

REGISTRATION REPORT

Part A

Risk Management

Product code/name(s):

CHECKMATE PUFFER CM/OFM

Active Substance(s):

(E,E)-8,10-dodecadien-1-ol 18.05% w/w

(Z)-8-Dodecen-1-yl-acetate 11.63 % w/w +

(E)-8-Dodecen-1-yl-acetate 0.75 % w/w +

(Z)-8-Dodecen-1-ol 0.12 % w/w

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(market authorisation)

Applicant: SUTERRA Europe Biocontrol S.L.

Date: 2017/12/05

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PART A – Risk Management

The company SUTERRA EUROPE BIOCONTROL S.L. has requested marketing authorisation in France for the product CHECKMATE PUFFER CM/OFM, containing (E,E)-8,10-dodecadien-1-ol, (Z)-8-dodecen-1-yl-acetate, (E)-8-dodecen-1-yl-acetate, (Z)-8-dodecen-1-ol for use as an attractant for pest control (mating disruption).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to CHECKMATE PUFFER CM/OFM where that data have not been considered in the EU review process. Otherwise assessments for the safe use of CHECKMATE PUFFER CM/OFM have been made using endpoints agreed in the EU review of Straight Chain Lepidopteran Pheromones (SCLPs).

This document describes the specific conditions of use and labelling required for France for the registration of CHECKMATE PUFFER CM/OFM.

Appendix 1 of this document provides a copy of the French decision.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

Appendix 3 of this document is a copy of the letter(s) of access.

1 DETAILS OF THE APPLICATION

1.1 Application Background

The present registration report concerns the evaluation of SUTERRA EUROPE BIOCONTROL S.L.'s application to market CHECKMATE PUFFER CM/OFM in France as an attractant for pest control (mating disruption) (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.

1.2 Active substance approval

SCLP - Straight Chain Lepidopteran Pheromones

Commission Implementing 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

Specific provisions of regulation were as follows :

PART A

Only uses as attractants may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on straight chain lepidopteran pheromones (SANCO/2633/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed shall be taken into account.

Conditions of use shall include, where appropriate, risk mitigation measures.

The notifier shall submit confirmatory information as regards:

(1) the genotoxic profile of aldehyde group compounds;

(2) exposure of humans and the environment resulting from the different ways of application of Straight Chain

Lepidopteran Pheromones as plant protection product, in comparison with natural background levels of those pheromones.

The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 31 December 2015 and the information set out in point (2) by 31 December 2016.⁷

An EFSA conclusion is available (EFSA Journal 2014; 12(1): 3524).

A Review Report is available (SANCO/2633/08 rev 12, 7 October 2016).

1.3 Regulatory Approach

The present application (2014-3636) 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, taking into account the worst-case uses (“risk envelope approach”)¹ – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017² provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally stated in the product authorisation, the minimum reentry delay 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French order.

The current document (dRR) based on Anses’ assessment of the application submitted for this product is in compliance with Regulation (EC) No 1107/2009³, Regulation (EU) No 918/2014 and French regulation.

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 relating to the regulatory compliance are based on the criteria indicated in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

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 “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁶ is to supply “minor” crops with registered plant

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 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 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte>

³ 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

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 <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

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

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.

1.4 Data Protection Claims

Where protection for data is being claimed for information supporting registration of CHECKMATE PUFFER CM/OFM, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION


2.1 Product Identity

| | |
|--------------------------------|--|
| Product name (code) | CHECKMATE PUFFER CM/OFM |
| Authorisation number | - |
| Function | Attractant for pest control (mating disruption) |
| Applicant | SUTERRA EUROPE BIOCONTROL S.L. |
| Composition | (E,E)-8,10-dodecadien-1-ol, (Z)-8-Dodecen-1-yl-acetate, (E)-8-Dodecen-1-yl-acetate, (Z)-8-Dodecen-1-ol |
| Formulation type (code) | AE |
| Packaging | Aerosol Dispensers made of steel : 115.2 g /dispenser 153.6 g /dispenser 192.0 g /dispenser 230.4 g /dispenser 268.8 g /dispenser 307.2 g /dispenser 345.6 g/dispenser 384.0 g/dispenser |

