



<b>IN CASE OF EMERGENCY</b> <b>Emergency Phone: (614) 276-4000</b>
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## Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Ipratropium Bromide Nasal Spray		
Chemical Name: 8-azoniabicyclo (3.2.1) octane,3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-, bromide, monohydrate ( <i>endo,syn</i> )-, (±)-		
Synonyms: None		
Molecular Formula: C <sub>20</sub> H <sub>30</sub> BrNO <sub>3</sub> • H <sub>2</sub> O		
Molecular Weight: 430.4		
CAS No: 22254-24-6		
Chemical Family: Anticholinergic agent		
Product Use: Relief from rhinorrhea associated with the common cold or seasonal allergic rhinitis		
Manufacturer's Name: <b>Boehringer Ingelheim Roxane Inc.</b>		
Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Ipratropium Bromide Monohydrate (active ingredient)	22254-24-6	None established
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as &lt;1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Liquid solution administered intranasally. Colorless aqueous solution that contains 0.03 or 0.06% active ingredient.  Odor: Little to none  <b>WARNING!</b> May be harmful if inhaled or swallowed. Accidental ingestion of large amounts may be fatal.	
Primary Route(s) of Entry	Inhalation	
Potential Health Effects:	Inhalation: May be harmful if inhaled. Inhalation may cause nasal dryness, nose bleeds, dry mouth/throat and other systemic effects.  Eye Contact: Not expected to be a hazard to the eye. Contact with eye may cause irritation, burning and redness.  Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.  Ingestion: May be harmful if ingested. Ingestion may cause abdominal pain, diarrhea and nausea.	
Toxicity Data:	See Section 11	
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by inhalation or ingestion may cause headache, swelling of lips and tongue, upper respiratory tract infection, nose bleeds, sore throat and blurred vision.	
Target Organs:	Nasal Passages	
4. FIRST AID MEASURES		

Eye Exposure	Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.				
Skin Exposure	Wash with soap and water. Get medical attention if symptoms occur.				
Ingestion	Call a physician or poison control center immediately.				
Inhalation	If breathing is difficult, move to fresh air. Get medical attention immediately.				
<b>5. FIRE AND EXPLOSION HAZARDS</b>					
Flammability	Lower: N/A		Upper: N/A		
Flash Point	Not available				
Extinguishing Media	Use water spray, carbon dioxide, dry chemical, foam or material appropriate for fire in surrounding area.				
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus.				
Unusual Fire/Explosion Hazards	Not Applicable				
Hazardous Combustion Products	Carbon dioxide, carbon monoxide, oxides of nitrogen, hydrogen bromide				
<b>6. ACCIDENTAL RELEASE INFORMATION</b>					
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED: Use appropriate personal protective equipment (see Section 8). Wipe up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.					
<b>7. PRECAUTIONS FOR SAFE HANDLING AND USE</b>					
Precautions Handling Significant Quantities of Liquid:	Observe good industrial hygiene practices.				
Storage	Store at 20° to 25°C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs. Avoid freezing.				
<b>8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT</b>					
Exposure Limits	None				
Engineering Controls	Not required when handling liquid or containers. Good ventilation should be used. Ventilation should be matched to conditions.				
Respiratory Protection	Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.				
Personal Protection	Not required when handling final product. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves				
Recommended Facilities	Eye wash, washing facilities				
<b>9. PHYSICAL / CHEMICAL CHARACTERISTICS</b>					
Appearance	Colorless aqueous solution	Melting point	Not available	Solubility in water	Soluble
Odor	Little to none	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	4.7	Density	Not available	Flammability Limits	Not available
<b>10. STABILITY AND REACTIVITY DATA</b>					

<b>Stability</b>	Stable
<b>Incompatibility</b>	None known
<b>Hazardous Decomposition</b>	Oxides of carbon, oxides of nitrogen, hydrogen bromide
<b>Conditions to Avoid</b>	Excessive heat, light
<b>Hazardous Polymerization</b>	Will not occur.
<b>11. TOXICOLOGICAL INFORMATION</b>	
<p><b>Acute Toxicity:</b></p> <p><b>Active Ingredient:</b>  Oral LD50 (rat): 1663 mg/kg  Oral LD50 (mouse): 1001 mg/kg</p> <p><b>Carcinogenicity:</b> Not listed as a carcinogen by NTP, IARC Monographs or OSHA.</p>	
<b>12. ENVIRONMENTAL IMPACT INFORMATION</b>	
No information is currently available on the environmental impact of this product.	
<b>13. DISPOSAL INFORMATION</b>	
<p><b>Waste Disposal Considerations:</b> Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.  At home: Discard away from children's reach.</p>	
<b>14. TRANSPORTATION INFORMATION</b>	
<p>This product is not subject to the regulations for the safe transport of hazardous chemicals.  DOT: Not regulated  TDG: Not regulated  IATA: Not regulated  IMDG: Not regulated</p>	
<b>15. REGULATORY INFORMATION</b>	
<p><b>DEA:</b> Ipratropium Bromide is not a controlled substance.</p> <p><b>FDA:</b> Ipratropium Bromide is an approved prescription medication.</p> <p><b>Inventory Status:</b>  This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&amp;D or drug use.  This material is not listed on the DSL Inventory but is exempt.</p>	
<b>16. OTHER DATA</b>	
<p><b>ABBREVIATIONS:</b>  N/A – not applicable</p> <p>Prepared by: Boehringer Ingelheim Roxane Inc.</p> <p><b>References:</b></p> <ol style="list-style-type: none"> <li>1. Ipratropium Bromide Nasal Spray, Package Insert, Boehringer Ingelheim Roxane Inc., Columbus, Ohio</li> <li>2. RTECS No. YM3700000 - 1-alpha-H,5-alpha-H-Tropanium, 3-alpha-hydroxy-8-isopropyl-, bromide, (+-)-tropate</li> <li>3. Ariel Webinsight. Regulatory and ChemExpert Database.</li> <li>4. PDR – Physicians Desk Reference</li> </ol>	
Date: New MSDS: 02/27/2002	Revised: 10/01/2008
<b>SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION</b>	

*The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated, it may pose hazards not mentioned in this MSDS. It is the users' responsibility to use the information according to the application. Boehringer Ingelheim Roxane Inc. assumes no responsibility or liability resulting from the use of this information.*