REGISTRATION REPORT

Part A

Risk Management

Product code: ABAMECTIN 1.8% EW

Product name(s): LAOTTA EW

Active Substance(s): Abamectin, 18 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: LAINCO S.A.

Date: 15/05/2018

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PART A – Risk Management

The company LAINCO S.A. has requested a label extension of marketing authorisation in France for the product LAOTTA EW (formulation code: ABAMECTINE 1.8% EW; marketing authorisation n° 2170336), containing 18 g/L abamectin for use as an insecticide and acaricide.

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 LAOTTA EW (ABAMECTINE 1.8% EW) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of LAOTTA EW (ABAMECTINE 1.8% EW) have been made using endpoints agreed in the EU peer review(s) of abamectin.

This document describes the specific conditions of use and labelling required for France for the registration of LAOTTA EW (ABAMECTINE 1.8% EW).

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 LAINCO S.A.'s application to market LAOTTA EW (ABAMECTINE 1.8% EW) in France as an insecticide and an acaricide (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 label extension of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Abamectine

Commission Implementing Regulation (EU) 2017/438 of 13 March 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance abamectin
Specific provisions of Regulation (EU) No 2017/438 were as follows : PART A Only uses as insecticide, acaricide and nematicide may be authorised. PART B In assessing applications to authorise plant protection products containing abamectin for uses other than citrus, lettuce and tomatoes, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information are provided before such an authorisation is granted. 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 abamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 and of the addendum to the review report on abamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed dated 24 January 2017 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

- the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment,
- the residues in food of plant origin and evaluate the dietary exposure of consumers,
- the protection of bees, non-target arthropods, soil organisms, birds, mammals and aquatic organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones and waiting periods, should be applied where appropriate.

The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water by two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.'

An EFSA conclusion is available (EFSA Journal 2016;14(5):4491).

A Review Report is available (SANCO/138/08 final, 11 July 2008 and SANTE/11617/2016, 24 January 2017).

1.3 Regulatory approach

The present application (2015-1065) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] 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")[2] – 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 [3] 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[4], 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[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

[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] 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

[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

[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

Finally, the French Order of 26 March 2014[6] 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[7] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of LAOTTA EW (ABAMECTINE 1.8% EW), 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

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

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

2 The applicant has provided letter(s) of access. DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	LAOTTA EW (ABAMECTINE 1.8% EW)
Authorisation number	2170336
Function	Insecticide and acaricide
Applicant	LAINCO S.A.
Composition	18 g/L abamectin
Formulation type (code)	Emulsion oil in water (EW)
Packaging	Packaging not changed

2.2 Classification and labelling

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

Classification not changed.

2.2.2 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).
Spe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters[8] to surface water bodies for maize.
Spe 3	To protect aquatic non-target arthropods respect an unsprayed buffer zone of 5 meters to non-agricultural land for maize.
Spe 8	Dangerous to bees/To protect bees and pollinating insects do not apply to crop plants when in flower or during the honeydew production period/Do not use where bees are actively foraging /Do not apply when flowering weeds are present.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[9]: refer to the Decision in Appendix 1 for the details
Re-entry period[10]: 6 hours
Pre-harvest interval[11]: - Maize (grain) : F- Application must be made at growth stage BBCH [16] at the latest
Other mitigation measures: - Forage from treated maize cannot be used for animal feeding.
The label must reflect the conditions of authorisation.

[8] The legal basis for this is **Titre III Article 12** 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]

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

[10] 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]

[11] 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.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

GAP rev. 2, date: 2018-06-28

PPP (product name/code):	**LAOTTA EW (ABAMECTINE 1.8% EW)**	Formulation type:	**EW** [a, b]
Active substance 1:	Abamectin	Conc. of as 1:	**18 g/L** [c]
Applicant:	**LAINCO** S.A.	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	insecticide and acaricide		

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)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg 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)													
5	France	Maize, sorghum, millet, moha (only grain)	F	Spider mites (*Panonychus ulmi*, *Tetranychus urticae*)	Tractor mounted boom sprayer	Maximum till 6 true leaf stage (BBCH 16)	a) 1 b) 1	-	a) 100 mL/hL **(= 0,4 L/ha)** b) 100 mL/hL	a) 7.2 g a.i./ha b) 7.2 g a.i./ha	300 / 400	**F**	**Acceptable except for forage**

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

LAOTTA EW (ABAMECTINE 1.8% EW) is an emulsion oil in water (EW). 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 and homogenous liquid, slightly viscous, with characteristic solvent odour. It is not explosive and has no oxidising properties. The product has a flash point > 79°C and a self-ignition temperature of 480°C. In aqueous solution (1%), it has a pH value of 5.3 at 25°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 2 years at ambient temperature when stored in HDPE/EVOH/HDPE bottle. As the stability was performed on HDPE/EVOH/HDPE packaging, the HDPE/PA/HDPE and HDPE/EVOH packagings can be considered as acceptable. Its technical characteristics are acceptable for a EW formulation.

