

REGISTRATION REPORT
Part A
Risk Management

Product code: SDX-LB3

Product name: CLICK LB-PRO (formely CLIP LB PRO)

Chemical active substance:

straight chain lepidopteran pheromone (SCLP),
(E,Z)-7,9-dodecadien-1-yl acetate, 98,0 g/kg (400 mg/dispenser)

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(NEW authorisation)

Applicant: Suterra Europe Biocontrol S.L.
Date: January 2021

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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 CLICK LB-PRO (product code: SDX-LB3), containing 400 mg/dispenser of (E,Z)-7,9-dodecadien-1-yl acetate, as a semiochemical (pheromone), for professional use.

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 information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to CLICK LB-Pro (product code: SDX-LB3) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CLICK LB-Pro (product code: SDX-LB3) have been made using endpoints agreed in the EU peer review of (E,Z)-7,9-dodecadien-1-yl acetate.

This document describes the specific conditions of use and labelling required for France for the registration of CLICK LB-Pro (product code: SDX-LB3).

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).

Appendix 3 of this document contains a copy of the Letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of Suterra Europe Biocontrol S.L.'s application to market CLICK LB-Pro (product code: SDX-LB3) in France as a semiochemical (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 MSs of the Southern zone.

The present application (2019-1201_2020-0878) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone for field uses, taking into account the worst-case uses ("risk envelope approach")¹ – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009², implementing regulations, and French regulations.

¹ 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](#)

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 (as amended for straight chain lepidopteran pheromones).

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. 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 conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011³, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

The applicant has provided a letter of access for the active substance.

1.3 Justification for submission of tests and studies

According to the applicant: “*Only physical-chemical, analytical and efficacy studies have been performed with the formulated product CLICK LB-Pro (product code: SDX-LB3) in support of this new authorisation. All the test performed are considered necessary to evaluate the characteristics and the efficacy of the product*”.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CLICK LB-PRO (product code: SDX-LB3), 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	SDX-LB3.
Product name in MS	CLICK LB-Pro (product code: SDX-LB3).
Authorisation number	2200914
Low risk (article 47)	No
Function	Semiochemical.
Applicant	Suterra Europe Biocontrol S.L.
Active substance(s) (incl. content)	98.0 g/kg (E,Z)-7,9-dodecadien-1-yl acetate, 400 mg/dispenser.
Formulation type	Vapour-releasing product [VP]
Packaging	PE containers in multilayer PET/PE/Al/PE/LDPE bags (100-250 dispensers/bag).
Coformulants of concern for national authorisations	-

³ 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 CLICK LB-Pro (product code: SDX-LB3) 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
Hazard pictograms:	 GHS07
Signal word:	Warning.
Hazard statement(s):	H315: Causes skin irritation.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use [EUH401]. Contains 2-hydroxy-4-octoxybenzophenone. May produce an allergic reaction [EUH208].

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.
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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 2017⁴ 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;
- 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 26 March 2014⁵ provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” 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 extrapolation⁶ 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:

The applicant is required to comply with the current applicable standard for clothing type PPE (ISO EN 27065)⁷.

Operator protection:

⁴ 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, modifié par l'arrêté du 27 décembre 2019 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

⁶ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

⁷ Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017

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-	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	
Re-entry period	Not applicable for this type of application.

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.

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 26 March 2014 (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: 2021-01-04

vapour-releasing product (VP)^(a, b)

98.0 g/kg 400 mg/dispenser^(c)



Formulation type:

Conc. of a.s. 1:

Professional use:

Non-professional use:



PPP (product name/code): CLICK LB-PRO (PRODUCT CODE: SDX-LB3)/SDX-LB3

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

Applicant: Suterra Europe Biocontrol S.L.

