

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 402

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Metipranolol Ophthalmic Solution 0.3%
Generic Name: Same
NDC No. 24208-402-05 (5 ml)
24208-402-10 (10 ml)

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

Drug Composition: Beta-adrenoceptor blocker (Reduces intraocular pressure in the eye)

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
Metipranolol	22664-55-7	NE	NE	0.3
Povidone	9003-39-8	10	15	≥1
Purified Water	NA	NE	NE	≥1
Hydrochloric Acid	7647-01-0	5 ppm Ceiling:	ACGH/OSHA	≥1
Ingredients <1% - Glycerin, Sodium Chloride, Edetate Disodium, Benzalkonium Chloride				

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless to light yellow, odorless solution. Potent medication. Individuals with asthma, cardiac disease and diabetes may be more susceptible to systemic effects. Patients taking phenothiazine and beta-adrenergic compounds can experience additive low blood pressure effects. Persons with various strong allergies can have an anaphylactic reaction to this preparation. Toxic by ingestion. May cause drowsiness. Avoid hazardous activities.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation, slight burning sensation on application and hypersensitivity (anaphylactic), especially in individuals subject to allergies. Adverse reactions in small numbers of individuals include headache, conjunctivitis, eyelid dermatitis, blepharitis, blurred vision, tearing, browache, photophobia, and edema. Because topically administered beta-adrenergic compounds may be absorbed systemically, (whole body) effects may include acute toxicity. Acute toxicity effects include severe respiratory distress (especially asthma sufferers), cardiac effects and rarely heart failure. Symptoms of thyroid overactivity (thyrotoxicosis), and low blood sugar (hypoglycemia) may be masked by the effects of metipranolol.

Skin: May cause irritation and hypersensitivity, including localized and generalized rash. Systemic absorption is possible with repeated or prolonged contact.

Ingestion: May cause irritation and hypersensitivity, especially in individuals with other allergies. Toxic by ingestion due to systemic absorption. Can also cause nausea and diarrhea.

Inhalation: May cause irritation and hypersensitivity. May cause systemic effects.

Chronic Effects: As with other topically administered ophthalmic drugs, metipranolol may be absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration, such as severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma, and death associated with cardiac failure. These have been reported with topical application of beta-adrenergic blocking agents. Metipranolol may mask signs (e.g. rapid heart beat) of thyrotoxicosis.

Target Organs: Eye, heart, skin, digestive and respiratory tract, brain and thyroid.

Medical Conditions Aggravated by Long Term Exposure:

- Patients with hypersensitivity to other beta-adrenergic agents may have reactions to metipranolol. Persons with a hypersensitivity to any component of this product. Patients conditions which may be affected include bronchial asthma, severe chronic pulmonary disease and cardiac disease.
- Beta adrenergic agents can mask the symptoms of hypoglycemia in diabetic patients. Metipranolol can mask signs (e.g. tachycardia) of thyrotoxicosis.
- It is not known if metipranolol is excreted in the milk of nursing mothers. Systemically administered beta-blockers are known to be excreted in human milk. Optipranolol has been shown to increase fetal resorption, fetal death, and delayed development when administered orally to rats at 50 mg/Kg during organogenesis. There are no well controlled studies in pregnant women. Optipranolol Ophthalmic Solution should be used in pregnant women if the potential benefit justifies the risk to the fetus.

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. Contact a physician.

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

Note to Physicians:

- Non-cardioselective beta-adrenoceptor blockers reduce cardiac output.
- Patients conditions which may be affected include bronchial asthma, severe chronic pulmonary disease, sinus bradycardia, second and third degree atrioventricular block, overt cardiac failure, cardiogenic shock or hypersensitivity to any component of this product.
- Beta adrenergic agents can mask the symptoms of hypoglycemia in diabetic patients.
- Metipranolol can mask signs (e.g. tachycardia) of thyrotoxicosis.
- Persons with a history of serious anaphylactic reactions may be more reactive to repeated contact to metipranolol, either accidental, diagnostic, or therapeutic. Patients with hypersensitivity reactions may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

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

Flammable Limits: Lower Flammable Limit: NE Upper Flammable Limit: NE

Autoignition Temperature: NE

Hazardous Products: Acetaldehyde, Crotonaldehyde, Acetone, Sulfur Dioxide (SO₂) 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: Notify your supervisor immediately. Minimize contact with spilled material. Keep other personnel away from the clean up area. Wear appropriate respiratory protection. Wear approved respirator and chemically compatible gloves. Use personal protective equipment. (Refer to Section 8) Squeegee, scoop, absorb or use a vacuum to clean up spill. Clean area with an alkaline cleaner/detergent. Dispose of waste material in accordance with Federal, State and Local regulations.

While not a RCRA hazardous waste, material should be disposed of according to Federal, State and Local regulations. Incineration is the preferred disposal method.

7. HANDLING AND STORAGE

This material should be handled and stored per label and other instructions to ensure product integrity.

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. Provide adequate local exhaust ventilation.

Hygienic Practices: Train employees concerning hazards and precautions. Wash hands and forearms after each use and use recommended personal protective equipment while handling.

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 to light yellowish.		
Boiling Point:	NE	Evaporation Rate:	NE
Melting Point:	NE	Vapor Density:	NE
Specific Gravity:	1.0	Vapor Pressure:	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: Acetaldehyde, crotonaldehyde, acetone, sulfur dioxide (SO₂) and 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 #

22664-55-7

Metipranolol

May cause irritation to eyes, skin, respiratory and digestive tract. Can cause hypersensitivity (anaphylactic) especially in individuals with a history of various strong allergic reactions. Systemic toxicity effects include inflammation and irritation of the eye, skin rash, itching or hives, headaches, vomiting, diarrhea, lethargy, lack of coordination and chest pain. Topical application of beta-adrenergic blocking agents have been reported to cause severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma, and death in association with cardiac failure. Symptoms of thyroid over activity (thyrotoxicosis) and low blood sugar (hypoglycemia) can be masked by the effects of metipranolol.

7647-01-0

Hydrochloric Acid

Hydrochloric acid is a severe irritant to eyes, skin, respiratory and digestive tract. Corrosive to all tissues. Ingestion effects include burns of the digestive tract, vomiting, chills and shock. Exposure to gas or fumes may cause immediate coughing, burning of the nose and throat, choking, dizziness, weakness and difficulty swallowing. Exposure to concentrations above 5 ppm can cause inflammation and ulcerations, headache and palpitations. Exposure to concentrations of 100 ppm or above is immediately hazardous to health. Effects after 6-8 hour latency period include tightness in the chest, air hunger, dizziness, frothing at the mouth, pulmonary edema (fluid in the lungs) and cyanosis. Severe exposure may cause circulatory shock, asphyxiation and death. Chronic exposure can cause dermatitis, respiratory or gastric disturbances e.g. pneumonia, asphyxia, ulceration or kidney,

liver or heart failure. Inhalation - Mouse LC₅₀ 2124 ppm/30 minutes; Oral-rabbit 900 Mg/Kg.

9003-39-8 **Povidone, USP**

Testing results indicated this chemical is not a skin sensitizer, primary irritant of the eyes, skin or respiratory tract. No symptoms of exposure recorded or expected. Oral-rat LD₅₀ >100,000 mg/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. 24208-402-05 (5 ml)
NDC No. 24208-402-10 (10 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