

REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for oxadiargyl according to Article 12 of Regulation (EC) No 396/2005¹

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance oxadiargyl. In order to assess the occurrence of oxadiargyl residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing. Hence, the MRL proposal derived by EFSA still requires further consideration by risk managers.

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KEY WORDS

oxadiargyl, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, oxadiazoles, herbicide

¹ On request from EFSA, Question No EFSA-Q-2008-596, approved on 22 October 2013.

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³ Acknowledgement: EFSA wishes to thank the rapporteur Member State Italy for the preparatory work on this scientific output.

Suggested citation: European Food Safety Authority, 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for oxadiargyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(10):3441, 27 pp. doi:10.2903/j.efsa.2013.3441

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Oxadiargyl was included in Annex I to Directive 91/414/EEC on 01 July 2003, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Italy, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 04 September 2009 and, after having considered several comments made by EFSA, the RMS provided on 24 June 2011 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC and the additional information provided by the RMS, EFSA issued on 22 May 2013 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 26 July 2013 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of oxadiargyl was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.008 mg/kg bw per d. No ARfD was deemed necessary.

Metabolism of oxadiargyl was investigated in three different crop groups following different kind of applications. Data are sufficient to define the relevant residue for enforcement and risk assessment in pulses and oilseeds as oxadiargyl. However, no validated analytical method for enforcement of this residue definition is available.

Regarding the magnitude of residues, a sufficient number of supervised residues trials is available to support the GAPs on sunflower reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in sunflower.

As quantifiable residues of oxadiargyl are not expected in sunflower seeds and total chronic exposure was found to represent less than 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing. Nevertheless, processing studies were carried out, and results indicated that residues will not concentrate during the industrial process yielding oil.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, barley and radishes. Although metabolism was found to be slightly different than for primary crops (increasing contribution of metabolite RP017272 at longer plant-back intervals) a specific residue definition for rotational crops was not considered relevant and residue levels crops are not expected to exceed 0.01 mg/kg, provided that oxadiargyl is applied in compliance with the GAPs reported in Appendix A.

Based on the uses reported by the RMS, no significant intake resulting from the pesticide use of oxadiargyl was calculated for dairy ruminant, meat ruminant, poultry or pig. There is therefore no need to further investigate occurrence of residues in livestock and there is no need to propose a residue definition or to set MRLs for products of animal origin.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 0.1% of the ADI (WHO Cluster diet B). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). The MRL of

sunflower seed is not recommended for inclusion in Annex II because it is not sufficiently supported by data and requires further consideration by risk managers (see summary table footnotes for details). In particular, this tentative MRL still needs to be confirmed by the following data:

- a validated analytical method for enforcement of oxadiargyl in food of plant origin.

If the above reported data gap is not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: oxadiargyl				
401050	Sunflower seed	0.01*	0.01*	Further consideration needed ^(a)
-	Other products from plant and/or animal origin	See Appendix C	-	Further consideration needed ^(b)

(*): Indicates that the MRL is set at the limit of analytical quantification.

(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; no CXL is available (combination E-I in Appendix D).

(b): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

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BACKGROUND

Regulation (EC) No 396/2005⁴ establishes the rules governing the setting as well as the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC⁵ before 02 September 2008. As oxadiargyl was included in Annex I to the above mentioned directive on 01 July 2003, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-596 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated while MRLs set out in Regulation (EC) No 396/2005 should accommodate for all uses authorised within the EU as well as uses authorised in third countries having a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to gain an overview on the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

Italy, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for oxadiargyl. The requested information was submitted to EFSA on 04 September 2009 and subsequently checked for completeness. On 24 June 2011, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 22 May 2013 and submitted to Member States (MS) for commenting. All MS comments received by 26 July 2013 were considered by EFSA in the finalisation of the reasoned opinion.

⁴ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

⁵ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32.

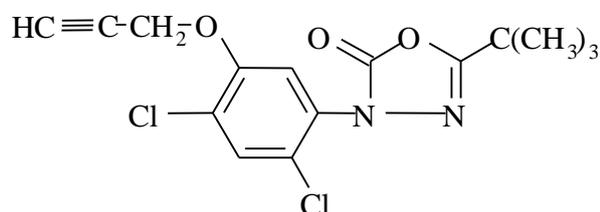
TERMS OF REFERENCE

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Oxadiargyl is the ISO common name for 5-*tert*-butyl-3-[2,4-dichloro-5-(prop-2-ynoxy)phenyl]-1,3,4-oxadiazol-2(3*H*)-one (IUPAC).



Oxadiargyl belongs to the group of oxadiazole compounds which are used as herbicides. It acts on weeds by inhibiting protoporphyrinogen IX oxidase, the enzyme that converts protoporphyrinogen IX into protoporphyrin IX, leading to the inhibition of the synthesis of chlorophyll.

Oxadiargyl was evaluated in the framework of Directive 91/414/EEC with Italy being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was a single pre-emergence/early post emergence treatment on sunflower at a maximum application rate of 400 g a.s./ha. Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2003/23/EC⁶, which entered into force on 01 July 2003. According to Regulation (EU) No 540/2011⁷, oxadiargyl is deemed to have been approved under Regulation (EC) No 1107/2009⁸. This approval is restricted to uses as herbicide only. As EFSA was not yet involved in the peer review of oxadiargyl, an EFSA Conclusion on this active substance is not available. Considering that by 31 July 2013 further support for this active substance was not notified to the European Commission, the approval will expire on 31 July 2016.

The EU MRLs for oxadiargyl are established in Annexes II and IIIB of Regulation (EC) No 396/2005. All existing EU MRLs, which are established for the parent compound only, are summarised in Appendix C to this document. CXLs for oxadiargyl are not available.

⁶ Commission Directive 2003/23/EC of 25 March 2003 amending Council Directive 91/414/EEC to include imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl and cyazofamid as active substances. OJ L 81, 28.3.2003, p. 39–42.

⁷ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

⁸ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ 309, 24.11.2009, p. 1–50.

