

# Nystatin SDS/MSDS (Safety Data Sheet)

## 1. PRODUCT AND COMPANY IDENTIFICATION

Product identifier

\* Product Name: Nystatin

\* Catalog Number: S1934

\* CAS Number: 1400-61-9

\* IUPAC Name: (1S,15S,16R,17R,18S,19E,21E,25E,27E,29E,31E)-33-[(2S,3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy-1,3,4,7,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,25,27,29,31-hexaene-36-carboxylic acid

Relevant identified uses and uses advised against

\* Identified uses: For research and development use only; laboratory chemicals; manufacture of substances.

\* Uses advised against: Not for pharmaceutical, household, or other unapproved uses.

Details of the supplier

\* Company: Selleck Chemicals

\* TollFree: +1 877 796-6397

\* Tel: +1 832 582-8158

\* Fax: +1 832 582-8590

Emergency telephone number

\* Emergency phone #: +1 832 582-8158

## 2. HAZARDS IDENTIFICATION

### 2.1 GHS classification in accordance with 29 CFR 1910 (OSHA HCS):

Acute toxicity (oral): Category 1. H300

Specific target organ toxicity (single exposure): Category 3. H335

Specific target organ toxicity (repeated exposure): Category 1. H372

### 2.2 GHS Label elements, including precautionary statements

Hazard Pictogram(s)



Signal Word

Danger

Hazard statement(s)

H300: Fatal if swallowed

H335: May cause respiratory irritation

H372: Causes damage to organs through prolonged or repeated exposure

Precautionary statement(s)

None.

|                   |                                                                                                                                                                                                                                                                                                                                         |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Prevention</b> | <p>P260: Do not breathe dust/fume/gas/mist/vapors/spray.</p> <p>P261: Avoid breathing dust/fume/gas/mist/vapors/spray.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p>                             |
| <b>Response</b>   | <p>P301+P316: IF SWALLOWED: Get emergency medical help immediately.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P319: Get medical help if you feel unwell.</p> <p>P321: Specific treatment (see information on this label and safety datasheet)).</p> <p>P330: Rinse mouth.</p> |
| <b>Storage</b>    | <p>P403+P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P405: Store locked up.</p>                                                                                                                                                                                                                        |
| <b>Disposal</b>   | <p>P501: P501 Dispose of contents/ container to an approved waste disposal plant.</p>                                                                                                                                                                                                                                                   |

### 2.3 Other hazards

None.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name: Nystatin

CAS Number: 1400-61-9

PubChem CID: 6433272

Molecular formula: C<sub>47</sub>H<sub>75</sub>NO<sub>17</sub>

Molecular weight: 926.1 g/mol

IUPAC name: (1S,15S,16R,17R,18S,19E,21E,25E,27E,29E,31E)-33-[(2S,3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy-1,3,4,7,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,25,27,29,31-hexaene-36-carboxylic acid

### 3.2 Mixtures

Not applicable (pure substance).

## 4. FIRST-AID MEASURES

### 4.1 Description of first aid measures

Inhalation: Move to fresh air. Keep at rest in a position comfortable for breathing. Seek medical attention if symptoms persist.

Skin contact: Wash with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation develops.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting unless directed by medical personnel. Seek medical attention.

### 4.2 Most important symptoms and effects, both acute and delayed

See Section 11 (Toxicological Information).

#### **4.3 Indication of any immediate medical attention and special treatment needed**

Treat symptomatically. Contact a poison control center or physician for severe exposure.

### **5. FIRE-FIGHTING MEASURES**

#### **5.1 Extinguishing media**

Suitable: Water spray, dry chemical, carbon dioxide (CO<sub>2</sub>), alcohol-resistant foam.

Unsuitable: None known.

#### **5.2 Specific hazards arising from the substance or mixture**

Combustible. Heating may produce toxic fumes.

#### **5.3 Advice for firefighters**

Wear self-contained breathing apparatus (SCBA) and full protective clothing.

Fight fire from upwind. Cool containers with water spray until fire is extinguished.

### **6. ACCIDENTAL RELEASE MEASURES**

#### **6.1 Personal precautions, protective equipment and emergency procedures**

Wear appropriate personal protective equipment (see Section 8).

Avoid breathing dust/vapor. Ensure adequate ventilation.

Evacuate personnel to safe areas. Keep people away from and upwind of spill.

WARNING: Highly toxic — only trained personnel should handle spills.

#### **6.2 Environmental precautions**

Prevent product from entering drains, waterways, or soil.

Contain spill with inert absorbent material.

#### **6.3 Methods and materials for containment and cleaning up**

SRP: At the time of review, criteria for land treatment or burial (sanitary landfill) disposal practices are subject to significant revision. Prior to implementing land disposal of waste residue (including waste sludge), consult with environmental regulatory agencies for guidance on acceptable disposal practices.

