

Decision on amending the MRLs for flutianil in or on various commodities

Import tolerance request

- GB MRL Decision Number: GB MRL 2022/018
- Date of entry into force: 14 October 2022

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Background

Competent authority

The risk assessment associated with amending the MRLs for Great Britain has been conducted by the Chemicals Regulation Division (CRD) of the Health and Safety Executive (HSE).

Application

Flutianil is an approved active substance in Great Britain.

In accordance with Article 6 of Regulation (EC) No 396/2005,¹ HSE received an application from Environmental Resources Management (ERM) on behalf of OAT Agrico Co. Ltd. to set import tolerances for the active substance flutianil in or on apples, cherries, strawberries, cucumbers and courgettes. This was to accommodate authorisations in the USA.

HSE as the competent authority drew up an Evaluation Report (ER) that included its Reasoned Opinion (RO) on the risk to consumers associated with amending the MRLs.

¹ Retained [Regulation \(EC\) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin](#) (as it applies in Great Britain, pursuant to the European Union (Withdrawal) Act 2018 and European Union (Withdrawal Agreement Act 2020). Great Britain ("GB") refers to England, Scotland and Wales.

Conclusion of the competent authority on the risk assessment

The competent authority concluded that the authorised uses of flutianil on apples, cherries (including sour cherries), strawberries, cucumbers and courgettes (including summer squashes) will not result in consumer exposures exceeding the toxicological reference values and therefore are unlikely to have harmful effects on human health.

Full details of the assessment, including the dietary exposure estimates and the list of endpoints, are outlined in the ER/RO (Application Reference Number COP 2018/00949): [Published new and raised GB MRLs list](#).

Decision on the application to amend the MRLs

In accordance with Article 14 of Regulation (EC) No 396/2005, the MRLs outlined in Table 1 will be amended in the GB MRL Statutory Register.

Table 1 MRLs to be amended in the GB MRL Statutory Register

| Product code | Product | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments |
|---|------------------|-------------------------|-------------------------------|---|
| Enforcement residue definition for products of plant origin: flutianil | | | | |
| 0130010 | Apples | 0.01* | 0.15 | The MRL is sufficiently supported by data. A risk to consumers is unlikely. |
| 0140020 | Cherries (sweet) | 0.01* | 0.40 | The MRL is sufficiently supported by data. The MRL for cherries (sweet) also applies to sour cherries. A risk to consumers is unlikely. |
| 0152000 | Strawberries | 0.01* | 0.30 | The MRL is sufficiently supported by data. A risk to consumers is unlikely. |
| 0232010 | Cucumbers | 0.01* | 0.03 | The MRL is derived by extrapolation of residues trials on cucumber and courgettes. |
| 0232030 | Courgettes | 0.01* | 0.03 | The MRL for courgettes also applies to summer squashes. A risk to consumers is unlikely. |

* Indicates that the MRL is set at the limit of quantification/determination

Date of entry into force

The MRLs shall enter into force and appear in the [GB MRL Statutory Register](#) on 14 October 2022.

The GB MRL Statutory Register should be consulted to verify the MRLs set and the legal provisions established.

All other MRLs remain unchanged in the Register.

The active substance and formulated product

Active substance

| | |
|------------------------------|---|
| ISO common name | Flutianil |
| Chemical name (IUPAC) | (<i>Z</i>)-[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]($\alpha,\alpha,\alpha,4$ -tetrafluoro- <i>m</i> -tolylthio)acetonitrile |

Formulated product

| | |
|----------------------------------|-------------------------------|
| Product name | Gatten |
| Formulation type and code | Emulsifiable concentrate (EC) |
| Active substance content | 50 g/L |
| Function | Fungicide |
| Effective against | Fungi |
| Field of use | Outdoor/USA |
| Application method | Foliar spray |

Full details of the Good Agricultural Practices (GAPs) are outlined in Appendix 1.

Appendix 1 – GAPs supported by the assessment

PPP (product name and/or code): Gatten

Active substance: Flutianil

Applicant: Environmental Resources Management (ERM) on behalf of OAT Agrico Co. Ltd.

| Crop and/or situation (a) | GB or Country For Import Tolerance | Product name | F or G Or I (b) | Pests or Group of pests controlled (c) | Preparation | | Application | | | | Application rate per treatment | | | PHI (days) (m) | Remarks |
|------------------------------|------------------------------------|--------------|-----------------|--|-------------|----------------|-------------------|---|--------------------|------------------------------------|--------------------------------|-------------------------|------------------------|----------------|-------------------------------------|
| | | | | | Type (d-f) | Conc. a.s. (i) | method kind (f-h) | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | kg a.s /hL min-max (l) | Water (L/ha) min-max | kg a.s./ha min-max (l) | | |
| Apples | USA | Gatten | F | Fungi | EC | 50 g/L | Foliar spray | Maturing fruit, 35 to 14 days pre-harvest | 4 | 7 days | 5 – 24 or 2 - 5 | 188 – 935 or 935 - 1900 | 45 | 14 | - |
| Cherries | USA | Gatten | F | Fungi | EC | 50 g/L | Foliar spray | Maturing fruit, 31 to 3 days pre-harvest | 4 | 7 days | 5 – 16 or 1.6 - 5 | 280 – 935 or 945 - 2800 | 45 | 3 | - |
| Strawberries | USA | Gatten | F | Fungi | EC | 50 g/L | Foliar spray | Maturing fruit, 28 to 0 days pre-harvest | 5 | 7 days | 2 - 10 | 460 - 1900 | 45 | 0 | A 0 day PHI is acceptable for an IT |
| Cucumbers | USA | Gatten | F | Fungi | EC | 50 g/L | Foliar spray | Maturing fruit, 28 to 0 days pre-harvest | 5 | 7 days | 5 – 16 | 280 - 935 | 45 | 0 | A 0 day PHI is acceptable for an IT |
| Courgettes (summer squashes) | USA | Gatten | F | Fungi | EC | 50 g/L | Foliar spray | Maturing fruit, 28 to 0 days pre-harvest | 5 | 7 days | 5 – 16 | 280 - 935 | 45 | 0 | A 0 day PHI is acceptable for an IT |

Decision on amending the MRLs for flutianil in or on various commodities

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|---|---|
| <p>(a) For crops, the GB and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) State if the use is outdoor, field use (F), glasshouse (G) or indoor use (I).</p> <p>(c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</p> <p>(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|---|---|

