

## Safety Data Sheet

### Section 1: Identification

#### Product identifier

- Product Name** • Ipratropium Bromide Nasal Spray, 0.03%  
**Product Code** • AB39816; Core No. 398; NDC 24208-0398-30

#### Relevant identified uses of the substance or mixture and uses advised against

- Recommended use** • Finished Pharmaceutical Product; Ipratropium bromide nasal solution is indicated for the symptomatic relief of rhinorrhea associated with allergic and nonallergic perennial rhinitis.
- Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

#### Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb  
1400 North Goodman Street  
Rochester, NY 14609  
United States  
bausch.com
- Telephone (General)** • 1-800-553-5340

#### Emergency telephone number

- Manufacturer** • 1-800-535-5053 - Infotrac

*This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.*

### Section 2: Hazard Identification

#### UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

#### Classification of the substance or mixture

- UN GHS** • Eye Irritation 2A

#### Label elements

**UN GHS**

#### WARNING



- Hazard statements** • May cause eye irritation

#### Precautionary statements

**Prevention** • Wear eye/face protection , .  
Wash thoroughly after handling.

**Response** • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
If eye irritation persists: Get medical advice/attention.

**Storage/Disposal** • Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

## Other hazards

UN GHS

- No data available

## Section 3 - Composition/Information on Ingredients

### Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

### Mixtures

| Composition                      |                                    |         |                                                                                |
|----------------------------------|------------------------------------|---------|--------------------------------------------------------------------------------|
| Chemical Name                    | Identifiers                        | %       | Classifications According to Regulation/Directive                              |
| Benzalkonium Chloride            | CAS:63449-41-2<br>EINECS:264-151-6 | < 0.1%  | UN GHS: Skin Corr. 1B; Acute Tox. Oral 4; Acute Tox. Dermal 4; Aquatic Acute 1 |
| Edetate Disodium Dihydrate       | CAS:139-33-3<br>EINECS:205-358-3   | < 0.1%  | UN GHS: NDA                                                                    |
| Iprratropium Bromide Monohydrate | CAS:66985-17-9<br>EC Number:       | 0.03%   | UN GHS: NDA                                                                    |
| Sodium chloride                  | CAS:7647-14-5<br>EINECS:231-598-3  | < 1%    | UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5                        |
| Water                            | CAS:7732-18-5<br>EINECS:231-791-2  | Balance | UN GHS: Classification criteria not met                                        |

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

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

## Section 4: First-Aid Measures

### Description of first aid measures

#### Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

#### Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

#### Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical

advice/attention.

## Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

## Most important symptoms and effects, both acute and delayed

- Be advised that temporary blurring of vision, precipitation or worsening of narrow-angle glaucoma, mydriasis, increased intraocular pressure, acute eye pain or discomfort, visual halos or colored images in association with red eyes from conjunctival and corneal congestion may result if ipratropium bromide nasal solution 0.03% (Nasal Spray) comes into direct contact with the eyes.

## Indication of any immediate medical attention and special treatment needed

### Notes to Physician

- Additional details are available on the product package insert or the Physicians Desk Reference.

## Section 5: Fire-Fighting Measures

### Extinguishing media

**Suitable Extinguishing Media** • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

**Unsuitable Extinguishing Media** • No data available

### Special hazards arising from the substance or mixture

**Unusual Fire and Explosion Hazards** • None known - product is not flammable or combustible.

**Hazardous Combustion Products** • No data available

### Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

## Section 6 - Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions** • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.

**Emergency Procedures** • No emergency procedures are expected to be necessary when used in accordance with product literature.

### Environmental precautions

- No data available

### Methods and material for containment and cleaning up

**Containment/Clean-up Measures** • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

## Section 7 - Handling and Storage

### Precautions for safe handling

**Handling** • No special handling is required. Refer to Section 8. Use only in accordance with product literature.

## Conditions for safe storage, including any incompatibilities

- Storage**
- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from freezing.

## Section 8 - Exposure Controls/Personal Protection

### Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product components.

### Exposure controls

- Engineering Measures/Controls**
- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

### Personal Protective Equipment

- Respiratory**
- No respiratory protection required during normal handling.
- Eye/Face**
- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.
- Hands**
- Gloves are not required under normal handling conditions.
- Skin/Body**
- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.
- Environmental Exposure Controls**
- No data available

## Section 9 - Physical and Chemical Properties

### Information on Physical and Chemical Properties

| Material Description                |                   |                  |                   |
|-------------------------------------|-------------------|------------------|-------------------|
| Physical Form                       | Liquid            | Color            | Clear Colorless . |
| Odor                                | No odor.          | Odor Threshold   | No data available |
| General Properties                  |                   |                  |                   |
| Boiling Point                       | No data available | Melting Point    | Not relevant      |
| Decomposition Temperature           | No data available | pH               | 4.7               |
| Specific Gravity/Relative Density   | = 1.004           | Water Solubility | Miscible          |
| Viscosity                           | No data available |                  |                   |
| Volatility                          |                   |                  |                   |
| Vapor Pressure                      | Not relevant      | Vapor Density    | Not relevant      |
| Evaporation Rate                    | No data available |                  |                   |
| Flammability                        |                   |                  |                   |
| Flash Point                         | Not relevant      | UEL              | Not relevant      |
| LEL                                 | Not relevant      | Autoignition     | Not relevant      |
| Environmental                       |                   |                  |                   |
| Octanol/Water Partition coefficient | No data available |                  |                   |

## Section 10: Stability and Reactivity

### Reactivity

- No dangerous reactions known.

