European Food Safety Authority

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CONCLUSION ON PESTICIDE PEER REVIEW

Peer review of the pesticide risk assessment of the active substance paraffin oil (CAS 8042-47-5, chain lengths C_{17}-C_{31}, boiling point 280-460°C)[1]

(Question No EFSA-Q-2008-684)

Issued on 19 December 2008

SUMMARY

Paraffin oil (CAS 8042-47-5, chain lengths C_{17}-C_{31}, boiling point 280-460°C) is one of 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 oil (CAS 8042-47-5) in accordance with the provisions of Article 21(1) of the Regulation (EC) No 2229/2004, which was received by the EFSA on 7 May 2008. The peer review was initiated on 30 June 2008 by dispatching the DAR for consultation of the Member States and the sole notifier Stähler International GmbH&Co.KG. 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 oil (CAS 8042-47-5, chain lengths C_{17}-C_{31}, boiling point 280-460°C). *EFSA Scientific Report* (2008) 220, 1-42

[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, grapes and ornamentals. Full details of the GAP can be found in the list of endpoints.

The representative formulated products for the evaluation were 'Para Sommer', it is currently not clear what the formulation type is and a data gap is set to address this.

Methods of analysis for food items are currently not required see section 3. For environmental matrices methods are not required for groundwater and air, for surface water a method is required for alkanes (chain lengths up to C31). For soil it is not concluded if a method is required or not, see sections 4 and 5.

Sufficient internationally accepted methods (e.g. ASTM and ISO) are available to characterise the technical material and formulated product. However, at this time the technical specification is not accepted, the method of manufacture is not known and there is no supporting batch data. Data gaps have been identified for vapour pressure and auto-flammability of the technical paraffin oil. For the formulation, data gaps have been identified for flash point and emulsion stability after shelf-life storage.

During the mammalian toxicology meeting, as no technical specification was agreed by the meeting on physical and chemical properties, concerns were raised over relevant impurities generally associated with these compounds. While it is not demonstrated that no concern is raised due to the impurity profile of the substance, paraffin oil has to be classified 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 could be conducted, as the experts considered that these specifications were not acceptable from the toxicological point of view.

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.

Paraffin oil has a low toxicity profile. No toxicological study was submitted or accepted. The experts agreed that no 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 reproduction. Also in line with the low toxicity of paraffin oils (of high purity), no ADI, AOEL or ARfD would be proposed, nor considered 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.

In soil under aerobic conditions this paraffin oil mixture exhibits moderate to medium persistence in terms of the time taken for carbon tetrachloride extracted alkanes to be mineralised. The alkanes in the mixture are classed as immobile in soil, on the basis of QSAR estimates and adsorption is not pH dependent. In a 55 cm deep microcosm study this paraffin oil mixture formed a layer at the water surface (spray application made), where it dissipated rapidly exhibiting low persistence in water. Sediment concentrations were not measured. The mechanism of the dissipation was not identified. Surface water exposure assessments are available using the SWASH drift calculator tool. A data gap is identified regarding the potential for water body associated sediment to be exposed and information on degradation/dissipation potential of this paraffin oil mixture in sediment. The potential for groundwater exposure from the applied for intended uses by alkanes up to C31 above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

Based on the available data, paraffin oil was proposed to be classified as toxic to aquatic organisms. The acute risk of paraffin oil to fish was assessed as low for all the relevant scenarios. Risk mitigation measures equivalent to 25m, 3m and 1m no–spray buffer zones were necessary to refine the risk for aquatic invertebrates and alga for the pome-fruit, grapevines and ornamental uses. The available information did not allow the risk to sediment dwelling organisms to be assessed.

Standard laboratory tests were conducted with the formulation ‘Para Sommer’ and the species *Coccinella septempunctata* (0 % effects on mortality; 58 % fecundity) and *Phytoseidus permisilis* on the leaves of *Phaseolus vulgaris* (69 % of mortality). Two extended laboratory studies with the standard indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* were submitted. The in-field HQ values were above the Annex VI trigger values, however the off-field HQs were below the triggers. Therefore, the in-field risk should be further addressed and risk mitigation measures should be considered.

Data gaps were identified after the peer review by EFSA to address the risk to soil non-target micro-organisms and to soil non-target macro-organisms.

The risk to birds and mammals, bees (with mitigation to avoid direct spraying of bees), non-target plants, and biological methods of sewage treatment was assessed as low.

Key words: paraffin, CAS 8042-47-5, peer review, risk assessment, pesticide, insecticide, acaricide.

TABLE OF CONTENTS

Summary 1
Table of Contents 4
Background 6
The Active Substance and the Formulated Product 7
Specific Conclusions of the Evaluation 7
1. Identity, physical/chemical/technical properties and methods of analysis 7
2. Mammalian toxicology 8
2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics) 8
2.2. Acute toxicity 8
2.3. Short-term toxicity 9
2.4. Genotoxicity 9
2.5. Long-term toxicity 9
2.6. Reproductive toxicity 9
2.7. Neurotoxicity 9
2.8. Further studies 9
2.9. Medical data 9
2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD) 10
2.11. Dermal absorption 10
2.12. Exposure to operators, workers and bystanders 10
3. Residues 10
4. Environmental fate and behaviour 10
4.1. Fate and behaviour in soil 11
4.1.1. Route of degradation in soil 11
4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products 11
4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products 11
4.2. Fate and behaviour in water 12
4.2.1. Surface water and sediment 12
4.2.2. Potential for ground water contamination of the active substance, their metabolites, degradation or reaction products 13
4.3. Fate and behaviour in air 14
5. Ecotoxicology 14
5.1. Risk to terrestrial vertebrates 14
5.2. Risk to aquatic organisms 15
5.3. Risk to bees 18
5.4. Risk to other arthropod species 18
5.5. Risk to earthworms 19
5.6. Risk to other soil non-target macro-organisms 19
5.7. Risk to soil non-target micro-organisms 19
5.8. Risk to other non-target-organisms (flora and fauna) 19
5.9. Risk to biological methods of sewage treatment 20
6. Residue definitions 20
List of studies to be generated, still ongoing or available but not peer reviewed 24
Conclusions and Recommendations 25
Critical areas of concern 27
Appendices 28
Appendix A – List of endpoints for the active substance and the representative formulation 28

Appendix B – List of Abbreviations 55
Appendix C – Used compound code(s)..... 59

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 oil (CAS 8042-47-5, chain lengths C17-C31, boiling point 280-460°C) is one of 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 oil (CAS 8042-47-5), hereafter referred to as the draft assessment report, received by the EFSA on 7 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 30 June 2008 to the Member States and to the main applicant Stähler International GmbH&Co.KG, 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, 2 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 November 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 paraffin oil CAS 8042-47-5 chain lengths C17-C31, boiling point 280-460°C. 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 'Para Sommer', it is currently not clear what the formulation type is and a data gap is set to address this.

The evaluated representative uses were as an insecticide and acaricide for use on pome fruit, stone fruit, grapes and ornamentals. 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 this material is not considered to be a quality parameter and it is therefore not presented here. The meeting of experts could not accept the specifications because there were critical parameters that were not tested. A data gap for the method of manufacture and 5-batch data was identified. If the specification issue is resolved, the data and supporting methods can also be used to control the quality of the plant protection product.

Currently it is not clear if this material contains relevant impurities and this will have to be clarified when a new specification and 5-batch study are provided.

The assessment of the physical/chemical data package identified 2 data gaps, auto-flammability and vapour pressure for the technical paraffin, and flash point and emulsion stability after storage for the formulation.