For the purpose of this MRL review, the critical uses of oxadiargyl currently authorised within the EU, have been collected by the RMS and reported in the PROFile (see Appendix A). They include a northern soil treatment and a southern foliar treatment on sunflower seed (similar to the GAPs supported in the framework of the peer review process). The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

During the Member State Consultation, Italy informed EFSA that the national authorisations for oxadiargyl, including the one reported as the critical use in southern Europe, have been revoked. However, as this decision comes along with a period of grace for disposal of stocks ending on 30 June 2014, EFSA is of the opinion that the use reported in the PROFile should still be taken into account. It can also not be excluded that pending the expiry of the active substance's approval at European level less critical uses will remain authorised in other EU Member States.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Italy, 1999, 2002) as well as the Review Report on oxadiargyl (EC, 2002). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011).

1. Methods of analysis

1.1. Methods for enforcement of residues in food of plant origin

During the peer review under Directive 91/414/EEC, an analytical method using GC-ECD and its ILV were available in plant matrices for the determination of oxadiargyl with an LOQ of 0.01 mg/kg in high oil content (sunflower), dry (rice), high water content (apple, potato) and acidic (grapes) commodities. Nevertheless, the number of tested samples is insufficient (n=3 or 4 for the ILV instead of the 5 required). A confirmatory method using GC-MS was mentioned but no detail was reported (Italy, 1999).

Additionally, an analytical method using GC-ECD was evaluated in plant matrices for the determination of oxadiargyl and validated with an LOQ of 0.01 mg/kg in high oil content (sunflower) commodities. Nevertheless, neither ILV nor confirmatory method was available (Italy, 1999).

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also reported for analysis of the oxadiargyl only with an LOQ of 0.01 mg/kg in high water content commodities (see Table 1-1; EURL, 2013).

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

Table 1-1: Recovery data for the analysis of oxadiargyl in different crop groups using the QuEChERS method in combination with HPLC-MS/MS (EURL, 2013)

Commodity group	Spiking levels (mg/kg)	Recoveries			No of labs
		Mean (%)	RSD (%)	n	
Watery commodities	0.01	115.6	17.0	5	1
	0.1	99.8	8.4	5	

Hence, there is no evidence that oxadiargyl can be enforced adequately in food of plant origin.

1.1. Methods for enforcement of residues in food of animal origin

During the peer review under Directive 91/414/EEC, an analytical method using GC-ECD and its ILV were available in food of animal origin for the determination of oxadiargyl and its metabolite RP025496¹⁰ with an LOQ of 0.01 mg/kg in milk, 0.02 mg/kg in meat, fat and eggs and 0.05 mg/kg in liver and kidney. These LOQs apply to each compound. Thus, the combined LOQs are of 0.02 mg/kg in milk, 0.04 mg/kg in meat, fat and eggs and 0.1 mg/kg in liver and kidney. A GC-MS method was used as confirmation but the method is not fully validated since it presents several deficiencies (number of tested samples insufficient, some mean recoveries and RSD out of the acceptable limits) (Italy, 1999; 2002).

However, considering the fact that there is no significant intake of residues by livestock, no residue definition and no MRLs were proposed for commodities of animal origin (section 3.2). Therefore, an analytical method for enforcement of residues in food of animal origin is not necessary.

2. Mammalian toxicology

The toxicological assessment of oxadiargyl was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2002). The toxicological reference values are summarized in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Oxadiargyl					
ADI	EC	2002	0.008 mg/kg bw per d	2-year rat	100
ARfD	EC	2002	Not allocated, not necessary		

¹⁰ RP 025496 : 5-*tert*-butyl-3-(2,4-dichloro-5-hydroxyphenyl)-1,3,4-oxadiazol-2(3*H*)-one, see appendix E

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of oxadiargyl was investigated for soil and foliar applications on pulses and oilseeds (sunflower), fruits and fruiting vegetables (lemon), and on cereals (rice) using ¹⁴C-phenyl labelled oxadiargyl (Italy, 1999). The characteristics of these studies are summarised in Table 3-1.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application and sampling details				
			Method, F or G ^(a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	Lemon	¹⁴ C]-phenyl oxadiargyl	Soil treatment	6.72	1	56	-
			Foliar spraying				
			Injection in fruits	40 mg/lemon		35	
Pulses and oilseeds	Sunflower	¹⁴ C]-phenyl oxadiargyl	Soil treatment	0.5	1	Interim growth stage and maturity	-
			Foliar spraying				
Cereals	Rice	¹⁴ C]-phenyl oxadiargyl	Soil treatment, G	0.3	1	Maturity	-
			Foliar spraying, G				

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

In sunflower the highest TRR was identified following post-emergence application in immature and mature whole plants (0.07 to 2.7 mg eq./kg respectively). The radioactivity was concentrated in the first 15 cm of the stem, with 0.4 to 7.4 mg eq./kg, respectively in immature and mature whole plants. Following pre-emergence application, TRR in mature whole plants was significantly lower (0.07 mg eq./kg respectively). In immature whole plant (for pre-emergence) and seeds (for both treatments), residues were too low for identification (0.003 mg eq./kg and 0.007-0.01 mg eq./kg respectively).

Following post-emergence application, extraction efficiency was sufficient (more than 75%TRR extracted). Oxadiargyl constituted the most important component of the residue in immature and mature whole plants (88 – 89 % TRR; 0.32 and 2.3 mg eq./kg). Following pre-emergence application, extraction efficiency was insufficient (53%TRR unextracted; 0.037 mg eq./kg). Oxadiargyl was the main component of the TRR in mature whole plant, accounting for 37 %TRR (0.026 mg eq./kg). Only relatively small amounts of metabolites were detected; none of which is expected to contribute significantly to the toxicological burden.

