

Chemicals Regulation Directorate

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Date 11 November 2009

<http://www.hse.gov.uk/>

Dear Mr Galloway

**COP 2009/01487 APPLICATION FOR THE USE OF 'BIOX-M' AS AN
EXPERIMENTAL POTATO SPROUT SUPPRESSANT: NO
DATA (EXPERIMENTAL) PROCEDURE**

Thank you for your application of 10 September 2009 for experimental approval for 'BIOX-M'. Ministers have agreed to grant an approval and consent until 30 November 2012 for:

Product name: BIOX-M (contains Plant oil- spearmint oil)

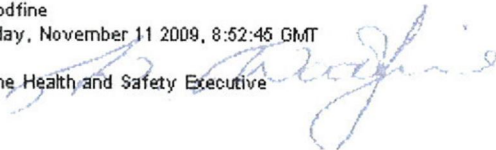
MAPP Number: 00000

The Notice of Approval is attached to this letter.

This product which is the subject of an approval for research and development purposes must only be stored, supplied or used by the approval holder or their agent(s). The number of agents should be kept to a minimum and must be advised of all conditions of approval.

Yours sincerely

Signed by: wendy woodfine
Signing time: Wednesday, November 11 2009, 8:52:46 GMT
Location: CRD York
Reason to sign: For the Health and Safety Executive



HSE Digital Signature

Lisa Moakes (Mrs)
Registration Branch

www.pesticides.gov.uk

APPROVAL AND CONSENT FOR A PLANT PROTECTION PRODUCT

FOOD AND ENVIRONMENT PROTECTION ACT 1985: PART III
PLANT PROTECTION PRODUCTS REGULATIONS 2005
PLANT PROTECTION PRODUCTS (SCOTLAND) REGULATIONS 2005
PLANT PROTECTION PRODUCTS (BASIC CONDITIONS) REGULATIONS 1997

Product name: BIOX-M

Formulation: a hot fogging concentrate formulation containing Spearmint Oil (containing ≥ 550 g / kg L-Carvone) details of which are specified in the 'Confidential Conditions' section (Appendix 3) of this approval.

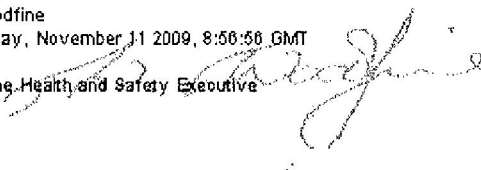
MAPP number: 00000

Approval holder: Xeda International , 2 Zone, Artisanale da la Crau, 13670 St Andiol, France.
(Registered company number: 305949802)

This approval ends: 30 November 2012

Extent of Approval: Great Britain

Signed by: wendy woodfine
Signing time: Wednesday, November 11 2009, 8:56:56 GMT
Location: CRD York
Reason to sign: For the Health and Safety Executive



HSE Digital Signature

(This and the attached Appendices 1 to 3 are signed by HSE for and on behalf of the Secretary of State, the Welsh and the Scottish Ministers)

Date of issue 11 November 2009.

EXPLANATORY NOTES

1. This Notice of Approval Number is 3093 of 2009.
2. Application reference number COP 2009/01487.

APPENDIX 1: CONDITIONS OF APPROVAL AND CONSENT

Failure to comply with the following conditions may result in revocation or suspension of approval or other enforcement action, including prosecution.

Use:

Field of use: **ONLY AS AN AGRICULTURAL SPROUT SUPPRESSANT IN FOOD STORAGE PRACTICE**

User: Professional

Crops/situations:	Maximum individual dose: (ml product / tonne)	Maximum total dose: (ml product / tonne)	Maximum number of treatments:	Latest time of application:
Potato (post harvest use)	90	390	-	12 days before removal from store

Maximum amount to be treated: 10,000 tonnes.

