



Revision Date: 02-01-2017

## SAFETY DATA SHEET

### SECTION 1: IDENTIFICATION

**Nephron Pharmaceuticals Corporation**  
 4500 12<sup>th</sup> Street Extension  
 West Columbia, SC 29172-3025

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

PRODUCT NAME: Albuterol Sulfate Inhalation Solution, 0.042%\* and 0.021%\*  
 \*potency expressed as albuterol, 1.5mg\*(0.042%) or 0.75mg (0.021%) 3mg albuterol sulfate  
 CHEMICAL NAME:  $\alpha^1$ -[tert-butylamino)-methyl]-4-hydroxy-m-xylene-  $\alpha$  -  $\alpha'$ -diol sulfate (2:1) (salt)  
 INN: Salbutamol  
 SUBSTANCE CLASS: Benzyl alcohol derivative: bronchodilator  
 INTENDED USE: Pharmaceutical product used as bronchodilator

### SECTION 2: HAZARD(S) IDENTIFICATION

The following adverse effects have been reported with medicinal use of Albuterol Sulfate Inhalation Solution, 0.042% or 0.021% may accompany unintentional exposure in sufficient dose: fine muscle tremors, muscle cramps, nausea/vomiting, headache, dizziness, nervousness, heartburn, and rapid pulse, palpitations, and increased blood pressure. Extremely rapid heartbeat, seizures, low serum potassium levels, and worsening of the symptoms of pre-existent cardiovascular (heart and blood vessel) conditions and diabetes are possible. Hypersensitivity reactions such as hives, skin rash, constriction of the air passages in the lungs, and swelling involving the skin and mucous membranes have been reported. (See Section 11, "Toxicological Information")

### SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

NAME: Albuterol Sulfate  
 CAS#: 51022-70-9  
 % w/v 0.042% or 0.021% albuterol sulfate  
 Other Limits: Not Established

NAME: Water for Injection  
 CAS# 7732-18-5

### SECTION 4: FIRST AID MEASURES

If In Eyes: Flush with large amounts of cool water for at least 15 minutes. Obtain medical attention.  
 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: If not breathing, give artificial respiration or CPR. If breathing is difficult, give oxygen. Obtain medical attention and remove to fresh air.  
 If Ingested: If awake and able to swallow, rinse mouth with water. Never give anything by mouth 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. Wash spill area (floor or other contact surfaces) with a suitable cleaning solvent, like ethanol.

## SECTION 7: HANDLING AND STORAGE

HANDLING:	Avoid contact with eyes, skin, and clothing.
STORAGE:	Protect from light and excessive heat 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, colorless and odorless.
PHYSICAL STATE:	Liquid.
MELTING POINT:	Not determined.
BOILING POINT:	Not determined.
SOLUBILITY/MISCIBILITY (%w/v):	The solubility of albuterol sulfate, the active ingredient, is 25% w/v in water. Albuterol sulfate is slightly soluble in ethanol, chloroform and ether.

## SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY:	Stable.
CONDITIONS TO AVOID:	Not determined.
INCOMPATIBILITY WITH OTHER MATERIALS:	No known incompatibilities have been identified for albuterol sulfate, the active ingredient in Albuterol Sulfate Inhalation Solution, 0.042% or 0.021%.

HAZARDOUS DECOMPOSITION PRODUCTS: Hazardous decomposition products have not been determined. Thermal decomposition products of albuterol sulfate, the active ingredient, include toxic and/or corrosive oxides of nitrogen.

## SECTION 11: TOXICOLOGICAL INFORMATION

**THE RISK OF HEALTH HAZARDS MAY BE REDUCED WHEN ALBUTEROL SULFATE INHALATION SOLUTION, 0.042% and 0.021% IS HANDLED IN UNIT DOSAGE FORM.**

**PHARMACOLOGICAL ACTIVITY:** The active component is albuterol sulfate. Albuterol sulfate is a  $\beta_2$ -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 albuterol sulfate, the estimated safe working level is an eight-hour time-weighted average (TWA) of 0.010mg/m<sup>3</sup> or 10 mcg/m<sup>3</sup>.

**ACUTE TOXICITY:** Overexposure to albuterol sulfate 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:** Albuterol sulfate causes eye irritation; avoid contact with the eyes. Albuterol sulfate is 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, difficulty breathing 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, 0.42% or 0.21% 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 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  $\beta$ -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, or other medications in the same therapeutic class ( $\beta_2$ -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**

<b>ENVIRONMENTAL FATE:</b>	Albuterol compartmentalizes into the aquatic environment.
<b>ENVIRONMENTAL EFFECTS:</b>	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.
<b>ENVIRONMENTAL TEST RESULTS:</b>	

STUDY NAME	RESULTS
Water Solubility	24.5% w/v at pH 7
Hydrolysis Rate	Does not hydrolyze
Vapor Pressure	$2 \times 10^{-5}$ Pascals at 25° C
Dissociation Constant	pKa = 9.14
n-Octanol/Water Partition Coefficient	$1.7 \times 10^{-3}$ at pH 7
UV/Visible Spectrum	15300 at 225 nm water 1500 at 225 nm in HCl 2400 at 244 nm in NaOH
Aerobic Biodegradation (soil)	Partial biodegradation in soil 38.7% maximum in clay loam
Aerobic Biodegradation (water)	Not readily biodegradable
Soil Adsorption/Desorption	Low adsorption <25%
Activated sludge respiration inhibition test	>830 mg at 3 hours
Five day bacterial inhibition	No effect at 18.5 mg/L
Acute toxicity to Daphnia	LC <sub>50</sub> = 243 mg at 48 hours No effect 83.2 mg/L

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>ROUTINE:</b>	Unused product should be disposed of at an approved facility in accordance with federal, state and local regulations.
<b>ACCIDENTAL RELEASE:</b>	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 0.042% or 0.021%
Proper Shipping Name:	Pharmaceutical for Interstate Commerce

**IATA/ICAO**

Proper Shipping Name:	Not Regulated
Safety Data Sheet	

**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: 08-21-2014	SUPERSEDES: 07-22-2004
REVISION DATE: 02-06-2015	SUPERSEDES: 08-21-2014
REVISION DATE: 02-01-2017	SUPERSEDES: 02-06-2015

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.