REGISTRATION REPORT

Part A

Risk Management

Product code: CS0063

Product name: WEINTEC

Chemical active substances:

(E,Z)-7,9-dodecadien-1-yl acetate, 210 mg/dispenser

(Z)-9-dodecen-1-yl acetate, 325 mg/dispenser

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: SEDQ HEALTHY CROPS, S.L.

Date: 16 06 2021

Table of Contents

PART A
RISK MANAGEMENT

1 Details of the application

The company SEDQ HEALTHY CROPS, S.L. has requested a marketing authorisation in France for the product WEINTEC (product code: CS0063), containing 325 mg/dispenser of (Z)-9-dodecen-1-yl acetate and 210 mg/dispenser of (E,Z)-7,9-dodecadien-1-yl acetate, as a mating-disruption product, for professional uses. Both active substances are straight-chain lepidopteran pheromones[1] (SCLPs).

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 SEDQ HEALTHY CROPS, S.L.'s application submitted on 2 June 2020 to market WEINTEC (CS0063) 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 (2020-1978) 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 WEINTEC (CS0063) has been made using endpoints agreed in the EU peer reviews of (Z)-9-dodecen-1-yl acetate and (E,Z)-7,9-dodecadien-1-yl acetate. It also includes assessment of data and information related to WEINTEC (CS0063) where those data have not been considered in the EU peer review process.

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

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

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1 REGULATION (EU) No 918/2014 of 22 August 2014 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance straight chain lepidopteran pheromones, as amended.

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.

This document also describes the specific conditions of use and labelling required for France for the registration of WEINTEC (CS0063).

1.2 Letters of Access

The applicant has provided a letter of access for active substance. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: "*WEINTEC (CS0063) is a new product never registered in the EU. All studies presented in this dossier are deemed necessary to support the registration in France*".

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of WEINTEC (CS0063), 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	CS0067.
Product name in MS	WEINTEC.
Authorisation number	2210421
Kind of use	Professional use.
Low risk product (article 47)	No.
Function	Mating disruption.
Applicant	SEDQ HEALTHY CROPS, S.L.
Active substance(s) (incl. content)	(E,Z)-7,9-dodecadien-1-yl acetate, 210 mg/dispenser, (Z)-9-dodecen-1-yl acetate, 325 mg/dispenser.
Formulation type	Vapour-releasing product (VP]).
Packaging	Folder bag in polyester/aluminium/polyethylene with or without kraft paper on the outside, containing 1, 5, 50, 100, 150, 200, 250, 300, 350 or 400 passive dispensers in polyethylene.
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

2.2 Conclusion

The evaluation of the application for WEINTEC (CS0063) 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. Hazardous to the aquatic environment - Chronic Hazard, category 3.
Hazard pictograms:	 GHS07
Signal word:	Warning.
Hazard statements:	H315: Causes skin irritation. H412: Harmful to aquatic life with long-lasting effects.
Precautionary statements:	***For the P phrases, refer to the existing legislation.***
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. Avoid contamination via drains from farmyards and roads.
	For other restrictions refer to 2.5.

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4 May 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.

Finally, the French Order of 26 March 2014[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

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/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

Re-entry period	Not applicable for this type of application.
Storage	Do not store the product in a room where the temperature may exceed -18 °C.

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.

GAP rev. 1, date: 16 june 2021

PPP (product name/code):	WEINTEC / CS0063	Formulation type:	VP [a, b]
Active substance 1:	(E,Z)-7,9-dodecadien-1-yl acetate*	Conc. of a.s. 1:	0.210 [c]
Active substance 2:	(Z)-9-dodecen-1-yl acetate**	Conc. of a.s. 2:	0.325 [c]
Safener:	/	Conc. of safener:	/
Synergist:	/	Conc. of synergist:	/
Applicant:	SEDQ HEALTHY CROPS, S.L.	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Mating disruption		

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)	dispensers/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	VITVI (*Vitis vinifera*)	F	POLYBO *Lobesia botrana* (European grapevine moth) CLYSAM *Eupoecilia ambiguella* (European grape berry moth)	Mating disruption, hand-positioned dispensers	Application before first flight, BBCH-01-13 Duration of protection: 180 days.	a) 1 b) 1	Not applicable	a) 400 b) 400	a) 84 * + 130 ** b) 84 * + 130 **	Not applicable	Not applicable	**Acceptable** Only against *Lobesia botrana* and *Eupoecilia ambiguella*

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/dispenser
(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 conducted in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of two hermetically closed plastic containers, each containing one of the active compounds used in this plant protection product (PPP).

