

APPENDIX 5

CONCLUSION ON PESTICIDE PEER REVIEW

Peer review of the pesticide risk assessment of the active substances paraffin oils¹

CAS 64742-46-7 chain lengths C₁₁-C₂₅

CAS 72623-86-0 chain lengths C₁₅-C₃₀

CAS 97862-82-3 chain lengths C₁₁-C₃₀

(Question No EFSA-Q-2008-687)

Issued on 19 December 2008

SUMMARY

Paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) are among the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004,² as amended by Regulation (EC) No 1095/2007.³ This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

Greece being the designated rapporteur Member State submitted the DAR on paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) in accordance with the provisions of Article 21(1) of the Regulation (EC) No 2229/2004, which was received by the EFSA on 6 May 2008. The peer review was initiated on 23 June 2008 by dispatching the DAR for consultation of the Member States and the sole notifier Total Fluides. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by the EFSA to identify the remaining issues. The identified issues as well as further information made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in October 2008.

¹ For citation purposes: Conclusion on pesticide peer review regarding the risk assessment of the active substance paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3). *EFSA Scientific Report* (2008) 216, 1-59

² OJ No L 379, 24.12.2004, p.13.

³ OJ L 246, 21.9.2007, p. 19.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in December 2008 leading to the conclusions as laid down in this report.

This conclusion was reached on the basis of the evaluation of the representative uses as an insecticide and acaricide for use on pome fruit, stone fruit, citrus and potato. Full details of the GAP can be found in the list of endpoints.

The representative formulated products for the evaluation were 'Citrole', 'Arb'hiver', 'Arbofine' and 'Finavestan TS', all emulsifiable concentrates (EC).

For food and environmental matrices there are data gaps and currently it is not clear whether methods will be required, see sections 2, 3, 4 and 5.

Sufficient internationally accepted methods (e.g. ASTM and ISO) are available to characterise the technical material and formulated product. However, numerous data gaps have been identified for the physical and chemical properties of the technical materials and plant protection products.

During the mammalian toxicology meeting, concerns were raised over relevant impurities that require classification of paraffin oils as **T "Toxic", carcinogenic category 2, R45 "May cause cancer"**. The meeting on toxicology confirmed that the impurities benzene and polyaromatic hydrocarbons are relevant and the specification as proposed by the notifier could not be accepted on toxicological grounds due to the high levels of relevant impurities. On this basis, no toxicological studies were required, no ADI, AOEL or ARfD were proposed and no risk assessment of operator, worker and bystander exposure were conducted.

It was noted however that if highly purified paraffin oils were considered (i.e. no concern would be raised from the impurity profile of the active substance), then no toxicological concern would be raised for consumers, operators, workers and bystanders. Sources of mineral oil are laxatives in pharmacy or oils used in food technology as release agents, for lubrication purposes, or as a substitute for fat. Paraffin oils are chemically inert substances, especially the straight chain (*n*) alkanes and on ingestion most of the mineral oil (about 98 % depending on the length of the C-chain) remains unabsorbed and is rapidly excreted, mostly unchanged, via faeces.

Acute toxicity studies have confirmed the low toxicity profile of paraffin oils. The experts agreed that no acute, short-term, long-term, genotoxicity or reproductive toxicity studies would be required, provided that no concern would be raised from the impurity profile of the

substance. Paraffin oils are not considered to be genotoxic, carcinogenic, neurotoxic or toxic to the reproduction. Considering the low toxicity of paraffin oils (of high purity), no ADI, AOEL or ARfD would be necessary, and no risk assessment for operators, workers and bystanders would be required.

The list of endpoints on mammalian toxicology has been filled in considering that the technical material does not contain unacceptable levels of relevant impurities.

No information on potential levels of residues in food or feed items were presented in the DAR.

A consumer risk assessment has not been performed due to the possible high level of polycyclic aromatic hydrocarbons. If these compounds are present then it would result in a toxicological classification that would mean that these compounds could not be registered as plant protection products. The risk to consumers can therefore not be finalised.

With regard to environmental fate and behaviour, no information was provided in the dossier, nor presented by the RMS in the DAR, except for results from ready biodegradability studies that were carried out using a sewage sludge inoculum. Therefore only crude and incomplete environmental exposure estimates for surface water (only spray drift route of entry assessed) and soil, based on the applied for uses, could be made. With the exception of the requirement for ready biodegradability data, all data requirements remain open. No conclusion on the potential for groundwater exposure can be made using the information in the DAR.

The acute TERs estimated for fish and *D. magna* were above the Annex VI trigger when a non-spray buffer zone of 25 m was applied for the pome fruit uses. However, acute TERs values were above the Annex VI trigger values without the use of any non-spray buffer zone for the other evaluated uses.

The acute TERs for alga were above the Annex VI trigger values without risk mitigation for all the evaluated uses. Therefore, risk mitigation measures or refined of aquatic risk assessment were required.

The experts at the meeting agreed that in absence of data addressing the risk to bees, mitigation measures should be taken to avoid the application in the presence of bees.

Two field studies were conducted with two different plant protection products 'SAM 501' and 'Arbofine'. The intension of the first study was to determine the efficacy of the product 'SAM 501' on red spider mites in apples trees as well as the effects on *Amblyseius andersoni* in apple tree during summer. The purpose of the second study was to assess the effects on

Typhlodromus pyri in apple orchards after the application of 'Arbofine' (1 x 2 hl/ha equivalent to 20.08 Kg a.s./ha). The meeting of the experts had some concern regarding the reliability of the *A. andersoni* study. The experts also expressed their concern regarding the second study which showed adverse effects on the *T. pyri* density (at least lasting 43 days) with only one application rate of 20 kg as/ha. The evaluated uses proposed in the GAP included the uses in citrus with 4 x 23.7 kg as/ha. The increase of adverse effects on *T. pyri* populations with repeated application should not be disregarded. The experts agreed that further information to address the risk to non-target arthropods was necessary or mitigation measures should be requested at Member State level.

A data gap was identified during the experts meeting for the notifier to address the acute risk to earthworms.

There was no valid study to evaluate in the DAR assess the effects of paraffin oils on soil non-target micro-organisms, or soil non-target macro-organisms. Data gaps for information to address these issues are identified. The risk to birds and mammals, non-target plants and biological method of sewage treatment was assessed as low.

Key words: paraffin, CAS 64742-46-7, 72623-86-0, 97862-82-3, peer review, risk assessment, pesticide, insecticide, acaricide.

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BACKGROUND

Commission Regulation (EC) No 2229/2004 laying down the detailed rules for the implementation of the fourth stage of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 1112/2002, as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3) are among the 295 substances of the fourth stage, covered by the amended Regulation (EC) No 2229/2004 designating Greece as rapporteur Member State.

In accordance with the provisions of Article 21(1) of the Regulation (EC) No 2229/2004, Greece submitted the report of its initial evaluation of the dossier on paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3), hereafter referred to as the draft assessment report, received by the EFSA on 6 May 2008. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 24(2) of the Regulation (EC) 1095/2007 on 23 June 2008 to the Member States and to the sole notifier Total Fluides, as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, the EFSA identified and agreed on lacking information to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in expert meetings in October 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in December 2008 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR).

In accordance with Article 24c(1) of the amended Regulation (EC) No 2229/2004, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period

provided for by the same Article. A list of the relevant endpoints for the active substance as well as the formulation is provided in appendix A.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received,
- the resulting reporting table (rev. 1-1, 1 September 2008),

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation,
- the evaluation table (rev. 2-1, 19 December 2008).

Given the importance of the draft assessment report including its addendum (compiled version of December 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

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 C₁₁-C₂₅, 'Banole 185' CAS 72623-86-0 with carbon chain lengths of C₁₅-C₃₀ and 'Banole 70' CAS 97862-82-3 with carbon chain lengths of C₁₁-C₃₀. Paraffin oils are alkanes and are therefore saturated hydrocarbons.

Paraffin oils work by forming a thin gas impermeable layer on insects and insect eggs which suffocates them. The representative formulated products for the evaluation were 'Citrole', 'Arb'hiver' 'Arbofine' and 'Finavestan TS', all emulsifiable concentrates (EC).

