nephron pharmaceuticals corporation

Revision date: 02-01-2017

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Nephron Pharmaceuticals Corporation
4500 12th Street Extension
West Columbia, SC 29172-3025

(803) 569-2800
(800) 443-4313 (24 hour contact)

PRODUCT NAME:	Ipratropium Bromide, 0.5 mg/ Albuterol Sulfate, 3.0 mg Inhalation Solution, USP
COMMON NAME:	Ipratropium Bromide/ Albuterol Sulfate
CHEMICAL NAME:	Ipratropium Bromide: 8-azoniabicyclo [3, 2, 1]-octane, 3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-, bromide (endo, syn)-, (±)-, monohydrate Albuterol Sulfate: '- [tert-butylamino-methyl] -4-hydroxy-m-xilene--'-diol sulfate (2:1) (salt)
INTENDED USE:	Pharmaceutical product used as bronchodilator

SECTION 2: HAZARD(S) IDENTIFICATION

ROUTE OF ENTRY: Inhalation, ingestion, eyes/skin contact.

TARGET ORGANS: Liver, GI tract, adrenals, male reproductive organs and eyes.

POTENTIAL HEALTH HAZARDS:

Contraindications:	Although rare, this product can cause immediate hypersensitivity in patient. Therefore, this product should not be used by patients who have had a previous allergic reaction to ipratropium bromide, albuterol sulfate or its derivatives.
Carcinogenicity:	(NTP) No (IARC) No (OSHA) No
Chronic Effects:	Possible hypersensitization (development of abnormal sensitivity).

SECTION 3: COMPOSITON / INFORMATION ON INGREDIENTS

NAME:	Ipratropium Bromide, 0.5 mg/ Albuterol Sulfate, 3.0 mg Inhalation Solution, USP
CAS#:	66985-17-9/ 51022-70-9
Other Limits:	Not Established
NAME:	Water for Injection
CAS#:	7732-18-5

SECTION 4: FIRST AID MEASURES

If In Eyes:	Remove contact lenses if necessary. Flush with large amounts of cool water for at least 15 minutes. Obtain medical attention if blurred vision or sensitivity to light occurs.
If On Skin:	Wash affected areas with soap and water after removing contaminated clothing. Obtain medical attention if contamination is significant and/or a skin reaction is evident.
If Inhaled:	May cause irritation and hypersensitivity (anaphylactic) in some individuals. Inhalation of a liquid preparation is not likely. Evaporation is minimal at controlled room temperatures. If not breathing, give artificial respiration or CPR. If breathing is difficult, give oxygen. Obtain medical

attention and remove to fresh air.

If Ingested: Flush mouth out with water. Never give anything by mouth or induce vomiting if unconscious or having convulsions. Obtain medical attention.

SECTION 5: FIRE FIGHTING MEASURES

FLASH POINT/TEST METHOD:	Unknown.
LEL/UEL:	Unknown.
SPECIAL PROPERTIES RELATED TO FIRE HAZARD:	None.
STORAGE OR HANDLING CONDITIONS TO BE AVOIDED:	Extreme Heat.
EXTINGUISHING MEDIA:	Water Spray, Multipurpose Dry Chemical.
FIRE-FIGHTING PROCEDURES:	Wear full protective clothing and use self-contained breathing apparatus (SCBA).

SECTION 6: ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE PROCEDURES (Liquid, Solid, Gas/Vapor):

Protective equipment may be necessary for spills, (See Section 8, “Exposure Controls / Personal Protection” for guidance).

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 carefully sweeping or wiping and place in a labeled, sealed container for disposal.

ACCIDENTAL RELEASE: Clean up spills immediately, observing precautions in Section 8 - “Exposure Controls / Personal Protection”. Remove or decontaminate all residues in accordance with federal, state and local regulations.

SECTION 7: HANDLING AND STORAGE

HANDLING: Avoid contact with eyes, skin, and clothing.

STORAGE: Store between 36° and 77° F. Discard if solution becomes discolored.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: No special ventilation required.

PERSONAL PROTECTION:

Respiratory:	Not required under normal conditions of therapeutic use. See Section 5 “ Fire-Fighting Measures” for respiratory protection in the event of a fire.
Eye:	Not required for recommended dosage and administration. Workers should wear adequate eye protection if splash hazard exists.
Clothing:	Adequate protective clothing should be worn to prevent occupational skin contact.
Gloves:	When routine handling or spill cleanup may result in skin contact, impermeable (e.g., latex) gloves should be worn.
Work Practices:	Special care should be taken to ensure that contaminated clothing, equipment and work surfaces are properly cleaned after use. Wash hands and other areas of skin contact thoroughly after handling this material. Contaminated clothing should be cleaned or disposed of.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR:	Clear, aqueous solution with a little or no odor.
PHYSICAL STATE:	Liquid.
MELTING POINT:	Not determined.

BOILING POINT:	Not determined.
SOLUBILITY/MISCIBILITY (%w/v):	Not determined.

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY:	Stable.
CONDITIONS TO AVOID:	Not determined.
INCOMPATIBILITY WITH OTHER MATERIALS:	No known incompatibilities have been identified for this product.
HAZARDOUS DECOMPOSITION PRODUCTS:	Hazardous decomposition products have not been determined.

SECTION 11: TOXICOLOGICAL INFORMATION

THE RISK OF HEALTH HAZARDS MAY BE REDUCED WHEN HANDLED IN UNIT DOSAGE FORM.

