

## 1. Identification

<b>Product identifier</b>	<b>Albuterol Sulfate</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1012633	
<b>CAS number</b>	51022-70-9	
<b>Synonyms</b>	Salbutamol sulfate	
<b>Chemical name</b>	1,3-Benzenedimethanol, alpha1-[[[1,1-dimethylethyl)amino)methyl]-4-hydroxy-, sulfate (2:1) (salt)	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Reproductive toxicity	Category 2
	Specific target organ toxicity, single exposure	Category 1 (cardiovascular system)
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Suspected of damaging fertility or the unborn child. Causes damage to organs (cardiovascular system).	
<b>Precautionary statement</b>		
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
<b>Response</b>	If exposed: Call a poison center/doctor. If exposed or concerned: Get medical advice/attention.	
<b>Storage</b>	Store locked up.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.	
<b>Supplemental information</b>	Potent pharmacologically active material.	

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Albuterol Sulfate	Salbutamol sulfate	51022-70-9	100

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Never give anything by mouth to a person who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
<b>Most important symptoms/effects, acute and delayed</b>	Cardiovascular effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Cardiac monitoring is recommended. Use of a cardioselective beta-receptor blocker may be considered. Use the receptor blocker with caution because it could induce severe bronchospasm or an asthmatic attack.
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Wear appropriate protective equipment and clothing during clean-up.
<b>Methods and materials for containment and cleaning up</b>	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

### Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

#### Industrial Use Material

Material	Type	Value
Albuterol Sulfate (CAS 51022-70-9)	TWA	0.01 mg/m3

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Crystalline powder.

#### Color

White.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

314.6 °F (157 °C)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Soluble.
<b>Solubility (other)</b>	Chloroform: Slightly soluble. Dichloromethane: Slightly soluble. Ethanol: Slightly soluble.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Amine.
<b>Dust explosion properties</b>	
<b>Minimum ignition energy (MIE) - dust cloud</b>	> 25 mJ
<b>Molecular formula</b>	C13H21NO3.1/2H2O4S
<b>Molecular weight</b>	144.18

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents. Alkalis. Strong acids.
<b>Hazardous decomposition products</b>	SOx. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Based on information from therapeutic use, this material may cause: Cardiovascular effects.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Based on information from therapeutic use, this material may cause: Cardiovascular effects.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Beta-2 adrenergic agonists: Changes in blood pressure, heart rhythm, or heart rate. Behavior, mood or mental changes. Gastrointestinal disturbances.

### Information on toxicological effects

#### Acute toxicity

Product	Species	Test Results
Albuterol Sulfate (CAS 51022-70-9)		
<b>Oral</b>		
LD50	Mouse	1950 mg/kg
	Rat	> 2500 mg/kg
<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.	
<b>Serious eye damage/eye irritation</b>	Knowledge about health hazard is incomplete.	
<b>Local effects</b>		
Skin irritation test		
Result: Irritant.		
Species: Guinea pig		
Severity: Slight.		
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.	
<b>Mutagenicity</b>		
Ames test		
Result: Negative.		
Micronucleus assay		
Result: Negative.		
Species: Mouse		
Mutagenicity, Human peripheral lymphocyte assay		
Result: Negative.		
Mutagenicity, Mutation test in yeast		
Result: Negative.		
<b>Carcinogenicity</b>	Knowledge about carcinogenicity is incomplete.	
2 mg/kg Carcinogenicity		
Result: Significant dose-related increase in the incidence of benign leiomyomas of the mesovarium when administered in diet.		
Species: Rat		
Test Duration: 2 years		
50 mg/kg Carcinogenicity		
Result: Negative.		
Species: Hamster		
Test Duration: 22 months		
500 mg/kg Carcinogenicity		
Result: Negative.		
Species: Mouse		
Test Duration: 18 months		
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Not listed.		
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Not regulated.		
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Not listed.		
<b>Reproductive toxicity</b>	Suspected of damaging fertility or the unborn child.	
<b>Reproductivity</b>		
50 mg/kg Reproductivity		
Result: Cranioschisis occurred when administered orally.		
Species: Rabbit		
50 mg/kg Reproductivity		
Result: No evidence of impaired fertility when administered orally.		
Species: Rat		
<b>Specific target organ toxicity - single exposure</b>	Causes damage to organs (cardiovascular system).	

<b>Specific target organ toxicity - repeated exposure</b>	Knowledge about health hazard is incomplete.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.
<b>Further information</b>	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

## 12. Ecological information

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

<b>Disposal instructions</b>	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.
<b>General information</b>	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

<b>US federal regulations</b>	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>SARA 304 Emergency release notification</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not regulated.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance</b>	Not listed.
<b>SARA 311/312 Hazardous chemical</b>	Yes

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**US state regulations**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision****Issue date** 09-20-2005**Revision date** 10-18-2018**Version #** 04**Further information** Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.**Disclaimer** USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.