Authorisation Number: 3427 of 2022

AUTHORISATION FOR A PLANT PROTECTION PRODUCT

PLANT PROTECTION PRODUCTS REGULATION (EC) No 1107/2009

Extent of Authorisation:	Great Britain and Northern Ireland
Product name:	Fytosave
Formulation:	a soluble concentrate formulation containing 12.5 g / l COS-OGA details of which are specified in the 'Confidential Conditions' section (Appendix 3) of this authorisation.
MAPP number:	18433
Authorisation holder:	FytoFend S.A., Rue Georges Legrand 6, 5032 Isnes, Belgium. (Registered company number: BE 0817.407.023)
This authorisation ends:	(a) 22 April 2031 except as set out in (b) and (c) below: (b) 22 October 2031 for sale and distribution of existing stocks (c) 22 October 2032 for the disposal, storage and use of existing stocks This authorisation will be withdrawn or amended before the end dates above if any of the active substances contained in this product are withdrawn from the Approvals Register or list of approved active substances included in Regulation (EU) No 540/2011, or if a decision is taken to withdraw or amend this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.

Lauren Purdy
2022.11.30 09:59:55 Z
HSE Digital Signature

This and the attached Appendices 1 to 3 are signed by the Health and Safety Executive for and on behalf of the Secretary of State, the Welsh Ministers, the Scottish Ministers and the Department of Agriculture, Environment and Rural Affairs in Northern Ireland.

Date of issue 30 November 2022.

EXPLANATORY NOTES

1. This product has been authorised in accordance with the Uniform Principles for product evaluation and agreed end points for the active substance.

2. This is Authorisation Number 3427 of 2022 and replaces Notice(s) of Authorisation Number(s) 0487 of 2018 which will begin a staged withdrawal from the end of the month of issue of this notice.

3. This authorisation, other than Appendix 3, will be published on HSE's website.

4. Application reference numbers COP 2021/00634 & 2021/00682.

5. In this notice Regulation (EC) No 1107/2009 means:
In relation to Great Britain, Regulation (EC) No 1107/2009 as it has effect in Great Britain
In relation to Northern Ireland, Regulation (EC) No 1107/2009 as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement

6. In this notice Regulation (EU) No 540/2011 means:
In relation to Northern Ireland, Regulation (EU) No 540/2011 as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement

7. In this notice Regulation (EC) No 1272/2008 means:
In relation to Great Britain, Regulation (EC) No 1272/2008 as it has effect in Great Britain
In relation to Northern Ireland, Regulation (EC) No 1272/2008 as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement

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 litre high density polyethylene container.

Label: The authorisation holder must only sell and supply the product with the agreed label (Co. ref.:FytoSave-draft label), which is the label submitted with the application on 5 December 2018 (HSE ref.: W001821273), label amendments as specified in Annex A to HSE's letter dated 30 November 2022 and labelling requirements according to the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (EC) No. 1272/2008 (see Appendix 3 of this authorisation).

Classification:

Labels must comply with the Regulation (EC) No 1272/2008. Based on the information held by HSE at the time of issue of this authorisation the classification requirements include:

Hazard Class and Category
Not required

Hazard Statement	
Not required	

Authorisation holders are reminded that they are responsible for ensuring that the classification complies with the Regulation (EC) No 1272/2008 and other information affecting the classification of the product.

Use:

Field of use: **ONLY AS A FUNGICIDE**

User: Professional

Crops/situations:	Maximum individual dose: (l product / ha)	Maximum total dose:	Maximum number of treatments: (per crop)	Latest time of application:
Aubergine (permanent protection with full enclosure), pepper and chilli (permanent protection with full enclosure), tomato (permanent protection with full enclosure)	2	-	5	Between 3 fully expanded leaves and ripening : fruits reach their typical full maturity colour (BBCH 13 - 89)
Courgette and summer squash (permanent protection with full enclosure), cucumber (permanent protection with full enclosure), melon (permanent protection with full enclosure), winter squash and pumpkin (permanent protection with full enclosure)	2	-	5	Between 3 fully expanded leaves and the third fruit has reached its size and typical shape (BBCH 13 - 73)

Other specific restrictions*:*

(1) A minimum interval of 7 days must be observed between applications.

(2) Treatment must only be made under ‘permanent protection’ situations which provide full enclosure (including continuous top and side barriers down to below ground level) and which are present and maintained over a number of years.

(3) Reasonable precautions must be taken to prevent access of birds, wild mammals and honey bees to treated crops.

(4) To minimise airborne environmental exposure, vents, doors and other openings must be closed

during and after application until the applied product has fully settled

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.hse.gov.uk/pesticides. 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 shall classify the product or update the label according to Regulation (EC) No 1272/2008 without undue delay following

- any change to the classification and labelling requirements required in the relevant legislation or;
- other information becoming available affecting the classification and labelling of the product.

In these cases HSE must be informed of the changes (refer to HSE's website at www.hse.gov.uk/pesticides 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). 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 Welsh Ministers, the Scottish Ministers and the Department of Agriculture, Environment and Rural Affairs 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 as it has effect by virtue of the Protocol on Ireland / Northern Ireland in the EU withdrawal agreement, authorisation holders must also tell the 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 Welsh Ministers, the Scottish Ministers or the Department of Agriculture, Environment and Rural Affairs in Northern Ireland in accordance with Regulation (EC) No 1107/2009.

APPENDIX 3: CONFIDENTIAL CONDITIONS OF AUTHORISATION

This section is confidential to the authorisation / permit holder. Therefore, it is not available to those other than the data owner and has been removed.