment.

Table 8.2-1: Critical Use (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications) a) per use b) per crop/ season (h)**	**L product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	DE	grape vine, utilization as table and grape vine	F	downy mildew of grapevine, *Plasmopara viticola*	spraying or fine spraying (low volume spraying)	BBCH 12-89	a) 6 b) 6 (7 days)	a) see below b)	a) see below b)	400 / 1600	15	

application rate

L product / ha			kg as/ha		
a) max. rate per appl.	basic application rate	1.5	a) max. rate per appl.	basic application rate	0.51
	BBCH 61	3.0		BBCH 61	1.03
	BBCH 71	4.5		BBCH 71	1.54
	BBCH 75	6.0		BBCH 75	2.05
b) max. total rate per crop/season		36.0	b) max. total rate per crop/season		12.3

Remarks:
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) All abbreviations used must be explained
- (e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (h) The minimum and maximum number of application possible under practical conditions of use must be provided
- (i) PHI - minimum pre-harvest interval
- (j) Remarks may include: Extent of use/economic importance/restrictions

8.2.2 Grapes

8.2.2.1 Residues in primary crops

The following table gives a brief overview of the supervised residue trials selected for the assessment of potassium phosphite in grapes. Data that has been previously evaluated at EU level is described in detail in the DAR (France, ASB2010-10598), the final addendum to the DAR (ASB2012-13621) and in EFSA´s Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonate (EFSA, ASB2012-16090). For the detailed evaluation of new/additional residue trials, it is referred to Appendix 2.

Table 8.2-2: Overview of the selected supervised residue trials for potassium phosphite in grapes

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (Phosphonic acid and its salts expressed as phosphonic acid)	Risk assessment (Phosphonic acid and its salts expressed as phosphonic acid)			
Grapes	NEU	Outdoor	16.7; 18.0; 19.9; 23.4; 26.8; 35.3; 36.0; 37.0	16.7; 18.0; 19.9; 23.4; 26.8; 35.3; 36.0; 37.0	25.1	37.0	-

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

8.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

8.2.2.3 Residues in processed commodities

The following table gives a brief overview of the results of processing studies for potassium phosphite in grapes. Those values that have already been described in detail in the DAR, Final Addendum 2012 (ASB2012-13621) are in italics. For the detailed evaluation of additional processing studies, it is referred to Appendix 2.

Table 8.2-3: Overview of the available processing studies for potassium phosphite in grapes

Processed commodity	Number of studies	Individual PFs (mg/kg)	Median PF [(a)]	Median CF [(b)]	Comments
Red wine	*2*		*1.2*		*PHI 54, only 2 trials*
White wine	*2*		*1.3*		*PHI 54, only 2 trials*
Must	2	1.24 (red wine) 0.88 (white wine)	1.06		PHI 14 (comparable to cGAP), only 2 trials
Pomace (wet)	2	1.02 (red wine) 1.98 (white wine)	1.50		PHI 14 (comparable to cGAP), only 2 trials
Wine, stored	2	1.36 (red wine) 1.28 (white wine)	1.32		PHI 14 (comparable to cGAP), only 2 trials
Wine, young	2	1.43 (red wine) 1.11 (white wine)	1.27		PHI 14 (comparable to cGAP), but only 2 trials, not a reliable PF

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

8.2.2.4 *Proposed pre-harvest intervals, withholding periods*

A PHI of 15 days as indicated in the GAP is acceptable.

8.3 Consumer intake and risk assessment

The consumer intake and risk assessment is based on the appropriate input values given in Table 8.3-1 and the toxicological reference values stated in Table 8.3-2. For the detailed calculation results it is referred to Appendix 3.

Table 8.3-1: Residue input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Table grapes	25.1	STMR	Not relevant	No ARfD has been allocated
Wine grapes	32.6	STMR-P (PF 1.3, EFSA, 2012, ASB2012-16090)	Not relevant	No ARfD has been allocated
All other commodities	various	MRLs as established in Reg. (EC) No 396/2005	Not considered	

Table 8.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	2.25 mg/kg bw (for phosphonic acid = phosphorous acid) [1] **2.52 mg/kg bw** (recalculated for fosetyl) [2]
TMDI (% ADI) according to EFSA PRIMo	73 % (based on DE child 2-4 years, based on mean body weight) MRLs for fosetyl-Al (sum of fosetyl and phosphorous acid, expressed as fosetyl) were used.
NTMDI (% ADI) according to NVSII	76 % (based on DE child 2-4 years, based on individual consumption/body weight ratios) MRLs for fosetyl-Al (sum of fosetyl and phosphorous acid, expressed as fosetyl) were used.
IEDI (EFSA PRIMo) (% ADI)	69 % (based on DE child 2-4 years, based on mean body weight)
NEDI (NVSII) (% ADI)	72 % (based on DE child 2-4 years, based on individual consumption/body weight ratios)
Factors included in IEDI and NEDI	STMR table grapes: 25.1 mg/kg STMR-P wine grapes: 32.6 mg/kg (PF 1.3)
ARfD	Not necessary
IESTI (EFSA PRIMo) (% ARfD)	No ARfD
NESTI (NVSII) (% ARfD)	No ARfD
Factors included in IESTI and NESTI	Not applicable

[1] NOTE: A corrigendum to the EFSA conclusion on fosetyl was published in June 2013 by considering a correction for the water content of the phosphorous material tested.

[2] NOTE: Since according to the current residues definition in Regulation (EC) No 396/2005 the residues are expressed as fosetyl, the ADI derived for phosphonic acid needs to be corrected, applying the molecular weight correction factor of 1.12

8.4 Proposed maximum residue levels (MRLs)

No new MRLs are required.

8.5 Conclusion

The data available are considered sufficient for risk assessment. Although in 4 of the 8 trials 5 rather than the 6 applications of the intended GAP were applied, the total amount applied (15.0 – 15.9 kg as/ha) exceeds that of the intended GAP (12.3 kg as/ha) and the trials were therefore included in the assessment. The minimal time interval between applications of the intended GAP (7 days) was not adhered to in two of the eight trials (13 – 15 days, Ipach, R., 2010). However, in these trials the residue levels were amongst the highest levels measured in all trials and were thus included in the assessment. An exceedance of the current MRL of 100 mg/kg as laid down in Reg. (EU) 396/2005 for fosetyl-A1 (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl), which covers also the active substance potassium phosphate, is not expected. An exceedence of the proposed MRL for potassium phosphonate of 90 mg/kg (EFSA, 2012, ASB2012-16090) is also not expected.

The chronic and the short-term intakes of potassium phosphite residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Germany agrees with the authorization of the intended use.

Appendix 1 Reference list

Table A 1: Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
All	EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance Potassium phosphonates EFSA Journal 2012;10(12):2963 ! EFSA-Q-2009-00317 ASB2012-16090			Add
All	France	2005	Potassium phosphite: (Draft Assessment Report) Vol. 1-4 ASB2010-10598			Add
All	France	2012	Potassium phosphonates: Final addendum to the Draft Assessment Report (DAR) - public version - ASB2012-13621			Add
OECD 6.2.1	Carswell, C.; Grant, B. R.; Theodorou, M. E.; Harris, J. et al.	1996	The fungicide Phosphonate disrupts the Phosphate starvation response in Brassica nigra seedlings BVL-2100268, ASB2009-4284	No	LIT	Yes
OECD 6.2.1	Förster, H.; Adaskaveg, J. E.; Kim, D. H.; Stanghellini, M. E.	1998	Effect of Phosphite on tomato and pepper plants and susceptibility of pepper to Phytophthora root and crown rot in hydroponic culture A2AS04P0601_14 BVL-2100275, ASB2010-1163	No	LIT	Yes
OECD 6.2.1	Garrec, J. P.; Barrois, A.	1992	Caracteristiques de la fixation et de la penetration corticale. Passage du phosphite dipotassique et de l?eau au travers d?ecorces isolees A2AS04P0601_06 BVL-2100212, ASB2010-1158	No	LIT	Yes
OECD 6.2.1	Ouimette, D. G.; Coffey, M. D.	1989	Phosphonate levels in avocado (Persea americana) seedlings and soil following treatment with Fosetyl-Al or Potassium phosphonate page 212-215 BVL-2088572, BVL-2088625, BVL-2100233, ASB2009-4287	No	LIT	Yes
OECD 6.2.1	Ouimette, D. G.; Coffey, M. D.	1990	Symplastic entry and phloem translocation of Phosphonate 0048-3575/90 BVL-2100242, ASB2009-4288	No	LIT	Yes
OECD 6.3	Pollmann, B.	2002	Determination of residues of Stamina after 6 applications in vines - 2 sites in Northern Italy, 2 sites in Southern France, 2 sites in Northern France and 2 sites in Southern Germany, 2001 20011174/E1-FPVI BVL-2088566, BVL-2100471, ASB2010-1087	Yes	LBG	Yes
OECD 6.3	Röser, K.	2004	Determination of residues of Phosphorous acid in grapes after 5 applications of LBG-01F34, active ingredient Potassium phosphite, at 4 sites in France 2003 20031178/F1-FPVI BVL-2100531, ASB2010-1164	Yes	LBG	Yes

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
OECD 6.3	Röser, K.	2004	Determination of residues of Phosphorous acid in grapes and processed goods after 5 applications of LBG-01F34, Active ingredient Potassium phosphite, at 4 sites in France, 2003 20031178/F2-FPVI BVL-2100536, BVL-2100665, ASB2010-1165	Yes	LBG	Yes
OECD 6.2.1	Schutte, G. C.; Bezuidenbout, J. J.; Kotze, J. M.	1991	Timing of application of Phosphonate fungicides using different application methods as determined by means of gas-liquid chromatography for phytophrhora root rot control of citrus A2AS04P0601_04 BVL-2100248, ASB2010-1156	No	LIT	Yes
OECD 6.2.1	Whiley, A. W.; Pegg, K. G.; Saranah, J. B.; Langdon, P. W.	1987	Influence of Phytophthora root rot on mineral nutrient concentrations in avocado leaves A2AS04P0601_05 BVL-2100307, BVL-2100650, ASB2010-1157	No	LIT	Yes
OECD 6.1	Witte, A.	2003	Determination of the storage stability of Phosphorous acid on laboratory-fortfied grapes 20011211/01-RSS BVL-2100195, ASB2010-1153	Yes	LBG	Yes
OECD: KIIA 6.3, OECD: KIIA 6.5.3	Ipach, R.	2010	Study on the residue behaviour of Phosphonic acid in grapes and grape process fractions after application of lbg 01f34 (mac 94700 f) under field conditions (germany, 2009) FCS01 BVL-2438081, BVL-2438088, ASB2012-510	Yes	FSG	Yes
OECD: LIIA Sec 4	Anon.	2010	Kaliumphosphit (Kaliumphosphonate: Reference list LII - Residues in or on treated products, food and feed - Tier 1, IIA-6 LII / Sec. 4 BVL-2421364, ASB2012-497	Yes	LBG	Yes
OECD: MIIIA1 Sec 4	Applicant	2013	Kaliumphosphit (Kaliumphosphonate) / Alginure Bio Schutz: Residues in or on treated products, food and feed - Tier 2, IIIA-8 - Draft Registration Report - Part B - Core assessment MIII / Sec. 4 BVL-2420985, BVL-2420987, ASB2013-6178	Yes	TIL	Yes

* Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

No further study on storage stability submitted/needed.

A 2.2 Residues in primary crops

A 2.2.1 Nature of residues

No further study on nature of residues submitted/needed.

A 2.2.2 Magnitude of residues in grape vine

Reference:	OECD KIIA 6.3
Report	Study on the residue behaviour of Phosphonic acid in grapes and grape process fractions after application of LGB01F34 (MAC94700 F) under field conditions (Germany, 2009), Ipach, R., 2010 ASB2012-510
Guideline(s):	Yes: BBA Guideline VI, 23-2.3.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 2: Residues of potassium phosphite in grape vine

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Potassium Phosphite
Crop / crop group : Grape Vine

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2011-12-15

Content of a.i.	(g/kg or g/l)	:	755 g/l
Formulation	(e.g. WP)	:	SL
Commercial product	(name)	:	LBG-01F34 **007207-00** treated with formulation LBG-01F34, SL (755 g/l Potassium phosphonates, which is equivalent to 504 g/l phosphorous acid, actual 499 g/l)
Applicant		:	Luxembourg Industries, Ltd.

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) :
Residues calculated as : Phosphorous acid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
FCS01, trial 1, processing Germany 67434 Diedesfeld 2010-12-21	Dornfelder (red variety)	1) 1997 (planting) 2) 3) 2009-09-28	3.2 3.3 3.2 3.1 3.1	843 871 857 829 829	0.38 0.38 0.38 0.38 0.38	2009-07-13 2009-07-27 2009-08-11 2009-08-24 2009-09-07[4)]	BBCH 85	grapes grapes, RAC must pomace, wet wine, stored wine, young stalk	29.4 37.3 24.1 35.3 43.9 36.0 48.0 50.5 31.8	0 8 21 14 14 14 14 14 14	4) spraying analytical method: FRESENIUS IF-09/01419442 (HPLC-MS/MS), LOQ's: all 0.5 mg/kg, max. sample storage: 12 months ASB2012-510
FCS01, trial 2, processing Germany 67489 Kirrweiler 2010-12-21	Müller-Thurgau (white variety)	1) 1981 (planting) 2) 3) 2009-09-21	3.0 3.1 3.1 3.1 3.0	806 819 826 813 806	0.38 0.38 0.38 0.38 0.38	2009-07-06 2009-07-20 2009-08-03 2009-08-17 2009-08-31[4)]	BBCH 85	grapes grapes, RAC must pomace, wet wine, stored wine, young	33.2 36.4 30.1 37.0 32.6 73.3 47.5 40.9	0 7 21 14 14 14 14 14	4) spraying analytical method: FRESENIUS IF-09/01419442 (HPLC-MS/MS), LOQ's: all 0.5 mg/kg, max. sample storage: 12 months ASB2012-510

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

Comments of zRMS:	Acceptable.

Reference:	OECD KIIA 6.3
Report	Determination of residues of Stamina after 6 applications in vines – 2 sites in Northern Italy, 2 sites in Southern France, 2 sites in Northern France and 2 sites in Southern Germany, 2001, ASB2010-1087
Guideline(s):	Yes: BBA (1990), IVA (1992), EU (1997)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 3: Residues of potassium phosphite in grape vine

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Potassium Phosphite
Crop / crop group : Grape Vine

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2009-07-31

Content of a.i.	(g/kg or g/l)	:	755 g/l
Formulation	(e.g. WP)	:	SL
Commercial product	(name)	:	LBG-01F34 **007207-00** (submitted to WN2 005386-00) treated with formulation STAMINA (LBG-01F34) SL (755 g/l Potassium phosphonates wich is equivalent to 504 g/l phosphorous acid, actual 501 g/l)
Applicant		:	Luxembourg Industries, Ltd.

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) :
Residues calculated as : Phosphorous acid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
20011174/E1-FPVI, trial F01N050R France 67140 Barr, Alsace 2002-04-10	Riesling (white variety)	1) 1950 (planting) 2) 3) 2001-09-21	3.0 2.8 3.2 3.0 3.2 3.0	804 738 836 794 849 788	0.38 0.38 0.38 0.38 0.38 0.38	2001-07-24 2001-08-01 2001-08-10 2001-08-20 2001-08-28 2001-09-06 4)	BBCH 85	grapes	<u>23.4</u>	15	4) spraying analytical method: DFG 522 (GC-PND), LOQ: 0.5 mg/kg, max. sample storage: 5 months ASB2010-1087
20011174/E1-FPVI, trial F01N051R France 67120 Dorlisheim, Alsace 2002-04-10	Auxerrois (white variety)	1) 1999 (planting) 2) 3) 2001-09-21	3.0 2.9 3.2 2.8 3.0 2.9	791 778 837 748 788 781	0.38 0.38 0.38 0.38 0.38 0.38	2001-07-24 2001-08-01 2001-08-10 2001-08-20 2001-08-28 2001-09-06 4)	BBCH 85	grapes	<u>19.9</u>	15	4) spraying analytical method: DFG 522 (GC-PND), LOQ: 0.5 mg/kg, max. sample storage: 5 months ASB2010-1087
20011174/E1-FPVI, trial G01N048R Germany 71717 Beilstein 2002-04-10	Riesling (white variety)	1) 1990 (planting) 2) 3) 2001-10-15	3.0 3.0 3.1 3.1 3.1 3.0	796 800 818 830 812 786	0.38 0.38 0.38 0.38 0.38 0.38	2001-08-14 2001-08-23 2001-08-31 2001-09-11 2001-09-19 2001-09-29 4)	BBCH 81-83	grapes	35.9 41.8 41.6 42.7 <u>26.8</u>	0 3 7 10 16	4) spraying analytical method: DFG 522 (GC-PND), LOQ: 0.5 mg/kg, max. sample storage: 4 months ASB2010-1087

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
20011174/E1-FPVI, trial G01N049R Germany 74348 Lauffen 2002-04-10	Riesling (white variety)	1) 1976 (planting) 2) 3) 2001-10-15	3.0 3.0 3.2 3.1 3.2 3.0	798 807 844 832 851 794	0.38 0.38 0.38 0.38 0.38 0.38	2001-08-14 2001-08-23 2001-08-31 2001-09-11 2001-09-19 2001-09-29 4)	BBCH 81-83	grapes	24.2 27.0 23.8 22.2 16.7	0 3 7 10 16	4) spraying analytical method: DFG 522 (GC-PND), LOQ: 0.5 mg/kg, max. sample storage: 4 months ASB2010-1087

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

Comments of zRMS:	Acceptable.

Reference:	OECD KIIA 6.3
Report	Determination of Residues of Phosphorous Acid in Grapes /and Processed Goods after 5 Applications of LBG-01F34, Active Ingredient Potassium Phosphite, at 4 Sites in France, 2003, RÖSER, K. (2004a/b): ASB2010-1164; ASB2010-1165
Guideline(s):	Yes: BBA Guideline IV, 3-3 (1990), EC Working document 1607/VI/97 rev. 1 (1997), SANCO/3029/99, rev. 4 (2000), IVA-Leitlinie – Rückstandsversuche, Prüfungen an Pflanzen (1992)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 4: Residues of potassium phosphite in grape vine

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY) (Application on agricultural and horticultural crops)			Active ingredient Crop / crop group	: :	Potassium Phosphite Grape Vine
Federal Institute for Risk Assessment, Berlin Federal Republic of Germany			Submission date	:	2009-07-31
Content of a.i.	(g/kg or g/l)	: 755 g/l	Indoors / outdoors	:	Outdoors (European North)
Formulation	(e.g. WP)	: SL	Other a.i. in formulation		
Commercial product	(name)	: LBG-01F34 **007207-00** (submitted to WN2 005386-00) treated with formulation LBG-01F34, SL (755 g/l Potassium phosphonates wich is equivalent to 504 g/l phosphorous acid)	(content and common name)	:	
Applicant		: Luxembourg Industries, Ltd.	Residues calculated as	:	Phosphorous acid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
20031178/F1-FPVI, trial F03N011R France 67140 Stotzheim, Alsace 2004-04-26	Pinot Noir (red variety)	1) 1998 (planting) 2) 2003-06-05 - 2003-06-11 3) 2003-09-23	2.9 3.0 3.1 3.1 3.0	877 908 938 935 919	0.33 0.33 0.33 0.33 0.33	2003-06-16 2003-06-26 2003-07-07 2003-07-16 2003-07-25[4)]	BBCH 79-81	bunch of grapes	54.0 55.0 43.0 36.0 14.0 17.0 24.0 16.0	0 1 7 14 28 40 50 60	4) spraying analytical method: DFG 522 (GC-PND), LOQ's: 0.5 mg/kg, max. sample storage: 5 months ASB2010-1164
20031178/F1-FPVI, trial F03N012R France 67120 Dorlisheim, Alsace 2004-04-26	Silvaner (white variety)	1) 1986 (planting) 2) 2003-05-31 - 2003-06-15 3) 2003-09-23	2.9 3.1 3.0 2.9 3.1	865 922 919 862 922	0.33 0.33 0.33 0.33 0.33	2003-06-17 2003-06-26 2003-07-07 2003-07-16 2003-07-25[4)]	BBCH 79	bunch of grapes	19.0 23.0 23.0 18.0 18.0 21.0 16.0 21.0	0 1 7 14 28 40 50 60	4) spraying analytical method: DFG 522 (GC-PND), LOQ's: 0.5 mg/kg, max. sample storage: 5 months ASB2010-1164
20031178/F2-FPVI, trial F03N015R, processing France 67140 Stotzheim, Alsace 2004-05-06	Pinot Noir (red variety)	1) 1998 (planting) 2) 2003-06-05 - 2003-06-11 3) 2003-09-23	3.0 3.0 3.1 3.0 2.9	896 916 920 909 868	0.33 0.33 0.33 0.33 0.33	2003-06-16 2003-06-26 2003-07-07 2003-07-16 2003-07-25[4)]	BBCH 79-81	bunch of grapes bunch of grapes, RAC must pomace, wet wine, young wine, bottled	64.0 47.0 43.0 47.0 108 48.0 50.0	0 60 54 54 54 54 54	4) spraying analytical method: DFG 522 (GC-PND), LOQ's: grapes 0.5 mg/kg, must/wine 5 mg/kg, pomace 10 mg/kg max. sample storage: 6 months ASB2010-1165

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
20031178/F2-FPVI, trial F03N016R, processing France 68000 Colmar, Alsace 2004-05-06	Riesling (white variety)	1) 1954 (planting) 2) 2003-05-30 - 2003-06-15 3) 2003-09-23	3.0 3.0 3.0 3.2 2.8	904 908 906 950 840	0.33 0.33 0.33 0.33 0.33	2003-06-16 2003-06-26 2003-07-07 2003-07-16 2003-07-25[4)]	BBCH 79	bunch of grapes bunch of grapes, RAC must pomace, wet wine, young wine, bottled	25.0 13.0 14.0 18.0 35.0 18.0 18.0	0 60 54 54 54 54 54	4) spraying analytical method: DFG 522 (GC-PND), LOQ's: grapes 0.5 mg/kg, must/wine 5 mg/kg, pomace 10 mg/kg max. sample storage: 6 months ASB2010-1165

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

Comments of zRMS:	Acceptable.

A 2.3 Residues in processed commodities

A 2.3.1 Magnitude of residues

Reference:	OECD KIIA 6.5.3
Report	Study on the residue behaviour of Phosphonic acid in grapes and grape process fractions after application of LGB01F34 (MAC94700 F) under field conditions (Germany, 2009), Ipach, R., 2010, Study Nr FCS01 (ASB2012-510)
Guideline(s):	Yes: BBA Guideline IV3-3.4 residue analysis-research on grapes, must and wine (1990); IVA-Guideline "Residue Analysis", Part IA (1992) and Part IB (1992) and Part III.; EU-GD SANCO/825/00-rev7, 17/03/04; Draft guidance EC doc. 8064/VI/-rev-4, 15/12/98; EU-GD SANCO/3029/99 rev4, 11/07/00; BBA guideline Residue analytical methods for post-registration control purposes, 21/07/98.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Two field trials on the magnitude of phosphonic acid residues in red and white grapes and in processed grape fractions (stems, fresh pomace, must and wine) were conducted in Germany. Five applications at the rate of 3 kg potassium phosphonate/ha were made in intervals of 13 – 15 days and specimens were taken at 0, 7, 14, and 21 days after the last application (BBCH 83 – 85) and analysed for phosphonic acid residues or processed to obtain pomace, must, stems and wine. Whole bunches of grapes were collected and transferred to the experimental cellar of the Test Facility. For wine making, the grapes were stemmed, crushed and pressed on the same day (harvest 14 DALA). For residue analysis, 1 kg pomace samples were taken immediately after pressing and frozen at or below -18°C. The must was sulphured with 50 mg SO2/L and left overnight to separate. For residue analysis 1 L must samples were taken and frozen at or below -18°C. For red wine, the crush was heated to ca. 70°C after sulphuring. Bottles of generated wine were stored in the cellar at room temperature until shipment for analysis.
The principle of the SGS internal analytical method consists in the extraction of the specimens using as extraction solvent methanol/ultrapure water with further homogenization, centrifugation and decantation. All specimens were analysed for residues of phosphonic acid by LC-MS/MS, the LOD was <0.05 mg/kg and the LOQ was 0.5 mg/kg.

Results and discussions

For validation of the analytical method, 17 control specimens were fortified at levels of 0.5/5/25/50/75/100 mg/kg yielding the mean recovery rate of 95 % (84.8 – 101.6 %), with a mean SD of 10.6. Measured residue levels and calculated processing factors are summarized in Table A 13.

Table A 5: Residue data from grape processing study with potassium phosphonite

RAC	Residues in RAC (mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*	Comments/ Reference
Grapes	35.3	14	Must Pomace (wet) Wine, stored Wine, young	43.9 36.0 48.0 50.5	1.24 1.02 1.36 1.43	
Grapes	37.0	14	Must Pomace (wet) Wine, stored Wine, young	32.6 73.3 47.5 40.9	0.88 1.98 1.28 1.11	

* processing factor

Figure A 1: Processing flowchart for grapes

Processing dates, Trial 1 (red wine making)

Activities and samplings	Grapes of Control plot	Grapes of Test item plot
Sampling date	**Sept 21, 09**	**Sept 21, 09**
Crushing	**Sept 21, 09 9:40**	**Sept 21, 09 9:50**
Stems sampling	**Sept 21, 09**	**Sept 21, 09**
Warm up 70 °C	**Sept 21, 09**	**Sept 21, 09**
Pressing	**Sept 22, 09 7:00**	**Sept 22, 09 8:00**
Pomace sampling	**Sept 22, 09**	**Sept 22, 09**
Must sampling	**Sept 23, 09**	**Sept 23, 09**
Sugar content must	**76 °Oe ***	**71 °Oe ***
Must acid	**6.4 g/L**	**6.1 g/L**
Adding of sugar	**49.4 g/l**	**49.4 g/l**
Filling of the fermentation balloons	**Sept 23, 09**	**Sept 23, 09**
End of fermentation	**Oct 09, 09**	**Oct 07, 09**
SO_2 - addition	**Oct 09, 09**	**Oct 09, 09**
1st separation with addition of Bentonit	**Oct 19, 09**	**Oct 20, 09**
2nd separation with bottling **Wine (separated) sampling**	**Jan 19, 10**	**Jan 19, 10**

* °Oe = ° Oechsle (German unity for must density)

Processing dates, Trial 2 (white wine making)

Activities and samplings	Grapes of Control plot	Grapes of Test item plot
Sampling date	**Sept 14, 09**	**Sept 14, 09**
Crushing	**Sept 14, 09 09:45**	**Sept 14, 09 10:40**
Pressing	**Sept 14, 09 09:55**	**Sept 14, 09 10:55**
Pomace sampling	**Sept 14, 09**	**Sept 14, 09**
Must sampling	**Sept 15, 09**	**Sept 15, 09**
Sugar content must	**76 °Oe ***	**76 °Oe ***
Must acid	**6.1 g/L**	**6.2 g/L**
Adding of sugar	**49.4 g/l**	**49.4 g/l**
Filling of the fermentation balloons	**Sept 14, 09**	**Sept 14, 09**
End of fermentation	**Oct 01, 09**	**Oct 06, 09**
SO_2 - addition	**Oct 02, 09**	**Oct 06, 09**
1st separation with addition of Bentonit	**Oct 21, 09**	**Oct 21, 09**
2nd separation with bottling **Wine (separated) sampling**	**Feb 09, 10**	**Feb 09, 10**

* °Oe = ° Oechsle (German unity for must density)

Dates are given for Trial 1, red wine making, and for Trial 2, white wine making, to show the steps in the processing procedure.

Conclusion

A concentration of potassium phosphate residues between ca. 1.3 – 1.5 was observed in wine and pomace. Although two trials are not sufficient for the calculation of robust processing factors, the factors calculated on the basis of results from these two trials confirm and support the processing factor for wine of 1.3 reported in EFSA´s Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonate (ASB2012-16090).

Comments of zRMS:	Acceptable.

A 2.4 Residues in rotational crops

No new study on residues in rotational crops has been submitted.

A 2.5 Residues in livestock

No new study on residues in livestock has been submitted.

A 2.6 Other studies/information

None

Appendix 3 Pesticide Residue Intake Model (PRIMo)

Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**2,52**	ARfD (mg/kg bw):	
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:	**2013**	Year of evaluation:	

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
11 69

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
69,2	DE child	35,9	Apples	11,3	Oranges	3,8	Tomatoes	
50,5	NL child	18,8	Apples	9,3	Oranges	7,0	Potatoes	
42,3	WHO Cluster diet B	12,2	Tomatoes	3,2	Potatoes	3,0	Apples	
33,2	FR toddler	7,8	Apples	6,0	Potatoes	6,0	Oranges	
28,9	IE adult	3,1	Oranges	2,7	Potatoes	2,4	Apples	
24,7	DK child	6,9	Apples	4,9	Cucumbers	2,9	Potatoes	
24,3	UK Toddler	5,9	Oranges	5,1	Apples	4,2	Potatoes	
24,1	FR infant	7,4	Apples	4,9	Potatoes	2,7	Oranges	
23,2	SE general population 90th percentile	5,0	Potatoes	3,1	Apples	3,0	Tomatoes	
23,0	ES child	6,5	Oranges	3,9	Tomatoes	3,4	Apples	
22,8	PT General population	6,3	Potatoes	3,6	Tomatoes	3,2	Wine grapes	
22,0	WHO regional European diet	4,8	Potatoes	4,4	Tomatoes	2,0	Apples	
20,8	WHO cluster diet D	4,8	Potatoes	4,0	Tomatoes	2,0	Apples	
20,4	WHO cluster diet E	4,6	Potatoes	2,5	Apples	2,1	Tomatoes	
20,2	NL general	4,4	Oranges	3,5	Apples	3,3	Potatoes	
18,3	UK Infant	4,7	Apples	3,9	Potatoes	3,9	Oranges	
17,9	WHO Cluster diet F	4,1	Potatoes	2,7	Tomatoes	2,6	Oranges	
17,6	ES adult	3,8	Oranges	3,1	Tomatoes	2,3	Apples	
17,6	IT kids/toddler	5,7	Tomatoes	2,6	Apples	1,4	Oranges	
17,2	PL general population	6,1	Apples	4,1	Potatoes	3,5	Tomatoes	
16,6	FR all population	5,2	Wine grapes	1,7	Tomatoes	1,4	Apples	
15,6	IT adult	4,6	Tomatoes	2,4	Apples	1,1	Lettuce	
14,8	LT adult	5,6	Apples	3,8	Potatoes	2,5	Tomatoes	
14,0	UK vegetarian	2,6	Oranges	2,5	Tomatoes	1,8	Apples	
11,7	DK adult	2,3	Apples	1,8	Wine grapes	1,7	Potatoes	
11,0	UK Adult	1,7	Tomatoes	1,7	Oranges	1,7	Potatoes	
10,6	FI adult	2,9	Oranges	1,7	Tomatoes	1,5	Potatoes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl) is unlikely to present a public health concern.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: Alginur Bio Schutz

Active Substance: Potassium Phosphonates 342 g/L

(228 g/L Phosphonic acid equivalents)

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Tilco Biochemie GmbH

Date: August 2017

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for the plant protection product Alginur Bio Schutz containing the active substance Potassium phosphonates.in its intended uses in vine according to Appendix 3.

National Addenda are included containing country specific assessments for some annex points.

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation Alginur Bio Schutz

Code	-
plant protection product	Alginur Bio Schutz
applicant	Tilco Biochemie GmbH
date of application	22/01/2013
Formulation type (WP, EC, SC, …; density)	Soluble concentrate (SL) relative density: 1.345
active substance	Potassium phosphonates
Concentration of as	342 g/L (228 g/L Phosphonic acid equivalents)

5.2 Proposed use pattern

The critical intended use for exposure assessment is presented in Table 5.2-1. It has been selected from the individual intended uses in the Central Zone for Alginur Bio Schutz. A list of all intended uses within the Central Zone is given in Appendix 3.

Table 5.2-1: Critical use pattern of Alginur Bio Schutz

Crop	Growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Max application rate (g as/ha)	Max soil effective application rate (g as/ha)
Vines	BBCH 12-68	Spray	6 applications 7 days interval BBCH 12 – 60: Interception: 40% Season:Spring BBCH 61-67: Interception: 70% Season: summer BBCH 68: Interception: 70% Season. summer	Single application rates: BBCH 12 – 60: 1.5 l/ha Alginure BioSchutz 513 g a.s/ha (342 g/ha phosphonic acid eq.) BBCH 61 - 67: 3 l/ha Alginure BioSchutz 1026 g a.s/ha (684 g/ha phosphonic acid eq.) BBCH 68: **4.5 l/ha Alginure BioSchutz** **1539 g a.s./ha (1026 g/ha phosphonic acid eq.)** Cumulative max. application rate: **27 g/L Alginure BioSchutz** 9234 g a.s./ha (6156 g a.s./ha phosphonic acid)	Single application rates: BBCH 12 – 60: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 61 - 67: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 68: **461.7 g a.s./ha (307.8 g/ha phosphonic acid eq.)** Cumulative max. application rate: 2770.2 g a.s./ha (1846.8 g a.s./ha phosphonic acid)

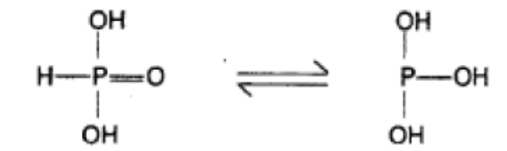
5.3 Information on the active substances

5.3.1 Potassium phosphonates

5.3.1.1 Identity, further information of Potassium phosphonates

Table 5.3-1: Identity, further information on Potassium phosphonates

Active substance (ISO common name)	Potassium phosphonates (formerly potassium phosphite)
IUPAC	Potassium hydrogen phosphonate and Dipotassium phosphonate
Function	Fungicide
Status under Reg. (EC) No 1107/2009	Approved
Date of approval	01/10/2013
Conditions of approval	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium phosphonates, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the risk to birds and mammals, - the risk of eutrophication of surface water, if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water. Conditions of use shall include risk mitigation measures, where appropriate. Conditions of use shall include risk mitigation measures, where appropriate.
Confirmatory data	The applicant shall submit confirmatory information as regards the long-term risk to insectivorous birds. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.
RMS	FR
Minimum purity of the active substance as manufactured (g/kg)	Technical concentrate (TK) with 31.6 to 32.6 % phosphonate ions (sum of hydrogen phosphonate and phosphonate ions) and 17.8 to 20.0 % potassium ≥ 990 g/kg on dry weight basis
Molecular formula	KH_2PO_3 [$HPO(OH)(O\text{-}K^+)$] and K_2HPO_3 [$HPO(O\text{-}K^+)^2$]
Molecular mass	Monopotassium phosphonate: 120.1g/mol and Dipotassium phosphonate: 158.2 g/mol Phosphonic acid: 80.5 g/mol

Structural formula	 In solution, phosphonic acid is formed from the hydrogen phosphonate and phosphonate ions. Phosphonic acid (active substance) occurs in the two tautomeric forms, phosphonic acid and phosphorous acid; the equilibrium favours the more stable phosphonic acid form:  phosphonic acid phosphorous acid

5.3.1.2 Physical and chemical properties of Potassium phosphonates

Physical and chemical properties of Potassiumphosphonates as agreed at EU level (see SANCO/ 10416/2013 rev 2 – 15 March 2013) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of Potassium phosphonates relevant for exposure assessment

Parameter	**Value**	**Reference**
Vapour pressure (at 20 °C) (Pa)	Not applicable	EFSA Journal 2012, 10(12): 2963
Henry's law constant (Pa × m³ × mol⁻¹)	Not applicable	EFSA Journal 2012, 10(12): 2963
Solubility in water (at 25 °C in mg/L)	Open For the solid salts, 25°C: KH_2PO_3: 192 g/100 g K_2HPO_3: 183 g/100 g For Phosphorous acid: 309 g/100 g @ 0°C 694 g/100 g @ 40°C	EFSA Journal 2012, 10(12): 2963 DAR (January 2005)
Partition co-efficient (at 25 °), log Pow	Not applicable	EFSA Journal 2012, 10(12): 2963
Dissociation constant, pKa	Phosphonic acid : $pK_1 = 2.0$, $pK_2 = 6.59$ Open	EFSA Journal 2012, 10(12): 2963
Hydrolytic degradation	Not applicable to an inorganic salt that is dissociated not hydrolysed	EFSA Journal 2012, 10(12): 2963

Photolytic degradation	Stable to direct aqueous photolytic degradation, no absorbance maxima in the UV/VIS	EFSA Journal 2012, 10(12): 2963
Quantum yield of direct phototransformation in water > 290 nm	Not calculated, No absorption after 200 nm	EFSA Journal 2012, 10(12): 2963
Photochemical oxidative degradation in air (calculation according to Atkinson)	Not relevant. There is no photochemical oxidation of the active substance Phosphorous acid: DT_{50}= 38.2 d (12-hr day; 1.5E6 OH/cm³) and 57.3 d (24-hr day, 0.5E6 OH/cm3) Calculation with AOP version 1.92	DAR (January 2005) Calculation of zRMS

5.3.1.3 Metabolites of Potassium phosphonates

Phosphate is the only relevant metabolite of potassium phosphonates (technical active substance) and phosphonic acid (actual active substance) in soil, surface water and sediment. Based on the criteria laid down in the EFSA guidance document Sanco/221/200-rev.10-final (2003) [1], phosphate is a metabolite of no concern for the groundwater. However, PECsw and PECsed values of phosphate ions were calculated for risk assessment of aquatic organisms.

5.4 Summary on input parameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Potassium phosphonates

No new studies have been submitted regarding route and rate of degradation in soil of potassium phosphonates by the applicant. The EU agreed DT_{50} values of phosphonic acid based on published and unprotected laboratory studies. The available DT_{50} values are considered sufficient by the zRMS for environmental exposure and risk assessment of Alginur Bio Schutz in its intended use in Vines.

However, a new GLP study (Völkel, 1998) on the degradation of phosphonic acid was submitted for EU approval of the active substance disodium phosphonate which also forms phosphonic acid as actual active substance. The study was considered acceptable by the RMS and is summarized in the DAR of disodium phosphonate from August 2009. In order to base the evaluation of phosphonic acid on all available data, the DT_{50} values of the new study will be used together with the EU approved DT_{50} values submitted for potassium phosphonates for environmental exposure and risk assessment of Alginur Bio Schutz.

The available DT_{50} values of phosphonic acid used for environmental exposure and risk assessment of potassium phosphonates are summarized in Table 5.4-1.

[1] Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

Table 5.4-1: Summary of aerobic degradation rates for phosphonic acid- laboratory studies (available EU agreed DT_{50} values for potassium phosphonates)

Soil type	pH	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Reference
San Joaquin clay loam soil	Not stated	28	Field capacity	96	319	196	1st order, r^2: 0.96	Adams & Conrad (1953)
US sandy loam	5.0	20	75% of 33kPa	133	442	88	1st order, r^2: 0.68	Lowden & Oddy (1999)
Hagenthal, clay loam	7.5	20	pF 2.0 – 2.5	179	750	-	DFOP, chi^2: 1.86 k1: 15.50854 k2: 0.00282 g: 0.1714	Völkel (1998)
				246	-	246	DFOP, slow phase	
Stolpe, Sandy Loam	6.3	20	pF 2.0 – 2.5	191	843	-	DFOP, chi^2: 6.76 k1: 0.07544 k2: 0.00247 g: 0.2011	
				281	-	281	DFOP, slow phase	
Vouvry II, silt loam	7.7	20	pF 2.0 – 2.5	29.65	98.50	29.7	SFO, chi2: 16.7%	
Geometric mean (n = 5)						**128.8**		
90th percentile (n=5)						**267**		

5.4.1.2 Field studies

Potassium Phosphonates

No field studies with potassium phosphonates are available.

5.4.2 Adsorption/desorption

Potassium Phosphonates

No new studies have been submitted regarding adsorption/desorption in soil of potassium phosphonates. The EU K_{doc} values of phosphonic acid based on a GLP study (Völkel, 2006) are considered sufficient by the zRMS for environmental exposure and risk assessment of Alginur Bio Schutz in its intended use in Vines. However, an additional GLP study (Völkel, 2008) was submitted for EU approval of the active substance Disodium phosphonate which also forms phosphonic acid as actual active substance. The study was considered acceptable by the RMS. For a summary of the study please refer to the DAR of Disodium phosphonate from August 2009. In order to base the evaluation of phosphonic acid on all available data, the adsorption parameter of the new study will be used together with the EU approved K_{doc} values submitted for potassium phosphonates for environmental exposure and risk assessment of Alginur Bio Schutz.

The available adsorption data of phosphonic acid used for environmental exposure and risk assessment of potassium phosphonates are summarized in Table 5.4-1.

Table 5.4-2: K_d, K_{doc} and 1/n (Freundlich exponent) values of phosphonic acid (available EU agreed K_d and K_{doc} values for potassium phosphonates)

Soil/ Soil Type	OC (%)	pH H_2O	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Mechthildshausen/ Loam	1.36	6.8	3.10^+	228^+	-	Völkel (2006)
Mussig/ Clay Loam	4.13	7.6	10.37^+	251^+	-	
Uffholtz/ Silty Clay Loam	2.67	5.0	15.67^+	587^+	-	
Speyer 2.2/ Sandy Loam	2.3	5.6	5.30^+	230^+	-	
Bretagne/ Silt Loam	1.95	5.5	18.96^+	972^+	-	
Vouvry II/ Silt Loam	1.7	7.7	4.177	246	0.88	Völkel (2008)
Hagenthal/ Clay Loam	1.18	7.5	12.82	1086	0.74	
Stolpe/ Sand	1.08	6.4	32.81	3038	$(0.66)^*$	
Fislis/ Silt Loam	2.6	7.2	5.01	193	0.78	
Mechtildshausen/ Loam	1.46	7.6	4.85	332	0.92	
Arithmetic mean (n=10)			**11.31**	**716.3**	**0.844**	

\+ adsorption values based on the lowest test concentration only (85 mg/L)
* 1/n values < 0.9 are considered as measurement artifact by the zRMS, thus the default value of 0.9 is used here

5.4.3 Rate of degradation in water and sediment

Potassium Phosphonates

No water/sediment study with potassium phosphonates was submitted for EU approval. According to the RMS, it is expected that phosphorous acid is rapidly adsorbed to the sediment where it could be slowly be oxidized to phosphate.