2.2 Classification and Labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

| | |
|------------------------------|---|
| Physical hazards | Aerosols Category 2, Aerosols Category 3 |
| Health hazards | Skin sensitisation cat. 1, Skin irritation cat. 2 |
| Environmental hazards | Aquatic Acute 1; Aquatic Chronic 2 |

| | | |
|--|---|--|
| Hazard pictograms |  | |
| Signal word | Warning | |
| Hazard statements | H317 | May cause an allergic skin reaction |
| | H315 | Causes skin irritation |
| | H400 | Very toxic to aquatic life |
| | H411 | Toxic to aquatic life with long lasting effects. |
| | H223 | Flammable aerosol |
| | H229 | Pressurized container: may burst if heated |
| Precautionary statements – | <i>For the P phrases, refer to the extant legislation</i> | |
| Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008) | | |

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

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

N/A : not registered in France.

2.2.3 Other phrases linked to the preparation

N/A : not registered in France.

2.3 Product uses

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”, 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.final, date: 2017/12/05

PPP (product name/code) CHECKMATE PUFFER CM/OFM

Active substance 1 (E,E)-8,10-dodecadien-1-ol

Active substance 2 (Z)-8-Dodecen-1-yl-acetate

Active substance 3 (E)-8-Dodecen-1-yl-acetate

Active substance 4 (Z)-8-Dodecen-1-ol

Formulation type: AE

Conc. of as 1: 18.05% w/w

Conc. of as 2 : 11.63 % w/w

Conc. of as 3 : 0.75 % w/w

Conc. of as 4 : 0.12 % w/w

Applicant: SUTERRA EUROPE BIOCONTROL S.L.
Zone(s): southern

professional use ☒
non professional use ☐

Verified by MS: y

| Crop and/or situation (a) | Zone | Product code | F G or I (b) | Pests or group of pests controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI (days) (l) | Remarks: (m) |
|---|------|-------------------------|--------------------------|---|------------------------|-----------------------|----------------------|--|-----------------------|--|--------------------------------|-----------------------|---|----------------------|--|
| | | | | | Type (d-f) | Conc. of a.s.* (i) | Method kind (f-h) | Growth stage and season (j) | Number min max (k) | Interval between applications (min) | Kg a.s./hL min max | water L/hL min max | kg a.s./ha min max | | |
| Pomefruit (apple, pears, quince, nashi, etc.) | FR | CHECKMATE PUFFER CM/OFM | F | <i>Cydia Pomonella</i> CARPO and <i>Grapholita molesta</i> LASPMO | AE (Aerosol dispenser) | 30.55 % w/w | Manual application | Before the flight of the first generation to the harvest | 1 | Not applicable | Not applicable | Not applicable | 0.0704 - 0.352 Kg (based on 115.2 g being the smallest size and 2 units/ha the lowest application rate and 384 g being the biggest size registered and 3units/ha the maximum application rate) | - | Not acceptable (new source not acceptable Decrease of individual minimum purity do not respect the content given in the regulation of SCLP (reg EU N°918/2014) |