The main data regarding the identity of this paraffin oil and its physical and chemical properties are given in appendix A.

None of the methods supplied for the technical material and the formulated product were accepted, however there are a large number of internationally accepted methods (e.g. ISO and ASTM) that can be used to characterise these sort of compounds. If these are used to produce the batch data and specification then additional validation data will not be necessary.

Methods of analysis for food items are currently not required see section 3. For environmental matrices methods are not required for groundwater and air, for surface water a method is required for alkanes (chain lengths up to C31). For soil it is not concluded if a method is required or not, see sections 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 8042-47-5)[4] was discussed at the PRAPeR 59 meeting of experts on mammalian toxicology in October 2008 on basis of the draft assessment report (April 2008).

No technical specification was agreed by the meeting on physical and chemical properties (PRAPeR 56) and concerns were raised over relevant impurities, for which no maximum limit could be set. The specification as proposed by the notifier could not be accepted on toxicological grounds due to its high levels of potentially relevant impurities. While it is not demonstrated that no concern is raised due to the impurity profile of the substance, paraffin oil has to be classified 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 could be conducted as the experts considered that these specifications were not acceptable from the toxicological point of view.

Main sources of information reported in the draft assessment report 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 acceptable 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 CO_2 or solubilisation by building a glucuronide.

2.2. Acute toxicity

Open literature data were presented, confirming the general knowledge that paraffin oil has low toxicity, either by the oral, dermal or inhalation route. It is not a skin or eye irritant, or a skin sensitising agent. No further study was required (a translation to English of the reports submitted in German was required for formal reasons).

[4] Notifier Stähler

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 potentially present in paraffin oils that could not be assessed. The experts concluded that no short term toxicity study was necessary if pure paraffin oils were considered, and that it is up to the notifier to demonstrate that the quality of the paraffin oils was of an acceptable technical standard, i.e. that no toxicological concern would be raised from the impurity profile of the substance.

2.4. Genotoxicity

No genotoxicity study was provided. No study was required, provided that no toxicological concern would be raised from the impurity profile of the active substance. Pure paraffin oils are not considered to have genotoxic potential.

2.5. Long-term toxicity

No study was provided. As discussed for the short term toxicity and genotoxicity testing, 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. However, according to the lack of data on the impurity profile of the active substance, it has to be considered as a **carcinogenic category 2 substance with risk phrase R45 "May cause cancer".**

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 either expected upon administration of pure paraffin oils. As discussed before, no study was considered necessary, provided that no toxicological concern would be raised from the impurity profile of the active substance.

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 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 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 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, while the levels of relevant impurities in the technical specification are not demonstrated to be of no concern, this is not acceptable for the risk assessment of paraffin oils, and the product could not be accepted 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

No study was provided. It is recognised that paraffin oils may accumulate in the *stratum corneum*. No dermal absorption value was needed as no risk assessment of operators, workers and bystanders was conducted.

2.12. Exposure to operators, workers and bystanders

No risk assessment of operators, workers and bystanders could be conducted. No AOEL was established based on the level of relevant impurities potentially present in the technical specification that 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

The RMS agreed with the applicant's argumentation that no specific study on the route of degradation was required as the substance is a mixture of hydrocarbons mainly alkanes with chain lengths in the range C_{17} to C_{31} which have a simple structure and will be biodegraded via oxidation and chain splitting. The final degradation product will be CO_2. The peer review of the member states accepted this argumentation.

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

Aerobic laboratory soil incubation experiments carried out at 20°C and 40% maximum water holding capacity (MWHC) carried out on 2 soils dosed with 'Promanal' (which was stated to be 75% CAS 8042-57-5) were available. Single first order DT_{50} (linear regression) that represent complete mineralisation of carbon tetrachloride extractable residue (quantified by IR spectra with 3 wave numbers, characteristic of carbon hydrogen bonds between 2912-2925 cm^{-1}), were estimated to be 43 days (2.29% organic carbon (OC) pH 5.6 sandy loam soil) and 87 days (0.85% OC soil pH 6.2 sandy loam). Clarification of the analytical methodology employed was provided in the evaluation table, note the original DAR erroneously indicated gas chromatography had been used. The meeting of member state experts agreed these data were sufficient to give an indication of the rate of degradation of carbon tetrachloride extractable alkanes in soil and that further information was not required.

The experts agreed the predicted environmental concentrations in soil in appendix A that had been calculated assuming a single first order DT_{50} of 87 days,

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

The soil adsorption of an alkane ($C_{24}H_{50}$) was estimated using quantitative structure activity relationship (QSAR) software[5]. This resulted in a calculated K_{doc} value of 9086000 mL/g. The member state experts agreed that due to the very high adsorption value estimated adsorption of the alkanes to soil would be high and that batch adsorption measurements were not required to conclude on the low soil leaching potential of the straight chain alkanes in paraffin oil. This conclusion was supported by their knowledge of the lipophilic nature of straight chain alkanes. In three soil (sieved) column leaching experiments no alkanes were determined in column eluate. It was noted that the limit of analytical detection in the eluant

[5] EPI-suite v3.12, part PCKOCWIN v1.66 (US-EPA, August 17 2004).

samples was quite high at 0.59mg/L but that this represented 0.012% of the dose applied to the top of the columns, so confirmed that these alkanes would be expected to exhibit low mobility.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

Information on the fate and behaviour of 'Para Sommer' (containing 75% C_{17} to C_{31} alkanes) in natural sediment water systems was provided in an indoor microcosm study (see section B.9.2.5/01 Addendum 1 to the DAR Vol. 3). This experiment consisted of a 55 cm deep water column overlying 20 cm of sediment (sandy loam 2.65-3.2%OC) where aquatic macrophytes and other organisms were present. The experiment was carried out at 20°C with a 14 hour light and 10 hour dark cycle (artificial illumination light energy and quality not reported). When spray applications were made, as expected (due to its density) a film of product was formed on the surface layer of the water. Water samples were taken from 2cm below the water surface and analysed by GC-MS. Results were expressed as both µg/L and µg/cm^2. Single first order DT_{50} (calculated by linear regression) that represent dissipation rates from this surface layer film were calculated to be 0.6 to 3.6 days (measured data from samples taken between 0.5 to 5 days after application, 3.6 days is the mean of replicated experiments where the individual values were 2.1 and 5 days). Macrophytes or sediment were not analysed for in the experiments so the sink for the dissipation of the residue is not known. It can be surmised that some of the alkanes volatilised to the atmosphere but the contribution of movement deeper into the water column, partitioning to macrophytes or partitioning to sediment is not known.

In a ready biodegradability study (OECD 301D) a product 'Promanal' that contained 76% C_{18} to C_{30} alkanes and 24% other components was demonstrated to achieve only 31% theoretical mineralisation within the 28 day window so a classification of 'not readily biodegradable' is necessary following the criteria of the test. It was also noted that if 25% of this mineralisation were to have been accounted for by the other components, as a worst case only 6 % of the alkanes from paraffin oil may have been mineralised in the test. The experts concluded that the results of this test do not provide any useful information on the potential for degradation in natural sediment water systems of C_{18} to C_{30} alkanes, as the inoculum used (sewage sludge) is not representative of natural systems and the uncertainty about how much of the mineralisation measured was for the paraffin alkanes and how much was other components in 'Promanal'. In addition the optimised mixed aerobic conditions of the study design cannot represent conditions in natural sediment water systems.

In summary the experts agreed that there was good evidence that for spray drift inputs to natural surface water, rapid dissipation between applications of alkanes C_{17} to C_{31} would be expected on the basis of the results from the microcosm experiment, such that concentrations at the water surface / in the water column were unlikely to be additive from multiple applications. However there was no clear evidence if sediment is, or is not going to be a significant sink for alkanes that arrive at the water surface via drift. If sediment will be a significant sink then there is no information available on what the possible persistence in aerobic sediment would be. Experts noted that because of the strong soil adsorption potential

of the alkanes, sediment exposure consequent from eroded soil input to surface water primarily from runoff but also possibly via drainage systems cannot be excluded.

The experts discussed the surface water exposure assessment as set out in section B.8.6.1 Addendum 1 to the DAR Vol. 3 that used the FOCUS surface water tools at steps 1 to 3. They agreed that these values could not be used in any risk assessment. It was clear that at steps 1 and 2 the assumptions regarding runoff and drainage were too worst case for such a lipophilic material. The assumption in this FOCUS surface water modelling framework at steps 3 and 4 of instantaneous partitioning to sediment was not pertinent to paraffin oils as this assumption will considerably underestimate the water column exposure that can occur via spray drift. In addition to these major considerations it was also noted that the use of a sediment water degradation rate of 45 days in the modelling could not be supported as it had been clarified that the source of this value was the ready biodegradability study that was concluded as not valid for this purpose.

The member state experts agreed that the most appropriate (within the remaining time available for the EFSA peer review) surface water exposure calculations for use in the risk assessment would be those that can be calculated assuming the spray drift route of entry to surface water and the SWASH drift calculator tool, assuming that even when the GAP recommends more than one application in a season that there will be no additive effect on water surface/water column concentrations from sequential applications. These are the values that are included in appendix A[6]. The values in appendix A include non spray buffer zones but only for distances that represent < 95% spray drift mitigation. It was agreed that the spray drift route of entry was likely to be the most important route of exposure compared to the drainage or runoff routes even when drift is mitigated. A data gap was identified for sediment exposure as a consequence of the uses applied for, to be addressed. In addition to the spray drift route of entry, sediment exposure from paraffin oils sorbed to eroded soil needs to be addressed. The degradation/dissipation potential in sediment between drift entries / any eroded soil loading would also be helpful information to characterise potential sediment exposure levels.

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

FOCUSPELMO 3.3.2 groundwater scenario calculations were provided by the applicant for the applied for intended use on apples. The case was made (and accepted by the peer review in this case) that this use pattern would be expected to cover the leaching risk for the other applied for intended uses. An assessment of the modelling was provided in B.8.6.2 Addendum 1 to the DAR Vol. 3. The main substance properties used as input were a single first order DT_{50} of 65 days and K_{oc} of 90860 mL/g (a worst case (lower) value than the available QSAR indicated could have been used) 1/n of 0.9 (default). Whilst following EU guidance / agreed evaluation approaches a 1/n of 1 (as a QSAR estimated K_{doc} was the source of the value used) and a single first order soil DT_{50} of 87 days (longest value as the data set is small, only 2 soils investigated) should have been used in simulations, the available modelling was accepted as demonstrating the potential for groundwater contamination would be low as a

[6] Note the PECsurface water and sediment calculations included in Addendum 2 to Volume 3 (dated November 2008) provided by the RMS after the meeting of experts are inappropriate, as they used a methodology that the member state experts had concluded would not reflect the fate and behaviour of paraffin oil.

consequence of the applied for intended uses. The indications from the modelled results were that in leachate leaving the top 1 m soil layer the 80th percentile annual average concentrations of alkanes up to C_{31}would be <0.001µg/L.

4.3. Fate and behaviour in air

Reliable values for the vapour pressure of this mixture of paraffin oils are not available but significant volatilisation to the atmosphere from plants soil and surface water would be expected. The applicant provided calculated estimates of the rate of breakdown of the alkane $C_{24}H_{50}$ that may occur in the upper atmosphere via photochemical oxidative reaction with hydroxyl radicals using the Atmospheric Oxidation Program[7] that uses the structure activity relationship developed by Atkinson. The resulting half life calculated was 4.15 hours (rate constant calculated to be 30.89×10^{-12} cm^3/molecule sec., hydroxyl radical concentration assumed 1.5×10^6 OH/cm^3). Thus it is expected that the C_{17}-C_{31} alkanes would not be expected to be subject to long range atmospheric transport.

5. Ecotoxicology

Paraffin oil (CAS 8042-47-5)[8] was discussed at the PRAPeR 58 meeting of experts for ecotoxicology in October 2008, on the basis of draft assessment report, and the addendum 1 Volume 3 B.8-B.9.

The representative uses evaluated were the uses as acaricide/insecticide in stone and pome fruit (apples, pears) in field, grapevines and field and ornamentals greenhouse.

Studies with the active substance were not available in the DAR. However due to the low water solubility of the paraffin oil, the meeting of experts agreed to use the plant protection product 'Para Sommer' (654 g/L of paraffin oil) in the tests.

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

Toxicity studies of paraffin oil to birds and mammals were not submitted. The member states experts at the PRAPeR 58 meeting discussed the risk assessment for birds and mammals. The RMS explained in the DAR that paraffin oil is used against immobile pest stages, including eggs, and that the activity is based on the non-toxic film-forming component paraffin oil. The

[7] AOPWIN v1.91
[8] Notifier Stähler

pests are covered with a thin coating which is non-pervious to air and stops the oxygen supply (suffocation and smothering) and therefore has a physical mode of action.

Paraffin oil has no chemical 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 human and animals, the aliphatic hydrocarbons are generally considered to be biochemically inert and are excreted unchanged.

The RMS also explained during the peer review that gastrointestinal absorption of the hydrocarbons in paraffin or mineral oils administered as undiluted products is very low with the result that Pharmaceutical minerals oils have for decades been used as a laxative intestinal lubricant in doses of up to 45ml (as an enema up to 120ml) without any harm, since they are quite inert substances, 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' is in accordance with the European Pharmacopeia and is also used in medicine and veterinary medicine or as a substitute for fat (maximum daily intake = 100 mg) without adverse health effects on proper use for some decades. It is also stated that that the quality of the paraffin oil CAS 8042-47-5 is according to the DAC (Deutschen Arzneimittel Codex) 1986, 6. Edition 1994 and to the European Pharmacopeia. The literature search on the toxicity profile of paraffin oil CAS 8042-47-5 (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 oil CAS 8042-47-5.

In reports by the FDA it is 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 agreed with the RMS argumentation 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 in relation to birds and mammals from oral intoxication with the paraffin oil.

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

5.2. Risk to aquatic organisms

Based on the available data, the paraffin oil formulation was proposed to be classified as toxic to aquatic organisms. Acute laboratory studies for two different fish species and for *Daphnia magna* were presented in the DAR. A 21-day fish prolonged toxicity test was conducted with the Rainbow trout. The lowest acute endpoint driving the aquatic risk assessment was observed in the studies with *D. magna*. The EC_{50} for *D. magna* was 1.71 mg 'Para Sommer'/L. Results from the fish prolonged toxicity test with 'Para Sommer' formulation showed that at the test concentration of 10 mg/L the formulation was not toxic to rainbow trout.

The acute TERs were calculated by EFSA after the peer review based on the new PECsw values estimated by EFSA after the fate and behaviour meeting. The acute TER values for fish were above the Annex VI trigger values in all the relevant scenarios. However, the acute TER values estimated for *D. magna* were below the Annex VI trigger values in all evaluated uses. Whereas TERs for algae were below the trigger values for the pome fruit uses, the acute TER values estimated for the grapevine and ornamental uses were above the Annex VI trigger value. Therefore, the acute risk of paraffin oil to fish was assessed as low. The first tier risk assessment indicated a potential high risk for aquatic invertebrates and also for algae.

