# SDS: Acetic Acid Otic Solution, USP

## SAFETY DATA SHEET

## 1. Identification

**Product Identifier:** Acetic Acid Otic Solution, USP

**Synonyms:** Methanecarboxylic acid * Ethanoic acid

**National Drug Code (NDC):** 52817-816-15

**Recommended Use:** Prescription Pharmaceutical Drug Product.

**Company:** TruPharma, LLC.
4100 West Kennedy Boulevard, Suite 220,
Tampa, Florida 33609

**Contact Telephone:** 1-877-541-5504

**E mail:** prodcomplaint@trupharma.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

## 2. Hazard(s) Identification

**Physical Hazards:** Not classifiable.
**Health Hazards:** Not classifiable.
**Symbol(s):** None.
**Signal Word:** None.
**Hazard Statement(s):** None.
**Precautionary Statement(s):** None.
**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

## 3. Composition/Information on Ingredients

| Chemical Name | CAS Number | Synonyms | Chemical Formula | Molecular Weight | Percentage |
|---|---|---|---|---|---|
| Acetic Acid | 64-19-7 | Methanecarboxylic acid * Ethanoic acid | $CH_3COOH$ | 60.05 | 2% |
| Propylene Glycol Diacetate | 623-84-7 | 1,2-Propanediol | $C_7H_{12}O_4$ | 160.16 | 3% |
| Benzethonium Chloride | 121-54-0 | Benzethonium Chloride | $C_{27}H_{42}ClNO_2$ | 448.15 | 0.02% |
| Sodium Acetate | 127-09-3 | Acetic acid, sodium salt | $C_2H_3NaO_2$ | 82.04 | 0.015% |

* The formula may also include Anyhydrous Citric Acid.

## 4. First Aid Measures

**Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Skin Contact:** Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Inhalation:** Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Protection of First-Aiders:** Use personal protective equipment (see section 8).

**Signs and Symptoms:** Solution is not considered hazardous under normal conditions.

**Medical Conditions Aggravated by Exposure:** As with all pharmaceutical, hypersensitivity is possible.

**Notes to Physician:** Treat supportively and symptomatically.

## 5. Firefighting Measures

**Suitable Extinguishing Media:** Use standard firefighting procedures depending on the source of the surrounding fire.

**Unsuitable Extinguishing Media:** Not determined.

**Specific Hazards Arising from the Chemical:**

**Hazardous Combustion Products:** Not determined.

**Other Specific Hazards:** Not determined.

**Special Protective Equipment/ Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

## 6. Accidental Release Measures

**Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Pick up in the most efficient manner. Soak up with sawdust, sand, oil dry or other absorbent material.

**Environmental Precautions:** No data available.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

## 7. Handling and Storage

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Keep container tightly closed. Store between 68°F – 77°F. Store according to label and/or product insert information.

**Specific End Use:** Pharmaceuticals.

## 8. Exposure Controls/Personal Protection

**Occupational Exposure Guidelines:**

| Common or Chemical Name | Employee Exposure Limits |
|---|---|
| Acetic Acid | OSHA PEL: 25 mg/$m^3$<br>OSHA PEL: 10 ppm<br>NIOSH REL: 25 mg/$m^3$<br>NIOSH STEL: 10 ppm; 37 mg/$m^3$; 15 ppm<br>ACGIH TLV: 15 ppm STEL<br>ACGIH TLV: 15 ppm TWA |
| Propylene Glycol Diacetate | WEEL: 25 mg/$m^3$ TWA (Aerosal) |
| Benzethonium Chloride | Not established. |
| Sodium Acetate | Not established. |

**Engineering Controls:** Not required for the normal use of this product. Engineering controls should be used as the primary means to control exposures.

| | |
|---|---|
| **Respiratory Protection:** | Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134). |
| **Eyes Protection:** | Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area. |
| **Hand Protection:** | Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. |
| **Skin Protection:** | Wear protective laboratory coat, apron, or disposable garment when working with large quantities. |

