

SAFETY DATA SHEET

Product Name: Nystatin Topical Powder, USP

Version: 00

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(Date)

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1. Identification:

Product Identifier: NYSTATIN TOPICAL POWDER, USP

Other means of Identification Synonyms: Nystatin, Mycostatin

Recommended use: This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions: No other uses are advised.

Manufacturer: Novitium Pharma LLC
70 Lake Drive, East Windsor, NJ – 08520
Online Assistance: www.novitiumpharma.com

2. Hazard(S) Identification:

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

Potential Acute 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.

3. Composition/Information on Ingredients:

Chemical Name	CAS Number	% by Weight
Nystatin Topical Micronized, USP	1400-61-9	2.00
Talc, USP	14807-96-6	98.00

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4. First-aid measures:

General Information:

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 exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate 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 amounts 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.

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.

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Firefighting Equipment/Instructions:

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

Specific remarks:

Not available.

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 point 13 of the SDS.

Release to air, water:

Not available.

Methods and Materials for Containment and Cleaning Up:

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

7. Handling and Storage:**Precautions for Safe 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.

Conditions for Safe Storage, including any Incompatibilities:

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°C to 25°C (68°F to 77°F) Refer to label instructions to ensure product integrity.

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

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8. Exposure Control/Personal Protection:

Biological Limit Values:

No biological exposure limits noted for the ingredients(s).

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.

Individual Protection Measures, such as Personal Protective Equipment:

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 (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.

9. Physical and Chemical Properties:

Appearance	White to off-white powder
Physical state	Solid
Form	Powder
Odor	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.

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
Condition to Avoid:	Avoid exposure to light, heat, air and moisture
Incompatible Materials:	Oxidizing agents

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Hazardous Decomposition Product:	When heated to decomposition, material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.
Corrosivity:	Non-corrosive in presence of glass
Polymerization:	Will not occur

11. Toxicological information:

Information on likely routes of exposure: Eye contact, inhalation and ingestion.

Symptoms:

Short term: Eye, skin, gastrointestinal, and/or respiratory tract irritation.

Long term: Possible hypersensitization.

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).

12. Ecological Information:

Ecotoxicity	Not available
Bioaccumulative 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 degradation	The products of degradation are more toxic.

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13. Disposal considerations:

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

14. Transport information:

DOT	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

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 (USA):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (USA):

Health: 2

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Flammability: 1

Reactivity: 0

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

16. Other Information:

Reference: 1. SDS of Nystatin Topical Powder, USP – X Gen

Other Special Considerations: Not Available

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Disclaimer: The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.



Drug Product Food Allergen Ingredients

Product Name/Allergen	Dairy/Lactose	Egg	Fish	Crustacean Shellfish	Animal Derivative	Tree Nuts	Wheat	Gluten	Peanuts	Soy/Soybeans	Sugar/Sucrose
Nystatin Topical Powder, USP	N	N	N	N	N	N	N	N	N	N	N

Please mark "Y" for yes, or "N" for no, if the drug product contains the listed ingredient, or any protein or source derived from those ingredients.

Verified By

Signature:

A handwritten signature in black ink, appearing to read "Shl", with a horizontal line drawn underneath.

Name/Title:

Sher Sarafdeen, Regulatory Affairs Specialist

Date:

04/23/18