REGISTRATION REPORT

Part A

Risk Management

Product code: AaS1017

Product name(s): ALGISIUM

Chemical active substance(s):

Potassium phosphonates, 342 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Tilco-Alginure GmbH

Date: 01/12/2023

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PART A
RISK MANAGEMENT

1 Details of the application

The company Tilco-Alginure GmbH has requested a marketing authorisation in France for the product ALGISIUM (formulation code: AaS1017), containing 342 g/L potassium phosphonates[1] as a fungicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of Tilco-Alginure GmbH's application submitted on 05/01/2022 to market ALGISIUM (AaS1017) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2021-2914) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of ALGISIUM (AaS1017) has been made using endpoints agreed in the EU peer review of potassium phosphonates. It also includes assessment of data and information related to ALGISIUM (AaS1017) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of ALGISIUM (AaS1017).

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1 Commission Implementing Regulation (EU) No 369/2013 of 22 April 2013 approving the active substance potassium phosphonates, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

2 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

3 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

4 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

1.2 Letters of Access

The applicant has provided equivalent studies to those essential for approval of the active substance Potassium phosphonate via a data matching table (DMT).

1.3 Justification for submission of tests and studies

According to the applicant: « Several new studies have been performed with ALGISIUM (AaS1017) in order to complete the data package. A full list of new studies with justifications for submission is given in Appendix 4. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ALGISIUM (AaS1017), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	AaS1017
Product name in MS	ALGISIUM
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	Tilco-Alginure GmbH
Active substance(s) (incl. content)	Potassium phosphonates, 342 g/L
Formulation type	Soluble concentrate [SL]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for ALGISIUM (AaS1017)resulted in the decision **to refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

N/A : no marketing authorisation granted.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[5] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Moreover, the French Order of 12 April 2021[6] provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision

[5] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[6] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021[8] on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop[9] when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted.

2.5.2 Specific restrictions linked to the intended uses

N/A : no marketing authorisation granted.

[7] SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

[8] Arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques - Légifrance (legifrance.gouv.fr)

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 01/12/2023

PPP (product name/code):	ALGISIUM / AaS1017	Formulation type:	SL [a, b]
Active substance 1:	Potassium phosphonates	Conc. of a.s. 1:	342 g/L [c]
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Tilco-Alginure GmbH	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													

AaS1017 / ALGISIUM
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	FR, IT, ES, PT	Vine	F	Downy mildew (*Plasmopara viticola*)	Spraying	BBCH 12-89	a) 6 b) 6	7 days	a) 4.5 L/ha b) 27 L/ha	a) 1.54 kg/ha b) 9.23 kg/ha	120 – 1200	14	**Non acceptable** (worker) Min-Max. use concentration: 0.4 – 1.3 L product/hL Application rate can be reduced depending on growth stage

Remarks table heading:

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

Remarks columns:

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

3 Background of authorisation decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of brown, non-viscous liquid, with a sweet odour. It is not explosive, has no oxidising properties. The product is not flammable/has no flash point of below the boiling point. It has a self ignition temperature of 530°C. In aqueous solution, it has a pH value around 6.36. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The product cannot stored under refrigerated conditions because after storage for 7 days at 0°C the phase separation occurred. The product should be labelled with a warning against exposure to low temperatures. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging. Its technical characteristics are acceptable for a SL formulation.

The following data are required in post registration:

- Surface tension and persistent foaming at 3.75% v/v
- Dilution stability at 3.75% v/v before and after storage
- Viscosity with the new thickener

3.2 Efficacy (Part B, Section 3)

Given the submitted data:
The efficacy of the product ALGISIUM (AaS1017) is considered satisfactory for the intended use.
The phytotoxicity of ALGISIUM (AaS1017) can be considered negligible for the intended uses.
The risks of negative impact on yield, quality, propagationand adjacent crops are considered negligible.
The risk of negative impact toward vinification process can be considered acceptable.
The risk of resistance development or appearance to potassium phosphonates is considered low.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance in the formulation are available and validated. As the active substance potassium phosphonates does not contain relevant impurity, no analytical method is required

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and this dossier and validated for the determination of residues of potassium phosphonates in plants, food of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Enpoints used in risk assessment

Agreed EU endpoints	
Active substance	Potassium phosphonte
AOEL systemic	5 mg/kg bw/d
AAOEL	/
Inhalation absorption	100%
Oral absorption	>60%
Vapour pressure	Not relevant
Reference	EFSA Journal 2012;10(12):2963 SANCO/10416/2013 rev 2, 15 March 2013
Dermal absorption (default)	Concentrate: 10%, Dilution: 50% (default values, EFSA 2017*)

*EFSA Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp.

3.4.1 Acute toxicity

ALGISIUM (AaS1017) containing 342 g/L Potassium phosphonate (228 g/L Phosponic acid equivalents) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin and eye and is not a skin sensitizer.

