SECTION 1. IDENTIFICATION

Product name : Ipratropium Bromide
Synonyms : Sch 1000 Br
Product code : 000000007432

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

SECTION 2. HAZARDS IDENTIFICATION

Acute toxicity (Oral) : Category 4

Hazard pictograms : !
Signal word : Warning
Hazard statements : H302 Harmful if swallowed.
Precautionary statements : Prevention:
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

| Substance / Mixture | Pure substance |

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.
Call a physician immediately.

In case of skin contact
Wash off immediately with plenty of water.
Cover wound with sterile dressing.
Call a physician immediately.

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
Rinse mouth.
Drink plenty of water.
Call a physician immediately.

Most important symptoms and effects, both acute and delayed
Dilatation of the pupil
Nausea
Vertigo
Harmful if swallowed.

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)
Safety Data Sheet

Ipratropium Bromide

Version 1.0
Revision Date: 06/03/2015
MSDS Number: 00000007432
Date of last issue: -
Date of first issue: 06/03/2015

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
- 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. Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Special protective equipment for firefighters: Self-contained breathing apparatus (EN 133) complete suit protecting against chemicals

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. Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Knock down dust with water spray jet.

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

Methods and materials for containment and cleaning up: Cleaning operations should be carried out only while wearing breathing apparatus. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Non-sparking tools should be used. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Clean-up methods - large spillage Dampen, pick up mechanically and dispose of. Clean-up methods - small spillage Use approved industrial vacuum cleaner for removal. Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Avoid dust formation.

Advice on safe handling: Provide sufficient air exchange and/or exhaust in work rooms. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Minimize dust generation and accumulation. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Breathing must be protected when large quantities are decanted without local exhaust ventilation. Keep container closed when not in use.

Conditions for safe storage: Keep tightly closed in a dry and cool place. Keep in a well-ventilated place. Protect from heat and direct sunlight. Jointless smooth floor

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

SECTION 8. EXPOSURE CONTROLS/PERSOAL 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-endo, 8-syn)-(3-(3-Hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-8- Azoniabicyclo(3.2.1)octane Bromide 22254-24-6</td>
<td>ECL</td>
<td>3A</td>
<td>15 µg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BIPC</td>
<td>1b</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ECL (BIPI Exposure Control Limit)

Contains no substances with occupational exposure limit values.

**Engineering measures**: It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

**Personal protective equipment**

Respiratory protection: Protecting mask (EN 136) particle filter P3 (EN 143)

Hand protection Material: Nitrile rubber
Break through time: 480 min
Glove thickness: 0.43 mm
Directive: Protective gloves against chemicals and micro-organisms
### Protective index

- Class 6

### Eye protection

- Safety glasses with side-shields
- (Not necessary when using full face mask)

### Skin and body protection

- Laboratory: laboratory coat; factory: disposable Overall.

### Protective measures

- Handle in accordance with good industrial hygiene and safety practice.
- Do not breathe dust.
- 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>5.0 - 6.7</td>
</tr>
<tr>
<td>Melting point/range</td>
<td>231 °C</td>
</tr>
<tr>
<td>Boiling point/boiling range</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Bulk density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Solubility(ies)
Water solubility : 72.4 g/l

Partition coefficient: n-octanol/water
Pow: 0.006

Auto-ignition temperature : 430 °C
Auto ignition temperature (raising of dust)

Decomposition temperature : to 180 °C
No exothermic reaction at temperature rise

Viscosity
Viscosity, dynamic : Not applicable

Explosive properties : Not tested

Oxidizing properties : No data available

Impact sensitivity : Not sensitive to impact

Molecular weight : 412.42 g/mol

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 : Dust may form explosive mixture in air.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Harmful if swallowed.

Product:
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.
Product:
Remarks: No data available

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

Product:
Remarks: No data available

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

Product:
Species: Guinea pig
Result: No alert for skin sensitization

Germ cell mutagenicity
Not classified based on available information.

Product:
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.

Product:
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.

Product:
Effects on fertility : Test Type: Pre- and Postnatal development study
Species: Rat
Dose: 10, 30 mg/kg
Application Route: Oral

Remarks: Experiments have shown no reproductive toxicity effects on laboratory animals.

Test Type: Study of Fertility and Early Embryonic Development
Species: Rat
Dose: 10, 30, 90 mg/kg
Application Route: Oral

Effects on foetal development:
Species: Rat
Application Route: Oral
Dose: 1, 10, 100, 1000 mg/kg
Remarks: Did not show teratogenic effects in animal experiments
Species: Rat
Application Route: inhalation
Dose: 0.5, 2, 8 mg/kg
Remarks: Did not show teratogenic effects in animal experiments
Species: Rabbit
Application Route: Oral
Dose: 5, 25, 125 mg/kg
Remarks: Did not show teratogenic effects in animal experiments
Species: Rabbit
Application Route: inhalation
Dose: 0.3, 0.9, 1.8 mg/kg
Remarks: Did not show teratogenic effects in animal experiments
Species: Rabbit
Application Route: intravenous
Dose: 0.5, 2, 8 mg/kg

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Not classified based on available information.

**Repeated dose toxicity**

**Product:**
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
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

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)): = 10.0 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

**Product:**
- **Biodegradability:** Result: Not readily biodegradable.
  - Biodegradation: ca. 37%
  - Exposure time: 47 d

Bioaccumulative potential

**Product:**
- **Bioaccumulation:** Remarks: Accumulation in organisms is not to be expected.

Mobility in soil

**Product:**
- **Distribution among environmental compartments:** Remarks: No data available

Other adverse effects

**Product:**
- **Results of PBT and vPvB assessment:** Non-classified vPvB substance Non-classified PBT substance
- **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.
- **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**
SAFETY DATA SHEET

Ipratropium Bromide

Version: 1.0
Revision Date: 06/03/2015
MSDS Number: 00000007432
Date of last issue: -
Date of first issue: 06/03/2015

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. 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
Ipratropiumbromide, anhydrous 22254-24-6 90 - 100 %

New Jersey Right To Know
Ipratropiumbromide, anhydrous 22254-24-6 90 - 100 %
**SAFETY DATA SHEET**

**Ipratropium Bromide**

**Version** 1.0  
**Revision Date:** 06/03/2015  
**MSDS Number:** 00000007432  
**Date of last issue:** -  
**Date of first issue:** 06/03/2015

---

**SECTION 16. OTHER INFORMATION**

**Further information**

**NFPA:**

- **Flammability:** 1
- **Health:** 0
- **Instability:** 1

**Special hazard.**

**HMIS III:**

- **HEALTH:** 1
- **FLAMMABILITY:** 1
- **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.

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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.