In rice, similar TRR levels were detected following either pre- or post-emergence application. The highest TRR was identified in straw (0.09-0.10 mg eq./kg) while the TRR in chaff was 0.02-0.03 mg eq/kg. In grain, residues were too low for identification (0.007-0.009 mg eq./kg). In straw, extraction efficiency was sufficient (more than 75%TRR extracted). The relevant residue in rice straw consisted

of oxadiargyl (21 – 33 % TRR; 0.02-0.03 mg eq./kg) and its metabolite RP017272 (7 - 12 % TRR; 0.007 – 0.011 mg eq./kg); 28-39%TRR remained unidentified. In chaff, extraction efficiency was insufficient (41-42%TRR unextracted; 0.01 mg eq./kg). Metabolite RP017272 was the main component of the TRR in rice chaff, accounting for 15.7 – 18.5 %TRR (<0.01 mg eq./kg). Only relatively small amounts of metabolites were detected; none of which is expected to contribute significantly to the toxicological burden.

In the lemon study, the soil treatment, the only method representative of a potential agricultural practice, leads to a very low TRR level in fruits (0.002 mg eq./kg). No further investigation was conducted for this application type. The application leading to the highest level of residues is the surface treatment (22.9 mg eq./kg) followed by injection in fruits (9.7 mg eq./kg). Through these application types, parent oxadiargyl represents 83-84 % of the TRR. Only relatively small amounts of metabolites were detected; none of which is expected to contribute significantly to the toxicological burden.

Based on the available studies, the residue for both enforcement and risk assessment is defined as oxadiargyl only. Considering that only the use on sunflower is authorised in Europe, these definitions are currently proposed for the group of pulses and oilseeds only. Validated analytical methods for enforcement of the proposed residue definition are not available (see also section 1.1). EFSA highlights that the residue definition might need to be reconsidered if other uses of oxadiargyl are supported in the future.

3.1.1.2. Magnitude of residues

According to the RMS, the active substance oxadiargyl is authorised on sunflower for soil application in northern Europe (pre-emergence) and for foliar treatment (post-emergence) in southern Europe (see Appendix A). To assess the magnitude of oxadiargyl residues resulting from these GAPs, EFSA considered all residues trials reported in the PROFile, including residues trials evaluated in the framework of the peer review (Italy, 1999). All available residues trials that, according to the RMS, comply with the authorised GAPs, are summarized in Table 3-2.

The number of residues trials and extrapolations were evaluated in view of the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for sunflower. However, the reduced number of residue trials is considered acceptable in this case because all results were all below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

The potential degradation of residues during storage of the residues trials samples was also assessed. In the framework of the peer review, storage stability of oxadiargyl was demonstrated for a period of 3 months at -18 °C in high oil commodities (Italy, 1999). According to the RMS, all residues trial samples reported in the PROFile were stored in compliance with the above reported storage conditions.

Consequently, the available residues data are considered sufficient to derive an MRL proposal as well as risk assessment values for sunflower seeds, the only commodity under evaluation (see also Table 3-2). However, this MRL proposal needs to be considered on a tentative basis only considering that a validated analytical method for enforcement of this MRL proposal is still missing (see also section 1).

Table 3-2: Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement	Risk assessment					
Enforcement and risk assessment residue definition: oxadiargyl									
Sunflower seed	NEU	Outdoor	5 x <0.01	5 x <0.01	0.01	0.01	0.01* (tentative)	1	Trials compliant with GAP.
	SEU	Outdoor	11 x <0.01	11 x <0.01	0.01	0.01	0.01* (tentative)	1	Trials compliant with GAP.

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

As quantifiable residues of oxadiargyl are not expected in sunflower seeds, and total chronic exposure was found to represent less than 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing. Nevertheless, processing studies were carried out, and results indicated that residues in cake and oil were always found to be below the LOQ, thus no concentration of residues is expected during the industrial process yielding oil.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Sunflower might be grown in rotation with other crops. During the peer review under Directive 91/414/EEC, it was also demonstrated in several degradation studies that oxadiargyl is persistent in soil and that DT₉₀ values range from 85 days to 233 days (laboratory studies) and from 42 days to 146 days (field studies), exceeding the trigger value of 100 days (Italy, 1999). A detailed assessment of the nature and magnitude of oxadiargyl residues is therefore considered relevant.

3.1.2.2. Nature of residues

The metabolism of oxadiargyl in rotational crops - lettuce, radish, barley - has been evaluated (Italy, 1999). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available. The characteristics of these studies are summarised in Table 3-4.

Table 3-3: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G ^(a)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals	Remarks
Leafy vegetables	Lettuce	[¹⁴ C]-Phenyl oxadiargyl	Soil application, F	0.4	30, 120/150, 365	Interim stage and maturity	
Root and tuber vegetables	Radishes	[¹⁴ C]-Phenyl oxadiargyl	Soil application, F	0.4	30, 120/150, 365	Interim stage and maturity	
Cereals	Barley	[¹⁴ C]-Phenyl oxadiargyl	Soil application, F	0.4	30, 120/150, 365	Interim stage and maturity	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

In mature lettuce and radish roots, TRR amounted to *ca.* 0.02-0.03 mg eq./kg, with a maximum TRR observed following a 120/150 day plant-back interval. In barley grain, TRR reached *ca.* 0.01 mg eq./kg in the 30 DAT sample, then decreased in the following plant-back intervals. No further investigation was conducted on this matrix. TRR in radish leaves reached *ca.* 0.05-0.06 mg eq./kg in 30 and 120 DAT samples, then decrease to 0.03 mg eq./kg. In barley forage, TRR decreased from 0.06 mg eq./kg to 0.01 mg eq./kg. In chaff, an increase of the TRR was observed, from 0.02 mg eq./kg in 30 and 120/150 DAT samples to 0.04 mg eq./kg in 365 DAT sample. The highest TRR was

observed in barley straw, decreasing from 0.11 mg eq./kg in straw to 0.07 in both 120/150 and 365 DAT samples.

