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Global Mineral Oil Regulations, Guidance Documents, Standards, etc...

This document is meant to provide members with

General Articles of Potential Interest

- [How Registrations Prove Lubricants Are Food Grade](#)
- [Food-Grade Lubricants and ISO 21469 Certification](#)
- [The Importance of Registrations to Food-Grade Lubricant End Users](#)
- [Mineral oils are safe for human health?](#)
- [Mineral oil hydrocarbons in food: a review](#)
- [Incidental contact lubricants for the food industry](#)
- [Food-Grade Lubricants Explained](#)

APAC

Australia/New Zealand

- [Analytical survey of mineral oil hydrocarbons in food and food packaging](#)
- [“Australia New Zealand Food Standards Code – Schedule 18 – Processing aids”](#) includes the use of “mineral oil based greases” as lubricants at GMP.

Hong Kong

- [Mineral Oil in Food Regulations](#) prohibits the sale of food with mineral oil as an ingredient, but if its inclusion is due to its use as a lubricant “on some surface with which the article of food has necessarily to come into contact in the course of its preparation” then it is ok as long as “the amount of mineral oil contained in any article of food does not exceed 0.2 parts by weight of mineral oil per 100 parts by weight of the article of food.”

Malaysia

- Per [179 General standard for edible fat and edible oil of the Malaysian Food Regulations 1985](#), “It shall not contain any mineral oil or any non-food grade fat or oil.”

Singapore

- Per the [Sale of Food Act \(Chapter 283, Section 56\(1\)\)](#), “mineral hydrocarbon means any hydrocarbon product, whether liquid, semi-liquid or solid, derived from petroleum or synthesized from petroleum gases and includes odourless light petroleum hydrocarbons, white mineral oils, halogenated hydrocarbons, petroleum jellies, hard paraffins and micro-crystalline waxes.” Mineral hydrocarbons are not to be used in the composition or preparation of any article of food intended for human consumption, and no foods containing any mineral hydrocarbon are to be sold for human consumption. A relevant exemption exists as follows, “by reason of the use of mineral hydrocarbon as a lubricant or greasing agent on some surface with which that food has necessarily to come into contact during the course of preparation if that food contains by reason thereof not more than 0.2 part by weight of mineral hydrocarbon per 100 parts by weight of the food.”

EUROPE

- [Proposed Draft Commission Regulation amending Regulation \(EU\) 2013/915 as regards maximum levels of mineral oil aromatic hydrocarbons \(MOAH\) in food](#)
 - [Annex](#)
 - [28 June 2024 News Alert](#)
 - [FAQ document on the draft regulatory measures on mineral oil hydrocarbons \(MOHs\) in food](#)
- [EFSA Panel on Contaminants in the Food Chain \(CONTAM\); Update of the Risk Assessment of Mineral Oil Hydrocarbons in Food. EFSA Journal 2023; 21\(9\):1–143.](#)
- [EFSA Panel on Contaminants in the Food Chain \(CONTAM\); Scientific Opinion on Mineral Oil Hydrocarbons in Food. EFSA Journal 2012;10\(6\):2704.](#)
- European Commission, Joint Research Centre, Bratinova, S., Hoekstra, E., Robouch, P., Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials – In the frame of Commission Recommendation (EU) 2017/84, Publications Office of the European Union, 2023, <https://data.europa.eu/doi/10.2760/963728>
- European Commission, Joint Research Centre, Hoekstra, E., Bratinova, S., Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials, Hoekstra, E.(editor), Bratinova, S.(editor), Publications Office, 2019, <https://data.europa.eu/doi/10.2760/208879>
- [Clarifications on the joint statement of 21 April 2022 of the Member States regarding the presence of Mineral Oil Aromatic Hydrocarbons in food, including food for infants and young children](#)
 - At the Standing Committee on Plants, Animals, Food and Feed, section Novel Food and Toxicological Safety of the Food Chain on 19 October 2022, the Member States agreed on some additional clarifications to the statement of 21 April 2022.
 - [Standing Committee on Plants, Animals, Food and Feed Section Novel Food and Toxicological Safety of the Food Chain 19 October 2022; Summary Report](#)
- [Joint statement of the Member States regarding the presence of Mineral Oil Aromatic Hydrocarbons \(MOAH\) in food, including food for infants and young children](#)
 - Following a request from Member States to define harmonised limits of quantification, the Standing Committee on Plants, Animals, Food and Feed, section Novel Food and Toxicological Safety of the Food Chain of 21 April 2022 issued a statement on the enforcement of MOAH in food, in which they agreed on uniform limits of quantification.
 - [Standing Committee on Plants, Animals, Food and Feed Section Novel Food and Toxicological Safety of the Food Chain 21 April 2022; Summary Report](#)

