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CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance paraffin oil (CAS 8042-47-5, chain lengths C_{17}–C_{31})

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Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, Greece, and co-rapporteur Member State, France, for the pesticide active substance paraffin oil are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of paraffin oil as an acaricide and insecticide on potatoes, ornamentals (flower bulbs) and orchards (pear/apple), on pome fruit and stone fruit, on field and permanent protected fruiting vegetables and on field and permanent protected roses and on citrus. The reliable end points appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are reported where identified.

KEYWORDS

acaricide, insecticide, paraffin oil, peer review, pesticide, risk assessment

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SUMMARY

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Paraffin oil is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Greece, and co-rapporteur Member State (co-RMS), France, received an application from the Paraffin oil TaskForce (including W. Neudorff GmbH KG, Belchim Crop Protection NV/SA and Comptoir Commercial des Lubrifiants) and Petroquimica Valenciana S.L. (Petroval S.L.) for the renewal of approval of the active substance paraffin oil.

An initial evaluation of the dossier on paraffin oil was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of paraffin oil according to the representative uses as an insecticide and acaricide on potatoes, flower bulbs (lily bulbs, tulip bulbs, hyacinth bulbs), orchards (pear/apple), field and permanent protected fruiting vegetables (Solanaceae, cucurbits), field and permanent protected roses, citrus (grapefruit, oranges, lemons, limes, mandarins), stone fruit (apricots, cherries, peaches, nectarines and plums) and pome fruit (apple, pear, quinces, nashi) crops as proposed at EU level result in a sufficient insecticidal and acaricidal efficacy against the target pests.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to identity, physical–chemical and technical properties of the active substance and the representative formulation and analytical methods.

In the area of **mammalian toxicology and non-dietary exposure**, the active substance is considered of low toxicity based on the available information. No critical areas of concern or issues that could not be finalised were identified.

As no hazardous properties and very low toxicity have been identified for paraffin oil, neither further exposure data nor consumer's risk assessment is required for the parent substance. With respect to the PAHs impurities, information on the proposed level or actual concentration data for PAHs in paraffin oil are not available. Once this information becomes available, a residue estimation is needed for the impurity (PAHs) using the approach based on application rate and yield rate to assess the risk to consumers from the presence of these impurities.

The data available on environmental fate and behaviour were sufficient to carry out the required **environmental exposure assessments** at EU level for the representative uses assessed.

In the area of **ecotoxicology**, low risk to birds and mammals, soil microorganisms, non-target terrestrial plants and organisms involved in biological methods for sewage treatment was concluded for all the representative uses. High risk to aquatic organisms, bees, non-target arthropods other than bees, earthworms and soil meso- and macro-fauna was indicated for some of the representative uses.

The active substance paraffin oil **does not meet the criteria for endocrine disruption** for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

BACKGROUND

Commission Implementing Regulation (EU) No 844/2012,[1] as amended by Commission Implementing Regulation (EU) No 2018/1659,[2] (hereinafter referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009.[3] This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS, Greece, and co-RMS, France, received an application from the Paraffin oil TaskForce (including W. Neudorff GmbH KG, Belchim Crop Protection NV/SA and Comptoir Commercial des Lubrifiants) and Petroquimica Valenciana S.L. (Petroval S.L.) for the renewal of approval of the active substance paraffin oil. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS (France), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on paraffin oil in the RAR, which was received by EFSA on 1 February 2021 (Greece, 2021).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, the Paraffin oil TaskForce (including W. Neudorff GmbH KG, Belchim Crop Protection NV/SA and Comptoir Commercial des Lubrifiants) and Petroquimica Valenciana S.L. (Petroval S.L.), for consultation and comments on 22 February 2022. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 23 April 2022. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicants were invited to respond to the comments received. The comments and the applicants' response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicants in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS on 24 June 2022. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in April–May 2024.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the formulation(s) for representative uses, evaluated on the basis of the representative uses of paraffin oil as an insecticide and acaricide on potatoes, flower bulbs (lily bulbs, tulip bulbs, hyacinth bulbs), orchards (pear/apple), field and permanent protected fruiting vegetables (Solanaceae, cucurbits), field and permanent protected roses, citrus (grapefruit, oranges, lemons, limes, mandarins), stone fruit (apricots, cherries, peaches, nectarines and plums) and pome fruit (apple, pear, quinces, nashi) crops, as proposed by the applicants. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for paraffin oil according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

[1]Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, pp. 26–32.

[2]Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

[3]Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, pp. 1–50.

A key supporting document to this conclusion is the peer review report (EFSA, 2024), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (4 July 2022);
- the evaluation table (31 May 2024);
- the report(s) of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Greece, 2023), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

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

The active substance and the formulation(s) for representative uses

The active substance for risk assessment is paraffin oil (CAS No 8042-47-5). There is no ISO common name for this substance. The common name used is white mineral oil (petroleum). The name used in the European Pharmacopoeia 6.0 is paraffin, light liquid -*Paraffin Perliquidum*. The active substance is a highly refined petroleum mineral oil consisting saturated hydrocarbons having carbon numbers predominantly in the range of C_{17} through C_{31}.

The formulations for representative uses supported for the evaluation were 'BCP405D/CCL742', an emulsifiable concentrate (EC) containing 802 g/L (940 g/kg) paraffin oil; 'NEU 1130 I EW' an emulsion, oil in water (EW) containing 546 g/L (600 g/kg) paraffin oil; and 'PL Paraffin oil 79% EC' an EC containing 790 g/L (940 g/kg) paraffin oil.

The information on the active substance and the formulations for representative uses, including the co-formulants in these formulations, was considered in the overall assessment during the peer review. None of the co-formulants is an unacceptable co-formulant listed in Annex III of Regulation (EC) No 1107/2009,[4] nor considered as an active substance in accordance with Regulation (EC) No 1107/2009. Details on the composition of the formulations cannot be reported in conclusions because of the provisions in Article 63(2)(d) of Regulation (EC) No 1107/2009; however, this information was fully available and evaluated during the peer review. A proposal for classification of the formulations according to Regulation (EC) 1272/2008 was provided by the applicant and assessed by the RMS (please see Volumes 3 CP of the RAR).

The representative uses evaluated for the formulation 'BCP405D/CCL742' were foliar spray applications using vehicle-mounted sprayer on potato, flower bulbs (lily bulbs, tulip bulbs, hyacinth bulbs) and orchards (pear/apple) crops against aphids as virus vectors (non-persistent viruses). The representative uses evaluated for the formulation 'NEU 1130 I EW' were foliar spray applications using vehicle-mounted sprayer (professional uses) or handheld sprayer (amateur uses) on pome fruit and stone fruit crops against scales and spider mites; on field and permanent protected fruiting vegetables (*Solanaceae, cucurbits*) crops against white flies, thrips and aphids; and on field and permanent protected roses against aphids. The representative uses evaluated for the formulation 'PL Paraffin oil 79% EC' were foliar spray applications using vehicle-mounted and handheld sprayer on citrus (grapefruit, oranges, lemons, limes, mandarins) against mites and scales and on stone fruit (apricots, cherries, peaches, nectarines and plums) and pome fruit (apple, pear, quinces, nashi) crops against scales. Full details of the good agricultural practice (GAP) can be found in the list of end points in Appendix B.