The evaluated representative uses were as an insecticide and acaricide for use on pome fruit, stone fruit, citrus and potato. Full details of the GAP can be found in the list of endpoints.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The purity of these materials is not considered to be a quality parameter and it is therefore not presented here. The meeting of experts accepted the specifications given in volume 4 of the DAR except the additional parameters of refractive index and benzene content should be added. It was also noted that 5 batch data were not available and this was identified as a data

gap for the three paraffin oils. However, these specifications were not accepted by mammalian toxicology and a mammalian toxicology data gap was identified.

The technical material contains polycyclic aromatic hydrocarbons which have to be considered as relevant impurities however, a maximum content has not been agreed by toxicology. Depending on the outcome of the 5 batch studies further relevant impurities might be identified.

The assessment of the phys/chem data package identified numerous deficiencies. The use of information from the MSDS and IUCLID databases was rejected by the meeting of experts as they are not original studies. A full list of the identified data gaps can be found below under the heading 'List of studies to be generated, still ongoing or available but not peer reviewed'.

It should be noted that the formulation 'Arbofine' contains another paraffin oil which is called a viscosity modifier. In reality this is part of the active material and this component may need further consideration.

The main data regarding the identity of these paraffin oils and their physical and chemical properties are given in appendix A.

Sufficient internationally accepted methods (e.g. ASTM and ISO) are available to characterise the technical material and formulated product.

For food and environmental matrices there are data gaps and it is currently not clear if methods will be required see sections 2, 3, 4 and 5.

A method of analysis for body fluids and tissues is not required as pure paraffin oils are not classified as toxic or highly toxic.

2. Mammalian toxicology

Paraffin oils (CAS 64742-46-7, 72623-86-0 and 977862-82-3) was discussed at the PRAPeR experts' meeting on mammalian toxicology (PRAPeR 59) in October 2008 on basis of the draft assessment report (April 2008) and the addendum 1 of September 2008.

The technical specification was provisionally agreed by the meeting on physical and chemical properties (PRAPeR 56, see section 1) but concerns were raised over relevant impurities. The meeting on toxicology confirmed that the impurities benzene and polyaromatic hydrocarbons are relevant and the specification as proposed by the notifier

could not be accepted on toxicological grounds due its high levels of relevant impurities, which would lead to the classification of paraffin oils as **T “Toxic”; carcinogenic category 2, R45 “May cause cancer”**. On this basis, no toxicological studies were required, no ADI, AOEL or ARfD were proposed and no risk assessment of operator, worker and bystander exposure were conducted.

The main sources of information reported in the DAR came from the open literature. Mineral oils are of variable composition depending on the boiling point of the fraction used; for food purposes usually liquid petrolatum or liquid paraffin is employed, which consists essentially of *n*-alkanes and some cyclic paraffins. Sources of mineral oil are laxatives in pharmacy or oils used in food technology as release agents, for lubrication purposes, or as a substitute for fat. Traces of *n*-alkanes are found naturally in plants.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

No study was submitted on toxicokinetics. Paraffin oils are chemically inert substances, especially the straight chain (*n*) alkanes and on ingestion most of the mineral oil (about 98 % depending on the length of the C-chain) remains unabsorbed and is rapidly excreted, mostly unchanged, via faeces. Once absorbed, it is slowly excreted and it may be deposited in body fat, kidneys, liver, brain and blood or in the *stratum corneum* when dermally administered. The biochemical transformation of paraffin may involve hydroxylation via cytochrome P450 mono-oxygenase to the respective alcohol and then further oxidation to carboxylic acids and CO₂ or solubilisation by building a glucuronide.

2.2. Acute toxicity

A number of acute toxicity studies were submitted, representative of some of the components of paraffin oils (mainly with Banole 185); some studies were not accepted as no information was available on the identity of the test substance. Acute oral and dermal toxicity studies, skin and eye irritation, and skin sensitisation test according to Magnusson & Kligman were submitted; no acute inhalation toxicity study was available. The experts considered that an acute inhalation toxicity study was not required since it would not provide additional information given the known low toxicological profile of the substance.

The studies confirmed that paraffin oils have low acute oral and dermal toxicity, presenting LD₅₀ consistently higher than 2000 mg/kg bw; no skin or eye irritation, or skin sensitisation was observed.

2.3. Short-term toxicity

No short-term toxicity studies were submitted. The experts discussed the need for toxicity testing considering the known toxicological profile of paraffin oils and taking into account that paraffin oils are sprayed in high quantity throughout the season on edible crops.

Concerns were raised over the level of impurities present in paraffin oils. The experts agreed that no short term toxicity study would be necessary if pure paraffin oils were considered due to its known low toxicological profile. It is up to the notifier to demonstrate that the quality of the paraffin oils is of an acceptable technical standard, i.e. that no toxicological concern would be raised from the impurity profile of the substance. Considering the level of relevant impurities proposed by the notifier, which was not considered acceptable by the experts for the risk assessment of paraffin oils, no further study was required.

2.4. Genotoxicity

Only one Ames test was presented and was not considered acceptable as the test substance was not sufficiently characterised and did not correspond to the proposed specification. Pure paraffin oils are not considered to have genotoxic potential.

2.5. Long-term toxicity

No study was provided. As discussed in relation to short term toxicity and genotoxicity, no study was considered necessary provided that no toxicological concern would be raised from the impurity profile of the active substance. Pure paraffin oils are not considered to present carcinogenic potential. Considering the level of carcinogenic impurities proposed by the notifier, which was not considered acceptable for the risk assessment of paraffin oils, no study was required.

2.6. Reproductive toxicity

No study was provided. It was also noted that mineral oils have been used extensively as solvent controls in teratogenicity studies causing no teratogenic effect. No adverse effect on fertility is expected upon administration of pure paraffin oils. No study would be necessary provided that no toxicological concern would be raised from the impurity profile of the active substance. No study was required considering the level of relevant impurities proposed by the notifier, which was not considered acceptable for the risk assessment of paraffin oils.

2.7. Neurotoxicity

No study was provided. Paraffin oils are not expected to be neurotoxic, based on the nature of the test substance and considering its use in pharmacy without adverse effects.

2.8. Further studies

No study is available.

2.9. Medical data

Although no reports were submitted, open literature data were taken into consideration.

Paraffin oils have been used in the pharmaceutical and medical area as a laxative since the beginning of the twentieth century. The mechanism of action involves a physical process, where the faeces in the gastrointestinal tract are wrapped with a soft layer and glide to the final destination. Strong abuse may result in Vitamin A and E deficiency since these vitamins are very lipophilic and show the tendency to be excreted easier with the faeces; interactions with mineral salts may lead to hypokalaemia followed by hypocalcaemia. Transient gastrointestinal effects such as irritation of the pharynx, oesophagus, stomach and small intestine may result from overexposure through oral ingestion. Case reports of exposed individuals provided evidence that mineral oils accumulate in the lymph nodes, liver, spleen and adipose tissue. Due to the chemical inertia of paraffin oils, no interaction with other compounds is expected. There is no epidemiological evidence to suggest that the use of liquid paraffin as a human medicine is associated with any cancer.

Aspiration of hydrocarbons into the lungs may result in disruption of the surface and bronchial epithelial cell barrier, leading to alveolar instability, and eventually hypoxia; no increased risk of lung cancer was found in workers exposed to oil mists. Prolonged dermal exposure may cause defatting of the skin.

2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD)

No ADI, AOEL or ARfD was proposed by the rapporteur Member State in the DAR.

The experts concluded that, considering the level of relevant impurities proposed by the notifier in the technical specification that was not considered acceptable for the risk assessment of paraffin oils, the substance could not be acceptable on toxicological grounds and no reference values could be proposed.

It was noted that if it could be demonstrated that paraffin oils are of high purity (i.e. 100 %), no toxicological concern would be raised and no ADI, AOEL and ARfD would be required.

2.11. Dermal absorption

An *in vitro* dermal absorption study on porcine skin was submitted, which was considered supplementary as the test material was not well characterised. None of the major hydrocarbon component could be found in the receptor fluid, indicating that no dermal absorption occurred, however, it is recognised that paraffin oils may accumulate in the *stratum corneum*. No dermal absorption value was needed as no risk assessment for operators, workers and bystanders was conducted.