A higher tier microcosm study was submitted by the applicant and not taken into consideration by the RMS in the DAR. The summary of the microcosm study (Wellham H. (2005) was included in the Addendum 1.

The microcosm study was performed in a semi-realistic aquatic microcosm with a sediment layer. 'Para Sommer' was applied once per year at the followings concentrations of 98, 310, 981, 3102 and 9810 µg a.s./L. *Daphnia longispina* was found to be the most sensitive zooplankton species. However, other *Phyllopoda, Copepoda, Rotifera* were not affected by the test substance. The zooplankton community NOEC- was set to 3102 µg /L. Significant emergence of *Culex pipiens* and other insects started two weeks after the application. No effects of the test substance could be found except for the highest application rate, where no insect emerged. No effects of the test substance were observed on phytoplankton abundance.

From the microcosm study a NOEC = 98 µg/L was proposed based on the most sensitive observed short-term effects on *Corixidae* and *Phyllopoda* at 310 µg /L. A NOEAEC of 3102 µg /L was proposed by the RMS taking into account that for all affected populations a potential for recovery could be demonstrated (*Daphnia longispina, Culex pipiens*). Member States experts expressed concern at using the NOEAEC value for risk assessment as this value was based on recovery effects, which had not been demonstrated for more than one application (according to the GAP 2 applications are intended for some uses). The experts proposed to use the lowest NOEC as the relevant endpoint (NOEC = 98 µg/L). Some of the experts considered that no real toxicity was expected but only physical effects due to the paraffin oil, especially for emergence of flying species. Moreover, the RMS expressed that the risk to aquatic organisms was less serious in nature since paraffin oil could not form a homogeneous layer in natural water bodies. It was more likely that patches of paraffin oil could be distributed over the water surface drifting apart by wind and current movements.

The experts at the meeting considered that due to the special characteristics of the substance and the microcosm the higher tier risk assessment, comparing the PECsw with NOEAEC and to establish an assessment factor was not appropriate. The RMS calculated the application rate that would raise concerns in light of the application rates that were used in the microcosm study, and NOEC and NOEAEC expressed as application rates.

Crown height	**MAX RATE**	**NOEC** (98 µg/L)
	g/m2	0.0539
1m	0.981	**5,49%**
2m	1.96	**2,75%**

3m	2.943	**1,83%**

During the meeting the RMS presented the following calculations:

550 L of water per mesocosm (1x1x0,55).

NOEC = 98 µg/L =53900 µg/550L = 53.9 mg/550L or 53.9 mg/m2 or 0.0539 gr/m2

NOAEC=3102 µg/L = 1706100 µg/550L =1.7061 gr/550L or 1.7061 gr/m2

MAX application rate = 500L/ha/m = 1m: 9.81 kg/ha, 2m: 19.6 kg/ha, 3m: 29.43 kg/ha = 1m: 9.81 g/ 10m2, 2m: 19.6 g/10m2, 3m: 29.43 g/m2 = 1m: 0.981 g/m2, 2m: 1.96 g/m2, 3m: 2.943 g/m2.

The application rate changed with the crown height, the maximum application rate was 29.43 kg as/ha at 3 m of crown height.

If 1.83% of the maximum application rate reached the surface of the microcosm, then the water concentration on the microcosm would reach an equivalent level to the NOEC of 0.0539 g /m2. The results indicated that some concerns may arise in the case of high drift towards aquatic systems. However, the meeting considered that the drift may be low, based on the mode of application (directed application), and because this is an oily substance.

The PRAPeR 58 meeting concluded that Member States may wish to request more accurate calculations of the drift based on the mode of application and uses of the product in order to set appropriate mitigation measures.

The member state experts at PRAPeR 57 considered that there was no evidence to indicate that drift may be low because large droplets would be formed for this substance because it is an oil (as discussed by ecotoxicology experts). The experts at the fate meeting agreed to use the standard EU agreed drift values that are included in the SWASH drift calculator. These values for drift have been used for other active substances that are oily liquids.

EFSA fate and behaviour experts have some concern with the procedure to perform the higher tier risk assessment proposed at the PRAPeR 58 expert meeting. For consistency of approach, it was considered that the PEC surface water values as agreed by PRAPeR 57 fate and behaviour experts, discussed at section 4.2.1 and included in Appendix A, should be used for the risk assessment. The drift route of entry would dominate potential surface water exposure.

After the PRAPeR 58 meeting EFSA evaluated the higher tier risk assessment using the TER approach based on the agreed endpoint from the microcosms (NOEC = 98 µg/L equivalent to 73 µg a.s./L or 40.5 mg a.s. /m^2) and the PECsw as calculated using the SWASH drift calculator (expressed as mg a.s./m^2).

The assessment factor (AF) was not discussed in the expert meeting, however taking into account the available data EFSA considers that an AF of 1-3 could be appropriate. The TER values were estimated to be 0.05, 0.12 and 1 based on 3m, 10m and 25m no-spray buffer zones respectively for the use on pome fruit. TERs were 4.5 based on 3m for the grapevine use, and a TER value of 1.6 was estimated for the ornamental use based on a 1m buffer zone.

EFSA noted after the expert meeting that the results of the microcosm study provide no information on sediment exposure (this was not measured in the study). There was no clear evidence if sediment was, or was not going to be a significant sink for alkanes that arrive at

the water surface via drift. If sediment could be a significant sink then there is no information available on what the possible persistence in aerobic sediment would be. EFSA considered that the effects on sediment-dwelling species were not addressed in the microcosm study, since no information was available on the amount of product present in the sediment. Therefore, EFSA identified a new data gap after the expert meeting for further information on the effects on sediment-dwelling species if sediment exposure cannot be excluded (for example a spiked-sediment *chironomus* study).

Overall it was concluded that, the acute risk of paraffin oil to fish was assessed as low for all the relevant scenarios. Risk mitigation measures equivalent to 25m, 3m and 1m no–spray buffer zones were necessary to refine the risk for aquatic invertebrates and algae for the pome-fruit, grapevine and ornamental uses. A new data gap was identified after the experts meeting for further information on the effects on sediment-dwelling species if sediment exposure cannot be excluded.

5.3. Risk to bees

A contact toxicity study was presented in the DAR, but the study was submitted in German and the RMS did not evaluate it. The applicant explained during the peer review process that two additional toxicity studies on bees were submitted by the applicant and not taken into account by the RMS. EFSA checked that the studies were submitted before the RMS sent the DAR to EFSA. Therefore these two studies could be used in the risk assessment for bees.

Acute contact and oral toxicity tests were conducted with 'Para Sommer' (Addendum 1). The results showed a LD_{50} >3813.655 µg a.s./bee and 1474.12 µg a.s./bee for contact and oral, respectively. The contact and oral Hazard Quotients (HQ) values were below the Annex VI trigger of 50 indicating a low risk to bees not present at the time of spraying. Member States may wish to consider risk mitigation to avoid applications during the time of active bee flight. The risk from residual paraffin oil is expected to be low based on the available data.

5.4. Risk to other arthropod species

Standard laboratory tests were conducted with formulated 'Para Sommer' and the species *Coccinella septempunctata* (0 % effects on mortality; 58 % fecundity) and *Phytoseidus permisilis* on the leaves of *Phaseolus vulgaris* (69 % of mortality).

