

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Revision 02

Prepared by: Gary Wong
Manager EHS
Core No. 030

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Sulfacetamide Sodium Ophthalmic Solution USP, 10%
Generic Name: Same
NDC No. 24208-670-04 (15 ml)

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

Drug Composition: Antimicrobial

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 Content	CAS #	TLV (mg/m ³)	PEL(mg/m ³) %
Sulfacetamide Sodium	6209-17-2	NE	NE 10

Ingredients <1% - Methylcellulose, Methylparaben, Propylparaben, Sodium Thiosulfate

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless solution.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation, stinging and burning. While the irritation may be transient, occasionally the treatment must be discontinued. Can cause hypersensitivity (anaphylactic) in some individuals.

Skin: May cause irritation and hypersensitivity in some individuals. Hypersensitivity reactions include headache, rash, hives (urticaria), photosensitivity and central nervous system effects.

Ingestion: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Hypersensitivity reactions include headache, rash, hives (urticaria), photosensitivity and central nervous system effects.

Inhalation: May cause irritation and hypersensitivity in some individuals. Inhalation of a liquid preparation is not likely. Evaporation of this preparation is minimal.

Chronic Effects: Ophthalmic ointments may retard corneal healing. Non-susceptible organisms, including fungi, may proliferate with the use of these preparations. Sulfonamides are inactivated by the para-aminobenzoic acid present in purulent exudates. Sensitization may occur when a sulfonamide is re-administered irrespective of the route of administration, and cross reactivity between sulfonamides.

Target Organs: Eyes, skin and central nervous system.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to any of the components of the product. If the patient is sensitive to one sulfonamide they may be sensitive to sulfacetamide sodium. An isolated case of Stevens-Johnson syndrome was reported in a patient who had experienced a previous drug reaction to an orally administered sulfonamide. Also a single instance of local hypersensitivity was reported, which progressed to a fatal syndrome, resembling systemic lupus erythematosus.

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. 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.

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.

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:	Clear, colorless solution.		
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 #

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.

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. 24208-670-04 (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.

NE - Not Established
< - Less Than
> - Greater Than