

To whom it may concern

Hamburg, 11th April 2023

Medicinal White Oils in the Foodstuffs and Cosmetic Industry

1. General

- Manufacturer/Delivery company: **Hansen & Rosenthal GmbH & Co. KG
Am Sandtorkai 64
20457 Hamburg
GERMANY**
- Raw material class: Pharmaceutical white oil according to Ph. Eur. USP latest edition
(Synonym: Paraffinum Liquidum, Food-grade white oil, Liquid Paraffin, White mineral oil),

2. Information about the manufacturing process

- Original raw material: Petroleum
- Description of the manufacturing process: Distillation, solvent extraction, dewaxing, high pressure hydrogenation (two-stage), batch-charge

Due to the manufacturing process no residues e.g. of solvents or catalysts are to be expected. The purity fulfils the requirements according to United States Pharmacopeia/National Formulary, European Pharmacopoeia, most recent edition and JECFA Monographs Vol. 4.

3. Description

Pharmaceutical white oils are not fluorescent, colourless, tasteless and odourless substances, which are used both in the pharmaceutical and cosmetic industry as well as in the food industry. The permission is country-specific. Fundamental technologic characteristics are:

- Chemically stable, pharmaceutical oils are substantially inert, except for the contact with strong oxidizing agents
- Resistant against hydrolytic degradation and autoxidation. This feature leads to above-average shelf life and a very low reactivity.
- The thermal stability is given under normal conditions of use.

- Free of preservatives, antioxidants, dye stuffs, complexation agents, organic solvents, heavy metals, silicones
- Very good separation of water and air
- Barrier effect against water evaporation or oxygen transfer
- Sterile due to its water content < 100 ppm
- It acts hydrophobic and inhibits the formation of microbiological organisms.
- Very good skin compatibility. Very low viscosities (e.g. less than 10 cSt/40 °C) may cause skin irritation. Toxic adverse effects are not known
- Application as optimal lubricant, defoamer, glossing agent and form release agent (the permission is country-specific).

4. Statutory regulations

4.1. EU

Framework Regulation (EC) 1935/2004 (replacing Framework Directive 89/109/EEC) determines requirements to be met by materials intended to come into contact with foodstuffs.

While this EU-Regulation contains general provisions applicable to all food contact materials, e.g. §17 on traceability, it refers to implementation measures containing the details for individual materials e.g. 2002/72/EC Plastics Directive which was replaced by the so called PIM (= EU Plastics Regulation 10/2011) on May 1st, 2011 and amended as Commission Regulation 1282/2011 on 28.11.11 and 1183/2012 on 30.11.2012. White mineral oils are listed and specified in Annex I, which means white mineral oils are permitted for the use in plastics for food contact applications according to Ref. No. 95883, see pt. 5, information about ADI values.

Most food contact materials or substances – other than plastics – like paper, elastomers, glass, metal, wood (including cork), textiles, adhesives, pigments, paraffin waxes are not yet covered by binding EU regulatory (Directive, Legislation). The risk assessment of these substances in regards of compliance with Framework Regulation (EC) 1935/2004 needs to be based on the respective national regulations or other regulatory information, e.g. non-binding EU Resolutions, national standards like the German BfR Recommendations for food contact materials (plastics, paper, rubbers, etc.) or other relevant standards, e.g. guidelines on printing inks, paper etc.

For lubricants related to food technology there is a standard European EN ISO 21469 “Security of machine lubricants with no foreseeable product contact – hygiene requirements (ISO 21459:2006)”.

In Annex A (informative) the national/international sources of approved substances for hygienic product contact are listed.

The first source is a JECFA Database: High viscosity medical white oil (see specification in 5.1 Current status regarding ADI for medicinal white oils with viscosity higher than Class I) is allowed as an additive with functional use as lubricant if the requirements of JECFA monograph for "Mineral Oil (High Viscosity from 1995 and updated in 2004) are met.

Another source is "United States Code of Federal regulation (CFR) part 21, § 178.3570, (see also item 4.4 USA)

4.2. COSMETICS EUROPE Recommendation No 14 dated 17.09.2018

This recommendation concerns mineral oil products as raw material for cosmetic lip care products, which are likely to be ingested in a significant manner.

