

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

MRLs evaluated to support new uses in GB and an import tolerance request

- GB MRL Decision Number: GB MRL 2023/001
- Date of entry into force: 19 January 2023

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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

Mefentrifluconazole 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 BASF plc to amend the existing MRLs for the active substance mefentrifluconazole in various commodities. This was to accommodate new uses in GB, future uses in GB and authorisations in the EU (ie Import Tolerances).

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 proposed uses and authorised uses in the EU of mefentrifluconazole on apples, pears, apricots, peaches, cherries, plums, grapes (table and wine), potatoes, sweet corn, sunflower seeds, rapeseeds, maize/corn, sugar beet roots, fodder beet and the resulting residue levels in products of animal origin will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

The active substance is fat soluble and the competent authority recommended that this information should be added as a footnote to all MRLs for mefentrifluconazole in the GB MRL Statutory Register.

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 2020/00825): [Published new and raised GB MRLs list](#)

Decision on the application to amend the MRLs

The MRLs for apples, pears and rapeseeds are to support new uses in GB and import tolerances for the EU. The MRLs for apricots, cherries, peaches, plums and grapes are to cover future extensions of authorisation for minor uses in GB, and as such the MRLs should only be adopted when the uses are authorised; however, the MRLs for these crops also accommodate authorisations in the EU and where considered as part of the import tolerance request. The MRLs for sunflower seeds and sugar beet roots are also to accommodate authorisations in the EU.

The existing MRLs for potatoes, sweet corn, maize/corn and honey support the current GB MRLs in force and therefore no amendments to the GB MRL Statutory Register are required.

The use on fodder beet is not being issued as an authorisation at this time; therefore the MRLs for products of animal origin based on the dietary burden of livestock excluding fodder beet will be adopted in GB.

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.

A footnote will be added to all MRLs for mefentrifluconazole to confirm the active substance is fat soluble.

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: mefentrifluconazole				
0130010	Apples	0.01*	0.4	The MRL is sufficiently supported by data. No health effects are expected.
0130020	Pears	0.01*	0.4	
0140010	Apricots	0.01*	0.7	
0140020	Cherries (sweet)	0.01*	2.0	
0140030	Peaches	0.01*	0.7	
0140040	Plums	0.01*	0.5	
0151010	Table grapes	0.01*	0.9	
0151020	Wine grapes	0.01*	0.9	
0401050	Sunflower seeds	0.01*	0.05	

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
0401060	Rapeseeds/canola seeds	0.01*	0.06	
0900010	Sugar beet roots	0.01*	0.06	
Enforcement residue definition for products of animal origin: mefentrifluconazole				
1011030	Swine: liver	0.01*	0.015	The MRL is sufficiently supported by data. No health effects are expected.
1011050	Swine: edible offals (other than liver and kidney)	0.01*	0.015	
1012040	Bovine: kidney	0.1	0.15	The MRL is sufficiently supported by data. No health effects are expected.
1012050	Bovine: edible offals (other than liver and kidney)	0.1	0.4	
1013050	Sheep: edible offals (other than liver or kidney)	0.3	0.7	The MRL is sufficiently supported by data. No health effects are expected.
1014050	Goat: edible offals (other than liver or kidney)	0.3	0.4	The MRL is sufficiently supported by data. No health effects are expected.
1015040	Equine: kidney	0.1	0.15	

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
1015050	Equine: edible offals (other than liver and kidney)	0.1	0.4	The MRL is sufficiently supported by data. No health effects are expected.
1017010	Other farmed terrestrial animals: muscle	0.01*	0.03	The MRL is sufficiently supported by data. No health effects are expected.
1017020	Other farmed terrestrial animals: fat tissue	0.01*	0.2	
1017030	Other farmed terrestrial animals: liver	0.01*	0.4	
1017040	Other farmed terrestrial animals: kidney	0.01*	0.15	
1017050	Other farmed terrestrial animals: edible offals (other than liver and kidney)	0.01*	0.4	

* 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 19 January 2023.

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.

Notification of the MRLs to be adopted

To meet the UK's international trade obligations, these trade enabling measures have been notified to the World Trade Organization (WTO). The WTO/SPS notification can be found at the following link and searching for mefentrifluconazole and United Kingdom as the notifying member:

[Home - ePing SPS&TBT platform \(epingalert.org\)](http://epingalert.org)

The active substance and formulated product

Active substance

ISO common name	Mefentrifluconazole
Chemical name (IUPAC)	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol

Formulated product

Product name	Belanty
Formulation type and code	Suspension Concentrate (SC)
Active substance content	75 g a.s./L
Function	Fungicide
Effective against	Various fungal diseases
Field of use	Outdoor/GB and outdoor/ EU
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): Belanty

Active substance: Mefentrifluconazole

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 Pears	GB N and S EU MS	Belanty Revyona	F	Various fungal diseases	SC	75 g/L	Spray-ing	BBCH 53-85	2	7	GB: 10 – 50 EU: 7.5 - 100	GB: 300-1500 EU: 150-2000	Max 0.150	28	
Apricots Cherries Peaches Nectarines Plums	GB N and S EU MS	Belanty Revyona	F	Various fungal diseases	SC	75 g/L	Spray-ing	BBCH 55-89	2	7	6.75-67.5	200-2000	0.135	3	
Table grapes Wine grapes	GB N EU MS	Belanty Revyona	F	Various fungal diseased	SC	75 g/L	Spray-ing	BBCH 14-83	2	10	12.5 - 150	100-1200	0.150	21	

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					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)		
Potatoes	GB N and S EU MS	Belanty Revyona	F	Various fungal diseased	SC	75 g/L	Spray- ing	BBCH 20- 97	3	7	GB: 23.5 - 47 EU: 23.5 - 94	GB: 200- 400 EU: 100- 400	0.094	3	
Sunflower seeds	N and S EU MS	Belanty Revyona Revyvit	F	Various fungal diseases	SC	75 g/L	Spray- ing	BBCH 31- 69	2	14	28.25 - 113	100- 400	0.113	-	
Rapeseeds	GB N and S EU MS	Belanty Revyona Revyvit	F	Various fungal diseases	SC	75 g/L	Spraying	BBCH 13- 75	2	14	37.5 - 150	100- 400	0.150	-	The maximum application rate is 1 x 112.5 g a.s./ha at BBCH 13-55 + 1 x 150 g a.s./ha at BBCH 57-75
Sugar beet	GB N EU MS	Belanty Revyona	F	Various fungal diseases	SC	75 g/L	Spray- ing	BBCH 39- 49	2	14	28.25 - 113	100- 400	0.113	28	
Fodder beet	GB	Belanty Revyona	F	Various fungal diseases	SC	75 g/L	Spray- ing	BBCH 39- 49	2	14	28.25 - 113	100- 400	0.113	28	The use is not being authorised at this time

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† Information is outlined in the ER/RO to confirm that authorisations for the GAP have been granted for EU MS that are in the Southern EU and Northern EU

<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. bentiavalicarb-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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