Data were submitted to conclude that the use of paraffin oil according to the representative uses proposed at EU level results in a sufficient insecticide and acaricide efficacy against the target pests, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

Conclusions of the evaluation

General aspects

With regard to the mammalian toxicity information available for the formulations for representative uses 'BCP405D/CCL742', 'NEU 1130 I EW' and 'PL Paraffin oil 79% EC', studies were performed for acute toxicity endpoints. With regard to the co-formulants contained in 'BCP405D/CCL742', 'NEU 1130 I EW' and 'Paraffin oil 79% EC', toxicological data were not available for all the components and were not assessed. Therefore, genotoxicity and repeated-dose toxicity information over the short- and long-term when assessing applications for PPP authorisation might be considered to reach a final conclusion on the safety assessment of 'BCP405D/CCL742', 'NEU 1130 I EW' and 'Paraffin oil 79% EC'. It is noted that the components are

[4]Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and Council listing co-formulants which are not accepted for inclusion in plant protection products. OJ L 74, 4.3.2021, pp. 7–26.

well below 10% in the formulations for representative use and that the available information (not covering all endpoints) on some of them in the ECHA database does not highlight concerns (see Section 10).[5]

Regarding ecotoxicology, suitable acute and chronic ecotoxicity data with the formulation for representative uses were available for the assessment of non-target organisms according to the requirements of Regulation (EU) No 284/2013,[6] except for birds and mammals. Pending on the outcome on the data gap identified in mammalian toxicology for the components in the formulations for representative uses, further consideration to non-target organisms may be necessary.[7]

1 | IDENTITY, PHYSICAL/CHEMICAL/TECHNICAL PROPERTIES AND METHODS OF ANALYSIS

The following guidance documents were followed in the production of this conclusion: European Commission (2000a, 2000b, 2010).

The proposed reference specification for paraffin oil is based on batch data from industrial scale productions. The submitted batch data complied with the criteria of the European Pharmacopoeia 6.0 for paraffin, light liquid – *Paraffinum Perliquidum*. The applicants and RMS proposed to maintain the current reference specification of the European Pharmacopoeia 6.0 for paraffin, light liquid – *Paraffinum Perliquidum*. The toxicological assessment concluded that Polycyclic Aromatic Hydrocarbons (PAHs) are relevant impurities (see Section 2). It is noted that a numerical threshold value for PAH content is not reported in the European Pharmacopoeia 6.0 specifications. A data gap is set for batch data to demonstrate compliance with the proposed PAH specification level of 0.3 mg/kg[8] and for a validated analytical method for the determination of PAH in the technical paraffin oil (see Section 10). It is noted that RMS disagreed with this data gap.[9] There is no FAO specification available for paraffin oil. It is proposed to update the reference specification from the first approval (i.e. European Pharmacopoeia 6.0 for paraffin, light liquid -*Paraffinum Perliquidum*) with the minimum purity of 1000 g/kg and PAHs as relevant impurities specified at maximum 0.3 mg/kg. The eco(toxicological) assessment supports the current and proposed reference specification (see Sections 2 and 5).

The main data regarding the identity of paraffin and its physical and chemical properties are given in Appendix B. A data gap was identified for the identity of the extraction solvent used during the manufacturing process of the technical paraffin oil by W. Neudorff GmbH KG (see Section 10). No data were provided on the surface tension at the highest in-use spray concentration of the formulation 'NEU 1130 I EW' and to demonstrate that 'NEU 1130 I EW' remains homogeneous during application (data gap, see Section 10). A data gap was set for the UV/visible absorption spectra, IR, NMR and MS spectra data for the relevant impurities' PAHs and for data on the content of relevant impurities, before and after storage, in the formulations for the representative uses (see Section 10).

Adequate methods are available for the generation of data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and in the formulation for representative uses and the impurities in the technical material. A data gap was set for validated analytical method for the determination of PAHs in the formulations for the representative uses (see Section 10).

Analytical methods for the determination of residues in plant materials, foodstuff of animal origin and drinking water are not required as no residue definitions are proposed for these matrices. Paraffin oil residues in surface water can be monitored with an GC-FID analytical method submitted by the Paraffin oil Task Force with a limit of quantification (LOQ) of 0.01 mg/L water. No monitoring method for residues in surface water was provided by the Petroquimica Valenciana S.L. (data gap, see Section 10). No analytical methods were provided for monitoring paraffin oil residues in soils, air and body fluids and tissues (data gap, see Section 10).

2 | MAMMALIAN TOXICITY

The toxicological profile of the active substance paraffin oil (CAS No. 8042-47-5) was discussed at the Pesticides Peer Review Experts' Teleconference (TC) 100 in April 2023. The assessment is based on the following guidance documents: SANCO/2012/11251-rev. 4 (EFSA, 2014b, 2017; EFSA Scientific Committee, 2011; EFSA Technical Report, 2020; European Commission, 2014b).

The current **reference specification** of the European Pharmacopoeia 6.0 for paraffin (light liquid-*Paraffinum Perliquidum*) is proposed (see Section 1). PAHs are relevant impurities in paraffin oils due to their genotoxic and carcinogenic properties. Based on the applicant and RMS proposed maximum level of 0.3 mg/kg, these were assessed for non-dietary exposure, resulting in a low concern for human health as acceptable.[10] It is noted, that no batch data were submitted to demonstrate

[5]Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.11) (EFSA, 2024).

[6]Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, pp. 85–152.

[7]Please refer to the Pesticides Peer Review Experts' TC 102 (discussion point 5.3) (EFSA, 2024).

[8]See Open point 1.3 in Section 1 Evaluation Table (EFSA, 2024).

[9]See point 1 in RMS comments on the draft EFSA Conclusion on Paraffin oil CAS 8042-47-5 (EFSA, 2024).

[10]Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.9) (EFSA, 2024).

compliance of the technical paraffin oil with the proposed PAH specification level of 0.3 mg/kg (see data gap in Sections 1 and 10).

No regulatory toxicity studies are available on paraffin oil CAS No 8042-47-5 (except one acute inhalation toxicity study in rats). Therefore, a weight-of-evidence toxicological assessment has been carried out, based on publicly available scientific publications and study reports on test materials consisting mainly of Mineral Oil Saturated Hydrocarbons (MOSH) and other substances considered appropriate surrogates.[11] In addition, the long-term use of highly purified white mineral oils in medicine, cosmetics and food[12,13,14,15] has been considered.

The oral **absorption** of MOSH in rats is estimated to account for 25% of the administered dose (based on absorption data of low doses of C_{26}–C_{29} n-alkanes and cycloalkanes, considered the most representative surrogate for this active substance).[16] **Excretion** occurs predominantly through the faecal route and secondly via urine. In the rat, MOSH have a limited **distribution** throughout the body, with the highest levels being reached in the liver, mesenteric lymph nodes and fat. **Accumulation** can occur in the same organs and tissues and it is described also in human. The main **metabolic** pathway is mediated by cytochrome P450 system, transforming alkanes into alcohols and then into the corresponding fatty acids, some of which follow the normal β-oxidation pathway; slower when the n-alkanes are branched or cyclic.

ADME studies on MOSH in the rat demonstrated notable difference in the toxicokinetic between rat strains, with Fischer-344 (F-344) showing higher bioavailability and accumulation potential as compared to Sprague Dawley (SD) rats. In vitro studies on hepatic microsomes suggest a similar metabolism of alkanes in various strain of rats and in humans, although humans would be more efficient than F-344 rats in oxidising n-alkanes.

