



# Material Safety Data Sheet

12601 Twinbrook Parkway  
Rockville, MD 20852 USA

Telephone calls: (301) 881-0666  
8:00am - 5:00pm EST Mon. - Fri.

Responsible Party: Roger Williams

## ATTENTION!

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

## NYSTATIN

Catalog Number: 1477003

Package Size: 200 mg

Revision Date:

June 16, 2003

### SECTION 1 - IDENTIFICATION

Common Name: Nystatin

Formula: Unknown

Synonym: Mycostatin; Nystatin A1

Chemical Name: Nystatin

CAS Number: 1400-61-9

RTECS Number: RF5950000

Chemical Family: Polyene antibiotic

Therapeutic Category: Antifungal

### SECTION 2 - INGREDIENT INFORMATION

Principle Components	Percent	Exposure Limits
Nystatin	Pure Material	n/f

### SECTION 3 - HEALTH HAZARD INFORMATION

**Usual Adult Dose:** The usual oral adult dose of nystatin is 200,000 to 400,000 Units in a lozenge, dissolved slowly in the mouth, four to five times a day. It has also been applied to the skin and intravaginally, as a cream.

**Adverse Effects:** Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** Adverse effects from very large doses may include nausea, vomiting, diarrhea, and stomach pain.

**Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization.

**Inhalation:** May cause irritation. Remove to fresh air.

**Eye:** May cause irritation. Avoid eye contact. Flush with copious quantities of water.

**Skin:** May cause irritation, but is not absorbed through the skin. Flush with copious quantities of water.

**Ingestion:** May cause irritation. Flush out mouth with water. This material is poorly absorbed from the gastrointestinal tract.

# NYSTATIN

Catalog Number: 1477003

Package Size: 200 mg

Revision Date:

June 16, 2003

Medical Conditions  
Aggravated by Exposure: Hypersensitivity to material.

Cross Sensitivity: n/f

Pregnancy Comments: Pregnancy studies in humans have not shown that nystatin causes adverse effects on the fetus, and animal studies have not been done.

Pregnancy Category: A (vaginal)

## SECTION 4 - FIRST AID MEASURES

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: n/f

## SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: 10 grams/kg

Oral Mouse: LD50: 8 grams/kg

Irritancy Data: n/f

Target Organ(s): n/f

Listed as a Carcinogen? NTP: No IARC: No OSHA: No

Other: No

## SECTION 6 - FIREFIGHTING MEASURES

Flash Point: n/f

Upper Flammable Limit: n/f

Auto-Ignition Temperature: n/f

Lower Flammable Limit: n/f

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

## SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: Avoid exposure to light, heat, moisture, and air.

Incompatibilities: Oxidizing agents.

Decomposition Products: When heated to decomposition material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.

Stable? Yes Hazardous Polymerization? No

## SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

# NYSTATIN

Catalog Number: 1477003

Package Size: 200 mg

Revision Date:

June 16, 2003

- Storage:** Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Store in a freezer.
- Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.
- Disposal:** Dispose of waste in accordance with all applicable Federal, State and local laws.

## SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

- Respiratory Protection:** When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.
- Ventilation:** No special ventilation requirements.
- Gloves:** Rubber
- Eye Protection:** Safety Glasses
- Protective Clothing:** Protect exposed skin.

## SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

NOTE: The data reported below is general information, and is not specific to the USP-Reference Standard Lot provided!

- Appearance and Odor:** Yellow to light tan powder; odor suggestive of cereal.
- Melting Point:** >160° C (decomposes without melting)
- Solubility in Water:** Very slightly soluble
- Boiling Point:** n/f
- Specific Gravity:** n/f
- Vapor Pressure:** n/f
- Vapor Density:** n/f
- Evaporation Rate:** n/f
- Reactivity in Water:** n/f
- % Volatile by Volume:** n/f