

# MATERIAL SAFETY DATA SHEET



**Product Name:** Triamcinolone Acetonide Ointment USP, 0.05%

**Effective Date:** November 08, 2019

**Version No.:** 00

## 1. IDENTIFICATION

<b>PRODUCT NAME</b>	Triamcinolone Acetonide Ointment USP, 0.05%
<b>MANUFACTURER NAME</b>	Encube Ethicals Pvt. Ltd. Plot No.C-1, Madkaim Industrial Estate Madkaim, Post-Mardol, Ponda, Goa – 403 404, India.
<b>CHEMICAL NAME (FOR ACTIVE INGREDIENT)</b>	Triamcinolone Acetonide
<b>CHEMICAL FAMILY (FOR ACTIVE INGREDIENT)</b>	Corticosteroid
<b>CHEMICAL FORMULA (FOR ACTIVE INGREDIENT)</b>	$C_{24}H_{31}FO_6$
<b>PRODUCT USE (INDICATION)</b>	Use for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatosis.

## 2. HAZARD(S) IDENTIFICATION

<b>PHYSICAL HAZARDS</b>	Not Classified
<b>HEALTH HAZARDS</b>	Reproductive Toxicity: Category 1B Skin corrosion/irritation: Category 2 Eye damage/irritation : Category 2 Carcinogenity: Category 2 STOT (Repeated Exposure): Category 2 (endocrine system)
<b>SIGNAL WORD</b>	Danger
<b>HAZARD STATEMENT</b>	May be harmful if swallowed. May cause allergic skin reactions. Suspected of causing genetic defects. Suspected of damaging fertility or the unborn child. Suspected of causing cancer.
<b>HAZARD SYMBOL</b>	The GHS hazard symbol for Health Hazard (H373), which consists of a black silhouette of a person with a starburst on their chest, enclosed in a red diamond-shaped border.

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## PRECAUTIONARY STATEMENTS

Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash hands and face thoroughly after handling. Do not eat, drink, or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace.

If exposure occurs: Get medical advice/attention.

## HAZARDS NOT OTHERWISE CLASSIFIED

None classified

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

<b>COMMON NAME / CHEMICAL NAME</b>	Triamcinolone Acetonide
<b>CAS NUMBER</b>	76-25-5
<b>CONCENTRATION</b>	0.05%
<b>OTHER INGREDIENTS</b>	Lanolin Alcohols, Light Mineral Oil, Mineral Oil, Ceresin Wax 155/165, White Petrolatum, Purified Water

## 4. FIRST-AID MEASURES

<b>EYE CONTACT</b>	Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately.
<b>SKIN CONTACT</b>	Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.
<b>INGESTION</b>	Toxicity is low after acute ingestion; gastrointestinal decontamination is generally not necessary. Seek medical advice and monitoring/treatment for allergic reactions.
<b>INHALATION</b>	If breathing is difficult, remove to fresh air. Watch for signs of respiratory insufficiency and assist ventilations if needed. Monitor for pulmonary edema and treat if necessary.

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## MOST IMPORTANT SYMPTOMS/EFFECTS

### ACUTE OR DELAYED

None Classified

### NOTES TO PHYSICIANS OR FIRST AID PROVIDERS

This product should only be given to patients by medical professionals educated in the therapy intended for this product. Treat any symptoms and eliminate exposure.

## 5. FIRE-FIGHTING MEASURES

### SUITABLE EXTINGUISHING MEDIA

Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

### UNSUITABLE EXTINGUISHING MEDIA

None known

### UNUSUAL FIRE AND EXPLOSION HAZARDS

No unusual fire or explosion hazards noted.

### SPECIAL FIRE FIGHTING PROCEDURES

Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.

## 6. ACCIDENTAL RELEASE MEASURES

### PERSONAL PRECAUTIONS

Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimized exposure to personnel. Personnel involved in the clean-up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Minimize the generation of aerosols. Remove all sources of heat and ignition.

### METHODS/MATERIALS USED FOR CONTAINMENT & CLEANING

Use a scraper or other device to remove and collect ointment. Minimize the generation of aerosols. Dampen remaining residue with water, then clean Spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

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## 7. HANDLING AND STORAGE

### HANDLING PRECAUTIONS

Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. Wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse. Destroy contaminated belts, shoes, and any other items that cannot be decontaminated.

### STORAGE PRECAUTIONS

When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. In case of insufficient ventilation, wear suitable respiratory protection. Keep this drug out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE GUIDELINES:

### ENGINEERING CONTROLS

In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

### PERSONAL PROTECTIVE EQUIPMENT (PPE)

#### EYE PROTECTION

Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

#### SKIN PROTECTION

Avoid unintended skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face

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## RESPIRATORY PROTECTION

shield, boots, or full body protection. A safety shower should be located in the work area.

