

Safety Data Sheet

acc. to OSHA HCS

1: Identification

- **1.1 Product identifier**
- **Trade name: Acetic Acid 5%**
- **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** Pharma excipient
- **1.3 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
- **1.4 Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2: Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 Health hazard

- | | | |
|---------------|------|--|
| Resp. Sens. 1 | H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Muta. 2 | H341 | Suspected of causing genetic defects. |
| Repr. 1A | H360 | May damage fertility or the unborn child. |
| STOT RE 2 | H373 | May cause damage to organs through prolonged or repeated exposure. |



GHS07

- | | | |
|---------------|---------|--|
| Skin Sens. 1 | H317 | May cause an allergic skin reaction. |
| STOT SE 3 | H 3 3 5 | - May cause respiratory irritation. May cause drowsiness or dizziness. |
| Eye Irrit. 2B | H336 | |
| | H320 | Causes eye irritation. |

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** The product is classified and labeled according to the CLP regulation.
- **Hazard pictograms** GHS07, GHS08
- **Signal word** Danger
- **Hazard statements**
H320 Causes eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.

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- H341 Suspected of causing genetic defects.
H360 May damage fertility or the unborn child.
H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.
H373 May cause damage to organs through prolonged or repeated exposure.

• **Precautionary statements**

- P260 Do not breathe dust/fume/gas/mist/vapors/spray.
P284 Wear respiratory protection.
P280 Wear protective gloves.
P321 Specific treatment (see on this label).
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P342+P311 If experiencing respiratory symptoms: Call a poison center/doctor.

• **2.3 Other hazards**

• **Results of PBT and vPvB assessment**

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

3: Composition/information on ingredients

• **3.2 Chemical characterization: Mixtures**

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

• **Dangerous components:**

| | | | |
|-------------------|--------------------------|---------------------|---------|
| CAS: 64-19-7 | Acetic acid glacial | Flam. Liq. 3, H226 | 2.5-10% |
| EINECS: 200-580-7 | Acidum aceticum glaciale | Skin Corr. 1A, H314 | |

4: First-aid measures

• **4.1 Description of first aid measures**

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
• **After skin contact:** Generally the product does not irritate the skin.
• **After eye contact:** Rinse opened eye for several minutes under running water.
• **After swallowing:** Rinse out mouth and then drink plenty of water.
• **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.

5: Fire-fighting measures

• **5.1 Extinguishing media**

• **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

• **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

• **5.3 Advice for firefighters**

- **Protective equipment:** No special measures required.

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6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **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).
- **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.

7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **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:** Store in cool, dry conditions in well sealed receptacles.
- **7.3 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 item 7.
- **8.1 Control parameters**

· **Components with limit values that require monitoring at the workplace:**

64-19-7 Acetic acid glacial

Acidum aceticum glaciale

| | |
|-----|---|
| PEL | Long-term value: 25 mg/m ³ , 10 ppm |
| REL | Short-term value: 37 mg/m ³ , 15 ppm Long-term value: 25 mg/m ³ , 10 ppm |
| TLV | Short-term value: 37 mg/m ³ , 15 ppm Long-term value: 25 mg/m ³ , 10 ppm |

- **Additional information:** The lists that were valid during the creation were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Fresh air mask
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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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:** Goggles recommended during refilling.

9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

| | |
|--------------------|------------------------------------|
| Form: | Fluid |
| Color: | According to product specification |
| · Odor: | Characteristic |
| · Odour threshold: | Not determined. |

· pH-value: Not determined.

· **Change in condition**

| | |
|------------------------------|-----------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | 100 °C (212 °F) |

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not applicable.

· Ignition temperature: 463 °C (865 °F)

· Decomposition temperature: Not determined.

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· **Explosion limits:**

| | |
|--------|-----------------|
| Lower: | Not determined. |
| Upper: | Not determined. |

· Vapor pressure: Not determined.

· Density at 20 °C (68 °F): 0.99956 g/cm³ (8.341 lbs/gal)

· Relative density: Not determined.

· Vapour density: Not determined.

· Evaporation rate: Not determined.

· **Solubility in / Miscibility with**

| | |
|--------|-----------------|
| Water: | Fully miscible. |
|--------|-----------------|

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- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not determined.
 - Kinematic:** Not determined.
- **Solvent content:**
 - Organic solvents:** 0.0 %
 - Water:** 95.0 %
 - VOC content:** 0.0 %
- **9.2 Other information** No further relevant information available.

10: Stability and reactivity

- **10.1 Reactivity**
- **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.

11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**

| | | |
|--------|------|--------------------|
| Oral | LD50 | 110333 mg/kg (rat) |
| Dermal | LD50 | 35333 mg/kg (rab) |

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

- **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.

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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.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

13: Disposal considerations

- **13.1 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

- | | |
|---|-----------------|
| · 14.1 UN-Number | - |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | - |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | - |
| · DOT, ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

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· UN "Model Regulation":

-

15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16: Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

- **Relevant phrases**
H226 Flammable liquid and vapor.
H314 Causes severe skin burns and eye damage.
- **Department issuing SDS:**
Fagron US
Quality Assurance
- **Contact:** QA@fagron.us
- **Date of preparation / last revision** 10/20/2015 / -
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport 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
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
Flam. Liq. 3: Flammable liquids, Hazard Category 3
Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A
Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B
Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Muta. 2: Germ cell mutagenicity, Hazard Category 2
Repr. 1A: Reproductive toxicity, Hazard Category 1A
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2
- *** Data compared to the previous version altered.**

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