During the peer-review the applicant suggested that two extended laboratory studies with the standard indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* were submitted and not taken into account by the RMS. Therefore these tests were included and assessed by the RMS in the Addendum 1. The LR_{50} values were estimated as 9.88 L/ha and 7.1 L/ha for *A. rhopalosiphi* and *T. pyri*, respectively.

The in-field HQs values were calculated as 4.55 and 6.34 and the off-field HQs were 1.0 and 0.72 (based on the worst case intended uses).

The experts during the meeting agreed that due to the high application rate, in-field HQ values were above the Annex VI trigger values, suggesting that a potential high risk was identified for in-field areas to non-target arthropods. However, the off-field HQs were below the Annex VI trigger indicating that the risk for non-target arthropods in the off-field areas was assessed as low.

A data gap was identified in the experts meeting for the applicant to further address the in-field risk for non-target arthropods.

5.5. Risk to earthworms

Acute toxicity to earthworms was tested with 'Para Sommer', a 14-d LC_{50} > 750 mg a.s./kg was observed in the study. The TER values were estimated based on the corrected LC_{50} in the Addendum 1, and were calculated with the new maximum initial PECs. The TERs were clearly above the Annex VI trigger values indicating that the risk to earthworms was low.

EFSA noted that the PECs for the pome-fruit and ornamental uses were changed after the PRAPeR 57 meeting. New maximum initial PEC values were presented in the Addendum 2 (PECs = 30.16 mg/kg for pome and stone-fruit and 25.158 mg /kg for ornamentals). Therefore the EFSA calculated the TER values of 12.5 and 15 for the pome/stone-fruit and ornamental uses, respectively.

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

No studies were available in the DAR, however, after the PRAPeR 58 meeting EFSA noted that the DT_{90f} in soil of paraffin oil was > 100 days. Therefore, a data gap was identified by EFSA for the applicant to address the risk to soil non-target macro-organisms.

5.7. Risk to soil non-target micro-organisms

No valid study to assess the effects of 'Para Sommer' to soil non-target micro-organisms was available in the DAR. However the experts during the meeting agreed that due to the properties of the paraffin oil it may be expected to reach the soil only at local points and not to penetrate the soil.

It was agreed during the PRAPeR 58 meeting to request the submission of further information to support this supposition (i.e. that the amount of product reaching the soil would be very low and at local points due to the mode of application).

EFSA fate and behaviour experts considered that the proposal made by the experts at the PRAPeR 58 that the amount of product reaching the soil was very low due to the mode of application was not appropriate considering 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 paraffin oil as outlined in the PEC soil calculations in appendix A. Therefore, a new data gap was identified by EFSA after the experts meeting for the risk to soil micro-organism to be addressed.

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

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

6.1. Soil

Definition for risk assessment:	alkanes (chain lengths up to C_{31})
Definition for monitoring:	data gaps need to be filled before a decision can be made, what, if any definition is needed.

6.2. Water

6.2.1. Ground water

Definition for exposure assessment:	alkanes (chain lengths C_5-C_{31})
Definition for monitoring:	Not necessary

6.2.2. Surface water

Definition for risk assessment	
in surface water:	alkanes (chain lengths up to C_{31})
in sediment:	data gaps need to be filled before this can be finalised
Definition for monitoring:	alkanes (chain lengths up to C_{31})

6.3. Air

Definition for risk assessment:	paraffin oil (chain lengths C_{17}-C_{31})
Definition for monitoring:	Not necessary

6.4. 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.

6.5. 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.

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

6.6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
alkanes (chain lengths up to C_{31})	moderate to medium persistence Single first order DT_{50} 43 and 87 days (20°C, 40%MWHC soil moisture)	Further information was required to address the risk to soil macro-organisms and soil micro-organisms

6.6.2 Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
alkanes (chain lengths C_5-C_{31})	Immobile K_{doc} for $C_{24}H_{50}$ 9086000 mL/g	No	Yes	No for C_5-C_{31} alkanes	Harmful to aquatic organisms.

6.6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
alkanes (chain lengths up to C_{31})	High potential risk was identified for the aquatic organisms.

6.6.4 Air

Compound (name and/or code)	Toxicology
paraffin oil (chain lengths C_{17}-C_{31})	Low toxicity by inhalation

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

- A specification that clearly defines the technical paraffin oil (relevant for all uses evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to chapter 1).
- Method of manufacture and 5 batch data for the technical paraffin oil (relevant for all uses evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to chapter 1).
- Vapour pressure and auto-flammability of the technical paraffin oil (relevant for all uses evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to chapter 1).
- Flash point and emulsion stability after shelf-life storage for the plant protection product (relevant for all uses evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to chapter 1).
- It should be clarified what the formulation type is according to CropLife International technical monograph No. 2-6th edition-May 2008 (relevant for all uses evaluated, data gap identified by meeting of experts October 2008, proposed submission date unknown, refer to chapter 1).
- Method of analysis for surface water (relevant for all uses evaluated, data gap identified by EFSA December 2008, proposed submission date unknown, refer to chapter 1).
- Additional information related to the similarity to the mineral oils used in human medicine (relevant for all representative uses evaluated; no submission date proposed by the notifier; refer to chapter 2)
- For formal reasons, applicant to submit a translation to English of the reports that were submitted in German to the RMS (relevant for all representative uses evaluated; no submission date proposed by the notifier; refer to point 2.1 and 2.2)
- Sediment exposure as a consequence of the uses evaluated to be addressed. In addition to spray drift entry, sediment exposure from paraffin oils sorbed to eroded soil needs to be addressed. The degradation/dissipation potential in sediment between drift entries / potential eroded soil loadings would also be helpful information to characterise sediment exposure levels. (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; refer to section 4.2.1)
- Further information on the risk to sediment-dwelling species should be provided (spiked-sediment study if sediment exposure cannot be excluded) (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 point 5.2).
- Data gap for the applicant to further address the in-field risk to non target arthropods and propose risk mitigation measures (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; new data gap was identified during the experts meeting; refer to point 5.4).

- Further information is necessary to refine the risk to non-target soil-macro-organisms (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 point 5.6).
- 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 point 5.7).

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, grapes and ornamentals. Full details of the GAP can be found in the list of end points.

The representative formulated products for the evaluation were 'Para Sommer', it is currently not clear what the formulation type is and a data gap is set to address this.

Methods of analysis for food items are currently not required see section 3. For environmental matrices methods are not required for groundwater and air, for surface water a method is required for alkanes (chain lengths up to C_{31}). For soil it is not concluded if a method is required or not, see sections 4 and 5.

Sufficient internationally accepted methods e.g. ASTM, ISO are available to characterise the technical material and formulated product. However, at this time the technical specification is not accepted, the method of manufacture is not known and there is no supporting batch data. Data gaps have been identified for vapour pressure and auto-flammability of the technical paraffin oil. For the formulation data gaps have been identified for flash point and emulsion stability after shelf-life storage.

During the mammalian toxicology meeting, as no technical specification was agreed by the meeting on physical and chemical properties, concerns were raised over relevant impurities generally associated with these compounds. While it is not demonstrated that no concern is raised due to the impurity profile of the substance, paraffin oil has to be classified 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 could be conducted as the experts considered that these specifications were not acceptable from the toxicological point of view.

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.

Paraffin oil has a low toxicity profile. No toxicological study was submitted or accepted. The experts agreed that no 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. Also in line with the low toxicity of paraffin oils (of high purity), no ADI, AOEL or ARfD would be proposed nor considered necessary, and no risk assessment for operators, workers and bystanders would be required.

