

APPROVED: 31 July 2015

PUBLISHED: 20 Aug 2015

doi:10.2903/j.efsa.2015.4209

Peer review of the pesticide risk assessment for the active substance dodine in light of confirmatory data submitted

European Food Safety Authority (EFSA)

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessment carried out by the competent authority of the rapporteur Member State Portugal, for the pesticide active substance dodine are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory data in ecotoxicology. The conclusions were reached on the basis of the evaluation of the representative uses as a fungicide on pome fruits and stone fruits. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Concerns are identified.

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Key words: dodine, peer review, confirmatory data, risk assessment, pesticide, fungicide

Requestor: European Commission

Question number: EFSA-Q-2015-00166

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Suggested citation: EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment for the active substance dodine in light of confirmatory data submitted. EFSA Journal 2015;13(8):4209, 15 pp. doi:10.2903/j.efsa.2015.4209

ISSN: 1831-4732

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Summary

Dodine was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/9/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on the long-term risk assessment for birds and mammals and the risk assessment in natural surface water systems by 31 May 2013.

In accordance with the specific provision, the applicant, Agriphar S.A., submitted an updated dossier in May 2013, which was evaluated by the designated rapporteur Member State (RMS), Portugal, in the form of two addenda to the draft assessment report. In compliance with the guidance document SANCO 5634/2009 rev.4.5, the RMS distributed the addenda to the Member States, the applicant and EFSA for comments on 29 November 2013. The RMS collated all comments in the format of a reporting table, which was submitted to the European Commission in March 2014.

Following consideration of the comments received, the European Commission requested EFSA to organise a peer review of the RMS's evaluation of the confirmatory data submitted in relation to ecotoxicology and to deliver its conclusions on the risk assessment for birds and mammals.

Overall, it is concluded that the confirmatory data submitted were not suitable to address the long-term risk to birds and mammals. A data gap and a critical area of concern were identified.

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Background

Dodine was included in Annex I to Directive 91/414/EEC¹ on 1 June 2011 by Commission Directive 2011/9/EU², and has been deemed to be approved under Regulation (EC) No 1107/2009³, in accordance with Commission Implementing Regulation (EU) No 540/2011⁴, as amended by Commission Implementing Regulation (EU) No 541/2011⁵. EFSA previously finalised a Conclusion on this active substance on 28 May 2010 (EFSA, 2010).

It was a specific provision of the approval that the applicant was required to submit to the European Commission by 31 May 2013 further studies on the long-term risk assessment for birds and mammals and the risk assessment in natural surface water systems where major metabolites have potentially formed.

In accordance with the specific provision, the applicant, Agriphar S.A., submitted an updated dossier in May 2013, which was evaluated by the designated rapporteur Member State (RMS), Portugal, in the form of two addenda to the draft assessment report (Portugal, 2013a,b). In compliance with the guidance document SANCO 5634/2009 rev.4.5 (European Commission, 2011), the RMS distributed the addenda to the Member States, the applicant and EFSA for comments on 29 November 2013. The RMS collated all comments in the format of a reporting table, which was submitted to the European Commission in March 2014.

Following consideration of the comments received, the European Commission requested EFSA to organise a peer review of the RMS's evaluation of the confirmatory data submitted in relation to ecotoxicology and to deliver its conclusions on the risk assessment for birds and mammals.

The relevant addendum and the reporting table were discussed at the Pesticides Peer Review Experts' Meeting 130 on ecotoxicology in May 2015. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting report.

A final consultation on the conclusions arising from the peer review took place with Member States via a written procedure in July 2015.

The conclusions laid down in this report were reached on the basis of the peer review of the RMS's evaluation of the confirmatory data submitted in relation to the risk assessment for birds and mammals. A key supporting document to this conclusion is the peer review report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the compilation of comments in the reporting table to the conclusion. The peer review report (EFSA, 2015) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the reporting table,
- the report of the scientific consultation with Member State experts,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its final confirmatory data addendum on ecotoxicology (Portugal, 2015) and the peer review report, these documents are considered as background documents to this conclusion.

¹ Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC). OJ L 230, 19.8.91, p. 1-32.

² Commission Directive 2011/9/EU of 1 February 2011 amending Council Directive 91/414/EEC to include dodine as active substance and amending Decision 2008/934/EC. OJ L 28, 2.2.2011, p. 36-39.

³ 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 L 309, 24.11.2009, p. 1-50.

⁴ 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.

⁵ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 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. 187-188.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Dodine is the ISO common name for 1-dodecylguanidinium acetate (IUPAC).

The representative formulated product for the original evaluation was 'Syllit 400 SC', a suspension concentrate (SC), containing 400 g/L dodine.

The representative uses evaluated comprise foliar spraying against scab in apples and pears, and against leaf curl and leaf spot diseases in peaches and cherries, respectively. Full details of the GAP can be found in the list of end points in Appendix A of this conclusion.