5.5 Estimation of concentrations in soil (PEC_{soil}) (KIIIA1 9.4)

PEC_{soil} calculations are based on the recommendations of the FOCUS workgroup on degradation kinetics. A soil bulk density of 1.5 g/cm^3, a soil depth of 5 cm and a tillage depth of 20 cm (arable crop)/5 cm (permanent crops) were assumed. The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in tables below.

Representative for the active substance Potassium phosphonates, PEC_{soil} values were calculated for phosphonic acid.

Table 5.5-1: Input parameters related to application for PEC_{Soil} calculations

Plant protection product	Alginur Bio Schutz
Crop:	Vines
Application rate:	6 x 4.5 l/ha = 6 x 6052.5* g/ha Alginur Bio Schutz 6 x 1539 g/ha potassium phosphonates (6 x 1026 g/ha phosphonic acid equivalents)
Crop interception:	70%
Number of application/interval:	6 applications/ 7 days interval
Soil relevant application rate	6 x 1815.7* g/ha Alginur Bio Schutz 5 x 461.7 g/ha potassium phosphonates (6 x 307.8 g/ha phosphonic acid equivalents)

* maximum cumulative application rate (L/ha) x relative density: 1345 g/L x (1-interception)

Table 5.5-2: Input parameter for phosphonic acid for PEC_{soil} calculation

Active substance	DT_{50} / DT_{90}	value in accordance to EU endpoint
Phosphonic acid	191/ 843 (DFOP, Maximum, Laboratory data, Parameter= k_1: 0.07544, k_2: 0.00247, g: 0.2011)	No (additional DT_{50} values available)

Due to the slow degradation of phosphonic acid in soil (DT_{90} > 365 d, SFO, Maximum, laboratory DT_{50} x 3.32 at 20°C and pF2), the accumulation potential of phosphonic acid needs to be considered. Therefore an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{bkgd}) considering a tillage depth of 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} for a soil depth of 5 cm.

Besides PEC_{act} values also PEC_{twa}, 21 d values are required for risk assessment. Additionally, PECact values were also calculated for the preparation assuming one accumulated application as a worst case assumption. The derived PEC_{act} and PEC_{twa},21 d values of phosphonic acid and the formulation Alginur Bio Schutz are presented in Table 5.5-3.

Table 5.5-3: Results of PEC_{soil} calculation for application of Alginur Bio Schutz for the intended use in Vines (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm)

active substance/ preparation	soil relevant application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa} 21 d (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Phosphonic acid	6 x 307.8 g/ha	2.0775	1.8291	5	1.2874	3.3649
Alginur Bio Schutz	6 x 1815.7* g/ha	12.2560	-	-	-	-

* maximum cumulative application rate (L/ha) x relative density: 1345 g/L x (1-interception)

5.6 Estimation of concentrations in surface water and sediment (PECsw/PECsed) (KIIIA1 9.7)

PEC_{sw} and PEC_{sed} calculations were provided by the applicant in two studies, the study O'Brien (2013b) and the study Wiglinghoff (2014). The studies are summarized below.

Study O'Brien (2013b):

Reference:	KIIIA 9.7.1
Author:	O'Brien, K.
Report:	Calculation of predicted environmental concentrations in surface water (PECsw) and sediment (PECsed) for phosphonic acid and phosphate ions representative substance Potassium phosphonates using FOCUS SW modelling software and scenarios
Date:	15.03.2013b
Guideline	Generic guidance for FOCUS surface water Scenarios (2011)
GLP:	Not applicable

Representative for the active substance Potassium phosphonates, PEC_{sw} and PEC_{sed} values were calculated for phosphonic acid and for phosphate ions. Potassium ions are considered to be of minor importance with regard to naturally occurring amounts in surface water and predicted concentrations are not investigated here.

FOCUS SW Step 1 & 2 calculations were performed for phosphonic acid, FOCUS SW step 1, 2 & 3 calculations were performed for phosphate ions. Step 1 and 2 calculations were performed with the model Step 1-2 in Focus, version 2.1, Step 3 calculations were performed using model Swash version 3.1.

The application related input parameter for PEC_{sw} and PEC_{sed} calculations are presented in Table 5.6-1.

Table 5.6-1: Input parameters related to application for $PEC_{sw/sed}$ calculations

Plant protection product	Alginur Bio Schutz
FOCUS Crop:	Vines, early application Vines, late application
FOCUS location:	Step 1: not relevant Step 2: North Europe Step 3: D6, R1, R2, R3 and R4
Application rate:	Early application: 6 x 1.5 L/ha Alginure Bio Schutz 6 x 342 g/ha phosphonic acid equivalents 6 x 403 g/ha phosphate ions* Late application: 6 x 6 L/ha Alginure Bio Schutz 6 x 1368 g/ha phosphonic acid equivalents 6 x 1613 g/ha phosphate ions*
Number of application/interval:	6 applications/ 7 days interval
Application time	Step 1: not relevant Step 2: Mar-May for early application Jun- Sep for late application Step 3: 10 days after emergence for early application

	65 days before harvest for late application (length of application window: 65 days)
Application method:	Spray
Crop interception:	Step 1: not relevant Step 2: Minimal crop cover for early application Full crop cover for late application Step 3: interception internally derived depending on growth stage

* Molar weight correction factor applied to the application rate: 94.9 (molecular weight of phosphate)/80.5 (molecular weight of phosphonic acid) = 1.179

The relevant input parameters for phosphonic acid and phosate ions used for PEC_{sw} and PEC_{sed} calculation are summarized in Table 5.6-2 and Table 5.6-3.

Table 5.6-2: Input parameters for phosphonic acid used for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	Phosphonic acid		
Molecular weight	80.5	yes	
Water solubility (mg/L)	1 875 000	yes	
Kf,oc (mL g-1)	10.7	yes	Arithmetic mean, Kd, n=5
	10000	yes	worst case default
DT_{50},soil (d)	196	yes	Laboratory, maximum, n= 2 (20°C, pF2, SFO)
DT_{50},water (d)	1000	yes	Default value
DT_{50},sed (d)	1000	yes	Default value
DT_{50},whole system (d)	1000	yes	Default value

Table 5.6-3: Input parameters for phosphate ions used for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	Phosphate ions		
Molecular weight	94.9	Yes	
Water solubility (mg/L)	1 875 000	yes	
Saturated vapour pressure (Pa)	1 x 10^{-20} (20°C)		Default worst case
Kf,oc (mL g-1)	10 / 10000	yes	Two sets of simulations with worst case default values

1/n (-)	1		default
DT_{50},soil (d)	1000	yes	Default value
DT_{50},water (d)	1000	yes	Default value
DT_{50},sed (d)	1000	yes	Default value
DT_{50},whole system (d)	1000	yes	Default value
DT_{50},crop (d)	10		default
Plant uptake	0		Conservative default value
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)		default

The days of application dates set by the Pesticide Application timing calculator (PAT) for Step 3 modelling of a single application of Alginure Bio Schutz are given in Table 5.6-4, the dates set by PAT for Step 3 modelling of 6 applications of Alginure Bio Schutz are given in Table 5.6-5.

Table 5.6-4: Application dates set by the PAT for Step 3 calculations of a single application of Alginure Bio Schutz to vines

FOCUS Crop	FOCUS Scenario	Water body	Possible days of application entered in SWASH	day of application set by SWASh
Vines, early	D6	Ditch	11 February to 13 March	27 February
	R1	Pond & Stream	25 April to 25 May	26 April
	R2	Steam	25 March to 24 April	22 April
	R3	Stream	11 April to 11 May	11 April
	R4	Stream	20 March to 19 April	21 March
Vines, late	D6	Ditch	11 October to 10 November	11 October
	R1	Pond & Stream	31 September to 30 October	06 October
	R2	Steam	31 August to 30 September	29 September
	R3	Stream	02 October to 01 November	02 October
	R4	Stream	21 August to 20 September	21 August

Table 5.6-5: Application dates set by the PAT for Step 3 calculations of 6 applications of Alginure Bio Schutz to vines

FOCUS Crop	FOCUS Scenario	Water body	Possible days of application entered in SWASH	day of application set by SWASh
Vines, early	D6	Ditch	11 February to 17 April	27 Feb/14 Mar/25 Mar/01 Apr/09 Apr/16 Apr
	R1	Pond & Stream	25 April to 29 June	26 Apr/08 May/15 May/31 May/12 Jun/24Jun
	R2	Steam	25 March to 29 May	30 Mar/22 Apr/29 Apr/06 May/20 May/27 May
	R3	Stream	11 April to 15 June	11 Apr/18 Apr/26 Apr/06 May/16 May/23 May

	R4	Stream	20 March to 24 May	20 Mar/28 Mar/29 Apr/06 May/13 May/20 May
Vines, late	D6	Ditch	06 September to 10 November	06 Oct/13 Oct/20 Oct/27 Oct/ 03 Nov/10 Nov
	R1	Pond & Stream	26 August to 30 October	26 Aug/02 Sep/17 Sep/24 Sep/01 Oct/08 Oct
	R2	Steam	27 July to 30 September	27 Jul/03 Aug/10 Aug/14 Sep/21 Sep/28 Sep
	R3	Stream	28 August to 01 November	28 Aug/23 Sep/01 Oct/08 Oct/22 Oct/29 Oct
	R4	Stream	17 July to 20 September	20 Jul/27 Jul/03 Aug/10 Aug/17 Aug/18 Sep

The calculated global maximum PEC_{sw} and PEC_{sed} Step 1 and 2 values of phosphonic acid and phosphate ions for the worst-case application scenarios of Alginur Bio Schutz in its intended use in vines are summarized in Table 5.6-6, Table 5.6-7, Table 5.6-8 and Table 5.6-9. The calculated global maximum PEC_{sw} and PEC_{sed} Step 3 values of phosphate ions are summarized in Table 5.6-10. No FOCUS Step 3 PECsw and PECsed were provided for phophonic acid for early and late applications of Alginure Bio Schutz in vines. Forp phosphate ions, no FOCUS Step 3 PECsw and PEC sed values were provided for late application of Alginure Bio Schutz in vines.

Table 5.6-6: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of phosphonic acid for the application of Alginur Bio Schutz in Vines -Early application (Koc = 10.7 mg/L)

FOCUS Crop	Application number and rate	FOCUS STEP	PECsw (µg/L)	PECsed (µg/kg)
Vines, early app.	6 x 342 g/ha	Step 1	692.8	74.05
	1 x 342 g/ha	Step 2, North Europe	16.34	1.745
	6 x 342 g/ha	Step 2, North Europe	90.66	9.686
Vines, late app	6 x 1368 g/ha	Step 1	2920	311.6
	1 x 1368 g/ha	Step 2, North Europe	62.76	6.692
	6 x 1368 g/ha	Step 2, North Europe	321.9	34.33

Table 5.6-7: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of phosphonic acid for the application of Alginur Bio Schutz in Vines -Early application (Koc = 10000 mg/L)

FOCUS Crop	Application number and rate	FOCUS STEP	PECsw (µg/L)	PECsed (µg/kg)
Vines, early app.	6 x 342 g/ha	Step 1	66.18	4900
	1 x 342 g/ha	Step 2, North Europe	3.077	115.4
	6 x 342 g/ha	Step 2, North Europe	6.926	640.6
Vines, late app	6 x 1368 g/ha	Step 1	410.5	20600
	1 x 1368 g/ha	Step 2, North Europe	36.61	442.6
	6 x 1368 g/ha	Step 2, North Europe	43.95	2270

Table 5.6-8: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of phosphate ions for the application of Alginur Bio Schutz in Vines -Early application (Koc = 10 mg/L)

FOCUS Crop	Application number and rate	FOCUS STEP	PECsw (µg/L)	PECsed (µg/kg)
Vines, early app.	6 x 403 g/ha	Step 1	817.2	81.63
	1 x 403 g/ha	Step 2, North Europe	19.45	1.942
	6 x 403 g/ha	Step 2, North Europe	112.4	11.23
Vines, late app	6 x 1613 g/ha	Step 1	3440	343.7
	1 x 1613 g/ha	Step 2, North Europe	74.41	7.417
	6 x 1613 g/ha	Step 2, North Europe	390.8	38.96

Table 5.6-9: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of phosphate ions for the application of Alginur Bio Schutz in Vines -Early application (Koc = 10000 mg/L)

FOCUS Crop	Application number and rate	FOCUS STEP	PECsw (µg/L)	PECsed (µg/kg)
Vines, early app.	6 x 403 g/ha	Step 1	77.99	5770
	1 x 403 g/ha	Step 2, North Europe	3.626	137.3
	6 x 403 g/ha	Step 2, North Europe	8.550	793.7
	6 x 1613 g/ha	Step 1	484.1	24300

Vines, late app	1 x 1613 g/ha	Step 2, North Europe	43.16	254.4
	6 x 1613 g/ha	Step 2, North Europe	51.82	2750

Table 5.6-10: Maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} of phosphate ions for the application of Alginur Bio Schutz in Vines -Early application (Koc = 10 mg/L)

FOCUS Crop	No. of applications	FOCUS Scenario	Water Body	PECsw (µg/L)	PECsed (µg/kg)
Vines, early app.	1	D6	Ditch	18.312	13.654
	1	R1	Pond	0.078	0.041
	1	R1	Stream	1.661	0.058
	1	R2	Stream	2.206	0.052
	1	R3	Stream	14.357	1.372
	1	R4	Stream	1.660	0.058
	6	D6	Ditch	136.76	104.95
	6	R1	Pond	0.476	0.290
	6	R1	Stream	13.253	1.219
	6	R2	Stream	4.480	0.505
	6	R3	Stream	30.189	2.891
	6	R4	Stream	5.517	0.454
Vines, late app	1	D6	Ditch	104.60	80.798
	1	R1	Pond	0.985	0.534
	1	R1	Stream	20.308	0.816
	1	R2	Stream	27.221	0.752
	1	R3	Stream	28.623	1.948
	1	R4	Stream	51.235	5.088
	6	D6	Ditch	633.2	485.4
	6	R1	Pond	3.941	2.431
	6	R1	Stream	16.097	0.834
	6	R2	Stream	21.577	0.701
	6	R3	Stream	77.560	7.794
	6	R4	Stream	87.873	8.701

Study Wiglinghoff (2013):

Reference:	KIIIA 9.7.1
Author:	Wiglinghoff, E.
Report:	Calculation of predicted environmental concentrations in surface water (PECsw) and sediment (PECsed) for phosphonic acid and phosphate ions representative for the active substance Potassium phosphonates using FOCUS SW modelling software and scenarios
Date:	01.06.2013
Guideline	Generic guidance for FOCUS surface water Scenarios (2011)
GLP:	Not applicable

Representative for the active substance Potassium phosphonates, PEC_{sw} and PEC_{sed} values were calculated for phosphonic acid and for phosphate ions. The additional calculations were performed only for late applications of Alginure Bio Schutz in vines starting with BBCH 50.

FOCUS SW Step 1 & 2 calculations were performed for phosphonic acid, FOCUS SW step 1, 2 & 3 calculations were performed for phosphate ions. Step 1 and 2 calculations were performed with the model Step 1-2 in Focus, version 2.1, Step 3 calculations were performed using the drift calculator 1.1, MACRO 4.4.2 and PRZM 1.5.6 and TOXSWA 3.3.1 all implemented in SWASH version 3.1.

The application related input parameter for PEC_{sw} and PEC_{sed} calculations are presented in Table 5.6-1.

Table 5.6-11: Application related input parameters for $PEC_{sw/sed}$ calculations

Plant protection product	Alginur Bio Schutz
FOCUS Crop:	Vines, late application
FOCUS location:	Step 1: not relevant Step 2: North Europe Step 3: D6, R1, R2, R3 and R4
Application rate:	Late application BBCH 50-70 (application scheme A) 6 x 3.0 l/ha Alginure Bio Schutz 6 x 684 g/ha phosphonic acid equivalents 6 x 806 g/ha + 275[a] phosphate ions* Late application BBCH 75-89 (application scheme B) 6 x 6.0 l/ha Alginure Bio Schutz 6 x 1368 g/ha phosphonic acid equivalents 6 x 1613 g/ha + 549[a] phosphate ions*
Number of application/interval:	6 applications/ 7 days interval
Application time	Step 1: not relevant Step 2: late application (June to September) Step 3: Application scheme A: late application 65 days before harvest (length of application window: 65 days) Application scheme B: late application 130 days before harvest

Application method:	Spray
Crop interception:	Step 1: not relevant Step 2: Full crop cover Step 3: interception internally derived depending on growth stage

a additional amount for additive
* Molar weight correction factor applied to the application rate: 94.9 (molecular weight of phosphate)/80.5 (molecular weight of phosphonic acid) = 1.179

The same input parameters for phosphonic acid and phosate ions as already used in the study O'Brien (2013b) were used for PEC_{sw} and PEC_{sed} calculation. The input parameter for phosphonic acid and phosate ions are summarized Table 5.6-2 and Table 5.6-3.

The days of application dates set by the Pesticide Application timing calculator (PAT) for Step 3 modelling of 6 applications of Alginure Bio Schutz are given in Table 5.6-12.

Table 5.6-12: Application dates set by the PAT for Step 3 calculations of multiple late applications of Alginure Bio Schutz to vines

FOCUS Crop	FOCUS Scenario	Water body	Possible days of application entered in SWASH	day of application set by SWASh
Vines, late (scheme A)	D6	Ditch	07 August to 06 September	03 Jul/10 Jul/17 Jul/24 Jul/31 Jul/07 Aug 1986
	R1	Pond & Stream	27 July to 26 August	27 Jun/05 Jul/12 Jul/19 Jul/26 Jul/03 Aug 1978
	R2	Steam	27 June to 27 July	23 May/01 Jun/10 Jun/19 Jun/26 Jun/ 03 Jul 1977
	R3	Stream	29 July to 28 August	24 Jun/01 Jul/31 Jul/07 Aug/14 Aug/26 Aug 1975
	R4	Stream	17 June to 17 July	13 May/20May/27 May/04 Jun/08 Jul/15 Jul 1984
Vines, late (scheme B)	D6	Ditch	11 October to 10 November	06 Oct/13 Oct/20 Oct/27 Oct/ 03 Nov/10 Nov 1986
	R1	Pond & Stream	31 September to 30 October	26 Aug/02 Sep/17 Sep/24 Sep/01 Oct/08 Oct 1978
	R2	Steam	31 August to 30 September	27 Jul/03 Aug/10 Aug/14 Sep/21 Sep/28 Sep 1989
	R3	Stream	02 October to 01 November	28 Aug/23 Sep/01 Oct/08 Oct/22 Oct/29 Oct 1975
	R4	Stream	21 August to 20 September	20 Jul/27 Jul/03 Aug/10 Aug/17 Aug/18 Sep 1985

The calculated global maximum PEC_{sw} and PEC_{sed} Step 1 and 2 values of phosphonic acid and phosphate ions for the late application scenarios of Alginur Bio Schutz in its intended use in vines are summarized in Table 5.6-13, Table 5.6-14, Table 5.6-15 and Table 5.6-16. The calculated global maximum PEC_{sw} and PEC_{sed} Step 3 values of phosphonic acid and phosphate ions are summarized in Table 5.6-17 and Table 5.6-18.

Table 5.6-13: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of phosphonic acid for the application of Alginur Bio Schutz in Vines - late application (Koc = 10.7 mg/L)

FOCUS Crop	Application number and rate	FOCUS STEP	PECsw (µg/L)	PECsed (µg/kg)
Vines, late (scheme A)	6 x 684 g/ha	Step 1	1460	155.79
	1 x 684 g/ha	Step 2, North Europe	31.38	3.35
	6 x 684 g/ha	Step 2, North Europe	160.93	17.16
Vines, late (scheme B)	6 x 1368 g/ha	Step 1	2920	311.6
	1 x 1368 g/ha	Step 2, North Europe	62.76	6.692
	6 x 1368 g/ha	Step 2, North Europe	321.9	34.33

Table 5.6-14: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of phosphonic acid for the application of Alginur Bio Schutz in Vines -late application (Koc = 10000 mg/L)

FOCUS Crop	Application number and rate	FOCUS STEP	PECsw (µg/L)	PECsed (µg/kg)
Vines, late (scheme A)	6 x 684 g/ha	Step 1	205.26	10 300
	1 x 684 g/ha	Step 2, North Europe	18.30	221.30
	6 x 684 g/ha	Step 2, North Europe	21.97	1140
Vines, late (scheme B)	6 x 1368 g/ha	Step 1	410.5	20 600
	1 x 1368 g/ha	Step 2, North Europe	36.61	442.6
	6 x 1368 g/ha	Step 2, North Europe	43.95	2270

Table 5.6-15: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of phosphate ions for the application of Alginur Bio Schutz in Vines -late application (Koc = 10 mg/L)

FOCUS Crop	Application number and rate	FOCUS STEP	PECsw (µg/L)	PECsed (µg/kg)
Vines, late (scheme A)	6 x 1081 g/ha	Step 1	2310	230.32
	1 x 1081 g/ha	Step 2, North Europe	49.87	4.97
	6 x 1081 g/ha	Step 2, North Europe	261.9	26.11
	6 x 2162 g/ha	Step 1	4610	460.65

Vines, late (scheme B)	1 x 2162 g/ha	Step 2, North Europe	99.74	9.94
	6 x 2162 g/ha	Step 2, North Europe	523.81	52.23

Table 5.6-16: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of phosphate ions for the application of Alginur Bio Schutz in Vines -late application (Koc = 10000 mg/L)

FOCUS Crop	Application number and rate	FOCUS STEP	PECsw (µg/L)	PECsed (µg/kg)
Vines, late (scheme A)	6 x 403 g/ha	Step 1	324.40	16300
	1 x 403 g/ha	Step 2, North Europe	28.93	351.44
	6 x 403 g/ha	Step 2, North Europe	34.73	1850
Vines, late (scheme B)	6 x 2162 g/ha	Step 1	648.81	32600
	1 x 2162 g/ha	Step 2, North Europe	57.86	702.87
	6 x 2162 g/ha	Step 2, North Europe	69.45	3690

Table 5.6-17: Maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} of phosphonic acid for a single and multiple applications of Alginur Bio Schutz in Vines -late application (Koc = 10 mg/L)

FOCUS Crop	No. of applications	FOCUS Scenario	Water Body	PECsw (µg/L)	PECsed (µg/kg)
Vines, late (scheme A)	1	D6	Ditch	11.748	8.028
	1	R1	Pond	0.418	0.227
	1	R1	Stream	8.377	0.242
	1	R2	Stream	11.543	0.323
	1	R3	Stream	12.138	0.636
	1	R4	Stream	8.611	0.349
	6	D6	Ditch	58.463	43.954
	6	R1	Pond	2.179	1.369
	6	R1	Stream	9.181	0.846
	6	R2	Stream	14.974	1.697
	6	R3	Stream	32.915	3.270
	6	R4	Stream	6.824	0.552
Vines, late (scheme B)	1	D6	Ditch	34.111	26.120
	1	R1	Pond	0.836	0.461
	1	R1	Stream	17.221	0.700
	1	R2	Stream	23.083	0.645
	1	R3	Stream	24.273	1.674
	1	R4	Stream	43.292	4.352
	6	D6	Ditch	233.434	171.339
	6	R1	Pond	3.342	2.102
	6	R1	Stream	13.653	0.717
	6	R2	Stream	18.301	0.602
	6	R3	Stream	61.363	6.677
	6	R4	Stream	73.359	7.356

Table 5.6-18: Maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} of phosphate ions for a single and multiple applications of Alginur Bio Schutz in Vines -late application (Koc = 10 mg/L)

FOCUS Crop	No. of applications	FOCUS Scenario	Water Body	PECsw (µg/L)	PECsed (µg/kg)
Vines, late (scheme A)	1	D6	Ditch	51.805	39.161
	1	R1	Pond	0.660	0.352
	1	R1	Stream	13.238	0.378
	1	R2	Stream	18.242	0.503
	1	R3	Stream	19.182	0.991
	1	R4	Stream	13.607	0.544
	6	D6	Ditch	293.681	221.692
	6	R1	Pond	3.440	2.117
	6	R1	Stream	15.511	1.302
	6	R2	Stream	23.742	2.652
	6	R3	Stream	54.305	5.305
	6	R4	Stream	10.788	0.935
Vines, late (scheme B)	1	D6	Ditch	139.915	107.956
	1	R1	Pond	1.321	0.714
	1	R1	Stream	27.224	1.091
	1	R2	Stream	36.491	1.006
	1	R3	Stream	38.371	2.603
	1	R4	Stream	68.618	6.798
	6	D6	Ditch	847.581	649.057
	6	R1	Pond	5.281	3.255
	6	R1	Stream	21.576	1.116
	6	R2	Stream	28.921	0.938
	6	R3	Stream	91.176	10.415
	6	R4	Stream	117.524	11.611

Comments of zRMS on the studies O'Brien (2013b) and Wiglinhoff (2013):

Highest application rates of Alginure BioSchutz, relevant for highest spray drift rates, according to the critical use pattern listed in Table 5.2-1 would be 6 x 4.5 L/ha Alginure BioSchutz (equivalent to 1539 g a.s./ha potassium phosphonates and 1026 g/ha phosphonic acid). However, an application of 5 x 3 l/ha Alginure BioSchutz (equivalent to 6 x 1026 g/ha potassium phosphonates and 6 x 684 g/ha phosphonic acid) together with 1 x 4.5 L/ha Alginure BioSchutz (equivalent to 1 x 1539 g/ha potassium phosphonates and 1 x 1026 g/ha phosphonic acid), since the highest application rate is only intended for BBCH 68. The intended application rates are generally lower than the modeled highest application rates for late application in the studies O'Brien (2013b) and Wiglinghoff (2013) of 6 x 6 L/ha Alginure BioSchutz (equivalent to 342 g/ha potassium phosphonates and 403 g/ha phosphonic acid). Thus, the PECsw and PECsed derived in the studies are considered as worst case covering the intended late applications of Alginure BioSchutz in vines.

However, exposure due to run-off and drainage might be higher in spring despite the lower intended application rate of 6 x 1.5 l/ha Alginure BioSchutz (equivalent to 6 x 513 g a.s/ha potassium phosphonates and 6 x 342 g/ha phosphonic acid). These application rates are equal to the application rates used in the study O'Brien (2013a). Thus, the PECsw and PECsed derived in the study O'Brien (2013b) are considered acceptable for the intended spring applications of Alginure BioSchutz in vines.

The chosen application dates chosen for spring (early) and summer (late) is also considered acceptable by the zRMS. However, it should be noted that PECsw and PECsed values derived with FOCUS SW are not used for authorization of PPP in Germany. Thus, the member states need to decide by themselves which of the modeled FOCUS scenarios are applicable for their climatic situation.

Also the substance related input parameters for phosphonic acid and phosphate ions chosen in the studies O'Brien (2013b) and Wiglinghoff (2013) are equal or more conservative than the input parameter, that would be chosen by the zRMS and are therefore acceptable.

Thus, the derived PECsw and PECsed values of the studies O'Brien (2013b) and Wiglinghoff (2013) are considered acceptable by the zRMS and will be used for risk assessment.

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for the active substance (Tier 1 and 2)

Groundwater contamination by direct leaching of the active substance and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

The PEC_{GW} of phosphoinc acid in ground water have been assessed by the applicant in the study O'Brien (2013a) using standard FOCUS scenarios to obtain outputs from the FOCUS PEARL 4.4.4. The study is summarized below.

Study O'Brien (2013a):

Reference:	KIIIA 9.6.1
Author:	O'Brien, K.
Report:	Calculation of predicted environmental concentrations in groundwater (PECGW) for phosphonic acid using the model software FOCUS PEARL 4.4.4
Date:	16.01.2013a
Guideline	FOCUS $_{GW}$ Generic Guidance for Tier 1, FOCUS Ground Water Assessments Version 2.0, January 2011
GLP:	Not applicable

The application related input parameters of Alginur Bio Schutz used for PECgw modelling are presented in Table 5.7-1 and Table 5.7-2.

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling

plant protection product	Alginur Bio Schutz
application rate (kg as/ha)	Early application (BBCH 12-60): 6 x 0.342 kg/ha phosphonic acid equivalents Late application (BBCH 75—89): 6 x 1.368 kg/ha phosphonic acid equivalents
interception (%)	Early application (BBCH 12-60):

	40% Late application (BBCH 75—89): 85%
Soil effecitve application rate (kg as/ha)	Early application (BBCH 12-60): 6 x 0.2052 kg/ha phosphonic acid equivalents Late application (BBCH 75—89): 6 x 0.2052 kg/ha phosphonic acid equivalents
crop (crop rotation)	Vines
relative application date	Early application: First application: 10 days after emergence Late application: First application: 35 days before harvest
Interval (d)	7
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
simulation period (years)	26

Table 5.7-2: Application timing used in the modelling study

Crop	Scenario	Application timing	
		1st appl. for grapevines, early	1st appl. for grapevines, late
Vines	Châteaudun	11 April	20 September
	Hamburg	11 May	18 September
	Kremsmünster	11 May	18 September
	Piacenza	11 April	20 September
	Porto	25 March	19 August
	Sevilla	10 April	19 October
	Thiva	25 March	08 September

Generally,, the standard FOCUS model parameterisations are not designed to simulate the leaching of inorganic compounds. However, the oxidation of phosphonic acid and its salts to phosphate had been demonstrated to be a microbially mediated process. Thus, the standard substance transformation rate factor reductions with depth down the soil profile and routines for adjusting substance transformation rate with changing soil moisture content and temperature were maintained by the applicant. This approach was therefore already considered acceptable for EU approval of potassium phosphonates.

However, since the adsorption of Phosphonic acid is not expected to be well correlated with the organic carbon content down the soil profile, the parameterisation for adsorption was modified by the applicant according to the approach also used for EU approval of Potassium phosphonates: Adsorption in the top soil layer was implemented based on the arithmetic mean of the EU agreed K_d values. Factors for adsorption down the soil profile were reduced using the same reduction factors as implemented in the scenarios for reducing substance transformation rates with increasing soil depth. The factor was 1 for up to 30 cm depth, 0.5 for the layer just below the plough layer (generally ca. 30 cm - 60 cm), 0.3 for the subsequent layer (generally 60 cm to 1 m) and 0.0 below 1 m depth. For each soil profile and horizon the "Non Default Factors for Depth Effect" for sorption (FacZSor) were set in PEARL accordingly. The factors for the effect of depth on transformation (FacZTra) remained unchanged for each soil horizon. The relevant FacZSor for each crop-relevant scenario are listed in Table 5.7-4.

Table 5.7-3: Factors for adsorption down the soil profile of each crop-relevant FOCUS groundwater scenario in FOCUS PEARL 4.4.3

Horizon	FacZSor						
	Châteaudun	Hamburg	Kremsmünster	Piacenza	Porto	Sevilla	Thiva
1	1	1	1	1	1	1	1
2	0.5	0.5	0.5	0.5	0.5	1	0.5
3	0.5	0.3	0.5	0.5	0.3	0.5	0.5
4	0.3	0.3	0.3	0.3	0	0.3	0.3
5	0	0.3	0	0.3	-	0	0.3
6	0	0	-	0	-	0	0

The relevant input parameters for phosphonic acid used for PEC_{gw} simulation are summarized in Table 5.7-4.

Table 5.7-4: Input parameters related to active substance for PEC_{GW} modelling

Parameter	Phosphonic acid	Remarks/Reference
molecular weight (g/mol)	80.5	EU agreed endpoint
Water solubility [mg L^{-1}]	187500	EU agreed endpoint
Molar enthalpy of dissolution [kJ mol^{-1}]	27	FOCUS recommendation
Vapour pressure [Pa]	1 x 10^{-20} (at 20°C)	Worst default value
Molar enthalpy of vaporization [kJ mol-^{1}]	95	FOCUS recommendation
Diffusion coefficient in water [m^2 d^{-1}]	4.3 x 10^{-5} (at 20°C)	FOCUS recommendation
Diffusion coefficient in gas [m^2 d^{-1}]	0.43 (at 20°C)	FOCUS recommendation
DT_{50} in soil (d)	196	EU agreed endpoint Laboratory data, Maximum (1st order, pF2,20°C, n=2)
K_f	10.7	EU agreed endpoint arithmetic mean, n=5
1/n	0.9	EU agreed endpoint default
pH dependency	No	EU agreed
plant uptake factor	0.5	EU agreed endpoint Default value for systemic compounds

The simulated PECgw for Phosphonite acid using FOCUS PEARL 4.4.3 are summarized in Table 5.7-5.

Table 5.7-5: PEC_{GW} at 1 m soil depth phosphonic acid for the application of Alginur Bio Schutz in Vines (Early application)

Crop	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PEARL 4.4.3
		Phosphonic acid
Vines	**Châteaudun**	0.237
	Hamburg	0.258
	Kremsmünster	0.561
	Piacenza	0.090
	Porto	0.353
	Sevilla	0.020
	Thiva	< 0.001

Table 5.7-6: PEC_{GW} at 1 m soil depth phosphonic acid for the application of Alginur Bio Schutz in Vines (Late application)

Crop	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PEARL 4.4.3
		Phosphonic acid
Vines	**Châteaudun**	0.260
	Hamburg	0.295
	Kremsmünster	0.626
	Piacenza	0.117
	Porto	0.478
	Sevilla	0.023
	Thiva	<0.001

Comments of zRMS on study O'Brien (2013a):

The substance related input parameters for phosphonic acid chosen in the study O'Brien (2013a) are equal or more conservative than the input parameter, that would be chosen by the zRMS and are therefore acceptable.

The critical use pattern chosen for early application of potassium phosphonate is equal to the intended critical use pattern of Alginur Bio Schutz given in Table 5.2-1 and is thus also acceptable by the zRMS. However, the soil related application rates chosen in the study O'Brien (2013a) for late application is smaller than the intended critical use pattern of Alginur Bio Schutz given in Table 5.2-1, since for a BBCH code of 68 one soil related application rate of 307.8 g/ha phosphonic acid will reach the soil. Thus, the zRMS repeated the groundwater modelling for the summer application of Alginure Bio Schutz (BBCH 61-68) assuming 5 applications of 205.2 g/ha phosphonic acid and one application of 307.8 g/ha phosphonic acid with an interval of 7 days between application. The application dates for the first application are presented in Table 5.7-7. For the remaining input parameters for PEARL 4.4.4 identical values as used in the study O'Brien (2013a) were chosen by the zRMS.

Table 5.7-7: Application timing used by the zRMS (summer application)

Crop	Scenario	Application timing
		1st appl. for grapevines, BBCH 61
Vines	Châteaudun	03/08
	Hamburg	17/07
	Kremsmünster	17/07
	Piacenza	03/08
	Porto	02/08
	Sevilla	21/06
	Thiva	0407

The modeled groundwater concentrations for phophonic acid for the intended summer application of Alginure Bio Schutz in vine are presented in Table 5.7-8.

Table 5.7-8: PEC_{GW} at 1 m soil depth phosphonic acid for the application of Alginur Bio Schutz in Vines (summer application)- calculation of zRMS

Crop	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PEARL 4.4.3
		Phosphonic acid
Vines	**Châteaudun**	0.291
	Hamburg	0.391
	Kremsmünster	0.689
	Piacenza	0.139
	Porto	0.520
	Sevilla	0.023
	Thiva	<0.001

According to the PEC_{GW} modelling with FOCUS PEARL 4.4.3, a groundwater contamination with the active substance phosphonic acid at concentrations ≥ 0.1 µg/L cannot be excluded for the FOCUS groundwater scenarios Châteaudun, Hamburg, Kremsmünster, Piacenza, Porto, Sevilla. For the FOCUS groundwater scenarios Thiva and Sevilla, a groundwater contamination at concentrations of ≥ 0.1 µg/L is not expected. Maximum simulated concentrations of phosphonic acid are 0.260 µg/L for the scenario Châteaudun, 0.295 µg/L for the scenario Hamburg, In concordance with the EFSA conclusions (EFSA Journal 2012; 10(12): 2963) on Potassium phosphonates, these predicted groundwater concentrations are far below a health based drinking water limit of 3 mg/L for phosphonic acid that was calculated following the WHO 2009[2] guideline.

[2] WHO (World Health Organization), 2009. WHO Guidelines for Drinking-water Quality, Policies and Procedures used in updating the WHO Guidelines for Drinking-water Quality, 33 pp.

5.7.2 Higher tier leaching assessment (Tier 3)

No lysimeter or field leaching studies were performed or are required necessary for Potassium phosphonates.

5.7.3 Summary of risk assessment for ground water

According to the PEC_{GW} modelling with FOCUS PEARL 4.4.3, a groundwater contamination with the active substance phosphonic acid at concentrations ≥ 0.1 µg/L can not be excluded for the FOCUS groundwater scenarios Châteaudun, Hamburg, Kremsmünster, Piacenza, Porto, Sevilla. For the FOCUS groundwater scenarios Thiva and Sevilla, a groundwater contamination at concentrations of ≥ 0.1 µg/L is not expected. Maximum simulated concentrations of phosphonic acid are 0.260 µg/L for the scenario Châteaudun, 0.295 µg/L for the scenario Hamburg, In concordance with the EFSA conclusions (EFSA Journal 2012; 10(12): 2963) on Potassium phosphonates, these predicted groundwater concentrations are far below a health based drinking water limit of 3 mg/L for phosphonic acid that was calculated following the WHO 2009[3] guideline which was applied by the Comission in SANCO/ 10416/2013 rev 2 – 15 March 2013 as threshold value for an acceptable risk for groundwater.

5.8 Potential of active substance for aerial transport

No data on the vapour pressure of potassium phosphonates were submitted or required for the Annex I inclusion.

[3] WHO (World Health Organization), 2009. WHO Guidelines for Drinking-water Quality, Policies and Procedures used in updating the WHO Guidelines for Drinking-water Quality, 33 pp.

Appendix 2 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status/ Usage*
OECD: KIIA 7.2.1	Völkel	1998	Na_2HPO_3 liquid solution. Degradation rate in three soils incubated under aerobic conditions report no. B30690 GLP: Yes Unpublished	Y	ISK	4)
OECD: KIIA 7.4.1	Völkel	2008	Na_2HPO_3 liquid solution. Adsorption/desorption on soil report no. B30701 GLP: Yes Unpublished	Y	IKS	4)
KIIIA 9.6.1	O'Brien, K.	2013a	Calculation of predicted environmental concentrations in groundwater (PECGW) for phosphonic acid using the model software FOCUS PEARL 4.4.4 Report-no. 486784-A3-090601-01 GLP/GEP: no Unpublished	Y	TILB	1)
KIIIA 9.7.1/ 01	O'Brien, K.	2013b	Calculation of predicted environmental concentrations in surface water (PECSW) and sediment (PECSED) for phosphonic acid and phosphate ions representative for the active substance Potassium phosphonates using FOCUS SW modelling software and scenarios Report-no. 486784-A3-090701-01 GLP/GEP: no Unpublised	Y	TILB	1)
KIIIA 9.7.1/ 02	Wiglinghoff, E.	2013	Calculation of predicted environmental concentrations in surface water (PECsw) and sediment (PECsed) for phosphonic acid and phosphate ions representative	Y	TILB	1)

			for the active substance Potassium phosphonates using FOCUS SW modelling software and scenarios			

TILB: Tilco Biochemie GmbH
ISK: ISK Biosciences Europe S.A
*
1) accepted (study valid and considered for evaluation)
2) not accepted (study not valid and not considered for evaluation)
3) not considered (study not relevant for evaluation)
4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5) supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 3 Detailed evaluation of newly submitted studies performed with the active substance

KIIA 7 Fate and Behaviour in the Environment – Active Substance

KIIA 7.1.1 Völkel (1998)

Reference:	KIIA 7.1.1
Author:	Völkel, W.
Report:	Na_2HPO_3 liquid solution. Degradation rate in three soils incubated under aerobic conditions
Date:	1998
Guideline(s):	SETAC (1995) ; OECD 307 (2002)
Deviations:	Purity of active substance only 35.13% (check with PCMA); Active substance was not radiolabelled; No mass balance available
GLP:	Yes
Acceptability:	Yes

The study was evaluated and considered acceptable by the RMS of Disodium phosphonates. For a summary of the study see revised DAR of Disodium phosphonates (November 2012).

KIIA 7.4.1 Völkel (2008)

Reference:	KIIA 7.4.1
Author:	Völkel, W.
Report:	Na_2HPO_3 liquid solution. Adsorption/desorption on soil
Date:	2008
Guideline(s):	SETAC (1995) ; OECD 307 (2002)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The study was evaluated and considered acceptable by the RMS of Disodium phosphonates. For a summary of the study see revised DAR of Disodium phosphonates (November 2012).

Appendix 4 GAP-Table of intended uses

GAP rev. (2), date: 2013-05-20

PPP (product name/code) Alginure Bio Schutz
Active substance Potassium Phosphonates
Formulation type: Soluble concentrate (SL)
Conc. of as: 342 g/L (228 g/L Phosphonic acid equivalents)

Applicant: Tilco Biochemie GmbH
Zone(s): Central EU
Professional use ☒
Non professional use ☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
					Application			**Application rate**				
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**	**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
001	DE	grape vine VITVI (utilisation as table and wine grape)	F	downy mildew of grapevine *Plasmopara viticola* PLASVI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 12-68	a) 6 (min. 7 days) b) 6 (min 7 days)	a) - base dose: 1.5 L/ha - BBCH 61: 3 L/ha - BBCH 68: 4.5 L/ha b) 27 L/ha	a)- base dose: 513 g as/ha - BBCH 61: 1026 g as/ha - BBCH 68: 1539 g as/ha b) 9234 g as/ha	max 400 L/ha max 800 L/ha max 1200 L/ha	15	

General remarks/explanations:
The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data). The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops). All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.

Make use of existing standards like EPPO and BBCH.
Product: Please indicate the specific variant of the active substance if relevant. If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks. As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions/location of use).
Formulation:
Type: *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1)].