Several metabolites were detected in all samples. In the 30 DAT samples of radish roots and lettuce, no component was detected at levels above 0.01 mg eq./kg and oxadiargyl was the main component of the TRR (28%TRR and 23%TRR, respectively in radish root and lettuce). An unknown polar compound (Unk1) was also detected in radish roots (17.5%TRR). In samples resulting from longer plant-back intervals, the proportion of oxadiargyl decreased as the proportion of metabolite RP017272¹¹ increased, together with an increase of Unk1 in radish root only. RP017272 was present in 120 DAT lettuce at 30%TRR (0.009 mg-eq/kg) while oxadiargyl was present at 26%TRR (0.008 mg-eq/kg). In 120 DAT radish root, RP017272 was present at 35%TRR (0.007 mg-eq/kg) and Unk1 at 18.2%TRR (0.004 mg-eq/kg) while oxadiargyl was present at 12.3%TRR (0.003 mg-eq/kg). In 365 DAT samples of lettuce, RP017272 is present at 39%TRR (0.004 mg eq/kg) while parent was present at 13.5%TRR (0.001 mg eq./kg). In 365 DAT radish root, RP017272 is present at 50%TRR (0.008 mg eq/kg), with no other compound present in significant amounts.

In radish leaves, Unk1 was the main component in 30 DAT sample (23%TRR; 0.015 mg eq./kg), oxadiargyl being present at 11%TRR (0.007 mg eq./kg). In 120 DAT sample, RP017272 was present at 28%TRR (0.017 mg eq./kg) and Unk1 at 25%TRR (0.015 mg eq./kg). In 365 DAT sample, RP017272 was present at 34%TRR (0.009 mg eq/kg). In barley straw, RP017272 was the main component in all samples, from 30%TRR (0.03 mg eq./kg) in 30 DAT sample to 58-61%TRR (0.04-0.05 mg eq./kg) in 120 and 365 DAT samples. In 120 DAT barley chaff, RP017272 was the main component, present at 65%TRR (0.015 mg eq./kg). No other compound was present in significant amounts.

Although metabolism was found to be slightly different than for primary crops (increasing contribution of metabolite RP017272 at longer plant-back intervals) a specific residue definition for rotational crops was not considered relevant and residue levels crops are not expected to exceed 0.01 mg/kg (see also section 3.1.2.3).

3.1.2.3. Magnitude of residues

Considering that rotation of sunflower with another crop at short plant-back intervals is rather unlikely, that oxadiargyl was applied to a bare soil with an application of 400 g a.s./ha and that at such application rates oxadargyl is usually applied in post-emergence where interception by the primary plants is expected (pre-emergence treatments are usually carried out at a lower application rate), it is expected that residues of oxadiargyl resulting from soil uptake will not exceed 0.01 mg/kg. Specific plant-back restrictions related to the use of oxadiargyl are therefore not required, provided that oxadiargyl is applied in compliance with the GAPs evaluated in the framework of this review (see Appendix A).

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Oxadiargyl is authorised for use on a crop that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarized in Table 3-4.

¹¹ 5-*tert*-butyl-3-(2,4-dichloro-5-methoxyphenyl)-1,3,4-oxadiazol-2(3*H*)-one. See Appendix E.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden	
	Input value (mg/kg)	Comment
Risk assessment residue definition: oxadiargyl		
Sunflower seed	0.01	Median residue
Sunflower seed meal	0.01	Median residue

The results of the calculations are reported in Table 3-5. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

Table 3-5: Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw per d)	Median dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: oxadiargyl					
Dairy ruminants	0.00013	0.00013	Sunflower seed	0.00352	N
Meat ruminants	0.00015	0.00015	Sunflower seed	0.00348	N
Poultry	0.00007	0.00007	Sunflower seed	0.00117	N
Pigs	0.00009	0.00009	Sunflower seed	0.00233	N

4. Consumer risk assessment

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The tentative median residue values selected for chronic intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Table 4-1: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: oxadiargyl		
Sunflower seed	0.01*	Median residue (tentative) ^(a)

(a): Use reported by the RMS is not fully supported by data but the risk assessment value derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for oxadiargyl (see Table 2-1); detailed results of the calculations are presented in Appendix B. The highest chronic exposure was calculated for WHO cluster diet B, representing 0.1 % of the ADI.

Based on the above calculations, EFSA concludes that for the use of oxadiargyl on sunflower seed some uncertainties remain due to the data gap identified in section 1 but considering a tentative MRL in the exposure calculation did not indicate a risk to consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of oxadiargyl was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.008 mg/kg bw per d. No ARfD was deemed necessary.

Metabolism of oxadiargyl was investigated in three different crop groups following different kind of applications. Data are sufficient to define the relevant residue for enforcement and risk assessment in pulses and oilseeds as oxadiargyl. However, no validated analytical method for enforcement of this residue definition is available.

Regarding the magnitude of residues, a sufficient number of supervised residues trials is available to support the GAPs on sunflower reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in sunflower.

As quantifiable residues of oxadiargyl are not expected in sunflower seeds and total chronic exposure was found to represent less than 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing. Nevertheless, processing studies were carried out, and results indicated that residues will not concentrate during the industrial process yielding oil.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, barley and radishes. Although metabolism was found to be slightly different than for primary crops (increasing contribution of metabolite RP017272 at longer plant-back intervals) a specific residue definition for rotational crops was not considered relevant and residue levels crops are not expected to exceed 0.01 mg/kg, provided that oxadiargyl is applied in compliance with the GAPs reported in Appendix A.

Based on the uses reported by the RMS, no significant intake resulting from the pesticide use of oxadiargyl was calculated for dairy ruminant, meat ruminant, poultry or pig. There is therefore no need to further investigate occurrence of residues in livestock and there is no need to propose a residue definition or to set MRLs for products of animal origin.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 0.1% of the ADI (WHO Cluster diet B). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). The MRL of sunflower seed is not recommended for inclusion in Annex II because it is not sufficiently supported

by data and requires further consideration by risk managers (see summary table footnotes for details). In particular, this tentative MRL still needs to be confirmed by the following data:

- a validated analytical method for enforcement of oxadiargyl in food of plant origin.

If the above reported data gap is not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: oxadiargyl				
401050	Sunflower seed	0.01*	0.01*	Further consideration needed ^(a)
-	Other products from plant and/or animal origin	See Appendix C	-	Further consideration needed ^(b)

(*): Indicates that the MRL is set at the limit of analytical quantification.

(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; no CXL is available (combination E-I in Appendix D).

(b): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on oxadiargyl prepared by the rapporteur Member State Italy in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 04 September 2009. Last updated on 24 June 2011.

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EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.

EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Number		Interval (days)		Min. rate			Max. rate	Rate Unit
							Conc.	Unit				Min.	Max.	Min.	Max.					
Sunflower seed	<i>Helianthus annuus</i>	NEU	Outdoor	FR	weeds	SC	37,5	g/L	Soil treatment - spraying	0	8		1			0,15	kg a.i./ha	n.a.	application: pre-emergence	

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Number		Interval (days)		Min. rate			Max. rate	Rate Unit
							Conc.	Unit				Min.	Max.	Min.	Max.					
Sunflower seed	<i>Helianthus annuus</i>	SEU	Outdoor	IT	weeds	SC	400,0	g/L	Foliar treatment - spraying	0	14		1			0,20	0,40	kg a.i./ha	n.a.	application: pre-emergence and early post-emergence (2-4 leaves)

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Oxadiargyl			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,008	ARID (mg/kg bw):	n.n.
Source of ADI:	COM	Source of ARID:	COM
Year of evaluation:	2003	Year of evaluation:	2003

Chronic risk assessment - refined calculations								
			TMDI (range) in % of ADI minimum - maximum					
			No of diets exceeding ADI: ---					
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)
0,1	WHO Cluster diet B	0,1	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,1	WHO cluster diet D	0,1	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	WHO cluster diet E	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	FR all population	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	PT General population	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	IE adult	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	FR toddler	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	WHO regional European diet	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	ES child	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	ES adult	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	WHO Cluster diet F	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	DE child	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	LT adult	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	FR infant	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	IT kids/toddler	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	NL child	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	IT adult	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	PL general population	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	NL general	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,0	DK adult	0,0	Sunflower seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	FI adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	FI adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	FI adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	FI adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	FI adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	FI adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	FI adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.
A long-term intake of residues of Oxadiargyl is unlikely to present a public health concern.

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 06/07/2011 16:23))

