REGISTRATION REPORT

Part A

Risk Management

Product code: CM-001 5% SC

Product name: KANPAI

Active substance:

chromafenozide, 50 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: ARYSTA LIFESCIENCE

Date: 2019/01/09

Table of Contents

PART A – Risk Management

The company ARYSTA LIFESCIENCE has requested marketing authorisation in France for the product KANPAI (product code: CM-001 5% SC), containing 50 g/L chromafenozide for use as an insecticide.

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 KANPAI (CM-001 5% SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of KANPAI (CM-001 5% SC) have been made using endpoints agreed in the EU peer review of chromafenozide.

This document describes the specific conditions of use and labelling required for France for the registration of KANPAI (CM-001 5% SC).

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 ARYSTA LIFESCIENCE's application to market KANPAI (CM-001 5% SC) in France as an insecticide (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

Chromafenozide

Commission Implementing Regulation (EU) No 2015/51 of 14 January 2015 approving the active substance chromafenozide, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and allowing Member States to extend provisional authorisations granted for that active substance
Specific provisions of Regulation (EU) No 2015/51 were as follows : 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 chromafenozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to groundwater, if the substance is applied under vulnerable soil or climatic conditions; (b) the risk to non-target Lepidoptera in off-crop areas; (c) the risk to sediment-dwelling organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the non-significance of the difference between the material used for ecotoxicological testing and the agreed specification of the technical material for the risk assessment; (2) the assessment of the risk to sediment dwelling organisms from metabolite M-010; (3) the leaching potential of metabolites M-006 and M-023 to groundwater. The applicant shall submit to the Commission, the Member States and the Authority the relevant information

requested under (1) by 30 September 2015 and under (2) and (3) by 31 March 2017.
An EFSA conclusion is available (EFSA Journal 2013;11(12):3461). A Review Report is available (SANCO/12127/2014 rev 1, 10 October 2014).

1.3 Regulatory approach

The present application (2015-1136) 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 out in the Decision letter.

The French Order of 4th May 2017[2] 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[3], implementing regulations, 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[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] 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 extrapolation[6] 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

[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/AGRG1632554A/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

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

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

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 KANPAI (CM-001 5% SC), 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 is the owner of the active substance.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	KANPAI (CM-001 5% SC)
Authorisation number	N/A : no registered in France
Function	Insecticide
Applicant	ARYSTA LIFESCIENCE
Composition	50 g/L chromafenozide
Formulation type (code)	Suspension concentrate (SC)
Packaging	N/A : no registered in France

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	-	
Environmental hazards	Hazardous to the aquatic environment - Chronic Hazard, category 3	
Hazard pictograms	-	
Signal word	-	
Hazard statements	H412	Harmful 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)	EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

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 : no registered in France:

2.2.3 Other phrases linked to the preparation

N/A : no registered in France.

2.3 Product uses

Please note:
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2019-01-09

PPP (product name/code):	**KANPAI (CM-001 5% SC)**	Formulation type:	**SC** [a, b]
Active substance:	Chromafenozide	Conc. of as:	**50 g/L** [c]
Applicant:	**ARYSTA LIFESCIENCE**	Professional use:	☒
Zone(s):	southern[d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	insecticide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	France	Grape	F	Tortrix moths (European grapevine moth): *Lobesia botrana,*	Tractor drawn air blast orchard sprayer, low volume Hand-held sprayer	BBCH 72-85	a) 1 b) 1	-	a) 2 L/ha b) 2 L/ha	a) Max 100 g a.s./ha b) Max. 100 g a.s./ha	200 - 400	21	**Not acceptable** (**groundwater, non-target arthropods**)
2	France	Grape	F	Tortrix moths (European grape berry moth) : *Eupoecilia ambiguella*	Tractor drawn air blast orchard sprayer, low volume Hand-held sprayer	BBCH 72-85	a) 1 b) 1	-	a) 2,5 L/ha b) 2,5 L/ha	a) Max 125 g a.s./ha b) Max. 125 g a.s./ha	200 - 400	21	**Not acceptable** (**groundwater, non-target arthropods, efficacy**)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/L
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

KANPAI (CM-001 5% SC) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a white viscous liquid, without characteristic odour. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature of 460 °C. In 1% aqueous solution, it has a pH value of 6.9 at 24 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf-life of at least two years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a suspension concentrate formulation.

The formulation is not classified for the physico-chemical aspect.

