

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code/name : ISOMATE-P**

**Active Substance(s):**

**(Z,Z)-3,13-octadecadienyl acetate: 32.4 mg/dispenser**

**(E,Z)-3,13-octadecadienyl acetate: 1.6 mg/dispenser**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

**Applicant: SUMI AGRO France**

**Date: 2018/06/11**

## Table of Contents

<b>1</b>	<b>DETAILS OF THE APPLICATION.....</b>	<b>3</b>
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH .....	4
1.4	DATA PROTECTION CLAIMS .....	5
1.5	LETTER(S) OF ACCESS .....	5
<b>2</b>	<b>DETAILS OF THE AUTHORISATION .....</b>	<b>5</b>
2.1	PRODUCT IDENTITY .....	5
2.2	CLASSIFICATION AND LABELLING.....	5
2.2.1	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008 .....</i>	<i>5</i>
2.2.2	<i>Other phrases in compliance with Regulation (EU) No 547/2011 .....</i>	<i>6</i>
2.2.3	<i>Other phrases linked to the preparation .....</i>	<i>6</i>
2.3	PRODUCT USES.....	7
<b>3</b>	<b>RISK MANAGEMENT.....</b>	<b>9</b>
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	9
3.1.1	<i>Physical and chemical properties .....</i>	<i>9</i>
3.1.2	<i>Methods of analysis .....</i>	<i>9</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>9</i>
3.1.3.1	<i>Acute Toxicity .....</i>	<i>9</i>
3.1.4	<i>Residues and Consumer Exposure .....</i>	<i>10</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>11</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>11</i>
3.1.7	<i>Efficacy .....</i>	<i>11</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT .....	12
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING .....	12
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 .....	12
3.4.1	<i>Post-authorisation monitoring .....</i>	<i>12</i>
3.4.2	<i>Post-authorisation data requirements .....</i>	<i>12</i>
3.4.3	<i>Label amendments .....</i>	<i>12</i>
	<b>APPENDIX 1 – COPY OF THE FRENCH DECISION .....</b>	<b>13</b>
	<b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT .....</b>	<b>18</b>
	<b>APPENDIX 3 – LETTER(S) OF ACCESS .....</b>	<b>20</b>

## PART A – Risk Management

The company SUMI AGRO FRANCE has requested marketing authorisation in France for the product ISOMATE-P, containing (Z,Z)-3,13-octadecadienyl acetate and (E,Z)-3,13-octadecadienyl acetate for use as an attractant/mating disruption for pest control.

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 peer review. It also includes assessment of data and information relating to ISOMATE-P where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ISOMATE-P have been made using endpoints agreed in the EU peer review(s) of Straight Chain Lepidopteran Pheromones (SCLPs).

This document describes the specific conditions of use and labelling required for France for the registration of ISOMATE-P.

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 SUMI AGRO FRANCE's application to market ISOMATE-P in France as an attractant/mating disruption for pest control (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

#### 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.’

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

A Review Report is available (SANCO/2633/08 rev13, 9 July 2017).

### 1.3 Regulatory approach

The present application (2014-1527) 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”)<sup>1</sup> – 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 out in the Decision letter.

The French Order of 4th May 2017<sup>2</sup> provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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 (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>3</sup>, implementing regulations, guidance documents and French regulations.

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 acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>4</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>5</sup> 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

<sup>1</sup> 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

<sup>2</sup> 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>

<sup>3</sup> 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

<sup>4</sup> 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

<sup>5</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

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 extrapolation<sup>6</sup> 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.

#### 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ISOMATE-P, 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

Not necessary: the applicant has provided sufficient data to show that access is not required.


### 2 DETAILS OF THE AUTHORISATION

#### 2.1 Product identity

<b>Product name (code)</b>	ISOMATE-P
<b>Authorisation number</b>	2180257
<b>Function</b>	Attractant for pest control (mating disruption)
<b>Applicant</b>	SUMI AGRO FRANCE
<b>Composition</b>	(Z,Z)-3,13-octadecadienyl acetate: 32.4 mg/dispenser (E,Z)-3,13-octadecadienyl acetate: 1.6 mg/dispenser
<b>Formulation type (code)</b>	Vapour releasing product (VP)
<b>Packaging</b>	Passive PEHD dispensers in vacuum-sealed aluminium bags made of nylon/aluminium/nylon/PELD (500 dispensers/bag).

