

MATERIAL SAFETY DATA SHEET

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 Core No. 314

1. PRODUCT AND COMPANY INFORMATION

Product Name: Flurbiprofen Sodium Ophthalmic Solution USP, 0.03%
Generic Name: Flurbiprofen Sodium Ophthalmic Solution USP, 0.03%
NDC No. 24208-314-25 (2.5 ml)

Legal Category: Prescription only medicine, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Anti-inflammatory/analgesic.

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
Flurbiprofen	5104-49-4	NE	NE	0.03
Polyvinyl alcohol	9002-89-5	NE	NE	≥1
Sodium Citrate, dihydrate	6132-04-3	NE	NE	≥1
Thimerosal	54-64-8	0.1	0.1 Ceiling	0.005
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Potassium Chloride, Sodium Chloride, Edetate Disodium, Citric Acid

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle packed in a cardboard box. Clear, colorless to light yellowish, solution. Contains Thimerosal. Decomposition product is mercury vapor. Toxic by oral route.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation. Repeated or prolonged exposure can cause hypersensitivity (anaphylactic) in some individuals. This preparation is for the eyes only.

Skin: May cause irritation. Repeated or prolonged exposure can cause hypersensitivity (anaphylactic) in some individuals.

Ingestion: May cause irritation. Large quantities can cause digestive tract or central nervous system disease, kidney dysfunction and hypertension. Toxic by oral route.

Inhalation: May cause irritation. Evaporation of this product is minimal. Vapor inhalation under controlled conditions does not pose a hazard.

Chronic Effects: May cause irritation and hypersensitivity in some individuals.

Target Organs: Eyes, central nervous system and kidneys.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to Flurbiprofen or any component of the product. Those persons with diminished renal function hypertension or dehydration may be more susceptible to the effects of overexposure.

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: Persons with dehydration, diminished renal function, and hypertension may be more susceptible to overexposure. 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, Mercury Vapors (Hg), Nitrogen Oxides (NO_x), Carbon Monoxide (CO) and Carbon Dioxide (CO₂), Fluorine (F⁻), Sulfur Oxides (SO_x).

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, colorless to light yellowish solution.		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Miscible	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, Mercury Vapors (Hg), Nitrogen Oxides (NO_x), Carbon Monoxide (CO) and Carbon Dioxide (CO₂), Fluorine (F⁻), Sulfur Oxides (SO_x).

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 #

5104-49-4

Flurbiprofen

May cause irritation to skin, lungs, digestive tract and eyes. Can cause hypersensitivity (anaphylactic) in some individuals. Toxic by ingestion, promotes digestive tract and central nervous system disease. Oral/mouse LD₅₀- 457 mg/kg, Oral/rat LD₅₀- 88 mg/kg.

9002-89-5

Polyvinyl Alcohol, (PVA)

Dust may cause irritation to the eyes and respiratory tract. Inhalation of dust can induce bronchitis or asthma attacks in some individuals. No known dermal effects due to acute exposure. No chronic effects are expected. Oral toxicity is low. Avoid ingestion. Oral-rat LD₅₀ 10,000 mg/kg.

54-64-8

Sodium Citrate Dihydrate

May cause irritation to eyes, skin, respiratory and digestive tract. Target organs are the central nervous system, kidneys and bones. Increased risk persons have impaired renal function, dehydration, sodium restricted diets or hypertension. This information may be based on general information regarding sodium salts. Ingestion of large doses can cause nausea, vomiting, convulsions, diarrhea, and hypernoia (hyper mental activity or imagination). Chronic exposure can cause urolithiasis (build-up of calcium deposits in the urinary tract) due to increased extraction of calcium from the bones.

6132-04-3

Thimerosal

May cause irritation to mucous membranes of lungs and eyes. Sensitization dermatitis can occur in persons previously exposed. Chemical burns can occur. May cause conjunctivitis in cases of chronic exposure. Contains mercury. Toxic by ingestion and possibly inhalation. Oral-rat LD₅₀ 75 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. All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

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. 24208-24208-314-25 (2.5 ml)

OSHA Designations: 29 CFR 1910.1000, Table Z
Mercury compounds listed

SARA TITLE III (Superfund Amendments and Reauthorization Act):

SECTION 302 Extremely Hazardous Substances: No Components Listed

SECTION 311, 312 Hazard Categories: NA

SECTION 313 Toxic Chemicals CAS# 54-64-8: Mercury compounds are subject to the reporting requirements of Section 313 of SARA Title III.

CALIFORNIA PROPOSITION 65: This product contains chemical(s) known to the State of California to cause reproductive / developmental toxicity: CAS# 5104-49-4 listed as Flurbiprofen, and CAS# 54-64-8, listed as mercury and mercury compounds.

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

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MSDS: Flurbiprofen Sodium Ophthalmic Solution USP, 0.03%

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