

# Material Safety Data Sheet

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

EN

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Publication: 25/03/2022

Revision: XX/XX/XXXX

Version: 00



## VASELINUM ALBUM

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

#### 1.1 Product identifier

Product name: Parafin, white soft  
Vaselineum album  
Witte vaseline  
Vaseline blanche  
Weißes Vaseline

N° CAS: Not available.

N° EC: Not available.

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

Identified uses: Active Pharmaceutical Ingredient or Excipient.

#### 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 substance is not classified according to the CLP regulation.

#### 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

This substance is not classified as PBT/vPvB by current EU criteria.

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## VASELINUM ALBUM

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Product name:	Parafin, white soft
IUPAC name:	Not available.
Synonyms:	Mixture of refined hydrocarbons, petrolatum Petroleum jelly
N° CAS:	Not available.
N° EC:	Not available.
Molecular Formula:	Not available.
Content:	100 %

Purified and wholly or nearly decolourised mixture of semi-solid hydrocarbons, obtained from petroleum. It may contain a suitable antioxidant. White soft paraffin described in this monograph is not suitable for oral use.

#### 3.2 Mixtures

Not applicable.

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

After inhalation:	Remove affected person from source of contamination. Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Rinse nose and mouth with water. Get medical attention if any discomfort continues.
After skin contact:	Remove affected person from source of contamination. Remove contaminated clothing. Wash the skin thoroughly with soap and water. Get medical attention promptly if symptoms occur after washing.
After eye contact:	Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes. Get medical attention promptly if symptoms occur after washing.
After ingestion:	Do not induce vomiting. Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention if any discomfort continues.

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

Skin contact: May be slightly irritating to skin.  
Eye contact: May cause temporary eye irritation.

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

Notes to doctor: No specific recommendations. If in doubt, get medical attention immediately.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog.
Unsuitable extinguishing media:	Not available.

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

Specific hazards: Oxides of the following substances: Carbon.

Hazardous combustion: Oxides of carbon. Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

### 5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Use protective equipment appropriate for surrounding materials.

Hazardous combustion products: Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Follow precautions for safe handling described in this safety data sheet. Avoid inhalation of vapours and contact with skin and eyes. Provide adequate ventilation.

#### For emergency responders

Follow precautions for safe handling described in this safety data sheet. Avoid inhalation of vapours and contact with skin and eyes. Provide adequate ventilation.

### 6.2 Environmental precautions

Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.

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

Absorb spillage with non-combustible, absorbent material. Collect and place in suitable waste disposal containers and seal securely. For waste disposal, see section 13. Flush contaminated area with plenty of water.

### 6.4 Reference to other sections

Wear protective clothing as described in section 8 of this Safety Data Sheet.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling: Avoid spilling, Avoid contact with skin and eyes.

Personal protection: Not available.

Technical protective measures: Provide adequate ventilation.

Handling: Not available.

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

Storage: Not available.

Conditions for safe storage, including any incompatibilities: Store in tightly-closed original container in a dry, cool and well-ventilated place.

Storage – away from: Store protected from light.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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## VASELINUM ALBUM

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

No exposure limits noted for ingredient(s).

#### 8.2 Exposure controls

##### Appropriate engineering control

Provide adequate ventilation.

Hygiene measures: Wash at the end of each work shift and before eating, smoking and using the toilet. When using do not eat, drink or smoke. Eye wash facilities and emergency shower must be available when handling this product.

##### Individual protection measures

Eye/face protection: Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible.

Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses.

Personal protective equipment for eye and face protection should comply with European Standard EN166.

Skin protection: Appropriate footwear and additional protective clothing complying with an approved standard should be worn if a risk assessment indicates skin contamination is possible.

Hand protection: Wear suitable protective clothing as protection against splashing or contamination. Chemical-resistant, impervious gloves complying with an approved standard should be worn if risk assessment indicates skin contact is possible.

The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about breakthrough time of the glove material.

To protect hands from chemical, gloves should comply with European Standard EN374.

Respiratory protection: No specific recommendations. Respiratory protection may be required if excessive airborne contamination occurs. EN 136/140/145/143/149

Thermal hazards: Not determined.

##### Environmental exposure control

Not available.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance: White or almost white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 38 – 80 °C

Initial boiling point: Not available.

Boiling range: Not available.

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Flash point:	> 150 °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:	0.79 – 0.85 (100 °C)
Solubility:	Slightly soluble in methylene chloride, practically insoluble in ethanol (96 per cent) and in glycerol.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

There are no known reactivity hazards associated with this product.

### 10.2 Chemical stability

Stable at normal ambient temperature.

### 10.3 Possibility of hazardous reactions

Not determined.

### 10.4 Conditions to avoid

Avoid excessive heat for prolonged periods of time.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Oxides of the following substances: Carbon.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity: Not available.

Skin corrosion/irritation: Not available.

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Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
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:	Not available.
Other:	Not available.

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

Eye contact:	May cause temporary eye irritation.
Skin contact:	May be slightly irritating to skin.
Inhalation:	May cause respiratory irritation.
Ingestion:	Ingestion may cause severe irritation of the mouth, the oesophagus and the gastrointestinal tract.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not considered toxic to fish.

### 12.2 Persistence and degradability

The product is not readily biodegradable.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

This substance is not classified as PBT/vPvB according to current EU criteria.

### 12.6 Other adverse effects

Not determined.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

General information: Do not puncture or incinerate even when empty. Waste should be treated as controlled waste.  
Disposal methods: Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

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## VASELINUM ALBUM

### SECTION 14: TRANSPORT INFORMATION

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

##### 14.1 UN Number

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

##### 14.2 UN proper shipping name

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

##### 14.3 Transport hazard class(es)

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

##### 14.4 Packing group

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

##### 14.5 Environmental hazards

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

##### 14.6 Special precautions for user

Not applicable.

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

Not applicable.

##### 14.8 Additional transport information

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

### 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.

Safety phrases: Not applicable.

#### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

### 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)

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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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