#### 2.2 Classification and labelling

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

<b>Physical hazards</b>	-
<b>Health hazards</b>	Skin irritation cat 2 Skin sensitisation cat 1
<b>Environmental hazards</b>	Aquatic Chronic 2
<b>Hazard pictograms</b>	
<b>Signal word</b>	Warning

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

	H315 Causes skin irritation H317 May cause an allergic skin reaction H411 Toxic to aquatic life with long-lasting effects	
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>	
<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>		

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

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

The authorisation of the product is linked for professional uses only to the following conditions:

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).
------	---

## 2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>7</sup> : refer to the Decision in Appendix 1 for the details
Re-entry period <sup>8</sup> : Not Applicable
Pre-harvest interval <sup>9</sup> : Not Applicable
Other mitigation measures: Do not store at a temperature above 5°C and protect from frost.
The label must reflect the conditions of authorisation.

<sup>7</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

<sup>8</sup> The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

<sup>9</sup> According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

## 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.

GAP, date: 2018-06-11

PPP (product name/code) **ISOMATE-P**  
active substance 1 **(Z,Z)-3,13-octadecadienyl acetate**  
Active substance 2 **(E,Z)-3,13-octadecadienyl acetate**

Formulation type: **VP (vapour releasing product in closed dispenser)**  
Conc. of as 1: **32.4 mg/dispenser**  
Conc. of as 2 : **1.6 mg/dispenser**

Applicant: **SUMI AGRO FRANCE**  
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 as  (i)	method kind  (f-h)	growth stage & season  (j)	number min max  (k)	interval between applications (min)	kg as/hL  min max	water L/ha  min max	kg as/ha  min max		
Pome fruits (apple, pear, quince, medlar, nashi, azarole)	Southern	ISOMATE-P	F	<i>Synanthedon myopaeformis</i>	VP	32.4 mg/dispenser of (Z,Z)-3,13- octadecadienyl acetate and 1.6 mg/dispenser of E,Z)-3,13- octadecadienyl acetate	Manual distribution of 250 dispensers per ha; uniform distribution throughout orchards.	Prior to moth emergence	1	N/A			8.5 g/ha [250 dispensers X (32.4+1.6 mg)]	N/A	Acceptable Only against <i>Synanthedon myopaeformis</i>

- 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 formulation ISOMATE-P is a dispenser type vapor releasing product [Code: VP]. All studies have been performed in accordance with the current requirements. The appearance of the product (content of the dispenser) is that of a yellow liquid. It is not explosive, has no oxidizing properties. It has a self-ignition temperature of 300°C. Shelf-life (2 years at 5°C or room temperature) is required in commercial packaging (PEHD dispenser in vacuum-sealed aluminum bags made of nylon/aluminum/nylon/PELD).

Its technical characteristics are acceptable for a dispenser type vapor releasing product (VP) formulation.

The formulation is not classified for the physical-chemical part.

The formulation must be stored at a temperature above or equal to 5°C and protected from frost.

##### **3.1.2 Methods of analysis**

###### **3.1.2.1 Analytical method for the formulation**

Analytical methods for the determination of active substances and impurities in the formulation are not available and are required.

###### **3.1.2.2 Analytical methods for residues**

Analytical methods for the determination of residues of ISOMATE-P in plants, foodstuff of animal origin, soil, water (surface and drinking) and air are not necessary.

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**

Since SCLPs are naturally occurring substances which are produced by insects, that they are effective at very low rates, are rapidly degraded and were shown to be of low toxicity and that the application technique via passive dispensers with release rates similar to the natural emission rates of insects presents negligible direct exposure by inhalation to humans, it was considered not necessary to set an Acceptable Operator Exposure Level (AOEL) for application of vapor releasing dispensers. No residue is expected following application by dispensers.

It is not necessary to set an ADI and ARfD in EU.

###### **3.1.3.1 Acute Toxicity**

No acute toxicity study were performed with ISOMATE-P, classification was based by calculation method. Old studies on the pheromone blend were provided however, they are considered to be unacceptable.