3.1.2 Methods of analysis

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

Analytical methods are available in this dossier and validated for the determination of residues of chromafenozide in plants (high water content, oily content, acid content), soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of chromafenozide in foodstuffs of animal origin are not necessary.

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

3.1.3 Mammalian Toxicology

The endpoints used in risk assessment are shown below:

Active substance: **chromafenozide**			
ADI	0.27 mg/kg bw/d		EU (2015)
ARfD	Not applicable		
AOEL	0.26 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* study performed on formulation:		
		Concentrate (tested) 50 g/L	Diluted formulation (tested) 2.24 g/L
	In vitro (human) %	1.6	63
		Concentrate (used in formulation) 50 g/L	Spray dilution (used in formulation) 0.3 g/L
	Dermal absorption endpoints	**1.6%**	**50%**

3.1.3.1 Acute Toxicity

KANPAI (CM-001 5% SC) has a low acute oral, inhalational and dermal toxicity. It is not irritating to the rabbit skin or eye, and is not a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Critical use patterns (worst cases) are summarised in the table below.

Crop	F/G[7]	Equipment	Application rate (L product/ha)	Spray dilution (L/ha)	Model
Grapes	F	Tractor mounted air assisted sprayer	2.5 L product/ha (125 g a.s./ha)	200-400	BBA
	F	Hand-held sprayer			BBA

Considering the proposed uses, operator systemic exposure was estimated using the German BBA model:

Crop	Equipment	PPE and/or working coverall	% AOEL chromafenozide
Grapes	Tractor mounted air assisted sprayer	Working coverall and gloves during mixing/loading and application	6
	Hand-held sprayer		3

According to the model calculations, it may be concluded that the risk for the operator using KANPAI (CM-001 5% SC) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure was estimated to be 1.5% of the AOEL of chromafenozide. It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to KANPAI (CM-001 5% SC).

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 14% of the AOEL of chromafenozide.

It may be concluded that, without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with KANPAI (CM-001 5% SC).

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

3.1.3.6 Relevance of metabolites

The metabolite M-010 is found above 0.1 µg/L but is not relevant from a toxicological point of view (EFSA conclusions).

Since the evaluation of the leaching potential of metabolites M006 and M023 is currently being evaluated at European level, the assessment of the risks of groundwater contamination for these metabolites cannot be finalized.

3.1.4 Residues and Consumer Exposure

Overall conclusion

The data available are considered sufficient for risk assessment purposes. Any exceedance of the current MRLs for chromafenozide as laid down in Regulation (EU) No 396/2005 is not expected.

The chronic and short-term intakes of chromafenozide residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

[7] Open field or glasshouse

As far as consumer health protection is concerned, France agrees with the authorization of the intended uses.

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

Summary for chromafenozide

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2015/401	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-2	Table grape and wine grape	Yes	Yes (17 NEU, 19 SEU)	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, should be given in column 1

As residues of chromafenozide do not exceed the trigger values defined in Regulation (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake is expected for livestock as grapes are not fed to livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for KANPAI (CM-001 5% SC)

Crop	PHI for KANPAI (CM-001 5% SC) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for KANPAI (CM-001 5% SC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		chromafenozide		
Table grape and wine grape	21 days	Yes	21 days	-

* Purpose of withholding period to be specified

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of chromafenozide and its metabolite M-010 in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw values derived for the active substance and its metabolite M-010 are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for chromafenozide and its metabolite M-010 do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on metabolites in groundwater when the preparation is applied every other year. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses under these conditions.

Regarding metabolites M-006 and M-024, PECgw calculations provided by the applicant could not be used due to some deviations identified by zRMS. As a consequence, the risk assessment of groundwater contamination cannot be finalised. **Then uses are not considered as acceptable in France.**

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for terrestrial vertebrates, earthworms, other soil macro-organisms and micro-organisms can be considered acceptable for the intended uses for KANPAI (CM-001 5% SC).

For aquatic organisms, the risk for the intended uses for KANPAI (CM-001 5% SC) is acceptable with mitigation measures.