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
100000	1. FRUIT FRESH OR FROZEN; NUTS	0.01*
110000	(i) Citrus fruit	0.01*
110010	Grapefruit (Shaddock, pomelos, sweeties, tangelo, ugli and other hybrids)	0.01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.01*
110030	Lemons (Citron, lemon)	0.01*
110040	Limes	0.01*
110050	Mandarins (Clementine, tangerine and other hybrids)	0.01*
110990	Others	0.01*
120000	(ii) Tree nuts (shelled or unshelled)	0.01*
120010	Almonds	0.01*
120020	Brazil nuts	0.01*
120030	Cashew nuts	0.01*
120040	Chestnuts	0.01*
120050	Coconuts	0.01*
120060	Hazelnuts (Filbert)	0.01*
120070	Macadamia	0.01*
120080	Pecans	0.01*
120090	Pine nuts	0.01*
120100	Pistachios	0.01*
120110	Walnuts	0.01*
120990	Others	0.01*
130000	(iii) Pome fruit	0.01*
130010	Apples (Crab apple)	0.01*
130020	Pears (Oriental pear)	0.01*
130030	Quinces	0.01*
130040	Medlar	0.01*
130050	Loquat	0.01*
130990	Others	0.01*
140000	(iv) Stone fruit	0.01*
140010	Apricots	0.01*
140020	Cherries (sweet cherries, sour cherries)	0.01*
140030	Peaches (Nectarines and similar hybrids)	0.01*
140040	Plums (Damson, greengage, mirabelle)	0.01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
140990	Others	0.01*
150000	(v) Berries & small fruit	0.01*
151000	(a) Table and wine grapes	0.01*
151010	Table grapes	0.01*
151020	Wine grapes	0.01*
152000	(b) Strawberries	0.01*
153000	(c) Cane fruit	0.01*
153010	Blackberries	0.01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0.01*
153030	Raspberries (Wineberries)	0.01*
153990	Others	0.01*
154000	(d) Other small fruit & berries	0.01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0.01*
154020	Cranberries	0.01*
154030	Currants (red, black and white)	0.01*
154040	Gooseberries (Including hybrids with other ribes species)	0.01*
154050	Rose hips	0.01*
154060	Mulberries (arbutus berry)	0.01*
154070	Azarole (mediterranean medlar)	0.01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0.01*
154990	Others	0.01*
160000	(vi) Miscellaneous fruit	0.01*
161000	(a) Edible peel	0.01*
161010	Dates	0.01*
161020	Figs	0.01*
161030	Table olives	0.01*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0.01*
161050	Carambola (Bilmbi)	0.01*
161060	Persimmon	0.01*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0.01*
161990	Others	0.01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
162000	(b) Inedible peel, small	0.01*
162010	Kiwi	0.01*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0.01*
162030	Passion fruit	0.01*
162040	Prickly pear (cactus fruit)	0.01*
162050	Star apple	0.01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0.01*
162990	Others	0.01*
163000	(c) Inedible peel, large	0.01*
163010	Avocados	0.01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.01*
163030	Mangoes	0.01*
163040	Papaya	0.01*
163050	Pomegranate	0.01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0.01*
163070	Guava	0.01*
163080	Pineapples	0.01*
163090	Bread fruit (Jackfruit)	0.01*
163100	Durian	0.01*
163110	Soursop (guanabana)	0.01*
163990	Others	0.01*
200000	2. VEGETABLES FRESH OR FROZEN	0.01*
210000	(i) Root and tuber vegetables	0.01*
211000	(a) Potatoes	0.01*
212000	(b) Tropical root and tuber vegetables	0.01*
212010	Cassava (Dasheen, eddloe (Japanese taro), tannia)	0.01*
212020	Sweet potatoes	0.01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0.01*
212040	Arrowroot	0.01*
212990	Others	0.01*
213000	(c) Other root and tuber	0.01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
	vegetables except sugar beet	
213010	Beetroot	0.01*
213020	Carrots	0.01*
213030	Celeriac	0.01*
213040	Horseradish	0.01*
213050	Jerusalem artichokes	0.01*
213060	Parsnips	0.01*
213070	Parsley root	0.01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0.01*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0.01*
213100	Swedes	0.01*
213110	Turnips	0.01*
213990	Others	0.01*
220000	(ii) Bulb vegetables	0.01*
220010	Garlic	0.01*
220020	Onions (Silverskin onions)	0.01*
220030	Shallots	0.01*
220040	Spring onions (Welsh onion and similar varieties)	0.01*
220990	Others	0.01*
230000	(iii) Fruiting vegetables	0.01*
231000	(a) Solanacea	0.01*
231010	Tomatoes (Cherry tomatoes,)	0.01*
231020	Peppers (Chilli peppers)	0.01*
231030	Aubergines (egg plants) (Pepino)	0.01*
231040	Okra, lady's fingers	0.01*
231990	Others	0.01*
232000	(b) Cucurbits - edible peel	0.01*
232010	Cucumbers	0.01*
232020	Gherkins	0.01*
232030	Courgettes (Summer squash, marrow (patisson))	0.01*
232990	Others	0.01*
233000	(c) Cucurbits-inedible peel	0.01*
233010	Melons (Kiwano)	0.01*
233020	Pumpkins (Winter squash)	0.01*
233030	Watermelons	0.01*
233990	Others	0.01*
234000	(d) Sweet corn	0.01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
239000	(e) Other fruiting vegetables	0.01*
240000	(iv) Brassica vegetables	0.01*
241000	(a) Flowering brassica	0.01*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.01*
241020	Cauliflower	0.01*
241990	Others	0.01*
242000	(b) Head brassica	0.01*
242010	Brussels sprouts	0.01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.01*
242990	Others	0.01*
243000	(c) Leafy brassica	0.01*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0.01*
243020	Kale (Borecole (curly kale), collards)	0.01*
243990	Others	0.01*
244000	(d) Kohlrabi	0.01*
250000	(v) Leaf vegetables & fresh herbs	0.01*
251000	(a) Lettuce and other salad plants including Brassicacea	0.01*
251010	Lamb's lettuce (Italian comsalad)	0.01*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0.01*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leave endive, sugar loaf)	0.01*
251040	Cress	0.01*
251050	Land cress	0.01*
251060	Rocket, Rucola (Wild rocket)	0.01*
251070	Red mustard	0.01*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0.01*
251990	Others	0.01*
252000	(b) Spinach & similar (leaves)	0.01*
252010	Spinach (New Zealand spinach, tumip greens (tumip tops))	0.01*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0.01*
252030	Beet leaves (chard) (Leaves of	0.01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
	beetroot)	
252990	Others	0.01*
253000	(c) Vine leaves (grape leaves)	0.01*
254000	(d) Water cress	0.01*
255000	(e) Witloof	0.01*
256000	(f) Herbs	0.01*
256010	Chervil	0.01*
256020	Chives	0.01*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0.01*
256040	Parsley	0.01*
256050	Sage (Winter savory, summer savory,)	0.01*
256060	Rosemary	0.01*
256070	Thyme (marjoram, oregano)	0.01*
256080	Basil (Balm leaves, mint, peppermint)	0.01*
256090	Bay leaves (laurel)	0.01*
256100	Tarragon (Hyssop)	0.01*
256990	Others	0.01*
260000	(vi) Legume vegetables (fresh)	0.01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.01*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.01*
260030	Peas (with pods) (Mangetout (sugar peas))	0.01*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.01*
260050	Lentils	0.01*
260990	Others	0.01*
270000	(vii) Stem vegetables (fresh)	0.01*
270010	Asparagus	0.01*
270020	Cardoons	0.01*
270030	Celery	0.01*
270040	Fennel	0.01*
270050	Globe artichokes	0.01*
270060	Leek	0.01*
270070	Rhubarb	0.01*
270080	Bamboo shoots	0.01*
270090	Palm hearts	0.01*
270990	Others	0.01*
280000	(viii) Fungi	0.01*
280010	Cultivated (Common mushroom,	0.01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
	Oyster mushroom, Shi-take)	
280020	Wild (Chanterelle, Truffle, Morel ,)	0.01*
280990	Others	0.01*
290000	(ix) Sea weeds	0.01*
300000	3. PULSES, DRY	0.01*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0.01*
300020	Lentils	0.01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0.01*
300040	Lupins	0.01*
300990	Others	0.01*
400000	4. OILSEEDS AND OILFRUITS	0.01*
401000	(i) Oilseeds	0.01*
401010	Linseed	0.01*
401020	Peanuts	0.01*
401030	Poppy seed	0.01*
401040	Sesame seed	0.01*
401050	Sunflower seed	0.01*
401060	Rape seed (Bird rapeseed, tumip rape)	0.01*
401070	Soya bean	0.01*
401080	Mustard seed	0.01*
401090	Cotton seed	0.01*
401100	Pumpkin seeds	0.01*
401110	Safflower	0.01*
401120	Borage	0.01*
401130	Gold of pleasure	0.01*
401140	Hempseed	0.01*
401150	Castor bean	0.01*
401990	Others	0.01*
402000	(ii) Oilfruits	0.01*
402010	Olives for oil production	0.01*
402020	Palm nuts (palmoil kernels)	0.01*
402030	Palmfruit	0.01*
402040	Kapok	0.01*
402990	Others	0.01*
500000	5. CEREALS	0.01*
500010	Barley	0.01*
500020	Buckwheat	0.01*
500030	Maize	0.01*
500040	Millet (Foxtail millet, tef)	0.01*
500050	Oats	0.01*
500060	Rice	0.01*
500070	Rye	0.01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
500080	Sorghum	0.01*
500090	Wheat (Spelt Triticale)	0.01*
500990	Others	0.01*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0.05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0.05*
620000	(ii) Coffee beans	0.05*
630000	(iii) Herbal infusions (dried)	0.05*
631000	(a) Flowers	0.05*
631010	Camomille flowers	0.05*
631020	Hybiscus flowers	0.05*
631030	Rose petals	0.05*
631040	Jasmine flowers	0.05*
631050	Lime (linden)	0.05*
631990	Others	0.05*
632000	(b) Leaves	0.05*
632010	Strawberry leaves	0.05*
632020	Rooibos leaves	0.05*
632030	Maté	0.05*
632990	Others	0.05*
633000	(c) Roots	0.05*
633010	Valerian root	0.05*
633020	Ginseng root	0.05*
633990	Others	0.05*
639000	(d) Other herbal infusions	0.05*
640000	(iv) Cocoa (fermented beans)	0.05*
650000	(v) Carob (st johns bread)	0.05*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0.05*
800000	8. SPICES	0.05*
810000	(i) Seeds	0.05*
810010	Anise	0.05*
810020	Black caraway	0.05*
810030	Celery seed (Lovage seed)	0.05*
810040	Coriander seed	0.05*
810050	Cumin seed	0.05*
810060	Dill seed	0.05*
810070	Fennel seed	0.05*
810080	Fenugreek	0.05*
810090	Nutmeg	0.05*
810990	Others	0.05*
820000	(ii) Fruits and berries	0.05*
820010	Allspice	0.05*
820020	Anise pepper (Japan pepper)	0.05*
820030	Caraway	0.05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
820040	Cardamom	0.05*
820050	Juniper berries	0.05*
820060	Pepper, black and white (Long pepper, pink pepper)	0.05*
820070	Vanilla pods	0.05*
820080	Tamarind	0.05*
820990	Others	0.05*
830000	(iii) Bark	0.05*
830010	Cinnamon (Cassia)	0.05*
830990	Others	0.05*
840000	(iv) Roots or rhizome	0.05*
840010	Liquorice	0.05*
840020	Ginger	0.05*
840030	Turmeric (Curcuma)	0.05*
840040	Horseradish	0.05*
840990	Others	0.05*
850000	(v) Buds	0.05*
850010	Cloves	0.05*
850020	Capers	0.05*
850990	Others	0.05*
860000	(vi) Flower stigma	0.05*
860010	Saffron	0.05*
860990	Others	0.05*
870000	(vii) Aril	0.05*
870010	Mace	0.05*
870990	Others	0.05*
900000	9. SUGAR PLANTS	0.01*
900010	Sugar beet (root)	0.01*
900020	Sugar cane	0.01*
900030	Chicory roots	0.01*
900990	Others	0.01*

