

EMERGENCY AUTHORISATION FOR A MINOR USE OF A PLANT PROTECTION PRODUCT

PLANT PROTECTION PRODUCTS REGULATION (EC) No 1107/2009

Extent of authorisation: England and Scotland Only

Product name: Tutavir

Active ingredient: *Phthorimaea operculella* granulovirus (PhopGV) as a suspension concentrate formulation 2×10^{13} OB (occlusion bodies) / L (522.96 g / L) as specified in the EU Dossier Doc J, dated February 2021 (HSE Ref.: W002084735)

Emergency authorisation holder: Horticulture Crop Protection (Registered Company no: 11073025)

Product owner: Andermatt Biocontrol UK Limited (Registered Company no. 10852467)

Marketing company: Andermatt Biocontrol UK Limited (Registered Company no. 10852467)

This emergency authorisation ends:

a) for placing on the market:

This product must only be placed on the market for the following agreed sale periods, not exceeding a total of 120 days:

i. 10 January 2024 to 19 January 2024

ii. 19 February 2024 to 07 June 2024

b) for use: 30 September 2024

c) for storage and disposal of stocks: 28 October 2024

This emergency authorisation can be withdrawn or amended before its end date if the requirements of the authorisation under Regulation 1007/2009 are no longer met. The requirements may no longer be met as a result of, for example, new information brought to the attention of the competent authority on the danger necessitating the use of the PPP, the effects of the PPP, or whether use of the PPP is limited and controlled. These examples are not exhaustive.

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 and the Scottish Ministers.

Date of issue: 10 January 2024

EXPLANATORY NOTES

1. This is emergency authorisation number 0148 of 2024.
2. This emergency authorisation will be published on HSE's website.
3. Application reference number: COP 2023/01659.
4. Persons using the product to which this emergency 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 emergency 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 emergency 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.

ADVISORY INFORMATION

IMPORTANT: When applying this product under the terms of this emergency 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.

IMPORTANT: The assessment undertaken to support this emergency authorisation has identified that the active substance meets at least one of the criteria for active substances that are exempt from MRLs. Therefore, MRLs do not apply to products treated in accordance with this emergency authorisation. A decision on including the active substance in Part 4 of the GB MRL Statutory Register (a list of active substances exempt from MRLs) will be made as part of the approval of the active substance.

This emergency authorisation relates to the use of 'Tutavir' as an insecticide for use on tomato grown under permanent protection with full enclosure to control South American Tomato Moth (*Tuta absoluta*) only. Application is to be made by broadcast sprayer with air assistance / variable geometry boom sprayer or by handheld application with a hydraulic nozzle in 200 to 1800 L water / ha. A 4 day application interval must be observed.

This emergency authorisation will end 30 September 2024 for use.

APPENDIX 1: CONDITIONS OF EMERGENCY AUTHORISATION

The conditions below are obligatory. They must be complied with when the emergency authorisation occurs. Failure to comply with the following conditions will result in the withdrawal or amendment of the emergency authorisation under Regulation (EC) No 1107/2009 and may result in other enforcement action, including prosecution. For the purposes of this emergency 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.

Packaging: The product may only be placed on the market in the following containers:

- i) 100 mL polyethylene terephthalate bottles

Label: The product may only be sold or supplied with the agreed label found in Appendix 4, which is the label agreed by HSE and Andermatt on 04 January 2024 (HSE Ref: W002112684) and labelling requirements according to the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (EC) No 1272/2008.

Use:

Field of use: **ONLY AS AN INSECTICIDE**

User: Professional

| Crops/situations: | Maximum individual dose: (ml product / ha) | Maximum total dose: | Maximum number of treatments: (per year) | Latest time of application: |
|---|--|---------------------|--|-----------------------------|
| Permanent protection with full enclosure tomato | 200 | - | 30 | 1 day before harvest |

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* when handling the concentrate or applying the product. *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.

Environmental protection:

- (1) 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.
- (2) Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.

Other specific restrictions:

- (1) This product must only be applied in accordance with the terms of this emergency authorisation, the product label and/or leaflet and any additional guidance on extensions of authorisation.
- (2) This product must only be applied for the control of South American Tomato Moth (*Tuta absoluta*) in accordance with the terms of this emergency authorisation, the product label and/or leaflet, the safety information provided by the product owner and any additional guidance on emergency authorisations.
- (3) This emergency authorisation is for use in England and Scotland only.
- (4) This product must only be placed on the market for the following agreed sale periods, not exceeding a total of 120 days:
 - i. 10 January 2024 to 19 January 2024
 - ii. 19 February 2024 to 07 June 2024
- (5) The use of 'Tutavir' must cease by 30 September 2024 and any additional unused stocks are to be recalled and collected by the product owner.

- (6) Contains *Phthorimaea operculella* granulovirus (PhopGV). Micro-organisms may have the potential to provoke sensitising reactions.

APPENDIX 2: GENERAL CONDITIONS FOR AN EMERGENCY AUTHORISATION

Failure to comply with the following conditions will result in the withdrawal or amendment of the emergency 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 and the Scottish Ministers, 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. 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 or the Scottish Ministers in accordance with Regulation (EC) No 1107/2009.

APPENDIX 3: STEWARDSHIP

This stewardship is prepared in accordance with the specific conditions of this emergency authorisation. It must be followed as a condition of the authorisation.

The terms of the emergency authorisation stewardship are:

Data must be collected and collated on the location of use and total amount of product used.

Stewardship records must be maintained and made available to the Chemicals Regulation Division of HSE on request and at the point of any subsequent application for this emergency use.

