

AUTHORISATION FOR A PLANT PROTECTION PRODUCT

PLANT PROTECTION PRODUCTS REGULATION (EC) No 1107/2009

Extent of Authorisation: Great Britain and Northern Ireland

Product name: Modif

Formulation: a water dispersible granule formulation containing 375 g / kg cyprodinil and 250 g / kg fludioxonil details of which are specified in the 'Confidential Conditions' section (Appendix 3) of this authorisation.

MAPP number: 18583

Authorisation holder: Life Scientific Limited, Block 4, Belfield Office Park, Beech Hill Road, Dublin 4, Ireland.
(Registered company number: 237489)

This authorisation ends:

- (a) 31 October 2023 except as set out in (b) and (c) below:
- (b) 30 April 2024 for sale and distribution of existing stocks
- (c) 30 April 2025 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This authorisation will be withdrawn or amended before the end dates above if any of the active substances contained in this product are withdrawn from the Approvals Register or list of approved active substances included in Regulation (EU) No 540/2011, or if a decision is taken to withdraw or amend this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.

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 5 May 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 0885 of 2022 and replaces Notice(s) of Authorisation Number(s) 0679 of 2020, 1037 of 2020, 2448 of 2020, 1234 of 2021, 2557 of 2021 and 0543 of 2022 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 number COP 2020/02035.
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 the following containers:

- i) polyethylene lined aluminium / polyethylene terephthalate / paper flexible pack holding 500 g to 1 kg of product in a cardboard/fibreboard outer. (liner is not detachable).
- ii) low density polyethylene / aluminium / polyamide / paper flexible pack holding 500 g to 1 kg of product in a cardboard/fibreboard outer. (liner is not detachable).

Label: The authorisation holder must only sell and supply the product with the agreed label, which is the label submitted with the application on 19 December 2020 (HSE ref.: W001997479), label amendments as specified. in Annex A to HSE's letter dated 5 May 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	
Hazardous to the aquatic environment - Acute 1	
Hazardous to the aquatic environment - Chronic 1	
Skin sensitisation, hazard category 1	

Hazard Statement	
H317	May cause an allergic skin reaction
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

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: (kg product / ha)	Maximum total dose:	Maximum number of treatments:	Latest time of application:
Broad bean - fresh, dwarf French bean, runner bean	1	-	2 per crop	14 days before harvest
Edible podded pea, vining pea	1	-	2 per crop	14 days before harvest
Combining pea (harvested dry), dwarf french bean (harvested dry), field bean	1	-	2 per crop	28 days before harvest
Strawberry	1	-	2 per crop	3 days before harvest
Blackberry, raspberry	1	-	3 per year	14 days before harvest
Bilberry, blackcurrant and redcurrant (outdoor), blueberry (outdoor), cranberry (outdoor), gooseberry (outdoor)	1	-	3 per year	10 days before harvest
Apple, pear, quince	0.8	-	3 per year	3 days before harvest
Ornamental plant production	1	-	3 per year	-
Ornamental plant production (protected)	0.8	-	3 per year	-

Crops/situations:	Maximum individual dose: (kg product / ha)	Maximum total dose:	Maximum number of treatments:	Latest time of application:
Carrot	0.8	-	3 per year	7 days before harvest
Celeriac	0.8	-	2 per year	14 days before harvest

Operator protection:

- (1) Spray equipment must only be used where the operator's normal working position is within a closed cab on a tractor or on a self-propelled sprayer when making air-assisted applications to top fruit.
- (2) Other engineering control of operator exposure must also be used where reasonably practicable in addition to the following personal protective equipment:
 - (a) Operators must wear suitable protective gloves when handling the product or handling contaminated surfaces.
 - (b) Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when applying by hand-held equipment.
- (3) However, other engineering controls in addition to those specified above may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection.

Environmental protection:

- (1) Since there is a risk to aquatic life from use, users not applying the statutory buffer zone must either themselves carry out or ensure that someone else has carried out a Local Environment Risk Assessment for Pesticides (LERAP) on their behalf before each spraying operation from a horizontal boom sprayer. Users must not allow direct spray from such sprayers to fall within 5m of the top of the bank of any static or flowing waterbody or within 1m of a ditch which is dry at the time of application (these distances to be measured as set out in the booklet 'Local Environment Risk

Assessment for Pesticides - Horizontal Boom Sprayers' and any amendments that are made to it) unless:

- (a) The LERAP indicates that a narrower buffer zone will be sufficient; and
- (b) Any measures indicated by the LERAP as justifying the narrower buffer zone are complied with in full and in accordance with any conditions applicable to them.

Spray must be aimed away from water.

Spray from hand-held sprayers must not be allowed to fall within 1 m of the top of the bank of a static or flowing waterbody. Spray must be aimed away from water.

- (2) Since there is a risk to aquatic life from use, users not applying the statutory buffer zone must either themselves carry out, or ensure that someone else has carried out a Local Environment Risk Assessment for Pesticides (LERAP) on their behalf before each spraying operation from a broadcast air-assisted sprayer.

For broadcast air-assisted applications to:

i) Blackberry, raspberry blueberry, bilberry, cranberry, redcurrant, whitecurrant, blackcurrant, gooseberry, ornamental plant production and forest nursery users must not allow direct spray from such sprayers to fall within 10 m of the top of the bank of any static or flowing waterbody or within 5 m of a ditch which is dry at the time of application

ii) Apple, crab apple, pear and quince, users must not allow direct spray from such sprayers to fall within 30 m of the top of the bank of any static or flowing waterbody or within 5 m of a ditch which is dry at the time of application

(these distances to be measured as set out in PSD's booklet 'Local Environment Risk Assessment for Pesticides - Broadcast Air-assisted Sprayers' - and any amendments that are made to it) unless:

- (a) The LERAP indicates that a narrower buffer zone will be sufficient; and

- (b) Any measures indicated by the LERAP as justifying the narrower buffer zone are complied with in full and in accordance with any conditions applicable to them. Spray must be aimed away from water.
- (3) The results of the LERAP must be recorded in written form and must be available for a period of three years for inspection to any person entitled to exercise enforcement powers under or in connection with the Plant Protection Products Regulations 2011 or the Plant Protection Products (Sustainable Use) Regulations 2012. (An electronic record will satisfy the requirement for a written record, providing it is similarly available for inspection and can be copied).
- (4) Detailed guidance on LERAPs and how to conduct a LERAP are contained in the booklets 'Local Environment Risk Assessment for Pesticides - Horizontal Boom Sprayers' and 'Local Environment Risk Assessment for Pesticides - Broadcast Air-Assisted Sprayers', available from HSE Chemicals Regulation Division's website. All LERAPs must be carried out in accordance with this Guidance and any amendments that are made to it.

Other specific restrictions:

This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme. Before each spraying operation from a horizontal boom sprayer, either a LERAP must be carried out in accordance with the 'Local Environment Risk Assessment for Pesticides Horizontal Boom Sprayers' booklet available from the HSE Chemicals Regulation Division's website or the statutory buffer zone must be maintained. The results of the LERAP must be recorded and kept available for three years.

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.