2.12. Exposure to operators, workers and bystanders

No risk assessment for operators, workers and bystanders could be conducted. No AOEL was established based on the level of relevant impurities proposed by the notifier, which was not considered acceptable for the risk assessment of paraffin oils.

The experts noted that if it could be demonstrated that paraffin oils are of high purity, no toxicological concern would be raised, the establishment of an AOEL would not be necessary and no risk assessment for operators, workers and bystanders would be required.

3. Residues

No information on potential levels of residues in food or feed items were presented in the DAR.

A consumer risk assessment has not been performed due to the possible high level of polycyclic aromatic hydrocarbons. If these compounds are present then it would result in a toxicological classification that would mean that these compounds could not be registered as Plant Protection Products. The risk to consumers can therefore not be finalised.

4. Environmental fate and behaviour

Paraffin oils were discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 57 in October 2008.

4.1. Fate and behaviour in soil

4.1.1. Route of degradation in soil

No information was provided in the dossier, nor presented by the RMS in the DAR Volume 3 section B.8. Information is required.

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

No information was provided in the dossier, nor presented by the RMS in the DAR Volume 3 section B.8. Information is required.

As no information on persistence in soil is available, the predicted environmental concentrations for soil in appendix A are those that will result from a single application but also a total annual dose (assuming all applications for a year are made at a single time).

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

No information was provided in the dossier, nor presented by the RMS in the DAR Volume 3 section B.8. Information is required.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

Generally no information was provided in the dossier, nor presented by the RMS in the DAR Volume 3 section B.8. Information is required.

A ready biodegradability study was provided for a mixture of paraffin oils (CAS 97862-82-3) with 3% of emulsifiers (the product 'Arb'hiver'), which indicated that this mixture was 'readily biodegradable' as 99.7% theoretical mineralisation was achieved at 28 days following OECD 302B.

A further ready biodegradability study was provided for a mixture of paraffin oils (CAS 72623-86-0) using OECD301B, this mixture was 'not readily biodegradable' as only 27% theoretical mineralisation was achieved in 10 days following the latency phase.

These two results for biodegradability for the different mixtures seem anomalous as CAS 97862-82-3 contains a significant proportion of CAS 72623-86-0.

The meeting of member state experts considered that ready biodegradability studies only have utility in providing information to support classification of a substance and do not provide any indication of behaviour in natural sediment water systems. This is because the tests involve the utilisation of a sewage sludge inoculum and optimised mixed aerobic conditions that do not reflect conditions in natural sediment water systems.

As no information on persistence in natural sediment water studies is available, the predicted environmental concentrations in appendix A are those that will result from a single application but also a total annual dose (assuming all applications for a year are made at a single time) as a consequence of spray drift only. The potential for inputs to surface water via the drainage or runoff routes of entry (both the contribution from the solute phase and from eroded soil) cannot be assessed without information being available on soil adsorption potential. The drift assumptions used are the standard agreed drift assumptions that are included in the SWASH drift calculator tool.

4.2.2. Potential for ground water contamination of the active substance, their metabolites, degradation or reaction products

No information was provided in the dossier, nor presented by the RMS in the DAR Volume 3 section B.8. Information is required.

4.3. Fate and behaviour in air

Reliable values for the vapour pressure of these paraffin oils are not available but significant volatilisation to the atmosphere from plants and soil would be expected. No information was provided in the dossier to address the potential for breakdown in air. The RMS made the case (in the DAR Volume 1 in the list of endpoints) that paraffin oils reaching the air can be expected to be rapidly degraded by photochemical oxidative reaction with hydroxyl radicals in the upper atmosphere, however no estimation of the rate of this reaction is available.

5. Ecotoxicology

Paraffin oils (CAS 64742-46-7, 72623-86-0, 97862-82-3) was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 58) in October 2008, on basis of the draft assessment report and the Addendum 1 Vol.3_B.6-B.8_B.9 (September 2008).

The representative uses evaluated are as an acaricide/insecticide in pome and stone fruits, apples, citrus and seed potato in field.

No studies with the active substance were available in the DAR, however due to the low water solubility of paraffin oil, it was considered acceptable to use the studies conducted with the representative formulated products 'Citrole' (96.3% g/L of CAS 64742-46-7), 'Arbofine' (73.9 % of CAS 64742-46-7), 'Arb'hiver' (96.9 % of CAS 97862-82-3, 77.5 % of CAS 64742-46-7 and 19.4% of CAS 64742-46-70) and 'Finavestan TS' (96.9 % CAS 72623-86-0).

Some studies were performed with different plant protection products (Hydroseal G3H, HDF 200, Ecolane 130, Total PSo, DEV 2002-8 and DEV 2002-9) that were not included in the representative uses. These studies were not considered in the risk assessment due to the lack of data on the specification.

The risk assessment was conducted according to the following guidance documents: Risk Assessment for Birds and Mammals. SANCO/4145/2000 September 2002; Aquatic Ecotoxicology, SANCO/3268/2001 rev.4 final, October 2002; Terrestrial Ecotoxicology, SANCO/10329/2002 rev.2 final, October 2002; Risk Assessment for non-target arthropods, ESCORT 2, March 2000, SETAC.

In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, new studies could not be considered in the peer review.

5.1. Risk to terrestrial vertebrates

A short-term toxicity study for birds and mammals using paraffin oil was submitted by the notifier. The member states experts at the PRAPeR 58 meeting discussed the risk assessment for birds and mammals. The RMS explained that paraffin oils' activity towards immobile pest stages is a physical effect based on the non-toxic film-forming component of paraffin oil.

The RMS explained during the meeting that paraffin oil has no chemically active groups, they are in general lipophilic molecules and are not highly reactive. Paraffins are chemically inert substances, especially the straight chain (*n*) alkanes, and on ingestion most of the mineral oil remains unabsorbed in the faeces. Small amounts of mineral oil are absorbed by the intestinal mucosa and are distributed throughout the body. A very small fraction may undergo further biochemical transformation. In both man and animals, the aliphatic hydrocarbons are generally considered to be biochemically inert and excreted unchanged.

RMS also explained during the peer review that gastrointestinal absorption of the hydrocarbons in paraffin or mineral oils administered as undiluted products was very low with the result that pharmaceutical mineral oils have for decades been used as a laxative intestinal lubricant in doses of up to 45 ml (as an enema up to 120 ml) without any harm, since it is quite an inert substance embedding the faeces in the gastrointestinal tract leading to a quick excretion, without doing any harm to the patient. The paraffin oil in Para Sommer was in accordance with the European pharmacopeia and was also used in medicine and veterinary medicine or as a substitute for fat (maximum daily intake = 100 mg) without reported adverse health effects from proper use for some decades. It was also stated that the quality of the paraffin oils (CAS 64742-46-7, 72623-86-0, 97862-82-3) was in accordance with the DAC (Deutschen Arzneimittel Codex) 1986, 6. Edition 1994 and the European Pharmacopoeia. The literature search on the toxicity profile of paraffin oils (CAS 64742-46-7, 72623-86-0, 97862-82-3) (WHO/IARC and US-EPA on the Aliphatic Solvents) it is noted that no health hazard concern exists for the white oils and aliphatic petroleum hydrocarbons consisting of various substances with different CAS numbers including paraffin oils (CAS 64742-46-7, 72623-86-0, 97862-82-3).

In reports by the FDA it was stated that technical white mineral oil may safely be used in food or as a component of non food articles intended for use in contact with food.

The experts' meeting agreed with the RMS proposal, and concluded that, even taking into account that the evaluated uses included outdoor spray application, and at the maximum

application rate, there was no concern for birds and mammals arising from oral intoxication with paraffin oil.

It was concluded that the risk for birds and mammals for the consumption of the paraffin oils was low.

5.2. Risk to aquatic organisms

Based on the available data with the plant protection product 'Arb'Hiver', paraffin oil was proposed to be classified as harmful to aquatic organisms. Acute laboratory studies with two different fish species (Rainbow trout and Common carp), *Daphnia magna* and alga were presented in the DAR. The lowest acute endpoint driving the aquatic risk assessment was observed in the studies with *D. magna*. The EC₅₀ for *D. magna* was 31.8 mg formulated/L.

