



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

**Paraffin oil CAS No 8042-47-5**

SANCO/2676/08 – final

28 January 2011

Review report for the active substance **paraffin oil CAS No 8042-47-5**  
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
28 January 2011  
in view of the inclusion of paraffin oil CAS No 8042-47-5 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 paraffin oil CAS No 8042-47-5, 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<sup>(1)</sup> 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<sup>(2)</sup> have laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. **Paraffin oil CAS No 8042-47-5** 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, W. Neudorff GmbH KG and Stähler International GmbH&Co.KG notified to the Commission their wish to secure the inclusion of the active substance paraffin oil CAS No 8042-47-5 in Annex I to the Directive for the chain lengths C<sub>18</sub>-C<sub>30</sub> and C<sub>17</sub>-C<sub>31</sub> respectively.

In Annex I to Regulation (EC) No 2229/2004 the Commission, designated Greece as rapporteur Member State to carry out the assessment of paraffin oil CAS No 8042-47-5 on the basis of the dossiers submitted by the notifiers. In Article 12 of Regulation (EC) No 2229/2004 the Commission specified furthermore that the deadline for the notifiers 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 June 2005.

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<sup>1</sup> OJ No L 168, 27.06.2002, p.14.

<sup>2</sup> 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 notifiers 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, W. Neudorff GmbH KG and Stähler International GmbH&Co.KG were considered to be the data submitters.

In accordance with the provisions of Article 21(1) of Regulation (EC) No 2229/2004, Greece submitted on 30 April and 7 May 2008 to the EFSA the reports of their examination, hereafter referred to as the draft assessment reports, including, as required, a recommendation concerning the possible inclusion of paraffin oil CAS No 8042-47-5 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 reports by all the Member States as well as by W. Neudorff GmbH KG and Stähler International GmbH&Co.KG being the data submitters, on 30 June 2008 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 conclusions on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance paraffin oil CAS No 8042-47-5 chain lengths C<sub>18</sub>-C<sub>30</sub><sup>3</sup> and C<sub>17</sub>-C<sub>31</sub><sup>4</sup> (finalised on 19 December 2008)]. These conclusions refer 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 28 January 2011.

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.

## 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 **Council Directive 2009/117/EC**<sup>5</sup> concerning the inclusion of paraffin oil CAS No 8042-47-5 in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing paraffin oil CAS No 8042-47-5 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.

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

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<sup>3</sup> EFSA Scientific Report (2008) 219, 1-30

<sup>4</sup> EFSA Scientific Report (2008) 220, 1-42

<sup>5</sup> OJ L 237, 9.9.2009, p. 11–14

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 paraffin oil CAS No 8042-47-5 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 paraffin oil CAS No 8042-47-5 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 Not applicable  
ARfD Not applicable  
AOEL Not applicable

As stated in the EFSA conclusions, for paraffin oils of high purity no toxicological concern is raised as regards the exposure to humans.

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 paraffin oil CAS No 8042-47-5 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 submitters 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.

#### **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 paraffin oil CAS No 8042-47-5.**

On the basis of the proposed and supported uses (as listed in Appendix II), no 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.

#### **7. List of studies to be generated**

Further studies were identified which were at this stage considered necessary in relation to the inclusion of paraffin oil CAS No 8042-47-5 in Annex I under the current inclusion conditions.

The concerned Member States shall request the submission of the specification of the technical material as commercially manufactured to verify the compliance with purity criteria of European Pharmacopoeia 6.0.

They shall ensure that the notifiers at whose request paraffin oil CAS No 8042-47-5 has been included in this annex provide such studies to the Commission by 30 June 2010.

This information was submitted and evaluated in line with the Guidance Document on the Finalisation of the Reference Specification for Technical Active Substances after the Peer Review<sup>6</sup>. On 28 January 2011 the Standing Committee on the Food Chain and Animal Health has taken note of the finalisation of the reference specification.

Some other 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 Conclusions.

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<sup>6</sup> Doc SANCO/6075/2009 rev 3 – July 2009

## **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 paraffin oil CAS No 8042-47-5 in Annex I of the Directive.

**APPENDIX I****Identity****Paraffin oil CAS No 8042-47-5**

<b>Common name (ISO)</b>	Paraffin Oil
<b>Chemical name (IUPAC)</b>	White mineral oil
<b>Chemical name (CA)</b>	White mineral oil / paraffin oil
<b>CIPAC No</b>	Not available
<b>CAS No</b>	8042-47-5
<b>EEC No</b>	232-455-8
<b>FAO SPECIFICATION</b>	None
<b>Minimum purity</b>	European Pharmacopoeia 6.0 purity criteria
<b>Molecular formula</b>	Not applicable
<b>Molecular mass</b>	Not applicable
<b>Structural formula</b>	Carbon range: C <sub>18</sub> -C <sub>30</sub> and C <sub>17</sub> -C <sub>31</sub>