| | | | | | | | | | | | | | | | |
|---------------------------|----|-------------------------|---|--|------------------------|-------------|--------------------|--|---|----------------|----------------|----------------|---|---|---|
| Peach, apricot, nectarine | FR | CHECKMATE PUFFER CM/OFM | F | <i>Cydia Pomonella</i> CARPO and <i>Grapholita molesta</i> LASPMO | AE (Aerosol dispenser) | 30.55 % w/w | Manual application | Before the flight of the first generation to the harvest | 1 | Not applicable | Not applicable | Not applicable | 0.0704 - 0.352 Kg (based on 115.2 g being the smallest size and 2 units/ha the lowest application rate and 384 g being the biggest size registered and 3units/ha the maximum application rate) | - | Not acceptable (new source not acceptable Decrease of individual minimum purity do not respect the content given in the regulation of SCLP (reg EU N°918/2014)) |
| Plum, jujube | FR | CHECKMATE PUFFER CM/OFM | F | <i>Grapholita molesta</i> LASPMO and <i>Cydia funebrana</i> LASPFU | AE (Aerosol dispenser) | 30.55 % w/w | Manual application | Before the flight of the first generation to the harvest | 1 | Not applicable | Not applicable | Not applicable | 0.0704 - 0.352 Kg (based on 115.2 g being the smallest size and 2 units/ha the lowest application rate and 384 g being the biggest size registered and 3units/ha the maximum application rate) | - | Not acceptable (new source not acceptable Decrease of individual minimum purity do not respect the content given in the regulation of SCLP (reg EU N°918/2014)) |

* SCLPs – (E,E)-8,10-dodecadien-1-ol and (Z)-8-Dodecen-1-yl acetate + (E)-8-Dodecen-1-yl acetate + (Z)-8-Dodecen-1-ol

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at 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
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

The specifications of the active substances “(Z)-8-Dodecen-1-yl-acetate + (E)-8-Dodecen-1-yl-acetate + (Z)-8-Dodecen-1-ol” used in the preparation CHECKMATE PUFFER CM-OFM are provided by Suterra. They have been evaluated and considered as not accepted at the French level because the decrease of the individual minimum purity compared with the content given in the regulation of SCLP (Reg. (EU) No 918/2014) means that the new origins cannot be considered similar to references sources.

The formulation CHECKMATE PUFFER CM/OFM is Aerosol Dispenser (AE). All studies have been performed in accordance with the current requirements. The appearance of the formulation is solid dispenser with yellow liquid content. It is not explosive and has no oxidizing properties. Flammability (flash point) and auto flammability properties were not submitted in the dossier; nevertheless the notifier has classified the preparation H223 and H229. The surface tension test and density are required. There is no high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 3 years at ambient temperature when stored in dispenser in steel. Its technical characteristics are acceptable for an Aerosol Dispenser (AE) formulation.

Due to the mode of application, it will be necessary to provide in post-authorization the internal pressure of the package. Moreover, it will be necessary to provide a test which demonstrates that the product is directly volatilized into the air at the outlet of the aerosol and that the active substance as droplets form does not fall on commodities or soil.

The formulation is classified for the physical-chemical part.

The formulation must be stored at a temperature below 40°C and protected of freeze.

3.1.2 Methods of analysis

Analytical methods for the determination of active substance and relevant impurity in the formulation are available and validated.

According to nature of active substance, no analytical methods are necessary for the determination of residues of (E,E)-8,10-dodecadien-1-ol + (Z)-8-Dodecen-1-yl-acetate + (E)-8-Dodecen-1-yl-acetate + (Z)-8-Dodecen-1-ol in plants, food of animal origin, soil, water (surface and drinking) and air.

The active substance is neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

Mammalian toxicology

Endpoints used in risk assessment

| | | |
|--|-----------------------------|---------|
| Active Substances: (E,E)-8,10-dodecadien-1-ol ; (Z)-8-Dodecen-1-yl-acetate; (E)-8-Dodecen-1-yl-acetate; (Z)-8-Dodecen-1-ol | | |
| ADI | Not applicable mg / kg bw/d | EU 2009 |
| ARfD | Not applicable mg/kg bw | |
| AOEL | Not applicable mg/kg bw/d | |
| Dermal absorption | No data available | |

3.1.3.1 Acute Toxicity

No acute toxicity study were performed with CHECKMATE PUFFER CM/OFM, classification was based by calculation method. Formulation has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to eye. However, a classification for skin irritating and skin sensitiser are applied.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

| Crop | F/G ⁷ | Equipment | Application rate | Spray dilution (L/ha) | Model |
|------------|------------------|-------------------|--|-----------------------|-------|
| Fruit crop | F | Aerosol dispenser | 3 units/ha 352 g active substances/ha | - | - |

No exposure model is adapted for the estimation operator, bystander/resident or worker exposures to semiochemicals. However, due to low toxicity of the formulation, dermal and inhalation exposure which are expected to be within in the range of naturally occurring background levels (375 g a.s/ha/season). Therefore, it can be concluded that the risk for operator, bystander/resident and worker is judged acceptable.

