

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code/name(s) : Biox-M Amateur**

**Chemical active substance(s):**

**Plant oils / Spearmint oil, 286 g/kg**

**Interzonal**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

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

**Date: 2019/01/11**

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## 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-M AMATEUR, containing 286 g/kg Spearmint oil for use as an anti-sprouting agent for non-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 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 BIOX-M AMATEUR where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of BIOX-M AMATEUR have been made using endpoints agreed in the EU peer review of Spearmint oil.

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

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 concerns the evaluation of Xeda International S.A.'s application to market BIOX-M AMATEUR in France as an anti-sprouting agent (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 (2017-2474) 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 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's 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.

<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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) 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 substance.

## 1.3 Justification for submission of tests and studies

According to the applicant : BIOX-M AMATEUR is based on spearmint oil evaluated at European level, with no MRL.

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 use.

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of BIOX-M AMATEUR, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-8.

# 2 Details of the authorisation decision

## 2.1 Product identity

Product code	Biox-M Amateur
Product name in MS	BIOX-M AMATEUR
Authorisation number	2180858
Low risk (article 47)	No
Function	Anti-sprouting agent
Applicant	Xeda International S.A.
Active substance(s) (incl. content)	Spearmint oil: 286 g/kg
Formulation type	Vapour releasing product [Code: VP]
Packaging	Inner bag: PE External hermetic envelop: three layers material PE – Aluminium – Polyester. Each external hermetic envelop contains 2, 4, 6, 8 or 10 bags of the preparation.
Coformulants of concern for national authorisations	/
Restrictions related to identity	No restriction.
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-M AMATEUR resulted in the decision to grant the authorization.

## 2.3 Substances of concern for national monitoring

Refer to 5.1.1.

## 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:	Skin sensitisation, Category 1
Hazard pictograms:	
Signal word:	Warning
Hazard statement(s):	H317 : May cause an allergic skin reaction.
Precautionary statement(s):	<i>For the P phrases, refer to the extant legislation</i>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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

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

refer to 2.5	
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### 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

## 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:

<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>

- 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**

The authorisation of the PPP is linked to the following conditions:

Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
-	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers
Other specific restrictions	
Re-entry period	Wait until the treated zone be substantially ventilated to re-enter.
Storage	The formulation must be stored at a temperature below 30 °C

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

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

<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" or "not finalised", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

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

Use should be crossed out when the applicant no longer supports this use.

PPP (product name/code):	BIOX-M AMATEUR				GAP rev. 1, date: 2019-01-11							
Active substance :	speamint oil				VP <sup>(a, b)</sup>							
Applicant:	Xeda International S.A.				Conc. of as 1: 286 g/kg <sup>(c)</sup>							
Zone(s):	Interzonal				Professional use: <input type="checkbox"/>							
Verified by MS:	yes				Non professional use: <input checked="" type="checkbox"/>							

Field of use:	Anti-sprouting												
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 destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f) Iz RMS Conclusion
					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	Potatoes	I	Anti-sprouting agent	Bags of granules placed in the potatoes storage box	At beginning of storage	1 plastic bag / 6 kg potatoes every two months during storage	60 days	a) 0.014 kg/6kg potatoes b) 0.042 kg/6kg potatoes	a) 4 g a.s. / 6 kg potatoes a) 12 g a.s. / 6 kg potatoes	-	Not applicable	post-harvest treatment <b>Acceptable</b>

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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.

**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 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-M AMATEUR is a Vapour releasing Product (VP). 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 plastic bag containing granules. It is expected not explosive and has no oxidising properties. The product is expected not flammable and not auto-flammable at ambient temperature. There is no effect of high temperature on the stability of the formulation, since after 18 weeks at 30 °C in the commercial packaging, the active ingredient content wasn't changed.

**The shelf life study (2 years at ambient temperature) is on going and should be provided in post registration.**

Its technical characteristics are acceptable for a VP formulation.

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

The formulation must be stored at a temperature below 30 °C.

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

Considering the data submitted:

The efficacy level of BIOX-M AMATEUR is considered as satisfying for the claimed use.

The selectivity level of BIOX-M AMATEUR is considered as acceptable for the claimed use.

In absence of taint study at the requested dose rate, a risk of negative impact on potato taint cannot be excluded.

This risk was already assessed under the professional conditions with the product BIOX-M; the results were an absence, or sometimes a taint effect.

As an anti-sprouting agent, the application of the product is not recommended on potatoes intended to propagation.

The risk of resistance is not relevant for an anti-sprouting agent.

Restrictions: /

Resistance monitoring data: /

Post-authorization data: /

Label: Recommendation to not 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 active substance in the formulation is available and validated. As the active substance Spearmint oil does not contain relevant impurity, no analytical method is required.