Conc. of as: g/kg or g/L
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.
Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.
Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.
Explanations to the particular columns:
No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.
Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order accordant to the zone they belong.
Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote). If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones. Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated. This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).
Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I) "Glasshouse" indicates that the respective trials are acceptable for all zones. As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated. [Remark: Greenhouse definitions are at the moment under evaluation]. Conditions include also information concerning the substrate (natural soil, artificial substrate).
Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated. In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually). If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.
Application details:
Method / Kind:
Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.
Timing of Application / Growth stage of crop & season:
Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).
Growth stage of crop (BBCH-code) – period, first and last treatment. Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition. BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column "pest or group of Pests controlled". In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.
Number of applications and interval between applications

a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.
It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.
Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:

a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.
Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.
For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.
Information concerning the sowing method (precision drilling, …) would be advantageous.
See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:

a)-(Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.
The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:

It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations. In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product. If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: Alginure Bio Schutz

Active Substance: Potassium Phosphonates 342 g/L (228 g/L Phosphonic acid equivalents)

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: Tilco Biochemie GmbH

Date: August 2017

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product Alginure Bio Schutz in its intended uses in Vines is documented in detail in the core assessment of the plant protection product Alginur BioSchutz performed by Germany.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product Alginure Bio Schutz in Germany according to use listed in Appendix 3.

Regarding PECgw relevant risk mitigation measures, if necessary, are documented in this document. PECsoil, PECsw are used for risk assessment to derive specific risk mitigation measures if necessary (see National addendum Germany, part B, section 6 and part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation Alginur BioSchutz

Code	-
plant protection product	Alginur Bio Schutz
applicant	Tilco Biochemie GmbH
date of application	22/01/2013
Formulation type (WP, EC, SC, …; density)	Soluble concentrate (SL) relative density: 1.345
active substances (as)	Potassium phosphonates
Concentration of as	342 g/L (228 g/L Phosphonic acid equivalents)

Data pool/task force	None
letter of access/cross reference	None

5.2 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) is presented in Table 5.2-1. Full details of the proposed uses that will be assessed is included in Appendix 3. For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL).

Table 5.2-1: Classification of intended uses in Germany for Alginur Bio Schutz

use No	Crop/ Growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Max aplication rate (g as/ha)	Max soil effective application rate (g as/ha)
001	grape vine BBCH 12-68	Spray	6 applications 7 days interval BBCH 12 – 60: Interception: 40% Season:Spring BBCH 61-67: Interception: 70% Season: summer BBCH 68: Interception: 70% Season. summer	<u>Single application rates:</u> BBCH 12 – 60: 513 g a.s/ha (342 g/ha phosphonic acid eq.) BBCH 61-67: 1026 g a.s/ha (684 g/ha phosphonic acid eq.) BBCH 68: **1539 g a.s./ha (1026 g/ha phosphonic acid eq.)** <u>Cumulative max. application rate:</u> 9234 g a.s./ha (6156 g a.s./ha phosphonic acid)	<u>Single application rates:</u> BBCH 12 – 60: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 61-67: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 68: 461.7 g a.s./ha (307.8 g/ha phosphonic acid eq.) <u>Cumulative max. application rate:</u> 2770.2 g a.s./ha (1846.8 g a.s./ha phosphonic acid)

5.3 Information on the active substances

5.3.1 Potassium phosphonates

Please refer to the core assessment, part B, section 5, point 5.3.1.

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

Potassium phosphonates

The DT_{50} values of phosphonic acid listed in the core assessment , part B, section 5, point 5.4.1.1 were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The statistical results for phosphonic acid according to the program INPUT DECISION 3.3 are listed in Table 5.4-1.

Table 5.4-1: Statistic values according to INPUT DECISION 3.3 for phosphonic acid for PEC_{GW} modelling

Does the active substance dissociate ?	Yes	
correlation DT_{50} and pH	Kendall-τ:-0.200 p-value: 0.806	not significant
coefficient of variation	63%	Sufficiently low
DT_{50} for PEC_{GW} (d)	128.8	geometric mean (n = 5)

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5.4.2 Adsorption/desorption

Potassium phosphonates

The K_{foc} values of potassium phosphonates listed in the core assessment, part B, section 5, point 5.4.were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The statistical results for phosphonic acid according to the program INPUT DECISION 3.3 are listed in Table 5.4-2.

Table 5.4-2: Statistic values according to INPUT DECISION 3.2 for potassium phosphonates for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs = 6.59	
correlation K_{foc} and pH	Kendall-τ: -0.180 p-value: 0.530	not significant
correlation K_f and pH	Kendall-τ: -0.405 p-value: 0.127	not significant
correlation K_f and oc	Kendall-τ: 0.022 p-value: 0.500	not significant
coefficient of variation K_{foc}	122%	too high (> 60%)
coefficient of variation Kf	82	sufficiently low (≤ 100%)
Correlation K_f and other soil parameters (clay, CEC)	CEC: Kendall-τ: 0.333 p-value: 0.105 Clay: Kendall-τ: 0.111 p-value: 0.721	not significant

K_{foc}/K_f for PEC_{GW} (n= 10)	For the active substance phosphonic acid, the coefficient of variation of the measured K_{foc} values is > 60% and no correlation could be found between the K_{foc} values and pH and between the K_f values and the oc content, the Clay and the CEC of the soils. Since the coefficient of variation of the measured K_f values is > 100%, the arithmetic mean of the K_f values (K_f = 11.31) of phosphonic acid is used for the first three soil horizons of the FOCUS scenario Hamburg in FOCUS PELMO 5.5.3 together with a default K_f value of zero for the soil horizons 4-6.	
1/n for PECgw (n = 5)	0.844	arithmetic mean all soils
K_{foc} for PEC_{SW} (n= 10)	224/ 905	10th percentile/ arithmetic mean

5.4.3 Rate of degradation in water/sediment

Potassium phosphonate

Please refer to the core assessment, part B, section 5, point 5.4.3.

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for Alginur Bio Schutz according to EU assessment considering 5 cm soil depth are given in the core assessment, part B, section 5, chapter 5.5.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc}$ < 500 a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc}$ > 500 a soil depth of 1 cm is applied. As soil bulk density 1.5 g $cm^{-3}$is assumed.

Due to the slow degradation of the active substance phosphonic acid in soil (DT_{90} > 365 d, 90th percentile, laboratory DT_{50} x 3.32 at 20°C and pF2), the accumulation potential of potassium phosphonates needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively depending on the Kfoc value of the active substance.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters for potassium phosphonates as presented in Table 5.5-1.

Table 5.5-1: Input parameters for phosphonic acid for PEC_{soil} calculation

Active substance	DT_{50}
Phosphonic acid	191/ 843 (DFOP, Maximum, Laboratory data, Parameter= k_1: 0.07544, k_2: 0.00247, g: 0.2011)

Additional $PEC_{soil,act}$ was calculated for the formulation Alginur Bio Schutz for a soil depth of 1 cm.

No short-term and long-term PEC_{soil} were calculated since $PEC_{soil,act}$ is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for potassium phosphonates and for the formulation Alginur Bio Schutz are summarized in Table 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation for the intended use in vine used for German risk assessment

plant protection product:		Alginur Bio Schutz				
use no		001				
Number of applications/application rate/ intervall		6 x 4.5 l/ha = 6 x 6052.5* g/ha Alginur Bio Schutz 6 x 1539 g/ha potassium phosphonates (6 x 1026 g/ha phosphonic acid equivalents)				
interval		7 d				
crop interception:		70%				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Phosphonic acid	6 x 307.8 g/ha	1	10.39	5	1.29	11.68
Alginur Bio Schutz	6 x 1815.7* g/ha	1	61.28	-	-	-

* maximum cumulative application rate (L/ha) x relative density: 1345 g/L x (1-interception)

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of phosphonic acid, representative for the active substance Potassium phosphonates, for the intended for uses of Alginur Bio Schutz in Vines using FOCUS Surface Water are given in the core assessment, part B, section 5, chapter 5.6.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the models EVA 2.1. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC_{SW} after exposure by spraydrift and deposition following volatilisation

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. Since no vapour pressure is available for phosphonic acid and phosphate ions, exposure of surface water due to deposition following volatilization was calculated using a worst case default vapour pressure assuming very high volatility of phosphonic acid and phosphonic ions.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 3. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall

90th percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

The endpoints of phosphonic acid used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-1.

Table 5.6-1 Endpoints of phosphonic acid used for the PEC_{SW} calculations with EVA 3

Parameter	Phosphonic acid	Reference
vapour pressure at 20 °C (Pa)	1 x 10^{-02}	worst case default value
Solubility in water (mg/L)	1875000	EU agreed endpoint
$DissT_{50}$ water (d)	1000	default value
DT_{50} water/sediment study, total system (d)	1000	default value
DT_{50} hydrolysis/photolysis (d)	1000	default value

The endpoints of phosphate ions used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 3 are summarized in .

Table 5.6-2 Endpoints of ..phosphate ions used for the PEC_{SW} calculations with EVA 3

Parameter	Phosphate ions	Reference
vapour pressure at 20 °C (Pa)	1 x 10^{-02}	worst case default value
Solubility in water (mg/L)	1875000	EU agreed endpoint for phosphonic acid
$DissT_{50}$ water (d)	1000	default value
DT_{50} water/sediment study, total system (d)	1000	default value
DT_{50} hydrolysis/photolysis (d)	1000	default value

The application related input parameter and the calculated PECsw values after exposure via spray drift and volatilization with subsequent deposition of the active substance phosphonic acid for the intended use of Alginur Bio Schutz in Vine are summarized in Table 5.6-3 and Table 5.6-4

The application related input parameter and the calculated PECsw values after exposure via spray drift and volatilization with subsequent deposition of phosphate ions for the intended use of Alginur Bio Schutz in Vine are summarized in Table 5.6-5 and Table 5.6-6.

Table 5.6-3 PEC$_{SW}$ for the active substance phosphonic acid after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1 for multiple applications of Alginur Bio Schutz

active substance	phosphonic acid							
use no:	001							
application rate/number of applications / interval	5 x 684 + 1 x 1026 g/ha phosphonic acid eq./ 7 days interval (BBCH 61-68 = worst case)							
interception	70%							
scenario/percentile:	Vine/ 70							
distance (m)	**PECsw via drift**		**PECsw via volatilisation**		**PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)**			
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**no drift reduction**	**50% reduction**	**75% reduction**	**90% reduction**
3	6.41	93.942	2.092%	4.742	98.684	51.713	28.227	14.136
5	2.85	41.768	1.876%	4.252	46.021	25.137	14.694	8.429
10	0.95	13.923	1.429%	3.239	17.161	10.200	6.719	4.631
15	0.50	7.328	1.088%	2.467	9.794	6.131	4.299	3.199
20	0.32	4.690	0.829%	1.879	6.568	4.224	3.051	2.348

Table 5.6-4 PEC$_{SW}$ for the active substance phosphonic acid after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 3 for a single application of Alginur Bio Schutz

active substance	phosphonic acid							
use no:	001							
application rate/number of applications / interval	1 x 1 x 1026 g/ha phosphonic acid eq. (BBCH 68 = worst case)							
interception	70%							
scenario/percentile:	Vine/ 90							
distance (m)	**PECsw via drift**		**PECsw via volatilisation**		**PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)**			
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**no drift reduction**	**50% reduction**	**75% reduction**	**90% reduction**
3	8.02	27.428	2.092%	7.113	34.541	20.827	13.970	9.855
5	3.62	12.380	1.876%	6.379	18.759	12.569	9.474	7.617
10	1.23	4.207	1.429%	4.858	9.065	6.961	5.910	5.279
15	0.65	2.223	1.088%	3.700	5.923	4.812	4.256	3.922
20	0.42	1.436	0.829%	2.818	4.254	3.536	3.177	2.962

Table 5.6-5 PEC_{SW} for phosphate ions after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 3 for multiple applications of Alginur Bio Schutz

active substance	Phosphate ions							
use no:	001							
application rate/number of applications / interval	5 x 806 + 1 x 1210 g/ha phosphate ions*/ 7 days interval (BBCH 61 - 68 = worst case)							
interception	70%							
scenario/percentile:	Vine/ 70							
distance (m)	**PECsw via drift**		**PECsw via volatilisation**		**PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)**			
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**no drift reduction**	**50% reduction**	**75% reduction**	**90% reduction**
3	6.41	110.719	2.092%	5.587	116.306	60.947	33.267	16.659
5	2.85	49.228	1.876%	5.011	54.239	29.625	17.318	9.934
10	0.95	16.409	1.429%	3.816	20.226	12.021	7.919	5.457
15	0.50	8.636	1.088%	2.907	11.543	7.225	5.066	3.770
20	0.32	5.527	0.829%	2.214	7.741	4.977	3.596	2.767

* Molar weight correction factor applied to the application rate: 94.9 (molecular weight of phosphate)/80.5 (molecular weight of phosphonic acid) = 1.179

Table 5.6-6 PEC_{SW} for phosphate ions after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 3 for a single application of Alginur Bio Schutz

active substance	Phosphate ions							
use no:	001							
application rate/number of applications / interval	1 x 1210 g/ha phosphate ions* (BBCH 68 = worst case)							
interception	70%							
scenario/percentile:	Vine/ 90							
distance (m)	**PECsw via drift**		**PECsw via volatilisation**		**PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)**			
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**no drift reduction**	**50% reduction**	**75% reduction**	**90% reduction**
3	8.02	32.347	2.092%	8.388	40.735	24.562	16.475	11.623
5	3.62	14.601	1.876%	7.523	22.123	14.823	11.173	8.983
10	1.23	4.961	1.429%	5.729	10.690	8.210	6.970	6.225
15	0.65	2.622	1.088%	4.364	6.985	5.674	5.019	4.626
20	0.42	1.694	0.829%	3.323	5.017	4.170	3.747	3.493

* Molar weight correction factor applied to the application rate: 94.9 (molecular weight of phosphate)/80.5 (molecular weight of phosphonic acid) = 1.179

For the active substance phosphonic acid and for the phosphate ions, calculated peak PEC_{sw} for multiple applications of Alginur Bio Schutz are higher than for a single application and are therefore used for risk assessment.

5.6.2 PEC_{SW} after exposure by surface run-off and drainage

The concentration of the active substance Phosphonic acid in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The parameters for phosphonic acid used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in Table 5.6-7. The parameters for phosphate ions used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in Table 5.6-8.

Table 5.6-7 Input parameters for phosphonic acid used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	Phosphonic acid	Reference
$K_{foc, Runoff}$	224	10^{th} percentile
$K_{foc, mobility class}$	721	arithm. mean
DT_{50} soil (d)	267	90th percentile, SFO, lab data at 20°C and pF2
Solubility in water (mg/L)	1875000	EU agreed endpoint for phosphonic acid

Table 5.6-8 Input parameters for phosphate ions used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	Phosphate ions	Reference
$K_{foc, Runoff}$	10	worst case default value
$K_{foc, mobility class}$	10	worst case default value
DT_{50} soil (d)	1000	worst case default value
Solubility in water (mg/L)	1875000	water solubility of phosphonic acid

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance phosphonic aicd and for phosphate ions for the intended use of Alginur Bio Schutz in Vine (worst case application rate) are summarized in Table 5.6-9 and Table 5.6-10.

Table 5.6-9 PEC$_{SW}$ of Phosphonic acid in an adjacent ditch due to surface run-off and drainage

Active substance:	Phosphonic acid	
Use No:	001	
Application rate:	5 x 205.2 + 1 x 370.8 g/ha phosphonic acid eq./ 7 days interval (BBCH 61 - 68 = worst case)	
interception	70%	
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch (PEC$_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch (PEC$_{ini\ Gesamtaustrag}$) (µg/L)**
0	2.83	3.14
5	2.45	2.72
10	2.10	2.19
20	1.47	1.51
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.19	
Spring/summer	0.06	

Table 5.6-10 PEC$_{SW}$ of phosphate ions in an adjacent ditch due to surface run-off and drainage

Active substance:	Phosphate ions	
Use No:	001	
Application rate:	6 x 806 + 1 x 1210 g/ha phosphate ions*/ 7 days interval (BBCH 75-89 = worst case)	
interception	85%	
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch (PEC$_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch (PEC$_{ini\ Gesamtaustrag}$) (µg/L)**
0	6.58	6.58
5	5.70	5.70
10	4.89	4.89
20	3.42	3.42
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.75	
Spring/summer	0.24	

* Molar weight correction factor applied to the application rate: 94.9 (molecular weight of phosphate)/80.5 (molecular weight of phosphonic acid) = 1.179

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of Phosphonic acid for the intended uses of Alginur Bio Schutz in Vines according to EU assessment using FOCUS PEARL 4.4.3 are given in the core assessment, part B, section 5, chapter 5.7.

For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is generally assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Hold et al, 2011, endpoints for groundwater modelling are derived with the program INPUT DECISION 3.1 and subsequent simulations are performed for the groundwater scenarios “Hamburg” or with the scenarios “Hamburg” and “Kremsmünster” of FOCUS PELMO 4.4.3.

In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

The German risk assessment for groundwater is given in the following chapters.

5.7.1 Direct leaching into groundwater

5.7.1.1 PEC_{GW} modelling

Table 5.7-1: Input parameters related to application of Alginure Bio Schutz to vine for PEC_{gw} calculations

Use No.	001
Crop	vine
Application rate	Early application (BBCH 12-60): 6 x 0.342 kg/ha phosphonic acid equivalents Late application (BBCH 75—89): 6 x 1.026 kg/ha phosphonic acid equivalents
Number of applications	6
Interval (d)	7
Crop interception (%)	Early application (BBCH 12-60): 50% Late application (BBCH > = 68): 70%
Soil-relevant Application rate	Early application (BBCH 12-60): 6 x 0.171 kg/ha phosphonic acid equivalents Late application (BBCH 83-89): 6 x 0.3078 kg/ha phosphonic acid equivalents

Relative application date	Early application (BBCH 12-60): 1st application: 11.05., 18.05., 25.05., 01.06., 08.06., 15.06. Late application (BBCH 83-89): 1st application:19.09. , 26.09., 03.10., 10.10., 17.10., 24.10
Frequency of application	annual
Models used for calculation	FOCUS PELMO 5.5.3

Table 5.7-2: Input parameters related to active substance phosponic acid for PEC_{gw} calculations

Parent	Phosphonic acid	Remarks/Reference to core assessment, part B, section 8
Molecular weight (g/mol)	80.5	Not applicable
DT_{50} in soil (d)*	128.8	Geometric mean of study datasets from LoEP and Disodium phosphonate LoEP, n=5, see core assessment section 5, Table 5.4-1
K_d/ K_f (mL/g)	11.31	Arithmetic mean Kf/Kd of adsorption study datasets from LoEP and Disodium phosphonate LoEP, n=10; used for soil horizon 1-3 of scenario Hamburg, see core assessment section 5, Table 5.4-2
	0	Default, used for soil horizon 0-6 of scenario Hamburg
1/n	0.844	Arithmetic mean of adsorption study datasets from LoEP and Disodium phosphonate LoEP, n=5, , see core assessment section 5, Table 5.4-2
Plant uptake factor	0	Worst case default

PEC_{gw} of potassium phosphonate due to direct leaching:

Table 5.7-3: PEC_{gw} for potassium phosphonate for the application of Alginure Bio Schutz in vine considered relevant for German exposure assessment

use No.	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3
		potassium phosphonate
001	Hamburg	<0.001

5.7.1.2 Experimental data to the leaching behaviour of the active aubstance Potassium phosphonates

No lysimeter or field leaching studies were performed or are required necessary for Potassium phosphonates.

5.7.1.3 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance phosphonic acid is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended use of Alginure Bio Schutz in vine according to use No 001.

Consequences for authorization:

None

5.7.2 Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

The input parameters for Phosphonic acid used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.01 are summarized in Table 5.7-4.

Table 5.7-4 Input parameters for Phosphonic acid used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	Phosphonic acid	Reference
$K_{foc,\ Runoff}$	721	arithm. mean
$K_{foc,\ mobility\ class}$	224	10th percentile, see Table 5.4.2
DT_{50} soil (d)	267	90th percentile, SFO, lab data at 20°C and pF2, see core assessment, section 5, Table 5.4-1
Solubility in water (mg/L)	1875000	EU agreed endpoint for phosphonic acid
Mobility class	3	
Reduction by bank filtration	90%	

The calculated PECgw for phosphonic acid after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-5.

Table 5.7-5 PEC_{gw} for phosphonic acid after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

<table>
<tr><th colspan="2">Active substance</th><th colspan="4">Phosphonic acid</th></tr>
<tr><th rowspan="3">Use No.</th><th rowspan="3">application rate interception</th><th colspan="4">PECgw due to</th></tr>
<tr><th colspan="2">run-off</th><th colspan="2">drainage</th></tr>
<tr><th>vegetated buffer strip (m)</th><th>bank filtrate (µg/L)</th><th>Time of application</th><th>bank filtrate (µg/L)</th></tr>
<tr><td rowspan="4">001</td><td rowspan="4">6 x 1026 g/ha phosphonic acid eq./ 7 days interval
70% interception</td><td>0</td><td>0.099</td><td rowspan="2">autumn/winter/ early spring</td><td rowspan="2">0.135</td></tr>
<tr><td>5</td><td>0.086</td></tr>
<tr><td>10</td><td>0.074</td><td rowspan="2">spring/summer</td><td rowspan="2">0.044</td></tr>
<tr><td>20</td><td>0.052</td></tr>
<tr><td colspan="2">required labelling</td><td colspan="4">None</td></tr>
</table>

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance phosphonic acid due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

None

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment were submitted.

Appendix 2 Detailed evaluation of studies relied upon

Please refer to Appendix 2 of the core assessment

Appendix 3 Table of Intended Uses in Germany

GAP rev. (2), date: 2014-05-20

PPP (product name/code)	**Alginure Bio Schutz**	**Formulation type:**	**SL**
active substance	**Kaliumphosphit (Kaliumphosphonate)**	**Conc. of as :**	**342 g/L**
Applicant:	**Tilco Biochemie GmbH**	**professional use**	☒
Zone(s):	**central/EU**	**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	grape vine VITVI (utilisation as table and wine grape)	F	downy mildew of grapevine *Plasmopara viticola* PLASVI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 12 - 68	a) 6 b) 6 (min 7 days)	a) - base dose: 1.5 L/ha - BBCH 61: 3 L/ha - BBCH 68: 4.5 L/ha b) 27 L/ha	a) - base dose: 513 g as/ha - BBCH 61: 1026 g as/ha - BBCH 68: 1539 g as/ha - b) 9234 g as/ha	max 400 L/ha max 800 L/ha max 1200 L/ha	15	

General remarks/explanations:
The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data). The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops). All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.
Make use of existing standards like EPPO and BBCH.
Product: Please indicate the specific variant of the active substance if relevant. If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks. As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions/location of use).
Formulation:
Type: *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
Refer to:
- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1].

Conc. of as: g/kg or g/L
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.
Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.
Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.
Explanations to the particular columns:
No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.
Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order accordant to the zone they belong.
Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote). If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones. Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated. This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).
Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I) "Glasshouse" indicates that the respective trials are acceptable for all zones. As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated. [Remark: Greenhouse definitions are at the moment under evaluation]. Conditions include also information concerning the substrate (natural soil, artificial substrate).
Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated. In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually). If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.
Application details:
Method / Kind:
Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.
Timing of Application / Growth stage of crop & season:
Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).
Growth stage of crop (BBCH-code) – period, first and last treatment. Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition. BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column "pest or group of Pests controlled". In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications

a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.

b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.

It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.

Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:

a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.

Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.

For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.

Information concerning the sowing method (precision drilling, …) would be advantageous.

See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:

a)-(Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.

The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:

It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations. In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".

PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product. If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: **Alginure Bio Schutz**
Active Substance: **Potassium Phosphonate 342 g/L**
(228 g/L Phosphonic acid equivalents)

Central Zone
Zonal Rapporteur Member State: Germany (DE)

CORE ASSESSMENT

Applicant: **Tilco Biochemie GmbH**
Date: **August 2017**

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Sec 6 ECOTOXICOLOGICAL STUDIES

This document reviews the ecotoxicological studies for the product Alginure Bio Schutz containing the active substance Potassium Phosphonate which is currently approved under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fulfills the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. For the active substance Potassium Phosphonate, the DAR (2005) and the EFSA conclusions (2012) are considered

Alginure Bio Schutz was not the representative formulation considered in the EU review process as part of the approval of the Potassium Phosphonate.

A full risk assessment according Commission Regulation (EU) No 546/2011 is provided.

Addenda are included containing country specific assessments for some annex points. In those cases this document should be read in conjunction with the relevant addenda.

The studies with the relevant endpoints for each non-target organism group were agreed during EU review process and are used for the risk assessment. Reference is made to the following documents, if not otherwise labelled with an asterisk:

Potassium Phosphonates: EFSA Journal 2012;10(12):2963

Full details of toxicity studies are provided in the respective EU DAR.

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

Appendix 2 of this document reports the detailed evaluation of studies relied upon.

Appendix 3 of this document is the table of intended uses for Alginure Bio Schutz.

Information on the detailed composition of Alginure Bio Schutz can be found in the confidential dossier of this submission (Registration Report - Part C).

6.1 Proposed use pattern and considered metabolites

Introduction

Section 6 of the submission summarises the ecotoxicological effects of the formulation Alginure Bio Schutz containing the active substance Potassium Phosphonate and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms. Full details or the proposed use patterns that will be assessed are shown in Appendix 3 of this document and summarized below. Moreover, an overview of the metabolites of Potassium Phosphonate that will be addressed in the risk assessment is given below.

6.1.1 Proposed use pattern

The critical GAP used for exposure assessment are presented in Table 6.1-1 that reports also a classification of intended uses for Alginure Bio Schutz (see also Section 5). A list of all intended uses within the Central Zone is given in Appendix 3.

Table 6.1-1: Critical use pattern of Alginure Bio Schutz

Crop	Growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Max single aplication rate (g as/ha)	Max single soil effective application rate (g as/ha)
Vines	BBCH 12-68	Spray	6 applications 7 days interval BBCH 12 – 60: Interception: 40% Season:Spring BBCH 61-67: Interception: 70% Season: summer BBCH 68: Interception: 70% Season. summer	<u>Single application rates:</u> BBCH 12 – 60: 1.5 l/ha Alginure BioSchutz 513 g a.s/ha (342 g/ha phosphonic acid eq.) BBCH 61 - 67: 3 l/ha Alginure BioSchutz 1026 g a.s/ha (684 g/ha phosphonic acid eq.) BBCH 68: **4.5 l/ha Alginure BioSchutz** **1539 g a.s./ha (1026 g/ha phosphonic acid eq.)** <u>Cumulative max. application rate:</u> **27 L/ha Alginure BioSchutz** 9234 g a.s./ha (6156 g a.s./ha phosphonic acid)	<u>Single application rates:</u> BBCH 12 – 60: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 61 - 67: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 68: **461.7 g a.s./ha (307.8 g/ha phosphonic acid eq.)** <u>Cumulative max. application rate:</u> 2770.2 g a.s./ha (1846.8 g a.s./ha phosphonic acid)

6.1.2 Consideration of metabolites

The occurrence and risk from potentially ecotoxicologically relevant metabolites have been considered in the EU review of Potassium Phosphonates.

Phosphate is the only relevant metabolite of potassium phosphonates (technical active substance) and phosphonic acid (actual active substance) in soil, surface water and sediment. Based on the criteria laid down in the EFSA guidance document Sanco/221/200-rev.10-final (2003) 1, phosphate is a metabolite of no concern for the groundwater. However, PECsw and PECsed values of phosphate ions were calculated for risk assessment of aquatic organisms. The risk to aquatic organisms assessed as low when groundwater becomes surface water.

6.2 Effects on Birds

6.2.1 Overview and summary

An avian acute oral study has been carried out with Potassium Phosphonates and a long-term reproduction study was listed in the EU-LoEP as bridging data from Fosetyl-Al. Full details of avian toxicity studies are provided in the respective EU DAR. The studies with the relevant acute and long-term endpoints were agreed during EU review process and are used for the risk assessment.

Effects on birds of Alginure Bio Schutz were not evaluated as part of the EU review of Potassium Phosphonates. However, the provision of further data on the formulation Alginure Bio Schutz is not considered essential as the available data on Potassium Phosphonates are deemed to be sufficient to assess the risk of birds exposed to Alginure Bio Schutz.

The risk assessment for effects on birds and other terrestrial vertebrates is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.2.1.1 Toxicity

The studies with the relevant acute and long-term endpoints which are used in the risk assessment procedure are listed in the following table.

Table 6.2-1: Toxicity of Potassium Phosphonates to birds with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Colinus virgianus	Potassium Phosphonates*	Acute	LD_{50} > 2250 mg a.s./kg bw/d	[redacted] 20.12.1999 286-113	47594
Colinus virgianus	Fosetyl-Al	Long-term	NOEC = 216 mg /kg bw	[redacted] 07.07.1999	48094

[1] Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

	[EU-LoEP: bridging data from fosetyl-Al]		equivalent to 149.04 mg phosphonic acid/ kg bw	171-183	

6.2.1.2 Exposure

Alginure Bio Schutz is a fungicide formulation containing Potassium Phosphonates as active substances. The product is formulated as a suspension concentrate. It will be used against Downey mildew (*Plasmora viticola*) in vines.

Exposure to standard generic focal species was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438)

$$\begin{aligned}\mathrm{DDD} &= \sum_i \frac{\mathrm{PD}_i \times \mathrm{FIR}_{total}}{\mathrm{bw}} \times \mathrm{RUD} \times \mathrm{AR} \times \mathrm{PT} \\ &= \sum_i \frac{\mathrm{FIR}_i}{\mathrm{bw}} \times \mathrm{RUD} \times \mathrm{AR} \times \mathrm{PT}\end{aligned}$$

where:

DDD = Daily dietary dose (mg/kg bw/day)
PDi = composition of diet obtained from treated area
FIRi = Food intake rate of indicator species i (g fresh weight/d)
bw = Body weight (g)
RUD = Residue per unit dose, bases on an application rate of 1 kg a.s./ha and assuming broadcast seedling
AR = Application rate (kg/ha)
PT = Proportion of diet obtained in the treated area (0…1)

In a first approach, it is assumed that birds do not avoid contaminated food items, that they feed exclusively in the treated area and on a single food type. Factors PT and PD are therefore equal to 1.

The risk assessment procedure follows a stepwise approach. A first screening step involves standard scenarios and default values for the exposure estimate, representing a “reasonable worst case”. If a potential risk is indicated in the screening step, then one or several refinement steps (Tier 1, Tier 2) may follow. According to the Guidance Document, no further assessment is required if all uses are safe in the screening step.

6.2.1.3 Risk Assessment –overall conclusions

For risk assessment purposes, a risk envelope approach was used to cover highest risk for birds from intended use in vines (see also Table 6.1-1). Therefore, application of 6 x 228 g/ha phosphonic acid eq. was considered.

Based on the presumptions of Tier 1, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substance Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds.

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is not required. Please refer to chapter 6.2.9.

6.2.2 Toxicity to exposure ratio for birds (K III A 10.2.1)

6.2.2.1 Acute toxicity to exposure ratio (TERA)

Screening step

In the screening step, the risk to indicator bird species from an exposure to Alginure Bio Schutz is assessed. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

To estimate the daily dietary doses, following equations were used:

Daily dietary dose (DDD):

$$DDD_{single\ application} = \text{application rate [kg a.s./ha]} \times \text{shortcut value}^{1}$$

[1] see section 4.1 of EFSA/2009/1438

In case of multiple applications, the daily dietary dose for a single application is multiplied with an appropriate multiple application factor for 90th percentile residue data (MAF_{90}; see Table 7 of EFSA/2009/1438).

$$DDD_{multiple\ application} = DDD_{single\ application} \times MAF_{90}{}^{1}$$

Toxicity exposure ratio (acute):

$$TER_A = \frac{LD_{50}\ \text{(mg/kg bw/day)}}{\text{Acute DDD (mg/kg bw/day)}}$$

The resulting TER_A values are summarised in the following table, along with the indicator species and the respective shortcut values.

Table 6.2-2: Acute screening risk assessment (TER_A) for birds. See text for details

Substance	Indicator species	Application rate (kg/ha)	Shortcut value acute	MAF	DDD (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
Potassium Phosphonates*	Small omnivorous bird	1.026	95.3	1.9	185.85	> 2250	**12.1**
TERs shown in bold fall below the relevant trigger.							

*(calculated as phosphonic acid equivalents)

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of birds to the active substance Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz does achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for birds, further refinement is not necessary.

6.2.2.2 Short -term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for birds under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity will not be conducted.

6.2.2.3 Long-term toxicity exposure ratio (TER_{LT})

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TERLT) in principle follows the same procedure as for the acute risk assessment. However, the defined daily dose is obtained by multiplying the application rate with the mean short-cut values (based on mean RUD according to the new Guidance Document; EFSA, 2009) as summarized in the following table.

Table 6.2-3: Avian indicator species for the intended uses of Alginure Bio Schutz and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
vines	small omnivorous bird	38.9

As stated in the guidance document, it is justified to apply a time-weighted average (TWA) factor of 0.53 based on a default observation interval of 21 days and a default DT_{50} of 10 days for the calculation of the DDD (daily dietary dose):

$$DDD_{\text{single application}} = \text{application rate [kg/ha]} \times \text{shortcut value} \times \text{TWA}^*$$

* see section 4.3 of EFSA/2009/1438

Toxicity exposure ratio (Long-term):

$$TER_{LT} = \frac{\text{NOEL (mg/kg bw/day)}}{\text{Long-term DDD (mg/kg bw/day)}}$$

The relevant lowest NOEL for the reproduction exposure scenario for Potassium Phosphonates is 149.04 mg phosphonic acid equivalents/kg bw/d. Full details of the avian toxicity studies are provided in the respective EU DAR. The relevant long-term endpoints is provided in the following table as well as calculated long-term toxicity exposure ratios (TER_{LT}) for birds exposed to Potassium Phosphonates following applications of Alginure Bio Schutz.

Table 6.2-4: Long-term screening risk assessment (TER_{LT}) for birds exposed to Alginure Bio Schutz according to the intended uses

Substance	Indicator bird	Application rate (kg/ha)	Shortcut value (long-term)	f_{TWA}	MAF	DDD (mg/kg bw/day)	NOEL (mg/kg bw/day)	TER_{LT}
Potassium Phosphonates tested as Fosetyl-Al [EU-LoEP: bridging data from fosetyl-Al]*	Small omnivorous bird	1.368	38.9	0.53	2.5	74.405	149.04	**2.0**
TERs shown in bold fall below the relevant trigger.								

* (calculated as phosphonic acid equivalents)

Based on the highly conservative presumptions of the screening step, the calculated TER values for the long-term risk resulting from an exposure of birds to the active substance Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz does not achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an unacceptable risk for birds, further refinement is necessary.

Tier 1

In the Tier 1 risk assessment step, the defined daily dietary doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009, Annex I). As for the indicator species, the generic focal species are considered to be representative for all species potentially at risk. In the Tier 1 assessment, a mixed diet approach is followed when appropriate and interception of the spray by the crop is taken into account for the calculation of residue levels for different food types.

If more than one generic focal species is relevant for the crop, the one that is relevant in terms of time of application or growth stage should be selected. If more than one generic focal species is relevant in terms of application time and growth stage, then the risk should be assessed for all relevant generic focal species. If the same generic focal species is relevant for several application times according to the BBCH growth stages, the risk assessment for this generic focal species is conducted once using the highest mean short-cut value, since this mirrors a realistic worst case scenario.

For potassium phosphonates the TER_{LT} was below the trigger of 5 in the screening step for the intended uses in vines. Therefore, a Tier 1 risk assessment step will be performed for these use.

The results of the reproductive Tier 1 risk assessments are summarized in the following tables.

Table 6.2-5: Avian generic focal species for the inteded use in vines of Alginure Bio Schutz and relevant shortcut values for long-term risk assessment

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (mean RUD)
Vines	BBCH 12 – 60:	Small insectivorous bird “redstart”	11.5
		Small granivorous bird "finch"	6.9

		Small omnivorous bird "lark"	6.5
	BBCH 61-68	Small insectivorous bird “redstart”	9.9
		Small granivorous bird "finch"	3.4
		Small omnivorous bird "lark"	3.3

Shortcut values in combination with application rate indicate that an assessment for 6 applications in vines BBCH 61-68 could be regarded as a worst case approach. The outcome of the Tier 1 risk assessment step is presented in the following table:

Table 6.2-6: Reproductive bird risk assessment of Alginure Bio Schutz uses in vines (Tier 1)

BBHC Stage	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (Mean RUD)	PT value	DDD (mg /kg bw/d)	NOEL (mg/kg bw/d)	TER
61 - 68	Small insectivorous bird “redstart”	1.026	1.86	9.9	-	18.936	149.04	7.9
	Small granivorous bird "finch"		1.86	3.4		6.503		22.9
	Small omnivorous bird "lark"		1.86	3.3		6.312		23.6
TERs shown in bold fall below the relevant trigger.								

* (calculated as phosphonic acid equivalents)

Based on refined Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of birds to Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for birds due to the intended use of Alginure Bio Schutz in vines according to the label. No further refinement is necessary.

6.2.3 Drinking water exposure

In case of intended uses in vines for Alginure Bio Schutz birds might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by birds (for further details please refer to chapter 5.5. of the Guidance Document). The puddle scenario has been taken into account to calculate the exposure concentration of Potassium Phosphonates formed on a field after rainfall. The ratios do not exceed the value of 50 (AR = 1368 g a.s/ha (worst-case; a.s. as phosphonic acid equivalents); long-term endpoint NOEL = 149.04 mg phosphonic acid equivalents /kg bw) for Potassium

Phosphonates (KOC = 453.6 mg/g for Potassium Phosphonites (Organic carbon normalised adsorption coefficient)), thus it is not necessary to conduct a drinking water risk assessment for birds.

6.2.4 Details on formulation type in proportion per item

6.2.4.1 Baits: Concentration of active substance in bait in mg/kg

Alginure Bio Schutz is not formulated as bait. The formulation is intended for use as a foliar spray, and therefore this information is not required.

6.2.4.2 Pellets, granules, prills or treated seed

Alginure Bio Schutz is not formulated as pellets, granules, prills or treated seeds. Alginure Bio Schutz is intended for use as a foliar spray, and therefore this information is not required.

6.2.5 Acute toxicity of the formulation

Avian toxicity tests with the formulation were not performed and are not considered necessary regarding toxicity and risk assessment of the active substance to birds as well as toxicity and risk assessment of the active substance and the formulated product to mammals.

6.2.6 Metabolites

Avian toxicity tests with metabolites of Potassium Phosphonates were not performed and are not considered necessary. Phosphate is the only relevant metabolite of potassium phosphonates (technical active substance) and phosphonic acid (actual active substance) in soil, surface water and sediment.

6.2.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of Alginure Bio Schutz pose no unacceptable acute or long-term risks to birds, and therefore further studies are not considered necessary.

6.2.8 Acceptance of bait, granules or treated seeds (palatability testing)

Alginure Bio Schutz is intended for use as a foliar spray, and therefore this information is not required.

6.2.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). According to DAR for Potassium Phosphonates is very low (-0.7699; pH = 7), the active substance is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

6.3.1 Overview and summary

The risk assessment for effects on mammals is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.3.1.1 Toxicity

Table 6.3-1: Toxicity of Potassium Phosphonates to mammals with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Rat	Potassium Phosphonates	Acute oral toxicity	LD_{50} = 5000 mg/kg bw (equivalent to 1736 mg phosphonic acid/kg bw)	[redacted] 02.05.2000 1263/013	81079
Rat	Fosetyl-Al [EU-LoEP: bridging data from fosetyl-Al]	Long-term	NOEL = 439 mg/kg bw (equivalent to 302.9 mg phosphonic acid/kg bw))	N.N.	70961
Rat	Alginure Bio Schutz	Acute oral toxicity	LD_{50} > 2000 mg product/kg bw (equivalent to 343.4 mg phosphonic acid/kg bw)*	[redacted] 19.12.2001 1495-001	82209

No deaths or sings of systemic toxicity were found during the study with the formulated product at the limit concentration of 2000 mg prod./kg bw. All animals showed expected body weight gains. No abnormalities were noted following individual necropsy. Therefore, the formulation is not expected to increase the toxicity and the risk assessment is based on the active ingredient.

6.3.1.2 Exposure

Exposure to standard generic indicator species was estimated according to the 'EC Guidance Document on Risk Assessment for Birds and Mammals Council (EFSA/2009/1438). Please see chapter 6.2.1.2 for detailed information on the estimation of daily intake rates.

6.3.1.3 Risk assessment –overall conclusions

Based on the presumptions of Tier 1, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to the active substance Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for mammals, no further refinement is necessary.

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is not required. Please refer to chapter 6.2.9.

6.3.2 Toxicity exposure ratio

6.3.2.1 Acute toxicity exposure ratio (TER_A)

Screening step

In the screening step, indicator species are used. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

For the estimation of Daily dietary doses (DDD) and the calculation of TER-values please refer to 6.2.2.1

Table 6.3-2: Acute screening risk assessment (TER_A) for mammals. See text for details

Substance	Indicator species	Application rate (kg/ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
Potassium Phosphonates *	Small herbivorous mammal	1.026	136.4	1.9	354.5	1736	**6.5**
TERs shown in bold fall below the relevant trigger.							

*calculated as phosphonic acid equivalents

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of mammals to the active substance Potassium Phosphonates and Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz does not achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an unacceptable risk for mammals due to the intended use of Alginure Bio Schutz in vines according to the label, further refinement is necessary.

Tier 1

In the Tier 1 risk assessment step, the defined daily doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009, Annex I). Please refer to chapter 6.2.2.1 for general considerations when choosing generic focal species.

The relevant short-cut values for assessed scenarios are summarized in the following table.

Table 6.3-3: Mammal generic focal species for the intended use in vines of Alginure Bio Schutz and relevant shortcut values

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (90th percentile RUD)
Vines	BBCH 12 – 60:	Large herbivorous mammal “lagomorph”	7.6
		Small insectivorous mammal “shrew”	7.6
		Small herbivorous mammal "vole"	81.9
		Small omnivorous mammal “mouse"	10.3
	BBCH 61-70 ; BBCH 71-74, BBCH 75-89:	Large herbivorous mammal “lagomorph”	8.1
		Small insectivorous mammal “shrew”	5.4
		Small herbivorous mammal "vole"	40.9
		Small omnivorous mammal “mouse"	5.2

Shortcut values indicate that an assessment for 6 applications in vines at BBCH 12-60 and at BBCH 75-89 could be regarded as a worst case approaches (highest application rate and highest shortcut value). The outcome of the Tier 1 risk assessment step is presented in the following table.