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

3.1.4 Residues and Consumer Exposure

As other active substances of the group “Straight Chain Lepidopteran Pheromones” (SCLPs), the toxicological profile of (E,E)-8,10-dodecadien-1-ol, (Z)-8-Dodecen-1-yl-acetate, (E)-8-Dodecen-1-yl-acetate, (Z)-8-Dodecen-1-ol were evaluated at EU level. Neither ADI nor ARfD was deemed necessary.

In the DAR (Austria, 2008), the intended uses for the Straight Chain Lepidopteran pheromones (SCLPs) include applications via closed passive retrievable dispensers (representative lead formulations ISOMATE CLR) as well as via spraying. Due to the nature of the SCLP active substance(s) and the application technique (closed dispenser), no residues are expected on or in any food or feeding stuff, which might be related to the use of SCLP’s.

According to OECD Series on Pesticides Number 12 (2002) an estimated density of codling moth females in orchards of 42.500-950.000 females/ha will lead to a total pheromone release of about 10-227.5 mg/ha/hr. For comparison, discrete pheromone dispensers used in mating disruption of this insect have a pheromone release rate of 32.5 mg/ha/hr (Touhey, unpublished report). Thus the release into the environment after application remains within the range of release from target pests during naturally occurring infestation events.

For the application via closed retrievable passive dispensers no residue data are required because of the unlikelihood of direct contact with food and the low probability of deposition on food or feed following atmospheric dilution.

A waiver for residue data was presented in the DAR and has been accepted in the review report for closed passive dispenser applications. Active dispensers are used in this dossier and are not covered by use assessed at EU level.

Conclusion

According to available data, intended uses of Checkmate Puffer CM/OFM are not fully supported by available data, and specific mitigation measures should apply.

- Dispensers must be set on other support than trees. Moreover, the spray must not be directed towards leaves or fruits.

3.1.5 Environmental fate and behaviour

⁷ Open field or glasshouse

As CHECKMATE PUFFER CM/OFM is applied in retrievable dispensers, no significant entry of the active substances into any environmental compartment (with the exception of the air) is expected to occur. In air the concentration of the active substance is not considered to exceed natural background concentrations. Therefore, no studies on the fate and behaviour of the product CHECKMATE PUFFER CM/OFM in the environment are required and no environmental risk assessment is deemed necessary for dispenser application according to the OECD Series on Pesticides No. 12 [Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control (OECD 2001)].

3.1.6 Ecotoxicology

CheckMate Puffer CM/OFM is used in stone fruit and any other affected crop for mating disruption of *Cydia pomonella* and *Grapholita molesta*, ones of the most important pests causing damage in pomefruit.

CheckMate Puffer CM/OFM is an AE formulation and its maximum application rate is 352 g as/ha/year.

According to OECD Series on Pesticides, No. 12 (ENV/JM/MONO(2001)12), the natural background level is estimated to be 375 g a.s./ha/year.

The risk following the use of CheckMate Puffer CM/OFM (as well as other SCLPs-based dispensers) with an application rate inside the natural background level is considered acceptable without the need to set any risk mitigation measures. It is important to recall that the dispensers are to be recollected at the end of the season.

3.1.7 Efficacy

CHECKMATE PUFFER CM / OFM is intended to be used for mating disruption of *Cydia pomonella* and *Grapholita molesta* on pome and stone fruits at the application dose of 2-3 puffers/ha (equivalent to 70 to 352 g a.s./ha/year, depending on the canister size and the number of puffers). Depending on the presence of the pest in the area, the most suitable container size is to be chosen. The product is an aerosol dispenser formulation (AE) to be manually applied as higher as possible (on a branch or on a pole at a height ranging from the top third of the plant up to 50 cm above the top of the plant). Only 1 application per year ensures mating disruption throughout the whole season. The dispensers are to be applied before the flight of the 1st generation of the first pest.

