

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

- **1.1 Product identifier**
- **Trade name: Acidi salicylici unguentum 5%**
- **Article number: 602612**
- **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** Pharmaceutical intermediate
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
FAGRON a.s.
Holická 1098/31m
779 00 Olomouc
Česká republika
- **Further information obtainable from:**
Tel.: +420 585 222 590
info@fagron.cz
- **1.4 Emergency telephone number:**
Toxikologické informační středisko,
Na Bojišti 1,
128 08 Praha 2
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),
e-mail:tis.cuni@cesnet.cz

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Eye Dam. 1 H318 Causes serious eye damage.
Repr. 2 H361d Suspected of damaging the unborn child.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS05 GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**
Salicylic acid
- **Hazard statements**
H318 Causes serious eye damage.
H361d Suspected of damaging the unborn child.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection/
hearing 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.
P310 Immediately call a POISON CENTER/doctor.
P308+P313 IF exposed or concerned: Get medical advice/attention.

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P405 Store locked up.
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.

· **Determination of endocrine-disrupting properties**

CAS: 69-72-7	Salicylic acid	List II; III
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SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

CAS: 69-72-7	Salicylic acid	3–≤5%
EINECS: 200-712-3	Repr. 2, H361d; Eye Dam. 1, H318; Acute Tox. 4, H302	

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

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation

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- **6.2 Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **6.3 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.
- **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**
Open and handle receptacle with care.
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.
- **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.
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.
Do not eat, drink, smoke or sniff while working.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Hand protection**



Protective gloves

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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**

Fluid

· **Colour:**

Light yellow

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

211°C (CAS: 69-72-7 Salicylic acid)

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

>150°C (CAS: 8009-03-8 Paraffin, yellow soft Vaselineum flavum)

· **Decomposition temperature:**

Not determined.

· **pH**

Not determined.

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **Dynamic:**

Not determined.

· **Solubility**

· **water:**

Fully miscible.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure at 20°C:**

<0,1 hPa (CAS: 8009-03-8 Paraffin, yellow soft Vaselineum flavum)

· **Density and/or relative density**

· **Density at 20°C:**

0,80168–0,94968 g/cm³

· **Relative density**

Not determined.

· **Bulk density:**

802–950 kg/m³

 **Fagron**

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Fagron
medicin
CZE

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· Vapour density	Not determined.
· 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:	
· VOC (EC)	0,00 %
· Solids content:	97,5 %
· Change in condition	
· Evaporation rate	Not determined.
· 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
· 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:			
ATE (Acute Toxicity Estimates)			
Oral	LD50	17820 mg/kg (rat)	

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CAS: 69-72-7 Salicylic acid

Oral LD50 891 mg/kg (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** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

CAS: 69-72-7 Salicylic acid

List II; III

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**
For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **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.

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.
 - **European waste catalogue**
- | | |
|------|------------------------|
| HP10 | Toxic for reproduction |
|------|------------------------|
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

CZE

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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.

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

· DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

· Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· 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

H302 Harmful if swallowed.

 **Fagron**
personalizing
medicine

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H318 Causes serious eye damage.
H361d Suspected of damaging the unborn child.

· **Department issuing SDS:** Fagron Česká republika

· **Contact:** msds@fagron.cz

· **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)

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

Repr. 2: Reproductive toxicity – Category 2

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