For non-target arthropods other than bees, the study reports of the additional studies were not provided and these studies could not be included in the risk assessment. Thus, the available toxicity data with the formulation is identical to the dataset from the European dossier and is not sufficient to adequately address the risk to the non-target lepidopteran species of the off-field area. Therefore, the risk assessment for non-target arthropods is not considered finalized for the intended uses of KANPAI (CM-001 5% SC). Then uses are not considered as acceptable in France.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy of KANPAI (CM-001 5% SC) is considered satisfactory for the claimed use against *Lobesia botrana*.
- **The data submitted are not sufficient to conclude on the efficacy of KANPAI (CM-001 5% SC) against *Eupoecilia ambiguella*.**
- The selectivity level of KANPAI (CM-001 5% SC) is considered satisfactory for all the claimed uses.
- The risk of negative impacts on yield, quality, transformation processes, propagation, succeeding crops, and adjacent crops are considered negligible.
- The risk of resistance appearance to chromafenozide does not require a monitoring for the claimed uses.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted**, due to a risck on groundwater, non-target arthropods and not sufficient to conclude on efficacy against *Eupoecilia ambiguella*. 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

N/A

Appendix 1 – Copy of the French Decision

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

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

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

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

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

de la société *ARYSTA LIFESCIENCE BENELUX SPRL*

enregistrée sous le *n°2015-1136*

Vu les conclusions de l'évaluation de l'Anses du 15 octobre 2018,

Considérant que les données disponibles ne permettent pas d'exclure un risque inacceptable de concentration en métabolites M-006 et M-023 dans les eaux souterraines supérieur aux valeurs définies dans le règlement (CE) n°546/2011 et un risque inacceptable pour les arthropodes non-cibles,

Considérant l'absence de données d'efficacité spécifiques sur *Eupoecilia ambiguella*,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 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.

KANPAI
AMM n°-

Page 1 sur 3

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Informations générales sur le produit	
Nom du produit	KANPAI
Type de produit	Produit de référence
Titulaire	ARYSTA LIFESCIENCE BENELUX SPRL Rue de Renory 26/1 B-4102 Ougrée Belgique
Formulation	Suspension concentrée (SC)
Contenant	50 g/L - chromafénozide
Numéro d'intrant	9873-2015.01
Numéro d'AMM	-
Fonction	Insecticide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 09 JAN. 2019

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)

KANPAI
AMM n°-

Page 2 sur 3

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703104 Vigne*Trt Part.Aer.*Tordeuses de la grappe	2,5 L/ha	1/an	21
	Motivation du refus : L'usage, est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable pour les eaux souterraines et pour les arthropodes non-cible. L'usage est également refusé au motif d'une absence de données d'efficacité spécifiques sur *Eupoecilia ambiguella*. L'usage est également refusé, à la dose de 2 L/ha visant *Lobesia botrana,* en raison de l'absence de données permettant d'exclure un risque inacceptable pour les eaux souterraines et pour les arthropodes non-cible.		

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

KANPAÏ

Homologué sous le numéro :	XXX
Composition:	Chromafenozide 50 g/l
Type de formulation :	Concentré soluble (SL)

Avant d'utiliser ce produit, lire attentivement l'étiquette.
L'utilisation de ce produit est réservée aux professionnels.

Quantité nette :	Usage professionnel : 1 et 5 L
Fabriqué par :	Nippon Kayaku Co. Ltd 1-1, Marunouchi 2-chome, Chiyoda-Ku TOKYO 100-0005 JAPON
Nom et adresse du détenteur de l'autorisation :	Arysta LifeScience S.A.S. Rte d'Artix BP 80 64150 Noguères FRANCE
Distribué en France par :	*à préciser*
Usage, type de produit :	Insecticide sur Vigne – Tordeuses Eudémis (*Lobesia botrana*) et Cochylis (*Eupoecilia ambiguella*)
Date de production (j-m-a): Numéro de lot :	Voir sur le bidon
Durée de vie du produit :	Dans son bidon original entreposé dans un endroit frais et sec : 2 ans.

Mode d'action :
KANPAÏ (Chromafenozide 5%) est un insecticide utilisé en traitement foliaire pour le contrôle sur vigne de la tordeuse Eudémis (*Lobesia botrana*) et de la tordeuse Cochylis (*Eupoecilia ambiguella*). Cette substance active appartient à la famille d'insecticides régulant la croissance des insectes : les diacylhydrazines.
KANPAÏ est un régulateur de croissance de l'insecte qui agit par contact et ingestion et induit des perturbations rapides du phénomène des mues. Après ingestion de la substance active par la larve, la prise alimentaire est arrêtée et une mue prématurée et incomplète est induite provoquant une issue fatale.
KANPAÏ agit par une induction rapide de symptômes : il s'agit d'un agoniste de l'Ecdysone. Souple d'utilisation, il peut être appliqué sur la vigne avant les premières pontes (pré-oviposition) jusqu'au début des éclosions.

