

MATERIAL SAFETY DATA SHEET

Issued: 09/07/94	Prepared by: Gary Wong
Revised: 04/27/05	Manager EHS
Revision: 03	Core No. 301

1. PRODUCT AND COMPANY INFORMATION

Product Name: Fluorescein Sodium & Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4%

Generic Name: Fluorescein Sodium & Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4%

NDC No. 24208-732-05 (5 ml)

Legal Category: Prescription only medicine, filled inside amber glass container suitable for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Fluorescent dye/topical anesthetic

BAUSCH & LOMB INCORPORATED
 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
Fluorescein	2321-07-5	NE	NE	0.25
Benoxinate HCL	5987-82-6	NE	NE	0.4
Boric Acid	10043-35-3	NE	NE	≥1
Chlorobutanol	57-15-8	NE	NE	≥1
Povidone	9003-39-8	NE	NE	≥1
Purified Water	7732-18-5	NE	NE	≥

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Amber glass bottle packed inside a cardboard box. Clear, orange colored solution with camphor like odor. May cause eye irritation. For eyes-only.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause temporary stinging, burning and conjunctival redness. Can induce hypersensitivity in some individuals. Some rare individuals develop a severe, immediate type, apparent hyper-allergenic corneal reaction, manifested by acute, intense diffuse inflammation of the outer skin of the eye (epithelial keratitis), a gray ground glass appearance, sloughing of large areas of dead skin (necrotic epithelium), corneal filaments and sometimes, inflammation of the iris (irititis) with inflammation of the membrane behind the cornea (descemetitis).

Skin: May cause irritation, dermatitis and hypersensitivity in some individuals.

Ingestion: May cause irritation and hypersensitivity in some individuals. Will produce a yellow or green discoloration to the mouth. Ingestion of large quantities can induce central nervous system depression, resulting in fatigue and narcosis.

Inhalation: Aspiration of the medication may produce irritation and hypersensitivity in some individuals. Vapor inhalation at controlled room temperature should not pose a hazard due to minimal evaporation.

Chronic Effects: Prolonged use may delay wound healing and is not recommended. It may cause permanent clouding of the eye (corneal opacification) with accompanying visual loss.

Target Organs: Eyes, skin and central nervous system.

Medical Conditions Aggravated by Long Term Exposure: This preparation should be used cautiously and sparingly in patients with cardiac disease, hypothyroidism or allergies. Avoid administration to patients with hypersensitivity to fluorescein sodium, benoxinate or any component of the product.

4. FIRST AID MEASURES

Eyes: 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 drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

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

Note to Physicians: Although exceedingly rare, cases have been reported of ocular anesthetics producing systemic toxicity manifested by central nervous system stimulation followed by depression. Prevent patient from rubbing eye while anesthetic is in effect. 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, nitrogen oxides (NO_x), carbon monoxide (CO) and carbon dioxide (CO₂).

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 contaminated 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: Clear orange solution, with camphor like odor.

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, nitrogen oxides (NO_x), carbon monoxide (CO) and carbon dioxide (CO₂).

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY

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 #

518-47-8 **Fluorescein Sodium**

May cause eye, skin and respiratory tract irritation. Repeated or prolonged exposure can cause hypersensitivity (anaphylactic) and allergic dermatitis (inflammation, and itching) in some individuals. Moderately toxic by ingestion. Oral-rat LD₅₀ 6721 mg/kg.

5987-82-6 **Benoxinate HCL**

May cause eye, skin and respiratory tract irritation. Can cause hypersensitivity (anaphylactic) in some individuals. Subcutaneous-rat LD₅₀ 60 mg/Kg.

10043-35-3 **Boric Acid**

Inhalation can cause coughing and chest discomfort. Dusts may irritate the skin. Harmful quantities may be absorbed through broken skin but is unlikely with intact skin. Ingestion can produce upset stomach and vomiting. Swallowing large quantities may be fatal and chronic exposure can cause hypersensitization (anaphylactic) in some individuals, central nervous system stimulation and erythematous flush (diffuse red skin rash). Oral-rat LD₅₀ 2660 mg/kg.

57-15-8 **Chlorobutanol**

May cause irritation to the skin, respiratory and digestive tract. Can be harmful by skin contact and ingestion. Ingestion of large doses can induce narcosis, unconsciousness and death. May be habit forming due to central nervous system depressant effect. Contact with the skin can cause local anesthesia. Oral-rat LD₅₀ 251 mg/Kg.

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9003-39-8

Povidone

Testing results indicated this chemical was not a skin sensitizer, or primary irritant of the eyes, skin or respiratory tract. No symptoms of exposure recorded or expected.

Oral-rat LD₅₀ >100,000 mg/kg.

12. ECOLOGICAL INFORMATION

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

13. DISPOAL 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. 24208-732-05 (5 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

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NE- Not Established

< - Less Than

> - Greater Than