

# BAUSCH & LOMB

Pharmaceutical Division

## MATERIAL SAFETY DATA SHEET

Issued: 02/07/03  
Revised: N/A  
Revision: Original

Prepared by: Gary Wong  
Manager EHS  
Core No. 399

### 1. PRODUCT AND COMPANY INFORMATION

**Product Name:** Ipratropium Bromide Nasal Solution 0.06% (Nasal Spray)  
**Generic Name:** Ipratropium Bromide Nasal Solution 0.06% (Nasal Spray)  
**NDC No.** 24208-399-15 (15ml)

**Legal Category:** Prescription only medicine filled in 15 ml bottle with spray attachment and overpacked inside a cardboard carton.

**Drug Composition:** Anticholinergic agent

BAUSCH & LOMB PHARMACEUTICALS, INC.  
8500 Hidden River Parkway  
Tampa, FL 33637

Information: (800) 323-0000 (M-F) 8am-5pm EST  
Emergency: (800) 227-1427 24 hrs

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Description Content	CAS #	TLV (mg/m <sup>3</sup> )	PEL (mg/m <sup>3</sup> )	%
Ipratropium Bromide	66985-17-9	NE	NE	0.06%
Purified Water	7732-18-5	NE	NE	≥ 1

Ingredients <1% - Sodium Chloride, Edetate Disodium Dihydrate, Benzalkonium Chloride

---

### 3. HAZARDS IDENTIFICATION

---

\*\*\*\*\*

#### EMERGENCY OVERVIEW

Clear colorless solution in plastic bottle with spray attachment. Presents little or no hazards if spilled and no unusual hazard if involved in fire.

\*\*\*\*\*

#### POTENTIAL HEALTH HAZARDS

**Carcinogenicity:** (NTP) No (IARC) No (OSHA) No

**Eye:** Do not spray Ipratropium Bromide Nasal Solution 0.06% (Nasal Spray) in your eyes. Patients should be advised that temporary blurring of vision, precipitation or worsening of narrow-angle glaucoma or eye pain may result if Ipratropium Bromide Nasal Solution 0.06% (Nasal Spray) comes into direct contact with the eyes.

**Skin:** May cause irritation.

**Ingestion:** Ipratropium Bromide is not well absorbed systemically after intranasal or oral administration. Following administration of a 20 mg oral dose (equivalent to ingesting more than two bottles of Ipratropium Bromide Nasal Solution 0.06% Nasal Spray) to 10 male volunteers, no change in heart rate or blood pressure was noted.

**Inhalation:** The most frequently reported nasal adverse events were transient episodes of nasal dryness or epistaxis.

**Chronic Effects:** Oral median lethal doses of Ipratropium Bromide were greater than: 1,000 mg/kg in mice (approximately 6,000 and 3,800 times the maximum recommended daily intranasal dose in adults and children, respectively, on a mg/m<sup>2</sup> basis) 1,700 mg/kg in rats (approximately 21,000 and 13,000 times the maximum recommended daily intranasal dose in adults and children, respectively, on a mg/m<sup>2</sup> basis) and 400 mg/kg in dogs (approximately 16,000 and 10,000 times the maximum recommended daily intranasal dose in adults and children, respectively, on a mg/m<sup>2</sup> basis).

**Target Organs:** Target organs of toxicity (0.06%) at repeated doses were liver, GI tract adrenals (rat), male reproductive organs and eyes (dog).

**Medical Conditions Aggravated by Long Term Exposure:** Ipratropium Bromide Nasal Solution 0.06% (Nasal Spray) was well tolerated by most patients. The most frequently reported adverse events were transient episodes of nasal dryness or

epistaxis. The majority of these adverse events (96%) were mild or moderate in nature, none was considered serious, and none resulted in hospitalization. No patient required treatment for nasal dryness, and only three patients (<1%) required treatment for epistaxis, which consisted of local application of pressure or a moisturizing agent (e.g., petroleum jelly). No patient receiving Ipratropium Bromide Nasal Solution 0.06% (Nasal Spray) was discontinued from the trial due to either nasal dryness or bleeding. Adverse events reported by less than 1% of the patients receiving Ipratropium Bromide Nasal Solution 0.06% (Nasal Spray) during the controlled clinical trials which are potentially related to Ipratropium Bromide's local effects or systemic anticholinergic effects include: taste perversion, nasal burning, conjunctivitis, coughing, dizziness, hoarseness, palpitation, pharyngitis, tachycardia, thirst, tinnitus and blurred vision. Additional anticholinergic effects noted with other Ipratropium Bromide dosage forms (Ipratropium Bromide inhalation solution, Ipratropium Bromide inhalation aerosol, and Ipratropium Bromide Nasal Solution 0.06% Nasal Spray include: precipitation or worsening of narrow-angle glaucoma, urinary retention, prostate disorders, constipation, and bowel obstruction. There were no reports of allergic-type reactions in the controlled clinical trials. Allergic-type reactions such as skin rash, angioedema of the tongue, lips and face, urticaria, laryngospasm and anaphylactic reactions have been reported with other Ipratropium Bromide products. No controlled trial was conducted to address the relative incidence of adverse events for three times daily versus four times daily therapy.

