

## Safety Data Sheet

### Nystatin Ointment USP 100,000 USP Nystatin Units Per Gram

Strength: 100,000

Pack Size: 15 gm,

NDC 72578-089-01,

USP Nystatin Units

Pack Size: 30 gm

NDC 72578-089-04

Revision No.: 00

#### Emergency Overview

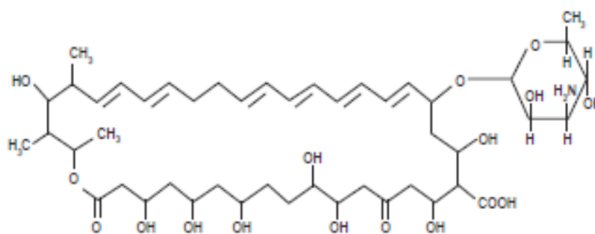
Nystatin Ointment USP 100,000 USP Nystatin units per gram intended for external preparation, contains Nystatin and excipients generally to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

#### Section 1 : Identification

**Product Name:** Nystatin Ointment USP 100,000 USP Nystatin Units per Gram

**Formula:**  $C_{47}H_{75}NO_{17}$

**Chemical Name:** (21E,23E,25E,27E,31E,33E)-20-[[[(3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy]-4,6,8,11,12,16,18,36-octahydroxy-35,37,38-trimethyl-2,14-dioxo-1-oxacyclooctatriaconta-21,23,25,27,31,33-hexaene-17-carboxylic acid



**Molecular Weight:** 926.107 g/mol

**Description:** Nystatin Ointment is for dermatologic use. Nystatin Ointment USP, for topical use only, contains 100,000 USP Nystatin Units per gram, in a white petrolatum and light mineral oil base.

**Dosage forms and strengths:** Ointment, Each gram of Nystatin Ointment contains 100,000 USP Nystatin units per gram and is available in two packs 15 gm, 30 gm.

#### Manufacturer / supplier identification

<b>Company</b>	Cadila Healthcare Ltd. Ahmedabad, India
<b>Address</b>	Cadila Healthcare, Ltd. Changodar (Topical Formulation facility) Plot No. 254, Opp. Laxmi Narayan Petrol Pump, N. H 8A, Ahmedabad -382210 India
<b>Contact for information</b>	Tel.:+91 2717-616430 Fax: +91 2717-616430
<b>Emergency Telephone No</b>	Tel.:+91 2717-616401
<b>Recommended use / Therapeutic Category</b>	Nystatin Ointment is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by <i>Candida albicans</i> and other susceptible <i>Candida</i> species.
<b>Restriction on Use / Contraindications</b>	Nystatin Ointment is not indicated for systemic, oral, intravaginal or ophthalmic use.

## Safety Data Sheet

### Nystatin Ointment USP 100,000 USP Nystatin Units Per Gram

Strength: 100,000

Pack Size: 15 gm,

NDC 72578-089-01,

USP Nystatin Units

Pack Size: 30 gm

NDC 72578-089-04

Revision No.: 00

## Section 2 : Hazard (s) Identification

### Dose and Administration

#### Adults and Pediatric Patients (Neonates and Older):

Apply liberally to affected areas twice daily or as indicated until healing is complete.

### Adverse effects

In the workplace, exposure via eye contact may cause irritation. Prolonged skin contact may cause redness or skin discomfort. Ingestion may be harmful. Inhalation is unlikely due to viscosity. In therapeutic use, the most common adverse effects reported are diarrhea, nausea, vomiting, gastrointestinal upset/disturbances. May cause adverse effects on skin, musculoskeletal, and cardiovascular system. Therapeutic use can result in increased susceptibility to infections and may exacerbate systemic fungal infections. Limited evidence of harm to fetus during pregnancy. These effects may be possible as a result of workplace exposure.

Other potential health hazards known from therapeutic use.

**Flammability Hazards:** This product is combustible and may ignite if exposed to direct flame or if highly heated for a prolonged period.

When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds, including carbon and nitrogen oxides. **Reactivity Hazards:** This product is not reactive.

**Environmental Hazards:** This product has not been tested for environmental effects; however, the active ingredient is very toxic to aquatic organisms. **Emergency Considerations:** Emergency responders should wear appropriate protection for situation to which they respond.

### Over Dose Effect

Topically applied Nystatin ointment can be absorbed in sufficient amount to produce systemic effects.

### Pregnancy Comments

There are no adequate and well-controlled studies of Nystatin in pregnant women; however, Nystatin may cause fetal harm when administered to a pregnant woman when used in topical preparations. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. In topical preparations, Nystatin is rated by the FDA for therapeutic risk as Pregnancy Risk Category C (refer to Definition of Terms for full category definitions).

## Safety Data Sheet

### Nystatin Ointment USP 100,000 USP Nystatin Units Per Gram

Strength: 100,000  
USP Nystatin Units

Pack Size: 15 gm,  
Pack Size: 30 gm

NDC 72578-089-01,  
NDC 72578-089-04

Revision No.: 00

#### Section 3: Composition / information on ingredients

Each gram contains:

Active: Nystatin (100,000 USP Nystatin units)

#### Section 4: First -aid measures

##### General

Contaminated individuals must be taken for medical attention if any adverse effects occur. Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, if necessary. Remove victim(s) to fresh air, as quickly as possible.

Take copy of product label and SDS to physician or other health professional with victim(s).

