

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code/name : BIOX-C**

**Chemical active substances:**

**Clove oil, 812 g/L**

**Spearmint oil, 203 g/L**

**Interzonal**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(New application)**

**Applicant: Xeda International S.A.**

**Date: 02/07/2019**

## Table of Contents

<b>1</b>	<b>Details of the application .....</b>	<b>4</b>
1.1	Application background.....	4
1.2	Letters of Access.....	5
1.3	Justification for submission of tests and studies .....	5
1.4	Data protection claims .....	5
<b>2</b>	<b>Details of the authorisation decision .....</b>	<b>5</b>
2.1	Product identity .....	5
2.2	Conclusion .....	6
2.3	Substances of concern for national monitoring .....	6
2.4	Classification and labelling.....	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008 .....	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011 .....	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009) .....	7
2.5	Risk management.....	7
2.5.1	Restrictions linked to the PPP .....	7
2.5.2	Specific restrictions linked to the intended uses .....	7
2.6	Intended uses (only NATIONAL GAP) .....	8
<b>3</b>	<b>Background of authorisation decision and risk management .....</b>	<b>10</b>
3.1	Physical and chemical properties (Part B, Section 2).....	10
3.2	Efficacy (Part B, Section 3) .....	10
3.3	Methods of analysis (Part B, Section 5).....	10
3.3.1	Analytical method for the formulation .....	10
3.3.2	Analytical methods for residues.....	11
3.4	Mammalian toxicology (Part B, Section 6) .....	11
3.4.1	Acute toxicity.....	11
3.4.2	Operator exposure .....	11
3.4.3	Worker exposure .....	12
3.4.4	Bystander and resident exposure .....	12
3.4.5	Combined exposure .....	13
3.4.6	Relevance of metabolites .....	13
3.5	Residues and consumer exposure (Part B, Section 7).....	13
3.6	Environmental fate and behaviour (Part B, Section 8) .....	15
3.7	Ecotoxicology (Part B, Section 9) .....	15
3.8	Relevance of metabolites (Part B, Section 10) .....	15
3.9	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009) .....	15
<b>4</b>	<b>Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....</b>	<b>15</b>

---

4.1.1	Post-authorisation monitoring.....	16
4.1.2	Post-authorisation data requirements .....	16
<b>Appendix 1</b>	<b>Copy of the product authorisation .....</b>	<b>17</b>
<b>Appendix 2</b>	<b>Copy of the product label.....</b>	<b>21</b>
<b>Appendix 3</b>	<b>Letter of Access .....</b>	<b>22</b>

## PART A

# RISK MANAGEMENT

### 1 Details of the application

The company Xeda International S.A. has requested marketing authorisation in France for the product BIOX-C, containing 812g/L Clove oil and 203g/L Spearmint oil, for use as a bactericide and fungicide agent in empty storage rooms for professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in the Registration Report, Parts B include the assessment of further data or information as required at national registration by the EU peer review. It also includes the assessment of data and information relating to BIOX-C where those data have not been considered in the EU peer review process. Otherwise the assessments for the safe uses of BIOX-C have been made using endpoints agreed in the EU peer review of both Spearmint oil and Clove oil.

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

Appendix 1 of this document provides a copy of the product authorisation.

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

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

Appendix 4 of this document is the list of data considered for national authorisation.

#### 1.1 Application background

The present registration report (RR) concerns the evaluation of Xeda International S.A.'s application to market BIOX-C in France as a bactericide and fungicide agent in empty storage rooms (product uses described under point 2.3). France acted as an interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

The present application (2017-3165) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the inter-zonal procedure for all Member States of the European Union, taking into account the worst-case uses ("risk envelope approach")<sup>1</sup> – the highest application rates over the European Union. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses'assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>2</sup>, 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)

<sup>1</sup> SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev.5.

<sup>2</sup> 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.

No 546/2011<sup>3</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

## 1.2 Letters of Access

Not necessary: the applicant is the owner of the active substances and PPP data.

## 1.3 Justification for submission of tests and studies

According to the applicant:

BIOX-C (BIOX-C) is based on clove oil and spearmint oil, two active substances evaluated at European level, with no MRL for both active substances.

Based on the intended application and composition of the product, new tests and studies were considered necessary to evaluate and demonstrate efficacy of the product for the intended uses.