MOSH have low **acute** toxicity by oral and dermal exposure and low acute toxicity by inhalation exposure. MOSH are neither skin or eye irritant, nor skin sensitisers. Testing for **photo(geno)toxicity** is not required as the active substance does not significantly absorb electromagnetic radiation in the range of 290–700 nm, as it would be required according to Regulation (EC) No 1107/2009.

In **short-term oral toxicity studies**, liver (micro)granulomas associated with necrotic cells, inflammatory (lymphocytic) infiltration and fibrosis were identified as MOSH-related adverse effects in F-344 rats. A no observed adverse effect level (NOAEL) of 22 mg/kg bw per day was set in F-344 female rats on the basis of a 90-day study. No adverse findings were seen in Sprague–Dawley (SD) rats and in the dog. The adverse liver findings observed in F-344 rats are of doubtful relevance to humans. Although the accumulation of mineral oils is known to occur in the liver of human following dietary intake, this is not associated to adverse histological findings, rather to lipogranulomas without relevant inflammatory component, largely asymptomatic, not progressing over years and not associated with abnormalities of clinical relevance (EFSA CONTAM Panel, 2012, 2023). Based on two **short-term inhalation toxicity studies** on SD rats, it was concluded that inhaled MOSH can induce mild responses in the lungs. The no observed adverse effect concentration (NOAEC) was determined to be 0.5 mg/L (500 mg/m^3) based on increased severity and diffuse distribution of alveolar macrophages and multifocal pneumonia at 1500 mg/m^3. The lowest observable adverse effect level (LOAEL) for **dermal local effects** is set at 125 mg/kg bw per day (adjusted for 60% paraffin content to 75 mg/kg bw per day) based on skin irritation observed in a 13-week dermal exposure study in SD rats. The NOAEL for systemic effects is 500 mg/kg bw per day based on the decrease in body weight at 2000 mg/kg bw per day (adjusted for 60% paraffin content to 300 mg/kg bw per day).[17]

The **genotoxicity** was assessed and agreed taking into account the summaries of the studies used for the REACH registration of paraffin oil (CAS No. 8042-47-5, not assessed by any authority),[18] read-across data from surrogate substances (covering the broad range of C-atoms C_{17}–C_{50} and the types of alkanes in the active substance), the data retrieved from open literature and QSAR analysis. Based on these data, the substance is considered unlikely to be mutagenic and clastogenic. It is noted that aneugenicity of the active substance was not investigated. A data gap was identified in experts' meeting and was not agreed by the RMS.[19] EFSA considers that a data waiver is acceptable for aneugenicity assessment, considering the low toxicological profile of the substance.

After **long-term exposure via oral route**, no MOSH-related chronic toxicity was identified in rats and the relevant **oral NOAELs is 1941/2291 mg/kg bw per day** based on a 2-year oral study on F-344 rats (the highest dose level tested, in males and females respectively). Following **long-term exposure via inhalation** (in SD rat, mouse, gerbil and dog), the lung was identified as target organ for chronic toxicity in SD rats and dogs, with the relevant **NOAEC set at 5 mg/m^3** in both species based on lung microgranulomas observed at a respirable aerosol concentration of 100 mg/m^3.[20]

[11]Paraffin oil can be regarded as a subclass of the MOSH group, where MOSH is an abbreviation for Mineral Oil Saturated Hydrocarbons and describes mixtures of saturated hydrocarbons derived from mineral oil through hydrogenation but without a definitive carbon range. Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.1) (EFSA, 2024).

[12]Paraffin oils are used as human medicine: https://doi.org/10.2903/j.efsa.2012.2704https://www.ema.europa.eu/en/documents/mrl-report/mineral-hydrocarbons-summary-report-committee-veterinary-medicinal-products_en.pdf.

[13]BFR, 2018. Highly refined mineral oils in cosmetics: Health risks are not to be expected according to current knowledge Updated BfR Opinion No. 008/2018 of 27 February 2018.

[14]EFSA 2023, Draft scientific opinion on the update of the risk assessment of mineral oil hydrocarbons in food.

[15]*EFSA Journal*, 2012; 10(6):2704, Scientific Opinion on Mineral Oil Hydrocarbons in Food, https://doi.org/10.2903/j.efsa.2012.2704.

[16]Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.1) (EFSA, 2024).

[17]Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.3) (EFSA, 2024).

[18]https://echa.europa.eu/it/substance-information/-/substanceinfo/100.029.500.

[19]Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.4) (EFSA, 2024).

[20]Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.6) (EFSA, 2024).

No MOSH treatment-related tumours were seen after long-term exposure in rats, and the relevant oral **NOAEL for carcinogenicity is 1941/2291 mg/kg bw per day** based on a 2-year oral study in F-344 rats (the highest dose level tested, in males and females). Although no long term-carcinogenicity study on MOSH by oral route in mice was provided, EFSA considers that such study can be waived considering: the absence of MOSH long-term toxicity/carcinogenicity in rats (via oral and inhalation routes) and mice (via dermal and inhalation routes); no evidence of cancer in humans despite the long-term use of highly purified white mineral oils in medicine and cosmetics, and the negative human epidemiology study on kerosene.[21]

Based on the available information, the substance was concluded unlikely to be carcinogenic in humans.

As regards **reproductive toxicity**, using a weight of evidence approach based on scientific literature, summaries publicly available in the REACH registration dossier on surrogate and information from a screening reproductive toxicity study on paraffin oil (CAS 8042-47-5) in SD rat after dermal application of 850 mg/kg bw per day, the substance was concluded unlikely to be a reproductive toxicant in humans. No developmental toxicity effects are expected based on a weight of evidence approach based on scientific literature indicating no concern for reproductive performance (fertility and sexual function) and development. EFSA concludes that a data waiver is acceptable for reproductive and developmental toxicity assessment considering the low toxicological profile of the substance.

The substance was concluded unlikely to be **neurotoxic or immunotoxic** in humans based on the lack of neurotoxicity or immunotoxicity in toxicity studies with MOSH via oral, dermal and inhalation routes of exposure and considering that no clinical and epidemiological evidence of adverse health effects of paraffin oil used in medicine and cosmetics is known. In addition, there is no structural similarity of paraffin oil to substances known for inducing neurotoxicity or delayed polyneuropathy.

Based on the available information, it was agreed that an acceptable daily intake (**ADI**) and an acute reference dose (**ARfD**) are not triggered based on the low toxicity of paraffin oil (CAS No 8042-47-5) in mammals, consisting of adverse liver findings observed in short-term oral toxicity studies in F-344 rats only, of doubtful significance for human. On the same basis, the derivation of acute acceptable operator exposure level (**AAOEL**) and acceptable operator exposure level (**AOEL**) was not considered necessary. Considering local adverse effects in the lungs following short-term and long-term inhalation exposure to MOSH, an acceptable operator exposure concentration (**AOEC**) was agreed at 5 mg/m^3.[22]

Based on the EFSA guidance of 2017 (EFSA, 2017), the default **dermal absorption** values were agreed to be applied i.e. 25% for the concentrate and 70% for the spray dilution of the representative products 'BCP 405D/CCL742', 'NEU 1130 I EW' and 'PL Paraffin oil 79% EC'.[23]

Based on the EFSA models (EFSA, 2014b for field uses and EFSA, 2022 for greenhouse uses), the **non-dietary inhalative exposure** estimates for the operators, workers, residents and bystanders are below the AOEC for all representative/intended uses of the three products.