This document is based on the scientific opinion issued by the Joint Expert Committee on Food additives (JECFA) of WHO in 2002 and 2012 and finally confirmed by European Food Safety Authority (EFSA) in 2013. White mineral oils (high viscosity and class I, see specification under section 5) have the allowance for this use. In the new version the purity criteria according to Ph. Eur. have been added to the specifications. Our products PIONIER 2071 and PIONIER 1115 are suitable for this use.

4.3. Germany

The German Food and Feed Code (LFGB) became effective as from 7th September 2005, replacing the German Food and Other Commodities Act (LMBG) from 1974 which is the German Framework legislation for feed, food and food contact materials. The corresponding implementation measure for details on food contact and consumer goods is the consumer goods legislation / ordinance BG-VO (= Bedarfsgegenstände-Verordnung).

In regards of food contact materials the more detailed provisions for compliance have been covered by the BfR Recommendations (earlier BGVV, before that: BGA), which have the legal status of a national standard = non-binding regulatory information. The BfR recommendations had been used and widely accepted to show compliance with relevant paragraphs of the corresponding German Framework legislation LMBG (later LFGB). BfR Recommendations are still applicable for those substances and materials which are not yet covered by binding EU law, e.g. catalysts, colorants, paper, rubbers etc.

Paraffin oils whose purity complies with the Article 155 of the BGA (now BfR), the DAB and the Ph. Eur. are permitted.

4.4. USA

The regulations of the American Food and Drug Administration FDA 21 CFR §178.3620 concerning the purity criteria a), b) or c) are valid for use in the range of indirect food contact.

The intended uses as additive for food packaging or production aid agent for food manufacturing are assigned through cross-reference to further paragraphs.

Lubricants with incidental food contact are subject to the paragraph FDA 21 CFR §178.3570. "Mineral oil" is listed with a maximal concentration of 10 ppm in foods.

The approval according to FDA 21 CFR §172.878 for direct food contact is given if the white oil is used as additive, as e.g. preservative for eggs (max. 0,1 %) and dried fruits (max. 0,02 %), anti-dusting agent for wheat, maize and other cereals (max. 0,02 %), mould releasing agents (max. 0,3 %) or bakeries (max. 0,15 %), etc.

Our products Pionier 2071 P and Pionier 4281 have been NSF (Nonfood Compounds Registration Program) registered as follows:

Produkt	Kategoriecode	Verwendung
PIONIER 2071 P	3H	"Release agents"
PIONIER 2071 P	H1	"Lubricants with incidental food contact"
PIONIER 2071	3H	Release agents
PIONIER 2071	H1	Lubricants with incidental food contact
PIONIER 2076 P	3H	"Release agents"
PIONIER 2076 P	H1	"Lubricants with incidental food contact"
PIONIER 2076	3H	Release agents
PIONIER 2076	H1	Lubricants with incidental food contact

The products registered in the category code 3H as "Release Agents" (food processing substances) are used on grills, loaf pans, cutters, boning benches, chopping boards, or other hard surfaces in contact with meat and poultry food products to prevent food from adhering during processing.

The category code H1 "Lubricants with incidental food contact" is related to preparations permitted for use as lubricants and anti-rust agents, or as release agents on gaskets or seals of tank closures, where there is possibility of incidental food contact shall be formulated in compliance with 21 CFR § 178.3570 and other sections referenced therein.

These listings can be viewed online: <http://info.nsf.org/USDA/Listings.asp?Company=C0227705>

The certificates of the registered products are available on demand.

5. Information about Acceptable Daily Intake (ADI) values:

In 1995 SCF = Scientific Committee for Food (now EFSA = European Food Safety Authority), of the European Commission tested the security of mineral oils and synthetic hydrocarbon oils and waxes intended for use as food additives, at food processing and for use in food packaging material. For

mineral hydrocarbon products, which in the course of 90-day study with rats showed no or minimum accumulation and no toxicity, SCF determined a temporary group-ADI-value of 0–4 mg/kg weight for white paraffinic oils.

SCF	
Temporary ADI 0– 4 mg/kg for medicinal paraffinic white oils with the following specification:	
Viscosity	> 8,5 mm ² /s at 100 °C
C-number after 5 % distillation	> 25 after 5 % distillation
Molecular weight	> 480

The Regulation (EC) No. 10/2011 (PM/Ref. 95883) adopts this recommendation. It refers to mineral oils approved for the manufacturing of plastics for food packaging.

The EFSA Journal published on 17 January 2013 established a group ADI of 12 mg/kg bw/day for the “medium viscosity mineral oil” (MVMO) with a kinematic viscosity between 8,5 – 11 mm²/s at 100°C.