3.4.2 Operator exposure

Considering proposed use, operator systemic exposure was estimated using the EFSA model[9]:

Model data		**Potassium Phosphonate**
	Level of PPE	**% AOEL**
Application : Tractor mounted upward spraying application outdoors to high crops (grapes)		
Application rate (kg as/ha)		1.54 kg a.s./ha
Spray ap-plication (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	3.50

[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

According to the model calculations, it can be concluded that the risk for the operator using ALGISIUM (AaS1017) is acceptable with a working coverall and gloves during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop hand harvesting (searching, reaching and picking) activities. Therefore, estimation of worker exposure was calculated according to AOEM model.

Model data		Potassium Phosphonate
	Level of PPE	**% AOEL**
Activity: Hand harvesting (searching, reaching and picking) Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Number of applications : 6 Interval between treatments: 7 days		
Application rate (kg as/ha)		1.54 kg a.s./ha
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 10100 cm2/person/h	**258.75**

There is unacceptable risk anticipated for the worker reentering into treated crops.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[10].
Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

[10] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

3.4.5 Resident exposure

Resident exposure was assessed according to EFSA model, with a distance of 10 metres from the spray boom and no drift reduction technology was considered.

Model data		Potassium Phosphonate
		% AOEL
Scenario: Buffer zone: 10 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Number of applications : 6 Interval between treatments: 7 days		
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	17,82
	Vapour (75th percentile)	0,02
	Surface deposits (75th percentile)	0,18
	Entry into treated crops (75th percentile)	10,81
	All pathways (mean)	20,49
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	9,88
	Vapour (75th percentile)	0,00
	Surface deposits (75th percentile)	0,08
	Entry into treated crops (75th percentile)	6,00
	All pathways (mean)	11,31

An acceptable risk was determined for resident (adult and child).

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

The data available are not considered sufficient for risk assessment.

An exceedance of the current MRL of 200 mg/kg on wine grapes and 100 mg/kg on table grapes for Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) as laid down in Reg. (EU) 396/2005 is not expected.

Considering that the active substance potassium phosphonates is systemic, in the absence of residue trials with honey, an exceedance of the current MRLs of 0.5* mg/kg for Fosetyl-Al in honey, as laid down in Reg. (EU) 396/2005, cannot be excluded for the use on grapevine. No MRL exceedance is awaited once the new proposed MRL of 100 mg/kg ; which is under discussion at SCOPAFF (PLAN/2023/138), will be voted. **In the meantime, the product ALGISIUM (AaS1017) should only be applied after the end of**

flowering (*ie.* after BBCH 69) of grapevine.

Since the setting of an ARfD was not deemed necessary for this active substance, no acute risk assessment was performed in the framework of this dossier.
The chronic intakes of potassium phosphonate residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, France zRMS agrees with the authorization of the intended uses on grapevine.

According to available data, the following specific mitigation measures is recommended:

- Other fungicide active substances than potassium phosphonates authorized on grapes (e.g. disodium phosphonate or fosetyl-al) can lead to the presence of phosphonic acid in harvested products. The accumulated use of these active substances on the same plots could lead to an exceedance of the in force MRLs. Consequently, it is recommended to limit the use of products containing these substances on grapevine to a total of 10.9 kg equivalent of phosphonic acid per hectare per year.

Information on ALGISIUM (AaS1017) (KCA 6.8)

Crop	PHI for ALGISIUM (AaS1017) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for ALGISIUM (AaS1017) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Potassium Phosphonates		
Grapevine	14	Yes	14	Waiting for the new MRL of 100 mg/kg to be voted (PLAN/2023/138), ALGISIUM (AaS1017) should only be applied after the end of flowering (after BBCH 69)

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

Not relevant.

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for phosphonic acid for the intended use patterns.

The PEC of phosphonic in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models and the endpoints established in the EU conclusions.

PEC_{SOIL} and PEC_{SW} derived for phosphonic are used for the ecotoxicological risk assessment. Potential risk for eutrophication was considered and mitigation measures are proposed.

PEC_{GW} for phosphonic acid do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses. Risk mitigations are required for aquatic organisms. Mitigation measures are required for aquatic organisms.

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document[11]. The risks are not acceptable at Tier 1 for all intended uses for adults (chronic) and larvae. No further data was provided to refine the risk assessment. Therefore, the risk assessment for honey bee adults and larvae cannot be finalized for all intended uses.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

The active substance potassium phosphonate is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

N/A : no marketing authorisation granted e.

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

[11] **EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees)** EFSA Journal 2013;11(7):3295

Appendix 1 Copy of the product authorisation

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AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail

Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) n° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***ALGISIUM***

de la société	*TILCO ALGINURE GMBH*
enregistrée sous le	*n° 2021-2914*

Vu les conclusions de l'évaluation de l'Anses du 19 octobre 2023,

Considérant que l'utilisation du produit peut entraîner un risque d'effet nocif pour le travailleur,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

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Informations générales sur le produit	
Nom du produit	ALGISIUM
Type de produit	Produit de référence
Titulaire	TILCO ALGINURE GMBH Holländerkoppel 1a 23858 REINFELD Allemagne
Formulation	Concentré soluble (SL)
Contenant	342 g/L - phosphonates de potassium
Numéro d'intrant	678-2021.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 30/11/2023