3 | RESIDUES

The assessment in the residue section is based on the following guidance documents: OECD (2009, 2011), European Commission (2011) and JMPR (2004, 2007). Paraffin oil was discussed at the Pesticides Peer Review Experts' TC 103 in April 2023.

Paraffin Oil (CAS 8042-47-59) is used as insecticide/acaricide in a variety of crops including crops intended for human and/or animal consumption (potatoes, pome and stone fruits, fruiting vegetables and citrus). No residue data were submitted by the applicants who requested an exemption based on several exposure and hazard characterisation arguments. The peer review identified the need:

1. to address the issue identified with respect to content of PAHs impurities in their sources and consumers exposure and risk assessment to these impurities.
2. to address the exposure of consumers to paraffin oil resulting from the uses proposed and provide information and data that allow to check if the criteria for inclusion of paraffin oil in Annex IV of Regulation (EC) No 396/2005 are met.

The applicant presented an estimation of worst-case residues of both the impurities PAHs and the paraffin oil based on residue unit doses (RUD) following the Birds and Mammals ecotoxicology guidance document (EFSA, 2009). The use of the RUD, and hence the proposed way of calculation the exposure is considered not appropriate for human risk assessment.[24] Providing that no concern would be raised from impurities, the active substance is considered of low toxicity based on the available information and the identification of toxicological reference values has been considered not necessary for paraffin oil based on its toxicological profile (see Section 2), no further exposure data and consumer's risk assessment is required for the parent substance.

[21]Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.5) (EFSA, 2024).

[22]Risk assessment is performed considering the MAK value of 5 mg/m^3 set by the German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area for pharmaceutical white mineral oil (CAS No 8042-47-5).

[23]Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.8) (EFSA, 2024).

[24]Please refer to the Pesticide Peer Review Experts' TC 103 (discussion point 3.1) (EFSA, 2024).

With respect to the PAHs impurities, neither information on the proposed level nor actual concentration data for PAHs in paraffin oil are available (see data gap in Section 1). Therefore, in the absence of such data and eventually data on background levels of PAHs from other sources, a reliable exposure calculation is not feasible. A residue estimation is therefore requested for the impurity (PAHs) using the approach based on application rate and yield rate (data gap, see Section 9).

Provided the data gaps identified with respect to the impurities, PAHs are satisfactorily addressed and no risk to consumers is demonstrated (see data gaps in Section 1 and above in Section 3), at least one of the five criteria for inclusion into Annex IV of Regulation (EC) No 396/2005 can be considered met for paraffin oil used as insecticide/acaricide (European Commission, 2015). In particular, the compound has no identified hazardous properties and is considered to show very low toxicity (Criterion 3 met).

4 | ENVIRONMENTAL FATE AND BEHAVIOUR

Paraffin oil was discussed at the Pesticides Peer Review Experts' TC 101 in April 2023.

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, paraffin oil exhibited moderate to high persistence. No major metabolites (> 10% applied test item) were formed. Being paraffin oil, a mixture of several hydrocarbons, mainly alkanes with chain lengths in the range C_{17}–C_{31}, the expected transformation products would be several alkanes with shorter carbon chain leading to a complete mineralisation to carbon dioxide as final product. Anaerobic soil incubations studies were not considered necessary based on the proposed uses and photodegradation does not play a role in the degradation of paraffin oil in soil. For the lipophilic nature of straight chain alkanes and their very low solubility in water, paraffin oil exhibited immobility in soil estimated deriving adsorption endpoints of alkanes from C_{17} to C_{31} using quantitative structure–activity relationship (QSAR) software KOCWIN v2.00. Although, based on results from soil laboratory incubations under aerobic conditions in the dark, field dissipation studies are triggered, they are not expected to provide relevant information because of the natural and anthropogenic occurrence of *n*-alkanes in the different environmental compartments, including soil.

For the physical properties of paraffin oil (high soil adsorption, volatilisation, low density and very slightly solubility in water also in presence of emulsifiers) and the difficulty to distinguish the applied product from the background levels in the aquatic environment, provided water/sediment studies following the OECD TG 308 (OECD, 2002) were considered not reliable. However, experts during the teleconference 101 meeting[25] agreed that further information would be necessary to address the rate of degradation of paraffin oil in the aquatic environment, particularly in the sediment compartment (data gap, see Section 10). As regard the route of degradation of paraffin oil, experts agreed also for the water and sediment compartments that the transformation products are alkanes with shorter carbon chain and carbon dioxide as the final degradation product. The surface water and sediment exposure assessments [Predicted environmental concentrations (PEC)] calculations, considering the risk envelope approach for the degradation in the aquatic systems, were carried for paraffin oil using the FOCUS (2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). For the above considerations on physico-chemical properties and for the physical mode of action of paraffin oil, Step 3 (and further) calculations were deemed not appropriate because of the instantaneous partitioning to sediment considered in TOXSWA. Step 2 calculations, with a drift-only scenario, do not consider instantaneous partitioning to the sediment, and therefore were considered appropriate. PEC_{sw} and PEC_{sed} values, expressed in mg/m^2 (for NEU 1130 I EW and BCP405D/CCL742 formulations) and in µg/L and µg/kg (for all three formulations), were calculated based on worst-case default values and considering spray drift mitigation measures (i.e. non-spray buffer zones + drift reduction nozzles) applied directly to Step 2. Arithmetically correct PEC_{sw} values that have drift mitigation greater than 95% (combining buffer zones and nozzles) are available in the RAR but have not been relied on for this conclusion (and have not been included in Appendix B), as using them contravenes the relevant FOCUS (2007) guidance.

For the representative protected use in permanent greenhouses, relevant for product NEU 1130 I EW applied to fruiting vegetables and roses in permanent greenhouses, the majority of the experts agreed that the necessary surface water exposure assessments [predicted environmental concentrations (PEC)] would only need to consider 0.1% emission via spray drift (no runoff or drainage considered) toward a static water body in line with the EU-level guidance documents, excluding contributions of drainage and run-off (EFSA, 2014a).

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4.[26] The potential for groundwater exposure from the representative uses by paraffin oil above the parametric drinking water limit of 0.1 µg/L and calculated according to the risk envelope approach, was concluded to be low in geoclimatic situations that are represented by all nine FOCUS groundwater scenarios.

The applicant provided appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water. The conclusion of this consideration was that paraffin oil would not be expected to undergo any substantial transformation due to oxidation/

[25]Please refer to the Pesticide Peer Review Experts' TC 101 (discussion point 4.1) (EFSA, 2024).

[26]Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

chlorination at the disinfection stage of usual water treatment processes, as *n*-alkanes are chemically inert under common conditions. Moreover, alkanes are also naturally occurring in surface waters.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix B of this conclusion. A key to the wording used to describe the persistence and mobility of the compounds assessed can be found in Appendix C of this conclusion.

5 | ECOTOXICOLOGY

The risk assessment was based on the following documents: European Commission (2002), SETAC (2001), EFSA (2009, 2013) and EFSA PPR Panel (2013).

Paraffin oil was discussed at the Pesticides Peer Review Experts' TC 102 in April 2023.

