REGISTRATION REPORT
Part A
Risk Management

Product code/name(s): Subvert®

Chemical active substance(s):

(E,Z)-7,9-dodecadien-1-yl acetate, 185.5 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Suterra Europe Biocontrol S.L.

Date: 15/10/2024

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PART A

RISK MANAGEMENT

1 Details of the application

The company SUTERRA EUROPE BIOCONTROL S.L. has requested a marketing authorisation in France for the product SUBVERT, containing 185.5 g/L of (E,Z)-7,9-dodecadienyl acetate[1] as a mating disruptor 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 SUTERRA EUROPE BIOCONTROL SL's application submitted on 02/02/2023 to market SUBVERT 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.

(E,Z)-7,9-dodecadienyl acetate is a low risk active substance, therefore SUBVERT shall be authorised as a low risk plant protection product where compliant with Article 47 of Regulation (EC) no 1107/2009.

The present application (2023-0932) 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 SUBVERT has been made using endpoints agreed in the EU peer review of SCLP. It also includes assessment of data and information related to SUBVERT 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.

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1 Commission Implementing Regulation (EU) 2022/1251 of 19 July 2022 renewing the approval of the active substances Straight Chain Lepidopteran Pheromones (acetates) as low-risk active substances, and Straight Chain Lepidopteran Pheromones (aldehydes and alcohols) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, 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

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 SUBVERT.

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the renewal of approval of the active substance.

1.3 Justification for submission of tests and studies

According to the applicant: « New data on the toxicity of the active substance (E,Z)-7,9-dodecadien-1-yl acetate on bees (chronic and developmental toxicity) have been generated due to France request during an art. 40 application for the product. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SUBVERT, 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	SFX-LB1
Product name in MS	Subvert
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	Yes
Function	Semiochemical (pheromone for mating disruption of *Lobesia botrana*)
Applicant	Suterra Europe Biocontrol S.L.
Active substance(s) (incl. content)	Straight Chain Lepidopteran Pheromone (No. 38): (E,Z)-7,9-dodecadienyl acetate; 185.5 g/L
Formulation type	Capsule suspension [CS]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	none
Restrictions related to identity	none

[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

Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for SUBVERT 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.

[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

Finally, 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
- 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.

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

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

None.

[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

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: 2024-10-15

PPP (product name/code):	SUBVERT	Formulation type:	CS
Active substance:	(E,Z)-7-9-dodecadienyl acetate	Conc. of as:	185.5 g/L
Safener:	None	Conc. of safener:	/
Synergist:	None	Conc. of synergist:	/
Applicant:	Suterra Europe Biocontrol S.L.	Professional use:	☒
Zone:	S-EU	Non professional use:	☐
Verified by MS:	yes/no		
Field of use:	mating disruption		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	**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** **RMS Conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number per crop/ season**	**Min. interval between applications (days)**	**L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha min/max**		
Zonal uses													

SUBVERT
Part A - National Assessment
FRANCE

1	S-EU FR (IT, ES, GR, PT)	Grapes	F	European Grapevine Moth (*Lobesia botrana*) POLYBO Adult males	High volume spraying application	Before the flight of the first generation to control till harvest.	a) 13 b) 13	14	a) 0.065 L/ha b) 0.845 L/ha (year)	a) 0.012 kg as/ha b) 0.156 kg as/ha (year)	200-1000	3	Not acceptable (composition,)
					Low volume spraying application by means of ultralow volume equipment (ULVA)						10-20		
2	S-EU FR (IT, ES, GR, PT)	Grapes	F	European Grapevine Moth (*Lobesia botrana*) POLYBO Adult males	High volume spraying application	Before the flight of the first generation to control till harvest.	a) 7 b) 7	28	a) 0.135 L/ha b) 0.945 L/ha (year)	a) 0.025 kg as/ha b) 0.175 kg as/ha (year)	200-1000	3	Not acceptable (composition)
					Low volume spraying application by means of ultralow volume equipment (ULVA)						10-20		

