

Decision on the new MRLs for oxathiapiprolin in or on various commodities

Import tolerance request

- GB MRL Decision Number: GB MRL 2025/013
- Date of entry into force: 20 June 2025

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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

Oxathiapiprolin is an approved active substance in Great Britain.

In accordance with Article 6 of Assimilated Regulation 396/2005,¹ HSE received an application from Corteva Agriscience (UK) to set import tolerances for the active substance oxathiapiprolin in or on table and wine grapes, onions, garlic, shallots, spring onions, tomatoes, sweet peppers/bell peppers, aubergines, okra/lady's fingers, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, broccoli, cauliflower, head cabbage, lamb's lettuce, escaroles, cresses, land cresses, rucola, red mustards, baby leaf crops, lettuces, spinaches, purslanes, chards/beet leaves, peas (with pods), peas (without pods), leeks, sunflower seeds, ginseng and hops. This was to accommodate authorisation in the USA, Canada and China.

In separate regulatory decisions, the GB MRLs for spring onions (GB MRL 2023/012) and hops (GB MRL 2025/001) have been raised to a level which accommodates the requested MRLs, and no further consideration was required. In addition, the requested MRL, and the CXL, for sunflower seeds are equivalent to the GB MRL; therefore, no further consideration was required in this case either.

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/MRL.

¹ <u>Assimilated Regulation No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin</u>

Conclusion of the competent authority on the risk assessment

The competent authority concluded that the authorised uses of oxathiapiprolin on table and wine grapes, onions, garlic, shallots, spring onions, tomatoes, sweet peppers/bell peppers, aubergines, okra/lady's fingers, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, broccoli, cauliflower, head cabbage, lamb's lettuce, escaroles, cresses, land cresses, rucola, red mustards, baby leaf crops, lettuces, spinaches, purslanes, chards/beet leaves, peas (with pods), peas (without pods), leeks, sunflower seeds, ginseng and hops will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

In separate regulatory decisions, the GB MRLs for spring onions (GB MRL 2023/012) and hops (GB MRL 2025/001) have been raised to a level which accommodates the requested MRLs. In addition, the requested MRL, and the CXL, for sunflower seeds are equivalent to the GB MRL. These GB MRLs remain unchanged.

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 2022/00707): <u>GB MRL publications spreadsheet</u>.

Decision on the application to amend the MRLs

In accordance with Article 14 of Assimilated Regulation 396/2005, the MRLs outlined in Table 1 will be amended in the GB MRL Statutory Register.

Product code	Product	Existing New or GB amended MRL GB MRL		Comments
		(mg/kg)	(mg/kg)	
Enforcement	residue defini	tion for pr	oducts of p	lant origin: oxathiapiprolin
0151000	Grapes	0.7	0.9	The MRL is based on the CXL. No health effects are expected.
0220010	Garlic	0.01*	0.04	The MRL is based on the CXL. No health effects are expected.
0220020	Onions	0.01*	0.04	The MRL is based on the CXL. No health effects are expected.
0220030	Shallots	0.01*	0.04	The MRL is based on the CXL. No health effects are expected.
0231010	Tomatoes	0.2	0.4	The MRL is based on the CXL. No health effects are expected.
0231020	Sweet peppers/ bell peppers	0.01*	0.4	The MRL is based on the CXL. No health effects are expected.
0231030	Aubergines/ eggplants	0.2	0.4	The MRL is based on the CXL. No health effects are expected.

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
0231040	Okra/ lady's fingers	0.01*	0.5	The MRL is based on extrapolation from sweet peppers/ bell peppers and the US/Can indoor GAP. No health effects are expected.
0232010	Cucumbers	0.1	0.2	The MRL is based on the CXL. No health effects are expected.
0232020	Gherkins	0.1	0.2	The MRL is based on the CXL. No health effects are expected.
0232030	Courgettes	0.1	0.2	The MRL is based on the CXL. No health effects are expected.
0233010	Melons	0.15	0.2	The MRL is based on the CXL. No health effects are expected.
0233020	Pumpkins	0.01*	0.2	The MRL is based on the CXL. No health effects are expected.
0233030	Watermelons	0.01*	0.2	The MRL is based on the CXL. No health effects are expected.
0241010	Broccoli	0.01*	1.5	The MRL is based on the CXL. No health effects are expected.
0241020	Cauliflower	0.01*	1.5	The MRL is based the US/Can GAP and is sufficiently supported by data. No health effects are expected.

