

REGISTRATION REPORT

Part A

Risk Management

Product code: /

Product name(s): SEMIOS LB PLUS AEROSOL

Chemical active substance(s):

(E,Z)-7,9-Dodecadien-1-yl acetate (CAS No. 54364-62-4)

117,4 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: SemiosBIO Technologies B.V.

Date: 07/03/2022

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Draft Label

Semios LB Plus Aerosol

Phéromone de confusion sexuelle pour lutter contre la tordeuse de la grappe
(*Lobesia botrana*)

Pulvérisateur Aérosol (AE)

Contient

-(E, Z)-7,9-dodecadien-1-yl acetate:

-

H222: Aérosol extrêmement inflammable

H280: Contient un gaz sous pression ; peut exploser sous l'effet de la chaleur.

H315: Causes skin irritation.

H319: Provoque une grave irritation oculaire.

H410: Very toxic to aquatic life with long lasting effects.

CAUTION ADVICE:

P210: Keep away from heat / sparks / open flames / heated surfaces —Do not smoke. P211: Do not spray on an open flame or other ignition source. P251: Pressurized container: do not pierce or burn, even after use. P261 Avoid breathing aerosols P273: Do not disperse in the environment. P391: Collect spilled material. P280: Wear protective gloves / protective clothing / eye protection / face protection. P403: Store in a well-ventilated place. P410 + P412: Protect from sunlight. Do not expose to temperatures above 50 ° C / 122 ° F. P501: Dispose of contents/container in accordance with national regulations.

ADDITIONAL INFORMATION:

EUH 401 - To avoid risks to humans and the environment, follow the instructions for use.

Authorization holder:

SEMIOS TECHNOLOGIES B.V.

Schiphol Boulevard 359, WTC Schiphol Airport, 1118J Schiphol, The Netherlands

Tel. 1-855-924-3282

Production and packaging workshop:

K-G Spray PAK INC., 8001 Keele Street, Vaughan ON, L4K 1Y8, Canada

Registration Ministry of Health n.

Content: 150 g - 307 g - 400 g

Lot no. on bottom of can



DANGER

PRECAUTIONARY STATEMENT:

Draft Label

Ensure adequate ventilation and use suitable gloves to handle the cylinders. Wash thoroughly with soap and water after handling the cylinders. In case of contact with eyes, rinse immediately with plenty of water. In case of contact with the skin wash thoroughly with soap and water. In case of persistent irritation, consult a doctor.

Use according to good company practices and industrial hygiene. Do not eat, drink, or smoke while handling the product.

INFORMATION FOR THE DOCTOR:

If you feel unwell, call your doctor for the usual first aid, and show the label if possible. **Warning: consult a Poison Control Centre.**

FEATURES:

The **Lobesia Eco Aerosol** is a product based on straight chain lepidopteran pheromones (SCLP) in aerosol cans for the control of European grapevine moth (*Lobesia botrana*) in grapes.

The **Lobesia Eco Aerosol** product is only to be used with Semios automatic dispensers.

ACTION MECHANISM:

The **Lobesia Eco Aerosol** is an insecticide product that acts by sexual confusion, creating fictitious and predominant pheromonic concentration in the air that divert males from the search for females, thus disturbing the mating phase.

DIRECTIONS FOR USE:

The Semios system is an integrated system and includes the detection and monitoring of environmental variables with devices positioned in the field (climatic stations, traps equipped with cameras, automatic aerosol dispensers and micro-climatic sensors) that transmit and are controlled from a centralized platform.

The individual Lobesia Eco Aerosol cylinders must be used in Semios automatic dispensers. Semios dispensers are programmable and remotely activated.

Apply the Lobesia Eco Aerosols within or above the upper third of the vine with the spray delivery nozzles/holes oriented away from the leaves and fruits at an average density of 2 cylinders per hectare. Their distribution must be homogeneous, and the positioning must be defined by consideration of the shape of the fields to be treated, the direction of the dominant wind, etc. In general, it is recommended to reinforce the density of the Lobesia Eco Aerosols at the vineyard edges, facing winds, or in areas of large infestations of European grapevine moth, up to a maximum of 5 cylinders per hectare.

