REGISTRATION REPORT
Part A
REVISION
Risk Management

Product code: BIOX-M

Active Substance: Spearmint Oil
100 % w/w or 930 – 950 g/L

COUNTRY: Germany
All Zones
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: XEDA International S.A.

Date: 30/09/2013

REVISION: 09/11/2015

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of BIOX-M containing Spearmint Oil in Germany.

The evaluation is required subsequent to the inclusion of Spearmint Oil on Annex I.
The risk assessment conclusions given below are based on the information, data and assessments provided in Registration Report, Part B Sections 1, 5 - 7 and Part C and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report includes assessment of further data and information as required at national registration by the EU review. It also includes assessment of data and information relating to BIOX-M where that data has not been considered in the EU review. Otherwise assessments for the safe use of BIOX-M have been made using endpoints agreed in the EU review of Spearmint Oil.
This document describes the specific conditions of use and labelling required for Germany for the registration of BIOX-M.

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

Appendix 2 of this document is a copy of the approved product label for Germany.

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 16 of Directive 91/414/EEC.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

Letter of access is not necessary.

1 Details of the application

1.1 Application background

This application has been submitted by GAB Consulting GmbH on behalf of XEDA International S.A. in July 2011.

Applicant details
Name: XEDA International S.A.
Street: 2 Zone Artisanale de la Crau
City: 13670 St Andiol
Country: France

Contact person: Michel Coëffic
Telephone No.: +33-(0)4 90 90 23 23
Telefax No.: +33-(0)4 90 90 23 20
e-mail: michelc@xeda.com

The application is for approval of BIOX-M, a hot fogging concentrate formulation containing 930 – 950 g/L Spearmint Oil for use as a plant growth regulator (sprout suppressant).

This Revision of the final Report was necessary after change of decision from non-authorisation to authorisation of the product.

1.2 Annex I inclusion

Spearmint oil (summarised as plant oils/spearmint oil) was included on Annex I of Directive 91/414/EEC on 01 09 2009 under Inclusion Directive 2008/127/EC and implemented under Regulation (EU) No 540/2011 which was amended under Regulation (EU) No 608/2012.

Only uses as plant growth regulator for postharvest treatment of potatoes may be authorised.

Member States shall ensure that authorisations provide that hot fogging is performed exclusively in professional storage facilities and that the best available techniques are applied to exclude the release into the environment of the product (fogging mist) during storage, transport, waste disposal and application.

The Annex I Inclusion Directive for Spearmint oil (Amendment under Regulation (EU) No 608/2012) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on plant oils/spearmint oil (SANCO/2624/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.

Conditions of use shall include, where appropriate, risk mitigation measures.

1.3 Regulatory approach

To obtain approval the product BIOX-M must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.
This application was submitted in order to allow the first approval of this product in Germany

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of BIOX-M, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1, 5 - 7 and Part C.

1.5 Letters of Access

Letter of Access is not necessary.

2 Details of the authorisation

2.1 Product identity

Product Name	BIOX-M
Authorization Number (for re-registration)	007502-00
Function	plant growth regulator (sprout suppressant)
Applicant	XEDA International S.A.
Composition	930 – 950 g/L spearmint oil
Formulation type	Hot fogging concentrate [Code: HN]
Packaging	5 L, 10 L and 20 L jerricans, HDPE

2.2 Classification and labelling

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

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

Hazard pictograms:	
GHS07	exclamation mark
GHS08	health hazard
Signal word:	
Danger	
Hazard statements:	
H304	May be fatal if swallowed and enters airways.
H317	May cause an allergic skin reaction
Precautionary statemtents:	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P270	Do no eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/ doctor/ ...
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P321	Specific treatment (see ... on this label).
P331	Do NOT induce vomiting.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P363	Wash contaminated clothing before reuse.
P501	Dispose of contents/container to ….
Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208 - Contains carvone. May produce allergic reactions.	

2.2.2 R and S phrases under Directive 2003/82/EC (Annex IV and V)

SP 1: Do not contaminate water with the product or its container.

2.2.3 Other phrases

2.2.3.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Ecosystem protection		
Efficacy and sustainable use		
NB663	Due to the manner in which authorisation governs application of the product, bees are not endangered.(B3)	
NN000	Due to the manner in which authorisation governs application of the product, populations of relevant beneficial organisms are not endangered.	

2.2.3.2 Specific restrictions linked to the intended uses

The authorisation of the PPP is linked to the following conditions (mandatory labelling):

SB001 Avoid any unnecessary contact with the product. Misuse can lead to health damage.

SB010 Keep out of children´s reach.

SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.
SE110	Wear tight fitting eye protection when handling the undiluted product.
SF138	Treated stores must not be entered without protective clothing and respiratory protection until 24 hours after treatment.
SF1472	During the period of action, rooms may only be entered with personal protective equipment including respiratory equipment. After the period of action/before the rooms are re-entered, they must be aired thoroughly.
SF183	Standard protective gloves must be worn for handling treated potatoes.
SS1201	Wear standard protective gloves (plant protection) when handling/applying the product.
SS2204	Wear a protective suit for plant protection products and sturdy shoes (e.g. rubber boots) when applying/handling the product.
SS520	Wear a cap with face screen when applying/handling the product ready for application.
SS6201	Wear a rubber apron when applying/handling the product.
ST4102	Wear half mask with combination filter AX-P2 (identification colour: brown/white) according to the BVL guideline "Personal protective equipment for handling plant protection products", current version, when applying/handling the product.
WH9152	The instructions for use must include a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.

2.3 Product uses

GAP-Table of intended uses for Germany

GAP rev. 1, date: 2011-12-30

PPP (product name/code)	**BIOX-M**	**Formulation type:**	**HN**
active substance 1	**Spearmint oil**	**Conc. of as 1:**	**930-950 g/L**
safener	**-**	**Conc. of safener:**	**-**
synergist	**-**	**Conc. of synergist:**	**-**
Applicant:	**XEDA International S. A.**	**professional use**	☒
Zone(s):	**EU**	**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	Germany	Potato (SOLTU) Except seed potato	F	Sprout suppression (YKEIM)	Thermal fogging	After beginning of storage	a) 11 (21 days) b) 11	a) first treatment 90 ml/t from second treatment 30 ml/t b) 390 ml/t	a) 85.32 g as/t 28.44 g as/t b) 369.72 g as/t			WH9152

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

3 Risk management

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

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:
BIOX-M is a light yellow translucent liquid with an odour like spearmint. It is not explosive, has no oxidising properties and is not self-igniting. In aqueous solution, it has a pH value around 5.3. Its stability as indicated by accelerated and real time storage testing is consistent with its suitability for use under normal conditions. Its technical properties are such that no particular problems are expected when it is used as recommended.

Implications for labelling: none

Compliance with FAO specifications:
There is no FAO specification for spearmint oil HN formulations.

Compliance with FAO guidelines:
The product BIOX-M complies with FAO guidelines, as far as could be assessed.

Compatibility of mixtures:
No tank mixtures are recommended..

Nature and characteristics of the packaging:
Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:
Information regarding the required protective clothing and equipment for the safe handling of BIOX-M has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

BIOX-M was a representative formulation in the EU review of Spearmint Oil. Analytical methods for determination of Spearmint Oil, impurities and relevance of CIPAC methods in BIOX-M were evaluated as part of the EU review of Spearmint Oil. All data are considered adequate.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

BIOX-M is the same product as assessed by RMS Sweden for inclusion of the active substance plant oils/spearmint oil into Annex I and is identical with the active ingredient. Spearmint oil was approved with Regulation (EU) No 608/2012. Temporarily spearmint oil is included in Annex IV of Regulation (EC) No 396/2005.

In the EFSA conclusion on spearmint oil (No 2541) a data gap for residue analytical methods for products of plant and animal origin and for soil, water and air was identified. Since the residue definitions for spearmint oil are still open (s. LoEP of the EFSA Conclusion) adequate residue analytical methods must be provided if residue definitions are set.

Additional to the studies already peer reviewed in the EU a study for the determination of spearmint oil in air has been provided. However, as the residue definition is still open this study has not been assessed and therefore no Part B Section 2 has been prepared.

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

BIOX-M is the same product as assessed by RMS Sweden for inclusion of the active substance plant oils/spearmint oil into Annex I. In addition, the active ingredient and the preparation are virtually identical.

EFSA organised a peer review of the pesticide risk assessment of the active substance and published its Conclusion (EFSA Journal 2012; 10(11):2541). During the assessment some data gaps and critical concerns were identified (7. List of studies to be generated, 9.2 Critical areas of concern).

Notwithstanding the identified lacks of information an updated Review Report (rev. 2) came to the overall conclusion that "there are clear indications that it may be expected that plant oils/spearmint oil does not have any harmful effects on human or animal health […]."

"The present review report contains the conclusions of the final examination by the Standing Committee." It was officially noted by the Standing Committee on the Food Chain and Animal Health on 1 June 2012 resulting in COMMISSION IMPLEMENTING REGULATION (EU) No 608/2012 from 6 July 2012 which confirms the Annex I listing for use as plant growth regulator for postharvest treatment of potatoes.

The review report and the confirmation of the Annex I listing currently represent the final result of the harmonised re-evaluation process of plant oils/spearmint oils. zRMS Germany regards itself bound to this decision.

Taking these considerations into account no additional evaluation was regarded necessary as the data package available has been fully assessed. Therefore no Part B Section 3 has been prepared. The requirements for classification and labeling are listed in chapter 2.2 of this document. For further details of the assessment please refer to the Review Report and the EFSA conclusion including their appendices and background documents.

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

Please refer to the comment and conclusions given under 3.1.3.

No new evaluation was regarded necessary as the data package available has been fully assessed. Therefore no Part B Section 4 has been prepared. For further details of the assessment please refer to the Review Report and the EFSA conclusion including their appendices and background documents.

Further it should be noted that spearmint oil is temporarily included in Annex IV of Reg. (EU) No 396/2005). Therefore until finalisation of Article 12 (1) procedure no MRLs are required for spearmint oil.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

The following chapters summarize specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of BIOX-M in Germany according to its intended use in post-harvest treatment of potatoes except seed potatoes (Use No. 00-001)

No metabolism studies with the active substance Spearmint oil in soil or water/sediment systems were available from Annex 1 inclusion and no new studies have submitted for this assessment. Hence no potentially metabolites were considered for environmental risk assessment.

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)

Since the plant protection product BIOX-M is intended to be used in post-harvest indoor-treatment of potatoes according to use No 00-001, no direct exposure of BIOX-M to soil is expected. Besides, no use of BIOX-M on seed potatoes is intended in Germany. Thus no PEC_{soil} values were calculated for BIOX-M or its active substance Spearmint oil.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PECGW) (Part B, Section 5, Point 9.6)

Since the plant protection product BIOX-M is intended to be used in post-harvest indoor-treatment of potatoes except seed potatoes, no direct exposure of the active substance to soil is expected in its intended use 00-001. Besides, no use of BIOX-M on seed potatoes in intended for authorization in Germany. Thus, groundwater contaminations with the active substance Spearmint oil via direct leaching or via surface run-off or drainage or via direct leaching are not expected for the intended use 00-001 of BIOX-M and no modelling has been performed.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PECSW) (Part B, Section 5, Points 9.7 and 9.8)

Since the plant protection product BIOX-M is intended to be used in post-harvest indoor-treatment of potatoes according to use No 00-001, no exposure of surface waters via run-off and drainage is expected. Since no use of BIOX-M on seed potatoes is intended in Germany, it is expected that wash water from the treated potatoes will be send to sewage plants were a complete degradation of the active substance Spearmint oil is assumed.

However, L-carvone, the main constituent of Spearmint oil has a vapour pressure of 17.3 Pa at 25°C and is considered volatile. Thus, exposure of surface water by L-carvone due to deposition following

volatilization needs to be considered. The concentration of the active substance Spearmint oil in a ditch adjacent to the depot was estimated using an empirical model from Tintrup gen. Suntrup et al (2004).

Assuming a standard water body with a depth of 0.3 m, a length of 100 m and a width of 1 m (Volume = 300 l/m^2) according to the dimensions used in FOCUS SW Step 1 calculations, and an average of 18 mg/m^3 L-Carvon in the air after application, PECsw values can be calculated from the derived deposition values. The derived deposition values together with the calculated PECsw values are summarized in Table 5.6-1.

Table 0.1.5-1: Estimated deposition of Spearmint oil at different distances from the depot and derived PECsw values for the deposition of Spearmint oil on surface water

Distance from Depot (m)	Deposition (% per m^2)	Deposition (g/m^2)	PECsw [mg/L]
0	1.627	0.00030	0.00100
5	1.256	0.00023	0.00077
10	0.914	0.00017	0.00056
20	0.514	0.00009	0.00032
50	0.091	0.00002	0.00006

The results for PEC surface water for the active substance were used for the ecotoxicological risk assessment.
Details are given in the Core Assessment and the National Addendum-Germany, Part B, Section 5, chapter 5.6.

3.1.5.4 Predicted Environmental Concentration in Air (PECAir) (Part B, Section 5, Point 9.9)

L-carvone, the main constituent of Spearmint oil, has an estimated vapour pressure of 17.3 Pa and is thus considered highly volatile. The calculated halflife in air is estimated to be 0.909 hours (Atkinson calculation). These data are derived from the EU Review of Carvone. Concentration in air was not estimated, because the risk for long-range transport is expected to be low based on the calculated halflife of carvone in air. For short-range transport and deposition see 3.1.5.3

Implications for labelling resulting from environmental fate assessment:

none

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of BIOX-M in Germany according to its intended use in post-harvest treatment of potatoes (use No. 00-001).

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Since Spearmint oil is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use 00-001. A risk assessment for effects on birds and other terrestrial vertebrates has not been carried out. However, a risk envelope approach has been conducted. This comes to the conclusion that the predicted risk for terrestrial vertebrates is acceptable.

For details see Part B, National Addendum-Germany, Section 6, chapters 6.2 and 6.3.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Results of aquatic risk assessment for the intended uses of BIOX-M in post-harvest treatment of potatoes based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.

For authorization in Germany, exposure assessment of surface water in this special case considers the two routes of entry (i) volatilisation with subsequent deposition and (ii) direct entry of wash water without treatment into a sewage plant in order to allow risk mitigation measures separately for each entry route.

1. Exposure by volatilisation and subsequent deposition

The calculation of concentrations in surface water was based on an approach from in Tintrup gen. Suntrup et al (2004)[1], who developed an empirical model for estimating the deposition of active substances from plant protection products with a vapour pressure of > 1 Pa at 20°C from depots. Trintrup gen. Suntrup et al (2004) measured a deposition of 1.256%/m^2 of the applied quantity/m^3 depot at a 5 m distance for the active substance dichlorvos. In order to extrapolate the deposition for greater distances, they developed the equation $y = 129.5e^{-0,0576x}$ where y is the percentage deposited per m^2 surface area and x is the relative variation from the 5 meter value in %. The equation is based on deposition measurements at 5, 20 and 50 m distance to the depot.

However, an additional study by Bartolomé (2009) was submitted that determined the concentration of L-Carvone, the main constituent of Spearmint oil, in a box storage depot immediately after application and 2h after application using the same application rate. Immediately after application, the authors measured an average of 1485 mg/m^3 L-Carvone in the air. However, already after 2 h this declined to an average of 18 mg/m^3 thus showing a dissipation of over 98%. Since the storage depot is only expected to be vented about 2-3 days after application, the measured 18 mg/m^3 can be assumed as worst case when estimating the PECsw values for Spearmint oil.

2. Exposure by direct entry of wash water

For calculation of the concentration of the active substance Spearmint oil in wash water, the use of 100 litre water per ton potatoes and the complete removal of the active substance from the potatoes was assumed. For the cumulative application rate of 390 mL/t BIOX-M, a concentration of 3.68 g/l Spearmint

[1] Tintrup gen. Suntrup, G., Fent, G., Kubiak, R.: "Emission of Pesticides from buildings - Validation of a volatilisation model for the short range deposition"; August 13, 2004, Sponsoring Agency: UBA (German Federal Environmental Agency); UFOPLAN-Ref. No.: FKZ 360 03 026; UBA-Texte 47/2004

oil would be found in the wash water. Since it is not expected that all Spearmint oil used for treatment remains on the potatoes at the end of the treatment, this is considered a worst case assumption.

The calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by the active substance Spearmint oil due to direct entry of wash water from treated potatoes to the use No 00-001 does not achieve the acceptability criteria of TER ≥ 100, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. However, the direct entry of wash water is deemed to be unlikely, since the potatoes are used for industrial processing thus the washing would take place at the industrial plant. For these plants a sewage plant for waste water treatment is mandatory. Since BIOX-M is not intended to be used on seed potatoes for German authorisation, a direct entry of wash water containing Spearmint oil into a surface water is not expected (see also RR CA Part B, Section 5.6).

Based on the relevant toxicity of the active substance Spearmint oil the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by volatilisation and subsequent deposition to BIOX-M according to the use No 00-001 achieve the acceptability criteria of TER ≥ 100, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2.

For details see Part B, National Addendum-Germany, Section 6, chapters 6.4.

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Effects on honey bees for BIOX-M were not evaluated as part of the EU review of Spearmint Oil. No data on BIOX-M or on Spearmint oil have been submitted by the applicant, because bees will not be exposed due to the solely indoor use of the product.

No risk assessment on arthropods other than bees could be conducted due to the non-availability of data. However, because of the high vapour pressure the risk is assumed to be low. Once deposition occurs, Spearmint-oil will evaporate again and the effect on non-target arthropods is negligible.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms (Part B, Section 6, Point 10.6)

No data on the effects of Spearmint-oil on soil microbial activity is available, thus no risk assessment could be conducted. However, since BIOX-M is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use, and exposure to soil microorganisms, although possible would be negligible.

3.1.6.5 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

No data on the effects of Spearmint-oil on soil microbial activity is available, thus no risk assessment could be conducted. However, since BIOX-M is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use, and exposure to soil microorganisms, although possible would be negligible.

3.1.6.6 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

No risk assessment on non-target plants could be conducted due to the non-availability of data. However because of the high vapour pressure the risk is assumed to be low. Once deposition occurs, Spearmint-oil will evaporate again and the effect on non-target plants is negligible.

Implications for labelling resulting from ecotoxicological assessment:

Relevant toxicity	Product: Biox-M (content 81.16 % L-Carvone) EC_{50} = 10.6 mg/L (*Daphnia magna*) NOEC = 5.0 mg/L
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	none
Risk phrases	R 52
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	no hazard symbol used
Signal word	No signal word used
Hazard statement	none
Other labels	
NB664	Due to the manner in which authorisation governs application of the product, bees are not endangered. (B3)
NN000	Due to the manner in which authorisation governs application of the product, populations of relevant beneficial organisms are not endangered.

3.1.7 Efficacy (Part B, Section 7, Point 8)

BIOX-M is intended for use in stored potatoes to inhibit sprouting. The first application (90 g product/t) is conducted approximately 6-15 days after harvest when wound healing is finished. Up to 10 subsequent applications of 30 g product/t follow every three weeks. BIOX-M is formulated for hot fogging (HN and contains > 55% (w/w) Carvone), it is applied with a Xeda electrofog equipment.

Information on the active ingredients (Uptake and mode of action)

The active substance of BIOX-M is Spearmint Oil, which has sprout suppressing and fungicidal properties. It is a mixture of various components with L-Carvone being the most prevalent. Spearmint Oil works by physically destroying sensitive sprout meristem tissue. Carvone inhibits sprout growth within 2 days. An extensive loss of the activity of 3-hydroxy-3-methylglutaryl Coenzyme A reductase, a key enzyme in the mevalonate pathway, occurs concomitantly with the inhibition of sprout growth. The enzyme activity decreases to less than 3% of the control after 4 days of treatment. Carvone is also part of the synthesis of phytohormones like gibberelin, absiscine and cytokinine, which e.g. influence the growth of the plant roots and inhibit the growth/sprouting of tubers. Since new sprouts continue to develop, repeated applications are required every three weeks.

Minimum effective dose rate tests (Dose justification)

Seven minimum effective dose trials were conducted with half the intended application rate in 2002/03 and 2010. A clear dose response is visible for all parameters and all storage times. The dose rate is suitable for an effective control of sprouting on potatoes.

Efficacy

A total of 10 effectiveness trials with the target rate intended for BIOX-M were conducted from 2002 to 2010 on a selection of different potato varieties. Effectiveness was evaluated based on counting sprouts of different length, weight of sprouts, sprout index and loss of tuber weight during storage. The test product was well comparable with the reference product applied by thermal fogging. Additionally a test on aged, already sprouted potatoes of different varieties demonstrated that also existing sprouts were successfully controlled with BIOX-M.

Effects on the yield and quality

A taint test was conducted on the varieties Bintje, Agata and Nicola in 2009, that were boiled in water or fried. No negative taste differentials with equally prepared potatoes from a reference product were detected. Moreover no negative influences on cooking qualities were recorded.

Phytotoxicity

In four selectivity trials with the intended and twice the intended dose no phytotoxic effects on the tuber could be found for BIOX-M. After evaporation of BIOX-M sprouting of seed potatoes is possible, no long-term effects are to be expected.

BIOX-M is well tolerated by most economically important potatoes varieties.

Adverse effects

There will be no exposure and therefore no risk to beneficial organisms, because BIOX-M is intended to be used only in indoor post-harvest treatments to control sprouting of potatoes.

Since the product is used as storage application indoors, the impact on adjacent or succeeding crops is not relevant for the intended use.

There is no potential for resistance development.

Implications for labelling resulting from efficacy assessment:

WH9152: The instructions for use must include a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.

3.2 Conclusions

With regard to residue analytical methods BIOX-M may be authorised. However, residue analytical methods have to be provided if residue definitions are set (cf. EFSA Conclusion (2541)).

With regards to toxicological and residue aspects no new data as compared to the re-evaluation as documented in the recent review report is available.

No adverse health effects for operators, workers, bystanders and residents are to be expected if used properly and according to the intended conditions of use.

With regards to residues BIOX-M may be authorised. A risk for consumers is not expected.

Further data requirements for toxicological and residue aspects are listed in the EFSA Conclusion (EFSA Journal 2012; 10(11):2541, Sec. 7 List of studies to be generated, Sec. 9.2 Critical areas of concern).

Based on the evaluation of the data submitted an adequate efficiency, a lack of adverse effects on treated crops and a sustainable use can be stated. An authorization can be granted.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

An authorization can be granted.

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

No further information is required

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 16 of Directive 91/414/EEC.

Appendix 3 – Letter of Access

Letter of access is not necessary.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

XEDA International S. A.
1397 Route nationale 7 - ZAC LA CRAU 1397
13670 SAINT-ANDIOL
FRANKREICH

Dr. Dietmar Gottschild
Referent

TELEFON +49 (0)531 299-3512
TELEFAX +49 (0)531 299-3002
E-MAIL dietmar.gottschild@bvl.bund.de

IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN (bitte bei Antwort angeben) 200.22100.007502-00/00.56253

DATUM 25.11.2015

ZV1 007502-00/00

BIOX-M

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Auf Ihren Widerspruch vom 30. Juli 2014 hebe ich meinen Bescheid vom 01. Juli 2014 (AZ: 200.22100.007502-00/00.56253) auf. Die Kosten des Widerspruchsverfahrens trage ich. Die zur zweckentsprechenden Rechtsverfolgung oder Rechtsverteidigung entstandenen notwendigen Aufwendungen werden Ihnen auf Antrag erstattet.

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff:	948 g/l	Grüne-Minze-Öl
Zulassungsnummer:	007502-00	
Versuchsbezeichnungen:	XED-00001-W-0-HN	
Antrag vom:	4. August 2011	

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 31. August 2020.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007502-00/00-001	Keimhemmung	Kartoffel	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 375 der Verordnung vom 31. August 2015 (BGBl. I S. 1474), festgesetzt:

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Verpackungen

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Kennzeichnungsauflagen:

(EB001-1)

SP 1: Mittel und/oder dessen Behälter nicht in Gewässer gelangen lassen.

(SB001)

Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB010)

Für Kinder unzugänglich aufbewahren.

(SB110)

Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

(SE110)
Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel.

(SF138)
Ein Begehen behandelter Lager ohne Körper- und Atemschutz ist erst 24 Std. nach Abschluss der Behandlung erlaubt.

(SF1472)
Räume während der Einwirkungszeit des Mittels nur mit Körper- und Atemschutz betreten. Nach der Einwirkungszeit/vor dem Aufenthalt von Personen in den Räumen diese gründlich lüften.

(SF183)
Beim Umgang mit behandelten Kartoffeln sind Universal-Schutzhandschuhe zu tragen.
(SS1201)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen bei Ausbringung/Handhabung des Mittels.

(SS2204)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z. B. Gummistiefel) tragen bei der Ausbringung/Handhabung des Mittels.

(SS520)
Kopfhaube mit Gesichtsschutz tragen bei der Ausbringung/Handhabung des anwendungsfertigen Mittels.

(SS6201)
Gummischürze tragen bei der Ausbringung/Handhabung des Mittels.

(ST4102)
Halbmaske mit Kombinationsfilter AX-P2 (Kennfarbe: braun/weiß) gemäß BVL-Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz, in der jeweils geltenden Fassung, tragen bei der Ausbringung/Handhabung des Mittels.

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 2.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

(S2) Gefahr

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS08) Gesundheitsgefahr

Gefahrenhinweise (H-Sätze):

(EUH 208-0176)

Enthält Carvone. Kann allergische Reaktionen hervorrufen.

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

(H304)

Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein.

(H317)

Kann allergische Hautreaktionen verursachen.

Sicherheitshinweise (P-Sätze):

(P261)

Einatmen von Staub/Rauch/Gas/Nebel/Dampf/Aerosol vermeiden.

(P270)

Bei Gebrauch nicht essen, trinken oder rauchen.

(P272)

Kontaminierte Arbeitskleidung nicht außerhalb des Arbeitsplatzes tragen.

(P280)
Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P301+P310)
BEI VERSCHLUCKEN: Sofort GIFTINFORMATIONSZENTRUM/Arzt/ ... anrufen.
(P302+P352)
BEI BERÜHRUNG MIT DER HAUT: Mit viel Wasser/... waschen.

(P321)
Besondere Behandlung (siehe ... auf diesem Kennzeichnungsetikett).

(P331)
KEIN Erbrechen herbeiführen.

(P333+P313)
Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

(P363)
Kontaminierte Kleidung vor erneutem Tragen waschen.

(P501)
Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen
Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):
- keine –

Hinweise
Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:
(NB663)
Aufgrund der durch die Zulassung festgelegten Anwendungen des Mittels werden Bienen nicht gefährdet (B3).

(NN000)
Aufgrund der durch die Zulassung festgelegten Anwendungen des Mittels werden Populationen relevanter Nutzorganismen nicht gefährdet.

Weitere Hinweise und Bemerkungen
Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Hinsichtlich der Gebühren des Zulassungsverfahrens erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Zustellung Klage bei dem Verwaltungsgericht Braunschweig, Wilhelmstraße 55, 38100 Braunschweig, erhoben werden.

