

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Loteprednol Etabonate Ophthalmic Suspension 0.5%
Identified uses of the substance or mixture	Pharmaceutical
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

Section 2: Hazard(s) Identification

Classification of the substance or mixture

Carcinogenicity	No carcinogen hazard identified.
Reproductive toxicity	Reproductive development toxicant hazard identified
Specific target organ toxicity - repeated exposure	No data available
Long-term (chronic) aquatic hazard	No data available

Label elements

Hazard pictograms



Signal word	Danger
Precautionary statements	Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Use personal protective equipment as required. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Keep tightly closed.
Other hazards	No data available.

Section 3: Composition/Information on Ingredients

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Ingredients	CAS No.	Ingredients	CAS No.
Loteprednol Etabonate, IH	82034-46-6	Tyloxapol, USP	25301-02-4
Povidone, USP	9003-39-8	Sodium Hydroxide, NF	1310-73-2
Benzalkonium Chloride Solution 50 %, NF	8001-54-5	Hydrochloric Acid, NF	7647-01-0
Edetate Disodium, USP	6381-92-6	Water for Injection, USP	7732-18-5
Glycerol, USP	56-81-5	Nitrogen NF	7727-37-9

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

General advice	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
Protection of first aiders	First Aid responders should pay attention to self-protection and use the recommended personal protective equipment when the potential for exposure exists.
Inhaled	No inhalation exposure expected with this formulation under normal conditions of use.
Skin contact	Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.
Eye contact	For accidental and nontherapeutic applications, flush eyes with copious amounts of water for at least 15 minutes.
If swallowed	No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Section 5: Fire-Fighting Measures

Specific hazards during firefighting	Exposure to combustion products may be a hazard to health.
Extinguishing Media	Small Fires: Dry chemical, CO2, water spray or regular foam. Large Fire: Water spray, fog or regular foam.
Special Firefighting Procedures	Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).
Hazardous Combustion Products	Not Available.

Section 6: Accidental Release Measures

Personal Precautions	No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.
Environmental Precautions	Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.
Clean-up Methods	Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

Section 7: Handling and Storage

Handling	No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.
Storage	Keep tightly closed. Store at room temperature 15-25 °C (59-77 °F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8: Exposure Controls/Personal Protection

Engineering Measures/Controls:	Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
Personal Protective Equipment:	<p>Respiratory: In the event of a bulk spill, and where risk assessment shows that air purifying respirators are appropriate, a NIOSH (US) or CEN (EU) certified air purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.</p> <p>Eye/Face: Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.</p> <p>Hands: Wear appropriate gloves.</p> <p>Skin/Body: No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.</p>

Section 9: Physical and Chemical Properties

HOW SUPPLIED

Loteprednol etabonate ophthalmic suspension is supplied in an opaque white LDPE bottle with a controlled drop tip with cap in the following sizes:

5 mL in a 7.5 mL Bottle (NDC 70748-300-01)

10 mL in a 10 mL Bottle (NDC 70748-300-02)

15 mL in a 15 mL Bottle (NDC 70748-300-03)

Odor	No odor
pH	No data available
Melting point/freezing point	No data available
Initial boiling point and boiling range	No data available
Flash points	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability (liquids)	No data available
Upper explosion limit / Upper flammability limit	No data available
Lower explosion limit / Lower flammability limit	No data available
Vapor pressure	No data available
Relative vapor density	No data available
Relative density	= 1.007 Water=1
Solubility(ies) Water solubility	No data available
partition coefficient: n octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Not explosive	No data available

Section 10: Stability and Reactivity

Stability	Stable under normal temperatures and pressures
Reactivity	No dangerous reaction known under conditions of normal use.
Hazardous reactions	No data available
Conditions to avoid	Extreme heat or cold. Do not freeze.
Hazardous decomposition products	No data available

Section 11: Toxicological Information

Inhalation	Acute (Immediate): Under normal conditions of use, no health effects are expected. Chronic (Delayed) :No data available.
Skin Contact	Immediate): Not expected to cause skin irritation. Chronic (Delayed) : No data available.

Ingestion	<p>Acute (Immediate): Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.</p> <p>Chronic (Delayed) : No data available.</p>
Eye Contact	<p>Acute (Immediate): Nonirritating to the eyes when used as directed. Ocular adverse reactions occurring in 515% of patients treated with loteprednol etabonate ophthalmic suspension 0.2%0.5%) in clinical studies included abnormal vision/blurring, burning on instillation, chemosis, discharge, dry eyes, epiphora, foreign body sensation, itching, injection, and photophobia. Other ocular adverse reactions occurring in less than 5% of patients include conjunctivitis, corneal abnormalities, eyelid erythema, keratoconjunctivitis, ocular irritation/pain/discomfort, papillae, and uveitis.</p> <p>Chronic (Delayed): Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. Refer to the product insert and/or product prescribing information or comprehensive</p>
Ingestion	<p>Acute (Immediate) Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.</p> <p>Chronic (Delayed) No data available.</p>
Carcinogenicity	No carcinogen hazard identified.
Reproduction toxicity	Reproductive development toxicant hazard identified

Section 12: Ecological Information

No data available

Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper Shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper Shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper Shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: 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.