

MSDS Number : 00913

Product Name: CLOBETASOL PROPIONATE

Product Code: CLOBETASOL ACTIVE

Version Date: 05/20/1994

TRANSPORTATION EMERGENCY.....(617) 821-6111 COPLEY PHARMACEUTICAL
(617) 575-7318

PRODUCT EMERGENCY.....(617) 821-6111 COPLEY PHARMACEUTICAL
COPLEY

1. CHEMICAL PRODUCT and COMPANY IDENTIFICATION

SYNONYMS: CLOBETASOL PROPIONATE;

(11-BETA, 16-BETA) - 21-CHLORO-9-FLUORO-11,17-DIHYDROXY-16-METHYL- PREGNA-1,4-DIENE-3,20-DIONE;
CHLORO-9-FLUORO-11.BETA.,17-DIHYDROXY-16.BETA.-
METHYLPREGNA-1,4-DIENE-3,20-DIONE 17-PROPIONATE;
CLOBESOL;
DERMOVAL;
DERMOVATE;
DERMOXIN;
DERMOXINALE;
TEMOVATE;
17-PROPIONATE

COPLEY PHARMACEUTICAL
25 JOHN ROAD
CANTON, MA 02021
UNITED STATES

PRODUCT USE:

Product Class: Corticosteroid; anti-inflammatory.

2. COMPOSITION / INFORMATION on INGREDIENTS

COMPONENT	CAS NUMBER	
CLOBETASOL PROPIONATE *	25122-46-7	100%

*OSHA hazardous according to 29 CFR 1910.1200

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

This product can be irritating to eyes and skin.
POTENTIAL HEALTH EFFECTS

ROUTES OF EXPOSURE:

Inhalation, skin and eyes.

SIGNS AND SYMPTOMS OF EXPOSURE:

Clobetasol propionate is a synthetic corticosteroid and possesses activity typical for this class of compounds. Absorption through the skin occurs; absorption through the lungs is possible (based on other corticosteroids). Acute exposure is not expected to cause symptoms or problems but chronic exposure can cause adrenal suppression and/or features of Cushing's syndrome as well as high blood sugar.

IMMEDIATE EFFECTS

SKIN:

Irritation.

EYES:

Irritation.

INHALATION:

May cause effects similar to dermal exposure.

INGESTION:

None.

DELAYED/LONG TERM EFFECTS

Longterm contact (via dermal or inhalation) can cause manifestation of Cushing's syndrome and/or reversible adrenal suppression.

CARCINOGENIC:

This compound is not listed by IARC, NTP or OSHA as a carcinogen. Carcinogenicity testing has not been conducted.

MUTAGENIC:

Clobetasol propionate has been found to be negative in the Ames test, with and without activation.

TERATOGENIC:

In animals Clobetasol propionate has been shown to cause embryotoxicity, fetal injury and teratogenic effects.

TARGET ORGAN EFFECTS:

Skin, eyes and endocrine system.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

Any existing hypersensitivity to Clobetasol Propionate.

4. FIRST AID MEASURES

Wash thoroughly with mild soap and water. If irritation or allergic reaction occur, contact a physician immediately.

Wash thoroughly with water for 15 minutes. If irritation persists, contact a physician.

Remove to fresh air. If irritation is severe or breathing is difficult, get medical attention. If not breathing, give artificial respiration and get medical attention immediately.

Consult a physician.

HAZARDOUS PRODUCTS OF COMBUSTION:

Compounds of carbon, hydrogen, fluorine and oxygen, including carbon monoxide and nitrogen oxides. The exact composition will depend on the conditions of combustion.

Alcohol foam, carbon dioxide, dry chemicals or water fog (fire extinguisher types A, B or C).

F#2G5A :yG :y0PQ :yE2Jf,f2T4J6T'A yQ :yG :y0P62(y :111"%@vy for fighting fires involving this material.

Wear appropriate respiratory protection to prevent signs and symptoms in Section 3 when responding to release or during cleanup activities. Use a wet mop or HEPA filter vacuum to pick up spilled product. Do not dry sweep as it will cause dust to become airborne.

Keep containers tightly closed. Protect containers from damage.

Utilize engineering controls and/or HEPA filtered or supplied air respiratory protection to maintain exposure below the recommended workplace exposure level. Utilize gloves and arm covers to minimize dermal exposure.

Chemical Formula: C25H32ClFO5

Appearance: White to cream colored

Physical Form: Crystalline powder

Solubility in water: Insoluble

Melting Point: 195.5°C - 197°C

Molecular Weight: 467

CHEMICAL STABILITY:

Stable.

CONDITIONS TO AVOID:

None known.

INCOMPATIBILITY:

None known.

HAZARDOUS DECOMPOSITION PRODUCTS:

None.

HAZARDOUS POLYMERIZATION:

None.

11. TOXICOLOGICAL INFORMATION

Oral LD50: (rat) > 3 gm/kg

Oral LD50: (mouse) > 3 gm/kg

Subcutaneous: (rat) 366 mg/kg

Subcutaneous: (rat) 500 mg/kg
Subcutaneous: (mouse) 82 mg/kg

Daily subcutaneous administration of clobetasol propionate

Daily subcutaneous administration of clobetasol propionate to pregnant mice and rabbits at doses of 1 mg/kg and 10

to pregnant mice and rabbits at doses of 1 mg/kg and $\mu\text{g/kg}$, respectively, induced cleft palate, skeletal

immaturity and an increased number of stillbirths and

fetal resorptions.

12. ECOLOGICAL INFORMATION

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No information available

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL INFORMATION:

Waste Disposal Information.
Waste Clobetasol Propionate should be incinerated.

14. TRANSPORT INFORMATION

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Clobetasol Propionate is not subject to transportation regulations.

15. REGULATORY INFORMATION

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Clobetasol Propionate is regulated under the Food, Drug and Cosmetic Act. Employees processing this compound should have

access to this MSDS per the OSHA Hazard Communication Standard.

16. OTHER INFORMATION
None.