TIME OF USE:

Apply the Lobesia Eco Aerosol before the start of the flight of the first generation. One application per year is sufficient to cover the annual cycle of the parasite. During this period, to obtain the greatest possible efficacy, the applications are carried out at night when the adults of the parasite are most active. The automatic daily dispensing cycle lasts a maximum of 12 hours, with an intermittent release of the pheromone at an average of 15-minute intervals. Lobesia Eco Aerosols are equipped with a valve and an automatic actuation designed to deliver a specifically calibrated dose of pheromone each time it is dispensed.

SAFETY INTERVAL - LACK TIME: NOT NECESSARY**CAUTION:**

To be used exclusively for the uses and conditions indicated on this label. Whoever uses the product is responsible for any damage resulting from the improper use of the preparation. Compliance with all the indications contained in this label is an essential condition to ensure the effectiveness of the treatment and to avoid damage to plants, people, and animals.

Draft Label

BEFORE USE READ THE PACKAGE LEAFLET

DISPOSE OF THE PACKAGING ACCORDING TO THE REGULATIONS IN FORCE

THE CONTAINER CANNOT BE REUSED

THE COMPLETELY EMPTY CONTAINER MUST NOT BE DISPERSED IN THE ENVIRONMENT

..... 24

PART A

RISK MANAGEMENT

1 Details of the application

The company SemiosBio Technologies B.V. has requested a marketing authorisation in France for the product SEMIOS LB PLUS AEROSOL (AE – aerosol dispenser), containing 117,4 g/kg (E,Z)-7,9-Dodecadien-1-yl acetate¹ as a mating disruptor for pest control 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 SemiosBio Technologies B.V. 's application submitted on 22/12/2020 to market SEMIOS LB PLUS AEROSOL 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 (2021-0052) 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 SEMIOS LB PLUS AEROSOL has been made using endpoints agreed in the EU peer review of SCLP. It also includes assessment of data and information related to SEMIOS LB PLUS AEROSOL 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 546/2011⁴, 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 SEMIOS LB PLUS AEROSOL.

¹ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

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

Not necessary: active substance data are not protected.

1.3 Justification for submission of tests and studies

According to the applicant: « The submitted tests and study reports are necessary for first authorisation of the product to show that the product conforms to the required physio-chemical properties after storage, is effective against the target pest while safe to the crop, humans, other non-target organisms and the environment.».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SEMIOS LB PLUS AEROSOL, 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	None
Product name in MS	SEMIOS LB PLUS AEROSOL
Authorisation number	2220045
Kind of use	Professional use
Low risk product (article 47)	No
Function	mating disruptor for pest control
Applicant	SemiosBio Technologies B.V
Active substance(s) (incl. content)	(E,Z)-7,9-Dodecadien-1-yl acetate (CAS No. 54364-62-4)
Formulation type	Aerosol dispenser [Code: AE]
Packaging	Aerosol dispensers in Polyethylene terephthalate-coated steel, containing 307 g formulation.
Coformulants of concern for national authorisations	/
Restrictions related to identity	/
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

SEMIOS LB PLUS AEROSOL
Part A - National Assessment

The evaluation of the application for SEMIOS LB PLUS AEROSOL 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:	Skin irritation, category 2 Aerosol, category 1
Hazard pictograms:	GHS07, GHS02 
Signal word:	Warning
Hazard statement(s):	H315: Causes skin irritation. H222: Extremely flammable aerosol H229: Pressurized container: may burst if heated
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

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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.

Finally, 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.

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

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	
	-
Other specific restrictions	

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/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

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

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Re-entry period	Not necessary
Storage	Store the product at a temperature above 0°C.
Risk mitigation measures	<ul style="list-style-type: none"> - Diffusion devices must be installed on supports other than grapes. In addition, they should not be aimed at the leaves or fruits.

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.

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Part A - National Assessment

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.

PPP (product name/code): SEMIOS LB PLUS AEROSOL

Formulation type: AE

Active substance 1: (E,Z)-7,9-Dodecadien-1-yl acetate (CAS No. 54364-62-4)

Conc. of a.s. : 11.74% w/w

Applicant: SemiosBio Technologies IncB.V..