##### 3.3.2 Analytical methods for residues

Considering the intended uses (a post-harvest anti-sprouting product on potatoes) analytical methods for the determination of residues of Spearmint oil in plants and in foodstuffs of animal origin, soil and water are not necessary.

**Analytical method for the determination of residue in air isn't available and will be required at the renewal of the active.**

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

#### Endpoints used in risk assessment

Active Substance: SPEAR MINT OIL			
ADI	Not applicable	EU (2009)	
ARfD	Not applicable		
AOEL	Not applicable		
AAOEL	-		
Dermal absorption**	Based on default values according to guidance on dermal absorption (Efsa 2012):	Concentrate (used in formulation) 286 g/kg	Spray dilution (used in formulation)
		<b>Dermal absorption endpoints %</b>	<b>25</b>
Oral absorption	No data available with Spearmint oil, only data from studies with (R)-carvone: Rapid and virtually complete		EFSA Journal 2012;10(11):2541

\*\*MM : not applicable for spearmint oil; 150.21 g/mol for main constituent @-carvone.

Log Pow: 2.4 for carvone (no data on spearmint oil)

#### 3.4.1 Acute toxicity

No data is available for BIOX-M AMATEUR containing 286g/kg spearmint oil.

#### 3.4.2 Operator exposure

BIOX-M AMATEUR is a “granule packed in sealed plastic bags” formulation. Due to the mode of application of this formulation type and to the nature of the product himself, the exposition of the operator (the amateur) is considered as negligible. Indeed, the operator only has to open the sealed aluminium bags containing 2-10 inner plastic bags. Then, the operator has to place the inner plastic bags between the potatoes. There is virtually no contact with the product / active substance based on the packaging and intended use.

Summary of critical use patterns (worst cases):

Crop type	F/G/I <sup>7</sup>	Equipment Application method	Maximum application rate	Minimum volume water (L/ha)
Potato	I	Granules packed in sealed plastic bags applied at begin- ning of storage	1 plastic bag (4 g as)/ 6 kg pota- toes every two months during storage Max 3 application/year	N/A

The proposed packaging has been described in sufficient details, and its compliance can therefore be finalised. In summary, compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users is considered to be acceptable.

#### 3.4.3 Worker exposure

BIOX-M AMATEUR is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user of the product.

<sup>7</sup> Open field, glasshouse or Indoor

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

Not relevant due to exclusive indoor use.

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

### **Overall conclusion**

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

The use of the active substance spearmint oil is approved and may be limited as plant growth regulator for postharvest treatment of potatoes.

Due to several data gap the consumer risk assessment cannot be finalised. Nevertheless spearmint oil residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

As far as consumer health protection is concerned, FR agrees with the authorization of the intended post-harvest uses as plant regulator on potato.

### **Data gaps**

This is a complete list of the data gaps related to consumer risk assessment, identified during the peer review process by EFSA 2012:

- Toxicological profile of spearmint oil except for acute toxicity (see section 2)
- A freezer storage stability study
- Data on the nature of residues of spearmint oil in potato tuber taking into account the critical use scenario
- Data and information to address residues in livestock or justification of the potential non-relevance of such data
- A sufficient number of critical GAP conforming residue trials with spearmint oil in potatoes, and possibly residue data on processed potatoes to sufficiently demonstrate reduction of residues

Although additional data might be useful, considering that the intended use as post-harvest on potato is in accordance with the EU approved use, and that the active substance is temporarily included in Annex IV, no additional data are required to support the intended use in home-gardening.

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

Considering the intended use for the preparation BIOX-M AMATEUR, exposure of environmental compartments to the active substance is considered negligible. Consequently, no risk assessment for environment and non-target organisms is deemed necessary.

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

BIOX-M AMATEUR is intended to be use in closed spaces (indoor) for the post-harvest treatments on potatoes (non-professional uses). No exposure of BIOX-M AMATEUR to non-target organisms is expected and thus, no risk assessment is performed.

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

BIOX-M AMATEUR is a post-harvest product that is only applied locally on potatoes indoor. As there is no direct or indirect contamination of soil, contamination of ground water with the active substance is not expected.

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

The active substance Spearmint oil is not approved as a candidate of substitution, therefore a comparative assessment is not foreseen.

## **5 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”.

### **5.1.1 Post-authorisation monitoring**

None.

### **5.1.2 Post-authorisation data requirements**

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

- The shelf life study (2 years at ambient temperature) is ongoing and should be provided in post registration.

## 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-M AMATEUR***

*de la société* XEDA INTERNATIONAL  
*enregistrée sous le* n°2017-2474

*Vu les conclusions de l'évaluation de l'Anses du 6 décembre 2018,*

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

La présente décision s'applique sans préjudice des autres dispositions applicables.

#### Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.



