

AUTHORISATION FOR A PLANT PROTECTION PRODUCT

PLANT PROTECTION PRODUCTS REGULATION (EC) No 1107/2009

Product name: Medallion TL

Formulation: a suspension concentrate formulation containing 125 g / l fludioxonil details of which are specified in the 'Confidential Conditions' section (Appendix 3) of this authorisation.

MAPP number: 15287

Authorisation holder: Syngenta UK Limited, CPC4, Capital Park, Fulbourn, Cambridge, Cambridgeshire, CB21 5XE. (Registered company number: 849037)

This authorisation ends:

- (a) 31 October 2019 except as set out in (b) and (c) below:
- (b) 30 April 2020 for sale and distribution of existing stocks
- (c) 30 April 2021 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This authorisation will be withdrawn or amended before the end dates above if any of the active substances contained in this product are withdrawn from the list of approved active substances included in Regulation (EU) No 540/2011, or if a decision is taken to withdraw or amend this authorisation under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: Wendy Woodfine
Signing time: Monday, January 13 2014, 8:3:13 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 13 January 2014.

EXPLANATORY NOTES

1. This product has been authorised in accordance with the Uniform Principles for product evaluation.
2. This is Authorisation Number 0091 of 2014 and replaces Notice(s) of Authorisation Number(s) 1073 of 2012 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 the website of the Chemicals Regulation Directorate of the HSE.
4. Application reference number COP 2013/01712.

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) 1 to 10 litre high density polyethylene container.
- ii) 1 to 10 litre polyethylene terephthalate container.

Label: The authorisation holder must only sell and supply the product with the agreed label submitted with the application on 5 May 2010 (HSE ref.: W001340458) and label amendments as specified in Annex A to HSE's letter dated 13 January 2014.

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 the CHIP classification and labelling requirements include:

N	Dangerous for the environment
R51	Toxic to aquatic organisms
R53	May cause long-term adverse effects in the aquatic environment
S13	Keep away from food, drink and animal feedingstuffs
S2	Keep out of reach of children
S20/21	When using do not eat, drink or smoke
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 FUNGICIDE**

User: Professional

Crops/situations:	Maximum individual dose: (l product / ha)	Maximum total dose:	Maximum number of treatments: (per year)	Latest time of application:
Amenity grassland, managed amenity turf	3	-	4	-

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) 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).

- (3) Detailed guidance on LERAPs and how to conduct a LERAP are contained in the booklet 'Local Environment Risk Assessment for Pesticides - Horizontal Boom Sprayers', available from HSE Chemicals Regulation Directorate's website. All LERAPs must be carried out in accordance with this Guidance and any amendments that are made to it.

Other specific restrictions:

- (1) 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 Directorate's website or the statutory buffer zone must be maintained. The results of the LERAP must be recorded and kept available for three years.
- (2) Non-returnable containers must not be re-used for any purpose.

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 and labelling under Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP) 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.

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.