Emergency authorisation Number: 1310 of 2021

EMERGENCY AUTHORISATION OF A PLANT PROTECTION PRODUCT

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

Extent of authorisation: England and Scotland

Product name: Exirel 10SE

Active ingredient: 100 g / I cyantraniliprole (a suspo-emulsion

formulation as detailed in the application form dated

12 January 2015 (HSE Ref.: W001652711))

Product authorisation holder: FMC Agro Limited (Registered Company no.

01973941)

Marketing company: FMC Agro Limited

This Emergency Authorisation starts: 28 June 2021

This Emergency Authorisation, for the specific use set out in this notice ends:

(a) for placing on the market and use: 26 October

2021

(b) for storage and disposal of stocks: 30 November

2021

This Emergency Authorisation will be withdrawn or amended before its end date if a decision is taken to withdraw or amend this Emergency Authorisation under Regulation (EC) No 1107/2009 on any other grounds.

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: 28 June 2021

EXPLANATORY NOTES

- 1. This is Emergency authorisation number 1310 of 2021.
- 2. This Emergency authorisation will be published on the website of the Chemicals Regulation Division of the HSE.
- 3. Application reference number: COP 2020/02033.
- 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

This Emergency Authorisation relates to the use of 'Exirel 10SE' as an insecticide for use on outdoor raspberry and blackberry to control spotted wing drosophila (*Drosophila suzukii*). Application is to be made by horizontal hydraulic boom and broadcast assisted sprayers in protected situations in 600 to 1500 L water /ha.

The relevant Department (Natural England or Scottish Natural Heritage) should be consulted prior to any application adjacent to designated sites, such as SSSI and NNR.

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: Those parties involved in the distribution and sale of goods should note that goods treated under the terms of this authorisation can only be legally marketed in Northern Ireland if they are in accordance with the statutory EU MRL set under Regulation (EC) No 396/2005. Growers are advised to draw this to the attention of distributors and retailers who are customers for their goods so that EU MRL breaches and potential enforcement against goods marketed in Northern Ireland is avoided.

Emergency Authorisation will not be renewed unless the following information is submitted:

- Trap count data must be linked with the decision to spray for all uses. The spray trigger criteria must not be based solely on the growth stage of the crop. Therefore, official spray trigger criteria used for cherry and plum must be refined and incorporate an appropriate pest threshold (along with a relevant method of monitoring) in conjunction with a relevant growth stage. Although it is accepted that there is no scientifically established threshold number, SWD must be in sufficient numbers to represent an appropriate threat. The refined spray trigger must also be supported with a relevant case or data to justify the criteria.
- Data on the location of use of the product (split by outdoor and protected crops) to confirm that the use is only in the stated regions. This must also include a summary of the number of sprays used under all relevant Article 53s and on how many sprays were used in the season. A survey of the users of this product for control of SWD would be an appropriate method to collect the data.

- An updated detailed, realistic insecticide spray programme, indicating where
 the requested product fits within that programme amended to reflect any
 changes in practice including any end of season applications. This should be
 in a calendar format with typical growth stage, when specific targets are an
 issue along with the timing for each spray application for each product/active.
- A case to explain the practices growers are employing to reduce the populations of SWD at the end of the season, during winter and also prior to the start of the next season.
- Information on ongoing data generation to support a standard authorisation of the product in the UK and timelines for submission.
- To address a data gap for the groundwater and drainflow assessments, information on the soil pH ranges all of the requested crops are typically grown in, along with an estimation on the proportion of those crops expected to be grown in the pH ranges 4.8 to 5.9.

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.

Sale and supply:

Packaging: The authorisation holder must only place this product on the market in:

i) 1 to 5 litre high density polyethylene container co-extruded with ethylene vinyl alcohol copolymer.

Label: The authorisation holder must only sell and supply the product with the

agreed label, which is the label agreed on 29 May 2020 (HSE ref.:

W001947059).

Use:

Field of use: ONLY AS AN INSECTICIDE

User: Professional

Crops/situations:	Maximum individual dose: (litres product / ha)	Maximum total dose:	Maximum number of treatments: (per year)	Latest time of application:
Outdoor and protected crops of blackberry and raspberry	0.9	-	2	3 days before harvest

Operator Protection:

(1) Broadcast air assisted sprayers must only be used where the operator's normal working position is within a closed cab with suitable in cab filtration when applying the product in protected situations

- *Closed cabin meeting European standard 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 control 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 handling the concentrate.
 - (b) Operators must wear suitable protective gloves when handling contaminated surfaces.
 - (c) Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when applying by a pedestrian controlled sprayer with vertical boom or where contact with treated foliage is unavoidable during application in protected situations.
 - (d) In protected situations, workers must wear suitable protective clothing in which arms, body and legs are fully covered when re-entering treated areas or handling treated protected crops or contaminated surfaces within 4 days of treatment. (See 'Other Specific Restrictions').
- (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, 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.

(2) Crops/situations with 5m buffer zone:

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 horizontal boom 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 guidance documents available from HSE Chemical Regulation Division's website 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.

Horizontal boom sprayers must be fitted with a minimum of three-star drift reduction technology.

- (3) Detailed guidance on LERAPs and how to conduct a LERAP are contained in the guidance documents 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.
- (4) 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.
- (5) 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).
- (6) Dangerous to bees. To protect bees and pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present.
- (7) To protect non target insects / arthropods, respect an unsprayed buffer zone of 10m to non-crop land when using broadcast air assisted sprayers which must be fitted with a minimum of three-star drift reducing technology.
- (8) To protect non target insects / arthropods, respect an unsprayed buffer zone of 5m to non-crop land when using horizontal boom sprayers which must be fitted with a minimum of three-star drift reducing technology.

Other specific restrictions:

- (1) This product must only be applied for the control of Spotted Wing Drosophila (*Drosophila suzukii*) in England and Scotland in accordance with the terms of this emergency authorisation and the product label and/or leaflet provided by the authorisation holder. The evidence of the decision to spray must be recorded along with where and how the product was applied.
- (2) A minimum interval of 10 days must be observed between applications.
- (3) This product must not be applied via hand-held equipment.
- (4) The buffer zones are NOT eligible for buffer zone reduction under the LERAP scheme.
- (5) The maximum spray concentration must not exceed 1.5 ml product per litre of water.
- (6) Managers must carry out a thermal comfort checklist (see:

http://www.hse.gov.uk/temperature/assets/docs/ther mal-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 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 Emergency 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.