Table 6.3-4: Assessment of the acute risk to mammals from Alginure Bio Schutz in the intended uses vines (Tier 1)

Substance	Crop / Stage	Generic Focal Species	Application Rate (kg a.s./ha)	MAF	Short cut Value (90th percentile)	DDD (mg a.s./kg bw/d)	LD_{50} (mg a.s./kg bw/d)	TER
Potassium Phosphonates*	BBCH 12 – 60	Small herbivorous mammal "vole"	0.342	1.9	81.9	53.2	1736	32.6
Potassium Phosphonates*	BBCH 75-89	Small herbivorous mammal "vole"	1.368	1.9	40.9	106.3	1736	16.3
TERs shown in bold fall below the relevant trigger.								

* calculated as phosphonic acid equivalents

Based on refined Tier 1 assessment step, the calculated TER values for the acute risk resulting from an exposure of mammals to Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for mammals due to the intended use of Alginure Bio Schutz in vines according to the label. No further refinement is necessary.

6.3.2.2 Short-term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for mammals under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity has not been performed.

6.3.2.3 Long-term toxicity exposure ratio (TER_{LT})

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) follows in principle the same procedure as for the acute risk assessment.

The defined daily dietary dose is obtained by multiplying the application rate with the mean short-cut value (based on the mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.3-5: Mammal generic focal species for the intended uses of Alginure Bio Schutz and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value
vines	Small herbivorous mammal	72.3

Please refer to section 6.2.2.3 for the equation employed in the estimation of the daily dietary doses and the calculation of TER-values.

The relevant lowest NOEL for the reproduction exposure scenario for Potassium Phosphonates is 302.9 mg phosphonic acid/kg bw. Full details of the toxicity studies are provided in the respective EU DAR. The following table reports the calculated long-term toxicity exposure ratios (TER_{LT}) for mammals exposed to Potassium Phosphonates following applications of Alginure Bio Schutz.

Table 6.3-6: Long-term screening risk assessment (TER_{LT}) for mammals exposed to Alginure Bio Schutz according to the intended uses

Substance	Indicator bird	Application rate (kg/ha)	Shortcut value (long-term)	f_{TWA}	MAF	DDD (mg/kg bw/day)	NOEL (mg/kg bw/day)	TER_{LT}
Fosetyl-Al [EU-LoEP: bridging data from fosetyl-Al] *	Small herbivorous mammal	1.026	72.3	0.53	2.5	138.289	302.9	**2.2**
TERs shown in bold fall below the relevant trigger.								

*(calculated as phosphonic acid equivalents)

Based on the highly conservative presumptions of the screening step, the calculated TER values for the long-term risk resulting from an exposure of mammals to the active substance Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz does not achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an unacceptable risk for mammals due to the intended use of Alginure Bio Schutz in vines according to the label, further refinement is necessary.

Tier 1 risk assessment

For the Tier 1 risk assessment, the defined daily doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009. Annex I). Please refer to section 6.2.2 for general consideration in the choice of generic focal species in risk assessment procedures.

The relevant short-cut values for scenarios evaluated are summarized in the following table.

Table 6.3-7: Mammal generic focal species for the intended uses of Alginure Bio Schutz and relevant shortcut values for long-term risk assessment

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (mean RUD)
Vines	BBCH 12 – 60	Large herbivorous mammal “lagomorph”	6.7
		Small insectivorous mammal “shrew”	4.2
		Small herbivorous mammal "vole"	43.4
		Small omnivorous mammal “mouse"	4.7
	BBCH 61-68	Large herbivorous mammal “lagomorph”	3.3
		Small insectivorous mammal “shrew”	1.9
		Small herbivorous mammal "vole"	21.7
		Small omnivorous mammal “mouse"	2.3

Shortcut values indicate that an assessment for 6 applications in vines at BBCH 12-60 and at BBCH 61-68 could be regarded as a worst case approach (highest application rate and highest shortcut value). The outcome of the Tier 1 risk assessment step is presented in the following table:

Table 6.3-8: Reproductive mammal risk assessment of Alginure Bio Schutz uses in vines (Tier 1)

Substance	Crop / Stage	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (Mean RUD)	PT value	DDD (mg/kg bw/d)	NOEL (mg/kg bw/d)	TER
Potassium Phosphonates*	BBCH 12 – 60	Small herbivorous mammal "vole"	0.342	1.86	43.4	-	27.671	302.9	10.9
Potassium Phosphonates*	BBCH 61-68	Small herbivorous mammal "vole"	1.026	1.86	21.7	-	41.506	302.9	7.3
TERs shown in bold fall below the relevant trigger.									

* calculated as phosphonic acid equivalents

Based on refined Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of mammals to Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for mammals due to the intended use of Alginure Bio Schutz in vines according to the label. No further refinement is necessary.

6.3.3 Drinking water exposure

In case of intended uses in vines for Alginure Bio Schutz might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by mammals (for further details please refer to chapter 5.5. of the Guidance Document). The puddle scenario has been taken into account to calculate the exposure concentration of Potassium Phosphonates formed on a field after rainfall. The ratios do not exceed the value of 50 (AR = 1368 g a.s/ha (worst-case; a.s. as phosphonic acid equivalents); long-term endpoint NOEL = 302,9 mg phosphonic acid equivalents /kg bw) for Potassium Phosphonates (KOC = 453.6 mg/g for Potassium Phosphonites (Organic carbon normalised adsorption coefficient)), thus it is not necessary to conduct a drinking water risk assessment for mammals.

6.3.4 Details on formulation type in proportion per item

Please refer to section 6.2.4 for details on the formulation type of Alginure Bio Schutz.

6.3.4.1 Baits: Concentration of active substance in bait in mg/kg

Please refer to section 6.2.4.

6.3.4.2 Pellets, granules, prills or treated seed

Please refer to section 6.2.4.

Amount of active substance in or on each item

Please refer to section 6.2.4.

Proportion of active substance LD50 per 100 items and per gram of items

Please refer to section 6.2.4.

Size and shape of pellet, granule or prill

Please refer to section 6.2.4.

6.3.5 Acute toxicity of the formulation

Please refer to section 6.3.1 for an overview of the submitted data on the toxicity of Alginure Bio Schutz to mammals and the outcome of the risk assessment for mammals.

6.3.6 Metabolites

Mammal toxicity tests with metabolites of Potassium Phosphonates were not performed and are not considered necessary. Phosphate is the only relevant metabolite of potassium phosphonates (technical active substance) and phosphonic acid (actual active substance) in soil, surface water and sediment.

6.3.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of Alginure Bio Schutz pose no unacceptable acute or long-term risks to mammals, and therefore further studies are not considered necessary.

6.3.8 Acceptance of bait, granules or treated seeds (palatability testing)

Alginure Bio Schutz is intended for use as a foliar spray, and therefore this information is not required.

6.3.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). According to DAR is very low (-0.7699; pH = 7), the active substance is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required.Effects on Aquatic Organisms

6.3.10 Overview and summary

The following EU agreed endpoints for aquatic organisms exposed to the active substances Potassium Phosphonates are reported in the lists of endpoints of the Conclusion on the Peer review of Potassium Phosphonates (EFSA Scientific Report 10(12): 2963 (2012); see table below).

The applicant provides further studies on the risk for aquatic organisms with the formulation Alginure Bio Schutz. Detailed study summaries for the studies performed with the formulated product Alginure Bio Schutz are presented in Appendix 2.

6.3.10.1 Toxicity

The endpoints for aquatic organisms relevant for the risk assessment are indicated in the following table.

Table 6.3-9: Ecotoxicological endpoints for aquatic species exposed to Potassium Phosphonates and Alginure Bio Schutz with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.

Acute toxicity to fish					
O.mykiss	Potassium Phosphonates	96 h, flow-through	LC_{50} > 118 mg a.s./L (mm)	[redacted] 03.12.1999 286A-108	47583
O.mykiss	Alginure Bio Schutz	96 h, flow-through	LC_{50} > 100 mg prod./L (corresponding to 17.74 mg Phosphonic acid equivalents/L, nom.) *	Gonsior, G., 14.08.2012 S11-03606	82198
Long term toxicity to fish					
O.mykiss	STAMINA (= LBG-01F34)	21 d; Juvenile Growth Test, flow-through	NOEC = 300 mg/L (nom); equivalent to 100 mg a.s./L (nom.)	[redacted] 12.12.2008 GAB-019/4-63	81083
Acute toxicity to aquatic invertebrates					
Daphnia magna	Potassium Phosphonates	48 h, flow-through	EC_{50} > 118 mg a.s./L (m.m.)	Sutherland, C.A., Kendall, T.Z., Krueger, H.O. 03.12.1999 286A-109	33184
Daphnia magna	Alginure Bio Schutz	48 h, flow-through	EC_{50} > 100 mg prod./L (corresponding to 17.74 mg Phosphonic acid equivalents/L, nom.) *	Weber, K., 2012 S11-03607	82197
Long term toxicity to aquatic invertebrates					
Daphnia magna	STAMINA (= LBG-01F34)	23 d, semi-static	NOEC = 292 mg/L (nom); equivalent to 100 mg a.s./L (nom.)	Stäbler, D. 26.07.2006 20051318/01-ARDm	81138
Toxicity to algae					
Desmodesmus subspicatus(formerly *Scenedesmus subspicatus)*	STAMINA (= LBG-01F34)	72 h, static	EbC_{50} = 452.2 mg/L (nom); equivalent to 146.7 mg a.s./L (nom.) ErC_{50} = 6779.8 mg/L (nom); equivalent to 2305.1 mg a.i./L*	Dengler, D. 15.11.2001 20001344/01-AADs	47584
Desmodesmus subspicatus(formerly *Scenedesmus subspicatus)*	Alginure Bio Schutz	72 h, static	EyC_{50} > 100 mg/L (nom); equivalent to 17.7 mg a.s./L (nom.) ErC_{50} > 100mg/L (nom); equivalent to 17.7 mg a.i./L E_bC_{50} = 109.7 mg formulation/L equivalent to 19.4 mg a.s./L (calculation with ToxRat: Mean percent increasing response)*	Weber, K., 2012 S11-03608	82196
Toxicity to aquatic plants					

Lemna gibba	Alginure Bio Schutz	7 d	Er/bC_{50} > 16.7 mg a.s./L (nom.) (corresponding to 100 mg formulation/L) *	Zawadsky, C., 2012 S12-02324	82208

* New study submitted by the applicant

6.3.10.2 Exposure

Alginure Bio Schutz is a fungicidal formulation containing Potassium Phosphonates as active substances. The product is formulated as suspension concentrate. According to the GAP table of intended uses (Appendix 3) it will be used against Downey mildew (*Plasmora viticola*) in vines. The applications are considered to take place at 6 events with a minimum 7 days between applications and with an increasing application rate each spray according to growth stages of the vines.

Aquatic organisms may be exposed to plant protection products as a result of emission from treated fields. When Alginure Bio Schutz is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by spraydrift during application, by run-off and drainage.

The predicted environmental concentrations in surface water (PEC_{SW}) have been calculated based on the application rates of 6 x 307.8 kg Potassium Phosphonates/ha (205.2 g/ha phosphonic acid eq.). The maximum application rate has been changed after the first approval phase. The applicant has not provided new PEC_{SW} calculations nor a risk assessment based on the changed maximum application rate. The six-fold application of 6 L/ha can be considered as a worst case and covers the application of 4.5 L/ha.

For details on the FOCUS modelling, see dRR CA Part B, Section 5.7.

6.3.10.3 Risk assessment –overall conclusions

Based on the FOCUS Step 1 PECs, the aquatic TER values for Potassium Phosphonates are above the trigger of 10, indicating a low and acceptable acute risk for aquatic organisms from Potassium Phosphonates following application of Alginure Bio Schutz at the proposed application rates.

If appropriate: According to Review report for the active substance potassium phosphonates; SANCO/10416/2013 rev 1; 29 January 2013 Member States shall pay particular attention to:

- the risk of eutrophication of surface water, if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water.

Conditions of use shall include risk mitigation measures, where appropriate.

→ significant increase with Alginure=> eutrophication due to application of Alginure Bio Schutz according to the intended uses cannot be excluded on basis of the data submitted.

TER values for the most sensitive aquatic organisms based on PEC_{SW} FOCUS calculations are summarized in the following table.

Table 6.3-10: Aquatic TER values for Potassium Phosphonates after applications of Alginure Bio Schutz

Test organism	EC_{50} NOE(AE)C	FOCUS Step	Scenario	Max. PEC_{SW} worst	TER_{LT}	Trigger

	(µg/L)			case (µg/L)		value
Potassium Phosphonates						
O. mykiss	100000	1	-	2920*	34	10
Alginure Bio Schutz						
D. subspicatus	19410	2	South Europe	321.9	60	10
TER-values in bold are below the relevant trigger						

* calculated for KOC=10 mg/L

According to the water framework directive (2000/60/EC) and the implementation law in Germany, the regulation for the protection of surface waters (Oberflächengewässerverordnung), the environmental quality standard representing a good ecological status of surface water bodies is 20 µg *ortho*-Phosphates/L or 50 µg total P/L. Based on the FOCUS Step 1 to 3 calculations these limits are exceeded in the D6, R3 and R4 scenarios. This in combination with the present results of the algae and *Lemna* studies indicates a potential risk of eutrophication in some European surface water bodies. The national approval for Alginure Bio Schutz in Germany will address this potential risk with risk mitigation measures like drift reduction techniques and buffer strips. For details see national addendum Section 6 Germany. Since no definition for an acceptable limit of eutrophication exists, other member states may decide differently.

6.3.11 Toxicity to Exposure ratio

The risk for aquatic organisms exposed to Potassium Phosphonates was assessed according to the intended uses.

As first step, the initial maximum PEC_{SW} values (Step 1) were compared to the relevant acute and long-term toxicity endpoints available for Potassium Phosphonates. Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint for Potassium Phosphonates is NOEC = 100 mg Potassium Phosphonates/L (*O. mykiss)*. For Alginure Bio Schutz, the relevant endpoint is EbC50 = 19.4 mg Potassium Phosphonates/L (*Desmodesmus subspicatus*). Risk assessment is driven by these endpoints; the ratio endpoint/corresponding safety factor is higher for all other organisms.

The applicant has not provided new PEC_{SW} calculations with the changed maximum application rate of 4.5 L/ha. The calculations based on the six-fold application of 6L/ha cover the lower maximum application rate.

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting TER values are presented in the following table.

Table 6.3-11: Aquatic organisms: PECsw for Potassium Phosphonates/Alginure Bio Schutz and relevant ecotoxicological endpoints for each organism group – Step 1 to 3 based on an application rate of 6 L/ha

Scenario	**PEC global max**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Fish acute**	**Invertebrates acute**	**Aquatic plants**
		O. mykiss	***O. mykiss***	***D. magna***	***D. magna***	***D. subspicatus***	***O. mykiss***	***D. magna***	***Lemna gibba***
FOCUS	**(µg/L)**	**LC_{50} (µg/L) > 118000**	**NOEC (µg/L) 100000**	**EC_{50} (µg/L) > 118000**	**NOEC (µg/L) 100000**	**E_bC_{50} (µg/L) 194100**	**LC_{50} (µg/L) > 17740**	**EC_{50} (µg/L) > 17740**	**EC_{50} (µg/L) > 16700**
Step 1	2920	**>40.4**	34.2	**>40.4**	34.2	**6.6**	**> 6.1**	**> 6.1**	**> 5.7**
Step 2									
N.Europe	62.76	> 1880	1593	> 1880	1593	309	> 283	> 283	> 266
S.Europe	321.9	> 367	311	> 367	311	60	**> 55**	**> 55**	> 52
Step 3									
D6/ditch	233.434	>506	428	>506	428	83	**>76**	**>76**	> 72
R1/pond	3.342	>35308	29922	>35308	29922	5808	>5308	>5308	> 4997
R1/stream	13.653	>8643	7324	>8643	7324	1422	>1299	>1299	> 1223
R2/stream	18.301	>6448	5464	>6448	5464	1061	>969	>969	> 913
R3/stream	61.363	>1923	1630	>1923	1630	316	>289	>289	> 272
R4/stream	73.359	>1609	1363	>1609	1363	265	>242	>242	> 228
TER criterion		**100**	**10**	**100**	**10**	**10**	**100**	**100**	**10**

TER values shown in bold fall below the relevant trigger.

Based on the calculated concentrations of Potassium Phosphonates in surface water (PEC_{SW} FOCUS Step 1 - 3), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 100 and TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles in all but one scenario. The D6 ditch scenario is below the trigger of 100, which indicates a potential risk. However, Alginure Bio Schutz is intended to be used throughout the growing season with application rates increasing with increasing growth stages. In addition to that the calculations are based on a six-fold application of 6 L/ha which is not intended anymore. The maximum application rate has been changed to 4.5 L/ha. This will result in much lower PEC_{SW} and thus higher TER values. It is considered that the risk will be acceptable with the lower application rate. Other Member states may come to a different conclusion.

6.3.12 Acute toxicity and chronic toxicity of the formulation

Please refer to section 6.3.10.1 for a summary of the provided studies on the effects of Alginure Bio Schutz on aquatic organisms. Section 6.3.11, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

6.3.13 Metabolites of Potassium Phosphonates

Please refer to section 6.1.2 for the assessment of the metabolites of Potassium Phosphonates that was performed during peer review of the active substance in view of its approval.

6.3.14 Accumulation in aquatic non-target organisms

Bioaccumulation of any of the active substances under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

6.4 Effects on Bees

Effects on bees for Alginure Bio Schutz were not evaluated as part of the EU review of potassium phosphonates or phosphonic acid. Therefore, all relevant data and assessments are provided here and are considered adequate.

Toxicity
Table 6.5-1 presents the results of laboratory bee toxicity studies with the formulation. Further details regarding the tests with the formulation are provided in section 6.5.2. For the sake of completeness the table also presents results of laboratory bee toxicity studies with the active substance. Other data submitted in support of the evaluation are not considered adequate and are not reported here.

Table 6.5-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
Alginure Bio Schutz	oral 48 h	> 1206 µg product/bee	Vergé, E. (2012) S11-03609
	contact 48 h	> 2000 µg product/bee	

potassium phosphonates	oral 48 h	> 145 µg a.s./bee*	Thompson, H. (1999) GQ3101, GQ3102
	contact 48 h	> 207 µg a.s./bee*	
phosphonic acid	oral 48 h	> 50.34 µg a.s./bee*	EFSA Scientific Report 10(12): 2963 (2012)
	contact 48 h	> 71.87 µg a.s/bee*	

* EU agreed endpoint

Exposure
The recommended use pattern for Alginure Bio Schutz includes application in grape vine at a maximum application rate of up to 4.5 L product/ha, equiv. to 6.05 g/ha.

Bees may be exposed to Alginure Bio Schutz by direct spraying while bees are foraging on flowers and weeds, through contact with fresh or dried residues or by oral uptake of contaminated pollen, nectar and honey dew.

Hazard quotients
Hazard quotients for oral and contact exposure according to EPPO (2003) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145) were calculated as follows:

Hazard Quotient = max. application rate [g product/ha] / LD_{50} [µg product/bee]

Table 6.5-2 Hazard quotients for honeybees

Test substance	Max. single application rate [g product/ha]	Exposure route	LD_{50} [µg product/bee]	Hazard quotient (HQ)	HQ trigger
Alginure Bio Schutz	8100*	oral	> 1206 µg	< 6	50
		contact	> 2000 µg	< 4	

Application rate was reduced for management reasons to 6.05 g/ha, equiv. to 4.5 L/ha.

Risk assessment
Due to the results of laboratory tests Alginure Bio Schutz is considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field. Bee brood testing is not required since the test item is not an IGR.

Overall conclusion:
It is concluded that Alginure Bio Schutz will not adversely affect bees or bee colonies when used as recommended.

6.5 Effects on Arthropods Other Than Bees

6.5.1 Overview and summary

Effects on arthropods other than bees for Alginure Bio Schutz were not evaluated as part of the EU review of Potassium Phosphonates. Data on Alginure Bio Schutz have been submitted by the applicant and are evaluated here. They are considered adequate to assess the risk for non-target arthropods following the use of Alginure Bio Schutz according to the intended uses.

6.5.1.1 Toxicity

The critical endpoints employed in the risk assessment for non-target arthropods are indicated in the table below.

Table 6.5-1: Toxicity of Potassium Phosphonates / Alginure Bio Schutz to non-target arthropods with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Aphidius rhopalosiphi	STAMINA (= LBG-01F34)	2 d glass plate	LR50 > 40 L/ha equivalent to LR50 > 20.2 kg a.i./ha Effect: Mortality: 12.8% Reproduction: 0%	Schuld, M. 22.05.2001 20001344/01-NLAp	47601
Typhlodromus pyri	STAMINA (= LBG-01F34)	7 d, extend. lab, apple leaves, mortality and reproduction	LR_{50} >16 L/ha equivalent to LR_{50} >8.1 kg a.i./ha Effect: Mortality: 10.8% Reproduction: 17%	Adelberger, I. 22.05.2001 20001344/01-NETp	30320
Aphidius rhopalosiphi	Alginure Bio Schutz	2 d, glass plate	LR_{50} > 198 kg prep./ha LR_{50} > 149.1 L/ha (equivalent to > 34.0 kg a.s./ha) * reevaluation with ToxRat: LR50 = 138 kg prod./ha (= 102.6 L product/ha) (equivalent to 23.4 kg phosphonic acid equ./ha)	Klug, T., 2012 S11-3610	82200
Typhlodromus pyri	Alginure Bio Schutz	7 d, glass plate	LR_{50} = 55900 g prep./ha LR_{50} 54.8 L/ha (equivalent to 12.5 kg a.s./ha) *	Höhn, P., 2012 S11-03611	82201

* New study submitted by the applicant

6.5.1.2 Exposure

In field

Non-target arthropods living in the crop can be exposed to residues from Alginure Bio Schutz by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items.

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of Alginure Bio Schutz is calculated according to published agreement after ESCORT 2 workshop (Candolfi et al. 2001[2] -hereafter referred to as 'Guidance Document') using the following equation:

$$PER_{in-field} = \text{Application rate (g a.s./ha)} \times \text{MAF}$$

where:

MAF = generic multiple application factor used to take into account the potential build-up of applied substances between applications. This factor integrates number of applications, application interval and degradation kinetics of the active substance

Default MAF values for given numbers of applications are listed in the Guidance Document. Since Alginure Bio Schutz will be applied 6 times in variable application schemes, the worst case application scheme giving the highest PER was identified and chosen for the risk assessment.

The maximum predicted environmental rate (PER) occurring in the field after application of Alginure Bio Schutz at the maximum application rate is presented in the following table.

Table 6.5-2: In-field predicted environmental rates (PER) for Alginure Bio Schutz, intended use vines

Substance	Application rate (L Product/ha)	in-field PER (kg Product/ha)
Alginure Bio Schutz (best case)	6 x 1.5	6.691*
Worst case	6 x 4.5	20.07*

*density: 1.345 g/cm^3

Off-field

Exposure of non-target arthropods living in non-target off-field areas to Alginure Bio Schutz will mainly be due to spray drift from field applications. Off-field predicted environmental rates (PER-values) were calculated from in-field PERs in conjunction with drift values published by the BBA (2000[3]) as shown in the following equation:

[2] Candolfi, M.P.; Barrett, K.L.; Campbell, P.; Forster, R.; Grandy, N.; Huet, M.C.; Lewis. G.; Oomen, P.A.; Schmuck, R.; Vogt, H. (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT2 Workshop European Standard Characteristics of Non-Target Arthropod Regulatory Testing. Wageningen, The Netherlands, 46 pp.

[3] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abtrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

$$Off-field\ PER = \frac{Maximum\ in-field\ PER\ x \left({drift\ percentile}/{100} \right)}{vegetation\ distribution\ factor\ (vdf)}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

To account for interception and dilution by three-dimensional vegetation in off-crop areas, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A dilution factor of 10 is recommended by the Guidance Document, but has been questioned. The risk assessment procedure here considers a dilution factor of 5 more appropriated. For endpoint resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor is not used.

Reduction of the amount of drift reaching the off-field areas can be achieved by implementing a in-field buffer strip of a given width. The drift rate at 3 m distance is 6.41 % of the application rate (70th percentile drift).

For the results of study with *T. pyri* exposed to Alginure Bio Schutz, a vegetation distribution factor has to be considered (study conducted in 2D environment).

The resulting PERoff-field values are shown in the following table.

Table 6.5-3: Off-field predicted environmental rates (PER) resulting from the intended uses of Alginure Bio Schutz

Study type	Max. rate (ml Prod./ha)	MAF	Maximum in-field PER (kg Prod./ha)	Drift rate (% appl. rate)	Vegetation distribution factor	Off-field PER (kg Prod./ha)
2-dimensional	6 x 1500	3.2	6.691*	6.41 %	5	0.0858
2-dimensional	6 x 4500	3.2	20.07*	6.41 %	5	0.26

*density: 1.345 g/L

Risk assessment –overall conclusions

The outcome of the risk assessment for non-target arthropods exposed to Alginure Bio Schutz is given in the table below.

Tier 1

Table 6.5-4: Maximum HQ and minimum TER values for arthropod species other than bees after uses of Alginure Bio Schutz in vines

Test substance	Species	Test type	Endpoint ER_{50} (kg Prod./ha)	Worst-case PER in-field (kg Prod./ha)	HQ In-field	PER off-field (3 m) (kg Prod./ha)	HQ Off-field	TER Off-field
Alginure Bio Schutz	Aphidius rhopalosiphi	Lab. 2D	138	20.07	0.15	0.26	0.002	2
	Typhlodromus pyri	Lab. 2D	55.9	20.07	0.36	0.26	0.005	2
HQ values in bold are abow the trigger								

Based on the calculated rates of Alginure Bio Schutz in in-field and off-field areas, the calculated HQ and TER values describing the potential risk resulting from an exposure of non-target arthropods to Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria HQ ≤ 2, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of Alginure Bio Schutz in vines according to the label.

6.5.2 Risk assessment for Arthropods other than Bees

6.5.2.1 In-field

Tier 1

The potential risk for non-target arthropods exposed in-field to Alginure Bio Schutz was assessed by calculating the hazard quotient (HQ = exposure/toxicity) as the ratio of the predicted environmental rate (PER) and the lowest lethal rate (LR50) estimated in standard toxicity tests with non-target arthropods according to the formula:

$$\text{In field HQ} = \frac{\text{In - field PER}}{LR_{50}}$$

The resulting HQ in-field values for the standard species are presented in the following table.

Table 6.5-5: Tier 1 in-field HQ values for non-target arthropods other than bees and acceptability criteria for Tier 1 data

Species	LR_{50} (kg Product/ha)	PER (kg Product/ha)	In-field HQ	Trigger value
Aphidius rhopalosiphi	138	20.07	0.15	2
Typhlodromus pyri	55.9	20.07	0.36	2
HQ values in bold are above the trigger				

The in-field HQ values for exposure to maximum residues for the representative species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are lower than the trigger value of 2 (Candolfi et al, 2001).

The results indicate that Alginure Bio Schutz poses low risk to non-target arthropods in-field following application according to the intended uses.

6.5.2.2 Off field

HQ approach

In order to assess the potential risk of Alginure Bio Schutz to non-target arthropods in off-field areas, the predicted environmental rate in the Off-field (see chapter 0) is compared to the toxicity endpoints according to the following formula:

$$Off - field\ \ HQ = \frac{Off - field\ PER}{LR_{50}} \times correction\ factor$$

where:

Correction factor (also 'safety factor') = amounts to 10 in conjunction with Tier I data from tests on glass plates; amounts to 5 for Tier II data from extended laboratory tests/field tests. The factor accounts for extrapolation from testing few representative species to the species diversity expected in off-crop areas.

Tier 1

Calculated HQ off-field values are given in the following table.

Table 6.5-6: Calculated off-field HQs for non-target arthropods and acceptability criteria for Tier 1 data

Species	Test type	L/ER50 (kg product/ha)	PER in-field (kg product/ha)	Distance (m)	PER off-field (kg product/ha)	PER off-field x correction factor (kg product/ha))	HQ	HQ trigger
Aphidius rhopalosiphi	2 D glass plate	138	20.07	3	0.26	1.25	0.002	2
Typhlodromus pyri	2 D glass plate	55.9		3			0.005	2

The off-field HQ values for *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger value, indicating that Alginure Bio Schutz does not pose an unacceptable risk to non-target arthropods in off-field areas.

TER approach

Additionally to the HQ-approach, the assessment of the risk to non-target arthropods due to an exposure to Alginure Bio Schutz was performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{L(E)R50\,(L\ product/ha)}{Off-field\ PER\,(L\ product/ha)}$$

The risk is considered acceptable if the values obtained are TER off-field > 10 when the ecotoxicological data resulted from Tier 1 tests on glass plates or TER off-field > 5 when the data were obtained in higher tier test (extended lab or field tests).

The resulting TER off-field values are given in the following table.

Table 6.5-7: Calculated TER values for non-target arthropods exposed to Alginure Bio Schutz in off-field areas according to intended uses

Species	Test type	Correction factor	L/ER_{50} (kg product/ha)	PER in-field (kg product/ha)	Distance (m)	PERoff-field (kg product/ha)	TER
Aphidius rhopalosiphi	2 D glass plate	5	138	20.07	3	0.26	531
Typhlodromus pyri	2 D glass plate	5	55.9		3		215
TER values in bold are below the trigger.							

Based on the calculated rates of Alginure Bio Schutz in off-field areas, the calculated TER values for the risk resulting from an exposure of non-target arthropods to Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of Alginure Bio Schutz in vines according to the label.

6.6 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.6.1 Overview and summary

Earthworms, other soil non-target macro and mesofauna as well as soil organisms involved in the breakdown of dead organic matter will be exposed to plant protection products containing Potassium Phosphonates whenever contamination of soil may occur as a result of the intended uses of Alginure Bio Schutz.

Effects on earthworms and other soil non-target organisms resulting from an exposure to Alginure Bio Schutz were not evaluated as part of the EU review of Potassium Phosphonates. All relevant study data for the assessment of the risk to earthworm and other soil non-target macro-and mesofauna from the inteded uses of Alginure Bio Schutz are provided here. New data are listed in Appendix 1 and summarized in Appendix 2 (new studies).

6.6.1.1 Toxicity

Table 6.6-1: Ecotoxicological endpoints for terrestrial non-target soil fauna and organic matter breakdown following exposure to Potassium Phosphonates and Alginure Bio Schutz with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Eisenia fetida	STAMINA (= LBG-01F34)	Acute 14 d	LC_{50} = 2920 mg LBG-0134F /kg soil dw (equivalent to 1000 mg a.i. /kg soil dw) Mortality[1)]	Kölzer, U. 19.04.2006 20051318/01-NLEf	81144
Eisenia fetida	Alginure Bio Schutz	Acute 14 d	LC_{50} > 10000 mg prep./kg soil d.w. (equivalent to LC_{50} >1717 mg a.s./kg soil dw) Mortality [1)]	Schöbinger, U., 2012 S11-03612	82204
Eisenia fetida	STAMINA (= LBG-01F34)	chronic 56 d	NOEC = 182.5 mg LBG-0134F /kg soil dw (equivalent to 62.5 mg a.i.) Reproduction [1)*] EC_{10} =149.1 mg LBG-0134F/kg soil (95%CI: 94.6-204.1) bzw. EC_{10}= 51.1 mg phosphonic acid equivalent/kg soil (95%CI: 32.4-69.9)	Kölzer, U. 10.07.2006 20051318/01-NREf	81145
Eisenia fetida	Alginure Bio Schutz	chronic 56 d; 10 % peat	NOEC = 720 mg prep./kg soil dw (NOEC = 128 mg a.s./kg soil dw) Reproduction	Wagenhoff, E., 2012 S12-02325	82205
Folsomia candida	Alginure Bio Schutz	chronic 28 d; 5 % peat	NOEC = 1983 mg prep./kg soil dw [*)] NOT VALID	Wagenhoff, E., 2012 S12-03362	82202

[*)] New study submitted by the applicant

The studies – except the marked new studies – represent the EU-Evaluation of the active substances Potassium Phosphonates. Detailed information on the toxicity to earthworms of the active substances can be found in the Draft Assessment Report on Potassium Phosphonates of 2005 provided by the Rapporteur member Finland, the EFSA Conclusion Report on Potassium Phosphonates of 2012.

The above cited new Folsomia study is not considered valid. This is due to the fact that the reference substance Boric acid results in an EC_{50} = 208.1 mg Boric acid/kg soil dw and a NOEC = 100 mg Boric acid/kg soil dw. The EC50 value is far from the recommended value of EC50 = 100 mg Boric acid/kg soil dw given in the GD. The exceeding of the recommended EC50 value suggests that an insensitive Folsomia strain has been used in this test. However, based on the effects observed in the high concentrations it may be concluded that these effects cover the significantly lower application rates (factor 50). Hence the test will be used for the risk assessment.

6.6.1.2 Exposure

According to the GAP, Alginure Bio Schutz is intended to be applied 6 times with a maximum application rate of 1.5 L formulation/ha (i.e. 1368 g/ha phosphonic acid eq.) /ha). It will be used against *Plasmopara viticola*.

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the active substances Potassium Phosphonates and the formulated product are presented in the table below.

All calculations assumed an even distribution of the substances in the top 5 cm horizon with a soil bulk density of 1.5 g/mL. Accumulation in the soil profile due to the persistence of Potassium Phosphonates was considered when necessary.

Table 6.6-2: Maximum predicted environmental concentrations in soil PEC_S[1)] for Potassium Phosphonates and Alginure Bio Schutz following application in the intended use in vines.

plant protection product:		Alginur Bio Schutz				
use no		001				
Number of applications/application rate/ intervall		6 x 4.5 l/ha = 6 x 6052.5* 5 x 3 L/ha + 1 x 4.5= 19.5 L/hag/ha Alginur Bio Schutz 6 x 1539 g/ha potassium phosphonates5 x 1026 + 1 x 1539 g a.s./ha (6 x 1026 g/ha phosphonic acid equivalents)(5 x 684 + 1 x 1026 g/ha phosphonic acid equivalents)				
interval		7 d				
crop interception:		70%				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Phosphonic acid	6 x 307.8 g/ha	2.0775	1.8291	5	1.2874	3.3649
Alginur Bio Schutz	6 x 1815.7* g/ha	12.2560	-	-	-	-

* maximum cumulative application rate (L/ha) x relative density: 1345 g/L x (1-interception)

1) PEC_{act} = maximum annual soil concentration for a soil depth of 5 cm
PEC_{bkgd}= background concentration in soil considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops)
PEC_{accu} = accumulated soil concentration

6.6.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.6-3: Ecotoxicological endpoints, PECsoil values and Toxicity to Exposure ratios to assess the risk for earthworms and other soil macro- and mesofauna following application of Alginure Bio Schutz according to the intended uses

Test substance	Intended use (g a.s./ha)	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg soil dw)	TER	TER trigger
Earthworms (*Eisenia fetida*)						
Potassium Phosphonates applied as STAMINA (= LBG-01F34)*	5 x 205.2 + 1 x 307.8 g a.s./haphosphonic acid equivalents	Acute	1000	3.3649	297	10
		Long-term	62.5		19	5
Alginure Bio Schutz	7868 Product/ha*	Acute	> 10000	12.256	816	10
		Long-term	720		59	5
Other soil meso-and macrofauna						
Collembola (*Folsomia candida*)						
Alginure Bio Schutz	7868 g/ha*	Long-term	1983	12.256	162	5
Organic matter breakdown (all organisms)						
Potassium Phosphonates	5 x 205.2 + 1 x 307.8 g a.s./haphosphonic acid equivalents	Long-term	No data provided.	-	-	5
TER values in bold are below the trigger						

* maximum cumulative application rate (L/ha) x relative density: 1345 g/L x (1-interception)

Based on the predicted concentrations of Potassium Phosphonates/Alginure Bio Schutz in soils, the TER values describing the acute and long-term risk for earthworms and other non-target soil organisms following exposure to Potassium Phosphonates /Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER $\geq$ 10 resp. TER $\geq$ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Alginure Bio Schutz in vines according to the label.

6.6.2 Toxicity to Exposure Ratio

6.6.2.1 Acute risk

The potential acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to Alginure Bio Schutz and Potassium Phosphonates was assessed by comparing the maximum PECsoil with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The resulting TER_A values are shown in Table 6.6-3 above.

6.6.2.2 Chronic risk

The Phosphonic acid degrades slowly with normalized DT_{90} values > 365 d. Therefore, a long term risk assessment is necessary (for details, see Section 5).

According to the Guidance Document on Terrestrial Ecotoxicology, a test for assessing effects on organic matter breakdown (litterbag) is required where:

- DT_{90fiel}d of the active substance is > 365 days or
- $DT_{90field}$ of the active substance is between 100 and 365 days and
  Effects on soil microflora > 25 % or TER_{LT} earthworm < 5
- or Collembola TER_{LT} < 5

These criteria are met for Phosphonic acid ($DT_{90\ lab.}$= 843 d). According to assessment scheme given in SANCO/10329/2002 rev2 final additional tests for assessing effects of Potassium Phosphonates on organic matter breakdown (litterbag) are currently required. However, in the light of current scientific and technical knowledge this functional test has to be considered as not fully appropriate to address the risk for soil macro-organisms (especially with respect to structural diversity). This new state of knowledge is also reflected in the current proposal for the revised annex II and III where the functional endpoint from a litterbag test is not any more considered as data appropriate requirement. Tests with the species *Folsomia candida* or *Hypoaspis aculeifer* are proposed to address the risk to soil macro organisms instead. The zRMS is of the opinion that according to Art. 29 (1)(e) the current state of scientific and technical knowledge should be considered in the product assessment and therefore prefers tests showing the effects of Potassium Phosphonates on soil macro-organisms such as collembola instead. The applicant provided a study with the formulation Alginure Bio Schutz on soil macro-organisms. Submitted data are reported in Table 6.6-1 indicating acceptable risk for organic matter breakdown after application of Alginure Bio Schutz.

The potential chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breackdown resulting from an exposure to Alginure Bio Schutz / Potassium Phosphonates as well as the major soil degradation products of Potassium Phosphonates was assessed by comparing the maximum PECsoil with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The resulting TER_{LT} values are shown in Table 6.6-3 above.

6.6.3 Residue content of earthworms

The determination of a log POW value is not applicable to Potassium Phosphonates as a hydrophilic polar compound. However, Potassium Phosphonates are very unlikely to bioaccumulate in earthworms due to the nature of Potassium Phosphonates (ion, polar) in combination with its low toxicity and extensive metabolism. Therefore, studies determining residue content of earthworms are not necessary.

6.7 Effects on Soil Microbial Activity

6.7.1 Overview and summary

Soil microorganisms will be exposed to plant protection products containing Potassium Phosphonates whenever contamination of soil may occur as a result of the intended uses of Alginure Bio Schutz.

Effects on soil microorganisms resulting from an exposure to Alginure Bio Schutz were not evaluated as part of the EU review of Potassium Phosphonates. All relevant study data for the assessment of the risk to soil microorganisms from the intended uses of Alginure Bio Schutz are provided here. New studies are listed in Appendix 1 and summarized in Appendix 2.

6.7.1.1 Toxicity

Table 6.7-1: Ecotoxicological endpoints for soil microbial activity following exposure to Potassium Phosphonates and Alginure Bio Schutz with indication to agreed endpoints

Process	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
N-tranformation	STAMINA (= LBG-01F34)	28 days at 7.87 and 78.67 mg LBG-0134F /kg soil (= 2.70 and 26.99 mg phosphonic acid equivalent/kg soil)	Deviation < 25%	Kölzer, U. 19.06.2006 20051318/01-ABMF	81164
C-transformation	STAMINA (= LBG-01F34)	28 days at 7.87 and 78.67 mg LBG-0134F /kg soil (= 2.70 and 26.99 mg phosphonic acid equivalent/kg soil)	Deviation < 25%	Kölzer, U. 19.06.2006 20051318/01-ABMF	81164
N-tranformation	Alginure Bio Schutz	9.915 and 99.15 kg prep./ha (corresponding to13.22 and 132.2 mg prep./kg soil)	Deviation < 25%	Schöbinger, U., 2012 S11-03613	82207
C-transformation	Alginure Bio Schutz	9.915 and 99.15 kg prep./ha (corresponding to13.22 and 132.2 mg prep./kg soil)	Deviation < 25%	Schöbinger, U., 2012 S11-03613	82207

*calculated as phosphonic acid equivalents
1) LOEP 08/2012
2) New study submitted by the applicant

6.7.1.2 Exposure

Please refer to section 6.6.1.2 above for the predicted environmental concentrations in soil (PECsoil) of Potassium Phosphonates.

6.7.1.3 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the formulation Alginure Bio Schutz and the active substance Potassium Phosphonates are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days of exposure.

The results of the comparison expressed as Margin of Safety (MoS) are presented in the following table.

Table 6.7-2: Summary of risk assessment for soil micro-organisms exposed to Alginure Bio Schutz / Potassium Phosphonates

Substance	Test type	Maximum initial PEC (mg/kg soil dw)	Effects <25% (mg/kg soil dw)	MoS
Potassium Phosphonates applied as STAMINA (= LBG-01F34)*	N transformation	3.2786	26.99 mg phosphonic acid equivalent/kg soil	8.2
	C transformation		26.99 mg phosphonic acid equivalent/kg soil	8.2
Alginure Bio Schutz	N transformation	11.6213	132.2	11.4
	C transformation		132.2	11.4

*calculated as phosphonic acid equivalents

For the active ingredient in Alginure Bio Schutz, Potassium Phosphonates, the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are at least 10-times higher than the corresponding maximum PEC in soil.

Based on the predicted concentrations of Potassium Phosphonates and Alginure Bio Schutz in soils, the risk to soil microbial processes following exposure to Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz is considered to be acceptable/ not acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2.

6.8 Effects on Non-Target Plants

6.8.1 Overview and summary

Effects on non-target plants resulting from an exposure to Alginure Bio Schutz were not evaluated as part of the EU review of Potassium Phosphonates. Therefore, all relevant study data for the assessment of the risk to non-target plants from the intended uses of Alginure Bio Schutz are provided here, listed in Appendix 1 and summarized Appendix 2 (new studies).