Die Klage muss den Kläger, den Beklagten und den Gegenstand des Klagebegehrens bezeichnen. Sie soll einen bestimmten Antrag enthalten. Die zur Begründung dienenden Tatsachen und Beweismittel sollen angegeben werden. Der Klage nebst Anlagen sollen so viele Abschriften beigefügt werden, dass alle Beteiligten eine Ausfertigung erhalten können.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 007502-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Keimhemmung

Pflanzen/-erzeugnisse/Objekte: Kartoffel

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Großlager
Anwendung im Haus- und Kleingartenbereich:	Nein
Erläuterung zur Kultur:	Ausgenommen Pflanzgut
Anwendungszeitpunkt:	Nach Lagerbeginn
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	11
- für die Kultur bzw. je Jahr:	11
- Abstand:	21 Tage
Anwendungstechnik:	heißnebeln
Aufwand:	
- erste Behandlung	90 ml/t
- ab zweiter Behandlung	30 ml/t

2.2 Sonstige Kennzeichnungsauflagen

(WH9152)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

2.3 Wartezeiten

(F)	Großlager: Kartoffel Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

REGISTRATION REPORT
Part B

Section 1: Identity, physical and chemical properties, other information

Detailed summary of the risk assessment

Product code: **BIOX-M**

Active Substance: **Spearmint Oil**
100 % w/w or **930 – 950 g/L**

All Zones
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **XEDA International S.A.**

Date: **30/09/2013**

Table of Contents

Introduction

This document summarises the information related to the identity, the physical and chemical properties, the data on application, further information and the classification for the product BIOX-M containing the active substance spearmint oil which was approved according to Regulation (EC) No 1107/2009.

This product was the representative formulation.
The product has been previously evaluated in France and Belgium according to Uniform Principles.

The following table provides the EU endpoints to be used in the evaluation.

Agreed EU End-points

End-Point	**Spearmint oil (Reg. (EU) No 608/2012)**
Purity of active substance	min. 550 g/kg as (R)-Carvone

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Appendix 2 of this document is the table of intended uses for BIOX-M.

Information on the detailed composition of BIOX-M can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

IIIA 1.1 Applicant

Name: XEDA International S.A.

Address: 2 Zone Artisanale de la Crau
13670 St Andiol
France

IIIA 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)

IIIA 1.2.1 Manufacturer(s) of the preparation

Name: XEDA International S.A.

Address: 2 Zone Artisanale de la Crau
13670 Saint-Andiol
France

IIIA 1.2.2 Manufacturer(s) of the active substance(s)

Confidential information - data provided separately (Part C).

IIIA 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

Spearmint oil 550 g/kg as (R)-Carvone

Further information is provided in Part C.

IIIA 1.3 Trade Names and Manufacturer's Code Numbers for the Preparation

Trade name: BIOX-M

Company code number: none mentioned

IIIA 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation

IIIA 1.4.1 Content of active substance and formulants

The formulation of BIOX-M was the representative formulation for the inclusion of spearmint oil in Annex I of Directive 91/414/EEC.

The active substance and the preparation are both the essential oil of *Mentha spicata*, i.e. in the context of the preparation; there is only one component, the active substance, Spearmint Oil. Spearmint Oil is a multi-component active substance of naturally variable composition and thus a specification for the active substance in the normal sense is not feasible, except in the context of a default 100% pure Spearmint Oil, irrespective of naturally variable composition.

Technical active substance:

content of technical spearmint oil	930 - 950 g/L	100 % w/w

The active substances in the formulation is not present in the form of a salt, ester, anion or cation.

Further information on the active substances and on the certified limits of formulants is considered confidential and is provided separately (Part C).

IIIA 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by regulation (EU) 2011/545.

IIIA 1.4.3 Common names and code numbers for the active substance(s)

Data Point	Type	Name/Code Number
1.4.3.1	Common name	Spearmint oil, *Mentha spicata* oil For main component (R)-carvone: (*R*)-5-isopropenyl-2-methylcyclohex-2-en-1-one.
1.4.3.2	CAS No.	For spearmint oil: 8008-79-5 (Spearmint extract: 84696-51-5) For main constituent (R)-carvone :6485-40-1
1.4.3.2	EINECS No.	No number for Spearmint oil (Spearmint extract: 283-656-2) For main constituent (R)-carvone : 229-352-5
1.4.3.2	CIPAC No.	Spearmint oil: 908

IIIA 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function.

The active substance and the preparation are both the essential oil of *Mentha spicata*, i.e. in the context of the preparation; there is only one component, the active substance Spearmint Oil.

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

This is not an EC data requirement/ not required regulation (EU) 2011/545.

IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern

There are no manufacturing impurities of toxicological or ecotoxicological concern.

IIIA 1.5 Type of Preparation and Code

Type : Hot fogging concentrate [Code : HN]

IIIA 1.6 Function

The product will be used as plant growth regulator (sprout suppressant).

IIIA 1.7 Other/Special Studies

None.

IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

The product BIOX-M was the representative formulation for the inclusion of the active substance spearmint oil into Annex I of Directive 91/414/EEC.

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 that of a light yellow translucent liquid with an odour like spearmint. It is not explosive, has no oxidising properties and is not self-igniting. In aqueous solution, it has a pH value around 5.3. The accelerated storage stability data and shelf life data indicate that the product is stable. Its technical characteristics are acceptable for a hot fogging concentrate formulation.

Tabelle 1: Summary of the physical, chemical and technical properties of the plant protection product

Test or study & Annex point	**Method used / deviations**	**Test material purity and specification**	**Findings**	**GLP Y/N**	**Reference**	**Acceptability / comments**
Colour, odour and physical state (IIIA 2.1)	Visual inspection	Spearmint Oil HN (80% w/w L-carvone) Batch No. 0000086325	Light yellow translucent liquid with an odour like spearmint. after acc. storage: light yellow, translucent	Y	Servajean, E. 2005a	Acceptable
Explosive properties (IIIA 2.2.1)	-	-	Not applicable – the oxygen balance (OB%) of the primary component of Spearmint Oil, L-carvone = -276.9, indicates a low potential for explosivity. In addition, there are no known phosphors (bond groupings known to confer explosivity) or auxoploses (explosivity-enhancing groups) in the structure of L-carvone. Taken together, this information indicates that experimental determination of the	-	-	Acceptable formulation is non explosive Oxygen balance < -200 is a sufficient criteria according to (EC) 1272/2008

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			explosive properties of Spearmint Oil is unnecessary.			
Oxidizing properties (IIIA 2.2.2)	-	-	Not applicable – the oxygen balance (OB%) of the primary component of Spearmint Oil, L-carvone = -276.9, indicates a low potential for oxidising properties. This information indicates that experimental determination of the oxidizing properties of Spearmint Oil is unnecessary.	-	-	Not acceptable. Test according A.21 should be conducted for clarity.
	EPA OPPTS 830.6314		No strong reaction with water, potassium permanganate, zinc dust or monoammonium phosphate		Servajean, E. 2005a	Study was accepted in EU evaluation, but is not appropriate to describe oxidizing properties.
Flash point (IIIA 2.3.1)	EEC A.9 (closed cup)	see above	92 °C	Y	Servajean, E. 2005a	Acceptable
Flammability (IIIA 2.3.2)	-	-	see 2.3.1	-	-	Acceptable.
Auto-flammability (IIIA 2.3.3)	-	-	Experience in use has shown that auto-flammability is not a cause for concern.	-	-	Not acceptable; study according A.15 is requested

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Acidity or alkalinity and pH (IIIA 2.4.1)	CIPAC MT 31.1	see above	initial: 0.023% w/w H_2SO_4 after acc. storage: 0.025 % after 24 month: 0.013 %	Y	Servajean, E. 2005a	Acceptable
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75.2	see above	initial: 5.32 (1 % in deionized water, 20 °C) after acc. storage: 5.05 after 24 month: 5.45	Y	Servajean, E. 2005a	Acceptable
Kinematic viscosity (IIIA 2.5.1)	OECD 114	see above	2.95 mm²/s (20 °C)	Y	Servajean, E. 2005a	Acceptable
Dynamic viscosity (IIIA 2.5.2)	-	-	not applicable, Newtonian liquid.	-	-	Acceptable.
Surface tension (IIIA 2.5.3)	EEC A.5	see above	31.1 mN/m (neat formulation, 25 °C)	Y	Servajean, E. 2005a	Acceptable
Relative density (IIIA 2.6.1)	EEC A.3 (pycnometer)	see above	Density: 0.948 g/mL at 20°C D^{20}_4=0.949	Y	Servajean, E. 2005a	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Bulk or tap density (IIIA 2.6.2)	-	-	not applicable, liquid formulation.	-	-	Acceptable.
Storage Stability after 14 days at 54° C (IIIA 2.7.1)	CIPAC MT 46	see above	Storage in a glass bottle. The content of l-Carvone does not decrease > 5 %. The changes of the physical and chemical properties are negligible.	Y	Servajean, E. 2005a	Acceptable.
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	-	-	Not required, because the preparation is not heat sensitive. (see IIIA 2.7.1)	-	-	Acceptable.
Minimum content after heat stability testing (IIIA 2.7.3)	-	-	Not required, because the content of the active substance in the preparation did not decrease by more than 5 % in heat stability testing. (see Point IIIA 2.7.1)	-	-	Acceptable.
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.1	see above	few granular brown solid material after 1 hour of storage, which still remained after 7 days of storage and thermal equilibrium at room temperature	Y	Servajean, E. 2005a	Acceptable (based on the composition). Formulation should not be stored below 0 °C (label).
Ambient temperature shelf life (IIIA 2.7.5)	CropLife International, Technical Monograph	see above	Storage material: not mentioned The content of the active substance does not decrease > 5 %. The	Y	Servajean, E. 2005b	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
	No. 17		changes of the physical and chemical properties are negligible.			
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	-	-	Please refer to 2.7.5	-	-	Acceptable.
Wettability (IIIA 2.8.1)	-	-	Not applicable as BIOX-M is not a solid preparation diluted before use.	-	-	Acceptable.
Persistence of foaming (IIIA 2.8.2)	-	-	Not applicable as BIOX-M is not a preparation to be diluted with water.	-	-	Acceptable.
Suspensibility (IIIA 2.8.3.1)	-	-	Not applicable as BIOX-M is not a water dispersible preparation.	-	-	Acceptable.
Spontaneity of dispersion (IIIA 2.8.3.2)	-	-	Not applicable as BIOX-M is not a water dispersible preparation.	-	-	Acceptable.
Dilution stability (IIIA 2.8.4)	-	-	Not applicable as BIOX-M is not a preparation to be diluted with water.	-	-	Acceptable.
Dry sieve test (IIIA 2.8.5.1)	-	-	Not applicable as BIOX-M is not a solid preparation.	-	-	Acceptable.
Wet sieve test	-	-	Not applicable as BIOX-M is not a	-	-	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.8.5.2)			water dispersible preparation.			
Particle size distribution (IIIA 2.8.6.1)	-	-	Not applicable as BIOX-M is a liquid formulation.	-	-	Acceptable.
Nominal size range of granules (IIIA 2.8.6.2)	-	-	Not applicable as BIOX-M is a liquid formulation.	-	-	Acceptable.
Dust content (IIIA 2.8.6.3)	-	-	Not applicable as BIOX-M is a liquid formulation.	-	-	Acceptable.
Particle size of dust (IIIA 2.8.6.4)	-	-	Not applicable as BIOX-M is a liquid formulation.	-	-	Acceptable.
Friability and attrition (IIIA 2.8.6.5)	-	-	Not applicable as BIOX-M is a liquid formulation.	-	-	Acceptable.
Emulsifiability (IIIA 2.8.7.1)	-	-	Not applicable as BIOX-M is not an emulsion, nor is it diluted and does not form an emulsion in use.	-	-	Acceptable
Emulsion stability (IIIA 2.8.7.2)						
Re-emulsifiability (IIIA 2.8.7.3)						
Stability of dilute						

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
emulsions (IIIA 2.8.7.4) Stability of emulsions (IIIA 2.8.7.5)						
Flowability (IIIA 2.8.8.1)	-	-	nNot applicable as BIOX-M is a liquid formulation.	-	-	Acceptable.
Pourability (including rinsed residue) (IIIA 2.8.8.2)	-	-	Not applicable as BIOX-M is not a suspension preparation.	-	-	Acceptable (based on the composition of the formulation)
Dustability following accelerated storage (IIIA 2.8.8.3)	-	-	Not applicable, liquid formulation!	-	-	Acceptable.
Physical compatibility of tank mixes (IIIA 2.9.1)	-	-	Not applicable as BIOX-M is not intended to be used with other products.	-	-	Acceptable.
Chemical compatibility of tank mixes (IIIA 2.9.2)	-	-	Not applicable as BIOX-M is not intended to be used with other products.	-	-	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Distribution to seed (IIIA 2.10.1)	-	-	Not applicable as BIOX-M is not a seed treatment preparation.	-	-	Acceptable
Adhesion to seeds (IIIA 2.10.2)	-	-	Not applicable as BIOX-M is not a seed treatment preparation.	-	-	Acceptable
Miscibility (IIIA 2.11)			Not required by regulation (EU) 2011/545.			Acceptable.
Dielectric breakdown (IIIA 2.12)			Not required by regulation (EU) 2011/545.			Acceptable.
Corrosion characteristics (IIIA 2.13)			Not required by regulation (EU) 2011/545.			Acceptable.
Container material (IIIA 2.14)			Not required by regulation (EU) 2011/545.			Acceptable.
Other/special studies (IIIA 2.15)			Not required by regulation (EU) 2011/545.			Acceptable.

IIIA 2.16 Summary and Evaluation of Data Presented Under Points 2.1 to 2.15

BIOX-M is a light yellow translucent liquid with an odour like spearmint. It is not explosive, has no oxidising properties and is not self-igniting. In aqueous solution, it has a pH value around 5.3. Its stability as indicated by accelerated and real time storage testing is consistent with its suitability for use under normal conditions. Its technical properties are such that no particular problems are expected when it is used as recommended.

Experimental testing of the product's physico-chemical and technical characteristics:

No experimental testing was considered necessary, based on the composition of the formulation.

Implications for labelling:

No labelling necessary due to known physical or chemical properties described above.

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

BIOX-M is used as growth regulator for post-harvest indoor use. The purpose is the preventing of sprouting in potatoes during storage.

IIIA 3.2 Nature of the Effects on Harmful Organisms

Harmful organisms arte not relevant in this case. Spearmint Oil works by physically destroying sensitive sprout meristem tissue.

IIIA 3.3 Details of Intended Use

IIIA 3.3.1 Details of existing and intended uses

BIOX-M is intended for use in stored potatoes to inhibit sprouting. The first application (90 ml product/t) is conducted approximately 6-15 days after harvest when wound healing is finished. Up to 10 subsequent applications of 30 ml product/t follow every three weeks. No use exists in Germany so far.

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

Harmful organisms are not relevant in this case.

IIIA 3.3.3 Effects achieved

BIOX-M is intended for use in stored potatoes to inhibit sprouting to protect quality during storage.

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

The first application (90 ml product/t) is conducted approximately 6-15 days after harvest, up to 10 subsequent applications of 30 ml product/t follow every three weeks.

IIIA 3.5 Concentration of the Active Substance in the Material Used

The active substance, Spearmint Oil, is used undiluted and is present at a concentration of 930 – 950 g/L.

IIIA 3.6 Method of Application, Type of Equipment Used and Volume of Diluent

BIOX-M is formulated for hot fogging (HN) and is applied with a Xeda electrofog equipment.

IIIA 3.7 Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection

IIIA 3.7.1 Maximum number of applications and their timings

The first application (90 ml product/t) is conducted approximately 6-15 days after harvest, up to 10 subsequent applications of 30 ml product/t follow every three weeks.

IIIA 3.7.2 Growth stages of crops or plants to be protected

Post-harvest application

IIIA 3.7.3 Development stages of the harmful organism concerned

Harmful organisms are not relevant in this case.

IIIA 3.7.4 Duration of protection afforded by each application

Duration of control is about 21 days.

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications

Considering a total of 11 applications, each lasting 21 days, plus 3 weeks of protection after the last application, a maximum protection of more than 200 days (6-7 months) is afforded.

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops

Succeeding crops are not relevant in this case.

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Succeeding crops are not relevant in this case.

IIIA 3.8.2 Limitations on choice of succeeding crops

Succeeding crops are not relevant in this case.

IIIA 3.8.3 Description of damage to rotational crops

Rotational crops are not relevant in this case.

IIIA 3.9 Proposed Instructions for Use as Printed on Labels

Please refer to Registration Report – Part A, Appendix 2 for the relevant country.

IIIA 3.10 Other/Special Studies

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

IIIA 4.1 Packaging and Compatibility with the Preparation

Packaging Summary

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

IIIA 4.1.1 Description and specification of the packaging

BIOX-M is packaged in 5L, 10L and 20 L Jerricans.

Materials:	Plastic; HDPE
Specifications:	
5 L	Length 193 mm × Width 140 mm × Height 301 mm; capacity 5.8 L
10 L	Length 232 mm × Width 192 mm × Height 321 mm; capacity 11.3 L
20 L	Length 262 mm × Width 272 mm × Height 404 mm; capacity 22.4 L
Shape:	Jerrican
Opening:	Neck inner diameter 45 mm screw cap with induction seal
Closure:	Specifications for natural thread DIN 60; safety closure.

IIIA 4.1.2 Suitability of the packaging and closures

The design type complies with the test requirements for packaging of the following international regulations for the transport of dangerous goods:

- the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)

- the Regulations on the International Transport of Dangerous Goods by Rail (RID)

- the International Maritime Dangerous Goods Code (IMDG Code)

- the Recommendations on the Transport of Dangerous Goods of the United Nations

- the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI) laid down in the IATA Dangerous Goods Regulations

IIIA 4.1.3 Resistance of the packaging material to its contents

No adverse findings were reported in the storage stability study (Point IIIA 2.7.5).

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

Application equipment should be cleaned using water. The following instructions can be followed:

- Immediately after fogging, empty the vacuum pipe and the pump lifting the tube above the pump; rinse with water. Any contamination on the outside of the fogging equipment should be removed by washing with clean water.

- Stop the pump.

- Stop the fan and turn on the equipment.

- Remove the vaporisation pipe and rinse it

IIIA 4.2.2 Effectiveness of the cleaning procedures

No specific information is available as to the effectiveness of the cleaning procedures proposed.

IIIA 4.3 Re-entry Periods to Protect Man, Livestock and the Environment

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop

No Pre-harvest interval (in days) foreseen..

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

Not applicable.

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated

24 hours after treatment. Where necessary, please consider Part A.

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs

Not applicable, spearmint oil is listed in Annex IV.

IIIA 4.3.5 Waiting period (in days) between application and handling of treated products

No waiting period (in days) foreseen. Due to limited information on residues standard protective gloves must be worn for handling treated potatoes.

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

Not applicable.

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used

It is recommended to verify that the sprouting of tubers has not occurred before treatment, that the potatoes are ripe, correctly de-earthed, and maintained at temperatures between 8 and 10°C at the moment of treatment.

Further specific limitations are defined through Part A, 2.2.3.2 Specific restrictions.

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

IIIA 4.4.1 Warehouse storage

Store the product at a temperature between -20 and 35°C in the original packaging, protect from light, in locked places and away from food, children and pets.

IIIA 4.4.2 User level storage

Keep out of the reach of children. Keep away from sources of heat and ignition. Keep only in original container. Minimum shelf life: 2 years.

IIIA 4.4.3 Transport

ADR/RID Classification:	Class 9 UN Number UN308, Packaging Group III Environmentally Hazardous Substance, Liquid, n.o.s.
IATA Classification:	Class 9 UN Number UN308, Packaging Group III Environmentally Hazardous Substance, Liquid, n.o.s.
IMDG Classification:	Class 9 UN Number UN308, Packaging Group III Environmentally Hazardous Substance, Liquid, n.o.s

IIIA 4.4.4 Fire

In case of fire use CO_2, dry powder..

IIIA 4.4.5 Nature of protective clothing proposed

The requirements for PPE are listed in Part A, Chapter 2.2.

IIIA 4.4.6 Characteristics of protective clothing proposed

No information is provided on the suitability of such clothing as its use is recommended on the basis of general advice for all plant protection products.

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

No information is provided on the suitability of such clothing as its use is recommended on the basis of general advice for all plant protection products.

IIIA 4.4.8 Procedures to minimise the generation of waste

Only purchase and store quantities of product required in the short term. Do not open larger containers than is necessary for immediate requirements.

IIIA 4.4.9 Combustion products likely to be generated in the event of fire

Hazardous gases, carbon monoxide and carbon dioxide and smokes.

Exposed to high temperatures, it can release dangerous decomposition products such as nitrogen oxides, carbon monoxide, carbon dioxide and smoke.

IIIA 4.5 Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use

IIIA 4.5.1 Containment of spillages

Prevent entry into drains, waters or soil. Use adsorbent material to collect liquid spillage (e.g. sand, chemical binder). Sweep up contaminated absorbent and place into sealable containers. Dig up heavily contaminated soil and place in drums. Use a damp cloth to clean floors and other objects after removal of contaminated absorbent and also place in sealable container.

Decontamination of water: There are no methods readily available for the neutralisation or decontamination of water.

Environmental precautions: Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal. Prevent any material from entering drains or waterways. Do not discharge into the natural environment or in the waters. This product is toxic to aquatic organisms

Methods for cleaning up: Absorb with liquid-binding material (sand, earth, vermiculite, diatomaceous earth)

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Please refer to Point IIIA 4.5.1.

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Dispose of all waste and contaminated clothing in the same manner as waste chemicals (i.e. via an authorised disposal facility).

IIIA 4.5.4 Protection of emergency workers and bystanders

Protection of emergency workers and bystanders: Use protective clothing as proposed (Point IIIA 4.4.5)

IIIA 4.5.5 First aid measures

Skin contact: Wash affected area with plenty of soap and water. Grossly contaminated clothing: Remove contaminated clothing. Wash before re-use.

Eye Contact: Immediately rinse with plenty of potable water / sterile eye wash solution for 10 to 20 minutes. Obtain medical advice.

Inhalation: Remove patient to fresh air.

Ingestion: Give water, avoid vomiting. Immediately obtain medical advice.

Medical advice: Over-exposure symptoms unknown. Only minor local symptoms are expected. No specific antidote. Treat symptomatically.

IIIA 4.6 Neutralisation Procedure for Use in the Event of Accidental Spillage

IIIA 4.6.1 Details of proposed procedures for small quantities

A neutralization procedure is not possible for the product.

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

See Point IIIA 4.6.1.

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

See Point IIIA 4.6.1.

IIIA 4.6.4 Details of proposed procedures for large quantities

See Point IIIA 4.6.1.

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

See Point IIIA 4.6.1.

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

See Point IIIA 4.6.1.

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

Not applicable as BIOX-M does not have a halogen content > 60%.

IIIA 4.8 Disposal Procedures for the Plant Protection Product

IIIA 4.8.1 Detailed instructions for safe disposal of product and its packaging

This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/safety data sheet.

Spills: Use absorbent paper, or other inert absorbent, to soak up the spill. The contaminated paper/absorbent should be sealed in a vapour-tight plastic bag before disposal. Prevent the liquid from entering drains and sewers. Large spills may be pumped into containers for disposal.

Waste code:

Do not contaminate ponds, waterways or ditches with chemical or used container. Disposal must be via a suitably licensed/permitted facility e.g. treatment facility or landfill site.

Packing must be disposed of in the same manner as the product.

IIIA 4.8.2 Methods other than controlled incineration for disposal

Waste code:

Do not contaminate ponds, waterways or ditches with chemical or used container. Disposal must be via a suitably licensed/permitted facility e.g. treatment facility or landfill site.

Packing must be disposed of in the same manner as the product.

Data to establish the effectiveness and safety of these methods is not specifically available for BIOX-M, as these methods are standard processes.

IIIA 4.9 Other/Special Studies

No additional studies were performed.

IIIA 11 FURTHER INFORMATION

IIIA 11.1 Information of Authorisations in Other Countries

For details please refer to Section 7: Efficacy Data and Information.

IIIA 11.2 Information on Established Maximum Residue Limits (MRL) in Other Countries

At European Level spearmint oil is temporarily included in Annex IV of Regulation (EC) No 396/2005 (see: EU Pesticides database, as published on June 8, 2010, Internet: http://ec.europa.eu/sanco_pesticides/public/index.cfm).

No specific MRLs are required.

IIIA 11.3 Justified Proposals for Classification and Labelling

Proposals for classification and labelling of BIOX-M in accordance with the EC Directive on dangerous preparations 1999/45/EC and Directive 2001/59/EC (as amended) are presented below:

Physico-chemical properties

Table 11.3-1 Physico-chemical properties

Study Type	Findings (triggered risk phrase)	Reference
Explosivity	Not explosive (-)	statement
Oxidizing properties	Not oxidizing (-)	statement
Flammability	not auto-flammable	statement

Toxicology

(Classification and labelling under Directive 99/45/EC)

Xn Harmful

Ecotoxicology/Environment

Table 11.3-3 Ecotoxicology/Environment

Study Type (duration)	**Results (triggered risk phrase)**	**Reference**
Invertebrates (Daphnia magna)	LC_{50} = 9,59 mg/L **(R 51)**	QSAR estimation
Biodegradation	The product contains the active substance carvone, which is not readily biodegradable **(R 53)**	QSAR estimation

IIIA 11.4 Proposals for Risk and Safety Phrases

Risk Phrases:
R43 May cause sensitisation by skin contact
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R65 Harmful: may cause lung damage if swallowed

Safety phrases:
S2 S 2: Keep out of the reach of children
S13 Keep away from food, drink and animal feeding stuffs
S20/21 When using do not eat, drink or smoke
S24 Avoid contact with skin
S35 This material and its container must be disposed of in a safe way.
S36/37 Wear suitable protective clothing and gloves.
S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.
S62 If swallowed, do not induce vomitting. Seek medical advice immediately and show this container or label

SP001 To avoid risks to man and the environment, comply with the instructions for use.

IIIA 11.5 Proposed Label

Please refer to Registration Report – Part A.

IIIA 11.6 Specimens of Proposed Packaging

Specimens of the packaging were not provided as there was no request.