Operator protection:

- (1) Application must only be made using equipment where the operator is outside the structure at the time of treatment.
- (2) Engineering control of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment:
 - (a) Operators must wear suitable protective clothing (coveralls), suitable protective gloves and face protection (faceshield) when handling the concentrate or applying the product.
 - (b) Operators must wear suitable protective clothing (coveralls), suitable protective gloves and suitable respiratory protective equipment* when re-entering treated areas before adequate ventilation. *Full facemask to at least EN 136 with a combination filter to at least EN141 A2P3, or equivalent.

- (3) However, other engineering controls in addition to those specified above may replace personal protective equipment if a COSHH assessment shows that they provide an equal or higher standard of protection.

Environmental protection:

- (1) Since this product is potentially harmful to fish or other aquatic life, surface waters or ditches must not be contaminated with chemical or used container.
- (2) Since there is a potential for the contamination of groundwater from use:
 - (a) Applications must not be made to sites with soils of high leaching potential. Details of the leaching potential of soils in England and Wales are given on Groundwater Vulnerability Maps available from the Stationery Office (for major and minor aquifers), and from the Environment Agency (for non-aquifer areas). In Scotland, a limited number of groundwater vulnerability maps are available. The Scottish Environment Protection Agency should be consulted for further information regarding these maps.
 - (b) In England and Wales applications must not be made to areas within a Zone 1 Groundwater Source Protection Zone or within 50m of other sources of groundwater used to supply drinking water. Details of 'Groundwater Source Protection Zones' in England and Wales are available on the Environment Agency's website (www.environment-agency.gov.uk). There are currently no Groundwater Source Protection Zones in Scotland.

If conditions (3)(a) and (3)(b) cannot be complied with at the trial site(s) selected, or there is any doubt about such compliance, the approval holder must contact the Environment Agency or Scottish Environment Protection Agency as appropriate. The agreement of the relevant Agency to the acceptability of the site selected must then be obtained before a trial is commenced.

- (3) Since this product is potentially harmful to game, wild birds and animals, precautions must be taken to protect them from harm. Applications must be made when mammals and birds are unlikely to forage in the area being treated. Spillages of chemical or treated seed must be recovered or buried.
- (4) Since there is a potential risk to non-target plants, insects or other arthropods from use, applications must not be made within 6m of the field boundary.
- (5) Any run-off from the treatment of land not intended to bear vegetation must be prevented from entering surface waters and disposed of appropriately.

Other specific restrictions:

- (1) Full records of all applications carried out under this Experimental Approval, including details of the specific sites treated and their Ordnance Survey grid references, must be kept for ten years following application.
- (2) Direct or indirect post-treatment exposure of humans or animals must be avoided wherever possible.

APPENDIX 2: GENERAL CONDITIONS OF APPROVAL AND CONSENT

Label:

The approval holder must follow the detailed requirements of all relevant Parts of 'The Labelling Handbook' available on HSE's website at www.pesticides.gov.uk.

Packaging:

The approval holder must design and construct the packaging and fastenings to make sure they are strong and solid throughout so they will not come apart and will safely withstand normal handling; they can be repeatedly refastened and the contents cannot accidentally escape; the contents cannot attack either the packaging or the fastenings or form harmful or dangerous compounds with them and they are unlikely to attract children or arouse their curiosity.

Adverse effects:

The Approval holder must immediately notify the Secretary of State, the Welsh and the Scottish Ministers (care of the Health and Safety Executive), if they have any new information on the potentially adverse effects of the approved product, or of residues of an active substance in that product when used in accordance with the conditions of this approval. For those products approved under the 'Plant Protection Products Regulations' approval holders must also tell the other relevant competent authorities of the EC Member States (a list of which is available from the Health and Safety Executive) and the EC Commission. Failure to comply with this requirement is an offence.

Provision of information:

The approval holder must comply with all requests for information required by Ministers in accordance with Section 16(11) of the Food and Environment Protection Act 1985.