Considering the data provided and the characteristics of the product:

- Efficacy of CHECKMATE PUFFER CM / OFM (2-3 devices/ha) is considered as supported on intended pome and stone fruits for the control of codling moth *Cydia pomonella* and oriental fruit moth *Grapholita molesta*.
- Active substances targeting oriental fruit moth are known to be also effective on the plum fruit moth *Cydia funebrana* (efficacy shown with passive dispensers, applied at 350-600 dispensers/ha, by various applicants, including Suterra with the test product Checkmate OFM-XL). On *Cydia funebrana* on plums, further efficacy data are requested (with the Checkmate Puffer CM / OFM or Checkmate Puffer OFM) – to be provided within 3 years,
- The risk of phytotoxicity on fruits is considered low, although burning marks can appear on leaves and fruits just close to the puffer (the spray should not be directed on the crop). No other unintentional effects are expected on treated crops and neighbouring crops.
- The risk of resistance is considered as very unlikely for this type of product.

Conclusions on efficacy - France

| Intended crops (in France) | Intended targets (in France) | Dose rate | Nber of applic | Application stage | Conclusion |
|-------------------------------|---------------------------------|-----------|-------------------|----------------------|------------|
|-------------------------------|---------------------------------|-----------|-------------------|----------------------|------------|

| Intended crops (in France) | Intended targets (in France) | Dose rate | Nber of applic | Application stage | Conclusion |
|---|---|-------------------|-------------------|--|--|
| Pome fruits (apple, pear, quince, nashi) | Codling moth (= CM) <i>Cydia pomonella</i> CARPPO | 2-3 puffers/ha | 1 | Before the flight of the first generation to the harvest | Acceptable |
| Stone fruits (peach, nectarine, apricot, plum) | Oriental fruit moth (= OFM) <i>Grapholita molesta</i> LASPMO | | | | |
| Plum | Plum fruit moth <i>Cydia funebrana</i> LASPFU Oriental fruit moth (= OFM) <i>Grapholita molesta</i> LASPMO | | | | Acceptable (ask of post-registration efficacy data on <i>Cydia funebrana</i>) |

3.2 Conclusions arising from French assessment

Taking into account the above assessment, considering that the specifications of the active substances have been considered as not acceptable, an authorisation cannot be granted. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A.

3.4 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

3.4.1 Post-authorisation monitoring

N/A.

3.4.2 Post-authorisation data requirements

N/A.

3.4.3 Label amendments (see label in Appendix 2):

N/A.

Appendix 1 – Copy of the French decision



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 règlement d'exécution (UE) N° 540/2011 de la Commission du 25 mai 2011 portant application du
règlement (CE) N° 1107/2009 du Parlement européen et du Conseil, en ce qui concerne la liste des substances
actives approuvées,*

*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
CHECKMATE PUFFER CM/OFM*

de la société SUTERRA EUROPE BIOCONTROL SL
enregistrée sous le n°2014-3636 et 2016-2740

Vu les conclusions de l'évaluation de l'Anses du 29 septembre 2017,

*Considérant que la pureté minimale spécifiée du mélange de (E/Z)- 8-dodécenyl acétate et de (Z)-8-dodécenol
ne respecte pas la pureté minimale retenue de 940 g/kg par le règlement d'approbation (UE) N° 540/2011
susvisé,*

*Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 paragraphe 1 point b) 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.

