

Authorisation Number: 1381 of 2020

**EMERGENCY AUTHORISATION FOR A PLANT PROTECTION
PRODUCT**

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

Product name: Exirel 10SE

Active ingredient: 100 g / l cyantraniliprole

Product authorisation holder: FMC Agro Limited (Registered Company no.
01973941)

Marketing company: FMC Agro Limited

This Emergency Authorisation starts: 10 June 2020

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

- (a) 7 October 2020 for placing on the market
- (b) 31 October 2020 for use
- (c) 30 November 2020 for storage and disposal of stocks

This Emergency Authorisation will be withdrawn or amended before its end date if a decision is taken to withdraw or amend this Emergency Authorisation under Regulation (EC) No 1107/2009 on any other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

Extent of authorisation: United Kingdom



Signed by: rachel.brown@hse.gov.uk
Signing time: Tuesday, June 9 2020, 10:44:12 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: 9 June 2020

EXPLANATORY NOTES

1. This is Emergency authorisation number 1381 of 2020.
2. This Emergency authorisation will be published on the website of the Chemicals Regulation Division of the HSE.
3. Application reference number: COP 2019/02459
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.

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

This Emergency Authorisation relates to the use of ‘Exirel 10SE’ as an insecticide for use on outdoor and protected blueberries to control spotted wing drosophila

(*Drosophila suzukii*). Application is to be made by broadcast air assisted sprayers and horizontal hydraulic boom sprayers in 500 - 1500 L water /ha. A 10 day interval between applications must be observed. The relevant Department (Natural England, Scottish Natural Heritage, Natural Resources Wales or The Department of Agriculture, Environment and Rural Affairs (DAERA, Northern Ireland) should be consulted prior to any application adjacent to designated sites, such as SSSI and NNR.

The Emergency Authorisation will expire on 7 October 2020 for use and will not be renewed unless the following information is submitted:

- Information on the area of crop affected in previous seasons. For example, how much of the protected crop and outdoor crop is grown in Scotland and the risk of infection so far North compared with the South East. Further evidence regarding the justification of protecting the national crop is required.
- A realistic and detailed spray programme for each crop and indicate where the requested product(s) fit within that programme is required again. This could be based on the spray programmes used in the 2015 to 2019 seasons.
- Details of the area of crop which is outdoor and under protection for the separate production systems of: plum and damson, raspberry and blackberry, and blueberry.
- Monitoring information on the usage of the product in relation to SWD trap counts including a discussion highlighting any correlations.
- Appropriate robust data and evidence on the effects on temperature and humidity from the use of SWD netting and its subsequent effect on blueberry production.

- 4 outdoor residues trials on outdoor blueberry conducted at the proposed GAP on blueberry are required. Alternatively, to support the whole subgroup of “other small fruits and berries”, the following trials are required:
 - 6 outdoor trials on currants (black, red and white); or
 - 4 outdoor trials on currants (black, red and white) and 2 outdoor trials on any representative of the subgroups:
 - Grapes
 - Other small fruits and berries.

These 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 guide-lines 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 monitoring) using a validated method of analysis. The validation data should be generated in accordance with SANCO 3029/99 rev.4 and the OECD guidance document on “Pesticide Residue Analytical Methods” (OECD, 2007). 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).

It should be noted that if an MRL application is required then the EFSA guidance available at the following link must also be followed and a completed evaluation report and application form sub-mitted: [SANTE/11509 /2013– rev. 5.2](#)

• **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**.

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 crop)	Latest time of application:
Protected and outdoor blueberry	0.9	-	2	3 days before harvest

The following Aquatic Buffer Zones must be observed:

Crops/situations:	Aquatic buffer zone distance (metres):	Comment:
Blueberry	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 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) 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) All sprayers must be fitted with three star drift reduction technology for all uses.
- (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 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) 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', 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) Where the buffer zone is greater than 5m then it must not be reduced under the broadcast air assisted sprayer LERAP scheme.
- (5) 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.

- (6) 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.
- (7) 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.
- (8) 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).
- (9) 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.
- (10) To protect non target insects / arthropods, respect an unsprayed buffer zone of 10m to non-crop land when using broadcast air assisted sprayers.
- (11) To protect non target insects / arthropods, respect an unsprayed buffer zone of 5m to non-crop land when using horizontal boom sprayers.

Other specific restrictions:

- (1) This product must only be applied for the control of Spotted Wing Drosophila (*Drosophila suzukii*) in

accordance with the terms of this emergency authorisation and the product label and/or leaflet provided by the authorisation holder.

- (1) This product must not be applied via hand-held equipment when used outdoors.
- (2) A minimum interval of 10 days must be observed between applications.
- (3) 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 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, 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 Emergency 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.