## Chemical stability

- Stable under normal temperatures and pressures.

## Possibility of hazardous reactions

- No data available

## Conditions to avoid

- Extreme heat or cold. Do not freeze.

## Incompatible materials

- None.

## Hazardous decomposition products

- None expected.

## Section 11 - Toxicological Information

### Information on toxicological effects

**Other Material Information** • Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

| Components                          |            |                                                                                                                                                           |
|-------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Benzalkonium Chloride (< 0.1%)      | 63449-41-2 | <b>Acute Toxicity:</b> Ingestion/Oral-Mouse LD50 • 150 mg/kg; <b>Behavioral:</b> <b>Somnolence (general depressed activity); Blood:</b> <b>Hemorrhage</b> |
| Edetate Disodium Dihydrate (< 0.1%) | 139-33-3   | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2 g/kg                                                                                                   |
| Sodium chloride (< 1%)              | 7647-14-5  | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 3000 mg/kg                                                                                               |

| GHS Properties                | Classification                           |
|-------------------------------|------------------------------------------|
| Acute toxicity                | UN GHS • Classification criteria not met |
| Aspiration Hazard             | UN GHS • Classification criteria not met |
| Carcinogenicity               | UN GHS • Classification criteria not met |
| Germ Cell Mutagenicity        | UN GHS • Classification criteria not met |
| Skin corrosion/Irritation     | UN GHS • Classification criteria not met |
| Skin sensitization            | UN GHS • Classification criteria not met |
| STOT-RE                       | UN GHS • Classification criteria not met |
| STOT-SE                       | UN GHS • Classification criteria not met |
| Toxicity for Reproduction     | UN GHS • Classification criteria not met |
| Respiratory sensitization     | UN GHS • Classification criteria not met |
| Serious eye damage/Irritation | UN GHS • Eye Irritation 2A               |

### Potential Health Effects

#### 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**

- Acute (Immediate)**
  - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
  - Under normal conditions of use, no health effects are expected.

**Eye**

- Acute (Immediate)**
  - Causes serious eye irritation. Temporary blurring of vision, precipitation or worsening of narrow-angle glaucoma, mydriasis, increased intraocular pressure, acute eye pain or discomfort, visual halos or colored images in association with red eyes from conjunctival and corneal congestion may result if ipratropium bromide nasal solution 0.03% (Nasal Spray) comes into direct contact with the eyes.
- Chronic (Delayed)**
  - No data available.

**Ingestion**

- Acute (Immediate)**
  - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
  - Under normal conditions of use, no health effects are expected.

**Other**

- Acute (Immediate)**
  - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
  - Under normal conditions of use, no health effects are expected.

**Section 12 - Ecological Information****Toxicity**

- This material has not been tested for environmental effects.

**Persistence and degradability**

- No data available

**Bioaccumulative potential**

- No data available

**Mobility in Soil**

- No data available

**Other adverse effects****Section 13 - Disposal Considerations****Waste treatment methods**

- Product waste**
  - Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.
- Packaging waste**
  - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

**Section 14 - Transport Information**

|          | UN number | UN proper shipping name | Transport hazard class (es) | Packing group | Environmental hazards |
|----------|-----------|-------------------------|-----------------------------|---------------|-----------------------|
| DOT      | NDA       | not regulated           | NDA                         | NDA           | NDA                   |
| TDG      | NDA       | not regulated           | NDA                         | NDA           | NDA                   |
| IMO/IMDG | NDA       | not regulated           | NDA                         | NDA           | NDA                   |

|           |     |               |     |     |     |
|-----------|-----|---------------|-----|-----|-----|
| IATA/ICAO | NDA | not regulated | NDA | NDA | NDA |
|-----------|-----|---------------|-----|-----|-----|

**Special precautions for user** • No data available

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** • No data available

## Section 15 - Regulatory Information

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**SARA Hazard Classifications** • No data available

| Inventory                       |            |            |           |      |
|---------------------------------|------------|------------|-----------|------|
| Component                       | CAS        | Canada DSL | EU EINECS | TSCA |
| Edetate Disodium Dihydrate      | 139-33-3   | Yes        | Yes       | Yes  |
| Benzalkonium Chloride           | 63449-41-2 | Yes        | Yes       | Yes  |
| Ipratropium Bromide Monohydrate | 66985-17-9 | No         | No        | No   |
| Sodium chloride                 | 7647-14-5  | Yes        | Yes       | Yes  |
| Water                           | 7732-18-5  | Yes        | Yes       | Yes  |