ISOMATE-P containing 32.4 mg (Z,Z)-3,13-octadecadienyl acetate/dispenser and 1.6 mg (E,Z)-3,13-octadecadienyl acetate/dispenser has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit eye by calculation method. However, classification for skin irritating and skin sensitizer are applied.

###### **3.1.3.2 Operator Exposure**

Summary of critical use patterns (worst cases):

Crop	F/G <sup>10</sup>	Equipment	Application kg/L product/ha (g as/ha)	rate Spray dilution (L/ha)	Model
Pome fruits	F	Manual distribution throughout orchards	250 dispenser/ha (8.5 g a.s./ha)	n.a.	n.a.

No exposure model is adapted for the estimation operator exposure to semiochemicals.

The proposed rate of application for ISOMATE-P is maximum 250 dispensers per hectare, each containing 34 mg of the mixture of 2 actives ingredients (32.4 mg of (Z,Z)-3,13-octadecadienyl acetate plus 1.6 mg of (E,Z)-3,13-octadecadienyl acetate). This corresponds to maximum 8.5 g of pheromones per hectare (34 mg as/dispenser \* 250 dispensers = 8500 mg as/ha = 8.5 g a.s./ha).

Direct dermal exposure of operators to the SCLP active substances can be considered as negligible since the blend is sealed in plastic dispensers. However, in order to minimize accidental contact of operators with a potential skin irritant, protective gloves are recommended.

The other possible contact would be through inhalation. This exposure is expected to be very low and within the range of naturally occurring background levels (375 g a.s/ha/season).

Therefore, it is concluded that the risk for the operator using ISOMATE-P is acceptable with the use of gloves during manipulation of dispensers.

### 3.1.3.3 Bystander Exposure

Bystander exposure to pheromone arising from the use of ISOMATE-P is expected to be within the range of naturally occurring background levels. Thus bystander exposure is considered to be negligible.

### 3.1.3.4 Worker Exposure

Worker exposure to pheromone arising from the use of ISOMATE-P is expected to be within the range of naturally occurring background levels. Thus worker exposure is considered to be negligible.

## 3.1.4 Residues and Consumer Exposure

### 3.1.4.1 Residues

As other active substances of the group “Straight Chain Lepidopteran Pheromones” (SCLPs), 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 retrievable dispensers (representative lead formulation ISOMATE-CLR) as well as via spraying. Due to the nature of the SCLP active substances and the application technique (closed passive dispensers), no residues are expected on or in any food or feeding stuff, which might be related to the use of SCLPs.

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 passive retrievable 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.

<sup>10</sup> Open field or glasshouse

#### 3.1.4.2 Consumer exposure

No toxicological reference values were considered necessary at European level.

Considering the absence of ADI and ARfD, consumer risk assessment was not calculated, and considered to be acceptable, taking into account the mode of application of ISOMATE-P using closed passive retrievable dispensers.

#### 3.1.4.3 Mitigation measures

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

#### 3.1.5 Environmental fate and behaviour

As ISOMATE-P 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 ISOMATE-P 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

The risk for non-target organisms is considered acceptable for this SCLPS product applied as a closed dispenser at a rate below the natural emissions of 375 g SCLPs/ha/yr indicated by the OECD Series on Pesticides (Number 12): Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control ENV/JM/MONO (2001).

#### 3.1.7 Efficacy

**Considering the data provided and the characteristics of the products:**

Considering the inhibition of insect catching, ISOMATE-P seems efficient for *Synanthedon myopaeformis* mating disruption. Efficacy was assessed in trials with a low level of pest pressure.

The selectivity evaluation is considered as not relevant for this type of product.

The evaluation of the impacts on processing procedures, on quality, on yield, on succeeding and adjacent crops is considered as not relevant for this type of product.

The risk of resistance development is considered as very unlikely for this type of product.

### **3.2 Conclusions arising from French assessment**

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

### **3.3 Substances of concern for national monitoring**

No information stated.

### **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**

No further information is required.

