

**Atrovent® Nasal Spray**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000029989      Date of last issue: -  
Date of first issue: 06/03/2015

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**SECTION 1. IDENTIFICATION**

Product name : Atrovent® Nasal Spray

Synonyms : Active ingredient: Ipratropium bromide monohydrate <= 1%  
Atrovent® unit dose vial, Atrovent® inhalation solution,  
Aerovent inhalation solution, Alovent inhalation solution,  
Ipatrin unit dose vial, Itrop® 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](mailto:EHS-service@boehringer-ingelheim.com)

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

**GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous components**

Chemical Name	CAS-No.	Concentration (%)
Ipratropium Bromide Monohydrate	66985-17-9	1

**Atrovent® Nasal Spray**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000029989      Date of last issue: -  
Date of first issue: 06/03/2015

---

**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
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**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 (CO<sub>2</sub>)
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.  
Can be released in case of fire:  
Carbon oxides  
Hydrogen fluoride  
Nitrogen oxides (NO<sub>x</sub>)  
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.
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**Atrovent® Nasal Spray**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000029989      Date of last issue: -  
Date of first issue: 06/03/2015

**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**

Components	Basis	Factor	Cateryory	Values	Remark
3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-8-azoniabicyclo(3.2.1)octane bromide monohydrate 66985-17-9	ECL		3A	15 µg/m <sup>3</sup>	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

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.

**Atrovent® Nasal Spray**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000029989	Date of first issue: 06/03/2015

---

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.

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**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

**Atrovent® Nasal Spray**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000029989      Date of last issue: -  
Date of first issue: 06/03/2015

---

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

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**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

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**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.

**Atrovent® Nasal Spray**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000029989      Date of last issue: -  
Date of first issue: 06/03/2015

---

**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.

**Atrovent® Nasal Spray**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000029989      Date of last issue: -  
Date of first issue: 06/03/2015

---

**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.

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**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

**Atrovent® Nasal Spray**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000029989	Date of first issue: 06/03/2015

---

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).

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**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.



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Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000029989	Date of first issue: 06/03/2015

---

**SECTION 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 SOCM 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. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater 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 %
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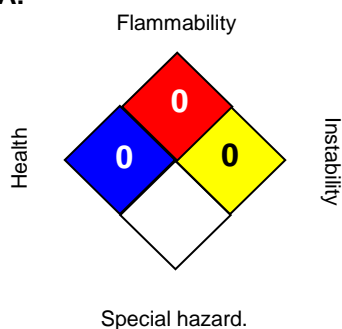
**New Jersey Right To Know**

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.

**Atrovent® Nasal Spray**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000029989      Date of last issue: -  
Date of first issue: 06/03/2015

**SECTION 16. OTHER INFORMATION****Further information****NFPA:****HMIS III:**

<b>HEALTH</b>	<b>0</b>
<b>FLAMMABILITY</b>	<b>0</b>
<b>PHYSICAL HAZARD</b>	<b>0</b>

0 = not significant, 1 = Slight,  
2 = Moderate, 3 = High  
4 = Extreme, \* = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version.  
Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.  
Revision Date : 06/03/2015

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.