SAFETY DATA SHEET

Atrovent® Nasal Spray

SECTION 1. IDENTIFICATION

Product name : Atrovent® Nasal Spray
Synonyms : Active ingredient: Ipratropium bromide monohydrate <= 1%
Aatrovent® unit dose vial, Atrovent® inhalation solution,
Aerovent inhalation solution, Aloveant inhalation solution,
Ipatrin unit dose vial, Ipertrop® ampoules, Atrovent® nasal spray

Product code : 000000029989

Manufacturer or supplier’s details
Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated
Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368

Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours
Routine Contact Number : (203) 778-7759

Recommended use of the chemical and restrictions on use
Recommended use : Solution for production of finished medicinal products.

Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION

Not a hazardous substance or mixture.

Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No.</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipratropium Bromide Monohydrate</td>
<td>66985-17-9</td>
<td>1</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice : Remove from exposure, lie down.
                 Take off immediately all contaminated clothing.
                 Victim to lie down in the recovery position, cover and keep him warm.
                 First Aid responders should pay attention to self-protection
                 and use the recommended protective clothing

If inhaled : Keep patient calm, remove to fresh air, seek medical attention.

In case of skin contact : Wash off thoroughly with ample water.
                        Seek medical attention.

In case of eye contact : Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

If swallowed : Rinse mouth immediately and then drink plenty of water, seek medical attention.

Most important symptoms and effects, both acute and delayed : None known.

Notes to physician : Observe the summary of product characteristics of proprietary medicinal products

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
                               Water
                               Dry chemical
                               Foam
                               Carbon dioxide (CO2)

Specific hazards during firefighting : In case of fire and/or explosion do not breathe fumes.
                                    Can be released in case of fire:
                                    Carbon oxides
                                    Hydrogen fluoride
                                    Nitrogen oxides (NOx)
                                    Hydrogen bromide (HBr)

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
                     Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for firefighters : Wear self-contained breathing apparatus and chemical-protective clothing.
SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation. High risk of slipping due to leakage/spillage of product.

Environmental precautions:
Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up:
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion:
No hazards which require special first aid measures.

Advice on safe handling:
Provide sufficient air exchange and/or exhaust in work rooms. Keep container closed when not in use.

Conditions for safe storage:
Protect from heat and direct sunlight. Keep container tightly closed. Jointless smooth floor.

Materials to avoid:
Keep away from food, drink and animal feedingstuffs. Advice on Segregation.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>Basis</th>
<th>Factor</th>
<th>Category</th>
<th>Values</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-8-azoniabicyclo(3.2.1)octane bromide monohydrate 66985-17-9</td>
<td>ECL</td>
<td>3A</td>
<td>ECL (BIPI Exposure Control Limit)</td>
<td>15 µg/m3</td>
<td></td>
</tr>
</tbody>
</table>

Contains no substances with occupational exposure limit values.

**Engineering measures**: Local exhaust

**Personal protective equipment**
Respiratory protection: Not required; except in case of aerosol formation.
Hand protection Material: Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.
    Directive: Protective gloves against chemicals and micro-organisms

Eye protection: Safety glasses with side-shields

Skin and body protection: Protective work clothing

Protective measures: Handle in accordance with good industrial hygiene and safety practice.
    Avoid contact with skin, eyes and clothing.

Hygiene measures: General industrial hygiene practice.
    Wash hands and face before breaks and immediately after handling the product.
    Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Colour: No data available
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/range: No data available
Boiling point/boiling range: No data available
Flash point: Not applicable
Evaporation rate: No data available
Flammability (solid, gas): does not ignite
Upper explosion limit: Not applicable
Lower explosion limit: Not applicable
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : Not applicable
Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : No data available

Explosive properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.
Chemical stability : No decomposition if stored and applied as directed.
Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.
Conditions to avoid : Extremes of temperature and direct sunlight.
Incompatible materials : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
Ipratropium Bromide Monohydrate:
Acute oral toxicity : LD50 (Rat, male and female): = 1,722 mg/kg
LD50 (Mouse, male and female): = 1,038 mg/kg

Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation
Not classified based on available information.
Components:
Ipratropium Bromide Monohydrate:
Remarks: No data available

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Ipratropium Bromide Monohydrate:
Remarks: No data available

Respiratory or skin sensitisation
Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

Components:
Ipratropium Bromide Monohydrate:
Species: Guinea pig
Result: No alert for skin sensitization

Germ cell mutagenicity
Not classified based on available information.

Components:
Ipratropium Bromide Monohydrate:
Genotoxicity in vitro: Test Type: Ames-test
Species: Salmonella typhimurium
Result: negative

Genotoxicity in vivo: Remarks: No data available

Carcinogenicity
Not classified based on available information.

Components:
Ipratropium Bromide Monohydrate:
Remarks: Did not show carcinogenic effects in animal experiments.

IARC
No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP
No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:
Ipratropium Bromide Monohydrate:
Species: Rat
NOAEL: 6 mg/kg
Application Route: Oral
Exposure time: 78 weeks

Species: Rat
NOAEL: 0.128 mg/kg
Application Route: Inhalation
Exposure time: 26 weeks

Species: dog
NOAEL: 1.5 mg/kg
Application Route: Oral
Exposure time: 13 weeks

Species: dog
NOAEL: 0.01 mg/kg
Application Route: Inhalation
Exposure time: 13 weeks

Species: Monkey
NOAEL: 0.8 mg/kg
Application Route: Inhalation
Exposure time: 6 weeks

Aspiration toxicity
Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Ipratropium Bromide Monohydrate:
Toxicity to fish : Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available
Toxicity to algae : Remarks: No data available
Toxicity to fish (Chronic toxicity) : Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC (Daphnia magna (Water flea)): = 3.16 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Lowest Observed Effect Concentration (Daphnia magna (Water flea)): = 10 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to bacteria:

NOEC (activated sludge): = 200 mg/l

NOEC (activated sludge, industrial): = 1,000 mg/l

Persistence and degradability
No data available

Bioaccumulative potential
Components:
Ipratropium Bromide Monohydrate:
Partition coefficient: n-octanol/water: Pow: 0.006

Mobility in soil
Product:
Distribution among environmental compartments: Remarks: No data available

Other adverse effects
Product:
Ozone-Depletion Potential: Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations. Must not be disposed off together with household garbage. Do not allow product to reach sewage system.

Contaminated packaging: Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.
SECTIONS 14. TRANSPORT INFORMATION

International Regulation
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 311/312 Hazards : Acute Health Hazard
SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC’s (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. Clean Water Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know
Non-hazardous galenic excipients Not Assigned 90 - 100 %

New Jersey Right To Know
Non-hazardous galenic excipients Not Assigned 90 - 100 %
Ipratropium Bromide Monohydrate 66985-17-9 1 - 5 %

California Prop 65
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.
Further information

NFPA:

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<tr>
<th></th>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
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<tbody>
<tr>
<td>0</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Special hazard: 0 = not significant, 1 = Slight, 2 = Moderate, 3 = High, 4 = Extreme, * = Chronic

HMIS III:

<table>
<thead>
<tr>
<th></th>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td>0</td>
<td>0</td>
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