### **7. HANDLING AND STORAGE**

#### **7.1 Precautions for safe handling**

Nystatin oral suspension and tablets should be stored in tight, light-resistant containers at room temperature (eg, 15-30 °C); exposure of the tablets to temperatures exceeding 40 °C and freezing of the oral suspension should be avoided. Nystatin powder should be stored in tight, light-resistant containers and refrigerated at 2-8 °C.

Most nystatin preparations for topical application to the skin should be stored at 15-30 °C and protected from freezing. Mycostatin® vaginal tablets should be stored at 2-15 °C. Nystatin lozenges for oral topical administration should be stored in tight, light-resistant containers and refrigerated at 2-8 °C.

#### **7.2 Conditions for safe storage, including any incompatibilities**

Nystatin oral suspension and tablets should be stored in tight, light-resistant containers at room temperature (eg, 15-30 °C); exposure of the tablets to temperatures exceeding 40 °C and freezing of the oral suspension should be avoided. Nystatin powder should be stored in tight, light-resistant containers and refrigerated at 2-8 °C.

Most nystatin preparations for topical application to the skin should be stored at 15-30 °C and protected from freezing. Mycostatin® vaginal tablets should be stored at 2-15 °C. Nystatin lozenges for oral topical administration should be stored in tight, light-resistant containers and refrigerated at 2-8 °C.

Store away from incompatible materials (see Section 10).

[Note: Specific storage temperature not available in public databases. Refer to supplier Certificate of Analysis (COA) for exact storage conditions.]

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **8.1 Exposure controls**

#### **8.1.1 Occupational exposure limits (OEL)**

OSHA PEL: Not established.

ACGIH TLV: Not established.

NIOSH REL: Not established.

No occupational exposure limit values are established for this substance.

Use the lowest feasible exposure level (ALARA principle).

#### **8.1.2 Appropriate engineering controls**

Use only in a chemical fume hood or with local exhaust ventilation.

Ensure adequate ventilation to keep airborne concentrations below exposure limits.

### **8.2 Individual protection measures**

#### **8.2.1 Eye/face protection**

Wear safety glasses with side shields.

#### **8.2.2 Skin protection**

Wear protective gloves. Recommended material: Nitrile rubber.

Wear suitable protective clothing (lab coat).

#### **8.2.3 Respiratory protection**

Use NIOSH-approved dust/mist respirator (N95 or higher) if ventilation is inadequate.

#### **8.2.4 Thermal hazards**

Not applicable.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

### **9.1 Information on basic physical and chemical properties**

a) Appearance: Light yellow powder

b) Odor: Odor suggestive of cereals

c) Odor threshold: No data available

d) pH: Amphoteric

e) Melting point/freezing point: Gradually decomp above 160 °C without melting by 250 °C

f) Initial boiling point and boiling range: No data available

g) Flash point: No data available

h) Evaporation rate: No data available

i) Flammability (solid, gas): No data available

j) Upper/lower flammability or explosive limits: No data available

- k) Vapor pressure: No data available
- l) Vapor density: No data available
- m) Relative density: No data available
- n) Water solubility: MW: 926.12 /Form not specified/
- o) Partition coefficient: n-octanol/water: Log P (n-octanol/water): -0.2
- p) Auto-ignition temperature: No data available
- q) Decomposition temperature: No data available
- r) Viscosity: No data available
- s) Explosive properties: No data available
- t) Oxidizing properties: No data available

## 9.2 Other information

Topological Polar Surface Area (TPSA): 320 Å<sup>2</sup>  
Complexity: 1620

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

No specific reactivity hazards identified under normal handling conditions.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No hazardous reactions under normal conditions.

### 10.4 Conditions to avoid

Avoid heat, sparks, open flames, direct sunlight, and moisture.  
Avoid strong oxidizing agents, strong acids, and strong bases.

### 10.5 Incompatible materials

Strong oxidizing agents, strong acids, strong bases.

### 10.6 Hazardous decomposition products

Thermal decomposition may produce: Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Nitrogen oxides (NO<sub>x</sub>).  
See also Section 5 (Fire-fighting measures) for combustion products.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity:

No acute toxicity data available.

#### Skin corrosion/irritation:

No data available.

#### Serious eye damage/eye irritation:

No data available.

**Respiratory or skin sensitization:**

No data available.

**Germ cell mutagenicity:**

No data available.

**Carcinogenicity:**

No data available.

**Reproductive toxicity:**

No data available.

**Specific target organ toxicity (single exposure):**

H372

**Specific target organ toxicity (repeated exposure):**

No data available.

**Aspiration hazard:**

No data available.