PHARMACOLOGICAL ACTIVITY:	The active component is albuterol sulfate. Albuterol sulfate is a β_2-adrenergic bronchodilator used for the therapeutic effect of bronchial smooth muscle relaxation. This product is used for the prevention and relief of bronchospasm in patients with reversible obstructive airway disease (asthma) and for acute attacks of bronchospasm.
OCCUPATIONAL EXPOSURE LIMITS:	For products, the estimated safe working level is an eight-hour time-weighted average (TWA) of 10 mcg/m^3.
ACUTE TOXICITY:	Overexposure to the drug in the occupational setting may result in the same adverse effects which have been observed when albuterol sulfate is used medically. (See “Repeat Dose Toxicity” and “Clinical Safety”, below). Albuterol sulfate may be absorbed following ingestion, inhalation, and to a limited extent, through the skin.
REPEAT DOSE TOXICITY:	When used medically the following adverse effects have been reported: fine muscle tremors (especially the hands), muscle cramps, nausea or vomiting, headache, vertigo (dizziness), nervousness, heartburn, and rapid pulse, palpitations, and increased blood pressure. Hypersensitivity reactions (ranging from mild to life-threatening), such as urticaria (hives), skin rash, bronchospasm (constriction of the air passages in the lungs), and angioedema (swelling involving the skin and mucous membranes) have rarely occurred. In addition, albuterol sulfate may cause significant changes in blood pressure, extremely rapid heartbeat, seizures, low potassium levels, and may exacerbate the symptoms of pre-existent cardiovascular (heart and blood vessel) conditions and diabetes.
IRRITATION:	Products can cause eye irritation; avoid contact with the eyes. Products are irritating to the nose and throat.
SENSITIZATION:	Rarely, exposure to albuterol sulfate can cause an allergic rash with redness and itching of the skin. Exposure by inhalation can cause an allergic rash, difficultybreat hing and swelling of the face and airways.
REPRODUCTIVE EFFECTS:	Albuterol sulfate causes birth defects in mice. Rare reports of cleft palate and limb defects have been received in offspring of patients being treated with albuterol sulfate. There are no adequate and well-controlled studies of the effects of albuterol sulfate in pregnant women. Albuterol sulfate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. For recommended dosage and administration, Albuterol Sulfate Inhalation Solution 3.0mg is classified as “Pregnancy Category C”. It is not known whether this drug is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue using the drug, taking into account the importance of the drug to the mother. Precautions should be taken to limit the exposure to Albuterol Sulfate Inhalation Solution, 3.0mg while pregnant or

nursing: medical evaluation of exposure and attention to compliance with standard operating procedures and/or other workplace health and safety directives is advised.

GENOTOXICITY: There is no evidence that albuterol sulfate is mutagenic (causing changes in genetic material) or impairs fertility in standard tests.

CARCINOGENICITY: Albuterol sulfate was not carcinogenic in standard tests with mice and hamsters. Albuterol sulfate causes benign tumors to rats treated daily for 2 years with doses which are much greater than the recommended maximum dose for human medical use. The relevance of this finding to humans is not known.

CLINICAL SAFETY: Individuals known to be hypersensitive to β-adrenergic agents like albuterol sulfate should not be exposed. Persons with cardiovascular disorders (including coronary artery disease, heart rhythm abnormalities and high blood pressure), seizure disorders (epilepsy) hyperthyroidism, or diabetes may experience worsening of symptoms from occupational exposure. Also, persons using Albuterol Sulfate Inhalation Solution, 3.0mg or other medications in the same therapeutic class (β_2-adrenergic receptor agonists), or taking monoamine oxidase inhibitors or tricyclic antidepressants, may have increased sensitivity to the effects of albuterol sulfate in the occupational setting.

SECTION 12: ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE: Albuterol compartmentalizes into the aquatic environment.

ENVIRONMENTAL EFFECTS: Albuterol is not readily biodegradable in water or soil and is unlikely to bioaccumulate. It has toxicity to receptors in the aqueous environment at levels greater than 83.2 mg/L.

SECTION 13: DISPOSAL CONSIDERATIONS

ROUTINE: Unused product should be disposed of at an approved facility in accordance with federal, state and local regulations.

ACCIDENTAL RELEASE: Clean up spills immediately, observing precautions in Section 8 - “Exposure Controls / Personal Protection”.
Remove or decontaminate all residues in accordance with federal, state and local regulations.

SECTION 14: TRANSPORT INFORMATION

Component 1 or Formulation 1: Albuterol Sulfate Inhalation Solution, 3.0mg

US Department of Transportation
Proper Shipping Name: Pharmaceutical for Interstate Commerce

IATA/ICAO
Proper Shipping Name: Not Regulated

IMDG
Proper Shipping Name: Not Regulated

RQ: None Marine Pollutant: No

SECTION 15: REGULATORY INFORMATION

EC PACKAGING AND LABELING FOR SUPPLY: Not applicable.

OTHER LEGISLATION: Not regulated.

SECTION 16: OTHER INFORMATION

REVISION DATE: 02-01-2017

REVISION DATE: 07-22-2004 SUPERSEDES: 01-23-2003
REVISION DATE: 06-26-2014 SUPERSEDES: 07-22-2004

REVISION DATE: 02-09-2015 SUPERSEDES: 06-26-2014
REVISION DATE: 02-01-2017 SUPERSEDES: 02-09-2015

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL, SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY, OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES. PLEASE REFER TO THE PRODUCT PACKAGE INSERT FOR INFORMATION REGARDING THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.