Decision on amending the MRLs for prohexadione in or on various oilseeds

New/raised MRLs and import tolerance requests

- GB MRL Decision Number: GB MRL 2021/006
- Date of entry into force: 27 July 2021

Contents

Background **2**

Competent authority 2

Application 2

Conclusion of the competent authority on the risk assessment **3**

Decision on the application to amend the MRLs **4**

The active substance and formulated product **6**

Appendix 1 – GAPs supported by the assessment **7**

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

Prohexadione (variant prohexadione-calcium) 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 SE to amend the existing MRLs for the active substance prohexadione in or on rapeseeds/canola seeds. The application also included a request to set import tolerances in or on various oilseeds. This was to accommodate authorisations in France and pending authorisations in Bulgaria and Croatia.

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 of prohexadione-calcium on oilseeds will not result in consumer exposures exceeding the toxicological reference values and therefore are 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 2019/01278).

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.

The ER/RO identified that the MRL for poppy seeds is supported by the available data. However, it was recommended that this MRL is only adopted once proof of authorisation in the exporting countries is provided. Therefore, the MRL for poppy seeds will not 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: prohexadione (acid) and its salts expressed as prohexadione-calcium				
0401010	Linseeds	0.01*	0.04	The MRL is derived by extrapolation of residue trials on sunflowers. A risk to consumers is unlikely.
0401060	Rapeseeds / canola seeds	0.01*	0.015	The MRL is sufficiently supported by data. A risk to consumers is unlikely.
0401080	Mustard seeds	0.01*	0.04	The MRL is derived by extrapolation of residue trials on sunflowers. A risk to consumers is unlikely.
0401130	Gold of pleasure seeds	0.01*	0.04	

* 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 the 27 July 2021.

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

ISO common name	Prohexadione (variant prohexadione-calcium)
Chemical name (IUPAC)	3,5-dioxo-4-propionylcyclohexanecarboxylic acid (variant: calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate)

Formulated product

Product name	Architect (BAS 678 01 F)
Formulation type and code	Suspo-emulsion (SE)
Active substance content	25 g/L
Function	Fungicide and plant growth regulator
Effective against	*Plenodomus lingam (Leptosphaeria maculans)* *Pyrenopeziza brassicae* *Kabatiella (Kabatiella lini)* *Septoria (Septoria linicola)* *Botrytis spp.*
Field of use	Outdoor/GB Outdoor/France
Application method	Foliar spray

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): Architect (BAS 678 01 F)
Active substance: Prohexadione (variant prohexadione-Ca)
Applicant: BASF SE

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)		
Oilseed rape	GB and France	BAS 678 01 F Architect	F	*Plenodomus lingam* (*Leptosphaeria maculans*) Pyrenopeziza brassicae Plant growth regulator	SE	25 g/L	Spraying	BBCH 13-20 & BBCH 21-59	Per use: 2 Per crop/season: 2	14 days	0.0125-0.050	100 – 400	Per application 0.050 Max. total rate per crop/season 0.100	-	Can be applied in tank-mix with ammonium sulphate (or a local water conditioner of comparable activity).
Linseed Mustard Gold of pleasure	France	BAS 678 01 F Architect	F	*Kabatiella (Kabatiella lini)* *Septoria (Septoria linicola)* *Botrytis spp.* Plant growth regulator	SE	25 g/L	Spraying	BBCH 21-59	Per use: 1 Per crop/season: 1	-	0.0125-0.050	100 - 400	Per application 0.050 Max. total rate per crop/season 0.050	-	Can be applied in tank-mix with ammonium sulphate (or a local water conditioner of comparable activity).

(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) (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide (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. 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). (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