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

3.1.2 Methods of analysis

Analytical method for the determination of the active substance in the formulation is available and validated. As the active substance abamectin does not contain relevant impurity, no analytical method is required.

Analytical methods are available in the Draft Assessment Report and this dossier and validated for the determination of the residues of abamectin in plants (high water, high acid and dry content matrices), soil, water (drinking and surface water) and air.

Analytical methods for the determination of the residues of abamectin in foodstuff of animal origin are not necessary.

The active substance is very toxic (T+), therefore an analytical method is available in the Draft Assessment Report and validated for the determination of residues of abamectin in tissues and body fluids.

3.1.3 Mammalian Toxicology

<table>
<tr><td colspan="4">Active Substance: abamectin</td></tr>
<tr><td>ADI</td><td colspan="2">0.0025 mg / kg bw/d</td><td rowspan="3">EU 2009</td></tr>
<tr><td>ARfD</td><td colspan="2">0.005 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.0025 mg/kg bw/d</td></tr>
<tr><td rowspan="5">Dermal absorption</td><td colspan="3">Based on an in vitro human study performed on a similar formulation but the report is not provided by applicant. Due to difficulties to reach a lower dilution, a default value of 10% is fixed for diluted product according to Efsa guidance (Efsa 2012)</td></tr>
<tr><td></td><td>Concentrate (tested)
21.2 g/L</td><td>Diluted formulation (tested)
1.82 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>3</td><td>4.2</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
18 g/L</td><td>Spray dilution
(used in formulation)
0.018 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>3</td><td>10</td></tr>
</table>

3.1.3.1 Acute Toxicity

Abamectin 1.8% EW containing 18 g/L abamectin has a low toxicity in respect to acute dermal and inhalation toxicity, it is not irritating to the rabbit skin or eye and not a skin sensitiser. However, Abamectin 1.8% EW must be classified for acute oral toxicity.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G	Equipment	Application rate	Spray dilution (L/ha)	Model
Maize	F	Tractor mounted/trailed boom sprayer, hydraulic nozzles	0.4 L/ha (7.2 g a.s./ha)	300-400	BBA

*covers pome fruits and grapes

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

Crop	Equipment	PPE and/or working coverall	% AOEL abamectin
Maize	Tractor mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	2.8

According to the model calculations, it can be concluded that the risk for the operator using LAOTTA EW (ABAMECTIN 1.8% EW) 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 is estimated to 1.1 % of the AOEL of abamectin.
It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to LAOTTA EW (ABAMECTIN 1.8% EW).

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to 1.4 % of the AOEL of abamectin.
It is 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 LAOTTA EW (ABAMECTIN 1.8% EW).

3.1.3.5 Resident Exposure

Residential exposure was assessed according to martin et al. approach. Exposure is estimated to 11 % and 21 % (adult and child) of the AOEL of abamectin.
It is concluded that there is no unacceptable risk to the resident exposed to LAOTTA EW (ABAMECTIN 1.8% EW).

3.1.4 Residues and Consumer Exposure

Overall conclusion
For maize (grain), the data available are considered sufficient for risk assessment. An exceedance of the proposed MRL of abamectin for these crops is not expected. The chronic and the short-term intakes of abamectin residues are unlikely to present a public health concern.

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

According to available data, the following mitigation measure is proposed:

- forage from treated maize cannot be used for animal feeding.

Summary of the evaluation

The product LAOTTA EW (ABAMECTINE 1.8% EW) is composed of abamectin.