Utilisation et doses d'application :

Cultures	Usages	Stades de croissance	Dose d'application a) dose max. par appl. b) dose max. totale par culture/saison	Nombre d'application	Intervalle de temps entre applications (min, jours)	Volume (l/ha)	DAR (jours)
Vigne	Tordeuse Eudemis (*Lobesia botrana)*	BBCH 72-85	a) 2 L produit / ha b) 2 L produit / ha	1	-	200-400	21
Vigne	Tordeuse Cochylis *(Eupoecilia ambiguella)*	BBCH 72-85	a) 2,5 L produit / ha b) 2,5 L produit / ha	1	-	200-400	21

RECOMMENDATIONS D'APPLICATION

Utiliser un équipement de pulvérisation propre, en bon état et bien calibré. Remplir la moitié du réservoir de pulvérisation avec de l'eau propre et commencer l'agitation. Ajouter la quantité nécessaire de produit formulé. Rincer tous les contenants, trois fois, et ajouter les lavages dans le réservoir de pulvérisation. Ajouter le reste de l'eau nécessaire et poursuivre l'agitation jusqu'à ce que la pulvérisation soit terminée. Il est conseillé d'utiliser un détergent à la fois avant et après l'utilisation du produit afin de s'assurer qu'il n'y a pas de résidus chimiques dans le réservoir qui puissent nuire aux récoltes.

Ne pas appliquer en cas de vent ou temps pluvieux

COMPATIBILITES

Suivre les recommandations des étiquettes de produits. Les réglementations nationales doivent être respectées lors de l'utilisation de KANPAÏ dans les mélanges en cuve. Cependant, différents facteurs peuvent affecter la compatibilité, il est donc recommandé de faire un mélange d'essai en utilisant la solution de l'eau destinée à la pulvérisation.

MANIPULATION

L'opérateur doit porter des vêtements de protection appropriés :
Porter un masque recouvrant tout le visage et muni d'un filtre pour vapeurs organiques, poudres et aérosols (filtre de type AP).
Porter des gants imperméables et résistants aux solvants organiques et aux produits chimiques (en conformité avec la norme EN 374) lors des phases de mélange, de chargement ou d'application du produit.

Porter de préférence un masque ou un pare visage et à défaut des lunettes de protection (norme EN 166).
Porter des vêtements de protection appropriés couvrant toutes les parties du corps lors de la phase d'application locale du produit à l'aide d'un pulvérisateur manuel.
Le port de chaussures ou de bottes à semelles antidérapantes est recommandé.

SAFETY MEASURES

Etiquetage relatif au Réglement (EC) 1272/2008 "CLP"

Pictogramme(s) de danger	Aucun
Mention(s) d'avertissement	Aucun
Mention(s) de danger	
H412/H413	Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401	Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
Precautionary statement(s)	
P102	Tenir hors de portée des enfants
P270	Ne pas manger, boire ou fumer en manipulant le produit
P273	Éviter le rejet dans l'environnement.
P261	Éviter de respirer les aérosols
P301+ 312	EN CAS D'INGESTION: Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise
P271	Utiliser seulement en plein air ou dans un endroit bien ventilé
SP phrase (s)	SP1: 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.)

Elimination des emballages:
Rincer correctement chaque emballage vide en utilisant un dispositif de rinçage intégré ou manuellement en rinçant trois fois, puis verser l'eau dans le réservoir du pulvérisateur.
Il est obligatoire d'envoyer les bidons vides à une entreprise de recyclage responsable de l'élimination des emballages vides (filières de traitement des déchets EcoDDS).

Avertissement:
Afin de prévenir l'apparition de souches résistantes au chromafenozide, il est recommandé d'utiliser le produit au bon stade d'application et d'adapter les doses d'application. Une dose réduite et/ou un mauvais stade d'application peuvent générer des populations résistantes.

Les recommandations et les indications d'utilisation de ce produit sont les résultats de nombreuses études et essais mis en place.
Cependant, lors de l'utilisation du produit, de nombreux facteurs peuvent intervenir (comme la préparation des mélanges, l'application, la météo, etc) qui ne sont pas sous notre contrôle.
La société garantit la composition, la formulation et le contenu.
L'utilisateur sera responsable des dommages (manque d'efficacité, la toxicité en général, les résidus, etc) résultant d'une non-conformité avec une partie ou le total des instructions données sur l'étiquette.

Appendix 3 – Letter(s) of Access

Not applicable.