Alembic Pharmaceuticals Limited

Safety Data Sheet
According to Regulation (EC) No. 1907/2006
Updated on 02-11-2025

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product name	:	**LOTEPREDNOL ETABONATE and TOBRAMYCIN Ophthalmic Suspension**
CAS No.	:	--
Identified uses	:	LOTEPREDNOL ETABONATE and TOBRAMYCIN ophthalmic suspension is a combination of loteprednol etabonate, a corticosteroid, and tobramycin, an aminoglycoside antibacterial, indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.
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2. HAZARDS IDENTIFICATION

Fire and Explosion: Not available

Environment No information is available about the potential of this product to produce adverse environmental effects.

Warnings:

Viral Infections:

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex Requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye

Intraocular Pressure (IOP) Increase:

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored.

Cataracts:

Use of corticosteroids may result in posterior subcapsular cataract formation.

Fungal Infections:

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Loteprednol etabonate and tobramycin ophthalmic suspension is a sterile, multiple dose topical anti-inflammatory corticosteroid and anti-infective combination for ophthalmic use. Both loteprednol etabonate and tobramycin are white to off-white powders.

Each mL contains:
Actives: Loteprednol Etabonate 5 mg (0.5%) and Tobramycin 3 mg (0.3%).
Inactives: Edetate Disodium, Glycerin, Povidone, Purified Water, Tyloxapol, and Benzalkonium Chloride 0.01% (preservative). Sulfuric Acid and/or Sodium Hydroxide may be added to adjust the pH to 5.5 to 6.2.
The suspension is essentially isotonic with a tonicity of 260 to 320 mOsm/kg.

4. FIRST AID MEASURES

Description of first aid measures

General advice - Consult a physician. Show this safety data sheet to the doctor in attendance.

Eye Contact

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Inhalation

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Ingestion

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards: Assume that this product is capable of sustaining combustion.

Extinguishing Media: Water spray, carbon dioxide, dry chemical powder or appropriate foam.

Special Firefighting Procedures:

For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

Hazardous Combustion Products: Hazardous combustion or decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

7. HANDLING AND STORAGE

Store upright at 15°C to 25°C (59°F to 77°F). PROTECT FROM FREEZING. SHAKE VIGOROUSLY BEFORE USING. After opening, loteprednol etabonate and tobramycin ophthalmic suspension 0.5%/0.3% can be used until the expiration date on the bottle.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Loteprednol Etabonate:

Molecular formula: $C_{24}H_{31}ClO_7$

Molecular Weight: 466.95

Chemical name:

Chloromethyl 17α-[(ethoxycarbonyl)oxy]-11β-hydroxy-3- oxoandrosta-1,4-diene-17β-carboxylate

OR

(11β,17α)-17-[(ethoxycarbonyl)oxy]-11-hydroxy-3-oxoandrosta-1,4-diene-17-carboxylic acid chloromethyl ester

Tobramycin:

Molecular formula: $C_{18}H_{37}N_5O_9$

Molecular Weight: 467.51

Chemical Name:
O-3-Amino-3-deoxy-α-D-glucopyranosyl-(1→4)-O-[2,6-diamino-2,3,6-trideoxy-α-D-ribo-hexopyranosyl-(1→6)]-2-deoxystreptamine

Loteprednol etabonate and tobramycin ophthalmic suspension 0.5%/0.3% is supplied in a white low density polyethylene plastic bottle with a white controlled drop tip and a white polypropylene cap in the following sizes:

NDC 62332-801-05 5 mL fill in a 5 mL bottle

NDC 62332-801-10 10 mL fill in a 10 mL bottle

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: No data available.

Possibility of Hazardous Reactions: No data available

Oxidizing Properties: No data available

Incompatible Materials: No data available

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Carcinogenesis
Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate or tobramycin.

Mutagenesis
Loteprednol etabonate was not genotoxic in vitro in the Ames test, the mouse lymphoma TK assay, a chromosome aberration test in human lymphocytes, or in an in vivo mouse micronucleus assay.

Impairment of Fertility
Oral treatment of female and male rats with 25 mg/kg/day of loteprednol etabonate (67 times the RHOD based on body surface area, assuming 100% absorption) prior to and during mating caused preimplantation loss and decreased the number of live fetuses/live births. The NOAEL for fertility in rats was 5 mg/kg/day (13 times the RHOD). Subcutaneous administration of male and female rats with tobramycin did not affect mating behavior or cause impairment of fertility at 100 mg/kg/day (450 times the RHOD based on body surface area, assuming 100% absorption).

12. ECOLOGICAL INFORMATION

Toxicity
No data available
Persistence and degradability
No data available
Bio accumulative potential
No data available

Mobility in soil
No data available

Results of PBT and vPvB assessment
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

DOT: Not regulated
ICAO/IATA: Not regulated
IMDG: Not regulated

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available

Chemical Safety Assessment
No data available.

16. OTHER INFORMATION

Further 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 for technically qualified personnel. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Alembic Pharmaceuticals Ltd. extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third-party use & shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.