## APPENDIX II

## List of uses supported by available data

Paraffin oil CAS No 8042-47-5 chain lengths C<sub>18</sub>-C<sub>30</sub>

Crop and/ or situation  (a)	Member State or Country	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 as  (i)	method kind  (f-h)	growth stage & season  (j)	number min max  (k)	interval between applications  (min)	kg as/hL  min max	water L/ha  min max	kg as/ha  min max		
Pome fruits	D	Promanal Neu	F	spider mites, scales	EW	546 g/L	spraying	BBCH 54-56	1	--	1.09	500-1500	5.46-16.38	--	Application rate and water volume according to plant height
Stone fruits	D	Promanal Neu	F	spider mites, scales	EW	546 g/L	spraying	BBCH 51-53	1	--	1.09	500-1500	5.46-16.38	--	Application rate and water volume according to plant height
Berry fruits (except strawberry)	D	Promanal Neu	F	spider mites, scales	EW	546 g/L	spraying	BBCH 51-53	1	--	1.09	500	5.46	--	
Grapevine	D	Promanal Neu	F	Spider mites	EW	546 g/L	spraying	BBCH 01-11	1	--	0.54	800	4.368	--	

Crop and/ or situation  (a)	Member State or Country	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 as  (i)	method kind  (f-h)	growth stage & season  (j)	number min max  (k)	interval between applications  (min)	kg as/hL  min max	water L/ha  min max	kg as/ha  min max		
Ornamentals	D	Promanal Neu	G  I	Spider mites, scales, mealybugs	EW	546 g/L	spraying		2	Depending on pest (see pest column):  7 days 14 days 14 days		Depending on plant height (see remarks column):  600 900 1200	Depending on plant height (see remarks column):  6.552 9.828 13.104	--	Application rate according to plant height:  <50cm 50-125cm >125cm
Woody ornamentals	D	Promanal Neu	F	Spider mites scales,	EW	546 g/L	spraying	BBCH 01-09	1	--		Depending on plant height (see remarks column):  600 900 1200	Depending on plant height (see remarks column):  6.552 9.828 13.104	--	Application rate according to plant height:  <50cm 50-125cm >125cm

Paraffin oil CAS No 8042-47-5 chain lengths C<sub>17</sub>-C<sub>31</sub>

Crop and/or situation (a)	Member State or Country	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 as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Pome fruits (apples, pears)	D	Para Sommer	F	spider mites	EW	654 g/L	spraying	BBCH 10-59	1	--	1.96	500-1500	Depending on the crown height: 1m: 9.8 kg/ha 2m: 19.6 kg/ha 3m: 29.43 kg/ha	Covered by application on timing	Application rate according to crown height
Pome fruits (apples, pears)	D	Para Sommer	F	scales (except San Jose scale)	EW	654 g/L	spraying	BBCH 69	1-2	10 days	1.31	500-1500	Depending on the crown height: 1m: 6.54 kg/ha 2m: 13.08 kg/ha 3m: 19.6 Kg/ha	Covered by application on timing	Application rate according to crown height
Stone fruits	D	Para Sommer	F	spider mites	EW	654 g/L	spraying	BBCH 10-59	1	--	1.96	500-1500	Depending on the crown height: 1m: 9.8 kg/ha 2m: 19.6 kg/ha 3m: 29.43 kg/ha	Covered by application on timing	Application rate according to crown height

Crop and/or situation (a)	Member State or Country	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 as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Stone fruits	D	Para Sommer	F	scales (except San Jose scale)	EW	654 g/L	spraying	BBCH 69	1-2	10 days	1.31	500-1500	Depending on the crown height: 1m: 6.54 kg/ha 2m: 13.08 kg/ha 3m: 19.6 Kg/ha	Covered by application timing	Application rate according to crown height
Grapevine	D	Para Sommer	F	Spider mites	EW	654 g/L	spraying	BBCH 05-07	1	--	0.65	400 800	2.616 kg/ha 5.232 kg/ha	Covered by application timing	
Ornamentals	D	Para Sommer	F G	scales	EW	654 g/L	spraying	Beginning of infestation	1-2	10 days	1.31	Depending on plant height:  <50cm: 600 >50cm: 1000	Depending on plant height:  7.848 kg/ha 13.080 kg/ha	Not relevant	

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) *e.g.* wettable powder (WP), emulsion, oil in water (EW)
  - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
  - (f) All abbreviations used must be explained
  - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (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
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions