

**SDS Identifier: *Nystatin and Triamcinolone Acetonide Ointment, USP*****SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION**

**Product Name** Nystatin and Triamcinolone Acetonide Ointment, USP  
**Recommended use and restricted use** Antifungal and Anti-bacterial  
For External use only  
**Distributed by:** **Lifestar Pharma LLC**  
1200 MacArthur Blvd  
Mahwah New Jersey 07430 USA  
**Emergency:** (888) 995-4337  
**Manufactured by:** **Encube Ethicals Private Limited**  
Plot No. C1 Madkaim Industrial Estate, Madkaim,  
Post Mardol, Ponda - Goa - 403 404 India.  
**Emergency:** +91 832239 223

**SECTION 2 – HAZARD(S) IDENTIFICATION**

Emergency overview: This mixture is a product regulated by the FDA. Within the meaning of the OSHA Hazard Communications Standard [29 CFR 1910.1200]: this product is not considered a hazard material when used in a manner which is consistent with the labeled directions.

**Eyes** Will cause irritation to the eyes  
**Skin** None  
**Inhalation** May cause irritation of nose and throat  
**Ingestion** May be harmful if swallowed

**SECTION 3 – COMPOSITION AND INGREDIENTS**

**Active Ingredient** Nystatin, CAS # 1400-61-9, LD50: 10 g/Kg  
Triamcinolone Acetonide, CAS # 76-25-5, LD50: 1451 mg/kg  
**Other Ingredients** White Petrolatum and Mineral Oil  
The product does not contain ingredients considered hazardous as defined by OSHA, 29 CFR 1910.1200 and/or WHMIS under the HPA.

**SECTION 4 – FIRST AID MEASURES**

**After Eye Contact** Immediately flush with plenty amounts of water for at least 15 minutes. Immediately remove any occlusion of the ointment with plenty of water. If irritation continues, seek medical attention.  
**After Skin Contact** Wash exposed areas with plenty amounts of water and remove all the occluded ointment from the skin. Extra care needs to be taken to clean folds, crevices, creases and groin. If adverse skin reactions occur, discontinue use. Seek medical attention.  
**After Inhalation** Remove from source of exposure. If signs of toxicity occur, seek medical attention or call Poison Control Center immediately.  
**After Ingestion** Flush out mouth with water, consult a physician immediately.

**SECTION 5 – FIRE FIGHTING MEASURES**

**Fire Fighting Instructions** Wear approved breathing apparatus and full protective turn out gear.  
**Explosion Hazards** When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and nitrogen oxides).

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**Extinguishing Media** Use extinguishing media appropriate to surrounding fire conditions, such as water spray, fog or foam. Do not use water jet.

**SECTION 6 – ACCIDENTAL RELEASE MEASURES**

**Personal Safeguards** Avoid excessive contact and contact with eyes. Wear safety goggles or shield.

**Environmental Precautions** Treat dispose in accordance with all regulations.  
This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

**Spill Clean-up Procedures** *Industrial / large spill:* Contain the source of the spill or leak if it is safe to do so. Use a shovel or non-combustible absorbent material to put the material into a convenient waste disposal container. Clean spill area thoroughly. Minimum Personal Protective Equipment should be triple gloves (rubber gloves over nitrile over latex gloves) rubber boots, face shield, and self-contained breathing apparatus. Decontaminate the area of the spill thoroughly using detergent and water.

*Household / small spill:* Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly. Wear gloves during clean-up. Decontaminate the area of the spill thoroughly using detergent and water.

**SECTION 7 – HANDLING AND STORAGE**

**Handling procedures** Avoid contact with eyes. Follow all SDS and label precautions.

**Storage** Store at 20°- 25°C (68°- 77°F)[see USP Controlled Room Temperature] Avoid freezing.

**Other Precautions** Avoid direct sunlight, and temperature above 40 °C. Protect from freezing, read label and package insert carefully.

**SECTION 8 – EXPOSURE CONTROLS, PERSONAL PROTECTION****Personal Protection Equipment:**

**Ventilation** Good general ventilation is sufficient to control airborne levels.

**Eye Protection** Wear safety glasses or goggles if eye contact is possible.

**Skin Protection** Wear protective clothing with long sleeves to avoid skin contact.

**Hand Protection** Wash hands and arms thoroughly with water after handling this product.

**Hand Protection** Wear protective gloves to avoid repeated skin contact.

**Respiratory Protection** Wear an appropriate respirator or mask.

**SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

**Description** Light yellow to buff colored ointment

**Specific Gravity** ~ 0.85 (Water is 1)

**pH** Not applicable

**Boiling Point:** Mixture

**Freezing Point** Below 50 °C

**Flash Point** Not available

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<b>Vapor Density</b>	Not available
<b>Vapor Pressure</b>	Not available
<b>Evaporation Rate</b>	Not available
<b>Solubility in Water</b>	Dispersible in hot water

**SECTION 10 – STABILITY AND REACTIVITY**

<b>Stable</b>	Yes under specified storage conditions.
<b>Hazardous Polymerization</b>	Will not occur
<b>Conditions to Avoid</b>	Excess heat, freezing, strong bases, acids and oxidizing agents
<b>Incompatibility</b>	Strong bases, acids and oxidizing agents
<b>Hazardous Decomposition</b>	If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides)

**SECTION 11 – TOXICOLOGICAL INFORMATION**

Individuals who have had allergic reactions to products containing any component of this product may experience allergic reactions to this product. This product may be mildly to moderately irritating. Hazardous Scale [0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe]

Health (blue)	1
Fire Hazard (Red)	1
Reactivity (Yellow)	0
Personal Protection	See section 8

**Acute and Chronic Toxicity**

<b>General Toxicity</b>	Data not available.
<b>Skin Sensitivity</b>	People with a history of hypersensitivity to any of its components, may be aggravated by this product.
<b>Eye Sensitivity</b>	Eye contact will cause irritation.
<b>Respiratory Sensitization</b>	Although unlikely, inhalation can irritate the respiratory system.
<b>Carcinogenicity</b>	Data not available.
<b>Mutagenicity/ Embryo / Reproductive Toxicity</b>	Data not available.
<b>Teratogenicity</b>	Data not available.

**SECTION 12 – ECOLOGICAL INFORMATION**

The environmental characteristics of this product have not been fully evaluated. Releases to the environment in pure form should be avoided.

**SECTION 13 – DISPOSAL INFORMATION**

<b>Product Disposal</b>	Dispose of in accordance with all applicable federal, state and local regulations.
<b>Packaging</b>	Disposal in compliance with official regulations. Handle packaging in the same way as the product itself. If not officially specified differently, packaging may be treated like household waste or recycled.

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**SECTION 14 – TRANSPORTATION INFORMATION**

Not regulated for transport under USDOT (transportation by land), IATA (transportation by sea) or IMDG (transportation by air) regulations.

**SECTION 15 – REGULATORY INFORMATION**

The product described in this SDS are regulated under the Federal Food, Drug and Cosmetics Act and are safe to use as per directions on container, box or accompanying literature (where applicable).

**SECTION 16 – OTHER INFORMATION**

The information contained in this Safety Data Sheet has been compiled from information believed to be accurate and from past experience. While we believe that the data presented is factual, Encube Ethicals Private Limited and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.

SDS prepared August 2017