CHECKMATE PUFFER CM/OFM
AMM n°-

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| Informations générales sur le produit | |
|---------------------------------------|--|
| Nom du produit | CHECKMATE PUFFER CM/OFM |
| Type de produit | Produit de référence |
| Titulaire | SUTERRA EUROPE BIOCONTROL SL Plaza América 2 Planta 9 46004 Valencia ESPAGNE |
| Formulation | Générateur d'aérosol (AE) |
| Contenant | 30,55 % phéromones de lépidoptère à chaîne linéaire (équivalent à 18,05 % de (E,E)-8,10-dodecadien-1-ol et 12,5 % d'un mélange de (E/Z)-8-dodécenyl acétate et de (Z)-8-dodécenol) |
| Numéro d'intrant | 676-2014.01 |
| Numéro d'AMM | - |
| Fonction | Attractif phéromone (confusion sexuelle) |
| Gamme d'usages | Professionnel |

A Maisons-Alfort, le

05 DEC. 2017

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

CHECKMATE PUFFER CM/OFM
AMM n°2170959

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| Liste des usages refusés | | | | |
|--|----------------------------|-------------------------------|-----------------------------|--|
| Usages | Dose d'emploi | Nombre maximum d'applications | Délai avant récolte (jours) | |
| 12553103 Pêcher*Trt Part.Aer.*Chenilles foreuses des fruits | 3 générateurs d'aérosol/ha | 1/an | - | |
| Motivation du refus : L'usage est refusé car la pureté minimale du mélange des phéromones de lépidoptères à chaîne linéaire ne respecte pas la pureté minimale prévue par le règlement (UE) n° 540/2011. | | | | |
| 12603103 Pommier*Trt Part.Aer.*Chenilles foreuses des fruits | 3 générateurs d'aérosol/ha | 1/an | - | |
| Motivation du refus : L'usage est refusé car la pureté minimale du mélange des phéromones de lépidoptères à chaîne linéaire ne respecte pas la pureté minimale prévue par le règlement (UE) n° 540/2011. | | | | |
| 12653102 Prunier*Trt Part.Aer.*Chenilles foreuses des fruits | 3 générateurs d'aérosol/ha | 1/an | - | |
| Motivation du refus : L'usage est refusé car la pureté minimale du mélange des phéromones de lépidoptères à chaîne linéaire ne respecte pas la pureté minimale prévue par le règlement (UE) n° 540/2011. | | | | |

CHECKMATE PUFFER CM/OFM
AMM n°.

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Appendix 2 – Copy of the draft product label as proposed by the applicant



PHÉROMONE DE CONFUSION SEXUELLE
Carpocapse (Cydia pomonella), Tordeuse Orientale du Pêcher (Grapholita molesta)

Utilisable en agriculture biologique, en application du règlement du Conseil n° 834/2007

CONSIGNES DE SÉCURITÉ :
Éviter le contact avec les yeux, la peau et les vêtements. Ne pas respirer les aérosols. Se laver les mains avec de l'eau et du savon après manipulation. Enlever les vêtements contaminés et les laver avant réutilisation. Empêcher la contamination de la nourriture humaine ou animale ou des boissons.

RENSEIGNEMENTS MÉDICAUX :
En cas d'irritation ou d'éruption cutanée : consulter un médecin.

EQUIPEMENTS DE PROTECTIONS INDIVIDUELLES :
Porter des gants de protection.

FORMULATION :
N° d'AMM :
DETENTEUR DE L'AMM :
COMPOSITION :
(E)-8,10-Dodecadien-1-ol :
(Z)-8-Dodecen-1-yl-acétate :
(E)-8-Dodecen-1-yl-acétate :
(Z)-8-Dodecen-1-ol :
Autres formulates :
Usages homologués :
Contenu net :
N° du lot et date de fabrication :
Date d'expiration :
Distribué par :
DE SANGOSSE S.A.S
Bonne BP5
47480 Pont-du-Casse
Tel: 05 53 69 36 36
Pictogrammes SGH

Générateur AEROSOL (AE)
Suterra Europe Biocontrol S.L.
jusqu'à 100 % p/p
Pommes/Tri-Plet-Aer/Chenilles foreuses des fruits
115.2-153.6-192-230.4-288.8-387.2-345.6-384 g ±
3 ans après la date de fabrication

Usine de fabrication :
Suterra, LLC
20960 NE Talus Place
97701 Bend, OR
(U.S.A.)