* 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

** SCLP (E,Z)-7-9-dodecadienyl acetate

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 a microencapsulated sprayable product, with a reddish-brown colour and a fruit-like odour. It is not explosive, it has no oxidising properties.
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 significantly. In addition, the effect of low temperature (freeze/thaw cycles for 4 days) on the product has also been tested, showing no impact on the active substance content nor in the technical properties of the product.
The stability data indicate a shelf-life of 2 years since neither the active substance content, nor the technical properties were changed significantly.
Following the comments received by ANSES during its evaluation for a Mutual Recognition (art. 40 of Reg. (EC) No. 1107/2009) a study investigating the integrity of the microcapsules has been carried out. The integrity of the microcapsules has been observed through microscope before and after application with a standard spray equipment and no significant difference in the appearance of the microcapsules was observed. A similar test had been conducted in the context of the EU Renewal of the active substance with the formulated representative product CheckMate CM-F. This product is a microcapsules suspension and the capsules have the same composition as those of the product Subvert. Also in the case of the product CheckMate CM-F, no significant difference in the capsule integrity or in the free active substance content was observed before and after application with a standard spray equipment. It can therefore be concluded that the microcapsules do no break after application of the product with spray equipment.
The technical characteristics of Subvert are acceptable for a capsule suspension [CS] formulation.
Commercial packaging: 0.5L or 1L F-PEHD bottles
No use in tank mixes has been recommended.
The intended concentration of use is 0.0065% v/v to 1.35% v/v.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

The effectiveness level of SUBVERT is considered acceptable for the requested use against *Lobesia botrana* in grapevine.

The phytotoxicity level of SUBVERT is considered negligible for the requested use.

The risks of negative impact on yield, quality, transformation-processes (wine-making) and propagation are considered negligible.

The risk of negative impact on adjacent crops is considered negligible.

The risk of resistance to (E,Z)-7,9-dodecadien-1-yl acetate does not require a monitoring for the requested use.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

GC-FID methods are presented for the free and total determination of (E,Z)-7,9-dodecadien-1-yl acetate in SUBVERT, a capsule suspension product, using hexadecane as internal standard.
Both methods were validated according to the guideline SANCO/3030/99 rev.5 and resulted sufficiently selective with a linear detector response. Precision was evaluated by means of five replicate sample analyses resulting in RSD% for total content equal to 1.42% at concentration of 19.67% w/w and Hr<1 and RDS% for free content equal to 1.75% at concentration of 0.36% w/w and Hr<1. Recovery was evaluated at three fortification levels and was equal to 98.1- 99.6% for all determinations. The methods are acceptable both for pre and post-registration purposes.

3.3.2 Analytical methods for residues

Not necessary, see RR partB7

3.4 Mammalian toxicology (Part B, Section 6)

Active substance(s) (incl. content)	**(E,Z)-7,9-dodecadienyl acetate** 185.5 g/L or 188.5g/kg
AOEL systemic	Not applicable. Exposure levels were compared to background release level.
Inhalation absorption	100%
Oral absorption	100%
Vapour pressure	17 mPa (at 20°C)
Reference	EFSA Journal 2021;19(6):6656 Renewal report for active substances that are Straight Chain Lepidopteran Pheromones finalised by the Standing Committee on Plants, Animals, Food and Feed on 18 May 2022, SANTE/10828/2021Rev 3.
Dermal absorption	Concentrate: 25% Dilution: 70%

3.4.1 Acute toxicity

SUBVERT has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to skin or eye and is a skin sensitizer.

3.4.2 Operator exposure

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model[8]:

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

		(E,Z)-7,9-dodecadienyl acetate	
Model data	**Level of PPE**	**Total exposure (mg/ha·h)**	**Comparison to background levels**
Tractor mounted spray application outdoors to high crops Application rate: 0.025 kg a.s./ha			
AOEM Body weight: 60 kg Treated area: 10 ha Exposure duration: 8h/day	Work wear (arms, body and legs covered) M/L and A	0.03 * 60 / 10 / 8 = **0.0255 mg/ha/h**	Exposure resulting from treatment is lower than background levels
Manual (knapsack) spray application outdoors to high crops Application rate: 0.025 kg a.s./ha			
AOEM Body weight: 60 kg Treated area: 10 ha Exposure duration: 8h/day	Work wear (arms, body and legs covered) M/L and A	0.05 * 60 / 10 / 8 = **0.0375 mg/ha/h**	Exposure resulting from treatment is lower than background levels

According to the EFSA model calculations, it can be concluded that the risk for the operator exposure to SUBVERT is below the natural background level. Hence no risk is expected for all intended uses with work wear 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 activities. Therefore, estimation of worker exposure was calculated according to the EFSA model.