6.8.1.1 Toxicity

Table 6.8-1: Ecotoxicological endpoints for non-target plants following exposure to Potassium Phosphonates and Alginure Bio Schutz with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date	ICS-No.

				Report No.	
Seedling emergence					
Solanum sp. *Phaseolus vulgaris* *Lolium perenne* *Helianthus annuus* *Brassica napus* *Allium cepa*	Alginure Bio Schutz (342 g/L Kaliumphosphit)	21 d Seedling emergence	ER50 : > 36 L product/ha * Biomasse	Peterek, S. 2013 S13-00342	84689
Vegetative vigour					
Allium cepa *Avena sativa* *Beta vulgaris* *Brassica napus* *Daucus carota* *Glycine max*	STAMINA (LBG-01F34)	Vegetative vigour	ER_{50} > 20.0 L STAMINA/ha equivalent to > 10.1 kg a.i./ha	Porch, J.R., Krueger, H.O., Martin, K.H. 16.12.2008 286-114	81165
Solanum sp. *Phaseolus vulgaris* *Lolium perenne* *Helianthus annuus* *Brassica napus* *Allium cepa*	Alginure Bio Schutz (342 g/L Kaliumphosphit)	21 d Vegetative vigour	ER50 : > 100 L product/ha NOER : < 6.25 L product/ha * Trockengewicht	Peterek, S. 2013 S13-00325	84690

* New study submited by the applicant

6.8.1.2 Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

PER off-field= Maximum in-field PER (including MAF) x %drift

For calculation of PER in-field, please refer to section 0, page 27.

The resulting maximum off-field predicted environmental rates (PER off-field) are summarized in the following table:

Table 6.8-2: Maximum off-field predicted environmental rates of Alginure Bio Schutz following intended uses

Maximum intended in-field rate	Maximum PERoff-field at 3 m (6.41 % drift)	Maximum PERoff-field at 5 m (2.85 % drift)	Maximum PERoff-field at 10 m (0.95% drift)
	(mL Alginure Bio Schutz/ha)		
6 x 4.5 L	923	410	137

6.8.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.8-3: Summary of risk assessment for non-target terrestrial plants exposed to Alginure Bio Schutz / Potassium Phosphonates

Endpoint	ER50 (L product/ha)	PERin-field (L product/ha)	Distance (m)	Exposure PERoff-field (L product/ha)	TER
Seedling emergence	> 36	14.4	3	0.923	> 39
Vegetative vigour	> 100		3	0.923	> 108

Based on the predicted rates of Alginure Bio Schutz in off-field areas, the TER values describing the risk for non-target plants following exposure to Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an unacceptable risk for non-target terrestrial plants due to the intended use of Alginure Bio Schutz in vines according to the label.

6.9 Other Non-Target Species (Flora and Fauna)

6.9.1 Overview and summary

6.9.1.1 Toxicity

6.9.1.2 Exposure

6.9.1.3 Risk assessment –overall conclusions

6.9.2 Toxicity to Exposure Ratio

6.10 Other/Special Studies

6.10.1 Laboratory studies

6.10.2 Field studies

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status/ Use*
KIIIA1 7.1.1	[redacted].	19.12.2001	Acute oral toxicity in the rat - acute toxic class method 1495-001 ICS: 82209	Y	TIL	1)
KIIIA 10.2.2.1/01	[redacted]	2012	Alginure Bio Schutz - Assessment of Toxic Effects on Rainbow Trout (Oncorhynchus mykiss) (Teleostei, Salmonidae) S11-03606 ICS: 82198	Y	TIL	1)
KIIIA 10.2.2.1/02	[redacted]	2012	Alginure Bio Schutz - Assessment of toxic effects on Rainbow trout (Oncorhynchus mykiss) (Teleostei, Salmonidae) - Specimen Analysis - S11-03890 ICS: 82199 GLP: yes Published: no	Y	TIL	5)
KIIIA 10.2.2.2/01	Weber, K.	2012a	Alginure Bio Schutz - Assessment of Toxic Effects on Daphnia magna using the 48 h Acute Immobilisation Test S11-03607 ICS: 82197 GLP: yes Published: no	Y	TIL	1)
KIIIA 10.2.2.3/01	Weber, K.	2012b	Alginure Bio Schutz - Testing of Effects to the Single Cell Green Alga Desmodesmus subspicatus S11-03608 ICS: 82196 GLP: yes Published: no	Y	TIL	1)
KIIIA 10.4.2.1/01	Verge, E.	2012	Alginure Bio Schutz - Acute Oral and Contact Toxicity to the Honeybee Apis mellifera L. in the Laboratory S11-03609 GLP: yes Published: no	Y	TIL	1)

KIIIA 10.5.1/01	Klug, T.	2012	Alginure Bio Schutz: Toxicity to the Aphid Parasitoid, Aphidius rhopalosiphi De Stefani Perez (Hymenoptera, Braconidae) in the Laboratory (Dose Response Test) S11-3610 ICS: 82200 GLP: yes Published: no	Y	TIL	1)
KIIIA 10.5.1/02	Höhn, P.	2012	Alginure Bio Schutz: Toxicity to the Predatory Mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the Laboratory (Dose Response Test) S11-03611 ICS: 82201 GLP: yes Published: no	Y	TIL	1)
KIIIA 10.6.2/01	Schöbinger, U.	2012a	Acute Toxicity of Alginure Bio Schutz on Earthworms, Eisenia fetida in Artificial Soil with 10 % Peat S11-03612 ICS: 82204 GLP: yes Published: no	Y	TIL	1)
KIIIA 10.6.3/01	Wagenhoff, E.	2012a	Sublethal Toxicity of Alginure Bio Schutz to the Earthworm Eisenia fetida in Artificial Soil with 10 % Peat S12-02325 ICS: 82205 GLP: yes Published: no	Y	TIL	1)
KIIIA 10.6.6/01	Wagenhoff, E.	2012b	Alginure Bio Schutz: Effects on the Reproductive Output of the Springtail Folsomia candida Willem (Collembola, Isotomidae) Using an Artificial Soil Test with 5 % Peat Content (Dose Response Test) S12-03362 ICS: 82202 GLP: yes Published: no	Y	TIL	1)
KIIIA 10.7.1/01	Schöbinger, U.	2012b	Effects of Alginure Bio Schutz on the Activity of the Soil Microflora S11-03613 ICS: 82207 GLP: yes Published: no	Y	TIL	1)
KIIIA 10.8.1/01	Schweizer, N.	2012	Statement on the phytotoxicity of Alginure Bio Schutz GA 784486-A3-100801-01 ICS: 82206 GLP/GEP: no Published: no	Y	TIL	5)

KIIIA 10.8.1/02	Peterek, S.	2013	Alginure Bio Schutz: Effects on the Vegetative Vigour of Non. Target Plant Species under Greenhouse Conditions S13-00325 ICS: 84690 GLP: yes Published: no	Y	6.11	1)
KIIIA 10.8.1/03	Peterek, S.	2013	Alginure Bio Schutz: Effects on the Seedlings Emergence of Non. Target Plant Species under Greenhouse Conditions S13-00342 ICS: 84689 GLP: yes Published: no	Y	TIL	1)
KIIIA 10.8.2.1/01	Zawadsky, C.	2012	Alginure Bio Schutz - Assessment of Toxic Effects on the Duckweed Lemna gibba in a Semi-Static Test S12-02324 ICS: 82208 GLP: yes Published: no	Y	TIL	1)

*
1) accepted (study valid and considered for evaluation)
2) not accepted (study not valid and not considered for evaluation)
3) not considered (study not relevant for evaluation)
4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5) supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of studies relied upon

Reports only studies, which

(a) have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance) or

(b) have been evaluated in a peer reviewed process at EU level but where in exceptional cases derived endpoints have to be revised in the light of current scientific and technical knowledge.

Studies evaluation are ordered according to OECD code numbers.

A2-1 Active substance (generally only relevant in the case that new annex II data is provided after Potassium Phosphonates approval)

No data submitted.

A2-2 Formulation

IIIA 7.1 Toxicological studies and Exposure Data and Information

IIIA 7.1.1 Acute oral toxicity of the preparation

KIIIA 7.1.1/1

Reference:	KIIIA 7.1.1/01
Report	Brunt, P. 19.12.2001 Acute oral toxicity in the rat - acute toxic class method 1495-001 ICS: 82209
Guideline(s):	
Deviations:	No (If yes, describe deviations from test guidelines)
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

For details on the study summary please refer to Section 3 CA.

IIIA 10.1 Effects on aquatic organisms

IIIA 10.2.2 Acute toxicity (aquatic) of the preparation

IIIA 10.2.2.1 Fish acute toxicity LC50, freshwater, cold-water species

KIIIA 10.2.2.1/01

Reference:	KIIIA 10.2.2.1/01
Report	Gonsior, G., 14.08.2012 Alginure Bio Schutz - Assessment of Toxic Effects on Rainbow Trout (Oncorhynchus mykiss) (Teleostei, Salmonidae)

	S11-03606 ICS: 82198
Guideline(s):	OECD-Guideline 203 for Testing of Chemicals (1992)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Materials and methods

Test Item: Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L resp. 177.4 g Phosphonic acid equivalents/kg)

Species Oncorhynchus mykiss (Walbaum), Rainbow trout

A static 96-hour limit test was performed to study the acute effects of Alginure Bio Schutz on rainbow trout. The test item was evaluated in a static test at concentrations of 0 and 100 mg/L. Test medium was prepared by dilution of the test item in test water and application of a defined volume of the stock solution to the test vessel. Seven organisms per test concentration were used.

Fish were observed at initiation of the test, and after 3, 6, 24, 48, 72 and 96 hours. pH-value, temperature and oxygen saturation were measured at the beginning of the test and every 24 hours. Water hardness of the untreated control was determined at the beginning of the test. Samples were taken at 0 hours (initial value) from fresh test solution, after 24, 48, 72 and 96 hours from aged test solution. The taken samples were stored and analysed in a separate study (please refer to Mende (2012), document KIIIA 10.2.2.1/02).

Since no mortality was observed, the evaluation of the toxicological data did not require the application of statistical methods. The NOEC was directly determined from the test results

Results and discussions

The test item concentration of 100 mg/L caused no mortality or non-lethal effects after 96 hours (**Table 6.10-1**). Therefore, the NOEC was laid down as the nominal test item concentration of 100 mg/L.

Table 6.10-1: Observed mortality of rainbow trout (*Oncorhynchus mykiss*) exposed to Alginure Bio Schutz for 96 hours in a static test

Nominal test item concentration [mg/L]	Mortality [%]			
	Test duration [h]			
	24	48	72	96
100	0	0	0	0
Control	0	0	0	0

Analytics

The limit concentration of Alginure Bio Schutz was analysed via HPLC at test start and test end. The recovery rate of the nominal limit concentration determined in a separate study was 99% at test start (17.5 mg a.s./L) and at test end, respectively. All effect levels are given based on nominal concentrations of the test item Alginure Bio Schutz.

Conclusion

No lethal or sublethal effects were observed in the control and in the test item concentration of 100 mg product/L. According to the results of the test, the LC_{50} (96 h) of the test item was determined to be > 100 mg/L. The NOEC (96 h) was observed at 100 mg/L.

(Gonsior, G., 2012)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	LC_{50} (96 h) prod. > 100 mg/L (corresponding to 17.7 mg Phosphonic acid equivalents/L; nominal)

IIIA 10.2.2.2 Acute toxicity (24 & 48 h) for Daphnia preferably Daphnia magna

KIIIA 10.2.2.2/01

Reference:	KIIIA 10.2.2.2/01
Report	Weber, K., 2012 Alginure Bio Schutz - Assessment of Toxic Effects on Daphnia magna using the 48 h Acute Immobilisation Test S11-03607 ICS: 82197
Guideline(s):	OECD-Guideline 202 for Testing of Chemicals (2004)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes. The mentioned document Mende (2012), document KIIIA 10.2.2.1/02 does not content the analytical data of the test wich is in study S11-03891. However, the study with the analytical results has been made available for zRMS. RMS added the toxic reference's results.

Executive summary

The aim of the study was to assess the acute effects of Alginure Bio Schutz on Daphnia magna in a static immobilization test over a period of 48 h. A static limit test with concentrations of 0 and 100 mg Alginure Bio Schutz/L was performed. Test medium was prepared solving the test item in test medium and application of a defined volume to each test vessel. Twenty organisms per test concentration (4 replicates of 5 animals each) were used. The immobility of the Daphnia was determined by visual observation after 24 und 48 hours.

At the limit concentration 100 mg/L Alginure Bio Schutz (corresponding to 17.7 mg Phosphonic acid equivalents/L; nominal) no effect was observed. According to the results of the test, the EC50 (48 h) was determined to be > 100 mg /L (nominal). The corresponding NOEC (48 h) was 100 mg /L (nominal).

<u>Materials and methods</u>

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content: Nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L resp. 177.4 g Phosphonic acid equivalents/kg)

Species *Daphnia magna* STRAUS (Clone V)

The immobilisation effect of Alginure Bio Schutz on Daphnia magna was tested in a 48 hour acute immobilisation test. A static limit test with concentrations of 0 and 100 mg/L was performed. Test medium was prepared solving the test item in test medium and application of a defined volume to each test vessel. Twenty organisms per test concentration (4 replicates of 5 animals each) were used.

The percentage immobility of the daphnids was determined in both concentration and control by visual observation after 24 and 48 hours of exposure under static conditions. pH value, temperature and oxygen saturation were measured at the beginning of the test and every 24 hours. Analytical samples were taken at 0 hours (initial value) from fresh test solution, after 24 and 48 hours from aged test solution. The taken samples were stored and analysed in a separate study (please refer to Mende (2012), document KIIIA 10.2.2.1/02).

Since no immobilisation was observed at the highest test item concentration of 100 mg/L, no statistical determination was indicated. The NOEC was directly determined from the test results.

<u>Results and discussions</u>

The percentage immobility, determined in all test item and control groups after 24 and 48 h under static conditions, is presented in Table 6.102-2. There was no effect observed.

Table 6.102-2: Observed immobilization rates of *Daphnia magna* exposed to Alginure Bio Schutz for 48 hours in a static test (n = 20, 4 replicates with 5 daphnids each)

Nominal test item concentration [mg/L]	Immobilization [%]									
	24 h					48 h				
	Replicates					Replicates				
	1	2	3	4	Mean	1	2	3	4	Mean
100	0	0	0	0	0	0	0	0	0	0
Control	0	0	0	0	0	0	0	0	0	0

Amended by RMS: Toxic reference item: Potassium dichromate at 1.0 and 2.0 mg/L with 5 and 100% mortality after 48 h, respectively.

Conclusion

At the limit concentration 100 mg/L (nominal) of the test item Alginure Bio Schutz (corresponding to 17.7 mg Phosphonic acid equivalents/L; nominal), no effect was observed in a static 48-hour-immobilization test with Daphnia magna. The 48-hour LC50 was exceeding 100 mg test item/L.

(Weber, K., 2012)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	48-hour LC_{50} ≥100 mg prod./L (corresponding to 17.7 mg Phosphonic acid equivalents/L; nominal)

IIIA 10.2.2.3 Effects on algal growth and growth rate

KIIIA 10.2.2.3/01

Reference:	KIIIA 10.2.2.3/01
Report	Weber, K., 2012 Alginure Bio Schutz - Testing of Effects to the Single Cell Green Alga Desmodesmus subspicatus S11-03608 ICS: 82196
Guideline(s):	OECD-Guideline No. 201 for Testing of Chemicals (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes, The mentioned document Mende (2012), document KIIIA 10.2.2.1/02 does not content the analytical data of the test wich is in study S11-03891. However, the study with the analytical results has been made available for zRMS. In order to take into acccount the possibility of eutrophication the EbC50 has been recalculated based on the observation of an increasing algal growth (> 50%).

Executive summary

The aim of the study was to assess the effects of Alginure Bio Schutz on growth rate and yield of the freshwater green alga Desmodesmus subspicatus over a period of 72 h. Three concentration levels of nominal 1, 10 and 100 mg/L and a control were tested. The cell density was determined spectrophotometrically after 0, 24, 48 and 72 hours.

No statistical significant inhibitory effects were determined up to 100 mg/L. Therefore, the EC50-value for the test item Alginure Bio Schutz is estimated to be > 100 mg/L for yield and for growth rate. The LOEC is estimated to be > 100 mg/L, the NOEC was determined to be 100 mg/L.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L resp. 177.4 g Phosphonic acid equivalents/kg)

Species *Desmodesmus subspicatus* CHODAT, strain SAG 86.81

AAP medium; pH adjusted to 7.5 ± 0.1; pH-values 6.84 - 7.11 at test start, 8.18 - 8.79 at test end

The aim of the study was to assess the effects of Alginure Bio Schutz on growth rate and yield of the freshwater green alga Desmodesmus subspicatus over a period of 72 h. The test was started (0 hours) by inoculation of a biomass of 5000 algal cells per mL test medium. Three concentration levels of nominal 1, 10 and 100 mg/L and a control were tested. Six replicates were tested for the 100 mg/L test item concentration and the control and the other test item dilutions were prepared with 3 replicates.

The cell density was determined spectrophotometrically after 0, 24, 48 and 72 hours by relating the fluorescence values to cell density values according to a calibration curve. Growth rate and yield after 72 hours were calculated from the cell density values. Measurements of pH-value were performed after 0 and 72 h. The temperature was measured after 0, 24, 48 and 72 h. Analytical samples were taken from all test concentrations and control in 24-hours intervals. The control and 100 mg/L were analyzed at 0 hours from fresh solution and after 3 days from aged test solution in a separate study (please refer to Mende (2012), document KIIIA 10.2.2.1/02)

The statistical evaluation for day 3 was performed for yield and growth rate using SAS® (2002 - 2008). The NOEC and LOEC were determined by using a multiple comparison method (Dunnett`s t-test). A test for normality of the data was performed by calculating the Shapiro-Wilk's statistic. A test for homogeneity of variance for the data was performed using the Levene-test.

The ErC50 and EyC50 values could not be determined since no inhibition up to 50% was observed.

Results and discussions

The results of the influence of Alginure Bio Schutz on the growth rate and yield of Desmodesmus subspicatus are presented in Table 6.103-3. No statistical inhibitory effects were observed on day 3 in any concentration.

Table 6.103-3: Influence of Alginure Bio Schutz on the growth of Desmodesmus subspicatus after 72 hours of exposure

	Growth rate		Yield	
Nominal test item concentration [mg/L]	**Mean growth rate [d-1]**	**Inhibition of growth rate [%]**	**Mean yield[× 104 cells/ml]**	**Inhibition of yield[%]**
Control	1.60	-	61.51	-
1	1.58	1.2	57.13	7.1
10	1.64	-2.2	67.56	-9.8
100	1.74	-8.1	91.19	-48.3
NOEC	100 mg/L		100 mg/L	
EyC50, ErC50	> 100 mg/L		> 100 mg/L	

Negative values indicate growth promotion

Conclusion

The influence of Alginure Bio Schutz on the growth of the freshwater green alga Desmodesmus subspicatus was assessed in a static dose-response test over 72 hours. No inhibitory effects were observed up to 100 mg/L at day 3. Therefore, the EC50-value for the test item Alginure Bio Schutz is estimated to be > 100 mg/L for yield and for growth rate. The LOEC is estimated to be > 100 mg/, the NOEC was determined to be 100 mg/L.

All validity criteria of OECD Guideline for Testing of Chemicals No. 201 were fulfilled.

(Weber, K., 2012)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable. > 50% enhancing, check risk of eutrophy. zRMS has recalculated the EyC50 value based on the observed effect of increased growth. This has been done with ToxRat Professional and a probit analysis.
Agreed Endpoints:	3-d EbC_{50} = 109.7 mg formulation/L (corresponding to 19.4 mg Phosphonic acid equivalents/L; nominal)

IIIA 10.4.1 Hazard quotients for bees

Refer to table 6.5-2.

IIIA 10.4.1.1 Oral exposure Q_{HO}

Refer to IIIA 10.4.1.

IIIA 10.4.1.2 Contact exposure Q_{HC}

Refer to IIIA 10.4.1.

IIIA 10.4.2 Acute toxicity of the formulation to bees

The following bee acute toxicity study performed on Alginure Bio Schutz is provided in support of the assessment and has not been previously evaluated. Since no major deviations from the guideline were reported which could have influenced the results of the study only a brief summary and the endpoints are presented below.

Report:	**KIIIA1 10.4.2.1/01** Vergé, E. (2012): Alginure Bio Schutz - Acute oral and contact toxicity to the honeybee *Apis mellifera* L. in the laboratory. Eurofins Agroscience Servies Niefern-Öschelbronn, Germany S11-03609
Document No:	S11-03609
Guidelines:	OECD 213 and 214
GLP	Yes

Materials and Methods
In a test under laboratory conditions Alginure Bio Schutz was offered to worker honey bees (*Apis mellifera* L.) in oral and contact route. Treatments with the test substance, the control and the reference item (dimethoate) were carried out in 5 replicates containing 10 bees each.

Test species:	Worker honey bees *Apis mellifera*
Test substance:	Alginure Bio Schutz (density: 1.328 g/cm^3) Content of a.s. nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L) Content of a.s. analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L)
Control:	oral: 50% aqueous sugar solution contact: mineral water
Toxic standard:	BAS 152 11 I (synonym Perfekthion, dimethoate, analysed 414.8 g/L) oral: 0.08, 0.11, 0.15, 0.20 µg a.s./bee contact: 0.10, 0.13, 0.17 and 0.26 µg a.s./bee dissolved in mineral water
Doses:	oral (Alginure Bio Schutz sucrose solution): 125, 250, 500, 1000 and 2000 µg product/bee contact (Alginure Bio Schutz dissolved in mineral water): 125, 250, 500, 1000 and 2000 µg product/bee
Bees per dose:	10
Replicates:	5

<u>Oral toxicity study:</u>
In a dose-response test, 5 replicates of 10 bees were fed with a sugar/water solution containing Alginure Bio Schutz. The tested concentration was 125, 250, 500, 1000 and 2000 µg product/bee. An untreated sugar/water solution was used as water control. Dimethoate was used as toxic standard. The test was conducted at darkness and a temperature of 23 - 24 °C and humidity between 42 and 70%. Biological observations including mortality and behavioural changes were recorded at 4, 24 and 48 hours after dosing. Results are based on nominal concentrations of the product per bee.

<u>Contact toxicity study:</u>
In a dose-response test, 5 replicates of 10 bees were exposed to Alginure Bio Schutz + mineral water, administered topically in a small droplet (2 µL) to the thorax of each bee. The tested concentration was 125, 250, 500, 1000 and 2000 µg product/bee. A group of bees treated with an equivalent volume of mineral water was used as water control. Dimethoate solved in mineral water was used as toxic standard. The test was conducted at darkness and a temperature of 23 - 24 °C and humidity between 42 and 70%. Biological observations, including mortality and behavioural changes were recorded at 4, 24 and 48 hours after application.

Findings
<u>Oral toxicity study:</u>

In the control group of the oral toxicity test no mortality occurred during the 48-hour observation period. After 24 hours there was 2% and 10.0% mortality occurred at 250 µg product/bee and at the highest dose level tested (2000 µg product/bee).
No sublethal effects were observed during the 48 hour observation period. The 24 hour oral LD_{50} value for dimethoate was 0.12 µg a.s./bee (95% confidence limits: 0.12 - 0.139 µg a.s./bee).

	Nominal test dose	Mean real test item dose	Mean mortality [%]	
			24 h	48 h
Test item [µg product/bee]	125	127.8	0.0	0.0
	250	282.8	2.0	2.0
	500	593.6	0.0	0.0
	1000	895.0	0.0	0.0
	2000	1206	10.0	10.0
Control	-	-	0.0	0.0
Reference item [µg a.s./bee]	0.08	0.08	14.0	24.0
	0.11	0.10	34.0	56.0
	0.15	0.13	58.0	66.0
	0.20	0.15	80.0	92.0

Contact toxicity study:
In the control group of the contact toxicity test 2.0% mortality occurred during the 48 hour observation period. At the highest concentration which was tested in the contact toxicity test with Alginure Bio Schutz (2000 µg a.s./bee) the mortality was 6% (corrected mortality 4.1%) after 48 hours. The 24 hour contact LD50 value for dimethoate was 0.16 µg a.s./bee (95% confidence limits: 0.156 - 0.212 µg a.s./bee).

	Nominal test dose	Mean mortality [%]		Mean corrected mortality [%]	
		24 h	48 h	24 h	48 h
Test item [µg product/bee]	125	0.0	2.0	0.0	0.0
	250	2.0	2.0	2.0	0.0
	500	0.0	2.0	0.0	0.0
	1000	0.0	0.0	0.0	-2.0
	2000	6.0	6.0	6.0	4.1
Control	---	0.0	0.0	-	-
Reference item [µg a.s./bee]	0.10	10.0	10.0	10.0	8.2
	0.13	32.0	42.0	32.0	40.8
	0.17	64.0	66.0	64.0	65.3
	0.26	88.0	88.0	88.0	87.8

Conclusions:
In a 48-hour acute oral and contact toxicity test, honeybees (*Apis mellifera*) were exposed to Alginure Bio Schutz. Under the conditions of this study, the acute oral LD_{50} (48 h) was > 1206 µg product/bee and the acute contact LD_{50} (48 h) was > 2000 µg product/bee.

IIIA 10.4.3 Effects on bees of residues on crops

Not required.

IIIA 10.4.4 Cage tests

Not required.

IIIA 10.4.5 Field tests

Not required.

IIIA 10.4.6 Investigation into special effects

Not required.

IIIA 10.4.7 Tunnel tests

Not required.

IIIA 10.5 Effects on arthropods other than bees

IIIA 10.5.1 Effects on sensitive species already tested, using artificial substrates

KIIIA 10.5.1/01

Reference:	KIIIA 10.5.1/01
Report	Klug, T., 2012 Alginure Bio Schutz: Toxicity to the Aphid Parasitoid, Aphidius rhopalosiphi De Stefani Perez (Hymenoptera, Braconidae) in the Laboratory (Dose Response Test) S11-3610 ICS 82200
Guideline(s):	According to Barrett et al. (1994), Candolfi et al. (2001) and Mead-Briggs et al. (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes. Reevaluation of test results using probit analysis.

Executive summary

The objective of the study was to determine the effects of Alginure Bio Schutz on mortality of adults of the parasitoid Aphidius rhopalosiphi De Stefani Perez under worst-case exposure conditions. For assessment of the mortality less than 48 h old wasps were exposed to glass plates treated with Alginure Bio Schutz. The test item was applied with a laboratory track sprayer at the following rates: 12.4, 24.8, 49.5, 99.0 and 198 kg product/ha in a spray volume of 200 L water/ha. The test was conducted with four replicates per treatment, containing 10 wasps each. The parasitoids were confined for 48 h and their condition was assessed after 2 h, 24 h and 48 h.

In order to confirm the efficacy of the test system, Perfekthion (0.3 ml/ha) was applied as a reference item. A water-treated control was also included in the test design.

With respect to the test results it can be concluded that Alginure Bio Schutz caused effects on mortality of Aphidius rhopalosiphi at a rate of 49.5, 99.0 and 198 kg Alginure Bio Schutz/ha. In these test item groups the spray deposits did not dry until the end of the exposure period and the parasitoids that died were found stuck in the droplets. The LR50 was determined to be > 198 kg Alginure Bio Schutz/ha.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Content of a.i. nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Content of a.i. analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L)

Reference item: Perfekthion (nominally 411.7 g/L dimethoate)

Species: *Aphidius rhopalosiphi* (Hymenoptera, Apidae)

Spray application was carried out once at the beginning of the test on glass plates. The test item was applied with a laboratory track sprayer at the following rates: 12.4, 24.8, 49.5, 99 and 198 kg product/ha in a spray volume of 200 L water/ha. Perfekthion (0.3 ml/ha) was applied as a reference item. A water-treated control was also included in the test design. After drying of the spray solution the test units were assembled and wasps were introduced. The test was conducted with four replicates per treatment, containing 10 wasps each.

The introduction of the test organisms for the highest test item application rate applied with 198.0 kg product/ha was done up to 4 hours after application instead of 1.5 hours because of the slow drying properties of the spray deposits. Nevertheless, at the time of introduction spray deposits at the application rates 99 and 198 kg product/ha had not dried completely.

Effects of the test item on vitality and behaviour were assessed after 2, 24 and 48 h. The environmental conditions during the exposure phase (temperature and humidity) were recorded continuously.

The percentage of mortality after 48 h was calculated for each replicate from the number of dead and moribund parasitoids in correlation to the number of released parasitoids. Fisher's Exact Test (right-sided, $p \leq 0.05$) was used to detect significant differences between mortality data of the test item group, reference item group and the control group.

The statistical software program SAS release 9.2 (SAS INSTITUTE INC, Ed. 2002-2008) was used for the statistical analysis.

Results and discussions

The mortality was determined after 2, 24 and 48 h. At test end (48 h) the control mortality was 2.5%. In the test item groups mean mortality was 5.0%, 17.5%, 42.5%, 47.5 % and 50.0%. The mortality was statistically significantly increased for the test item groups applied with 49.5, 99.0 and 198.0 kg Alginure Bio Schutz/ha. Dead parasitoids were mainly found in dried or still remaining droplets of the spray solution applied. The mortality in the reference item was 100.0%. The LR50 was determined to be > 198 kg Alginure Bio Schutz/ha.

Results of the effects of Alginure Bio Schutz on the vitality of the aphid parasitoid Aphidius rhopalosiphi are listed in the Table 6.10-4below.

Table 6.10-4: Mortality of the wasps

Test item concentration [kg product/ha]	Mean mortality after 48 h [%]	Mean corrected mortality after 48 h [%]
Control	2.5	-
12.4	5	2.6
24.8	17.5	15.4
49.5	42.5[ab]	41.0
99.0	47.5[ab]	46.2
198	50[ab]	48.7
Reference (0.3 ml product/ha)	100.0[a]	100.0

SD = Standard Deviation
a Statistically significant effects compared to the control (Fisher's Exact Test, right-sided, p ± 0.05)
b Test organisms were observed to stick to the layer of test item

Conclusion

With respect to the test results it can be concluded that Alginure Bio Schutz caused effects on mortality of Aphidius rhopalosiphi at a rate of 49.5, 99.0 and 198.0 kg Alginure Bio Schutz/ha. In these test item groups the spray deposits did not dry until the end of the exposure period and the parasitoids that died were found stuck in the droplets. The LR50 was determined to be > 198 kg Alginure Bio Schutz/ha.

(Klug, T., 2012)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable. 5 h after application of the test item the spray deposits had not dried completely. Nevertheless the mites have been introduced. The mortality assessed could be caused by direct toxic action of the product or by sticking to its residues or by a combination of both (sticking enhancing contamination). In any of these cases it is the toxic action of the product. It is likely that the component will not dry faster in natural invironment after a spray application.
Agreed Endpoints:	Reevaluation of test results using probit analysis (Toxrat 2.10): LR_{50} = 138 kg prod./ha

KIIIA 10.5.1/02

Reference:	KIIIA 10.5.1/02
Report	Höhn, P., 2012 Alginure Bio Schutz: Toxicity to the Predatory Mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the Laboratory (Dose Response Test) S11-03611 ICS 82201
Guideline(s):	According to Barrett et al. (1994), Candolfi et al. (2001) and Blümel et al. (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes. Reevaluation of test results using probit analysis.

Executive summary

The objective of the study was to determine the effects of Alginure Bio Schutz on mortality of the predatory mite Typhlodromus pyri Scheuten under worst-case exposure conditions. For assessment of the mortality protonymphs (age: ≤ 24 hours) were exposed to glass plates treated with Alginure Bio Schutz. The test item was applied with a laboratory track sprayer at the following rates: 12.4, 24.8, 49.5, 99.0 and 198 kg product/ha in a spray volume of 200 L water/ha. The test was conducted with four replicates per treatment, containing 20 protonymphs each. The mortality and escaping rate of the juvenile mites was assessed up to the adult stage, on day 3 and day 7 of exposure. On day 7, the sex ratio was determined.

In order to confirm the efficacy of the test system, Perfekthion (12 ml/ha) was applied as a reference item. A water-treated control was also included in the test design.

With respect to the test results it can be concluded that Alginure Bio Schutz caused mortality of Typhlodromus pyri at all application rates applied. The LR50 was determined to be 72.76 kg Alginure Bio Schutz/ha (confidence interval: 41.41 to 98.65 kg Alginure Bio Schutz/ha). The mites were observed to stick to the test item on the glass plates at rates of 49.5 kg Alginure Bio Schutz/ha and higher. The observed mortality cannot be explained by a toxic effect alone, also mechanic effects due to stickiness of the test item must be considered.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Content of a.i. nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Content of a.i. analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L)

Reference item: Perfekthion (analysed: 411.7 g/L dimethoate)

Species *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae)

Spray application was carried out once at the beginning of the test on glass plates. The test item was applied with a laboratory track sprayer at the following rates: 12.4, 24.8, 49.5, 99.0 and 198 kg product/ha in a spray volume of 200 L water/ha. Perfekthion (12 ml/ha) was applied as a reference item. A water-treated control was also included in the test design. After drying of the spray solution the test units were set up and protonymphs were transferred onto the test units. The test was conducted with four replicates per treatment, containing 20 protonymphs each.

The introduction of the test organisms for the test item application rates 49.5, 99.0 and 198.0 kg product/ha was done between approximately 3 to 5 hours after application instead of 1.5 hours because of the slow drying properties of the spray deposits. Nevertheless, at the time of introduction spray deposits had not dried completely in order to limit the period between application and exposure.

Effects of the test item on vitality and behaviour were assessed on day 3 and day 7 of exposure. Dead and surviving mites were counted. The number of escaped mites was determined. The environmental conditions during the exposure phase (temperature and humidity) were recorded continuously.

The percentage of mortality (mean value and standard deviation) after 3 and 7 days were calculated for each replicate from the number of dead plus escaped mites in relation to the number of introduced protonymphs. Fisher's Exact Test (one-tailed, $\alpha = 0.05$) was used to detect significant differences between Bonferroni-Holms corrected mortality data of test item treatment group and the control group.

The LR50 was determined with a Probit procedure (normal model).

The statistical software program SAS release 9.2 (SAS INSTITUTE INC, Ed. 2002-2008) was used for the statistical analysis.

Results and discussions

The mortality was determined after 3 and 7 days. At test end (7 days) the control mortality was 2.5%. The mean mortality (defined as the number of dead and escaped mites) of Typhlodromus pyri after exposure to the glass plates treated with 12.4, 24.8, 49.5, 99.0 and 198.0 kg Alginure Bio Schutz/ha was 20.0%, 25.0%, 47.5%, 67.5% and 82.5%. In the reference item group the mean mortality was 100.0%. Thus, for Alginure Bio Schutz the corrected mortality was calculated as 17.9%, 23.1%, 46.2%, 66.7% and 82.1%. In the reference item group the corrected mortality was 100.0 %. The mortality in the Alginure Bio Schutz treatment was statistically significantly increased compared to the control for all test item treatment groups tested (Fisher's Exact Test, Bonferroni-Holms corrected, one tailed, $\alpha = 0.05$). Significant effects were also observed in the reference item group. Dead mites were mainly found in dried or still remaining droplets of the spray solution

Results of the effects of Alginure Bio Schutz on the vitality of the predatory mite Typhlodromus pyri Scheuten are listed in the Table 10.5.1-2 below.

Table 10.5.1-2 Mortality of the protonymphs

Test item concentration [kg product/ha]	Mean mortality after 7 days [%] ± SD	Mean corrected mortality after 7 days [%]
Control	2.5 ± 2.9	-
12.4	20.0a ± 14.7	17.9
24.8	25.0a ± 10.8	23.1
49.5	47.5ab ± 6.5	46.2
99.0	67.5ab ± 15.0	66.7
198	82.5ab ± 6.5	82.1
Reference (12 ml Perfekthion/ha)	100.0a ± 0.0	100.0

SD = Standard Deviation
a Statistically significantly increased compared to the control (Fisher's Exact Test, one tailed, p ± 0.05)
b Test organisms were observed to stick to the layer of test item

Conclusion

This study simulated worst case conditions for the exposure of Typhlodromus pyri to Alginure Bio Schutz. All validity criteria were met, therefore the results obtained can be considered as valid for the simulated worst case scenario.

With respect to the test results it can be concluded that Alginure Bio Schutz caused mortality of Typhlodromus pyri at all application rates applied. The LR50 was determined to be 72.76 kg Alginure Bio Schutz/ha (confidence interval: 41.41 to 98.65 kg Alginure Bio Schutz/ha). The mites were observed to stick to the test item on the glass plates at rates of 49.5 kg Alginure Bio Schutz/ha and higher. The observed mortality cannot be explained by a toxic effect alone, also mechanic effects due to stickiness of the test item must be considered.

(Höhn, P., 2012)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	Reevaluation of test results using probit analysis (Toxrat 2.10): LR_{50}= 55.9 kg prod./ha (95% confidence interval: 46.2 to 68.2 kg Alginure Bio Schutz/ha)

IIIA 10.6 Effects on earthworms and other makro soil-organisms

IIIA 10.6.2 Acute toxicity to earthworms

KIIIA 10.6.2/01

Reference:	KIIIA 10.6.2/01
Report	Schöbinger, U., 2012 Acute Toxicity of Alginure Bio Schutz on Earthworms, Eisenia fetida in Artificial Soil with 10 % Peat S11-03612 ICS 82204
Guideline(s):	According to OECD 207 (1984), ISO 11268-1 (1993), EC-method C.8. (88/302/EEC) 1988)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive summary

The objective of the study was to determine the effects of the acute toxicity of Alginure Bio Schutz on the earthworm Eisenia fetida in a laboratory test with artificial soil. In order to determine the median lethal concentration of the test item, a range-finding test with five different concentrations of Alginure Bio Schutz (1, 10, 100, 1000 and 10000 mg/kg soil d.w.) and a definitive test with five different concentrations of Alginure Bio Schutz (1000, 1780, 3160, 5620 and 10000 mg/kg soil d.w.) were carried out. For each treatment group, four replicates with 10 earthworms each were tested. A toxic reference item (2-chloroacetamide) is tested regularly in the testing facility in a separate study to confirm the sensitivity of the earthworms against compounds with known effects under the test conditions. Earthworm mortality and behavioural changes were recorded after 7 and again after 14 days. The assessment of earthworm weight was carried out immediately before exposure to the test item and at the end of the 14 day exposure period.

Aliquots of wet artificial soil were mixed with the test item at different concentrations and filled into 1 L volume glass vessels. For each treatment group four glass vessels were prepared and ten adult earthworms (age between two and twelve months with clitellum) were added respectively. Aliquots treated with deionised water served as control.

In the absence of mortality the LC50 of Alginure Bio Schutz could not be calculated and was therefore determined to be above 10000 mg/kg soil dry weight. No abnormal behaviour was observed. No mortality was observed in the control group. The biomass development was statistically significantly inhibited at the test concentrations of 5620 and 10000 mg/kg soil dry weight compared to the control treatment (Dunnett's t-Test, two-tailed; $p \leq 0.05$). The concentration with no observed effect (NOEC) of the test item with respect to mortality, loss of body weight and other symptoms was found to be 3160 mg/kg soil dw after 14 days of exposure. Since all validity criteria in this study could be met, the results obtained can be considered as valid.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Content of a.i. nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Content of a.i. analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L)

Reference item: 2-chloroacetamide

Species *Eisenia fetida andrei*

A preliminary non-GLP test was performed with five different concentrations of Alginure Bio Schutz (1, 10, 100, 1000 and 10000 mg/kg soil d.w.). The definitive study was also conducted with five different concentrations of Alginure Bio Schutz (1000, 1780, 3160, 5620 and 10000 mg/kg soil d.w.).

At the beginning of the test, aliquots of wet artificial soil were mixed with the test item at the different concentrations and filled into 1 L volume glass vessels. For each treatment group of the definitive test, four replicates with 10 earthworms each were tested. A toxic reference item (2-chloroacetamide) is tested regularly in the testing facility in a separate study to confirm the sensitivity of the earthworms against compounds with known effects under the test conditions. Aliquots treated with deionised water served as control.

Earthworm weight was recorded for each test organism individually before introduction to the test substrate and at the end of the test. Biomass development of surviving worms was recorded as absolute weight and as relative body weight compared with the initial weight. The earthworm mortality after exposure to the test item was calculated as difference between the number of earthworms per replicate after seven and 14 days and earthworms in the corresponding replicate at the beginning of the test. Behavioural abnormalities (e.g. lethargy, absence of burrowing) were also reported. Water content and pH value of the test substrate were determined from samples taken at study initiation and at study termination.

Treatment means and standard deviations were calculated. Test on normality and homoscedasticity of data using Shapiro-Wilks and Bartlett's test followed by Dunnett's t-Test (body weight change) was performed. The LC50 could not be calculated. The statistical calculations were done using SAS® Version 9.2 (2002-2008).

Results and discussions

In the range-finding test, after 14 days of exposure to the test item no mortality was observed in the test item treatment groups at 1.0, 10, 100, 1000 and 10000 mg/kg soil dry weight and the control group. The body weight change of the test organisms in the test item treatment groups was between 2.17 % (10 mg/kg soil dry weight) and - 20.0 % (10000 mg/kg soil dry weight) compared to the initial weight. In the control group the average body weight change was 1.19 % of the initial weight.

In the definitive test, after 14 days of exposure to the test item no mortality was observed in the control or in the test item treatment groups of 1000, 1780, 3160 and 10 000 mg/kg sdw. In the test item treatment group of 5620 mg/kg sdw one earthworm was missing after 7 days of exposure and therefore counted as dead. Since the mortality in this test item treatment group was within the acceptable range for control mortality, it was considered as not relevant. Therefore the LC50 was determined to be greater than 10000 mg/kg soil dry weight. The NOEC for mortality was determined to be 10 000 mg/kg soil dry weight and the LOEC for mortality to be greater than 10000 mg/kg soil dry weight.

The body weight change was determined as the difference between initial and final mean values of body weight per treatment group which were calculated from the mean values per replicate. The body weight change of the test organisms in the test item treatment groups was between - 6.24 % (1780 mg/kg soil dry weight) and - 19.7 % (10000 mg/kg soil dry weight) compared to the initial weight. In the control group the average body weight change was - 8.30 % of the initial weight. The biomass development at the test concentrations of 5620 and 10000 mg/kg soil dry weight was found to be statistically significantly reduced compared to the control treatment (Dunnett's t-Test, two-tailed; $p \leq 0.05$). The NOEC for body weight change was determined to be 3160 mg/kg soil dry weight. The LOEC for body weight change was determined to be 5620 mg/kg soil dry weight.