Mention d'Avertissement
Mentions de Danger

Conseils de Prudence

Élimination :
Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Éliminer les emballages vides via les collectes organisées par des distributeurs partenaires de la filière ADOVALOR.

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.

CARACTÉRISTIQUES
CheckMate® Puffer® CM/OFM est une phéromone conditionnée en aérosol pour la confusion sexuelle du Carposapse des pommes et des poires (Cydia pomonella) et du Tordeuse Orientale du Pêcher (Grapholita molesta).

MODE D'EMPLOI

| Culture | Dose | Organisme nuisible |
|------------|---------------|--|
| Pommier | 2-3 unités/ha | Carpocapse des pommes et des poires (Cydia pomonella) et Tordeuse Orientale du Pêcher (Grapholita molesta) |
| Poirier | 2-3 unités/ha | Carpocapse des pommes et des poires (Cydia pomonella) et Tordeuse Orientale du Pêcher (Grapholita molesta) |
| Cognassier | N/A | |

CheckMate Puffer CM/OFM est utilisable en Agriculture Biologique conformément au règlement (CE) n°834/2007. Le produit est la réplique d'une phéromone naturelle. Dans les conditions d'emploi préconisées par le fabricant, aucun effet secondaire indésirable n'est attendu sur les fruits récoltés, sur les cultures limitrophes et les organismes non-cibles. Limites maximales de résidus : se reporter aux LMR établies au Niveau de l'Union Européenne (consultables à l'adresse : http://ec.europa.eu/food/food/pesticides/pesticides_eu_db/).

Ne pas appliquer plus de 375 grammes de substance active par hectare et par an.

Pour de meilleurs résultats, placer les Puffers, au plus tard, au début des vols de nuisibles cibles, ou aux premières captures d'adultes dans les pièges, et continuer pendant toute la période des nuisibles ensemble. Les bouteilles doivent être placées dans des cabines spécifiques de libération automatique (Puffer Aérosol Cabinet) qui assurent la diffusion de phéromones, indépendamment des conditions météorologiques. N'activer le Puffer Aérosol Cabinet qu'au moment du déploiement du produit. S'assurer de tenir le vaporisateur à distance lors de la manipulation du produit pour éviter une pulvérisation accidentelle. Placer CheckMate Puffer CM / OFM activé manuellement sur une branche ou sur un poteau à une hauteur allant des deux tiers supérieurs de la plante jusqu'à 50 cm au-dessus de la plante. Prévoir de l'espace pour la croissance de canopée en cours de saison. Placer le produit de manière à éviter la pulvérisation sur le feuillage ou les fruits. Répandre CheckMate Puffer CM/OFM, en tenant compte de : la forme et la taille des champs à traiter, la direction des vents dominants et le type de protection contre les ravageurs cibles adoptée en parcelles voisines. Celles-ci peuvent être sources de migration des femelles déjà fécondées dans la parcelle en confusion. En général, il est recommandé de répartir les diffuseurs de manière homogène et de renforcer les bordures du verger exposées aux vents dominants. Si nécessaire, contacter votre fournisseur habituel et DE SANGOSSE pour évaluer les caractéristiques de votre verger, la bonne position et le nombre de Puffers à appliquer dans le verger.

NOTES D'UTILISATION : CheckMate Puffer CM/OFM est un agent de confusion sexuelle interférant avec la capacité des mâles à trouver des partenaires femelles. Il n'a aucune action directe sur les adultes, les larves et les femelles porteuses d'œufs. Si la mise en place des diffuseurs est réalisée après le début des premiers vols, protéger le verger par un traitement insecticide ou d'autres méthodes de contrôle efficaces contre les larves jusqu'à la fin des éclosions. La migration des papillons femelles provenant de sources d'infestation externes adjacentes n'est pas affectée par le produit et peut réduire le niveau de contrôle. Toujours assurer un suivi précis et régulier de l'infestation en relevant les pièges et en observant les feuilles et les fruits, en particulier aux limites du verger. Compléter la confusion sexuelle avec des insecticides autant qu'il sera nécessaire, autant dans le verger affecté que dans les sources d'infestation externes adjacentes.