Summary for abamectin

Use-No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg (EU) 2016/1003	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
4	Maize	Yes	Yes	Yes	Yes	Yes	No	No	Mitigation measure on forage

As residues of abamectin do not exceed the trigger values defined in Reg (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 was calculated for livestock (considering that the mitigation measure on maize is applied). Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for abamectin 1.8% EW

Information on Abamectin 1.8% EW

Crop	PHI for abamectin 1.8% EW proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for abamectin 1.8% EW proposed by zRMS	zRMS Comments (if different PHI proposed)
		abamectin		
Maize	F** (BBCH 16)	Yes	/	

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

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 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 of abamectin and its metabolites 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.
PEC soil and PECsw derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.
PECgw for abamectin and its metabolite do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[12].
Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.
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(s) and its/their metabolites 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 birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of LAOTTA EW (ABAMECTINE 1.8% EW) is considered as satisfactory for the claimed use.
- the phytotoxicity level of LAOTTA EW (ABAMECTINE 1.8% EW) is considered as negligible for the claimed use.
- the risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops are considered as negligible.
- the risk of resistance development or appearance to abamectin does not require a monitoring for the claimed use.

[12] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

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

No further information is required.

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

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Décision relative à une demande d'extension d'usage 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'extension d'usage majeur du produit phytopharmaceutique ***LAOTTA EW***

de la société *LAINCO S.A.*

enregistrée sous le *n°2015-1065*

Vu les conclusions de l'évaluation de l'Anses du 1er décembre 2017,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** à compter de la présente décision aux usages fixés par la présente décision.

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.

LAOTTA EW
AMM n°2170336

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Informations générales sur le produit	
Nom du produit	LAOTTA EW
Type de produit	Produit de référence
Titulaire	LAINCO S.A. Av. Compositor Bizet, 8-12 Pol. Ind. Can Jardi 08191 RUBI Barcelona ESPAGNE
Formulation	Emulsion de type aqueux (EW)
Contenant	18 g/L - abamectine
Numéro d'intrant	922-2013.01
Numéro d'AMM	2170336
Fonctions	Insecticide, acaricide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

La présente décision peut être retirée ou modifiée si des éléments le justifient.

A Maisons-Alfort, le 15 MAI 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)

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ANNEXE I : Modalités d'autorisation du produit

Liste des nouveaux 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 Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15553106 Maïs*Trt Part.Aer.* Acariens	**0,4 L/ha**	**1/an**	jusqu'au stade BBCH 16	F (BBCH 16)	5	5	-	-
	Uniquement pour la production de grains.							

LAOTTA EW
AMM n°2170336

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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

Dans le cadre d'une application à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

• pendant l'application

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Pour le travailleur, porter

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

LAOTTA EW
AMM n°2170336

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alimentation, environnement, travail

Délai de rentrée en application de l'arrêté du 4 mai 2017 :
- 6 heures pour les usages en plein champ

Respect des limites maximales de résidus (LMR)
Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Ne pas utiliser le fourrage de "maïs" traité en alimentation animale.

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.

Protection de la faune
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau pour les usages sur "maïs".

- SPe 3 : Pour protéger les arthropodes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente pour les usages sur "maïs".

- SPe 8 : Dangereux pour les abeilles. Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer durant la floraison et les périodes de production d'exsudat. Ne pas utiliser en présence d'abeilles. Ne pas appliquer lorsque des adventices en fleur sont présentes.

LAOTTA EW
AMM n°2170336

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

LAOTTA EW

Autorisation de Mise sur le Marché n : délivrée le
Détenteur AMM : LAINCO S.A.
Avda. Bizet, 8-12, 08191 Rubi – Barcelona - Espagne

INSECTICIDE – émulsion de type aqueux contenant 18g/l d'abamectin
Usage réservé aux professionnels

Ce produit est un insecticide qui ne persiste ni ne s'accumule sur les végétaux, sur le sol et dans l'eau. Il Est obtenu par fermentation d'un micro-organisme du sol : *Streptomyces avermitilis*. Il possède un mode d'action original d'où l'absence de résistances croisées avec les autres insecticides et acaricides. Il agit par ingestion et dans une moindre mesure par contact sur les formes mobiles d'acariens et sur les insectes piqueurs. Il possède une longue persistance d'action.

Il s'emploie après mise en suspension dans l'eau. Agiter légèrement en versant le produit dans la cuve.
Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels.
Traiter suivant les avis des stations d'avertissements agricoles de votre région.
Les limites maximales en résidus sont consultables à l'adresse suivante: http://e-phy.agriculture.gouv.fr
Elimination du produit et de l'emballage : Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique.

