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### **Peer review of the efficacy as a fungicide of the active substances paraffin oils (CAS 64742-46-7 chain lengths C<sub>11</sub>–C<sub>25</sub>, CAS 72623-86-0 chain lengths C<sub>15</sub>–C<sub>30</sub> and CAS 97862-82-3 chain lengths C<sub>11</sub>–C<sub>30</sub>)**

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#### **Abstract**

The conclusions of EFSA following the peer review of the initial efficacy assessment and consideration of the effects of water treatment used for the production of drinking water on any residues that might be in raw water carried out by the competent authority of the rapporteur Member State Greece for the pesticide active substances paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council for an amendment in approval conditions. The conclusions were reached on the basis of the evaluation of the efficacy of paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) as a fungicide. The reliable endpoints are presented.

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## Summary

Paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) are existing active substances for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the rapporteur Member State (RMS), Greece, received an application from Total Fluides on 30 September 2014 to amend the conditions of approval. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 25 October 2018.

An initial evaluation of the dossier on paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) submitted to amend the conditions of approval to add use as a fungicide to the existing approval as an insecticide and acaricide was provided by the RMS in a draft assessment report (DAR) and subsequently, a peer review of the RMS evaluation was conducted by EFSA in accordance with Article 12 of Regulation (EC) No 1107/2009. The following conclusions are derived.

The use of paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) according to the information submitted, results in a sufficient fungicidal efficacy against the target plant disease caused by the fungus powdery mildew (*Erysiphe necator*).

Information submitted in relation to addressing the approval criterion regarding there being no immediate or delayed harmful effects on human health, including that of vulnerable groups, or animal health through drinking water (taking into account substances resulting from water treatment) was considered sufficient to conclude that water treatment would not result in the formation of any novel substances being present in drinking water that would require assessment of risk to humans or animals consuming the water.

Data gaps and issues identified in the approval conclusion (EFSA, 2008) have not been addressed by this evaluation and are still applicable.

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## Background

Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>1</sup> (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States (MS) and the applicant(s) for comments on the initial evaluation in the draft assessment report (DAR), provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

Paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) are existing active substances for which, in accordance with Article 7 of the Regulation, the RMS, Greece (hereinafter referred to as the 'RMS'), received an application from Total Fluides on 30 September 2014 to amend the conditions of approval of the active substances paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3). Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 25 October 2018.

The RMS provided its initial evaluation of the dossier on paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) in the DAR, which was received by EFSA on 6 February 2018 (Greece, 2018). The peer review was initiated on 5 November 2018 by dispatching the DAR to the MS and the applicant, Total Fluides, for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 23 June 2020. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether paraffin oil (CAS 64742-46-7, 72623-86-0 and 97862-82-3) can be expected to meet the approval criteria provided for in Article 4 of the Regulation, taking into consideration recital (10) of the Regulation and in particular to amend the conditions of approval to add use as a fungicide to the existing approval as an insecticide and acaricide.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with MS via a written procedure in July-August 2021.

This conclusion report summarises the outcome of the peer review of the efficacy assessment on the active substances paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) as a fungicides.

A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2021), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report 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 comments received on the DAR;
- the reporting table (12 November 2020);

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<sup>1</sup> Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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.

- the evaluation table (6 September 2021);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR, including its revisions (Greece, 2021), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

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

## The active substance and the formulated product

This conclusion deals with three paraffin oils 'Banole 50' CAS 64742-46-7 with carbon chain lengths of  $C_{11}$ – $C_{25}$ , 'Banole 185' CAS 72623-86-0 with carbon chain lengths of  $C_{15}$ – $C_{30}$  and 'Banole 70' CAS 97862-82-3 with carbon chain lengths of  $C_{11}$ – $C_{30}$ . 'Bannole 70' CAS 97862-82-3 is a blend of the other two materials. All three of the substances are complex mixtures. Paraffin oils are alkanes and are therefore saturated hydrocarbons.

The use for which efficacy trials of paraffin oils as a fungicide were provided comprised field applications by spraying with tractor-mounted equipment on grapevine crops against Powdery mildew (*Erysiphe necator*) in the Southern Europe (SEU). Full details of this Good Agricultural Practice (GAP) can be found in the list of end points in Appendix A.

Paraffin oils work as a fungicide by forming a thin physical barrier between fungal spores and the plant and reducing conidia germination. The information submitted on fungicidal efficacy was accepted as demonstrating a sufficient fungicidal efficacy against the plant disease caused by the fungus powdery mildew (*E. necator*). Though the trials only tested emulsifiable concentrate (EC) formulations containing 'Banole 50' CAS 64742-46-7, it was accepted to read across this conclusion to the other paraffin oil materials that are the subject of this conclusion. The representative formulated products discussed in the DAR provided by the RMS<sup>2</sup> were 'CITROLE', 'FINAVESTAN TS', 'ARB'HIVER' and 'ARBOFINE' all EC. Note that the applicant Total Fluides reported that 'ARB'HIVER' and 'ARBOFINE' are no longer marketed by their manufacturer Total.

