



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

2-phenylphenol

SANCO/10698/09 – rev. 2

28 October 2010¹

Final

Review report for the active substance **2-phenylphenol**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
27 November 2009
in view of the inclusion of 2-phenylphenol in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of 2-phenylphenol, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 1112/2002⁽²⁾ laying down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, and Regulation (EC) No 2229/2004⁽³⁾ have laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. **2-phenylphenol** is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 in Regulation (EC) No 1112/2002, LANXESS Deutschland GmbH notified to the Commission of their wish to secure the inclusion of the active substance 2-phenylphenol in Annex I to the Directive.

In Annex I to Regulation (EC) No 2229/2004 the Commission, designated the Spain as rapporteur Member State to carry out the assessment of 2-phenylphenol on the basis of the dossiers submitted by the notifier. In Article 12 of Regulation (EC) No 2229/2004 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required, as well as for other parties with regard to further technical and scientific information was 30 November 2005.

¹ On 28 October 2010, the Standing Committee on Food Chain and Animal Health has taken note of the revision 2 of the review report on the extension of inclusion as laid down in chapters 1, 6 and 7.

² OJ No L 168, 27.06.2002, p.14.

³ OJ No L 379, 24.12.2004, p.13. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.09.2007, p. 19).

The notifier submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore LANXESS Deutschland GmbH was considered to be the sole data submitter.

In accordance with the provisions of Article 21(1) of Regulation (EC) No 2229/2004, the Spain submitted on 11 February 2008 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of 2-phenylphenol in Annex I to the Directive.

In accordance with the provisions of Article 24 of Regulation (EC) No 2229/2004 as last amended by Regulation (EC) 1095/2007, the EFSA organised the consultation on the draft assessment report by all the Member States (on 17 March 2008) as well as by LANXESS Deutschland GmbH (on 17 March 2008) being the sole data submitter, by making it available.

In accordance with the provisions of Article 24 of Regulation (EC) No 2229/2004 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance 2-phenylphenol (finalised 19 December 2008)⁴]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 25 of Regulation (EC) No 2229/2004, the Commission referred a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 27 November 2009.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

In June 2010 the notifier submitted information on application techniques, other than those supported in the original dossier. This information was evaluated by the rapporteur Member State, which prepared in August 2010 an addendum to the Draft Assessment Report for 2-phenylphenol. The evaluation carried out by Spain concluded that the restriction to drench chambers uses laid down in Directive 2009/160/EC is no longer needed. The other Member States and EFSA were consulted on the addendum to the Draft Assessment Report and did not raise any point which would exclude the extension of the use.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2009/160/EC⁵ concerning the inclusion of 2-phenylphenol in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing 2-phenylphenol they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

⁴ EFSA Scientific Report (2008) n 217, 1-98.

⁵ OJ L 338, 19.12.2009, p. 83–86.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 26 of Regulation (EC) No 2229/2004, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing 2-phenylphenol will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each plant protection product containing 2-phenylphenol for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI 0,4 mg/kg bw/day
ARfD Not allocated
AOEL 0,4 mg/kg bw/day

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a child is less than 5.7% of the Acceptable Daily Intake (ADI), based on the German diet (EFSA model, German diet). Additional intake from water is not expected to give rise to intake problems.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity

The identity of 2-phenylphenol is given in Appendix I.

At the time of the evaluation no FAO specification was allocated.

The review has established that for the active substance notified by the main data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing 2-phenylphenol.

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States should pay particular attention:

- to the protection of operators and workers and ensure that conditions of use prescribe the application of adequate personal protective equipment;

- to put in place appropriate waste management practices to handle the waste solution remaining after application, including the cleaning water of the drenching system. Member States permitting the release of waste water into the sewage system, shall ensure that a local risk assessment is carried out.

7. List of studies to be generated

The Member States concerned shall ensure that the notifier submits to the Commission further information :

- on the potential for skin depigmentation for workers and consumers due to possible exposure to the metabolite 2-phenylhydroquinone (PHQ) on citrus peel,
- to confirm that the analytical method applied in residue trials correctly quantifies the residues of 2-phenylphenol, PHQ and their conjugates.

They shall ensure that the notifier provides such information to the Commission by 31 December 2011.

Furthermore, the Member States concerned shall ensure that the notifier submits to the Commission further information to confirm the residue levels occurring with application techniques other than those in drench chambers..

They shall ensure that the notifier provides such information to the Commission by 31 December 2012.

Some others endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Scientific report (page 28).

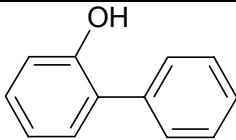
8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for 2-phenylphenol in Annex I of the Directive.

APPENDIX I**Identity****2-phenylphenol**

Common name (ISO)	2-phenylphenol (ISO 765) (a common name is not required according to ISO) Synonyms: biphenyl-2-ol (EINECS name), ortho-phenylphenol, OPP
Chemical name (IUPAC)	biphenyl-2-ol
Chemical name (CA)	[1,1'-Biphenyl]-2-ol
CIPAC No	246
CAS No	90-43-7
EEC No	201-993-5
FAO SPECIFICATION	No data available
Minimum purity	998 g/kg
Molecular formula	C ₁₂ H ₁₀ O
Molecular mass	170.2 g/mol
Structural formula	

APPENDIX II

List of uses supported by available data

2-PHENYLPHENOL

Crop and/or situation	Member State, Country or Region	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			DAT (days)	Remarks
					Type	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	g as/hL (l) min – max	water L/ha min – max	g as/ha (l) min – max		
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	g as/hL (l) min – max	water L/ha min – max	g as/ha (l) min – max	(m)	
citrus fruit (CIDSS) post-harvest treatment	Spain (RMS)	AGF/1-04	I	Fruit-rotting fungi	EC	100 g/L	drench (in a closed drenching chamber)	85 (citrus)	1	not applicable	600 mg a.s./l treatment solution	not applicable	not applicable	Citrus fruit: 0 days	

<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 suckling 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. fluoroxypr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-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 application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) DAT Days after treatment</p>
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