### Informations générales sur le produit

Nom du produit	BIOX-M AMATEUR
Type de produit	Produit de référence
Titulaire	XEDA INTERNATIONAL 1397 RN 7, ZAC LA CRAU, 13670 SAINT ANDIOL, France
Formulation	Produit diffuseur de vapeur (VP)
Contenant	286 g/kg - huile de menthe verte
Numéro d'intrant	877-2017.01
Numéro d'AMM	2180858
Fonction	Inhibiteur de germination
Gamme d'usage	Amateur / emploi autorisé dans les jardins

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 août 2023.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

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

A Maisons-Alfort le, 11 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)



## ANNEXE I : Modalités d'autorisation du produit

<b>Vente et distribution</b>	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Sacs refermables en polyéthylène/aluminium/polyester	Contenant 2, 4, 6, 8 ou 10 sachets de 14 g en polyéthylène

<b>Classification du produit</b>	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Sensibilisants cutanés - Catégorie 1	H317 : Peut provoquer une allergie cutanée
Pour les phrases P se référer à la réglementation en vigueur.	
<b>Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.</b>	



### Liste des usages autorisés

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
15654808 Pomme de terre*Trit Prod. Rec.* Limit. Destruct. Germes	2,33 g/kg	3/an	-	-	-	-	-	-

Un sachet (14 g de produit) pour 6 kg de pommes de terre.  
Intervalle minimum entre les applications : 60 jours



## Conditions d'emploi du produit

### Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 30°C.

### Délai de rentrée:

- Bien ventiler avant de rentrer dans les lieux stockant les récoltes traitées.

### Protection de l'environnement (milieux, faune et flore)

#### Protection de l'eau

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les sachets non utilisés.

## Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Référence (mois)
Fournir les résultats de l'étude, en cours de réalisation, concernant la stabilité au stockage pendant 2 ans, à température ambiante.	24	-

## Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

### LABEL TEXT

#### FRONT SIDE

ANTI-GERMES Pommes de terre

BIOX-M AMATEUR

4 sachets individuels

Utilisable en agriculture biologique en application du règlement (CE) n°834/2007

#### BACK SIDE

L'Anti-Germes **BIOX-M AMATEUR** est utilisable en agriculture biologique et d'origine naturelle, l'huile de menthe. Il permet de prolonger la conservation des pommes de terre après récolte. Il va retarder l'apparition et le développement des germes favorisant une conservation plus longue et la meilleure qualité des pommes de terre pendant leur conservation. Il permet également un effet rattrapage et permet de « brûler » les germes déjà apparus sur certaines variétés.

- Prolonge la conservation des pommes de terre : 1 sachet pour 2 mois sans germes
- S'applique après la récolte, lors de la conservation
- Sachets pré-dosé : facile à l'emploi et sans contact avec le produit

Période d'emploi : Toute l'année

#### MODE ET DOSE D'EMPLOI

Déchirer l'emballage hermétique et insérer les sachets individuels, sans les ouvrir, au milieu des pommes de terre, en les répartissant de manière homogène au niveau du tas de tubercules. Il est nécessaire de recouvrir les pommes de terre d'un voile non étanche laissant les pommes de terre respirer, mais permettant de limiter les pertes de produit par évaporation. Refermer correctement l'emballage hermétique après ouverture.

Dose d'emploi : un sachet individuel pour 6 kg de pommes de terre, à renouveler tous les 2 mois, dans la limite de 3 par an.

#### PRÉCAUTIONS D'EMPLOI

Protéger votre peau (gants, vêtements couvrants) pendant toutes les phases de manipulation du produit.

Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.

Conserver le produit dans son emballage d'origine, à l'abri de l'humidité.

Réemploi de l'emballage interdit. Ne pas jeter dans les poubelles ménagères, mais éliminer l'emballage avec ou sans produit en déchèterie ou par un organisme agréé.

#### INFORMATIONS REGLEMENTAIRES

Nom homologué : **BIOX-M Amateur**

A.M.M. n° xxxxxxxx – Emploi autorisé dans les jardins

Détenteur de l'A.M.M. : Xeda International 1397 RN 7, ZA la Crau 13670 Saint Andiol

Composition : 286 g/kg (28.6% m/m huile de menthe)

Formulation : VP

Type d'action : Régulateur de croissance

Usage et dose autorisé : Pomme de terre\*Trt Prod. Réc.\*Limit. Destruct. Germes

Dose = 1 sachet / 6 kg de pomme de terre

NMA = 3/an

N° de lot et Date de fabrication : voir indications sur l'emballage.

**V/ PAVE SECURITE**

**BIOX-M Amateur**

EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

P101 En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.

P102 Tenir hors de portée des enfants

P501 Eliminer le contenu/récipient dans une déchèterie ou par un organisme agréé.

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

En cas d'urgence appeler le 15 ou le centre anti-poison.

Distribué par :

Masse net : 56 g (soit 4 sachets de 14 g)

Réf. : xxx

Gencod : xxxxxxxx

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

Not applicable.