REGISTRATION REPORT

Part A

Risk Management

Product name: GINKO

E,E-8,10-dodecadien-1-ol (codlemone): 254 mg/dispenser
dodecan-1-ol: 132 mg/dispenser

1-tetradecanol: 31 mg/dispenser

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT

Applicant: **SUMI AGRO FRANCE**

Date: **04/12/2015**

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PART A – Risk Management

The company SUMI AGRO FRANCE has requested marketing authorisation in France for the product GINKO, containing 254 mg/dispenser E,E-8,10-dodecadien-1-ol, 132 mg/dispenser dodecan-1-ol and 31 mg/dispenser 1-tetradecanol for a use as mating disruption product.

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 GINKO where that data have not been considered in the EU review process. Otherwise assessments for the safe use of GINKO have been made using endpoints agreed in the EU review of E,E-8,10-dodecadien-1-ol, dodecan-1-ol and 1-tetradecanol.

This document describes the specific conditions of use and labelling required for France for the registration of GINKO

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 use GINKO in France as a mating disruption product (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 renewal of authorisation after approbation of active substance of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

E,E-8,10-dodecadien-1-ol, 1-ol, dodecan-1-ol and 1-tetradecanol (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.

A Review Report is available (SANCO/2633/08 – rev. 7 12 December 2014).

1.3 Regulatory Approach

The present application (2014-1654) (French authorisation n° 2000536) was evaluated by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) [1] (application ref. 2014-1654) in the context of the voluntary zonal procedure for all Member States of the Southern zone taking into account the worst-case uses ("risk envelope approach")[2]. Where risk mitigation measures are proposed, they are adapted to the use in France.

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

The French Order of 12 September 2006[3] 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 re-entry 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 (RR) based on Anses' assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], implementing regulations, Commission Directive 2008/127/EC of 18 December 2008 and French regulation.

[1] French Food Safety Agency, Afssa, before 1 July 2010

[2] 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

[3] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570

[4] 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

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) No546/2011 [5], and are expressed as "acceptable" or "unacceptable" in accordance with those criteria.

The decision, as duplicated 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 GINKO, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letters of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. 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	GINKO
Authorisation number	n° 2000536
Function	Mating disruption product
Applicant	SUMI AGRO FRANCE
Composition	254 mg/dispenser E,E-8,10-dodecadien-1-ol, 132 mg/dispenser dodecan-1-ol and 31 mg/dispenser 1-tetradecanol
Formulation type	Vapour releasing Product [Code: VP]
Packaging	HDPE dispensers packed in vacuum-sealed aluminium bags (5 layers laminated- from outer layer- with Nylon, aluminium, nylon, low density polyethylene (LDPE) and linear low density polyethylene (LLDPE)).

[5] 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

2.2 Classification and Labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Physical hazards	No classification required	
Health hazards	Xi	Irritant
Environmental hazards	N	Dangerous for the environment
Risk phrases	R 38	Irritating to skin
	R 50	Very toxic to aquatic organisms
Safety phrases	S 61	Avoid release to the environment. Refer to special instructions/safety data sheets.

2.2.2 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards	No classification required	
Health hazards	Skin irrit. Cat 2	
Environmental hazards	Aquatic Chronic 2; Aquatic Acute 1	
Hazard pictograms		
Signal word	Warning	
	H315	Causes skin irritation.
	H400	Very toxic to aquatic life
	H411	Toxic to aquatic life with long lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

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

The authorisation of the preparation 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).