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Appendix 1: List of data used in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 4.1.1/01	Anonymous	2001	PACKAGING SPECIFICATION 5 L JERRYCAN - Xeda International S.A. Report-no. n/a GLP/GEP: no Published: no	yes	XED	1
KIIIA 4.1.1/02	Anonymous	2009a	PACKAGING SPECIFICATION 10 L JERRYCAN - Xeda International S.A. Report-no. n/a GLP/GEP: no Published: no	yes	XED	1
KIIIA 4.1.1/03	Anonymous	2009b	PACKAGING SPECIFICATION 20 L JERRYCAN - Xeda International S.A. Report-no. n/a GLP/GEP: no Published: no	yes	XED	1
KIIIA 4.4.1/01	Anonymous	2010	MATERIAL SAFTEY DATA SHEET - BIOX-M - Xeda International S.A. Report-no. version No 3 GLP/GEP: no Published: no	yes	XED	1

Annex point/ reference No	**Author(s)**	**Year**	**Title** **Source (where different from company)** Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	**Data protection claimed**	**Owner**	**How considered in dRR** Study-Status / Usage*
IIIA 2.1 2.3.1 2.4.1 2.4.2 2.5.1 2.5.3 2.6.1 2.7.1 2.7.4	Servajean, E.	2005a	GLP ANALYSIS OF THE PHYSICO-CHEMICAL PROPERTIES OF SPEARMINT OIL HN. PART 1: PHYSICO-CHEMICAL PROPERTIES UPON RECEIPT AND AFTER ACCELERATED STORAGE CONDITIONS Phytosafe s.a.r.l., Pau, France Xeda International S.A. Report-no. 05-13-007-ES-Part 1 GLP: yes Published: no	yes	XED	1
IIIA 2.7.5	Servajean, E.	2005b	GLP ANALYSIS OF THE PHYSICO-CHEMICAL PROPERTIES OF A HN FORMULATION PART 2: PHYSICO-CHEMICAL PROPERTIES AFTER 24 MONTHS OF STORAGE AT ROOM TEMPERATURE Phytosafe s.a.r.l., Pau, France Xeda International S.A. Report-no. 05-13-007-ES-Part 2 GLP: yes Published: no	yes	XED	1

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2: Critical Uses – justification and GAP tables

GAP-Table of intended uses for Germany

GAP rev. 1, date: 2011-12-30

PPP (product name/code)	**BIOX-M**	**Formulation type:**	**HN**
active substance 1	**Spearmint oil**	**Conc. of as 1:**	930 – 950 **g/L**
safener -		**Conc. of safener:**	**-**
synergist	**-**	**Conc. of synergist:**	**-**
Applicant:	**XEDA International S. A.**	**professional use**	☒
Zone(s): EU		**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	Germany	Potato (SOLTU) Except seed potato	F	Sprout suppression (YKEIM)	Thermal fogging	After beginning of storage	a) 11 (21 days) b) 11	a) first treatment 90 ml/t from second treatment 30 ml/t b) 390 ml/t	a) 85.32 g as/t 28.44 g as/t b) 369.72 g as/t			No authorization in Germany

GAP-Table of intended uses for all other MS

GAP rev. 1, date: 2011-12-30

PPP (product name/code)	**BIOX-M**	**Formulation type:**	**HN**
active substance 1	**Spearmint oil**	**Conc. of as 1:**	**930-950 g/L**
safener -		**Conc. of safener:**	**-**
synergist	**-**	**Conc. of synergist:**	**-**
Applicant:	**XEDA International S. A.**	**professional use**	☒
Zone(s):EU		**non professional use**	☐

Verified by MS: no

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	mL a.s./t min max	water L/ha min max	g as/ha min max		
Potatoes	Central (Germany)	BIOX-M	I	Sprouting	HN	930 - 950 g/L	Thermal fogging	Post harvest (BBCH 99)	1 to 11	3 weeks	30-90 (corresp. to 30 – 90 mL product/tonne)	N/A	N/A	N/A	Post harvest treatment Initial application of 90 mL product /t between 6 and 15 days after harvesting followed by 10 subsequent applications of 30 mL product /tonne at 21-days intervals

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: BIOX-M

Active Substance: Spermint Oil 930 - 950 g/L

All Zones
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: XEDA International S.A.

Date: Sept/2015

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for the plant protection product BIOX-M containing the active substance spearmint oil in its intended uses in potatoes according to Appendix 3.

National Addenda are included containing country specific assessments for some annex points.

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation BIOX-M

plant protection product	BIOX-M
applicant	XEDA International S.A.
date of application	Not applicable, indoor treatment for storage
Formulation type (WP, EC, SC, …; density)	HN
active substance	Spearmint Oil
Concentration of as	945 g/L

5.2 Proposed use pattern

The critical GAP used for exposure assessment is presented in Table 5.2-1. It has been selected from the individual GAPs for the EU in the intended uses in potatoes. A list of all intended uses within the EU is given in Appendix 3.

Table 5.2-1: Critical use pattern of BIOX-M

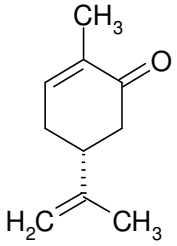
Crop	**Application method**	**Number of applications, Minimum application interval, application timing, growth stage, interception**	**Application rate, cumulative**	**Soil effective application rate, cumulative**
Potatoes (exept seed potatoes)	Thermal fogging	11 applications 21 d intervall BBCH 99 (post harvest) 100% interception	1 x 90 ml/t + 10 x 30 ml/t = 390 ml/t BIOX-M 1 x 85.05 g/t + 10 x 28.35 g/t = 368.55 g/t Spearmint oil	Not applicable, indoor treatment

5.3 Information on the active substance

5.3.1.1 Identity, further information of Spearmint oil

Table 5.3-1: Identity, further information on spearmint oil

Active substance (ISO common name)	Spearmint oil (not ISO)
IUPAC	IUPAC-name not applicable for spearmint oil, since it is a mixture of several different compounds For main constituent (R)-carvone (55 – 80% according to DAR, Vol 1 (2007)): (R)-5-isopropenyl-2-methylcyclohex-2-en-1-one
Function (e.g. fungicide)	plant growth regulator
Status under Reg. (EC) No 1107/2009	Approved
Date of approval	01/09/2009
Conditions of approval	PART A Only uses as plant growth regulator for postharvest treatment of potatoes may be authorised. Member States shall ensure that authorisations provide that hot fogging is performed exclusively in professional storage facilities and that the best available techniques are applied to exclude the release into the environment of the product (fogging mist) during storage, transport, waste disposal and application. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on plant oils/spearmint oil (SANCO/2624/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures
Confirmatory data	None
RMS	SE
Minimum purity of the active substance as manufactured (g/kg)	Spearmint Oil is a multi-component active substance of naturally variable composition and thus a purity specification for the active substance in the normal sense is not feasible.
Molecular formula	For spearmint oil: Not applicable For main constituent (R)-carvone : $C_{10}H_{14}O$
Molecular mass	Not applicable for spearmint oil For main constituent (R)-carvone : 150.21 g/mol
Structural formula	Structural formula Not applicable for Spearmint oil (R)-Carvone main constituent of Spearmint oil:

5.3.1.2 Physical and chemical properties of Spearmint oil

Physical and chemical properties of spearmint oil as agreed at EU level (see SANCO/2624/08 – rev 2, 01/06/2012 and the herein cited EFSA conclusion with LoEP EFSA Journal 2012: 10(2):2541) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of spearmint oil relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 25 °C in Pa)	No data for Spearmint oil Estimation with MPBPWIN v 1.42 for R-Carvone: 17.3	SANCO/2624/08 – rev 2, 01/06/2012 SANCO/2624/08 – rev 2, 01/06/2012
Henry's law constant (at 25 °C in ($Pa \times m^3 \times mol^{-1}$)	No data for Spearmint oil Estimation with HENRY v3.10 for R-Carvone: 7.1 – 7.8	SANCO/2624/08 – rev 2, 01/06/2012 DAR Vol3, B8
Solubility in water (at 25 °C in mg/L)	No data for Spearmint oil Estimation with WSKOW v.1.41 for R-Carvone: 367.1 Estimation with EPIWIN v3.20 for R-Carvone: 1310	SANCO/2624/08 – rev 2, 01/06/2012 SANCO/2624/08 – rev 2, 01/06/2012 DAR Vol3, B8
Partition co-efficient, log P_{OW}	No data for Spearmint oil For Carvone: 2.4	SANCO/2624/08 – rev 2, 01/06/2012 DAR Vol1, B8
Dissociation constant, pKa	No data for Spearmint oil Not applicable for Carvone	SANCO/2624/08 – rev 2, 01/06/2012 DAR Vol3, Appendix 4
Hydrolytic degradation	No data available	SANCO/2624/08 – rev 2, 01/06/2012

Aquous photolytic degradation	No data available	SANCO/2624/08 – rev 2, 01/06/2012
Quantum yield of direct phototransformation in water > 290 nm	No data available	SANCO/2624/08 – rev 2, 01/06/2012
Photochemical oxidative degradation in air (calculation according to Atkinson)	For carvone: DT_{50} =1.5 – 3 h (AOP version: v1.92, 0.5 × 10^6 radicals/cm³, 24 h day) For R-limonene: DT_{50} =0.884 h (AOP version: v1.92, 1.5 × 10^6 radicals/cm³, 12 h day)	SANCO/2624/08 – rev 2, 01/06/2012

5.3.1.3 Metabolites of Spearmint oil

No metabolism studies with Spearmint oil in soil or water/sediment systems were submitted for Annex 1 inclusion. Spearmint oil is a multi-component active substance consisting of 28 different compounds. The main constituent is (R)-carvone (alternative names: L-carvone, (-)-carvone). with 55 – 80% w/w. All other compounds (e.g. R-limonene) of the active substance were given in concentration ranges <10% w/w (SANCO/2624/08 – rev 2, 01/06/2012). Thus, the zRMS considers it as acceptable to use (R)-carvone as exemplary substance to assess the environmental fate of Spearmint oil for the intended used of the plant protection product BIOX-M.

5.4 Summary on Input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

No studies are available regarding the route and rate of degradation in soil of Spearmint oil. For Annex 1 inclusion of Spearmint oil, the degradation of the predominant component of Spearmint oil, (R)-carvone, in soil was estimated using quantitative structure activity relationship calculations (QSAR). The estimated DT_{50} of R-Carvone in soil estimated by a Level III Fugacity model is 30 d (SANCO/2624/08 – rev 2, 01/06/2012).

5.4.1.2 Field studies

No field studies with Spearmint oil are available for this assessment.

5.4.2 Adsorption/desorption

No studies on the adsorption/ desorption of Spearmint oil or its main constituent R-Carvone in soil are available. For Annex 1 inclusion of Spearmint oil, the adsorption of (R)-carvone in soil was estimated

using QSAR. The estimated Koc values for (R)-carvone are between 124 (PCKOC v1.66) - and 210 (Level III Fugacity Model) (References: SANCO/2624/08 – rev 2, 01/06/2012 & DAR, Vol3, B8)

5.4.3 Rate of degradation in water

No water/sediment studies with Spearmint oil or its main constituent R-Carvone are available. For Annex 1 inclusion of Spearmint oil, the degradation of (R)-Carvone in water and sediment was estimated using QSAR. The estimated DT50 value of (R)-carvone in water is 15 d, the estimated half life in sediment is 135 d by the Level III Fugacity model (Reference: SANCO/2624/08 – rev 2, 01/06/2012).

Since R-Carvone is volatile with an estimated vapour pressure of 17.3 Pa and an estimated Henry's constant of 7.1 – 7.8 Pa m3/mol (see Table 5.3-2), additional dissipation times from surface waters via volatilization were estimated. Volatilization DissT50 of R-Carvone from water in a river of 1 m depth, with current velocity of 1 m/sec and wind velocity of 5 m/sec has been estimated as ca. 10.5 hours, while its Volatilization DissT50 from water in a lake of 1 m depth, with current velocity of 0.05 m/sec and wind velocity of 0.5 m/sec has been estimated as ca. 9 days (Reference: DAR Vol 3, B8).

5.5 Estimation of concentrations in soil (PEC_{soil}) (KIIIA1 9.4)

Since Spearmint oil is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use. Besides, no use of BIOX-M on seed potatoes is intended for authorization in Germany. Thus no PECsoil values are required for BIOX-M or its active substance Spearmint oil.

5.6 Estimation of concentrations in surface water and sediment (PEC_{sw}/PEC_{sed}) (KIIIA1 9.7)

BIOX-M is intended to be used for a post-harvest indoor treatment. Thus, no direct exposure of surface water via spray drift, run-off or drainage is expected. However, three possible entry path ways of Spearmint oil into surface water have been identified by the ZRMS.

5.6.1 Entry via Volatilization with subsequent deposition

Since L-carvone, the main constituent of Spearmint oil, has an estimated vapour pressure of 17.3 Pa, it is considered highly volatile. A possible entry pathway of Spearmint oil into surface water is therefore volatilization of L-carvone from the depot during or after the treatment of the potatoes with subsequent deposition onto surface waters. According to the applicant, the depots used for treatment will not be closed gastight. They will be closed during and 2-3 days after application, but will be opened to the fresh air afterwards.

However, no agreed EU program for estimating the exposure of surface water by active substances via volatilization with subsequent deposition is available. An estimation of PECsw values from this entry path can be found in the National Addendum of Germany, where this pathway is usually included in the risk assessment.

5.6.2 Direct entry of wash water from treated potatoes

The active substance Spearmint oil could enter surface water, if treated potatoes are washed before further processing and the wash water is discharged directly into surface water bodies (after deposition of the soil in a sedimentation basin) instead of a sewage plant for further treatment.

However, a direct discharge of the wash water into a surface water body without previous treatment in a sewage plant is considered unlikely by the zRMS. For treatment of the wash water in a sewage plant, sufficient degradation of the active substance Spearmint oil is assumed by the zRMS.

5.6.3 Entry via run-off and drainage of residues from treated seed potatoes

Residues of Spearmint oil might enter surface waters when treated potatoes are used as seed potatoes. Therefore, an attempt was made to calculate worst case initial PECsw values for Spearmint oil using FOCUS SW Step 1&2.

Worst case initial PECsw calculations were performed on the assumption that treated seed potatoes with a maximum L-Carvone marker residue of 1.84 mg/kg are planted out leaving all of the volatile L-Carvone residues in the top 5 cm of soil. Residues of 1.84 mg/kg unpeeled potatoes were found in residues studies submitted for Annex 1 inclusion (see DAR, Vol3, B 7). Seed tuber planting rates are maximally 7.5 tonnes/ha for seed production/canning (McConnell (2003), Seed rate, Potatoes (Solanum tuberosum), The Agricultural Notebook (20th Edition), p. 111). Assuming 7500 kg of seed potatoes contain 1.84 mg/kg L-Carvone, the load to soil will be 7500 x 1.84 = 13800 mg/ha, equivalent to an application rate of 13.8 g/ha to the soil surface.

Substance specific input parameter for the main constituent of the active substance, L-carvone used for FOCUS SW calculations are summarized in Table 5.6-1. Estimated QSAR values have more uncertainty than experimentally measured values. Thus, EFSA suggests applying an uncertainty factor of 10 to the estimated DT_{50} and Koc values of L-carvone for calculating PEC values. However, L-carvone is very volatile and large amounts of the compound will not enter the surface water at the time when the run-off or drainage event occur but will have been released into the atmosphere instead. Thus, assuming a DT_{50} of 300 days in soil is considered an unrealistic worst case assumption by the zRMS. PECsw calculations for this assessment were therefore performed using the estimated DT_{50} value in soil without applying a safety factor and using default values or applying a QSAR factor according to the EFSA conclusion for the degradation in water/sediment systems and the Koc value.

Table 5.6-1: Input parameters for L-carvone, the main constituent of the active substance Sparmint oil for $PEC_{SW/sed}$ calculations

Parameter	Endpoint used for $PEC_{SW/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Water solubility (mg/L)	367.1	not stated	Estimated value (see Table 5.3.2)
$DT_{50,soil}$ (d)	30	no	Estimated value (see Point 5.4.1.1)
$DT_{50,wholesystem}$ (d)	1000	yes	default
$DT_{50,water}$ (d)	1000	yes	default
$DT_{50,sed}$ (d)	1000	yes	default
$K_{f,oc}$ (mL g^{-1})	12.4	yes	Estimated value (see Point 5.4.2) divided by 10 (uncertainty factor)

Application related input parameters and results of FOCUS SW Step1&2 calculations for the worst-case scenario are summarized in Table 5.6-2.

Table 5.6-2: Summary of highest global maximum FOCUS surface water PEC_{SW} and PEC_{sed} values

Plant protection product:	BIOX-M
Active Substance	L-Carvone as main conistituent of Spearmint oil
Crop	No drift (incorporation or seed treatment)

Crop interception	No interception	
Application time	March to May	
Number of applications	1	
Application rate:	13.8 g/ha	
FOCUS STEP 1	**PEC_{SW} (µg/L)**	**PEC_{SED} (µg/kg)**
	Actual, 0 h	**Actual, 0 h**
	4.5252	0.5611
FOCUS STEP 2 Scenario	**PEC_{SW} (µg/L)**	**PEC_{SED} (µg/kg)**
	Actual, 0 h	**Actual, 0 h**
Southern Europe, Mar - May	1.6503	0.2046
Northern Europe, Mar - May	0.8251	0.1023

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance (Tier 1 and 2)

Groundwater contamination by direct leaching of active substances and their metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

BIOX-M is intended to be used for a post-harvest indoor treatment. Thus, no direct exposure of groundwater by direct leaching through soil is expected. However, Residues of Spearmint oil might enter the groundwaters when treated potatoes are used as seed potatoes. Therefore, an attempt was made to calculate worst case initial PECgw values for Spearmint oil using FOCUS PELMO 5.5.3.

PECgw calculations were performed on the assumption that treated seed potatoes with a maximum L-Carvone marker residue of 1.84 mg/kg are planted out leaving all of the volatile L-Carvone residues in the top 5 cm of soil. Seed tuber planting rates are maximally 7.5 tonnes/ha for seed production/canning (McConnell (2003), Seed rate, Potatoes (Solanum tuberosum), The Agricultural Notebook (20th Edition), p. 111). Assuming 7500 kg of seed potatoes contain 1.84 mg/kg L-Carvone, the load to soil will be 7500 x 1.84 = 13800 mg/ha, equivalent to an application rate of 13.8 g/ha to the soil surface.

Substance specific input parameter for the main constituent of the active substance, L-carvone used for FOCUS SW calculations are summarized in Table 5.7-1. Estimated QSAR values have more uncertainty than experimentally measured values. Thus, EFSA suggests applying an uncertainty factor of 10 to the estimated DT_{50} and Koc values of L-carvone for calculating PEC values. However, L-carvone is very volatile and large amounts of the compound will be released into the atmosphere before leaching into deeper soil layers. Thus, assuming a DT_{50} of 300 days in soil is considered an unrealistic worst case assumption by the zRMS. PECgw calculations for this assessment were performed using the estimated DT_{50} value in soil without applying a safety factor and only applying the QSAR factor according to the EFSA conclusion to the estimated worst-case Koc value.

Table 5.7-1: Input parameters related to active substance for PEC_{GW} modelling

Parent	**L-Carvone as main consituent of Spearmint oil**	**Remarks/Reference**
molecular mass	150.21 g/mol	See Table 5.3-2
DT_{50} in soil (d)	30	estimated value (see 5.4.1.1)

K_{foc}	12.4	Estimated value (see Point 5.4.2) divided by 10 (uncertainty factor)
1/n	1.0	Default factor for compounds without measured K_f values
Plant Uptake factor	0	Default for non-systemic active substances

The application related input parameter for the groundwater modeling are summarized in Table 5.7-2.

Table 5.7-2: Input parameters related to application for PEC_{GW} modelling

crop	potatoes
application rate (kg as/ha)	0.0138
Application depth (cm)	5
date of application	5 days before 1st emergence in the year
interception (%)	0
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
simulation period (years)	26

The results of the groundwater simulation for L-carvone, the main constitutent of the active substance Spearmint oil for the case that treated potatoes are used as seed potatoes are summarized in Table 5.7-3.

Table 5.7-3: PEC_{GW} at 1 m soil depth for L-carvone, the main constituent of Spearmint oil

crop	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3**
		L-carvone
Seed potatoes	**Châteaudun**	0.317
	Hamburg	0.532
	Jokioinen	0.730
	Kremsmünster	0.496
	Okehampton	0.492
	Piacenza	0.236
	Porto	0.204
	Sevilla	0.104
	Thiva	0.134

According to the PEC_{GW} modeling with FOCUS PELMO 5.5.3, a groundwater contamination with L-carvone the main constituent of Spearmint oil at a concentration of ≥ 0.1 µg/L cannot be excluded for the FOCUS groundwater scenarios Châteaudun, Hamburg, Joikoinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva in cases where with Spearmint oil treated potatoes are used as seed potatoes.

5.7.2 Higher tier leaching assessment (Tier 3)

No lysimeter or field leaching studies with Spearmint oil are available.

5.7.3 Summary of risk assessment for ground water

BIOX-M is intended to be used for a post-harvest indoor treatment. Thus, no direct exposure of groundwater by direct leaching through soil is expected. However, Residues of Spearmint oil might enter the groundwater when treated potatoes are used as seed potatoes.

Results of modeling with FOCUS PELMO 5.5.3 show that a groundwater contamination with L-carvone the main constituent of Spearmint oil at a concentration of ≥ 0.1 µg/L cannot be excluded for the FOCUS groundwater scenarios Châteaudun, Hamburg, Joikoinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva in cases where with Spearmint oil treated potatoes are used as seed potatoes.

5.8 Potential of active substance for aerial transport

The vapour pressure at 20 °C of the L-carvone, the main constituent of the active substance Spearmintoil is > 10^{-4} Pa. Hence L-carvone is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of surface water and terrestrial non-target areas by l-carvone due to deposition following volatilization should be considered in cases where the intended use takes place in depots without sufficient air filtering. For the estimated deposition of Spearmint oil on terrestrial non-target areas and surface waters for the intended use of BIOX-M see Point 5.6.1.1 of this document.

Appendix 1 List of data submitted in support of the evaluation

During the objection process the company submitted one study.

Annex point/reference No	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Report-No.** **GLP or GEP status (where relevant),** **Published or not** **Authority registration No**	**Data protection claimed**	**Owner**	**How considered in dRR Study-Status/ Use**
KIIIA1 7.11	Bartolomé, J.	2009	Spearmint Oil: Determination of atmospheric concentrations of Spearmint Oil (Marker residue L-Carvone) applied to commercially stored potatoes in the UK in 2008 WMS0005 GLP	Y	XEDA	Accepted
KIIA 7.7	Servajean, E.	2015	Ready biodegradability of Biox-M, Closed-bottle test (CEE C4.e)	Y	XEDA	Accepted

Appendix 2 Detailed evaluation of studies relied upon

Appendix 3 Table of Intended Uses justification and GAP tables

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Potatoes (SOLTU) Exept seed potato	All zones (Germany)	BIOX-M	I	Sprouting	HN	930 - 950 g/L	Thermal fogging	Post harvest (BBCH 99)	1 to 11	3 weeks	30-90 (corresp. to 30 – 90 mL product/tonne)	N/A	N/A	N/A	Post harvest treatment Initial application of 90 mL product /T between 6 and 15 days after harvesting followed by 10 subsequent applications of 30 mL product /tonne at 21-days intervals

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: BIOX-M

Active Substance: Spermint Oil 930 - 950 g/L

All Zones
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: **XEDA International S.A.**

Date: **Sept/2015**

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product BIOX-M in its intended uses in potatoes is documented in detail in the core assessment of the plant protection product BIOX-M dated from the 07/09/2012 performed by Germany.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product BIOX-M in Germany according to uses listed in Appendix 3.

Regarding PECgw relevant risk mitigation measures, if necessary, are documented in this document. PECsoil, PECsw are used for risk assessment to derive specific risk mitigation measures if necessary (see Part B Section 6 National addendum and Part A).

5.1 General Information on the formulation

For general information on the formulation BIOX-M please refer to Table 5.1-1 of the Core Assessment, Part B, Section 5.

5.2 Proposed use pattern

For administrative purposes, each intended use of a new plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 2 of this Addendum.

The critical use patterns of BIOX-M in its intended use in potatoes used for exposure assessment in Germany are presented in Table 5.2-1. The first column summarizes the use numbers of the intended uses, that are covered with the respective critical use pattern.

Table 5.2-1: Classification of intended uses in Germany for BIOX-M

use No	Crop	Application method Drift scenario	Number of applications Minimum application interval Application time/ growth stage interception	Application rate, cumulative	Soil effective application rate, cumulative
00-001	Potatoes except seed potatoes	Thermal fogging/ Indoor	11 applications 21 d intervall BBCH 99 (post harvest) 100% interception	1 x 90 ml/t + 10 x 30 ml/t = 390 ml/t	Not applicable, indoor treatment

5.3 Information on the active substances

5.3.1.1 Identity, further information of Spearmint oil

Please refer the core assessment, part B, section 5, point 5.3.1.1 of the plant protection product BIOX-M.

5.3.1.2 Physical and chemical properties of Spearmint oil

Please refer the core assessment, part B, section 5, point 5.3.1.2 of the plant protection product BIOX-M.

5.3.1.3 Metabolites of Spearmint oil

Please refer the core assessment, part B, section 5, point 5.3.1.3 of the plant protection product BIOX-M.

Summary on input parameters for environmental exposure assessment

5.4 Summary on Input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

Please refer the core assessment, part B, section 5, point 5.4.1 of the plant protection product BIOX-M.

5.4.2 Adsorption/desorption

Please refer the core assessment, part B, section 5, point 5.4.2 of the plant protection product BIOX-M.

5.4.3 Rate of degradation in water

Please refer the core assessment, part B, section 5, point 5.4.2 of the plant protection product BIOX-M.

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Since Spearmint oil is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use. Besides, no use of BIOX-M on seed potatoes is intended for authorization in Germany. Thus no PECsoil values are required for BIOX-M or its active substance Spearmint oil.

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

BIOX-M is intended to be used for a post-harvest indoor treatment. Thus, no direct exposure of surface water via spray drift, run-off or drainage is expected. Besides, no use of BIOX-M on seed potatoes is intended for authorization in Germany. Thus, only two of the identified entry path ways in the core assessment are applicable for the intended use 00-001 in Germany: (i) entry via volatilization with subsequent deposition and (ii) Direct entry of wash water without treatment in a sewage plant.

5.6.1 Entry via Volatilization with subsequent deposition

L-carvone, the main constituent of Spearmint oil, has an estimated vapour pressure of 17.3 Pa and is thus considered highly volatile. The calculation of PECsw after exposure via volatilization with subsequent deposition of volatile substances is usually performed using the model EVA 2.1. However, regarding the indoor use of plant protection products, EVA 2.1 is only applicable for assessing the use in greenhouses, where application rates occur to plants in g/ha surface area. BIOX-M is intended to be used in storage depots that will be completely filled with potatoes. Thus, an application rate in g/ha is not available or applicable.

Thus, an attempt was made by the zRMS to estimate the amount of Spearmint oil deposited to surface water and terrestrial non- target areas after volatilization from the depot using an approach from Tintrup

gen. Suntrup et al (2004)[1]. Tintrup gen. Sintrup (2004) developed an empirical model for estimating the deposition of active substances from plant protection products with a vapour pressure of > 1 Pa at 20°C from depots. In their experiment, they measured a deposition of 1.256%/m^2 of the applied quantity/m^3 depot at a 5 m distance for the active substance dichlorvos, which exhibits a vapour pressure similar to the vapour pressure of L-carvone. In order to extrapolate the deposition for greater distances, they developed the equation $y = 129.5e^{-0,0576x}$ where y is the percentage deposited per m^2 surface area and x is the relative variation from the 5 meter value in %. The equation is based on deposition measurements of dichlorvos at 5, 20 and 50 m distance to the depot.

To estimate the amount of Spearmint oil used in a depot for a single application, it was assumed that a depot would be filled to 50% with potatoes. As average bulk volume of potatoes, 0.75 t/m^3 was used. Thus, for the maximum single application rate of 90 ml BIOX-M per t potatoes according to the critical use, 54 ml BIOX-M would be used per m^3 depot. For a concentration of 945 g Spearmint oil per litre BIOX-M, this amounts to 31.9 g Spearmint oil per m^3 depot.

However, an additional study Bartolomé (2009) was submitted that determined the concentration of L-Carvone, the main constituent of Spearmint oil, in a box storage depot immediately after application and 2h after application using the same application rate. Immediately after application, the authors measured an average of 1485 mg/m^3 L-Carvon in the air. However, already after 2 h this declined to an average of 18 mg/m^3 thus showing an dissipation of over 98%. Since the storage depot is only expected to be vented about 2-3 days after application, the measured 18 mg/m^3 can be assumed as worst case when estimating the PECsw values for Spearmint oil.

Assuming a standard water body with a depth of 0.3 m, a length of 100 m and a width of 1 m (Volume = 300 l/m^2) according to the dimensions used in FOCUS SW Step 1 calculations, PECsw values can be calculated from the derived deposition values. The derived deposition values together with the calculated PECsw values are summarized in Table 5.6-1.

