

**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: Luna Privilege

Active ingredient: 500 g / l Fluopyram

MAPP number: 18393

Product authorisation holder: Bayer CropScience Limited (Registered Company
no. 218826)

Marketing company: Bayer CropScience 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If the authorisation of the above product is withdrawn or amended, this Extension of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This Extension of authorisation will be withdrawn or amended before its end date if
any of the active substances contained in the product are withdrawn from the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The circumstances in which this Extension of authorisation will be withdrawn or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 Luna
Privilege with MAPP 18393 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: 12 February 2021

EXPLANATORY NOTES

1. This is Extension of authorisation number 0289 of 2021.
2. This Extension of authorisation will be published on HSE's website.
3. Application reference number: COP 2020/00779
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 'Luna Privilege' (M18393) for use as a fungicide on ornamental plant production for the control of powdery mildew and botrytis. Applications to be made by horizontal boom sprayer (protected and outdoor), broadcast sprayer with air assistance (outdoor), handheld application (protected) in a water volume of 300 to 1500 litres water/ha.

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. 'Luna Privilege' contains the SDHI fungicide fluopyram. 'Luna Privilege' should be used in accordance with FRAC guidelines for SDHI fungicides. Applications of 'Luna Privelege' should be made in alternation with a product which does not contain an active substance with an SDHI mode of action. SDHI fungicides should be used preventively or at the early stages of disease development.

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: (litres product / ha)	Maximum total dose:	Maximum number of treatments: (per year)	Latest time of application:
Outdoor ornamental plant production	0.225	-	2	BBCH 89
Protected ornamental plant production	0.225	-	2	BBCH 89

The following Aquatic Buffer Zones must be observed:

Crops/situations:	Aquatic buffer zone distance (metres):	Comment:
Ornamental plant production	10	see Environmental Protection Phrase 1

Operator Protection:

- (1) Broadcast air assisted sprayers must only be used where the operator's normal working position is within a closed cab with a suitable in-cab filtration system* during application in protected situations.
*Closed cabin meeting at least EN 15695 category 3

- (2) 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.
- (3) Other engineering controls of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment:
- (a) Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when applying using pedestrian-controlled equipment with a vertical boom or where contact with treated foliage is unavoidable during application in protected situations.
 - (b) Operators must wear suitable protective gloves when applying by hand-held equipment in outdoor situations.
 - (c) Workers must wear suitable protective gloves* when handling treated crops within 2 weeks after treatment in outdoor situations.
*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-organisms.
 - (d) Workers must wear suitable protective clothing in which arms, body and legs are fully covered and suitable protective gloves* when re-entering treated areas, handling treated crops or contaminated surfaces within 5 weeks after treatment in protected situations .
*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-organisms.

- (4) 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) Crops/situations with >5m buffer zone:

Since there is a risk to aquatic life from use, direct spray from horizontal boom and hand held sprayers must not be allowed to fall within the distance specified for the crop of the top of the bank of any static or flowing waterbody or within 1m of the top of a ditch which is dry at the time of application.

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. Users must not allow direct spray from such sprayers to fall within 10m of the top of the bank of any static or flowing waterbody or within 5m 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 - 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) Buffer zones must be measured in accordance with the guidance set out in the HSE Chemicals Regulation Division's website and any amendments made to it.

- (4) 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).
- (5) Detailed guidance on LERAPs and how to conduct a LERAP are contained in the booklet 'Local Environment Risk Assessment for Pesticides - Broadcast Air-assisted Sprayers' (Ref: PB6533), 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.
- (6) Where the buffer zone is greater than 5m then it must not be reduced under the LERAP scheme.

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) This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme for broadcast air-assisted sprayers. Before each spraying operation from a broadcast air-assisted sprayer, either a LERAP must be carried out in accordance with the 'Local Environment Risk Assessment for Pesticides Broadcast Air-Assisted 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.
- (3) The requirements for aquatic buffer zones do not apply where the product is to be applied under permanent protection with full enclosure as defined in the Crop Definitions document and in accordance with restrictions 6 to 7 below.

- (4) 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/greenhouses 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.
- (5) This product or any fluopyram containing product must not be applied to areas where cardoon, celery, Florence fennels and crops belonging to the category 'other stem vegetables' in the Crop Definitions document will be planted within 365 days of treatment.
- (6) Treatment made under 'permanent protection' are those 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.
- (7) To minimise airborne environmental exposure, vents, doors and other openings must be closed during and after application until the applied product has fully settled.

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.