BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

Issued:	09/07/94	Prepared by:	Gary Wong
Revised:	01/29/01		Manager EHS
Revision:	01	Core No. 288	

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Fluorometholone Ophthalmic Suspension USP, 0.1%
Generic Name: Same
NDC No. 24208-288-05 (5 ml)
24208-288-10 (10 ml)
24208-288-15 (15 ml)

Legal Category: Prescription only medicine, filled inside plastic bottle suitable for dispensing, and overpacked 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
Fluorometholone	426-13-1	NE	NE	0.1
Polyvinyl Alcohol	9002-89-5	NE	NE	$\geq$1
Purified Water	7732-18-5	NE	NE	$\geq$1

Ingredients <1% - Sodium Phosphate, Sodium Chloride, Edetate Disodium, Polysorbate 80, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

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EMERGENCY OVERVIEW

Plastic bottle in cardboard box. White, to pale yellow suspension. Toxic by ingestion.

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POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation, burning sensation on installation and hypersensitivity (anaphylactic) in some individuals. It has been shown, though not in humans, that large doses or prolonged topical administration, glucocorticoids may be systemically adsorbed by pregnant mothers and produce fetal abnormalities. 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 diffused 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 hyper-glycemia.

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 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 can be aggravated.
- 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 may 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. Seek professional assistance.

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

Note to Physicians: None.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: 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 15^0-30^0 C (59^0- 86^0 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:	White to pale yellow 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 #

426-13-1 **Fluorometholone**
May cause irritation to eyes, skin and respiratory tract. Prolonged or repeated contact can cause hypersensitivity (anaphylactic) in some individuals. Can cause allergic reaction if inhaled, ingested or on contact with the skin. Adverse reactions include suppression of adrenal gland secretions, Cushing's syndrome (fatigue, skin discoloration, obesity), water retention, electrolyte imbalance and hyper-glycemia. Oral-mouse LD_{50} 2.0 gm/kg.

9002-89-5 **Polyvinyl Alcohol**
Dust may cause irritation to eyes and respiratory tract. No known effects by skin contact or ingestion. Degradation products of stored material are methanol (PEL=260 mg/M^3) and methyl acetate (TLV=200 ppm). Decomposition products are acetaldehyde, crotonaldehyde and acetone. Oral-rat LD_{50} >10 mg/kg. Acetaldehyde: CAS# 75-07-0; TLV=100 ppm; Suspected Carcinogen. Crotonaldyhyde: CAS# 4170-30-3; PEL=2 ppm; Suspected Carcinogen. Acetone: CAS# 67-64-1; TLV= 750

ppm.

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. 24208-288-05 (5 ml)
NDC No. 24208-288-10 (10 ml)
NDC No. 24208-288-15 (15 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.

NA – Not Applicable
NE- Not Established
< - Less Than
> - Greater Than