Decision on amending the MRL for oxathiapiprolin in or on blueberries

Import tolerance request

- GB MRL Decision Number: GB MRL 2022/003
- Date of entry into force: 22 March 2022
Decision on amending the MRL for oxathiapiproline in or on blueberries

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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

Oxathiapiprolin 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 DuPont Crop Protection (UK) Ltd to set an import tolerance for the active substance oxathiapiprolin in or on blueberries. This was to accommodate an authorisation 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 MRL.

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 use of oxathiapiprolin on blueberries will not result in consumer exposures exceeding the toxicological reference value 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 2021/00205).
Decision on the application to amend the MRL

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

<table>
<thead>
<tr>
<th>Product code</th>
<th>Product</th>
<th>Existing GB MRL (mg/kg)</th>
<th>New or amended GB MRL (mg/kg)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>0154010</td>
<td>Blueberries</td>
<td>0.01*</td>
<td>0.5</td>
<td>The MRL is sufficiently supported by data. A risk to consumers is unlikely.</td>
</tr>
</tbody>
</table>

* 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 22 March 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

<table>
<thead>
<tr>
<th>ISO common name</th>
<th>Oxathiapiprolin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name (IUPAC)</td>
<td>1-(4-{4-[5-(2,6-Difluorophenyl)-4,5-dihydroisoxazol-3-yl]-1,3-thiazol-2-yl}piperidin-1-yl)-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]ethanone</td>
</tr>
</tbody>
</table>

## Formulated product

<table>
<thead>
<tr>
<th>Product name</th>
<th>Orondis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation type and code</td>
<td>SC</td>
</tr>
<tr>
<td>Active substance content</td>
<td>200 g a.s/L</td>
</tr>
<tr>
<td>Function</td>
<td>Fungicide</td>
</tr>
<tr>
<td>Effective against</td>
<td>Phytophthora spp</td>
</tr>
<tr>
<td>Field of use</td>
<td>Outdoor, USA</td>
</tr>
<tr>
<td>Application method</td>
<td>Soil drench, soil directed spray, through irrigation water (micro-sprinkler, drip, or flood).</td>
</tr>
</tbody>
</table>

Full details of the Good Agricultural Practices (GAPs) are outlined in Appendix 1.
## Appendix 1 – GAPs supported by the assessment

**PPP:**
- Active substance: Orondis
- Applicant: DuPont Crop Protection (UK) Ltd

<table>
<thead>
<tr>
<th>Crop and/or situation (a)</th>
<th>GB or Country For Import Tolerance</th>
<th>Product name</th>
<th>F or G or I (b)</th>
<th>Pests or Group of pests controlled (c)</th>
<th>Preparation Type (d-f)</th>
<th>Conc. a.s. (g)</th>
<th>Application method kind (h)</th>
<th>range of growth stages &amp; season (j)</th>
<th>number min-max (k)</th>
<th>Interval between application (min)</th>
<th>Application rate per treatment kg a.s./ha (l)</th>
<th>PHI (days) (m)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blueberry</td>
<td>USA</td>
<td>Orondis</td>
<td>F</td>
<td>Phytophthora spp</td>
<td>SC</td>
<td>200 g a.s/L</td>
<td>Soil drench, soil directed spray, through irrigation water (micro-sprinkler, drip, or flood).</td>
<td>New or established plantings</td>
<td>1-2</td>
<td>7-30 days</td>
<td>48 - 200kg a.s./ha</td>
<td>Minimum of 140 L/ha</td>
<td>67-280</td>
</tr>
</tbody>
</table>

(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)
(b) State if the use is outdoor, field use (F) or glass house (G) or indoor use (I).
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(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. benthiavalcarb-isopropyl).
(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
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(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
(m) PHI - minimum pre-harvest interval