## 1.4 Data protection claims

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

# 2 Details of the authorisation decision

## 2.1 Product identity

Product code	BIOX-C
Product name in MS	BIOX-C
Authorisation number	N/A : no marketing authorisation granted
Low risk (article 47)	No
Function	fungicide and bactericide
Applicant	Xeda International S.A.
Active substance(s) (incl. content)	Clove oil: 812 g/L Spearmint oil: 203 g/L
Formulation type	Hot fogging concentrate (HN)
Packaging	-
Coformulants of concern for national authorisations	/
Restrictions related to identity	It should contain less than 0,1 % w/w methyl-eugenol
Mandatory tank mixtures	None
Recommended tank mixtures	None

<sup>3</sup> COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

## 2.2 Conclusion

The evaluation of the application for BIOX-C resulted in the decision to refuse the authorization. The reasons for the refusal are:

- A shortage of analysis method for relevant impurity: methyl-eugenol.
- A potential risk for worker.
- Lack of justification of minimum effective dose.

## 2.3 Substances of concern for national monitoring

No information stated.

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aspiration toxicity category 1 Skin sensitisation category 1 Skin irritation category 2 Serious eye damage category 1 Acute toxicity (inhalation) category 4 Aquatic Chronic category 2
Hazard pictograms:	
Signal word:	Danger
Hazard statement(s):	H304 May be fatal if swallowed and enters airways H317 May cause an allergic skin reaction. H315 Causes skin irritation H318 Causes serious eye damage H332 Harmful if inhaled H411 Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the extant legislation</i>
Additional labelling phrases:	-

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

### 2.4.2 Standard phrases under Regulation (EU) No 547/2011

N/A: Not registered in France.

### **2.4.3      Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)**

N/A: Not registered in France.

## **2.5            Risk management**

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

The French Order of 4th May 2017<sup>4</sup> 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 metres;
- unless formally stated in the product authorisation, the minimum re-entry period 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.

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

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>6</sup> is to supply “minor” crops with registered plant protection products.

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

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

### **2.5.1        Restrictions linked to the PPP**

N/A: Not registered in France.

### **2.5.2        Specific restrictions linked to the intended uses**

N/A: Not registered in France.

<sup>4</sup> Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>.

<sup>5</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>.

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

## 2.6 Intended uses (only NATIONAL GAP)

**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 izRMS. Those uses are then granted in France.

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

GAP rev. 1, date: 2019-07-02

PPP (product name/code):	BIOX-C (BIOX-C)		Formulation type:	HN	
Active substance 1:	Clove oil		Conc. of as 1:	812 g/L	
Active substance 2:	Spearmint oil		Conc. of as 2:	203 g/L	
Safener:	NA		Conc. of safener:	NA	
Synergist:	NA		Conc. of synergist:	NA	
Applicant:	Xeda International		Professional use:	<input checked="" type="checkbox"/>	
Zone(s):	interzonal		Non professional use:	<input type="checkbox"/>	
Verified by MS:	No				

Field of use: Fungicide and bactericide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. <sup>(e)</sup>	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 <sup>(f)</sup>
					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		
<b>Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)</b>													
1	FR	Disinfection of empty storage rooms before stocking again fruits or vegetables	I	Fungi and bacteria	Thermofogging	Not applicable: application in empty storage room	1	NA	5-10 ml/m <sup>3</sup>	5-10 g/m <sup>3</sup>	NA	NA	<b>Not acceptable</b> (no analytical method for relevant impurity in the product, worker and efficacy - minimum effective dose)

<b>Remarks table heading:</b>	(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 authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
<b>Remarks columns:</b>	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 use 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/m <sup>3</sup> 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 Background of authorisation decision and risk management

#### 3.1 Physical and chemical properties (Part B, Section 2)

BIOX-C is a hot fogging concentrate (HN). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a yellow translucent liquid. It is not explosive and has no oxidising properties. The product is not flammable regarding the flash point of eugenol and spearmint oil. It is expected not auto-flammable. It has a pH value of 3.3 at ambient temperature. There is no effect of high temperature on the stability of the formulation, since after 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 the commercial packaging.

As a study of storage at 0°C for 7 days is not available the mention “Protect from frost” should be added on the label.

Its technical characteristics are acceptable for an HN formulation.

The formulation is classified H304 cat. 1.

#### 3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- With only 1 trial on bacteria for the justification of the dose, data provided are not considered sufficient. **Further efficacy trials are considered necessary to conclude on the minimum effective dose.**
- the efficacy level of BIOX-C is considered as satisfactory for the intended use to reduce the level of contamination of bacteria and fungi pathogens .
- the risk of the development of resistance or appearance to clove oil and spearmint oil is considered very low for the intended use.