Table 5.6-1: Estimated deposition of Spearmint oil at different distances from the depot and derived PECsw values for the deposition of Spearmint oil on surface water

Distance from Depot (m)	Deposition (% per m^2)	Deposition (g/m^2)	PECsw [mg/L]
0	1.627	0.00030	0.00100
5	1.256	0.00023	0.00077
10	0.914	0.00017	0.00056
20	0.514	0.00009	0.00032
50	0.091	0.00002	0.00006

5.6.2 Direct entry of wash water from treated potatoes

For authorization of BIOX-M in Germany, not use on seed potatoes is intended. Potatoes treated with BIOX-M are only intended for industrial processing. Thus, the washing of the potatoes would take place at the industrial plant. For these plants a sewage plant for waste water treatment is mandatory. Since BIOX-M is not intended to be used on seed potatoes for German authorization, an direct entry of wash water containing Spearmint oil into a surface water is not expected.

[1] Tintrup gen. Suntrup, G., Fent, G., Kubiak, R.: "Emission of Pesticides from buildings - Validation of a volatilisation model for the short range deposition"; August 13, 2004, Sponsoring Agency: UBA (German Federal Environmental Agency); UFOPLAN-Ref. No.: FKZ 360 03 026; UBA-Texte 47/2004

For treatment of the wash water in a sewage plant, sufficient degradation of the active substance Spearmint oil is assumed.

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Since Spearmint oil is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use. Besides, no use of BIOX-M on seed potatoes is intended for authorization in Germany. Thus, groundwater contaminations with the active substance Spearmint oil via direct leaching or via surface run-off or drainage or via direct leaching are not expected for the intended use 00-001 of BIOX-M and no modeling has been performed

Consequences for authorization:

None

Appendix 1 List of data submitted in support of the evaluation

No additional data have been submitted for national assessment.

Appendix 2 Detailed evaluation of studies relied upon

No additional data have been submitted for national assessment.

Appendix 3 Table of Intended Uses in Germany (according to BVL 26/08/2011)

PPP (product name/code) BIOX-M **Formulation type:** **HN**
active substance 1 **Spearmint Oil** **Conc. of as 1:** **948 g/L**

Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	mL product / tonne a) max. rate per appl. b) max. total rate per crop/season	ml as/t a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
00-001	DE	Potatoes with the exception of seed potatoes	I	Prevention of Sprouting	Thermal fogging	Post harvest	a) & b) 11 (21 d intervall)	a) & b) first treatment: 90 ml/t subsequent treatments: 30 ml/t	a) & b) first treatment: 90 ml/t subsequent treatments: 30 ml/t	N/A	N/A	

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies

Detailed summary of the risk assessment

Product code: BIOX-M
Active Substance: Spermint Oil 930 - 950 g/L

All Zones
Zonal Rapporteur Member State: Germany (DE)

CORE ASSESSMENT

Applicant: XEDA International S.A.
Date: September 2015

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Sec 6 ECOTOXICOLOGICAL STUDIES

This document reviews the ecotoxicological studies for the product BIOX-M containing the active substance Spearmint Oil, which is currently approved under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fulfills the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2.

BIOX-M was the representative formulation considered in the EU review process as part of the approval of the Spearmint Oil.

A full risk assessment according Commission Regulation (EU) No 546/2011 is provided.

Addenda are included containing country specific assessments for some annex points. In those cases this document should be read in conjunction with the relevant addenda.

Where appropriate, this document refers to the conclusions of the EFSA, especially when data on the active substance is relied upon in the risk assessment of the formulation. Each section will begin with a table providing the EU endpoints used in this evaluation.

Appendix 1 of this document contains the list of references included in this document in support of the evaluation.

Appendix 2 of this document reports the detailed evaluation of studies relied upon.

Appendix 18 of this document is the table of intended uses for BIOX-M.

Information on the detailed composition of BIOX-M can be found in the confidential dossier of this submission (Registration Report - Part C).

6.1 Proposed use pattern and considered metabolites

Introduction

Section 6 of the submission summarises the ecotoxicological effects of the formulation BIOX-M containing the active substance Spearmint oil and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms. Full details or the proposed use patterns that will be assessed are shown in Appendix 3 of this document and summarized below. Moreover, an overview of the metabolites of Spearmint oil that will be addressed in the risk assessment is given below.

6.1.1 Proposed use pattern

The critical GAP used for exposure assessment is presented in Table 6.1-1. It has been selected from the individual GAPs for the EU in the intended uses in potatoes. A list of all intended uses within the EU is given in Appendix 3.

Table 6.1-1: Critical use pattern of BIOX-M

Crop	Application method	Number of applications, Minimum application interval, application timing, growth stage, interception	Application rate, cumulative	Soil effective application rate, cumulative
Potatoes (exept seed potatoes)	Thermal fogging	11 applications 21 d intervall BBCH 99 (post harvest) 100% interception	1 x 90 ml/t + 10 x 30 ml/t = 390 ml/t 1 x 85.05 g/t + 10 x 28.35 g/t = 368.55 g/t Spearmint oil	Not applicable, indoor treatment

6.1.2 Consideration of metabolites

No metabolism studies with Spearmint oil in soil or water/sediment systems were submitted for Annex 1 inclusion. Spearmint oil is a multi-component active substance consisting of 28 different compounds. The main constituent is (R)-carvone (alternative names: L-carvone, (-)-carvone). with 55 – 80% w/w. All other compounds (e.g. R-limonene) of the active substance were given in concentration ranges <10% w/w (SANCO/2624/08 – rev 2, 01/06/2012). Therefore, the occurrence and risk from potentially ecotoxicologically relevant metabolites (carvone (expected to (R)-carvone), (R)-limonene, dihydrocarveol (unstated stereochemistry), cis-dihydrocarveol acetate, trans-dihydrocarvone, ß-caryophyllene, and 22 other less prominent constituents) have not been considered in the EU review of Spearmint Oil.

6.2 Effects on Birds

6.2.1 Overview and summary

No avian acute oral and long-term reproduction studies are available with Spearmint Oil or the product BIOX-M.

Effects on birds of BIOX-M were not evaluated as part of the EU review of Spearmint Oil. However, the provision of further data on the formulation BIOX-M is not considered essential as the available data on Spearmint Oil are deemed to be sufficient to assess the risk of birds exposed to BIOX-M.

6.2.1.1 Toxicity

No avian acute oral and long-term reproduction studies are available with Spearmint Oil or the product BIOX-M.

6.2.1.2 Exposure

Since Spearmint oil is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use.

BIOX-M is a formulation containing Spearmint Oil as active substance. The product is formulated as a suspension concentrate. It will be used only in indoor post-harvest treatments to control sprouting in potatoes.

6.2.1.3 Risk Assessment –overall conclusions

For risk assessment purposes, a risk envelope approach was used to cover highest risk for birds from the intended use (see also Table 6.1-1, page 5).

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is not required. Please refer to chapter 6.2.9.

6.2.2 Toxicity to exposure ratio for birds (K III A 10.2.1)

6.2.2.1 Acute toxicity to exposure ratio (TER_A)

Please refer to Point 6.2.1.

6.2.2.2 Short -term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for birds under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity will not be conducted.

6.2.2.3 Long-term toxicity exposure ratio (TER_{LT})

Please refer to Point 6.2.1.

6.2.3 Drinking water exposure

In case of indoor post-harvest treatments uses as intend for BIOX-M birds are not deemed to be exposed via drinking water from puddles.

6.2.4 Details on formulation type in proportion per item

6.2.4.1 Baits: Concentration of active substance in bait in mg/kg

Not applicable as BIOX-M is a hot fogging concentrate and not a bait.

6.2.4.2 Pellets, granules, prills or treated seed

Not applicable as BIOX-M is a hot fogging concentrate and not a pellet, granule, prill or treated seed.

6.2.5 Acute toxicity of the formulation

Avian toxicity tests with the formulation were not performed. Please refer to Point 6.2.1 for an overview of the risk assessment for birds.

6.2.6 Metabolites

Avian toxicity tests with metabolites of Spearmint Oil were not performed. Please refer to Point 6.2.1 for an overview of the risk assessment for birds.

6.2.7 Supervised cage or field trials

No further studies are considered necessary. Please refer to Point 6.2.1 for an overview of the risk assessment for birds.

6.2.8 Acceptance of bait, granules or treated seeds (palatability testing)

BIOX-M is intended for use as a hot fogging concentrate and therefore this information is not required.

6.2.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). The log K_{ow} value of Spearmint Oil was not evaluated. However, the log P_{OW} of L-Carvone is 2.4 (DAR Spearmint Oil, Vol. 1, List of endpoints, August 2008) but the log K_{ow} values may be >3 for other components of spearmint oil and metabolites of R-carvone.

Since Spearmint oil is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use, and exposure to birds, although possible, would be negligible. Although treated seed potato tubers are subsequently planted out, they are then covered by soil

and essentially unavailable to foraging birds, thus exposure to residues in the planted out potato tubers is contra-indicated.

Concerning the exposure via volatilization and deposition there is a possibility that Spearmint-oil evaporates out of the storage rooms through gaps in the building, when opening doors, ventilating or opening for fresh air. However, there is no agreed model in the EU, thus this scenario is only considered in the national addendum for Germany.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

6.3.1 Overview and summary

No mammalian acute study is available with Spearmint Oil or the product BIOX-M.

Effects on mammals of BIOX-M were not evaluated as part of the EU review of Spearmint Oil. However, the provision of further data on the formulation BIOX-M is not considered essential as the available data on Spearmint Oil are deemed to be sufficient to assess the risk of mammals exposed to BIOX-M.

6.3.1.1 Toxicity

A mammalian acute oral study has been carried out with L-Carvone. A summary of the relevant endpoint is provided below.

Table 6.3-1: Toxicity of L-Carvone to mammals with reference to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**
Rat	Spearmint Oil	Acute oral toxicity	LD50 >2000 mg a.i./kg bw/d[1]	Mullaney, 2005	none
Rat	L-Carvone	1 year chronic oral	NOAEL = 125 mg/kg BW/d[2]	Hagan et al., 1967	none

1) EFSA conclusion (active substance plant oils/spearmint oil), EFSA Journal 2012;10(2):2541

2) DAR Spearmint-oil June 2007, Vol. 3 B.6.10.3.1.1

6.3.1.2 Exposure

Since Spearmint oil is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use.

BIOX-M is a formulation containing Spearmint Oil as active substances. The product is formulated as a suspension concentrate. It will be used only in indoor post-harvest treatments to control sprouting in potatoes.

6.3.1.3 Risk assessment –overall conclusions

There is no requirement for the calculation of TER-values for indoor post-harvest applications for mammals under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438), thus a risk assessment has not been performed.

Drinking water risk assessment

An assessment of the risk from drinking water is not required. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is not required. Please refer to chapter 6.2.9.

6.3.2 Toxicity exposure ratio

6.3.2.1 Acute toxicity exposure ratio (TER_A)

Please refer to Point 6.3.1.

6.3.2.2 Short-term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for mammals under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity has not been performed.

6.3.2.3 Long-term toxicity exposure ratio (TER_{LT})

Please refer to Point 6.3.1.

6.3.3 Drinking water exposure

In case of indoor post-harvest treatments uses as intend for BIOX-M mammals are not deemed to be exposed via drinking water from puddles.

6.3.4 Details on formulation type in proportion per item

Please refer to section 6.2.4 for details on the formulation type of BIOX-M.

6.3.4.1 Baits: Concentration of active substance in bait in mg/kg

Please refer to section 6.2.4.

6.3.4.2 Pellets, granules, prills or treated seed

Please refer to section 6.2.4.

Amount of active substance in or on each item

Please refer to section 6.2.4.

Proportion of active substance LD50 per 100 items and per gram of items

Please refer to section 6.2.4.

Size and shape of pellet, granule or prill

Please refer to section 6.2.4.

6.3.5 Acute toxicity of the formulation

Mammal toxicity tests with the formulation were not performed and are not considered necessary. Please refer to section 6.3.1 for an overview of the risk assessment for mammals.

6.3.6 Metabolites

Mammal toxicity tests with metabolites of Spearmint Oil were not performed and are not considered necessary. Please refer to section 6.3.1 for an overview of the risk assessment for mammals.

6.3.7 Supervised cage or field trials

No further studies are considered necessary. Please refer to section 6.3.1 for an overview of the risk assessment for mammals.

6.3.8 Acceptance of bait, granules or treated seeds (palatability testing)

BIOX-M is intended for use as a hot fogging concentrate, and therefore this information is not required.

6.3.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). The log K_{ow} value of Spearmint Oil was not evaluated. However, the log POW of L-Carvone is 2.4 (DAR Spearmint Oil, Vol. 1, List of endpoints, August 2008) but the log K_{ow} values may be >3 for other components of spearmint oil and metabolites of R-carvone.

Since Spearmint-oil is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use, and exposure to mammals, although possible, would be negligible. Although treated seed potato tubers are subsequently planted out, they are then covered by soil and essentially unavailable to foraging mammals, thus exposure to residues in the planted out potato tubers is contra-indicated.

Concerning the exposure via volatilization and deposition there is a possibility that Spearmint-oil evaporates out of the storage rooms through gaps in the building, when opening doors, ventilating or opening for fresh air. However, there is no agreed model in the EU, thus this scenario is only considered in the national addendum for Germany.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

No aquatic study is available with Spearmint Oil or the product BIOX-M.

Effects on aquatic organisms of BIOX-M were not evaluated as part of the EU review of Spearmint Oil. The DAR on Spearmint oil (June 2007 Vol. 3 B.9.2) provides QSAR estimations (ECOSAR v0.99h) of the toxicity to aquatic organisms.

6.4.1.1 Toxicity

The endpoints (no experimental data available, values based on QSAR estimations (ECOSAR v0.99h)) for aquatic organisms relevant for the risk assessment are indicated in the following table.

Table 6.4-1: Ecotoxicological endpoints for aquatic species exposed to R-Carvone with indication to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Date author Report No.**	**ICS-No.**
Acute toxicity					
O.mykiss	R-Carvone	Acute	LC50 (96h) = QSAR estimation: 20.3-32.9 mg/L[1]	n.n.	none
Invertebrate (Daphnia magna)	R-Carvone	Acute	EC50 (96h) = QSAR estimation: 9.59-15.1 mg/L[1]	n.n.	none
Daphnia magna	Biox-M (81.16 % L-Carvone)	2 d acute	EC50 : 10.6 mg/L[2)] Mortality Nominal	Servajean, E. 2014 14-13-045-ES	87029
Algae	R-Carvone	Acute	EC50 (96h) = QSAR estimation: 4.58-7.36 mg/L[1]	n.n.	none
Desmodesmus subspicatus	Biox-M (81.16% L-Carvone)	72 h semistatic	ErC50 : 42.8 mg/L[2)] Growth rate EyC50 : 26.3 mg/L NOEyC : 11.3 mg/L Biomass real	Servajean, E. 2015 14-13-044-ES	87030
Chronic toxicity					
Freshwater fish	R-Carvone	Chronic	"Chronic toxicity value" = QSAR estimation: 1.092-2.034 mg/L[3)]	n.n.	none

Invertebrate (Daphnia magna)	R-Carvone	Chronic	"Chronic toxicity value" = QSAR estimation: 1.254-2.233 mg/L [3)]	n.n.	none
Algae	R-Carvone	Chronic	"Chronic toxicity value" = QSAR estimation: 2.063-3.214 mg/L [3)]	n.n.	none

1) EFSA conclusion (active substance plant oils/spearmint oil), EFSA Journal 2012;10(2):2541

2) New study submitted by the applicant

3) DAR Spearmint-oil June 2007, Vol. 3 B.9.2

6.4.1.2 Exposure

BIOX-M is a formulation intended to be used for a post-harvest indoor treatment containing Spearmint Oil as active substance. Thus, no direct exposure of surface water via spray drift, run-off or drainage is expected. However, several possible entry path ways of Spearmint oil into surface water have been identified and an attempt was made to calculate worst-case initial PECsw values for these path ways (see core assessment, part B, section 5, point 5.6. Since the possible entry path ways would happen at different occasions, they were calculated separately.

Aquatic organisms may be exposed to plant protection products as a result of emission from treated areas. When BIOX-M is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by volatilization with subsequent deposition, by direct entry of wash water from treated potatoes as well as via run-off and drainage from treated seed potatoes.

The predicted environmental concentrations in surface water (PEC_{SW}) have been calculated separately for the different entry routes based on the application rates of BIOX-M. For details see dRR CA Part B, Section 5.7.

Table 6.4-2: PECsw values for the deposition of Spearmint oil on surface water at different distances from the depot for possible entry paths

Run-off and drainage of residues from treated seed potatoes	FOCUS STEP 1	PEC_{SW} (µg/L), Actual, 0 h	4.5252
		PEC_{SED} (µg/kg), Actual, 0 h	0.5611
	FOCUS STEP 2 Southern Europe, Mar - May	PEC_{SW} (µg/L), Actual, 0 h	1.6503
		PEC_{SED} (µg/kg), Actual, 0 h	0.2046
	FOCUS STEP 2 Northern Europe, Mar - May	PEC_{SW} (µg/L), Actual, 0 h	0.8251
		PEC_{SED} (µg/kg), Actual, 0 h	0.1023

6.4.1.3 Risk assessment –overall conclusions

Based on the FOCUS Step 1 PECsw, the aquatic TER values for Spearmint Oil are above the trigger of 10, indicating a low and acceptable risk for aquatic organisms from Spearmint in the relevant FOCUS Surface Water Scenarios following application of BIOX-M at the proposed application rates.

TER values for the most sensitive aquatic organisms based on PEC_{SW} FOCUS calculations are summarized in the following table.

Table 6.4-3: Aquatic TER values for Spearmint Oil after applications of BIOX-M

Test organism	EC_{50} (µg/L)	Setting		Scenario / Distance	Max. PEC_{SW} worst case (µg/L)	TER_{LT}	Trigger value
Spearmint Oil							
Incertebrate (Daphnia magna)	10600	Run-off and drainage from treated seed potatoes	FOCUS Step 1	-	4.5252	2342	100
			FOCUS Step 2	N-EU, Mar.-May	1.6503	6423	
TER-values in bold are below the relevant trigger							

6.4.2 Toxicity to Exposure ratio

The risk for aquatic organisms exposed to Spearmint Oil was assessed according to the intended uses.

As first step, the initial maximum PEC_{SW} values (Step 1 and 2) were compared to the relevant acute and long-term toxicity endpoints available for Spearmint Oil. Based on all QSAR-estimations on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint for Spearmint Oil is EC_{50} = 9.59 mg Spearmint Oil/L (*Invertebrates).* Risk assessment is driven by this endpoint; the ratio endpoint/corresponding safety factor is higher for all other organisms.

In the table below, the TER values relative to the most sensitive endpoint of each organisms' group are given.

6.4-4: Aquatic organisms: PECsw for Spearmint Oil and relevant ecotoxicological endpoints for each organism' group.

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae
		QSAR	***QSAR***	***Daphnia magna***	***Daphnia magna***	***Desmodesmus subspicatus***
		LC_{50} (µg/L) 20300	**NOEC (µg/L) 1092**	**EC_{50} (µg/L) 10600**	**NOEC (µg/L) 1254**	**E_yC_{50} (µg/L) 26300**
FOCUS Step 1						
	4.5252	4486	241.3	2342	277.1	5812
FOCUS Step 2						
North Europe	1.6503	12300.8	661.7	6423	759.9	15936

South Europe	0.8251	24603.1	1323.5	12847	1519.8	31875
TER criterion		100	10	100	10	10

Based on the calculated concentrations of Spearmint Oil in surface water (PEC_{SW} FOCUS Step 1 and 2), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to Spearmint Oil according to the GAP of the formulation BIOX-M achieve the acceptability criteria TER ≥ 100 and TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of BIOX-M in post-harvest potatoes in storage rooms according to the label. However, an exposition via volatilisation and deposition as well as wash water is possible. Since there are no agreed models for the EU, these exposition scenarios are only considered in the national addendum for Germany.

6.4.3 Acute toxicity and chronic toxicity of the formulation

Please refer to section 6.4.1.1 for a summary of the provided studies on the effects of BIOX-M on aquatic organisms. Section 6.4.2, page 13, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

6.4.4 Metabolites of Spearmint Oil

Please refer to section 6.1.2, page 5 for the assessment of the metabolites of Spearmint Oil that was performed during peer review of the active substance in view of its approval.

There are no relevant metabolites of Spearmint Oil occurring in surface water or sediment.

6.4.5 Accumulation in aquatic non-target organisms

Bioaccumulation of Spearmint-oil under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

6.5 Effects on Bees

Effects on honey bees for BIOX-M were not evaluated as part of the EU review of Spearmint Oil. No data on BIOX-M or on Spearmint oil have been submitted by the applicant, because bees will not be exposed due to the solely indoor use of the product. A label is assigned stating that due to the manner in which authorisation governs application of the product, bees are not endangered.

6.6 Effects on Arthropods Other Than Bees

6.6.1 Overview and summary

Effects on arthropods other than bees for BIOX-M were not evaluated as part of the EU review of Spearmint Oil. No data on BIOX-M or on Spearmint oil have been submitted by the applicant.

6.6.1.1 Toxicity

No data on BIOX-M or on Spearmint oil have been submitted by the applicant.

6.6.1.2 Exposure

In field

Non-target arthropods living in the crop can be exposed to residues from BIOX-M by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items. Since BIOX-M is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use. Thus an in-field exposure has not been evaluated.

Off-field

Exposure of non-target arthropods living in non-target off-field areas to BIOX-M can only occur due to volatilisation and deposition by evaporating through gaps in the building, when opening doors or opening for fresh air. Since no data on non-target arthropods are available, no risk assessment could be conducted. However due to the high vapour pressure of the active ingredient Spearmint-oil it can be assumed that once deposition occurs, the substance will volatilise again and the effect on non-target arthropods is negligible.

6.6.1.3 Risk assessment –overall conclusions

No risk assessment on arthropods other than bees could be conducted due to the non-availability of data. However, because of the high vapour pressure the risk is assumed to be low. Once deposition occurs, Spearmint-oil will evaporate again and the effect on non-target arthropods is negligible.

6.7 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.7.1 Overview and summary

Earthworms, other soil non-target macro and mesofauna as well as soil organisms involved in the breakdown of dead organic matter will be exposed to plant protection products containing Spearmint Oil whenever contamination of soil may occur as a result of the intended uses of BIOX-M.

Effects on earthworms and other soil non-target organisms resulting from an exposure to Spearmint Oil / BIOX-M were not evaluated as part of the EU review of Spearmint Oil. No data for the assessment of the risk to earthworm and other soil non-target macro-and mesofauna from the intended uses of BIOX-M are provided here.

6.7.1.1 Exposure

Since BIOX-M is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use.

BIOX-M is a formulation containing Spearmint Oil as active substance. The product is formulated as a suspension concentrate. It will be used only in indoor post-harvest treatments to control sprouting in

potatoes. Hence, no direct exposure of the active substance to soil is expected in its intended use and consequently no risk assessment is performed.

6.7.2 Residue content of earthworms

The log Kow values of Spearmint Oil was not evaluated. However, the log POW of L-Carvone is 2.4 (DAR Spearmint Oil, Vol. 1, List of endpoints, August 2008) but the log K_{ow} values may be >3 for other components of spearmint oil and metabolites of R-carvone.

Since Spearmint oil is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use, and exposure to earthworms, although possible, would be negligible. Although treated seed potato tubers are subsequently planted out, they are then covered by soil and essentially unavailable to foraging birds, thus exposure to residues in the planted out potato tubers is contra-indicated. Thus, Spearmint Oil is not deemed to bioaccumulate in earthworms. Therefore, studies determining residue content of Spearmint Oil in earthworms are not necessary.

6.8 Effects on Soil Microbial Activity

6.8.1 Overview and summary

Soil microorganisms will be exposed to plant protection products containing Spearmint Oil whenever contamination of soil may occur as a result of the intended uses of BIOX-M. Since BIOX-M is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use, and exposure to soil microorganisms, although possible would be negligible.

Effects on soil microorganisms resulting from an exposure to Spearmint Oil / BIOX-M were not evaluated as part of the EU review of Spearmint Oil. No data for the assessment of the risk to soil microorganisms from the intended uses of BIOX-M were provided.

6.8.1.1 Toxicity

No data for the assessment of the risk to soil microorganisms from the intended uses of BIOX-M were provided by the applicant.

6.8.1.2 Exposure

Please refer to section 6.7.1.1 above for the predicted environmental concentrations in soil (PECsoil) of Spearmint Oil.

6.8.1.3 Risk assessment –overall conclusions

No data on the effects of Spearmint-oil on soil microbial activity is available, thus no risk assessment could be conducted. However, since BIOX-M is intended to be used for a post-harvest indoor treatment, no direct exposure of the active substance to soil is expected in its intended use, and exposure to soil microorganisms, although possible would be negligible.

6.9 Effects on Non-Target Plants

6.9.1 Overview and summary

Effects on non-target plants resulting from an exposure to Spearmint Oil / BIOX-M were not evaluated as part of the EU review of Spearmint Oil. Moreover, no data for the assessment of the risk to non-target plants from the intended uses of BIOX-M was provided by the applicant.

6.9.1.1 Toxicity

No data for the assessment of the risk to non-target plants from the intended uses of BIOX-M is available.

6.9.1.2 Exposure

Exposure of non-target plants in non-target off-field areas to BIOX-M can only occur due to volatilisation and deposition by evaporating through gaps in the building, when opening doors or opening for fresh air. Since no data on non-target plants are available, no risk assessment could be conducted. However due to the high vapour pressure of the active ingredient Spearmint-oil it can be assumed that once deposition occurs, the substance will volatilise again and the effect on non-target plants is negligible.

6.9.1.3 Risk assessment –TER values and overall conclusions

No risk assessment on non-target plants could be conducted due to the non-availability of data. However because of the high vapour pressure the risk is assumed to be low. Once deposition occurs, Spearmint-oil will evaporate again and the effect on non-target plants is negligible.

6.10 Other Non-Target Species (Flora and Fauna)

6.10.1 Overview and summary

6.10.1.1 Toxicity

6.10.1.2 Exposure

6.10.1.3 Risk assessment –overall conclusions

6.10.2 Toxicity to Exposure Ratio

6.11 Other/Special Studies

6.11.1 Laboratory studies

6.11.2 Field studies

Appendix 1 List of data submitted in support of the evaluation

During the objection process the company submitted two studies.

Annex point/reference No	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Report-No.** **GLP or GEP status (where relevant),** **Published or not** **Authority registration No**	**Data protection claimed**	**Owner**	**How considered in dRR Study-Status/ Use**
KIIA 8.3.1.1	Servajean, E.	2014	Daphnia sp. Acute immobilization test with Biox-M No. 14-13-045-ES GLP ICS-Lit. 87029	Y	XEDA	Accepted
KIIA 8.4	Servajean, E.	2015	Fresh water algae, growth inhibition test with Biox-M No. 14-13-044-ES GLP ICS-Lit. 87030	Y	XEDA	Accepted

Appendix 2 Detailed evaluation of studies relied upon

IIA 8.3 Toxicity to aquatic species other than fish

IIA 8.3.1 Acute toxicity to aquatic invertebrates

KIIA 8.3.1

Appendix 3	Reference:	Appendix 4	KIIA 8.3.1.1

Appendix 5 Report	Appendix 6 Servajean, E., 2014, Daphnia sp. Acue immobilization test with Biox-M Appendix 7 14-13-045-ES ICS- No. 87029

Appendix 8 Guideline(s):	Appendix 9 OECD Guideline for testing of chemicals, section 2, No. 202; "Daphnia sp., acute immobilisation test"

Appendix 10 Deviations:	Appendix 11 No

Appendix 12 GLP:	Appendix 13 Yes

Appendix 14	Acceptability:	Appendix 15	Yes

Appendix 16 Original study evaluation revised by zRMS	Appendix 17 No

Comments of zRMS

Study Comments:	The applicant has not provided a study summary, therefore it is not documented here. For details please see the original study report.
Agreed Endpoints:	EC_{50} (48 h, static)= 10.6 mg/L (nom.)