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
0242020	Head cabbage	0.01*	0.7	The MRL is based on the CXL. No health effects are expected.
0251000 (except 0251020)	Lettuces and salad plants (except lettuces)	0.01*	5	The MRL is based the US/Can GAP and is sufficiently supported by data.
0251020	Lettuces	0.3	5	The MRL is based on the CXL. No health effects are expected.
0252000 (except 0251010)	Spinaches and similar leaves (except spinaches)	0.01*	15	The MRL is based the US/Can GAP and is sufficiently supported by data.
0251010	Spinaches	0.01*	15	The MRL is based on the CXL. No health effects are expected.
0260030	Peas (with pods)	0.01*	1	The MRL is based on the CXL. No health effects are expected.
0260040	Peas (without pods)	0.01*	0.05	The MRL is based on the CXL. No health effects are expected.
0270060	Leeks	0.01*	2	The MRL is based on the CXL. No health effects are expected.
0633020	Ginseng	0.05*	0.15	The MRL is based on the CXL. No health effects are expected.

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

Date of entry into force

The MRLs/MRL shall enter into force and appear in the <u>GB MRL Statutory Register</u> on 20 June 2025.

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 oxathiapiprolin and United Kingdom as the notifying member:

Home - ePing SPS&TBT platform (epingalert.org)

The active substance and formulated product

Active substance

ISO common name	Oxathiapiprolin
Chemical name (IUPAC)	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

Formulated product

Product name	Zorvec Enicade
Formulation type and code	Oil dispersion (OD)
Active substance content	100 g/L
Function	Fungicide
Effective against	Plasmopara viticola, downy mildew, Peronospora
	destructor, Pseudoperonospora cubensis,
	Phytophthora capsica, Pseudoperonospora,
	Phytophthora cactorum, Bremia lactucae, Peronospora
	farinosa, Peronospora viciae, Phytophthora phaseoli,
	Plasmopora halstedii, Peronospora humuli, and
	Peronospora parasitica
Field of use	Canada, China, EU, and United States – outdoor and
	protected
Application method	Foliar spray and/or soil application

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): Zorvec Enicade Active substance: Oxathiapiprolin

Crop and/or	GB or	F,G or	Pests or Group of pests	Prepa	aration	Application				Applie treatn	cation rate nent	per	PHI (days	Remark s
situation (a)	Country For Import	l (b)	controlled (c)	Typ e (d-f)	Conc a.s.	method kind (f-h)	range of growth stages & season	numbe r min-	Interval between applicatio	g a.s /hL min-	Water (L/ha) min-max	g a.s./ha min-) (m)	
	Toleranc e				(i)		(j)	max (k)	n (min)	max (I)		max (I)		
Wine grapes	NEU/ SEU	F	Plasmopara viticola	OD	100 g/L	Hydraulic sprayer with/without air assistance/ atomizer/ backpack	BBCH 13-89 (spring/ summer)	1-2	10	4	400/160 0	60	14	
Table grapes Wine grapes	China	F	Downy mildew	OD	100 g/L	Hydraulic sprayer with/without air assistance/atomizer/backp ack	Before disease infection	2	10	4-5	750	a)37. 5 b)75	21	Basis of CXL
Flowering brassica: Broccoli, cauliflower	CAN/ USA	F	Peronospora parasitica	OD	100 g/L	Foliar broadcast	Full season	1-4	5	-	Min 2 (aerial)- min 10 (ground)	8.8- 35	0	Basis of CXL
Head brassica: head cabbage, Brussels sprouts	CAN/ USA	F	Peronospora parasitica	OD	100 g/L	Foliar broadcast	Full season	1-4	5	-	Min 2 (aerial)- min 10 (ground)	8.8- 35	0	Basis of CXL

