

EXTENSION OF AUTHORISATION FOR A MINOR USE OF A PLANT PROTECTION PRODUCT

PLANT PROTECTION PRODUCTS REGULATION (EC) No 1107/2009

Extent of authorisation:	Great Britain and Northern Ireland
Product name:	BOTECTOR
Active ingredient:	2.5x10 ⁹ CFU/g (500 g/kg) <i>Aureobasidium pullulans</i> strain DSM 14940 and 2.5x10 ⁹ CFU/g (500 g/kg) <i>Aureobasidium pullulans</i> strain DSM 14941
MAPP number:	20000
Product authorisation holder:	SAN Agrow Holding GmbH (Registered Company no. 256216p)
Marketing company:	Masstock Arable (UK) Limited

This Extension of authorisation ends: on the final expiry date of use for the authorised product

If the authorisation of the above product is withdrawn or amended, this Extension of authorisation will end on the same date as the authorisation for the product.

This Extension of authorisation will be withdrawn or amended before its end date if any of the active substances contained in the product are withdrawn from the Approvals Register or list of approved active substances included in Regulation (EU) No 540/2011, or if a decision is taken to withdraw or amend this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

The circumstances in which this Extension of authorisation will be withdrawn or amended are set out in Regulation (EC) No 1107/2009.

This extension of authorisation for minor uses applies to all authorised parallel trade products issued under Article 52 of Regulation (EC) No 1107/2009 for which BOTECTOR with MAPP 20000 is the reference product.

HSE Digital Signature

This and the attached Appendices 1 and 2 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: 25 April 2024

EXPLANATORY NOTES

1. This is Extension of authorisation number 0937 of 2024 and supersedes 0825 of 2024.
2. This Extension of authorisation will be published on HSE's website.
3. Application reference number: COP 2023/00292
4. Persons using the product to which this Extension of authorisation applies should acquaint themselves with and observe all requirements contained in the Regulation (EC) No 1107/2009, including the duty on the holder of any Extension of authorisation to notify information on potentially dangerous effects, a contravention of which is a criminal offence under those Regulations.
5. Neither the efficacy nor the phytotoxicity of the product for which this Extension of authorisation has been granted has been assessed and, as such, the user bears the risk in respect of failures concerning its efficacy and phytotoxicity.
6. 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.
7. 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.

ADVISORY INFORMATION

This Extension of authorisation relates to the use of 'BOTECTOR' (M20000) grey mould (*Botrytis cinerea*) to be applied via Horizontal boom sprayer, Variable geometry boom sprayer, and Hand-held application - hydraulic nozzle, in 400 to 2000 litres water per hectare.

Contains *A. pullulans* strain DSM 14940 and DSM 14941. Micro-organisms may have the potential to provoke sensitising reactions.

IMPORTANT: When applying this product under the terms of this Extension of authorisation, comply with any resistance guidance or restrictions stated on the product label.

Total reliance on one pesticide will hasten the development of resistance. Pesticides of different chemical types or alternative control measures should be included in the planned programme. Alternating with different modes of action is a recognised anti-resistance strategy.

APPENDIX 1: CONDITIONS OF EXTENSION OF AUTHORISATION

The conditions below are obligatory. They must be complied with when the Extension of authorisation occurs. Failure to comply with the following conditions will result in the withdrawal or amendment of the Extension of authorisation under Regulation (EC) No 1107/2009 and may result in other enforcement action, including prosecution. For the purposes of this Extension of authorisation only, the conditions and/or requirements shown below supersede any corresponding conditions and/or requirements set out on the label or otherwise provided for under the product authorisation **which would otherwise apply**.

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:
Permanent protection with full enclosure crops of aubergine, courgette and summer squash, cucumber, gherkin, pepper and chilli	1	-	6	Fully ripe: fruits have typical fully ripe colour (BBCH 89) and/or Pre Harvest Interval of 1 day (see OSR 3)

Operator Protection:

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

Operators must wear suitable protective clothing (coveralls), suitable protective gloves and suitable respiratory protective equipment*.

*Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

- (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) This product must only be applied in accordance with the terms of this extension of authorisation, the product label and/or leaflet and any additional guidance on extensions of authorisation.
- (2) A minimum interval of 2 days must be observed between applications.
- (3) A minimum interval of 1 day must elapse between application and harvest.

APPENDIX 2: GENERAL CONDITIONS FOR AN EXTENSION OF AUTHORISATION

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

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 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 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.