

Chemicals Regulation Directorate

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Date 12 November 2012

Reference 2011/01848

Dear Mrs Hudson

COP 2011/01848

**AUTHORISATION FOR THE USE OF 'BIOX-M' AS A SPROUT
SUPPRESSANT ON WARE POTATOES: DATA (MUTUAL
RECOGNITION) STREAM.**

Thank you for your application of 22 December 2011 for authorisation of 'Biox-M'. Ministers have agreed to grant an Authorisation under Regulation (EC) No. 1107/2009 until 31 August 2020 for:

Product name:	Biox-M	(contains spearmint oil)
MAPP Number:	16021	

The Authorisation is attached to this letter.

Assessment to Uniform Principles

This product has been authorised in accordance with the Uniform Principles and agreed EU end points for product evaluation and is based on mutual recognition of the French authorisation for 'Biox-M' with authorisation number 2100194.

Label amendments

The authorised product label must reflect the CHIP classification detailed in the authorisation.

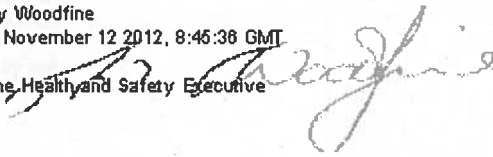
Label amendments appear at Annex A to this letter.

Data lists

We list the data you submitted to support this application in Annex B. In this list, we also tell you which data were used to support the evaluation, and the data protection expiry date for each study.

Yours sincerely

Signed by: Mrs Wendy Woodfine
Signing time: Monday, November 12 2012, 8:45:36 GMT
Location: CRD York
Reason to sign: For the Health and Safety Executive



HSE Digital Signature

Rosie Wilson
Pesticides Branch

www.pesticides.gov.uk

The authorised product label for 'Biox-M' must consist of the draft label text submitted by Compliance Services International on 22 December 2011 (HSE ref.: W001256798), the label amendments shown below and the classification detailed in the authorisation:

Label amendments

- (i) The unique Registration number MAPP 16021 must appear on the label and in close proximity to the product trade name.
- (ii) The maximum total dose must be amended from 390 to 360 ml of product per tonne of potatoes.
- (iii) In SAFETY PRECAUTIONS section under 'Operator Protection', the following amendments must be made:

- (a) The existing PPE phrases must be deleted and appear as follows

'Engineering control of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment:

WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS) AND SUITABLE PROTECTIVE GLOVES AND SUITABLE RESPIRATORY PROTECTIVE EQUIPMENT* when handling the concentrate or handling contaminated surfaces. *Full facemask to at least EN 136 with a combination filter to at least EN141 A2P3, or equivalent.

WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS WITH HOOD), SUITABLE PROTECTIVE GLOVES, RUBBER BOOTS, EYE PROTECTION (GOGGLES) 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.

Workers must wear suitable protective gloves when handling treated material.

However, engineering controls may replace personal protective equipment if a COSHH assessment shows that they provide an equal or higher standard of protection.'

- (b) The phrase 'KEEP UNPROTECTED PERSONS OUT OF TREATED AREAS for at least 24hr after application' must be deleted and replaced with

'KEEP OUT OF STORE DURING TREATMENT'

- (iv) All references to use of the product on seed potatoes should be removed from the label - which should refer only to use on ware potatoes.
- (v) The phrases 'Avoid release to the environment' and 'Dispose of contents/container in accordance with local/national regulations' should be removed and replaced by:
- 'This material and its container must be disposed of in a safe way.'
- 'Use appropriate containment to avoid environmental contamination.'
- (vi) The phrase 'DANGEROUS TO FISH OR OTHER AQUATIC LIFE. Do not contaminate surface waters or ditches with chemical or used container' must be removed and replaced by:
- 'Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from yards and roads'.
- (vii) The following phrase must appear under 'SAFETY PRECAUTIONS: Environmental protection':
- 'The use of this product on ware potatoes may result in discharge of spearmint oil into receiving waters from plants washing treated potatoes. Concentration limits for spearmint oil, or the active ingredient L-carvone, may need to be applied to any discharge Permits at washing plants.'
- (viii) Under 'PROBLEM CONTROLLED', the following phrase must appear after '...treatment of potatoes.': 'Do not use on potato tubers intended for use as seed potatoes.'
- (ix) Under 'METHOD OF APPLICATION', the following phrase (or similar wording with the same meaning) must appear: 'Biox-M must only be applied by specialist contractors using appropriate application equipment.'
- (x) The following phrases must appear at an appropriate place:
- a) 'Consult processor before using on crops intended for processing.'

AUTHORISATION FOR A PLANT PROTECTION PRODUCT

PLANT PROTECTION PRODUCTS REGULATION (EC) No 1107/2009

Product name: BIOX-M

Formulation: a hot fogging concentrate formulation containing 100 % w/w Spearmint Oil details of which are specified in the 'Confidential Conditions' section (Appendix 3) of this authorisation.

MAPP number: 16021

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

Marketing company: Juno (Plant Protection) Ltd, Little Mill Farm, Underlyn Lane, Marden, Kent, TN12 9AT.