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Crop and/or	GB or Country For Import Toleranc e	F,G or	Group of pests controlled	Preparation		Application				Appli treatn	cation rate	per	PHI (days	Remark s
situation (a)		l (b)		Typ e (d-f)	Conc a.s. (i)	method kind (f-h)	range of growth stages & season (j)	numbe r min- max (k)	Interval between applicatio n (min)	g a.s /hL min- max (I)	Water (L/ha) min-max	g a.s./ha min- max (I)) (m)	
Bulb vegetable s: onions, garlic, shallots, spring onions	A	F	Peronospora destructor	OD	100 g/L	Foliar broadcast	Full season	1-4	5	-	Min 2 (aerial)- min 10 (ground)	8.8- 35	0	Basis of CXL
Leek														
Onions, garlic	NEU	F	Peronospora destructor	OD	100 g/L	Hydraulic sprayer	BBCH 13-PHI (spring/summe r)	1-3	7	2.5- 10	200-800	20	7	
Cucurbit vegetable s with edible peel: cucumber s, courgettes , gherkins	CAN/ USA	F/ G	Pseudoperonospo ra cubensis, Phytophthora capsici	OD	100 g/L	Foliar broadcast	Full season	1-4	3 (5 for P.capsici)	-	Min 2 (aerial)- min 10 (ground)	4.4- 35	0	Basis of CXL
Cucurbit vegetable s with inedible peel: Melons, Pumpkins, Water-	CAN/ USA	F/ G	Pseudoperonospo ra cubensis, Phytophthora capsici	OD	100 g/L	Foliar broadcast	Full season	1-4	3 (5 for P.capsici)	-	Min 2 (aerial)- min 10 (ground)	4.4- 35	0	Basis of CXL
melons Solanacea	CAN/	F/	Pseudoperonospo	OD	100	Foliar broadcast	Full season	1-4	5	-	Min 2	4.4-	0	Basis
: tomatoes, peppers, aubergine s, okra	USA	G	ra		g/L						(aerial)-	35		of CXL

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Crop and/or	GB or	F,G or	Pests or Group of pests	Prepa	aration	Application	pplication					Application rate per treatment				
situation (a)	Country For Import Toleranc e	l (b)	controlled (c)	Typ e (d-f)	Conc a.s. (i)	method kind (f-h)	range of growth stages & season (j)	numbe r min- max (k)	Interval between applicatio n (min)	g a.s /hL min- max (I)	Water (L/ha) min-max	g a.s./ha min- max (I)	(days) (m)	-		
Peppers	EU	G	Phytophthora capsici	OD	100 g/L	Hydraulic sprayer ±air assistance, atomizer	BBCH 15-89	1-3	7	2.5- 5	500- 1000	25	3			
Ginseng	CAN/ USA	F	Phytophthora cactorum	OD	100 g/L	Foliar broadcast	Full season	1-4	14	-	Min 2 (aerial)- min 10 (ground)	35- 280	14	Basis of CXL		
Lettuces and salad plants: lamb's lettuce, lettuces, escaroles, cress and other sprouts and shoots, land cress, rucola, red mustards,	USA	F	Bremia lactucae, Peronospora farinosa	OD	100 g/L	Foliar broadcast	Full season	1-4	3	-	Min 2 (aerial)- min 10 (ground)	4.4- 35	0	Basis of CXL		
Peas with pods	CAN/ USA	F	Peronospora viciae, Phytophthora phaseoli	OD	100 g/L	Foliar broadcast	Full season	1-4	5	-	Min 2 (aerial)- min 10 (ground)	18-35	0	Basis of CXL		
Peas without pods	CAN/ USA	F	Peronospora viciae, Phytophthora phaseoli	OD	100 g/L	Foliar broadcast	Full season	1-4	5	-	Min 2 (aerial)- min 10 (ground)	18-35	0	Basis of CXL		
Sunflower	NEU/ SEU	F	Plasmopora halstedii	FS	200 g/L	Seed treatment	BBCH 00	1	-	-	-	1.69	n.a.			
Hops	NEU	F	Peronospora humuli	OD	100 g/L	Hydraulic sprayer with air assistance	BBCH 37-85	1-2	10	7.1 4	70-2800	50	14			

(a)	For crops, the GB and Codex classifications (both) should be taken into account;	(i) g/kg or g/L. Normally the rate should be given for the active substance (according							
where re	elevant, the use situation should be described (e.g. fumigation of a structure)	to ISO) and not for the variant in order to compare the rate for same active substances used							
(b)	State if the use is outdoor, field use (F), glasshouse (G) or indoor use (I).	in different variants (e.g. fluroxypyr). In certain cases, where only one variant is synthesised,							
(c)	e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds	it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).							
(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages							
(e)	CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008.	of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on							
Catalog	ue of pesticide	season at time of application							
(f)	All abbreviations used must be explained	(k) Indicate the minimum and maximum number of applications possible under							
(g)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting,	practical conditions of use							
drench		(I) The values should be given in g or kg whatever gives the more manageable							
(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the	number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha							
plant- ty	pe of equipment used must be indicated	(m) PHI - minimum pre-harvest interval							