#### **3.4.2 Post-authorisation data requirements**

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

- Storage and shelf life (2 years at 5°C or room temperature) is required in commercial packaging (PEHD dispenser in vacuum-sealed aluminum bags made of nylon/aluminum/nylon/PELD).
- Validation data according to the guidance SANCO/3030/99 of the method used for the determination of active substances ((Z,Z)-3,13-octadecadienyl acetate and (E,Z)-3,13-octadecadienyl acetate) in the formulation ISOMATE-P or any other method completely validated.

#### **3.4.3 Label amendments**

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

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

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **ISOMATE-P***

*de la société SUMI AGRO France*

*enregistrée sous le n°2014-1527*

*Vu les conclusions de l'évaluation de l'Anses du 4 mai 2018,*

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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	ISOMATE-P
Type de produit	Produit de référence
Titulaire	SUMI AGRO France 251 Rue du Faubourg Saint-Martin 75010 PARIS FRANCE
Formulation	Diffuseur de vapeur (VP)
Contenant	34 mg/diffuseur - phéromones de lépidoptères à chaîne linéaire (équivalent à 32,4 mg/diffuseur de (Z,Z)-3,13-octadécadiényl acétate et 1,6 mg/diffuseur de (E,Z)-3,13-octadécadiényl acétate)
Numéro d'intrant	9649-2014.01
Numéro d'AMM	2180257
Fonction	Attractif phéromone (confusion sexuelle)
Gamme d'usages	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 qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 août 2021.

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

11 JUIN 2018

**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)



## 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
Diffuseurs en PEHD emballés sous vide dans des sacs multicouches thermo-scellés en nylon/aluminium/nylon/polyéthylène basse densité	500 diffuseurs/sac

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
Sensibilisants cutanés - Catégorie 1	H317 : Peut provoquer une allergie cutanée
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets à long terme
Pour les phrases P se référer à la réglementation en vigueur.	
<b>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.</b>	





### Liste des usages autorisés

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 Traitee aquatique (mètres)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles
12603170 Pommier*Trt Part.Aer.*Insectes xylophages	250 diffuseurs/ha	1/an	-	Non applicable	-	-	-	-

Efficacité montrée sur *Synanthedon myopaeformis*





## Conditions d'emploi du produit

### Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 5°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

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-3.

### *Délai de rentrée :*

Non applicable.

### 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.

## Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Réurrence (mois)
Fournir les résultats de l'étude concernant la stabilité au stockage pendant 2 ans dans l'emballage commercial.	24	-
Fournir les données de validation d'une méthode pour la détermination du (Z,Z)-3,13-octadécadiényl acétate et du (E,Z)-3,13-octadécadiényl acétate dans le produit.	24	-

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

### ISOMATE®-P

DIFFUSEUR DE PHEROMONES POUR LA LUTTE PAR CONFUSION SEXUELLE CONTRE  
LA SESIE DU POMMIER (*SYNANTHEDON MYOPAEFORMIS*)

#### COMPOSITION ET FORMULATION

ISOMATE®-P est un diffuseur de phéromones pour la lutte par confusion sexuelle contre la sésie du pommier (*Synanthedon myopaeformis*) en vergers de fruits à pépins. L'apport de phéromone dans l'atmosphère de la parcelle désoriente les papillons mâles, empêche leur accouplement avec les femelles et permet ainsi de rompre le cycle avant l'apparition du stade nuisible.

■ Composition:

Z, Z-3,13 octadecadienyl acetate (0.0324 g par diffuseur)

E, Z-3,13 octadecadienyl acetate (0.0016 g par diffuseur)

■ Formulation: VP (produit diffuseur de vapeur)

■ Autorisation de vente et usages : A.M.M. n° -----

Usages autorisés :

12603170 Pommier \* Traitement des Parties Aériennes \* Insectes xylophages

Compte tenu de la composition du mélange phéromonal qu'il contient, ISOMATE®-P ne pourra être utilisé que pour contrôler la sésie du pommier, comme indiqué ci-après :

Cultures	Ravageur	Dose d'application
Fruits à pépins (Pommier, poirier, cognassier, nashi)	Sésie du pommier ( <i>Synanthedon myopaeformis</i> )	250 diffuseurs par hectare*

\* Lire les instructions concernant la protection renforcée des bordures à prévoir en sus

Remarque : ISOMATE®-P ne permet pas de confuser la sésie du groseillier (*Synanthedon tipuliformis*)

ISOMATE®-P est utilisable en agriculture biologique

#### NON CLASSE

P273: Eviter le rejet dans l'environnement.

