

**Emergency authorisation Number: 1074 of 2023**

## **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 / l 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)

Emergency authorisation holder: Horticulture Crop Protection Ltd, Rural Innovation Centre, Avenue H, Stoneleigh Park, Kenilworth, CV8 2LG

This Emergency Authorisation starts: 17 May 2023

This Emergency authorisation ends:

- (a) for placing on the market: 14 September 2023
- (b) for use: 30 September 2023
- (c) for storage and disposal of stocks: 30 October 2023

This emergency authorisation can be withdrawn or amended before its end date if the requirements of authorisation under Regulation 1107/2009 are no longer met.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 (“HSE”) for and on behalf of the Secretary of State and the Scottish Ministers.

Date of issue: 17 May 2023

### **EXPLANATORY NOTES**

1. This is Emergency authorisation number 1074 of 2023.
2. This Emergency authorisation will be published on the website of the Chemicals Regulation Division of the HSE.
3. Application reference number: COP 2022/02429
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.
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 cherry (including rain cover) to control Spotted Wing *Drosophila* (*Drosophila suzukii*).

Application is to be made by broadcast air-assisted sprayers / orchard sprayers in a minimum water volume of 1000 to 1200 litres/ha. The timing of application is from BBCH 81 (beginning of fruit colouring) to BBCH 87 (fruit ripe for picking).

**IMPORTANT:** When applying this product under the terms of this Article 53 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.

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.

## APPENDIX 1: CONDITIONS OF EMERGENCY AUTHORISATION

The conditions below are obligatory. They must be complied with when the product is placed on the market and used pursuant to this Emergency authorisation. Failure to comply with the following conditions is likely to 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.

### Sale and supply:

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

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

Label: The product may only be sold or supplied with the agreed label, which is the label agreed with FMC Agro Limited on 19 April 2023 (HSE ref.: W002036144).

### 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:
GB Only: outdoor with temporary rain covers cherry	0.9	-	2	7 days before 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 clothing (coveralls) and suitable protective gloves when handling the concentrate.

- (b) Operators must wear suitable protective gloves when handling contaminated surfaces.
- (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) 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 **15m** 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.

Spray must be aimed away from water.

- (2) 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).
- (3) 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.

- (4) 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.
- (5) To protect non target insects / arthropods respect an unsprayed buffer zone of **20m** to non-crop land when using **broadcast air assisted sprayers** which must be fitted with a minimum of **three-star drift reduction technology**.

Other specific restrictions:

- (1) This product must only be applied in accordance with the terms of this Emergency Authorisation and the product label.
- (2) This product must only be applied for the control of spotted wing drosophila (*Drosophila suzukii*) in England and Scotland.
- (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) A minimum interval of 14 days must be observed between applications.

## **APPENDIX 2: GENERAL CONDITIONS FOR AN EMERGENCY AUTHORISATION**

Failure to comply with the following conditions is likely to 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.

Stewardship records will 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 stewardship and the requirements for any subsequent application for this use stated below:

<b>Component of a strategy for controlled use:</b>	<b>Responsibilities:</b>
Overall stewardship approach	HCP Ltd
Communication to industry on authorisation conditions	HCP Ltd together with Love Fresh Cherries, agronomists, growers and other relevant stakeholders.
Managing product supply and amendments to product label if required	FMC
Advice on best practice for product use	FMC
Monitoring pest pressure and recording product use.	NIAB monitoring of SWD population and fecundity to provide risk alerts. Fruit flotation test for larvae by growers / agronomists to trigger sprays. Growers record product use.
Disposal of unused product at end of 120-day authorisation period	FMC
Collation of data if required by CRD	HCP Ltd together with data gathered and provided by the Love Fresh Cherries, agronomists, growers and other relevant stakeholders

- Data on the volume of product supplied will be collated by the manufacturer.
- Areas treated with the product will be collated by HCP Ltd in collaboration with agronomists, crop associations and other relevant industry stakeholders.
- 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.
- The date SWD are observed in the crop is to be recorded as the trigger to spray.



- An update on the progress of research on Spotted Wing Drosophila should be presented annually. HSE delegate attendance at the SWD Working Group meeting should continue as the means to address this requirement. A brief summary of progress should be included in any subsequent application for this use.
- To support any future authorisations in 2023 or beyond on protected cherry, including the use of rain covers, 8 protected residues trials conducted at the proposed GAP on cherry are required. See below for further information.

#### Residues Trials:

In accordance with the HSE's crop definitions list, the presence of a non-permeable cover at the time of application means the use of rain covers is considered a protected use. To support any future authorisations on protected cherry, including the use of rain covers, 8 protected residue trials conducted at the proposed GAP on cherry are required.