		(E,Z)-7,9-dodecadienyl acetate	
Model data	**Level of PPE**	**Total exposure (mg/ha·h)**	**Comparison to background levels**
Hand harvesting Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 28 days			
Number of applications and application rate: 7 x 0.025 kg a.s./ha			
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.1 * 60 / 1 / 8 **= 0.75 mg/ha/h**	Exposure resulting from treatment is lower than background levels
Hand harvesting Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate: 13 x 0.012 kg a.s./ha			
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.1 * 60 / 1 / 8 **= 0.75 mg/ha/h**	Exposure resulting from treatment is lower than background levels

According to the EFSA model calculations, it can be concluded that the risk for the worker exposure to SUBVERT is below the natural background level. Hence no risk is expected for all intended uses with work wear.

For details of personal protective equipment for workers, 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[9].
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*."

[9] 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 the EFSA model without mitigation measures, (i.e. without drift reduction technology and a buffer zone of 10 meters).

		(E,Z)-7,9-dodecadienyl acetate
Model data		**Total absorbed dose (mg/kg bw/day)**
Spray application outdoors to high crops Buffer zone: 10(m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 28 days		
Number of applications and application rate		7 x 0.025 kg a.s./ha
Resident child Body weight: 10 kg	Drift (75th perc.)	0.01 * 10 / 1 / 24 = **0.0042 mg/ha/h**
	Vapour (75th perc.)	0.01 * 10 / 1 / 24 = **0.0042 mg/ha/h**
	Deposits (75th perc.)	0.0001 * 10 / 1 / 2 = **0.0005 mg/ha/h**
	Re-entry (75th perc.)	0.006 * 10 / 1 / 0.25 = **0.24 mg/ha/h**
	Sum (mean)	~~0.02~~ 0.0042 + 0.0042 + 0.0005 + 0.24 = **0.25 mg/ha/h**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.007 *60 / 1 / 24 = **0.0175 mg/ha/h**
	Vapour (75th perc.)	0.004 * 60 / 1 / 24 = **0.01 mg/ha/h**
	Deposits (75th perc.)	5e^{-05} * 60 / 1 / 2 = **0.0015 mg/ha/h**
	Re-entry (75th perc.)	0.003 * 60 / 1 / 0.25 = **0.72 mg/ha/h**
	Sum (mean)	~~0.01~~ 0.0175 + 0.01 + 0.0015 + 0.72 = **0.749 mg/ha/h**
Spray application outdoors to high crops Buffer zone: 10(m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 14 days		
Number of applications and application rate		13 x 0.012 kg a.s./ha
Resident child Body weight: 10 kg	Drift (75th perc.)	0.006 * 10 / 1 / 24 = **0.0025 mg/ha/h**
	Vapour (75th perc.)	0.01 * 10 / 1 / 24 = **0.0042 mg/ha/h**
	Deposits (75th perc.)	9e^{-05} * 10 / 1 / 2 = **0.00045 mg/ha/h**
	Re-entry (75th perc.)	0.005 * 10 / 1 / 0.25 = **0.2 mg/ha/h**
	Sum (mean)	~~0.02~~ 0.0025 + 0.0042 + 0.00045 + 0.2 = **0.21 mg/ha/h**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.003 * 60 / 1 / 24 = **0.0075 mg/ha/h**
	Vapour (75th perc.)	0.004 * 60 / 1 / 24 = **0.01 mg/ha/h**
	Deposits (75th perc.)	4e^{-05} * 60 / 1 / 2 = **0.0012 mg/ha/h**
	Re-entry (75th perc.)	0.003 * 60 / 1 / 0.25 = **0.72 mg/ha/h**
	Sum (mean)	~~0.008~~ 0.0075 + 0.01 + 0.0012 + 0.72 = **0.74 mg/ha/h**
Spray application outdoors to high crops Minimum volume of water : 10 l		