P280: Porter des gants.

P501: Éliminer le contenu/récipient dans une installation d'élimination des déchets agréée.

EUH 401: Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

SP1 : Ne pas polluer l'eau avec le produit ou son emballage

Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

Fiches de sécurité disponibles sur [www.quickfds.com](http://www.quickfds.com) ou tél: 01 53 67 68 53

#### CONDITIONS DE STOCKAGE

Conserver les diffuseurs dans leur emballage d'origine non ouvert, dans un local frais et sec à l'abri de la lumière. Pour un stockage de longue durée, la température ne doit pas dépasser 5°C.



**SUMI AGRO France S.A.S.**  
25, boulevard de l'Amiral Bruix  
75782 PARIS Cedex 16  
tél: 01 53 67 68 40, télécopie: 01 53 67 68 41

Contenance:  
sachets de 500 diffuseurs

N° de lot :

© Marque déposée Shin-Etsu. Importé du Japon, fabriqué par Shin-Etsu Chemical Co., Ltd. Tokyo, Japan

## INSTRUCTIONS D'EMPLOI

Le diffuseur ISOMATE®-P est recommandé pour la lutte contre la sésie du pommier en vergers de fruits à pépins.

La zone traitée doit être de forme compacte et avoir une surface minimale de 2 à 3 hectares. Le potentiel d'infestation doit être modéré et l'environnement proche ne doit pas comporter de foyers fortement infestés. Il est souhaitable de protéger par confusion sexuelle avec ISOMATE®-P une surface aussi étendue que possible, incluant plusieurs parcelles contiguës ou proches les unes des autres.

### ● APPLICATION

Epoque et mode d'application:

Appliquer ISOMATE®-P juste avant le début du vol de sésie du pommier dans la région.

Respecter la dose d'application recommandée. Appliquer les diffuseurs à raison de 250 unités par hectare en les répartissant de façon homogène sur la parcelle, placés en quinconce, et en veillant à les poser à une hauteur de 1,5 à 2 mètres, sur du bois de 2 ans.

Précautions complémentaires impératives:

- Renforcer la protection des bordures en doublant la densité de pose sur les rangs de bordure et sur les arbres en bouts de rangs. Placer des diffuseurs sur les haies et brise-vents, les arbres isolés à proximité du verger, et à l'emplacement des arbres manquants.

- Dans le cas où des parcelles contiguës portent des cultures colonisées par la sésie du pommier non protégées par confusion sexuelle, prévoir une zone tampon d'au moins 30 mètres protégée par des diffuseurs.

- S'il existe des foyers infestés proches de la parcelle protégée, des femelles fécondées venant de ces foyers peuvent pénétrer sur la parcelle et affecter le résultat. Ces foyers peuvent être : des parcelles mal protégées, vergers abandonnés, arbres isolés d'essences susceptibles d'être colonisées par la sésie (Rosacées arbustives, en particulier pommier, poirier, cognassier, sorbier, aubépine).

### ● SUIVI APRES APPLICATION

Il est nécessaire de s'assurer du bon fonctionnement de la méthode et de l'absence de perturbations éventuelles liées à l'environnement extérieur à la parcelle. Pour cela un suivi de la parcelle est recommandé :

- Pose d'un piège sexuel et relevé périodique des captures. Ces dernières sont normalement inhibées par la confusion et il ne doit pas y avoir de captures, mêmes limitées.

- La sésie étant un ravageur à cycle bisannuel (une génération tous les 2 ans), une première vérification de l'efficacité est possible à partir de la troisième année. Elle pourra s'effectuer par observation des dépouilles nymphales en fin de saison, à partir de mi septembre par exemple.

### ● INTERVENTIONS INSECTICIDES COMPLÉMENTAIRES

Assurer les interventions insecticides indispensables pour le contrôle des autres ravageurs.

**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 données issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur.

### **Appendix 3 – Letter(s) of Access**

Not applicable