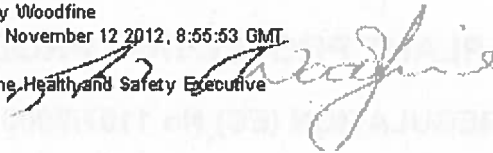
This authorisation ends:

- (a) 31 August 2020 except as set out in (b) and (c) below:
- (b) 28 February 2021 for sale and distribution of existing stocks
- (c) 28 February 2022 for the disposal, storage and use of existing stocks

This authorisation will be withdrawn or amended before the end dates above if any of the active substances contained in this product are withdrawn from the list of approved active substances included in Regulation (EU) No 540/2011, or if a decision is taken to withdraw or amend this authorisation under Regulation (EC) No 1107/2009 on any other grounds.

Extent of Authorisation: United Kingdom

Signed by: Mrs Wendy Woodfine
Signing time: Monday, November 12 2012, 8:55:53 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 the Health and Safety Executive ("HSE") for and on behalf of the Secretary of State, the Welsh Ministers, the Scottish Ministers and the Department of Agriculture and Rural Development in Northern Ireland.

Date of issue 12 November 2012.

EXPLANATORY NOTES

1. This product has been authorised in accordance with the Uniform Principles for product evaluation.
2. This is Authorisation Number 2717 of 2012.
3. This authorisation, other than Appendix 3, will be published on the website of the Chemicals Regulation Directorate of the HSE.
4. Application reference number COP 2011/01848.

APPENDIX 1: CONDITIONS OF AUTHORISATION

Failure to comply with the following conditions will result in the withdrawal or amendment of the authorisation under Regulation (EC) No 1107/2009 and may result in other enforcement action, including prosecution.

Placing on the market:

Packaging: The authorisation holder must only place this product on the market in 5 to 20 litre high density polyethylene container.

Label: The authorisation holder must only sell and supply the product with the agreed label, which is the label submitted with the application on 22 December 2011 (HSE ref.: W001256798) and label amendments as specified in Annex A to HSE's letter dated 12 November 2012.

Classification and labelling:

Labels must comply with the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP). CHIP implements Directives 67/548/EEC (the 'Dangerous Substances Directive') and 1999/45/EC (the 'Dangerous Preparations Directive') in the UK. Based on the information available to us we consider the CHIP classification and labelling requirements to include:

N	Dangerous for the environment
Xn	Harmful
R43	May cause sensitisation by skin contact
R50	Very toxic to aquatic organisms
R53	May cause long-term adverse effects in the aquatic environment
R65	Harmful: may cause lung damage if swallowed*
S35	This material and its container must be disposed of in a safe way
S57	Use appropriate containment to avoid environmental contamination
	To avoid risks to man and the environment comply with the instructions for use

Use:

Field of use: ONLY AS A SPROUT SUPPRESSANT

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	360	-	-

Operator protection:

- (1) 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 suitable respiratory protective equipment* when handling the concentrate or handling contaminated surfaces. *Full facemask to at least EN 136 with a combination filter to at least EN141 A2P3, or equivalent.
 - (b) Workers must wear suitable protective clothing (coveralls with hood), suitable protective gloves, rubber boots, eye protection (goggles) 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.
 - (c) Workers must wear suitable protective gloves when handling treated material.
- (2) However, engineering controls may replace personal protective equipment if a COSHH assessment shows that they provide an equal or higher standard of protection.

Other specific restrictions:

- (1) A minimum interval of 21 days must be observed between applications.
- (2) The use of this product on ware potatoes may result in discharge of spearmint oil into receiving waters from plants washing treated potatoes. Concentration limits for spearmint oil or the active ingredient L-carvone, may need to be applied to any discharge Permits at washing plants.

APPENDIX 2: GENERAL CONDITIONS OF AUTHORISATION

Failure to comply with the following conditions will result in the withdrawal or amendment of the authorisation under Regulation (EC) No 1107/2009 and may result in other enforcement action, including prosecution.

Label:

The authorisation holder must follow the detailed requirements of all relevant Parts of 'The Labelling Handbook' available on HSE's website at www.pesticides.gov.uk. The authorisation holder must not make any amendments to the authorised label that are not consistent with the existing authorised use(s) and authorised label text. Classification is based on the information held by HSE. Authorisation holders can update the classification as long as HSE are informed of the changes (refer to HSE's website at www.pesticides.gov.uk for details).

Packaging:

The authorisation 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.

Mixing:

The authorisation holder must ensure that any plant protection or adjuvant product(s) recommended for mixing with this product are authorised or have an official List Entry for use in the UK (refer to HSE's website at www.pesticides.gov.uk and 'The Pesticides Register Database' and 'Adjuvant Information Database'). The authorisation holder must ensure that any tank mix recommendations comprising this product and any other plant protection or adjuvant product(s) are supported by data as referenced in the compatibility assurance statement for this product.

Adverse effects:

The authorisation holder must immediately notify the Secretary of State, the Scottish Ministers and the Department of Agriculture and Rural Development in Northern Ireland (care of the Health and Safety Executive), if they have any new information on the potentially adverse effects of the authorised product, or of residues of an active substance in that product when used in accordance with the conditions of this authorisation. For those products authorised under Regulation (EC) No 1107/2009 authorisation 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 authorisation holder must comply with all requests for information required by, or on behalf of, the Secretary of State, the Scottish Ministers or the Department of Agriculture and Rural Development in Northern Ireland in accordance with Regulation (EC) No 1107/2009.