Restrictions: /

Resistance monitoring data: /

Post-authorization data: /

Label: Recommendation not to apply on potatoes intended to propagation.

#### 3.3 Methods of analysis (Part B, Section 5)

##### 3.3.1 Analytical method for the formulation

Analytical method for the determination of the lead marker for the active substances clove oil and spearmint oil in the formulation is available and validated. As the active substance spearmint oil does not contain relevant impurity, no analytical method is required.

**No analytical method for the determination of the relevant impurity methyl-eugenol for the active substance clove oil in the preparation is submitted.**

### 3.3.2 Analytical methods for residues

Considering the intended uses (inert surfaces of building and equipment) analytical methods for the determination of residues of spearmint oil in plants, foodstuffs of animal origin, soil and water are not necessary.

## 3.4 Mammalian toxicology (Part B, Section 6)

### Endpoints used in risk assessment

Active Substance: Clove oil			
ADI	1 mg/kg body weight/day	EFSA (2012)	
ARfD	not applicable		
AOEL	1 mg/kg body weight/day		
Dermal absorption		Concentrate (used in formulation) 812 g/L	-
	<b>Dermal absorption endpoints %</b>	<b>25</b>	-

Active Substance: Spearmint oil			
ADI	0.252 mg/kg body weight/day	ANSES (2010)	
ARfD	Not applicable		
AOEL	0.252 mg/kg body weight/day		
Dermal absorption		Concentrate (used in formulation) 203 g/L	-
	<b>Dermal absorption endpoints %</b>	<b>25</b>	-

### 3.4.1 Acute toxicity

BIOX-C containing 821g/L clove oil and 203g/L spearmint oil has a low toxicity in respect to acute oral and dermal toxicity, but BIOX-C is considered as harmful by inhalation and is irritating to the skin and eye and is also a skin sensitiser. The classification of BIOX-C has been determined by calculation.

### 3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop	F/G <sup>7</sup>	Equipment	Application rate kg product/m <sup>3</sup> (g as/m <sup>3</sup> )	Spray dilution (L/ha)	Model
Fruit and vegetable storage	G*	Thermonebulization	0.01 kg/product /m <sup>3</sup> (8 g clove oil /m <sup>3</sup> 2 g spearmint oil /m <sup>3</sup> )	Undiluted product	Calculations

\* Closed building

The operator exposure calculation has been performed by the applicant with modification of the EFSA model. The adjustment of this model (1ha represents 100m<sup>3</sup>) enables to determine the operator exposure during the mix/loading operation during which the operator loads the fogger application device with undiluted BIOX-C.

<sup>7</sup> Open field or glasshouse.

Considering proposed uses, operator systemic exposure was estimated using the modified EFSA model:

Crop	Equipment	PPE and/or working coverall	% AOEL clove oil	% AOEL spearmint oil
Fruit and vegetable storage	Thermonebulization	Working coverall and gloves during mixing/loading and application	2	3

According to the model calculations, it can be concluded that the risk for the operator using BIOX-C is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading.

The operator during the application is unlikely to be exposed to the fogged product.

In conclusion, according to the model calculations, it can be concluded that the risk for the operator using BIOX-C is acceptable with a working coverall (90% protection factor) and gloves.

### **3.4.3 Worker exposure**

The worker exposure calculation proposed by the applicant with the EFSA model is not adapted to estimate this kind of exposure:

- The dislodgeable foliar residues value of 2.4 $\mu$ g/kg clove oil and 0.6 $\mu$ g/kg spearmint oil have been used, but no justification or explanation has been provided. The default DFR value is 3  $\mu$ g/cm<sup>2</sup> of foliage/kg as applied/ha. Furthermore, DFR value is not relevant in this case since BIOX-C is not used on crops.
- Likewise, the TC of 1400cm<sup>2</sup>/h corresponds to worker treated areas for inspection/irrigation activities. Thus, this parameter is not relevant.
- The default dermal absorption values is 25% for the concentrate and 75% for the diluted product. BIOX-C is not diluted thus, 25% should be used.

**Overall, izRMS considers that the EFSA model is not relevant to estimate the worker exposure.**

**The worker exposure is considered not finalized by the izRMS, so unacceptable risk cannot be excluded.**

### **3.4.4 Bystander and resident exposure**

In the absence of the AAOEL for clove and spearmint oil, it is considered that the risk assessment for the bystander is covered by the resident risk assessment.

Indeed, only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): “No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”

Considering the intended use, the exposure of bystanders or residents by both inhalation and dermal routes is considered negligible.