Conclusions of the evaluation

The applicant has submitted to the European Commission by the deadline of 31 May 2013 studies as regards:

- the long-term risk assessment for birds and mammals;
- the risk assessment in natural surface water systems where major metabolites have potentially formed.

The assessment of the information was presented in confirmatory data addenda (Portugal, 2013a,b).

The ecotoxicological risk assessment was performed according to EFSA, 2009.

A low acute risk was identified to **birds** on the basis of first tier level assessments for the representative uses, while a high long-term risk was indicated for several exposure scenarios (i.e. insectivorous and granivorous birds, see Appendix A). The first-tier risk assessment indicated a high acute risk for herbivorous **mammals** and also a high long-term risk to mammals for different exposure scenarios (i.e. herbivorous, frugivorous and omnivorous mammals, see Appendix A). As regards the acute risk assessment, a refinement was available and considered acceptable in the previous peer review (EFSA, 2010).

Long-term risk assessment refinements were available in the confirmatory data package, which were discussed at the Pesticides Peer Review Experts' Meeting 130 on ecotoxicology in May 2015. These refinements considered focal species and ecological data. It was noted that 'generic focal species' were used as 'specific focal species' without relevant data to justify this approach. In addition, the experts considered the mean PT value for the insectivorous blue tit (*Parus caeruleus*) uncertain and recommended the use of the 90th percentile PT to cover the uncertainties of the data set. For mammals, the experts agreed that the refinements (i.e. specific focal species, PT and PD values) proposed were not supported by any data and therefore the tier II risk assessment was considered not appropriate.

New measured residue data in vegetation and arthropods in orchards were available and reported in the revised addendum (Portugal, 2015). These data were considered not sufficient to refine the default parameters (i.e. RUDs, MAF and ftwa) and therefore were not used for higher tier assessment.

Overall, the data provided within the confirmatory data set were considered not sufficient to address the long-term risk to birds and mammals. A data gap was identified for further risk refinement.

Data gaps

This is a list of data gaps identified in the focused peer review process of confirmatory data. Data gaps identified in the previously finalised EFSA Conclusion on this active substance (EFSA, 2010) that were not part of the focussed peer review process of confirmatory data remain unchanged.

- The long-term risk to birds and mammals should be further addressed (relevant for all representative uses).

Concerns

1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011⁶, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

None identified for the representative uses.

2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

1. A high long-term risk to birds and mammals was identified for all representative uses.

3. Overview of the concerns identified for each representative use considered

Table 1: Overview of concerns

Representative use		Apple/pear (BBCH 01 til 28 days before harvest)	Apple/pear (BBCH 01 til 60 days before harvest)	Peach	Cherry
	Risk to wild non-target terrestrial vertebrates	Risk identified	X ¹	X ¹	X ¹
	Assessment not finalised				

Columns are grey if no safe use can be identified. The superscript numbers in this table relate to the numbered points indicated in Sections 1 and 2. Where there is no superscript number, see Section on 'Conclusions of the evaluation' for further information.

⁶ 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, 11.6.2011, p. 127-175.

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- Portugal, 2015. Final confirmatory data addendum to Volume 3 B9 of the Draft Assessment Report (DAR) on dodine, June 2015. Available online: www.efsa.europa.eu

Abbreviations

a.s.	active substance
BBCH	Biologische Bundesanstalt, Bundessortenamt und CHEmische Industrie
bw	body weight
DAR	draft assessment report
DDD	daily dietary dose
DT ₅₀	period required for 50 % dissipation (define method of estimation)
EU	European Union
f(twa)	time-weighted average factor
GAP	good agricultural practice
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
MAF	multiple application factor
PD	proportion of different food types
PT	proportion of diet obtained in the treated area
RMS	rappporteur Member State
RUD	residue per unit dose
SC	suspension concentrate
TER	toxicity exposure ratio
TWA	time-weighted average

Appendix A – List of end points for the active substance and the representative formulation