The notifier and the RMS considered that the risk to aquatic organisms was less serious in nature since paraffin oil did not form a homogeneous layer in natural waterbodies. It was more likely that patches of paraffin oil were distributed over the water surface drifting apart by wind and current movements. Therefore the RMS and the notifier considered that it was not necessary to perform the formal quantitative risk assessment (TER).

Experts at the PRAPeR 58 meeting discussed the risk assessment for aquatic organisms and agreed that the risk should be addressed further and that these arguments alone were not sufficient. A new data gap was agreed during the PRAPeR 58 meeting for the notifier to further address the risk based on better evidence for the low exposure they propose occurs.

The Fate and Behaviour experts at the PRAPeR 57 meeting agreed to use the standard SWASH drift calculator values for these paraffin oils. These values for drift have been used for other active substances that are oily liquids.

After the PRAPeR 58 meeting EFSA estimated the TER for the first tier risk assessment for aquatic organisms, based on the endpoints from the DAR. EFSA also estimated the PEC_{sw} in line with the recommendations of the PRAPeR 57 meeting that are included in appendix A.

The acute TERs estimated for fish and *D. magna* were above the Annex VI trigger when a no-spray buffer zone of 25m was applied for the pome fruit uses. The acute TERs values were also above the Annex VI trigger values without the use of any no-spray buffer zone for the other evaluated uses.

The acute TERs for alga were above the Annex VI trigger values without the use of any no-spray buffer zone for all the evaluated uses.

Therefore, risk mitigation measures or alternatively further data to refine the risk assessment to aquatic organisms are needed.

It was recommended by the fate experts that the risk of paraffin oil in sediment should be considered as it was considered to adsorb strongly to the sediment. Therefore a new data gap was identified by the EFSA after the peer review for the notifier to address the risk to sediment-dwelling species.

5.3. Risk to bees

A laboratory test on toxicity of Total-PSO to honeybees was not considered valid due to the lack of data on this preparation. No additional toxicity studies were presented in the DAR. The experts at the meeting agreed that in absence of data, mitigation measures should be taken to avoid the exposure of bees.

5.4. Risk to other arthropod species

Two field studies were conducted with two different plant protection products 'SAM 501' and 'Arbofine' (Addendum 1). The intention of the first study was to determine the efficacy of the product 'SAM 501' on red spider mites in apples trees as well as the effects on *Amblyseius andersoni* in apple tree during summer. The results of the test showed that the number of mobile forms of *A. andersoni* from the trials treated with 'SAM 501' were comparable with the non-treated control rows. The 'SAM 501' was slightly toxic to *A. andersoni*. The intention of the second study was to assess the effects on *Typhlodromus pyri* in apple orchards after the application of 'Arbofine' (1 x 2 HI/ha equivalent to 20.08 Kg a.s./ha). The results showed that *T. pyri* density decreased after the treatment. However, at the end of the test (43 days after the treatment) full recovery was observed for *T. pyri*.

The meeting of experts discussed the risk assessment for non-target arthropods. The experts had some concern regarding the reliability of the *A. andersoni* study, since the study did not cover the maximum application rate proposed for the intended uses. Furthermore, it was not clear to the experts which substances were used in the test. The substance tested was 'SAM 501' however no information on its composition was available. The experts also expressed concern with regard to the second study, which showed adverse effects on the *T. pyri* population (lasting at least 43 days) with only one application rate of 20 kg as/ha. The evaluated uses proposed in the GAP included the uses in Citrus with 4 x 23.7 kg as/ha. The increase of adverse effects on *T. pyri* populations with repeated applications should not be disregarded.

The experts agreed that further information to address the risk to non-target arthropods is necessary or mitigation measures should be requested at Member State level.

5.5. Risk to earthworms

An acute toxicity study with two products 'DEV 2002-8' and 'DEV 2002-9' was available, however the results of the test were not reliable because the identity of the test substance was not available. A new data gap was identified during the experts meeting for the notifier to address the risk to earthworms.

5.6. Risk to other soil non-target macro-organisms

After the PRAPeR 58 expert meeting EFSA noted that a data gap was identified in the PRAPeR 57 meeting by the fate experts for the notifier to provide the information on route and rate of degradation of the paraffin oils in soil.

A data gap was identified by EFSA after the meeting, for the notifier to address the risk to soil non-target macro-organisms.

5.7. Risk to soil non-target micro-organisms

There was no valid study to assess the effects of paraffin oils to soil non-target micro-organisms in the DAR. However the experts during the meeting agreed that due to the properties of paraffin oil it was expected to reach the soil on restricted areas and was not expected to penetrate the soil. It was agreed during the PRAPeR 58 meeting to request the submission of further information that might support this supposition (i.e. that the amount of product reaching the soil would be very low and only at local points due to the mode of application).

EFSA Fate and Behaviour experts considered that the proposal made by the experts at PRAPeR 58 that the amount of product reaching the soil was very low due to the mode of application was not appropriate considering that the method of application being assessed was simply indicated to be 'spraying'. The fate meeting of experts PRAPeR 57 agreed to use the standard soil exposure approaches for the paraffin oils as outlined in the PEC soil calculations in appendix A. Therefore, a new data gap was identified by EFSA after the experts meeting to address the risk to soil micro-organisms.

5.8. Risk to other non-target-organisms (flora and fauna)

Studies to assess the effects of paraffin oil on non-target plants were not available in the DAR. The experts during the meeting estimated a low drift due to the method of application and considering the physical-chemical properties of the paraffin oil. The main intended use of paraffin oil is as an acaricide/insecticide; therefore no further information is necessary to address the risk to non-target plants. The risk to non-target plants was considered to be low.

5.9. Risk to biological methods of sewage treatment

Studies to assess the potential adverse effects of paraffin oil on biological methods of sewage treatment were not presented in the DAR. However, the experts during the meeting agreed that the transfer to sewage treatments should be low with the intended uses. Therefore data are not necessary. If the product is applied according to the GAP, the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definition for risk assessment: alkanes (chain lengths up to C₃₀)
Definition for monitoring: data gaps need to be filled before a decision can be made, what, if any definition is needed.

Water

Ground water

Definition for exposure assessment: alkanes (chain lengths C₅-C₃₀)
Definition for monitoring: data gaps need to be filled before a decision can be made, what, if any definition is needed.

Surface water

Definition for risk assessment
in surface water: alkanes (chain lengths up to C₃₀)
in sediment: Data gaps need to be filled before this can be finalised
Definition for monitoring: data gaps need to be filled before a decision can be made, what, if any definition is needed.

Air

Definition for risk assessment: paraffin oils (chain lengths C₁₁-C₃₀)
Definition for monitoring: data gaps need to be filled before a decision can be made, what, if any definition is needed.

Food of plant origin

Definition for risk assessment: data gaps need to be filled before a decision can be made, what, if any definition is needed.

Definition for monitoring: data gaps need to be filled before a decision can be made, what, if any definition is needed.

Food of animal origin

Definition for risk assessment: data gaps need to be filled before a decision can be made, what, if any definition is needed.

Definition for monitoring: data gaps need to be filled before a decision can be made, what, if any definition is needed.

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
alkanes (chain lengths up to C ₃₀)	Data gap	Further information was required to address the risk to earthworms, soil macro-organisms and soil micro-organisms

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L 1m depth for the representative uses	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
alkanes (chain lengths C ₅ -C ₃₀)	Data gap	Not expected but formally a data gap	Yes	No for C ₅ -C ₃₀ alkanes	Harmful to aquatic organisms

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
alkanes (chain lengths up to C ₃₀)	High potential risk was identified to aquatic organisms.