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment [6]: refer to the Decision in Appendix 1 for the details
Re-entry period: not relevant to this application [7]
It is recommended to store the preparation bellow 5°C

[6] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[7] The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

2.3 Product uses (Authorised GAP and uses in France)

Please note: The GAP Table below reports the intended uses proposed by the applicant, evaluated and concluded as safe uses by France as zRMS.
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. 1, date: 2015-10/07

PPP (product name/code)	**GINKO**	**Formulation type:**	**VP**
active substance	**E,E-8,10-dodecadien-1-ol**	**Conc. of as 1:**	**254 mg/disperser**
	Dodecan-1-ol	**Conc. of as 2:**	**132 mg/disperser**
	1-tetradecanol	**Conc. of as 3:**	**31 mg/disperser**
safener	**Not applicable**	**Conc. of safener:**	**Not applicable**
synergist	**Not applicable**	**Conc. of synergist :**	**Not applicable**
Applicant:	**SUMI AGRO France** **25 Boulevard de l'Amiral Bruix** **75782 Paris cedex 16** **France**	**professional use** **non professional use**	☒ ☐
Zone:	**Southern EU**		
Verified by MS:	**France**		

Crop and/or situation (a)	Member State or Country	Product name	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)	No. (k)	g a.s./hL	water L/ha min max	g a.s./ha (i)		
Pome fruits (Apple, pear, quince, nashi)	France	GINKO	F	Codling moth (*Cydia pomonella*)	VP	E,E-8,10-dodecadien-1-ol 254 mg/dispenser + Dodecan-1-ol 132 mg/dispenser + 1-tetradecanol 31 mg/dispenser	Manual distribution of 500 dispensers per ha; uniform distribution throughout orchards.	Prior to moth emergence (Mid-April to early may)	1	n.a.	n.a	209 [127 + 66 + 15.5]	n.a.	Acceptable Label: 500 dispensers/ha

Crop and/or situation (a)	Member State or Country	Product name	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)	No. (k)	g a.s./hL	water L/ha min max	g a.s./ha (i)		
Walnuts	France	GINKO	F	Codling moth (*Cydia pomonella*)	VP	E,E-8,10-dodecadien-1-ol 254 mg/dispenser + Dodecan-1-ol 132 mg/dispenser + 1-tetradecanol 31 mg/dispenser	Manual distribution of 500 dispensers per ha; uniform distribution throughout orchards.	Prior to moth emergence (Mid-April to early may)	1	n.a.	n.a	209 [127 + 66 + 15.5]	n.a.	Acceptable Label: 500 dispensers/ha

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 sucking insects, soil born insects, foliar fungi, <pathogen name>
(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 (Part B, Section 1, Points 2 and 4)

The formulation GINKO is a vapour 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 oxidising properties. It has a self ignition temperature of 300°C. Stability data indicate a shelf life of at least 2 years at 5°C (dispenser in PEHD). Its technical characteristics are acceptable for a dispenser type vapour releasing product (VP) formulation.
The formulation is not classified for the physical-chemical part.
The formulation must be stored below 5°C.

3.1.2 Methods of analysis (Part B, Section 2)

Analytical methods for the determination of active substances and impurities in the formulation are available and validated.

Analytical methods for the determination of residues of GINKO 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 resides in biological fluids and tissues.

3.1.3 Mammalian toxicology (Part B, Section 3,)

3.1.3.1 Acute toxicity (Part B, Section 3)

The studies provided were performed with codling moth pheromone (corresponding of 97% of the preparation), except for skin sensitisation assay performed with GINKO.

Taking into account the toxicological properties of the active substances and given their concentrations in the preparation, GINKO is classified Xi, R38 according to the Directive 99/45/CE and Skin Irrit. Cat 2 H315 according to the regulation 1272/2008.

3.1.3.2 Dermal Absorption (Part B, Section 3)

No study on dermal absorption has been submitted. According to 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)12, data on dermal absorption are "required if the use description information demonstrates significant exposure potential and/or if toxicity tests or published data indicate a concern. Solid-matrix dispensers are unlikely to represent significant exposure potential, but some sprayed applications might."
Thus, the dermal absorption data requirements can be waived for GINKO.

3.1.3.3 Operator exposure (Part B, Section 3)

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.

3.1.3.4 Bystander exposure (Part B, Section 3)
Bystander exposure to pheromone arising from the use of GINKO is expected to be within the range of naturally occurring background levels. Thus bystander exposure is considered to be negligible.