The list of end-point 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.

The information available on the environmental fate and behaviour in the environment of this paraffin oil (primarily alkanes C_{17}-C_{31}) is considered sufficient to complete an environmental exposure assessment at the EU level with the notable exception that further information is required before the exposure assessment of sediments in water bodies adjacent to treated crops can be finalised. For the applied for intended uses the potential for groundwater exposure by alkanes up to C_{31} above the parametric drinking water limit of 0.1 µg/L for pesticides was assessed as low.

The acute risk of paraffin oil to fish was assessed as low for all the relevant scenarios. Risk mitigation measures equivalent to 25m, 3m and 1m no–spray buffer zones were necessary to refine the risk for aquatic invertebrates and alga for the pome fruit, grapevine and ornamental uses.

Standard laboratory tests were conducted with formulated ‘Para Sommer’ and the species *Coccinella septempunctata* (0 % effects on mortality; 58 % fecundity) and *Phytoseidus permisilis* on the leaves of *Phaseolus vulgaris* (69 % of mortality). Two extended laboratory studies with the standard indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* were submitted. The in field HQs values were above the Annex VI trigger values, however, off-field HQs were below the triggers. Therefore, the in-field risk should be further addressed and risk mitigation measures should be considered.

Data gaps were identified after the peer review by EFSA to address the risk to soil non-target micro-organisms and soil non-target macro-organisms.

The risk to birds and mammals, bees (with mitigation to avoid direct spraying of bees), non-target plants, biological methods of sewage treatment and earthworms was assessed as low.

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- Risk mitigation measures equivalent to 25m no spray buffer zones are necessary to protect aquatic organisms for the pome fruit use (refer to point 5.2).
- To avoid application at a time corresponding to active bee flight to mitigate any risk to bees (refer to point 5.3)

CRITICAL AREAS OF CONCERN

- There is no specification, method of manufacture or 5-batch data for this material so the identity of this paraffin oil is in question.
- The risk assessment for consumers can not be finalised.
- While it is not demonstrated that no concern is raised due to the impurity profile of the substance, paraffin oil has to be classified as **T "toxic", carcinogenic category 2, R45 "May cause cancer"**. On this basis the experts considered that these specifications were not acceptable from the toxicological point of view, and no toxicological studies were required, no ADI, AOEL or ARfD were proposed and no risk assessment for operator, worker and bystander exposure could be conducted.
- High risk was identified for aquatic organisms.
- 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.
- Information to address the in field 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 and soil non-target macro-organisms is not available.

APPENDICES

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
Function (*e.g.* fungicide)	Acaricide and Insecticide

Rapporteur Member State	Greece
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Paraffin Oil
Chemical name (CA) ‡	Paraffin Oil
CIPAC No ‡	n.a.
CAS No ‡	8042-47-5
EC No (EINECS or ELINCS) ‡	232-455-8
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	Not applicable however it should be noted that there is no specification for this paraffin oil.
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Open
Molecular formula ‡	Not available, mixture of C-chains
Molecular mass ‡	Not applicable
Structural formula ‡	Carbon range: C_{17}-C_{31}

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	-18°C
Boiling point (state purity) ‡	280 – 460°C
Temperature of decomposition (state purity)	Not applicable
Appearance (state purity) ‡	Colourless, viscous liquid, oily smell
Vapour pressure (state temperature, state purity) ‡	Open
Henry's law constant ‡	Not applicable
Solubility in water (state temperature, state purity and pH) ‡	0.01 mg/l in water
Solubility in organic solvents ‡ (state temperature, state purity)	Statement: soluble in every non polar organic solvent.
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable
Partition co-efficient ‡ (state temperature, pH and purity)	Not applicable
Dissociation constant (state purity) ‡	Not applicable
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	UV/VIS: (200nm-400nm): No conclusion can be reached
Flammability ‡ (state purity)	Open
Explosive properties ‡ (state purity)	No explosive properties (expert statement)
Oxidising properties ‡ (state purity)	No oxidising properties (expert statement)

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

Summary of representative uses evaluated (*paraffin oil*)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Pome fruits (apples, pears)	D	Para Sommer	F	spider mites	~~EC~~ ~~or~~ EW ‡	654 g/L	spraying	BBCH 10-59	1	--	1.96	500-1500	Depending on the crown height: 1m: 9.8 kg/ha 2m: 19.6 kg/ha 3m: 29.43 kg/ha	Covered by application timing	Application rate according to crown height [1]
Pome fruits (apples, pears)	D	Para Sommer	F	scales (except San Jose scale)	~~EC~~ ~~or~~ EW ‡	654 g/L	spraying	BBCH 69	1-2	10 days	1.31	500-1500	Depending on the crown height: 1m: 6.54 kg/ha 2m: 13.08 kg/ha 3m: 19.6 Kg/ha	Covered by application timing	Application rate according to crown height [1]
Stone fruits	D	Para Sommer	F	spider mites	~~EC~~ ~~or~~ EW ‡	654 g/L	spraying	BBCH 10-59	1	--	1.96	500-1500	Depending on the crown height: 1m: 9.8 kg/ha 2m: 19.6 kg/ha 3m: 29.43 kg/ha	Covered by application timing	Application rate according to crown height

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

[1]Due to the possible 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, (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants

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

	the use situation should be described (e.g. fumigation of a structure)		- type of equipment used must be indicated
(b)	Outdoor or field use (F), glasshouse application (G) or indoor application(I)	(i)	g/kg or g/l
(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds	(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
(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)		
(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
(f)	All abbreviations used must be explained		
(g)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
		(m)	Remarks may include: Extent of use/economic importance/restriction

‡ End point 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)	Open.
Impurities in technical as (analytical technique)	Open.
Plant protection product (analytical technique)	Open.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		-
Food of animal origin		-
Soil		Open
Water	surface	Alkanes (chain lengths up to C_{31})
	drinking/ground	Not required
Air		Not required
Blood		Not required

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	No analytical method is required as no residue definition is proposed.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No analytical method is required as no residue definition is proposed.
Soil (principle of method and LOQ)	No acceptable method was submitted.
Water (principle of method and LOQ)	No acceptable method was submitted.
Air (principle of method and LOQ)	Not required.
Body fluids and tissues (principle of method and LOQ)	Paraffin oil is not classified as toxic or highly toxic, no analytical method is required for its determination in body fluids and tissues.

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

	RMS/peer review proposal
Active substance	RMS proposal: 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 *stratum corneum* (skin)
Potential for accumulation ‡	Not expected to accumulate
Rate and extent of excretion ‡	It is excreted *via* 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 LD_{50} oral ‡	Low acute oral toxicity	
Rat LD_{50} dermal ‡	Low dermal toxicity	
Rat LC_{50} 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 inhalation 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-	

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)

No data – not required, not expected to be neurotoxic	
No data – not required	
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 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. Due to the chemical inertia of paraffin oil no interaction with other compounds are expected.
Studies performed on metabolites or impurities ‡	No data – not required

Medical data‡ (Annex IIA, point 5.9)

Reports form manufacturing personnel: No reports submitted Symptoms from overexposure of the general population: • *Inhalation exposure (after reconstruction of houses involving painting walls and wood):* 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) • *Oral uptake (used as laxatives in pharmacy):* transient gastrointestinal effects, resulting from irritation of pharynx, oesophagus, stomach and small intestine; the uptake in the blood system is very low. • *Dermal exposure (as creams and ointments in pharmacy and cosmetics):* 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 *via* the skin – most remaining in the *stratum corneum*

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)