Each of these dispensers has its own commercial name: LOBETEC®[8], the dispenser containing (E,Z)-7,9-dodecadien-1-yl acetate, and EUPOTEC, the dispenser containing (Z)-9-dodecen-1-yl acetate. WEINTEC (CS0063) is a dual dispenser consisting of one unit of each of these two types of dispenser. The studies on physical, chemical and technical properties relevant for this submission were conducted separately for each of the dispensers.

WEINTEC (CS0063) forms a closed system that emits from the interior of the dispensers to the surface, in which, according to the applicant, the active substances (E,Z)-7,9-dodecadien-1-yl acetate and (Z)-9-dodecen-1-yl acetate are volatilised.

The product is not explosive, has no oxidising properties and is not flammable. WEINTEC (CS0063) is intended to be stored at -18 °C maximum, and in the stability measurements conducted up to now (a storage test conducted for 7 days at 0 °C, and an accelerated storage study conducted at 54 °C for 14 days), neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at -18 °C when stored in the original packaging material (polyester + aluminium + polyethylene bags).

The technical characteristics of WEINTEC (CS0063) are acceptable for a vapour-releasing product (VP) formulation.

This product is sold as a ready-to-use plant protection product. Given its characteristics, no dilution is needed before deployment in the field.

Only the manufacturing site for each a.s. recognised at European level must be used to manufacture WEINTEC (CS0063).

3.2 Efficacy (Part B, Section 3)

The level of efficacy of WEINTEC (CS0063) is considered acceptable to control *Lobesia botrana* and *Eupoecilia ambiguella* on grapevine.

In the absence of direct contact with the vegetation, no phytotoxicity is expected on the target crop.

The risk of the development or appearance of resistance to (E,Z)-7,9-dodecadien-1-yl acetate and (Z)-9-dodecen-1-yl acetate is considered to be very low.

[8] LOBETEC® was the first mating disruption plant protection product registered by SEDQ. It is currently authorised in France (country which acted as zRMS for Southern Europe Regulatory Zone –AMM 2170435), Spain, Italy, Portugal, Greece and Cyprus.
The product here presented is our first dual-dispenser vapour-releasing product, intended for the simultaneous control of two pests affecting vineyards by mating disruption, where "half of the product" is the already assessed LOBETEC® vapour-releasing product.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods in the studies E15019 and E18105 for the determination of the (E,Z)-7,9-dodecadien-1-yl acetate in LOBETEC® dispenser and (Z)-9-dodecen-1-yl acetate in EUPOTEC dispenser are considered to be validated.

3.3.2 Analytical methods for residues

Due to the specific closed-system design of WEINTEC (CS0063)'s dual dispenser, there is no contact between the active substances, (E,Z)-7,9-dodecadien-1-yl acetate and (Z)-9-dodecen-1-yl acetate, and the crops in-tended to be protected. Therefore no residues in grapes at harvest, nor in the environment (soil, water or sediment) are expected.

There is thus no need for methods of analysis in agricultural products nor in environmental matrices.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints		
Active substances	(E,Z)-7,9-dodecadien-1-yl acetate	(Z)-9-dodecen-1-yl acetate
AOEL systemic	Not allocated – not required	Not allocated – not required
Inhalation absorption	No data available – not required (no relevant exposure to be expected)	No data available – not required (no relevant exposure to be expected)
Oral absorption	No data available – not required (no relevant oral exposure to be expected)	No data available – not required (no relevant oral exposure to be expected)
Dermal absorption	No data available – not required (no relevant dermal exposure to be expected)	No data available – not required (no relevant dermal exposure to be expected)
Vapour pressure	0.00008 to 6.93 Pa at 20 °C.	0.00008 to 6.93 Pa at 20 °C.
Reference	Review report for active substance SCLP's. SANCO 2633/08-rev. 14 20/07/2018 EFSA Conclusion EFSA Journal 2014;12(1):3524	Review report for active substance SCLP's. SANCO 2633/08- rev. 14 20/07/2018 EFSA Conclusion EFSA Journal 2014;12(1):3524

