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_{18}-C_{30}, reliable boiling point range not available)[1]

(Question No EFSA-Q-2008-682)

Issued on 19 December 2008

SUMMARY

Paraffin oil (CAS 8042-47-5, chain lengths C_{18}-C_{30}, reliable boiling point range not available), 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 30 April 2008. The peer review was initiated on 30 June 2008 by dispatching the DAR for consultation of the Member States and the sole notifier W. Neudorff GmbH 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.

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, berry fruits (except strawberry), grapes and ornamentals. Full details of the GAP can be found in the list of endpoints.

[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 C18-C30, reliable boiling point range not available). *EFSA Scientific Report* (2008) 219, 1-61.
[2] OJ L379, 24.12.2004, p.13.
[3] OJ L246, 21.9.2007, p. 19.

The representative formulated products for the evaluation were 'Promanal Neu', an oil in water emulsion (EW).

Methods of analysis for food items are currently not required see sections 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_{30}). 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 and there is no supporting batch data. Data gaps have been identified for autoflammability, flash point and a shelf-life study.

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. The specification, as proposed by the notifier, could be accepted on toxicological grounds if its high purity is confirmed by the section on physical and chemical properties. However, while this is not demonstrated, paraffin oils have 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 pharmacology or oils are 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, except an acute inhalation toxicity study in the rat. The experts agreed that no acute, short-term, long-term, genotoxicity or reproductive toxicity studies would be required, provided that no concern would be raised from the impurity profile of the substance. Paraffin oils are not considered to be genotoxic, carcinogenic, neurotoxic or toxic to the reproduction. 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 endpoint 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 C_{30} 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 very toxic to aquatic organisms. EFSA re-calculated the TERs after the expert meeting, with the new PEC_{sw} and included the values in the final list of endpoints. A high potential acute and chronic risk was identified for *Daphnia magna* for all the intended uses. Risk mitigation measures were applied to refine the risk in the grapevine and ornamental uses. However, even using the widest no-spray buffer zones (25m for streams and ditches for the pome fruit and grapevine uses and 30m for stream and ditches for the use on ornamentals), the acute and chronic TERs for *Daphnia* did not meet the Annex VI trigger values for all the intended uses, except for the acute TERs estimated for the grapevine use when a 25m no-spray buffer zone was applied. Further information is necessary to address the risk to aquatic invertebrates for all of the intended uses. The TERs for fish and alga exceeded the Annex VI trigger value based on the use of a 20m no-spray buffer zone for the pome fruit use. However, the TERs estimated for fish and alga were above the Annex VI trigger values without the use of no-spray buffer zones. The risk for fish and algae was assessed to be low for the grapevine and ornamental uses. However, mitigation measures equivalent to 20m are necessary to refine the risk for fish and alga with respect to the pome fruit use. The available information did not allow the risk to sediment dwelling organisms to be assessed.

The experts meeting agreed that, in absence of data, mitigation measures should be taken to avoid exposure to bees.

Herbicidal effects of the formulation “Promanal Neu” on vegetative vigour were investigated in tests with six plant species. The lowest ER_{50} value was observed for *Allium cepa* ER_{50} > 17.64 kg a.s./ha for vegetative vigour. The TERs were 4.8 and 5.4 for post-emergence treatments based on PECs from spray drift at 3m and 5m no-spray buffer zones, respectively.

There was no valid study evaluated in the DAR to assess the effects of paraffin oil on soil non-target macro-organisms. A data gap for information to address this issue was identified.

The risk to birds and mammals, non-target arthropods, earthworms, soil non-target micro-organisms and biological methods of sewage treatment were assessed as low.

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

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BACKGROUND

Commission Regulation (EC) No 2229/2004 laying down the detailed rules for the implementation of the fourth stage of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 1112/2002, as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Paraffin oil (CAS 8042-47-5, chain lengths C_{18}-C_{30}, reliable boiling point range not available) 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 30 April 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 sole applicant W. Neudorff GmbH 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, 1 September 2008),

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

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

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

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

This conclusion deals with paraffin oil CAS 8042-47-5 chain lengths C_{18}-C_{30}, reliable boiling point range not available. Paraffin oils are alkanes and therefore are 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 'Promanal Neu', an oil in water emulsion (EW).

The evaluated representative uses were as an insecticide and acaricide for use on pome fruit, stone fruit, berry fruits (except strawberry), 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 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 a 5-batch study are provided.

The assessment of the phys/chem data package identified 3 data gaps autoflammability, flash point and a shelf-life study. EFSA deleted the boiling range from the endpoints as the result was found to be unreliable. The boiling range was taken from the decomposition study where the test is conducted in a sealed vessel. The endotherm seen at 408-412 is not a boiling event but is likely to be some form of polymerisation. A new data gap is not necessary, as this is already covered by the specification data gap.

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,

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 sections 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 C30). 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 oil (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 generally associated with this substance. The specification as proposed by the notifier would be acceptable on toxicological grounds if its high purity can be confirmed by the section on physical and chemical properties. However while this has not been demonstrated, paraffin oil has to be classified as **T** "**Toxic**"; **carcinogenic category 2, R45** "**May cause cancer**". Such specification could not be accepted on toxicological grounds and on this basis, no toxicological studies would be required, no ADI, AOEL or ARfD would be proposed and no risk assessment of operator, worker and bystander exposure could be conducted.