This publication confirmed also the evaluation of a group ADI of 12 mg/kg bw/day for the “high viscosity mineral oil” (HVMO) with a kinematic viscosity > or = 11 mm²/s at 100 °C from EFSA Journal 2009, see 5.1.1. This exposure assessment supersedes the previous assessment of HVMO performed by the ANS Panel in 2009 (EFSA, 2009).

The Panel considered the dietary exposure to MVNO and/or HVMO with a typical range from 0,9–5,2 mg/kg bw/day for the proposed uses across all population groups. High intake estimates a range from 1,6–10,1 mg/kg bw/day.

The level of polycyclic aromatic hydrocarbons (PAHs) is based on the maximum limit for benzo(a)pyrene of 50 µg/kg in accordance with the PAH limit set for E905 microcrystalline wax (EU Regulation 231/2012). Related to the ADI of 12 mg/kg bw/day, a daily exposure of less than 0,5 ng/kg bw/day of benzo(a)pyrene results, which is of no concern compared to the estimated median of 3,9 ng/kg bw/day of benzo(a)pyrene. The last value is derived from the Scientific Opinion of EFSA Panel on Contaminants in the Food Chain on PAHs in food

Also the Joint FAO (Food and Agriculture Organization of the United Nation)/WHO (World Health Organization) – (JECFA= Expert Committee on Food Additives) published ADI values (Mineral oil Monographs, February 1995, June 1998, June 2002 and June 2012) and describe specifications for medicinal oils as follows:

JECFA Monograph dated June 2012, INS No 905e	
Prepared at the 76 th JECFA (2012), published in FAO JECFA Monograph 13.	
An ADI 0–10 mg/kg (was established at the 59 th JECFA meeting) for medicinal white oils Class I with the following specifications:	
Viscosity	8,5 – 11 mm ² /s at 100 °C
C-number after 5 % distillation	> 25 after 5 % distillation
Boiling point after 5 % distil off	> 391 °C
Molecular weight	480 – 500

JECFA dated 4–13 June 2002
temporary ADI 0–0,01 mg/kg until 2006 for medicinal white oils Class II with the following specifications:

Viscosity	7,0 – 8,5 mm ² /s at 100°C
C-number after 5 % distillation	> 22 after 5 % distillation
Boiling point after 5 % distil off	> 356 °C
Molecular weight	400 – 480

JECFA dated 4–13 June 2002
temporary ADI 0–0,01 mg/kg until 2006 for medicinal white oils Class III with the following specifications:

Viscosity	3,0–7,0 mm ² /s at 100°C
C-number after 5 % distillation	> 17 after 5 % distillation
Boiling point after 5 % distil off	> 287 °C
Molecular weight	300 – 400

At the 76th JECFA meeting on the 5–14 June 2012 the temporary ADI for medium and low viscosity mineral oil, Class II and Class III were withdrawn. Therefore these products are not permitted to be used as a food additive or in lip care products.

Our products PIONIER 2071 and PIONIER 1115 are in accordance with the specifications of the JECFA monograph 13 (2012) class I for medicinal white oils.

5.1. Current status regarding ADI for medicinal white oils with viscosity higher than Class I

5.1.1. EFSA

EFSA determines fixed acceptable daily intake (ADI) of 12 mg per kg weight per day for white mineral oils of higher viscosity:

EFSA Journal 2009 ADI 12 mg/kg for medicinal paraffinic white oils with the following specifications:	
Viscosity	≥ 11 mm ² /s (cSt) at 100 °C
C-number after 5 % distillation	> 28 after 5 % distillation
Molecular weight	> 500
Purity	see methods

The ADI value is based on NOAEL-value of 1200 mg per kg weight per day, the highest dose level tested in a long-term study on toxicity and carcinogenicity at F344 rats, in which the uncertainty factor of 100 was applied. At white mineral oils, this ADI value replaces the temporary group-ADI-value of 0–4 mg per kg weight per day, which was previously determined by SCF for white paraffinic oils manufactured from raw materials on the basis of mineral oil hydrocarbons.

