

# Decision on amending the MRL for prothioconazole in or on sugar beet roots

MRL evaluated to support a new use in GB

- GB MRL Decision Number: GB MRL 2022/010
- Date of entry into force: 1 September 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

Prothioconazole is an approved active substance in Great Britain.

In accordance with Article 6 of Regulation (EC) No 396/2005,<sup>1</sup> HSE received an application from Bayer CropScience Limited on 20 June 2022 to amend the existing MRL for the active substance prothioconazole in or on sugar beet roots.

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 MRL.

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<sup>1</sup> 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 use of prothioconazole on sugar beet will not result in consumer exposures exceeding the toxicological reference values and therefore is 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 2022/01188): [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 MRL outlined in Table 1 will be amended in the GB MRL Statutory Register.

**Table 1 MRL 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
<b>Enforcement residue definition for products of plant origin: prothioconazole-desthio (sum of isomers)</b>				
0900010	Sugar beet roots	0.01*	0.03	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

## Date of entry into force

The MRL shall enter into force and appear in the [GB MRL Statutory Register](#) on 1 September 2022, in accordance with the date from which the PPP is authorised for use.

**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

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

### Formulated product

<b>Product name</b>	Caligula
<b>Formulation type and code</b>	Suspo-emulsion (SE)
<b>Active substance content</b>	125 g/L
<b>Function</b>	Fungicide
<b>Effective against</b>	<i>Cercospora beticola</i> <i>Erysiphe betae</i> <i>Ramularia beticola</i> <i>Uromyces betae</i> <i>Stemphylium sp.</i>
<b>Field of use</b>	Outdoor/GB
<b>Application method</b>	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): Caligula  
 Active substance: Prothioconazole  
 Applicant: Bayer CropScience Limited

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)		
Sugar beet	GB	Caligula	F	<i>Cercospora beticola</i> <i>Erysiphe betae</i> <i>Ramularia beticola</i> <i>Uromyces betae</i> <i>Stemphylium sp.</i>	SE	125 g/L prothioconazole (+ 125 g/L fluopyram)	Spray	31-49	1	-	0.0375 – 0.125	120 – 400	0.150	7	Sugar beet tops must not be fed to livestock

<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. 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>
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