3.1.3.5 Worker exposure (Part B, Section 3)
Worker exposure to pheromone arising from the use of GINKO 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 (Part B, Section 4)

3.1.4.1 Residues (Part B, Section 4)
As other active substances of the group "Straight Chain Lepidopterian Pheromones" (SCLPs), the toxicological profiles of E,E-8,10-dodecadienol, dodecan-1-ol, tetradecanol were evaluated at EU level. Neither ADI nor ARfD were 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). 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 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 dispenser applications.

3.1.4.2 Consumer exposure (Part B, Section 4)
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 GINKO using closed retrievable dispensers.

3.1.4.3 Mitigation measures (Part B, Section 4)
According to available data, no specific mitigation measures should apply.

3.1.5 Environmental fate and behaviour (Part B, Section 5)

As GINKO 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 behavior of the product GINKO 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 (Part B, Section 6)

The OECD Monograph 12 suggests that an application threshold of up to 375 g SCLPs/ha/yr is considered appropriate to reflect the natural concentration levels of SCLPs. That means that outdoor application rates up to 375 g a.s./ha/yr can generally be considered to result in exposure levels, which are comparable to natural emissions and therefore safe for non-target species. The application rate of GINKO (209 g/ha/yr) is lower than the natural concentrations level of SCLPs and the risks for all non-target organisms is considered negligible.

3.1.7 Efficacy (Part B, Section 7)

The product complies with the Uniform Principles.

Pheromone release

Data provided show a regular release of pheromones by the dispensers – during a period of minimum 5 months, even under difficult climatic conditions. The release is however influenced by different factors (the properties of the dispenser itself, the environment and the climatic conditions in particular warm temperatures and wind velocity).

Dose justification

For this type of product and due to the difficulties of mating disruption experimentation, the absence of field trials for dose justification can be accepted. For dispensers, the dose rate is a compromise between the number of dispensers per hectare and the amount of active substances per dispenser. The objective is to ensure a sufficient and regular level of release into the atmosphere of the orchard to be able to confuse the male of the target pest. The density of dispensers needs to be increased when a risk is identified on plot borders.
In case of ISOMATE-C and GINKO, the dose rate per hectare is very similar (200 and 209 g/ha respectively), although the number of dispensers is different (500 and 1000 dispensers/ha respectively). In practice, the most recent dispensers GINKO are preferred because the time required for the application is reduced.

Efficacy

A total of 34 field efficacy trials were submitted. Trials were carried out in France, mainly in the south-east part (Mediterranean EPPO climatic zone). The efficacy demonstration is considered acceptable for both products, on all intended uses. To ensure the success of this method, specific recommendations of use should to be respected.

Unintended side effects: Not expected.

Effects on beneficial organisms:
The use of the products is compatible with other IPM methods. The absence or the reduction of the insecticide applications in the orchards contribute to the establishment of a better balance between the populations of pests and their predators and parasites. However, for the same reasons, a recrudescence of secondary pests can appear.

Crops	Pest	Method of application	Maximum application rate per treatment	Maximum number of application per use	Maximum number of application per crop	Opinion of France for efficacy section	Comments
Pome fruits (apple, pear, quince, nashi)	*Cydia pomonella*	Manual distribution throughout orchards.	500 dispensers/ha	1	1	Acceptable	
Walnuts	*Cydia pomonella*	Manual distribution throughout orchards.	500 dispensers/ha	1	1	Acceptable	

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 authorisation.

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

No further information is required.

3.4.3 Label amendments (see label in Appendix 2):

The draft label proposed by the applicant in appendix 2 should 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

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Décision relative à une demande de renouvellement de l'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 de renouvellement de l'autorisation de mise sur le marché du produit phytopharmaceutique ***GINKO***

de la société *SUMI AGRO FRANCE SAS*

enregistrée sous le *n°2014-1654*

Vu l'avis de l'Anses du 28 mai 2015,

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.