Main sources of information reported in the draft assessment report came from the open literature, based on the claim that the active substance is of the same quality as the pharmaceutical form (i.e. according to the European Pharmacopoeia). Mineral oils are of variable composition depending on the boiling point of the fraction used; for food purposes usually liquid petrolatum or liquid paraffin is employed, which consists essentially of *n*-alkanes and some cyclic paraffins. Sources of mineral oil are laxatives in pharmacy or oils used in food technology as release agents, for lubrication purposes, or as a substitute for fat. Traces of *n*-alkanes are found naturally in plants.

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

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

[4] Notifier Neudorff

2.2. Acute toxicity

An acute inhalation toxicity study in rat was submitted which resulted in a 4-hour LC_{50} higher than 5.47 mg/L air. This partly confirmed the general knowledge that paraffin oil has low acute 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.

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_{18} to C_{30} 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 regarding the IR wave numbers was provided in the evaluation table. 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 a range of alkanes between $C_{19}H_{40}$ and $C_{28}H_{58}$ was estimated using quantitative structure activity relationship (QSAR) software[5]. This resulted in a calculated

[5] PCKOCWIN v1.66.

K_{doc} value of 426000[6] to 105000000 mL/g. The member state experts agreed that due to the very high adsorption value estimated that 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 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 for Paraffin oil (CAS 8042-47-5) (NOT ASU) Vol. 3)[7]. This experiment consisted of a 55 cm deep water column overlying 20cm 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 5.2% other organic 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 5.2% of this mineralisation were to have been accounted for by the other components, as a worst case only 25.8 % 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.

[6] Note in the DAR this value is incorrectly reported as 462000mL/g

[7] Member states should note that this study is not contained within the dossier provided by this applicant (Neudorff) but was provided by the applicant Stähler.

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_{18} to C_{30} 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 that just considered the spray drift route of entry to surface water and noted that some mistakes had been made in the calculations presented in the DAR. 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 (just ornamentals) recommends more than one application in a season that there will be no additive effect on water surface/water column concentrations from sequential applications. Therefore new PEC were provided for the spray drift route of entry in addendum 2 to Volume 3, Annex B.8. However, EFSA identified a few errors in these calculations as well. The values that are included in appendix A have been corrected to reflect the calculations that were requested by the member state experts. 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 2.2.2 groundwater scenario calculations were provided by the applicant for the applied for intended use on pome and stone fruit. 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. The main substance properties used as input were a single first order DT_{50} of 87 days and K_{oc} of 462000mL/g, 1/n of 0.9 (default). Whilst following EU guidance / agreed evaluation approaches a K_{oc} of 426000 mL/g and 1/n of 1 (as a QSAR estimated K_{doc} was the source of the value used) should have been used in simulations, the available modelling was accepted as demonstrating the potential for groundwater contamination would be low as a consequence of the applied for intended uses. The indications from the modelled results were that in leachate leaving the top 1m soil layer the 80th percentile annual average concentrations of alkanes up to C_{30}would be <0.001µg/L.

4.3. Fate and behaviour in air

The vapour pressure of two components of this paraffin oil are 9.23×10^{-3} Pa ($C_{22}H_{46}$) and 4.72×10^{-3} Pa ($C_{23}H_{48}$) at 25°C, indicating significant volatilisation to the atmosphere from plants, soil and surface water would be expected[8]. In section B.8.7 of Vol. 3 of the DAR for Paraffin oil (CAS 8042-47-5) (NOT ASU)[9] an estimate of the rate of breakdown of the alkane $C_{24}H_{50}$ in the upper atmosphere was provided. This estimate calculated the potential rate of breakdown via photochemical oxidative reaction with hydroxyl radicals using the Atmospheric Oxidation Program[10] 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_{18}-C_{30} alkanes would not be expected to be subject to long range atmospheric transport.

5. Ecotoxicology

Paraffin oil (CAS 8042-47-5)[11] was discussed at the PRAPeR 58 meeting of experts for ecotoxicology in October 2008, on the basis of the DAR, and the addendum 1 Volume 3 B.5-B.9.

The representative uses evaluated were as an acaricide/insecticide in pome and stone fruits, berry fruits, grapevines and woody ornamentals in field and greenhouse ornamentals.

Studies with the active substance were not available in the DAR, however due to the low water solubility of the paraffin oil, the experts at the meeting agreed that to use the plant protection product 'Promanal Neu' (546 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

No toxicity studies of paraffin oil to birds and mammals were submitted. The member states experts during the PRAPeR 58 meeting discussed the risk assessment for birds and mammals. The RMS explained in the DAR that "Promanal Neu" activity towards immobile pest stages in based on the non-toxic film-forming component paraffin oil.

[8] FOCUS (2008). "Pesticides in Air: Considerations for Exposure Assessment". Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 2008.327 pp.
[9] Member states should note that this calculation is not contained within the dossier provided by this applicant (Neudorff) but was provided by the applicant Staehler.
[10] AOPWIN v1.91
[11] Notifier Neudorff

Paraffin oils have no chemical active groups, they are in general lipophilic molecules and 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 mineral 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 "Promanal Neu" 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 pharmaceutical book. 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 consisted by 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` meeting agreed with the RMS proposal, and concluded that, even taking into account that the evaluated uses included outdoor spray application, at the maximum application rate, there was no concern for birds and mammals from oral intoxication with paraffin oil.