Air

Compound (name and/or code)	Toxicology
paraffin oils (chain lengths C ₁₁ -C ₃₀)	Low toxicity by inhalation

**LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER
REVIEWED**

- The refractive index and maximum benzene content of each technical paraffin oil (relevant for all uses evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- 5 batch data for each technical paraffin oil (relevant for all uses evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- UV/Vis, GC-MS, and infra-Red spectra of each technical paraffin oil (relevant for all uses evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- Stability in air, relative density, solubility in water, solubility in organic solvents, partition co-efficient and flash point 'Banole 70' (relevant for all uses of 'Banole 70' evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- Boiling point, temperature of decomposition, relative density, vapour pressure, water solubility, partition co-efficient and flash point for 'Banole 50' (relevant for all uses of 'Banole 50' evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- Boiling point, temperature of decomposition, relative density, water solubility, partition co-efficient and flash point for 'Banole 185' (relevant for all uses of 'Banole 185' evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- Information on the explosive properties, low temperature stability, pH, surface tension, accelerated storage study, shelf life study, persistent foam, flash point, relative density and viscosity for 'Citrole'. (relevant for all uses of 'Citrole' evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- Explosive properties, surface tension, persistent foam, shelf life and viscosity of 'Arbhiver' (relevant for all uses of 'Arbhiver' evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- Explosive properties, pH, surface tension, shelf life, flash point, viscosity and relative density for 'Arbofine' (relevant for all uses of 'Arbofine' evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- Explosive properties, pH, surface tension, accelerated storage stability, low temperature stability, shelf life, persistent foam, emulsion characteristics and flash point for 'Finavestan TS' (relevant for all uses of 'Finavestan TS' evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to section 1).
- Additional information related to the similarity of the mineral oils used in human medicine and Banoles (relevant for all representative uses evaluated; no submission date proposed by the notifier; refer to section 2).

- Information on route and rate of degradation of paraffin oils in soil and soil adsorption. Soil exposure assessments from the applied for uses that incorporate this information (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; refer to section 4.1).
- Information on route and rate of degradation of paraffin oils in natural surface water and sediments. Exposure assessments for natural surface water and sediment from the applied for uses that incorporates this information and information on soil adsorption and persistence. Assessment on the potential for groundwater exposure from the applied for intended uses (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; refer to section 4.2).
- Information on the rate of degradation of paraffin oils in the upper atmosphere (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; refer to section 4.3).
- Further information is required to address the risk to aquatic organisms including sediment-dwelling species (relevant for all representative uses, submission date proposed by the notifier: unknown ; data gap was identified by EFSA after the expert meeting; refer to section 5.2).
- Further information was required to address the risk to earthworms (relevant for all representative uses evaluated); submission date proposed by the notifier: unknown; data gap was identified during the experts meeting; refer to section 5.5).
- Further information to address the risk to non-target soil-micro-organisms should be provided (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; new data gap was identified after the experts meeting by EFSA; refer to section 5.7).
- Further information to address the risk to non-target soil-macro-organisms should be provided (relevant for all representative uses t evaluated; submission date proposed by the notifier: unknown; new data gap was identified after the experts meeting by EFSA; refer to section 5.6).
- Further information to address the risk to non-target arthropods (relevant for all representative uses evaluated); submission date proposed by the notifier: unknown; data gap was identified during the experts meeting; refer to section 5.4).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

This conclusion was reached on the basis of the evaluation of the representative uses as an insecticide and acaricide for use on pome fruit, stone fruit, citrus and potato. Full details of the GAP can be found in the list of endpoints.

The representative formulated products for the evaluation were ‘Citrole’, ‘Arb’hiver’ ‘Arbofine’ and ‘Finavestan TS’, emulsifiable concentrates (EC).

For food and environmental matrices there are data gaps and currently it is not clear whether methods will be required, see sections 2, 3, 4 and 5.

Sufficient internationally accepted methods (e.g. ASTM and ISO) are available to characterise the technical material and formulated product. However, numerous data gaps have been identified for the physical and chemical properties of the technical materials and plant protection products.

During the mammalian toxicology meeting, concerns were raised over relevant impurities that require classification of paraffin oils as **T “Toxic”, carcinogenic category 2, R45 “May cause cancer”**. The meeting on toxicology confirmed that the impurities benzene and polyaromatic hydrocarbons are relevant and the specification as proposed by the notifier could not be accepted on toxicological grounds due to the high levels of relevant impurities. On this basis, no toxicological studies were required, no ADI, AOEL or ARfD were proposed and no risk assessment of operator, worker and bystander exposure were conducted.

It was noted however that if highly purified paraffin oils were considered (i.e. no concern would be raised from the impurity profile of the active substance), then no toxicological concern would be raised for consumers, operators, workers and bystanders. Sources of mineral oil are laxatives in pharmacy or oils used in food technology as release agents, for lubrication purposes, or as a substitute for fat. Paraffin oils are chemically inert substances, especially the straight chain (*n*) alkanes and on ingestion most of the mineral oil (about 98 % depending on the length of the C-chain) remains unabsorbed and is rapidly excreted, mostly unchanged, via faeces.

Acute toxicity studies have confirmed the low toxicity profile of paraffin oils. The experts agreed that no acute, short-term, long-term, genotoxicity or reproductive toxicity studies would be required, provided that no concern would be raised from the impurity profile of the substance. Paraffin oils are not considered to be genotoxic, carcinogenic, neurotoxic or toxic to the reproduction. Considering the low toxicity of paraffin oils (of high purity), no ADI, AOEL or ARfD would be necessary, and no risk assessment for operators, workers and bystanders would be required.

The list of endpoints on mammalian toxicology has been filled in considering that the technical material does not contain unacceptable levels of relevant impurities.

No information on potential levels of residues in food or feed items were presented in the DAR.

A consumer risk assessment has not been performed due to the possible high level of polycyclic aromatic hydrocarbons. If these compounds are present then it would result in a toxicological classification that would mean that these compounds could not be registered as Plant Protection Products. The risk to consumers can therefore not be finalised.

With regard to environmental fate and behaviour no information was provided in the dossier, nor presented by the RMS in the DAR, except for results from ready biodegradability studies that were carried out using a sewage sludge inoculum. Therefore only crude and incomplete environmental exposure estimates for surface water (only spray drift route of entry assessed) and soil, based on the applied for uses, could be made. With the exception of the requirement for ready biodegradability data, all data requirements remain open. No conclusion on the potential for groundwater exposure can be made using the information in the DAR.

The acute TERs estimated for fish and *D. magna* were above the Annex VI trigger when a non-spray buffer zone of 25 m was applied for the pome fruit uses. However, acute TERs values were above the Annex VI trigger values without the use of any non-spray buffer zone for the other evaluated uses.

The acute TERs for alga were above the Annex VI trigger values without risk mitigation for all the evaluated uses. Therefore, risk mitigation measures or refined of aquatic risk assessment were required.

The experts at the meeting agreed that in absence of data addressing the risk to bees, mitigation measures should be taken to avoid the application in the presence of bees.

Two field studies were conducted with two different plant protection products 'SAM 501' and 'Arbofine'. The intention of the first study was to determine the efficacy of the product 'SAM 501' on red spider mites in apples trees as well as the effects on *Amblyseius andersoni* in apple tree during summer. The purpose of the second study was to assess the effects on *Typhlodromus pyri* in apple orchards after the application of 'Arbofine' (1 x 2 hl/ha equivalent to 20.08 Kg a.s./ha). The meeting of the experts had some concern regarding the reliable of the *A. andersoni* study. The experts also expressed its concern regarding to the second study showed adverse effects on the *T. pyri* density (at least lasting 43 days) with only one application rate of 20 kg as/ha. The evaluated uses proposed in the GAP included the uses in citrus with 4 x 23.7 kg as/ha. The increase of adverse effects on *T. pyri* populations with repeated application should not be disregarded. The experts agreed that further information to address the risk to non-target arthropods was necessary or mitigation measures should be requested at Member State level.

A data gap was identified during the experts meeting for the notifier to address the acute risk to earthworms.

There was no valid study evaluated in the DAR to assess the effects of paraffin oils on soil non-target micro-organisms, or soil non-target macro-organisms. Data gaps for information to address these issues are identified.

The risk to birds and mammals, non-target plants and biological method of sewage treatment was assessed as low.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- Risk mitigation measures equivalent to 25 m no-spray buffer zone or a refined aquatic risk assessment are needed for the pome-fruit use (refer to section 5.2).
- Mitigation measures should be taken to avoid the exposure of bees (refer to section 5.3).

