

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: 23 june 2025

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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 (product code: AaS1017), containing 342 g/L potassium phosphonates¹ 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 (product code: 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 updated version concerns the evaluation of new data submitted by Tilco-Alginure GmbH on 28/03/2024 for the Physical and chemical properties, Methods of analysis, Residues, Mammalian toxicology and Ecotoxicology sections (application 2024-1110).

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 1107/2009², 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 (product code: 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 (product code: 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.

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](#)

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The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, 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 (product code: AaS1017).

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 (product code: AaS1017) in order to complete the data package ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ALGISIUM (product code: 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	2250358
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	HDPE container (10 L)
Coformulants of concern for national authorisations	-

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

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Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for PRODUCT NAME resulted in the **decision to grant 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

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

Hazard class(es), categories:	No classification for the human health No classification for the environment
Hazard pictograms:	/
Signal word:	/
Hazard statement(s):	No classification for the human health No classification for the environment
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	/

See Part C for justifications of the classification and labelling proposals.

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

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
	For other restrictions refer to 2.5

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 2017⁵ 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 2021⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- 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 extrapolation⁷ 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 2021⁸ 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 crop⁹ 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.

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> ; <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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

⁸ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

⁹ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters with an unsprayed vegetated buffer zone of 5 meters to surface water bodies for use on grapevines. ¹⁰
SPe 8	To protect bees and other pollinating insects, do not use in presence of bees and other pollinating insects, do not apply to crop plants when in flower, do not apply when flowering weeds are present.
Other specific restrictions	
Re-entry period	6 hours
Storage	Protect from frost (> 0°C)
SPa 1	-
Risk mitigation measures	Several fungicidal active substances (fosetyl-Al, potassium phosphonates and disodium phosphonate) may lead to the presence of phosphonic acid in harvested products. The cumulated uses of these active substances on the same crop might lead to an exceedance of the MRL set jointly for these 3 active substances.
Risk mitigation measures	Bystander and resident protection : Respect an unsprayed zone of 10 meters from the extremity of the boom and : - areas where bystanders are present during treatment - areas where residents could be present

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

¹⁰ The unsprayed vegetated buffer zone is applied in order to limit risk from eutrophication.

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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” or “not finalised”, 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: 23 june 2025

PPP (product name/code): ALGISIUM / AaS1017
Active substance 1: Potassium phosphonates
Safener: -
Synergist: -
Applicant: Tilco-Alginure GmbH
Zone(s): Southern Zone ^(d)
Verified by MS: Yes
Field of use: Fungicide

Formulation type: SL ^(a, b)
Conc. of a.s. 1: 342 g/L ^(c)
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non-professional use: ☐

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, 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 ⁽ⁱ⁾
					Method/Ki nd	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)													

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, 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/Ki nd	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/ma x		
1	FR, IT, ES, PT	Vine	F	Downy mildew (<i>Plasma- para viticola</i>)	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	Acceptable 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 preparation is not a foaming product. Following dilution, a phase separation was noted after 30 min. However, the diluted product is homogeneous after mixing. It should be recommended to stir the diluted preparation during the application. The product cannot be 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.

3.2 Efficacy (Part B, Section 3)

Given the submitted data:

The efficacy of the product ALGISIUM (product code: AaS1017) is considered satisfactory for the intended use.

The phytotoxicity of ALGISIUM (product code: AaS1017) can be considered negligible for the intended uses.

The risks of negative impact on yield, quality, propagation and 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. Analytical methods for risk assessment (residues (honey), ecotoxicological and toxicological studies) are fit for purpose.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	Potassium phosphonate
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	Concentrate: 11%, Dilution: 2.8%

3.4.1 Acute toxicity

ALGISIUM (product code: 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 model¹¹:

Model data		Potassium Phosphonate
	Level of PPE	% AOEL
Application : Tractor mounted upward spraying application outdoors to high crops (grapes)		
Application rate (kg as/ha)		1.55475 kg a.s./ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall during mix/loading and application	2,3

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

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

¹¹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2022;20(1):7032)

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop such as inspection, irrigation or hand harvesting activities. Therefore, estimation of worker exposure was calculated according to EFSA model 2022.

Model data		Potassium Phosphonate
	Level of PPE	% AOEL
Viticulture – Inspection, irrigation /outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between application : 7 days		
Application rate		6 x 1.55475 kg a.s./ha
Body weight: 60 kg	Workwear (arms, body and legs covered) and gloves TC : 1250 cm ² /h	1,8
Viticulture - Hand harvesting / outdoor Work rate: 8 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days		
Application rate (kg as/ha)		6 x 1.55475 kg a.s./ha
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	57,5

According to the model calculation, there is no 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

In the absence of the AAOEL determined for potassium phosphonates, it is considered that the risk assessment for the bystander is covered by the resident risk assessment. Indeed, only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and by-standers in risk assessment for plant protection products (EFSA Journal 2022;20(1):7032): “*When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. 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.*”

3.4.5 Resident exposure

Resident exposure was assessed according to EFSA model 2022, with a distance of 10 metres from the spray boom and no drift reduction technology was considered.