It was concluded that the risk for birds and mammals for 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 very toxic to aquatic organisms. Acute laboratory studies for Rainbow trout (*Oncorhynchus mykiss*), Golden Ite (*Leuciscus idus*), *Daphnia magna* and alga were presented in the DAR. A 21-day fish prolonged toxicity test was conducted with the *Salmo gairdneri*, and a reproduction test with *D. magna*. The lowest acute endpoint driving the aquatic risk assessment was observed in the studies with *D. magna*. The 48-hours EC50 for *D. magna* was 144 µg a.s./L. Results from the fish prolonged toxicity test with the 'Para Sommer' showed that at the test concentration (10 mg/L) the formulation did not show toxicity to rainbow trout.

An indoor study microcosm with the plant protection product 'Para Sommer' (containing 75% C_{17} to C_{31} alkanes) in natural sediment water systems was provided (see section B.9.2.5/01

Addendum 1 to the DAR for Paraffin oil (CAS 8042-47-5) (NOT ASU) Vol. 3)[12]. However, results of this study could not be taken into account in the present dossier due to the different composition of the 'Para Sommer' used.

The acute and chronic TERs included in the DAR were calculated based on the initial concentrations in surface water after a single application. PECs were calculated at different no-spray buffer zones, based on the worst-case scenario. However, the PEC_{sw} used to estimate the TERs for the aquatic organisms were not considered reliable by the fate and behaviour experts. Updated PEC_{sw} are presented in the list of endpoints (see Appendix A).

The PRAPeR 58 experts 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 was 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.

After the expert meeting EFSA re-calculated the TERs with the new PEC_{sw} and included the values in the updated list of endpoints (see Appendix A). Even using the widest no-spray buffer zones (25m for streams and ditches for the pome fruit and grapevines uses, and 30m for stream and ditches for the ornamental uses), the acute and chronic TERs for *Daphnia* did not meet the Annex VI trigger values for all the intended uses, except for the acute TERs estimated for the grapevine use when a 25m no-spray buffer zone was applied. Further information is necessary to address the risk to aquatic invertebrates for all of the intended uses.

The TERs for fish and alga exceeded the Annex VI trigger value based on the used of 20m and 3m non-spray buffer zones for the pome fruit use. However, the TERs estimated for fish and alga were above the Annex VI trigger values without the use of no-spray buffer zones for the uses in grapevine and ornamentals.

Overall it was concluded that the acute and chronic risk to *Daphnia magna* was assessed to be high and requires further refinement.

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

5.3. Risk to bees

No acute oral and contact toxicity studies were presented in the DAR. The experts at the PRAPeR 58 meeting agreed that, in absence of data, mitigation measures should be taken to avoid the exposure to bees.

5.4. Risk to other arthropod species

Standard laboratory studies with 'Promanal Neu' and three species of non-target arthropods, including the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*, were considered in the risk assessment. The lowest LR50 value was obtained from the *T. pyri* study (LR_{50} =5.36 kg a.s/ha).

The in-field Hazard Quotient (HQ) values were calculated as 3.05 and 0.93 for *T. pyri* and *A. rhopalosiphi*, respectively. The off-field HQs were 0.77 and 0.27 for *T. pyri* and *A. rhopalosiphi*, respectively. The in-field and off-field HQ were below the Annex VI trigger values, except for the in-field HQ for *T. pyri*.

The RMS proposed that according to the literature *T. pyri* over-winter as mated adult females on trees wherever they can find a protective site (bark crevices, spurs). Adult females only emerge from these over-wintering sites at the beginning of May. Therefore, the possible effects on *T. pyri* were negligible because 'Promanal Neu' will only be applied outdoors during the early spring.

Overall conclusion the risk to non-target arthropods was considered to be low.

5.5. Risk to earthworms

An acute toxicity study with earthworms (*Eisinea foetida*) using 'Promanal Neu' indicated a 28-d LC50 of > 733.46 mg a.s./kg. A sub-lethal study with 'Promanal Neu' was presented in the DAR. The acute and long-term TER values estimated, based on the corrected endpoint and on the use of the initial maximum PECs values, were above the Annex VI trigger values (Addendum 1).

Overall it is concluded that the acute and chronic risk to earthworms is assessed to be low for the intended uses of paraffin oil.

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

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

5.7. Risk to soil non-target micro-organisms

No effects of >25 % on soil respiration and nitrification were observed in tests with technical 'Promanal Neu' up to a concentration of 160 L/ha, indicating a low risk to soil non-target micro-organisms for the representative uses evaluated.

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

Herbicidal effects of the formulation 'Promanal Neu' on vegetative vigour were investigated in tests with six plant species. The lowest ER50 value was observed for *Allium cepa* ER50 > 17.64 kg a.s./ha for vegetative vigour. The TERs were 4.8 and 5.4 for post-emergence treatment based on PECs from spray drift at 3m and 5m no-spray buffer zones, respectively.

Member State experts expected a low drift due to the mode of application, however this should be confirmed. A data gap was identified during the PRAPeR 58 for the submission of data to confirm the assumption of low exposure due to low drift.

Fate and behaviour experts considered that the concern expressed by the experts at the PRAPeR 58 meeting (based on the mode of application of the substance the drift may be low) was not an ecotoxicological area of concern. Therefore EFSA considers that the data gap proposed in the meeting was not necessary to address the risk assessment for the non-target plants.

Overall it was concluded that risk mitigation measures, equivalent to a 5m no-spray buffer zone, are necessary to refine the high risk to non-target plants.

