

Section 1: Identification

Common Name/Trade Name	NYSTATIN USP	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours) NSW Poisons Information Centre: 131 126 (24 hours)
Distributor Name	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au	
Product Synonym(s)	Nystatin is an antifungal substance obtained by fermentation using certain strains of <i>Streptomyces noursei</i> as the production micro-organism. It contains mainly tetraenes, the principal component being: C1 S,3R,4R,7R,9R, 11 R,15S,16R, 17R, 18S, 19E,21 E,25E,27E,29E,31 E,33R,35S,36R, 37S)-33-[(3-amino-3,6-dideoxy-β-D-mannopyranosyl)oxy]-1,3,4,7,9,11,17,37octahydroxy-15, 16, 18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaeonta19,21,25,27,29,31-hexaene-36-carboxylic acid (nystatin Al).	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Not a hazardous substance or mixture.
Signal Word	None
Hazard Statement(s)	N/A
Pictogram(s)	N/A
Precautionary Statement(s)	N/A
Hazards Not Otherwise Classified	Prolonged or repeated exposure may cause allergic reactions. Allergic reactions have been reported very rarely. Since the absorption of nystatin from the gastro-intestinal tract is negligible, accidental ingestion causes no systemic toxicity.
Ingredient(s) with Unknown Toxicity	No data available

Section 3: Composition/Information on Ingredients

Chemical Name	Nystatin
Common Name	Nystatin
CAS Number	1400-61-9
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	No data available.
If Inhaled	Remove to fresh air. Rest. Get medical advice/attention if you feel unwell.
In Case of Skin Contact	Remove contaminated clothing and shoes. Wash the exposed skin with mild soap and tap water. Wash contaminated clothing before reuse.
In Case of Eye Contact	Check for and remove any contact lenses. Immediately flush eyes with tap water for several minutes, keeping eyelids open. Do not use an eye ointment. Get medical advice/attention if eye irritation persists.
If Swallowed	Rinse mouth provided person is conscious. If swallowed, seek medical advice and show this safety data sheet or label.
Most Important Symptoms and Effects	Symptoms/injuries: None known. Indication of any immediate medical attention and special treatment needed In all cases of doubt, or when symptoms persist, seek medical attention. Potential adverse human health effects and symptoms: Allergic reactions (erythema) and pruritus have been very rarely notices. Cutaneous rashes have been rarely reported. Gastro-intestinal adverse reactions: rare nausea, vomiting, diarrhea. The acute overdose by ingestion (swallowing) may include diarrhea and/or gastrointestinal discomfort. Supportive treatment is recommended. RTECS No.: RF5950000 (See RTECS site for complete information.) Occupational exposure to nystatin may occur through inhalation and dermal contact with this substance at workplaces where nystatin is produced or used.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Suitable extinguishing media: Carbon dioxide, dry chemical powder, or foam as appropriate for surrounding fire and materials. Unsuitable extinguishing media: Do not use a heavy water stream.
Special Hazards Arising From the Substance/Mixture	Under fire conditions, may produce toxic fumes of carbon monoxide, carbon dioxide and oxides of nitrogen.
Special PPE and/or Precautions for Firefighters	Observe general rules for preventive fire protection. Do not inhale combustion gases. Do not enter fire area without proper protective equipment for firefighters, including respiratory protection.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Wear suitable personal protective equipment. Avoid dust formation. Minimize direct contact with skin or eyes and prevent inhalation of dust.
Methods and Materials Used for Containment	Collect powder using vacuum equipment designed specifically for dust or use appropriate tools to put the material in a suitable waste disposal container. Avoid dust formation. Clean the contaminated surface by water/detergent and dispose according to local and regional authority requirements.
Cleanup Procedures	Collect powder using vacuum equipment designed specifically for dust or use appropriate tools to put the material in a suitable waste disposal container. Avoid dust formation. Clean the contaminated surface by water/detergent and dispose according to local and regional authority requirements.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid all unnecessary exposure. Handle in accordance with good industrial hygiene and safety procedures. Avoid generating dusts while handling the product and mixing. Wear suitable protective equipment. Wash hands after handling. Do not eat, drink and smoke in work areas.
Conditions for Safe Storage	For long term storage: Store in the original package, protected from light, at a temperature between 2 and 8°C. Incompatible products: Strong oxidizing agents.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Occupational exposure limits: Not required.
Appropriate Engineering Controls	No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that dusts are minimized.
PPE - Eye/Face Protection	If dust occurs: chemical goggles or safety glasses.
PPE - Skin Protection	Protective gloves. Wear suitable protective clothing.
PPE - Body Protection	Protective gloves. Wear suitable protective clothing.
PPE - Respiratory Protection	No special protective equipment required. If dust occurs: dust mask (class P1).

Section 9: Physical and Chemical Properties

Appearance	Physical state: Solid. Color / Physical state at 20°C: Yellow or slightly brownish powder, hygroscopic.
Upper/Lower Flammability or Explosive Limits	No data available
Odor	Suggestive of cereals.
Vapor Pressure	No data available
Odor Threshold	No data available
Vapor Density	No data available
pH	Between 6.0 and 8.0 in a 3% aqueous suspension.
Relative Density	No data available
Melting Point/Freezing Point	Gradually decomposition above 160 C, without melting by 250°C.
Solubility	Practically insoluble in water, freely soluble in dimethylformamide and in dimethyl sulphoxide, slightly soluble in methanol, practically insoluble in alcohol.
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	log P octanol / water: 7.08
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	Stable under normal conditions.
Chemical Stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal conditions. Hazardous polymerization: Will not occur.
Conditions to Avoid	Heat. Light. Moisture. Air.
Incompatible Materials	Materials to avoid: Strong oxidizers
Hazardous Decomposition Products	Hazardous combustion products: carbon monoxide, carbon dioxide, nitrogen oxides.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	This product is not hazardous. Nystatin is not absorbed from the gastrointestinal tract and following topical administration to intact skin or mucous membranes. Oral LD50 mice: 8 g/kg. Oral LD50 rats: 10 g/kg.
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	Not classified. pH: 6-8.
Serious Eye Damage/Irritation	Not classified. pH: 6-8.
Respiratory or Skin Sensitization	Not classified.
Germ Cell Mutagenicity	Not classified.
Carcinogenicity IARC	Not classified.
Carcinogenicity ACGIH	Not classified.
Carcinogenicity NTP	Not classified.
Carcinogenicity OSHA	Not classified.
Reproductive Toxicity	Not classified.
Specific Target Organ Toxicity - Single Exposure	Not classified.
Specific Target Organ Toxicity - Repeated Exposure	Not classified.
Aspiration Hazard	Not classified.

Section 12: Ecological Information

Toxicity	Quantitative data on the ecological effect of this product are not available. No ecological damage caused by this product has been reported to date. Observe local environmental regulations.
Persistence and Degradability	No additional information available.
Bio-accumulative Potential	Log Pow: 7,08 at 20°C.
Mobility in Soil	No additional information available
Other Adverse Effects	No additional information available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Dispose of this material and its container at special waste collection point. Incinerate in an approved facility. Dispose in a safe manner in accordance with local/national regulations.
Waste Treatment Methods Packaging	Dispose of this material and its container at special waste collection point. Incinerate in an approved facility. Dispose in a safe manner in accordance with local/national regulations.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

No REACH Annex XVII restrictions. No National Regulations restrictions.

Section 16: Other Information

Additional Information	N/A
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