CRITICAL AREAS OF CONCERN

- The risk assessment for consumers can not be finalised.
- Insufficient specification details; the proposed specification presents unacceptable levels of relevant impurities that would lead to classification of the active substance as T, toxic; carcinogenic category 2, R45 “May cause cancer”. On this basis, no reference values were established and the operator, worker and bystander exposure risk assessment was not finalised.
- A groundwater exposure assessment is not available.
- The risk to sediment dwelling organisms cannot be assessed because an assessment of the potential for sediment exposure is not available and information to assess the hazard to sediment dwelling organisms is not available.
- An assessment of the potential for long-range atmospheric transport is not available.
- High risk was identified to aquatic organisms. Therefore, risk mitigation measures or a refinement of the aquatic risk assessment is outstanding.
- Information to address the risk to non-target arthropods to inform the need for, or indicate the extent of any mitigation measures is not available.
- Information to address the risk to soil non-target micro-organisms, soil non-target soil macro-organisms and earthworms is not available.

APPENDIX A – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Paraffin Oil (64742-46-7)	Paraffin Oil (72623-86-0)	Paraffin Oil (97862-82-3)
Function (e.g. fungicide)	Acaricide and Insecticide	Acaricide and Insecticide	Acaricide and Insecticide
Rapporteur Member State	Greece	Greece	Greece
Co-rapporteur Member State	-	-	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Paraffin oil	Paraffin oil	Paraffin oil
Chemical name (CA) ‡	Paraffin oil	Paraffin oil	Paraffin oil
CIPAC No ‡	-	-	-
CAS No ‡	64742-46-7	72623-86-0	97862-82-3
EC No (EINECS or ELINCS) ‡	265-148-2	276-737-9	308-132-3
FAO Specification (including year of publication) ‡	None	None	None
Minimum purity of the active substance as manufactured ‡	Not applicable	Not applicable	Not applicable
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Polycyclic aromatic hydrocarbons maximum content open Open for possible others	Polycyclic aromatic hydrocarbons maximum content open Open for possible others	Polycyclic aromatic hydrocarbons maximum content open Open for possible others
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

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical and chemical properties (Annex IIA, point 2)

	Paraffin Oil (64742-46-7)	Paraffin Oil (72623-86-0)	Paraffin Oil (97862-82-3)
Melting point (state purity) ‡	Not reported	Not reported	Not reported
Boiling point (state purity) ‡	Open	Open	Not reported
Temperature of decomposition (state purity)	Open	Open	Not reported
Appearance (state purity) ‡	Liquid light yellow	Liquid, yellow to amber	Liquid colorless to light yellow
Vapour pressure (state temperature, state purity) ‡	Open	1.4×10^{-3} Pa at 25 °C	Not reported
Henry's law constant ‡	Not reported.	Not reported.	Not reported
Solubility in water (state temperature, state purity and pH) ‡	Open	Open	Open
Solubility in organic solvents ‡ (state temperature, state purity)	Propan-2-ol: >1kg/L n-heptane: >1kg/L p-xylene: >1kg/L 1,2-dichloroethane: >1kg/L Ethyl acetate: >1kg/L at 20±2°C	Propan-2-ol: 224 g/l (flask method) n-heptane: >1kg/L p-xylene: >1kg/L 1,2-dichloroethane: >1kg/L Ethyl acetate: >1kg/L at 20±2°C	Open
Surface tension ‡ (state concentration and temperature, state purity)	Not reported due to water insolubility	Not reported due to water insolubility	Not reported due to water insolubility
Partition co-efficient ‡ (state temperature, pH and purity)	Open	Open	Open

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Dissociation constant (state purity) ‡	Not reported (cannot be determined due to the insolubility in water)	Not reported (cannot be determined due to the insolubility in water)	Not reported (cannot be determined due to the insolubility in water)
UV/VIS absorption (max.) incl. ϵ ‡ (state purity, pH)	Not reported.	Not reported.	Not reported.
Flammability ‡ (state purity)	Open	Open	Open
Explosive properties ‡ (state purity)	No explosive properties (statement)	No explosive properties (statement)	No explosive properties (statement)
Oxidising properties ‡ (state purity)	No oxidising properties (statement)	No oxidising properties (statement)	No oxidising properties (statement)

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of representative uses evaluated (paraffin oil Cas 64742-46-7, Cas 97862-82-3 and Cas 72623-86-0)

(a) Crop and/or situation	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 (g/l) (f)	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	
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	[1]

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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 (g/l) (l)	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
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	[1]
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	[1]
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	[1]
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	[1]
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	[1]

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop and/or situation (a)	Member State or Country	Product name (b)	F or I (c)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment		PHI (days) (l)	Remarks: (m)	
					Type of as (g/l) (d-f)	Conc. of as (g/l) (l)	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	[1]
Seed potato	France	Finavestan TS	F	To prevent transmission 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	[1]

[1] Due to the high level of impurities this paraffin oil can not be accepted as a Plant Protection Product.

- Remarks:
- (a) For crops, Codex (or other, e.g. EU) classifications 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 sucking insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIF/AP 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/restriction

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Internationally accepted standard methods are available.	Internationally accepted standard methods are available.	Internationally accepted standard methods are available.
Impurities in technical as (analytical technique)	Internationally accepted standard methods are available.	Internationally accepted standard methods are available.	Internationally accepted standard methods are available.
Plant protection product (analytical technique)	Internationally accepted standard methods are available.	Internationally accepted standard methods are available.	Internationally accepted standard methods are available.

Analytical methods for residues (Annex IIA, point 4.2)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Open	Open	Open
Food of animal origin	Open	Open	Open
Soil	Open	Open	Open
Water surface	Open	Open	Open
drinking/ground	Open	Open	Open
Air	Open	Open	Open
Blood	No residue definition is proposed	No residue definition is proposed	No residue definition is proposed

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Open	Open	Open
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Open	Open	Open
Soil (principle of	Open	Open	Open

method and LOQ)			
Water (principle of method and LOQ)	Open	Open	Open
Air (principle of method and LOQ)	Open	Open	Open
Body fluids and tissues (principle of method and LOQ)	Open	Open	Open

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	Paraffin Oil (64742-46-7)	Paraffin Oil (72623-86-0)	Paraffin Oil (97862-82-3)
	RMS/peer review proposal		
Active substance	None	None	None

Impact on Human and Animal Health

The data included below were based on the assumption that no toxicological concern was raised over the impurity profile of the active substance, while this has not been demonstrated, they are not applicable

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Poor absorption after ingestion; most of it by the small intestine (approx. 2%)
Distribution ‡	It may be deposited in body fat (ingestion or inhalation), in kidneys, liver, brain and blood (inhalation) or in <i>stratum corneum</i> (skin)
Potential for accumulation ‡	Not expected to accumulate
Rate and extent of excretion ‡	It is excreted <i>via</i> faeces almost unchanged (paraffin oils are commonly used as laxatives due to their physical properties)
Metabolism in animals ‡	A very small fraction may undergo further biochemical transformation (hydroxylation via cytochrome P450 monooxygenase to the respective alcohol; it may then be further oxidized to carboxylic acids, and further to CO ₂ or be solubilised by building a glucuronide.)
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound
Toxicologically relevant compounds ‡ (environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD50 oral ‡	Low acute oral toxicity	
Rat LD50 dermal ‡	Low dermal toxicity	
Rat LC50 inhalation ‡	Low inhalation toxicity	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Not a skin sensitiser	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Limited animal data indicating low subchronic toxicity after oral, dermal and inhalative route	
Relevant oral NOAEL ‡	Insufficient data – not required	
Relevant dermal NOAEL ‡	Insufficient data – not required	
Relevant inhalation NOAEL ‡	Insufficient data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Paraffin oils have no genotoxic potential	
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Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Limited animal data indicating low chronic toxicity after oral route	
Relevant NOAEL ‡	Insufficient data – not required	
Carcinogenicity ‡	Paraffin oils are not considered carcinogenic	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No adverse effects on fertility are expected	
Relevant parental NOAEL ‡	No data – not required	
Relevant reproductive NOAEL ‡	No data – not required	
Relevant offspring NOAEL ‡	No data – not required	

Developmental toxicity

Developmental target / critical effect ‡	No teratogenic effects are expected	
Relevant maternal NOAEL ‡	No data – not required	
Relevant developmental NOAEL ‡	No data – not required	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data – not required; not expected to be neurotoxic	
Repeated neurotoxicity ‡	No data – not required	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Paraffin oil is widely used in the pharmaceutical and medical area as a laxative. The mechanism of action involves a physical process, where the faeces in the gastrointestinal tract are wrapped with a soft layer and glide to the final destination. The only interactions in the body after strong	
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Studies performed on metabolites or impurities ‡	<p>abuse may result in Vitamin A and E deficiency, since these vitamins are also very lipophilic and show the tendency to be excreted easier with the faeces and interactions with mineral salts, leading to hypokalaemia followed by hypocalcaemia, after ingestion.</p> <p>Due to the chemical inertia of paraffin oil no interaction with other compounds are expected.</p>
	No data – not required