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AMM n°2000536

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Informations générales sur le produit	
Nom du produit	GINKO
Type de produit	Produit de référence
Titulaire	SUMI AGRO FRANCE SAS 25 Boulevard de l'Amiral Bruix, 75782 Paris Cedex 16 PARIS
Formulation	Produit diffuseur de vapeur (VP)
Contenant	254 mg/diffuseur - (E, E) 8, 10-dodécadien-1-ol (codlémone) 132 mg/diffuseur - 1-dodécanol 31 mg/diffuseur - 1-tétradécanol
Numéro d'intrant	2000536
Numéro d'AMM	2000536
Fonction	Attractif phéromone (produit de confusion sexuelle)
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à trois 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 30 novembre 2019.

A défaut pour le titulaire de demander le 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, l'autorisation de mise sur le marché est échue de plein droit. Le dépôt d'une demande de renouvellement prolonge de plein droit l'autorisation de mise sur le marché 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 04 DEC. 2015

Françoise WEBER
Directrice générale adjointe 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 ne peut mettre sur le marché le produit que conditionné dans les emballages suivants :	
Emballage	**Contenance**
Diffuseurs en polyéthylène haute densité conditionnés dans un sac en aluminium scellé composé de 5 couches en nylon/aluminium/nylon/polyéthylène basse densité et polyéthylène basse densité linéaire.	400 diffuseurs/sac

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Corrosion/irritation cutanée, catégorie 2	H315 : Provoque une irritation cutanée
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
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.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité avec la classification retenue ci-dessus, et de ses éventuelles évolutions.	

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Liste des usages autorisés

Usages	Dose maximale d'emploi	Nombre maximal d'applications	Epoque d'application	Délai avant récolte (jour(s))	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12603103 Pommier*Trt Part.Aer.*Chenilles foreuses des fruits	**500 diffuseurs/ha**	**1/an**	Mi-avril à début mai	-	-	-	-	-
	Uniquement contre le carpocapse *(Cydia pomonella)*							
12453101 Noyer*Trt Part.Aer.*Chenilles foreuses des fruits	**500 diffuseurs/ha**	**1/an**	Mi-avril à début mai	-	-	-	-	-
	Uniquement contre le carpocapse *(Cydia pomonella)*							

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Conditions d'emploi du produit

Stockage et manipulation du produit

Il est recommandé de ne pas stocker à plus de 5°C.

Protection de l'opérateur et du travailleur

Il convient de rappeler que 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 complémentaires comme les protections individuelles.

En tout état de cause, le port de combinaison de travail dédiée ou d'équipement de protection individuelle (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

- Pendant la phase de pose des diffuseurs :
  - Gants en nitrile certifiés EN 374-3 ;
  - Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m².

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].

