

ANNEXE 6



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3

SANCO/2676/08 – final

28 January 2011

Review report for the active substances **paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3**

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 oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS
No 97862-82-3 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 oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3, 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⁽¹⁾ 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⁽²⁾ have laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. **Paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3** are one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 in Regulation (EC) No 1112/2002, Total Fluides notified to the Commission their wish to secure the inclusion of the active substances paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 in Annex I to the Directive.

In Annex I to Regulation (EC) No 2229/2004 the Commission, designated Greece as rapporteur Member State to carry out the assessment of paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 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

¹ OJ No L 168, 27.06.2002, p.14.

² 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).

dossiers required, as well as for other parties with regard to further technical and scientific information was 30 June 2005.

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, Total Fluides was considered to be the sole data submitter.

In accordance with the provisions of Article 21(1) of Regulation (EC) No 2229/2004, Greece submitted on 6 May 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 paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 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 as well as by Total Fluides being the data submitter, on 23 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 conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substances paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 (finalised on 19 December 2008)³]. 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 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 2009/116/EC**⁴ concerning the inclusion of paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 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

³ EFSA Scientific Report (2008) 216, 1-33

⁴ OJ L 237, 9.9.2009, p. 7–10

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 oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 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 oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 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 oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 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 oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3.

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 oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 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 notifier at whose request paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 have 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 Review⁵. On 28 January 2011 the Standing Committee on the Food Chain and Animal Health has taken note of the finalisation of the reference specification.

⁵ Doc SANCO/6075/2009 rev 3 – July 2009

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.

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 oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 in Annex I of the Directive.

APPENDIX I**Identity****Paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3**

Common name (ISO)	Paraffin Oil (64742-46-7)	Paraffin Oil (72623-86-0)	Paraffin Oil (97862-82-3)
Chemical name (IUPAC)	Paraffin oil	Paraffin oil	Paraffin oil
Chemical name (CA)	Paraffin oil	Paraffin oil	Paraffin oil
CIPAC No	Not available	Not available	Not available
CAS No	64742-46-7	72623-86-0	97862-82-3
EEC No	265-148-2	276-737-9	308-132-3
FAO SPECIFICATION	None	None	None
Minimum purity	European Pharmacopoeia 6.0 purity criteria	European Pharmacopoeia 6.0 purity criteria	European Pharmacopoeia 6.0 purity criteria
Molecular formula	Not applicable.	Not applicable.	Not applicable.
Molecular mass	Not applicable.	Not applicable.	Not applicable.
Structural formula	Carbon range: C ₁₁ - C ₂₅	Carbon range: C ₁₅ - C ₃₀	Carbon range: C ₁₁ - C ₃₀

APPENDIX II

List of uses supported by available data

Paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3

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)	
					Type (d-f)	Conc. of as (g/l) (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
Fruit trees (pome fruit, stone fruit)	France	Arb'hiver	F	Mites, scale insects & aphids (winter stages)	EC	800	Orchard air blast sprayer	BBCH 0-11	2	15 days	0.8-2	800-1000	6.4-20	none
Fruit trees (pome fruit, stone fruit)	Poland	Catane 800 SC (identical to Arb'hiver)	F	Mites, scale insects & aphids (winter stages)	EC	800	Orchard air blast sprayer	BBCH 0-11	2	15 days	1.6	500-1000	8.0-16	none
Fruit trees (pome fruit, stone fruit)	Hungary	Catane 800 SC (identical to Arb'hiver)	F	Mites, scale insects & aphids (winter stages)	EC	800	Orchard air blast sprayer	BBCH 0-11	2	15 days	2	500-1000	10-20	none

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)
					Type (d-f)	Conc. of as (g/l) (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applicatio ns (min)	Kg as/hL min max	water L/ha min max	kg as/ha min max	
Fruit trees (pome fruit, stone fruit)	Portugal	Arb'hiver		Mites, scale insects & aphids (winter stages)	EC	800	Orchard air blast sprayer	BBCH 0-11	2	15 days	0.8-2	800-1000	6.4-20	none
Fruit trees (pome fruit, stone fruit), citrus	Greece	Arb'hiver		Mites, scale insects & aphids (winter stages)	EC	800	Orchard air blast sprayer	BBCH 69-81	4	15 days	0.8-1.04	800-1000	6.4-10.4	none
Apples	France	Arbofine	F	Red spider mites (larvae & adults)	EC	800	Orchard air blast sprayer	BBCH 69-85	2	15 days	1.6	800-1000	12.8-16	none
Citrus	France	Citrole	F	Mites, scale insects & aphids (larvae plus adults in spring/ summer)	EC	790	Orchard air blast sprayer	BBCH 69-81	4	15 days	1.58	1000-1500	15.8-23.7	none

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)
					Type (d-f)	Conc. of as (g/l) (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applicatio ns (min)	Kg as/hL min max	water L/ha min max	kg as/ha min max	
Citrus	Spain	Citrole	F	Mites, scale insects & aphids (larvae plus adults in spring/ summer)	EC	790	Orchard air blast sprayer	BBCH 69-81	4	15 days	1.58	1000-1500	15.8-23.7	none
Citrus	Portugal	Citrole	F	Mites, scale insects & aphids (larvae plus adults in spring/ summer)	EC	790	Orchard air blast sprayer	BBCH 69-81	4	15 days	1.58	1000-1500	15.8-23.7	none
Citrus	Italy	Citrole	F	Mites, scale insects & aphids (larvae plus adults in spring/ summer)	EC	790	Orchard air blast sprayer	BBCH 69-81	4	15 days	1.185- 1.58	1000-1500	11.8-23.7	20

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)
					Type (d-f)	Conc. of as (g/l) (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applicatio ns (min)	Kg as/hL min max	water L/ha min max	kg as/ha min max	
Citrus	Italy	Ovispray	F	Mites, scale insects & aphids (winter stages)	EC	790	Orchard air blast sprayer	BBCH 69-81	4	15 days	1.185- 1.58	1000-1500	11.8-23.7	20
Seed potato	France	Finavestan TS	F	To prevent transmiss ion of Y virus by aphids	EC	831	Orchard air blast sprayer		6	6-10 days	3.324- 4.155	300	9.97-12.6	none

- 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), emulsifiable concentrate (EC), granule (GR)
 - (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

