

## SAFETY DATA SHEET

**Manufactured and Distributed by:**

Encube Ethicals Pvt. Ltd.

Plot No. C-1, Madkaim Ind. Estate, Madkaim,

Post: Mardol, Ponda, Goa - 403 404, India.

### 1. IDENTIFICATION

**Product identifier:** Desonide Ointment**Manufacturer Name:** Encube Ethicals Pvt Ltd  
**Address:** Plot No.C-1, Madkaim Industrial Estate  
Madkaim, Post- Mardol, Ponda.  
Goa – 403 404, India.**Telephone number:** +91-0832-6618600**Chemical name** Pregna-1,4-diene-3,20-dione, 11,21-dihydroxy-16,17-[(1-methylethylidene)]  
bis(oxy)]-,(11 $\beta$ , 16 $\alpha$ )-**Synonym(s)** Desfluorotriamcinolone acetonide**Recommended use:** Human drug – topical corticosteroid for dermatologic use.**Restrictions on use:** Use only as Directed

### 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Not Hazardous

**Label Elements:**

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

### 3. COMPOSITION / INFORMATION ON INGREDIENT

Common name / Chemical name	CAS No.	Concentration
Desonide	638-94-8	0.05%



#### 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

**Skin contact:** This product is intended for use on the skin. For unintended contact, wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids for several minutes. Get medical attention if irritation persists.

**Ingestion:** Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

**Most important symptoms/effects, acute and delayed:** May cause mild eye and skin irritation. Ingestion may cause gastrointestinal effects such as nausea or diarrhea.

**Indication of immediate medical attention and special treatment, if necessary:** Medical attention is recommended for ingestion.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use any media that is suitable for the surrounding fire.

**Specific hazards arising from the chemical:** Product is not flammable or combustible but may burn in a fire.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

#### 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid the generation of mists. Avoid eye contact. Avoid unintended contact with skin. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging.



## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure guidelines:

Desonide	0.75 ug/m3 TWA
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**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to minimize exposures levels.

### Individual protection measures:

**Respiratory protection:** None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor/particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** None required for normal use. Impervious gloves recommended for manufacturing operations.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.

**Other:** None known.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance (physical state, color, etc.):** White Ointment.

<b>Odor threshold:</b> Not determined	<b>pH:</b> Not determined
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not determined
<b>Flash point:</b> >200°F / 93.3°C	<b>Evaporation rate:</b> Not determined
<b>Flammability (solid, gas):</b> Not applicable	<b>VOC:</b> Not determined
<b>Flammable limits: LEL:</b> Not determined	<b>UEL:</b> Not determined
<b>Vapor pressure:</b> Not determined	<b>Vapor density:</b> Not determined
<b>Relative density:</b> Not determined	<b>Solubility(ies):</b> Not determined
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available
<b>Decomposition temperature:</b> Not available	<b>Viscosity:</b> Not determined



**10. STABILITY AND REACTIVITY**

**Reactivity:** Not reactive under normal conditions of use.  
**Chemical stability:** Stable.  
**Possibility of hazardous reactions:** None known.  
**Conditions to avoid:** None known.  
**Incompatible materials:** Avoid oxidizing agents.  
**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

**11. TOXICOLOGICAL INFORMATION**

**Acute effects of exposure:**  
**Inhalation:** Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.  
**Ingestion:** Swallowing may cause gastrointestinal distress with nausea and diarrhea.  
**Skin contact:** No adverse effects are expected. Minor irritation is possible.  
**Eye contact:** Contact may cause irritation.  
**Chronic Effects:** None known.  
**Sensitization:** Components are not known to be sensitizers. Allergic reactions may occur in some users.

**Germ Cell Mutagenicity:** No adverse effects are expected. Components are not germ cell mutagens.  
**Reproductive Toxicity:** No adverse effects are expected. 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 in laboratory animals. Animal reproductive studies have not been conducted with Desonide.

**Carcinogenicity:** None of the components are listed as carcinogens by IARC, NTP or OSHA.

**Acute Toxicity Values:**  
Desonide: LD50 oral mouse 3710 mg/kg.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity values:** No data is available  
**Persistence and degradability:** No data is available  
**Bioaccumulative potential:** No data is available  
**Mobility in soil:** No data is available.  
**Other adverse effects:** None known.

**13. DISPOSAL CONSIDERATIONS**

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

**14. TRANSPORT INFORMATION**

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			





<b>IMDG</b>		Not Regulated			
<b>IATA</b>		Not Regulated			

**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

## 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Not Hazardous

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

**Canadian WHMIS Classification:** Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

## 16. OTHER INFORMATION

**NFPA Rating:** Health = 1      Flammability = 1      Instability = 0

**HMIS Rating:** Health = 1      Flammability = 1      Physical Hazard = 0

**SDS Revision History:** New SDS.

**Date of preparation:** October 03, 2018

**Disclaimer:** This SDS 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**



**Authorized Signatory**

A handwritten signature in blue ink, appearing to read "Chirag Mistri", with a horizontal line underneath.

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