GINKO
AMM n°2000536

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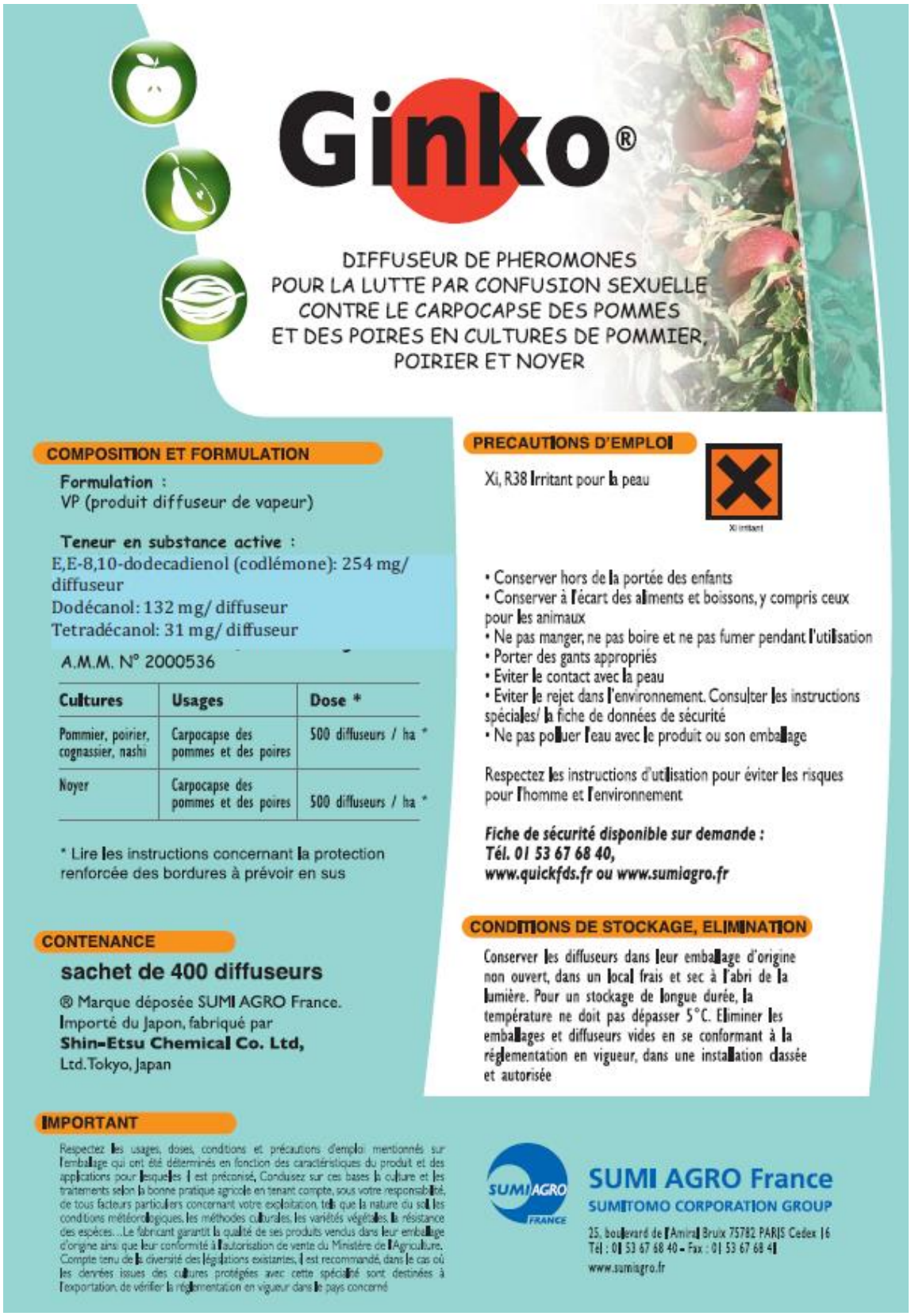
Appendix 2 – Copy of the draft product label as proposed by the applicant



Ginko®

DIFFUSEUR DE PHEROMONES
POUR LA LUTTE PAR CONFUSION SEXUELLE
CONTRE LE CARPOCAPSE DES POMMES
ET DES POIRES EN CULTURES DE POMMIER,
POIRIER ET NOYER

COMPOSITION ET FORMULATION

Formulation :
VP (produit diffuseur de vapeur)

Teneur en substance active :
E,E-8,10-dodecadienol (codlémone): 254 mg/ diffuseur
Dodécanol: 132 mg/ diffuseur
Tetradécanol: 31 mg/ diffuseur

A.M.M. N° 2000536

Cultures	Usages	Dose *
Pommier, poirier, cognassier, nashi	Carpocapse des pommes et des poires	500 diffuseurs / ha *
Noyer	Carpocapse des pommes et des poires	500 diffuseurs / ha *

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

PRECAUTIONS D'EMPLOI

Xi, R38 Irritant pour la peau

Xi irritant

- Conserver hors de la portée des enfants
- Conserver à l'écart des aliments et boissons, y compris ceux pour les animaux
- Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation
- Porter des gants appropriés
- Eviter le contact avec la peau
- Eviter le rejet dans l'environnement. Consulter les instructions spéciales/ la fiche de données de sécurité
- 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

Fiche de sécurité disponible sur demande :
Tél. 01 53 67 68 40,
www.quickfds.fr ou www.sumiagro.fr

CONDITIONS DE STOCKAGE, ELIMINATION

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. Eliminer les emballages et diffuseurs vides en se conformant à la réglementation en vigueur, dans une installation classée et autorisée

