

Ipratropium Bromide Albuterol Sulfate Inhalation Solution

Safety Data Sheet

Revision date: 1/10/2013

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product name : Ipratropium Bromide Albuterol Sulfate Inhalation Solution

Use of the substance/mixture : Bronchodilator

Manufacturer:

The Ritedose Corporation
1 Technology Circle
Columbia, SC 29203
Telephone: 803-806-3300

Emergency number: :
803-935-4196

SECTION 2: Hazards identification

GHS Classification

Not Classified

GHS Label Elements

Symbols : Not Classified
Signal word : None
Hazard Statement : None
Precautionary statements : None

SECTION 3: Composition/information on ingredients

Component	Substance class	Chemical formula	M.W.	Approximate percent weight/weight	CAS
Ipratropium Bromide	Anticholinergic Bronchodilator		430.4	0.017	66985-17-9
Albuterol Sulfate	Bronchodilator		576.71	0.083	51022-70-9

Excipients:

Sodium Chloride
Purified Water, USP
Hydrochloric acid

SECTION 4: First aid measures

Description of first aid measures

First-aid measures after inhalation : If unintentional inhalation or overdose occurs, seek medical attention and remove to fresh air. If individual stops breathing, administer CPR and seek medical attention.

First-aid measures after skin contact : Wash affected areas with soap and water after removing contaminated clothing. Obtain medical attention if symptoms or irritation persist.

First-aid measures after eye contact : Flush with large amounts of cool water for at least 15 minutes. Obtain medical attention.

First-aid measures after ingestion : If individual is conscious, rinse mouth with water. Never give anything by mouth to an unconscious person or to any individual having convulsions.

Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : May cause respiratory irritation.

Symptoms/injuries after skin contact : May cause skin irritation.

Symptoms/injuries after eye contact : May cause eye irritation.

Symptoms/injuries after ingestion : May be harmful if swallowed.

Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media : Water spray, multipurpose dry chemical.

Unsuitable extinguishing media : None.

Special hazards arising from the substance or mixture

Fire hazard : Not applicable.

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Explosion hazard : Not applicable.
Reactivity : None.

Advice for firefighters

Protection during firefighting : Firefighters should wear protective clothing and use SCBA in the event of a fire where bulk quantities are stored.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

General measures : Use appropriate personal protection when handling spills

Environmental precautions

Prevent entry to sewers and public waters.

Methods and material for containment and cleaning up

For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, collect spillage by collecting with inert absorbent material and place in a labeled, sealed container for disposal. Wash spill area with soap and water.

SECTION 7: Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Surfaces should be cleaned if contaminated with substance.

Conditions for safe storage, including any incompatibilities

Store in airtight container. Protect vials from light and extreme heat.

SECTION 8: Exposure controls/personal protection

Component exposure limits

Hydrogen chloride (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³

Exposure controls

Appropriate engineering controls : No special ventilation required.
Hand protection : When routine handling or spill cleanup may result in skin contact, impermeable gloves should be worn. Wash hands thoroughly after handling material.
Eye protection : Not required for recommended dosage and administration.
Skin and body protection : Adequate clothing should be worn to prevent occupational skin contact.
Respiratory protection : Not required under normal conditions of therapeutic use.

SECTION 9: Physical and chemical properties

Physical state : Liquid
Appearance : Clear, colorless solution
Odour : Odorless
Evaporation rate : Not determined
Melting point : Not applicable
Boiling point : 100°C
Flash point : Not applicable
Solubility in water : Soluble

SECTION 10: Stability and reactivity

Reactivity

None.

Chemical stability

The product is stable at normal handling- and storage conditions.

Possibility of hazardous reactions

Will not occur.

Conditions to avoid

No conditions contributing to instability are known to exist.

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Incompatible materials

Not determined.

Hazardous decomposition products

Not determined.

SECTION 11: Toxicological information

Summary of risk: : This product is intended for therapeutic uses only when prescribe by a physician. Potential adverse reactions from prescribed doses and over does are described in package insert.

Ipratropium bromide (22254-24-6)	
LD50 oral rat	1663 mg/kg
ATE (oral)	1663 mg/kg

Bis[(tert-butyl)(.beta.,3,4-trihydroxyphenethyl)ammonium] sulphate (51022-70-9)	
LD50 oral rat	> 2500 mg/kg

Sodium chloride (7647-14-5)	
LD50 oral rat	3 g/kg
LD50 dermal rabbit	> 10 g/kg
LC50 inhalation rat (mg/l)	> 42 g/m ³ (Exposure time: 1 h)
ATE (oral)	3000000 mg/kg

Hydrogen chloride (7647-01-0)	
LD50 oral rat	700 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 inhalation rat (ppm)	3124 ppm (Exposure time: 1 h)

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg

Skin corrosion/irritation : May cause skin irritation.
Serious eye damage/irritation : May cause eye irritation.
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

Hydrogen chloride (7647-01-0)	
IARC group	3

Reproductive toxicity : Not classified
Specific target organ toxicity (single exposure) : Not classified
Specific target organ toxicity (repeated exposure) : Not classified
Aspiration hazard : Not classified

SECTION 12: Ecological information

Toxicity

Products administered to patients present a negligible impact on the environment.

Sodium chloride (7647-14-5)	
LC50 fishes 1	5560 - 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 - 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Hydrogen chloride (7647-01-0)	
LC50 fishes 1	282 mg/l (Exposure time: 96 h - Species: Gambusia affinis [static])

Persistence and degradability

No additional information available

Bioaccumulative potential

Sodium chloride (7647-14-5)	
BCF fish 1	(no bioaccumulation)

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Mobility in soil

No additional information available

Other adverse effects

No additional information available

SECTION 13: Disposal considerations

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.
EPA Designation RCRA Hazardous Waste: Not Listed
SARA Title III Not Listed

SECTION 14: Transport information

US Department of Transportation

Proper shipping name: Not Regulated

IATA/ICAO

Proper Shipping Name: Not Regulated

IMDG:

Proper shipping name: Not Regulated

RQ: None

Marine Pollutant: NO

SECTION 15: Regulatory information

Component Analysis

This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 302.4) and/or CERCLA (40 CFR 302.4)

Hydrochloric Acid: CERCLA: 5000 lbs

State Regulations

Component Analysis—State

The following appear on one or more of the following state hazardous substance lists:

Component	CAS	State
Hydrochloric acid	7647-01-0	MA, NJ, Penn

Component Analysis—Inventory

Component	CAS #	TSCA	EEC
Water	7732-18-5	Yes	EINECS
Sodium Chloride	7647-14-5	Yes	EINECS
Hydrochloric acid	7647-14-5	Yes	EINECS
Albuterol Sulfate	51022-70-9	No	EINECS
Ipratropium Bromide	22254-24-6	NO	EINECS

SECTION 16: Other information

See current package insert for use of the product. The Ritedose Corporation will assume no liability for the improper use of this product.