### 3.4.5 Combined exposure

The combined toxicological effect of these active substances has not been investigated with regard to the repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from **Erreur ! Source du renvoi introuvable.** converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators – EFSA model	Clove oil	0.3577
	Spearmint oil	0.4848
	<b>Cumulative risk Operators (HI)</b>	<b>0.8425</b>
Workers – EFSA model	Clove oil	
	Spearmint oil	
	<b>Cumulative risk Workers (HI)</b>	
Bystander No estimation (see <b>Erreur ! Source du renvoi introuvable.</b> )	Clove oil	-
	Spearmint oil	-
	<b>Cumulative risk Bystander – Adult (HI)</b>	-
Resident – Adult No estimation (see <b>Erreur ! Source du renvoi introuvable.</b> )	Clove oil	-
	Spearmint oil	-
	<b>Cumulative risk Resident – Adult (HI)</b>	-
Resident – Child No estimation (see <b>Erreur ! Source du renvoi introuvable.</b> )	Clove oil	-
	Spearmint oil	-
	<b>Cumulative risk Resident – Child (HI)</b>	-

In conclusion, this evaluation could not be performed due to lack of data for the worker. For the operator, the Hazard Index is < 1. Thus, the combined exposure to all active substances in BIOX-C is not expected to present a risk for operators, bystanders and residents.

### 3.4.6 Relevance of metabolites

Not relevant.

## 3.5 Residues and consumer exposure (Part B, Section 7)

### Overall conclusion

The active substances clove oil and spearmint oil are included in Annex IV, pending finalisation of their evaluation under Directive 91/414/EEC or Regulation (EC) No 1107/2009 and pending the availability of EFSA's reasoned opinion in accordance with Article 12 (1) of Regulation (EC) No 396/2005. As a consequence, no MRL are set. For clove oil no ARfD was set, and for spearmint oil currently not ADI or ARfD are available.

As far as consumer health protection is concerned, FR agrees with the authorization of the intended uses in empty

storage rooms before storage of fruits and vegetables.

### Summary of the evaluation

The preparation BIOX-C is composed of clove oil and spearmint.

#### Toxicological reference values for the dietary risk assessment of active substances

Reference value	Source	Year	Value	Study relied upon	Safety factor
Clove oil - Eugenol					
ADI	EFSA	2012	1.0 mg/kg bw/d	rat & rabbit developmental	100
ARfD	EFSA	2012	not necessary		
Spearmint oil					
ADI	Database insufficient to derive value (EFSA 2012)				
ARfD	Database insufficient to derive value (EFSA 2012)				

#### Summary for clove oil

Use-No.*	Crop/situation	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance No MRL set	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Disinfection by thermofogging of empty storage rooms before stocking fruits or vegetables.	No	No	-	No	No	No	No	SA included in Annex IV

No study investigating the clove oil residues in processed commodities are available. Nevertheless, as quantifiable level of residue was analysed in residue trials, these studies would be recommended.

No study investigating the clove oil residues in livestock commodities are available. Nevertheless, as the livestock may be exposed to clove oil residues, these studies would be recommended.

As the plant protection product is intended for a use indoor, no further investigation in rotational crop are necessary.

Nevertheless, considering the intended indoor use with one application by thermofogging, in close empty building, and as clove oil is an Annex IV active substance without MRL, awaiting review in line in Art 12, no additional data is considered necessary in framework of this dossier.

#### Summary for spearmint oil

Use-No.*	Crop/situation	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance No MRL set	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Disinfection by thermofogging of empty storage rooms before stocking fruits or vegetables.	No	No	-	No	No	No	No	SA included in Annex IV

No study investigating the spearmint oil residues in processed commodities are available. Nevertheless, as quantifiable level of residue was analysed in residue trials, these studies would be recommended.

No study investigating the spearmint oil residues in livestock commodities are available. Nevertheless, as the livestock may be exposed to clove oil residues, these studies would be recommended.

As the plant protection product is intended for a use indoor, no further investigation in rotational crop are necessary.

Nevertheless, considering the intended indoor use with one application by thermofogging, in close empty building, and as spearmint oil is an Annex IV active substance without MRL, awaiting review in line in Art 12, no additional data is considered necessary in framework of this dossier.

#### Summary for BIOX-C

Crop/situation	PHI for BI-OX-C proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for BIOX-C proposed by zRMS	zRMS Comments (if different PHI proposed)
		Clove oil	Spearmint oil		
Disinfection by thermofogging of empty storage rooms before stocking fruits or vegetables.	-	-	-		

#### Waiting periods before planting succeeding crops

NR: not relevant.

