

MATERIAL SAFETY DATA SHEET



Product Name: Clobetasol Propionate Cream USP, 0.05%

Revision Date: September 22, 2020

Version No.: 00

1. IDENTIFICATION

Product Name	Clobetasol Propionate Cream USP, 0.05%
Manufacturer Name	Encube Ethicals Pvt. Ltd.
Address	Plot No.C-1, Madkaim Industrial Estate Madkaim, Post- Mardol, Ponda, Goa – 403 404, India.
Chemical name	Pregna-1,4-diene-3,20-dione, 21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-, (11 β ,16 β) (USP) 21-Chloro-9-fluoro-11 β ,17-dihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17-propionate (USP) 21-chloro-9-fluoro-11 β , hydroxy-16 β -methyl-3,20-dioxopregna-1,4-dien-17-yl propanoate (Ph Eur)
Recommended use	Human drug – Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses
Restrictions on use	Use only as directed by the physician.

2. HAZARD(S) IDENTIFICATION

Physical Hazards	Not classifiable
Health Hazards	Not classifiable
Symbol(s)	None
Signal Word	None
Hazard Statement(s)	None
Precautionary Statement(s)	None
Hazards Not Otherwise Classified	Not classifiable
Supplementary Information	While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. COMPOSITION / INFORMATION ON INGREDIENT

Common name / Chemical name	Clobetasol Propionate
Synonyms	Clobetasol 17-propionate

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Chemical Formula	C ₂₅ H ₃₂ ClFO ₅
Molecular Weight	467.0
CAS No.	25122-46-7
Concentration	0.05%
Other Ingredients	Propylene Glycol, Glyceryl Stearate/ PEG -100 Stearate, Cetostearyl Alcohol, Mono and Di Glyceride, White Wax, Sodium Citrate Anhydrous, Citric Acid Anhydrous, Chlorocresol, Purified water

4. FIRST-AID MEASURES

Inhalation	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin contact	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Eye contact	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Ingestion	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Protection of First-Aiders	Use personal protective equipment (see section 8)
Signs and Symptoms	Cream is intended for topical use only under guidance of a physician. Cream is not considered hazardous under normal conditions.

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Medical Conditions Aggravated by Exposure See package insert for detailed information.

Other Health Warnings For external use only. Avoid contact with eyes or lips.

Notes to Physician Not available.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing Media Use water, carbon dioxide, dry chemical or foam as necessary.

Unsuitable extinguishing Wear full protective clothing and use self-contained breathing apparatus (SCBA).

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products None

Other Specific Hazards Not determined

Special Protective Equipment Precautions for Fire fighters Not available

6. ACCIDENTAL RELEASE MEASURES

Personal Precaution Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment For personal protection see section 8.

Methods for Cleaning Up Pick up in the most efficient manner. Contain or absorb small spills. Larger spills must be contained to prevent spreading and absorption. Residue must be placed in a non-reactive container. Area should be washed well with water. If appropriate, use protective equipment during spill clean-up

Environmental Precautions No data available

Reference to Other Sections Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

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.

Conditions for Safe Storage, Including Any Incompatibilities Store cream between 15° and 30°C (59°-86°F). Clobetasol propionate cream should not refrigerated.

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Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit - Lower	No data available
Flammability Limit - Upper	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative Density	0.850 - 1.050
Solubility in Water	Insoluble in water
Partition coefficient: n-octanol/water	No data available
Decomposition temperature	No data available
Auto-ignition Point	No data available
Viscosity	250000 - 700000 cPs

10. STABILITY AND REACTIVITY

Reactivity	No data available
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	No data available
Incompatible materials	No data available
Hazardous decomposition products	Does not undergo explosive decomposition.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

General Information	The active component in Clobetasol Propionate Cream USP, 0.05% is Clobetasol propionate, a super high potency synthetic corticosteroid. These Clobetasol products are used medically for the short-term treatment of redness and itching of the skin in allergic and other skin diseases, which are corticosteroid-responsive. See package insert for detailed information.
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Inhalation	No data available
Ingestion	Possible gastrointestinal irritant
Skin Contact	Possible skin irritation
Eye Contact	Possible eye irritation
Symptoms Related to the Physical, Chemical and Toxicological Characteristics	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	No data available
Acute Toxicity – Oral	No data available
Acute Toxicity – Dermal	No data available
Acute Toxicity – Inhalation	No data available
Corrosivity	No data available
Dermal Irritation	No data available
Eye Irritation	No data available
Sensitization	No data available
Toxicokinetics/Metabolism	No data available
Target Organ Effects	No data available
Reproductive Effects	No data available
Carcinogenicity	No data available
National Toxicology Program (NTP)	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC)	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA)	Not considered to be a carcinogen.
Mutagenicity	No data available
Aspiration Hazard	No data available

12. ECOLOGICAL INFORMATION

Ecotoxicity

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Aquatic	No data available
Terrestrial	No data available
Persistence and degradability	No data available
Bio-accumulative potential	No data available
Mobility in soil	No data available
Mobility in Environment	No data available
Other adverse effects	No data available

13. DISPOSAL CONSIDERATIONS

Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

UN Number	Not applicable
UN Proper Shipping Name	Not applicable
Transport Hazard Class(es)	Not applicable
Packing Group	Not applicable
Department of Transportation	Not regulated as a hazardous material.
International Air Transport Association (IATA)	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG)	Not regulated as a dangerous good

15. REGULATORY INFORMATION

US Federal Regulations

Toxic Substance Control Act (TSCA)	Not listed.
CERCLA Hazardous Substance and Reportable Quantity	Not listed.
SARA 313	Not listed.
SARA 302	Not listed.

State Regulations

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California Proposition 65

Not listed.

16. OTHER INFORMATION

NFPA Rating

Health 1

Flammability 1

Reactivity 0

Contact Information

Encube Ethicals, Inc.
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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