

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
Manufactured by:	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
Other Ingredients	Triamcinolone Acetonide, CAS # 76-25-5, LD50: 1451 mg/kg 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.

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. 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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Vapor Density	Not available
Vapor Pressure	Not available
Evaporation Rate	Not available
Solubility in Water	Dispersible in hot water

SECTION 10 – STABILITY AND REACTIVITY

Stable	Yes under specified storage conditions.
Hazardous Polymerization	Will not occur
Conditions to Avoid	Excess heat, freezing, strong bases, acids and oxidizing agents
Incompatibility	Strong bases, acids and oxidizing agents
Hazardous Decomposition	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
General Toxicity

Data not available.

Skin Sensitivity

People with a history of hypersensitivity to any of its components, may be aggravated by this product.

Eye Sensitivity

Eye contact will cause irritation.

Respiratory Sensitization

Although unlikely, inhalation can irritate the respiratory system.

Carcinogenicity

Data not available.

Mutagenicity/ Embryo /

Data not available.

Reproductive Toxicity

Data not available.

Teratogenicity

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
Product Disposal

Dispose of in accordance with all applicable federal, state and local regulations.

Packaging

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