

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 051

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Atropine Sulfate Ophthalmic Ointment USP, 1%
Generic Name: Same
NDC No. 24208-825-55 (3.5 gm)

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

Drug Composition: Mydriatic (Opens pupil)

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 |
|--------------------|-----------|--------------------------|-------------------------|-----------|
| Atropine Sulfate | 55-48-1 | NE | NE | ≥1 |
| Lanolin, Anhydrous | 8006-54-0 | NE | NE | ≥1 |
| Mineral Oil | 8042-47-5 | 5(mist) | 5 | ≥1 |
| White Petrolatum | 8009-03-8 | NE | NE | ≥1 |
| Purified Water | 7732-18-5 | NE | NE | ≥1 |

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Tube packed in a cardboard box. Translucent, colorless to light yellow ointment. Contains highly potent, active ingredient, atropine. Atropine is an intense poison. Do not engage in hazardous activity while under the influence. May cause temporary light sensitivity. Avoid mouth and skin contact. Toxic by ingestion and skin contact.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation and hypersensitivity (anaphylactic) in some individuals. May cause temporary light sensitivity. Overdosage (systemic toxicity) is manifested by flushing and dryness of the skin (a rash may be present in children), blurred vision, a rapid and irregular pulse, fever, abdominal distension in infants, mental aberration (hallucinations) unusual drowsiness, tachycardia, hyperpyrexia, vasodilation, urinary retention, diminished gastric motility and decreased secretion in salivary and sweat glands, pharynx, bronchi, nasal passages and loss of neuromuscular coordination. Severe reactions are manifested by low blood pressure (hypotension) with progressive respiratory depression. Coma and death have been reported in the very young. The main symptoms are drowsiness leading to coma. Atropine poisoning is rarely fatal. Once the drug is withdrawn, the mechanism of overdosage is self limiting.

Skin: May cause irritation and hypersensitivity in some individuals. Toxic systemic effects may be induced by skin contact.

Ingestion: May cause irritation, vomiting, diarrhea and hypersensitivity in some individuals. Ingestion atropine sulfate may induce systemic toxicity effects.

Inhalation: May cause irritation and hypersensitivity in some individuals.

Chronic Effects: May cause irritation and hypersensitivity. Prolonged application may produce local irritation characterized by follicular conjunctivitis, vascular congestion, edema, exudate, and an eczematoid dermatitis. Severe reactions are manifested by hypotension with progressive respiratory depression. Coma and death have been reported in the very young.

Target Organs: Eyes, central nervous system, respiratory, and digestive tract.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to any of the components of the product. Persons with a previous history of susceptibility to belladonna alkaloids may produce systemic symptoms of atropine poisoning. Animal reproduction studies have not been performed with atropine. It is also not known whether atropine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Atropine should be given to pregnant woman only if clearly needed.

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:

- Atropine may interfere with the antiglaucoma and miotic actions of ophthalmic cholinesterase inhibitors.
- Atropine is contraindicated in cases of primary and narrow angle glaucoma or anatomical narrow angles.
- Atropine may interfere with the antiglaucoma and miotic actions of ophthalmic cholinesterase inhibitors.
- It is not known whether this drug is excreted in the milk of nursing mothers, so caution should be exercised when prescribing atropine sulfate.
- CNS disturbances are more likely in young, premature, or small infants.
- 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 fog and foam for surrounding materials. Water spray will froth if sprayed into the burning material.

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 materials and use current Material Safety Data Sheets

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

Skin Protection: Thick rubber 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: | Translucent, colorless to light yellow ointment. | | |
| Boiling Point: | NE | Evaporation Rate: | NE |
| Specific Gravity: | NE | Vapor Density: | NE |
| Vapor Pressure: | NE | Viscosity: | NE |
| Water Solubility: | Immiscible | 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 the raw materials of the product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

CAS #

55-48-1 **Atropine Sulfate**

May cause irritation, hypersensitivity (anaphylactic) in some individuals, and temporary light sensitivity. Overdosage (systemic toxicity) is manifested as follows: flushing and dryness of the skin, mouth, nose, throat and bronchi, blurred vision, a rapid and irregular pulse, fever, abdominal distension in infants, mental aberration (hallucinations) unusual drowsiness, hyperpyrexia, urinary retention, diminished gastric motility and loss of neuromuscular coordination. Severe reactions are manifested by low blood pressure (hypotension) with progressive respiratory depression. May cause coma and death. Animal reproduction studies have not been

performed with atropine. Oral-rat LD₅₀ 622 mg/kg, IV-rat LD₅₀ 41 mg/kg.

8042-47-5 **Mineral Oil**

May cause mild irritation to the eyes or skin. Can cause irritation if mist is inhaled and act as a laxative if ingested in large quantities, causing abdominal cramps and diarrhea. Inhalation control for oil mists 5 mg/M³.

8006-54-0 **Lanolin, Anhydrous**

May cause skin and digestive tract irritation and hypersensitivity (anaphylactic) in some individuals. Oral-rat LD₅₀ >46.5 cc/kg.

8009-03-8 **White Petrolatum**

May cause irritation to the eyes and inhalation can also cause irritation. Mist levels regulated as an oil mist at TLV 5 mg/M³.

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. 24208-825-55 (3.5 gm)

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