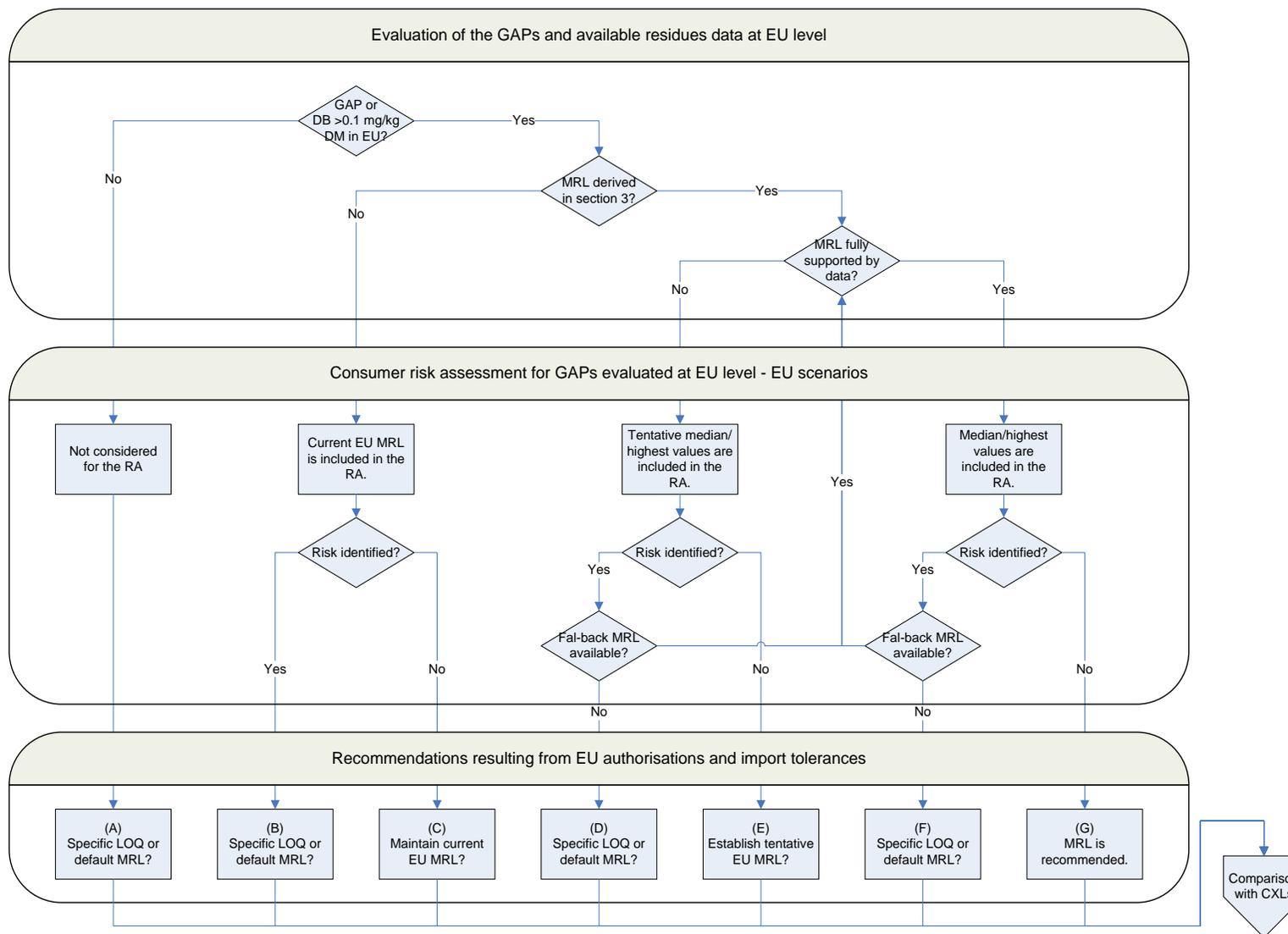
Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	