Reduced data sets of trials may be applicable if the intended use gives rise to residues <LOQ or a zero residue situation. In the latter case the zero residue situation must be fully supported on the basis of the available plant metabolism data.

#### Guidance/Guidelines

The trials must be conducted in accordance with the EU guidance document SANCO 7525/VI/95 - rev.10.3 (13 June 2017) and the relevant OECD guidelines and guidance documents as listed in Commission Communication 2013/C 95/01. All relevant crop samples must be analysed and residues determined using the correct residue definitions (for risk assessment and enforcement) using a validated method of analysis. The validation data should be generated in accordance with SANTE/2020/12830 rev. 1 and the OECD guidance document on "Pesticide Residue Analytical Methods" (OECD, 2007).

For NI, residue trials must take into account the EU guidance document SANTE/2019/12752.

Evidence of extraction efficiency, in accordance with SANTE 2017/10632, may need to be provided.

Additional data requirements may also be triggered depending on the outcome of the residue levels and the studies supporting them (e.g. freezer storage stability data, magnitude of residues in livestock and processed commodities).

HSE has outlined the guidance/guidelines that apply at this time. However, applicants must comply with any new guidance/guidelines that are applicable at the actual date of submission of any new application to HSE, noting different guidance/guidelines may be applicable in GB and NI.

#### MRLs

Further information is available on the HSE website for when a new GB MRL is required [[MRLs and import tolerances](#)]. An MRL application form must be submitted and when relevant an ER/RO must be completed.

If a new MRL is required for NI, then an application will need to be submitted to an EU MS. Information on the EU process for MRL setting is available here: [Maximum Residue Levels | Food Safety \(europa.eu\)](#).

### Further information

It should be noted that depending on the data requirements applied for the approval/renewal of the active, then it may be possible to support a GAP with residues data generated in compliance with Regulation (EU) No 544/2011 and the associated guidance. Information is outlined in the guidance document on the transitional measures available at the link below:

[SANTE/11509/2013– rev. 5.2](#)

However, HSE encourages applicants to generate residues data in accordance with the requirements outlined above to help ensure the data will be accepted in any future active/product and MRL reviews.

### Additional information:

In accordance with CRD's crop definitions list, the presence of a non-permeable cover at the time of application means the use of rain covers is considered a protected use.

The applicant has previously been made aware that the approach to use outdoor cyantraniliprole trials to support a protected use is a non-standard approach hence the data requirement set above however the applicant can be reminded to this effect. EFSA concluded that there is insufficient evidence to demonstrate that indoor uses of cyantraniliprole lead to higher residues than outdoor uses (EFSA Journal 2017;15(11):5061). However, this was in the context of setting an MRL. Given the residues for the outdoor use (MRL required 0.5 mg/kg) are significantly below the current MRL in force (6 mg/kg), there is not a concern of a potential MRL exceedance. There are also no consumer intake concerns. EFSA concluded that indoor and outdoor datasets belong to the same population (for beans with pods and strawberries). Therefore, in the context of this emergency authorisation, the trials on outdoor cherries can be used to support the protected use. Normally protected trials are required to support a protected use, such as the use of rain covers on cherries hence the data requirement set above.

There is a risk that outdoor trials may not be acceptable to support a protected use, such as the use of rain covers on cherries, in future, particularly if the application was for a non-emergency authorisation, if there were greater uncertainty regarding consumer exposure, if the residues arising from the use were closer to the MRL, or the use were to become the cGAP.

The applicant should be made aware that the trials would not support a standard MRL on cherries (sweet) based on current guidance, as the trials are worst-case in terms of PHI compared to the GAP.

As part of the assessment, exposure to processing degradation products IN-N5M09 and IN-F6L99 was estimated using limited processing data and non-standard extrapolation of available processing factors. Please note that the conclusions were made in the context of emergency authorisations. ER/ROs for cyantraniliprole in/on various commodities have been published at [New MRLs \(hse.gov.uk\)](#), the most recent being [The evaluation of new MRLs for cyantraniliprole in or on various commodities](#). The exposure estimates would need to be considered for any additional or more critical uses. Therefore, we would like to make you aware that, for future applications for uses of cyantraniliprole, it may be necessary to generate additional processing data to reliably estimate/refine estimates of exposure to IN-N5M09 and IN-F6L99 in processed commodities.

## APPENDIX 5: PRODUCT LABEL



### EXIREL® 10SE

A suspo-emulsion formulation containing 100 g/litre cyantraniliprole for control of Spotted Wing Drosophila (*Drosophila suzukii*) in cherries.

For UK use only, under the terms of an emergency authorisation issued according to Article 53 of Regulation (EC) no 1107/2009. Users must comply with all conditions of the emergency authorisation as detailed below.