Model data		Potassium Phosphonate
		% AOEL
Scenario: Tractor mounted, upward spraying, viticulture Buffer zone: 10 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days		
Number and application rate		6 x 1.55475 kg a.s./ha
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	1
	Vapour (75th percentile)	0.02
	Surface deposits (75th percentile)	0.06
	Entry into treated crops (75th percentile)	2.4
	Sum (mean)	2.7
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	0.6
	Vapour (75th percentile)	0.005
	Surface deposits (75th percentile)	0.02
	Entry into treated crops (75th percentile)	1.3
	Sum (mean)	1.5

According to the model calculation, 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 considered sufficient for risk assessment.

An exceedance of the MRL of 150 mg/kg on wine grapes and 100 mg/kg on table grapes for phosphonic acid and its salts expressed as phosphonic acid as laid down in Reg. (EC) 396/2005¹² is not expected. An exceedance of the MRLs of 100 mg/kg in honey for phosphonic acid and its salts expressed as phosphonic acid, as laid down in Reg. (EC) 396/2005¹, is not expected for the use on grapevine.

Since the setting of an ARfD was not deemed necessary for potassium phosphonates, 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.

¹² As modified by Regulation (EU) 2024/2619, which entry into force is the 29th of April 2025

Information on AaS1017 (KCA 6.8)

Crop	PHI for AaS1017 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for AaS1017 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Potassium Phosphonates		
Grape-vine	14	Yes	14	/

* 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 DT₅₀ 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 Document¹³. The risks are not acceptable at Tier 1 for all intended uses for adults (chronic) and larvae. The applicant provided a higher-tier study to refine the risk assessment. However, the applicant did not demonstrate access to this study. 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.

¹³ 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

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

None.

5.1.2 Post-authorisation data requirements

none

Appendix 1 Copy of the product authorisation

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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 réglementaire,

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

de la société TILCO-ALGINURE GMBH

enregistrée sous le n° 2024-1110

Vu les conclusions de l'évaluation de l'Anses du 19 mai 2025,

La mise sur le marché du produit phytopharmaceutique désigné ci-après est autorisée en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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 (équivalent à 228 g/L d'acide phosphonique)
Numéro d'intrant	293-2024.01
Numéro d'AMM	2250358
Fonction	Fongicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 janvier 2027.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) n° 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 23/08/2025

DocuSigned by:

AE2B1AB55A42454

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

ANNEXE : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bidons en polyéthylène haute densité	10 L

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la réglementation en vigueur.
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

Liste des usages autorisés

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	4,5 L/ha	6/an	entre les stades BBCH 12 et BBCH 89	14	5 (DVP 5)	-	-	Emploi interdit
Intervalle minimum entre les applications : 7 jours.								

DVP : Dispositif Végétalisé Permanent.

Emploi possible ou interdit = usage autorisé ou interdit durant la floraison et sur les zones de butinage, pour les cultures attractives en plein champ ou sous abri ouvert, dans les conditions fixées par l'arrêté du 20/11/2021.

Conditions d'emploi du produit

Stockage et manipulation du produit

- Stocker le produit à une température supérieure à 0°C.

Protection de l'opérateur et du travailleur

Pour l'opérateur, porter

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles ;
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage) ;
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur pneumatique

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 heures

Protection des personnes présentes et des résidents (au sens du règlement (UE) n° 284/2013)

Pour les usages sur vigne, respecter une distance d'au moins 10 mètres entre le dernier rang traité et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

- Plusieurs substances actives fongicides (fosétyl d'aluminium, phosphonates de potassium et phosphonate de disodium) peuvent engendrer la présence d'acide phosphonique dans les produits récoltés. L'utilisation cumulée sur la même culture de ces substances actives est susceptible de conduire à un dépassement des LMR fixées conjointement pour ces substances actives.
- Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.
- SPe 8 : Peut être dangereux pour les abeilles - Pour protéger les abeilles et autres insectes pollinisateurs, ne pas utiliser en présence d'abeilles et autres pollinisateurs, ne pas appliquer durant la période de floraison des cultures attractives, ne pas appliquer lorsque des adventices en fleur sont présentes.

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-Algimure GmbH, Hollanderkoppel 1a, 23858 Reinfeld, Allemagne
Tél: +49 (0)4533 208000 www.algimure.de info@algimure.de

10 L

Domaine d'utilisation A 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.

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.