ATTENTION

Contient de l'abamectin

H302 Nocif en cas d'ingestion
H411 Toxique pour les organismes aquatiques, entraine des effets à long terme

P102 Tenir hors de portée des enfants
P260 Ne pas respirer les vapeurs
P264 Se laver les mains soigneusement après manipulation
P270 Ne pas manger, boire ou fumer en manipulant le produit
P280 Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage
P301+ P312 EN CAS D'INGESTION: Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise
P330 Rincer la bouche
P273 Éviter le rejet dans l'environnement
P391 Recueillir le produit répandu

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 (Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via des systèmes d'évacuation des eaux à partir des cours de ferme ou des routes).
SPe3 Pour protéger les organismes aquatiques respecter une zone non traitée de 20 mètres pour les pommiers, poiriers et fruitiers à noyau. Les zones non traités peuvent être réduites si on emploi des équipements de limitation de la dérive.
Délai de rentrée des travailleurs sur la parcelle : 6 heures après le traitement.

LAINCO S.A. Avda. Bizet, 8-12, 08191 Rubi – Barcelona - Espagne
N° d'appel centre anti poison : 01 40 05 48 48 **N° vert Phyt-attitude: 08 00 88 78 87**

Conserver hors de la portée des enfants. Conserver à l'écart des aliments et boissons y compris ceux pour animaux.

REMARQUES : Respectez les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage, qui ont été déterminés en fonction des caractéristiques et des applications pour lesquelles le produit 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 ces produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché du Ministère de l'Agriculture.
La société ne sera pas responsable des pertes ou des dégâts occasionnés par une utilisation non conforme à ses recommandations. L'utilisateur assume tous les risques associés à un tel usage, non conforme à ces recommandations.

N° DE LOT : voir sur emballage **Volume : 1L**

Cultures & usages	Nb max application*	Interv. min entre 2 appl. (jours)	Dose d'emploi	Délai avant récolte (jours)
Fruitiers à pépins (pommier, poirier, cognassier, néflier...) : acariens (*Tetranychus urticae, Panonychus ulmi*) Traitement des parties aériennes avec une bouillie de 750 à 1200L/ha	2	15	0.375 à 1.2 L/ha	3
Poirier : psylle (*Cacopsylla pyri*) Traitement des parties aériennes avec une bouillie de 750 à 1200L/ha	2	15	0.375 à 1.2 L/ha	3
Fruitiers à noyau (abricotier, pêcher/nectarinier, cerisier, prunier) Traitement des parties aériennes avec une bouillie de 1000 à 1500L/ha	1	-	0.5 à 1.5 L/ha	7
Maïs : acariens (*Tetranychus urticae, Panonychus ulmi*) Traitement des parties aériennes avec une bouillie de 300-400L/ha	1	-	0.3 à 0.4 L/ha	NA

Appendix 3 – Letter(s) of Access

Provided

Section 7

OECD/EU Annex Point	Author	Year	Title Source (when different from company) Company, Report no. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study	Data protection claimed Y/N	Owner
IIIA 6.1.2/ 01 IIIA 6.1.3/ 01	Scripnic, V.	2014	Evaluate efficacy and selectivity of Abamectin 1.8% EW for the control of mites on maize Portugal 2014 Syntech Research, Portugal Report n°: SRPT14-007-138AE -02 GEP: Yes Published: No	N	Y	Industrias Afrasa S.A.
IIIA 6.1.2/ 02 IIIA 6.1.3/ 02	Scripnic, V.	2014	Evaluate efficacy and selectivity of Abamectin 1.8% EW for the control of mites on maize Portugal 2014 Syntech Research, Portugal Report n°: SRPT14-008-138AE -02 GEP: Yes Published: No	N	Y	Industrias Afrasa S.A.
IIIA 6.0/02 IIIA 6.1.2/ 03 IIIA 6.1.3/ 03	Rovetto.I.	2014	Evaluate efficacy and selectivity of several products for the control of mites on maize Sagea SR, Italy Report n°: SRIT14-705-138AE -03 GEP: Yes Published: No	N	Y	Industrias Afrasa S.A.
IIIA 6.0/03 IIIA 6.1.2/ 04 IIIA 6.1.3/ 04	Plau, A.	2014	Efficacy and selectivity study of the formulations Abamectin 1.8% EW against Tetranychus urticae on corn, Spain 2014 Industrias Afraa, S.A., Spain Report n°: ENE0203 -01, -02, -03 & -04 GEP: Yes Published: No	N	Y	Industrias Afrasa S.A.

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