

SAFETY DATA SHEET

Identification 1.

> Product Identifier: Albuterol Sulfate Syrup

Synonyms: Salbutamol Sulfate

National Drug Code (NDC): 50383-740-16

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.

1925 West Field Court, Suite 300

Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

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

2. Hazard(s) Identification

> **Physical Hazards:** Combustible liquid Category 4

Health Hazards: Not classifiable.

Symbol(s): None.

Signal Word: Warning.

Hazard Statement(s): H227 Combustible liquid.

Precautionary Statement(s): Keep away from flames and hot surfaces. No P210

smoking.

P280 Wear protective gloves/eye protection/ face

protection.

P370 In case of fire: Use water, carbon dioxide, dry

chemical or foam as necessary to extinguish.

P378

P403 Store in a well-ventilated place. Keep cool.

P235

P501 Dispose of contents/container in accordance

with local/regional/national/international

regulations.

Hazards Not Otherwise Classified:

Not classifiable.

Supplementary Information: None.



3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Albuterol Sulfate	51022-70-9	Salbutamol sulfate	$(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$	576.71	0.04%

^{*}The formula also contains Citric Acid Anhydrous, FD & C Yellow No. 6, Hydroxypropyl Methylcellulose, Orange Flavor, Purified Water, Saccharin, Sodium Benzoate, and Sodium Citrate.

4. First Aid Measures

Ingastian.	If a narrow versite place them in the recovery position as
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 intended for human consumption under
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guidance of a physician. Solution is not considered

hazardous under normal conditions.



5.

SDS: Albuterol Sulfate Syrup

Medical Conditions Aggravated

by Exposure: WARNINGS: Immediate hypersensitivity reactions may occur after administration of Albuterol, as demonstrated

by rare causes of urticarial, angioedema, rash, bronchospasm, and oropharyngeal edema. Albuterol,

like other beta-adrenergic agonists, can produce a significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure, symptoms,

and/or electrocardiographic changes.

Other Health Warnings: The expected symptoms with overdosage are those of

excessive beta-stimulation and/or occurrence of exaggeration of any of the symptoms listed under.

Notes to Physician:

Firefighting Measures

Treat supportively and symptomatically.

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as

necessary.

Unsuitable Extinguishing Media: With small quantities use carbon dioxide extinguisher.

For large fires use ample quantities of water with dry

chemicals or foam as necessary.

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 lightly closed. Store between 36°F –

86°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		
Albuterol Sulfate	0.01 mg/m ³ TWA		

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

Physical State/Color:Yellow liquid.Odor:Orange flavor.Odor Threshold:No data available.

pH: 3.5 – 4.5.

Melting Point:No data available.Freezing Point:No data available.Boiling Point:No data available.

Flash Point: >150°F.

Evaporation Rate: Same as water.
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: >1.

Relative Density: No data available. Solubility(ies): Soluble in water.

Partition Coefficient

(n-octanol/water):No data available.Auto-Ignition Temperature:No data available.Decomposition Temperature:No data available.Viscosity:No data available.

Special Gravity: 1.00390.

10. Stability and Reactivity

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.

Hazardous Decomposition

Products: Does not undergo explosive decomposition.

Hazardous Polymerization: Will not occur.

11. <u>Toxicological Information</u>

Information on the Likely Routes of Exposure:

Inhalation:No data availableIngestion:No data available.Skin Contact:No data available.Eye Contact:No data available.



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. No data available. Corrosivity: **Dermal Irritation:** No data available. **Eve 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

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

13. Disposal Considerations

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

14. Transport Information

UN Number:
UN Proper Shipping Name:
Transport Hazard Class(es):
Packing Group:

Not applicable.
Not applicable.
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:

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: 0 Flammability: 2 Reactivity: 0

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