Results of the effects of Alginure Bio Schutz on the mortality and bodyweight of the earthworm Eisenia fetida are listed in the Tables 10.6.2-1 and 10.6.2-2 below.

Table 10.6.2.-1 Earthworm mortality after exposure to Alginure Bio Schutz (definitive test)

Test item concentration [mg product/kg sdw]	Mean mortality [%]	
	Day 7	Day 14
Control	0	0
1000	0	0
1780	0	0
3160	0	0
5620	2.5	2.5
10000	0	0
NOEC	10000 mg product/kg sdw	
LOEC	> 10000 mg product/kg sdw	
LC50	> 10000 mg product/kg sdw	

sdw = soil dry weight

Table 10.6.2.-2 Earthworm body weight change after exposure to Alginure Bio Schutz (definitive test)

Test item concentration [mg product/kg sdw]	Mean body weight [mg/worm] ± SD		Mean body weight change [%]
	Day 0	**Day 14**	
Control	362.6 ± 9.5	332.5 ± 6.3	- 8.3
1000	370.7 ± 13.8	324.4 ± 15.9	- 12.5
1780	360.5 ± 11.3	338.0 ± 8.8	- 6.2

3160	365.5 ± 10.6	327.9 ± 12.5	- 10.3
5620	373.0 ± 10.2	321.1 ± 21.0	- 13.9*
10000	370.5 ± 16.9	297.6 ± 12.6	- 19.7*
NOEC	3160 mg product/kg sdw		
LOEC	5620 mg product/kg sdw		

sdw = soil dry weight
SD = standard deviation
* statistically significantly different from the control (Dunnett's t-Test, two-tailed; $p \leq 0.05$)

<u>Conclusion</u>

In this 14-day toxicity study with Alginure Bio Schutz to earthworms (Eisenia fetida) the LC50 could not be calculated and was therefore determined to be above 10,000 mg/kg soil dry weight.

Since no statistically significant mortality was observed for any of the test item concentrations as compared to the control, the NOEC and LOEC for mortality were determined to be 10,000 and above 10,000 mg/kg soil dry weight, respectively.

For the biomass development statistically significant effects were observed for the two highest test item concentrations. Therefore, the NOEC and LOEC for body weight change – corresponding to the overall NOEC and LOEC – were determined to be 3160 and 5620 mg/kg soil dry weight, respectively.

(Schöbinger, U., 2012)

<u>Comments of zRMS [Commenting box]</u>

Study Comments:	The study is acceptable.
Agreed Endpoints:	LC_{50} > 10,000 mg prod./kg soil dry weight NOEC = 5620 mg prod./kg soil dry weight

IIIA 10.6.3 Sublethal effects on earthworms

KIIIA 10.6.3/01

Reference:	KIIIA 10.6.3/01
Report	Wagenhoff, E., 2012 Sublethal Toxicity of Alginure Bio Schutz to the Earthworm Eisenia fetida in Artificial Soil with 10 % Peat S12-02325 ICS 82205
Guideline(s):	According to OECD 222 (2004), ISO 11268-2 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes

<u>Executive summary</u>

The objective of the study is the assessment of the side effects of Alginure Bio Schutz on reproduction and growth of Eisenia fetida and the determination of the NOEC (no observed effect concentration), the LOEC (lowest observed effect concentration), the EC10, EC20 and the EC50.

The NOEC for reproduction was therefore determined as 720 mg Alginure Bio Schutz/kg soil dry weight. The LOEC for reproduction could not be determined. The NOEC and LOEC for body weight change – corresponding to the overall NOEC and LOEC – were determined as 320 and 480 mg Alginure Bio Schutz/kg soil dry weight, respectively. The EC50 for reproduction could not be calculated, but is considered to be above the highest test item concentration of 720 mg/kg soil dry weight.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Content of a.i. nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Content of a.i. analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L)

Reference item: Carbendazim (formulated as Twist WP; tested in the testing facility as a separate toxic reference item study)

Species *Eisenia fetida andrei*

Relative humidity Water content at test initiation 22.6% - 23.5% (of soil dry weight) and 21.4% - 23.2% at test termination

The test was carried out with five test concentrations (142, 213, 320, 480 and 720 mg/kg soil dry weight) and one control with deionised water. For the control eight replicates and for each test item concentration four replicates were used, containing ten earthworms each. One day before test start, adult earthworms were transferred from the rearing medium into moist, untreated artificial soil after recording the individual weight of the earthworms. Each container was incubated under test conditions for 56 days.

One day after application, the earthworms were fed by uniformly distributing four gram finely ground cow manure per vessel on the soil surface. After test start feeding and re-moistening were conducted once a week. On the 28-day assessment, after removal of the adult worms, 4 g food were added for the reproduction test and the test units were moistened with four gram deionised water per vessel. Offspring was not fed during the remaining 28 days of the study. The moisture of the substrate was adjusted weekly by reweighing the test units.

At the beginning of the test and 56 days after application approx. 10 g equivalents from each treatment group were removed to determine soil water content.

Earthworm weight was recorded for each test organism individually before introduction to the test substrate and after 28 days. Biomass development of surviving worms was recorded as absolute weight and as relative body weight compared with the initial weight. The earthworm mortality after exposure to the test item was calculated as difference between the number of earthworms per replicate 28 days and earthworms in the corresponding replicate at the beginning of the test. Any physical or pathological symptoms or distinct changes in the behaviour of the earthworms were recorded. At the end of the study (after 56 days) the number of juveniles per test container for each treatment group was recorded.

Water content and pH value of the test substrate were recorded from samples taken on the day of application and at study termination (day 56).

Mortality was given in per cent per treatment group after four weeks. Reproduction was evaluated as number of juveniles per replicate and mean number per treatment group after eight weeks. Earthworm body weight was recorded individually at test initiation and after four weeks of exposure. Body weight change was reported as absolute weight change and in mean per cent per treatment group. Data of the mean weight change per replicate in per cent were used for statistical evaluation.

The data were tested for normality using Shapiro-Wilks test. Homoscedasticity was tested using Levene's test for body weight change and reproduction. For body weight change and reproduction Williams Test (two-tailed; $p \geq 0.05$) and Dunnett's t-Test (left-sided; $p \geq 0.05$) were used, respectively. Statistical calculations were done using SAS Version 9.2 (2002-2008).

<u>Results and discussions</u>

After 28 days no mortality was observed in the control and in the test item treatment groups of 142, 320, 480 and 720 mg/kg soil dry weight. Mortality of 2.5 % (one missing earthworm) was observed at 213 mg/kg soil dry weight.

The body weight change was statistically significantly different from the control in the test item treatment groups of 480 and 720 mg/kg soil dry weight (Williams Test, two-tailed, $p \leq 0.05$).

The number of the juveniles was not statistically significantly different from the control in any of test item groups (Dunnett's t-Test, left-sided, $p \leq 0.05$).

The treatment with the reference item 'Twist WP' (0.840 kg/ha equivalent to 0.490 kg carbendazim/ha) tested as a separate study resulted in a statistically significant reduction in reproduction of E. fetida (t-Test, $p \leq 0.05$) of 57.4% and a statistically significant body weight change compared to the control (t-Test, $p \leq 0.05$). There was no significant effect on mortality.

Results of the effects of Alginure Bio Schutz on the mortality, bodyweight change and reproduction of the earthworm Eisenia fetida are listed in Table 10.6.2-1 below.

Table 10.6.2.-1 Effect of Alginure Bio Schutz on Eisenia fetida mortality, body weight change and reproduction

Test item concentration [mg product/kg sdw]	Mortality [%]	Mean weight change [%]a	Reproduction [%] (deviation from control)
Control	0	+3.6	-
143	0	+1.7	+2.3
213	2.5	+7.3	+6.6
320	0	+5.5	-6.1
480	0	+7.6*	-6.5
720	0	+7.7*	-11.6
Endpoints [mg/kg sdw]			
NOECbody weight change	320		
LOECbody weight change	480		

NOECreproduction	720
LOECreproduction	-
Overall NOEC	320
Overall LOEC	480
EC50	> 720

sdw = soil dry weight
a a positive value indicates an increase in weight
* statistically significantly different from the control (Williams Test; two-tailed for body weight change, $p \geq 0.05$)

Conclusion

After 28 days the body weight increase was statistically significantly different to the control for the two highest test item concentrations of 480 and 720 mg/kg soil dry weight. After 56 days the number of juveniles was not statistically significantly affected in the test item concentration up to 720 mg/kg soil dry weight.

The NOEC for reproduction was therefore determined as 720 mg Alginure Bio Schutz/kg soil dry weight. The LOEC for reproduction could not be determined. The NOEC and LOEC for body weight change – corresponding to the overall NOEC and LOEC – were determined as 320 and 480 mg Alginure Bio Schutz/kg soil dry weight, respectively. The EC50 for reproduction could not be calculated, but is considered to be above the highest test item concentration of 720 mg/kg soil dry weight.

(Wagenhoff, E., 2012)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	56-d NOEC = 720 mg prod. /kg soil dw (Reproduction) 28-d NOEC = 320 mg prod. /kg soil dw (Bodymass change)

IIIA 10.6.6 Effects on other soil non-target macro-organisms

KIIIA 10.6.6/01 Effects on other soil non-target macro-organisms

Reference:	KIIIA 10.6.6/01
Report	Wagenhoff, E., 2012 Alginure Bio Schutz: Effects on the Reproductive Output of the Springtail Folsomia candida Willem (Collembola, Isotomidae) Using an Artificial Soil Test with 5 % Peat Content (Dose Response Test) S12-03362 ICS 82202
Guideline(s):	OECD 232 (2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes

Executive summary

The objective of the study is to assess the effect of Alginure Bio Schutz on survival and the reproductive output of the springtail Folsomia candida Willem (Collembola, Isotomidae) in a dose-response test in treated artificial soil for 28 days and the determination of the NOEC (no observed effect concentration), the LOEC (lowest observed effect concentration), if possible the EC10, the EC20 and the EC50 (effect concentrations for 10, 20 and 50% effect, respectively).

The test was performed in a defined artificial soil substrate with 5 % peat. The range-finding test was performed with 1, 10, 100, 1000 and 10000 mg test item/kg soil dry weight. In the definitive test, five concentrations (189, 340, 612, 1102 and 1983 mg Alginure Bio Schutz/kg soil dry weight) and one control were tested at 4 replicates/concentration with 10 Collembola each (8 replicates for the control). Adult mortality, behavioural effects and reproduction were assessed after 28 d. The effects of the reference item Boric Acid were investigated in a separate study.

Alginure Bio Schutz caused no significant effects on mortality or reproduction of Folsomia candida up to and including the highest test concentration of 1983 mg test item/kg soil dry weight. Therefore, the 28-day NOEC for mortality and reproduction was determined to be 1983 mg Alginure Bio Schutz/kg soil dry weight. The 28-day LOEC for mortality and reproduction as well as the LC50 and the EC10, EC20 and EC50 could not be determined. Thus, the LC50 as well as the EC20 and EC50 were assumed to be greater than 1983 mg Alginure Bio Schutz/kg soil dry weight, the highest rate tested.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Content of a.i. nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Content of a.i. analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L)

Species *Folsomia candida* Willem (Collembola, Isotomidae)

Reference item: Boric Acid

At the beginning of the test, 9 - 11 days old juvenile springtails were transferred to the exposure units. At days 1 and 14, approximately 3 mg of granulated yeast were added to each exposure unit. The range-finding test was performed with 1, 10, 100, 1000 and 10000 mg test item/kg soil dry weight. In the definitive test, five concentrations (189, 340, 612, 1102 and 1983 mg Alginure Bio Schutz/kg soil dry weight) and one control were tested in treated artificial soil for 28 days at 4 replicates/concentration with 10 Collembola each (8 replicates for the control). One replicate/treatment group (without test organisms) was conducted for the determination of pH and water content. The effects of the reference item Boric Acid were investigated in a separate study.

After the experimental incubation period, the number of adult and juvenile Collembola was assessed by flotation.

Adult mortality, behavioural effects and reproduction were assessed after 28 d. The number of adult and juvenile Collembola was assessed by flotation.. To facilitate counting, photos of the water surface were taken with a digital camera. Adult and juvenile springtails were counted by two different persons on the screen of a pen tablet (Genius Mouse Pen 8 x 6) and a mousotron software program (mousotron 5.0).

At the beginning and end of the test the soil water content was determined for each treatment group. Additionally, exposure units were weighed at start, after 14 days and at test end in order to check the water loss. Water losses were compensated after 14 days.

Statistical analysis on mortality was conducted using Fisher's Exact Test (Bonferroni Holms corrected, right-sided, $p \leq 0.05$). Concerning reproductive output, the test item groups were compared to the control using Dunntt's t-Test (left-sided, $p \leq 0.05$). Data were tested for normality (Shapiro-Wilk test, $p > 0.05$) and homoscedascity (Levene test, $p > 0.05$).

Statistical analyses were conducted using the program SAS INSTITUTE INC. 2002-2008. SAS® Proprietary Software 9.2.

Results and discussions

The results of the definitive test performed with Alginure Bio Schutz are given in Table 10.5.1-1.

Mortality in the water control was 3.8 % and the mean number of juveniles in the control was 958.4 per replicate. Therefore, the study was deemed valid.

A reference item (active substance: Boric Acid) was tested to confirm sensitivity of the test organisms in a separate study. The NOEC for mortality was determined to be 180.0 mg Boric Acid/kg soil dry weight and the LOEC to be 324.0 mg Boric Acid/kg soil dry weight. The NOEC for reproductive output was determined to be 100.0 mg Boric Acid/kg soil dry weight and the LOEC to be 180.0 mg Boric Acid/kg soil dry weight. The EC50 was calculated as 208.1 mg Boric Acid/kg soil dry weight, which is within the expected range according to historical facility data.

Mortalities of up to 7.5% were observed in the test item treated groups, which were not statistically significantly different compared to the control, where 15% of the Collembola died (Fisher's Exact Test, $p \leq 0.05$).

The reproduction of the collembolans exposed to Alginure Bio Schutz was not statistically significantly different compared to the control up to and including the highest test concentration of 1983 mg test item/kg soil dry weight (Dunnett's t-test, $p \leq 0.05$).

Table 10.5.1-1 Effects of Alginure Bio Schutz on Collembola (Folsomia candida) in a 28-day reproduction study

Alginure Bio Schutz [mg/kg soil dry weight]	control	189	340	612	1102	1983
Mean mortality [%] on day 281	3.8	2.5	0.0	0.0	5.0	7.5
Mean no. of juveniles on day 282	958.4	1009.9	860.9	943.4	1019.0	1004.9
Reduction in reproductive output [%] on day 28	-	-5.4	10.2	1.6	-6.3	-4.9
Endpoints [mg test item/kg soil dry weight]						
NOEC (mortality)	1983					
LOEC (mortality)	n.c.					
LC50 (mortality	> 1983					
NOEC (reproduction)	1983					

LOEC (reproduction)	n.c.
EC10 (reproduction)	n.c.
EC20 (reproduction)	> 1983
EC50 (reproduction)	> 1983

a all values not significantly different compared to the control (Fisher's Exact Test, $p \leq 0.05$, right sided)
b all values not significantly different compared to the control (Dunnett's t-test, $p \leq 0.05$, left-sided)
c Reduction in reproductive output according to Abbot (1925) compared to the control. A negative value indicates higher reproduction in the test item group compared to the control.
n.c. not calculable

Conclusion

Alginure Bio Schutz caused no significant effects on mortality or reproduction of Folsomia candida up to and including the highest test concentration of 1983 mg test item/kg soil dry weight.

Therefore, the 28-day NOEC for mortality and reproduction was determined to be 1983 mg Alginure Bio Schutz/kg soil dry weight. The 28-day LOEC for mortality and reproduction as well as the LC50 and the EC10, EC20 and EC50 could not be determined. Thus, the LC50 as well as the EC20 and EC50 were assumed to be greater than 1983 mg Alginure Bio Schutz/kg soil dry weight, the highest rate tested.

(Wagenhoff, 2012)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	28-d NOEC = 1983 mg prod./kg sdw (reproduction) The results of the tests with the reference substance (EC50 = 208.1 mg Boric Acid/kg soil drw; NOEC=100 mg Boric Acid/kg soil drw) indicate that the folsomia stain used is not as sensitive as required in OECD according to Guideline (EC50= 100 mg Boric Acid/kg soil drw). However, the test shows a dose-response relationship and an EC50 can be derived. With regard to very low exposure the test can be used to adress the risk.

IIIA 10.7 Effects on soil microbial activity

IIIA 10.7.1 Laboratory test to investigate impact on soil microbial activity

KIIIA 10.7.1/01

Reference:	KIIIA 10.7.1/01
Report	Schöbinger, U., 2012 Effects of Alginure Bio Schutz on the Activity of the Soil Microflora S11-03613 ICS 82207
Guideline(s):	OECD Guideline 216 and 217 (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive summary

The effects of Alginure Bio Schutz on the carbon transformation (part 1) as well as on the nitrogen transformation (part 2) of soil microorganisms were determined over a period of 28 days. The test item was applied via demineralised water at 7.5 L/ha (corresponding to 9.915 kg product/ha and 13.22 mg/kg soil dry weight) and 75 L/ha (corresponding to 99.15 kg product/ha and 132.2 mg/kg soil dry weight). Untreated silty sand soil was tested as control. Three replicates per test group and control were tested. Sodium Chloride is routinely tested as toxic reference item. In part 1 of the study, the effects of the test item on the metabolic activity of the microbial biomass measured as glucose induced respiration were measured. In part 2, the effects of the test item on the metabolic activity of the nitrogen-N formation rate (nitrate) were measured. Effects were assessed on the day of treatment (day 0) and subsequently after 7, 14 and 28 days.

Based on the results of this study the test item has no adverse effect on soil respiration (day 28) and on nitrogen turnover (day 28; < 25 % deviation between treatments and control) in a field soil up to 132.2 mg/kg soil dry weight.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Content of a.i. nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Content of a.i. analysed: 353.4 g Potassium Phosphonates/L (235.6 g Phosphonic acid equivalents/L)

Reference item: sodium chloride

Test

Soil A common agricultural soil type (batch F2.3 3711) was used in the study. The sampling site was not cultivated since 2006, the last crop was pumpkin in 2005. For at least five years prior to soil sampling no plant protection products had been applied to the sampling site. No organic fertilizer had been applied to the site for at least six months prior to soil sampling. No mineral fertilizer had been applied to the site for four years prior to soil sampling.

For a detailed soil description please refer to Table 10.7.1-1 below.

Source LUFA (Landwirtschaftliche Untersuchungs- und Forschungsanstalt), Obere Langgasse 40, 67346 Speyer, Germany

Test vessel Glass bottles closed loosely with screw caps

Temperature 20 ± 2°C

pH values Nitrogen turnover: 7.35 - 7.54

Short-term respiration: 7.11 -7.36

Soil moisture content At experimental starting the soil was adjusted to 45% of its maximal water holding capacity. All replicates were checked once per week for water losses by evaporation. Compensation with demineralised water was done.

Photoperiod 24 h darkness

Study Design and Methods

Conducted at Eurofins Agroscience Services EcoChem GmbH, Eutinger Str. 24, 75223 Niefern-Öschelbronn, Germany

In-life dates 02.03.2011-31.03.2011

Prior to the initiation of the study, the moisture content of the soil was determined and the amount of water needed to adjust the soil moisture content to 45% WHCmax was calculated. For the nitrogen turnover, the soil was mixed with the ground lucerne meal before application to give a final concentration of 0.5 % of the soil dry weight. For the short-term respiration, the amount of glucose needed to obtain maximal short-term rates of respiration in the test soil was determined prior to the beginning of the test.

Two test item concentrations (corresponding to 9.915 kg product/ha and 13.22 mg/kg soil dry weight, and 99.15 kg product/ha and 132.2 mg/kg soil dry weight, respectively) were prepared and applied to the surface of the soil. For the control soil a corresponding amount of deionised water was added. The soil was mixed to ensure a homogeneous incorporation of the test item in the soil. Afterwards the soil was distributed to the replicates (three per test group and control for each test).

All replicates were checked once per week for water losses by evaporation by re-weighing the bottles and water will be added to adjust vessels to the starting weight.

Measurements of respiration rates and nitrogen content (as nitrate-N of nitrate formation) were carried out after 0, 7, 14 and 28 days.

Part 1: For short-term respiration measurements, soil aliquots of each replicate were amended with glucose (400 mg/100 g soil) to produce an immediate maximum respiratory response. The oxygen consumption was measured for 24 consecutive hours. The total quantities of oxygen consumption during the 24 h were calculated based on the difference of pressure between start and end of the measurement period. Mean respiration rates were calculated for each treatment.

Part 2: The effect of the test item on nitrogen turnover in the soil was assessed by comparing the mean levels of NO3- and nitrate formation rate for each treatment group in individual time intervals to those of the control.

The pH value and soil dry weight were determined in one representative sample per treatment and sampling date after 0, 7, 14 and 28 days.

The results of the nitrification (based on the nitrate-N content on day 28, nitrate-N formation rate of treated soils between the 14 day sampling and the 28 day sampling and the whole study period (0 day to 28 day)) and short-term respiration measurements (last sampling: 28 days) were tested for normality using Shapiro-Wilk's test and residual analysis (Zar, 1999). Homogeneity of variances was tested using Levene's test or Bartlett's test. For the nitrogen turnover (nitrate-N formation rate of the last sampling interval (14 day sampling to 28 day sampling), for the nitrate-N formation rate of the whole study period (0 day sampling to 28 day sampling) and for the short-term respiration the data comply with the requirements for a multiple-t-test. Hence the Dunnett's t-Test (two-tailed) was used to analyse the data for significance. The statistical software program SAS version 9.2 (Ed. 2002 - 2008) was used for the statistical analysis.

Table 10.7.1-1 Soil parameters of test soil

Soil batch	F2.3 3711
Soil texture	medium loamy sand
Sampling depth	0 - 20 cm
pH value	7.11
Dry weight (%)	98.8
Maximum water holding capacity [g/100 g DW]	37.47
Organic carbon content [%]	0.77
Microbial biomass [%] of total organic carbon	12.7
Nitrate-N [mg NO3-N/kg DW]	8.88
Total inorganic Nitrogen [% N]	0.09
Cation exchange capacity [meq/100 g]	10.3

Results and discussions

Part 1 (short-term respiration): Alginure Bio Schutz did not significantly affect the soil microbial carbon transformation at the test item rates 13.22 and 132.2 mg/kg soil dry weight (< 25 % deviation from the control at day 28; refer to Table 10.7.1-2).

Table 10.7.1-2 Effects of Alginure Bio Schutz on the glucose-induced respiration rate

	Test concentration [mg/kg soil dry weight]				
	Control	13.22		132.2	
Day	**Mean respiration rate [mg O2 •(kg soil DW d)-1] ± SD**	**Mean respiration rate [mg O2 (kg soil DW d)-1] ± SD**	**Deviation compared to control [%]**	**Mean respiration rate [mg O2 (kg soil DW d)-1] ± SD**	**Deviation compared to control [%]**
0	20.2	17.8	-11.9	16.2	-19.8
7	20.2	18.5	-8.4	19.0	-5.9
14	20.6	18.7	-9.2	19.5	-5.3
28	18.2	18.1	+0.5	17.8	-2.2

negative values = increase, positive values = inhibition

Part 2 (nitrogen turnover): Changes of nitrate-N contents and nitrate-N formation rates (expressed as nominal mean values and as percent of the control group) are given in Table 10.7.1-3. Alginure Bio Schutz did not significantly affect the microbial nitrate formation rate at the test item rates 13.22 and 132.2 mg/kg soil dry weight (< 25 % deviation from the control at day 28).

Table 10.7.1-3 Effects of Alginure Bio Schutz on soil nitrogen transformation

	Test concentration [mg/kg soil dry weight]				
	Control	13.22		132.2	
Soil nitrate content					
Day	**Mean nitrate-N [mg/kg sdw]**	**Mean nitrate-N [mg/kg sdw]**	**Deviation compared to control [%]**	**Mean nitrate-N [mg/kg sdw]**	**Deviation compared to control [%]**
0	8.9	9.4	5.6	9.4	5.5
7	7.3	7.8	6.8	6.9	-5.5
14	21.3	22.1	3.8	20.5	-3.8
28	36.7	37.2	1.4	32.7*	-10.9
Nitrate formation rate					
Day	**Mean Nitrate-N formation rate [mg/kg sdw/d]**	**Mean Nitrate-N formation rate [mg/kg sdw/d]**	**Deviation compared to control [%]**	**Mean Nitrate-N formation rate [mg/kg sdw/d]**	**Deviation compared to control [%]**
0 - 7	-0.2	-0.2	0.0	-0.4	-57.0
7 - 14	2.0	2.0	2.0	1.9	-3.0
14 - 28	1.1	1.1	1.8	0.9	-20.8

negative values = increase, positive values = inhibition
sdw = soil dry weight

Conclusion

Alginure Bio Schutz did not affect the soil microbial carbon transformation nor the soil microbial nitrogen transformation (no differences ≥ 25 %) when applied up to 132.2 mg/kg soil dry weight throughout 28 days of exposure. The obtained results indicate that Alginure Bio Schutz is not expected to cause any long term detrimental effects on carbon and nitrogen transformation in soil under normal conditions.

(Schöbinger, U., 2012)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	Effects < 25% at 9.915 and 99.15 kg formulation/ha corresponding to 13.22 and 132.2 mg formulation/kg dw soil

IIIA 10.8 Effects on non-target plants

IIIA 10.8.1.2 Vegetative vigour

KIIIA 10.8.1/01

Reference:	KIIIA 10.8.1/01
Report	Peterek, S., 2013 Alginure Bio Schutz: Effects on the Vegetative Vigour of Non-Target Plant Species under Greenhouse Conditions S13-00325

	ICS 84690
Guideline(s):	Yes OECD 227 (2006)
Deviations:	Yes: Temperature and hunidity out of range at some recordings.
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive summary

The effects of Alginure Bio Schutz on the vegetative vigour of six plant species were determined over a period of 21 days. The test item was applied at five rates ranging from 6.25 to 100 L product/ha. Results were compared to a water treated control. Each treatment group consisted of a total of 30 plants, sprayed at BBCH growth stages 12-13. The test duration was 21 days after application. During this period, plants were assessed for mortality and phytotoxicity symptoms on day 7, 14 and 21. The effects on plant shoot dry weight were determined at test termination.

Validity criteria were fulfilled for all six species tested. Based on the results of this study the test item did not result in any effects of mortality in any test species when compared to the control. Since no reduction ≥ 50% was observed in any of the six species tested for dry biomass the ER_{50}-values were estimated to be above 100 L product/ha.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Content of a.i. nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Conducted at a controlled environment greenhouse in 75245 Göbrichen, Germany

In-life dates 17.07.2013-12.08.2013

Test organism

Species: *Allium cepa*
Lolium perenne
Brassica napus
Helianthus annuus
Phaseola vulgaris
Solanum Lycopersicon

Initial population: 6 replicates of 5 plants (30 plants total) per each treatment and control
Test chamber: Plastic pots ø 15 cm with 5 plants per pot each
Test concentrations: control, 6.25, 12.5, 25, 50, and 100 L product/ha
Environmental conditions:
Temperature: 15-36 °C

Humidity: 29-87%
Photoperiod: 16 hours, regulated by a lux sensor. Natural light complemented by high pressure sodium lamps to maintain a minimum light intensity of 11500 Lux.
Observations:

Plants of each species were observed7, 14 and 21 days after application in order to determine the number of dead plants and to visually assess any phytotoxic symptoms. A numerical rating was assigned to help characterise changes in the plants' morphology including necrosis, chlorosis or any other characteristic that is clearly a response of the plants to the treatment. The grades range from 1 to 5 where 1 indicates normal plant appearance, 2 indicates plants with slight symptoms, 3 indicates plants with moderate symptoms, 4 indicates plants with severe symptoms and 5 indicates plants being totally affected by the observed symptom. Mortality of emerged plants per replicate (= pot) was recorded.

At the end of the observation period surviving plants were clipped at soil level. The number of living plants/replicate was determined. The dw if the shoot portion of all surviving plants of each replicate was measured after drying.

Statistics:

A statistical evaluation of potential effects of the test item application on growth of young plants and young plant condition were made. NOER was defined as the highest application rate of the test item used in the study that showed no statistically significant ($p \leq 0.05$) adverse effect on a variable of interest.

<u>Results and discussions</u>

Validity criteria:

All validity criteria were fulfilled for all species tested. Therefore the study was classified as valid.

Mortality:

There was no mortality in any test species after treatment with the test item.

Pytotoxicity:

No symptoms of phytotoxicity in any treatment group were observed in the species *Allium cepa, Lolium perenne* and *Brassica napus*. The species *Helianthus annuus, Phaseola vulgaris* and *Solanum lycopersicum* were slightly to strongly affected by phytotoxic symptoms. Except for the species *Helianthus annuus,* these symptoms of phytotoxicity occurred only on the treated leaves and not on new grown plant shoot material and therefore the phytotoxicity decreased over the test period.

Biomass

An application of the test item resulted in no significant effects on biomass in the monocotyledonous and dicotyledonous species *Allium cepa, Brassica napus, Helianthus annuus* and *Solanum lycopersicum.* The most sensitive species was *Phaseolus vulgaris* showing statistically significant biomass inhibitions up to 36.0% at the highest rate of 100 L product/ha. Statistically significant inhibitions were observed for this species at all rates tested except at the application rate of 12.5 L product/ha. For *Lolium perenne* a statistically significant inhibition of dry biomass (23.7%) was observed at the application rate of 25 L product/ha. As no significant reductions in biomass were exhibited at the two highest rates of 50 and 100 L product/ha, the inhibition at the test item rate 25 L product/ha seems not to be dose-related and the NOER is therefore assumed to be at the highest application rate.

Conclusion

An application of Alginure Bio Schutz to plant species at BBCH growth stage 12.13, at rates ranging from 6.25 up to 100 L product/ha did not result in any mortality in any test species when compared to the control.

Table 10.8.1-1 Effects rates of Alginure Bio Schutz on dry biomass on day 21 [L product/ha]

Species	**Dry Biomass**		
p ≤ 0.5	**LOER**	**NOER**	**ER_{50}**
Allium cepa	> 100	100	> 100[1)]
Brassica napus	> 100	100	> 100[1)]
Helianthus annuus	> 100	100	> 100[1)]
Lolium perenne	> 100	100[2)]	> 100[1)]
Phaseolus vulgaris	6.25	< 6.25	> 100[1)]
Solanum lycopersicum	> 100	100	> 100[1)]

1) ER rates are estimated to be above the highest test item rate

2) as the inhibition rate of dry biomass at the test item rate 25 L product/ha seems not to be dose-related, the NOER is assumed to be at highest application rate.

(Peterek, S., 2013)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable. The study does not fulfil the recommendations according to the GD with respect to number of plants per pot. However, this is notconsidered relevant for the intended uses (max. 27 L/ha in vines), since effects > 50% might be observed with guideline compliant amount of plants per pot, these would need to be < 6.5 L product/ha in order to result in an unacceptable risk. Hence the study is suitable for concluding on the risk of Alginure Bio Schutz to the vegetative vigour of terrestrial non-target plants.
Agreed Endpoints:	ER_{50} (21 d) > 100 L product/ha (*Paseolus vulgaris*) NOER < 6.25 L product/ha(*Paseolus vulgaris*)

IIIA 10.8.1.3 Seedling emergence

KIIIA 10.8.1/02

Reference:	KIIIA 10.8.1/02
Report	Peterek, S., 2013 Alginure Bio Schutz: Effects on the Seedling Emergence of Non-Target Plant Species under Greenhouse Conditions S13-00325 ICS 84689
Guideline(s):	Yes OECD 208 (2006)

Deviations:	Yes: Temperature and hunidity out of range at some recordings.
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive summary

The effects of Alginure Bio Schutz on the seedling emergence of six plant species were determined over a period of 21 days. The test item was applied at an application rate of 36 L product/ha. Results were compared to a water treated control. Each treatment group consisted of a total of 30 plants. The test duration was 21 days after 50% of the plants had emerged. During this period, plants were assessed for emergence, mortality and phytotoxicity symptoms on day 7, 14 and 21. The effects on plant shoot dry weight were determined at test termination.

Validity criteria were fulfilled for all six species tested. Based on the results of this study the test item resulted only in very slight effects on emergence, mortality, phytotoxicity and dry biomass of any test species when compared to the control.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32111

Active ingredient(s)/Content

Content of a.i. nominal: 342 g Potassium Phosphonates/L (228 g Phosphonic acid equivalents/L)

Conducted at a controlled environment greenhouse in 75245 Göbrichen, Germany

In-life dates 18.07.2013-22.08.2013

Test organism

Species: *Allium cepa*
Lolium perenne
Brassica napus
Helianthus annuus
Phaseola vulgaris
Solanum Lycopersicon

Initial population: 6 replicates of 5 seeds (30 seeds total) per each treatment and control

Test chamber: Plastic pots ø 15 cm with 5 plants per pot each

Test concentrations: control, 36 L product/ha

Environmental conditions:

Temperature: 15-36 °C

Humidity: 29-87%

Photoperiod: 16 hours, regulated by a lux sensor. Natural light complemented by high pressure sodium lamps to maintain a minimum light intensity of 11500 Lux.

Observations:

Plant pots for a species were observed7, 14 and 21 days after at least 50 % of the seeds had emerged in the control of that species in order to determine the emergence of seedlings and to visually assess any phytotoxic symptoms. A gradual rating was assigned to help characterise changes in the plants' morphology including necrosis, chlorosis or any other characteristic that is clearly a response of the plants to the treatment. The grades range from 1 to 5 where 1 indicates normal plant appearance, 2 indicates plants with slight symptoms, 3 indicates plants with moderate symptoms, 4 indicates plants with severe symptoms and 5 indicates plants being totally affected by the observed symptom. The types of phytotoxic symptoms were described. Mortality of emerged plants per replicate (= pot) was recorded.

At the end of the observation period surviving plants were clipped at soil level. The number of living plants/replicate was determined. The dw if the shoot portion of all surviving plants of each replicate was measured after drying.

Statistics:

A statistical evaluation of potential effects of the test item application on emergence, growth of young plants and young plant condition were made. The variables were defined as the total number of emerged plants per pot (emergence) and total dry weight of plants above ground per pot (Biomass). Statistical analysis was performed using the program SAS version 9.2.

Results and discussions

Validity criteria:

All validity criteria were fulfilled for all species tested. Therefore the study was classified as valid.

Seedling emergence:

Seedling emergence was not statistically significantly reduced compared to the control in all species tested on any of the three assessment dates. The most sensitive was *Lolium perenne* showing an emergence reduction of 25 % on the second and third assessment date.

Mortality:

The only two test species where plants died were *Allium cepa* (4 plants up to day 14) and *Helianthus annuus* (1 plant on day 7). There was no mortality in any of the other test species after treatment with the test item.

Pytotoxicity:

There were no symptoms of phytotoxicity in five of the tested plant species on any assessment date. The only species which was slightly affected (stunted growing) after application on the third assessment day was *Allium cepa*.

Biomass

An application of the test item resulted in no significant effects on biomass in the monocotyledonous and dicotyledonous species *Brassica napus, Helianthus annuus, Lolium perenne, Phaseolus vulgaris* and *Solanum lycopersicum.* The most sensitive species was *Allium cepa* showing a significant biomass inhibition of 35.3% at the application rate of 36 L product/ha.

Conclusion

An application of Alginure Bio Schutz to soil where seeds of the test species had been sown shortly before at the application rate 36 L product/ha resulted only in very slight effects on emergence, mortality, phytotoxicity and dry biomass of any test species when compared to the control.

The most sensitive regarding seedling emergence was *Lolium perenne* showing an emergence reduction of 25 % on the second and third assessment date.

The most sensitive species regarding dry biomass was *Allium cepa* showing a statistically significant biomass inhibition of 35.3% at the application rate of 36 L product/ha.

Table 10.8.1-2 Inhibition of seedling emergence and dry biomass (%) after 21 days relative to control plants

Species	**Seedling emergence**	**Dry Biomass**
Allium cepa	-3.8	35.3*
Brassica napus	14.3	-14.3
Helianthus annuus	-7.9	-17.7
Lolium perenne	25.0	11.3
Phaseolus vulgaris	0.0	0.1
Solanum lycopersicum	-33.4	-3.3

* significantly different conpared to the control

Negative values indicate enhanced effects compared to the control.

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable. The study does not fulfil the recommendations according to the GD with respect to number of plants per pot. However, for the most sensitive species Lolium perenne and Allium cepa the recommendations were fulfilled. Hence the study is suitable for concluding on the risk of Alginure Bio Schutz to the seedling emergence of terrestrial non-target plants.
Agreed Endpoints:	ER_{50} (21 d) > 36 L product/ha (*Allium cepa*) NOER < 36 L product/ha(*Allium cepa*)

IIIA 10.8.2 Effects on non-target aquatic plants

IIIA 10.8.2.1 Aquatic plant growth - Lemna

KIIIA 10.8.2.1/01

Reference:	KIIIA 10.8.2.1/01

Report	Zawadsky, C., 2012 Alginure Bio Schutz - Assessment of Toxic Effects on the Duckweed Lemna gibba in a Semi-Static Test S12-02324 ICS 82208
Guideline(s):	OECD 221 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation	No

Executive summary

The inhibitory effect of the test item Alginure Bio Schutz on the vegetative growth of the freshwater aquatic plant Lemna gibba was determined in a semi-static dose-response test. In the definitive test, cultures of Lemna gibba were exposed to four concentrations of 0.1, 1.0, 10 and 100 mg test item/L and a control under defined conditions. The inhibition of growth in relation to control cultures was determined over a test period of 7 days.

The 7-day ErC50 and EyC50 were determined to be > 100 mg test item/L for frond number and dry weight, respectively. The 7-day NOErC and NOEyC were determined to be 100 mg test item/L for frond number and dry weight, respectively. The 7-day LOErC and LOEyC were determined to be > 100 mg test item/L for frond number and dry weight, respectively.

Materials and methods

Test Item Alginure Bio Schutz; Batch no. 32104; CAS# 13598-36-2

Active ingredient(s)/Content

nominal: 342 g/L (228 g Phosphonic acid equivalents/L)

analysed: 332 g /L (221.3 g Phosphonic acid equivalents/L, 166.6 g Phosphonic acid equivalents/kg)

Species *Lemna gibba* G3

Plants of Lemna gibba were allowed to grow as monocultures in different concentrations of test item over a period of 7 days in order to quantify test item-related differences in plant growth over this period, based on increase of frond numbers and biomass production.

Before test start, colonies consisting of 3 - 4 fronds were transferred from the inoculum culture to the test vessels. Each test vessel contained a total of 12 fronds. The size of plants and fronds was nearly identical in each test vessel. Renewals of test media were made in order to prevent nutrient depletion and to avoid extremes of pH which might otherwise compromise the test and to maintain concentrations of the test item. In the semi-static 7-days test, the colonies were transferred to new test solutions on days three and five.

Three replicate vessels were prepared for each test item concentration and six replicate vessels for the control.

Frond numbers in each test vessel were determined at the start of the test. Frond numbers and the appearance of the colonies were checked on t = 0, 3, 5 and 7 days in the main test as well as any change in plant development, frond size, necrosis or mortality and additional observations of test media or other abnormalities.

The dry weight of the fronds was determined at the end of the test. A representative batch of two times 12 fronds from the culture used for the test was dried to receive the dry weight for the test start.

Temperature and pH-value were measured in the control and each test concentration in one replicate of fresh test solution and also of the aged test solutions. Light intensity was measured once during the test.

Analytical samples were taken from all test concentrations and control at start (t = 0d) and end (t = 7d) of the test and after 3 and 5 days from new and aged solutions. The samples were taken at the same occasions when the colonies were transferred to new test solutions. The analysis of samples from the test water was performed in the analytical laboratories of the testing facility. The content of the active ingredient in the treatment solution samples was determined by analysing with HPLC-MS/MS.

Means of frond number for each test concentration at each observation time and the specific growth rate (µ) for exponentially growing cultures for each replicate were calculated. Percent inhibition of growth rate (%IR) were determined for each test concentration. The mean doubling time (Td) of the culture in the control group or treatment was calculated from the growth rate. Effects on yield were determined on the basis of frond numbers and dry weight in each treatment and control at the start and end of the test. For each test concentration and control, a mean value for yield was calculated. The mean percent inhibition in yield (%Iy) was calculated for each treatment group.

The statistical evaluation for day 7 was performed for frond numbers, yield of frond numbers, growth rate of frond numbers, dry weight and yield of dry weight. Since no inhibitory effects were observed up to the highest test item concentration of 100 mg test item/L, no values for EC10 and EC50 could be calculated. The EC10 and EC50 values are therefore determined to be > 100 mg/L.

The NOEC and LOEC were determined by using a multiple comparison method (Dunnett t-test left sided). The final LOEC and NOEC were estimated on the base of all parameters. The evaluation of data was performed by SAS®.

Results and discussions

Results of the effects of Alginure Bio Schutz on the vegetative growth of the freshwater aquatic plant Lemna gibba are summarized in Table 10.8.2.1-1 below.

No significant inhibitory effects were determined for frond numbers, yield of frond numbers, growth rate, dry weight and yield of dry weight up to 100 mg/L.

Table 10.8.2.1-1 Influence of Alginure Bio Schutz on the growth of *Lemna gibba*

	Growth rate (frond number) [mg/L]	**Yield (frond number) [mg/L]**	**Growth rate (dry weight) [mg/L]**	**Yield (dry weight) [mg/L]**
7-day EC50 (95% confidence	> 100 (-)	> 100 (-)	> 100 (-)	> 100 (-)

interval)				
7-day EC10 (95% confidence interval)	> 100(-)	> 100 (-)	> 100(-)	> 100(-)
7-day NOEC	100	100	100	100
7-day LOEC	> 100	> 100	> 100	> 100

Values refer to nominal test concentrations
- not applicable

Analytical results

A summary of the analytical results is given in Table 10.8.2.1-2 below.

