



Material Safety Data Sheet

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Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

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NYSTATIN

Catalog Number: 1477003

Revision Date:

November 13, 2006

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Nystatin

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

Adverse Effects: Adverse effects may include nausea, vomiting, diarrhea, and stomach pain. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

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

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material.

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Nystatin

Formula: n/f

Synonym: Mycostatin

Chemical Name: Nystatin

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CAS: 1400-61-9

RTECS Number: RF5950000

Chemical Family: Polyene antibiotic

Therapeutic Category: Antifungal

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

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.. Flush with copious quantities of water. This material is not absorbed through skin or mucous membranes when applied topically.

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

General First Aid Procedures: 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.

Note to Physicians

Overdose Treatment: For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.

SECTION 5 - FIREFIGHTING MEASURES

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 6 - ACCIDENTAL RELEASE MEASURES

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.

SECTION 7 - HANDLING AND STORAGE

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.

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.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

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.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: Yellow to light tan powder; odor suggestive of cereals

Odor Threshold: n/f

pH: 6.0 - 8.0 (3% aqueous suspension)

Melting Range: >160° C (decomposes without melting)

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Practically insoluble

Fat Solubility: n/f

Other Solubility: Freely soluble in dimethylformamide and in dimethyl sulfoxide; slightly soluble in methanol, in n-propyl alcohol, and in n-butyl alcohol; practically insoluble in alcohol; insoluble in chloroform and in ether

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: n/f

Molecular Weight: n/f

SECTION 10 - STABILITY AND REACTIVITY

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 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 10 grams/kg

Oral Mouse: LD50: 8 grams/kg

Other Toxicity Data: n/f

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: No

Mutagenicity Data: Nystatin was negative for chromosomal aberrations in mold (*Neurospora crassa*).

Reproductive and Developmental Effects: Several large studies, including the Collaborative Drug Surveillance Program of 401 women, found no increase in the frequency of birth defects among infants born to women treated with nystatin during pregnancy. The frequency of birth defects was not increased among the offspring of rats given 8 to 230 times the unusual human oral dose of nystatin during pregnancy. The oral dose of nystatin is 500,000 to 1,000,000 units three times a day.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: COD: 1.2 mg/O2/mg
Bioaccumulation in aquatic organisms is expected.

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: EINECS # 215-749-0
Safety Phrases: S22, S24/25

SECTION 16 - OTHER INFORMATION

Revision: 13-Nov-06

Previous Revision Date: 16-Jun-03