## 9. Physical and Chemical Properties

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|---|---|
| **Physical State/Color:** | Viscous Clear Solution. |
| | No data available. |
| **Odor:** | No data available. |
| **Odor Threshold:** | 2.0 - 4.0 |
| **pH:** | No data available. |
| **Melting Point:** | No data available. |
| **Freezing Point:** | No data available. |
| **Boiling Point:** | Nonflammable. |
| **Flash Point:** | Same as water. |
| **Evaporation Rate:** | No data available. |
| **Flammability (solid, gas):** | No data available. |
| **Flammability Limit - Lower:** | No data available. |
| **Flammability Limit - Upper:** | No data available. |
| **Vapor Pressure:** | No data available. |
| **Vapor Density:** | No data available. |
| **Relative Density:** | Soluble in water. |
| **Solubility(ies):** | |
| **Partition Coefficient (n-octanol/water):** | No data available. |
| **Auto-Ignition Temperature:** | No data available. |
| **Decomposition Temperature:** | No data available. |
| **Viscosity:** | 15.0 - 60.0 cps. |
| **Specific Gravity:** | No data available. |

## 10. Stability and Reactivity

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|---|---|
| **Reactivity:** | No data available. |
| **Chemical Stability:** | Stable under recommended storage conditions. Avoid sources of ignition. |
| **Possibility of Hazardous Reactions:** | No data available. |
| **Conditions to Avoid (e.g., static discharge, shock, or vibration):** | No data available. |
| **Incompatible Materials:** | Strong oxidizer. Avoid excessive heat. |
| **Hazardous Decomposition Products:** | Does not undergo explosive decomposition. |
| **Hazardous Polymerization:** | Will not occur. |

## 11. Toxicological Information

**Information on the Likely Routes of Exposure:**

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|---|---|
| **Inhalation:** | No data available. |
| **Ingestion:** | Harmful if swallowed. |
| **Skin Contact:** | No data available. |
| **Eye Contact:** | May cause irritation of the eyes by prolonged skin contact. |
| **Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** | See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated. |
| **Delayed and Immediate Effects of Exposure:** | No data available. |
| **Acute Toxicity – Oral:** | No data available. |
| **Acute Toxicity – Dermal:** | No data available. |
| **Acute Toxicity – Inhalation:** | No data available. |
| **Corrosivity:** | No data available. |
| **Dermal Irritation:** | No data available. |
| **Eye Irritation:** | No data available. |
| **Sensitization:** | No data available. |
| **Toxicokinetics/Metabolism:** | No data available. |
| **Target Organ Effects:** | No data available. |
| **Reproductive Effects:** | No data available. |
| **Carcinogenicity:** | No data available. |

| | |
|---|---|
| National Toxicology Program (NTP): | Not considered to be a carcinogen. |
| International Agency for Research On Cancer (IARC): | Not considered to be a carcinogen. |
| Occupational Safety and Health Administration (OSHA): | Not considered to be a carcinogen. |
| **Mutagenicity:** | No data available. |
| **Aspiration Hazard:** | No data available. |

## 12. Ecological Information

### Ecotoxicity

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|---|---|
| **Aquatic:** | No data available. |
| **Terrestrial:** | No data available. |
| **Persistence and Degradability:** | No data available. |
| **Bioaccumulative Potential:** | No data available. |
| **Mobility in Soil:** | No data available. |
| **Mobility in Environment:** | No data available. |
| **Other Adverse Effects:** | No data available. |

## 13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

## 14. Transport Information

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|---|---|
| **UN Number:** | Not applicable. |
| **UN Proper Shipping Name:** | Not applicable. |
| **Transport Hazard Class(es):** | Not applicable. |
| **Packing Group:** | Not applicable. |
| **Department of Transportation:** | Not regulated as a hazardous material. |
| **International Air Transport Association (IATA):** | Not regulated as a dangerous good. |
| **International Maritime Dangerous Good (IMDG):** | Not regulated as a dangerous good. |

## 15. Regulatory Information

### US Federal Regulations:

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|---|---|
| **Toxic Substance Control Act (TSCA):** | Not listed. |
| **CERCLA Hazardous Substance and Reportable Quantity:** | Not listed. |
| **SARA 313:** | Not listed. |
| **SARA 302:** | Not listed. |

**State Regulations**

**California Proposition 65:** Not listed.

## 16. Other Information

**NFPA Rating:**

| | |
|---|---|
| Health: | 1 |
| Flammability: | 0 |
| Reactivity: | 0 |

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