

## Section 1: Identification

<b>Common Name/Trade Name</b>	NYSTATIN USP	
<b>Supplier Information</b>	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	<b>IN CASE OF EMERGENCY:</b> Chemtrec 1 (800) 424-9300 (24 hours) NSW Poisons Information Centre: 131 126 (24 hours)
<b>Distributor Name</b>	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: <a href="mailto:bellacorp@bellacorp.com.au">bellacorp@bellacorp.com.au</a>	
<b>Product Synonym(s)</b>	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: CI 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[3.3.1]nonatriaeonta19,21,25,27,29,31-hexaene-36-carboxylic acid (nystatin Al).	
<b>Relevant Use(s) of Product</b>	Manufacture or Compounding of Substances	

## Section 2: Hazards Identification

<b>Classification of Substance or Mixture</b>	Not a hazardous substance or mixture.
<b>Signal Word</b>	None
<b>Hazard Statement(s)</b>	N/A
<b>Pictogram(s)</b>	N/A
<b>Precautionary Statement(s)</b>	N/A
<b>Hazards Not Otherwise Classified</b>	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.
<b>Ingredient(s) with Unknown Toxicity</b>	No data available

## Section 3: Composition/Information on Ingredients

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

## Section 4: First Aid Measures

<b>General Advice</b>	No data available.
<b>If Inhaled</b>	Remove to fresh air. Rest. Get medical advice/attention if you feel unwell.
<b>In Case of Skin Contact</b>	Remove contaminated clothing and shoes. Wash the exposed skin with mild soap and tap water. Wash contaminated clothing before reuse.
<b>In Case of Eye Contact</b>	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.
<b>If Swallowed</b>	Rinse mouth provided person is conscious. If swallowed, seek medical advice and show this safety data sheet or label.
<b>Most Important Symptoms and Effects</b>	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

<b>Suitable Extinguishing Media</b>	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.
<b>Special Hazards Arising From the Substance/Mixture</b>	Under fire conditions, may produce toxic fumes of carbon monoxide, carbon dioxide and oxides of nitrogen.
<b>Special PPE and/or Precautions for Firefighters</b>	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

<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	Wear suitable personal protective equipment. Avoid dust formation. Minimize direct contact with skin or eyes and prevent inhalation of dust.
<b>Methods and Materials Used for Containment</b>	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.
<b>Cleanup Procedures</b>	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

<b>Precautions for Safe Handling</b>	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.
<b>Conditions for Safe Storage</b>	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

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

## Section 9: Physical and Chemical Properties

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

## Section 10: Stability and Reactivity

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

## Section 11: Toxicological Information

<b>Acute Toxicity - LD50 Oral</b>	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.
<b>Acute Toxicity - Inhalation</b>	No data available
<b>Acute Toxicity - Dermal</b>	No data available
<b>Acute Toxicity - Eye</b>	No data available
<b>Skin Corrosion/Irritation</b>	Not classified. pH: 6-8.
<b>Serious Eye Damage/Irritation</b>	Not classified. pH: 6-8.
<b>Respiratory or Skin Sensitization</b>	Not classified.
<b>Germ Cell Mutagenicity</b>	Not classified.
<b>Carcinogenicity IARC</b>	Not classified.
<b>Carcinogenicity ACGIH</b>	Not classified.
<b>Carcinogenicity NTP</b>	Not classified.
<b>Carcinogenicity OSHA</b>	Not classified.
<b>Reproductive Toxicity</b>	Not classified.
<b>Specific Target Organ Toxicity - Single Exposure</b>	Not classified.
<b>Specific Target Organ Toxicity - Repeated Exposure</b>	Not classified.
<b>Aspiration Hazard</b>	Not classified.

## Section 12: Ecological Information

<b>Toxicity</b>	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.
<b>Persistence and Degradability</b>	No additional information available.
<b>Bio-accumulative Potential</b>	Log Pow: 7,08 at 20°C.
<b>Mobility in Soil</b>	No additional information available
<b>Other Adverse Effects</b>	No additional information available

## Section 13: Disposal Considerations

<b>Waste Treatment Methods Product</b>	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.
<b>Waste Treatment Methods Packaging</b>	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.
<b>Special Precautions Landfill or Incinerations</b>	No data available
<b>Other Information</b>	No data available

## Section 14: Transport Information

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

## Section 15: Regulatory Information

No REACH Annex XVII restrictions. No National Regulations restrictions.

## Section 16: Other Information

<b>Additional Information</b>	N/A
<b>Prepared By</b>	Scarlotte Smith
<b>Revision Date</b>	02/26/2021 10:26

### Disclaimer

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