

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 347

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Albuterol Sulfate Inhalation Solution, 0.5%
Generic Name: Same
NDC No. 24208-347-20 (20 ml)

Legal Category: Prescription only medicine, filled in 20 mL bottle with dropper assembly and overpacked inside a cardboard carton.

Drug Composition: Anti-spasmodic, bronchodilator.

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
Albuterol Sulfate	51022-70-9	NE	NE	0.6
Purified Water	7732-18-5	NE	NE	>1

Ingredients <1% - Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Glass bottle with dropper assembly in cardboard box. Clear colorless to light yellow solution. Toxic by ingestion. Presents little or no hazard if spilled and no unusual hazard if involved in fire.

POTENTIAL HEALTH HAZARDS

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

Eye: No data.

Systemic: This drug is absorbed systemically.

Skin: No data.

Ingestion: No data.

Inhalation: No data.

Chronic Effects: No data.

Target Organs: NE.

Medical Conditions Aggravated by Long Term Exposure:

- Anaphylactic cross-reactions may occur.
- Appropriate measures should be taken if this occurs.
- Hypersensitivity to any of the ingredients of the medication.

4. FIRST AID MEASURES

Remove from exposure and in the event of any untoward events, obtain appropriate medical attention. Persons developing serious hypersensitivity reactions must receive immediate medical attention.

Eyes: May produce responses in sensitive individuals, if given undiluted. Flush with water for at least 15 minutes. Contact a physician.

Skin: May cause irritation, if exposed undiluted. Remove all contaminated

clothing and wash skin with soap and water for at least 20 minutes. Contact physician if skin becomes irritated.

Ingestion: This product contains materials which may cause the following effects upon ingestion, if ingested undiluted: may cause fine muscular tremors affecting especially the hands. An increase in pulse rate along with palpitations and dilation of the blood vessels of the skin producing a fall in blood pressure with associated light-headedness and dizziness. Flush out mouth with water and induce vomiting, if conscious. Contact physician.

Inhalation: May cause irritation of respiratory tract, if exposed undiluted. Remove person to fresh air, and if breathing stops, use artificial respiration. Contact a physician.

Note to Physicians: Additional details are available on the package insert or in the Physicians Desk Reference.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: > 200 °F (>93°C)

Autoignition Temperature: N/A

Flammable Limits: Lower flammable limit: N/A Upper flammable limit: N/A

Unusual Fire and Explosion Hazards: Under normal conditions of use this material does not present a significant fire or explosion hazard.

Hazardous Products: When heated to decomposition, material emits toxic fumes.

Extinguishing Media: Dry chemical, carbon dioxide, water spray or fog, and water.

Fire Fighting Instructions: As with all fires, evacuate personnel to safe area. Firefighters should wear self-contained breathing apparatus (SCBA) and protective clothing. Use water spray to keep fire-exposed containers cool.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Notify your supervisor immediately. Minimize contact with spilled material. Keep other personnel away from the clean up area. Wear appropriate respiratory protection. Wear approved respirator and chemically compatible gloves. Use personal protective equipment. (Refer to Section 8) Squeegee, scoop, absorb or use a vacuum to clean up spill. Clean area with an alkaline cleaner/detergent. Dispose of waste material in accordance with Federal,

State and Local regulations.

While not a RCRA hazardous waste, material should be disposed of according to Federal, State and Local regulations. Incineration is the preferred disposal method.

7. HANDLING AND STORAGE

This material should be handled and stored per label and other instructions to ensure product integrity.

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 approximately 2⁰-25⁰ C (36⁰- 77⁰ F).). Protect from light. Store in a cool dry well ventilated area. **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. Provide adequate local exhaust ventilation.

Hygienic Practices: Train employees concerning hazards and precautions. Wash hands and forearms after each use and use recommended personal protective equipment while handling.

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 to light yellow solution; odorless.		
Boiling Point:	N/A	Evaporation Rate:	N/A
Specific Gravity	As water	Vapor Density:	As water
Vapor Pressure:	As water	Viscosity:	As water
pH:	Approx. 4	Solubility in water:	Soluble

10. STABILITY AND REACTIVITY

Chemical Stability: Product has a shelf life that is temperature dependent.

Conditions to avoid: Extreme heat or cold. Avoid freezing and open flames.

Incompatibility: Oxidizers, strong acids and bases.

Hazardous Decomposition Products: Toxic fumes when heated to decomposition; carbon monoxide and carbon dioxide.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

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

CAS #

51022-70-9 **Albuterol Sulfate**

Albuterol may cause paradoxical, bronchospasm; fatalities have been reported with excessive use of inhaled sympathomimetic drugs. Albuterol was teratogenic in mice when given at doses corresponding to 14 times the human dose, and in rabbits at 2800 times the maximum human inhalation dose.

Albuterol may cause the following adverse reactions: palpitations, tachycardia, increased blood pressure, tremors, nausea, dizziness, heartburn, nervousness,

vomiting, headache, angina, insomnia, vertigo, and dryness or irritation of the throat. Rare cases of urticaria, rash, bronchospasm, oropharyngeal edema have also been reported.

Exposure is cautioned for those with cardiovascular disorders, including coronary insufficiency and hypertension, in those with hyperthyroidism or diabetes mellitus, ketoacidosis and in those who are unusually responsive to sympathomimetic amines.

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: Not Listed

SARA Title III: Not Listed

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste
(40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication.
NDC No. 24208-347-20 (20 ml)

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: 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
N/A – Not Applicable
< - Less Than
> - Greater Than