Buffer zone: 10(m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 28 days		
Number of applications and application rate		7 x 0.025 kg a.s./ha
Resident child Body weight: 10 kg	Drift (75th perc.)	0.2 * 10 / 1 / 24 = **0.083 mg/ha/h**
	Vapour (75th perc.)	0.01 * 10 / 1 / 24 = **0.0042 mg/ha/h**
	Deposits (75th perc.)	0.0001 *10/1/2 = **0.0005 mg/ha/h**
	Re-entry (75th perc.)	0.006 *10/1/0.25 = **0.24 mg/ha/h**
	Sum (mean)	~~0.2~~ 0.083 + 0.0042 + 0.0005 + 0.24 = **0.328 mg/ha/h**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.1 * 60 / 1 / 24 = **0.25 mg/ha/h**
	Vapour (75th perc.)	0.004 * 60 / 1 / 24 = **0.01 mg/ha/h**
	Deposits (75th perc.)	5e^{-05} * 60 / 1 / 2 = **0.0015 mg/ha/h**
	Re-entry (75th perc.)	0.003 * 60 / 1 / 0.25 = **0.72 mg/ha/h**
	Sum (mean)	~~0.1~~ 0.25 + 0.01 + 0.0015 +0.72 = **0.98 mg/ha/h**
Spray application outdoors to high crops Minimum volume of water : 10 l Buffer zone: 10(m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 14 days		
Number of applications and application rate		13 x 0.012 kg a.s./ha
Resident child Body weight: 10 kg	Drift (75th perc.)	0.1 * 10 / 1 / 24 = **0.042 mg/ha/h**
	Vapour (75th perc.)	0.001 * 10 / 1 / 24 = **0.0042 mg/ha/h**
	Deposits (75th perc.)	9e^{-05} *10/1/2 = **0.00045 mg/ha/h**
	Re-entry (75th perc.)	0.005 *10/1/0.25 = **0.2 mg/ha/h**
	Sum (mean)	~~0.09~~ 0.042 + 0.0042 + 0.00045 + 0.2 = **0.25 mg/ha/h**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.06 * 60 / 1 / 24 = **0.15 mg/ha/h**
	Vapour (75th perc.)	0.004 * 60 / 1 / 24 = **0.01 mg/ha/h**
	Deposits (75th perc.)	4e^{-05} * 60 / 1 / 2 = **0.0012 mg/ha/h**
	Re-entry (75th perc.)	0.003 * 60 / 1 / 0.25 = **0.72 mg/ha/h**
	Sum (mean)	~~0.05~~ 0.15 + 0.01 + 0.0015 + 0.72 = **0.88 mg/ha/h**

According to the EFSA model calculations, it can be concluded that the risk for the resident exposure to SUBVERT is below the natural background level. Hence no risk is expected for all intended uses.

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. SCLPs including (E,Z)-7,9-dodecadienyl acetate are included in Annex IV of Regulation (CE) No 396/2005 that regroups active substances for which no MRL are necessary. The investigation of residues and consumer exposure estimates are not necessary.

The chronic and the short-term intakes of (E,Z)-7,9-dodecadienyl acetate residues are unlikely to present a public health concern. As far as consumer health protection is concerned, zRMS agreed with the authorization of the intended use.

According to available data, no specific mitigation measures should apply when the product is used according to the proposed GAP.

Information on Subvert (KCA 6.8)

Crop	PHI for Subvert proposed by applicant	PHI sufficiently supported for (E,Z)-7,9-dodecadienyl acetate	PHI for Subvert proposed by zRMS	zRMS Comments (if different PHI proposed)
Grapes	3 days	Yes	Not applicable	

Waiting period 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 and the requirements of Guidance document on semiochemicals (SANTE/12815/2014).

The PEC of (E,Z)-7-9-dodecadien-1-yl acetate and its metabolite 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 or agreed in the assessment based on new data provided.
PECsoil and PECsw derived for the active substance are used for the ecotoxicological risk assessment. PECsw calculations for metabolite (E,Z)-7,9-dodecadienol, required according to Regulation 284/2013, were not provided by the applicant.
PECgw for (E,Z)-7-9-dodecadien-1-yl acetate and its metabolite are not expected to 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.