Zone(s): SEUProfessional use: Yes

Verified by MS: No

Field of use: mating disruptor for pest control

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1	2	3	4	5	6	7	8	9	10	11	12
Use- No *	Mem ber state(s)	Crop and/or situa- tion (crop desti- na- tion/pu rpose of crop)	F, Fn, Fpn G, Gn , Gpn or I	Pests of Group of pests con- trolled (addition- ally: devel- opmental stages of the pest or pest group)	Application				Application		Remarks: e.g. g safener/synergist per ha RMS CONCLUSIONS
					Method / kind	Tim- ing/Gro wth stage of crop & season	Max. number a) Per use b) Per crop/season	Min. in- terval be- tween ap- plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	
1	FR	Grapes	F	European grapevine moth (<i>Lobesia botrana</i>) POLYBO	Inter- mittent aerosol release	Prior to grape- vine moth flight	a) 5 active dispensers/ha	-			Mating disruption pheromone Acceptable

Remarks
table head-
ing:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife, International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/L

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks
columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For, the crops 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).

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 transparent light-yellow oily liquid of low viscosity with a faint solvent smell with a mild fruity undertone odour. It is not explosive, has no oxidising properties. The product is classified as: H229 Pressurised container: may burst if heated. The product has a flash point of 15.2°C. The product is classified as: H222 Extremely flammable aerosol. No self-ignition test was performed as the product is pressurised aerosol dispenser. As the product is not water-based no pH value could be measured. There is no effect of low and high temperature on the stability of the formulation, since after 9 days at 4°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. In the absence of data at 0°C, SEMIOS LB PLUS AEROSOL must be protected to freeze. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in lined aluminium aerosol dispensers (as an interim shelf-life based on the accelerated storage results). The ambient storage stability assay is ongoing and will be reported at the renewal. Its technical characteristics are acceptable for an AE formulation.

The product is not intended to be mixed with any other products.

3.2 Efficacy (Part B, Section 3)

The level of efficacy of the product SEMIOS LB PLUS AEROSOL is considered acceptable to control *Lobesia botrana* on grapevine.

The product SEMIOS LB PLUS AEROSOL may induce slight phytotoxicity symptoms on the vines nearby without consequences for the whole plot. The risk of phytotoxicity is thus considered negligible on the plot. The risks of negative impact on yield, quality, winemaking and adjacent crops are considered negligible. The risk of development or appearance of resistance to (E,Z)-7,9-dodecadien-1-yl acetate is considered very low.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of active ingredient (E,Z)-7,9-Dodecadien-1-yl acetate in SEMIOS LB PLUS AEROSOL product is considered as validated according to SANCO/3030/99 rev.5.

3.3.2 Analytical methods for residues

No residue definition is available for (E,Z)-7,9-Dodecadien-1-yl acetate, therefore no methods are presented.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

SEMIOS LB PLUS AEROSOL, containing 4.70 mg/puff of (E,Z)-7,9-dodecadien-1-yl acetate, has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is irritating to the skin and not irritating to the eye. SEMIOS LB PLUS AEROSOL is not a skin sensitiser.

3.4.2 Operator exposure

Due to the formulation type (Aerosol releasing product in dispenser) which limits the direct contact with the product, and the level of emission comparable with the natural background levels, there is no unacceptable risk for the operator.

3.4.3 Worker exposure

Due to the formulation type (Aerosol releasing product in dispenser) which limits the direct contact with the preparation, and the level of emission comparable with the natural background levels, there is no unacceptable risk for the worker

3.4.4 Bystander exposure and worker

Due to the formulation type (Aerosol releasing product in dispenser) which limits the direct contact with the product, and the level of emission comparable with the natural background levels, there is no unacceptable risk for the resident and the bystander.

3.4.5 Combined exposure

Not relevant

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for (E,Z)-7,9-Dodecadien-1-yl acetate, as laid down in Regulation 396/2005, is not expected.

The chronic and the short-term intakes of (E,Z)-7,9-Dodecadien-1-yl acetate 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 use.

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Summary for SEMIOS LB PLUS AEROSOL

Table Information on SEMIOS LB PLUS AEROSOL (KCA 6.8)

Crop	PHI SEMIOS LB PLUS AEROSOL proposed by applicant	PHI/ Withholding period* sufficiently supported for (E,Z)-7,9-Dodecadien-1-yl acetate	PHI for SEMIOS LB PLUS AEROSOL proposed by zRMS	zRMS Comments (if different PHI proposed)
Grapes	-	NR		

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Not relevant

3.6 Environmental fate and behaviour (Part B, Section 8) & Ecotoxicology Part B, Section 9)

The fate and behaviour in the environment and ecotoxicology sections have been evaluated according to the requirements of Guidance document on semiochemicals (SANTE/12815/2014).