Zone(s): Southern Zone^(d)

Verified by MS: Yes

Field of use: Semiochemical

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR-	Grapes (table grape, wine grape, raisins)	F	European grapevine moth <i>Lobesia botrana</i> (POLYBO) Adult males	HH Manual distribution of 200 dispensers/ha	Before the flight of the first generation, to control until harvest	a) 1 b) 1	-	a) 200 dispens- ers/ha b) 200 dispens- ers/ha	a) 80 b) 80	-	Not applicable	Acceptable for <i>Lobesia botrana</i> only

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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/m ³ 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)

This product is a hand-applied dispenser. All studies have been performed in accordance with the current requirements and the results are deemed acceptable.

The appearance of the product is a hermetically closed plastic (polyethylene) container, with the active substance contained inside it. CLICK LB-Pro (product code: SDX-LB3) forms a closed system that emits to the surface from the interior of the dispenser. It is not explosive and has no oxidising properties. The product is not flammable. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, the active substance content was not changed. **The stability study of two years at ambient temperature in the commercial packaging is ongoing.**

The technical characteristics of CLICK LB-Pro (product code: SDX-LB3) are acceptable for a vapour-releasing product [VP] formulation.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

Considering the data submitted:

The efficacy of CLICK LB-Pro (product code: SDX-LB3) is considered satisfactory for the requested use.

The risk of resistance developing or appearing is considered to be very low.

The phytotoxicity level of CLICK LB-Pro (product code: SDX-LB3) is considered negligible for the requested use.

The risks of negative impact on adjacent crops are negligible.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The method (Lodi, M. 2018) for the determination of the active substance by GC-FID in the plant protection product CLICK LB-Pro (product code: SDX-LB3) is considered acceptable. The method was validated for linearity, repeatability, accuracy and specificity according to SANCO/3030/99 Rev. 4.

3.4.2 Analytical methods for residues

Due to the specific closed-system design of the CLICK LB-Pro (product code: SDX-LB3) dispenser, there

is no contact between the active substances and the protected crop; therefore no residue in fruits at harvest, nor in the environment (soil, water or sediment) are expected.

Therefore there is no need for methods of analysis in fruits and environmental matrices.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

CLICK LB-Pro (product code: SDX-LB3), containing 98 g/kg (E,Z)-7,9-dodecadien-1-yl acetate, has a low acute oral, inhalational and dermal toxicity.. It is not considered to be a skin sensitisier or eye irritant, however it is considered to be a skin irritant.

3.5.2 Operator exposure

Due to the formulation type (retrievable dispenser), which limits the direct contact with the product, plus the low toxicity of the active substance, and the level of emission comparable with the natural background, the exposure after using CLICK LB-Pro (product code: SDX-LB3) is judged to be negligible.

Therefore the risk to the operator is considered acceptable.

3.5.3 Worker exposure

For exactly the same reasons, the risk to workers is considered acceptable.

3.5.4 Bystander and resident exposure

For exactly the same reasons, the risk to residents is considered acceptable.

The bystander exposure level is covered by that of the resident.

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

According to the guidance documents ENV/JM/MONO(2017)33 and SANTE/12815/2014, “*when the exposure route is by the vapour phase only* (retrievable passive dispensers as CLICK LB-Pro (product code: SDX-LB3)) and where the exposure caused by the use of the plant protection product is similar (within one order of magnitude) to natural exposure levels of the semiochemical”, the risk characterisation is limited to physico-chemical, analytical and efficacy data.

In addition, the application type, with retrievable closed dispensers, makes it very unlikely that direct contact with food occurs; there is low probability of deposition on food or feed, following atmospheric dilution.

Finally, in consideration of the toxicological profile of CLICK LB-Pro (product code: SDX-LB3), no residues following an application of CLICK LB-Pro (product code: SDX-LB3) are expected to occur.

The data available are considered sufficient for risk assessment.

The chronic and short-term intakes of (E,Z)-7,9-dodecadien-1-yl acetate residues are unlikely to present a

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public health concern. As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended use.

According to the available data, no specific mitigation measures should apply.

Data gaps

None.

The product CLICK LB-Pro (product code: SDX-LB3) contains the SCLP (E,Z)-7,9-dodecadien-1-yl acetate (9.8 % w/w). No toxicological reference values or maximum residue levels are set for SCLPs.

