

1 Identification

- **Product identifier**
- **Trade name:** Ondřejova mast
- **Article number:** 601354
- **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
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Services B.V.
Molenwerk 13, UITGEEEST, 1911DB
Netherlands
Phone: +31251361400

- Supplier
Azelis Australia
Suite 217
117 Old Pittwater Road
Brookvale
NSW 2100
Australia
Phone: +61 0299392188
Fax: +61 0299392799
e-mail: info@azelis.com.au
- **Further information obtainable from:** info@fagron.com.au
- **Emergency telephone number:**
In case of emergency, please call your local poisons:
Emergency Australia: 13 11 26
Emergency NZ: 0800 764 766 (0800 POISON)

- 1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE: +44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65 3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333 (English only)

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Flam. Liq. 4 H227 Combustible liquid.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Dam. 1 H318 Causes serious eye damage.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Repr. 2 H361d Suspected of damaging the unborn child.
STOT SE 1 H370 Causes damage to organs.
STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.

- **Label elements**

- **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

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· **Hazard pictograms**



· **Signal word** Danger

· **Hazard-determining components of labelling:**

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 the unborn child.
Causes damage to organs.
Causes damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

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.
Specific treatment (see on this label).
Take off contaminated clothing and wash it before reuse.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 8012-95-1	Paraffinum liquidum	50–≤100%
CAS: 8002-74-2	Vaseline Album Paraffinum solidum Paraffin, white soft	25–≤50%
CAS: 90063-37-9	Lavender, Lavandula angustifolia, ext. Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317; Flam. Liq. 4, H227	10–≤25%
CAS: 69-72-7	Salicylic acid Repr. 2, H361d; STOT SE 1, H370; STOT RE 1, H372; Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317	10%

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

4 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

- **Suitable extinguishing agents:**
CO₂, 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.
- **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 neutralising 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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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 fire - and explosion protection:** Keep respiratory protective device available.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.

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

CAS: 8012-95-1 Paraffinum liquidum

WES Long-term value: 5 mg/m ³
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CAS: 8002-74-2 Vaselinum Album Paraffinum solidum Paraffin, white soft

WES Long-term value: 2 mg/m ³
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- **Additional information:** The lists valid during the making were used as basis.
- **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.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
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

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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

· **General Information**

· **Appearance:**

- | | |
|---|---|
| · Form: | Pasty |
| · Colour: | Yellowish |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |
| · pH-value: | Not determined. |
| · Change in condition | |
| · Melting point/freezing point: | Undetermined. |
| · Initial boiling point and boiling range: | 211°C |
| · Flash point: | 66°C |
| · Flammability (solid, gas): | Not applicable. |
| · Auto-ignition temperature: | >290°C |
| · Decomposition temperature: | Not determined. |
| · Ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Explosion limits: | |
| · Lower: | 0.6 Vol % |
| · Upper: | 6.5 Vol % |
| · Vapour pressure at 20°C: | >0.1 hPa |
| · Density at 20°C: | ~0.83445~0.9441 g/cm ³ |
| · Bulk density: | ~823~933 kg/m ³ |
| · Relative density | Not determined. |
| · Vapour 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 (EC) | 0.00 % |
| · Solids content: | 860.4 % |

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

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **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** Based on available data, the classification criteria are not met.

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

ATE (Acute Toxicity Estimates)

Oral	LD50	8910 mg/kg (rat)
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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)
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- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye damage.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Suspected of damaging the unborn child.
- **STOT-single exposure** Causes damage to organs.
- **STOT-repeated exposure** Causes damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish

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- **Additional ecological information:**
- **General notes:**
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Harmful to aquatic organisms
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.
- **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 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.

14 Transport information

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

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15 Regulatory information

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

• Australian Inventory of Industrial Chemicals	
CAS: 8012-95-1	Paraffinum liquidum
CAS: 8006-54-0	HydroLano™ Lanolin anhydrous Lanolinum anhydricum
CAS: 8002-74-2	Vaselinum Album Paraffinum solidum Paraffin, white soft
CAS: 90063-37-9	Lavender, Lavandula angustifolia, ext.
CAS: 57-88-5	Cholesterol Cholesterolum
CAS: 69-72-7	Salicylic acid
CAS: 8012-89-3	Beeswax white - Cera alba Beeswax,yellow - Cera flava
CAS: 9005-65-6	Polysorbate 80

- Standard for the Uniform Scheduling of Medicines and Poisons

CAS: 69-72-7	Salicylic acid	S3
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- Australia: Priority Existing Chemicals

None of the ingredients is listed.

- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- National regulations:
- Other regulations, limitations and prohibitive regulations
Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)
- 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.

- Relevant phrases

H227 Combustible liquid.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H361d Suspected of damaging the unborn child.
H370 Causes damage to organs.
H372 Causes damage to organs through prolonged or repeated exposure.

- Department issuing SDS: Product Safety Department

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· **Contact:**

· **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

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)

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

Flam. Liq. 4: Flammable liquids – Category 4

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 2: Reproductive toxicity – Category 2

STOT SE 1: Specific target organ toxicity (single exposure) – Category 1

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

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