- [Commission Recommendation \(EU\) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food](#)
- [Commission Regulation 1333/2008](#) on food additives lays down rules of additives in food. It uses a positive list system; only the indicated substances in Annex II and III can be used, and only for specific applications. White mineral oils are not listed and cannot be used as food additives in the EU, not even following the “Carry-over” principle (section 18, 1 of EC Reg 1333 2008). Certain paraffin oils and microcrystalline waxes can be used for specific purposes (and not for encapsulation or dietary supplements).
- Note that EFSA published a Scientific Opinion in 2009 “[Use of high viscosity white mineral oils as food additive](#)“, in which applications for high viscosity mineral oil are proposed, including its use in capsules and tablets of concentrates of flavourings, spices, condiments nutrients excluding confectionary, as well as special dietary food, but only as firming agent, preservative and glazing agent. We are not aware that the EC has approved these proposed uses for white mineral oils, which in any case do not specify the use as lubricants in encapsulation or other steps in the formulation of omega-3 oils (bottling, complex formulations). The Scientific Opinion indicated that mineral oil exposure exceeds the ADI, and this may be the reason that mineral oils are not permitted as food additives in the EU.
- The BLL (German Spitzenverband der Lebensmittelwirtschaft, now called [Lebensmittelverband Deutschland](#), or German Food Federation), developed a mitigation guidance document “[Toolbox for Preventing the Transfer of Undesired Mineral Oil Hydrocarbons into Food](#)” (2017), which indicates that in the case of predictable food contact, mineral oils should not be used, and only vegetable oils or substances according to Commission Regulation 1333/20008 should be used (for the purpose of machine lubrication or as release/anti-sticking agents).

NO.	SOURCE	ROUTE OF ENTRY/ CAUSE	SUBSTANCE	NOTES/EXAMPLES	REFERENCE
e	Release agents Anti-sticking agents	Paraffin oils or white oils for machine maintenances or as release oils for bakery moulds and sheets	MOSH/MOAH MOSH analogues (MORE)	Use of medicinal white oils; in the case of predicable food contact, only vegetable oils or substances according to Regulation (EC) No 1333/2008 are permitted.	

- Lebensmittelverband Deutschland (Food Federation Germany) recently (Dec 2023) published an updated set of benchmark levels for MOH in foods - [link](#)

United Kingdom

- [The Mineral Hydrocarbons in Food Regulations 1966](#) bans the use of mineral oil as a direct food additive. It is not known (*to be checked*) if this was also implemented in the EU. Before this regulation, mineral/white oil was used as processing aid/food additive for bread cutting,

and as confectionery release agent (jelly cubes etc.). In the EU, mineral oils are clearly not permitted to be in direct use with food – meaning as a lubricant for gelatin in soft gel capsules. But potential, incidental, food contact is currently possible.

NORTH AMERICA

Canada

- [Food and Drug Regulations](https://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf) permit the use of mineral oil as a food additive for specific food uses, but it doesn't appear that it is approved for use as a general lubricant with incidental food contact at a maximum level
https://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf

United States

- Per [21 CFR 172.878](#), white mineral oil may be safely used in food in accordance with the conditions outlined in the regulation. Among its permitted uses and associated limitations are the following:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
As a release agent, binder, and lubricant in or on capsules and tablets containing concentrates of flavoring, spices, condiments, and nutrients intended for addition to food, excluding confectionery	Not to exceed 0.6% of the capsule or tablet
As a release agent, binder, and lubricant in or on capsules and tablets containing food for special dietary use	Not to exceed 0.6% of the capsule or tablet

- Per [21 CFR 178.3570](#), mineral oil is permitted for use as a lubricant with incidental food contact as long as the addition to food does not exceed 10 ppm. Mineral oil “may be may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.”
- Per [21 CFR 178.3620](#), mineral oil may be safely used as a component of nonfood articles intended for use in contact with food, provided it meets the specifications prescribed in § 172.878 of chapter 21 and such use complies with any applicable limitations in parts 170 through 189 chapter 21. The use of white mineral oil in or on food itself, including the use of white mineral oil as a protective coating or release agent for food, is subject to the provisions of § 172.878 of chapter 21.

SOUTH AMERICA

Chile

Per Article 152 of [REGLAMENTO SANITARIO DE LOS ALIMENTOS DTO. N° 977/96](#), mineral oil (high, medium and low viscosity) (INS# 905a, d, e, f, g) may be used as

waterproofing additives or coating substances with a maximum limit of 3 g/kg. This regulation does not permit the use of mineral oil for direct addition to food.

Standards

- ISO 21469 2006 - Safety of machinery - Lubricants with incidental product contact - <https://www.iso.org/standard/35884.html>

Certification Schemes

- [NSF](#) (USA)
- [2Probity](#) (Sweden)

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