The batches used in the regulatory dossier ecotoxicity studies were demonstrated to be in compliance with the proposed reference specification. It is noted that no batch data were submitted to demonstrate compliance of the technical paraffin oil with the proposed PAH specification level of 0.3 mg/kg (see data gap in Sections 1 and 10).

The uses of paraffin oil in fruiting vegetables and roses include uses in professional and non-professional greenhouses. For the non-professional uses, greenhouses were considered 'semi-protected' and consequently exposure of non-target organisms could not be excluded. For the professional uses in greenhouses, the applicant clarified that these are permanent structures.[27] For such uses, low risk could be concluded for birds, mammals, honeybees, non-target arthropods other than bees and non-target terrestrial plants on the basis of limited exposure.

A separate risk assessment for the professional and non-professional field uses in pome fruit, fruiting vegetables and roses with 'NEU 1130 I EW' were not available.

Toxicity studies with the active substance or any of the formulations for representative uses were not available for **birds** and **wild mammals**; therefore, no quantitative risk assessments were performed. Considering other available information, such as (i) the history of safe use of paraffin oil as food and veterinary medicine; (ii) that paraffin oils are chemically inert substrates with no toxophore group; and (iii) that the insecticidal mode of action against target organisms is physical rather than chemical, it was concluded that the acute and long-term risks to birds and wild mammals from all the representative uses of paraffin oil is low for all possible exposure scenarios.

The available data package for assessing the effects of paraffin oil on **aquatic organisms** consisted of toxicity studies for fish,[28] aquatic invertebrates and algae with at least one of the formulations for representative uses.[29] A chronic study with paraffin oil with the aquatic invertebrate *Daphnia magna* was also available. At the experts' meeting, the experts agreed that there was insufficient evidence to consider that the three formulations for representative uses were equivalent after looking at their composition.[30] Therefore, endpoints from studies with a formulation for representative uses could only be used in the aquatic risk assessment for that specific formulation. However, specific considerations were made for fish for animal welfare reasons.[31]

A mesocosm study with the formulation for representative uses 'BCP405D/CCL742' was available.[32] The experts agreed (i) that the mesocosm study could only be used in the higher tier risk assessment for the representative uses with 'BCP405D/CCL742' as extrapolation from that formulation to 'NEU 1130 I EW' and 'PL Paraffin oil 79% EC' was not sufficiently justified; (ii) that the study could cover the risk assessment for sediment-dwelling organisms; and (iii) to express the endpoint as nominal a.s./m^2 and using an ETO-RAC with an assessment of 3 for single and multiple applications (for up to six applications).[33] No fully reliable chronic studies with **sediment-dwelling organisms** were available since the studies with paraffin oil and 'BCP405D/CCL742' were categorised as supportive (i.e. to be used qualitatively) by the experts due to the lack and intermediate analytical measurements.[34]

For the representative uses with 'BCP405D/CCL742', low risk to all aquatic organisms was concluded at $FOCUS_{sw}$ Step 2 for the uses in ornamentals and in potatoes (single application at 12 kg a.s./ha) with the implementation of risk mitigation measures (5 m no-spray buffer zone or 75% drift reducing nozzles, see Table 5) whereas high risk was indicated at $FOCUS_{sw}$ Step 2 for all uses in orchards (early and late applications). For the uses in potatoes at 10 × 12 kg a.s./ha, the risk assessment

[27]For further information, see paraffin oil reporting table 5(208).

[28]The acute endpoints for fish were agreed by the experts. Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.4) (EFSA, 2024).

[29]After the Pesticides Peer Review Experts' TC 102 (EFSA, 2024), the RMS confirmed that the formulated product remained homogeneus upon agitation in the test systems and, therefore, the tier 1 risk assessment could be performed using endpoints expressed as µg/L (see discussion point 5.1).

[30]Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.4) (EFSA, 2024).

[31]The experts agreed (i) to perform a chronic risk assessment for fish for the representative uses with 'BCP405D' and 'PL Paraffin oil 79% EC' using the endpoint from the study with 'NEU 1130 I EW'; (ii) to use the acute endpoint from the study with 'BCP405D' could be used in the risk assessment for the uses with 'PL Paraffin oil 79% EC'.

[32]A mesocosm study with the representative formulation 'NEU 1130 I EW' was also available. However, considering all limitations and uncertainties identified in that study, the majority of experts agreed that the endpoint from the study could not be used in the higher tier risk assessment. Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.2) (EFSA, 2024).

[33]For the representative uses with more than six applications, the experts agreed that the applicant would need to provide an uncertainty analysis for covering both the exposure and the effect assessment. Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.3) (EFSA, 2024).

[34]Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.5) (EFSA, 2024).

for the sediment-dwelling organisms could not be finalised since no valid tier 1 studies were available and the mesocosm study did not cover the application regime (**data gap**, see Section 9).[35]

For the representative uses with 'NEU 1130 I EW', high risk to fish (either chronic or acute and chronic) and aquatic invertebrates (acute and chronic) was concluded at $FOCUS_{sw}$ Step 2 for all professional and non-professional field uses in pome/stone fruits at 2 × 6.55 kg a.s./ha, fruiting vegetables at 2 × 10.9 kg a.s./ha and roses. High acute risk to aquatic invertebrates was indicated at $FOCUS_{sw}$ Step 2 for the professional and non-professional greenhouse uses in fruiting vegetables and roses while low risk to fish (acute and chronic) and aquatic invertebrates (chronic) was indicated for such uses. The risk assessment for algae and sediment-dwelling organisms could not be finalised for any of the uses of 'NEU 1130 I EW' in the absence of valid studies (**data gap**, see Section 9).

For the representative uses with 'PL Paraffin oil 79% EC', high risk was indicated for fish, aquatic invertebrates (both acute and chronic) and algae at $FOCUS_{sw}$ Step 1 for the uses in citrus crops and in pome/stone fruits (early and late applications) while the risk to sediment-dwelling organisms could not be finalised for any of the uses in the absence of valid studies (**data gap**, see Section 9).

No major surface water and sediment metabolites were identified and, therefore, a risk assessment was not triggered.

