

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Acetic Acid 2% in Aqueous Aluminum Acetate Otic Solution
Generic Name: Same
NDC No. 24208-615-77 (60 ml)

Legal Category: Prescription only medicine, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Antimicrobial

BAUSCH & LOMB PHARMACEUTICALS, INC.

8500 Hidden River Parkway

Tampa, FL 33637

Information: (800) 323-0000 (M-F) 8am-5pm EST

Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m ³)	PEL(mg/m ³)	% Content
Acetic acid	64-19-7	25	25	2
Aluminum Sulfate	10043-01-3	2(as Al)	NE	<1
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Boric Acid, Calcium Carbonate, Sodium Hydroxide

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle inside a cardboard box. Clear, colorless solution with a slight odor of acetic acid. For ears only. May cause burning sensation in eyes.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: (NTP) No (IARC) No (OSHA) No

Ear: May cause irritation and hypersensitivity in some individuals. For ears only.

Eye: Avoid contact with the eyes. May cause irritation and hypersensitivity in some individuals.

Skin: May cause irritation, and repeated or prolonged contact may induce hypersensitivity (anaphylactic) in some individuals.

Ingestion: May cause irritation and hypersensitivity in some individuals.

Inhalation: Aspiration of this medication may cause irritation to the respiratory tract and hypersensitivity may develop in some individuals.

Chronic Effects: Some individuals may develop irritation or sensitivity.

Target Organs: Ears.

Medical Conditions Aggravated by Long Term Exposure Hypersensitivity to any of the components of the product. Patients with perforated tympanic membranes are not indicated for use of this or any external ear medication.

4. FIRST AID MEASURES

Eyes: Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

Skin: Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

Ingestion: Wash out mouth and drink plenty of water and bland fluids. Do not give anything to an unconscious person. Contact physician.

Inhalation: Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

Note to Physicians: None.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Acetic Acid, Sulfuric Acid, toxic fumes and Sulfur Oxides (SO_x).

Extinguishing Media: Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

7. HANDLING AND STORAGE

Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 15⁰-30⁰ C (59⁰- 86⁰ F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

Skin Protection: Thick impermeable gloves and protective clothing.

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

Warning: **Do not use air purifying respirators in oxygen depleted environments.** No respiratory protection is required in the clinical or home environment.

Other: None

Ventilation: Recommended

Contaminated Equipment: Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor: Clear, colorless solution with a slight odor of acetic acid.

Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Miscible	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold.

Incompatibility: This product has no incompatibilities except those of water e.g. strong acids, bases, alkali metals, alkali hydrides.

Hazardous Decomposition Products: Acetic acid, sulfuric acid, and toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

Summary of Risks: Toxicological information refers to the raw materials of the product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

CAS #

7784-31-8 **Aluminum Sulfate**

May cause irritation to the eyes, skin, respiratory and digestive tract. Forms sulfuric acid on hydrolysis. Dust inhalation can cause coughing, sneezing, sore throat and breathing difficulty. Prolonged skin contact may cause irritation. Ingestion may induce nausea and vomiting. Eye contact can cause mechanical irritation due to crystals, and solutions may cause severe burns. No known long term effects expected. Oral-mouse LD₅₀ 6027 mg/kg (Anhydrous).

64-19-7 **Acetic Acid**

Flammable liquid that may cause permanent eye damage and severe burns to tissue. Inhalation can cause headache, coughing, chest pain, respiratory distress and failure. Ingestion may cause diarrhea, shock and death. Oral-rat LD₅₀ 3310 mg/kg, Inhalation-mouse LC₅₀ 5620 ppm.

12. ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

13. DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

EPA Designations: RCRA Hazardous Waste: Acetic acid-Not Listed, Aluminum Sulfate-Not Listed.

SARA Title III: Acetic acid-Listed, Aluminum sulfate-Listed.

14. TRANSPORTATION INFORMATION

Transportation Data: (49 CFR 172.101, .203) Acetic acid: DOT DESIGNATIONS; Listed chemical. Concentration required for hazardous material classification is a minimum of 10%. Product concentration claim for acetic acid is 2%.

15. REGULATORY INFORMATION

DOT Designations: (49 CFR 172.101, .203) Acetic acid-Listed. Aluminum sulfate-Listed. Reportable quantity is 5000 pounds or 2270 kilograms. Product as marketed is not classified as a hazardous material.

EPA Designations: RCRA Hazardous Waste
 (40 CFR 261.33) Acetic acid- Not Listed.

FDA Designations: Prescription only medication.
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OSHA Designations: (29 CFR 1910.1000, Table Z)
Acetic acid-Listed.

SARA Title III: Acetic acid-Listed under Section 304 of CERCLA.
Reportable quantity is 5000 pounds. Acetic acid is Not
Listed under Section 313 Toxic Release Reporting.
Aluminum sulfate-Listed under Section 304 of CERCLA.
Reportable quantity is 5000 pounds. Aluminum sulfate is
not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established

< - Less Than

> - Greater Than

> - Greater Than