

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

PLANT PROTECTION PRODUCTS REGULATION (EC) No. 1107/2009

Product name: Azatin

Active ingredient: 217 g / l azadirachtin

MAPP number: 18301

Product authorisation holder: Mitsui AgriScience International S.A/B.V (Registered Company no. 0474 482 923)

Marketing company: Certis

This Extension of authorisation ends: on the final expiry date of use for the authorised product (unless otherwise stated)

If the authorisation of the above product is withdrawn or amended before the end date above, this Extension of authorisation will end on the same date as the authorisation for the product. This Extension of authorisation will be withdrawn or amended before its end date if a decision is taken to withdraw or amend this Extension of authorisation under Regulation (EC) No 1107/2009 on any other grounds.

Extent of authorisation: United Kingdom

This extension of authorisation for minor uses applies to all UK parallel trade products issued under Article 52 of Regulation (EC) No 1107/2009 for which Azatin with MAPP 18301 is the reference product.



Signed by: rachel.brown@hse.gov.uk
Signing time: Thursday, May 14 2020, 13:7:22 GMT
Location: CRD York
Reason to sign: For the Health and Safety Executive

HSE Digital Signature

This and the attached Appendices 1 and 2 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, Environment and Rural Affairs in Northern Ireland.

Date of issue: 14 May 2020

EXPLANATORY NOTES

1. This is Extension of authorisation number 1265 of 2020.
2. This Extension of authorisation will be published on the website of the Chemicals Regulation Division of the HSE.
3. Application reference number: COP 2019/02012
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.

ADVISORY INFORMATION

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.

This Extension of Authorisation relates to the use of 'Azatin' (M18301) on tomato and aubergine (grown under permanent protection with full enclosure) for the control of *Tuta absoluta* (1TUTAG), Whitefly (TRIAVA, BEMITA, 1ALEYF). Applications must be made via horizontal or vertical boom sprayers in a minimum water volume of 1000 litres water per hectare and the maximum individual dose of 1.68 l/ha must not be exceeded.

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 AN INSECTICIDE**

User: Professional

Crops/situations:	Maximum individual dose: (ml product / 100 litres of water)	Maximum total dose:	Maximum number of treatments: (per year)	Latest time of application:
Permanent protection with full enclosure crops of aubergine, tomato	140	-	20 (20 applications divided over 5 blocks of applications with 42 days between each block of application. Each block to consist of a maximum of 4 applications with 7 days between each individual application.)	3 days prior to harvest

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 gloves and face protection (faceshield) when handling the concentrate.

- (b) Operators must wear suitable protective gloves when applying by hand-held equipment.
- (c) Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when applying using pedestrian-controlled sprayer with vertical boom or where contact with treated foliage is unavoidable during application in protected situations.
- (d) Operators must only use vehicle mounted or trailed horizontal or vertical boom sprayers where the operator's normal working position is within a closed cab with a suitable in-cab filtration system* or suitable respiratory protective equipment** must be worn during application in protected situations.

*Closed cabin meeting at least EN 15695 category 3

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

- (e) Workers must wear suitable protective clothing in which arms, body and legs are fully covered and suitable protective gloves* when re-entering treated areas or handling treated crops or contaminated surfaces within 8 weeks after treatment. *Meeting at least glove safety standard EN374-2:2019, Level 2 and CE category III. Such gloves can be identified by a CE Mark with four digits below, and the EN374 pictogram for micro-biological hazards. (See 'Other Specific Restrictions').

- (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 7 days must be observed between applications within a block (i.e. 4 consecutive sprays represents a block) and 42 days between blocks.

- (3) 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.
- (4) Reasonable precautions must be taken to prevent access of birds, wild mammals and bees to treated crops.
- (5) To minimise airborne environmental exposure, vents, doors and other openings must be closed during and after application until the applied product has fully settled.
- (6) A maximum individual dose of 1.68 L/ha must not be exceeded.
- (7) Crops grown in organic media may not be treated until BBCH 20 or later.
- (8) To protect ground water, a minimum interval of 39 days after final treatment must be observed before planting out of containerised plants.
- (9) The use of this product in recirculating water systems in a glasshouse may result in dilute pesticide waste that requires disposal. All dilute pesticide waste must be disposed of safely and legally to protect humans, wildlife and the environment, especially groundwater and surface water. Pesticide disposal advice is detailed in the 'Code of Practice for Using Plant Protection Products.
- (10) Managers must carry out a thermal comfort checklist (see - <http://www.hse.gov.uk/temperature/assets/docs/thermal-comfort-checklist.pdf>) prior to worker re-entry tasks. If needed, an additional heat stress check list and associated risk assessment must be undertaken (see- <http://www.hse.gov.uk/temperature/assets/docs/heat-stress-checklist.pdf>) and the records retained. Temperature and humidity inside tunnels should be monitored during re-entry tasks. If conditions become such that there is a risk of heat related illness, or workers complain of ill effects, then work must cease until the risk is reduced. It is not acceptable for workers to remove clothing and continue working.

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 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 Extension of 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, Environment and Rural Affairs in Northern Ireland in accordance with Regulation (EC) No 1107/2009.