### 3.6 Environmental fate and behaviour (Part B, Section 8)

Considering the intended use for the preparation BIOX-C, exposure of the environmental compartments to the active substances is considered negligible. Consequently, no risk assessment for environment is deemed necessary.

### 3.7 Ecotoxicology (Part B, Section 9)

Considering the intended uses for the preparation BIOX-C, exposure of non-target organisms to the active substances is considered negligible. Consequently, no risk assessment for non-target organisms is deemed necessary.

### 3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

### 3.9 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The actives substances spearmint oil and clove oil are not approved as a candidate of substitution, therefore a comparative assessment is not foreseen.

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

When the conclusions of the assessment is « Not acceptable », please refer to relevant summary under point 3

“Background of authorisation decision and risk management”.

**4.1.1 Post-authorisation monitoring**

N/A: Not registered in France.

**4.1.2 Post-authorisation data requirements**

N/A: Not registered in France.

## Appendix 1 Copy of the product authorisation



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

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

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

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

*de la société XEDA INTERNATIONAL  
enregistrée sous le n°2017-3165*

*Vu les conclusions de l'évaluation de l'Anses du 27 février 2019,*

*Considérant l'absence de méthode de détermination de l'impureté pertinente méthyleugénol dans le produit,*

*Considérant que les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour le travailleur,*

*Considérant l'absence de justification de la dose d'emploi revendiquée,*

*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.



<b>Informations générales sur le produit</b>	
<b>Nom du produit</b>	BIOX-C
<b>Type de produit</b>	Produit de référence
<b>Titulaire</b>	XEDA INTERNATIONAL 1397 RN 7 ZAC LA CRAU 13670 SAINT ANDIOL France
<b>Formulation</b>	Produit pour nébulisation à chaud (HN)
Contenant	812 g/L - essence de girofle 203 g/L - huile de menthe verte
<b>Numéro d'intrant</b>	1152-2017.01
<b>Numéro d'AMM</b>	-
<b>Fonctions</b>	Fongicide, bactéricide
<b>Gamme d'usage</b>	Professionnel

A Maisons-Alfort le, 02 JUIL. 2019

**Caroline SEMAILLE**

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



## ANNEXE I : Conditions de mise sur le marché demandées

### Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00201017 Cultures fruitières* Désinfection* Locx Struct. Matér. (POV)	10 mL/m <sup>3</sup>	1/an	-
<b>Motivation du refus :</b> L'usage est refusé au motif qu'aucune méthode de détermination de l'impureté pertinente méthyleugénol dans le produit n'a été fournie. Il est également refusé en raison d'un manque de données permettant d'exclure un risque d'effet nocif pour le travailleur et de justifier la dose retenue.			
01101032 Cultures légumières* Désinfection* Locx Struct. Matér. (POV)	10 mL/m <sup>3</sup>	1/an	-
<b>Motivation du refus :</b> L'usage est refusé au motif qu'aucune méthode de détermination de l'impureté pertinente méthyleugénol dans le produit n'a été fournie. Il est également refusé en raison d'un manque de données permettant d'exclure un risque d'effet nocif pour le travailleur et de justifier la dose retenue.			
11016001 Traitements généraux* Désinfection* Locx Struct. Matér. (POV)	10 mL/m <sup>3</sup>	1/an	-
<b>Motivation du refus :</b> L'usage est refusé puisqu'il est transformé en l'usage n°509993330 mieux adapté aux données disponibles.			



### Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>50993730</b> Traitements généraux* Desinfection* Sacs Emballages (POV)	10 mL/m <sup>3</sup>	1/an	-
<b>Motivation du refus :</b> L'usage est refusé car non pertinent pour un produit phytopharmaceutique (usage biocide).			
<b>50993630</b> Traitements généraux* Fumigation (desinfection)* Locx Struct. Matér. (POV)	10 mL/m <sup>3</sup>	1/an	-
<b>Motivation du refus :</b> L'usage est refusé au motif qu'aucune méthode de détermination de l'impureté pertinente méthyleugénol dans le produit n'a été fournie. Il est également refusé en raison d'un manque de données permettant d'exclure un risque d'effet nocif pour le travailleur et de justifier la dose retenue.			

## **Appendix 2 Copy of the product label**

No draft product label has been sent by the notifier. The label shall reflect the detailed conditions stipulated in the Decision.

### **Appendix 3 Letter of Access**

Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request.