3.4.1 Acute toxicity

WEINTEC (CS0063), containing 0.210 g/dispenser (E,Z)-7,9-dodecadien-1-yl acetate and 0.325 g/dispenser (Z)-9-dodecen-1-yl acetate, has a low acute oral, inhalational and dermal toxicity, is not irritating to the eye or a skin sensitiser. It is irritating to the skin.

3.4.2 Operator exposure

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

3.4.3 Worker exposure

Due to the formulation type (vapour-releasing product in dispenser), which limits direct contact with the product, the low toxicity of active substances, and the level of emission comparable with natural background levels, there is no unacceptable risk for the worker.

3.4.4 Bystander and resident exposure

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

3.4.5 Combined exposure

Not relevant, given the natural emission of those pheromones.

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

Overall conclusion

The data available are considered sufficient for risk assessment. No exceedance of the current MRL of 0.01 mg/kg for both (E,Z)-7,9-dodecadien-1-yl acetate and (Z)-9-dodecen-1-yl acetate, as laid down in Regulation No 396/2005, is expected.

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

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

The review report SANCO/2633/08-rev 14; 20 July 2018 indicated "[…] *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* […]". Therefore France as zRMS considers that no unacceptable risk for the environment is expected from the use of the product WEINTEC (CS0063) (VP

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 substances (Z)-9-dodecen-1-yl acetate and (E,Z)-7,9-dodecadien-1-yl acetate are not approved as candidates 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.

Appendix 1 Copy of the product authorisation

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

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

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

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

de la société	*SEDQ HEALTHY CROPS, S.L.*
enregistrée sous le	*n° 2020-1978*

Vu les conclusions de l'évaluation de l'Anses du 21 avril 2021,

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.

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Informations générales sur le produit	
Nom du produit	WEINTEC
Type de produit	Produit de référence
Titulaire	SEDQ HEALTHY CROPS, S.L. C/Llull, 41 08005 BARCELONE Espagne
Formulation	Produit diffuseur de vapeur (VP)
Contenant	535 mg/diffuseur - phéromones de lépidoptères à chaine linéaire (équivalent à 210 mg/diffuseur de (E,Z)-7,9-dodécadien-1-yl acétate et 325 mg/diffuseur de (Z)-9-dodécen-1-yl acétate)
Numéro d'intrant	481-2020.01
Numéro d'AMM	2210421
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

16 JUIN 2021

Charlotte GRASTILLEUR
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 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 polyester / aluminium / polyéthylène	1 ; 5 ; 50 ; 100 ; 150 ; 200 ; 250 ; 300 ; 350 ou 400 diffuseurs en polyéthylène / sachet
Sachets multicouches en polyester / aluminium / polyéthylène / papier	1 ; 5 ; 50 ; 100 ; 150 ; 200 ; 250 ; 300 ; 350 ou 400 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
Dangers pour le milieu aquatique - Danger chronique, catégorie 3	H412 : Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la règlementation 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**.	

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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)	Mention abeilles
12703104 Vigne*Trt Part.Aer.* Tordeuses de la grappe	**400 diffuseurs/ ha**	**1/an**	-	-	-	-	-	-
	Installation avant le début du vol de première génération. Efficacité montrée sur eudémis (*Lobesia botrana*) et cochylis (*Eupoecilia ambiguella*).							

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Stocker le produit à une température inférieure à -18 °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 diffuseurs**

- 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).

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. 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

Inhalation
En cas d'inhalation, amener la personne à l'air libre. Si les troubles se prolongent, consulter un médecin.

En cas de perte de la Fiche de données de sécurité, celle-ci peut vous être à nouveau fournie sur simple appel Tel. +34 937190471. No d'appel centre anti poison 0140054848

En cas d'urgence, appeler 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).

Date de fabrication/n° de lot : voir sur l'emballage

Important
Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...
Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.
Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.