IIA 8.4 Effects on algal growth

KIIA 8.4

Reference:	KIIA 8.4
Report	Servajean, E., 2015, Fresh water algae, growth inhibitiontest with Biox-M 14-13-044-ES ICS- No. 87030
Guideline(s):	OECD Guideline for testing of chemicals, section 2, No. 201; "Freshwater alga and cyanobacteria, growth inhibition test"
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Comments of zRMS

Study Comments:	The applicant has not provided a study summary, therefore it is not documented here. For details please see the original study report.
Agreed Endpoints:	E_rC_{50} (static renewal, 72 h) = 42.8 mg/L (Growth rate, mean measured) E_yC_{50} (static renewal, 72 h) = 26.3 mg/L (Biomass, mean measured) NOE_yC (static renewal, 72 h) = 11.3 mg/L (Biomass, mean measured)

Appendix 18 Table of Intended Uses justification and GAP tables

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Potatoes (exept seed potatoes)	All zones (Germany)	BIOX-M	I	Sprouting	HN	930 - 950 g/L	Thermal fogging	Post harvest (BBCH 99)	1 to 11	3 weeks	30-90 (corresp. to 30 – 90 mL product/tonne)	N/A	N/A	N/A	Post harvest treatment Initial application of 90 mL product /T between 6 and 15 days after harvesting followed by 10 subsequent applications of 30 mL product /tonne at 21-days intervals

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies

Detailed summary of the risk assessment

Product code: BIOX-M
Active Substance: Spermint Oil 930 - 950 g/L

All Zones
Zonal Rapporteur Member State: Germany (DE)

NATIONAL ADDENDUM- Germany

Applicant: XEDA International S.A.
Date: September 2015 (revised)

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Sec 6 ECOTOXICOLOGICAL STUDIES

A review of the ecotoxicological studies for the product BIOX-M and the active substance Spearmint oil as well as the risk assessment for BIOX-M in its intended uses in potatoes is documented in detail in the core assessment of the plant protection product BIOX-M dated from the 07/09/2012 performed by Germany.

This document comprises the risk assessment for non-target organisms for authorization of the plant protection product BIOX-M in Germany according to uses listed in Appendix 3.

Relevant national risk mitigation measures, if necessary, are documented in this document.
For general information on the formulation BIOX-M please refer to Table 5.1-1 of the Core Assessment, Part B, Section 5.

6.1 Proposed use pattern and considered metabolites

Introduction

The ecotoxicological risk assessment of the plant protection product BIOX-M in its intended uses in potatoes is documented in detail in the core assessment of the plant protection product BIOX-M dated from the 07/09/2012 performed by Germany.

This document comprises the ecotoxicological risk assessment for authorization of the plant protection product BIOX-M in Germany according to uses listed in Appendix 3.

6.1.1 Proposed use pattern

For administrative purposes, each intended use of a new plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 2 of this Addendum.

The critical use patterns of BIOX-M in its intended use in potatoes used for exposure assessment in Germany are presented in Table 6.1-1. The first column summarizes the use numbers of the intended uses, that are covered with the respective critical use pattern.

Table 6.1-1: Classification of intended uses in Germany for BIOX-M

use No	Crop	Application method Drift scenario	Number of applications Minimum application interval Application time/ growth stage interception	Application rate, cumulative	Soil effective application rate, cumulative
00-001	Potatoes Except seed potatoes	Thermal fogging/ Indoor	11 applications 21 d intervall BBCH 99 (post harvest) 100% interception	1 x 90 ml/t + 10 x 30 ml/t = 390 ml/t 1 x 85.05 g/t + 10 x 28.35 g/t = 368.55 g/t Spearmint oil	Not applicable, indoor treatment

6.1.2 Consideration of metabolites

Please refer the core assessment, part B, section 6, point 6.1.2 of the plant protection product BIOX-M.

6.2 Effects on Birds

6.2.1 Overview and summary

Please refer to the core assessment, part B, section 6 for the central zone.

6.2.2 Drinking water exposure

Please refer to the core assessment, part B, section 6, point 6.2.3 of the plant protection product BIOX-M.

6.2.3 Details on formulation type in proportion per item

Please refer to the core assessment, part B, section 6, point 6.2.4 of the plant protection product BIOX-M.

6.2.4 Acute toxicity of the formulation

Avian toxicity tests with the formulation were not performed and are not considered necessary. Please refer to the core assessment, part B, section 6, point 6.2.1 of the plant protection product BIOX-M for an overview of the risk assessment for birds.

6.2.5 Metabolites

Avian toxicity tests with metabolites of Spearmint Oil were not performed. Please refer to the core assessment, part B, section 6, point 6.2.1 for an overview of the risk assessment for birds.

6.2.6 Supervised cage or field trials

No further studies are considered necessary. Please refer to Point 6.2.1 for an overview of the risk assessment for birds.

6.2.7 Acceptance of bait, granules or treated seeds (palatability testing)

BIOX-M is intended for use as a a hot fogging concentrate and therefore this information is not required.

6.2.8 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). The log K_{ow} value of Spearmint Oil was not evaluated. However, the log POW of L-Carvone is 2.4 (DAR Spearmint Oil, Vol. 1, List of endpoints, August 2008) but the log K_{ow} values may be >3 for other components of spearmint oil and metabolites of R-carvone.

Since Spearmint oil is intended to be used for a post-harvest indoor treatment of Potatoes except seed potatoes, no direct exposure of the active substance to soil is expected in its intended use and exposure to birds, although possible, would be negligible. Concerning the exposure via volatilization and deposition there is a possibility that Spearmint-oil evaporates out of the storage rooms through gaps in the building, when opening doors, ventilating or opening for fresh air. However, once a deposition occurs onto plants, soil or surface waters it will rapidly evaporate again. According to the DAR Vol. 1 on Spearmint-oil (June 2007), the daily intake of Spearmint-oil in the US is 0.458 mg/kg BW/d. Various products contain Spearmint-oil. The DAR gives some examples of how much Spearmint-oil different products can contain: Non-alcoholic beverages 136 mg/kg, Fruit juice 550 mg/kg, hard candy 1605 mg/kg and Chewing gum 7913 mg/kg. Calculated PEC_{sw} values range between 2.77 mg/L for 0 m and 0.16 mg/L for 50 m distance. Thus, predicted environmental concentrations in surface waters are lower about factors of 50 and up

compared to human food products. The risk for birds from secondary poisoning through Spearmint-oil is estimated to be acceptable.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

6.3.1 Overview and summary

Please refer to the core assessment, part B, section 6, point 6.3.1 of the plant protection product BIOX-M.

6.3.2 Toxicity exposure ratio

Please refer to the core assessment, part B, section 6, Point 6.3.2 of the plant protection product BIOX-M.

6.3.3 Drinking water exposure

In case of indoor post-harvest treatments uses as intend for BIOX-M mammals are not deemed to be exposed via drinking water from puddles.

6.3.4 Details on formulation type in proportion per item

Please refer to section 6.2.3 for details on the formulation type of BIOX-M.

6.3.5 Acute toxicity of the formulation

Mammal toxicity tests with the formulation were not performed and are not considered necessary. Please refer to section 6.3.1 for an overview of the risk assessment for mammals.

6.3.6 Metabolites

Mammal toxicity tests with metabolites of Spearmint Oil were not performed and are not considered necessary. Please refer to section 6.3.1 for an overview of the risk assessment for mammals.

6.3.7 Supervised cage or field trials

No further studies are not considered necessary. Please refer to section 6.3.1 for an overview of the risk assessment for mammals.

6.3.8 Acceptance of bait, granules or treated seeds (palatability testing)

BIOX-M is intended for use as a hot fogging concentrate, and therefore this information is not required.

6.3.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). The log K_{ow} value of Spearmint Oil was not evaluated. However, the log POW of L-Carvone is 2.4 (DAR Spearmint Oil, Vol. 1, List of endpoints, August 2008) but the log K_{ow} values may be >3 for other components of spearmint oil and metabolites of R-carvone.

Since Spearmint oil is intended to be used for a post-harvest indoor treatment of Potatoes except seed potatoes, no direct exposure of the active substance to soil is expected in its intended use and exposure to mammals, although possible, would be negligible.

Concerning the exposure via volatilization and deposition there is a possibility that Spearmint-oil evaporates out of the storage rooms through gaps in the building, when opening doors, ventilating or opening for fresh air. However, once a deposition occurs onto plants, soil or surface waters it will rapidly evaporate again. According to the DAR Vol. 1 on Spearmint-oil (June 2007), the daily intake of Spearmint-oil in the US is 0.458 mg/kg BW/d. Various products contain Spearmint-oil. The DAR gives some examples of how much Spearmint-oil different products can contain: Non-alcoholic beverages 136 mg/kg, Fruit juice 550 mg/kg, hard candy 1605 mg/kg and Chewing gum 7913 mg/kg. Calculated PEC_{sw} values range between 2.77 mg/L for 0 m and 0.16 mg/L for 50 m distance. Thus, predicted environmental concentrations in surface waters are lower about factors of 50 and up compared to human food products. The risk for mammals from secondary poisoning through Spearmint-oil is estimated to be acceptable.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

No aquatic study is available with Spearmint oil or the product BIOX-M.

Effects on aquatic organisms of BIOX-M were not evaluated as part of the EU review of SPeamint oil. The DAR on Spearmint oil (June 2007 Vol. 3 B.9.2) provides QSAR estimations (ECOSAR v0.99h) of the toxicity to aquatic organisms.

6.4.1.1 Toxicity

The endpoints (no experimental data available, values based on QSAR estimations (ECOSAR v0.99h)) for aquatic organisms relevant for the risk assessment are indicated in the following table.

Table 6.4-1: Ecotoxicological endpoints for aquatic species exposed to R-Carvone with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.
Acute toxicity					
O.mykiss	R-Carvone	Acute	LC50 (96h) = QSAR estimation: 20.3-32.9 mg/L[1]	n.n.	none
Invertebrate (Daphnia magna)	R-Carvone	Acute	EC50 (96h) = QSAR estimation: 9.59-15.1 mg/L[1]	n.n.	none
Daphnia magna	Biox-M (81.16 % L-Carvone)	2 d acute	EC50 : 10.6 mg/L[2)] Mortality Nominal	Servajean, E. 2014 14-13-045-ES	87029
Algae	R-Carvone	Acute	EC50 (96h) = QSAR	n.n.	none

			estimation: 4.58-7.36 mg/L[1]		
Desmodesmus subspicatus	Biox-M (81.16% L-Carvone)	72 h semistatic	ErC50 : 42.8 mg/L[2)] Growth rate EyC50 : 26.3 mg/L NOEyC : 11.3 mg/L Biomass real	Servajean, E. 2015 14-13-044-ES	87030
Chronic toxicity					
Freshwater fish	R-Carvone	Chronic	"Chronic toxicity value" = QSAR estimation: 1.092-2.034 mg/L[3)]	n.n.	none
Invertebrate (Daphnia magna)	R-Carvone	Chronic	"Chronic toxicity value" = QSAR estimation: 1.254-2.233 mg/L [3)]	n.n.	none
Algae	R-Carvone	Chronic	"Chronic toxicity value" = QSAR estimation: 2.063-3.214 mg/L [3)]	n.n.	none

1) EFSA conclusion (active substance plant oils/spearmint oil), EFSA Journal 2012;10(2):2541

2) New study submitted by the applicant

3) DAR Spearmint-oil June 2007, Vol. 3 B.9.2

6.4.1.2 Exposure

BIOX-M is a formulation intended to be used for a post-harvest indoor treatment containing Spearmint Oil as active substance. Thus, no direct exposure of surface water via spray drift, run-off or drainage is expected. However, several possible entry path ways of Spearmint oil into surface water have been identified and an attempt was made to calculate worst-case initial PECsw values for these path ways (see core assessment, part B, section 5, point 5.6. Since the possible entry path ways would happen at different occasions, they were calculated separately.

Aquatic organisms may be exposed to plant protection products as a result of emission from treated areas. When BIOX-M is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by volatilization with subsequent deposition, by direct entry of wash water from treated potatoes as well as via run-off and drainage from treated seed potatoes.

The predicted environmental concentrations in surface water (PEC_{SW}) have been calculated separately for the different entry routes based on the application rates of BIOX-M. For details see dRR CA Part B, Section 5.7.

Table 6.4-2: PECsw values for the deposition of Spearmint oil on surface water at different distances from the depot for possible entry paths

Volatilisation/Deposition	PECsw [mg/L] (Distance from Depot)		0.00100 (0 m) 0.00077 (5 m) 0.00056 (10 m) 0.00032 (20 m) 0.00006 (50 m)
Direct entry of wash water from treated potatoes	PECsw [mg/L]		368
Run-off and drainage of residues from treated seed potatoes	FOCUS STEP 1	PEC_{SW} (µg/L), Actual, 0 h	4.5252
		PEC_{SED} (µg/kg), Actual, 0 h	0.5611
	FOCUS STEP 2 Southern Europe, Mar - May	PEC_{SW} (µg/L), Actual, 0 h	1.6503
		PEC_{SED} (µg/kg), Actual, 0 h	0.2046
	FOCUS STEP 2 Northern Europe, Mar - May	PEC_{SW} (µg/L), Actual, 0 h	0.8251
		PEC_{SED} (µg/kg), Actual, 0 h	0.1023

6.4.1.3 Risk assessment –overall conclusions

According to the PEC_{sw} values derived from volatilization and deposition as well as direct entry from wash water, the TER values for Spearmint oil are below the trigger of 10, indicating an unacceptable risk for aquatic organisms from Spearmint oil following application of BIOX-M at the proposed application rate. However, the direct entry of wash water is deemed to be unlikely, since the potatoes are used for industrial processing thus the washing would take place at the industrial plant. For these plants a sewage plant for waste water treatment is mandatory. Since BIOX-M is not intended to be used on seed potatoes for German authorisation, a direct entry of wash water containing Spearmint oil into a surface water is not expected (see also dRR NA Part B, Section 5.6).

TER values for the most sensitive aquatic organisms based on PEC_{SW} FOCUS calculations are summarized in the following table.

Table 6.4-3: Aquatic TER values for Spearmint oil after applications of BIOX-M.

Test organism	**EC_{50} (µg/L)**	**Setting**	**Scenario / Distance**	**Max. PEC_{SW} worst case (µg/L)**	**TER**	**Trigger value**
Spearmint Oil						
Invertebrates (Daphnia magna)	10600	Volatilisation/Deposition	0 m	1.00	10600	100
			5 m	0.77	13766	
			10 m	0.56	18929	
			20 m	0.32	33125	
			50 m	0.06	176667	
		Direct entry from wash water		368000	**0.029**	

TER-values in bold are below the relevant trigger

6.4.2 Toxicity to Exposure ratio

The risk for aquatic organisms exposed to Spearmint oil was assessed according to the intended uses.

Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint for Spearmint oil is EC_{50} = 10.6 mg Biox-M/L (*Daphnia magna).* Risk assessment is driven by this endpoint; the ratio endpoint/corresponding safety factor is higher for all other organisms. The calculated TER values are given in Table 6.4-3 and are above the trigger value of TER ≥ 100 indicating an acceptable risk to aquatic organisms.

6.4.3 Acute toxicity and chronic toxicity of the formulation

Please refer to section 6.4.1.1 for a summary of the provided studies on the effects of BIOX-M on aquatic organisms. Section 6.4.2, page 10, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

6.4.4 Metabolites of Spearmint oil

There are no relevant metabolites of Spearmint oil occurring in surface water or sediment.

6.4.5 Accumulation in aquatic non-target organisms

Bioaccumulation of any of the active substances under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

6.5 Effects on Bees

Please refer to the core assessment, part B, section 6 for the central zone.

6.6 Effects on Arthropods Other Than Bees

Please refer to the core assessment, part B, section 6 for the central zone.

6.7 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

Please refer to the core assessment, part B, section 6 for the central zone.

6.8 Effects on Soil Microbial Activity

Please refer to the core assessment, part B, section 6 for the central zone.

6.9 Effects on Non-Target Plants

Please refer to the core assessment, part B, section 6 for the central zone.

Appendix 1 List of data submitted in support of the evaluation

Please refer to the CA.

Appendix 2 Detailed evaluation of studies relied upon

Please refer to the CA.

Appendix 3 Table of Intended Uses in Germany (according to BVL 26/08/2011)

PPP (product name/code)	BIOX-M	**Formulation type:**	**HN**
active substance 1	**Spearmint Oil**	**Conc. of as 1:**	**948 g/L**

Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate	
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	mL product / tonne a) max. rate per appl. b) max. total rate per crop/season	ml as/t a) max. per ap b) max. t rate per crop/seas
00-001	DE	Potatoes with the exception of seed potatoes	I	Prevention of Sprouting	Thermal fogging	Post harvest	a) & b) 11 (21 d intervall)	a) & b) first treatment: 90 ml/t subsequent treatments: 30 ml/t	a) & b) fir treatment: ml/t subsequen treatments ml/t

Remarks:

(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)	(i)	g/kg or g/l
(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at last treatm Blackwell, ISBN 3-8263-3
(c)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds		time of application
(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximu
(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		of use must be provided
(f)	All abbreviations used must be explained	(l)	PHI - minimum pre-harves
(g)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	(m)	Remarks may include: Ext
(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated		

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: BIOX-M

Reg. No.: ZV1 007502-00/00

Active Substance: Spearmint oil 930 – 950 g /L

All Zones

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: XEDA International S.A.

Date: 2011 July

Evaluator: Julius Kühn-Institut

Date: 2013-04-03

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

This document summarises the information related to the efficacy for the plant protection product BIOX-M containing the active substance Spearmint Oil which was included into Annex I of Directive 91/414/EEC as set out in Commission Directive 2008/127/EC (OJ L 344, 18/12/2008, p.89-111). BIOX-M prevents the sprouting of potatoes during storage under refrigerated or controlled air (CA) conditions. Multiple applications are necessary for long-term control. Applications are made every 3 weeks. The room is closed during and 2-3 days after application, but open for fresh air afterwards.
BIOX-M is a hot fogging concentrate (HN) to be applied using EW XEDA ELECTROFOG hot fogging equipment. The product is used in bulk storage, box or box pallets' storage. In box storage up to 6 boxes of 1m height are stacked in the middle of the store room. In bulk storage the maximum stacking height is 4m.
Germany is the ZRMS and belongs according to Regulation EC No. 1107/2009 to the central zone (zone B). The applicant named no other member states as cMS.

Recent registration situation/history of the PPP

BIOX-M is not registered in Germany. The product was already evaluated as the 'representative formulation' during the Annex I inclusion.
The applicant mentioned that BIOX-M has been previously evaluated in France and Belgium according to Uniform Principles.

Information on the active ingredients (Uptake and mode of action)

The active substance of BIOX-M is Spearmint Oil, which has sprout suppressing and fungicidal properties. It is a mixture of various components with L-Carvone being the most prevalent. According to the applicant the active substance is used undiluted at a concentration of 930 – 950 g/L. Spearmint Oil contains 55-85% (w/w) of L-Carvone which belongs to the terpenes. BIOX-M contains at least 550 g/kg L-Carvone.
Spearmint Oil works by physically destroying sensitive sprout meristem tissue. Carvone inhibits sprout growth within 2 days. An extensive loss of the activity of 3-hydroxy-3-methylglutaryl Coenzyme A reductase, a key enzyme in the mevalonate pathway, occurs concomitantly with the inhibition of sprout growth. The enzyme activity decreases to less than 3% of the control after 4 days of treatment. Carvone is also part of the synthesis of phytohormones like gibberelin, absiscine and cytokinine, which e.g. influence the growth of the plant roots and inhibit the growth/sprouting of tubers. Since new sprouts continue to develop, repeated applications are required every three weeks.

Formulations used in this dossier:

Treatment Name	Active Substances	g as/L or %	Formulation
L-Carvone 300 g/L	L-Carvone	300 g/L	HN
L-Carvone 250 g/L	L-Carvone	250 g/L	HN
BIOX-M	L-Carvone	>550 g/kg	HN

D-Carvone (an isomer of L-Carvone) is registered as anti-sprouting agent in The Netherlands under the trade name of TALENT (Certis-Luxan). Generally BIOX-M is suitable for all production destinations (table potato, potato crisps and starch potato) of potatoes, but the treatment of seed potatoes is not intended.

Information on crops and pests

The applicant noted that this point is not applicable as BIOX-M is used for the control of sprouting in potatoes.
Sprouting control in potatoes is a major use in Germany. Usually potato storage in Germany is in boxes with 6m stacking height and in bulk storage with max. 4 m stacking height. For using BIOX-M, and usual in Germany is an airflow system. Air exchange is up to 150 $m^3/(t*h)$ only in the initial wound healing period, later 30 to 60 $m^3/(t*h)$ is sufficient. Storage temperature depends on the destination of the potatoes (2-10°C) with rel. humidity of 90-95%. Air flow has to be guaranteed for an effective use of BIOX-M.
The applicant noted that no adverse effects after the removal from storage are known. By treating the potatoes the susceptibility to wounding after storage will be decreased.

Potatoes should have a set skin and be largely free from soil/debris. BIOX-M should not be applied to potatoes until they are dry and cured; generally 6-15 days post harvest. Stores should be loaded as quickly as possible to ensure that the curing time is not unnecessarily extended and that the first potatoes loaded have not started to sprout before the last potatoes are cured. After loading the store ensure all surface moisture is removed by use of ventilation. The 1st application should be applied before sprouting is visible. Sprout control efficacy may be reduced if storage temperature is above 10°C.
Do not remove potatoes for sale or processing for at least 12 days after application.

Information on the intended uses (2012-09-06)

AWG-No.	**007502-00/00-001**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	potato(SOLTU)
Notes on crop	except seed potato
Pest(s)/target(s)/aim(s)	Sprout depression (YKEIM)
Area of use	large storage room
Time of treatment	after beginning of storage
Max. number of treatments for the use	11
Max. number of treatments per crop or season	11
Interval between treatments	21 (days)
Application technique/type of treatment	hot fogging
Dose rate(s) in amount of water to be used	first treatment 90 ml/t from second treatment 30 ml/t

IIIA1 6.1 Efficacy data

IIIA1 6.1.1 Preliminary range-finding tests

Preliminary range finding tests were conducted with a formulation containing 250-300 g/L L-Carvone (formulation HN, hot fogging concentrate), because the active substance is well known for its sprout suppressing and fungicidal properties. A summary on data of trial sites and application details is given in Appendix 4.1. Effectiveness trials were conducted with the potato varieties Bintje and Nicola in 1995/96, 1996/97 and 1998/99 for storage periods of 3 to 6 months. These trials included partially phytotoxicity evaluations (also for the variety Roseval), the results of which can be found in Appendix 7. The product was applied 5 to 13 times with initial applica-

tion rates of 25 ppm or 45 ppm L-Carvone, followed mainly by rates of 10-15 ppm L-Carvone (for details see Appendix 4.1). For the results please see Appendix 5.1. For these preliminary trials with a product containing less L-Carvone (250-300 g/L) than BIOX-M it can be concluded that the variants with L-Carvone were at least comparable to the reference product (thermal fogging) for the first 3 months. For the evaluation after 6 months the L-Carvone was a bit weaker than the thermal fogging reference in the trials of 1995-1997, while in 1998/99 L-Carvone was comparable to both reference product even after 6 months.

The Spearmint Oil containing 55-85% (w/w) of L-Carvone was submitted by XEDA for inclusion to Annex I of Directive 91/414/EEC (Directive 2006/74/EC). BIOX-M contains at least 550 g/kg L-Carvone.

IIIA1 6.1.2 Minimum effective dose tests

The minimum effective dose was approached and extrapolated based on experiences gained at XEDA with the sprout suppressing treatment of potatoes by hot fogging with Chlorpropham (MRL used to be 5 ppm and is now 10 ppm) targeting at a residue content of L-Carvone of 3 to 5 ppm.
According to its technical data sheet the product TALENT containing 95% D-Carvone is recommended by LUXAN for the sprout suppression in potatoes with 10 to 25 mL/t and an MRL of 10 mg/kg in the Netherlands.
BIOX-M is to be used in stored potatoes at application rates of 30-90 g product/t as post-harvest treatment with an interval of 3 weeks between applications. The initial application of 90 mL product/t between 6 and 15 days after harvesting is followed by up to 10 subsequent applications of 30 mL product/t at 21-days intervals.

A total of seven minimum effective dose trials were conducted with half the intended application rate. Details on trial data can be found in Appendix 4.2. Results per trial are among the effectiveness data in Appendix 5.2. A summary of results on trials with minimum effective dose data is compiled in Appendix 6.2. The data is split into three independent overviews: one for 3 months, 6 months and 8-9 months storage time, each. Evaluations were done for percentage of not sprouted tubers, percentage of tubers with sprouts > 2 mm, total weight of sprouts, sprout index and loss of tuber weight. A clear dose response is visible for all parameters and all storage times, if effectiveness results for the intended dose (N) and half the intended dose (1/2 N) are compared.

IIIA1 6.1.3 Efficacy tests

BIOX-M is intended for use in stored potatoes to inhibit sprouting. The first application (90 g product/t) is conducted approximately 6-15 days after harvest when wound healing is finished. Up to 10 subsequent applications of 30 g product/T follow every three weeks. Details on trial data can be found in Table 6.1.3-1.

Table 6.1.3-1 Overview of tests that have been carried out

Purpose	Year [a)]	Country	Short description
Preliminary trials (Point IIIA 6.1.1)	1995/96	France	(1) tests by contract companies (1); rate: 2x25, 8x12 ppm L-Carvone (250 g/L)
	1996/97	France	(2) tests by contract companies (2); rate: 2x25, 1x12, 10x10 ppm L-Carvone (300 g/L)
	1998	France	(2) tests by contract companies (2); rate: 1x45, 7x15 ppm L-Carvone (300 g/L)

Efficacy of the target rate (Point IIIA 6.1.3)	2002/03	France	(3) tests by contract companies (3); rate: 1x90, 10x30 ppm Spearmint Oil
	2004/05	France	(3) tests by contract companies (3); rate: 1x90, 10x30 ppm Spearmint Oil
	2010	Belgium	(4) tests by contract companies (4); rate: 1x90, 10x30 ppm Spearmint Oil
Efficacy of the target rate – Additional trials (Point IIIA 6.1.3)	2008/09	France	(3) tests by contract companies (3); rate: 1x100, 4x75 ppm Spearmint Oil
	2008	Israel	(6) tests by contract companies (6), rate: 1x50 ppm Spearmint Oil
Minimum effective dose (Point IIIA 6.1.2)	2002/03	France	(3) tests by contract companies (3); rates: N) 1x90, 10x30 ppm Spearmint Oil, ½N) 1x45, 10x15 ppm Spearmint Oil
	2010	Belgium	(4) tests by contract companies (4); rates: N) 1x90, 10x30 ppm Spearmint Oil, ½N) 1x45, 10x15 ppm Spearmint Oil, 2N)) 1x180, 10x60 ppm Spearmint Oil
Crop tolerance (phytotoxicity) (Point IIIA 6.2.1)	1995/96	France	(3) tests by contract companies (3); rate: 2x25, 8x12 ppm L-Carvone (250 g/L)
	1996/97	France	(2) tests by contract companies (2); rate: 2x25, 1x12, 10x10 ppm L-Carvone (300 g/L)
	2010	Belgium	(4) tests by contract companies (4); rates: N) 1x90, 10x30 ppm Spearmint Oil, 2N)) 1x180, 10x60 ppm Spearmint Oil
Yield - Quality (Point IIIA 6.1.4)	2008/09	France	(3) tests by contract companies (3); rate: 1x100, 4x75 ppm Spearmint Oil=> with taint testing
	2010	Belgium	(4) tests by contract companies (4); rates: N) 1x90, 10x30 ppm Spearmint Oil, ½N) 1x45, 10x15 ppm Spearmint Oil, 2N)) 1x180, 10x60 ppm Spearmint Oil=> with assessments on internal sprouting

a) Year of establishing the trial

BIOX-M is to be used in stored potatoes at application rates of 30-90 g product/t as post-harvest treatment with an interval of 3 weeks between applications. The initial application of 90 mL product/t between 6 and 15 days after harvesting is followed by up to 10 subsequent applications of 30 mL product/t at 21-days intervals.
All data on trials site and application details for effectiveness trials is summarized in Appendix 4.2. Results per trial are summarized in Appendix 5.2, and a summary of effectiveness trials per variety is given in Appendix 6.1.