Medical data‡ (Annex IIA, point 5.9)

<p><u>Reports from manufacturing personnel</u>: No reports submitted</p>
<p><u>Symptoms from overexposure of the general population</u>:</p> <ul style="list-style-type: none"> • <i>Inhalation exposure (after reconstruction of houses involving painting walls and wood)</i>: aspirated hydrocarbons descript surface and bronchial epithelial cell barrier, leading to alveolar instability, early distal airway closer and eventually hypoxia; controversial data on the potential neurotoxic effects (secondary to pulmonary hypoxia) • <i>Oral uptake (used as laxatives in pharmacy)</i>: transient gastrointestinal effects, resulting from irritation of pharynx, oesophagus, stomach and small intestine; the uptake in the blood system is very low. • <i>Dermal exposure (as creams and ointments in pharmacy and cosmetics)</i>: effects due to “defatting” of the skin, secondary to prolonged exposure; cutaneous absorption is considered insignificant, as much as a prolonged exposure does not occur.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	Not established – not required		
AOEL ‡	Not established – not required		
ARfD ‡	Not established – not required		

Dermal absorption‡ (Annex IIIA, point 7.3)

Poorly absorbed <i>via</i> the skin – most remaining in

the <i>stratum corneum</i>

Exposure scenarios (Annex IIIA, point 7.2)

Operator

No concern

Workers

No concern

Bystanders

No concern

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

Paraffin oil (CAS 64742-46-7, 72623-86-0,
97862-82-3)

RMS/peer review proposal

Not concluded (pending on final specification)
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Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Open
Rotational crops	Open
Metabolism in rotational crops similar to metabolism in primary crops?	Open
Processed commodities	Open
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Open
Plant residue definition for monitoring	Open
Plant residue definition for risk assessment	Open
Conversion factor (monitoring to risk assessment)	Open

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Open
Time needed to reach a plateau concentration in milk and eggs	Open
Animal residue definition for monitoring	Open
Animal residue definition for risk assessment	Open
Conversion factor (monitoring to risk assessment)	Open
Metabolism in rat and ruminant similar (yes/no)	Open
Fat soluble residue: (yes/no)	Open

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Open

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Open

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Open		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			
Metabolism studies indicate potential level of			

residues \geq 0.01 mg/kg in edible tissues (yes/no)

	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingsuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

No supervised trials were conducted since Paraffin Oil is exempted from the requirement of residues data.

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Open						

(a) Numbers of trials in which particular residue levels were reported e.g. 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	Open
TMDI (% ADI) according to WHO European diet	Open
TMDI (% ADI) according to national (to be specified) diets	Open
IEDI (WHO European Diet) (% ADI)	Open
NEDI (specify diet) (% ADI)	Open
Factors included in IEDI and NEDI	Open
ARfD	Open
IESTI (% ARfD)	Open
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Open
Factors included in IESTI and NESTI	Open

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Open				

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Open

Chapter 5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1)

Mineralization after 100 days ‡	no experimental data available
Non-extractable residues after 100 days ‡	no experimental data available
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No information on breakdown products available

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.2)

Anaerobic degradation ‡	no experimental data available
Mineralization after 100 days	
Non-extractable residues after 100 days	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	no experimental data available
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	no experimental data available

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

no experimental data available

Soil adsorption/desorption (Annex IIA, point 7.1.2)

no experimental data available

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡

Aged residues leaching ‡

Lysimeter/ field leaching studies ‡

no experimental data available
no experimental data available
no experimental data available

PEC (soil) (Annex IIIA, point 9.1.3)

Parent in Citrus

Method of calculation	DT50: not available 5 cm soil depth, soil bulk density 1.5 g/cm ³
Application data	Paraffin oil, 23.7 kg a.s./ha/treatment; 1 application/yr, 50% plant interception
PEC initial	15.8 mg/kg

Method of calculation	DT50: not available 5 cm soil depth, soil bulk density 1.5 g/cm ³
Application data	Paraffin oil, 4 x 23.7 kg a.s./ha/treatment; Calculated as 1 application/yr, of 94.8kg a.s./ha 50% plant interception
PEC initial	63.2 mg/kg

Parent in **Potato seed**

Method of calculation	DT50: not available 5 cm soil depth, soil bulk density 1.5 g/cm ³
Application data	Paraffin oil, 12.6 kg a.s./ha/treatment; 1 application/yr, 0% plant interception
PEC initial	17.1 mg/kg

Method of calculation	DT50: not available 5 cm soil depth, soil bulk density 1.5 g/cm ³
Application data	Paraffin oil, 6 x 12.6 kg a.s./ha/treatment; Calculated as 1 application/yr, of 75.6kg a.s./ha 0% plant interception
PEC initial	100.8 mg/kg

Route and rate of degradation in water (Annex IIA, point 7.2.1)

No data/information

No data on the route of degradation of Banoles in water are available. However, based on the hydrocarbon structure it can be assumed that hydrolytic degradation is not a relevant pathway.

Readily biodegradable ‡
(yes/no)

CAS 97862-82-3+3%emulsifier : readily biodegradable CAS 72623-860: not readily biodegradable

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Surface water

Method of calculation	SWASH drift calculator
Application rate	Paraffin oil, 1x 20 kg a.s./ha
Main routes of entry	Drift only assessed, data gap for runoff and drainage. Air assisted broadcast sprayer

3 m buffer zone, drift rate 23.6% (early application)	PEC initial = 472mg/m² or 1573 µg/l
10 m buffer zone, drift rate 11.39% (early application)	PEC initial = 228mg/m² or 759 µg/l
25 m buffer zone, drift rate 1.54% (early application)	PEC initial = 30.7mg/m² or 102 µg/l
Method of calculation	SWASH drift calculator
Application rate	Paraffin oil, 2 x 20-kg a.s./ha/yr; Calculated as 1 application/yr, of 40kg a.s./ha
Main routes of entry	Drift only assessed, data gap for runoff and drainage. Air assisted broadcast sprayer
3 m buffer zone, drift rate 20.3% (early application)	PEC initial = 811.7mg/m² or 2706 µg/l
10 m buffer zone, drift rate 9.24% (early application)	PEC initial = 369.6mg/m² or 1232 µg/l
25 m buffer zone, drift rate 1.33 % (early application)	PEC initial = 53.2mg/m² or 177 µg/l

Note whilst the highest application rate and number of application requested is for citrus, the citrus use results in lower PEC_{sw} as the perennial crop canopy of Citrus results in lower drift (i.e. only the lower 'late drift' values are pertinent for citrus)

Method of calculation	SWASH drift calculator
Application rate	Paraffin oil, 1x 12.6 kg a.s./ha
Main routes of entry	Drift only assessed, data gap for runoff and drainage. Standard hydraulic sprayer

1 m buffer zone, drift rate 1.59%	PEC initial = 20.1mg/m² or 67 µg/l
35 m buffer zone, drift rate 0.084%	PEC initial = 1.06mg/m² or 3.5 µg/l
Method of calculation	SWASH drift calculator
Application rate	Paraffin oil, 6 x 12.6-kg a.s./ha/yr; Calculated as 1 application/yr, of 75.6kg a.s./ha
Main routes of entry	Drift only assessed, data gap for runoff and drainage. Standard hydraulic sprayer
1 m buffer zone, drift rate 0.94%	PEC initial = 70.9mg/m² or 236 µg/l
35 m buffer zone, drift rate 0.048 %	PEC initial = 3.65mg/m² or 12 µg/l
PEC sediment:	data gap

PEC (ground water) (Annex IIIA, point 9.2.1)

Not calculated Data gap

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	no experimental data available
Quantum yield of direct phototransformation	no experimental data available
Photochemical oxidative degradation in air ‡	no experimental data available
Volatilisation ‡	no experimental data available
Metabolites	None

PEC (air)

Method of calculation	No data/information
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PEC_(a)

Maximum concentration

negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered

Soil: alkanes (chain lengths up to C₃₀)
Surface Water: alkanes (chain lengths up to C₃₀)
Sediment: alkanes (chain lengths up to C₃₀)
Ground water alkanes (chain lengths C₅ to C₃₀)
Air: paraffin oils (chain lengths C₁₁ to C₃₀)

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)

No data provided - none requested

Surface water (indicate location and type of study)

No data provided - none requested

Ground water (indicate location and type of study)

No data provided - none requested

Air (indicate location and type of study)

Data should be reported if available

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

CAS 97862-82-3 with 3% of emulsifiers (the product 'ARBHIVER'): readily biodegradable
CAS 72623-86-0: not readily biodegradable so candidate for R53.

