

MATERIAL SAFETY DATA SHEET**Product Name:** Clobetasol Propionate Ointment USP, 0.05%**Revision Date:** January 22, 2020**Version No.:** 00**1. IDENTIFICATION**

Product Identifier

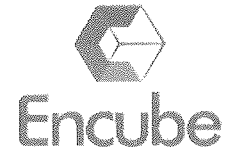
Product Name: Clobetasol Propionate Ointment USP, 0.05%

Chemical Family: --

Relevant Identified uses of the Substance or Mixture
Uses advised against intended use: Anti inflammatory, Anti-pruritic and VasoconstrictiveCompany Name: For External use only
Encube Ethicals Private Limited
Plot No. C1 Madkaim Industrial Estate, Madkaim,
Post Mardol, Ponda - Goa - 403 404 India.
Emergency: +91 832239 223**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 labelled directions

Eyes Will cause irritation to the eyes
Skin May cause skin irritation or redness
Inhalation Unlikely due to viscosity of the product.
Ingestion May be harmful
Other Hazards No data available**3. COMPOSITION / INFORMATION ON INGREDIENT**Common name / Chemical name Clobetasol Propionate
CAS No. 25122-46-7
Concentration 0.05%
Other Ingredients Propylene Glycol, Sorbitan Sesquioleate and White Petrolatum.**4. FIRST-AID MEASURES****Description of first aid measures**Eye Contact: Rinse cautiously with water for at least 15 minutes.
Remove contact lenses, if present and easy to do.
Continue rinsing. If eye irritation persists: Get medical

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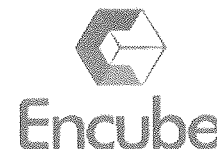
| | |
|--|---|
| Skin Contact: | advice/attention. Remove contaminated clothing immediately. For accidental and non-therapeutic exposures, immediately flush skin with large amounts of water. If irritation (redness, rash, blistering) develops, get medical attention. If skin irritation occurs get medical advice/attention. |
| Inhalation: | Remove from source of exposure. Move individual(s) to fresh air. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention or call Poison Control Center immediately. |
| Ingestion: | This product is not intended for ingestion. In case of accidental ingestion, flush out mouth with water (only if the person is conscious), consult POISON CENTER or a physician immediately. |
| Medical Conditions Aggravated By Exposure: | None Known |
| Indication of the Immediate Medical Attention Special treatment Needed Notes to Physician: | Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. |
| 5. FIRE-FIGHTING MEASURES | |
| Fire Fighting Instructions: | Wear approved breathing apparatus and full protective turn out gear. Assume that this product is capable of sustaining combustion. |
| Explosion Hazards: | No data available. |
| Extinguishing Media: | Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide or alcohol-resistant foam. |

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Advice for Fire- Fighters

For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Safeguards

Avoid excessive contact and contact with eyes. Wear appropriate protective clothing and equipment such as safety goggles or shield or as described in Section 8.

Environmental Precautions

Prevent product from entering sewer or confined spaces, waterways, soil, surface drainage systems or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

Methods and Material for Containment and Cleaning up measures for cleaning/collecting:

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.

7. HANDLING AND STORAGE

MATERIAL SAFETY DATA SHEET**Product Name:** Clobetasol Propionate Ointment USP, 0.05%**Revision Date:** January 22, 2020**Version No.:** 00**Precautions for Safe Handling:****Handling procedures**

All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. Appropriate personal protective equipment must be worn (see Section 8, exposure controls and personal protection). Use only with adequate ventilation. Wash thoroughly after handling. Keep containers closed when not in use. Follow all SDS and label precautions. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

Storage

Store at 20 – 25 °C (68 – 77 °F) excursions permitted between 15 – 30°C (59 – 86 °F); [see USP Controlled Room Temperature] to maintain product integrity. Protect containers from physical damage. Keep containers tightly closed when not in use. Avoid temperatures above 40 °C.

Other Precautions

Avoid direct sunlight. Read label and package insert carefully.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Engineering Controls****Ventilation**

Good general ventilation is sufficient to control airborne levels.

Personal Protection Equipment:**Eye Protection**

Chemical safety goggles recommended if contact with the drug product is possible.

Skin Protection

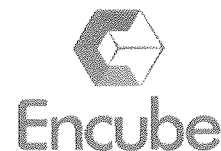
Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.

Hand Protection

Not normally needed during normal use. Wear protective gloves when handling bulk product. Chemically compatible gloves are recommended. Use handling practices that minimize direct hand contact.

Respiratory Protection

Wear an appropriate respirator or mask.

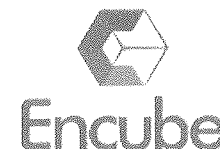
MATERIAL SAFETY DATA SHEET**Product Name:** Clobetasol Propionate Ointment USP, 0.05%**Revision Date:** January 22, 2020**Version No.:** 00**9. PHYSICAL AND CHEMICAL PROPERTIES**

| | |
|---------------------|--|
| Description | White ointment |
| Specific Gravity | ~ 0.85 (Water is 1) |
| pH | Not applicable |
| Boiling Point: | No data available |
| Freezing Point | No data available |
| Flash Point | No data available |
| Vapor Density | No data available |
| Vapor Pressure | No data available |
| Evaporation Rate | No data available |
| Solubility in Water | Not soluble. Dispersible in hot water. |

10. STABILITY AND REACTIVITY

| | |
|-------------------------------------|--|
| Stable | Not reactive under normal conditions of use. |
| Hazardous Polymerization | Stable under normal temperature and pressure. |
| Conditions to Avoid Incompatibility | Excess heat, strong bases, acids and oxidizing agents. Acids, strong oxidizers, and other chemicals that could affect its performance should be avoided. |
| Hazardous decomposition products | If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon dioxide, carbon monoxide, hydrogen chloride and hydrogen fluoride). |

11. TOXICOLOGICAL INFORMATION

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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

Chronic: Repeated skin contact may cause dermatitis (dry, red skin)

Eye Sensitivity

Eye contact will cause irritation.

Respiratory Sensitization

No data available.

Carcinogenicity

Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate. Studies in the rat following subcutaneous administration at dosage levels up to 50 mcg/kg per day revealed that the females exhibited an increase in the number of resorbed embryos and a decrease in the number of living foetuses at the highest dose

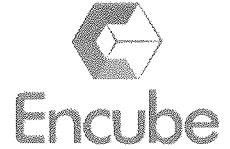
**Mutagenicity/ Embryo /
Reproductive Toxicity**

Clobetasol propionate was non-mutagenic in three different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay, and the E. coli B WP2 fluctuation test.

Teratogenicity

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals. Clobetasol propionate has not been tested for teratogenicity when applied topically; however, it is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rabbit and mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent. There are rated by the FDA for therapeutic risk as Pregnancy Risk Category C (Animal reproduction studies have shown an adverse effect on the foetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks).

12. ECOLOGICAL INFORMATION

MATERIAL SAFETY DATA SHEET**Product Name:** Clobetasol Propionate Ointment USP, 0.05%**Revision Date:** January 22, 2020**Version No.:** 00**Environmental Overview**

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

13. DISPOSAL CONSIDERATIONS**Waste Treatment Methods**

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

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.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

The product described in this SDS are regulated under the Federal Food, Drug and Cosmetics Act and are safe 1 directions on container, box or accompanying literature (where applicable).

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**Compiled by:**

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Approved by:

A handwritten signature in black ink, followed by the date "22-01-2020" written below it.