

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 353

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: ALREX®
Generic Name: Loteprednol Etabonate Ophthalmic Suspension, 0.2% (Sterile)
NDC No. 24208-353-05 (5 ml)
24208-353-10 (10 ml)

Legal Category: Prescription only medicine, filled in dropper-tipped plastic bottle suitable for dispensing, and over-packed inside a cardboard carton.

Drug Composition: Glucocorticoid

BAUSCH & LOMB PHARMACEUTICALS, INC.

8500 Hidden River Parkway
Tampa, FL 33637

Information: (800) 323-0000 (M-F) 8am-5pm EST
Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

| Description | CAS # | TLV (mg/m ³) | PEL(mg/m ³) | % Content |
|-----------------------|--|--------------------------|--|-----------|
| Loteprednol etabonate | 82034- | NE | NE | 0.2 |
| Glycerin | 56-81-5 | 10 (mist) | 15 (Total mist) 5 (Respirable Fraction) | ≥1 |
| Povidone | 9003-39-8 | NE | NE | ≥1 |
| Purified Water | 7732-18-5 | NE | NE | ≥1 |
| Ingredients | <1% - Tyloxapol, Edetate Disodium, Benzalkonium Chloride | | | |

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle in cardboard box. Milky white suspension. Toxic by ingestion.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: (NTP) No (IARC) No (OSHA) No

Eye: May cause irritation, burning sensation on instillation and hypersensitivity (anaphylactic) in some individuals. Studies in animals indicate that topical adrenocoids, when used in large amounts, can be systemically absorbed and can cause fetal abnormalities. Clinical studies indicate that ocular applied loteprednol etabonate (0.5%) does not result in detectable plasma drug levels.

Systemic: Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Systemic toxicity reactions include reversible hypothalamic-pituitary-adrenal axis gland suppression, manifestations of Cushing's syndrome, intercranial hypertension, hyperglycemia and glycosuria in some patients.

Skin: May cause irritation and localized hypersensitivity in some individuals with itching, swelling and diffuse redness of the skin.

Ingestion: May cause irritation and hypersensitivity in some individuals. Large doses can induce vomiting, diarrhea, adrenal gland suppression, Cushing's syndrome, water retention, electrolyte imbalance and hyperglycemia.

Inhalation: May cause irritation and hypersensitivity in some individuals.

Chronic Effects: May cause hypersensitivity. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels and absence of response to ACTH stimulation. Prolonged ocular use can result in elevation of intraocular pressure, with damage to the optic nerve, defects in visual acuity and fields of vision and/or in posterior subcapsular cataract formation. It may also aid in the establishment of secondary ocular infections from fungi or viruses liberated from ocular tissues.

Target Organs: Eyes, skin, digestive tract, kidney and brain.

Medical Conditions Aggravated by Long Term Exposure:

- Anaphylactic cross-reactions may occur for glucocorticoids.
- Preexisting conjunctival or systemic fungal infections may be aggravated.
- Appropriate measures should be taken if this occurs.
- Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella and other viral diseases of the cornea and conjunctiva.
- Tuberculosis of the eye.
- Fungal diseases of the ocular structures.
- Hypersensitivity to any of the ingredients of the medication.
- Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.
- Acute purulent untreated infection of the eye can be masked or activity enhanced by the presence of corticosteroid medication.

4. FIRST AID MEASURES

Eyes: If not prescribed this medication, rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

Skin: Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

Ingestion: Wash out mouth and give plenty of water and bland fluids. Do not give anything to an unconscious person. Contact a physician.

Inhalation: Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician immediately.

Note to Physicians: Additional details are available on the package insert or in the Physicians Desk Reference.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Emits toxic fumes.

Extinguishing Media: Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

7. HANDLING AND STORAGE

Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 15⁰-30⁰ C (59⁰- 86⁰ F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

Skin Protection: Thick impermeable gloves and protective clothing.

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

Warning: Do not use air purifying respirators in oxygen depleted environments. No respiratory protection is required in the clinical or home environment.

Other: None

Ventilation: Recommended

Contaminated Equipment: Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater

system or according to Federal, State and Local regulations.

9. CHEMICAL & PHYSICAL PROPERTIES

| | | | |
|--------------------|-------------------------|-----------------------------|----|
| Appearance & Odor: | Milky white suspension. | | |
| Boiling Point: | NE | Evaporation Rate: | NE |
| Specific Gravity: | 1.0 | Vapor Density: | NE |
| Vapor Pressure: | NE | Viscosity: | NE |
| Water Solubility: | Complete | Percent Volatile by Volume: | <1 |

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold.

Incompatibility: This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Hazardous Decomposition Products: Emits toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

Summary of Risks: Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

CAS #

82034-46-6 **Loteprednol Etabonate**

May cause irritation to the eyes, skin and respiratory tract. Can cause hypersensitivity (anaphylactic) in some individuals. Adverse reactions to corticosteroids include suppression of adrenal gland secretion, Cushing's syndrome, water retention, electrolyte imbalance and hyper-glycemia. Studies in animals indicate that topical adrenocorticoids, when used in large amounts, can be systemically absorbed and can cause fetal abnormalities. Immune suppression may result from chronic high doses.

56-81-5 **Glycerin**

May cause irritation to eyes and skin. Repeated or prolonged exposure can cause dermatitis or eye conjunctivitis. Inhalation is not likely due to low evaporation rate, but fumes may cause irritation and defatting of the tissues. Ingestion can cause headache, restlessness, insomnia, dizziness, vomiting, diarrhea and fever. Large

doses can cause hemolysis, hemoglobinuria, hyperglycemia, glycosuria, renal failure, convulsions, narcosis and paralysis. Oral-rat LD₅₀ 12,600 mg/kg. Decomposition release corrosive fumes of acrolein. Avoid open flame and extreme heat. Incompatibilities include strong acids, strong oxidizers, metal oxides and metal hydrides.

9003-09-8

Povidone

Acute: Prolonged or repeated contact may cause skin or eye irritation. Inhalation may result in respiratory irritation. Ingestion may result in gastric disturbances.

Chronic: Due to presence of a synthetic by product, chronic over-exposure may result in liver or kidney injury.

12. ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

13. DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

EPA Designations: RCRA Hazardous Waste: Not Listed

SARA Title III: Not Listed

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste
(40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication.
NDC No. 24208-05 (5 ml)
NDC No. 24208-10 (10 ml)

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established

< - Less Than

> - Greater Than