5.9. Risk to biological methods of sewage treatment

A study with 'HDF 200' was available, however the results of the test were not reliable because the identity of the test substance was not stated. Therefore, there were no reliable studies available to assess the potential adverse effects of paraffin oil on biological methods of sewage treatment. However, the experts during the meeting agreed that the transfer to sewage treatments should be low with the intended uses. Therefore the 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_{30})
Definition for monitoring:	a data gap needs 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_{30})
Definition for monitoring:	Not necessary

6.2.2. Surface water

Definition for risk assessment	
in surface water:	alkanes (chain lengths up to C_{30})
in sediment:	data gaps need to be filled before this can be finalised
Definition for monitoring:	alkanes (chain lengths up to C_{30})

6.3. Air

Definition for risk assessment:	paraffin oil (chain lengths C_{18}-C_{30})
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_{30})	moderate to medium persistence Single first order DT_{50} 43 and 87 days (20°C, 40%MWHC soil moisture)	Risk of paraffin oil to earthworms and soil micro-organisms was assessed to be low for the intended uses of the paraffin oil. There is a data gap to address the risk to non-target macro-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_{30})	Immobile K_{doc} for $C_{19}H_{40}$ 426000 mL/g and $C_{28}H_{58}$ 105000000 mL/g	No	Yes	No for C_5-C_{30} alkanes	Very Toxic to aquatic organism

6.6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
alkanes (chain lengths up to C_{30})	High risk was identified for the aquatic organisms.

6.6.4. Air

Compound (name and/or code)	Toxicology
paraffin oil (chain lengths C_{18}-C_{30})	Rat 4-hour LC_{50} inhalation > 5.47 mg/L air (no classification is proposed)

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 section 1).
- 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 section 1).
- Auto-flammability and flash point 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 section 1).
- Shelf life study 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 section 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 section 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 section 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)
- To refine the risk to aquatic invertebrates, further information is required (relevant for all evaluated uses; submission date proposed by the notifier: unknown ; new data gap was identified by the EFSA after the peer review refer to section 5.2)
- Further information is require to the applicant to address the risk to sediment-dwelling species should be provided (if sediment exposure cannot be excluded), (relevant for all representative uses, submission date proposed by the notifier: unknown ; data gap was identified by EFSA after the expert meeting; refer to section 5.2)
- Further information to address the risk to non-target soil-macro-organisms should be provided (relevant for all representative uses t evaluated; submission date proposed by the notifier: unknown; new data gap was identified after the experts meeting by EFSA; refer to section 5.6)

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, berry fruits (except strawberry), grapes and ornamentals. Full details of the GAP can be found in the list of endpoints.

The representative formulated products for the evaluation were 'Promanal Neu', an oil in water emulsion (EW).

Methods of analysis for food items are currently not required see sections 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_{30}). 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 and there is no supporting batch data. Data gaps have been identified for autoflammability, flash point and a shelf life study.

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. The specification, as proposed by the notifier, could be accepted on toxicological grounds if its high purity is confirmed by the section on physical and chemical properties. However, while this is not demonstrated, paraffin oils have 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 pharmacology or oils are 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, except an acute inhalation toxicity study in the rat. The experts agreed that no acute, short-term, long-term, genotoxicity or reproductive toxicity studies would be required, provided that no concern would be raised from the impurity profile of the substance. Paraffin oils are not considered to be genotoxic, carcinogenic, neurotoxic or toxic to the reproduction. 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 endpoint 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_{18}-C_{30}) 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_{30} above the parametric drinking water limit of 0.1 µg/L for pesticides was assessed as low.

Based on the available data, paraffin oil was proposed to be classified as very toxic to aquatic organisms. EFSA re-calculated the TERs after the expert meeting with the new PEC_{sw} and included the values in the final list of endpoints. A high potential acute and chronic risk was identified for *Daphnia magna* for all of the intended uses. Risk mitigation measures were applied to refine the risk in the grapevine and ornamental uses. However, even using the widest no-spray buffer zones (25m for streams and ditches for the pome-fruit and grapevine uses and 30m for stream and ditches for the ornamental uses), the acute and chronic TERs for *Daphnia* did not meet the Annex VI trigger values for all the intended uses, except for the acute TERs estimated for grapevines when a 25m no-spray buffer zone is applied. Further information is necessary to address the risk to aquatic invertebrates with respect to all of the intended uses. The TERs for fish and alga exceeded the Annex VI trigger value based on the use of a 20m no-spray buffer zone for the pome fruit use. However, the TERs estimated for fish and alga were above the Annex VI trigger values without the use of no-spray buffer zones. The risk for fish and algae was assessed to be low for the grapevine and ornamental uses. However, mitigation measures equivalent to 20m are necessary to refine the risk to fish and alga in the pome-fruit use. The available information did not allow the risk to sediment dwelling organisms to be assessed.

The experts' meeting agreed that, in absence of data, mitigation measures should be taken to avoid exposure to bees.

Herbicidal effects of the formulation 'Promanal Neu' on vegetative vigour were investigated in tests with six plant species. The lowest ER50 value was observed for *Allium cepa* ER50 > 17.64 kg a.s./ha for vegetative vigour. The TERs were 4.8 and 5.4 for post-emergence treatments based on PECs from spray drift at 3m and 5m no-spray buffer zones, respectively.

There was no valid study evaluated in the DAR to assess the effects of paraffin oil on soil non-target macro-organisms. A data gap for information to address this issues was identified.

The risk to birds and mammals, non-target arthropods, earthworms, soil non-target micro-organisms and biological methods of sewage treatment were assessed as low.

