

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Ipratropium Nasal Spray
Identified uses of the substance or mixture	Pharmaceutical
Manufacturer	Lupin Limited Pithampur (M.P.) – 454 775 INDIA.
Distributor	Lupin Pharmaceuticals, Inc. Naples, FL 34108 United States.

Section 2: Hazard(s) Identification

Health	May be harmful if swallowed. May cause eye irritation (based on components). Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Environment	No data available
Precautionary statements	IF ON SKIN: Wash with plenty of soap and water If skin irritation occurs: Get medical advice/attention IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses. If eye irritation persists: Get medical advice/attention Take off contaminated clothing and wash it before reuse. Do not handle until all safety precautions have been read and understood.
Other hazards	No data available.

Section 3: Composition/Information on Ingredients

Ipratropium Bromide Nasal Solution 0.03%, 0.06%

Ingredients	CAS No.	Ingredients	CAS No.
Ipratropium bromide USP	22254-24-6	Hydrochloric acid NF	7647-01-0
Sodium Chloride USP	7647-14-5	Sodium hydroxide NF	1310-73-2
Disodium edetate dihydrate. (Edetate disodium) USP	6381-92-6	Purified Water USP	7732-18-5
Benzalkonium chloride NF	8001-54-5	-	-

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

Inhalation	Remove the affected person to a well-ventilated area and get immediate medical attention. If you experience excessive nasal dryness or episodes of nasal bleeding contact your doctor.
Skin contact	Immediately remove all contaminated clothing, including footwear. Flush the affected area with copious amounts of water for at least 15 minutes. If irritation or rash develops, get medical attention.
Eye contact	Do not spray in the eyes. Remove contact lenses if necessary. Flush eyes with large amounts of running water for at least 15 minutes. If you accidentally spray ipratropium bromide nasal solution in your eyes, you may experience a temporary blurring of vision, visual halos or colored images in association with red eyes from conjunctival and corneal congestion, development or worsening of narrow-angle glaucoma, pupil dilation, or acute eye pain/discomfort, and increased sensitivity to light, which may last a few hours. Should acute eye pain or blurred vision occur, contact your doctor.
If swallowed	Rinse mouth out with copious amounts of water. Do not induce vomiting or give anything by mouth to an unconscious or convulsing person. Seek immediate medical attention.

Section 5: Fire-Fighting Measures

Specific hazards during firefighting	None known product is not flammable or combustible.
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Special Firefighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire.

Section 6: Accidental Release Measures

Personal Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Ensure adequate ventilation.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Clean-up Methods	Sweep/wipe up and containerize spill material in a compatible container. Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Dispose according to applicable regulations.

Section 7: Handling and Storage

Handling	No special handling is required. Refer to Section 8. Use only in accordance with the product information insert.
Storage	Store tightly closed at 20° to 25°C (68° to 77°F). Avoid freezing. Keep out of the reach of children.

Section 8: Exposure Controls/Personal Protection

Engineering Measures/Controls:	General exhaust is adequate under normal operating conditions. None needed for finished product.
Personal Protective Equipment:	<p>Respiratory: Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.</p> <p>Eye/Face: Avoid contact with the eye. No special controls or personal protection required under conditions of intended use.</p> <p>Skin/Body: No special personal protection required under conditions of intended use.</p>

Section 9: Physical and Chemical Properties

HOW SUPPLIED	<p>Ipratropium Bromide Nasal Solution 0.06%: It is supplied as a clear, colorless solution in a white high-density polyethylene (HDPE) bottle fitted with a metered nasal spray pump, a white safety clip to prevent accidental discharge of the spray, and a clear plastic dust cap. It contains 16.6 g of product formulation, 165 sprays, each delivering 42 mcg of ipratropium bromide per spray (70 mL).</p> <p>Ipratropium Bromide Nasal Solution 0.06 % is available in the following configurations: Nasal Spray, 42 mcg/spray NDC 70748-337-01: Bottle of 15 mL (165 metered sprays) in a carton</p> <p>Ipratropium Bromide Nasal Solution 0.03%: It is supplied as a clear, colorless solution in a white high-density polyethylene (HDPE) bottle fitted with a white and clear metered nasal spray pump, a white safety clip to prevent accidental discharge of the spray, and a clear plastic dust cap. It contains 31.1 g of product formulation, 345 sprays, each delivering 21 mcg (70 mL) of ipratropium per spray</p> <p>Ipratropium Bromide Nasal Solution, 0.03% Nasal Spray, 21 mcg/spray NDC 70748-336-01: Bottle of 30 mL (345 metered sprays) in a carton.</p>
Appearance	Aerosol, Colorless.
Odor	No information available
pH	No information available
Melting point/freezing point	No information available

Initial boiling point and boiling range	No information available
Flash points	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability (liquids)	No information available
Upper explosion limit / Upper flammability limit	No information available
Lower explosion limit / Lower flammability limit	No information available
Vapor pressure	13,171 hPa (50 °C)
Relative vapor density	No information available
Relative density	No information available
Solubility & Water solubility	Soluble in water
Partition coefficient	No information available
Auto-ignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available
Explosive properties	No information available

Section 10: Stability and Reactivity

Stability	Stable under normal conditions of use.
Reactivity	No dangerous reactions known.
Hazardous reactions	No data available.
Conditions to avoid	None known. Hazardous Polymerization will not occur.
Hazardous decomposition products	When heated to decomposition or under fire conditions, material may emit toxic fumes.

Section 11: Toxicological Information

Inhalation	Acute Immediate - Local effects on nasal membranes such as dryness. Minimal systemic absorption. Chronic (Delayed) - Under normal conditions of use, no health effects are expected.
Skin Contact	Under normal conditions of use, no health effects are expected.
Ingestion	Under normal conditions of use, no health effects are expected.
Eye Contact	you may experience a temporary blurring of vision, visual halos or colored images in association with red eyes from conjunctival and corneal congestion, development or worsening of narrow-angle glaucoma, pupil dilation, or acute eye pain/discomfort, and increased sensitivity to light, which may last a few hours. Should acute eye pain or blurred vision occur, contact your doctor.
Carcinogenicity	Not classified based on available information.
Reproduction toxicity	Not classified based on available information.

Section 12: Ecological Information

Eco toxicity	The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.
Reactivity	No dangerous reactions known
Hazardous reactions	No data available
Conditions to avoid	Releases to the environment should be avoided.
Hazardous decomposition products	When heated to decomposition or under fire conditions, material may emit toxic fumes.

Section 13: Disposal Considerations

Dispose of material according to federal, state, and local disposal regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper Shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper Shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper Shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.