Acute (oral and contact) toxicity studies with **bees** (*Apis mellifera*) were available with all three formulations for representative uses. A low acute risk from contact exposure was indicated for all representative uses following either the European Commission (2002) or the EFSA (2013) risk assessment schemes, except for those uses in orchards with the formulation 'BCP405D/CCL742' for which high acute contact risk was indicated following European Commission (2002). However, at the meeting, the experts considered that the standard acute contact studies (i.e. following the OECD test guideline 214) in which a 1 or 2 µL droplet of test substance is applied onto the bee thorax do not sufficiently address the risk resulting from bees being over sprayed with paraffin oil considering its physical mode of action (i.e. paraffin oil enters the insect's cuticle, dissolving the internal lipids and eventually reaching internal cell structures).[36] The experts also considered that the available semi-field (tunnel) tests (two studies with 'BCP405D/CCL742' and one study with 'PL Paraffin oil 79% EC') did not resolve the uncertainties related to the standard laboratory studies given their inconsistent results on bee mortality following test item application. Therefore, the acute risk from acute contact exposure could not be assessed for any of the representative uses of paraffin oil (**data gap**, Section 9). A low acute risk from oral exposure to paraffin oil could be concluded for all formulations for representative uses on the basis of the outcome of the European Commission (2002) and EFSA (2013) risk assessment schemes or after considering the right-censored endpoints and the closeness of the exposure/toxicity ratios to the trigger values and/or the intended time of application of paraffin oil.[37] Chronic adult and larval (22-day repeated exposure) studies with honey bees were available with 'BCP405D/CCL742' and 'PL Paraffin oil 79% EC' but not with the formulation for representative uses 'NEU 1130 I EW'. The transferability of endpoints across the different representative formulations for the risk assessment of bees was discussed at the experts' meeting.[38] The experts considered that, with the available evidence, it was not possible to properly assess the comparability between formulations and that the risk assessment for the uses with one formulation should be performed considering only endpoints derived from studies with that same formulation. The validity of the larval toxicity test on 'BCP405D/CCL742' was also discussed and confirmed at the meeting.[39] The tier 1 risk assessment indicated high chronic risk to honeybee adults for all representative uses with 'BCP405D/CCL742' whereas low chronic risk could be concluded for the uses with 'PL Paraffin oil 79% EC'. High chronic risk to honeybee larvae was indicated for all representative uses with 'BCP405D' and 'PL Paraffin oil 79% EC'. No reliable data/evidence were available to further refine the chronic risk to bees. For the representative uses with 'NEU 1130 I EW', the chronic risk assessment for bees could not be finalised in the absence of chronic and larval data with that formulation (**data gap**, Section 9).[40] A suitable assessment of accumulative and sublethal effects was not available (**data gap** for sublethal effects, see Section 10). No relevant metabolites in pollen and nectar were identified. Toxicity studies and risk assessments for non-*Apis* bees were not available.

To address the risk for **non-target arthropods other than bees**, extended laboratory studies with the formulations for representative uses 'BCP405D/CCL742', 'NEU 1130 I EW' and 'PL Paraffin oil 79% EC' were available with the standard species, *Aphidius rhopalosiphi* and *Typhlodromus pyri*, and the ladybird beetle *Coccinella septempunctata*. An extended toxicity test was also provided with the parasitic wasp *Diaeretiella rapae* and 'NEU 1130 I EW'. Aged residue studies with *A. rhopalosiphi*, *T. pyri* and *C. septempunctata* were also provided with some of the formulations. Tier 1 (glass plate) studies were not available. At the meeting, the experts discussed whether all plausible routes of exposure were sufficiently covered by the available toxicity studies considering the representative uses and the mechanical mode of action of paraffin oil.[41] The experts agreed that the available dataset, based on high tier laboratory studies where the test species had been exposed to either fresh or dried residues sprayed on glass plates or plant leaves, could be used to assess the in-field recovery of non-target arthropods. However, the experts also considered that such standard tests were not designed to evaluate potential effects

[35]Low risk to fish and aquatic invertebrates (acute and chronic) could be reached with risk mitigation measures (Table 5) for the uses in potatoes when considering six applications at 12.030 kg a.s./ha.

[36]Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.7) (EFSA, 2024).

[37]See RAR Volume 3 – B.9 (PPP) – BCP405 D and PL Paraffin oil 79% EC.

[38]Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.7) (EFSA, 2024).

[39]Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.8) (EFSA, 2024).

[40]A Member State did not share the evaluation by EFSA and the rapporteur Member State. Please refer to the Evaluation Table Section 5 Data requirement 5.13 (EFSA, 2024).

[41]Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.6) (EFSA, 2024).

of sprayed insecticides with a physical mode of action like paraffin oil in the off-field area as exposure via drift could be underestimated. Low in-field risk was concluded for the representative uses with 'BCP 405 D/CCL742' in orchards, ornamental bulbs and potatoes and for the uses with 'PL Paraffin oil 79% EC' in pome and stone fruits while high in-field risk was indicated for the uses with 'NEU 1130 I EW' in fruiting vegetables, pome and stone fruits and roses and for the uses with 'PL Paraffin oil 79% EC' in citrus crops in the absence of additional high tier studies. Considering the outcome of the experts' meeting, the off-field risk assessment for non-target arthropods other than bees could not be finalised for any of the representative uses (**data gap**; Section 9).

Chronic toxicity studies were conducted with **earthworms** (*Eisenia fetida*) and **soil meso- and macro-fauna** (the collembola *Folsomia candida* and the predatory mite *Hypoaspis aculeifer*) for the three formulations for representative uses. The relevance of the oversprayed studies with *E. fetida* as well as the selection of the endpoints and the application of a correction factor of 2 for the risk assessment for all groups of soil organisms were agreed by the experts.[42]

Based on the available data and the outcome of the tier 1 risk assessment, low chronic risk to earthworms and soil meso- and macrofauna (other than earthworms) was concluded for all representative uses, except for the field uses with 'NEU 1130 I EW' in fruiting vegetables at 2 × 10.9 kg a.s./ha (high risk identified for earthworms) and for the uses with 'BCP405D/CCL742' in potatoes at 10 × 12.26 kg a.s./ha (high risk identified for *F. candida*). The risk to earthworms could not be refined in the absence of any relevant higher tier studies.[43] A collembola field study conducted in grassland in Germany with 'BCP405D/CCL742' was available. However, after considering that some trends suggesting potential negative effects in abundance and biomass in some of the sampled species were observed even 1 year after application, the majority of experts agreed that the study could not be used for demonstrating lack of effects of 'BCP405D/CCL742' to collembolans.[44] Therefore, high risk to Collembola was concluded for the uses with 'BCP405D/CCL742' in potatoes at 10 × 12.26 kg a.s./ha.

Studies on the effects of the three formulations on **soil microorganisms** were available. Based on the available data, the risk to soil microorganisms was considered low for all representative uses.

No relevant soil metabolites were identified for paraffin oil and, therefore, a risk assessment was not triggered.

Vegetative vigour studies with the three formulations for representative uses were available to assess the risk for **non-target terrestrial plants**. On the basis of the available studies and risk assessment, low risk was be concluded for all representative uses of paraffin oil.

Low risk to organisms involved in biological methods for **sewage treatment** could also be concluded for all representative uses.

6 | ENDOCRINE DISRUPTION PROPERTIES

With regard to the assessment of the endocrine disruption (ED) potential of paraffin oil **for humans and non-target organisms** according to the ECHA/EFSA guidance (2018), this was discussed at the Pesticide Peer Review Experts' TC 102 (April 2023), where it was agreed that additional data do not appear to be scientifically necessary based on the following considerations:

- The low solubility of the substance in water makes it difficult to conduct proper testing on aquatic organisms (see Section 4);
- Paraffin oil has a physical mode of action (it acts as a physical barrier by contact) and has no chemical active group;
- the history of safe use of paraffin oil as cosmetic ingredients,[45] food[46,47] and as pharmaceutical product[48];
- in the available in vivo studies on representative surrogate of mineral oils, although of limited reliability, low mammalian toxicity is observed and no evidence of treatment-related findings on organs/tissues in the assessed EATS-mediated parameters are observed;
- There was no concern for ED activity in the available in vitro studies and in silico modelling;
- No evidence for ED properties of paraffin oil could be found in the open literature.

Based on the available information, it can be concluded that it is unlikely that paraffin oil meets the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

[42]Please refer to the Pesticide Peer Review Experts' TC 102 (discussion points 5.9 and 5.12) (EFSA, 2024).

[43]Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.10) (EFSA, 2024).

[44]Please refer to the Pesticide Peer Review Experts' TC 102 (discussion point 5.11) (EFSA, 2024).