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

- Risk mitigation measures, equivalent to 20m no-spray buffer zone, are necessary to mitigate the high risk to fish and algae for the pome-fruit use. The widest no-spray buffer zone risk mitigation measures were not sufficient to refine the risk to aquatic invertebrates for all the intended uses (refer to section 5.2).
- Mitigation measures should be taken to avoid the exposure of bees (refer to section 5.3).
- Risk mitigation measures, equivalent to 5m no-spray buffer zone, are necessary to refine the high risk to non-target plants (refer to section 5.8).

CRITICAL AREAS OF CONCERN

- There is no specification or 5-batch data for this material so the identity of this paraffin oil is in question.
- The consumer risk assessment can not be finalised.
- The toxicological dossier is based on the claim that paraffin oils are similar to mineral oils used in human medicine; however, at least regarding the levels of relevant impurities, this could not be confirmed. While this is not demonstrated, the specification is not acceptable from the toxicological point of view and the substance has to be classified as **T** "**Toxic**"; **carcinogenic category 2**, **R45** "**May cause cancer**" On this basis, no reference values were established and the risk assessment for operators, workers and bystanders was not finalised.
- Information to address the risk to sediment dwellers was not available.
- Information to address the risk to soil non-target macro-organisms was 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)	Insecticide and acaricide

Rapporteur Member State	Greece
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	White mineral oil
Chemical name (CA) ‡	White mineral oil / 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 applicable
Molecular mass ‡	Not applicable
Structural formula ‡	Carbon range: C_{18}-C_{30}

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	-27.9 °C - -28.4 °C (100%)
Boiling point (state purity) ‡	Open
Temperature of decomposition (state purity)	No decomposition up to 450 °C (100%)
Appearance (state purity) ‡	Light colourless, liquid, odourless (100%)

Vapour pressure (state temperature, state purity) ‡	9.23×10^{-3} Pa (Docosane) 4.72×10^{-3} Pa (Tricosane) at 25 °C
Henry's law constant ‡	15.3×10^{6} Pa m^3/mole
Solubility in water (state temperature, state purity and pH) ‡	The water solubility of Nonadecane (highest volatile part of Paraffinic oil) was estimated at 2.97×10^{-5} mg/l.
Solubility in organic solvents ‡ (state temperature, state purity)	Practically insoluble in polar solvents like Ethanol Soluble in chlorated hydrocarbons like ether and Chloroform.
Surface tension ‡ (state concentration and temperature, state purity)	29.6 mN/m at 20 °C
Partition co-efficient ‡ (state temperature, pH and purity)	Not applicable as practical not soluble in water
Dissociation constant (state purity) ‡	Due to the low water solubility of Paraffin oil the dissociation could not be determined
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	**UV/VIS: (190nm-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)

Summary of representative uses evaluated (*paraffin oil*)

Crop and/ or situation (a)	Member State or Country	Product name	FG or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Pome fruits	D	Promanal Neu	F	spider mites, scales	EW	546 g/L	spraying	BBCH 54-56	1	--	1.09	500-1500	5.46-16.38	--	Application rate and water volume according to plant height [1]
Stone fruits	D	Promanal Neu	F	spider mites, scales	EW	546 g/L	spraying	BBCH 51-53	1	--	1.09	500-1500	5.46-16.38	--	Application rate and water volume according to plant height [1]
Berry fruits (except strawberry)	D	Promanal Neu	F	spider mites, scales	EW	546 g/L	spraying	BBCH 51-53	1	--	1.09	500	5.46	--	[1]

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		
Grapevine	D	Promanal Neu	F	Spider mites	EW	546 g/L	spraying	BBCH 01-11	1	--	0.54	800	4.368	--	
Ornamentals	D	Promanal Neu	G I	spider mites, scales, mealybugs	EW	546 g/L	spraying		2	Depending on pest (see pest column): 7 days 14 days 14 days		Depending on plant height (see remarks column): 600 900 1200	Depending on plant height (see remarks column): 6.552 9.828 13.104	--	Application rate according to plant height: <50cm 50-125cm >125cm [1]
Woody ornamentals	D	Promanal Neu	F	Spider mites scales,	EW	546 g/L	spraying	BBCH 01-09	1	--		Depending on plant height (see remarks column): 600 900 1200	Depending on plant height (see remarks column): 6.552 9.828 13.104	--	Application rate according to plant height: <50cm 50-125cm >125cm [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, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application(I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell,

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restriction

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_{30})
	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 method was submitted.
Water (principle of method and LOQ)	No method was submitted.
Air (principle of method and LOQ)	Method not fully validated.
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)

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

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Paraffin oil is widely used in the pharmaceutical and medical area as a laxative. The mechanism of action involves a physical process, where the

	faeces in the gastrointestinal tract are wrapped with a soft layer and glide to the final destination. The only interactions in the body after strong 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) Neudorff	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	Open	Open	Open

level)			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Open	Open	Open
	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 is exempted from the requirement of residues data.

