


1 Identification

- **Product identifier**
- **Trade name:** Hydrophile Salbe
- **Article number:** 602521
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
Eye Irritation 2A H319 Causes serious eye irritation.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS07
- **Signal word** Warning
- **Hazard statements**
Causes serious eye irritation.
- **Precautionary statements**
Wash thoroughly after handling.
Wear eye protection / face protection.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



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· HMIS-ratings (scale 0 - 4)

HEALTH	2	Health = *2
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

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

3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 8002-74-2	Vaselinum Album Paraffinum solidum Paraffin, white soft	25–≤50%
CAS: 8012-95-1	Paraffinum liquidum	25–≤50%
CAS: 68955-20-4	Cetostearyl alcohol (type A), emulsifying Alcohol cetylicus et stearylicus emulsificans A	25–≤50%

4 First-aid measures

- 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.
- Information for doctor:
- Most important symptoms and effects, both acute and delayed
No further relevant information available.
- Indication of any immediate medical attention and special treatment needed
No further relevant information available.

5 Fire-fighting measures

- Extinguishing media
- Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- Special hazards arising from the substance or mixture
Formation of toxic gases is possible during heating or in case of fire.
- Advice for firefighters
- Protective equipment:
Wear fully protective suit.

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Wear self-contained respiratory protective device.

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6 Accidental release measures

• Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Wear protective equipment. Keep unprotected persons away.

• 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.

• Methods and material for containment and cleaning up:

Use neutralizing agent.

Dispose of the collected material according to regulations.

Dispose contaminated material as waste according to section 13.

• 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.

• Protective Action Criteria for Chemicals

• PAC-1:

None of the ingredients is listed.

• PAC-2:

None of the ingredients is listed.

• PAC-3:

None of the ingredients is listed.

7 Handling and storage

• Handling:

• Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Thorough dedusting.

• Information about protection against explosions and fires: No special measures required.

• 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 receptacle tightly sealed.

• Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see section 7.

• Control parameters

• Components with limit values that require monitoring at the workplace:

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

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At this time, the remaining constituent has no known exposure limits.

CAS: 8002-74-2 Vaselineum Album	
Paraffinum solidum	
Paraffin, white soft	
REL	Long-term value: 2 mg/m ³
TLV	Long-term value: 2 mg/m ³
CAS: 8012-95-1 Paraffinum liquidum	
REL	Long-term value: 5 mg/m ³
REL	Short-term value: 10 mg/m ³
	Long-term value: 5 mg/m ³
	oil mist
TLV	L

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **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.

· **Breathing equipment:**

Suitable respiratory protective device recommended.

Filter P1

· **Protection of hands:**



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 protection:**



Tightly sealed goggles

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- **Body protection:** Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Pasty
Color:	According to product specification
· Odor:	Characteristic
· Odor threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	>315°C (>599°F)
· Flash point:	>150°C (>302°F)
· Flammability (solid, gaseous):	Not determined.
· Auto igniting:	>300°C (>572°F)
· Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	0.6 Vol %
Upper:	6.5 Vol %
· Vapor pressure at 20°C (68°F):	>0.1 hPa
· Density at 20°C (68°F):	~0.86145–~0.86745 g/cm ³ (~7.1888–~7.23887 lbs/gal)
· Bulk density:	~873 kg/m ³
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Soluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
VOC content:	0.00 %
Solids content:	100.0 %

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· **Other information** No further relevant information available.

10 Stability and reactivity

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

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

CAS: 8012-95-1 Paraffinum liquidum

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50/4 h	>5 mg/l (rat)

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

Oral	LD50	>5000 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Strong irritant with the danger of severe eye injury.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.

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- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Harmful to aquatic organisms
Must not reach bodies of water or drainage ditch undiluted or unneutralized.
Water hazard class 2 (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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

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

14 Transport information

· UN-Number	
· DOT, IMDG, IATA	not regulated
· UN proper shipping name	
· DOT, IMDG, IATA	not regulated
· Transport hazard class(es)	
· DOT, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· DOT, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

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· UN "Model Regulation": not regulated

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

No further relevant information available.

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

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

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.

· **Department issuing SDS:**

Fagron US
Quality Assurance

· **Contact:** QA@fagron.us

· **Date of preparation / last revision** 02/28/2024

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· **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
DOT: US Department of Transportation
IATA: International Air Transport Association
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

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