	RMS/peer review proposal
Paraffin oil (CAS 8042-47-5) Staehler	Not concluded (pending on final specification)

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:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Open	Open	Open

Metabolism studies indicate potential level of residues ≥ 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 feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

No supervised trials were conducted since Paraffin Oil can be 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 (OECD data point number IIA 7.1.1)

Mineralization after 100 days	no experimental data available
Non-extractable residues after 100 days	no experime no experimental data available
Relevant metabolites- name and/or code, % of applied (range and maximum)	None

Route of degradation in soil - supplemental studies (OECD data point numbers IIA 7.1.2 and IIA 7.1.3)

Anaerobic degradation	no experimental data available
Soil photolysis	no experimental data available

Rate of degradation in soil (OECD data point numbers IIA 7.2, IIA 7.3, IIIA 9.1 and IIIA 9.2)

Method of calculation	
Laboratory studies (range or median, with n value, with r^2 value)	• 43 d in Speyer soil and • 87 d in Stutensee soil (single first order calculated by linear regression)
Degradation in the saturated zone:	no experimental data available
Field studies (state location, range or median with n value)	no experimental data available
Soil accumulation and plateau concentration	no experimental data available

Soil adsorption/desorption (OECD data point numbers IIA 7.4.1 and IIA 7.4.2)

K_F /Koc	no experimental data available
K_{doc}	no experimental data available 9086000 mL/g (QSAR estimate)
pH dependence (yes / no) (if yes type of dependence)	no experimental data available pH dependence not expected

Mobility in soil (OECD data point numbers IIA 7.4.3 – IIA 7.4.8 and IIIA 9.3.1 – IIIA 9.3.3)

Column leaching	No residues in column eluant, though the limit of analytical detection in the eluant samples was quite high at 0.59mg/L
Aged residues leaching	no experimental data available
Lysimeter/ field leaching studies	no experimental data available

PEC (soil) (Annex IIIA, point 9.1.3)

Parent in pome and stone fruit)

Method of calculation	DT_{50} 87 days (longest available) SFO kinetics

	5 cm soil depth, soil bulk density 1.5 g/cm^3
Application rate	19.6 kg a.s./ha per treatment (2); (gives a higher PEC than 1x29.43 kg a.s./ha) 40% interception to plants; 2 applications per season; 10-day interval between applications

Days after application	Actual Con. (mg/kg)	Time weighted average Con. (mg/kg)
0	30.159	30.159
1	29.920	30.039
2	29.682	29.920
4	29.213	29.684
7	28.523	29.334
14	26.976	28.538
21	25.513	27.771
28	24.129	27.032
42	21.582	25.632
50	21.582	25.632

Parent in ornamentals

Method of calculation	DT_{50} 87 days (longest available) SFO kinetics 5 cm soil depth, soil bulk density 1.5 g/cm^3
Application rate	13.08 kg a.s./ha per treatment; 25% interception to plants (leafy vegelables); 2 applications per season; 10-day interval between applications

Days after application	Actual Con. (mg/kg)	Time weighted average Con. (mg/kg)
0	25.158	25.158
1	24.959	25.058
2	24.761	24.959
4	24.369	24.762
7	23.794	24.470
14	22.503	23.806
21	21.282	23.166
28	20.128	22.550
42	18.003	21.382
50	16.892	20.751
100	11.341	17.342

Route and rate of degradation in water (OECD data point numbers IIA 2.9 & IIA 7.5 to IIA 7.9)

Hydrolysis of active substance and relevant metabolites (DT50) (state pH and temperature)	no experimental data available
Photolytic degradation of active substance and relevant metabolites	no experimental data available
Readily biodegradable (yes/no)	No
Degradation in water/sediment - DT50 water - DT90 water (20°C) - DT50 whole system - DT90 whole system	Dissipation from water surface (top 2cm) single first order DT50 0.6 to 3.6 days in a 55cm deep microcosm study.
Mineralisation	no experimental data available
Non-extractable residues	no experimental data available
Distribution in water / sediment systems (active substance)	no experimental data available as sediment was not analysed in the available microcosm study.
Distribution in water / sediment systems (metabolites)	no experimental data available

PEC (surface water) (OECD data point numbers IIIA 9.8.1 – IIIA 9.8.6)

Method of calculation	SWASH drift calculator
Application rate	Paraffin oil, 1x 29.43 kg a.s./ha pome fruit
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 = 694mg/m^2 or 2315 µg/l**
10 m buffer zone, drift rate 11.39% (early application)	**PEC initial = 335mg/m^2 or 1117 µg/l**
25 m buffer zone, drift rate 1.54% (early application)	**PEC initial = 45.2 mg/m^2 or 150.6 µg/l**

Method of calculation	SWASH drift calculator
Application rate	Paraffin oil, 1x 5.232 kg a.s./ha grapes
Main routes of entry	Drift only assessed, data gap for runoff and drainage. broadcast sprayer
3 m buffer zone, drift rate 1.72% (early application)	**PEC initial = 8.99mg/m^2 or 30 µg/l**
10 m buffer zone, drift rate 0.36% (early application)	**PEC initial = 1.89mg/m^2 or 6.3 µg/l**
25 m buffer zone, drift rate 0.086% (early application)	**PEC initial = 0.45 mg/m^2 or 1.51 µg/l**

Method of calculation	SWASH drift calculator
Application rate	Paraffin oil, 1x 13.08 kg a.s./ha ornamentals
Main routes of entry	Drift only assessed, data gap for runoff and drainage. Standard hydraulic sprayer
1 m buffer zone, drift rate 1.927%	**PEC initial = 25.2mg/m^2 or 84 µg/l**
35 m buffer zone, drift rate 0.084%	**PEC initial = 1.1mg/m^2 or 3.7 µg/l**

PEC (sediment):	Data gap

PEC (ground water) (OECD data point IIIA 9.6)

Method of calculation and type of study (*e.g.* Modelling, monitoring, lysimeter)	PELMO 3.22
Application rate	29.43 kg/ha Paraffin oil in pome/stone fruit
Application time	spring

Parameter	Paraffin oil phys.-chem. values
Molecular mass	338.67
Vapour pressure	10^{-4} Pa
Water solubility	< 0.01 mg/l
Koc	90860 (no higher value was accepted by the model)
Freundlich 1/n (default)	0.90
Plant uptake (default)	0.5
DT_{50}	65 d
Application rate	29.43 kg a.i./ha every year
Application time	default (crop scenario apples)
Crop	apples
Crop-specific values	default
all other values	default

PEC(gw)
Simulated mean concentrations of Paraffin oil in percolate after 20 years all 9 FOCUS groundwater scenarios < 0.001µg/L

Fate and behaviour in air (OECD data point numbers IIA 7.10 and IIIA 9.9)

Direct photolysis in air	Not relevant
Quantum yield of direct phototransformation	Not relevant
Photochemical oxidative degradation in air	Atkinson half life 4.15 hours (assuming OH concentration of $1.5x10^6$ molecules cm^3)
Volatilization	no experimental data available

PEC (air)

Method of calculation	Not calculated, volatilisation expected

PEC(a)

Maximum concentration	Not calculated

Definition of the Residue (OECD data point number IIA 7.11)

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 C_{31}) Surface Water: alkanes (chain lengths up to C_{31}) Sediment: alkanes (chain lengths up to C_{31}) Ground water: alkanes (chain lengths C_5 to C_{31}) Air: paraffin oil (chain lengths C_{17} to C_{31})

Monitoring data, if available (OECD data point number IIA 7.12)

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

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

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
Long term toxicity to mammals	No data available
Acute toxicity to birds	No data available
Dietary toxicity to birds	No data available
Long term toxicity to birds	No data available

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

*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
Rainbow trout	Para Sommer	acute, 96h	LC_{50}	*547 mg product/L (= 410 mg a.i./L)*
Carp	Para Sommer	acute, 96h	LC_{50}	704.13 mg product/L (=528 mg a.i./L)
Daphnia magna	Para Sommer	acute, 48h	EC_{50}	1.71 mg product /L (=1.28 mg a.i./l).
Rainbow trout	Para Sommer	Prolonged, 21d	NOEC	10 mg product /L (=7.5 mg a.i./l).

