

# MATERIAL SAFETY DATA SHEET



**Product Name:** Fluocinolone Acetonide Topical Solution USP, 0.01%


**Revision Date:** October 30, 2019

**Version No.:** 02

## 1. IDENTIFICATION

Product Name	Fluocinolone Acetonide Topical Solution USP, 0.01%
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,6,9-difluoro-11,21-dihydroxy-16, 17-[(1-methylethylidene)bis(oxy)]-,(6alpha,11beta,16alpha)-
Recommended use	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

Classification	
Physical	Not classified
Health	Acute toxicity, oral: Category 4 Reproductive toxicity: Category 2 Specific target organ toxicity, repeated exposure: Category 1 (endocrine system)
OSHA hazard(s)	Not classified
Label Elements	
Signal word	Danger
Hazard statement	Harmful if swallowed. Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

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Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention.
Storage	Store locked up
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	Not classified

## 3. COMPOSITION / INFORMATION ON INGREDIENT

Common name / Chemical name	Fluocinolone Acetonide
CAS No.	67-73-2
Concentration	0.01%
Other Ingredients	Anhydrous citric acid and propylene glycol.

## 4. FIRST-AID MEASURES

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse.
General information	<p>Fluid and electrolyte disturbances. Mood or mental changes.</p> <p>Treatment of corticosteroid overdose should be symptomatic and supportive and may include the following: Toxicity is low after acute ingestion. Gastrointestinal decontamination is generally not necessary. (Poisindex)</p> <p>Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.</p>

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## 5. FIRE-FIGHTING MEASURES

Extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO <sub>2</sub> .
Unsuitable extinguishing media	None known
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for fire-fighters	Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

## 7. HANDLING AND STORAGE

Precautions for safe handling	As a general rule, when handling USP Reference Standards, 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. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store at room temperature 15-25°C (59-77°F); avoid freezing and excessive heat above 40°C (104°F).

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines	
Fluocinolone Acetonide	0.04 Micrograms/m <sup>3</sup> TWA
Biological limit values	No biological exposure limits noted for the ingredient(s)

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## Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

## Individual protection measures

### Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

### Eye/ face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

### Other

For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.)

Clear transparent solution

Odor

Odorless

Odor threshold

Not available.

Melting point/freezing point

509 - 525.2 °F (265 - 274 °C) (with decomposition)

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Flash point	Not available
Flammability (solid, gas)	Not applicable
Flammable limits: LEL	Not available
Vapor pressure	< 0.0000001 kPa at 25 °C
Relative density	Not available
Partition coefficient: (n-octanol/water)	2.48
Solubility of water	Insoluble
Decomposition temperature	Not available
pH	3.5 - 5.0
Boiling Point	Not available
Evaporation rate	Not available
VOC	Not available
Viscosity	25 - 65 cPs
Chemical family	Corticosteroid
Molecular formula	C <sub>24</sub> H <sub>30</sub> F <sub>2</sub> O <sub>6</sub>
Molecular Weight	452.5 g/mol
Solubility (other)	Soluble in acetone, in methanol, and in ethanol; slightly soluble in ether and in chloroform; practically insoluble in hexane; sparingly soluble in dichloromethane.
Specific Gravity	0.950 - 1.150

## 10. STABILITY AND REACTIVITY

Reactivity	No reactivity hazards known
Chemical stability	Stable
Possibility of hazardous reactions	None known
Conditions to avoid	None known
Incompatible materials	Avoid oxidizing agents
Hazardous decomposition products	F-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

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## 11. TOXICOLOGICAL INFORMATION

Acute effects of exposure

Inhalation

Due to lack of data the classification is not possible

Ingestion

Harmful if swallowed

Skin contact

No adverse effects are expected. Minor irritation is possible.

Eye contact

Based on available data, the classification criteria are not met.

Symptoms related to the physical, chemical, and toxicological characteristics

Corticosteroids: Nausea. Vomiting. Headache. Acne. Increased hair growth. Lightheadedness. Weakness. Increased sweating. Eye pain. Vision changes. Mental or behavioral changes. Swelling. Numbness. Infection. Delayed wound healing. Thinning skin. Bruising. Purple lines on skin. Bone fractures. Back pain. Joint pain or stiffness. Increased appetite. Redistribution of body fat. Menstrual irregularities. Impotence. Tremors.

Delayed and immediate effects of exposure

Corticosteroids: Fluid and electrolyte imbalance. Cushing's syndrome. Adrenal suppression

Cross sensitivity

Persons sensitive to other corticosteroids may also be sensitive to this material

Medical conditions aggravated by exposure

Corticosteroids: Heart disease. High blood pressure. Diabetes. Epilepsy. Glaucoma Hypothyroidism. Osteoporosis. Peptic ulcer. Systemic fungal infection. Mental disorders. Impaired liver or kidney function.

Acute toxicity

Harmful if swallowed.

Acute

Oral , LD<sub>50</sub>

Rat: 400 – 1200 mg/kg

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Respiratory sensitization

Due to lack of data the classification is not possible

Skin sensitization

Due to lack of data the classification is not possible

Germ cell mutagenicity

Due to lack of data the classification is not possible

Data from germ cell mutagenicity tests were not found.

Mutagenicity

Ames test Result: Negative.

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	In vivo mouse bone marrow micronucleus test Result: Negative.
	Mouse lymphoma TK assay Result: Negative.
	Syrian hamster embryo cell transformation assay, viral enhanced Result: Positive
Carcinogenicity	Due to lack of data the classification is not possible.  This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive toxicity	Suspected of damaging fertility or the unborn child. Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in the incidence of cleft palate was seen in some human studies. Infants born to mothers who received substantial doses of corticosteroids during pregnancy should be observed for signs of hypoadrenalism.  <b>Reproductivity:</b> 0.05 mg/kg/day Reproductivity and development study in rabbits and rats, administered subcutaneously during gestation. Result: Maternal toxicity, fetal death and teratogenicity. 0.125 mg/kg Reproductivity and development study in rabbits, administered subcutaneously during gestation.  Result: Maternal toxicity and fetal death.
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	Causes damage to organs (endocrine system) through prolonged or repeated exposure.
Aspiration hazard	Based on available data, the classification criteria are not met.

## 12. ECOLOGICAL INFORMATION

Eco-toxicity values	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bio-accumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

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## 13. DISPOSAL CONSIDERATIONS

Disposal considerations	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Not available.
Hazardous waste code	Not available.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. TRANSPORT INFORMATION

DOT	Not regulated as a hazardous material by DOT.
IATA	Not regulated as a dangerous good.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.

## 15. REGULATORY INFORMATION

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on Toxic Substance Control Act (TSCA).
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - Yes
	Delayed Hazard - No
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard -
	No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No



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Other federal regulations	Not regulated.
Safe Drinking Water Act (SDWA) Food and Drug Administration (FDA)	Not regulated.
US state regulations	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## 16. OTHER INFORMATION

Contact Information	Encube Ethicals, Inc. 200 Meredith Avenue, Suite 101A, Durham, NC27713, USA <a href="https://www.encubeethicals.com/">https://www.encubeethicals.com/</a>
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**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**