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 review for active substances and 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, bees and other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms and non-target plants are acceptable for the intended uses.

For aquatic organisms, the risk assessment cannot be finalized in absence of toxicity data on algae and in absence of risk assessment for its relevant metabolite (E,Z)-7,9-dodecadienol.

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 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

N/A : no marketing authorisation granted .

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

Appendix 1 Copy of the product authorisation

Docusign Envelope ID: 0BC80874-7E0B-4D3F-9D87-0ECCF4798553

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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 règlementaire,

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

de la société	*SUTERRA EUROPE BIOCONTROL SL*
enregistrée sous le	*n° 2023-0932*

Vu les conclusions de l'évaluation de l'Anses du 11 avril 2024,

Considérant qu'en application de l'article 27 du règlement (CE) n° 1107/2009, les coformulants inscrits à l'annexe III de ce règlement ne peuvent pas entrer dans la composition d'un produit phytopharmaceutique,

Considérant que les éléments disponibles relatifs à la composition du produit ne permettent pas de s'assurer que le produit SUBVERT ne contient pas de coformulant figurant à l'annexe III du règlement (CE) n° 1107/2009,

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	SUBVERT
Type de produit	Produit de référence
Titulaire	SUTERRA EUROPE BIOCONTROL SL Planta 9 Plaza América 2 46004 VALENCE Espagne
Formulation	Suspension de capsules (CS)
Contenant	185,5 g/L - phéromones de lépidoptère à chaîne linéaire (sous forme de (E,Z)-7,9-dodécadien-1-yl acétate)
Numéro d'intrant	183-2023.01
Numéro d'AMM	-
Fonction	Attractif phéromone (confusion sexuelle)
Gamme d'usage	Professionnel
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) n° 1107/2009

A Maisons-Alfort, le 15/10/2024

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)**
12703104 Vigne*Trt Part.Aer.*Tordeuses de la grappe	0,135 L/ha	7/an	3
	Motivation du refus : L'usage, à la dose pleine et en fractionnement, est refusé car les données disponibles ne permettent pas de s'assurer que le produit ne contient pas de coformulant figurant à l'annexe III du règlement (CE) n° 1107/2009.		

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.

Subvert®

PHÉROMONE DE CONFUSION SEXUELLE Tordeuse de la grappe *(Lobesia botrana)*
Produit suspension de capsules (CS)

N° D'AMM XXX — DETENTEUR DE L'AMM: Suterra Europe Biocontrol S.L.

COMPOSITION:

(E,Z)-7,9-Dodecadien-1-yl acetate	18.85% p/p (=185.5 g/L)
Autres formulants:	jusqu'au 100 % p/p

Suterra®

Registré et Distribué par :
Suterra Europe Biocontrol S.L.
Plaza América nº 2, Planta 9, 46004 (Valencia) Spain
Tel : +34 96 395 67 43

Usine de fabrication :
Suterra, LLC
20950 NE Talus Place
97701 Bend, OR, U.S.A

Pictogrammes SGH  Mention d'Avertissement Attention

Mentions de Danger	H317 : Peut provoquer une réaction cutanée allergique H412 : Nocif pour les organismes aquatiques, entraîne des effets à long terme
Conseils de Prudence	P273 : Éviter le rejet dans l'environnement P280 : Porter des gants de protection P302+352 : En cas de contact avec la peau : laver abondamment à l'eau et au savon P501 : Eliminer le récipient conformément à la réglementation nationale.

RESPECTEZ LES INSTRUCTIONS D'UTILISATION POUR EVITER LES RISQUES POUR LA SANTE HUMAINE ET L'ENVIRONNEMENT.

Produit réservé aux utilisateurs professionnels

PRECAUTIONS D'EMPLOI
Éviter le contact avec les yeux, la peau et les vêtements. Se laver avec du savon et de l'eau après l'utilisation du produit. Enlever les vêtements contaminés et les laver avant de les réutiliser. Prévenir la contamination des aliments, des aliments pour animaux, de l'eau potable et des ustensiles de cuisine. Ne pas polluer l'eau avec le produit ou son emballage (SP1).