Chapter 6: Effects on Non-target Species

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

Acute toxicity to mammals	No data available ¹
Long term toxicity to mammals	No data available ¹
Acute toxicity to birds	No data available ¹
Dietary toxicity to birds	LC50 > 5000 ppm (>1038 mg/kg bw/day)
Long term toxicity to birds	No data available ¹

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application Rate (kg a.s./ha)	Category (e.g., insectivorous bird)	Time-scale	ETE	TER	Annex VI Trigger
Citrus 4 x 23.7 Kg (15day interval)	Small insectivore	Short term	>714.79	>1.45*	10

*The experts' meeting agreed that at the maximum application rate, birds and mammals were not a concern from oral intoxication with the paraffin oil.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Test organism	Test item	Test/duration	End-point	Toxicity value
<i>Cyprinus carpio</i>	Arb'Hiver	Acute 96 hr	LC ₅₀	>100 mg product/L
<i>Oncorhynchus mykiss</i>	Arb'Hiver	Acute 96 hr	LC ₅₀	>100 mg product/L
<i>Daphnia magna</i>	Arb'Hiver	Acute 48 hr	EC ₅₀	31.8 mg product /L
<i>Scenedesmus subspicatus</i>	Arb'Hiver	72 hr	EC ₅₀	89.9 mg product/L

Toxicity/exposure ratios for the most sensitive aquatic organisms (OECD data point IIIA 10.2)

N° /Application	Test	Test species	Endpoint	Result	Distanc	Drift	PEC _{sw, i}	TER
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¹ Exposure expected to be negligible

n rate	substance			(mg a.i. /L)	e (m)	(%)	(µg a.i./L)	
1* 20	Arb'Hiver	<i>.O mykiss</i>	LC50	96.9	3	23.6	1573	62
	Arb'Hiver	<i>O. mykiss</i>	LC50	96.9	10	11.4	759	127
	Arb'Hiver	<i>D magna</i>	EC ₅₀	30.8	3	23.6	1573	19.6
	Arb'Hiver	<i>D. magna</i>	EC ₅₀	30.8	10	11.4	759	40.6
	Arb'Hiver	<i>D. magna</i>	EC ₅₀	30.8	25	1.54	102	301
	Arb'Hiver	Alga	EC ₅₀	87.11	3	23.6	1573	40.5
2*20	Arb'Hiver	<i>.O mykiss</i>	LC50	96.9	3	20.3	2706	36
	Arb'Hiver	<i>O. mykiss</i>	LC50	96.9	10	9.24	1232	78.6
	Arb'Hiver	<i>O. mykiss</i>	LC50	96.9	25	1.33	177	547
	Arb'Hiver	<i>D magna</i>	EC ₅₀	30.8	3	20.3	2706	11.4
	Arb'Hiver	<i>D. magna</i>	EC ₅₀	30.8	10	9.24	1232	25
	Arb'Hiver	<i>D. magna</i>	EC ₅₀	30.8	25	1.33	177	174
1*12.6	Arb'Hiver	<i>O. mykiss</i>	LC50	96.9	1	1.59	67	1446
	Arb'Hiver	<i>D magna</i>	EC ₅₀	30.8	1	1.59	67	459
	Arb'Hiver	Alga	EC ₅₀	87.11	1	1.59	67	1300
6*12.6	Arb'Hiver	<i>O. mykiss</i>	LC50	96.9	1	0.94	236	410
	Arb'Hiver	<i>D magna</i>	EC ₅₀	30.8	1	0.94	236	130
	Arb'Hiver	Algae	EC ₅₀	87.11	1	0.94	236	369

Bioconcentration

Bioconcentration factor (BCF)

Annex VI Trigger for the
bioconcentration factor

Clearance time (CT₅₀)
(CT₉₀)

Level of residues (%) in organisms after
the 14 day depuration phase

No data available. Not required.
Not required
Not required
Not required

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	No data available
Acute contact toxicity	No data available

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Test substance	Exposure route	Endpoint	Maximum single application rate	Hazard quotient	Annex VI trigger

Field or semi-field tests

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Test	Test species	Summary of design	Endpoints

Effects on other arthropod species (OECD data points IIA 8.8.1, IIA 8.8.2 and IIIA 10.5)

Test substance	Test species	Time-scale	Endpoint	Exposure scenario	Exposure	HQ or TER

Field or semi-field tests

Two field studies were conducted with formulated SAM 501 and with Arbofine. The item of the first was to determine the efficacy of the product SAM 501 on red spider mites in apples trees against Red Spider Mite as well as the effects on *Amblyseius andersoni* in summer. The item of the second study was to assess the effects on *Typhlodromus pyri pyri* in apple orchards of the application of Arbofine. The results of the test showed that the number of mobile forms of from the trials treated with SAM 501 were comparable with the non-treated control rows. The SAM 501 was slightly toxic to *A. andersoni*.

The experts had some concern regarding the reliable of the *A. andersoni* study, The experts of Member States had also a concern regarding to the fact that the second study showed adverse effects on the *T. pyri* population (at least lasting 43 days) with only one application rate of 20 kg as/ha. The evaluated uses proposed in the GAP included the uses in Citrus with 4 x 23.7 kg as/ha. The increasing of the adverse effects on *T. pyri* populations, with these repeated applications should not be discarded.

The experts agreed that further information to address the risk to non-target arthropods is necessary or mitigation measures should be requested at Member State level.

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Test	Test item	Endpoint	(mg a.s./kg soil)
Data gap			
Field or semi-field tests			
Other soil macro-organisms			
Data gap			

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg a.s./ha)	Crop	Test item	Time-scale	TER	Annex VI Trigger

Effects on soil micro-organisms (OECD data point IIA 8.10 and IIIA 10.7)

Nitrogen turnover,

Carbon mineralization

No data available

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

The main used as insecticide excludes. In conclusion, the risk of paraffin oils to non-target terrestrial plants is acceptable for the intended uses.

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	Endpoint
Activated sludge	No data available

Classification and labelling	Paraffin oil: no data available
for the environment	Product: R52/R53

APPENDIX B – LIST OF ABBREVIATIONS

ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
μg	microgram
μm	micrometer (micron)
a.s.	active substance
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstract Service
cGAP	critical good agricultural practice
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT ₅₀	period required for 50 percent disappearance (define method of estimation)
DT ₉₀	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC ₅₀	effective concentration (biomass)
EC ₅₀	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER ₅₀	emergence rate/effective rate, median
ErC ₅₀	effective concentration (growth rate)
EU	European Union
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography

	or high performance liquid chromatography
HQ	hazard quotient
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC ₅₀	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
PD	proportion of different food types
PEC	predicted environmental concentration
PEC _{air}	predicted environmental concentration in air
PEC _{gw}	predicted environmental concentration in ground water
PEC _{sed}	predicted environmental concentration in sediment
PEC _{soil}	predicted environmental concentration in soil
PEC _{sw}	predicted environmental concentration in surface water
pH	pH-value
PHI	pre-harvest interval
pK _a	negative logarithm (to the base 10) of the dissociation constant
P _{ow}	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
PT	proportion of diet obtained in the treated area
r ²	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate

SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
TER	toxicity exposure ratio
TER _A	toxicity exposure ratio for acute exposure
TER _{LT}	toxicity exposure ratio following chronic exposure
TER _{ST}	toxicity exposure ratio following repeated exposure
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TWA	time weighted average
UV	ultraviolet
W/S	water/sediment
WG	water dispersible granule
WHO	World Health Organisation
yr	year

APPENDIX C – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
N/A		

