

# Material Safety Data Sheet

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

EN

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## PARAFFINUM PERLIQUIDUM

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

#### 1.1 Product identifier

Product name:	Paraffin light liquid Paraffinum perliquidum Paraffine licht vloeibaar Paraffine liquid légère Paraffin flüssig leicht
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

Asp. Tox. 1	H304
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#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H304 May be fatal if swallowed and enters airways.

Precautionary statements: Not applicable.

Additional applicable label elements: Not applicable.

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### 2.3 Other hazards

No.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Paraffin light liquid
IUPAC name:	White mineral oil (petroleum)
Synonyms:	White mineral oil
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

After inhalation:	Fresh air. Get medical attention if symptoms occur.
After skin contact:	Rinse contaminated skin with plenty of water. Remove contaminated clothing and shoes.
After eye contact:	Immediately flush eyes with plenty of water. Check for and remove any contact lenses. Continue to rinse at least 10 minutes. Get medical attention if irritation occurs.
After ingestion:	Get medical attention immediately. Call a poison centre or physician. Wash out mouth with water. Remove victim to fresh air. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

### 4.2 Most important symptoms and effects, both acute and delayed

#### Potential acute health effects

Ingestion: May be fatal if swallowed and enters airways.

Inhalation: No known significant effects or critical hazards.

Skin contact: No known significant effects or critical hazards.

Eye contact: No known significant effects or critical hazards.

#### Over-exposure signs

Ingestion: Adverse symptoms may include the following: nausea or vomiting.

Skin contact: Repeated skin exposure can produce local skin destruction or dermatitis.

### 4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

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### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Use an extinguishing agent suitable for the surrounding fire: Foam, water fog, dry chemical powder, carbon dioxide, other inert gases, sand or earth.
Unsuitable extinguishing media:	Direct water jets, simultaneous use of foam and water on the same surface is to be avoided as water destroys the foam.

#### 5.2 Special hazards arising from the substance/mixture

In a fire or if heated, a pressure increase will occur and the container may burst.  
Carbon oxides (CO, CO<sub>2</sub>), smoke and irritating vapours as products of incomplete combustion.

#### 5.3 Advice for firefighters

Surrounding fires:	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. Additional information: Do not pressurise, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.
Protection against fire:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus with a full face-piece operated in positive pressure mode. Clothing for fire-fighters conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.
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. Put on appropriate personal protective equipment. Avoid breathing vapour or mist. Provide adequate ventilation.

##### For emergency responders

Do not touch or walk through spilt material. Put on appropriate personal protective equipment. Avoid breathing vapour or mist. Provide adequate ventilation.

#### 6.2 Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution.

#### 6.3 Methods and material for containment and cleaning up

Small spill: Stop leak if without risk. Move container from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill: Stop leak if without risk. Move container from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillage into an effluent treatment plant or proceed as follows: Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via licensed waste disposal contractor.

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### 6.4 Reference to other sections

Not available.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Put on appropriate personal protective equipment. Do not swallow. Avoid contact with eyes, skin and clothing. Keep in the original container and tightly closed when not in use.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Advice on general occupational hygiene: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store in original container protected from direct sunlight in a dry, cool and well-ventilated area. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.
Storage – away from:	Store protected from light. Store away from incompatible materials and food and drink.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### Occupational exposure limits

White mineral oil TWA: 5 mg/m<sup>3</sup>, (Inhalable fraction) 8 hours.

#### Recommended monitoring procedures

If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.

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### Derived effect levels

Type	Exposure	Value	Population	Effects
DNEL	Long term dermal	220 mg/kg bw/day	Workers	Systemic
DNEL	Long term inhalation	160 mg/m <sup>3</sup>	Workers	Systemic
DNEL	Long term dermal	92 mg/kg bw/day	Man via the environment	Systemic
DNEL	Long term inhalation	35 mg/m <sup>3</sup>	Man via the environment	Systemic
DNEL	Long term oral	40 mg/kg bw/day	Man via the environment	Systemic

DNEL Summary: Long-term systemic effects include non-reproductive effects and developmental/reproductive effects. Lowest DNEL is shown.

### 8.2 Exposure controls

#### Appropriate engineering control

No special ventilation requirements.

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Hygienic measures: Change contaminated clothing. Wash hands after working with substances.

#### Individual protection measures

Eye/face protection: Safety spectacles.

Skin protection: Protective suit.

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

Hand protection: PVC or nitrile rubber gloves if splashes are likely to occur.

Respiratory protection: Required when vapours/aerosols are generated.

Thermal hazards: Not determined.

#### Environmental exposure control

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection.

## 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: Neutral.

Odour threshold: Not available.

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pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	> 180 °C
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:	0.810 to 0.875
Solubility:	Slightly soluble in ethanol (96 per cent), miscible with hydrocarbons.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Kinematic: ca. 16 mm <sup>2</sup> /s at 40 °C
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Density: ca. 0.85 g/cm<sup>3</sup> at 15 °C

Pour point: ca. – 21 °C

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

### 10.2 Chemical stability

The product is stable.

### 10.3 Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Reactive with oxidising agents.

### 10.6 Hazardous decomposition products

May release Cox, smoke and irritating vapours when heated to decomposition.

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### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Dermal LD <sub>50</sub> (rabbit): > 2000 mg/kg Oral LD <sub>50</sub> (rat): > 5000 mg/kg Inhalation LC <sub>50</sub> Dusts and mists (rat): > 5000 mg/m <sup>3</sup> (4 hours)
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	All components listed in Annex VI to which Note L applies, and contained in the product, have been shown to contain less than 3% DMSO extractables as measured by IP346.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Aspiration hazard – Category 1
Other:	Not available.

#### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	No known significant effects or critical hazards.
Skin contact:	No known significant effects or critical hazards. Repeated skin exposure can produce local skin destruction or dermatitis.
Inhalation:	No known significant effects or critical hazards.
Ingestion:	May be fatal if swallowed and enters airways. Adverse symptoms may include the following: nausea or vomiting.
Aspiration:	Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

EC <sub>50</sub> 48 hours (Daphnia)	> 100 mg/L
LC <sub>50</sub> 96 hours (fish)	> 100 mg/L
NOEC 72 hours (Algae)	≥ 100 mg/L
NOEC 48 hours (Daphnia)	≥ 100 mg/L
NOEC 96 hours (Fish)	≤ 100 mg/L

#### 12.2 Persistence and degradability

>60 % - readily – 28 days: Activated sludge (OECD 301 B)

#### 12.3 Bioaccumulative potential

Not available.

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### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

PBT: No.

vPvB: Not available.

### 12.6 Other adverse effects

No known significant effects or critical hazards.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Methods of disposal: Significant quantities of waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Packaging: The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

## 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.



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### 14.8 Additional transport information

No hazardous goods according UN, IMO, ADR/RID und IATA/ICAO.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful

Risk phrases:

R65 Harmful: may cause lung damage if swallowed.

Safety phrases:

Not applicable.

### 15.2 Chemical safety assessment

Complete.

## 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.

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### 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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