PREMIERS SECOURS
En cas d'urgence, appelez le 15 ou le Centre Antipoison puis signalez vos symptômes au réseau Phyt'attitude, N° vert : 0 800 887 887 (appel gratuit depuis un poste fixe)".

EQUIPEMENTS DE PROTECTIONS INDIVIDUELLES
Pour l'opérateur, porter pendant la phase de pose des diffuseurs des gants de protection en caoutchouc ou en pvc.

INSTRUCTIONS POUR L'ELIMINATION
Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Interdiction de réutiliser les emballages vides. Éliminer les emballages vides via les collectes organisées par des distributeurs partenaires de la filière ADIVALOR.

Contenu net : 450 – 900 mL
N° du lot :
Date de fabrication :
Date d'expiration :

CARACTÉRISTIQUES
CheckMate Flow Vitis est une produit suspension de capsules (CS) pour la confusion sexuelle de la Tordeuse de la grappe *(Lobesia botrana)*.

USAGES HOMOLOGUÉS
CheckMate Flow Vitis est utilisé pour le contrôle de la Tordeuse de la grappe *(Lobesia botrana)* dans les vignes.
12703104 : Vigne*Trt Part.Aer.*Tordeuses de la grappe

MÉTHODE D'APPLICATION
Appliquer le produit avec un équipement d'application standard à volume élevé. Un équipement à ultra bas volume (UBV) peut également être utilisé. Le volume d'eau doit être sélectionné pour assurer une couverture complète de la plantation, en évitant les gouttes excessives, allant de 10 à 1000 L selon le type d'équipement d'application et la phénologie de la culture.
Agiter fortement le produit avant l'utilisation et appliquer le produit immédiatement après la préparation.
Le taux d'application varie entre 65 et 135 ml de produit/ha par application (équivalent à 12-25 g/ha).
Une nouvelle application est recommandée en cas de pluie

MODE D'EMPLOI
CheckMate Flow Vitis est un produit de confusion sexuel qui interfère avec la capacité des mâles de *L. botrana* à trouver des femelles et à s'accoupler. Il n'affecte pas directement les œufs, les larves ou les femelles gravides. Si l'application se produit après le début du premier vol, l'application d'insecticides supplémentaires peut être nécessaire. L'immigration de femelles à partir de sources externes d'infestation n'est pas affectée par le produit et peut réduire le niveau de contrôle.
L'utilisation de CheckMate Flow Vitis doit toujours avoir lieu dans le contexte d'une stratégie de lutte intégrée contre les ravageurs. L'utilisation d'autres mesures de lutte contre les ravageurs peut être nécessaire et doit être basée sur une surveillance appropriée des ravageurs et un dépistage sur le terrain
Intervalle post-récolte : 3 jours.
Aucun effet phytotoxique n'a été observé dans les vignobles.

RECOMMANDATIONS DE STOCKAGE
Ne pas utiliser les diffuseurs provenant d'emballages défectueux, percés ou restés ouverts.

IMPORTANT
Si CheckMate Flow Vitis est utilisé conjointement avec d'autres produits, l'intervalle de pré-récolte le plus long doit être respecté. Le respect des mesures de précaution des produits les plus toxiques est également requis.
En cas d'empoisonnement, informez votre médecin de tous les produits mélangés.
CheckMate Flow Vitis doit être utilisé exclusivement pour les utilisations et les conditions énoncées dans la présente étiquette. Toute personne qui utilise le produit est responsable de tous les dommages causés par une mauvaise application. Se conformer à toutes les informations contenues dans cette étiquette est essentiel pour assurer l'efficacité du traitement et pour éviter d'endommager les plantes, les humains et les animaux.

NE PAS APPLIQUER PAR PULVÉRISATION AÉRIENNE
LE PRODUIT NE DOIT PAS ÊTRE VENDU QUE DE SON CONTENANT ORIGINAL
DISPOSER SELON LES LOIS LOCALES
L'EMBALLAGE VIDE NE DOIT PAS ÊTRE RE-UTILISÉ