

Ipratropium Bromide

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000007432 Date of last issue: -
Date of first issue: 06/03/2015

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**GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Acute toxicity (Oral) : Category 4

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

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.

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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 (CO ₂)
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- 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 (NO_x)
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.
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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.

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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/PERSONAL PROTECTION**Components with workplace control parameters**

Components	Basis	Factor	Cateryory	Values	Remark
(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	ECL		3A	15 µg/m ³	
	BIPC		1b		
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

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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

Appearance	: powder
Colour	: white
Odour	: odourless
Odour Threshold	: No data available
pH	: 5.0 - 6.7
Melting point/range	: 231 °C
Boiling point/boiling range	: Not applicable
Flash point	: Not applicable
Evaporation rate	: Not applicable
Flammability (solid, gas)	: No data available
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: Not applicable
Relative density	: No data available
Bulk density	: No data available

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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.

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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

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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

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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.

Product:

No data available

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

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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.
Untamminated 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**

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- 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

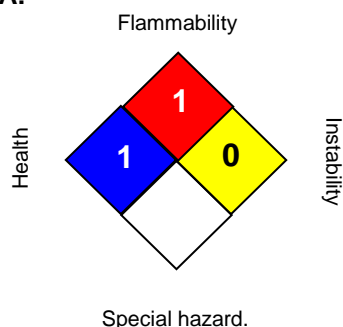
Ipratropiumbromide, anhydrous	22254-24-6	90 - 100 %
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New Jersey Right To Know

Ipratropiumbromide, anhydrous	22254-24-6	90 - 100 %
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SECTION 16. OTHER INFORMATION**Further information****NFPA:****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.

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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.