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

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

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

ADI	Open
TMDI (% ADI) according to WHO European diet	Open
TMDI (% ADI) according to national (to be specified) diets	Open
IEDI (WHO European Diet) (% ADI)	Open
NEDI (specify diet) (% ADI)	Open
Factors included in IEDI and NEDI	Open

ARfD	Open
IESTI (% ARfD)	Open
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Open
Factors included in IESTI and NESTI	Open

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

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

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

Open

Chapter 5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (OECD data point IIA 7.1.1)

Mineralization after 100 days	no experimental data available
Non-extractable residues after 100 days	no experimental data available
Relevant metabolites [28]- name and/or code, % of applied (range and maximum)	None

Route of degradation in soil – anaerobic & photolysis (OECD data points IIA 7.1.2 & IIA 7.1.3)

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

Rate of degradation in soil (OECD data points IIA 7.2, IIA 7.3, IIIA 9.1 & IIIA 9.2)

Method of calculation	First order rate kinetics
Laboratory studies (range or median, with n value, with r^2 value)	• DT_{50} (20°C, aerobic): 43 d in Speyer soil and • 87 d in Stutensee soil (single first order calculated by linear regression)
	DT_{90lab} (20°C, aerobic): not reached after 100 days
	DT_{50lab} (10°C, aerobic): 191.4 days
	DT_{50lab} (20°C, anaerobic): 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 points IIA 7.4.1 & IIA 7.4.2)

K_F /K_{oc}	no experimental data available
K_{doc}	no experimental data available 426000 mL/g (for $C_{19}H_{40}$ QSAR estimate) 105000000 mL/g (for $C_{28}H_{58}$ QSAR estimate)
pH dependence (yes / no) (if yes type of dependence)	no experimental data available

Mobility in soil (OECD data points IIA 7.4.3 to IIA 7.4.8 and IIIA 9.3)

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) (OECD data point IIIA 9.4)

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	16.38 kg a.s./ha 50% crop interception assumed

PEC$_{(s)}$	Single application Actual (mg a.s./kg)	Single application Time weighted average (mg a.s. /kg)
Initial	10.92	10.92
Short term 24h	10.83	10.88
2d	10.75	10.83
4d	10.58	10.75
Long term 7d	10.33	10.62
28d	8.74	9.79
50d	7.33	9.01
100d	4.92	7.53

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	no experimental data available
Photolytic degradation of active substance and relevant metabolites	no experimental data available
Readily biodegradable (yes/no)	Not readily biodegradable
Degradation in - DT_{50} water water/sediment - DT_{90} water	no experimental data available in the dossier of this applicant Dissipation from water surface (top 2cm) single

- DT_{50} whole system - DT_{90} whole system	first order DT50 0.6 to 3.6 days in a 55cm deep microcosm study[13].
Mineralization	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 IIIA 9.7)

Calculations with the FOCUS SWASH Drift calculator for Paraffinic oil were performed in order to predict the initial concentrations of residues in static water body via spray drift.

Key application data used in the calculations

Application rate	Up to 30 L Promanal Neu corresp. to 16.38 kg Paraffinic oil/ha pome / stone fruit 4.368 kg Paraffinic oil/ha grapevine 6.552 kg Paraffinic oil/ha ornamentals<50cm
Number of applications	1/year used in all calculations as the worst case drift based on microcosm evidence that dissipation between applications occurs (Note 2 applications /year are requested for ornamentals)*
Crop:	**FOCUS crop scenario**
Pome fruit	Pome / stone fruit early
Stone fruit	Pome /stone fruit early
Berry fruits (except strawberry)	Covered by pome / stone fruit
Grapevines	Vines, early

[13] Information taken from the dossier of the applicant Staehler (see Addendum 1 to the DAR for Paraffin oil (CAS 8042-47-5) (NOT ASU) Vol. 3)

Ornamentals (multiple application), though drift value from a single application assumed in accordance with guidance	Height < 50 cm: vegetables, leafy Height > 50 cm : pome/stone fruit
Woody ornamentals	Height < 50 cm: vegetables, leafy Height > 50 cm : covered by pome/stone fruit

Drift loading onto water body ditch after application of Paraffinic oil to different crops using FOCUS drift rates

Crop scenario	**Distance from edge of field to water body [m] (FOCUS default values)**	**Drift rate [%]**	**Nominal concentration in water resulting from drift event [µg a.s./L]**	**Mass loading per drift event [mg a.s./m² of water surface area]**
Pome/stone fruit, early single application	3.5	23.5987	1288.4870	386.5461
Grapevines, early single application	3.5	1.7184	25.0197	7.5059
Ornamentals, drift for Vegetables, leafy assumed single application	1	1.9274	42.0942	12.6283

Drift loading onto water body pond after application of Paraffinic oil to different crops using FOCUS drift rates

Crop scenario	Distance from edge of field to water body [m] (FOCUS default values)	Drift rate [%]	Nominal concentration in water resulting from drift event [µg a.s./L]	Mass loading per drift event [mg a.s./m² of water surface area]
Pome/stone fruit, early single application	6	4.7297	77.4721	77.4721
Grapevines, early single application	6	0.1933	0.8443	0.8443
Ornamentals, drift for Vegetables, leafy assumed single application	3.5	0.2191	1.4353	1.4353

Drift loading onto water body stream after application of Paraffinic oil to different crops using FOCUS drift rates

Crop scenario	Distance from edge of field to water body [m] (FOCUS default values)	Drift rate [%]	Nominal concentration in water resulting from drift event [µg a.s./L]	Mass loading per drift event [mg a.s./m² of water surface area]
Pome/stone fruit, early single application	4	21.5826	1178.4116	353.5235
Grapevines, early single application	4	1.4186	20.6547	6.1964
Ornamentals, drift for Vegetables, leafy assumed single application	1.5	1.4304	**31.2391**	9.3717

Drift loadings onto water body ditch and stream after application of Paraffinic oil to different crops under consideration of buffer zones