CONTENANCE

sachet de 400 diffuseurs

® Marque déposée SUMI AGRO France.
Importé du Japon, fabriqué par
Shin-Etsu Chemical Co. Ltd,
Ltd. Tokyo, Japan

IMPORTANT

Respectez 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 concerné

SUMI AGRO FRANCE

SUMI AGRO France
SUMITOMO CORPORATION GROUP
25, boulevard de l'Amiral Bruix 75782 PARIS Cedex 16
Tél : 01 53 67 68 40 - Fax : 01 53 67 68 41
www.sumiagro.fr

INSTRUCTIONS D'EMPLOI

Il est essentiel que toutes les recommandations ci-après soient respectées

La zone traitée doit être homogène, de forme compacte, et avoir une **surface minimale de 3 hectares pour le pommier et le poirier, 2 ha pour le noyer**. Le potentiel d'infestation doit être modéré (pas plus de 1 à 2% de fruits attaqués à la récolte l'année précédente) et **l'environnement proche ne doit pas comporter de foyers fortement infestés.**

EPOQUE D'APPLICATION :

La méthode est strictement préventive. L'apport de phéromone dans l'atmosphère de la parcelle désoriente les papillons mâles, empêche leur accouplement et permet ainsi de rompre le cycle avant l'apparition du stade nuisible. Afin d'éviter tout accouplement de carpocapse, **il est essentiel d'appliquer les diffuseurs avant le début du vol de la première génération.** Au cas où la pose serait retardée par rapport à cette recommandation (déconseillé), assurer une protection insecticide correctement positionnée.
Dans le cas du noyer : il est en outre nécessaire de tenir compte du stade de la culture et une application anticipée, au stade végétatif Df/Df2 (déploiement complet des premières feuilles), permettra un positionnement commode des diffuseurs sans risque d'abîmer les jeunes pousses.
Une seule pose de GINKO® assure une diffusion sur toute la période de risque carpocapse.

METHODE D'APPLICATION :

- ***Pommier, poirier :*** installer impérativement les diffuseurs **dans le tiers supérieur des arbres**, sur du bois de 2 ans.
- ***Noyer :*** répartir les diffuseurs à 60% dans le tiers supérieur des arbres, et 40% à mi-hauteur (variétés traditionnelles, arbres de grande hauteur), ou uniquement dans le tiers supérieur (variétés conduites en axe, hauteur modérée).

DOSE :

1 = **Appliquer 500 diffuseurs par hectare**, répartis de façon homogène sur la parcelle, et en quinconce d'un rang à l'autre. Dans l'arbre, bien les positionner selon les indications du paragraphe précédent.

2 = **Renforcer la protection des bordures :**
Pommier, poirier : doubler la densité de diffuseurs sur les rangs de bordure, et poser 1 diffuseur par arbre sur au moins 5 arbres en bouts de rangs. Renforcer la densité de pose sur les pointes de la parcelle.
Noyer : sur variétés traditionnelles en gobelet, multiplier par 1,5 la dose sur la bordure la plus exposée au vent dominant. Sur variétés conduites en axe : multiplier par 1,5 la dose sur les arbres des rangs de bordure et des bouts de rangs.

3 = **Poser les diffuseurs additionnels requis en fonction de l'environnement :**
GINKO® empêche l'accouplement du carpocapse. Cependant, s'il existe des foyers très infestés à moins de 200-300 m, des femelles fécondées peuvent pénétrer sur la parcelle et affecter le résultat. Ces foyers peuvent être en particulier : parcelles mal protégées, vergers abandonnés, pommiers-poiriers-cognassiers-noyers isolés. Il est donc recommandé de :
- Mettre sous confusion des entités de vergers aussi larges que possible et non pas seulement un bloc d'une parcelle traitée classiquement,
- Poser des diffuseurs sur les haies et brise-vents, les arbres isolés hôtes du carpocapse à proximité, et veiller à ce que tout foyer potentiel de contamination soit protégé.

