MATERIAL SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: **Hydrocortisone Valerate Cream, USP 0.2%**

Manufacturer Name: Encube Ethicals Pvt. Ltd.
Plot No.C-1, Madkaim Industrial Estate Madkaim,
Post- Mardol, Ponda,
Goa – 403 404, India.

Recommended Use: Hydrocortisone valerate cream USP, 0.2% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in adult patients.

Restrictions on Use: Hydrocortisone valerate cream USP, 0.2% is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

SUBSTANCE CLASS: Synthetic steroids

FORMULA: $C_{26}H_{38}O_6$

M.W.: 446.58

SECTION 2: HAZARD(S) IDENTIFICATION

Adverse Effects: The incidence of adverse effects from the therapeutic use of corticosteroids increases with dose and duration of exposure; effects are rare with administration of less than three weeks. The mineralocorticoid actions of this material may cause disruption of fluid and electrolyte imbalance, causing swelling, increased blood pressure, confusion, lightheadedness, nausea, vomiting, numbness, and tremors. Glucocorticoid effects may include bone fractures, back pain, joint pain or stiffness, weakness, high blood pressure, increased appetite, infection, delayed wound healing, thinning skin, bruising, purple lines on skin, increased hair growth, acne, redistribution of body fat, menstrual irregularities, impotence, headache, increased sweating, eye pain, change in vision, and mental or behavioral changes. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Overexposure may lead to adverse effects listed above.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization, adrenal suppression, immune system depression, and hypercorticism or Cushing's syndrome. Withdrawal effects after chronic exposure is discontinued include fever, muscle pain, joint pain, and malaise.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, heart disease, high blood pressure, diabetes, epilepsy, glaucoma, hypothyroidism, osteoporosis, peptic ulcer, mental disorders, or impaired liver or kidney function.

Cross Sensitivity: Persons sensitive to one corticosteroid may be sensitive to this material also.

Target Organs: Endocrine system, immune system.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient:	Hydrocortisone valerate CAS#: 57524-89-7
Inactive Ingredients:	Carbomer 940, dibasic sodium phosphate, methylparaben, polyoxyl 2 stearyl ether, propylene glycol, purified water, sodium lauryl sulfate, steareth-100, stearyl alcohol and white petrolatum.

SECTION 4: FIRST-AID MEASURES

Eye:	Rinse immediately with plenty of water for at least 15 minutes. If redness or irritation persists, contact a doctor.
Skin:	Wash contaminated area with soap and water. Seek medical attention if symptoms persist
Ingestion:	If inadvertently swallowed, seek medical advice immediately and show this container or label.
Inhalation:	Remove to fresh air, support breathing (give oxygen or artificial respiration).

SECTION 5: FIRE-FIGHTING MEASURES

Flash Point:	Non flammable
Extinguishing Media:	Water spray, carbon dioxide, or dry chemical
Special Fire Fighting Procedures:	Wear protective clothing, and approved self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED: Wear protective equipment, ventilate area, keep out of drains and waterways, small spill should be absorbed with the appropriate absorbent material, large spills can be vacuumed or scooped and placed in a suitable container for later disposal.

SECTION 7: HANDLING AND STORAGE

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

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

PERSONAL PROTECTION:

Respiratory:	NIOSH approved respirator.
Eye:	Safety goggles.
Clothing:	Appropriate laboratory apparel.
Gloves:	Rubber
WORK PRACTICES:	Observe good personal practices and recommend procedures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT:	N/A
PHYSICAL STATE (liquid/solid/gas):	Solid
SPECIFIC GRAVITY (H2O=1):	N/A
EVAPORATION RATE (Butyl Acetate=1):	N/A
SOLUBILITY:	Water soluble
APPEARANCE:	Smooth white cream
ODOR DESCRIPTION:	Odorless

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability:	Stable
Conditions to Avoid:	Excessive heat
Incompatibility with other Materials:	N/A
Hazardous Decomposition Products:	Carbon monoxide, carbon dioxide, sulfur oxides, and nitrogen oxides
Hazardous Reactions:	No

SECTION 11: TOXICOLOGICAL INFORMATION

LD50 LC50 Mixture:	TDLO (ORAL HUMAN) = 1400 MG/KG/20D.
Reports of Carcinogenicity:	This compound contains no ingredients at concentrations of 0.1% or greater that are carcinogens or suspect carcinogens.

SECTION 12: ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose of waste in accordance with all Federal, State and local laws.

SECTION 14: TRANSPORT INFORMATION

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, US or European ground transport purposes

SECTION 15: REGULATORY INFORMATION

NTP:	No
IARC:	No
OSHA:	No

SECTION 16: OTHER INFORMATION

Contact: Encube Ethicals Inc.
200 Meredith Avenue, Suite 101A, Durham, NC 27713, USA

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D I S C L A I M E R

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).