Microcosm or mesocosm tests (higher-tier data):

Microcosm:

At nominal conc. in two replicates of 98, 310, 981, 3102 and 9810 µg a.s./L, applied in semi-realistic aquatic microcosms with a sediment layer of approx. 20 cm height and overlaying water body of approx.:

Based on the most sensitive observed short-term effects on Corixidae and Phyllopoda at 310 µg/L, the total NOEC was determined to be 98 µg/L. Potential recovery of sensitive species could be demonstrated up to 3102 µg/L. Aquatic larvae of flying insects (different midges,

mayflies) were not affected. The film on the surface layer showed a quick degradation in the microcosm (DT50 around 2 days),
The experts at the PRAPeR 58 discussed about the endpoint derived in the microcosm which proposed a NOEAEC of 3102 µg a.s./L. Member States experts expressed their concern to use the NOEAEC value for risk assessment as this value is based on recovery effects, which have not been demonstrated for more than one application (according to the GAP, 2 applications are intended for some uses). The experts proposed to used the lowest NOEC as the relevant endpoint NOEC = 98 µg a.s./L.

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

Calculation Method	Buffer zonn		Maximum PEC_{SW} (µg/L)	Taxonomic group	Toxicity LC_{50} (µg/L)	TER_{st}	Annex VI Trigger
SWASH							
	3 m		2315[1]	fish	410000	177	100
	3 m		30[2]	fish	410000	13666	100
	3 m		84[3]	fish	410000	4880	100
	3 m		2315[1]	*Daphnia magna*	1280	**0.55**	100
	3 m		30[2]	*Daphnia magna*	1280	**42.6**	100
	3 m		84[3]	*Daphnia magna*	1280	**15**	100
	3 m		2315[1]	alga	7500	**3.2**	100
	3 m		30[2]	alga	7500	250	100
	3 m		84[3]	alga	7500	89.2	10
			11.460	fish	410000	35776	100
			11.458	fish	410000	35782	100
			11.460	fish	410000	35776	100

1- PECsw for pome-fruit scenario
2- PECsw for grapes
3- PECsw for ornamentals.

Microcosm

Calculation Method		Buffer zone (m)	Maximum PEC_{SW} (mg /m^2)	Taxonomic group	Toxicity EC_{50} (mg /m^2)	TER_a	Annex VI Trigger
PECsw drift	Pome fruit	3	694	Microcosm	40.5	0.05	1-3
		10	335	Microcosm	40.5	0.12	1-3
		25	45.2	Microcosm	40.5	**1**	1-3
	Grapes	3	8.99	Microcosm	40.5	**4.5**	1-3
		10	1.89	Microcosm	40.5	**21.4**	1-3
		25	0.45	Microcosm	40.5	**90**	1-3
	Ornamentals	1	25.2	Microcosm	40.5	**1.6**	1-3
		35 m	1.1	Microcosm	40.5	**36.8**	1-3

Bioconcentration

Bioconcentration factor (BCF)	No data available. Not required.
Annex VI Trigger for the bioconcentration factor	Not required
Clearance time (CT_{50}) (CT_{90})	Not required
Level of residues (%) in organisms after the 14 day depuration phase	Not required

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

Acute oral toxicity	LD_{50} >3813.655 µg prod./bee
Acute contact toxicity	LD_{50}=1474.12 µg prod./bee

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

Test substance	Exposure route	Endpoint (µg prod./bee)	Maximum single application rate (g prod./ha)	Hazard quotient	Annex VI trigger
Para Sommer	Contact	>3813.655	39537	<10.3	<50
Para Sommer	Oral	1474.12	39537	26.8	<50

Field or semi-field tests

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

Test	Test species	Dose rate	Endpoints
Laboratory test			
Para Sommer (750 g/l)	*Coccinella septempunctata*	15 l/200 l Water (7.5 %)	Mortality: 0% Fertility=58.3%
Promanal (760 g/l)	*Chrysoperla carnea*	3%	Mortality: 37.7% Fertility=31.2% E=46.9%
Extended lab test			
Para Sommer	*Typhlodromus pyri*	0.7, 1.4, 2.81, 5.62, 11.25, 22.5 and 45	LR_{50} (L/ha)=7.1 L/ha
Para Sommer	*Aphidius rhopalosiphi*	0.7, 1.4, 2.81, 5.62, 11.25, 22.5 and 45	LR_{50} (L/ha)=9.88 L/ha
Para Sommer (750 g/l)	*Phytoseiulus persimilis*	2%	Mortality: 69% E=60.6%

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
Para Sommer	*Typhlodromus pyri*	14 d	LR_{50} (L/ha)=7.1 L/ha	In field	45 L/ha	**6,34**
Para Sommer	*Aphidius rhopalosiphi*	48h	LR_{50} (L/ha)=9.88 L/ha	In field	45 L/ha	**4,55**
Para Sommer	*Typhlodromus pyri*	14 d	LR_{50} (L/ha)=7.1 L/ha	Off-field	45 L/ha	**0.72**
Para Sommer	*Aphidius rhopalosiphi*	48h	LR_{50} (L/ha)=9.88 L/ha	Off-field	45 L/ha	**1.0**

Field or semi-field tests

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

Test	Test item	Endpoint	(mg a.s./kg soil)
Acute toxicity	Para Sommer	LC_{50} $LC_{50\ corr}$	> 750 > 375
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)	Test item	Time-scale	TER	Annex VI Trigger
2 x 19.6	Para Sommer	14 d	> 12.5	10
13.08	Para Sommer	14 d	>15	10

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 terrestrial plants including toxicity/exposure ratios (Annex IIIA, point 10.8)

Test item	Test	Most sensitive species	Applic. rate kg a.s./ha	Buffer distance (meters)	Drift value [a] (%)	PEC_{drift} (kg a.s./ha)	ER_{50} (kg a.s./ha)	TER

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: R51/R53

APPENDIX B – LIST OF ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µm	micrometer (micron)
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAR	draft assessment report
DAA	days after application
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
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EbC_{50}	effective concentration (biomass)
ErC_{50}	effective concentration (growth rate)
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
EU	European Union
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
f(twa)	time weighted average factor
g	gram
GAP	good agricultural practice
GC-MS	gas chromatography-mass spectrometry
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
K_{oc}	organic carbon adsorption coefficient
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC_{50}	lethal concentration, median
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
MAF	multiple application factor
µm	micrometer (micron)
µg	microgram
mg	milligram
mL	millilitre
M/L	mixing and loading
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
OC	organic carbon content
OM	organic matter content
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{soil}	predicted environmental concentration in soil
$PEC_{sed.}$	predicted environmental concentration in sediment
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground 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 n-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
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RMS	rapporteur member state
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_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TWA	time weighted average
UV	ultraviolet

WHO	World Health Organisation
WG	water dispersible granule
W/S	water/sediment
yr	year

APPENDIX C – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
N/A		