

Decision on amending the MRL for prothioconazole in/on celeriacs/turnip rooted celeries

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Background

Competent authority

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

Application

Prothioconazole is an approved active substance in Great Britain.

In accordance with Article 6 of Regulation (EC) No 396/2005¹, HSE received an application from the Agriculture and Horticulture Development Board (AHDB) to amend the existing MRL for the active substance prothioconazole in or on celeriacs/turnip rooted celeries.

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 the 1st January 2021², recommending the MRL proposed by HSE.

Conclusion of the competent authority on the risk assessment

The competent authority concluded that the proposed use of prothioconazole on celeriacs/turnip rooted celeries 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 RO.

Decision on the application to amend the MRL

In accordance with Article 14 of Regulation (EC) No 396/2005¹, the MRL outlined in table 1 will be amended in the GB MRL Statutory Register.

In the EFSA RO, separate considerations were also presented to raise the MRL for a use on rapeseeds in the EU and of the evaluation of supplementary information requirements (MRL confirmatory data). Decisions on these assessments will be taken forward separately.

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

Product Code	Product/commodity	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comment
Enforcement residue definition for products of plant origin: prothioconazole: prothioconazole-desthio (sum of isomers)				
0213030	Celeriacs/turnip rooted celeries	0.01*	0.1	The MRL is sufficiently supported by data. A risk to consumers is unlikely.

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

The MRL shall enter into force on the date as indicated in the [GB MRL Statutory Register](#).

All other MRLs remain unchanged in the Register.

Links to supporting documents

[EFSA RO on the modification of the existing MRL for prothioconazole in celeriacs](#)

The active substance and formulated product

Active substance

ISO common name	Prothioconazole
Chemical name (IUPAC)	(<i>RS</i>)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione

Formulated product

Product name	Rudis
Formulation type and code	Suspension Concentrate (SC)
Active substance content	480 g/L
Function	Fungicide
Effective against	Septoria
Field of use	Outdoor/GB
Application method	Spraying

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

Appendix 1: Good Agricultural Practice (GAP) table

PPP (product name and/or code): Rudis
 Active substance: Prothioconazole
 Applicant: AHDB

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)		
Celeriacs/ turnip rooted celeries	GB	Rudis	F	septoria	SC	480 g/L	Spray	May _ October	3	14 - 21 days	0.038 – 0.096	200 - 500	0.192	21	Application May - October

<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. fluoroxypr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialicarb-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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Appendix 2: Additional information on this document

GB MRL Decision Number: GB MRL 2021/001

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.