

Decision on amending the MRLs for flutriafol in or on cucurbits with inedible peel

MRLs evaluated to support an import tolerance request

- GB MRL Decision Number: GB MRL 2022/001
- Date of entry into force: 28 January 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

Flutriafol 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 FMC Agricultural Solutions A/S to set import tolerances for the active substance flutriafol in cucurbits with inedible peel, to accommodate an authorisation in the USA.

HSE as the competent authority drew up an Evaluation Report (ER) that included the assessment of the risk to consumers associated with amending the MRL. The ER was submitted to the European Food Safety Authority and a Reasoned Opinion (RO) was delivered prior to 1 January 2021.²

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.

² MRLs for ongoing applications are implemented using the transitional provisions outlined in Schedule 1, Part 3 of the S.I 2019 No. 557. [UK Statutory Instrument 2019 No 557](#)

Conclusion of the competent authority on the risk assessment

The competent authority concluded that the proposed use of flutriafol on cucurbits with inedible peel will not result in consumer exposures exceeding the toxicological reference values and therefore is unlikely to have harmful effects on human health. This conclusion is supported by the RO published by the European Food Safety Authority.

Full details of the assessment, including the dietary exposure estimates and the list of endpoints, are outlined in the EFSA RO.³

³ EFSA (European Food Safety Authority), 2020. Evaluation of confirmatory data following the Article 12 MRL review and setting import tolerance for flutriafol in cucurbits (inedible peel). EFSA Journal 2020; 18(12):6315. [EFSA RO on the evaluation of confirmatory data and setting an IT for flutriafol in cucurbits with inedible peel](#)

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: flutriafol				
0233010	Melons	0.2	0.3	The MRL is sufficiently supported by data. A risk to consumers is unlikely. The footnote in the register related to MRL supplementary information requirements will be deleted.
0233020	Pumpkins	0.01*	0.3	The MRL is derived by the extrapolation of the residue trials conducted on melons. A risk to consumers is unlikely.
0233030	Watermelons	0.2	0.3	The MRL is derived by the extrapolation of the residue trials conducted on melons. A risk to consumers is unlikely. The footnote in the register related to MRL supplementary information requirements will be deleted.

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
0233990	Others – cucurbits with inedible peel	0.01*	0.3	The MRL is derived by the extrapolation of the residue trials conducted on melons. 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 28 January 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.

Footnotes related to MRL supplementary information requirements

The current GB MRLs for melons and watermelons include the following footnote:

The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it.

The footnote arises as a result of the MRL review conducted in 2014 that identified the following data gap:

8 residue trials on melons supporting the indoor GAP on melons and watermelons and 8 residue trials on melons supporting the southern outdoor GAP on melons and watermelons

As the MRLs for melons and watermelons are being amended and the new MRLs are supported by a complete set of residue trials, the footnotes can be deleted from the GB MRL Statutory Register.

In the EFSA RO a consideration was also presented on the evaluation of supplementary information requirements (MRL confirmatory data) for other products. Decisions on these assessments will be taken forward separately.

The active substance and formulated product

Active substance

ISO common name	Flutriafol
Chemical name (IUPAC)	(RS)-2,4'-difluoro- α -(1H-1,2,4-triazol-1-ylmethyl)benzhydryl alcohol

Formulated product

Product name	Flutriafol 250 G/L
Formulation type and code	SC
Active substance content	250 g/L
Function	Fungicide
Effective against	Powdery mildew <i>P. macularis</i> <i>S. macularis</i>
Field of use	Outdoor/USA
Application method	Spraying

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): Flutriafol 250 G/L

Active substance: Flutriafol

Applicant: FMC Agricultural Solutions A/S

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)	g a.s /hL min-max (l)	Water (L/ha) min-max	kg a.s./ha min-max (l)		
Cucurbits with inedible peel	USA	Flutriafol 250 G/L	F	Powdery mildew <i>P. macularis</i> <i>S. macularis</i>	SC	250 g/L	Foliar spray	-	1-4	7-14 days	27.4 – 272	47 - 467	0.128	0	Used with a non-ionic surfactant

<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) or glass house (G) or indoor use (I).</p> <p>(c) e.g. biting and sucking insects, soil born 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. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialvalicarb-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>
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