---

#### **4. FIRST AID MEASURES**

---

**Eyes:** Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

**Skin:** Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

**Ingestion:** Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

**Inhalation:** Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

#### **Note to Physicians:**

**Pregnancy:** TERATOGENIC EFFECTS Pregnancy Category B. Oral reproduction studies were performed at doses of 10 mg/kg in mice, 1,000 mg/kg in rats and 125 mg/kg in rabbits. These doses correspond, in each species respectively, to approximately 60, 12,000, and 3,000 times the maximum recommended daily intranasal dose in adults on a mg/m<sup>2</sup> basis. Inhalation reproduction studies were conducted in rats and rabbits at doses of 1.5 and 1.8 mg/kg, respectively

(approximately 20 and 45 times, respectively, the maximum recommended daily intranasal dose in adults on a mg/m<sup>2</sup> basis). These studies demonstrated no evidence of teratogenic effects as a result of Ipratropium Bromide. At oral doses above 90 mg/kg in rats (approximately 1,100 times the maximum recommended daily intranasal dose in adults on a mg/m<sup>2</sup> basis) embryotoxicity was observed as increased resorption. This effect is not considered relevant to human use due to the large doses at which it was observed and the difference in route of administration. However, no adequate or well controlled studies have been conducted in pregnant women. Because animal reproduction studies are not always predictive of human response, Ipratropium Bromide should be used during pregnancy only if clearly needed.

**Nursing Mothers:** It is known that some Ipratropium Bromide is systemically absorbed following nasal administration; however the portion which may be excreted in human milk is unknown. Although lipid-insoluble quaternary bases pass into breast milk, the minimal systemic absorption makes it unlikely that Ipratropium Bromide would reach the infant in an amount sufficient to cause a clinical effect. However, because many drugs are excreted in human milk, caution should be exercised when Ipratropium Bromide Nasal Solution 0.06% Nasal Spray is administered to a nursing woman.

Additional details are available on the package insert or in the [Physicians Desk Reference](#).

---

## 5. FIRE FIGHTING MEASURES

---

**Flammable Properties:** Flash point: NE Method: NE

**Hazardous Products:** CO, CO<sub>2</sub>, NO<sub>x</sub>, HBr

**Extinguishing Media:** Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

**Fire Fighting Instructions:** Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

---

## 6. ACCIDENTAL RELEASE MEASURES

---

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

---

## 7. HANDLING AND STORAGE

---

**Handling:** Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

**Storage:** Store product upright in original containers with the cap tightly closed at a controlled room temperature 15<sup>0</sup>-30<sup>0</sup> C (59<sup>0</sup>- 86<sup>0</sup> F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

---

## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

---

**Engineering Controls:** In the 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 Material Safety Data Sheets.

**Eye Protection:** (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

**Skin Protection:** Thick impermeable gloves and protective clothing.

**Respiratory Protection:** (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

**Warning:** **Do not use air-purifying respirators in oxygen-depleted environments.** No respiratory protection is required in the clinical or home environment.

**Other:** None

**Ventilation:** Recommended

**Contaminated Equipment:** Wash contaminated clothing separately. Wash contaminated equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

---

## 9. CHEMICAL & PHYSICAL PROPERTIES

---

Appearance & Odor:	Clear, colorless solution		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Miscible	Percent Volatile by Volume:	<1

---

## 10. STABILITY AND REACTIVITY

---

**Chemical Stability:** Stable

**Conditions to avoid:** Extreme heat or cold.

**Incompatibility:** This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

**Hazardous Decomposition Products:** CO, CO<sub>2</sub>, NO<sub>x</sub>, HBr

**Hazardous Polymerization:** Should not occur.

---

## 11. TOXICOLOGY

---

**Summary of Risks:** Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material

CAS # 66985-17-9 **Ipratropium Bromide**

Oral median lethal doses of Ipratropium Bromide were greater than 1,000 mg/kg in mice (approximately 16,000 and 9,500 times the maximum recommended daily intranasal dose in adults and children, respectively, on a mg/m<sup>2</sup> basis), 1,700 mg/kg in rats (approximately 55,000 and 32,000 times the maximum recommended daily intranasal dose in adults and children, respectively, on a mg/m<sup>2</sup> basis), and 400 mg/kg in dogs (approximately 43,000 and 25,000 times the maximum recommended daily intranasal dose in adults and children, respectively, on a mg/m<sup>2</sup> basis).

---

## 12. ECOLOGICAL INFORMATION

---

**Chemical Fate Information:** Product administered to patients presents a negligible impact on the environment.

---

## 13. DISPOAL INFORMATION

---

**Dispose of material according to Federal, State, and Local regulations.** The method typically used is incineration.

**EPA Designations:** RCRA Hazardous Waste: Not Listed

**SARA Title III:** Not Listed

---

**14. TRANSPORTATION INFORMATION**

---

**Transportation Data:** Not classified as hazardous by DOT regulations.

---

**15. REGULATORY INFORMATION**

---

**DOT Designations:** Not classified as hazardous by DOT regulations.

**EPA Designations:** RCRA Hazardous Waste  
(40 CFR 261.33) Not Listed

**FDA Designations:** Prescription only medication.  
NDC No. 24208-399-15 (15ml)

**OSHA Designations:** (29 CFR 1910.1000, Table Z)  
Not Listed

**SARA Title III:** Not listed under Section 313 of Toxic Release Reporting.

**CALIFORNIA PROPOSITION 65:** Not Listed

---

**16. OTHER INFORMATION**

---

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established

< - Less Than

> - Greater Than