

MATERIAL SAFETY DATA SHEET

Issued: 09/07/04	Prepared by: Gary Wong
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Revision: 01	Core No. 107

1. PRODUCT AND COMPANY INFORMATION

Product Name: Nystatin Oral Suspension
Generic Name: Nystatin Oral Suspension, USP
 100,000 units per ml
NDC No. 24208-960 – 94, 473 ml
 24208-960 – 67, 60 ml

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

Drug Composition: Antifungal/antibiotic

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
Nystatin, USP	1400-61-9	NE	NE	≥3
Glycerin, USP	56-81-5	10	NE	≥1
Sodium Citrate, USP	6132-04-3	NE	NE	≥1
Sucrose, NF	57-50-1	NE	15	≥1

Ingredients <1%, Cherry Flavor, Citric Acid, Methylparaben, Peppermint Flavor, Propylparaben, Carboxymethylcellulose Sodium

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Glass or plastic bottle in a cardboard carton. Orange, viscous suspension, with slightly sweet, cherry odor. Oral medication only. May irritate eyes. On decomposition product may liberate acrolein (107-02-8 TLV=0.23 mg/m³).

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation and hypersensitivity (anaphylactic) in some individuals.

Skin: May cause irritation and hypersensitivity (anaphylactic) in some individuals.

Ingestion: This is an oral preparation and may cause hypersensitivity in some individuals. Ingestion of large doses has occasionally caused diarrhea, gastrointestinal distress, nausea, and vomiting.

Inhalation: May cause irritation to the respiratory tract and hypersensitivity in some individuals.

Chronic Effects: Nystatin is virtually nontoxic and nonsensitizing and is tolerated by all age groups including infants, even on prolonged administration.

Target Organs: Gastrointestinal tract

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to any of the components of the product.

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: Toxic fumes, sulfur oxides (SO_x), acrolein (107-02-8 TLV=0.23 mg/m³).

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 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: Yellow-orange, viscous suspension, with a slightly sweet cherry odor.

Boiling Point:	NE	Evaporation Rate:	e.g. water
Specific Gravity:	>1.0	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: Toxic fumes, sulfur oxides (SO_x), acrolein (107-02-8 TLV=0.23 mg/m³).

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 #

May cause irritation to mucous membranes and hypersensitivity (anaphylactic) in some individuals. Possible allergic reaction when in contact with eyes, skin, digestive and respiratory tract.

56-81-5 **Glycerin**

May cause irritation to eyes and skin. Repeated or prolonged exposure can 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.

6132-04-3 **Sodium Citrate**

May cause irritation to eyes, skin, respiratory and digestive tract. Target organs are the central nervous system, kidneys and bones. Increased risk persons have impaired renal function, dehydration, sodium restricted diets or hypertension. This information may be based on general information regarding sodium salts. Ingestion of large doses can cause nausea, vomiting, convulsions, diarrhea and hypernoia (hyper mental activity or imagination). Chronic exposure can cause urolithiasis (build-up of calcium deposits in the urinary tract) due to increased extraction of calcium from the bones.

57-50-1 **Sucrose**

This substance is considered to be non-toxic. Oral-rat LD₅₀ 29.7 gm/kg.

12. ECOLOGICAL INFORMATION

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

13. DISPOAL 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. 24208-960 – 94, 473 ml
24208-960 – 67, 60 ml
- OSHA Designations:** (29 CFR 1910.1000, Table Z)
Nystatin-Not Listed, Glycerin-Listed, Sodium Citrate-Not
Listed, Sucrose-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