No unacceptable risk for the environment and non-target organisms is expected from the use of the product SEMIOS LB PLUS AEROSOL (AE dispenser) according to the intended uses.

3.7 Relevance of metabolites (Part B, Section 10)

Not required. Please refer to environmental fate and behaviour above.

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

The active substance SCLP 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

DocuSign Envelope ID: 1F000D3F-5DBC-4BB3-914D-DF49431E66BD



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 **SEMIOS LB PLUS AEROSOL***

de la société SEMIOSBIO TECHNOLOGIES B.V.

enregistrée sous le n° 2021-0052

Vu les conclusions de l'évaluation de l'Anses du 17 janvier 2022,

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.

SEMIOS LB PLUS AEROSOL

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DocuSign Envelope ID: 1F00D3F-5DBC-4BB3-914D-DF49431E66BD



Informations générales sur le produit	
Nom du produit	SEMIOS LB PLUS AEROSOL
Type de produit	Produit de référence
Titulaire	SEMIOSBIO TECHNOLOGIES B.V. Schiphol Boulevard 359 WTC Schiphol Airport SCHIPHOL, 1118BJ Pays-Bas
Formulation	Générateur d'aérosol (AE)
Contenant	117,4 g/kg - phéromones de lépidoptères à chaîne linéaire (sous forme de (E,Z)-7,9-dodécadien-1-yl acétate)
Numéro d'intrant	018-2021.01
Numéro d'AMM	2220045
Fonction	Attractif phéromone (confusion sexuelle)
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 août 2023.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 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 07/03/2022

DocuSigned by:

 AE281A065A42454...
 Directrice générale déléguée
 en charge du pôle produits réglementés
 Agence nationale de sécurité sanitaire de
 l'alimentation, de l'environnement et du travail (ANSES)

SEMIOS LB PLUS AEROSOL
 AMM n° 2220045

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SEMIOS LB PLUS AEROSOL
Part A - National Assessment

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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
Bouteilles de gaz sous pression en acier revêtu de polyéthylène téréphtalate	307 g

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Aérosols - Catégorie 1	H222 : Aérosol extrêmement inflammable H229 : Récipient sous pression : peut éclater sous l'effet de la chaleur
Corrosion cutanée/irritation cutanée - Catégorie 2	H315 : Provoque une irritation cutanée
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.	

SEMIOS LB PLUS AEROSOL

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Liste des usages autorisés En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ. 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)
12703104 Vigne* Trt Part.Aer.* Tordeuses de la grappe	5 diffuseurs actifs/ha	-	-	-	-	-	-	Non concerné
	Efficacité montrée sur eudémis de la vigne (<i>Lobesia botrana</i>). Installation avant le début du premier vol.							

SEMOS LB PLUS AEROSOL

Part A - National Assessment

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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

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.

Pour l'opérateur, porter

Lors de la manipulation des générateurs d'aérosol :

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

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

- Non nécessaire.

Respect des limites maximales de résidus (LMR)

- Les générateurs d'aérosol doivent être installés sur des supports autres que la culture. De plus, ils ne doivent pas être dirigés vers les feuilles ou les fruits.

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.

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.

Draft Label

Semios LB Plus Aerosol

Phéromone de confusion sexuelle pour lutter contre la tordeuse de la grappe
(*Lobesia botrana*)

Pulvérisateur Aérosol (AE)

Contient

-(E, Z)-7,9-dodecadien-1-yl acetate:

-

H222: Aérosol extrêmement inflammable

H280: Contient un gaz sous pression ; peut exploser sous l'effet de la chaleur.

H315: Causes skin irritation.

H319: Provoque une grave irritation oculaire.

H410: Very toxic to aquatic life with long lasting effects.

