

MATERIAL SAFETY DATA SHEET

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 Core No. 317

1. PRODUCT AND COMPANY INFORMATION

Product Name: Sulfacetamide Sodium & Prednisolone Sodium Phosphate Ophthalmic Solution 10%/0.23% (prednisolone phosphate)
Generic Name: Sulfacetamide Sodium & Prednisolone Sodium Phosphate Ophthalmic Solution 10%/0.23% (prednisolone phosphate)
NDC No. 24208-317-05 (5 ml)
 24208-317-10 (10 ml)
Legal Category: Prescription only medicine, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Antibacterial/ Glucocorticoid

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
Prednisolone Sodium phosphate	125-02-0	NE	NE	0.25
Sulfacetamide	6209-17-2	NE	NE	10.0
Thimerosal	54-64-8	0.1	0.1 Ceiling	0.01
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Polaxamer 407, Boric Acid, Edetate Disodium

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle packed in a cardboard box. Clear, colorless to slightly yellow, solution. Contains thimerosal. Decomposition product mercury vapor. Toxic by ingestion.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation. Repeated or prolonged exposure can cause hypersensitivity and or conjunctivitis in some individuals. This preparation is only for the eyes. It has been shown, though not in humans, that through large doses or prolonged topical administration, glucocorticoids may be systemically adsorbed by pregnant mothers and produce fetal abnormalities. Systematically 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.

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

Ingestion: May cause irritation. Repeated or prolonged exposure can cause hypersensitivity in some individuals. Large doses may induce vomiting, diarrhea, adrenal gland suppression, Cushing's syndrome, water retention, electrolyte imbalance and hyper-glycemia.

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

Chronic Effects: Hypersensitivity reactions include rash, itching, photosensitivity, inflammation, drug fever, nervous system effects and headache. Can also cause conjunctivitis.

Target Organs: Eyes, skin and central nervous system.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity (anaphylactic) to Sulfacetamide Sodium, Prednisolone Sodium Phosphate or any of the components of the product. Individuals sensitive to one sulfonamide may be sensitive to another. Persons hypersensitive to furosemide, sulfones, thiazide

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diuretics, sulfonylureas or carbonic anhydrase inhibitors may be hypersensitive to sulfonamides also. Individuals with dermatitis.

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: 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), Sulfur Oxides (SO_x) and 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 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 slightly yellow solution.

Boiling Point: NE Evaporation Rate: NE

Specific Gravity: 1.0 Vapor Density: NE

Vapor Pressure: NE Viscosity: NE

Water Solubility: NE Percent Volatile by Volume: <1

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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), Sulfur Oxides (SO_x) and toxic fumes.

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 # 125-02-0

Prednisolone Sodium Phosphate

May cause irritation to eyes, skin and respiratory tract. Prolonged or repeated contact can cause hypersensitivity (anaphylactic) in some individuals. May cause allergic reaction if inhaled, ingested or on contact with the skin. Adverse reactions include suppression of adrenal gland secretion, Cushing's syndrome (fatigue, skin discoloration, obesity), water retention, electrolyte imbalance and hyper-glycemia. Oral-mouse LD₅₀ 2.0 gm/kg.

6209-17-2

Sulfacetamide Sodium Monohydrate

May cause eye, skin and respiratory tract irritation. Repeated or prolonged contact can cause hypersensitivity (anaphylactic) in some individuals. Allergic reactions may be manifested by rash, headaches, itching white bumps (urticaria), photosensitivity, drug fever, inflammation of blood or lymph vessels (vasculitis) and central nervous system effects. May be absorbed through skin, inhalation, ingestion or mucous membranes. Oral-rabbit LD₅₀ 5.0 gm/kg.

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.

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12. ECOLOGICAL INFORMATION

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

13. DISPOAL INFORMATION

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.
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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# 125-02-0, listed as Prednisolone sodium phosphate, and CAS# 54-64-8, listed as Mercury and mercury compounds.

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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