Material and methods:
A set of 2x3 trials with the intended dose of 1x90 ppm Spearmint Oil, followed by 10x30 ppm Spearmint Oil and the varieties Bintje, Nicola and Monalisa was conducted in France at Arvalis – Institut du vegetal (formerly ITCF-ITPT) in 2002 to 2005. In these trials BIOX-M was tested in comparison with the reference products CIPC Powder, formulated as DP, containing 1% Chlorpropham, called "powder reference" or RP^P and Xedamate aerosol 88, formulated as HN, containing 200 g/L Chlorpropham, called "thermal reference" or RP^T. Treatments with BIOX-M and Xedamate were realized with the Xeda fogging equipment "Electrofog Xeda". After an initial wound healing period the potatoes were stored at 7.5°C. First treatment was 15 days after start of storage and subsequently every 3 weeks.

Assessments were made 3, 6 and 8 months after beginning of storage. For the assessment tubers were classified according to the different lengths of their sprouts to "germination classes" as follows:

Germination classes:
0: not sprouted
1: beginning of sprouting (white bud stage)
2: sprouts < 2 mm
3: sprouts 2-5 mm
4: sprouts 5-10 mm
5: sprouts > 10 mm
Further assessments were concerning total weight of sprouts > 2 mm (g), sprout index and loss of tuber weight (%) during storage. For the calculation of the sprout index see Appendix 5.2.

A further set of 4 effectiveness trials with the intended dose of 1x90 ppm Spearmint Oil, followed by 10x 30 ppm Spearmint Oil was conducted in Belgium in 2010 at REDEBEL S.A. with the varieties Bintje, Santana, Asterix and Innovator. For these Belgian trials it was noted that the fogging temperature for the first three applications was too high, to the effect that the test product could not be fully effective in the beginning. This has to be taken into account when evaluating the results. In these trials BIOX-M was tested in comparison with the reference product Xedamate 60, formulated as HN, containing 636 g/L Chlorpropham, called "thermal reference" or RP^T. Treatments with BIOX-M and Xedamate were realized with the Xeda fogging equipment "Electrofog Cedax". After an initial wound healing period the potatoes were stored at 8-10°C. First treatment was 10 days after start of storage and subsequently every 3 weeks.

Assessments were made 114, 168 and 259 DAA, i.e. 3.8, 5.6 and 8.6 months after beginning of storage. For the assessment tubers were classified according to the different lengths of their sprouts to "sprouting classes" as follows:

Sprouting classes:
0: not sprouted
1: sprouts 1-3 mm
2: sprouts 3-10 mm
3: sprouts 10-20 mm
4: sprouts > 20 mm
Further assessments were concerning total weight of sprouts (g/100 tubers), sprout index, loss of tuber weight (%) during storage and internal sprouting. For the calculation of the sprout index see Appendix 5.2.

As additional trials we present a further set of 3 trials conducted in France at Arvalis – Institut du vegetal (formerly ITCF-ITPT) in 2008/09 with a dose of 1x100 ppm and 4x 75 ppm and an application interval of 6 weeks. These are also the trials the material for taint testing (compare IIIA Point 6.1.4) originates from. The trials were conducted with the varieties Bintje, Agata and Nicola following the same modus as the other trials from this institute.

Further on a set of additional trials from Israel conducted in 2009 on a wide choice of further varieties is presented. However these trials were conducted with potatoes already germinated. The burning of sprouts 5 DAA and the elongation of sprouts 15 DAA were assessed.

The conducted trials follow the relevant EPPO standard PP 1/164 "Sprout suppression in potato; at storage or in store application"; PP 1/135 "Phytotoxicity assessment"; PP 17152 "Design and analysis of efficacy evaluation trials and PP 1/181 "Conduct and reporting of efficacy evaluation trials".

Results:

Results per trial are summarized in Appendix 5.2, and a summary of effectiveness trials (excluding the additional trials) per variety and storage time is given in Appendix 6.1. The following Ta-

ble 6.1.3-2 is extracted from Appendix 6.1 and summarizes the average sprout inhibition for all varieties compared to the relevant untreated variant. The average effectiveness based on total weight of sprouts is 96% even after 8-9 months storage time. Concerning the sprout index, the effectiveness of BIOX-M is 77-91% on average with a slight decrease with storage time. The effectiveness concerning loss of tuber weight is increasing with storage time. From Appendix 5.2 it can furthermore be concluded that the effectiveness of BIOX-M is well comparable with the reference product applied by thermal fogging (RP^T) in all trials, in many trials also with the reference product applied as powder (RP^P).

Table 6.1.3-2 Average potato sprout inhibition (data from effectiveness trials / BIOX M / intended dose / effectiveness in % compared to untreated) (extracted from Appendix 6.1)

Storage time	3 months	6 months	8-9 months
No. of trials (Trial No.)	10	10	10
Class 0 (% of not sprouted tubers)	40.11 a)	28.93 a)	31.55 a)
Classes 3-5 (% tubers with sprouts > 2 mm)	83.31 a)	82.05 a)	60.59 a)
Total weight of sprouts (g)	96.32	98.71	96.11
Sprout index	87.47	90.69	76.58
Loss of tuber weight (%)	11.56	45.07	49.31

a) For this assessment only seven trials are evaluated.

From the Israeli trial (2009) with already sprouted tubers it can be concluded that BIOX-M successfully destroyed existing sprouts for all tested varieties. BIOX-M successfully stopped sprout elongation for 15 days after application (see Appendix 5.2).

BIOX-M is effective for all cultivars, so cultivar specific recommendations are not intended. The differences observed between cultivars establish themselves in the different start of sprouting. The selected experimental cultivars are all included in the official German descriptive list of varieties 2010 for potatoes.

IIIA1 6.1.4 Effects on yield and quality

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

BIOX-M is an anti-sprouting for post-harvest use. The purpose of this kind of product is to maintain the quality of the tubers by protecting them during storage against sprouting.

Taint testing
Furthermore a taint testing study was conducted (Person, 2009 and Martin, 2009).

Material and methods
Potato samples of the varieties Bintje, Agata and Nicola, originating from trial no. Paris_090601 (Martin, 2009) as described in Appendix 4.2, were taken 6 or 30 days after last treatment with BIOX-M and boiled in water or prepared as French fries. The prepared potatoes were compared

to detect taste differentials with equally prepared potatoes from a reference variant. The aim of this study is to define the possible existence of negative organoleptic deviations on potatoes treated with mint oil in comparison with potatoes treated with the CEB reference, the late being the taste test check. Furthermore cooking performances were evaluated on the same prepared potatoes. The culinary tests were made in order to define the possible incidence of phytosanitary treatments on the culinary aptitudes of potatoes when steamed or fried.
The average indexes obtained with the samples treated with the formulation tested are statistically similar to the ones obtained with samples treated with the reference formulation

The conducted taint tests following the requirements of EPPO standard PP 1/242 “Taint tests”

Results
For a summary of the results please refer to Appendix 8. Table A 8-1 gives the results of the organoleptic test.
Whatever variety tested after cooking -boiled in water or fried- the jury did not note any significant difference in flavour between the samples treated with the test formulation and the samples treated with the reference formulation. The results enable us to conclude that the treatment with mint oil does not cause significant modifications on the flavour of potatoes in comparison with potatoes treated with the reference formulation.
Table A 8-2 gives the results of the cooking test. From the results it can be concluded that the treatment with mint oil does not cause significant modifications of the potato culinary aptitude in comparison with potatoes treated with the reference formulation.

Internal sprouting
In the effectiveness trials conducted in Belgium internal sprouting was observed beginning with the storage time 5.6 months. Internal sprouting was found in the BIOX-M treatments as well as in the treatments with the references product Xedamate 60 HN. Assessment results for this phenomenon can be found in the relevant data sheets of Appendix 5.2.
Internal sprouting is an additional sporadic effect depending of a lot of criteria: climatic pre harvest conditions, harvest period, storage conditions and so on. For these Belgian trials it can be assumed that the too high temperature of first applications (230-235°C in place of 170-190°C) is another factor why internal sprouts were observed in BIOX M treatments.

IIIA1 6.1.4.2 Effects on the processing procedure

Please refer to Point IIIA 6.1.4.1.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Not relevant. Since BIOX-M is used in storage, after harvest of the crops, adverse effects on the yield can be excluded.

BIOX-M reduces the loss of tuber weight during storage. This effect is presented under Points 6.1.1 to 6.1.3 as one aspect of effectiveness evaluation.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

Phytotoxicity was assessed in several effectiveness trials. For a summary of results of phytotoxicity evaluations please refer to Appendix 7. Varieties tested for phytotoxicity were Bintje, Nicola,

Roseval, Santana, Asterix and Innovator. Results are given in percent of affected tubers and compared to reference products. In Table A7-1 results from preliminary trials conducted with a product containing 250 and 300 g/L L-Carvone are presented. Some phytotoxicity, always less than in the reference variants, was observed here. In Table A7-2 results from the Belgian effectiveness trials are presented. BIOX-M was applied here with up to twice the intended dose. No phytotoxicity was recorded at all, even for the double dose.
It can therefore be concluded that BIOX-M is not phytotoxic to the tuber itself, but only affects the sprouts.

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

Effects on relevant beneficial organisms
There will be no exposure to beneficial organisms, because BIOX-M is intended to be used only in indoor post-harvest treatments to control sprouting of potatoes.

Effects on soil quality
Effects on soil macro-organisms being used as indicators of soil quality
Effects on earthworms
There will be no exposure to earthworms, because BIOX-M is intended to be used only in indoor post-harvest treatments to control sprouting.

Effects on other non-target macro-organisms
There will be no exposure to earthworms, because BIOX-M is intended to be used only in indoor post-harvest treatments to control sprouting.

Effects on organic matter breakdown
There will be no exposure to earthworms, because BIOX-M is intended to be used only in indoor post-harvest treatments to control sprouting.

Effects on soil micro-organisms being used as indicators of soil quality
There will be no exposure to non-target micro-organisms, because BIOX-M is intended to be used only in indoor postharvest treatment to control sprouting.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

In the intended use seed potato is excluded.
However the applicant says that seed potatoes can be treated with BIOX-M. After evaporation of BIOX-M sprouting is possible. This is the reason of the re-treatments of the potatoes during long storage.

IIIA1 6.2.6 Impact on succeeding crops

The product is used as storage application indoors. The impact on succeeding crops is therefore not relevant for the intended use.

IIIA1 6.2.7 Impact on other plants including adjacent crops

The product is used as storage application indoors. The impact on succeeding crops is therefore not relevant for the intended use.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

No problem of resistance or cross resistance in case of anti-sprouting is expected, because the potato crop would need a resistance development.

IIIA1 6.3 Economics

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.5 Other/special studies

No additional information is considered relevant.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

BIOX-M is intended for use in stored potatoes to inhibit sprouting. The first application (90 g product/t) is conducted approximately 6-15 days after harvest when wound healing is finished. Up to 10 subsequent applications of 30 g product/t follow every three weeks. BIOX-M is formulated for hot fogging (HN and contains > 55% (w/w) Carvone), it is applied with a Xeda electrofog equipment.

Seven minimum effective dose trials were conducted with half the intended application rate in 2002/03 and 2010. A clear dose response is visible for all parameters and all storage times.

A total of 10 effectiveness trials with the target rate intended for BIOX-M were conducted from 2002 to 2010 on a selection of different potato varieties. Effectiveness was evaluated based on counting sprouts of different length, weight of sprouts, sprout index and loss of tuber weight during storage. The test product was well comparable with the reference product applied by thermal fogging. Additionally a test on aged, already sprouted potatoes of different varieties demonstrated that also existing sprouts were successfully controlled with BIOX-M.

A taint test was conducted on the varieties Bintje, Agata and Nicola in 2009, that were boiled in water or fried. No negative taste differentials with equally prepared potatoes from a reference product were detected. Moreover no negative influences on cooking qualities were recorded.

In four selectivity trials with the intended and twice the intended dose no phytotoxic effects on the tuber could be found for BIOX-M.

Because the crop would need to develop resistance, there is no potential for resistance development.

BIOX-M is well tolerated by most economically important potatoes varieties. The dose rate is suitable for an effective control of sprouting on potatoes.

Table 6.6-1 Overall summary of available efficacy data [a)]

Target	Potato varieties	Application rate	Storage time (months)	No. of trials	Average effectiveness (total weight of sprouts)
Potato sprouting during storage	Bintje, Nicola, Monalisa, Santana, Asterix, Innovator	1x90, 10x30 ppm	3	7	>96%
Potato sprouting during storage	Bintje, Nicola, Monalisa, Santana, Asterix, Innovator	1x90, 10x30 ppm	6	7	>99%
Potato sprouting during storage	Bintje, Nicola, Monalisa, Santana, Asterix, Innovator	1x90, 10x30 ppm	8-9	7	>96%

Extracted from Appendix 6.1, sheet (4/4)

IIIA1 6.7 List of test facilities including the corresponding certificates

Official testing station	Address	GEP (certificate)	Concerned studies (year)
ITCF-ITPT, Secteur Equipment & Conservation Pomme de Terre	2 chaussée Brunehaut, 80200 ESTREES-MONS France	Yes (KIIIA 6.7/01)	ITCF-ITPT 95-96 (1995-1996) ITCF_ITPT 96-97 (1997) GIEDA INH PDT/MM/9801 (1999)
Arvalis – Institut du vegetal Secteur Equipment & Conservation Pomme de Terre	2 chaussée Brunehaut Estrées-Mons -BP 156 80203 Peronne Cedex France (ARV)	Yes (KIIIA 6.7/01)	Peronne_031201 (2003) Peronne_050701 (2005) Paris_090601 (2009)
Redebel s.a.- n.v.	Rue de Chassart 4 B-6221 SAINT-AMAND Belgium (RED)	Yes (KIIIA 6.7/01)	R010-10R (2010) R011-10R (2010) R012-10R (2010) R013-10R (2010)
The Centre for Potato Research in Hot Cli-	Israel	-	Negev_011109

mates Ltd.			

Appendix 1: List of data submitted in support of the evaluation

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
MIIIA1 Sec 6	XEDA International S.A.	Draft Registration Report - Part B - BIOX-M - DE - Section 6- Ecotoxicology - Core assessment	2011	226199
MIIIA1 Sec 6	XEDA International S.A.	Draft Registration Report - Part B - BIOX-M - DE - Section 6- Ecotoxicology - National addenda	2011	226201
MIIIA1 Sec 7	XEDA International S.A.	Draft Registration Report - Part B - BIOX-M - DE - Section 7- Efficacy Data and Information - Core assessment	2011	226203
MIIA Sec 6	Anonymous	Document M-II Section 6	2008	226209
MIIIA1 Sec 6	XEDA International S.A.	Draft Registration Report - Part B - BIOX-M - DE - Section 6- Ecotoxicology - Core assessment	2011	226217
MIIIA1 Sec 7	XEDA International S.A.	Draft Registration Report - Part B - BIOX-M - DE - Section 7- Efficacy Data and Information - Core assessment	2011	226219
MIIIA1 Sec 6	XEDA International S.A.	Draft Registration Report - Part B - BIOX-M - DE - Section 6- Ecotoxicology - National addenda	2011	226225
KIIIA1 6.1.1	Anonymous	Experimentation d'un inhibiteur de germination de la pomme de terre, d'origine naturelle, applique en cours de conversation	1995	226247
KIIIA1 6.1.1	Anonymous	Efficacite antigerminative et test de selectivite d'un produit d'origine naturelle (L-carvone) propose par la societe xeda	1997	INH PDT MM 9703 226249

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.1	Anonymous	Etude de l'efficacite antigerminative d'une matiere active d'origine naturelle appliquee en cours de conservation de la pomme de terre proposee par la societe xeda	1999	GIEDA INH PDT/MM/ 9801 226251
KIIIA1 6.1.2	Anonymous	Efficacite antigerminative sur pomme de terre d#une nouvelle molecule d'origine naturelle	2003	226253
KIIIA1 6.1.2	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Bintje	2010	R010-10R 226254
KIIIA1 6.1.2	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Santana	2010	R011-10R 226255
KIIIA1 6.1.2	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Asterix	2010	R012-10R 226256
KIIIA1 6.1.2	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Innovator	2010	R013-10R 226258
KIIIA1 6.1.3	Anonymous	Efficacite antigerminative sur pomme de terre d#une nouvelle molecule d'origine naturelle	2003	226260
KIIIA1 6.1.3	Anonymous	Efficacite antigerminative sur pomme de terre d#une nouvelle molecule d'origine naturelle	2005	226262
KIIIA1 6.1.3	Martin, M.	Efficacité de l'huile de menthe (L-carvone) contre la germination des pommes de terre	2009	226264

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Bintje	2010	R010-10R 226266
KIIIA1 6.1.3	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Santana	2010	R011-10R 226268
KIIIA1 6.1.3	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Asterix	2010	R012-10R 226270
KIIIA1 6.1.3	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Innovator	2010	R013-10R 226272
KIIIA1 6.1.3	Nachmias, A., Amitay, R.	Efficacy of BIOX-M as a potato sprouts arrestor	2009	226274
KIIIA1 6.1.4.1	Martin, M.	Efficacité de l'huile de menthe (L-carvone) contre la germination des pommes de terre	2009	226276
KIIIA1 6.1.4.1	Person, N.	Evaluation sensorielle de "Pommes de terre ayant recu un traitement phytosanitaire"	2009	ES09-223 226278
KIIIA1 6.1.4.1	Person, N.	Sensory test / Taste test concerning "Potatoes having received a phytosanitary treatment"	2009	ES09-223-Translation 226280
KIIIA1 6.2.1	Anonymous	Experimentation d'un inhibiteur de germination de la pomme de terre, d'origine naturelle, applique en cours de conversation	1995	226282

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.2.1	Anonymous	Efficacite antigerminative et test de selectivite d'un produit d'origine naturelle (L-carvone) propose par la societe xeda	1997	INH PDT MM 9703 226284
KIIIA1 6.2.1	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Bintje	2010	R010-10R 226286
KIIIA1 6.2.1	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Santana	2010	R011-10R 226288
KIIIA1 6.2.1	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Asterix	2010	R012-10R 226290
KIIIA1 6.2.1	Reynens, P.	BIOX-M used as a aprout suppressant in potato - Minimum effective dose - Variety: Innovator	2010	R013-10R 226292
KIIIA1 6.7	Bruß, A.	GEP- and GLP-Certificates	2011	385654-A3-0607-DE 226293
KIIIA1 3.9	Anonymous	User Manual - Elletrofog EWB7500	2005	226294
KIIIA1 3.9	Anonymous	Fiche Technique - Electrofog Xeda Modele	2009	226295
KIIIA1 6	Anonymous	Boxstore with forced wall system with or without cooling	1900	Picture_01 272856

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6	Anonymous	Example of system for bulk storage technology	1900	Picture_02 272857
KIIIA1 6	Anonymous	German boxstore system	1900	Picture_03 272858
KIIIA1 6	Anonymous	Modern farm store bulk storage	1900	Picture_04 272859
KIIIA1 6	Schuhmann, P., Krummbiegel, D., Pötke, E.	Klimaführung in Kartoffellagern	2001	272860
KIIIA1 6.1.4.1	Bruß, A.	BIOX-M (Spearmint Oil), Statement concerning further data request by BVL, Annex point KIII A 6.1.4.1, impact on the quality of plants and plant products	2012	385654-A3-06010401-01-DE 272861
KIIIA1 6.1	Bruß, A.	BIOX-M (Spearmint Oil), Statement concerning further data request by BVL, Annex Point KIII A 6.1 Efficacy data	2012	385654-A3-0601-01-DE 272862
KIIIA1 3.9	Anonymous	Label BIOX-M	2012	272863
KIIIA1 3.9	Anonymous	Label BIOX-M German translation	2012	272864

Appendix 2: GAP tables

GAP rev. 1, date: 2011-12-30

PPP (product name/code)	**BIOX-M**	**Formulation: Type:**	**HN**
active substance 1	**Spearmint oil**	**Conc. of as 1:**	**948 g/l**

Applicant:	**XEDA International S. A.**	**professional use**	☒	**non professional use**	☐
Zone(s):	**northern/central/southern**				
Verified by MS:	**yes**				

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max		
001	Germany	Potato (SOLTU) Except seed potato;	F	Sprout suppression (YKEIM)	Thermal fogging	After beginning of storage	a) 11 (21 days) b) 11	a) first treatment 90 ml/t from second treatment 30 ml/t b) 390 ml/t	a) 85.32 g as/t 28.44 g as/t b) 369.72 g as/t			

Appendix 4.1: Summary of data on trial sites and application details - stored potatoes / sprout suppression – preliminary trials

Test report (1) Year of report	Trial location(2); Crop; Variety N/A (3)	Testing Unit (4)	Test method (5); Storage conditions Plot size [t or m³]; Temperature of stored product	Treatment			
				Growth stage (6) 1st application	Total number Interval	Test product Application rate (ppm L-Carvone) a)	Total storage time
ITCF_ITPT 95-96 1996	Centre d'Expérimentation ITCF-ITPT de VILLERS SAINT CHRISTOPHE, France Potato I) Bintje II) Nicola b) III) Roseval b) N	ITCF-ITPT, Secteur Equipment & Conservation Pomme de Terre, 80200 ESTREES-MONS France (ITCF-ITPT)	CEB and in house methods Net bags in pallet boxes in storage cells, "letter box" system for a homogenous air distribution into the boxes Plot size: 40 t 7.5°C	Post harvest	A) 5 B) 8 2-4 weeks	L-Carvone (250 g/L) A) 1x25 ppm 4x12 ppm => Σ 73 ppm B) 1x25 ppm 7x12 ppm => Σ 109 ppm	A) 3 months B) 5 months
ITCF_ITPT 96-97 INH PDT MM 9703 1997	Centre d'Expérimentation ITCF-ITPT de VILLERS SAINT CHRISTOPHE, France Potato I) Bintje II) Nicola N	ITCF-ITPT, Secteur Equipment & Conservation Pomme de Terre, 80200 ESTREES-MONS France (ITCF-ITPT)	CEB and in house methods Net bags in pallet boxes in storage cells, "letter box" system for a homogenous air distribution into the boxes Plot size: not stated 7°C	Post harvest 15-21 days after harvest	A) 5 B) 13 10-14 days	L-Carvone (300 g/L) A) 2x25 ppm 1x12 ppm 2x10 ppm => Σ 72 ppm B) 2x25 ppm 1x12 ppm 10x10 ppm => Σ 162 ppm	A) 3 months B) 6 months
GIEDA INH PDT/MM/9801 1999	Centre d'Expérimentation ITCF-ITPT de VILLERS SAINT CHRISTOPHE, France Potato I) Bintje II) Nicola N	ITCF-ITPT, Secteur Equipment & Conservation Pomme de Terre, 80200 ESTREES-MONS France; (ITCF-ITPT)	CEB Net bags in pallet boxes in storage cells Plot size: 12 t 7°C	Post harvest 27 days after harvest	A) 3 B) 8 21-23 days	L-Carvone (300 g/L) A) 1x45 ppm 2x15 ppm => Σ 60 ppm B) 1x45 ppm 7x15 ppm => Σ 150 ppm	A) 3 months B) 6 months

a) Please note: For the preliminary trials the application rate is given in ppm L-Carvone, while for the effectiveness trials with the intended product BIOX-M (**Appendix 4.2**) the application rate is given in ppm Spearmint Oil with the product BIOX-M containing >550 g/kg L-Carvone.
b) The varieties Nicola and Roseval are only tested for phytotoxicity.