Crop scenario	Buffer width [m]	Drift rate [%]	Nominal concentration in water resulting from drift event [µg a.s./L]	Mass loading per drift event [mg a.s./m² of water surface area]
Pome/stone fruit, early single application	10	11.3873	621.7440	186.5232
	20	2.6039	142.1709	42.6513
	25	1.5356	83.8423	25.1527
Grapevines, early single application	10	0.3606	5.2509	1.5753
	20	0.1228	1.7885	0.5366
	25	0.0865	1.2590	0.3777
Ornamentals, drift for Vegetables, leafy assumed single application	10	0.2771	6.0513	1.8154
	20	0.1440	3.1441	0.9432
	25	0.1163	2.5397	0.7619
	30	0.0976	2.1318	0.6395

Drift loadings onto water body pond after application of Paraffinic oil to different crops under consideration of buffer zones

Crop scenario	Buffer width [m]	Drift rate [%]	Nominal concentration in water resulting from drift event [µg a.s./L]	Mass loading per drift event [mg a.s./m² of water surface area]
Pome/stone fruit, early single application	10	2.9197	47.8242	47.8242
	20	0.9442	15.4666	15.4666
	30	0.4571	7.4880	7.4880
	40	0.2661	4.3586	4.3586
Grapevines, early single application	10	0.1216	0.5312	0.5312
	20	0.0598	0.2614	0.2614
	30	0.0376	0.1645	0.1645
	40	0.0265	0.1158	0.1158
	50	0.0199	0.0871	0.0871

	60	0.0157	0.0686	0.0686
	70	0.0128	0.0557	0.0557
	80	0.0106	0.0464	0.0464
Ornamentals, drift for Vegetables, leafy assumed single application	10	0.1363	0.8929	0.8929
	20	0.0910	0.5962	0.5962
	30	0.0693	0.454	0.454
	40	0.0562	0.3683	0.3683
	50	0.0474	0.3106	0.3106
	60	0.0410	0.2688	0.2688
	70	0.0362	0.2371	0.2371
	80	0.0324	0.2123	0.2123
	90	0.0293	0.1922	0.1922
	100	0.0268	0.1756	0.1756

PEC (sediment)

Method of calculation	Data gap

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	FOCUS PELMO 2.2.2. The scenario apples was used as worst-case scenario to represent the intended use of application on places with trees. Single first order soil DT50 87 days, Koc 462000mL/g 1/n 0.9
Application rate	16.38 (kg a.i./ha, once per year in 26 consecutive years, application on April 01

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 points IIA 7.10 and IIIA 9.9)

Direct photolysis in air	no data available
Quantum yield of direct phototransformation	no data available
Photochemical oxidative degradation in air	Atkinson half life 4.15 hours (assuming OH concentration of $1.5x10^6$ molecules cm^3)[14]
Volatilization	no data available

PEC (air)

Method of calculation	Not calculated, volatilisation expected

PEC (a)

Maximum concentration	Not relevant

Definition of the Residue (OECD data point IIA 7.11)

[14] Information taken from the dossier of the applicant Staehler (see DAR for Paraffin oil (CAS 8042-47-5) (NOT ASU) Vol. 3)

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_{30}) Surface Water: alkanes (chain lengths up to C_{30}) Sediment: alkanes (chain lengths up to C_{30}) Ground water: alkanes (chain lengths C_5 to C_{30}) Air: paraffin oil (chain lengths C_{18} to C_{30})

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

Soil (indicate location and type of study)	no data available
Surface water (indicate location and type of study)	no data available
Ground water (indicate location and type of study)	no data available
Air (indicate location and type of study)	no data available

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	
Long term toxicity to mammals	No data available[1]
Acute toxicity to birds	No data available[1]
Dietary toxicity to birds	No data available[1]
Long term toxicity to birds	No data available[1]

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

Application Rate (kg a.s./ha)	Category (*e.g.*, insectivorous bird)	Time-scale	ETE	TER*	Annex VI Trigger

*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
Oncorhynchus mykiss	Promanal Neu	Acute 96 hr	NOEC	100 mg product/L (= 64.6 mg a.i./L, measured)
Leuciscus idus	Promanal Neu	Acute 96 hr	NOEC	100 mg product/L (=62.7 mg product/L, measured or 40.5 mg a.i./L)
Daphnia magna	Promanal Neu	Acute 48 hr	EC_{50}	240 µg product /L (=144 µg a.i./l, nominaL).
Daphnia magna	Promanal Neu	21-day chronic	NOEC	0.0156 mg/L, nominal (=8 µg/L, measured or 5.16 µg a.i./L)
Desmodesmus subspicatus	Promanal Neu	72 hr	NOEC	100 mg product/L (nominal) (=61.8 mg product/L, measured or 39.92 µg a.i./L)

1

Toxicity/exposure ratios for the most sensitive aquatic organisms (OECD data point IIIA 10.2)
Application rate: 16.38 kg a.i./ha

Test substance	Test species	Endpoint	Result (µg a.i. /L)	Distance (m)	PECsw, i (µg a.i./L)	TER
Promanal Neu 588 g/l a.i.	*Leuciscus idus* / *Oncorhynchus mykiss*	LC50, acute static, 96 h	> 40500	5	1288.5	> 31.4
				10	621.74	> 65.14
				20	142.2	**> 284.9**
Promanal Neu 60% a.i.	*Daphnia sp.*	EC50, acute static, 48 h	144	3	1288.5	0.011|
				4	1178	0.12
				10	621.74	0.23
				20	142.2	1
				25	83.8	1.7
Promanal Neu 588 g/l a.i.	*Daphnia magna*	NOEC, long-term, semi-static	5.16 reproduction	3	1288.5	0.004
				5	1178	0.0043
				10	621.74	0.0083
				15	142.2	0.036
				20	83.8	0.06
Promanal Neu 588 g/l a.i.	*Scenedesmus subspicatus*	NOEC, 72 h, static	39920	3	1288.5	**31**

