

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 124

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Antipyrine and Benzocaine Otic Solution USP
Generic Name: Same
NDC No. 24208-561-62 (10 ml)

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

Drug Composition: Local anesthetic combination

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
Antipyrine	60-80-0	NE	NE	5.4
Benzocaine	94-09-7	NE	NE	1.4
Glycerin	56-81-5	NE	NE	≥1
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Oxyquinolin Sulfate

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Amber glass bottle in a cardboard box. Clear yellow, very viscous solution with a characteristic odor.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation to the mucous membranes and hypersensitivity. Repeated or prolonged exposure can cause conjunctivitis.

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

Ingestion: May cause irritation and hypersensitivity. Moderately toxic by ingestion, but large quantities may induce headache, dizziness, drowsiness, insomnia, vomiting, diarrhea, kidney failure and numbness in nose and throat.

Inhalation: May cause irritation and hypersensitivity. Inhalation of vapors, given off at high temperatures, can cause defatting and irritation of the mucous membranes.

Chronic Effects:

- Antipyrine may cause methemoglobinemia (low blood oxygen levels). After repeated exposures, skin rashes can develop which may last for several weeks.
- May cause hypersensitivity in some individuals.

Target Organs: Respiratory and digestive tract and kidneys.

Medical Conditions Aggravated by Long Term Exposure:

- Individuals sensitive to ester-type local anesthetics (e.g. butacaine, butamben, chlorprocaine, tetracaine, propoxycaine) or to PABA may be hypersensitive to antipyrine and benzocaine.
- It is not known if Antipyrine and Benzocaine Otic Solution can cause fetal harm or impair reproductive capacity. This medication should only be given to pregnant women if clearly needed.
- It is not known if this drug is excreted in human milk, so caution should be exercised when administering this medication.

4. FIRST AID MEASURES

Eyes: If not prescribed this medication, 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 give plenty of water and bland fluids. Seek professional assistance.

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

Note to Physicians: None

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Toxic Fumes and acrolein.

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 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 yellow very viscous solution with a characteristic odor.		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Soluble	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: Toxic fumes and acrolein.

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 #

60-80-0

Antipyrine

May cause irritation and hypersensitivity (anaphylactic). Individuals sensitive to other local anesthetics, such as benzocaine, may also be allergic to antipyrine. May cause methemoglobinemia. Repeated exposure can cause skin rashes which may last for several weeks. Studies indicate probability of toxicity by ingestion, inhalation and skin contact. Oral-rat LD₅₀ 1800 mg/kg. IV-mouse LD₅₀ 500 mg/kg.

94-09-7

Benzocaine

May cause irritation to eyes, skin and respiratory tract, and cause hypersensitivity (anaphylactic) in some individuals. Effects include numbness in nose and throat, drowsiness and dizziness. Can cause central nervous system stimulation. Persons sensitive to other ester-type local anesthetics (e.g. butacaine, butamben, chlorocaine, tetracaine, propoxycaine) or PABA may also be sensitive to benzocaine. Oral-rabbit LD₅₀ 1159 mg/Kg.

56-81-5

Glycerin

May cause irritation to eyes and skin. Repeated or prolonged exposure may cause dermatitis and eye conjunctivitis. Inhalation is not likely due to low evaporation rate, but fumes may cause irritation and defatting of the tissues. Ingestion can cause headache, restlessness, insomnia, dizziness, vomiting, diarrhea and fever. Large doses can cause hemolysis, hemoglobinuria, hyperglycemia, glycosuria, renal failure, convulsions, narcosis and paralysis. Oral-rat LD₅₀ 12,600 mg/kg. Decomposition releases corrosive fumes of acrolein. Avoid open flame and extreme heat. Incompatibilities include strong acids, strong oxidizers, metal oxides and metal hydrides.

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. 24208-561-62 (10 ml)

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

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