SECTION 1. IDENTIFICATION

Product name: Atrovent® Metered Aerosol with CFC

Synonyms: Active ingredient: Ipratropium bromide monohydrate
Atrovent® Metered Aerosol, Ipratropio, Alovent®

Product code: 000000031473

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

SECTION 2. HAZARDS IDENTIFICATION


Hazard statements: H420 Harms public health and the environment by destroying ozone in the upper atmosphere.

Precautionary statements: Disposal:
P501 Dispose of contents/ container to an approved incineration plant.

Other hazards
The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity: 99%

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Pure substance

<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>&lt;= 0.1</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 : Move to fresh air.
If symptoms persist, call a physician.

In case of skin contact : No hazards anticipated.

In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.
Call a physician immediately.

If swallowed : Swallowing is not regarded as possible way of exposition.

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
Foam
Dry chemical
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
Nitrogen oxides (NOx)

Further information : Cool endangered containers with water spray jet.
Fire or intense heat may cause violent rupture of packages.
Product itself is non-combustible.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Special protective equipment for firefighters : In case of fire and/or explosion do not breathe fumes.
Wear self-contained breathing apparatus and chemical-protective clothing.
SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Wear personal protective equipment. Refer to protective measures listed in sections 7 and 8.

Environmental precautions: No special environmental precautions required.

Methods and materials for containment and cleaning up: Allow to evaporate. Pick up and transfer to properly labelled containers.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: Keep away from heat and sources of ignition.

Advice on safe handling: Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition - No smoking. Keep away from children.

Conditions for safe storage: Store in original container. Protect from heat and direct sunlight.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters:

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</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>15 µg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BIPC</td>
<td>1b</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ECL (BIP Exposure Control Limit)

<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>Dichlorotetrafluoroethane</td>
<td>76-14-2</td>
<td>1,000 ppm</td>
<td>TRGS 900</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Trichlorofluoromethane

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Value</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>7,000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>TWAEV</td>
<td>1,000 ppm</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td>6,990 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>7,000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td>7,000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td>7,000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td>7,000 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

(Y = A risk of foetal disease must not be expected with the compliance of AGW and BGW threshold values.)

### Dichlorodifluoromethane

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Value</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>4,950 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>TWAEV</td>
<td>1,000 ppm</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td>4,950 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>4,950 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td>4,950 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td>4,950 mg/m³</td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>1,000 ppm</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td>4,950 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

(Y = A risk of foetal disease must not be expected with the compliance of AGW and BGW threshold values.)

Contains no substances with occupational exposure limit values.

**Engineering measures**

: Local exhaust
Personal protective equipment

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection Material: Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.
Hand protection Directive: Protective gloves against chemicals and micro-organisms

Eye protection: Safety glasses with side-shields

Skin and body protection: Protective work clothing

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

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: aerosol

Colour: colourless

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: No data available

Lower explosion limit: No data available

Vapour pressure: 13,171 hPa (50 ºC)

Relative vapour density: No data available
Relative density : No data available
Density : Not applicable
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : Keep away from sources of ignition - No smoking. Heating can release hazardous gases.
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 decomposition if stored and applied as directed.
Conditions to avoid : Extremes of temperature and direct sunlight.
Incompatible materials : No data available
Hazardous decomposition products : Hydrogen fluoride
  Fluorine phosgene

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

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
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: Warning: Manufactured with /$/, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.

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

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

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>75-69-4</td>
<td></td>
<td>5000</td>
<td></td>
</tr>
</tbody>
</table>

SARA 311/312 Hazards: No SARA Hazards
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313: The following components are subject to reporting levels established by SARA Title III, Section 313:
- Trichlorofluoromethane 75-69-4 53 %
- Dichlorodifluoromethane 75-71-8 24 %
- Dichlorotetrafluoroethane 76-14-2 22 %

Clean Air Act
Warning: Manufactured with $/$, a substance which harms public health and environment by destroying ozone in the upper atmosphere.
Ozone-Depletion Potential: CFC-11 75-69-4
- Trichlorofluoromethane 75-69-4
- CFC-12 75-71-8
- Dichlorodifluoromethane 75-71-8
- CFC-114 76-14-2
- CFC-114 76-14-2
- Dichlorotetrafluoroethane 76-14-2
- Dichlorotetrafluoroethane 76-14-2

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).
The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC’s (40 CFR 60.489):

- Trichlorofluoromethane 75-69-4 53 %
- Dichlorodifluoromethane 75-71-8 24 %

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 contains the following toxic pollutants listed under the U.S. Clean Water Act Section 307

- Trichlorofluoromethane 75-69-4 53 %
- Dichlorodifluoromethane 75-71-8 24 %

Massachusetts Right To Know

- Trichlorofluoromethane 75-69-4 50 - 70 %
- Dichlorodifluoromethane 75-71-8 20 - 30 %
- Dichlorotetrafluoroethane 76-14-2 20 - 30 %

Pennsylvania Right To Know

- Non-hazardous galenic excipients Not Assigned 90 - 100 %
- Trichlorofluoromethane 75-69-4 50 - 70 %
- Dichlorodifluoromethane 75-71-8 20 - 30 %
- Dichlorotetrafluoroethane 76-14-2 20 - 30 %

New Jersey Right To Know

- Non-hazardous galenic excipients Not Assigned 90 - 100 %
- Trichlorofluoromethane 75-69-4 50 - 70 %
- Dichlorodifluoromethane 75-71-8 20 - 30 %
- Dichlorotetrafluoroethane 76-14-2 20 - 30 %

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.
SECTION 16. OTHER INFORMATION

Further information

NFPA:

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

HMIS III:

- **HEALTH**: 0
- **FLAMMABILITY**: 0
- **PHYSICAL HAZARD**: 0

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.