Bristol-Myers Squibb Company

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

BRISTOL-MYERS SQUIBB
WORLDWIDE MEDICINES GROUP
P.O. BOX 191
NEW BRUNSWICK, NJ 08903
(732) 519-3683

December 18, 2000

Product Identification Mycostatin Topical Powder

Chemical Name: Nystatin

Synonym: Nystatin Topical Powder USP
How Supplied: Yellowish-white powder supplied in plastic squeeze bottles providing, in each gram, 100,000 units of nystatin.
Product Use: for topical fungal infections.
Chemical Family: antifungal antibiotic.
Molecular Formula: C46H83NO18 CAS NUMBER: 1400-61-9

EMERGENCY CONTACTS

Transportation: CHEMTREC (800)424-9300. For all international transpotation emergencies call Chemtrac at (703)527-3887, collect call accepted.

EMERGENCY OVERVIEW: Yellowish-white powder. Contains nystatin, an antifungal antibiotic which is quite toxic after systemic injection. Minimize potential for inhalation.

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2. COMPOSITION/ INFORMATION ON INGREDIENTS

COMPONENTS	HAZARDOUS (Y/N)	CONCENTRATION (wt%)	CAS NUMBERS	EXPOSURE GUIDELINE
Nystatin	Y	2.5 (100,000 U\g)	1400-61-9	None
Talc	N	> 1	14807-96-6	2mg\m3 ACGIH TLV TWA (1)

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(1) ACGIH TLV TWA - American Conference of Governmental Industrial Hygienists Threshold Limit Value Time Weighted Average.

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3. HEALTH HAZARDS IDENTIFICATION

EFFECTS OF OVEREXPOSURE

Routes of Entry:

1. Inhalation: Under normal conditions, this product is contained within plastic bottles and inhalation would not be expected to occur. However, if material becomes airborne there is potential for inhalation. Nystatin is not absorbed from some mucous membranes, however the potential for absorption after inhalation is not known.

2. Skin contact: Under normal conditions, this product is contained within plastic bottles and skin contact would not be expected to occur. Exposure may occur via skin contact if the bottles break or spill and if

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HEALTH HAZARDS IDENTIFICATION (CONTINUED)

gloves and protective clothing are not worn. Nystatin is not absorbed through intact skin.

3. *Ingestion:* Ingestion of large quantities of this material in an occupational setting would not be expected to occur. Ingestion of trace amounts of the material might occur if material contacts the hands and hands are not washed prior to eating drinking or smoking. Nystatin is poorly absorbed from the gastrointestinal tract.

Acute

Ingestion: At therapeutic doses, adverse effects associated with nystatin occur infrequently. High oral doses, however, have produced adverse gastrointestinal effects, including mild and transitory nausea, vomiting, gastrointestinal distress, and diarrhea. Hypersensitivity reactions have been reported very rarely.

Inhalation: Talc is a nuisance dust. Nystatin is quite toxic after systemic injection. The potential for inhalation of this material should be minimized. There is no information concerning the potential for this material to produce symptoms after inhalation.

Skin Contact
a. Toxic: At therapeutic doses, adverse reactions to topically applied nystatin are infrequent, even during prolonged use.
b. Irritation: When applied as directed, mycostatin powder is non-irritating to skin. However, after frequent and repeated exposure, this product may cause irritation in some sensitive individuals. Nystatin has caused skin irritation rarely.
c. Sensitization: Hypersensitivity reactions to nystatin have been reported only rarely.

Eye Contact: Material has not been tested for eye irritation. In the absence of this information, the material should be handled as a potential eye irritant.

Chronic: Adverse reactions to topically applied nystatin are very infrequent, even during prolonged use.

Exposure Guideline Summary: An exposure guideline has not been established for nystatin.

Carcinogen Lists IARC: No NTP: No OSHA: No

Target Organs: None known.

Medical Conditions Aggravated by Exposure: None known.

Medical Surveillance Recommendation: None.

4. FIRST AID MEASURES

Ingestion: Get medical attention immediately.

Inhalation: Remove exposed person to fresh air. If not breathing give artificial respiration. If breathing is difficult administer oxygen. Get medical attention.

FIRST AID MEASURES (CONTINUED)

Skin Contact: Wash with soap and water. Get medical attention if irritation (redness, itching, or swelling) develops or persists.

Eye Contact: Hold eyelids apart and flush with plenty of water for 15 minutes. Get medical attention.

Note to physicians: None.

5. FIRE FIGHTING MEASURES

Flash point: Not applicable.
Autoignition Temperature: Not applicable.
Flammability Limits
LEL: Not applicable.
UEL: Not applicable.

Combustibility of Dusts: Fine powders are considered to be combustible. Provide appropriate bonding and grounding protection to control static charges. Powder handling equipment such as dust collectors, dryers and mills may require additional protective measures (i.e. explosion venting).

Extinguishing Media: In case of fire use water, carbon dioxide, foam or dry chemical.

Firefighting Instructions: Firefighters should wear self contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Evacuate personnel to upwind direction, remove unneeded material and cool container(s) with water from a maximum distance.

Hazardous Combustion Products: May include CO, CO2, and NOx.

Unusual Hazards: See combustion products. Avoid sparks, heat and/or open flame.

6. ACCIDENTAL RELEASE MEASURES

Spill/Clean-up:

Collect material to minimize dust generation; use wet mop, damp sponge or HEPA vacuum. Place collected material into a container for disposal. Impermeable gloves (latex or nitrile) and eye protection should be worn as a minimum precaution. Additional protective clothing\equipment may be needed depending on the extent of the spill. The spill area should be ventilated and decontaminated after material has been picked up.