CheckMate Puffer CM / OFM libère C. pomonella et G. molesta phéromones sexuelles pour perturber le comportement d'accouplement des ravageurs. Par conséquent, cette technologie est très spécifique à ces espèces, et il n'affecte pas les autres espèces.

CheckMate® et Puffer® marques déposées par Suterra® LLC, U.S.A

Appendix 3 – Letter(s) of Access



The IBMA Pheromones Task Force Coordinator
Suffolk House, Chapel Road Broughton
COWBRIDGE South Glamorgan, UK
CF71 7QR
November 2014

Anses-DPR-UGAmm,
14 rue Pierre et Marie Curie,
94701 MAISONS-ALFORT Cedex
FRANCE

TO WHOM IT MAY CONCERN

Letter of Access to annex II data of Straight Chain Lepidopteran Pheromones (SCLPs) Dossier

Dear Madam or Sir,

The following companies are Members of the IBMA Pheromones Task Force, constituted for submitting a joint dossier for the inclusion in Annex I of Dir. 91/414 for Straight Chain Lepidopteran Pheromones (SCLPs): AgriSense-BCS Ltd, Laboratorios Agrochem SL, BASF SE, Certis Europe BV, DKSH Switzerland Ltd, Exosect Limited, Isagro S.p.A., Russell Fine Chemicals Ltd, Shin-Etsu International Europe B V (represented by CBC-Europe), Sociedad Espanola de Desarrollos Químicos, S.L. (SEDQ), Suterra LLC.

These companies have agreed to grant Letters of Access among themselves, their affiliates and to interested third parties. For the sake of simplicity these companies have authorised the Coordinator of the IBMA Pheromones Task Force to grant such Letters of Access.

Therefore:

The signee, Coordinator of the IBMA Pheromones Task Force, acting for and on behalf of Members of the IBMA Pheromones Task Force, hereby agrees that the files, data, studies, summaries and assessments (hereafter referred to as the „**Dossier**“) owned and submitted by Member companies of the IBMA Pheromones Task Force in support of the registration of Straight Chain Lepidopteran Pheromones (SCLPs) as active ingredients, may be referred to by you in order to grant registration to

SUTERRA Europe Biocontrol S.L. - C/de la Imaginacio', num. 7-9 – Gava' business park – 08850 Gava' (Barcelona) Spain (hereafter referred to as „**Company**“)

For the Product:

| | |
|------------------------------|--|
| CheckMate® Puffer® CM/OFM | E,E-8,10-Dodecadienol 18.05% w/w and (Z)-8-Dodecen-1-yl-acetate 11.63% w/w + (E)-8-Dodecen-1-yl-acetate 0.75% w/w + (Z)-8-Dodecen-1-ol 0.12% w/w |
|------------------------------|--|

(hereafter referred to as „**Product**“)

The right to refer to the Dossier is subject to the following restrictions:

1. The right of referral only gives access to the Dossier of the Compounds.
2. The right of referral only gives access for the registration of the Product in FRANCE.
3. The right of referral is solely granted to Company and is neither transferable nor sub-licensable to any further companies or other legal or natural entities.
4. The Dossier contains valuable information. The Dossier shall remain strictly confidential and must not be viewed or copied either in writing or by electronic means or otherwise disclosed to any third party including the Company. This Letter of Access does not authorize Company and its employees or any person other than the competent authority personnel to receive any copies of the Dossier nor to inspect or view the Dossier or any summary thereof in whole or in part. Therefore, neither any regulatory authority nor Company shall be entitled to disclose the Dossier to any third party, nor to allow its use by any third party, unless the signee has given its prior written approval to such disclosure or use.
5. This Letter of Access shall in no event be construed as granting Company any property rights whatsoever to the Dossier.



Dr. Robin P. Sheppard

Coordinator of the IBMA Pheromones Task Force
Acting for and on behalf of Members of the IBMA Pheromones Task Force