## 11.2 Additional information

**Carcinogen classification:**

No indication of carcinogenicity to humans (not listed by IARC).

**Exposure routes:**

Oral, topical(intravaginal). Nystatin is not absorbed from intact skin or mucous membrane.

**Signs and symptoms of exposure:**

Diarrhea (including one case of bloody diarrhea), nausea, vomiting, gastrointestinal upset/disturbances. Rash, including urticaria has been reported rarely. (L1873)

Data source: Hazardous Substances Data Bank (HSDB) via PubChem.

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

Nystatin's production and use as an antibiotic, feed additive, experimental teratogen, and a veterinarian medication may result in its release to the environment through various waste streams. Nystatin is formed from *Streptomyces noursei*, *S. aureus*, and other *Streptomyces* species. If released to air, an estimated vapor pressure of  $8.7 \times 10^{-7}$  mm Hg at 25 °C indicates nystatin will exist in both the vapor and particulate phases in the atmosphere. Vapor-phase nystatin will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 1.5 hours. Reaction with ozone is also expected to occur; the half-life for this reaction is estimated to be 2.6 hours. Particulate-phase nystatin will be removed from the atmosphere by wet or dry deposition. Nystatin may be susceptible to direct photolysis by sunlight. If released to soil, nystatin is expected to have moderate mobility based upon an estimated Koc of 170. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of  $2.0 \times 10^{-7}$  atm-cu m/mole. Nystatin is not expected to volatilize from dry soil surfaces based upon its vapor pressure. A 4% degradation in 28 days using the Closed Bottle test indicates that biodegradation is not an important environmental fate process. If released into water, nystatin is expected to adsorb slightly to suspended solids and sediment based upon the esti

### 12.2 Persistence and degradability

No data available.

### 12.3 Bioaccumulative potential

Log P (n-octanol/water): -0.2

Low potential for bioaccumulation (Log P < 3).

#### **12.4 Mobility in soil**

No data available.

#### **12.5 Results of PBT and vPvB assessment**

PBT/vPvB assessment not available.

#### **12.6 Other adverse effects**

No other adverse ecological effects identified.

### **13. DISPOSAL CONSIDERATIONS**

#### **13.1 Waste treatment methods**

Waste Treatment Methods: Waste material must be disposed of in accordance with national and local regulations. Leave chemicals in original containers and do not mix with other waste. Handle uncleaned containers in the same manner as the product itself.

### **14. TRANSPORT INFORMATION**

#### **14.1 UN number**

Not regulated as dangerous goods (research quantities typically exempt).

#### **14.2 UN proper shipping name**

Not subject to transport regulations (small quantities for research use).

#### **14.3 Transport hazard class(es)**

Not classified as dangerous goods for transport (research quantities).

#### **14.4 Packing group**

Not applicable (not regulated as dangerous goods in typical research quantities).

#### **14.5 Environmental hazards**

Marine pollutant: No (not classified as environmentally hazardous per GHS).

#### **14.6 Special precautions for user**

Transport in original packaging. Ensure containers are tightly sealed.

For bulk or commercial quantities, consult applicable transport regulations (DOT, IATA, IMDG).

#### **14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable.

### **15. REGULATORY INFORMATION**

#### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

US EPA / TSCA: Subject to EPA TSCA regulations

EU ECHA / REACH: Not available in public databases.

**SARA 302 Components:**

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 Components:**

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**SARA 311/312 Hazards:**

Acute (short-term) health hazard

Chronic (long-term) health hazard

**Massachusetts Right To Know Components:**

This material contains components subject to the Massachusetts Right to Know Act. See Section 2 for hazard classification.

**Pennsylvania Right To Know Components:**

This material contains components subject to the Pennsylvania Right to Know Act. See Section 2 for hazard classification.

**New Jersey Right To Know Components:**

This material contains components subject to the New Jersey Right to Know Act. See Section 2 for hazard classification.

**California Prop. 65 Components:**

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**Other regulatory listings:**

- FDA Requirements: The Approved Drug Products with Therapeutic Equivalence Evaluations List identifies currently marketed prescription drug products, incl nystatin, approved on the basis of safety and effectiveness by FDA under sections 505 of the Federal Food, Drug, and Cosmetic Act.

Drug products containing certai

**15.2 Chemical safety assessment**

A chemical safety assessment has not been carried out for this substance.

For research-use-only compounds, no CSA is required under REACH Annex I.

**16. OTHER INFORMATION**

Revision Date: 2026/09/08

Further Information: The information provided is believed to be correct but is not exhaustive and should be used only as a guideline based on current knowledge. It does not represent a guarantee of the properties of the product. Selleck Chemicals Corporation and its Affiliates shall not be held liable for any damage resulting from handling or contact with the product.