## Canada

### Labor

#### Canada - WHMIS - Classifications of Substances

|                                   |            |                                                                                  |
|-----------------------------------|------------|----------------------------------------------------------------------------------|
| • Edetate Disodium Dihydrate      | 139-33-3   | Uncontrolled product according to WHMIS classification criteria (including 3.5%) |
| • Benzalkonium Chloride           | 63449-41-2 | Not Listed                                                                       |
| • Sodium chloride                 | 7647-14-5  | Uncontrolled product according to WHMIS classification criteria                  |
| • Water                           | 7732-18-5  | Uncontrolled product according to WHMIS classification criteria                  |
| • Ipratropium Bromide Monohydrate | 66985-17-9 | Not Listed                                                                       |

## Europe

### Other

#### EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

|                                   |            |                          |
|-----------------------------------|------------|--------------------------|
| • Edetate Disodium Dihydrate      | 139-33-3   | Not Listed               |
| • Benzalkonium Chloride           | 63449-41-2 | Xn; R21/22 C; R34 N; R50 |
| • Sodium chloride                 | 7647-14-5  | Not Listed               |
| • Water                           | 7732-18-5  | Not Listed               |
| • Ipratropium Bromide Monohydrate | 66985-17-9 | Not Listed               |

#### EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

|                              |            |                                        |
|------------------------------|------------|----------------------------------------|
| • Edetate Disodium Dihydrate | 139-33-3   | Not Listed                             |
| • Benzalkonium Chloride      | 63449-41-2 | C N R:21/22-34-50 S:(2)-36/37/39-45-61 |
| • Sodium chloride            | 7647-14-5  | Not Listed                             |

|                                   |            |            |
|-----------------------------------|------------|------------|
| • Water                           | 7732-18-5  | Not Listed |
| • Ipratropium Bromide Monohydrate | 66985-17-9 | Not Listed |

**EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases**

|                                   |            |                      |
|-----------------------------------|------------|----------------------|
| • Edetate Disodium Dihydrate      | 139-33-3   | Not Listed           |
| • Benzalkonium Chloride           | 63449-41-2 | S:(2)-36/37/39-45-61 |
| • Sodium chloride                 | 7647-14-5  | Not Listed           |
| • Water                           | 7732-18-5  | Not Listed           |
| • Ipratropium Bromide Monohydrate | 66985-17-9 | Not Listed           |

**United States****Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

|                                   |            |            |
|-----------------------------------|------------|------------|
| • Edetate Disodium Dihydrate      | 139-33-3   | Not Listed |
| • Benzalkonium Chloride           | 63449-41-2 | Not Listed |
| • Sodium chloride                 | 7647-14-5  | Not Listed |
| • Water                           | 7732-18-5  | Not Listed |
| • Ipratropium Bromide Monohydrate | 66985-17-9 | Not Listed |

**United States - California****Environment****U.S. - California - Proposition 65 - Carcinogens List**

|                                   |            |            |
|-----------------------------------|------------|------------|
| • Edetate Disodium Dihydrate      | 139-33-3   | Not Listed |
| • Benzalkonium Chloride           | 63449-41-2 | Not Listed |
| • Sodium chloride                 | 7647-14-5  | Not Listed |
| • Water                           | 7732-18-5  | Not Listed |
| • Ipratropium Bromide Monohydrate | 66985-17-9 | Not Listed |

**U.S. - California - Proposition 65 - Developmental Toxicity**

|                                   |            |            |
|-----------------------------------|------------|------------|
| • Edetate Disodium Dihydrate      | 139-33-3   | Not Listed |
| • Benzalkonium Chloride           | 63449-41-2 | Not Listed |
| • Sodium chloride                 | 7647-14-5  | Not Listed |
| • Water                           | 7732-18-5  | Not Listed |
| • Ipratropium Bromide Monohydrate | 66985-17-9 | Not Listed |

**U.S. - California - Proposition 65 - Reproductive Toxicity - Female**

|                                   |            |            |
|-----------------------------------|------------|------------|
| • Edetate Disodium Dihydrate      | 139-33-3   | Not Listed |
| • Benzalkonium Chloride           | 63449-41-2 | Not Listed |
| • Sodium chloride                 | 7647-14-5  | Not Listed |
| • Water                           | 7732-18-5  | Not Listed |
| • Ipratropium Bromide Monohydrate | 66985-17-9 | Not Listed |

**U.S. - California - Proposition 65 - Reproductive Toxicity - Male**

|                                   |            |            |
|-----------------------------------|------------|------------|
| • Edetate Disodium Dihydrate      | 139-33-3   | Not Listed |
| • Benzalkonium Chloride           | 63449-41-2 | Not Listed |
| • Sodium chloride                 | 7647-14-5  | Not Listed |
| • Water                           | 7732-18-5  | Not Listed |
| • Ipratropium Bromide Monohydrate | 66985-17-9 | Not Listed |

**Section 16 - Other Information**



**Last Revision Date**

- 14/May/2015

**Preparation Date**

- 14/May/2015

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