SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME NYSTATIN, USP/EP
PRODUCT CODE 0242
SUPPLIER MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063

MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2

MEDISCA Australia PTY LTD
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
Unit 7, Heritage Business Park
5-9 Ricketty Street, Mascot, NSW 2020

MEDISCA UK Limited
Tel.: 0800.029.4641
33 St. James’s Square, London, United Kingdom SW1Y 4JS

EMERGENCY PHONE CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126
National Chemical Emergency Centre 44(0)1235239670

USES Antifungal, antibiotic

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION Based on available data, the classification criteria are not met.
PICTOGRAM Not Applicable
SIGNAL WORD Not applicable
HAZARD STATEMENT(S) May cause an allergic skin reaction.
May cause long lasting harmful effects to aquatic life.
ADVERSE PHYSICOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS Repeated exposure may cause skin dryness or cracking.
PRECAUTIONARY STATEMENT(S) Prevention
Avoid breathing dust, fume, gas, mist, vapors, spray.
Wear protective gloves.
Avoid release to the environment
Response
IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Storage Not applicable
Disposal Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION Health Hazard 1 Flammability 0
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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<td>SYNONYM</td>
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There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES
Chemical family: Polyene antibiotic.
Macrolide antifungal antibiotic complex produced by Streptomyces noursei, S. aureus, and other Streptomyces species. The biologically active components of the complex are nystatin A1, A2, and A3.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT
Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT
Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED
Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED
Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL
Not applicable.

FLAMMABLE PROPERTIES
May be combustible at high temperature.

HAZARDOUS COMBUSTION PRODUCTS
Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES
SAFETY DATA SHEET

PERSONAL PRECAUTIONS
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT
On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS
See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE
Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS
Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in tight, light-resistant containers between 2° to 8 °C.

SPECIFIC END USE(S)
See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: NYSTATIN CAS #: 1400-61-9

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N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. Thermal Hazards: For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.
**SAFETY DATA SHEET**

**SPECIFIC ENGINEERING CONTROLS**
Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### PHYSICAL STATE
Solid

#### DESCRIPTION
Yellow to light tan powder, with characteristic odor. Is hygroscopic, and is affected by long exposure to light, heat, and air.

#### SOLUBILITY
Freely soluble in dimethylformamide and in dimethyl sulfoxide; very slightly soluble in methanol; practically insoluble or insoluble in water, in alcohol, in n-propyl alcohol, in n-butyl alcohol, in chloroform, and in ether.

#### ODOR
Characteristic odor suggestive of cereals

#### FLAMMABILITY
May be combustible at high temperature

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<th><strong>ODOR THRESHOLD</strong></th>
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</table>

The physical data presented above are typical values and should not be construed as a specification.

### SECTION 10: STABILITY AND REACTIVITY

#### REACTIVITY
Not established.

#### CHEMICAL STABILITY
Stable under recommended storage conditions.

#### INCOMPATIBLE MATERIALS
Strong oxidants.

#### HAZARDOUS DECOMPOSITION PRODUCTS
Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.

#### HAZARDOUS POLYMERIZATION
Will not occur.

#### POSSIBILITY OF HAZARDOUS REACTION
Not established.

#### CONDITIONS TO AVOID
Moisture, sunlight and extreme temperatures.

### SECTION 11: TOXICOLOGICAL INFORMATION
SAFETY DATA SHEET

ACUTE TOXICITY

Oral: Rat: LD50: (mg/kg): 10 000
Dermal: Rabbit LD50: (mg/kg): Not available
Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

Due to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE IRRITATION

Due to lack of data the classification is not possible.

REPRODUCTIVE SENSITIZATION

SKIN SENSITIZATION

Based on available data, the classification criteria are not met.
Allergic reactions have been reported very rarely. Generalised pustular eruptions were reported in 3 patients after oral nystatin. Subsequent sensitivity testing revealed delayed (type IV) hypersensitivity to nystatin.

GERM CELL MUTAGENICITY

OSHA
NYSTATIN is not listed.
NTP
NYSTATIN is not listed.
IARC
NYSTATIN is not evaluated.
California Proposition 65
This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

Due to lack of data the classification is not possible.

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met.
Oral: Rat: Lowest published toxic dose: 9 days pregnant: 100 mg/kg
Intravenous: Dog: Lowest published toxic dose: 90 days pregnant: 180 mg/kg

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.
Not expected to present a significant hazard under anticipated conditions of normal use.

SIGNS AND SYMPTOMS OF EXPOSURE

Nausea, vomiting, and diarrhoea have occasionally been reported after oral use. Rashes, including urticaria, have occurred and Stevens-Johnson syndrome has been reported rarely.

POTENTIAL HEALTH EFFECTS

Inhalation
May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion
Absorption by the gastro-intestinal tract is poor, therefore systemic toxicity by accidental ingestion is not expected. Causes gastrointestinal disturbances: Nausea. Vomiting. Diarrhea. Stomach pain.

Skin
Not absorbed by the skin and mucous membranes. May cause skin irritation. May cause an allergic skin reaction.

Eyes
May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

High potential to bioaccumulate: Log Pow: 7.08 (20°C)
MOBILITY IN SOIL

Water solubility: 360 mg/L (24°C)

Henry's Law constant: 2.0X10^-7 atm-cu m/mole (Volatileization of nystatin from moist soil surfaces is not expected; volatilization from water surfaces is not expected to be an important fate).

OTHER ADVERSE EFFECTS

May cause long-lasting harmful effects to aquatic life.

This product is not intended to be released into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA

HAZCHEM

Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not listed

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
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N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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N/L = Not Listed

EU REGULATIONS
**SAFETY DATA SHEET**

**Chemical Name & CAS**

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</table>

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SECTION 16: OTHER INFORMATION**

**REFERENCES**

Available upon request

**ABBREVIATIONS AND ACRONYMS**


**LAST REVISION**

06/2019

**SUPERSEDES**

01/2019

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

**SUPPLEMENTARY INFORMATION**

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.