SEE SECTION 8 FOR PROTECTIVE CLOTHING AND EQUIPMENT TO BE WORN DURING SPILL CLEAN-UP.

7. HANDLING AND STORAGE

Handling Precautions: Avoid inhalation, skin or eye contact with this material. Do not break or spill bottles.

Container Requirements: Plastic squeeze bottles as described in Section 1.

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HANDLING AND STORAGE (CONTINUED)

Storage Conditions: Store at room temperature under low humidity and in the absence of light. Avoid excessive heat. Keep bottle tightly closed. Nystatin deteriorates on exposure to heat, light, moisture, or air.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Ventilation Requirements: Keep airborne concentration below ACGIH limits by enclosure of processes or local exhaust ventilation, as required.

Respiratory Protection: When engineering controls are not sufficient to control exposure, wear NIOSH-approved respiratory protection to control employee exposure; self-contained breathing apparatus should be available for emergency use.

Eye Protection: Wear safety glasses (ANSI Z87.1).

Protective Gloves: Wear impervious gloves (latex or nitrile) if the potential exists for dermal contact.

Special Clothing: Wear protective coveralls whenever the potential for dusty conditions exist.

Hygiene: Wash hands after handling compound and before eating, smoking, using lavatory, and at the end of day.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Physical State/Color: Yellowish-white powder supplied in plastic squeeze bottles.
Boiling point: Not available.
Evaporation rate: Not applicable.
Flash point: Not applicable.
Freezing point: Not available.
Melting point (degrees C): Not available.
Octanol/water partition coefficient: Not available.
Odor (threshold): Practically odorless.
pH: Not applicable.
Solubility in water: Nystatin is slightly soluble in water.
Specific gravity: Not available.
Vapor density: If adequate temperature caused the mycostatin topical powder to volatilize, its vapor density would be much greater than 1 (heavier than air).
Vapor Pressure: Negligible.
Viscosity: Solid.

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions. Nystatin deteriorates on exposure to heat, light, moisture, or air.

Incompatibilities: None known.

Conditions of Reactivity: None known.

Hazardous Decomposition Products: May include CO, CO2, and NOx.

STABILITY AND REACTIVITY (CONTINUED)

Hazardous Polymerization: Will not occur.

Explosion data relative to mechanical impact: No specific data but material is not expected to pose a hazard after mechanical impact.

Explosion data relative to static discharge: No specific data on this product. Pure nystatin powder, however, was found to have relatively strong dust explosion properties. Minimize the potential for dust generation. Evaluate processing equipment to eliminate static electricity and implement controls to avoid excessive temperatures.

11. TOXICOLOGICAL INFORMATION (for nystatin)

RTECS NUMBER (U.S.): RF5950000

ACUTE

LD 50:
Acute oral LD50 (rat) = 10,000 mg/kg;
Acute oral LD50 (mouse) = 8,000 mg/kg;
Acute ip LD50 (mouse) = 24.3 mg/kg;
Acute ip LD50 (mouse) = 4.4 mg/kg;
Acute sc LD50 (mouse) = 120 mg/kg;
Acute iv LD50 (mouse) = 3 mg/kg.

LC 50: No information.

CHRONIC

Carcinogenicity: Nystatin has not been tested for carcinogenicity.

Mutagenicity: There is one report of a study in which nystatin was tested in mice after injection at a dose of 50 mg/kg using bone marrow cytogenetic analysis. Chromatid constrictions and gaps, and non-random chromosomal breaks were observed in this study. The data are of limited value due to the study design.

Teratogenicity: No adverse fetal effects or delayed complications (i.e. effects on growth, development, and functional maturation during childhood) have been attributed to nystatin in infants born to women treated with nystatin vaginal tablets during pregnancy.

Reproductive Effects: No information exists on reproductive effects of nystatin.

Toxicological synergistic products: None known.

12. ECOLOGICAL INFORMATION

Ecotoxicological Information: No information.

Chemical Fate Information: No information.

13. DISPOSAL CONSIDERATIONS

Disposal: Dispose of in accordance with National, State, Local and applicable country regulations.

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14. TRANSPORT INFORMATION

DOMESTIC
Hazard Class (UN NUMBER): Not a D.O.T. regulated material.
Proper shipping name: Not applicable.
Label requirements: Not applicable.
Placard requirements: Not applicable.
Limited Quantity Exemption: Not applicable.

INTERNATIONAL
Hazard Class (UN NUMBER or PIN NUMBER): Not a regulated material.
Proper shipping name: Not applicable.
Label requirements: Not applicable.
Placard requirements: Not applicable.
Limited Quantity Exemption: Not applicable.

15. REGULATORY/STATUTORY INFORMATION -- not meant to be all inclusive

U.S. Federal: None noted.

International: None noted.

EC Labeling: None noted.

16. OTHER INFORMATION

December 18, 2000: The MSDS dated 3/4/94 was revised to change telephone numbers.

Therapeutic agents are intended for use under direction of a physician and/or under the conditions of use described on the label. As a general precaution, personnel who handle drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances.

This material safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities. It does not address the therapeutic use of this material. Information concerning the therapeutic use of this drug substance should be obtained from formulated product package inserts and other appropriate references.

The information contained in this MSDS is believed to be accurate and represents the best information available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.