Appendix 4.2: Summary of data on trials site and application details - stored potatoes / sprout inhibition (1/4)

Test report (1) Year of report	**Trial location(2); Crop; Variety N/A (3)**	**Testing Unit (4)**	**Test method (5); Storage conditions Plot size [t or m³]; Temperature of stored product**	**Treatment**			
				Growth stage (6) 1st application	**Total number Interval**	**Test product Application rate (ppm a.i. (Spearmint Oil))**	**Total storage time**
Peronne_031201 2003	Centre d'Expérimentation Nord-Picardie d'Arvalis – Institut du vegetal/ ITPT à VILLERS SAINT CHRISTOPHE, France Potato I) Bintje II) Nicola III) Monalisa Stored potatoes in pallet boxes N	Arvalis – Institut du vegetal Secteur Equipment & Conservation Pomme de Terre, 80203 Peronne Cedex France (ARV)	CEB and in house methods Net bags in pallet boxes in storage cells, "letter box" system for a homogenous air distribution into the boxes Plot size: 11 t per storage cell 7.5°C	Post harvest 15 days after start of storage	A) 4 B) 7 C) 11 3 weeks	XEDA HM Nat (550 g/L) A1) 1x90 ppm, 3x30 ppm => Σ 180 ppm A½) 1x45ppm, 3x15 ppm => Σ 90 ppm B1) 1x90 ppm, 6x30 ppm => Σ 270 ppm B½) 1x45ppm, 6x15 ppm => Σ 135 ppm C1) 1x90 ppm, 10x30 ppm => Σ 390 ppm C½) 1x45ppm, 10x15 ppm => Σ 195 ppm	A) 3 months B) 6 months C) 8 months

Appendix 4.2: Summary of data on trials site and application details - stored potatoes / sprout inhibition (2/4)

Test report (1) Year of report	Trial location(2); Crop; Variety N/A (3)	Testing Unit (4)	Test method (5); Storage conditions Plot size [t or m³]; Temperature of stored product	Treatment			
				Growth stage (6) 1st application	Total number Interval	Test product Application rate (ppm a.i. (Spearmint Oil))	Total storage time
Peronne_050701 2005	Centre d'Expérimentation Nord-Picardie d'Arvalis – Institut du vegetal/ ITPT à VILLERS SAINT CHRISTOPHE, France Potato I) Bintje II) Nicola III) Monalisa Stored potatoes in pallet boxes N	Arvalis – Institut du vegetal Secteur Equipment & Conservation Pomme de Terre, 80203 Peronne Cedex France (ARV)	CEB and in house methods Net bags in pallet boxes in storage cells, "letter box" system for a homogenous air distribution into the boxes Plot size: 12 t per storage cell 7.5°C	Post harvest 15 days after start of storage	A) 4 B) 8 C) 11 3 weeks	XEDA HM Nat (550 g/L L-Carvone) A) 1x90 ppm, 3x30 ppm => Σ 150 ppm B) 1x90 ppm, 7x30 ppm => Σ 300 ppm C) 1x90 ppm, 10x30 ppm => Σ 390 ppm	A) 3 months B) 6 months C) 9 months
Paris_090601 b) 2009	Centre d'Expérimentation Nord-Picardie d'Arvalis – Institut du vegetal/ ITPT à VILLERS SAINT CHRISTOPHE, France Potato I) Agata II) Bintje III) Nicola Stored potatoes in pallet boxes N	Arvalis – Institut du vegetal Secteur Equipment & Conservation Pomme de Terre, 80203 Peronne Cedex France (ARV)	CEB and in house methods Net bags in pallet boxes in storage cells, "letter box" system for a homogenous air distribution into the boxes Plot size: 12 t per storage cell 7.5°C	Post harvest 15 days after start of storage	A) 2 B) 4 C) 5 6 weeks	XEDA HM Nat (550 g/L L-Carvone) A) 1x100 ppm, 1x75 ppm => Σ 175 ppm B) 1x100 ppm, 3x75 ppm => Σ 325 ppm C) 1x100 ppm, 4x75 ppm => Σ 400 ppm	A) 3 months B) 6 months C) 8 months

Appendix 4.2: Summary of data on trials site and application details - stored potatoes / sprout inhibition (3/4)

Test report (1) Year of report	Trial location(2); Crop; Variety N/A (3)	Testing Unit (4)	Test method (5); Storage conditions Plot size [t or m³]; Temperature of stored product	Treatment			
				Growth stage (6) 1st application	Total number Interval	Test product Application rate (ppm a.i. (Spearmint Oil))	Total storage time
R010-10R 2010	REDEBEL S.A. facilities B-6221 SAINT-AMAND Belgium Potato Bintje Stored potatoes in storage cells N	REDEBEL S.A.- n.v. Rue de Chassart 4 B-6221 SAINT-AMAND Belgium (RED)	Guideline: not stated Sample size: 12 nets of 15 kg potatoes in storage cells Plot size: 3.5 t per cell 8-10°C	Post harvest 10 days after start of storage	A) 5 B) 8 C) 11 3 weeks	BIOX-M (65-85% L-Carvone) A1N) 1x 90 ppm, 10x 30 ppm A½N) 1x45 ppm, 10 x 15 ppm A2N) 1x 180 ppm, 10x 60 ppm	A) 114 days (3.8 months) a) B) 168 days (=> 5.6 months) C) 259 days (=> 8.6 months)
R011-10R 2010	REDEBEL S.A. facilities B-6221 SAINT-AMAND Belgium Potato Santana Stored potatoes in storage cells N	REDEBEL S.A.- n.v. Rue de Chassart 4 B-6221 SAINT-AMAND Belgium (RED)	Guideline: not stated Sample size: 12 nets of 15 kg potatoes in storage cells Plot size: 3.5 t per cell 8-10°C	Post harvest 10 days after start of storage	A) 5 B) 8 C) 11 3 weeks	BIOX-M (65-85% L-Carvone) A1N) 1x 90 ppm, 10x 30 ppm A½N) 1x45 ppm, 10 x 15 ppm A2N) 1x 180 ppm, 10x 60 ppm	A) 114 days (3.8 months) B) 169 days (=> 5.6 months) C) 259 days (=> 8.6 months)

Appendix 4.2: Summary of data on trials site and application details - stored potatoes / sprout inhibition (4/4)

Test report (1) Year of report	Trial location(2); Crop; Variety N/A (3)	Testing Unit (4)	Test method (5); Storage conditions Plot size [t or m³]; Temperature of stored product	Treatment			
				Growth stage (6) 1st application	Total number Interval	Test product Application rate (ppm a.i. (Spearmint Oil))	Total storage time
R012-10R 2010	REDEBEL S.A. facilities B-6221 SAINT-AMAND Belgium Potato Asterix N	REDEBEL S.A.- n.v. Rue de Chassart 4 B-6221 SAINT-AMAND Belgium (RED)	Guideline: not stated Sample size: 12 nets of 15 kg potatoes in storage cells Plot size: 3.5 t per cell 8-10°C	Post harvest 10 days after start of storage	A) 5 B) 8 C) 11 3 weeks	BIOX-M (65-85% L-Carvone) A1N) 1x 90 ppm, 10x 30 ppm A½N) 1x45 ppm, 10 x 15 ppm A2N) 1x 180 ppm, 10x 60 ppm	A) 114 days (3.8 months) B) 169 days (=> 5.6 months) C) 259 days (=> 8.6 months)
R013-10R 2010	REDEBEL S.A. facilities B-6221 SAINT-AMAND Belgium Potato Innovator N	REDEBEL S.A.- n.v. Rue de Chassart 4 B-6221 SAINT-AMAND Belgium (RED)	Guideline: not stated Sample size: 12 nets of 15 kg potatoes in storage cells Plot size: 3.5 t per cell 8-10°C	Post harvest 10 days after start of storage	A) 5 B) 8 C) 11 3 weeks	BIOX-M (65-85% L-Carvone) A1N) 1x 90 ppm, 10x 30 ppm A½N) 1x45 ppm, 10 x 15 ppm A2N) 1x 180 ppm, 10x 60 ppm	A) 114 days (3.8 months) B) 169 days (=> 5.6 months) C) 259 days (=> 8.6 months)
Negev_011109 2009	EGO Potato producers, Negev, Israel Potato I) Charlotte II) Maris Pees III) Annabelle IV) Vivaldi V) Lady Chlair VI) Odem	The Centre for Potato Research in Hot Climates Ltd.	Guideline: not stated Sample size: 12 nets of 15 kg potatoes in storage cells Plot size: 400 kg aerated plastic boxes inside a 12 t container 8°C	Post harvest 3.11.2009 Approx. 110 days after start of storage	1	BIOX-M (65-85% L-Carvone) 1x 50 ppm	5 DAA 15 DAA c)

Notes: (1): test report number including the year of report (e.g. PM 96/1).
(2): precise place of the trial followed by the country (e.g. Rheims, FR.)
(3): N = Natural infestation, A = Artificial inoculation.
(4): Trial responsible entity / officially recognized organization.
(5): Test guideline used (e.g. EPPO PP 1/32).

(6): Crop growth stage at application timing (e.g. BBCH 31-BBCH 50) / target growth stage (e.g. egg, adult, pre-emergence, post-emergence).
a) Storage time is DAA (days after application) plus 10 days (time from beginning of storage until 1st application)
b) This trial was not conducted with the intended dose and application interval. It is therefore not included in Appendix 6.1.
c) In this trial aged potato material was treated (approximately 110 days after harvest). Potatoes were already germinated and 5 and 15 days after application the effects on these aged potatoes were assessed. This trial was not conducted with the intended dose and application interval. It is therefore not included in Appendix 6.1.

Appendix 5.1: Summary of data on effectiveness trials per use (stored potatoes / sprout inhibition) -preliminary trials (1/5)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Untreated	L-Carvone (250 g/L) Σ 109 ppm	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
ITCF_ITPT 95-96	Sprout inhibition	6x100 tubers								**Germination classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts > 5 mm
		Potatoes l) Bintje	Class 0 (% of not sprouted tubers)	10.01.1996 08.03.1996	3 months 5 months	37.0 3.0	22.5 19.6	66.3 50.0	30.5 36.4	
			Class 1: (% tubers at beginning of sprouting (white bud stage))	10.01.1996 08.03.1996	3 months 5 months	8.7 4.5	40.8 a) 57.0	17.0 a) 36.5	39.2 a) 56.5	L-Carvone presents a quite good effectiveness comparable to RP[T] for the first 3 months.
			Classes 2&3 (% tubers with sprouts < 5 mm)	10.01.1996 08.03.1996	3 months 5 months	7.8 11.5	6.0 a) 15.0	4.0 a) 2.0	3.7 a) 5.5	
			Class 4:	10.01.1996	3 months	46.5	95.6	99.6	97.8	

			(% tubers with sprouts > 5 mm)	08.03.1996	5 months	81.2	92.9	100.0	99.1	
			Classes 2-4: (% tubers with sprouts having passed the white bud stage	10.01.1996 08.03.1996	3 months 5 months	54.3 92.7	85.3 77.6	92.3 97.8	91.3 93.3	

Notes a) Percentage of tubers in this class. (In this case no effectiveness was calculated.)

Appendix 5.1: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) -preliminary trials (2/5)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Untreated	L-Carvone (300 g/L) Σ 162 ppm	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
ITCF_ITPT 96-97	Sprout inhibition	6x100 tubers								**Germination classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts > 5 mm
		Potatoes I) Bintje	Class 0 (% of not sprouted tubers)	15./16.01.1997 5./6.05.1997	3 months 6 months	40.3 0.0	77.2 4.0	94.0 1.3	94.6 1.2	L-Carvone presents a quite good effectiveness comparable to RP[T] for the first 3 months. After 6 months the effectiveness is a bit weaker than for RP[T].
			Classes 3&4	15./16.01.1	3 months	18.6	93.5	100.0	97.3	

			(% tubers with sprouts > 2 mm)	997 5./6.05.1997	6 months	100.0	45.0	83.7	82.0	
			Total weight of sprouts > 2mm (g)	15./16.01.1997 5./6.05.1997	3 months 6 months	0.6 436.3	95.0 90.4	100.0 99.4	95.0 96.6	
			Loss of tuber weight (%)	15./16.01.1997 5./6.05.1997	3 months 6 months	2.8 5.4	2.4 a) 3.3	3.1 a) 4.1	2.7 a) 4.1	

Notes: a) Loss of tuber weight in % (In this case no effectiveness was calculated.)

Appendix 5.1: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) -preliminary trials (3/5)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Untreated	L-Carvone (300 g/L) Σ 162 ppm	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
ITCF_ITPT 96-97	Sprout inhibition	6x100 tubers								**Germination classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm

										4: sprouts > 5 mm
		Potatoes II) Nicola	Loss of tuber weight (%)	15./16.01.1997 5./6.05.1997	3 months 6 months	1.7 5.7	2.8 a) 3.8	1.8 a) 3.5	3.9 a) 4.1	L-Carvone presents a quite good effectiveness comparable to RP[T] for the first 3 months. After 6 months the effectiveness is a bit weaker than for RP[T].
			Class 0 (% of not sprouted tubers)	15./16.01.1997 5./6.05.1997	3 months 6 months	57.8 0.0	65.6 94.4	0.0 99.8	80.4 0.0	
			Classes 3&4 (% tubers with sprouts > 2 mm)	15./16.01.1997 5./6.05.1997	3 months 6 months	19.6 100.0	0.0 49.3	98.5 84.8	0.0 89.7	
			Total weight of sprouts > 2mm (g)	15./16.01.1997 5./6.05.1997	3 months 6 months	2.03 650.7	0.0 99.8	99.5 98.8	0.0 99.4	

Notes: a) Loss of tuber weight in % (In this case no effectiveness was calculated.)

Appendix 5.1: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) -preliminary trials (4/5)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Untreated	L-Carvone (300 g/L) Σ 150 ppm	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	

							treated			
GIE DA INH PDT/ MM/ 9801	Sprout inhi-bition	6x100 tubers								**Germination classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts > 5 mm
		Potatoes I) Bintje	Class 0 (% of not sprouted tubers)	Not stated Not stated	3 months 6 months	99.8 100.0	0.5 0.0	1.5 2.5	2.5 0.0	L-Carvone presents a quite good effectiveness compara-ble to both reference products.
			Classes 3&4 (% tubers with sprouts > 2 mm)	Not stated Not stated	3 months 6 months	83.0 100.0	98.4 99.5	99.0 100.0	96.5 99.5	
			Total weight of sprouts > 2mm (g)	Not stated Not stated	3 months 6 months	5.00 485.0	99.6 100.0	99.4 100.0	99.0 100.0	
			Sprout index (0-100) [b)]	Not stated Not stated	3 months 6 months	65.0 99.8	86.9 94.7	87.7 95.1	87.1 94.7	

Notes: b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0*(no sprout) + 0.5*(white bud stage) + 1*(sprouts<2mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm))*100 / 7.5*(total number of tubers)

Appendix 5.1: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) -preliminary trials (5/5)

Test re-port	**Target effect**	**Sample size: Stored prod-ucts**	**Reference base for effective-ness evalua-tion**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Un-treated	L-Car-vone (300 g/L) Σ 150 ppm	Reference (Powder)	Reference (Thermo)	
							Effec-tive-ness in % of un-	Effectiveness in % of un-treated	Effective-ness in % of untreat-ed	

							treated			
GIE DA INH PDT/ MM/ 9801	Sprout inhi-bition	6x100 tubers								**Germination classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts > 5 mm
		Potatoes II) Nicola	Class 0 (% of not sprouted tubers)	Not stated Not stated	3 months 6 months	0.0 0.0	0.3 0.0	0.0 1.5	0.0 0.0	
			Classes 3&4 (% tubers with sprouts > 2 mm)	Not stated Not stated	3 months 6 months	99.7 100.0	99.3 100.0	96.3 96.5	95.3 96.7	L-Carvone presents a quite good effectiveness compara-ble to both reference products.
			Total weight of sprouts > 2 mm (g)	Not stated Not stated	3 months 6 months	85.8 1139.2	100.0 100.0	100.0 100.0	100.0 99.9	
			Sprout index (0-100) [b)]	Not stated Not stated	3 months 6 months	94.6 100.0	91.5 95.0	88.7 92.7	88.8 91.9	

Notes: b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0*(no sprout) + 0.5*(white bud stage) + 1*(sprouts <2 mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm))*100 / 7.5*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes / sprout inhibition) (1/14)

Test report	Target effect	Sample size: Stored products	Reference base for effectiveness evaluation	Efficacy evaluation							Remarks
				Assessment dates	Storage time	Untreated	XEDA HM Nat (550 g/L) 1 N	XEDA HM Nat (550 g/L) ½ N	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
Peronne_031201	Sprout inhibition	Sample size: not stated									**Germination classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts 5-10 mm 5: sprouts > 10 mm
		Potatoes I) Bintje	Class 0 (% of not sprouted tubers)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	13.9 0 0	25.0 15.7 24.2	12.5 1.0 0.0	29.1 1.8 0.4	22.8 2.3 0.0	The test product at dose N (TP^N) is fully comparable with the reference (powder) (RP^P) and better than the reference (thermal) (RP^T) in terms of tubers in classes 3-5 and total weight of sprouts. Concerning sprouting index TP^N is a bit weaker than RP^P but better than RP^T. Loss of tuber
			Classes 3-5 (% tubers with sprouts > 2 mm)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	64.8 99.96 100	57.7 85.0 48.3	34.3 25.8 14.7	72.7 80.9 54.6	59.1 43.1 8.5	
			Total weight of	16.-20.12.02	3 months	10.3 195.0	87.1 99.6	70.2 81.9	97.8 99.9	94.6 95.2	

			sprouts > 2mm (g)	10.-14.03.03 19.-24.05.03	6 months 8 months	497.9	98.2	62.7	99.8	74.2	weight is highest for RP^P. Test product at half the intended dose ($TP^{1/2}$) is considerably weaker in all cases.
			Sprout index (0-100) [b)]	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	52.2 98.68 100	73.5 91.2 76.8	59.9 42.7 22.3	88.8 92.2 87.4	65.4 65.0 24.0	
			Loss of tuber weight (%)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	3.2 5.35 8.1	2.82 [a)] 3.6 5.2	2.69 [a)] 3.4 5.2	4.05 [a)] 6.1 8.9	3.04 [a)] 4.2 5.1	

Notes: a) Loss of tuber weight in % (In this case no effectiveness was calculated.)
b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0.5*(white bud stage) + 1*(sprouts < 2 mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm) + 15*(sprouts >10 mm))*100 / 15*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (2/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**							**Remarks**
				Assessment dates	Storage time	Untreated	XEDA HM Nat (550 g/L) 1 N	XEDA HM Nat (550 g/L) ½ N	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
Peronne_031201	Sprout inhibition	Sample size: not stated									**Sprouting classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm

											4: sprouts 5-10 mm 5: sprouts > 10 mm
		Potatoes II) Nicola	Class 0 (% of not sprouted tubers)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	4.4 0.0 0.0	42.8 28.8 33.3	30.4 7.8 0.0	3.1 1.0 0.0	16.7 7.0 0.0	
			Classes 3-5 (% tubers with sprouts > 2 mm)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	71.19 99.8 100.0	96.3 92.0 75.1	86.2 64.4 25.3	94.1 99.8 100.0	84.7 79.5 56.4	Initially TP^N is more efficacious than all other variants. After 8 months TP^N is fully comparable with RP^p and better than RP^T in terms of total weight of sprouts and % of non sprouted tubers. Concerning sprouting index TP^N is a bit weaker than RP^P but better than RP^T. Loss of tuber weight is highest for RP^P. $TP^{1/2}$ is considerably weaker in all cases.
			Total weight of sprouts > 2mm (g)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	10.67 399.0 873.4	99.5 99.9 99.1	96.8 97.3 74.8	99.8 100.0 100.0	97.8 99.4 92.1	
			Sprout index (0-100) [b)]	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	51.97 99.3 100.0	94.9 94.6 85.2	88.6 73.1 30.5	89.9 95.8 95.7	87.8 86.2 66.2	
			Loss of tuber weight (%)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	3.14 5.22 8.2	2.7 [a)] 3.6 5.0	2.7 3.4 4.6	4.1 6.4 8.6	2.9 3.5 4.3	

Notes a) Loss of tuber weight in % (In this case no effectiveness was calculated.)
b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0.5*(white bud stage) + 1*(sprouts<2mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm) + 15*(sprouts >10mm))*100 / 15*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (3/14)

Test report	Target effect	Sample size: Stored products	Reference base for effectiveness evaluation	Efficacy evaluation							Remarks
				Assessment dates	Storage time	Untreated	XEDA HM Nat (550 g/L) 1 N	XEDA HM Nat (550 g/L) ½ N	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
Peronne_031201	Sprout inhibition	Sample size: not stated									**Sprouting classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts 5-10 mm 5: sprouts > 10 mm
		Potatoes III) Monalisa	Class 0 (% of not sprouted tubers)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	37.97 0.28 0.0	92.2 70.8 67.2	82.3 32.8 7.2	36.4 16.2 0.0	66.5 42.1 0.0	After 8 months TP^N is fully comparable with RP^P and better than RP^T in terms of total weight of sprouts and sprout index. Concerning tuber in classes 3-5 TP^N is a bit weaker than RP^P but better than RP^T. Loss of tuber weight is highest for RP^P. $TP^{1/2}$ is considerably weaker in all cases.
			Classes 3-5 (% tubers with sprouts > 2 mm)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	15.56 98.52 100.0	98.1 97.9 88.8	86.8 65.0 44.1	100.0 84.4 100.0	93.6 90.3 58.4	
			Total weight of sprouts > 2mm (g)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	0.45 82.22 368.3	100.0 99.8 99.4	75.6 91.6 72.0	100.0 100.0 100.0	95.6 96.3 84.2	
			Sprout	16.-	3	6.73	96.7	84.8	78.6	85.9	

			index (0-100) [b)]	20.12.02 10.-14.03.03 19.-24.05.03	months 6 months 8 months	89.2 99.9	97.9 94.7	76.9 54.8	96.2 96.0	92.6 69.1	
			Loss of tuber weight (%)	16.-20.12.02 10.-14.03.03 19.-24.05.03	3 months 6 months 8 months	2.78 4.4 7.0	2.15 [a)] 3.2 5.1	2.34 3.1 4.4	3.64 5.0 6.8	2.34 3.4 5.4	

Notes: a) Loss of tuber weight in % (In this case no effectiveness was calculated.)
b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0.5*(white bud stage) + 1*(sprouts <2 mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm) + 15*(sprouts >10 mm))*100 / 15*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (4/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Untreated	XEDA HM Nat (550 g/L) 1 N	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
Peronne_050701	Sprout inhibition	Sample size: not stated								**Germination classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts 5-10 mm 5: sprouts > 10 mm
		Potatoes I) Bintje	Class 0 (% of not	09.-12.12.03 18.-30.03.04	3 months 6 months	3.19 0.0	2.8 3.9	4.2 0.0	2.4 1.8	The test product at dose N (TP^N) is fully

			sprouted tubers)	07.-09.06.04	9 months	0.0	9.2	3.0	0.7	comparable with the reference (thermal) (RP^T) and (a bit) weaker than the reference (powder) (RP^P) in terms of total weight of sprouts and sprout index. Loss of tuber weight is highest for TP^N and RP^T.
			Classes 3-5 (% tubers with sprouts > 2 mm)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	76.05 100.0 100.0	53.1 44.5 31.3	66.7 72.9 55.0	29.6 59.6 41.2	
			Total weight of sprouts > 2mm (g)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	16.82 568.27 1132.1	81.0 98.6 91.8	96.4 99.8 99.8	71.8 99.4 92.7	
			Sprout index (0-100) [b)]	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	54.15 100.0 100.0	66.7 73.7 49.6	83.4 90.9 85.5	36.3 81.8 52.4	
			Loss of tuber weight (%)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	1.61 10.1 18.41	2.88 [a)] 5.18 8.05	1.83 3.23 5.18	2.57 4.12 7.23	

Notes: a) Loss of tuber weight in % (In this case no effectiveness was calculated.)
b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0.5*(white bud stage) + 1*(sprouts <2 mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm) + 15*(sprouts >10 mm))*100 / 15*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (5/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Untreated	XEDA HM Nat (550 g/L) 1 N	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
Peronne_050701	Sprout inhibition	Sample size: not stated								**Sprouting classes:** 0: not sprouted 1: beginning of sprouting (white bud stage)

										2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts 5-10 mm 5: sprouts > 10 mm
		Potatoes II) Nicola	Class 0 (% of not sprouted tubers)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	1.39 0.0 0.0	22.3 15.1 12.4	3.3 0.2 3.4	0.6 5.3 4.1	TP^N is more efficacious than all other variants concerning not sprouted tubers. After 9 months TP^N has 95% effectiveness concerning total weight of sprouts. Concerning sprouting index TP^N is weaker than RP^P and RP^T due to significantly more tubers with sprouts >10 mm, although the number of tubers without sprout is the lowest. After 9 months loss of tuber weight is higher for TP^N than for other treated variants.
			Classes 3-5 (% tubers with sprouts > 2 mm)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	81.43 100.0 100.0	98.4 80.0 43.2	99.7 100.0 99.4	76.8 88.0 64.5	
			Total weight of sprouts > 2mm (g)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	27.15 879.81 1587.36	99.9 99.6 94.7	100.0 100.0 100.0	96.1 99.8 98.1	
			Sprout index (0-100) [b)]	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	64.62 100.0 100.0	95.2 87.5 49.3	94.5 96.2 95.5	79.5 92.1 76.1	
			Loss of tuber weight (%)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	2.69 15.42 24.67	1.56 [a)] 3.78 5.74	2.34 4.17 5.4	2.48 3.97 4.96	

Notes a) Loss of tuber weight in % (In this case no effectiveness was calculated.)
b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0.5*(white bud stage) + 1*(sprouts <2 mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm) + 15*(sprouts >10 mm))*100 / 15*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (6/14)

Test report	Target effect	Sample size: Stored products	Reference base for effectiveness evaluation	Efficacy evaluation						Remarks
				Assessment dates	Storage time	Untreated	XEDA HM Nat (550 g/L) 1 N	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
Peronne_050701	Sprout inhibition	Sample size: not stated								**Sprouting classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts 5-10 mm 5: sprouts > 10 mm
		Potatoes III) Monalisa	Class 0 (% of not sprouted tubers)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	6.53 0.26 0.0	55.5 39.3 43.0	41.4 2.8 21.0	17.2 16.0 12.8	TP^N is more efficacious than all other variants with 43% not sprouted tubers after 9 months. Concerning total weight of sprouts TP^N is well comparable with both RPs with 99% effectiveness after 9 months. Concerning all parameters TP^N is well comparable with RP^T.
			Classes 3-5 (% tubers with sprouts > 2 mm)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	51.69 99.48 100.0	96.3 92.9 76.8	100.0 99.4 99.5	89.1 93.3 82.6	
			Total weight of sprouts > 2 mm (g)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	3.01 416.18 828.56	95.7 99.7 98.6	100.0 100.0 100.0	95.7 99.9 98.4	

			Sprout index (0-100) [b)]	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	18.1 99.29 100.0	88.3 93.4 82.0	89.1 95.9 96.9	76.7 94.9 87.1	
			Loss of tuber weight (%)	09.-12.12.03 18.-30.03.04 07.-09.06.04	3 months 6 months 9 months	1.27 7.78 14.28	1.75 [a)] 2.71 4.17	1.42 [a)] 3.07 4.68	1.31 [a)] 2.64 3.98	

Notes: a) Loss of tuber weight in % (In this case no effectiveness was calculated.)
b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0.5*(white bud stage) + 1*(sprouts<2mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm) + 15*(sprouts >10 mm))*100 / 15*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (7/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Untreated	XEDA HM Nat (550 g/L) 1x100, 4x75 ppm	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
Paris_090601	Sprout inhibition	Sample size: not stated								**Germination classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts 5-10 mm

										5: sprouts > 10 mm
		Potatoes I) Agata	Class 0 (% of not sprouted tubers)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	2.06 0.0 0.0	44.5 78.2 77.8	28.5 6.5 9.1	21.3 2.0 5.5	TP^N is more efficacious than all other variants with 78% not sprouted tubers after 9 months. Concerning total weight of sprouts TP^N is highly efficacious with 99% effectiveness after 9 months. Concerning all parameters TP^N is well comparable with RP^P and better than RP^T.
			Classes 3-5 (% tubers with sprouts > 2 mm)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	82.71 92.51 100.0	94.0 88.6 84.5	94.2 89.8 86.1	72.2 55.1 53.9	
			Total weight of sprouts > 2mm (g)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	57.62 296.62 448.54	99.4 99.7 99.4	99.6 99.9 99.9	97.3 98.4 98.8	
			Sprout index (0-100) [b)]	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	64.58 88.92 100.0	93.7 93.6 94.1	93.3 93.2 93.4	81.2 74.4 70.4	
			Loss of tuber weight (%)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	2.3 6.7 5.5	2.0 [a)] 3.7 4.5	1.5 [a)] 2.6 3.3	2.0 [a)] 3.6 4.3	

Notes: a) Loss of tuber weight in % (In this case no effectiveness was calculated.)
b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0.5*(white bud stage) + 1*(sprouts<2mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm) + 15*(sprouts >10mm))*100 / 15*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (8/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Untreated	XEDA HM Nat (550 g/L) 1x100, 4x75 ppm	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of	Effectiveness in % of	Effectiveness in % of un-	

							untreated	untreated	treated	
Par-is_090601	Sprout inhibi-tion	Sample size: not stated								**Sprouting classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts 5-10 mm 5: sprouts > 10 mm
		Potatoes II) Bintje	Class 0 (% of not sprouted tubers)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	67.22 0.14 0.25	2.7 89.2 96.4	52.4 6.8 9.3	34.3 7.5 3.6	TP^N is more efficacious than all other variants with 96% not sprouted tubers after 9 months. Concerning total weight of sprouts TP^N is highly efficacious with 100% effectiveness after 9 months. Concerning all parameters TP^N is mostly better than both RPs.
			Classes 3-5 (% tubers with sprouts > 2 mm)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	17.24 94.75 99.75	98.6 97.4 99.4	98.4 74.3 76.4	94.5 85.7 44.5	
			Total weight of sprouts > 2mm (g)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	3.84 212.23 461.06	99.5 99.6 100.0	99.7 94.0 97.2	99.5 98.6 96.5	
			Sprout index (0-100) [b)]	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	12.24 93.5 99.75	90.3 98.4 99.7	94.9 80.6 82.7	92.2 88.1 71.8	
			Loss of tuber weight (%)	12.-15.12.09 01.-07.04.09	3 months 6 months	3.6 6.3 6.9	2.7 [a)] 3.8 5.2	2.0 [a)] 3.4 4.5	2.9 [a)] 4.5 6.2	

