

Safety Data Sheet

acc. to OSHA HCS

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Printing date 02/27/2024
Reviewed on 02/27/2024

1 Identification

- **Product identifier**
- **Trade name:** Ondřejova mast
- **Article number:** 601354
- **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**
Flammable Liquids 4 H227 Combustible liquid.
Skin Irritation 2 H315 Causes skin irritation.
Eye Damage 1 H318 Causes serious eye damage.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.
Toxic to Reproduction 2 H361 Suspected of damaging fertility or the unborn child.

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



GHS05 GHS07 GHS08

- **Signal word** Danger
- **Hazard-determining components of labeling:**
Salicylic acid
Lavender, Lavandula angustifolia, ext.
- **Hazard statements**
Combustible liquid.
Causes skin irritation.
Causes serious eye damage.
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.

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· Precautionary statements

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Keep away from flames and hot surfaces. – No smoking.
Avoid breathing dust/fume/gas/mist/vapors/spray
Wash thoroughly after handling.
Contaminated work clothing must not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a poison center/doctor.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see on this label).
Take off contaminated clothing and wash it before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.
In case of fire: Use CO₂, powder or water spray to extinguish.
Store in a well-ventilated place. Keep cool.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· Classification system:

· NFPA ratings (scale 0 - 4)



Health = 3
Fire = 2
Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = *3
Fire = 2
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: 8012-95-1	Paraffinum liquidum	50–≤100%
CAS: 8002-74-2	Vaselinum Album Paraffinum solidum Paraffin, white soft	25–≤50%
CAS: 90063-37-9	Lavender, Lavandula angustifolia, ext.	10–≤25%

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CAS: 69-72-7

Salicylic acid

5–≤10%

4 First-aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
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:** If symptoms persist consult doctor.
- **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:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
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.
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralizing agent.
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **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.

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· **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.

Open and handle receptacle with care.

Prevent formation of aerosols.

· **Information about protection against explosions and fires:**

Keep respiratory protective device available.

· **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.

At this time, the other constituents have no known exposure limits.

CAS: 8012-95-1 Paraffinum liquidum

PEL Long-term value: 5 mg/m³

REL Short-term value: 10 mg/m³

Long-term value: 5 mg/m³

oil mist

TLV L

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

REL Long-term value: 2 mg/m³

TLV Long-term value: 2 mg/m³

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

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- **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.
Store protective clothing separately.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
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

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

· Form:	Pasty
· Color:	Yellowish
· Odor:	Characteristic
· Odor threshold:	Not determined.
- **pH-value:** Not determined.

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· Change in condition Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	211°C (411.8°F)
· Flash point:	66°C (150.8°F)
· Flammability (solid, gaseous):	Not applicable.
· Auto igniting:	>290°C (>554°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):	~0.83445--~0.9441 g/cm ³ (~6.96349--~7.87851 lbs/gal)
· Bulk density:	~823--~933 kg/m ³
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity: Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content: VOC content:	0.00 % 0.0 g/l / 0.00 lb/gal
Solids content:	860.4 %
· 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.

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11 Toxicological information

- Information on toxicological effects

- Acute toxicity:

- LD/LC50 values that are relevant for classification:

ATE (Acute Toxicity Estimate)		
Oral	LD50	8910 mg/kg (rat)

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: 69-72-7 Salicylic acid		
Oral	LD50	891 mg/kg (rat)

- 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: Sensitization possible through skin contact.

- 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)		
CAS: 57-88-5	Cholesterol Cholesterolum	3

- 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.
- 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:

Must not reach bodies of water or drainage ditch undiluted or unneutralized.
Harmful to aquatic organisms
Water hazard class 2 (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.

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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.
· 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.

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· TSCA (Toxic Substances Control Act):		
CAS: 8012-95-1	Paraffinum liquidum	ACTIVE
CAS: 8006-54-0	HydroLano™ Lanolin anhydrous Lanolinum anhydricum	ACTIVE
CAS: 8002-74-2	Vaselinum Album Paraffinum solidum Paraffin, white soft	ACTIVE
CAS: 57-88-5	Cholesterol Cholesterolum	ACTIVE
CAS: 69-72-7	Salicylic acid	ACTIVE
CAS: 8012-89-3	Beeswax white - Cera alba Beeswax,yellow - Cera flava	ACTIVE
CAS: 9005-65-6	Polysorbate 80	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** 02/27/2024

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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

Flammable Liquids 4: Flammable liquids – Category 4

Skin Irritation 2: Skin corrosion/irritation – Category 2

Eye Damage 1: Serious eye damage/eye irritation – Category 1

Sensitization - Skin 1: Skin sensitisation – Category 1

Toxic to Reproduction 2: Reproductive toxicity – Category 2

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