

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Hydrophile Salbe
- **Article number:** 602521
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron UK Ltd
4B Coquet St
Newcastle upon Tyne
England NE1 2QB
Tel. 0845 6522525
- **Further information obtainable from:**
Emergency response telephone number:
+44 (0) 845 652 2525
- **1.4 Emergency telephone number:**
Emergency response telephone number:
+44 (0) 845 652 2525

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Eye Irrit. 2 H319 Causes serious eye irritation.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard statements**
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
P264 Wash thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P337+P313 If eye irritation persists: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local/regional/national/
international regulations.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

• **Dangerous components:**

CAS: 8002-74-2 EINECS: 232-315-6	Vaselinum Album Paraffinum solidum Paraffin, white soft substance with a Community workplace exposure limit	25–≤50%
CAS: 68955-20-4 EINECS: 273-258-7	Cetostearyl alcohol (type A), emulsifying Alcohol cetylicus et stearyllicus emulsificans A Eye Dam. 1, H318; Skin Irrit. 2, H315; Aquatic Chronic 3, H412 Specific concentration limits: Skin Irrit. 2; H315: C ≥ 55 % Eye Dam. 1; H318: C ≥ 55 % Eye Irrit. 2; H319: 20 % ≤ C < 55 %	25–≤50%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Seek immediate medical advice.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.

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- **5.3 Advice for firefighters**
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Use neutralising agent.
Dispose of the material collected according to regulations.
Dispose contaminated material as waste according to section 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Thorough dedusting.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

CAS: 8002-74-2 Vaselineum Album
Paraffinum solidum
Paraffin, white soft

WEL	Short-term value: 6 mg/m ³ Long-term value: 2 mg/m ³
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- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.

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- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
Suitable respiratory protective device recommended.
Filter P1
- **Hand protection**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection**



Tightly sealed goggles

- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** >315°C (CAS: 8002-74-2 Vaselineum Album
Paraffinum solidum
Paraffin, white soft)
- **Flammability** Not determined.

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· Lower and upper explosion limit	
· Lower:	0.6 Vol % (CAS: 8012-95-1 Paraffinum liquidum)
· Upper:	6.5 Vol % (CAS: 8012-95-1 Paraffinum liquidum)
· Flash point:	>150°C (CAS: 8002-74-2 Vaselinum Album Paraffinum solidum Paraffin, white soft)
· Auto-ignition temperature:	>300°C (CAS: 8002-74-2 Vaselinum Album Paraffinum solidum Paraffin, white soft)
· Decomposition temperature:	Not determined.
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20°C:	>0.1 hPa (CAS: 8012-95-1 Paraffinum liquidum)
· Density and/or relative density	
· Density at 20°C:	~0.86145–~0.86745 g/cm ³
· Relative density	Not determined.
· Bulk density:	~873 kg/m ³
· Vapour density	Not applicable.

· 9.2 Other information	
· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Solids content:	100.0 %
· Change in condition	
· Evaporation rate	Not applicable.

· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void

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· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

CAS: 68955-20-4 Cetostearyl alcohol (type A), emulsifying
Alcohol cetylicus et stearylicus emulsificans A

Oral LD50 >5000 mg/kg (rat)

- **Serious eye damage/irritation** Causes serious eye irritation.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.

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- **12.7 Other adverse effects**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Harmful to aquatic organisms
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· 14.1 UN number or ID number	
· ADR, IMDG, IATA	not regulated
· 14.2 UN proper shipping name	
· ADR, IMDG, IATA	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· 14.4 Packing group	
· ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**

H315 Causes skin irritation.
H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.

- **Department issuing SDS:**

Fagron UK
Quality Assurance

- **Contact:** quality@fagron.co.uk

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

- *** Data compared to the previous version altered.**

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