



IN CASE OF EMERGENCY CALL:
National Poison Control 800-222-1222

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Nystatin Oral Suspension
CAS No: 1400-61-9
Chemical Name:
Chemical Formula: $C_{47}H_{75}NO_{17}$
Molecular Weight: 926.13
Product Use: Treatment of candidiasis in the oral cavity.

Manufacturer's Name: VistaPharm, Inc.
Address: 7265 Ulmerton Road
Largo, FL 33771

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Nystatin USP(100,000 units per ml) active ingredient

Please refer to current package insert for other components.

3. HAZARDS IDENTIFICATION

Primary Route of Entry: Ingestion: at therapeutic doses, adverse effects associated with nystatin occur infrequently.

Overdoseage: High oral doses have produced adverse gastrointestinal effects, including mild and transitory nausea, vomiting, gastrointestinal distress, and diarrhea. Hypersensitivity reactions have been reported very rarely.

Medical Conditions Aggravated by Exposure: Contraindicated in patients with a history of hypersensitivity to any of its components.

4. FIRST AID MEASURES

Eye Exposure: Flush with running water for 15 minutes holding eyelid open. Then contact physician.

Skin Exposure: Remove contaminated area with water. If skin irritation occurs, contact physician.

Inhalation: Remove to fresh air and contact physician or poison control center.

Ingestion: Overuse: Contact a physician or poison control center.

Special Protection Information

Ventilation:	Not required under normal conditions of therapeutic use.
Respiratory Protection:	Not required under normal conditions of therapeutic use.
Protective Gloves and Clothing:	Not required under normal conditions of therapeutic use.
Eye Protection:	Safety glasses recommended.

5. FIRE AND EXPLOSION HAZARD

This product does not pose a fire hazard.

Flash Point:	Not determined.
Extinguishing Media:	Water spray, multipurpose dry chemical, carbon dioxide or foam as appropriate for the surrounding fire or material.
Fire Fighting Procedures:	Use self contained breathing apparatus and protective clothing.
Hazardous Combustion Products:	Not determined.

6. ACCIDENTAL RELEASE MEASURES

If Material is Spilled or Released:	Wearing suitable protective clothing, absorb liquid on to appropriate absorbent material and place into a container for disposal. Impermeable gloves 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.
-------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

7. HANDLING AND STORAGE

Handling:	Observe good industrial hygiene practices. Shake well before using.
Storage:	Store at controlled temperature of 20° to 25°C (68° to 77°F). Keep out of reach from children.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

OSHA Exposure Limits:	None
Engineering Controls:	Not required when handling liquid or containers. Good ventilation should be use. Ventilation should be matched to conditions.
Respiratory Protection:	Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.
Personal Protection:	Not required when handling final product. If containers are compromised or exposure is likely wear: goggles, lab coat, and gloves.

Recommended Facilities: Eye wash, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Light creamy yellow-colored, cherry-flavored
Melting Point (deg. C): Not determined.
Boiling Point (deg. C): Not determined.
Solubility: Insoluble
pH Range: Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Stable
Conditions to Avoid: Not determined.
Incompatibility: Not determined.
Hazardous Decomposition: May produce noxious or toxic products.
Hazardous Polymerization: Does not occur.

11. TOXICOLOGICAL INFORMATION

Other Studies:

Pregnancy: **Teratogenic Effects Category C**
Animal reproduction studies have not been conducted with nystatin oral suspension. It is also not known whether nystatin oral suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nystatin oral suspension should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether nystatin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when nystatin is administered to a nursing woman.

Pediatrics: See dosage and administration.

12. ECOLOGICAL INFORMATION

Environmental Effects: Not determined.

13. WASTE DISPOSAL INFORMATION

Waste Disposal Considerations: Dispose of this material in accordance with applicable international, national, state and local waste disposal regulations.

At Home: Discard away from children's reach.

14. TRANSPORTATION INFORMATION

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.

15. REGULATORY INFORMATION

FDA: Nystatin Oral Suspension is an approved prescription medication.

Inventory Status: The material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.
This material is not listed on the DSL Inventory but is exempt.

16. DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. VistaPharm, Inc. assumes no responsibility for the use of this information.

Date: May 2010

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION