

## SAFETY DATA SHEET

### 1. IDENTIFICATION

**Product identifier:** Nystop, USP (Nystatin Topical Powder)

**Synonym:** 3W6

**Manufacturer Name:** Perrigo Company  
**Address:** 515 Eastern Avenue  
 Allegan, MI 49010 USA

**Telephone number:** 269-673-8451

**Emergency phone number:** 888-464-2986

**Recommended use:** Human drug for treatment of fungal infection – prescription only.

**Restrictions on use:** Use only as directed.

**Date of Preparation:** April 8, 2014

### 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Not Hazardous

**Label Elements:**

**Not hazardous in accordance with the GHS and OSHA Hazcom 2012.**

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Nystatin	1400-61-9	2.4%
Talc	14807-96-6	97.6%

### 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

**Skin contact:** This product is intended for use on the skin. For unintended contact, wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

**Most important symptoms/effects, acute and delayed:** May cause eye irritation.

**Indication of immediate medical attention and special treatment, if necessary:** Immediate medical attention is not required. For unintended exposure, seek medical advice.

## 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use any media that is suitable for the surrounding fire.

**Specific hazards arising from the chemical:** Product is not flammable or combustible.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Contain and collect in a manner that minimizes the generation of airborne dust. Vacuuming with a HEPA filtered vacuum is recommended. Place in appropriate container for disposal. Clean area thoroughly.

## 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid the generation of airborne dust. Avoid contact with eyes and clothing and unintended skin contact. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure guidelines:

Nystatin	100 ug/m3 TWA Perrigo OEL
Talc	2 mg/m3 (respirable) TWA ACGIH TLV 20 mppcf TWA OSHA PEL

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to minimize exposures levels.

### Individual protection measures:

**Respiratory protection:** None needed under normal use conditions. If exposure levels are exceeded or irritation is experienced, a NIOSH approved particulate or supplied air respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** This product is intended for use on the skin. Impervious gloves recommended for handling this product other than for use.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.

**Other:** None known.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance (physical state, color, etc.):** Pale yellow free-flowing powder.

**Odor:** No odor

<b>Odor threshold:</b> Not applicable	<b>pH:</b> Not applicable
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not applicable
<b>Flash point:</b> Not applicable	<b>Evaporation rate:</b> Not applicable
<b>Flammability (solid, gas):</b> Not applicable	<b>VOC:</b> 0
<b>Flammable limits: LEL:</b> Not applicable	<b>UEL:</b> Not applicable
<b>Vapor pressure:</b> Not applicable	<b>Vapor density:</b> Not applicable
<b>Relative density:</b> 2.4-2.6	<b>Solubility(ies):</b> Insoluble in water
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not applicable
<b>Decomposition temperature:</b> Not available	<b>Viscosity:</b> Not applicable

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** None known.

**Conditions to avoid:** None known.

**Incompatible materials:** None known.

**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

**Inhalation:** Inhalation of dusts may cause minor irritation of the mucous membranes and upper respiratory tract.

**Ingestion:** Swallowing may cause gastrointestinal irritation. No serious adverse effects are expected.

**Skin contact:** No adverse effects are expected. Some users have reported skin irritation with burning, stinging or pain.

**Eye contact:** Contact may cause mild irritation with redness and tearing.

**Chronic Effects:** Long term overexposure to respirable talc may cause a lung pneumoconiosis called talcosis with symptoms of reduced lung capacity and shortness of breath.

**Sensitization:** Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.

**Germ Cell Mutagenicity:** No data available.

**Reproductive Toxicity:** No data available.

**Carcinogenicity:** None of the components are listed as carcinogens by IARC, NTP or OSHA.

**Acute Toxicity Values:**

Nystatin: LD50 oral rat 10 g/kg

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity values:** No data is available

**Persistence and degradability:** No data is available

**Bioaccumulative potential:** No data is available

**Mobility in soil:** No data is available.

**Other adverse effects:** None known.

### 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

### 14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
<b>DOT</b>		Not Regulated			
<b>TDG</b>		Not Regulated			
<b>IMDG</b>		Not Regulated			
<b>IATA</b>		Not Regulated			

**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

### 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Not Hazardous

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

**Canadian WHMIS Classification:** Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

### 16. OTHER INFORMATION

**NFPA Rating:** Health = 1      Flammability = 0      Instability = 0  
**HMIS Rating:** Health = 1      Flammability = 0      Physical Hazard = 0

**SDS Revision History:** New SDS

**Date of preparation:** April 8, 2014

**Date of last revision:** New SDS

**Disclaimer :** This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).