

**SAFETY DATA SHEET**

**1. Identification**

**Product Identifier:** Nystatin Oral Suspension, USP

**Synonyms:** Mycostatin

**National Drug Code (NDC):** 50383-587-16  
50383-587-66

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com


**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

**2. Hazard(s) Identification**

**Physical Hazards:** Combustible liquid Category 4

**Health Hazards:** Harmful if swallowed Category 4



**Symbol(s):** 

**Signal Word:** Warning.

**Hazard Statement(s):** H227 Combustible liquid.  
H302 Harmful if swallowed.

**Precautionary Statement(s):** P210 Keep away from flames and hot surfaces. No smoking.  
P280 Wear protective gloves/eye protection/ face protection.  
P370 + P378 In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary to extinguish.  
P403 + P235 Store in a well-ventilated place. Keep cool.  
P264 Wash hands thoroughly after handling.

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- P270 Do not eat, drink or smoke when using this product.
- P301 IF SWALLOWED: Call a POISON CENTER/doctor/ if you feel unwell.  
+  
P312
- P330 Rinse mouth.
- P501 Dispose of contents/container in accordance with local/regional/national/ international regulations.

**Hazards Not Otherwise Classified:** Not classifiable.  
**Supplementary Information:** None.

### 3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Nystatin	1400-61-9	Mycostatin	C <sub>47</sub> H <sub>75</sub> NO <sub>17</sub>	926.13	100,000 Units

\*The formula also contains Methylparaben, 0.12% and Propylparaben, 0.03% as preservatives, Alcohol (less than 1% v/v), Carboxymethylcellulose Sodium, Cherry Flavor, Citric Acid, Glycerin, Peppermint Flavor, Purified Water, and Sodium Citrate. Citric Acid and/or Sodium Hydroxide may be used to adjust pH (5.3 – 7.5).

### 4. First Aid Measures

**Ingestion:**

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

**Eye Contact:**

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Skin Contact:**

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

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<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Gastrointestinal symptoms including diarrhea, gastrointestinal distress, nausea, vomiting and burning of the mouth have been reported. Hypersensitivity reactions including rash, pruritus, and anaphylactoid reaction have also been reported.
<b>Medical Conditions Aggravated by Exposure:</b>	None.
<b>Notes to Physician:</b>	Patient should be advised to retain nystatin in the mouth for as long as possible and to continue its use for at least 2 days after symptoms have subsided. There should be no interruption or discontinuation of the medication until the prescribed course of treatment is completed, even though symptomatic relief may occur within a few days. If symptoms of local irritation develop, the physician should be notified immediately.

### 5. Firefighting Measures

<b>Suitable Extinguishing Media:</b>	Use water, carbon dioxide, dry chemical or foam as necessary.
<b>Unsuitable Extinguishing Media:</b>	With small quantities use carbon dioxide extinguisher. For large fires use ample quantities of water with dry chemicals or foam as necessary.

#### Specific Hazards Arising from the Chemical:

<b>Hazardous Combustion Products:</b>	None.
<b>Other Specific Hazards:</b>	Not determined.
<b>Special Protective Equipment/Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

### 6. Accidental Release Measures

<b>Personal Precautions:</b>	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.
<b>Methods for Cleaning Up:</b>	Data not available.
<b>Environmental Precautions:</b>	No data available.

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**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. Handling and Storage

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store between 59°F – 86°F. Protect from freezing. Store according to label and/or product insert information.

**Specific End Use:** Pharmaceuticals.

### 8. Exposure Controls/Personal Protection

**Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Nystatin	Not established.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Eyes Protection:** Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Hand Protection:** Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin Protection:** Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

**9. Physical and Chemical Properties**

<b>Physical State/Color:</b>	Yellow milky suspension.
<b>Odor:</b>	Cherry-like aroma.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	5.3 – 7.5.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	>150°F.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Insoluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

**Other Information:**

TYPICAL PROPERTIES

Loss on drying %:	3.8%.
pH in water:	6.9.

Microbiological assay:

I.U. per mg	5060
I.U. per mg of dry product	5156

**10. Stability and Reactivity**

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	Will not occur.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	No data available.
<b>Incompatible Materials:</b>	Strong oxidizer.
<b>Hazardous Decomposition Products:</b>	Does not undergo explosive decomposition.

**11. Toxicological Information**

**Information on the Likely Routes of Exposure:**

<b>Inhalation:</b>	No data available.
<b>Ingestion:</b>	No data available.
<b>Skin Contact:</b>	No data available.

<b>Eye Contact:</b>	No data available.
<b>Symptoms Related to the Physical, Chemical and Toxicological Characteristics:</b>	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
<b>Delayed and Immediate Effects of Exposure:</b>	No data available.
<b>Acute Toxicity – Oral:</b>	No data available.
<b>Acute Toxicity – Dermal:</b>	No data available.
<b>Acute Toxicity – Inhalation:</b>	No data available.
<b>Corrosivity:</b>	No data available.
<b>Dermal Irritation:</b>	No data available.
<b>Eye Irritation:</b>	No data available.
<b>Sensitization:</b>	No data available.
<b>Toxicokinetics/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	No data available.
<b>Reproductive Effects:</b>	No data available.
<b>Carcinogenicity:</b>	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
<b>Mutagenicity:</b>	No data available.
<b>Aspiration Hazard:</b>	No data available.

**12. Ecological Information**

**Ecotoxicity**

<b>Aquatic:</b>	No data available.
<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

**13. Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

**14. Transport Information**

<b>UN Number:</b>	Not applicable.
<b>UN Proper Shipping Name:</b>	Not applicable.
<b>Transport Hazard Class(es):</b>	Not applicable.
<b>Packing Group:</b>	Not applicable.

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**Department of Transportation:** Not regulated as a hazardous material.

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

### 15. Regulatory Information

#### US Federal Regulations:

**Toxic Substance Control Act (TSCA):** Not listed.

**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.

**SARA 313:** Not listed.  
**SARA 302:** Not listed.

#### State Regulations

**California Proposition 65:** Not listed.

### 16. Other Information

**NFPA Rating:**  
Health: 0  
Flammability: 2  
Reactivity: 0

**Revision Date:** 05/21/2015

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