				25.-29.05.09	8 months					

Notes: a) Loss of tuber weight in % (In this case no effectiveness was calculated.)
b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0.5*(white bud stage) + 1*(sprouts < 2mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm) + 15*(sprouts >10 mm))*100 / 15*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (9/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**						**Remarks**
				Assessment dates	Storage time	Untreated	XEDA HM Nat (550 g/L) 1x100, 4x75 ppm	Reference (Powder)	Reference (Thermo)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
Paris_090601	Sprout inhibition	Sample size: not stated								**Sprouting classes:** 0: not sprouted 1: beginning of sprouting (white bud stage) 2: sprouts < 2 mm 3: sprouts 2-5 mm 4: sprouts 5-10 mm 5: sprouts > 10 mm
		Potatoes III) Nicola	Class 0 (% of not sprouted tubers)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	35.74 0.0 0.0	60.5 94.3 96.3	39.2 6.3 13.4	40.0 9.0 5.2	TP^N is more efficacious than all other variants with 96% not sprouted tubers after 9 months. Concerning total weight of sprouts TP^N is highly efficacious with 100% effectiveness after 9 months. Concerning all parameters TP^N is mostly better than both RPs.
			Classes 3-5 (% tubers with sprouts >	12.-15.12.09 01.-07.04.09 25.-	3 months 6 months 8	20.44 86.18 100.0	100.0 98.3 98.5	96.9 97.7 96.7	99.1 89.4 86.2	

			2 mm)	29.05.09	months					
			Total weight of sprouts > 2mm (g)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	3.71 254.17 718.91	99.7 100.0 100.0	98.4 99.9 99.7	100.0 99.5 98.8	
			Sprout index (0-100) [b)]	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	15.9 83.41 100.0	94.7 99.3 99.5	90.1 94.5 94.4	90.9 90.2 86.9	
			Loss of tuber weight (%)	12.-15.12.09 01.-07.04.09 25.-29.05.09	3 months 6 months 8 months	4.7 [a)] 7.3 8.4	3.6 [a)] 5.4 5.5	2.6 [a)] 4.3 4.3	3.4 [a)] 4.7 4.2	

Notes: a) Loss of tuber weight in % (In this case no effectiveness was calculated.)
b) A sprout index is calculated. It varies between 0 and 100. **Sprout index**= (0.5*(white bud stage) + 1*(sprouts <2 mm) + 3*(sprouts 2-5 mm) + 7.5*(sprouts >5 mm) + 15*(sprouts >10 mm))*100 / 15*(total number of tubers)

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (10/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**							**Remarks**
				Assessment dates	Storage time	Untreated	BIOX-M (65-85%) 1 N	BIOX-M (65-85%) ½ N	BIOX-M (65-85%) 2 N	Reference (Xedamate 60 HN)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
R010-10R	Sprout inhibition	Sample size: 12 nets of 15 kg potatoes									**Sprouting classes:** 0: not sprouted 1: sprouts 1-3 mm

											2: sprouts 3-10 mm 3: sprouts 10-20 mm 4: sprouts > 20 mm
		Potatoes Bintje	Total weight of sprouts (g/100 tubers)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	182.9 469.3 857.9	100.0 98.0 94.2	81.0 93.0 85.8	100.0 99.2 99.0	100.0 99.6 98.6	The dose effect of BIOX-M was clearly established throughout the assessment period. The N dose of BIOX-M showed results, always equivalent to the reference Xedamate 60. In terms of tuber weight loss, no major or significant difference was highlighted between all the treatments throughout the assessment
			Sprout index (0-100) [b)]	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	75 187.5 125.0	88.8 92.3 73.5	77.9 89.5 60.6	91.6 96.1 94.1	91.6 93.0 91.1	
			Loss of tuber weight (%)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	3.7 9.1 17.6	3.7 6.0 10.7	4 5.4 13.2	4.9 7.8 12.2	3.4 6.6 10.8	
			Internal sprouting (%)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	0 0 0	0 [c)] 3.0 15.0	0 0 7.0	0 6.0 9.0	0 0 3.0	

											period.

Notes: a) Loss of tuber weight in %: Weight of tubers at beginning of storage minus weight of tubers **and** sprouts at end of storage. (In this case no effectiveness was calculated.)
b) A sprout index is calculated on the basis of the sprout classes. For class 4 the average length of the sprouts was calculated. The sprout index represents the geometric mean of the length of the sprouts.
c) Internal sprouting in percent, no calculation of efficacy.

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (11/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**							**Remarks**
				Assessment dates	Storage time	Untreated	BIOX-M (65-85%) 1 N	BIOX-M (65-85%) ½ N	BIOX-M (65-85%) 2 N	Reference (Xedamate 60 HN)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
R011-10R	Sprout inhibition	Sample size: 12 nets of 15 kg potatoes									**Sprouting classes:** 0: not sprouted 1: sprouts 1-3 mm 2: sprouts 3-10 mm 3: sprouts 10-20 mm 4: sprouts > 20 mm
		Potatoes Santana	Total weight of sprouts (g/100 tubers)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	245.6 610.1 1915.8	100.0 98.1 93.3	86.9 95.8 94.6	100.0 98.9 98.7	100.0 99.6 98.8	The dose effect of BIOX-M was clearly established throughout the assessment period. TP^{N} and TP^{2N}
			Sprout index (0-100) [b)]	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months	70.0 115.3 142.5	96.4 93.6 87.4	74.0 85.3 88.2	95.7 97.7 93.2	96.6 93.6 90.5	

					8.6 months						showed results equivalent to the reference Xedamate 60 (RP^T). After 8 months in storage, TP^N and $TP^{1/2}$ showed a significant higher sprout weight in comparison with TP^{2N} and RP^T. In terms of tuber weight loss, no major or significant difference was highlighted between all the treatments throughout the assessment period.
			Loss of tuber weight (%)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	6.6 10.8 9.1	7.6 a) 6.9 11.0	5.3 6.3 11.0	6.8 8.7 13.6	7.4 7.0 10.1	
			Internal sprouting (%)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	0 0 0	0 8.0 c) 14.0	0 0 8.0	0 5.0 16.0	0 0 10.1	

Notes: a) Loss of tuber weight in %: Weight of tubers at beginning of storage minus weight of tubers **and** sprouts at end of storage. (In this case no effectiveness was calculated.)

b) A sprout index is calculated on the basis of the sprout classes. For class 4 the average length of the sprouts was calculated. The sprout index represents the geometric mean of the length of the sprouts.
c) Internal sprouting in percent, no calculation of efficacy.

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (12/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**							**Remarks**
				Assessment dates	Storage time	Untreated	BIOX-M (65-85%) 1 N	BIOX-M (65-85%) ½ N	BIOX-M (65-85%) 2 N	Reference (Xedamate 60 HN)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
R012-10R	Sprout inhibition	Sample size: 12 nets of 15 kg potatoes									**Sprouting classes:** 0: not sprouted 1: sprouts 1-3 mm 2: sprouts 3-10 mm 3: sprouts 10-20 mm 4: sprouts > 20 mm
		Potatoes Asterix	Total weight of sprouts (g/100 tubers)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	277.4 900.7 2082.6	100.0 96.9 94.2	79.8 90.8 84.9	100.0 98.4 93.1	100.0 99.5 97.9	The dose effect of BIOX-M was clearly established throughout the assessment period. TP^N showed results equivalent to the ref-
			Sprout index (0-100) [b)]	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	50.0 157.5 200.0	82.0 90.4 78.2	64.8 78.3 70.9	82.4 95.0 92.0	89.0 92.7 89.2	
			Loss of tuber	03.02.10	3.8	7.7	4.8 [a)]	6.1	8.0	6.3	

			weight (%)	29.03.10 28.06.10	months 5.6 months 8.6 months	9.8 15.9	8.6 11.6	9.3 14.0	11.2 15.6	8.9 11.8	erence Xedamate 60 (RP^T). In terms of tuber weight loss, no major or significant difference was high-lighted between all the treat-ments throughout the as-sessment period.
			Internal sprouting (%)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	0 0 0	0 2.0 c) 11.0	0 0 2.0	0 2.0 12.0	0 0 2.0	

Notes: a) Loss of tuber weight in %: Weight of tubers at beginning of storage minus weight of tubers **and** sprouts at end of storage. (In this case no effectiveness was calculated.)
b) A sprout index is calculated on the basis of the sprout classes. For class 4 the average length of the sprouts was calculated. The sprout index represents the geometric mean of the length of the sprouts.
c) Internal sprouting in percent, no calculation of efficacy.

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (13/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Efficacy evaluation**							**Remarks**
				Assessment dates	Storage time	Untreated	BIOX-M (65-85%) 1 N	BIOX-M (65-85%) ½ N	BIOX-M (65-85%) 2 N	Reference (Xedamate-60 HN)	
							Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	Effectiveness in % of untreated	
R013-10R	Sprout inhibition	Sample size: 12 nets of 15 kg potatoes									**Sprouting classes:** 0: not sprouted 1: sprouts

											1-3 mm 2: sprouts 3-10 mm 3: sprouts 10-20 mm 4: sprouts > 20 mm
		Potatoes Innovator	Total weight of sprouts (g/100 tubers)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	138.7 693.4 3468.9	100.0 96.9 97.5	97.5 94.4 89.8	100.0 98.4 96.0	100.0 96.8 96.1	The dose effect of BIOX-M was clearly established throughout the assessment period. TP^N and TP^{2N} showed results equivalent to the reference Xedamate 60 (RP^T). In terms of tuber weight loss, no major or significant difference was highlighted between all the treatments throughout the assessment
			Sprout index (0-100) [b)]	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	43.8 165.0 2000	92.2 92.2 89.2	87.4 88.6 86.1	89.7 95.8 95.9	95.9 95.6 89.7	
			Loss of tuber weight (%)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	5.3 9.2 9.5	5.2 7.1 10.2	5.4 7.2 11.2	6.1 8.2 11.5	5.2 8.1 10.1	
			Internal sprouting (%)	03.02.10 29.03.10 28.06.10	3.8 months 5.6 months 8.6 months	0 0 0	0 4.0 16.0	0 0 11.0	0 5.0 20.0	0 0 8.0	

											period.

Notes: a) Loss of tuber weight in %: Weight of tubers at beginning of storage minus weight of tubers **and** sprouts at end of storage. (In this case no effectiveness was calculated.)
b) A sprout index is calculated on the basis of the sprout classes. For class 4 the average length of the sprouts was calculated. The sprout index represents the geometric mean of the length of the sprouts.
c) Internal sprouting in percent, no calculation of efficacy.

Appendix 5.2: Summary of data on effectiveness trials per use (stored potatoes/ sprout inhibition) (14/14)

Test report	**Target effect**	**Sample size: Stored products**	**Reference base for effectiveness evaluation**	**Variety**	**Efficacy evaluation**				**Remarks**
					Assessment dates	Storage time DAA	Untreated	L-Carvone (65-85%) 50 ppm	
Negev_011109	Sprout inhibition	Sample size: 12 nets of 15 kg potatoes			Approx.110 days				
		Potatoes	Burnt sprouts (%)	Charlotte Maris Peer Annabelle Vivaldi Lady Chlair Odem Saline	5		5.5 38.8 1.2 6.2	100 100 100 89 91 95 94	BIOX-M successfully destroyed existing sprouts for all tested varieties. BIOX-M successfully stopped sprout elongation for 15 days after application.
			Sprout elongation (mm/14 days)	Charlotte Maris Peer Annabelle Vivaldi Lady Chlair Odem	15		7 18 21 14	0 0 0 0 0 0	

Notes:

Appendix 6.1: Summary of detailed data on potato sprout inhibition effectiveness trials (BIOX M / intended dose / storage time approx. 3 months / effectiveness in % compared to untreated) (1/4)

Variety	Nicola			Bintje			Monalisa			Santana	Asterix	Innovator
No. of trials (Trial No.)	2 (Peronne_031201, Peronne_050701)			3 (Peronne_031201, Peronne_050701, R010-10R)			2 (Peronne_031201, Peronne_050701)			1 (R011-10R)	1 (R012-10R)	1 (R013-10R)
	Average	min	max	Average	min	max	Average	min	max			
Class 0 (% of not sprouted tubers)	32.56	22.29	42.82	13.88 b)	2.77	25.00	73.89	55.53	92.25	-	-	-
Classes 3-5 (% tubers with sprouts > 2 mm)	97.35	96.26	98.44	55.39 b)	53.07	57.70	97.21	96.34	98.07	-	-	-
Total weight of sprouts	99.69	99.53	99.85	89.38	81.03	100.00	97.84	95.68	100.00	100.0	100.0	100.0
Sprout index	95.04	94.92	95.16	76.33	66.69	88.80	92.51	88.29	96.73	96.4	82.0	92.2
Loss of tuber weight (%) c)	27.55	13.10	42.00	Not defined a)	Not defined a)	15.90	Not defined a)	Not defined a)	22.70	Not defined	37.7	1.9

a) An increased loss of tuber weight in the treated variant compared to the untreated variant would mathematically lead to a negative efficacy. In these cases the product was assumed to have no effect on tuber weight rather than a negative one.
b) For this assessment only two trials are evaluated.
c) In contrast to the presentation in Appendix 5 in the tables in Appendix 6 the loss of tuber weight is presented as percentage of the untreated variant.

Appendix 6.1: Summary of detailed data on potato sprout inhibition effectiveness trials (BIOX M / intended dose / storage time approx. 6 months / effectiveness in % compared to untreated) (2/4)

Variety	Nicola			Bintje			Monalisa			Santana	Asterix	Innovator
No. of trials (Trial No.)	2 (Peronne_031201, Peronne_050701)			3 (Peronne_031201, Peronne_050701, R010-10R)			2 (Peronne_031201, Peronne_050701)			1 (R011-10R)	1 (R012-10R)	1 (R013-10R)
	Average	min	max	Average	min	max	Average	min	max			
Class 0 (% of not sprouted	21.97	15.14	28.79	9.78 b)	3.88	15.67	55.05	39.33	70.77	-	-	-

tubers)												
Classes 3-5 (% tubers with sprouts > 2 mm)	85.99	79.97	92.00	64.77 b)	44.52	85.01	95.41	92.93	97.88	-	-	-
Total weight of sprouts (g)	99.74	99.58	99.90	98.73	97.98	99.61	99.77	99.74	99.81	98.1	96.9	96.9
Sprout index	91.05	87.54	94.55	85.74	73.72	92.32	95.66	93.44	97.87	93.6	90.4	92.2
Loss of tuber weight (%)	53.25	31.00	75.50	38.49	32.70	48.70	46.75	28.30	65.20	36.1	12.2	22.8

c) For this assessment only two trials are evaluated.

Appendix 6.1: Summary of detailed data on potato sprout inhibition <u>effectiveness</u> trials (BIOX M / intended dose / storage time 8-9 months / effectiveness in % compared to untreated) (3/4)

Variety	**Nicola**			**Bintje**			**Monalisa**			**Santana**	**Asterix**	**Innovator**
No. of trials (Trial No.)	2 (Peronne_031201, Peronne_050701)			3 (Peronne_031201, Peronne_050701, R010-10R)			2 (Peronne_031201, Peronne_050701)			1 (R011-10R)	1 (R012-10R)	1 (R013-10R)
	Average	**min**	**max**	**Average**	**min**	**max**	**Average**	**min**	**max**			
Class 0 (% of not sprouted tubers)	22.89	12.44	33.33	16.67 b)	9.18	24.16	55.09	42.99	67.18	-	-	-
Classes 3-5 (% tubers with sprouts > 2 mm)	59.15	43.22	75.08	39.78 b)	31.27	48.28	82.83	76.82	88.84	-	-	-
Total weight of sprouts (g)	96.89	94.69	99.09	94.71	91.76	98.22	99.02	98.64	99.41	93.3	94.2	97.5
Sprout index	67.25	49.33	85.16	66.64	49.63	76.77	88.31	81.95	94.67	87.4	78.2	89.2
Loss of tuber weight (%)	57.85	39.00	76.70	43.83	36.00	56.30	49.00	27.20	70.80	Not defined a)	27.0	Not defined a)

a) An increased loss of tuber weight in the treated variant compared to the untreated variant would mathematically lead to a negative efficacy. In these cases the product was assumed to have no effect on tuber weight rather than a negative one.
b) For this assessment only two trials are evaluated.

Appendix 6.1: Summary of detailed data on potato sprout inhibition <u>effectiveness</u> trials (BIOX M / intended dose / effectiveness in % compared to untreated) (4/4)

Storage time	**3 months**			**6 months**			**8-9 months**		
No. of trials (Trial No.)	10 (3xPeronne_031201, 3xPeronne_050701, R010-10R, R011-10R, R012-10R, R013-10R)			10 (3xPeronne_031201, 3xPeronne_050701, R010-10R, R011-10R, R012-10R, R013-10R)			10 (3xPeronne_031201, 3xPeronne_050701, R010-10R, R011-10R, R012-10R, R013-10R)		
	Average	**min**	**max**	**Average**	**min**	**max**	**Average**	**min**	**max**
Class 0 (% of not sprouted tubers)	40.11 b)	2.77	92.25	28.93 b)	3.88	70.77	31.55 b)	9.18	67.18
Classes 3-5 (% tubers with sprouts > 2 mm)	83.31 b)	53.07	98.44	82.05 b)	44.52	97.88	60.59 b)	31.27	88.84
Total weight of sprouts (g)	96.32	81.03	100.00	98.71	96.87	99.90	96.11	91.76	99.41
Sprout index	87.47	66.69	96.73	90.69	73.72	97.87	76.58	49.33	94.67
Loss of tuber weight (%)	11.56	Not defined a)	42.00	45.07	28.30	75.50	49.31	27.20	76.70

a) An increased loss of tuber weight in the treated variant compared to the untreated variant would mathematically lead to a negative efficacy. In these cases the product was assumed to have no effect on tuber weight rather than a negative one.
b) For this assessment only seven trials are evaluated.

Appendix 6.2: Summary of detailed data on potato sprout inhibition <u>minimum effective dose</u> trials (BIOX-M / storage time 3 months / effectiveness in % compared to untreated) (1/3)

Variety	**N**			**½ N**			**2 N**		
No. of trials (Trial No.)	7 (3xPeronne_031201, R010-10R, R011-10R, R012-10R, R013-10R)			7 (3xPeronne_031201, R010-10R, R011-10R, R012-10R, R013-10R)			4 (R010-10R, R011-10R, R012-10R, R013-10R)		
	Average	**min**	**max**	**Average**	**min**	**max**	**Average**	**min**	**max**
Class 0 (% of not sprouted tubers)	53.36 b)	25.00	92.25	41.73 b)	12.50	82.25	-	-	-
Classes 3-5 (% tubers with sprouts > 2 mm)	84.01 b)	57.70	98.07	69.09 b)	34.30	86.76	-	-	-
Total weight of sprouts	98.09	87.10	100.00	83.97	70.20	97.55	100.00	100.00	100.00
Sprout index	89.23	73.50	96.73	76.78	59.90	88.63	89.86	82.40	95.71
Loss of tuber weight (%)	11.88	Not defined a)	37.66	10.89	Not defined a)	20.78	Not defined a)	Not defined a)	Not defined a)

a) An increased loss of tuber weight in the treated variant compared to the untreated variant would mathematically lead to a negative efficacy. In these cases the product was assumed to have no effect on tuber weight rather than a negative one.
b) For this assessment only three trials were evaluated.

Appendix 6.2: Summary of detailed data on potato sprout inhibition <u>minimum effective dose</u> trials (BIOX-M / storage time 6 months / effectiveness in % compared to untreated) (2/3)

Variety	**N**			**½ N**			**2 N**		
No. of trials (Trial No.)	7 (3xPeronne_031201, R010-10R, R011-10R, R012-10R, R013-10R)			7 (3xPeronne_031201, R010-10R, R011-10R, R012-10R, R013-10R)			4 (R010-10R, R011-10R, R012-10R, R013-10R)		
	Average	**min**	**max**	**Average**	**min**	**max**	**Average**	**min**	**max**
Class 0 (% of not sprouted tubers)	38.41 b)	15.67	70.77	13.83 b)	0.96	32.79	-	-	-
Classes 3-5 (% tubers with sprouts > 2 mm)	91.63 b)	85.01	97.88	51.75 b)	25.79	65.00	-	-	-
Total weight of	98.46	96.87	99.90	92.12	81.95	97.31	98.73	98.36	99.17

sprouts									
Sprout index	93.16	90.41	97.87	76.36	42.68	89.49	96.14	94.98	97.66
Loss of tuber weight (%)	28.18	12.24	36.11	29.96	5.10	41.67	7.58	Not defined [a)]	19.44

a) An increased loss of tuber weight in the treated variant compared to the untreated variant would mathematically lead to a negative efficacy. In these cases the product was assumed to have no effect on tuber weight rather than a negative one.
b) For this assessment only three trials were evaluated.

Appendix 6.2: Summary of detailed data on potato sprout inhibition <u>minimum effective dose</u> trials (BIOX M / storage time 8-9 months / effectiveness in % compared to untreated) (3/3)

Variety	**N**			**½ N**			**2 N**		
No. of trials (Trial No.)	7 (3xPeronne_031201, R010-10R, R011-10R, R012-10R, R013-10R)			7 (3xPeronne_031201, R010-10R, R011-10R, R012-10R, R013-10R)			4 (R010-10R, R011-10R, R012-10R, R013-10R)		
	Average	**min**	**max**	**Average**	**min**	**max**	**Average**	**min**	**max**
Class 0 (% of not sprouted tubers)	41.56 [b)]	24.16	67.18	2.41 [b)]	0.00	7.22	-	-	-
Classes 3-5 (% tubers with sprouts > 2 mm)	70.73 [b)]	48.28	88.84	28.01 [b)]	14.69	44.08	-	-	-
Total weight of sprouts	96.57	93.34	99.41	80.65	62.70	94.60	96.69	93.10	99.00
Sprout index	83.55	73.52	94.67	59.05	22.34	88.21	93.77	91.95	95.85
Loss of tuber weight (%)	20.04	Not defined [a)]	39.20	16.61	Not defined [a)]	44.34	Not defined [a)]	Not defined [a)]	30.68

a) An increased loss of tuber weight in the treated variant compared to the untreated variant would mathematically lead to a negative efficacy. In these cases the product was assumed to have no effect on tuber weight rather than a negative one.
b) For this assessment only three trials were evaluated.

Appendix 7: Summary of phytotoxicity trials data in summary form

Table A7-1: Phytotoxicity symptoms (in % of affected tubers; further trial details in Appendices 4&5) (1/2)

Trial no.	Variety	Assessment date	DALA (for TP)	Dose	Dose (a.i.) for TP	Untreated (C)	Test product (TP)	Reference product (Powder) (RP^P)	Reference product (Thermal) (RP^T)
ITCF_ITPT 95-96	Bintje	10.01.1996	1	N	1x25 ppm + 4x12 ppm	0.0	0.0	0.0	0.0
		08.03.1996	2	N	1x25 ppm + 7x12 ppm	0.2	0.0	0.3	0.0
	Nicola	10.01.1996	1	N	1x25 ppm + 7x12 ppm	Not assessed	7.5	Not assessed	29.5
		08.03.1996	2	N	1x25 ppm + 7x12 ppm	Not assessed	9.0	Not assessed	32.0
	Roseval	10.01.1996	1	N	1x25 ppm + 7x12 ppm	Not assessed	0.0	Not assessed	1.5
		08.03.1996	2	N	1x25 ppm + 7x12 ppm	Not assessed	0.0	Not assessed	0.0
ITCF-ITPT96-97 [a]	Bintje	C: 18.04.97 TP: 30.12.96 RP^P: 15.04.97 RP^T: 14.01.97	20	N	1x25 ppm	0.0	1.0	0.5	0.0
			20	2N	1x50 ppm	-	0.2	1.0	0.0
			20	3N	1x75 ppm	-	0.2	0.0	0.0
	Nicola	C: 18.04.97 TP: 30.12.96 RP^P: 15.04.97 RP^T: 14.01.97	20	N	1x25 ppm	0.0	0.2	5.7	0.0
			20	2N	1x50 ppm	-	0.2	10.7	0.0
			20	3N	1x75 ppm	-	1.2	2.5	0.0

a) Application rates of this trial are different for effectiveness and phytotoxicity evaluations. Therefore application rates of this **Table A 7-1** are different from those in **Table 4.1**.

Table A7-1: Phytotoxicity symptoms (in % of affected tubers; further trial details in Appendices 4&5) (2/2)

Trial no.	Variety	Assessment date	DALA	Dose	Dose (a.i.) for TP	Untreated (C)	Test product (TP)	Reference product (Powder) (RP^P)	Reference product (Thermal) (RP^T)
R010-10R	Bintje	03.02.2010 29.03.2010 28.06.2010	104 158 249	N	1x90 ppm + 10x30 ppm	0	0	-	0
		03.02.2010 29.03.2010 28.06.2010	104 158 249	2N	1x 180 ppm + 10x60 ppm	0	0	-	0
R010-11R	Santana	03.02.2010 29.03.2010 28.06.2010	104 158 249	N	1x90 ppm + 10x30 ppm	0	0	-	0
		03.02.2010 29.03.2010 28.06.2010	104 158 249	2N	1x 180 ppm + 10x60 ppm	0	0	-	0
R010-12R	Asterix	03.02.2010 29.03.2010 28.06.2010	104 158 249	N	1x90 ppm + 10x30 ppm	0	0	-	0
		03.02.2010 29.03.2010 28.06.2010	104 158 249	2N	1x 180 ppm + 10x60 ppm	0	0	-	0
R010-13R	Innovator	03.02.2010 29.03.2010 28.06.2010	104 158 249	N	1x90 ppm + 10x30 ppm	0	0	-	0
		03.02.2010 29.03.2010 28.06.2010	104 158 249	2N	1x 180 ppm + 10x60	0	0	-	0

					ppm				

Appendix 8: Summary of taint testing trials data

Table A8-1: Organoleptic test (deviation from untreated sample [a) b)])

Variety	Preparation	Days after last treatment	Test product	Reference product
Bintje, Lot 2	French fries	6	0.05	0.0
	Boiled in water	6	0.16	0.0
Bintje, Lot 1	French fries	30	0.08	0.08
Agata	Boiled in water	30	0.22	0.08
Nicola	Boiled in water	30	0.47	0.50

a) Evaluation scale: 0 to 4, only bad taste is considered.
b) Trial reference: Paris_090601 (cf. **Appendix 4.2**) and Person (2009, study no. ES09-223)

Table A8-2: Culinary and technological analysis [a) b)])

Variety	Preparation	Days after last treatment	Assessment criterion	Test product	Reference product
Bintje, Lot 1	French fries	30	Frying qualities	1.89	1.89
Agata	Boiled in water	30	Cooking qualities	0.26	0.20
	Boiled in water	30	Blackening	3.14	3.06
Nicola	Boiled in water	30	Cooking qualities	0.01	0.01
	Boiled in water	30	Blackening	2.58	2.35

a) Evaluation scale: 0 to 5
b) Trial reference: Paris_090601 (cf. **Appendix 4.2**) and Person (2009, study no. ES09-223)

Appendix 9: List of abbreviations

DALA days after last application
n.s. not stated
RP reference product
RP^P reference product (powder)
RP^T reference product (thermal)
TP test product