## Conclusions of the evaluation

### 1. Identity, physical/chemical/technical properties and methods of analysis

New information regarding identity, physical/chemical/technical properties and methods of analysis was not assessed in this application to amend the approval conditions to enable use as a fungicide.

### 2. Mammalian toxicity

Information regarding mammalian toxicity was not assessed in this application to amend the approval conditions to enable use as a fungicide. A non-dietary exposure assessment specific to the good agricultural practice on grapes was not provided, so was not reviewed, as it was agreed by risk managers that this was out of the scope of the evaluation.

### 3. Residues

Information regarding residues was not assessed in this application to amend the approval conditions to enable use as a fungicide. A consumer risk assessment specific to the good agricultural practice on grapes was not provided, so was not reviewed, as it was agreed by risk managers that this was out of the scope of the evaluation.

### 4. Environmental fate and behaviour

The usual range of environmental exposure assessments was not assessed in this application to amend the approval conditions to enable use as a fungicide. An environmental exposure assessment

<sup>2</sup> Note that the available efficacy trials discussed above were not carried out with any of these representative products.

specific to the GAP on grapes was not provided, so was not reviewed, as it was agreed by risk managers that this was out of the scope of the evaluation.

However, as use as a fungicide has the potential to increase the extent of use, information was requested and assessed in relation to the approval criterion regarding there being no immediate or delayed harmful effects on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment). The applicant provided appropriate information indicating that when surface water is abstracted for the production of drinking water, the processes of coagulation, flocculation, sedimentation and rapid sand filtration before the disinfection stage of water treatment, would lead in substances resulting from water treatment of paraffin oil origin being absent from drinking water that originates from surface water. Regarding groundwater, due to the high lipophilicity, adsorption to soil of paraffin oils and their soil degradation products would be a process expected to result in low groundwater concentrations. Satisfactory qualitative information also indicated that paraffin oils and their microbially mediated breakdown products would not be expected to undergo any substantial transformation due to chlorination or oxidation by ozone at the disinfection stage of water treatment processes, due to the stability of saturated alkane chains to oxidation at the temperatures involved in water treatment.

## 5. Ecotoxicology

An environmental risk assessment was not assessed in this application to amend the approval conditions to enable use as a fungicide. An environmental risk assessment specific to the good agricultural practice on grapes was not provided, so was not reviewed, as it was agreed by risk managers that this was out of the scope of the evaluation.

## 6. Endocrine disruption properties

Endocrine-disrupting properties according to the ECHA/EFSA Guidance (2018) were not assessed in this application to amend the approval conditions to enable use as a fungicide. It was agreed by risk managers that this was out of the scope of the evaluation.

## 7. Particular conditions proposed to be taken into account by risk managers

Risk mitigation measures (RMMs) identified following consideration of MS and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level).

Particular conditions are not proposed considering the scope of this evaluation. However the RMM already identified in the approval conclusion (EFSA, 2008) are still applicable.

## 8. Concerns and related data gaps

### 8.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of 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<sup>3</sup> and if the issue is of such importance that it could, when

<sup>3</sup> 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.

finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

**The following issues or assessments that could not be finalized have been identified:**

- 1) Though nothing has been identified within the scope of this evaluation, the assessments that could not be finalised identified in the approval conclusion (EFSA, 2008) are still applicable. These were in the areas of the specification of the active substances, operator, worker, bystander, consumer, aquatic organism, non-target arthropod, earthworm, soil macro- and microorganism risk, the potential for groundwater exposure and potential for long- range atmospheric transport.

## 8.2. Critical areas of concern

An issue is listed as a critical area of concern if 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 if this assessment does not permit the conclusion 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 if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion 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 if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

**The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:**

**Critical areas of concern were not identified within the scope of this evaluation.**

## 9. List of other outstanding issues

**Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.**

**These data gaps refer only to the representative uses assessed and are listed in the order of the sections:**

- Data gaps can be found in the section 'List of studies to be generated, still ongoing or available but not peer reviewed' in the approval conclusion (EFSA, 2008).

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## Abbreviations

CAS	Chemical Abstracts Service
DAR	draft assessment report
EC	emulsifiable concentrate
ECHA	European Chemicals Agency
GAP	Good Agricultural Practice
MS	Member State
RMM	risk mitigation measures
SEU	Southern Europe

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

Appendix A can be found in the online version of this output ('Supporting information' section):  
<https://doi.org/10.2903/j.efsa.2021.6876>