

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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PARAFFINUM LIQUIDUM

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Paraffin, liquid Paraffinum liquidum Paraffine, vloeibaar Paraffine liquide Dickflüssiges Paraffin
N° CAS:	8042-47-5
N° EC:	232-455-8

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FRAVER NV Keizershoek 336 2550 Kontich Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

The product is not classified as hazardous according to Regulation (EC) No 1272/2008.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Physico-chemical properties: Contaminated floors become exceptionally smooth.

Environmental properties: The product can form an oil film on the water surface, which can stop oxygen exchange.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Paraffin, liquid
IUPAC name:	Not available.
Synonyms:	Mineral oil White mineral oil (petroleum)
N° CAS:	8042-47-5
N° EC:	232-455-8
Molecular Formula:	Not available.
Content:	100% Purified mixture of liquid saturated hydrocarbons obtained from petroleum.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	If symptoms are severe or persistent, seek medical or emergency assistance immediately.
After inhalation:	Move the victim to fresh air and put him in a position where he can breathe comfortably. If breathing has stopped, give artificial respiration.
After skin contact:	Wash immediately with soap and plenty of water and remove all contaminated clothing and shoes. Wash contaminated clothing before reuse.
After eye contact:	Rinse immediately with plenty of water. After initial rinsing, remove contact lenses, if any, and continue rinsing for at least 15 minutes. Keep eyes open while rinsing.
After ingestion:	Clean mouth with water. Do not induce vomiting. Never give a drink (or food) to an unconscious person. Immediately call a physician or poison control centre.
Self-protection of the first aider:	First aiders must protect themselves. See section 8 for further details. Do not apply mouth-to-mouth resuscitation if the victim has swallowed or inhaled the substance; apply artificial respiration using a mask fitted with a one-way valve or other correct medical respirator.

4.2 Most important symptoms and effects, both acute and delayed

Contact with eyes: Not classified based on available data.

Skin contact: Not classified based on available data.

Inhalation: Not classified based on available data. Inhalation of vapours in high concentrations may cause irritation of the respiratory organs.

Ingestion: Not classified based on available data. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor: Treat symptomatically.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Carbon dioxide (CO ₂), ABC powder, foam, water spray or water mist.
Unsuitable extinguishing media:	Do not use a solid water stream as it may explode and spread the fire.

5.2 Special hazards arising from the substance/mixture

Incomplete combustion and thermolysis can produce gases of varying toxicity such as CO, CO₂, various hydrocarbons, aldehydes and soot. These can be very dangerous when inhaled in closed spaces or at high concentration.

5.3 Advice for firefighters

Surrounding fires:	Cool containers/tanks with water spray. Combustion residues and contaminated extinguishing water must be disposed of in accordance with local regulations.
Protection against fire:	Wear self-contained breathing apparatus and protective clothing.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Do not touch or walk through spilt material. Contaminated floors become extremely slippery. Use personal protective equipment. Ensure adequate ventilation. Remove all ignition sources.

For emergency responders

Do not touch or walk through spilt material. Contaminated floors become extremely slippery. Use personal protective equipment. Ensure adequate ventilation. Remove all ignition sources.

6.2 Environmental precautions

The product must not contaminate groundwater. Prevent leakage into waterways, sewers, basements or confined spaces. In case of significant leaks which cannot be contained, the local authority must be informed.

6.3 Methods and material for containment and cleaning up

Methods for containment: Containment to collect large spills of liquids. If necessary, contain the product with dry earth, sand or equivalent non-combustible materials.

Methods of cleaning up: Dispose of contents/container in accordance with local regulations. In case of soil contamination, remove the contaminated soil for treatment or disposal in accordance with local regulations.

6.4 Reference to other sections

Personal protective equipment: See section 8 for more details.
Waste treatment: See section 13 for more details.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Hygiene measures: Strict health conditions must be observed by personnel likely to come into contact with the product. Do not eat, drink or smoke when using. Wash hands before every break and immediately after using the product. Clean equipment, workplace and clothing regularly. Do not use paint stripper, solvent or fuel.
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Personal protection:

Do not wipe hands with used cleaning rags. Do not put rags soaked with products into the pockets of work clothing.

For personal protection, see section 8.

Technical protective measures:

Fire and explosion prevention: Take precautions against static electricity discharges.

Handling:

Use only in well-ventilated areas. Do not inhale vapours or spray mist. Avoid contact with eyes, skin and clothing.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Store in a walled-in area. Store in tightly closed packaging. Store preferably in the original packaging: when changing packaging, attach all hazard labels, if any, to the new packaging. Do not remove any hazard labels from the (also empty) packaging.

Conditions for safe storage, including any incompatibilities:

Keep away from food, drink and animal feed. Installations should be designed in such a way that accidental spillage (e.g. due to a defective seal) of product on hot engine covers or electrical contacts is avoided. Store at room temperature. Protect from moisture.

Materials to avoid: Strong oxidising agents.

Storage – away from:

Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure limits

Mineral oil fog: USA: OSHA (PEL) TWA 5 mg/m³, NIOSH (REL) TWA 5 mg/m³, STEL 10 mg/m³, ACGIH (TLV) TWA 5 mg/m³ (heavily refined)

DNEL Employee (industrial/professional)

Long-term, systemic effects: 220 mg/kg/8h (dermal); 160 mg/m³/8h (aerosol - inhalation)

DNEL Consumer

Long-term, systemic effects: 92 mg/kg/8h (dermal); 35 mg/m³/8h (aerosol - inhalation); 40 mg/kg/24h (oral)

8.2 Exposure controls

Appropriate engineering control

Apply engineering measures to comply with occupational exposure limits. Ensure adequate ventilation, especially in confined areas. When working in confined spaces (tanks, containers, etc.) provide breathing air and appropriate protective equipment.