Information on CLICK LB-Pro (product code: SDX-LB3) (KCA 6.8)

Crop	PHI for CLICK LB-Pro (product code: SDX-LB3) requested by applicant	PHI/withholding period sufficiently supported for	PHI for CLICK LB-Pro (product code: SDX-LB3) proposed by zRMS
		(E,Z)-7,9-dodecadien-1-yl acetate	
Grape	0 days	Yes	Not necessary

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

The fate and behaviour in the environment have been evaluated according to the requirements of the guidance document on semiochemicals, SANTE/12815/2014.

Based on the review report (SANCO/2633/08-rev 14; 20 July 2018) which indicated that “[...] SCLP, when they are applied via retrievable size dispensers, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment [...]”, France as zRMS considers that no unacceptable risk for the environment is expected from the use of the product CLICK LB-Pro (product code: SDX-LB3) (VP dispenser) according to the intended uses.

3.8 Relevance of metabolites (Part B, Section 10)

Not needed.

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

The active substance (E,Z)-7,9-dodecadien-1-yl acetate 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

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- the final results of the long term stability study (two years at ambient temperature) of the product CLICK LB-Pro (product code: SDX-LB3) in its commercial packaging.

Appendix 1 Copy of the product authorisation



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 et la demande associée du produit phytopharmaceutique CLICK LB-PRO

de la société SUTERRA EUROPE BIOCONTROL SL
enregistrées sous les n° 2019-1201 et 2020-0878

Vu les conclusions de l'évaluation de l'Anses du 4 novembre 2020,

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 précisées 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	CLICK LB-PRO
Type de produit	Produit de référence
Titulaire	SUTERRA EUROPE BIOCONTROL SL Plaza América núm 2, Planta 9 46004 Valencia Espagne
Formulation	Produit diffuseur de vapeur (VP)
Contenant	98 g/kg - phéromones de lépidoptères à chaîne linéaire (sous forme de (E,Z)-7,9-dodécadien-1-yl acétate)
Numéro d'intrant	118-2019.01
Numéro d'AMM	2200914
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 2022.

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 **05 JAN. 2021**

Caroline SEMAILLE
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 I : 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
Sachets multicouches en polyéthylène téréphtalate / polyéthylène / aluminium / polyéthylène	100 ; 250 diffuseurs en polyéthylène/sachet

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Corrosion cutanée/irritation cutanée - Catégorie 2	H315 : Provoque une irritation cutanée
EHH208 : Contient de la 2-hydroxy-4-octoxybenzophenone. Peut produire une réaction allergique	
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 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 non arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12703104 Vigne*TT Part Aer.* Tordeuses de la grappe	200 diffuseurs/ ha	1/an	-	-	-	-	-	-

Efficacité montrée sur *Lobesia botrana*.

Installation avant le début du vol de première génération.



Conditions d'emploi du produit

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

Dans le cadre d'une application effectuée avec diffuseur

• Lors de la manipulation des diffuseurs :

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants 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 :

- Non nécessaire.

Respect des limites maximales de résidus (LMR)

Compte tenu de la méthode d'application du produit, il n'est pas nécessaire de fixer de délai avant récolte pour les usages autorisés.

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.

SDX-LB3/CLICK LB-Pro
Part A - National Assessment
FRANCE

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.