Table 10.8.2.1-2 Summary of analytical results

Test item concentration (nominal) [mg/L]	Phosphonic acid equivalents nominal (mg/L)	Sampling	Phosphonic acid equivalents analysed	
			mg/L	% of nominal
control	0.00	0 d fresh	n.d.	-
		3 d aged	n.d.	-
		3 d fresh	n.d.	-
		5 d aged	n.d.	-
		5 d fresh	n.d.	-
		7 d aged	n.d.	-
100	16.7	0 d fresh	14.5	87
		3 d aged	14.7	88
		3 d fresh	15.9	95
		5 d aged	16.7	100
		5 d fresh	13.7	82
		7 d aged	14.5	87

- not calculated
n.d. not detectable
LOQ = 0.833 mg/L Phosphonic acid equivalents, corresponding to 5.00 mg/L Alginure Bio Schutz

The mean measured content of Phosphonic acid equivalents in the samples was 90% of nominal. Therefore, the toxicological endpoints were evaluated using nominal concentrations of the test item.

Conclusion

The test is valid, since the doubling time of frond numbers in the control is 1.59 d (38.2 h). This is less than 2.5 d (60 h) as required by OECD guideline.

The 7-day ErC50 and EyC50 were determined to be > 100 mg test item/L for frond number and dry weight, respectively (16.7 mg phosphonic acid equivalents/L; nominal). The 7-day NOErC and NOEyC were determined to be 100 mg test item/L for frond number and dry weight, respectively. The 7-day LOErC and LOEyC were determined to be > 100 mg test item/L for frond number and dry weight, respectively.

(Zawadsky, C., 2012)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	7-day ErC50 and EyC_{50} > 100 mg prod./L for frond number and dry weight, respectively (16.7 mg phosphonic acid equivalents/L); nominal

Appendix 3 Table of Intended Uses justification and GAP tables

Alginure Bio Schutz **GAP rev.1, date: 2013-Jan-15**

PPP (product name/code) Alginure Bio Schutz **Formulation type:** Soluble concentrate (SL)
Active substance Potassium Phosphonates **Conc. of as:** 342 g/L (228 g/L Phosphonic acid equivalents)

Applicant: Tilco Biochemie GmbH **Professional use** ☒
Zone(s): Central EU **Non professional use** ☐

Verified by MS: no

1	2	3	4	5	6	7	8	10	11	12	13	14
					Application			**Application rate**				
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**	**PHI (days)**	**Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures**
1	DE	*Vitis vinifera* VITVI (Vine)	F	Fungicide Downey mildew (*Plasmora viticola*)	Spraying	BBCH 12-89	a) 6 (7 days) b) 6 (7 days)	a) 6 L b) 36 L	a) 2.05 (1.37) kg/ha b) 12.31 (8.2) kg/ha	400 -1600 L/ha	15	Theoretical max. application amount per season: 36 L/ha Normally in practice max 27 L/ha Basic amount: 1.5 L/ha in 400L GS61: 3 L/ha in 800L GS71: 4.5 L/ha in 1200L GS75: 6 L/ha in 1600L

REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code: **Alginure Bio Schutz**

Active Substance: **Potassium Phosphonate 342 g/L (228 g/L Phosphonic acid equivalents)**

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM

Applicant: **Tilco Biochemie GmbH**

Date: **August 2017**

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product Alginure Bio Schutz in its intended uses in vines is documented in detail in the core assessment of the plant protection product Alginure Bio Schutz dated from July 2014 performed by zRMS Germany.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product Alginure Bio Schutz in Germany according to the uses listed in Appendix 2.

General information on the formulation Alginure Bio Schutz can be found in Table 5.1-1of Section 5 of the National addendum Germany (April 2013).

6.1 Proposed use pattern and considered metabolites

6.1.1 Grouping of intended uses for risk assessment

Full details of the proposed use pattern of the formulation Alginure Bio Schutz that will be assessed are presented in Appendix 1 and summarized in the table below. The intended uses in Germany are covered by the core assessment performed by zRMS Germany.

The following table lists the grouping of the intended uses in order to perform a risk envelope approach.

Table 6.1-1: Critical use pattern of Alginure Bio Schutz

Crop	**Growth stage**	**Application method / Drift scenario**	**Number of applications, Minimum application interval, interception, application time (season)**	**Max single aplication rate (g as/ha)**	**Max single soil effective application rate (g as/ha)**
Vines	BBCH 12-68	Spray	6 applications 7 days interval BBCH 12 – 60: Interception: 40% Season:Spring BBCH 61-67: Interception: 70% Season: summer BBCH 68: Interception: 70% Season. summer	Single application rates: BBCH 12 – 60: 1.5 l/ha Alginure BioSchutz 513 g a.s/ha (342 g/ha phosphonic acid eq.) BBCH 61 - 67: 3 l/ha Alginure BioSchutz 1026 g a.s/ha (684 g/ha phosphonic acid eq.) BBCH 68: **4.5 l/ha Alginure BioSchutz** **1539 g a.s./ha (1026 g/ha phosphonic acid eq.)** Cumulative max. application rate: **27 L/ha Alginure BioSchutz** 9234 g a.s./ha (6156 g a.s./ha phosphonic acid)	Single application rates: BBCH 12 – 60: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 61 - 67: 307.8 g a.s/ha (205.2 g/ha phosphonic acid eq.) BBCH 68: **461.7 g a.s./ha (307.8 g/ha phosphonic acid eq.)** Cumulative max. application rate: 2770.2 g a.s./ha (1846.8 g a.s./ha phosphonic acid)

6.1.2 Consideration of metabolites

Please refer to the core assessment.

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Please refer to the core assessment.

Consequences for authorization:

None.

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Please refer to the core assessment.

Consequences for authorization:

None.

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Please refer to the core assessment.

Consequences for authorization:

None.

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

6.5.1 Overview

Results of aquatic risk assessment for the intended for uses of Alginure Bio Schutz in vines based on FOCUS Surface Water PEC values is presented in the Core assessment, Part B, Section 6, chapter 6.4.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route. Hence, aquatic risk assessment differs from those in the core assessment.

The risk assessment for aquatic organism for authorization of Alginure Bio Schutz is outlined in the following chapters.

6.5.2 Toxicity

Please refer to the core assessment.

6.5.3 Justification for new endpoints

Please refer to the core assessment.

6.5.4 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance Document on Aquatic Ecotoxicology", as provided by the Commission Services (SANCO/3268/2001 rev.4 (final), 17 October 2002).

6.5.4.1 TER values for the entry into surface water via spraydrift and deposition following volatilization

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. Potassium Phosphonates has a vapour pressure of > 10^{-4} Pa and is therefore classified as volatile. Hence, deposition following volatilization has been considered. The input parameters for Potassium Phosphonates are given in Section 5.

Several ecotoxicological endpoints are available to assess the risk of the active substances Potassium Phosphonates, and the formulation Alginure Bio Schutz (see chapter 6.5.2).

Table 6.5-1: Risk assessment for Potassium Phosphonates for aquatic organisms for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:			Potassium Phosphonates (Phosphonic acid equivalents)					
Crop/Application rate:			Vines / 5 x 684 + 1 x 1026 g a.s./ha					
Growth stage and season			BBCH 61-68					
Intended use:			001					
DT_{50} water (SFO):			1000 d					
PEC-selection:			actual					
Drift-Percentile:			70^{th}					
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
3	6.41%	93.942	2.092%	4.742	98.684	51.713	28.227	14.136
5	2.85%	41.768	1.876%	4.252	46.021	25.137	14.694	8.429
10	0.95%	13.923	1.429%	3.239	17.161	10.200	6.719	4.631
15	0.50%	7.328	1.088%	2.467	9.794	6.131	4.299	3.199
20	0.32%	4.690	0.829%	1.879	6.568	4.224	3.051	2.348
Relevant toxicity endpoint: E_bC_{50} = 19410 µg a.i./L (*Desmodesmus subspicatus*) Relevant TER: 10								
Buffer zone [m]					**TER**			
3					**196.7**	**375.3**	**687.6**	**1373.1**
Risk mitigation measures			none					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.2 *TER values for the entry into surface water via run-off and drainage*

The concentration of the active substance Potassium Phosphonates in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01. The input parameters for Potassium Phosphonates for exposure modelling with EXPOSIT 3.01 are given in the German National Addendum Section 5, chapter 5.6.2.

Table 6.5-2: Risk assessment for Potassium Phosphonates for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	Potassium Phosphonates (Phosphonic acid equivalents)	
Application rate:	5 x 205.2 + 1 x 307.8 g a.s./ha	
Intended use	001	
Relevant toxicity endpoint:	E_bC_{50} = 19410 µg a.s./L (*Desmodesmus subspicatus*)	
Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	2.83	> 1000
5	2.45	> 1000
10	2.1	> 1000
20	1.47	> 1000
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	0.19	> 1000
Spring/summer	0.06	> 1000
Risk mitigation measures	none	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.3 *Consideration of Metabolites*

Please refer to the core assessment.

6.5.5 Overall conclusions

Based on the calculated concentrations of Potassium phosphonates in surface water (EVA 3, EXPOSIT 3.0.1), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to Potassium Phosphonates according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of Alginure Bio Schutz in vines according to the label.

According to the water framework directive (2000/60/EC) and the implementation law in Germany, the regulation for the protection of surface waters (Oberflächengewässerverordnung), the environmental quality standard representing a good ecological status of surface water bodies is 20 µg *ortho*-Phosphates/L or 50 µg total P/L. Based on the EVA 3 calculations these limits are exceeded in case no risk mitigation measures are implemented. In addition to that the present algae and *Lemna* studies indicate a potential risk of eutrophication. The inclusion directive for Potassium Phosphonates states that member states shall pay particular attention to the risk or eutriphication of surface water. Since no definition for an acceptable limit of eutrophication exists, the environmental quality standard representing a good ecological status of surface water bodies for *ortho*-phosphates is taken as limit value for setting risk mitigation measures.

Consequences for authorization:

For the authorization of the plant protection product Alginure Bio Schutz following labeling and conditions of use are mandatory:

Conditions for use

Alginure Bio Schutz	NW 468
use No. 00-001	NW 605/606 (90%: *m, 75%: 5 m, 50% and common: 10 m)

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Please refer to the core assessment.

Consequences for authorization:

None.

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

Please refer to the core assessment.

Consequences for authorization:

None.

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Please refer to the core assessment.

6.8.1 Justification for new endpoints

Please refer to the core assessment.

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the active substances Potassium Phosphonates and the major soil degradation products are presented in the table below.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g $cm^{-3}$is assumed.

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to Alginure Bio Schutz/Potassium Phosphonates was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breackdown resulting from an exposure to Alginure Bio Schutz/Potassium Phosphonates was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The results of the risk assessment are summarized in the following table.

Table 6.8-1: TER values for earthworms and other soil macro- and mesofauna (Tier-1) for the use in vines

Species	**Test item**	**Time scale**	**Endpoint** [mg/kg soil dw]	**Max. PEC_{SOIL}** [mg/kg soil dw]	**TER**
Eisenia fetida	Potassium Phosphonates	Acute	1000	11.63	86

Eisenia fetida	Potassium Phosphonates	Chronic	62.5	11.63	5.4
Eisenia fetida	Alginure Bio Schutz	Acute	> 10 000	61.28	163
Eisenia fetida	Alginure Bio Schutz	Chronic	720	61.28	12
Folsomia candida	Alginure Bio Schutz	Long-term	1983	61.28	32

TER values shown in bold fall below the relevant trigger.

6.8.3 Higher tier risk assessment

Not relevant.

6.8.4 Overall conclusions

Based on the predicted concentrations of Potassium Phosphonates/Alginure Bio Schutz in soils, the TER values describing the acute and long-term risk for earthworms and other non-target soil organisms following exposure to Potassium Phosphonates /Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Alginure Bio Schutz in vines according to the label.

Consequences for authorization:

None.

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Please refer to the core assessment.

6.9.1 Justification for new endpoints

Please refer to the core assessment.

6.9.2 Risk assessment

The evaluation of the risk for earthworms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Please refer to above for the predicted environmental concentrations in soil (PEC_{SOIL}) of Potassium Phosphonates and Alginure Bio Schutz.

The results of the risk assessment are summarized in the following table.

Table 6.9-1: Risk assessment for effects on soil micro-organisms

Test substance	Test concentration (adverse effects < 25%) [mg/kg]	PEC_{SOIL} [mg/kg]	Risk acceptable [yes/no]
Alginure Bio Schutz	132.2	11.6213	yes

6.9.3 Overall conclusions

Based on the predicted concentrations of Potassium Phosphonates/Alginure Bio Schutz in soils, the risk to soil microbial processes following exposure to Potassium Phosphonates /Alginure Bio Schutz according to the GAP of the formulation Alginure Bio Schutz is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2.

Consequences for authorization:

None.

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Please refer to the core assessment.

Consequences for authorization:

None.

Appendix 1 Table of Intended Uses in Germany

GAP rev. (2), date: 2014-05-20

PPP (product name/code)	**Alginure Bio Schutz**	**Formulation type:**	**SL**
active substance	**Kaliumphosphit (Kaliumphosphonate)**	**Conc. of as :**	**342 g/L**
Applicant:	**Tilco Biochemie GmbH**	**professional use**	☒
Zone(s):	**central/EU**	**non professional use**	☐

Verified by MS: **yes**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	grape vine VITVI (utilisation as table and wine grape)	F	downy mildew of grapevine *Plasmopara viticola* PLASVI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 12 - 68	a) 6 b) 6 (min 7 days)	a) - base dose: 1.5 L/ha - BBCH 61: 3 L/ha - BBCH 68: 4.5 L/ha b) 27 L/ha	a) - base dose: 513 g as/ha - BBCH 61: 1026 g as/ha - BBCH 68: 1539 g as/ha - b) 9234 g as/ha	max 400 L/ha max 800 L/ha max 1200 L/ha	15	

General remarks/explanations:
The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data). The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops). All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.
Make use of existing standards like EPPO and BBCH.
Product: Please indicate the specific variant of the active substance if relevant. If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks. As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions/location of use).

Formulation:
Type: *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
Refer to:
- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1)].

Conc. of as: g/kg or g/L
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.
Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.
Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) “EU” should be chosen.

Explanations to the particular columns:
No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.
Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order accordant to the zone they belong.
Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote). If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a “joint list” of crop groups for the zones. Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated. This column should also include when indicated information concerning “crop destination or purpose of crop” and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).
Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I) “Glasshouse” indicates that the respective trials are acceptable for all zones. As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated. [Remark: Greenhouse definitions are at the moment under evaluation]. Conditions include also information concerning the substrate (natural soil, artificial substrate).
Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated. In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually). If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:
Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).
Growth stage of crop (BBCH-code) – period, first and last treatment. Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition. BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column "pest or group of Pests controlled". In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications
a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.
It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.
Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:
a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.
Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.
For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.
Information concerning the sowing method (precision drilling, …) would be advantageous.
See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:
a)-(Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.
The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:
It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations. In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).
Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product. If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory

GAP rev. (2), date: 2014-05-20

PPP (product name/code)	**Alginure Bio Schutz**	**Formulation type:**	**SL**
active substance	**Kaliumphosphit (Kaliumphosphonate)**	**Conc. of as :**	**342 g/L**
Applicant:	**Tilco Biochemie GmbH**	**professional use**	☒
Zone(s):	**central/EU**	**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	grape vine VITVI (utilisation as table and wine grape)	F	downy mildew of grape-vine *Plasmopara viticola* PLASVI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 12 - 68	a) 6 b) 6 (min 7 days)	a) - base dose: 1.5 L/ha - BBCH 61: 3 L/ha - BBCH 68: 4.5 L/ha b) 27 L/ha	a) - base dose: 513 g as/ha - BBCH 61: 1026 g as/ha - BBCH 68: 1539 g as/ha - b) 9234 g as/ha	max 400 L/ha max 800 L/ha max 1200 L/ha	15	

General remarks/explanations:
The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data). The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops). All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.
Make use of existing standards like EPPO and BBCH.
Product: Please indicate the specific variant of the active substance if relevant. If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks. As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions/location of use).

Formulation:
Type: *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
Refer to:
- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1].

Conc. of as: g/kg or g/L
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.
Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.
Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.

Explanations to the particular columns:
No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.
Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order accordant to the zone they belong.
Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote). If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones. Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated. This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).
Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I) "Glasshouse" indicates that the respective trials are acceptable for all zones. As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated. [Remark: Greenhouse definitions are at the moment under evaluation]. Conditions include also information concerning the substrate (natural soil, artificial substrate).
Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated. In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually). If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:
Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).
Growth stage of crop (BBCH-code) – period, first and last treatment. Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition. BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column "pest or group of Pests controlled". In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications
a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.
It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.
Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:
a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.
Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.
For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.
Information concerning the sowing method (precision drilling, …) would be advantageous.
See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:
a)-(Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.
The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:
It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations. In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).
Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product. If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory

REGISTRATION REPORT
Part B
Section 7: Efficacy Data and Information
Detailed Summary

Product Code: Alginure Bio Schutz

Reg. No.: ZV1 007839-00/00

Active Substance: Potassium Phosphonates 342 g/L

(228 g/L Phosphonic acid equivalents)

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Tilco Biochemie GmbH

Date: December 2012

Evaluator: Julius Kühn-Institut

Date: 2015-07-31

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

Alginure Bio Schutz (Frutogard) was up to now registered as a plant strengthener in Germany (list number 5075-00). According to Regulation (EC) No. 1107/2009, § 2, it will have to be considered as a plant protection product in future. Tilco Biochemie therefore intends to apply for the further use of this product as a plant protection product.
Alginure Bio Schutz is identical with Frutogard. Frutogard is the trade name of the distributor Spiess-Urania in Germany. The trade name Semafort also identical with Alginure Bio Schutz is used in France by the distributor Tribo technologies.
The source of Potassium phosphonates is the technical concentrate produced by Luxembourg Industries Ltd., the main notifier of this active ingredient. Tilco Biochemie holds a corresponding letter of access to the Annex II data package of Luxembourg.

Information on the active ingredients (Uptake and mode of action)

Though the target site for direct toxicity is not known, potassium phosphonates affects phosphate utilization by the organism leading to accumulation of pyrophosphate. It is also firmly established that in many plant species the potassium phosphonates activates a systemic acquired resistance (SAR) response in the plant as shown by induction of pathogenesis-related (PR) proteins. Therefore, a site of action for potassium phosphonates can be seen in the fungus, not in the plant, but it is suggested that the plants natural defence system plays a critical role in pathogen growth. The mode of action might be best described as mixed rather than direct or indirect.

As far as known, potassium phosphite acts in two ways. On one hand free phosphite-anions (HPO3 2-) can directly cause an inhibition of mycelial growth in different fungal pathogens and especially in oomycetes. On the other hand phosphonate or phosphate obviously induce the stimulation of the plants own defense mechanisms. It is supposed that phosphite competes with phosphate in the plant and thus affects the metabolism. Phosphite is transported by the same mechanism in the plant as phosphate. It accumulates in the plant to a level below acute toxicity to the pathogen. In case of infestation of the plant with a pathogen phosphite is then transported into the pathogen where it causes changes in the metabolism and in the composition of membranes and cell walls. The fungal surface is thereby modified in a way that a compatible host-pathogen-interaction is prevented and the plants' defense mechanisms are induced.

Information on crops and pests

Plasmopara viticola

Plasmopara viticola, also known as the grape downy mildew is considered to be the most devastating grape pathogen in North America and Europe. This fungus was originally observed in the United States about 1834 and is most abundantly found in the northern and mid western areas of the United States. Shortly after this first observation the pathogen was introduced to the European countries where it played a devastating role in the yield and production of their grapes, and consequently their wine. France was among the first of the European countries to gain experience in dealing with the pathogen. Within just a few years of the pathogen's introduction the French attempted to graft American root stock to their own vines in order to produce a more resistant strain of grape. Depending on the year, production of grapes in France has been estimated to be at a loss of 50% or more. Because of numbers and results like these, downy mildew has been considered the most devastating fungal disease to affect European vineyards.
Downy mildew attacks all green parts of the vines with stomata, especially the young leaves. In situations of heavy infestations, the foliage dies. This reduces the supply to the grapes, which delays fruit maturity and reduces the amount of sugar.
Downy mildew requires optimum conditions to reproduce and infect. A warm, moist, and humid environment is required.

Information on the intended uses

See Appendix 2.

IIIA1 6.1 Efficacy data

IIIA1 6.1.1 Preliminary range-finding tests

No preliminary range-finding tests were presented here.

IIIA1 6.1.2 Minimum effective dose tests

No results of screening tests are presented here.
The experiences with Alginure Bio Schutz as plant strengthener in Germany over the last years implicate that the minimum effective dose is applied here. Nevertheless, explicit trials will be necessary for a potential renewal of this application.

IIIA1 6.1.3 Efficacy tests

Proposed label claim	Alginure Bio Schutz (Frutogard) provides a good suppression of *Plasmopara viticola*. in vine at a dosage of 1.5 to 6 kg/ha. First application should be carried out at the beginning of infestation. Up to 6 foliar applications are recommended with a minimum interval of 7 days.

Data on the effectiveness of Alginure Bio Schutz against *Plasmopara viticola* are presented from 15 trials.
Alginure Bio Schutz is identical with Frutogard. Frutogard is the trade name of the distributor Spiess-Urania in Germany. The trade name Semafort also identical with Alginure Bio Schutz is used in France by the distributor Tribo technologies.
Alginure Bio Schutz was sprayed several times with application rates of up to 6 kg/ha. The water volume used was depending on the leaf wall area. The effectiveness of Alginure Bio Schutz was assessed by counting the number of infected leaves and fruits. Best effectiveness can be reached if applied early in the season and may be followed by application of a copper fungicide later in the season. In several trials, copper was integrated with reduced amounts later in the season. These variants showed a sufficient effectiveness (leaves: 90.8%, grapes: 80%) and were well comparable to other fungicides e.g. copper (leaves: 93.5%, grapes: 82%). The applicant showed all details in the BAD.
In conclusion, Alginure Bio Schutz is considered to be a tool in the treatment against *Plasmopara viticola* especially in organic vine growing. Furthermore, Alginure Bio Schutz might be an element in the control strategy of *Plasmopara viticola* in the light of reducing the application amount of copper.

IIIA1 6.1.4 Effects on yield and quality

Alginure Bio Schutz is on the market as a plant strengthener for many years and no adverse effects have been reported. Furthermore, Phosphonates were first investigated as fertilizers in Germany and the U.S. during the 1930s and 40s and marketed as a source of phosphorus and potassium fertilizer. Therefore, it is not assumed that adverse effects on yield quantity or quality occur. However, in 3 efficacy trails the sugar content was measured and there were no significant effect due to the treatment with Alginure Bio Schutz compared to the standards. For details please refer to Table 6.1.4.1-1.
Furthermore, Heibertshausen investigated over three years (2005-2007, location “Mäuerchen”) the possible impact of Alginure Bio Schutz (Frutogard) on the sugar content at the Forschungsanstalt Geisenheim. For details please refer to Table 6.1.4.1-2.

Table 6.1.4.1-1: Sugar content of grapes (° Oe)

Test report	Assessment dates	Untreated	Sugar content in ° Oe			Remarks
			Product Frutogard	Standard		
			3 applica-tions with 2.25-4.5 L/ha followed by 2 application of 3.75 kg/ha Funguran	5 × Fun-guran with 1.5-3.75 kg/ha	5 × Dithane 1.2-3.0 kg/ha	
6.1.3.1/07 Trial-No: 02221901, 2002	26.09.02	-	86	90	86.5	
6.1.3.1/09 Trial-No: 02221001, 2002	34.09.02	73	77.5	76	76	
6.1.3.1/10 Trial-No: 02221002, 2002	24.09.02	72	76.5	73	72	

Table 6.1.4.1-1: Sugar content of grapes (° Brix)

Test report	Sugar content in Brix			Remarks
	Product Frutogard	Standard		
	4 applications Frutogard until BBCH 68 followed by 1.7 kg/ha Cu/ha per year	Cuprozin flüssig (3 kg/ha)	Folpan WDG	
6.1.3.1/11 Mäuerchen, 2005	22.55	21.8	22.05	
6.1.3.1/11 Mäuerchen, 2006	25.36	25.58	24.92	
6.1.3.1/11 Mäuerchen, 2007	21.8	20.7	21.8	

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

Alginure Bio Schutz has been on the market as a plant strengthener for many years and no adverse effects have been reported.

IIIA1 6.1.4.2 Effects on the processing procedure

Grapes are normally processed. However, Alginure Bio Schutz is on the market as a plant strengthener for many years and no adverse effects have been reported. Furthermore, Phosphonates were first investigated as fertilizers in Germany and the U.S. during the 1930s and 40s and marketed as a source of phosphorus and potassium fertilizer.
Hence, effects on transformation processes are not expected.
However, Heibertshausen investigated over three years (2005-2007, location "Mäuerchen") the possible impact of Alginure Bio Schutz (Frutogard) on vinification and taint at the Forschungsanstalt Geisenheim. In all three years the fermentation of the different treated vines was uniformly. Also the sensory testing of the wines showed no negative effects due to the treatment with Frutogard. For more details please refer to Table 6.1.4.2-1. For more details on the analytics of the vines please refer to Table 6.1.4.2-2.

The submitted results are estimated as sufficient due to the early stage in which the last application is planned (BBCH 68).
No further experiments for testing the influence on the fermentation process or the taste of wine are deemed to be necessary.

Table 6.1.4.2-1: Quality index

Test report	Assessment dates	Quality index			Remarks
		Product Frutogard	Standard		
		4 applications Frutogard until BBCH 68 followed by 1.7 kg/ha Cu/ha per year	Cuprozin flüssig (3 kg/ha)	Folpan WDG	
6.1.3.1/11 Mäuerchen, 2005	12.05.06	2.4	2.7	2.8	
6.1.3.1/11 Mäuerchen, 2006	22.11.07	2.0	2.6	2.3	
6.1.3.1/11 Mäuerchen, 2007	26.06.08	2.4	2.5	2.0	

Table 6.1.4.2-2: Wine analytics

Test report	Parameters	Product Frutogard	Standard		Remarks
		4 applications Frutogard until BBCH 68 followed by 1.7 kg/ha Cu/ha per year	Cuprozin flüssig (3 kg/ha)	Folpan WDG	
6.1.3.1/11 Mäuerchen, 2005	Alcohol %Vol	14.1	13.1	13.4	
	Acidity g/L	7.0	7.1	7.3	
	pH-value	3.2	3.2	3.2	
	Tartaric acid g/L	2.9	3.1	3.0	
6.1.3.1/11 Mäuerchen, 2006	Alcohol %Vol	15.1	15.2	14.6	
	Acidity g/L	8.5	8.0	9.0	
	pH-value	3.2	3.2	3.1	
	Tartaric acid g/L	2.0	2.0	2.4	
6.1.3.1/11 Mäuerchen, 2007	Alcohol %Vol	12.9	12.8	12.9	
	Acidity g/L	8.6	8.7	8.3	
	pH-value	2.6	2.6	2.6	
	Tartaric acid g/L	4.0	4.1	4.0	

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Alginure Bio Schutz is on the market as a plant strengthener for many years and no adverse effects have been reported. Furthermore, phosphonates were first investigated as fertilizers in Germany and the U.S. during the 1930s and 40s and marketed as a source of phosphorus and potassium fertilizer. Therefore it is not assumed that adverse effects on yield quantity or quality occur.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

Due to its mode of action as a plant strengthener with fungicidal properties and its fast degradation on the plants no phytotoxicity is to be expected with Alginure Bio Schutz. In all Efficacy trials, no signs of phytotoxicity were reported.

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

Effects on relevant beneficial organisms

The toxicity of Alginure Bio Schutz (342 g/L potassium phosphonates) on beneficial organisms has been investigated by carrying out tests under laboratory conditions on *Aphidius rhopalosiphi* and *Typhlodromus pyri*.

The results of these tests (Table 6.2.4-1 and Table 6.2.4-2) indicate that unacceptable effects on survival of the beneficial organisms *Aphidius rhopalosiphi* and *Typhlodromus pyri* are not expected, when Alginure Bio Schutz is applied according to the recommended use pattern. But, results to sublethal effects of Alginure Bio Schutz on *Aphidius rhopalosiphi* and *Typhlodromus pyri* are not available.

Therefore, the submitted results for Stamina (755 g/L potassium phosphonates) are used for evaluation. These results are presented in Table 6.2.4-3 and Table 6.2.4-4. On the basis of these results no effects ≥ 25% are expected for populations of *Aphidius rhopalosiphi* and *Typhlodromus pyri*, when Alginure Bio Schutz is applied according to the recommended use pattern, i.e. 6 applications of 1.5 L/ha - 4.5 L/ha (corresponding to 6 x 0.513 kg/ha to 1.539 kg/ha potassium phosphonates) in viticulture. *Aphidius rhopalosiphi* is not a relevant antagonist in the proposed crop. The results for *Aphidius rhopalosiphi* indicate that the recommended applications of Alginure Bio Schutz are not harmful for populations of relevant beneficial insect species.

Table 6.2.4-1: Effects of Alginure Bio Schutz on *Aphidius rhopalosiphi* (exposed stage: male and female) in a laboratory test (substrate: glass)

Application rate [L/ha]	Corrected mortality [%]	Effect on parasitisation rate [%]	Reference
9.337	2.6	-[1)]	Höhn, P., 2012 S11-03610
18.675	15.4	-[1)]	
36.898	41.0	-[1)]	
74.548	46.2	-[1)]	
149.096	48.7	-[1)]	

[1)] Not determined

Table 6.2.4-2: Effects of Alginure Bio Schutz on *Typhlodromus pyri* (exposed stage: protonymph) in a laboratory test (substrate: glass)

Application rate [L/ha]	Corrected mortality [%]	Effect on egg production [%]	Reference
9.337	17.9	-[1]	Höhn, P., 2012 S11-03611
18.675	23.1	-[1]	
36.898	46.2	-[1]	
74.548	66.7	-[1]	
149.096	82.1	-[1]	
LR_{50}: 54.789 L/ha (95% Confidence limits: 31.182 L/ha – 74.285 L/ha)			

[1] Not determined

Table 6.2.4-3: Effects of potassium phosphonates applied as Stamina on *Aphidius rhopalosiphi* (exposed stage: males and females) in a laboratory test (substrate: glass)

Application rate [kg/ha]	Corrected mortality [%]	Effect on parasitisation rate [%]	Reference
30.20	12.8	-39.9	Schuld, M., 2001 Final report 20001344/01-NLAp

Table 6.2.4-4: Effects of potassium phosphonates applied as Stamina on *Typhlodromus pyri* (exposed stage: protonymph) in an extended laboratory test (substrate: bean leaves)

Application rate [kg/ha]	Corrected mortality [%]	Effect on egg production [%]	Reference
12.08	10.8	17.2	Adelberg, I., 2001 Final report 20001344/01-NETp

Conclusions:
Alginure Bio Schutz is classified as not harmful for populations of *Typhlodromus pyri*.
Alginure Bio Schutz is classified as not harmful for populations of relevant beneficial insect species.

Effects on soil quality
Effects on soil macro-organisms being used as indicators of soil quality

Effects on earthworms

Information:
The product Alginure Bio Schutz contains the active substance potassium phosphonates which is to be included in the Annex to Commission Implementing Regulation (EU) No 540/2011.
Alginure Bio Schutz contains the active substance Potassium Phosphonates at 342 g/L, this is equivalent to an amount of 228 g/L phosphonic acid equivalent.
Since potassium is irrelevant for risk assessments due to its very low toxicity and natural occurrence, only the *phosphonic acid* equivalent is considered in the risk assessment modelling. Phosphonic acid equivalent represents salts of potassium and predominantly hydrogen phos-

phonate and phosphonate (the possible salts of phosphonic acid). Therefore, the amount of 228 g phosphonic acid equivalent/L product is considered in the risk assessment to estimate a possible hazard for organisms and environment.

Use pattern
The formulated product Alginure Bio Schutz is a foliar fungicide to be applied after emergence to grapevines. It can be applied to vines throughout the growing season (BBCH 12-89) with the application rate increasing with increasing growth stages.
The formulated product Alginure Bio Schutz is applied after emergence to grapevines with maximum 6 applications of 6 L product/ha (corresponding to 2.052 kg/ha potassium phosphonates or 1.368 kg phosphonic acid equivalents/ha).

Exposure and risk assessment
No negative effects have been reported on beneficial organism during the efficacy testing of Alginure Bio Schutz.

Table 6.2.4-3: Toxicity/exposure ratios for earthworms and other soil non-target macro-organisms

Test substance	Use pattern	Species	Test type	Endpoint [mg/kg soil d.w.] (corrected)	PEC_S [mg/kg soil d.w.]	TER	TER risk assessment trigger
LBG-0134F	Vineyard, max. 6 × 6 L, 7 days interval	*Eisenia fetida*	Acute	$LC_{50\ corr}$ > 500 [a]	3.089 [a]	162	10
Alginure Bio Schutz	Vineyard, max. 6 × 6 L, 7 days interval	*Eisenia fetida*	Acute	$LC_{50\ corr}$ > 5000	18.215	274	
LBG-0134F	Vineyard, max. 6 × 6 L, 7 days interval	*Eisenia fetida*	Chronic	$NOEC_{corr}$ = 31.3 [a]	3.089 [a]	10.1	5
Alginure Bio Schutz	Vineyard, max. 6 × 6 L, 7 days interval	*Eisenia fetida*	Chronic	$NOEC_{corr}$ = 360	18.215	19.8	
Alginure Bio Schutz	Vineyard, max. 6 × 6 L, 7 days interval	*Folsomia candida*	Chronic	$NOEC_{corr}$ = 992	18.215	54.5	

a a.s. in phosphonic acid equivalents

The acute and chronic TER values for potassium phosphonates are greater than the relevant triggers of 10 and 5, respectively, indicating an acceptable risk to earthworms following application of Alginure Bio Schutz for the proposed use in vineyards.
In this context the applicant mentions that *normally in practice max. 27 L/ha* are applied while a max. amount per season of 36 L/ha is possible.

Overall conclusion with respect to effects on soil macro-organisms

No precautions are regarded necessary to minimise contamination of the terrestrial environment or protect non-target terrestrial organisms.
According to the studies conducted with Alginure Bio Schutz/phosphonic acid (relevant substance for risk assessment) it is concluded that the proposed use of the product will not pose an unacceptable risk to populations of earthworms and collembola, when applied according to the recommended use pattern.

Instructions and information: None

Effects on soil quality
Effects on soil micro-organisms being used as indicators of soil quality

Effects on soil non-target micro-organisms exposed to Interface
The product Alginure Bio Schutz contains the active substance potassium phosphonates which is to be included in the Annex to Commission Implementing Regulation (EU) No 540/2011.
Alginure Bio Schutz contains the active substance Potassium Phosphonates at 342 g/L, this is equivalent to an amount of 228 g/L phosphonic acid equivalent.
The effects of Alginure Bio Schutz on soil micro-organisms were assessed and endpoints are used in the risk assessment in addition to active substance data on toxicity to soil micro-organisms (Table 6.2.4-4).

Table 6.2.4-4: Ecotoxicological endpoints for soil micro-organisms

Test item	Test design[1]	EU agreed endpoints	Reference
Potassium Phosphonates	C	No significant effect > 25% at day 28 at 2.7 mg and 26.99 mg product/kg soil dw. (equivalent to 10 and 100 L product/ha)	EFSA Scientific Report 10(12): 2963 (2012)
	N		

[1] C = Carbon mineralization, N = Nitrogen transformation.

Table 6.2.4-: Risk assessment for soil microflora functions

Test substance	NOEC [mg/kg] (< 25% effect at 28 d)	Maximum PEC_{soil} [mg/kg]	MoS*
Alginure Bio Schutz	132.2	9.108	14.5

* Margin of Safety (factor: NOEC/PEC).

Alginure Bio Schutz had no significant effect on soil micro-organisms at 132 mg product/kg d.w. soil (equivalent to 23.53 mg phosphonic acid/kg soil). This is 15 times higher than the maximum PEC_{max} of 9.108 mg/kg d.w. soil following the worst-case application to vine.
An acceptable risk to soil microbial activity can be concluded for the proposed use of Alginure Bio Schutz.

Overall conclusion with respect to effects on soil quality
There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality when Alginure Bio Schutz is used according to the recommended use pattern.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

No adverse effects on parts of plants used for propagation purposes are expected since Alginure Bio Schutz is a plant strengthener with fungicidal properties.

IIIA1 6.2.6 Impact on succeeding crops

Grapes are a permanent culture. Therefore, the impact on succeeding crops can be excluded.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Due to its mode of action as a plant strengthener with fungicidal properties, no negative effect on other plants is to be expected with Alginure Bio Schutz.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

The Fungicide Resistance Action Committee (FRAC, 2012) evaluated phosphite fungicides (e.g. Fosetyl-Al and phosphorous acid) as a low risk group with few resistance cases reported in only few species.
Two factors are probably responsible for the reduced resistance risk with phosphonate products: First the mode of action in target fungi may involve several sites and second the involvement of host defenses in disease suppression. Both of these factors create a broad front against disease development, and a difficult hurdle for pathogens to overcome through resistance.
However, in order to avoid any risk of resistance, it is proposed to rotate Alginure Bio Schutz with fungicides with other mode of actions (e.g. copper) during the season.

IIIA1 6.3 Economics

Currently in Germany a significant increase in organically farmed vineyards can be noticed and a growing number of winemakers that are willing to change to organic farming. This includes some of the leading wine producers who are members of the Association of German Predicate Wine Estates (VDP). This development is increasing the demand for organically produced food and beverages (including wine) (Kauer et al., 2008)[1].
Therefore, the need for plant protection measures that secure yield and quality is especially important in organic growing, because only a very limited number of products are available. Alginure Bio Schutz is one of the product that are currently allowed to be used in organic farming and many years of practical experience show that Alginure Bio Schutz is an product for organic wine growers.

IIIA1 6.4 Benefits

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

IIIA1 6.4.1 Survey of alternative pest control measures

In general, the number of organic pesticides is very limited. In organic vine growing only products based on the active substance copper are currently available against *Plasmopara viticola*. Therefore, Alginure Bio Schutz is an important alternative and complement in organic wine growing.

IIIA1 6.4.2 Compatibility with current management practices including IPM

Alginure Bio Schutz is an important tool in organic vine growing and is often used in combination with fungicides that are based on copper or sulphur. Due to the use of Alginure Bio Schutz the amount of copper per ha can be reduced: Refer also to Point IIIA 6.4.3.

[1] KAUER, R., FADER, B. und WOLFF, M. (2008): Aktuelle Situation der Bekämpfung von Plasmopara viticola in der Praxis des ökologischen Weinbaus in Deutschland. Fachgespräch: „Bedeutung von Kupfer für den Pflanzenschutz, insbesondere für den Ökologischen Landbau – Reduktions- und Ersatzstrategien", Berlin-Dahlem. 142: 21-26.

IIIA1 6.4.3 Contribution to risk reduction

In organic viticulture normally shorter application intervals are required due to less efficient products compared to integrated pest management.
According to the Sustainable Use Directive (2009/128/EC) a reduction of the application amounts is desired. This is especially true for the use of pesticides based on copper. For several years, the government requires a drastic reduction of the copper entry and a lot of research is conducted to follow these “Copper Minimising strategy”.
In Europe currently the maximum amount for organic viticulture is 6 kg copper/ ha per year or 30 kg copper/ ha in five years (Regulation EEC No 2092/91 Annex II B, since 01/01/2009 Regulation (EC) No 834/2007). The German associations for ecological viticulture have limited the use of copper to 3 kg/ha per year and 15 kg ha in five years.
In many German growing areas these provisions can only be met if other products can be used as alternative or in mixture with copper products in order to reduce the application amount of copper. Therefore, Alginure Bio Schutz is an element in the control strategy of *Plasmopara viticola* in vine without any alternatives.

IIIA1 6.5 Other/special studies

No additional information is considered relevant.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

Efficacy Data and Information on the Plant Protection Product
Public available data and own experimental data of the applicant were presented in a BAD and in Caddy K-documents. GEP requirements were fulfilled and EPPO-Guidelines considered. The assessment is valid for the Maritime EPPO Zone in the Central zone. The application modalities were outlined appropriately and the biology of the host has been considered appropriately.

Preliminary range-finding tests
Preliminary range finding tests were not documented and are not deemed to be necessary; the product was already on the market as plant strengthener in Germany.

Minimum effective dose tests
The minimum effective dose was not approved by experiments. Explicit experiments should be elaborated until a potential renewal of the product.

Efficacy tests
Sufficient efficacy has been approved. Due to the application modalities the disease cannot be controlled with the product alone.

Effects on yield and quality
With respect to the quality of plants or plant products no adverse effects have been observed.

Impact on the quality of plants and plant products
Alginure Bio Schutz has been on the market as a plant strengthener for many years and no adverse effects have been reported.

Effects on the processing procedure
Concerning the processing procedure no adverse effects are expected.

Phytotoxicity to host crop
Phytotoxicity to target plants has not been observed.

Adverse effects on beneficial organisms (other than bees)

Alginure Bio Schutz is classified as not harmful for populations of the predatory mite *Typhlodromus pyri* as well as not harmful for populations of relevant beneficial insect species.

There is no indication of any unacceptable adverse effects on soil macro- or soil microorganisms relevant for the maintenance of soil quality when Alginure Bio Schutz is used according to the recommended use pattern.

Possible development of resistance or cross-resistance

The resistance risk is low. Due to the application characteristics the product will be changed with other products.

6.3-6.5:

In general, the number of organic pesticides is very limited. In organic vine growing only products based on the active substance copper are currently available against *Plasmopara viticola*. Therefore, Alginure Bio Schutz can be used as an alternative and complement in organic wine growing.