General information individual protection measures: Protective technical solutions must be implemented and used before personal protective equipment is considered. The recommendations for personal protective equipment apply to the product AS SUPPLIED. In case of mixtures or formulations, it is recommended to consult the suppliers of the personal protective equipment.

Individual protection measures

Eye/face protection: If there is a risk of splashes, wear: Safety glasses with side-shields. EN 166.

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Skin protection:	Wear suitable protective clothing. Protective shoes or boots. Long-sleeved clothing. Type 4/6.
Hand protection:	Hydrocarbon-tight gloves: Fluorinated rubber. Nitrile rubber. In case of prolonged contact with the product, it is recommended to wear gloves complying with EN 420 and EN 374 standards that protect for at least 480 minutes and have a thickness of at least 0.38 mm. These values are only indicative. The level of protection is determined by the glove material, the technical characteristics, the resistance to chemicals handled, the correct use and the frequency of replacement. Observe the instructions regarding permeability and drenching time, as provided by the supplier of the gloves. Also take into account specific local conditions of use, such as danger of cuts, wear and tear and contact time.
Respiratory protection:	None under normal use. When exposed to concentrations above the exposure limit, sufficient approved respiratory protection must be worn. Respiratory mask with combination filter for vapour/dust particles (EN 14387). Type A/P1. Attention: The filters have a limited duration of use. Respiratory equipment must be used in strict accordance with the manufacturer's instructions and the regulations governing selection and use.
Thermal hazards:	Not determined.
Environmental exposure control	
The product must not run off into sewers, watercourses or soil.	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Colourless, transparent, oily liquid, free from fluorescence in daylight.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	Not applicable.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	> 240 °C (method: ASTM D 92) > 464 °F (method: ASTM D 92)
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	0.870 (15 °C)
Solubility:	Slightly soluble in ethanol (96 per cent), miscible with hydrocarbons.
Solubility in water:	Practically insoluble in water.

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Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Kinematic: 68 mm ² /s (40 °C)
Explosive properties:	Non-explosive.
Oxidising properties:	Not applicable.

9.2 Other information

Density: 870 kg/m³ (15 °C)
Possibility of hazardous reactions: None with normal handling.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None in normal processing.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions have been observed under normal conditions of use.

10.4 Conditions to avoid

Keep away from naked flames, hot surfaces and sources of ignition.
Keep away from heat and sparks.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

Incomplete combustion and thermolysis can produce more or less toxic gases such as CO, CO₂, various hydrocarbons, aldehydes, etc., as well as soot. Other decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ : > 5000 mg/kg bw (rat) Skin (conditions) LD ₅₀ : > 2000 mg/kg bw (rabbit) Inhalation LC ₅₀ (4h): > 5000 mg/m ³ air (aerosol) (rat)
Skin corrosion/irritation:	Not classified based on available data.
Serious eye damage/irritation:	Not classified based on available data.
Respiratory/skin sensitisation:	Not classified based on available data.
Germ cell mutagenicity:	Not classified based on available data.
Carcinogenicity:	Not classified based on available data.
Reproductive toxicity:	Not classified based on available data.

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Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not classified based on available data.
STOT-repeated exposure:	Not classified based on available data.
Aspiration Hazard:	Not classified based on available data.
Other:	Other adverse effects: Characteristic skin lesions (rash) may occur as a result of prolonged and repeated contact, including with contaminated clothing.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not classified based on available data.
Skin contact:	Not classified based on available data.
Inhalation:	Not classified based on available data. Inhalation of vapours in high concentrations may cause irritation of the respiratory organs.
Ingestion:	Not classified based on available data. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not classified based on available data.

Acute aquatic toxicity - data on ingredients

Toxicity to algae: EL_{50} (48h) > 100 mg (*Pseudokirchnerella subcapitata* - OECD 201)

Toxicity to daphnia and other aquatic non-diverse species: EL_{50} (48h) > 100 mg/l (*Daphnia magna* - OECD 202)

Toxicity to fish: LL_{50} (96h) > 100 mg/l (*Oncorhynchus mykiss* - OECD 203)

Chronic aquatic toxicity - data on ingredients

Toxicity to daphnia and other non-living aquatic animals: NOEL (21d) 10 mg/l (*Daphnia magna* - OECD 211)

Toxicity to fish: NOEL (14/21d) > 1000 mg/l (*Oncorhynchus mykiss* - QSAR Petrotox)

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil: Considering the physical/chemical properties, the product generally diffuses little in the soil.

Air: There is little loss through evaporation.

Water: The product is insoluble and floats on water.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste of residues/unused products: Must not be released into the environment. Do not empty into drains. Dispose of in accordance with European Directives on waste and hazardous waste. Reuse where possible rather than discard or incinerate. After use, this oil must be disposed of at a waste oil collection point. Improper disposal may be dangerous for the environment. Mixing with foreign substances such as solvents, brake fluids and coolants is prohibited.

Contaminated packaging: Empty containers should be taken to an authorised waste disposal centre for reuse or disposal.

EWC waste no.: According to the European Waste List, waste codes are not product-specific, but application-specific. Waste codes must be assigned by the user, based on the application for which the product has been used. The following waste codes are only suggestions: 13 02 05.

Other information: Refer to Section 8 for safety and protective measures for waste handling personnel.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not regulated.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

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Safety phrases: Not applicable.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

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