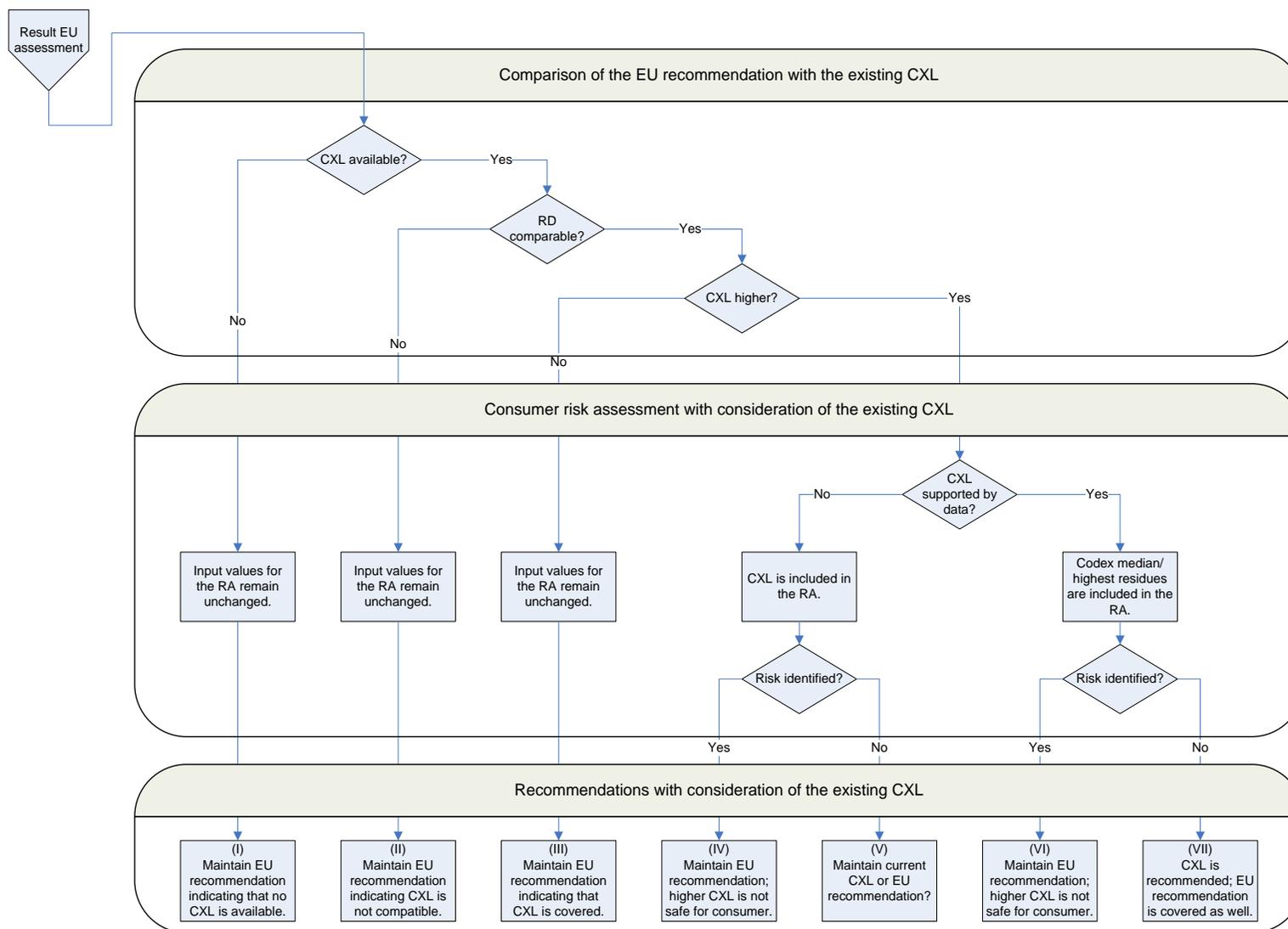
Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Oxadiargyl
	added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

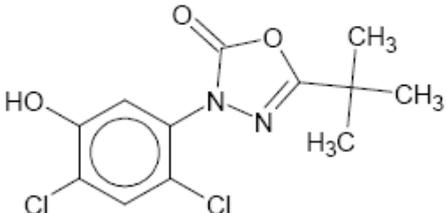
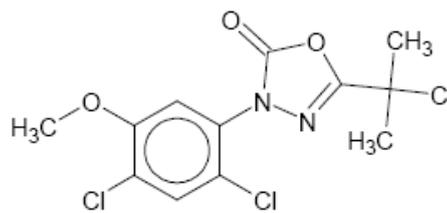
(*) Indicates lower limit of analytical determination

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS





APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
RP 025496	<i>5-tert-butyl-3-(2,4-dichloro-5-hydroxyphenyl)-1,3,4-oxadiazol-2(3H)-one</i>	 <p>The structure shows a central 1,3,4-oxadiazol-2(3H)-one ring. The 3-position of the ring is substituted with a tert-butyl group (C(CH₃)₃). The 5-position of the ring is substituted with a phenyl ring. This phenyl ring has a hydroxyl group (HO-) at the 5-position and two chlorine atoms (Cl) at the 2 and 4 positions.</p>
RP 017272	<i>5-tert-butyl-3-(2,4-dichloro-5-methoxyphenyl)-1,3,4-oxadiazol-2(3H)-one</i>	 <p>The structure shows a central 1,3,4-oxadiazol-2(3H)-one ring. The 3-position of the ring is substituted with a tert-butyl group (C(CH₃)₃). The 5-position of the ring is substituted with a phenyl ring. This phenyl ring has a methoxy group (H₃C-O-) at the 5-position and two chlorine atoms (Cl) at the 2 and 4 positions.</p>

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-ECD	gas chromatography coupled with electron capture detection
GC-MS	gas chromatography coupled with mass spectrometry detection
ha	hectare
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
ILV	independent laboratory validation
ISO	International Organization for Standardization

IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
PHI	pre-harvest interval
PROFile	Pesticide Residue Overview File
PRIMo	(EFSA) Pesticide Residues Intake Model
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RMS	rapporteur Member State
RSD	relative standard deviation
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organisation