IIIA1 6.7 List of test facilities including the corresponding certificates

Official testing station	Address	GEP certificate
Union Invivo	83 Avenue de la Grand Armée 75782 Paris Cedex 16, France	no
Association pour la Recherche et le Développement en Viticulture Durable (ARD-VD)	33175, Gradigan, France	no
FREDON Bourgogne	21, Rue Jean Baptiste Gambut-Zi Beaune Vignolle-21200 Beaune, France	no
SARL VitaConsult	Rue du pré Neuf ; 44190 Gorges, France	no
Spiess-Urania Chemicals GmbH	Hauptstraße 4, 67271 Klein-karlbach. Germany	yes
RP Freiburg	Merzhauser Straße 119. 79100 Freiburg	yes

Appendix 1: List of data submitted in support of the evaluation

Annex **Point**	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
Document LIIIA1	TILCO BIOCHEMIE GMBH	2013	Reference List submitted LIII - listed by Annex Point N/O N 2420329/305498	J		Y
Document LIIIA1	TILCO BIOCHEMIE GMBH	2013	Reference list submitted LIII - listed by Annex Point, Confidential data O/O N 2420332/305499	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
Document LIIIA1	TILCO BIOCHEMIE GMBH	2013	Reference list submitted LIII - listed by Annex Point, Confidential data O/O N 2420337/305500	J		Y
Document LIIIA1	TILCO BIOCHEMIE GMBH	2013	Reference List submitted LIII - listed by Annex Point N/O N 2420338/305501	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
Document N	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part A - Alginure BioSchutz - DE - Risk Management - National Assessment N/O N 2420433/305502	J		Y
Document N	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part A - Alginure BioSchutz - DE - Risk Management - National Assessment N/O N 2420434/305503	J		Y

Annex Point	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
MIIIA1 Sec 6	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part B - Alginure BioSchutz - DE- Section 6 - Ecotoxicology - National addendum (WORD Version) N/O N 2420455/305506	J		Y
MIIIA1 Sec 6	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part B - Alginure BioSchutz - DE - Section 6 - Ecotoxicology - National addendum N/O N 2420456/305507	J		Y

Annex **Point**	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
MIIIA1 Sec 1	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part B - Alginure BioSchutz - DE - Section 1 - Identity, physical and chemical properties, other information - Core assessment N/O N 2420968/305508	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
MIIIA1 Sec 1	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part B - Alginure BioSchutz - DE - Section 1 - Identity, physical and chemical properties, other information - Core assessment N/O N 2420969/305509	J		Y
MIIIA1 Sec 6	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part B - Alginure BioSchutz - DE - Section 6 - Ecotoxicology -- Core assessment (WORD Version) N/O N 2420988/305512	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
MIIIA1 Sec 6	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part B - Alginure BioSchutz - DE - Section 6 - Ecotoxicology -- Core assessment N/O N 2420990/305513	J		Y
MIIIA1 Sec 7	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part B - Alginure BioSchutz - DE - Section 7 - Efficacy Data and Information - Core assessment J/O N 2421002/305514	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
MIIIA1 Sec 7	TILCO BIOCHEMIE GMBH	2013	Draft Registration Report - Part B - Alginure BioSchutz - DE - Section 7 - Efficacy Data and Information - Core assessment J/O N 2421003/305515	J		Y
Document N	TILCO BIOCHEMIE GMBH	2013	Form for use in checking zonal 'Applications for completeness (Reg.(EC) 1107/2009) N/O N 2421286/305516	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.1.3	Anonymous	2013	Effective value of the TTF5 formulation, alone or in combination, in the scope of a grapevine mildew control program on vine-stock in 2007 N/N N 2422873/305517	J		Y
KIIIA1 6.1.3	Anonymous	2007	Tests on vine-stock in 2007. Association pour la recherche durable (ARD-VD) [Association for research and development in sustainable wine-growing] N/N N 2422907/305518	J		Y

Annex Point	**Author**	**Year**	**Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.**	**Data protection claimed (J=Yes O=Open N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIA 8.8.2.2	Adelberger, I.	2001	Stamina: Toxicity to the pretadory mite, Typhlodromus pyri, Scheuten (Acari, Phytoseiidae) using an extended laboratory test 20001344/01-NETp J/N N 2422910/305519	J		Y
KIIA 8.8.2.1	Schuld, M.	2001	Stamina: Acute toxicity tp the aphid parasitoid, Aphidius rhopalosiphi (Hymenpera, Braconidae) DeStaefani-Perez in the laboratory 20001344/01-NLAp J/N N 2422923/305526	J		Y

Annex **Point**	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIA 8.12	Porch, J.R., Krueger, H.O., Martin, K.H.	2008	Potassium Phosphate: A toxicity test to determine the effects of the test substance on vegetative vigor of six species of plants 286-114 J/N N 2422924/305527	J		Y
KIIIA1 6.1.3	Paupelard, L.	2008	Grape downy mildew year 2008 2008-15 N/N N 2422926/305528	J		Y

Annex **Point**	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIIA1 6.1.3	Anonymous	2008	Test report-subject:grape downy mildew N/N N 2422930/305529	J		Y
KIIIA1 6.1.3	Jacob, S.	2006	Efficacy of TTF5 compared with a copper contact fungicide in 2006 on Pinot Noir vine-stock 2006-30 N/N N 2422932/305530	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.1.3	Anonymous	2004	Plasmopara viticola F032210002 N/N N 2422939/305531	J		Y
KIIIA1 6.1.3	Huber, W.	2002	Frutogaurd for the control of downy mildew (Plasmopara Viticola) on grapes F02221901 N/J N 2422950/305532	J		Y

Annex Point	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIIA1 6.1.3	Huber, W.	2002	Frutogard for the control of downy mildew (Plasmopara Viticola) on grapes F02221902 N/J N 2422956/305533	J		Y
KIIIA1 6.1.3	Huber, W.	2002	Frutogard for the control of downy mildew (Plasmopara Viticola) on grapes F02221001 N/J N 2422958/305534	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.1.3	Huber, W.	2002	Frutogard for the control of downy mildew (Plasmopara Viticola) on grapes F02221002 N/J N 2422961/305535	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.1.3	Heibertshausen, D.S.	2009	Befallsreduzierung von Plasmopara Viticola (Berk&Curt ex de bary) Berl. & de toni in ökologischen Weinbau auf der Basis von Maßnahmen zur Kupferminimierung und Verfahren der induzierten Resistenz N/N N 2422964/305536	J		Y

Annex Point	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIIA1 6.1.3	Bleyer, W.	2011	Frutogard for the control of downy mildew (Plasmopara Viticola) on grapes ZulFPero.2010 N/J N 2422967/305537	J		Y
KIIIA1 6.1.4	Huber, W.	2002	Frutogaurd for the control of downy mildew (Plasmopara Viticola) on grapes F02221901 N/J N 2422986/305538	J		Y

Annex Point	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIIA1 6.1.4	Huber, W.	2002	Frutogard for the control of downy mildew (Plasmopara Viticola) on grapes F02221001 N/J N 2422987/305539	J		Y
KIIIA1 6.1.4	Huber, W.	2002	Frutogard for the control of downy mildew (Plasmopara Viticola) on grapes F02221002 N/J N 2422988/305540	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.1.4	Heibertshausen, D.S.	2009	Befallsreduzierung von Plasmopara Viticola (Berk&Curt ex de bary) Berl. & de toni in ökologischen Weinbau auf der Basis von Maßnahmen zur Kupferminimierung und Verfahren der induzierten Resistenz N/N N 2422990/305541	J		Y
KIIIA1 6	Anonymous	2012	Registration Report Part B 784486-A3-060000-01-NU N/N N 2423009/305542	J		Y

Annex Point	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIIA1 10.5.1	Höhn, P.	2012	Alginure Bio Schutz - Toxicity to the aphid parasitoid, Aphidius rhopalosiphi De Stefani Perez (Hymenoptera, Braconidae) in the laboratory (Dose Response Test) S11-03610 O/O N 2424476/305543	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 10.5.1	Höhn, P.	2013	Alginure Bio Schutz - Toxicity to the predatory mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the laboratory (Dose Response Test) S11-03611 J/O N 2424481/305544	J		Y
KIIIA1 10.8.1	Schweizer, N.	2013	Alginure Bio Schutz - Statement on the phytotoxicity of Alginure Bio Schutz 784486-A3-100801-01 O/O N 2424544/305549	J		Y

Annex **Point**	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
Document J	Tilco Biochemie GmbH	2013	dRR part C Alginure Bio Schutz N/O N 2425072/305551	J		Y
Document J	Scharafat, I.	2012	Composition of Alginure Bio Schutz N/O N 2425077/305555	J		Y

Annex **Point**	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIIA1 4.1.1	Baumann, H., Loidl, D.	2004	UN-Zulassungsschein: Kanisterbauart 10 L N/O N 2425091/305556	J		Y
KIIIA1 4.1.1	Baumann, H., Loidl, D.	2004	Zulassungsschein Kanister 10l (380g) 302.097 N/O N 2425092/305557	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 4.1.1	Anonymous	2011	Produktinformation PE-Kanister 10 L P6820 N/O N 2425093/305558	J		Y
KIIIA1 4.1.1	Anonymous	2005	SABIC HDPE B5205 Produkt info N/O N 2425094/305559	J		Y
KIIIA1 4.1.1	Anonymous	2005	SABIC HDPE B5210 Produkt info N/O N 2425095/305560	J		Y

Annex Point	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
Document J	Tilco Biochemie GmbH	2013	dRR part C Alginure Bio Schutz N/O N 2425104/305562	J		Y
MIIIA1 Sec 6	Tilco Biochemie GmbH	2014	Registration Report - Part B - Alginure BioSchutz - DE - Section 6 - Ecotoxicology -- Core assessment N/N N 2563440/337038	J		Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 10.8.1.2	Peterek, S.	2013	Alginure Bio Schutz: Effects on the Vegetative Vigour of Non.Target Plant Species under Greenhouse Conditions S13-00325 O/O N 2563443/337039	J		Y
KIIIA1 10.8.1.3	Peterek, S.	2013	Alginure Bio Schutz: Effects on the Seedlings Emergence of Non.Target Plant Species under Greenhouse Conditions S13-00342 O/O J 2563444/337040	J		Y

Annex **Point**	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIIA1 6	Anonymous	2013	Alginure Bio Schutz BAD Report-no.: 784486-A3-060000-01-NU 366067	J		Y
KIIIA1 6.7	Anonymous	2014	Alginure Bio Schutz Table of Testing facilities 367096			

Appendix 2: GAP table

GAP-Table of intended uses for Germany

GAP rev. (2), date: 2014-05-20

PPP (product name/code)	**Alginure Bio Schutz**	**Formulation type:**	**SL**
active substance	**Kaliumphosphit (Kaliumphosphonate)**	**Conc. of as :**	**342 g/L**
Applicant:	**Applicant Tilco Biochemie GmbH**	**professional use**	☒
Zone(s): central/EU		**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	grape vine VITVI (utilisation as table and wine grape)	F	downy mildew of grapevine *Plasmopara viticola* PLASVI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 12 - 68	a) 6 b) 6 (min 7 days)	a) - base dose: 1.5 L/ha - BBCH 61: 3 L/ha - BBCH 68: 4.5 L/ha b) 27 L/ha	a) - base dose: 513 g as/ha - BBCH 61: 1026 g as/ha - BBCH 71: 1539 g as/ha b) 9234 g as/ha	max 400 L/ha max 800 L/ha max 1200 L/ha	15	

General remarks/explanations:
The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data). The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops). All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.
Make use of existing standards like EPPO and BBCH.

Product: Please indicate the specific variant of the active substance if relevant. If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks. As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions/location of use).
Formulation:
Type: *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1)].

Conc. of as: g/kg or g/L
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.
Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.
Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.
Explanations to the particular columns:
No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.
Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order accordant to the zone they belong.
Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote).
If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones. Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated. This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).
Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I) "Glasshouse" indicates that the respective trials are acceptable for all zones. As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated. [Remark: Greenhouse definitions are at the moment under evaluation]. Conditions include also information concerning the substrate (natural soil, artificial substrate).
Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated. In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually). If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.
Application details:
Method / Kind:
Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.
Timing of Application / Growth stage of crop & season:
Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).
Growth stage of crop (BBCH-code) – period, first and last treatment. Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition. BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column "pest or group of Pests controlled". In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.
Number of applications and interval between applications
a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.
It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.
Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.
Application rate:

Application rate of the product per ha:
a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.
Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.
For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.
Information concerning the sowing method (precision drilling, …) would be advantageous.
See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).
Application rate of the active substance per ha:
a)-(Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.
The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.
Water L/ha:
It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations. In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).
Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product. If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory.

Appendix 3: Summary of data on trials site and application details for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (1/5)-(5/5)

Appendix 3: Summary of data on trials site and application details for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (1/5)

Test report (1)	Trial location(2); Crop; Soil; F/G (3); N/A (4)	Testing Unit (5)	Test method (6); Plot size [t or m³] Sample size (7)	Treatment			
				Growth stage (8)	Interval	Total number	Spray volume (L/ha)
6.1.3.1/01 2007	Epfig, Bas Rhin (67), Alsace, France Grapevine, Pinot Gris - F N	Union In Vivo, Paris, France	n.a. n.a. n.a.	Before flowering (May to June)	15-18 days	3	320
6.1.3.1/01 2007	Haute Goulaine (44), Pays-de-la-Loire, France Grapevine, Muscadet - F N	Union In Vivo, Paris, France	n.a. n.a. n.a.	May to July	11-14 days	6	170
6.1.3.1/02 2007	Château Lestrille (33), France Grapevine, Merlot Loamy F N		Sample size 100 leaves or flowers/fruits on 5 vines (max. 100)	April to July	7-13 days	8	100
6.1.3.1/03 2008	Sainte Marie la Blanche (21), France Grapevine, Pinot Noir Loamy F A	Fédération Régionale de Défense contre les Organismens Nuisibles (Fredon) de Bourgogne, Beaune, France	CEB No. 7, RCB design (4 replicates) 50 m²	Eichhorn and Lorenz scale 05-06 to 35 (April to August)	6-14 days	12	200-300

Appendix 3: Summary of data on trials site and application details for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (2/5)

Test report (1)	**Trial location(2); Crop; Soil; F/G (3); N/A (4)**	**Testing Unit (5)**	**Test method (6); Plot size [t or m³] Sample size (7)**	**Treatment**			
				Growth stage (8)	**Interval**	**Total number**	**Spray volume (L/ha)**
6.1.3.1/04 2008	Coursay, Monnieres (44), France Grapevine, Melon de Bourgogne - F N	SARL Vita-Consult, Gorges, France	RCB design (4 replicates)	May-August	8-18 days	8	135-200
6.1.3.1/05 2006	Sainte Marie la Blanche (21), France Grapevine, Pinot Noir - F A	Fredon Bourgogne, France	CEB No. 7, RCB (4 replicates) 50 m²	Eichhorn and Lorenz scale 06-07 to 35 (April to August)	6-11 (28) days	11	n.a.

Notes: (1): test report number including the year of establishing the trial (2): precise place of the trial followed by the country (3): F = field trial, G = protected crop (4): N = Natural infestation, A = Artificial inoculation. (5): Trial responsible entity / officially recognized organization. (6): Test guideline used . (7): Sample size per plot. (8): Crop growth stage at application timing

Appendix 3: Summary of data on trials site and application details for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (3/5)

Test report (1)	Trial location(2); Crop; Soil; F/G (3); N/A (4)	Testing Unit (5)	Test method (6); Plot size [t or m³] Sample size (7)	Treatment			
				Growth stage (8)	Interval	Total number	Spray volume (L/ha)
6.1.3.1/06 F03221002 2004	In der Froschau 1a, 76831 Ingelheim, Germany, Grapevine, Müller Thurgau sL F N	Weinbau-Versuchsstation Kleinkarlbach, 67271 Klein-karlbach.	4 replicates, min 22.8 m2, 100 leafs and grapes	55-77	13-15 days	4	450-750
6.1.3.1/07 Trial-No: 02221901 2002	74388 Talheim-Haigern, Germany, Grapevine, Kerner - F N	Spiess-Urania Chemicals GmbH, Haupt-strasse 4, 67271 Klein-karlbach.	EPPO PP 1/31 (3), RCB (4 replicates) 28,8 m²	57-77	14	3	300-750
6.1.3.1/08 Trial-No: 02221902 2002	74223 Flein, Germany, Grapevine, Pinot meunier - F N	Spiess-Urania Chemicals GmbH, Haupt-strasse 4, 67271 Klein-karlbach.	EPPO PP 1/31 (3), RCB (4 replicates) 19,8 m²	55-77	14	3	300-750

Notes: (1): test report number including the year of establishing the trial (2): precise place of the trial followed by the country (3): F = field trial, G = protected crop (4): N = Natural infestation, A = Artificial inoculation. (5): Trial responsible entity / officially recognized organization. (6): Test guideline used . (7): Sample size per plot. (8): Crop growth stage at application

Appendix 3: Summary of data on trials site and application details for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (4/5)

Test report (1)	**Trial location(2); Crop; Soil; F/G (3); N/A (4)**	**Testing Unit (5)**	**Test method (6); Plot size [t or m³] Sample size (7)**	**Treatment**			
				Growth stage (8)	**Interval**	**Total number**	**Spray volume (L/ha)**
6.1.3.1/09 Trial-No: 02221001 2002	76831 Appenhofen, Germany, Grapevine, Müller-Thurgau - F N	Spiess-Urania Chemicals GmbH, Hauptstrasse 4, 67271 Kleinkarlbach.	EPPO PP 1/31 (3), RCB (4 replicates) 37.7 m²	57-77	14	3	300-750
6.1.3.1/10 Trial-No: 02221002 2002	76831 Ingenheim, Germany, Grapevine, Müller-Thurgau - F N	Spiess-Urania Chemicals GmbH, Hauptstrasse 4, 67271 Kleinkarlbach.	EPPO PP 1/31 (3), RCB (4 replicates) 27.4 m²	55-75	14	3	300-750

Notes: (1): test report number including the year of establishing the trial (2): precise place of the trial followed by the country (3): F = field trial, G = protected crop (4): N = Natural infestation, A = Artificial inoculation. (5): Trial responsible entity / officially recognized organization. (6): Test guideline used . (7): Sample size per plot. (8): Crop growth stage at application

Appendix 3: Summary of data on trials site and application details for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (5/5)

Test report (1)	Trial location(2); Crop; Soil; F/G (3); N/A (4)	Testing Unit (5)	Test method (6); Plot size [t or m³] Sample size (7)	Treatment			
				Growth stage (8)	Inter-val	Total num-ber	Spray vol-ume (L/ha)
6.1.3.1/11 Mäuerchen 2005	65366 Geisenheim, Germany, Grapevine, Riesling - F N	Forschungsanstalt Geisenheim Von-Lade-Straße 1 65366 Geisenheim	EPPO PP 1/3, RCB (4 repli-cates) 32.8 m²	55-68	8-10	4	600-1200
6.1.3.1/11 Mäuerchen 2007	65366 Geisenheim, Germany, Grapevine, Riesling - F N	Forschungsanstalt Geisenheim Von-Lade-Straße 1 65366 Geisenheim	EPPO PP 1/3, RCB (4 repli-cates) 32.8 m²	15-68	10-16	4	100-1000
6.1.3.1/11 Mäuerchen 2008	65366 Geisenheim, Germany, Grapevine, Riesling - F N	Forschungsanstalt Geisenheim Von-Lade-Straße 1 65366 Geisenheim	EPPO PP 1/3, RCB (4 repli-cates) 32.8 m²	55-68	8-12	3	600-1200
6.1.3.1/12 ZuFPero,2010,Freiburg,1	Merzhauserstr.119 79100 Freiburg Germany, Grapevine, Müller Thurgau sL F N	Weinbauinstitut Gottfried Bleyer, Merzhauserstr.119 79100 Freiburg	EPPO PP 1/31 (3), RCB (4 repli-cates) 200 m²	13-69	7-14	5	400-800

Notes: (1): test report number including the year of establishing the trial (2): precise place of the trial followed by the country (3): F = field trial, G = protected crop (4): N = Natural infestation, A = Artificial inoculation. (5): Trial responsible entity / officially recognized organization. (6): Test guideline used . (7): Sample size per plot. (8): Crop growth stage at application

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (1/15)-(15/15

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (1/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	DAT	Untreated (3)	Efficacy treatments (4)				Remarks (5)
					Product TTF5		Standard		
					3 × 4 L/ha	3 × 2 L/ha + Acryptane 1.5 L/ha	3 × Valiant flash 3 L/ha	3 × Acryptane 500 3 L/ha	
6.1.3.1/01 Bas Rhin (67), 2007	Frequency (%, percentage of leaves attacked) Intensity (%, percentage of leaf surface attacked) Mean intensity (%, = frequency × intensity)	20.07.07	31 DALA 31 DALA 31 DALA	75 39 30	64.0 41.0 80	90.7 64.1 96	94.7 76.9 99	85.3 56.4 95	Efficacy according to Abbott calculated from values in the report Alginure Bio Schutz as an organic fungicide reduces/supresses *Plasmopara viticola* infection quite well. The comparison to the effectiveness against a conventional fungicide has to be evaluated carefully

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (2/15)

Test report (1)	Assessed part and variable (2)	As-sess-ment dates	DAT	Untreat-ed (3)	Efficacy treatments (4)				Remarks (5)
					Product TTF5		Standard		
					6 × 4 L/ha	6 × 2 L/ha + Acryptane 1.5 L/ha	6 × Mikal flash 4 L/ha	6 × Acryptane 500 3 L/ha	
6.1.3.1/01	Frequency (%, per-	27.06.0	1 DAA	83	66.3*	89.2*	79.5*	43.4*	* Efficacy
Haute	centage of leaves	7	5						according to
Goulaine	attacked)			36	81	97	93	75	Abbott cal-
(44)	Mean intensity (%, =		1 DAA						culated from
2007	frequency × intensi-		5	41	0*	68.3*	36.6*	43.9*	values in
	ty)								the report
	Frequency (%, per-		1 DAA	22	0	88	46	54	
	centage of berries		5						
	attacked)			92	58.7*	69.6*	63.0*	43.5*	
	Mean intensity (%, =		1 DAA						
	frequency × intensi-		5	45	72	85	87	68	
	ty)								
	Frequency (%, per-		14	52	0*	80.8*	65.4*	50.0*	
	centage of leaves		DALA						
	attacked)			40	9	90	75	61	
	Mean intensity (%, =		14						
	frequency × intensi-		DALA						
	ty)								
	Frequency (%, per-		14						
	centage of berries		DALA						
	attacked)								
	Mean intensity (%, =		14						
	frequency × intensi-		DALA						
	ty)								

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (3/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	BT DAT	Untreated (3)	Efficacy treatments (4)		Remarks (5)
					Product	Standard	
					8 x Sémafort* 1.6-4 L/ha	Spray sequence (7 applications)	
6.1.3.1/02	Frequency (%, percentage of leaves attacked)	05.06.07		11.3	82.3	100	*at treatment 6 with Fastime (2 kg/ha) and at treatment 8 with Nordox (1 kg/ha) Efficacy according to Abbott calculated from results in the report.
		13.06.07		19.0	92.1	100	
		21.06.07		81.0	86.4	71.9	
		05.07.07		87.67	89.7	72.6	
		16.07.07		98.33	64.7	66.9	
	Mean intensity (%, = frequency × intensity on leaves)	05.06.07		0.8	78.8	100	
		13.06.07		2.43	100	100	
		21.06.07		12.50	94.4	89.2	
		05.07.07		19.27	96.9	90.0	
		16.07.07		24.12	90.8	90.3	
	Frequency (%, percentage of berries attacked)	05.06.07		21.70	60.8	98.6	
		13.06.07		35.20	63.8	99.1	
		21.06.07		89.20	59.6	99.7	
		05.07.07		100	37.0	97.3	
		16.07.07		100	25.3	96.0	
	Mean intensity (%, = frequency × intensity on berries)	05.06.07		4.3	76.7	100	
		13.06.07		18.3	80.9	100	
		21.06.07		36.7	70.0	100	
		05.07.07		86.67	73.6	99.7	
		16.07.07		98.09	56.9	99.6	

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (4/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	BT DAT	Untreated (3)	Efficacy treatments (4)			Remarks (5)
					Product		Standard	
					6 × Sémafort 4 L/ha*	4 × Semarfort 4 L/ha followed by 2 × Acryptane 0.75 L/ha*	9 × Acryptane 1.5 L/ha**	
6.1.3.1/03	Frequency No of leaves attacked (10 vines) % of leaves attacked (10 vines) % of leaves attacked (10 vines) % of leaves attacked (10 vines) % of leaves attacked (10 vines) Intensity Number of spots (on 10 vines) % of attacked surface % of attacked surface % of attacked surface Frequency % of berries attacked (10 vines) % of berries attacked (10 vines) Intensity Number of spots	20.06.08 26.06.08 10.07.08 17.07.08 24.07.08 20.06.08 26.06.08 10.07.08 17.07.08 26.06.08 24.07.08 26.06.08 24.07.		279.25 82.5 stopped stopped stopped 1842.75 22.55 stopped stopped 73.72 97.75 26.54 62.50	75.4 77.6 *(11.75)* *(37.25)* *(72.50)* 83.5 89.5 *(0.74)* *(3.29)* 39.3 6.14 64.0 52.42	87.2 64.5 *(18.25)* *(28.00)* *(45.00)* 91.9 80.3 *(1.48)* *(1.97)* 64.4 18.41 82.5 65.73	77.0 80.3 *(54.75)* *(73.75)* *(5.50)* 89.3 89.7 *(7.07)* *(11.30)* 100 86.7 100 97.71	* followed by 2 × Pantheos (2 kg/ha), 2 × Champ flo (3-3.5 L/ha, 1 × Kocide 200 (3 kg/ha) ** followed by 2 × Champ flo (3-3.5 L/ha, 1 × Kocide 2000 (3 kg/ha)

	(on 10 vines) % of attacked surface	08						

Notes:(1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment

- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (5/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	BT DAT	Untreated (3)	Efficacy treatments (4)			Remarks (5)
					Product	Product	Product	
					8 × Semafort 4-5 L/ha followed by 1 × Remiltine S Pepite (3 kg/ha)	3 × Semafort (4 L/ha) followed by 4 × Semafort (2 L/ha) + Dithane-Neotech (1.85 kg/ha) followed by 1 × Semafort (2 L/ha) + Aviso Cup DF (2.5 kg/ha) followed by 1 × Remiltine S Pepite (3 kg/ha)	3 × Semafort (4 L/ha) followed by 2 × Fastime (2 kg/ha) followed by 2 × Aviso DF (2.5 kg/ha) followed by 2 × TTF8 (4 L/ha)	
6.1.3.1/04 2008	% of leaves attacked	30.05.	4 DAA4	59	76	72	80	Alginure Bio Schutz as an organic fungicide reduces/supresses *Plasmopara viticola* infection quite well. The comparison to the effectiveness against a spray combination with conventional fungicide has to be evaluated carefully
	Mean number of spots	30.05.	4 DAA4	74.33	76	83	89	
	% of leaves attacked	11.07.	10 DAA6	35	52	63	58	
	Mean intensity on leaves (%)	11.07.	10 DAA6	2.91	68	87	70	
	% of berries attacked	11.07.	10 DAA6	66	20	13	18	
	Mean intensity on berries (%)	11.07.	10 DAA6	52.75	37	40	42	

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment

- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (6/15)

<table>
<tr><th rowspan="3">Test report (1)</th><th rowspan="3">Assessed part and variable (2)</th><th rowspan="3">As-sess-ment dates</th><th rowspan="3">BT DAT</th><th rowspan="3">Un-treated (3)</th><th colspan="2">Efficacy treatments (4)</th><th rowspan="3">Remarks (5)</th></tr>
<tr><th>Product TTF5</th><th>Standard Champ flo</th></tr>
<tr><th>9 × 3 L/ha</th><th>9 × 1.7 L/ha</th></tr>
<tr><td>6.1.3.1/
05
2006</td><td>Frequency
No of leaves attacked
(10 vines)
No of leaves attacked
(10 vines)
% of leaves attacked

Intensity
No of spots (10 vines)
No of spots (10 vines)
% of attacked leaf surface

Frequency
% of berries attacked (100 berries)
% of berries attacked

Intensity
% mean attack
% mean attack</td><td>
30.06.
06.07.
20.07.

15.06.
06.07.
20.07

13.07.
02.08.

13.07.
02.08.</td><td>
4
DAA8
10
DAA8
7
DAA1
0

4
DAA8
10
DAA8
7
DAA1
0

7
DAA9
10
DAA1
0

7
DAA9
10
DAA1
0</td><td>
61.5
291.5
94.25

146.25
1298.5
30.83

52.75
97.75

11.38
41.43</td><td>
88.6
76.8
24.4

92.0
87.2
57.1

47.4
3.1

79.1
28.5</td><td>
96.7
82.5
89.7

97.8
93.3
97.0

95.3
50.6

98.1
89.4</td><td>Alginure Bio Schutz as an organic fungicide reduces/supresses Plasmopara viticola infection quite well. The comparison to the effectiveness against a conventional fungicide has to be evaluated carefully.</td></tr>
</table>

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (7/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	DAT	Untreated (3)	Efficacy treatments (4)			Remarks (5)
					Product Frutogard	Standard		
					4 applications with 3.3, 4.5, 4.5 and 5.6 L/ha. followed by 4 application of 0.3% Dacor	4 × Phosfik 0.5% followed by 4 × Dacor 0.3%	8 × Dithane 0.4%	
6.1.3.1/06 F03221002 2004	Frequency (%, percentage of leaves attacked, 100, Abott) Disease severity leaves (100, Abott)	19.08.003	7 DAT7	(99.25) -	31 85	9.5 83	25.7 82	
	Frequency (%, percentage of berries attacked, 100, Abbott) Disease severity grapes (100 grapes, Abbott)			(81.5) -	78.5 94	78.5 94	87.7 95	

Notes:(1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (8/15)

Test report (1)	Assessed part and variable (2)	Assess-ment dates	DAT	Un-treated (3)	Efficacy treatments (4)			Re-marks (5)
					Product Frutogard	Standard		
					3 applications with 2.25-4.5 L/ha followed by 2 application of 3.75 kg/ha Funguran	5 × Fungu-ran with 1.5-3.75 kg/ha	5 × Dithane 1.2-3.0 kg/ha	
6.1.3.1/07 Trial-No: 02221901 2002	% of infected leaf area (50 leaves per plot, Abbott)	18.07.2002 05.09.2002	9 DAT3 29 DAT5	(12.3) (70.1)	99 92	49 95	81 95	
	% of infected bunch area, 50 grapes per plot (%, Abbott)	18.07.2002	9 DAT3	(32)	86	90	86.5	

Notes:(1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (9/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	DAT	Untreated (3)	Efficacy treatments (4)			Remarks (5)
					Product Frutogard	Standard		
					3 applications with 2.25-4.5 L/ha followed by 2 application of 3.75 kg/ha Funguran	5 × Funguran with 1.5-3.75 kg/ha	5 × Dithane 1.2-3.0 kg/ha	
6.1.3.1/08 Trial-No: 02221902 2002	% of infected leaf area (50 leaves per plot, Abbott)	05.09.2002	29 DAT5	(62.5)	86	91	96	
	% of infected bunch area, 50 grapes per plot (%, Abbott)	07.08.2002	0 DAT5	(29.6)	93	80	98	

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (10/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	DAT	Untreated (3)	Efficacy treatments (4)			Remarks (5)
					Product Frutogard	Standard		
					3 applications with 2.25-4.5 L/ha followed by 2 application of 3.75 kg/ha Funguran	5 × Funguran with 1.5-3.75 kg/ha	5 × Dithane 1.2-3.0 kg/ha	
6.1.3.1/09 Trial-No: 02221001 2002	% of infected leaf area (50 leaves per plot, Abbott)	30.07.2002 23.09.2002	13 DAT4 55 DAT5	(31.1) (74.6)	86 91	95 100	97 97	
	% of infected bunch area, 50 grapes per plot (%, Abbott)	30.07.2002	13 DAT5	(49.4)	77.5	76	76	

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (11/15)

Test report (1)	Assessed part and variable (2)	As-sess-ment dates	DAT	Un-treated (3)	Efficacy treatments (4)			Re-marks (5)
					Product Frutogard	Standard		
					3 applications with 2.25-4.5 L/ha followed by 2 application of 3.75 kg/ha Funguran	5 × Fungu-ran with 1.5-3.75 kg/ha	5 × Ditha ne 1.2-3.0 kg/ha	
6.1.3.1/10 Trial-No: 02221002 2002	% of infected leaf area (50 leaves per plot, Abbott)	31.07. 2002	0 DAT5	(24.4)	70	96	98	
		23.09. 2002	54 DAT5	(79.3)	93	99	97	
	% of infected bunch area, 50 grapes per plot (%, Abbott)	31.07. 2002	0 DAT5	(47.5)	75	92	98	

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (12/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	DAT	Untreated (3)	Efficacy treatments (4): Product Frutogard – 4 applications Frutogard until BBCH 68 followed by 1.7 kg/ha Cu/ha per year	Efficacy treatments (4): Standard – Cuprozin flüssig (3 kg/ha)	Efficacy treatments (4): Standard – Folpan WDG	Remarks (5)
6.1.3.1/11 Mäuerchen 2005	Frequency % of leaves attacked (100 leaves)	22.06.2005	18 DAT5	(17.5)	(13.75)	(16.5)	(5.5)	
	Intensity % of attacked leaf surface (100 leaves)			(0.6)	43	0	0	
	Frequency % of berries attacked (100 berries)			(9.25)	(6.25)	(9.0)	(10.25)	
	Intensity % of attacked berries (100 berries)			(7.19)	26	0	0	
	Frequency % of leaves attacked (100 leaves)	27.07.2005	2 DAT7	(37.75)	(24.25)	(25.25)	(14.0)	
	Intensity % of attacked leaf surface (100 leaves)			(4.19)	80	67	78	
	Frequency % of berries attacked (100 berries)			(44.5)	(33.25)	(31.25)	(14.0)	
	Intensity % of attacked berries (100 berries)			(22.78)	52	33	45	
	Frequency % of leaves attacked (100 leaves)	23.08.2005	7 DAT9	(62.0)	(20.0)	(18.0)	(4.25)	
	Intensity % of attacked leaf surface (100 leaves)			(4.17)	73	78	86	
	Frequency % of berries attacked (100 berries)			(0.75)	(31.75)	(26.25)	(5.75)	
	Intensity			(12.66)	44	34	63	

Test report (1)	Assessed part and variable (2)	Assessment dates	DAT	Untreated (3)	Efficacy treatments (4)			Remarks (5)
					Product Frutogard	Standard		
					4 applications Frutogard until BBCH 68 followed by 1.7 kg/ha Cu/ha per year	Cuprozin flüssig (3 kg/ha)	Folpan WDG	
	% of attacked berries (100 berries)							

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (13/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	DAT	Untreated (3)	Efficacy treatments (4)			Remarks (5)
					Product Frutogard	Standard		
					4 applications Frutogard until BBCH 68 followed by 1.7 kg/ha Cu/ha per year	Cuprozin flüssig (3 kg/ha)	Folpan WDG	
6.1.3.1/11 Mäuerchen 2007	Frequency % of leaves attacked (100 leaves) Intensity % of attacked leaf surface (100 leaves)	07.2007	DAT8	(23) (1)	(1) 100	(0) 100	(0) 100	

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (14/15)

Test report (1)	Assessed part and variable (2)	As-sess-ment dates	DAT	Un-treated (3)	Efficacy treatments (4)			Re-marks (5)
					Product Frutogard	Standard		
					4 applications Frutogard until BBCH 68 fol-lowed by 1.7 kg/ha Cu/ha per year	Cupro-zin flüssig (3 kg/ha)	Folpan WDG	
6.1.3.1/11 Mäuerchen 2008	Frequency % of leaves attacked (100 leaves) Intensity % of attacked leaf surface (100 leaves)	08.2008	DAT8	(13) (0.3)	(0) 100	(0.3) 100	(0) 100	

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 4: Summary of data on effectiveness trials per use for Alginure Bio Schutz (Vine Plasmopara viticola) (PLASVI) (15/15)

Test report (1)	Assessed part and variable (2)	Assessment dates	DAT	Untreated (3)	Efficacy treatments (4)			Remarks (5)
					Product Frutogard	Standard		
					5 × 4L/ha	Folpan 80 WDG Basis 0.4 kg/ha	Melody Combi	
6.1.3.1/12 ZuFPero, 2010,Freiburg,1	% of infected leaf area (100 leaves per plot)	28.06.2010	3DAT5	(49.39)	(1.4)	(1.96)	(0.27)	
	Frequency % of leaves attacked (100 leaves)			(99.75)	(18.5)	(27.25)	(5.75)	
	% of infected leaf area (100 leaves per plot, Abbott)			-	97.16	95.9	99.45	
	% of infected grapes (100 grapes per plot)			(82.5)	(8.13)	(0)	(0)	
	Frequency % of grapes attacked (100 leaves)			(98.5)	(20.5)	(0)	(0)	
	% of infected grapes (100 leaves per plot, Abbott)			-	90.15	100	100	

Notes: (1): Test report number including the year of establishing the trial
(2): Plant part assessed and criteria for assessment.
(3): Severity of incidence of harmful organisms of the untreated.
(4): Efficacy (%)
(5): Relevant conclusions on effectiveness.
BT: Before treatment, DAT: days after treatment
- Disease severity

Appendix 5: Summary of detailed data on effectiveness trials

Appendix 5: Table A 5-1: Summary of Plasmopara viticola effectiveness trials with Alginure Bio Schutz (Grapes, French trials)

Target pest (1)	**Number of trials (2)** **Trial numbers**	**Assessment**	**Efficacy achieved with** **Alginure Bio Schutz**		**Efficacy reference product**		**Remark**
			mean (3)	**limits (4)**	**mean (3)**	**limits (4)**	
Plasmopara viticola	6 trials 6.1.3.1/01 6.1.3.1/02 6.1.3.1/03 6.1.3.1/04 6.1.3.1/05	Mean intensity infection on leaves (%)	76	57-91	88	68-97	In the French trial Alginure Bio Schutz was applied normally not in mixtures

Notes: (1): Target pest found in the trials (common and scientific name)
(2): Number of trials in which the pest was found
(3): Mean efficacy in the totality of trials (%); days after last application
(4): Limits of efficacy observed (%); days after last application

Appendix 5: Table A 5-1: Summary of Plasmopara viticola effectiveness trials with Alginure Bio Schutz (Grapes, German trials)

Target pes (1)	**Number of trials (2) Trial numbers**	**Assessment**	**Efficacy achieved with Alginure Bio Schutz**		**Efficacy reference product**		**Remark**
			mean (3)	**limits (4)**	**mean (3)**	**limits (4)**	
Plasmopara viticola	9 trials 6.1.3.1/06 6.1.3.1/07 6.1.3.1/08 6.1.3.1/09 6.1.3.1/10 6.1.3.1/11 6.1.3.1/12	infection on leaves (%)	90.8	73-100	93.5	83-100	Alginure Bio Schutz was normally applied in the beginning of infestation/vegetation period and followed by reduced copper applications
	7 trials 6.1.3.1/06 6.1.3.1/07 6.1.3.1/08 6.1.3.1/09 6.1.3.1/10 6.1.3.1/11 (2005 only) 6.1.3.1/12	infection on grapes (%)	80	44-94	82	63-94	

Notes: (1): Target pest found in the trials (common and scientific name)
(2): Number of trials in which the pest was found
(3): Mean efficacy in the totality of trials (%); days after last application
(4): Limits of efficacy observed (%); days after last application

Appendix 6: List of abbreviations

BT	before treatment
DAT	days after treatment
DAA	Day after application
n.a.	not available

Appendix 7: Letter from DLR Rheinland- Pfalz and Evovin

Donnerstag, 6. Dezember 2012

Ökologischer Weinbau

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Frutogard im ökologischen Weinbau

Die diesjährige Rebschutzsaison hat wieder deutlich gemacht, dass die wirksame Bekämpfung der Rebenperonospora im Hinblick auf die Minimierung des Einsatzes von Kupfer ohne phosphonathaltige Mittel (Frutogard) nicht möglich ist.

Zurzeit ist der Einsatz von 3 kg/ha und Jahr Kupfer zulässig. Bei hohem Infektionsdruck zur Blüte wie in diesem Jahr kommt es in Befallslagen zu Ertragsausfällen bis hin zum Totalverlust der Ernte wenn eine Bekämpfung der Rebenperonospora nur mit den erlaubten Kupfermengen stattfindet. Dies zeigen Versuche und Praxiserfahrungen in Betrieben, die auf den Einsatz von Frutogard verzichtet haben.

Da in Zukunft eine weitere Reduzierung der eingesetzten Kupfermenge angestrebt wird, werden die Öko-Weinbaubetriebe noch stärker auf den Einsatz phosphonathaltiger Mittel wie Frutogard angewiesen sein, um wirtschaftlichen Weinbau betreiben zu können. Wird dies im Jahr 2013 und in Zukunft nicht mehr möglich sein, gefährdet dies in vielen Regionen die Existenz ökologisch wirtschaftender Weinbaubetriebe.

Beate Fader
Offizialberatung ökologischer Weinbau Rheinland-Pfalz

1/1

Frutogard im ökologischen Weinbau

Der Einsatz phosphonathaltiger Pflanzenstärkungsmittel (Frutogard) ist über Jahre hinweg bereits eine bewährte Methode, den Einsatz von Kupfer im ökologischen Weinbau zu reduzieren.

Die diesjährige Rebschutzsaison hat zudem deutlich gemacht, dass die wirksame Bekämpfung der Rebenperonospora im Hinblick auf die Minimierung des Einsatzes von Kupfer ohne phosphonathaltige Mittel (Frutogard) nicht möglich ist.

Zurzeit ist der Einsatz von 3 kg/ha und Jahr Kupfer zulässig. Bei hohem Infektionsdruck zur Blüte, wie in diesem Jahr, kommt es in Befallslagen zu Ertragsausfällen bis hin zum Totalverlust der Ernte wenn eine Bekämpfung der Rebenperonospora nur mit den erlaubten Kupfermengen stattfindet. Dies zeigen Versuche und Praxiserfahrungen in Betrieben, die auf den Einsatz von Frutogard verzichtet haben.

Da in Zukunft eine weitere Reduzierung der eingesetzten Kupfermenge angestrebt wird, werden die Öko-Weinbaubetriebe noch stärker auf den Einsatz phosphonathaltiger Mittel wie Frutogard angewiesen sein, um wirtschaftlichen Weinbau betreiben zu können. Wird dies im Jahr 2013 und in Zukunft nicht mehr möglich sein, gefährdet dies in vielen Regionen die Existenz ökologisch wirtschaftender Weinbaubetriebe.

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