The following table provides a summary of controlled use, with further details of each component provided below.

| Component of a strategy for controlled use: | Responsibilities: |
|--|---|
| Communication to industry on authorisation conditions | Horticulture Crop Protection Ltd. with British Tomato Growers Association (BTGA). |
| Managing and recording product supply and amendments to product label | Andermatt Biocontrol UK Limited |
| Advice on best practice for product use | Andermatt Biocontrol UK Limited / Biobest |
| Monitoring pest pressure, recording product use, and submission to BTGA for data collation | Tomato growers and agronomists |
| Disposal of unused product at end of 120-day authorisation period | Andermatt Biocontrol UK Limited |
| Collation of data | BTGA for HCP Ltd |

Overall stewardship approach and communication to industry

Overall responsibility for stewardship and communication is with Horticulture Crop Protection (HCP) Ltd. Communication with growers will be made via British Tomato Growers' Association contact databases.

HCP Ltd. will work closely with Dr Phil Morley (Technical Officer for British Tomato Growers Association), Andermatt UK, Biobest, and each individual business to ensure optimal use of the product.

Andermatt will record distribution of Tutavir, supplying the product only as needed, and manage recall of unused product.

The BTGA will work with HCP, Andermatt and the growers to ensure compliance with the conditions of an emergency authorisation, and advocate for best practice.

Product supply

The intended route of product supply of Tutavir is direct from the product owner (or via relevant distributors) to tomato growers. Andermatt Biocontrol UK Limited will co-ordinate the appropriate recall and collection of all unused product after the authorised use period.

APPENDIX 4: HSE AGREED PRODUCT

Hard label copy

TUTAVIR®

Suspension concentrate containing 2×10^{13} OB (occlusion bodies) of *Phthorimaea operculella* granulovirus per litre

Net content: 100mL

Emergency Authorisation 01659 of 2023

For the control of South American Tomato Moth (*Tuta absoluta*) on tomato under permanent protection with full enclosure.

| IMPORTANT INFORMATION | | | | | |
|---|---|--|--|---|---|
| For use only as a professional insecticide | | | | | |
| Crop | Pests controlled | Maximum individual dose: (ml product/ha) | Maximum number of treatments: (per year) | Minimum interval between applications: (days) | Latest time of application |
| Tomato (Permanent protection with full enclosure) | Tomato leafminer (<i>Tuta absoluta</i>) | 200 | 30 | 4 | 1 day before harvest and 30 th September |

Other Specific Restrictions

This product must only be applied in accordance with the terms of this emergency authorisation, the product label and/or leaflet and any additional guidance on emergency authorisation.

This product must only be applied for the control of South American Tomato Moth (*Tuta absoluta*) in accordance with the terms of this emergency authorisation, the product label and/or leaflet, the safety information provided by the product owner and any additional guidance on emergency authorisations.

The use of TUTAVIR® must cease by 30 September 2024 and any additional unused stocks are to be recalled and collected by the product owner.

Contains *Phthorimaea operculella* granulovirus (PhopGV). Micro-organisms may have the potential to provoke sensitising reactions.

To avoid risks to human health and the environment comply with the instructions for use.

READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION

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LABEL

PRODUCTS.

Safety precautions

Resistance

To delay development of resistant populations to new active substances, a spray programme including the most efficacious insecticides and alternating modes of action against consecutive pest generations is recommended.

Operator Protection

Operators must wear suitable protective clothing (coveralls), suitable protective gloves and suitable respiratory protective equipment* when handling the concentrate or applying the product.

*Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent. However, engineering controls may replace personal protective equipment if a COSHH assessment shows that they provide an equal or higher standard of protection.

Environmental Protection

Do not contaminate water with this product or its container. Do not clean application equipment near surface water. Avoid contamination via drains near farmyards and roads.

Storage and disposal

Keep in original container, tightly closed, in a cool and safe place and out of direct sunlight. TUTAVIR® contains active baculovirus. Store under chilled conditions of $\leq 5^{\circ}\text{C}$. Ensure the product is used before the expiry date shown on the bottle cap.

Directions for use

IMPORTANT: This information is approved as part of the product label. All instructions within this section must be read carefully in order to obtain safe use of this product. N.B. The effectiveness and crop safety of this product has not been assessed. The safety of this product on populations of introduced beneficials has not been evaluated.

Product only to be used between 15th January and 30th September.

TUTAVIR® is a biological insecticide based on *Phthorimaea operculella granulovirus* for use against *Tuta absoluta* (Tomato leafminer) in protected tomato. TUTAVIR® acts only by ingestion, not by contact.

TUTAVIR® targets the larvae of the Tomato leafminer (*Tuta absoluta*) and requires oral ingestion, meaning that the timing of the application of the product is important. Apply as soon as first moth trap catches occur or first mines are detected. Only apply during the period of establishment of *Macrolophus pygmaeus*.

Apply 200 ml/ha of TUTAVIR® as a foliar application, diluted in 200 – 1800 l/ha of water, depending on the crop and its stage of growth.

TUTAVIR® should be applied in enough water to ensure good coverage of the crop, including the undersides of leaves, but not to the point of runoff.

Repeat applications may be required with a minimum 4 day interval until the *Macrolophus pygmaeus* population has become established.

Cleaning of the spray equipment

Rinse the application equipment thoroughly with water a minimum of three times and dispose of washings safely.

Pre-harvest interval

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Allow a minimum of 1 day between the application of TUTAVIR® and harvest.

For advice on medical emergencies, fires, spillages or chemical hazards ONLY - phone 0870 190 6777
For technical information and non-emergency advice call +44 (0)1273 082195

TUTAVIR® is a registered trademark of Andermatt Group AG.

TUTAVIR hard label draft

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