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire
de l'alimentation, de l'environnement et du travail (ANSES)

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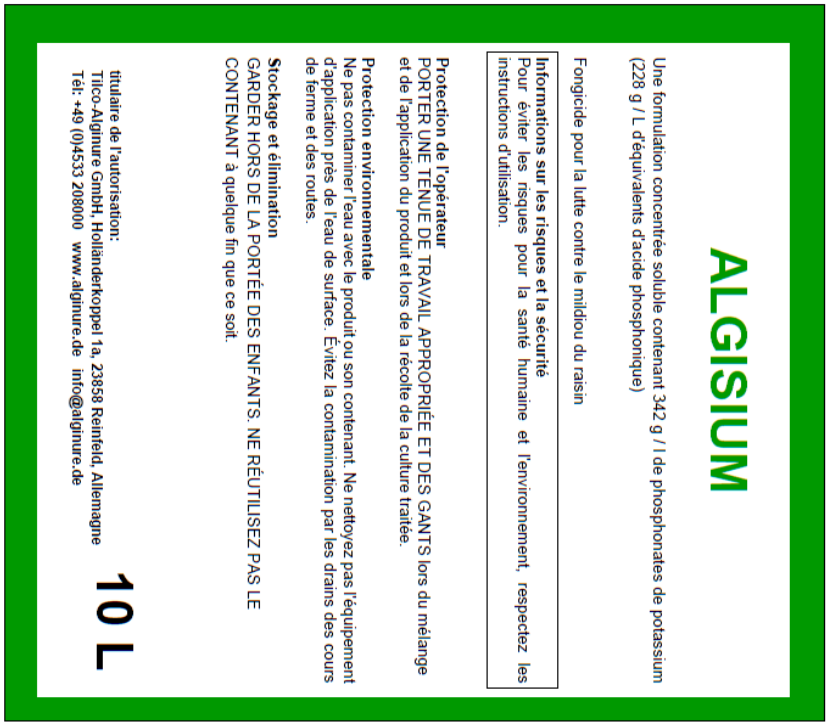
ANNEXE : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	4,5 L/ha	6/an	14
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur.		

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.



ALGISIUM

Une formulation concentrée soluble contenant 342 g / l de phosphonates de potassium (228 g / L d'équivalents d'acide phosphonique)

Fongicide pour la lutte contre le mildiou du raisin

Informations sur les risques et la sécurité
Pour éviter les risques pour la santé humaine et l'environnement, respectez les instructions d'utilisation.

Protection de l'opérateur
PORTER UNE TENUE DE TRAVAIL APPROPRIÉE ET DES GANTS lors du mélange et de l'application du produit et lors de la récolte de la culture traitée.

Protection environnementale
Ne pas contaminer l'eau avec le produit ou son contenant. Ne nettoyez pas l'équipement d'application près de l'eau de surface. Évitez la contamination par les drains des cours de ferme et des routes.

Stockage et élimination
GARDER HORS DE LA PORTÉE DES ENFANTS. NE RÉUTILISEZ PAS LE CONTENANT à quelque fin que ce soit.

titulaire de l'autorisation:
Tilco-Alginure GmbH, Hollanderkoppel 1a, 23858 Reinfeld, Allemagne
Tél: +49 (0)4533 208000 www.alginure.de info@alginure.de

10 L

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Domaine d'utilisation À UTILISER UNIQUEMENT COMME FONGICIDE PROFESSIONNEL.
Recadrer Pour une utilisation sur les raisins de table et de cuve.
Dose individuelle maximale 4,5 litres de produit dans 350 à 1200 litres d'eau / ha
Nombre maximum de traitements 6 par culture
Dose totale maximale 27 litres produit/ha saison
Dernière heure d'application Stade de croissance BBCH 89 14 jours avant la récolte
Restrictions spécifiques Intervalle minimum de 7 jours entre les applications.
LIRE L'ÉTIQUETTE AVANT L'UTILISATION. L'UTILISATION DE CE PRODUIT D'UNE MANIÈRE INCOMPATIBLE AVEC L'ÉTIQUETTE PEUT ÊTRE UNE INFRACTION.

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MODE D'EMPLOI

Contrôle de l'usine maladie
Algisium est un fongicide aux propriétés curatives à utiliser dans les raisins pour lutter contre le mildiou.

Résistance
FRAC code phosphonates de potassium: P7 / mode d'action: inconnu

Crop Information
Algisium peut être appliqué sur la vigne infestée du stade de croissance 12 à 89.

Moment de la demande
Commencer l'application en cas d'infection à risque ou en suivant les références du service d'avertissement.

Taux d'application:

appliquer 4.5 l Algisium dans 350 – 1200 litres d'eau par hectare.
Dans de plus petites quantités d'eau, ne dépassez pas la concentration de 1,3 %.

Intervalle entre les applications: 7 jours

Mélange et application
Technique d'application: pulvérisation

La solution de pulvérisation doit être utilisée le jour du mélange et ne doit pas être laissée toute la nuit.

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