



Safety Data Sheet

Nystatin Topical Powder, USP

Section 1: Chemical Product and Company Identification

Product Name: Nystatin Topical Powder, USP

Chemical Name(s): Nystatin

Synonym: Mycostatin

CAS Number: 1400-61-9

RTECS #: RF5950000

Trade Name: Nystatin Topical Powder, USP

Chemical Formula: $C_{47}H_{75}NO_{17}$



Health	2
Fire	1
Reactivity	0
Personal Protection	E

Contact Information:

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

Technical Assistance: 607-562-2700

Online Assistance: www.x-gen

Emergency phone number:

National Poison Control

1-800-222-1222

**For information regarding recommended uses and restrictions on usage refer to the product package insert.

Section 2: Hazard Identification

Hazard pictograms (GHS-US):



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

Potential Chronic Health Effects: Possible hypersensitization

Carcinogenic Effects: Not available

Mutagenic Effects: Not available

Teratogenic Effects: Not available

Developmental Toxicity: Not available

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.

Section 3: Composition and Information on Ingredients

Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Nystatin Topical Micronized, USP	1400-61-9	2.00
Talc, USP	14807-96-6	98.00

Section 4: First Aid Measures

General: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

Inhalation: If inhaled, may cause irritation. Remove to fresh air. Seek medical attention immediately.

Skin contact: May cause irritation. Flush with copious amounts of water. This material is not absorbed through skin or mucous membranes when applied topically. Seek medical attention immediately.

Eye contact: May cause irritation. Avoid eye contact. Flush with copious quantities of water. Seek medical attention immediately.

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

Notes to physician: Seek product package insert for complete information.

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: Fire Fighting Measures

Flammability of the product: May be combustible at high temperatures.

Combustion Products: Not available

Unusual Fire and Explosion Hazards: Not expected to be flammable

Extinguishing Media and Instruction:

Small fire: Use DRY chemical powder. **Large fire:** Use water spray, fog, carbon dioxide or foam as appropriate for surrounding fire and materials. DO NOT use water jet.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Special remarks on fire hazard: Not available

Special remarks on explosion hazard: Not available

Section 6: Accidental Release Measures

Release to land:

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

Large spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum with caution to avoid generation of dust during clean-up. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

Release to air: Not available

Release to water: Not available

Protective equipment: Keep unnecessary personnel away. Wear approved respiratory protection, chemically compatible gloves and protective clothing such as protective coveralls and shoe covers for spills.

Section 7: Handling and Storage

Handling: As a general rule, when handling Nystatin Topical Powder, USP, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material.

Keep locked up. Keep away from heat, sources of ignition and oxidizing agents. Empty containers pose a fire risk, evaporate the residue under a fume hood. DO NOT ingest. DO NOT breathe dust. Wear suitable protective clothing. Use only in accordance with directions.

Storage: Keep container tightly closed. Keep container in a cool, dry, well ventilated area (see USP CRT storage conditions). Protect from light and store at controlled room temperature 20° - 25°C (68° - 77°F). Refer to label instructions to ensure product integrity.

Incompatibilities: Avoid extreme heat, sparks, open flames, moisture and light.

Section 8: Exposure Controls / Personal Protection

Engineering controls: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protection: Safety glasses. Lab coat. Gloves. Dust respirator. Be sure to use an approved/certified respirator or equivalent. **In case of Large Spill:** Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Respiratory protection: Under normal use, respirators are not required. If dusts are generated, use a disposable mask (N95). Persons wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

Exposure limit: Not available

Section 9: Physical and Chemical Properties

Physical appearance: Powder

Color: Yellow to light tan powder

Molecular Weight: mixture

Taste: Not available

Odor: Suggestive of cereals.

Odor Threshold: Not available

pH: Not available

Melting Point: Not available

Freezing Point: Not available

Boiling Point: Not available

Flash Point: Not available

Evaporation rate: Not available

Flammability: Not available

Upper Flammable Limit: Not available

Lower Flammable Limit: Not available

Vapor Pressure: Not available

Vapor Density: Not available

Relative density: Not available

Partition Coefficient: Not available

Auto-Ignition Temperature: Not available

Decomposition Temperature: Not available

Viscosity: Not available

Dispersion Properties: Not available

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.

Section 10: Stability and Reactivity

Reactivity: Stable under normal conditions of use

Chemical stability: The product is stable under normal conditions of use

Possibility of hazardous reaction: Not available

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

Incompatible materials: Oxidizing agents

Hazardous decomposition products: When heated to decomposition material emits toxic fumes of NO_x. Emits toxic fumes under fire conditions.

Corrosivity: Non-corrosive in presence of glass.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of exposure: Eye contact, inhalation, and ingestion.

Symptoms:

Short term: Eye, skin, gastrointestinal, and/or respiratory tract irritation. **Long term:** Possible hyper sensitization.

Reproductive toxicity: 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.

FDA Pregnancy Category: A

Toxicity to animals:

Oral Rat: LD50: 10 grams/kg

Oral Mouse: LD50: 8 grams/kg

Measures of toxicity: Not available

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).

Section 12: Ecological Information

Ecotoxicity: Not available

Bioaccumulation potential: Bioaccumulation in aquatic organisms is expected.

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The products of degradation are more toxic.

Section 13: Disposal Information

Waste classification: Not available

Waste from residues/unused products: Dispose of waste in accordance with all applicable federal, state and local laws.

Waste Disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Section 14: Transport Information

DOT Classification: Not a DOT controlled Material (United States).

UN Number: Not available

UN Shipping name: Not available

Transport hazard class: Not available

Packing Group: Not available

Environmental hazard: Not available

Transport in bulk: Not available

Special precautions needed with transport: Not available

Section 15: Regulatory Information

Federal and State Regulations: Not available

Other Regulations: Not available

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): R36 – Irritating to eyes

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Protective Equipment: Gloves. Lab coat. Safety glasses. Dust Respirator. Be sure to use an approved/certified respirator or equivalent.

Section 16: Other Information

References: Not available

Created: 1/30/2015

Last Updated: 3/27/2015

Prepared & Approved by: X-GEN Pharmaceuticals, Inc., Safety Committee

The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.