 <p>Click LB-Pro</p> <p>PHÉROMONE DE CONFUSION SEXUELLE Tordeuse de la grappe (<i>Lobesia botrana</i>) Produit diffuseur de vapeur (VP)</p>		<p>CARACTÉRISTIQUES CLICK LB-Pro est une produit diffuseur de vapeur (VP) pour la confusion sexuelle de la Tordeuse de la grappe (<i>Lobesia botrana</i>).</p> <p>USAGES HOMOLOGUÉS CLICK LB-Pro est utilisé pour le contrôle de la Tordeuse de la grappe (<i>Lobesia botrana</i>) dans les vignes et dans des autres cultures où l'insecte peut se présenter. 12703104 : Vigne*Trt Part.Aer.*Tordeuses de la grappe</p>
N° D'AMM XXX	DETENTEUR DE L'AMM: Suterra Europe Biocontrol S.L.	MÉTHODE D'APPLICATION Le dosage d'application recommandé de CLICK LB-Pro est de 200 diffuseurs par hectare. Une application par an est suffisante pour couvrir le cycle complet de l'insecte.
COMPOSITION:	(E,Z)-7,9-Dodecadien-1-yl acetate 9,8% p/p Autres formulant: jusqu'au 100 % p/p	MODE D'EMPLOI L'application du Click LB-Pro doit être effectuée avant ou au moment du biofix (début du vol de la génération hivernale). Accrochez les diffuseurs des fils, des sarments ou des branches de vigne (évitez l'exposition directe au soleil). Répartir les diffuseurs dans tout le vignoble pour obtenir le dosage d'application. Click LB-Pro est un produit pour la confusion sexuelle qui interfère avec la capacité des tordeuses de la grappe males de trouver les femelles et, en conséquence, de copuler. Les phéromones n'ont aucun effet sur les œufs, larves ou femelles fécondées. Si l'on soupçonne la présence de femelles accouplées avant l'application, il faut traiter adéquatement le champ avec des insecticides qui permettent de lutter efficacement contre les larves et les œufs de ces femelles accouplées. La migration de femelles de sources externes d'infestation adjacentes n'est pas affectée par l'utilisation du produit et ça peut réduire le niveau de contrôle. L'utilisation de Click LB-Pro doit être toujours utilisé dans le contexte d'un programme de Lutte Intégrée. L'utilisation de autres mesures de control peut être nécessaire et doit être basé à une surveillance adéquate des ravageurs sur le terrain.
Registré et Distribué par : Suterra Europe Biocontrol S.L. Plaza América nº 2, Planta 9, 46004 (Valencia) Spain Tel : +34 96 395 67 43 Pictogrammes SGH	Usine de fabrication : Suterra, LLC 20950 NE Talus Place 97701 Bend, OR, U.S.A	Intervalle post-récolte : 0 jours. Aucun effet phytotoxique n'a été observé dans les vignobles. Produit utilisable en agriculture biologique, en application du Règlement (EC) No 889/2008.
Mentions de Danger Conseils de Prudence	P264 : Se laver les mains soigneusement après manipulation. P270 : Ne pas manger, boire ou fumer lors de l'utilisation de ce produit. P273 : Eviter le rejet dans l'environnement. P501 : Eliminer le récipient conformément à la réglementation nationale.	RECOMMANDATIONS DE STOCKAGE Ne pas utiliser les diffuseurs provenant d'emballages défectueux, percés ou restés ouverts.
RESPECTEZ LES INSTRUCTIONS D'UTILISATION POUR EVITER LES RISQUES POUR LA SANTE HUMAINE ET L'ENVIRONNEMENT.		IMPORTANT Click LB-Pro 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.
<p>Produit réservé aux utilisateurs professionnels</p> <p>PRÉCAUTIONS D'EMPLOI Éviter le contact avec les yeux, la peau et les vêtements. Se laver avec du savon et de l'eau après avoir placé les aérosols. 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).</p> <p>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).</p> <p>EQUIPEMENTS DE PROTECTIONS INDIVIDUELLES Pour l'opérateur, porter pendant la phase de pose des diffuseurs des gants de protection en caoutchouc ou en pvc.</p> <p>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. Eliminer les emballages vides via les collectes organisées par des distributeurs partenaires de la filière ADIVALOR.</p>		<p>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-UTILISE</p>
<p>Contenu net : 100-250 diffuseurs par sachet. Jusqu'à 20 sacs/boîte ou jusqu'à 5 sacs/seau.</p> <p>N° du lot : Date de fabrication : Date d'expiration :</p>		<p>©Suterra LLC. Tous les droits sont réservés. CheckMate[®], Puffer[™] et Suterra[™] sont marques déposées par Suterra[™] LLC, U.S.A</p>

Appendix 3 Letter of Access

Provided upon request.