5.1.2. JECFA

An ADI of 0–20 mg/kg was established at the 44th JECFA (1995) for white mineral oils of higher viscosity, INS No 905e

JECFA Monograph 1 (2006)
Prepared at the 44th JECFA (1995), published in FNP 52 Add.3 (1995). Metal and arsenic specifications revised at the 63rd JECFA (2004) additional to the following specifications:

Viscosity	≥ 11 mm ² /s (cSt) at 100 °C
C-number after 5 % distillation	> 28 after 5 % distillation

Molecular weight	> 500
Boiling point after 5 % distil off	> 422 °C
Purity	see methods

Functional uses: release agent, lubricant, protective coating

6. MOSH and MOAH

Our products are derived from mineral oil refining. They consist of predominantly saturated hydrocarbon classes and small residual amounts of aromatic hydrocarbons, which are characteristic due to the origin of the products. There are two types of aromatic hydrocarbons. The 3–7 rings polycyclic aromatic hydrocarbons, which are potentially carcinogenic and completely removed during the refining process and the 1–2 rings highly alkylated aromatics (mono- and di- aromatics), which are harmless. This residual amount of aromatic hydrocarbons is extremely low, ensured by the purity tests done according the USP, Ph.Eur. and FDA.

The terms MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons) have their origin in the detection of traces of mineral oils in food. They were used to describe chromatographic peaks in food analysis. The MOSH and MOAH fractions are also found in products other than mineral oil. For example, C23– C33 n-alkanes are present in fruits, vegetables or edible oils up to 100 mg/kg.

The traces of mineral oils could be caused by uncontrolled sources, e.g. from manufacturing or packaging or from products lawfully used and permitted according to legislation.

For these reasons the MOSH and MOAH terms are confusing, they do not correspond to the mineral oil products placed on the market, but the presence of the fractions is practically unavoidable. Because they are only traces, the only established method for quantifying MOSH and MOAH is with LC/GC–FID. This method allows the separation of aliphatic (MOSH) and aromatic (MOAH) hydrocarbons. We see a further characterisation of the aromatic components, in particular a differentiation between the determination or quantification of the 1–2 rings of highly alkylated aromatics and 3–7 rings of polycyclic aromatic hydrocarbons as necessary for an accurate risk assessment.

Available test results of MOSH and MOAH are mostly based on house methods of the test institutes. Therefore, we can't make any certification or specification of the MOAH content in our products, available data is from single tests and not validated. We recommend specifying the content of polycyclic aromatic compounds by the compliance with pharmaceutical monographs (USP, Ph. Eur.) or FDA.

We feel obliged as a manufacturer and supplier to ensure that our products do not endanger the health of the consumer. Through different projects in various committees, we work to ensure that health risks will also be ruled out with certainty in the future. More information related to this issue can be found under the following links:

“Mineraloils are safe for human health?” (PDF)

<https://nextcloud.hur.com/index.php/s/RA5PZEHFJQLXkAs> (Password: Hur-PS-2023)

“Mineral oils–from cradle to clean” (Video)

<https://nextcloud.hur.com/index.php/s/424ag3XX2t9fdb3> (Password: Hur-PS-2023)

According to the BfR Opinion No. 008/2018 of 27.02.2018 (Federal Institute for Risk Assessment), there is no health concern by using highly purified mineral oil based products:

<https://www.bfr.bund.de/cm/349/highly-refined-mineral-oils-in-cosmetics-health-risks-are-not-to-be-expected-according-to-current-knowledge.pdf>

BfR published in January 2020 the Article “Mineral oil in food, cosmetic products, and in products regulated by other legislations” in Critical Reviews in Toxicology ([DOI: 10.1080/10408444.2019.1694862](https://doi.org/10.1080/10408444.2019.1694862)) Here are the conclusions on the safety of MOSH and MOAH:

“Evidence from more recent autopsy and biopsy studies, along with information on decreasing food contamination levels, indicates a low risk for adverse hepatic lesions that may arise from the retention of MOSH in the liver. With respect to MOAH, at present there is no indication of any carcinogenic effects in animals dermally or orally exposed to highly refined mineral oils and waxes. Such products are used not only in cosmetics but also in medicinal products and as additives in food contact materials. The safety of these mineral oil-containing products is thus indirectly documented by their prevalent and long-term use, with a simultaneous lack of clinical and epidemiological evidence for adverse health effects.”

7. Further information

H&R Company supplies a wide range of petroleum products: white oils, base oils, paraffin waxes, petroleum jellies, bitumen, etc.

Please consult our web site <https://www.hur.com/en/> for more information and do not hesitate to contact us. We help you to find your customized speciality.

Daniela Heber, Product Safety

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