



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 Inhalation Solution, 0.02%
 COMMON NAME: Ipratropium Bromide
 CHEMICAL NAME: 8-azoniabicyclo[3.2.1]-octane,3-(3-hydroxy-1oxo-2-phenylpropoxy)-8-methl-8-(1-methylethyl)-,bromide, monohydrate (endo,syn)-,(±)
 INN: Ipratropium Bromide
 SUBSTANCE CLASS:
 INTENDED USE: Pharmaceutical Use for Inhalation

SECTION 2: HAZARD(S) IDENTIFICATION

Carcinogenicity: (NTP) No (IARC) No (OSHA) No
 Eye: No known significant effects or critical hazards, may cause irritation.
 Skin: No known significant effects or critical hazards, may cause irritation.
 Ingestion: No known significant effects or critical hazards.
 Inhalation: No known significant effects or critical hazards, may cause respiratory irritation.
 Chronic Effects: No known significant effects or critical hazards.
 Target Organs: No known significant effects or critical hazards.
 Medical Conditions Aggravated by long Exposure: No known significant effects or critical hazards.
 (See Section 11, "Toxicological Information")

SECTION 3: COMPOSITON / INFORMATION ON INGREDIENTS

NAME: Ipratropium Bromide
 CAS#: 22254-24-6
 % w/v 0.02%
 GW Limits Not Established
 Other Limits: Not Established

Name: Water for Injection
 CAS# 7732-18-5
 % w/v 99.98%

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: 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, carbon dioxide, and foam for surrounding fire and materials.
FIRE-FIGHTING PROCEDURES:	Wear full protective clothing and use self-contained breathing apparatus (SCBA). Use water spray to keep fire exposed containers cool.

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).

Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent materials to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

SECTION 7: HANDLING AND STORAGE

HANDLING:	No special protective equipment or procedures are required in the clinical or home environment, Wash thoroughly after handling.
STORAGE:	Protect from light, Store between 59° and 86° F. Discard if solution becomes discolored.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: In manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Safety Data Sheets.

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 goggles or 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 with soap and water after handling this material. Contaminated clothing should be cleaned or disposed of. Release rinse water into an approved wastewater system according to Federal, State and Local regulations.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR:	Clear, colorless solution with little or no odor.
PHYSICAL STATE:	Liquid Solution
Safety Data Sheet	

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

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable.
CONDITIONS TO AVOID: None known.
INCOMPATIBILITY WITH OTHER MATERIALS: Iodine
HAZARDOUS DECOMPOSITION PRODUCTS: When heated to decomposition or under fire conditions, material emits toxic fumes of bromide.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see the SDS on raw chemical material.

SECTION 12: ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE: Not known
ENVIRONMENTAL EFFECTS: Not known
ENVIRONMENTAL TEST RESULTS: N/A

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: Ipratropium Bromide 0.02%

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

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: 03-10-2014 SUPERSEDES: 07-22-2004
REVISION DATE: 06-19-2014 SUPERSEDES: 03-10-2014
REVISION DATE: 02-04-2015 SUPERSEDES: 06-19-2014

REVISION DATE: 02-01-2017

SUPERSEDES: 02-04-2015

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.