Summary of representative uses evaluated for the original approval (dodine)*

Crop and/or situation (a)	EU Area	Product name	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					type (d-f)	conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	min. interval between applications (days)	kg a.s./hl min max	Water L/ha min max	kg a.s./ha min max		
Apple/pear	EU (North-South)	Syllit 400 SC	F	Scab (<i>Venturia inaequalis</i> / <i>Venturia pir</i>)	SC	400 g/l	Foliar spray	from bud opening (BBCH 01) til 28 days before harvest	4 (2+2) max *	repeat after 7-10 days	0.045 - 0.18	500 - 1500L	0.68 - 0.90	28	1.7 – 2.25 L Syllit/ha * max. 2 consecutive applications with a minimum of 5 weeks between application 2 and 3.
Apple/pear (alternative GAP, cf ADI/ARfD settings)	EU (North-South)	Syllit 400 SC	F	Scab (<i>Venturia inaequalis</i> / <i>Venturia pir</i>)	SC	400 g/l	Foliar spray	from bud opening (BBCH 01) til 60 days before harvest	4 (2+2) max	repeat after 7-10 days	0.045 - 0.18	500 - 1500L	0.68 - 0.90	60	1.7 – 2.25 L Syllit/ha * max. 2 consecutive applications with a minimum of 5 weeks between application 2 and 3.
Peach	EU-South	Syllit 400 SC	F	Peach Leaf curl (<i>Taphrina deformans</i>)	SC	400 g/l	Foliar spray	from bud swelling (BBCH 01) til petal fall (BBCH 69)	2 max	repeat after 7-10 days	0.06 - 0.18	500 - 1500L	0.90	75	2.25 L Syllit/ha
Cherry	EU (North-South)	Syllit 400 SC	F	Cherry leaf spot (<i>Blumeriella jaapii</i> = <i>Coccomyces hiemalis</i>)	SC	400 g/l	Foliar spray	from flower opening (BBCH 60) til 2 weeks before harvest (BBCH 79) AND after harvest	4 (2+2) max *	repeat after 7-10 days	0.05 – 0.16	500 - 1500L	0.8	14	2 L Syllit/ha * max. 2 consecutive applications pre-harvest + max. 2 consecutive applications post-harvest (treatment of the trees, not of the fruits) with a minimum of 5 weeks between application 2 and 3.

* EFSA, 2010

<p>(a) For crops, the EU 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) Outdoor or field use (F), greenhouse application (G) or indoor application (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) GCPF Codes - GIFAP Technical Monograph No 2, 1989</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. benthialdicarb-isopropyl).</p> <p>(j) Growth stage at 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) PHI - minimum pre-harvest interval</p> <p>(m) Remarks may include: Extent of use/economic importance/restrictions</p>
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Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw per day)	End point (mg/kg bw per day)
Birds				
<i>Anas platyrhynchos</i>	a.s.	Acute	-	857
<i>Quail</i>	a.s.	Acute		981
Geomean				917
	Preparation	Acute	-	-
	Metabolite 1	Acute	-	-
	a.s.	Short-term	280	2263
	a.s.	Long-term	17*	200
Mammals				
Rat	a.s.	Acute	851	-
Mice	a.s.	Acute	1354	
Geomean			1073	
	Preparation	Acute	-	-
	Metabolite 1	Acute	-	-
	a.s. (2-generations)	Long-term	26**	-
	a.s. (Teratogenicity)	Long-term	45	
Additional higher tier studies				
Not submitted				

*NOEL of 17.0 (16.96) mg/kg/d based on mean food intake ratio per individual and day from raw data in the study report (previous agreed value was 20 mg/kg bw per day)

**value amended (previous agreed value was 18.6 mg/kg bw per day)

Application rate (kg a.s./ha)	Crop	Category	Time-scale	TER	Annex VI Trigger
		Large herbivorous mammals BBCH \geq 40		80.6 (Tier I)	
		Small omnivorous mammals BBCH < 10		49.2 (Tier I)	
		Small omnivorous mammals BBCH 10 - 19		61.3 (Tier I)	
		Small omnivorous mammals BBCH 20 - 40		82.2 (Tier I)	
		Small omnivorous mammals BBCH \geq 40		162.8 (Tier I)	
0.9*	orchards	Small insectivorous mammals BBCH < 10	Long-term – rat = 26 mg/kg per day	17.8 (Tier I)	5
		Small herbivorous mammals BBCH < 10		0.5 (Tier I)	
		Small herbivorous mammals BBCH 10 - 19		0.6 (Tier I)	
		Small herbivorous mammals BBCH 20 - 40		0.8 (Tier I)	
		Small herbivorous mammals BBCH \geq 40		1.6 (Tier I)	
		Frugivorous mammal BBCH 71-79		1.5 (Tier I)	
		Large herbivorous mammals BBCH < 10		2.4 (Tier I)	
		Large herbivorous mammals BBCH 10 - 19		2.9 (Tier I)	
		Large herbivorous mammals BBCH 20 - 40		3.9 (Tier I)	
		Large herbivorous mammals BBCH \geq 40		7.8 (Tier I)	
		Small omnivorous mammals BBCH < 10		4.3 (Tier I)	
		Small omnivorous mammals BBCH 10 - 19		5.4 (Tier I)	
		Small omnivorous mammals BBCH 20 - 40		7.2 (Tier I)	
		Small omnivorous mammals BBCH \geq 40		14.7 (Tier I)	

* 2 applications with 7 days interval.

** risk considered as low based on EFSA, 2010

Values in **bold** are below the trigger values.