If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>APPEARANCE</b>	A white to off white, smooth, homogeneous ointment, free from foreign particles and without any phase separation.
<b>FLASH POINT</b>	Not Established
<b>AUTOIGNITION TEMPERATURE</b>	Not Established
<b>BOILING POINT</b>	Not Established
<b>% VOLATILE</b>	Not Established
<b>VISCOSITY</b>	400500 – 750000 cPs
<b>pH</b>	5- 7.5
<b>MELTING POINT</b>	Not Established
<b>VAPOR PRESSURE (mmHg)</b>	Not Established
<b>EVAPORATION RATE (H<sub>2</sub>O=1)</b>	Not established
<b>VAPOR DENSITY (air=1)</b>	Not Established
<b>LOWER FLAMMABILITY LIMIT</b>	Not Established
<b>OCTANOL/H<sub>2</sub>O PARTITION COEFFICIENT</b>	Not Established
<b>POUR POINT</b>	Not Established
<b>% SOLUBILITY IN WATER</b>	Not Established
<b>SPECIFIC GRAVITY (H<sub>2</sub>O=1)</b>	0.850 - 1.100
<b>UPPER FLAMMABILITY LIMIT</b>	Not Established

## 10. STABILITY AND REACTIVITY

<b>REACTIVITY</b>	No reactivity hazards known
<b>CHEMICAL STABILITY</b>	Material is stable under normal conditions.

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## **POSSIBLE OF HAZARDOUS REACTIONS**

No dangerous reaction known under conditions of normal use.

## **CONDITIONS TO AVOID**

Avoid heat and flame

## **UNCOMPATIBLE MATERIALS**

Acids, caustics, and other chemicals that could affect its performance should be avoided.

## **HAZARDOUS DECOMPOSITION PRODUCTS**

Under fire conditions, thermal decomposition may generate irritating and/or toxic fumes or gases (i.e. carbon oxide and hydrogen fluoride).

## **11. TOXICOLOGICAL INFORMATION**

### **INFORMATION ON LIKELY ROUTES OF EXPOSURE**

#### **INGESTION**

In an occupational setting, ingestion of this product is unlikely. Ingestion may cause irritation.

#### **INHALATION**

Although unlikely due to product form, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon exposure to fresh air.

#### **SKIN CONTACT**

Avoid contact with skin. Causes irritation and can be absorbed through the skin in sufficient quantities to cause systemic effects. Other effects may include impaired wound healing, skin atrophy, acne, increased sweating, hypopigmentation, hyperpigmentation, and dermatitis.

#### **EYE CONTACT**

Avoid contact with eyes. May cause irritation of the eyes.

## **SIGNS AND SYMPTOMS OF OVEREXPOSURE**

May include decreased or blurred vision, frequent urination, increased thirst, loss of appetite, indigestion, nervousness or restlessness, and trouble sleeping. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

## **CHRONIC EFFECTS**

May include possible hypersensitization, acne or other skin problems, hip or shoulder pain, fullness in the face, swelling of feet or lower legs, menstrual irregularities, nausea, vomiting, irregular heartbeat, muscle cramps, weakness, osteoporosis, increased susceptibility to infection, psychosis, and eye problems.

## **ACUTE TOXICITY VALUES**

LD 50 for Triamcinolone Acetonide (oral, mouse) = 5 g/kg

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## 12. ECOLOGICAL INFORMATION

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This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility.

## 13. DISPOSAL CONSIDERATIONS

### WASTE DISPOSAL METHOD

It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials.

### WASTE DISPOSAL CONTAINERS

Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations.

## 14. TRANSPORT INFORMATION

### U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS

This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

## 15. REGULATORY INFORMATION

### U.S. FEDERAL REGULATIONS

#### TOXIC SUBSTANCE CONTROL ACT (TSCA)

All components of this product are included on the TSCA inventory.

#### CLEAN WATER ACT (CWA)

There are no ingredients in this mixture listed in the Clean Water Act.

#### CLEAN AIR ACT (CAA)

There are no ingredients in this mixture listed under the Clean Air Act.

#### SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT)

There are no ingredients in this mixture listed under SARA.

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## STATE REGULATIONS

This product does not contain chemicals known to the State of California to cause cancer, birth defects, or reproductive harm.

## INTERNATIONAL REGULATIONS

### CANADIAN ENVIRONMENTAL PROTECTION ACT

Triamcinolone Acetonide is not listed on the Canadian Domestic Substances List (DSL).

### CANADIAN WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEMS (WHMIS)

Triamcinolone Acetonide is not listed in WHMIS.

### EUROPEAN INVENTORY OF EXISTING CHEMICALS (EINECS):

Triamcinolone Acetonide is included in EINECS

### EU CLASSIFICATION

European labeling in accordance with EC directives

### EU RISK (R) AND SAFETY (S) PHRASES (OCCUPATIONAL EXPOSURE)

R38 Irritation to skin

R43 May cause sensitization by skin contact

R61 May cause harm to unborn child

S2 Keep out of the reach of children

S36/27 Wear suitable protective clothing and gloves.

## 16. OTHER INFORMATION

### CONTACT INFORMATION

Encube Ethicals, Inc.  
200 Meredith Avenue, Suite 101A, Durham,  
NC27713, USA  
<https://www.encubeethicals.com>

**Disclaimer:** This material safety data sheet has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

**End of Safety Data Sheet**