The (COSHH) Control of Substances Hazardous to Health Regulations may apply to the use of this product at work.

### SAFETY PRECAUTIONS

#### OPERATOR PROTECTION

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) and suitable protective gloves when handling the concentrate.

Operators must wear suitable protective gloves when handling contaminated surfaces.

However, engineering controls may replace personal protective equipment if a COSHH assessment shows that they provide an equal or higher standard of protection

WHEN USING DO NOT EAT, DRINK OR SMOKE.

WASH HANDS/EXPOSED SKIN before eating and drinking/smoking/after work.

IF YOU FEEL UNWELL, seek medical advice immediately (show the label where possible).

#### ENVIRONMENTAL PROTECTION

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.

RISK TO NON-TARGET INSECTS OR OTHER ARTHROPODS. See Directions for use.

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from broadcast air-assisted sprayers to fall within 15 m of the top of the bank of a static or flowing waterbody, or within 5m of the top of a ditch which is dry at the time of application. Aim spray away from water.

This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme. Before each spraying operation from a broadcast air-assisted sprayer, either a LERAP must be carried out in accordance with CRD's published guidance or the statutory buffer zone must be maintained. The results of the LERAP must be recorded and kept available for three years

#### STORAGE AND DISPOSAL

KEEP AWAY FROM FOOD DRINK AND ANIMAL FEEDING STUFFS  
 KEEP OUT OF REACH OF CHILDREN  
 KEEP IN ORIGINAL CONTAINER, tightly closed, in a safe place  
 DO NOT RE-USE CONTAINER FOR ANY OTHER PURPOSE

Approval holder:  
 FMC Agro Limited. Rectors Lane, Pentre, Flintshire, CH5 2DH

Marketing company:  
 FMC Agro Limited. Rectors Lane, Pentre, Flintshire, CH5 2DH  
 Tel: (01438) 734450  
 Email: Flintshire.enquiry@fmc.com  
 Technical Helpline: 01423 205011


**Emergency No.s - Medical Incidents Involving Crop Protection Products:** England & Wales: 111, Scotland: 08454 24 24 24, Northern Ireland: Local GP or Pharmacist, Republic of Ireland: 01 837 9964.

**Healthcare professionals seeking poisons information:** [www.toxbase.org](http://www.toxbase.org).

**Emergency No.s - Transportation, Warehousing & After Sale Incidents:** CHEMTREC help centre

Dialling from the UK and NI: 0870 820 0418, Dialling from Ireland: 01 901 4670

Contents: 1 to 5 litres



**Warning**  
**May cause an allergic skin reaction.**  
**Very toxic to aquatic life with long lasting effects.**  
 Avoid breathing spray  
 Contaminated work clothing should not be allowed out of the workplace  
 If skin irritation or rash occurs: Get medical attention  
 Wash contaminated clothing before reuse  
 Collect spillage  
 Dispose of contents / container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste  
 Contains 1,2-Benzisothiazolin-3-one. (Proxel GXL). May cause allergic reactions  
**To avoid risk to man and the environment, comply with the instructions for use.**

<b>IMPORTANT INFORMATION</b>			
FOR USE ONLY AS A PROFESSIONAL INSECTICIDE			
Crops	Max. Individual dose (L/ha)	Max. number of treatments per year	Latest time of application
Cherry (outdoor, including under rain covers)	0.9	2	7 days pre-harvest
<b>Other Specific Restrictions</b>			
Applications must be made in a minimum water volume of 1000 l/ha. A minimum interval of 14 days must be observed between applications.			

A maximum of one application must be observed after 31 July 2020.

**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 PRODUCTS**

## 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 and successful use of this product.**

### RESTRICTIONS

- EXIREL 10SE must not be applied to any crop suffering from stress as a result of drought, waterlogging, low temperatures, pest or disease attack, nutrient or lime deficiency or other factors reducing crop growth.
- Good agricultural practice advises that EXIREL 10SE should be used when bees are less active *i.e.* early morning or late evening.
- To protect non target insects / arthropods respect an unsprayed buffer zone of 20m to non-crop land.
- This product must not be applied via hand-held equipment.
- Broadcast air-assisted sprayers must be fitted with three-star drift reduction technology for all uses.

### INSECT CONTROL

EXIREL 10SE is a Group 28 anthranilic insecticide used for control of certain chewing and sucking insect pests in the listed crops. Activity is by ingestion and contact. Paralysis of the pest occurs within a few hours of exposure and results in cessation of movement and feeding. Final control can take 3-6 days.

EXIREL 10SE may be used as part of an Integrated Pest Management (IPM) program, which can include biological, cultural, and genetic practices, aimed at preventing economic pest damage. IPM principles and practices include field scouting or other detection methods, correct target pest identification, population monitoring, rotation of insecticides with different modes-of-action, and treating when target pest populations reach locally determined action thresholds. Consult your crop adviser to determine appropriate action treatment threshold levels for treating specific pest/crop or site systems in your area.