[45]BFR, 2018. Highly refined mineral oils in cosmetics: Health risks are not to be expected according to current knowledge Updated BfR Opinion No. 008/2018 of 27 February 2018.

[46]EFSA 2023, Draft scientific opinion on the update of the risk assessment of mineral oil hydrocarbons in food.

[47]EFSA Journal, 2012; 10(6):2704, Scientific Opinion on Mineral Oil Hydrocarbons in Food, https://doi.org/10.2903/j.efsa.2012.2704.

[48]Paraffin oils are used as human medicine: https://doi.org/10.2903/j.efsa.2012.2704https://www.ema.europa.eu/en/documents/mrl-report/mineral-hydrocarbons-summary-report-committee-veterinary-medicinal-products_en.pdf.

7 | OVERVIEW OF THE RISK ASSESSMENT OF COMPOUNDS LISTED IN RESIDUE DEFINITIONS TRIGGERING ASSESSMENT OF EFFECTS DATA FOR THE ENVIRONMENTAL COMPARTMENTS (TABLES 1–4)

TABLE 1 Soil.

Compound (name and/or code)	Ecotoxicology
Paraffin oil	- High risk for the field uses with 'NEU 1130 I EW' in fruiting vegetables at 2 × 10.9 kg a.s./ha (earthworms) and for the uses with 'BCP405D/CCL742' in potatoes at 10 × 12.26 kg a.s./ha (Collembola) - Low risk for all remaining representative uses

TABLE 2 Groundwater.[a]

Compound (name and/or code)	>0.1 μg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/relevance Step 3a	Hazard identified Steps 3b and 3c	Consumer RA triggered Steps 4 and 5	Human health relevance
Paraffin oil	No	Yes	–	–	Yes

[a]Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).

[b]FOCUS scenarios or relevant lysimeter. Ranges indicated for FOCUS scenarios include the result from the model giving the highest concentration at each scenario, as needed to comply with European Commission (2014a) guidance.

TABLE 3 Surface water and sediment.

Compound (name and/or code)	Ecotoxicology
Paraffin oil	- Low risk to aquatic organisms for the uses on ornamentals and potatoes (single application of 12 kg a.s./ha) with 'BCP405D/CCL742' - High risk for all remaining representative uses[a]

[a]For those remaining uses, the risk assessment could not be finalised for some aquatic taxa.

TABLE 4 Air.

Compound (name and/or code)	Toxicology
Paraffin oil	Low acute inhalation toxicity LC_{50} > 5 mg/L

8 | PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT BY RISK MANAGERS

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

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

8.1 | Particular conditions proposed for the representative uses evaluated

TABLE 5 Risk mitigation measures (RMM) proposed for the representative uses assessed.

Representative use	'BCP405D/CCL742' on potatoes (1 × 12.26 kg a.s./ha) and ornamental bulbs
Risk to aquatic organisms	RMM equivalent to 5 m no spray buffer or 75% drift reducing nozzles[a]

[a]At $FOCUS_{sw}$ Step 2.

9 | CONCERNS AND RELATED DATA GAPS

9.1 | Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[49] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

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

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

1. The consumer dietary risk assessment could not be concluded with respect to the relevant impurities PAHs.

    a. A residue estimation is requested for the impurity (PAHs) using the approach based on application rate and yield rate (see Section 3).

2. The risk assessment for some aquatic taxa could not be concluded.

    a. Further data to address the aquatic risk to sediment-dwelling organisms (relevant for all representative uses with 'PL Paraffin oil 79% EC' and the uses in potatoes at 10 × 12 kg a.s./ha with 'BCP405D/CCL742', see Section 5) and the risk to algae and sediment-dwelling organisms (relevant for all representative uses with 'NEU 1130 I EW', see Section 5).

3. The acute risk assessment for bees from contact exposure could not be concluded.

    a. Further data are needed to address the acute risk to honeybees from contact exposure (relevant for all representative field uses and non-professional uses in greenhouses, see Section 5).

4. The chronic risk assessment for bees could not be concluded.

    a. Further data are needed to address the chronic risk for honeybee adults and larvae (relevant for all representative field uses and non-professional uses in greenhouses with formulation 'NEU 1130 I EW', see Section 5).

5. The off-field risk assessment for non-target arthropods other than bees could not be concluded.

    a. Further data are needed to address the off-field risk (relevant for all representative field uses and non-professional uses in greenhouses, see Section 5).

9.2 | Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

[49]Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, pp. 127–175.

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

No critical area of concern has been identified.

9.3 | Overview of the concerns identified for each representative use considered (Table 6)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 6.)

TABLE 6 Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios.

		BCP405D/CCL742				PL paraffin oil 79% EC			NEU 1130 I EW	
		Ornamental bulbs (Fp)	Potato (Fp)		Orchards (Fp)	Citrus (F)	Stone fruits (F)	Pome fruits (F)	Pome fruit/Stone fruit (Fp, Fn)	
Representative use		1 × 12.26 kg a.s./ha	10 × 12.26 kg a.s./ha	1 × 12.26 kg a.s./ha	1 × 32.68 kg a.s./ha	1 × 23.70 kg a.s./ha	1 × 11.85 kg a.s./ha	1 × 11.85 kg a.s./ha	2 × 6.55 kg a.s./ha	1 × 6.55 kg a.s./ha
Operator risk	Risk identified									
	Assessment not finalised									
Worker risk	Risk identified									
	Assessment not finalised									
Resident/ bystander risk	Risk identified									
	Assessment not finalised									
Consumer risk	Risk identified									
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Risk to wild non-target terrestrial vertebrates	Risk identified									
	Assessment not finalised									
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	X[a]	X[a,c]	X[a]	X[a]	X[a,b]	X[a]	X[a]	X[b]	X[b]
	Assessment not finalised	X[3,5]	X[3,5]	X[3,5]	X[3,5]	X[3,5]	X[3,5]	X[3,5]	X[3,4,5]	X[3,4,5]
Risk to aquatic organisms	Risk identified		X		X	X	X	X	X	X
	Assessment not finalised		X[2]			X[2]	X[2]	X[2]	X[2]	X[2]
Groundwater exposure to active substance	Legal parametric value breached									
	Assessment not finalised									
Groundwater exposure to metabolites	Legal parametric value breached									
	Parametric value of 10 µg/L breached									
	Assessment not finalised									

(Continues)

TABLE 6 (Continued)

Representative use		NEU 1130 I EW								
		Fruiting vegetables (Fp, Fn)		Fruiting vegetables (Gp)		Fruiting vegetables (Gn)		Roses (Fp, Fn)	Roses (Gp)	Roses (Gn)
		2×10.9 kg a.s./ha	1×10.9 kg a.s./ha	2×6.55 kg a.s./ha	1×6.55 kg a.s./ha	2×6.55 kg a.s./ha	1×6.55 kg a.s./ha	1×10.9 kg a.s./ha	1×6.55 kg a.s./ha	1×6.55 kg a.s./ha
Operator risk	Risk identified									
	Assessment not finalised									
Worker risk	Risk identified									
	Assessment not finalised									
Resident/ bystander risk	Risk identified									
	Assessment not finalised									
Consumer risk	Risk identified									
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Risk to wild non-target terrestrial vertebrates	Risk identified	X	X	X	X	X	X	X	X	X
	Assessment not finalised									
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	X[b,c]	X[b]			X[b]	X[b]	X[b]		X[b]
	Assessment not finalised	X[3,4,5]	X[3,4,5]			X[3,4,5]	X[3,4,5]	X[3,4,5]		X[3,4,5]
Risk to aquatic organisms	Risk identified									
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]
Groundwater exposure to active substance	Legal parametric value breached									
	Assessment not finalised									
Groundwater exposure to metabolites	Legal parametric value breached									
	Parametric value of 10 µg/L breached									
	Assessment not finalised									

Note: The superscript numbers relate to the numbered points indicated in Section 9.1.