Application rate: (grapevines)

Test substance	Test species	Endpoint	Result (µg a.i. /L)	Distance (m)	PECsw, i (µg a.i./L)	TER
Promanal Neu 588 g/l a.i.	*Leuciscus idus* / *Oncorhynchus mykiss*	LC50, acute static, 96 h	> 40500	3.5	25.0197	**1618.724**

Promanal Neu 60% a.i.	*Daphnia sp.*	EC50, acute static, 48 h	144	3	25.01975.	5.75
				4	20.6547	6.971779
				10	5.2509	27.42387
				20	1.7885	80.5144
				25	1.2	**114.3765**
Promanal Neu 588 g/l a.i.	*Daphnia magna*	NOEC, long-term, semi-static	5.16 reproduction	3	25.01975.	0.2
				4	20.6547	0.25
				10	5.2509	0.98
				20	1.7885	2.9
				25	83.8	4.1
Promanal Neu 588 g/l a.i.	*Scenedesmus subspicatus*	NOEC, 72 h, static	39920	3	1288.5	**1595.5**

Application rate: ornamentals

Test substance	**Test species**	**Endpoint**	**Result (µg a.i. /L)**	**Distance (m)**	**PECsw, i (µg a.i./L)**	**TER**
Promanal Neu 588 g/l a.i.	*Leuciscus idus* *Oncorhynchus mykiss*	LC50, acute static, 96 h	> 40500	1	42.1	**961.9952**
Promanal Neu 60% a.i.	*Daphnia sp.*	EC50, acute static, 48 h	144	1	42.1	3.420428
				1.5	31.23	4.610951
				20	3.1	46.45161
				25	2.5	57.6
				30	2.13	67.6
Promanal Neu 588 g/l a.i.	*Daphnia magna*	NOEC, long-term, semi-	5.16 reproduction	3	42.1	0.12
				4	31.23	0.25

		static		20	3.1	0.852893
				25	2.5	1.664516
				30	2.13	2.6
Promanal Neu 588 g/l a.i.	*Scenedesmus subspicatus*	NOEC, 72 h, static	39920	1	**42.1**	**961.9952**

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	No data available
Acute contact toxicity	No data available

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

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

Field or semi-field tests

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

Test	Test species	Summary of design	Endpoints
Promanal Neu (56.2% w/w)	*Typhlodromus pyri*	LR_{50}, 7 d	5.36 kg a.i./ha
Promanal Neu (588 g/l)	*Aphidius rhopalosiphi*	NOEL, 48 h	17.64 kg a.i./ha

Promanal Neu (588 g/l)	*Diaeretiella rapae*	LR_{50}, 48 h	> 17.64 kg a.i./ha

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

Test substance	Test species	Time-scale	Endpoint	Exposure scenario	Exposure	HQ or TER
Promanal Neu (56.2% w/w)	*Typhlodromus pyri*	LR_{50}, 7 d	5.36 kg a.i./ha	In-crop	16.38 kg a.i./ha	**3.05**
				Off-crop*	4.78 kg a.i./ha	0.77
Promanal Neu (588 g/l)	*Aphidius rhopalosiphi*	NOEL, 48 h	17.64 kg a.i./ha	In-crop	16.38 kg a.i./ha	0.93
				Off-crop*	4.78 kg a.i./ha	0.27
	Diaeretiella rapae	LR_{50}, 48 h	> 17.64 kg a.i./ha	In-crop	16.38 kg a.i./ha	> 0.93
				Off-crop*	4.78 kg a.i./ha	> 0.27

* Off crop exposure was considered at 3 m distance, assuming 29.20% drift, an inter-specific uncertainty factor of 10 was considered for off-crop HQ calculation

** assuming a relative density of 0.91 g/cm^3 for Paraffinic Oil

Field or semi-field tests
Not required.

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

Test	Test item	Endpoint	(mg a.s./kg soil)
Acute toxicity	Promanal Neu	LC_{50} LC_{50} corr	> 733.46 > 366.73
Reproductive toxicity	Promanal Neu	NOEC NOEC corr	116.13

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
16.38 (588 g a.i./l)	Promanal Neu	14 d	> 33.58	10
16.38 (588 g a.i./l)	Promanal Neu	56 d	10.63	5

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

Nitrogen turnover, dehydrogenase activity	All effects < 25% within 28 days at rates of 32 and 160 l Promanal Neu/ha

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
Promanal Neu	Vegeta-tive vigour	*Raphanus sativus*, *Lycopersicon esculentum*, *Pisum sativum*, *Daucus carota*, *Allium cepa* and *Avena sativa*	16.38	3	29.2	4.8	>17.64	**3.69**
				5	15.73	3.3	>17.64	5.41

[a] Drift estimates are based on 90th percentile values for field crops (BBA 2000).

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: R50/R53

APPENDIX B – LIST OF ABBREVIATIONS

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

HPLC	high pressure liquid chromatography or high performance liquid chromatography
HQ	hazard quotient
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PEC_{STP}	predicted environmental concentration in sewage treatment plant
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
r^2	coefficient of determination

RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
STP	sewage treatment plant
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TWA	time weighted average
UV	ultraviolet
W/S	water/sediment
WG	water dispersible granule
WHO	World Health Organisation
yr	year

APPENDIX C – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
N/A		