

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Tiotropium Bromide Inhalation Powder 18 mcg/ capsule
Manufacturer	Lupin Limited Pithampur (M.P.) - 454 775 India
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Classification	
Danger	Harmful if swallowed Causes Skin Irritation Causes serious eye irritation
	Acute Toxicity (Oral) Category 5, Serious Eye Damage/Eye Irritation Category 2B, Hazardous to the Aquatic Environment Acute Hazard Category 3 Not Available.

Section 3: Composition/Information on Ingredients

Drug Substance:

Name	CAS No.	Quantity in per Capsule
Tiotropium (bromide)	136310-93-5	18 mcg
Lactose Monohydrate NF	64044-51-5	-

Section 4: First-Aid Measures

General advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
Eye contact	In-case of eye contact, immediately flush eyes with fresh running water. Ensure complete irrigation of the eye by keeping eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin Contact	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water. Use Soap. Obtain medical attention if skin reaction occurs.
Inhalation	Remove to fresh air and keep patient at rest.

Ingestion In case of accidental ingestion, wash out mouth with copious amounts of water. Do not induce vomiting unless directed by medical personnel. Observe the patient carefully. Never give anything by mouth to an unconscious person. Seek medical attention immediately

Note to physicians Treat symptomatically

Section 5: Fire-Fighting Measures

Suitable extinguishing media Use foam, carbon dioxide, dry chemical powder.

Advise for fire fighters During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Hazardous combustion products Hydrogen bromide. Carbon oxides. Nitrogen oxides (NOx) Sulfur oxides. May emit poisonous, corrosive fumes.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. Avoid raising and breathing vapor or fumes and provide adequate ventilation.

Rubber gloves (Nitrile, Powder free latex), Chemical goggles, Face shield, Coveralls, PAPR, full face respirator with P3 filter, shoe covers.

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and material containment and cleaning up for Clean up waste regularly and abnormal spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Disposal Methods Dispose of in accordance with local, state, and national regulations.

Section 7: Handling and Storage

Handling and storage Should not be exposed to extreme temperature or moisture.

Precautions for safe handling

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some
- other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)
- Minimize airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.
- Establish good housekeeping practices.
- Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
- Store in original containers.

- Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes.
Store away from incompatible materials and foodstuff containers.

Handling Advice on safe handling Handle in accordance with good industrial hygiene and safety practice

Conditions for safe storage, including any incompatibilities

Storage conditions Container
Glass container is suitable for laboratory quantities
Polyethylene or polypropylene container.
Check all containers are clearly labelled and free from leaks.

Keep container tightly closed. Store as directed by product packaging.

Storage Avoid reaction with oxidizing agents

Section 8: Exposure Controls/Personal Protection

Exposure controls/personal protection

Personal protection Use appropriate personal protective equipment for protection.

Appropriate engineering controls Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.
HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes, or vapors.
Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.
A fume hood or vented balance enclosure is recommended for weighing/transferring quantities exceeding 500 mg.

Individual protection measures, such as personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands & Skin Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. Double gloving should be considered. PVC gloves.
Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present. polychloroprene. nitrile rubber. butyl rubber.
wear disposable coverall of low permeability and disposable shoe covers

Eyes Wear Chemical goggles. Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.

Respiratory protection If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

Appearance White opaque Cap / White

HOW SUPPLIED

Tiotropium bromide inhalation powder consists of tiotropium bromide inhalation powder capsules and the LupinHaler device. Tiotropium bromide inhalation powder capsules contain 18 mcg of tiotropium in a hypromellose capsule with white opaque cap and white opaque body, imprinted with "LU" on cap and "T18" on body.

The LupinHaler device is a white color inhaler with a green piercing button. It is also imprinted with LupinHaler, Tiotropium Bromide Inhalation Powder and the LUPIN company Logo. It is also imprinted to indicate that Tiotropium Bromide Inhalation Powder Capsules should not be stored in the LupinHaler device and that the LupinHaler device is only to be used with Tiotropium Bromide Inhalation Powder Capsules.

Tiotropium bromide inhalation powder capsules are packaged in an aluminum/aluminum blister card and joined along a perforated-cut line. Tiotropium bromide inhalation powder capsules should always be stored in the blister and only removed immediately before use. The drug should be used immediately after the packaging over an individual tiotropium bromide inhalation powder capsule is opened.

The following packages are available:

- Carton containing 30 Tiotropium Bromide Inhalation Powder Capsules (3 unit dose blister cards NDC 68180-964-11) and 1 LupinHaler inhalation device (NDC 68180-964-12)

Odor	Not available
Odor threshold	Not available
Melting point/Freezing Point	218-220 degree centigrade
Boiling point	Not applicable
Flash point	Not available
Evaporation rate	Not applicable
Flammability (solid, gas)	Not available
Flammability Limit in Air	Not available
Explosive properties	Not available
Explosive properties	Not available
Oxidizing properties	Not available
Vapor pressure	Negligible
Vapor density	Not applicable
Molecular Weight	472.4 g/mol
Water solubility	Partly miscible
Solubility in other solvent	Soluble in methanol
Partition coefficient	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity, kinematic	Not applicable
Viscosity, dynamic	Not applicable
Upper flammability limit	Not available
Lower flammability limit	Not available

Section 10: Stability and Reactivity

Reactivity	No data available
Chemical stability	Stable under normal conditions of use
Possibility of hazardous reactions	None known.
Incompatible materials	Keep away from strong oxidizers.
Hazardous decomposition products	Hydrogen bromide. Carbon oxides. Nitrogen oxides (NOx) Sulfur oxides.

Section 11: Toxicological Information

Toxicological information

Acute toxicity	Irritant to skin and mucous membranes
Information on toxicological effects	IARC (International Agency for Research on Cancer) Substance is not listed. NTP (National Toxicology Program) Substance is not listed.

Section 12: Ecological Information

Avoid release into the environment. Runoff from fire control or dilution water may cause pollution

Eco toxicity	Not available.
Persistence and degradability	Not available.
Bioaccumulation	Not available.
Mobility	Not available.
Other adverse effects	Not available.

Section 13: Disposal Considerations

Disposal Considerations

Disposal of wastes: Disposal should be in accordance with applicable regional, national, and local laws and regulations.

Section 14: Transport Information

Transport Information

Not Regulated

Section 15: Regulatory Information

Regulatory Information

NA

Section 16: Other Information

Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.