Important : en cas de présence de parcelle contiguë de pommier, poirier ou noyer protégée uniquement par insecticides, **ménager une zone tampon de 30 m protégée à la fois par insecticides et confusion sexuelle** (le plus simple est de poser des diffuseurs sur 30 m dans la parcelle contiguë).

APPLICATIONS INSECTICIDES COMPLEMENTAIRES :

1. Pommier, poirier :
1.1 Sur carpocapse :
- **Assurer une protection complémentaire insecticide ciblée sur les pics de risque**, à adapter en fonction de la pression d'infestation. Utiliser pour cela des insecticides choisis conformément aux recommandations officielles de stratégie anti-résistance et en fonction du besoin éventuel d'efficacité simultanée sur d'autres ravageurs présents.
- **Intervenir en fonction de l'évolution constatée lors des contrôles**, si des captures sont relevées dans les pièges sexuels à codlémone placés en parcelle confusée, ou si des piqûres sont observées sur fruits. Avec les capsules CM-DA Combo qui capturent davantage, 3 à 5 captures par semaine doivent inciter à effectuer un contrôle visuel sur fruits suivi d'une décision éventuelle d'intervention.

1.2 Sur les autres ravageurs :
Surveiller la parcelle et intervenir si nécessaire contre les autres ravageurs éventuellement présents. Porter une grande attention aux Lépidoptères : tordeuse de la pelure, tordeuse orientale, autres tordeuses.

2. Noyer :
Intervenir en fonction de l'évolution constatée lors des contrôles, si des captures sont relevées dans les pièges sexuels placés dans la parcelle, ou si des piqûres sont observées sur fruits.

SUIVI APRES APPLICATION

Un suivi de la parcelle à intervalles réguliers (toutes les 1 à 2 semaines selon la période de risque carpocapse) est **impératif**, pour :
- Vérifier la bonne efficacité de la confusion : **relevé des pièges sexuels et contrôles périodiques sur fruits** (500 à 1000 fruits par unité culturale homogène de 3 à 4 ha, à observer principalement sur les zones à risque : bordures, haut des arbres, fruits accolés...). Dans le cas du noyer ce type d'observation est plus difficile à réaliser, mais prévoir un contrôle précis au moins en fin de première génération.
- **Surveiller l'évolution des autres ravageurs**, en particulier sur pommier et poirier les tordeuses, mineuses, zeuzère.

Attention: GINKO® est spécifique du carpocapse des pommes et des poires (*Cydia pomonella*) et ne permet en aucun cas le contrôle d'autres ravageurs.

Appendix 3 – Letter(s) of Access

IBMA
International Biocontrol Manufacturers' Association

02 AVR. 2014

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

March 2014

ANSES-DPR-UGAmm
253 Avenue du Général Leclerc
94701 Maison-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. In addition, the Task Force has agreed to provide Letters of Access on a commercial basis to companies who are **not** members of the Task Force. For the sake of simplicity, members of the Task Force 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:

SUMI AGRO FRANCE S.A.S., 25 Boulevard de l'Amiral Bruix, 75782 PARIS CEDEX 16, FRANCE (hereafter referred to as „Company")

2014 - 0752 Cop

For the Product:

'GINKO' – SCLP Vapour Dispenser **Reg N° AMM N° 2000536**

(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 active substances of the product.
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 any Company, or 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 SUMI AGRO FRANCE S.A.S 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 prior written approval to such disclosure or use.
5. This Letter of Access shall in no event be construed as granting SUMI AGRO FRANCE S.A.S any property rights whatsoever to the Dossier.
6. SUMI AGRO FRANCE S.A.S hereby agrees to withdraw this Letter of Access, and accepts that the registration of the product noted above will be revoked by the national authority:
    - When the product noted above, no longer uses Active Substance(s) supplied by Task Force member(s)
    - When SUMI AGRO FRANCE S.A.S no longer markets the product noted above.

For and on behalf of SUMI AGRO FRANCE S.A.S

Signed by SUMI AGRO FRANCE S.A.S representative ..... Jean-Louis Vilenhaus

R P Sheppard

Dr. Robin P. Sheppard

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