**Skin Exposure:** If adverse skin effects occur, discontinue use. Seek medical attention.

**Eye Exposure:** If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

**Inhalation:** If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

**Ingestion:** If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

##### Signs and Symptoms

Ointment is intended for topical use only under guidance of a physician. Ointment is not considered hazardous under normal conditions.

##### Overdose Treatment

Topically applied Nystatin ointment can be absorbed in sufficient amounts to product systemic effects

**Safety Data Sheet**

**Nystatin Ointment USP 100,000 USP Nystatin Units Per Gram**

**Strength:** 100,000  
USP Nystatin Units

**Pack Size:** 15 gm,  
**Pack Size:** 30 gm

**NDC** 72578-089-01,  
**NDC** 72578-089-04

**Revision No.:** 00

**Section 5: Fire -fighting measures**

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water is recommended for fires involving packaging.
<b>Special Firefighting procedures</b>	Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.
<b>Hazardous Combustion products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

**Section 6: Accidental Release Measures**

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of Hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination procedures</b>	No specific decontamination or detoxification procedures have been identified for this product.

## Safety Data Sheet

### Nystatin Ointment USP 100,000 USP Nystatin Units Per Gram

Strength: 100,000

Pack Size: 15 gm,

NDC 72578-089-01,

USP Nystatin Units

Pack Size: 30 gm

NDC 72578-089-04

Revision No.: 00

#### Section 7: Handling and Storage

##### **HANDLING**

###### **General Requirements**

No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

##### **STORAGE**

No storage requirements necessary for occupational hazards. Follow storage instructions described in the product insert to maintain efficacy.

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

Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices

###### **Storage Conditions**

Store at controlled room temperature 15° - 30°C (59° to 86°F), Do not refrigerate.

#### Section 8: Exposure controls/personal protection

##### **Exposure Controls**

Control Levels are established for operations involving this material based upon the OEL/Hazard Category and the outcome of a site- or Operation-specific risk assessment.

##### **Personal Protective Equipment**

###### **Eye Protection**

Wear approved safety glasses with side shields if eye contact is possible.

###### **Other Equipment or Procedures**

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

#### Section 9: Physical and chemical properties

##### **Appearance Physical form**

Nystatin ointment (100,000 USP Nystatin Units per gram) is a yellow colored ointment is supplied in 15g and 30g tubes.

#### Section 10: Stability and reactivity

##### **Stability**

This product is expected to be stable

##### **Conditions to avoid**

None for normal handling of the product

## Safety Data Sheet

### Nystatin Ointment USP 100,000 USP Nystatin Units Per Gram

Strength: 100,000  
USP Nystatin Units

Pack Size: 15 gm,  
Pack Size: 30 gm

NDC 72578-089-01,  
NDC 72578-089-04

Revision No.: 00

## Section 11: Toxicological information

<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>Skin Effects</b>	This product may irritate contaminated tissue.
<b>Eye Effects</b>	This product may cause irritation via inhalation or eye contact.
<b>Target Organ Effects</b>	<i>Acute: Occupational Exposure:</i> Skin. <i>Therapeutic Doses:</i> Skin, fetal harm. <i>Chronic: Occupational Exposure:</i> Skin. <i>Therapeutic Doses:</i> Skin and other organs as described under 'Other Potential Health Effects'.
<b>Sensitization</b>	In therapeutic use by other routes, Nystatin has caused bronchospasm, facial swelling, rash, hives (rarely), and Stevens-Johnson (very rarely) have been reported.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions. Assessment based upon effects of structurally similar substances
<b>Carcinogenicity</b>	No components are listed as carcinogens
<b>Reproductive Effects</b>	There have been no studies to whether Nystatin affects fertility in males or females. It is not known whether Nystatin is excreted in human milk. Because there is potential for adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.
<b>Pharmacological Effects</b>	In therapeutic use, the most common adverse effects reported are diarrhea, nausea, vomiting, gastrointestinal upset / disturbances. May cause adverse effects on skin, musculoskeletal, and cardiovascular system. Limited evidence of harm to fetus during pregnancy. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known.
<b>Other Adverse Effects</b>	Other adverse effects reported from therapeutic use described by body system are provided below. <ul style="list-style-type: none"><li>• <b>Cardiovascular System:</b> Rapid heart beat.</li><li>• <b>Gastrointestinal System:</b> Diarrhea (including one case of bloody diarrhea), nausea, vomiting, gastrointestinal upset/disturbances.</li><li>• <b>Hypersensitivity Reactions:</b> Bronchospasm, facial swelling.</li><li>• <b>Musculoskeletal System:</b> Muscle pain.</li><li>• <b>Reproductive System:</b> Possible harm to fetus during pregnancy.</li><li>• <b>Skin:</b> Rash, including hives has been reported rarely. Stevens-Johnson syndrome has been reported very rarely.</li></ul>

## Section 12: Ecological information

<b>Summary</b>	No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.
----------------	--

## Safety Data Sheet

### Nystatin Ointment USP 100,000 USP Nystatin Units Per Gram

**Strength:** 100,000

**Pack Size:** 15 gm,

**NDC** 72578-089-01,

USP Nystatin Units

**Pack Size:** 30 gm

**NDC** 72578-089-04

**Revision No.:** 00

#### Section 13: Disposal consideration

<b>Disposal recommendation</b>	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this product.

#### Section 14: Transport information

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

##### **UN Classification and Labelling Transport Information**

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

#### Section 15: Regulatory information

Generic Medicine. NDC no - 72578-089-01 (15 gm), 72578-089-04 (30 gm)

#### Section 16: Other information

None

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product

**Date of issue:** 06/06/2020

**Supersedes edition:** New Edition