CAUTION ADVICE:

P210: Keep away from heat / sparks / open flames / heated surfaces —Do not smoke. P211: Do not spray on an open flame or other ignition source. P251: Pressurized container: do not pierce or burn, even after use. P261 Avoid breathing aerosols P273: Do not disperse in the environment. P391: Collect spilled material. P280: Wear protective gloves / protective clothing / eye protection / face protection. P403: Store in a well-ventilated place. P410 + P412: Protect from sunlight. Do not expose to temperatures above 50 ° C / 122 ° F. P501: Dispose of contents/container in accordance with national regulations.

ADDITIONAL INFORMATION:

EUH 401 - To avoid risks to humans and the environment, follow the instructions for use.

Authorization holder:

SEMIOS TECHNOLOGIES B.V.

Schiphol Boulevard 359, WTC Schiphol Airport, 1118J Schiphol, The Netherlands

Tel. 1-855-924-3282

Production and packaging workshop:

K-G Spray PAK INC., 8001 Keele Street, Vaughan ON, L4K 1Y8, Canada

Registration Ministry of Health n.

Content: 150 g - 307 g - 400 g

Lot no. on bottom of can



DANGER

PRECAUTIONARY STATEMENT:

SEMIOS LB PLUS AEROSOL
Part A - National Assessment

Draft Label

Ensure adequate ventilation and use suitable gloves to handle the cylinders. Wash thoroughly with soap and water after handling the cylinders. In case of contact with eyes, rinse immediately with plenty of water. In case of contact with the skin wash thoroughly with soap and water. In case of persistent irritation, consult a doctor.

Use according to good company practices and industrial hygiene. Do not eat, drink, or smoke while handling the product.

INFORMATION FOR THE DOCTOR:

If you feel unwell, call your doctor for the usual first aid, and show the label if possible. **Warning: consult a Poison Control Centre.**

FEATURES:

The **Lobesia Eco Aerosol** is a product based on straight chain lepidopteran pheromones (SCLP) in aerosol cans for the control of European grapevine moth (*Lobesia botrana*) in grapes.

The **Lobesia Eco Aerosol** product is only to be used with Semios automatic dispensers.

ACTION MECHANISM:

The **Lobesia Eco Aerosol** is an insecticide product that acts by sexual confusion, creating fictitious and predominant pheromonic concentrations in the air that divert males from the search for females, thus disturbing the mating phase.

DIRECTIONS FOR USE:

The Semios system is an integrated system and includes the detection and monitoring of environmental variables with devices positioned in the field (climatic stations, traps equipped with cameras, automatic aerosol dispensers and micro-climatic sensors) that transmit and are controlled from a centralized platform.

The individual Lobesia Eco Aerosol cylinders must be used in Semios automatic dispensers. Semios dispensers are programmable and remotely activated.

Apply the Lobesia Eco Aerosols within or above the upper third of the vine with the spray delivery nozzles/holes oriented away from the leaves and fruits at an average density of 2 cylinders per hectare. Their distribution must be homogeneous, and the positioning must be defined in consideration of the shape of the fields to be treated, the direction of the dominant wind, etc. In general, it is recommended to reinforce the density of the Lobesia Eco Aerosols at the vineyard edges, facing winds, or in areas of large infestations of European grapevine moth, up to a maximum of 5 cylinders per hectare.

TIME OF USE:

Apply the Lobesia Eco Aerosol before the start of the flight of the first generation. One application per year is sufficient to cover the annual cycle of the parasite. During this period, to obtain the greatest possible efficacy, the applications are carried out at night when the adults of the parasite are most active. The automatic daily dispensing cycle lasts a maximum of 12 hours, with an intermittent release of the pheromone at an average of 15-minute intervals. Lobesia Eco Aerosols are equipped with a valve and an automatic actuation designed to deliver a specifically calibrated dose of pheromone each time it is dispensed.

SAFETY INTERVAL - LACK TIME: NOT NECESSARY

CAUTION:

To be used exclusively for the uses and conditions indicated on this label. Whoever uses the product is responsible for any damage resulting from the improper use of the preparation. Compliance with all the indications contained in this label is an essential condition to ensure the effectiveness of the treatment and to avoid damage to plants, people, and animals.

Draft Label

BEFORE USE READ THE PACKAGE LEAFLET

DISPOSE OF THE PACKAGING ACCORDING TO THE REGULATIONS IN FORCE

THE CONTAINER CANNOT BE REUSED

THE COMPLETELY EMPTY CONTAINER MUST NOT BE DISPERSED IN THE ENVIRONMENT