

1 Identification

- **Product identifier**
- **Trade name:** Acidi salicylici unguentum 5%
- **Article number:** 602612
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Pharmaceutical intermediate
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Services B.V.
Molenwerk 13, UITGEEST, 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**
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 2 H371 May cause damage to organs.
STOT RE 2 H373 May cause 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).
- **Hazard pictograms**



GHS05



GHS07



GHS08

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- **Signal word** Danger
- **Hazard-determining components of labelling:**
Salicylic acid
- **Hazard statements**
Causes serious eye damage.
May cause an allergic skin reaction.
Suspected of damaging the unborn child.
May cause damage to organs.
May cause 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: 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 | 3–≤5% |
| CAS: 8012-95-1 | Paraffinum liquidum | 1–≤3% |

- **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; consult doctor in case of complaints.
- **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

- **Suitable extinguishing agents:**
Use fire extinguishing methods suitable to surrounding conditions.

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- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation
- **Environmental precautions:**
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.
Dispose of the material collected according to regulations.
- **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.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Open and handle receptacle with care.
Ensure good ventilation/exhaustion at the workplace.
- **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 |
|--|

- **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.
Avoid contact with the eyes and skin.
Pregnant women should strictly avoid inhalation or skin contact.

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- Do not eat, drink, smoke or sniff while working.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **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

- **General Information**

- **Appearance:**

- **Form:** Pasty
- **Colour:** Light yellow
- **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:** >150°C
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure at 20°C:** <0.1 hPa
- **Density at 20°C:** 0.80168–0.94968 g/cm³
- **Bulk density:** 802–950 kg/m³
- **Relative density** Not determined.
- **Vapour density** Not determined.

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| | |
|--|-----------------|
| · 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: | 97.5 % |

· **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 | 17820 mg/kg (rat) |
|------|------|-------------------|

CAS: 69-72-7 Salicylic acid

| | | |
|------|------|-----------------|
| Oral | LD50 | 891 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) |

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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** May cause damage to organs.
- **STOT-repeated exposure** May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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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.
- **Additional ecological information:**
- **General notes:**
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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: 69-72-7 | Salicylic acid |
| CAS: 8012-95-1 | Paraffinum liquidum |

| | | |
|---|----------------|----|
| · Standard for the Uniform Scheduling of Medicines and Poisons | | |
| CAS: 69-72-7 | Salicylic acid | S3 |

| | |
|---|--|
| · 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**
H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
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
- **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
Acute Tox. 4: Acute toxicity – Category 4
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
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 SE 2: Specific target organ toxicity (single exposure) – Category 2
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2