Abbreviations: F, field uses; Fn, non-professional field uses; Fp, professional field uses; Gn, non-professional greenhouse uses; Gp, professional greenhouse uses.

[a]High chronic risk identified for bees based on the EFSA (2013) guidance document.

[b]High in-field risk identified for non-target arthropods other than bees.

[c]High risk identified for soil organisms.

10 | LIST OF OTHER OUTSTANDING ISSUES

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

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

- For all the components of the formulations for representative uses 'BCP405D/CCL742', 'NEU 1130 I EW' and 'Paraffin oil 79% EC', genotoxicity and repeated-dose toxicity information over the short- and long-term was not available; therefore, in order to allow a final conclusion on the safety assessment of 'BCP405D/CCL742', 'NEU 1130 I EW' and 'Paraffin oil 79% EC', genotoxicity and repeated dose toxicity data for the components (short and long term) might be considered for further assessment (to be confirmed by Member States; when assessing applications for PPP authorisation; relevant for all representative uses evaluated; see Section 'General aspects').

- Batch data to demonstrate compliance of technical paraffin oil with the proposed specification PAH level of 0.3 mg/kg (relevant for all representative uses, see Section 1).
- Data on the identity of the extraction solvent used during the manufacturing process of the technical paraffin oil by W. Neudorff GmbH KG (see Section 1, relevant for the representative uses of the product 'NEU 1130 I EW').
- Data on the surface tension at the highest in-use spray concentration i.e. 6.7% (v/v) of the formulation 'NEU 1130 I EW' and data to demonstrate that 'NEU 1130 I EW' remains homogeneous during application (relevant for the representative uses of the formulation 'NEU 1130 I EW', see Section 1).
- UV/visible absorption spectra, IR, NMR and MS spectra data for PAHs (data gap relevant for all representative uses, see Section 1).
- Data on the content of PAHs, before and after storage, in the formulations for the representative uses (data gap relevant for all representative uses, see Section 1).
- Validated analytical methods for the determination of PAHs in the technical paraffin oil and the formulations for the representative uses (relevant for all representative uses, see Section 1).
- An analytical method for monitoring paraffin oil residues in surface water (relevant for Petroquimica Valenciana S.L. and the representative uses of the formulation 'PL PARAFFIN OIL 79% EC', see Section 1).
- Analytical methods for monitoring paraffin oil residues in soil, air, body fluids and tissues (relevant for all representative uses, see Section 1).
- Reliable data on the rate of degradation of paraffin oil in the aquatic environment, particularly in the sediment compartment (relevant for all representative uses, see Section 4).
- Proposed additional soil degradation study including the kinetic assessment was not provided by the applicant Petroquimica Valenciana S.L. (relevant for applicant PTQ and the representative uses of the formulation 'PL PARAFFIN OIL79% EC', see Evaluation Table Section 4 in the peer review report EFSA, 2024).
- Further data are needed to address the risk to honeybees from sublethal effects (relevant for all representative field uses and non-professional uses in greenhouses, see Section 5).

ABBREVIATIONS

1/*n*	slope of Freundlich isotherm
a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
CI	confidence interval
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
ECHA	European Chemicals Agency
EEC	European Economic Community
f(twa)	time-weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
HQ	hazard quotient
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification
mm	millimetre (also used for mean measured concentrations)
mN	milli-Newton
MRL	maximum residue level
MS	mass spectrometry
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment

PEC_{sw}	predicted environmental concentration in surface water
pF2	pF value of 2 (suction pressure that defines field capacity soil moisture)
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TG	test guideline
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
TWA	time-weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water-dispersible granule
WHO	World Health Organisation

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CONFLICT OF INTEREST
If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR
European Commission

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APPENDIX A

Consideration of cut-off criteria for paraffin oil according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[a]
CMR	Carcinogenicity (C)	Paraffin oil CAS 8042-05 is unlikely to be carcinogenic according to point 3.6.3 of Annex II of Regulation (EC) 1107/2009 based on the available information and the assessment carried out. It is noted that a data gap has been established regarding the levels of relevant impurities (PAHs)
	Mutagenicity (M)	Paraffin oil CAS 8042-05 is unlikely to be mutagenic according to point 3.6.2 of Annex II of Regulation (EC) 1107/2009 based on the assessment carried out. It is noted that a data gap has been established regarding the levels of relevant impurities (PAHs)
	Toxic for Reproduction (R)	Paraffin oil CAS 8042-05 is unlikely to be carcinogenic according to point 3.6.3 of Annex II of Regulation (EC) 1107/2009 based on the available information and the assessment carried out. It is noted that a data gap has been established regarding the levels of relevant impurities (PAHs)
Endocrine disrupting properties		Endocrine disruption (ED) assessment for the EATS-modalities was agreed to be waived based on an overall weight of evidence. This included the low toxicity of paraffin oil (CAS No 8042-47-5) in mammals, the lack of accumulation in endocrine organs, the lack of evidence from the open literature for endocrine disrupting effects from paraffin oil either directly with an endocrine disrupting mode of action or indirectly through accumulation in endocrine organs or tissues, and QSAR data. Regarding endocrine activity, there is no information in the US-EPA Chemicals Dashboard on thyroid modality[b]
POP	**Persistence** **Bioaccumulation** **Long-range transport**	Paraffin oil is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009
PBT	**Persistence** **Bioaccumulation** **Toxicity**	Paraffin oil is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009
vPvB	**Persistence** **Bioaccumulation**	Paraffin oil is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009

[a]Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

[b]Please refer to the Pesticide Peer Review Experts' TC 100 (discussion point 2.10) (EFSA, 2024).

APPENDIX B

List of end points for the active substance and the formulation(s) for representative uses

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2024.8913.

APPENDIX C

Wording EFSA used in Section 4 of this conclusion, in relation to DT and Koc 'classes' exhibited by each compound assessed

Wording	DT_{50} normalised to 20°C for laboratory incubations[a] or not normalised DT_{50} for field studies (SFO equivalent, when biphasic, the DT_{90} was divided by 3.32 to estimate the DT_{50} when deciding on the wording to use)
Very low persistence	< 1 day
Low persistence	1 to < 10 days
Moderate persistence	10 to < 60 days
Medium persistence	60 to < 100 days
High persistence	100 days to < 1 year
very high persistence	A year or more

Note: These classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

[a]For laboratory soil incubations, normalisation was also to field capacity soil moisture (pF2/10 kPa). For laboratory sediment water system incubations, the whole system DT values were used.

Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0–50
High mobility	51–150
Medium mobility	151–500
Low mobility	501–2000
Slight mobility	2001–5000
Immobile	> 5000

Note: Based on McCall et al. (1980).

APPENDIX D

Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChiKey	Structural formula
Not applicable		