

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 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
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
RECOMMENDED USES	Manufacturing and Compounding
RESTRICTIONS ON USE	Not applicable

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. Repeated exposure may cause skin dryness or cracking.							
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS								
PRECAUTIONARY STATEMENT(S)	Prevention Response Storage Disposal	Avoid breathing dust, fume, gas, mist, vapors, spray. Wear protective gloves. Avoid release to the environment IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Not applicable Dispose of contents and/or container in accordance with local regulations.						
HMIS CLASSIFICATION	Health Hazard Reactivity	<table border="1"> <tr> <td>1</td> <td>Flammability</td> <td>0</td> </tr> <tr> <td>0</td> <td>Personal Protection</td> <td>E</td> </tr> </table>	1	Flammability	0	0	Personal Protection	E
1	Flammability	0						
0	Personal Protection	E						

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Nystatin A
BOTANICAL NAME	Not applicable
SYNONYM	Mycostatin
CHEMICAL FORMULA	C ₄₇ H ₇₅ NO ₁₇
CHEMICAL FAMILY	Polyene antibiotic
CAS NUMBER	1400-61-9
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	926.09
COMPOSITION	

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
NYSTATIN	1400-61-9	215-749-0	100

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	Macrolide antifungal antibiotic complex produced by <i>Streptomyces noursei</i> , <i>S. aureus</i> , and other <i>Streptomyces</i> 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	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	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, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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

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. Store at 2°-8°C, short term excursions such as during shipping, up to 25°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

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.
SPECIFIC ENGINEERING CONTROLS	Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.
BIOLOGICAL MONITORING	Not available
CONTROL BANDING	Not available

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				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	160°C, 320°F
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	900°C, 1652°F
log P (OCTANOL-WATER)	7.08 (20°C)	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	160°C, 320°F (decomposes)
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	6.0 - 8.0 (3%)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	15 g/m ³
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	0.0000001 kPa (25°C)	VISCOSITY	Not available

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

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.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
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	Due to lack of data the classification is not possible.
CARCINOGENICITY	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.
SIGNS AND SYMPTOMS OF EXPOSURE	ROUTES OF EXPOSURE: Oral, Topical EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available DELAYED HEALTH EFFECT FROM EXPOSURE: Not available 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

ECOTOXICITY	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 (Volatilization 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

DISPOSAL METHODS 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

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
NYSTATIN 1400-61-9	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
NYSTATIN 1400-61-9	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
NYSTATIN 1400-61-9	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

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

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

01/2023

SUPERSEDES

01/2021

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.

Medisca[®]