### RESISTANCE

When insecticides with the same mode of action are used repeatedly over several years in the same field, naturally occurring less sensitive strains may survive, propagate and become dominant in that field. An insect is considered resistant to an insecticide if it survives a correctly applied treatment at the recommended dose and timing under normal weather conditions and a validation test with a suitable bioassay confirms the lack of activity. When resistance occurs, recommended rates fail to suppress the pest population below economic thresholds. Development of resistance can be avoided or delayed by alternating or mixing products having different modes of action. Tank-mixtures with other effective insecticides for the target pests may also be recommended. For additional information on insect resistance monitoring, visit the Insecticide Resistance Action Committee (IRAC) on the web at (<http://www.irac-online.org>).

EXIREL 10SE is an IRAC Group 28 Insecticide (ryanodine receptor modulator - diamide). Repeated and exclusive use of EXIREL 10SE may lead to the build-up of resistant strains of insects in some crops. Some insects are known to develop resistance to products used repeatedly for control. Because the development of resistance cannot be predicted, this product may be used as part of resistant management strategies established for the use

area. These strategies may include incorporation of cultural and biological control practices, alternation of mode-of-action classes of insecticides on succeeding generations and targeting the most susceptible life stage. Consult your local or area agricultural authorities for details and follow the recommended IRAC guidance for use of ryanodine receptor modulator – diamide insecticides (<http://www.irc-online.org>).

Best practices for resistance management of Group 28 insecticides include;

- Avoid using the same mode of action (same IRAC group number) on consecutive generations of insect pests.
- Make no more than 2 applications of Group 28 products per generation to the same insect species on a crop. Application to the next generation of target pest(s) must be with an effective product with a different mode of action (non-Group 28 insecticide).
- Avoid using less than the labelled rates of EXIREL 10SE
- Target the most susceptible insect life stages, whenever possible.
- Monitor insect populations for product effectiveness. If resistance to this product develops in your area, this product, or other products with a similar mode of action, may not provide adequate control.
- If poor performance cannot be attributed to improper application or extreme weather conditions, a resistant strain of insect may be present. If you experience difficulty with control and resistance is a reasonable cause, immediately consult your supplier or agricultural advisor for the best alternate method of control for your area.

#### TIMING

Apply at early stages of pest infestation, typically and depending on the pest species, at egg laying to when the first larvae are present.

#### MIXING

Before using EXIREL 10SE, make sure that the spraying equipment is clean. EXIREL 10SE mixes easily with water, but the following mixing procedure should be followed: Quarter fill the spray tank with clean water, start the agitation and add the required quantity of EXIREL 10SE directly to the tank without prior creaming. Continue agitation while topping up the tank and while spraying.

#### RATES OF USE

Crops	Pests	Rate (L/ha)	Usage
Cherry	Spotted wing drosophila ( <i>Drosophila suzukii</i> )	0.9	Apply in 1000-1200 L water/ha A minimum interval of 14 days must be observed between applications per season. A maximum of one application must be observed after 31 July 2020.

#### SPRAY VOLUME

It is important that an adequate water volume is used to ensure complete coverage of the leaves. Where tree height and/or canopy density is reduced, the dose (and water volume) should be adjusted in accordance with an appropriate dose adjustment scheme, for example PACE. However, if reducing the dose according to tree height or canopy density, do not use

less than the minimum recommended rate for the crop. Consult your specialist advisor for further information. Further information on the PACE scheme is available from HDC, or see the HDC fact sheet available from HSE's website <http://www.pesticides.gov.uk/HDC.pdf>

#### SPRAY TANK CLEAN-OUT

Immediately after application, completely drain spray equipment. Thoroughly rinse sprayer and flush the hoses, boom and nozzles with clean water. Loosen and physically remove visible deposits. Remove and clean nozzles, screens and strainers. Flush the entire system with clean water. Take all necessary safety precautions when cleaning equipment. Do not clean near wells or water sources. Consult label tank cleanup procedures for all tank mix partners and be sure to use the most rigorous procedure recommended.

#### **NOTICE TO BUYER**

All goods supplied by us are of a high grade and we believe them to be suitable for any purpose for which we expressly supply them, but as we cannot exercise control over their mixing or use, all conditions and warranties, statutory or otherwise, as to the quality or fitness for any purpose of our goods are excluded and no responsibility will be accepted by us for any damage or injury whatsoever arising from their storage, handling, application or use.

**Effectiveness and crop safety of this product has not been assessed.**

All other trademarks are duly acknowledged

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