

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

<b>Material</b>	<b>Clobetasol Propionate Lotion, 0.05%</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Pithampur (M.P.) - 454 775 INDIA
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States  Tel. 001-410-576-2000 Fax. 001-410-576-2221

### Section 2: Hazard(s) Identification

#### Section 2, Hazard(s) identification

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	None
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### Section 3: Composition/Information on Ingredients

#### Section 3, Composition/information on ingredients

<b>Ingredients</b>	<b>CAS</b>
Clobetasol Propionate USP	25122-46-7

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

<b>Ingestion</b>	Flush out mouth with water, consult a physician immediately.
<b>Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention or call Poison Control Center immediately

<b>Skin Contact</b>	Wash exposed areas with plenty amounts of water. If adverse skin occur, discontinue use. Seek medical attention.
<b>Eye Contact</b>	Immediately flush with plenty amounts of water for at least 15 minutes. If irritation continues, seek medical attention
<b>NOTES TO HEALTH PROFESSIONALS</b>	
<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
<b>OVERDOSAGE</b>	Typically applied clobetasol propionate lotion, 0.05% can be absorbed in sufficient amount to produce systemic effects.

## Section 5: Fire-Fighting Measures

<b>Section 5, Fire-fighting measures</b>	
<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
<b>Extinguishing Media</b>	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

## Section 6: Accidental Release Measures

<b>Section 6, Accidental release measures</b>	
<b>Personal Precautions</b>	Avoid excessive contact and contact with eyes. Wear safety goggles or shield.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

## Section 7: Handling and Storage

### Section 7, Handling and storage

#### Handling

No special control measures required for the normal handling of this product.  
Avoid contact with eyes

#### Storage

Store at 25°C (77°F): excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].  
Protect from freezing.

## Section 8: Exposure Controls/Personal Protection

### Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

## Section 9: Physical and Chemical Properties

### Section 9, Physical and chemical properties

#### Physical Form

Clobetasol propionate lotion, 0.05% is a white to off white, opaque to translucent lotion, supplied in the following sizes:

2 fl oz/59 mL NDC 68180-536-01 high density polyethylene bottles  
4 fl oz/118 mL NDC 68180-536-02 high density polyethylene bottles

## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Section 11, Toxicological information

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Clobetasol propionate was not carcinogenic to rats when topically applied for 2 years at concentrations up to 0.005% which corresponded to doses up to 11 mcg/kg/day (ratio of animal dose to proposed human dose of 0.03 on a mg/m<sup>2</sup>/day basis).

Clobetasol propionate at concentrations up to 0.001% did not increase the rate of formation of ultra violet light-induced skin tumors when topically applied to hairless mice 5 days per week for a period of 40 weeks.

Clobetasol propionate was negative in the *in vitro* mammalian chromosomal aberration test and in the *in vivo* mammalian erythrocyte micronucleus test.

The effect of subcutaneously administered clobetasol propionate on fertility and general reproductive toxicity was studied in rats at doses of 0, 12.5, 25, and 50 mcg/kg/day. Males were treated beginning 70 days before mating and females beginning 15 days before mating through day 7 of gestation. A dosage level of less than 12.5 mcg/kg/day clobetasol propionate was considered to be the no-observed-effect-level (NOEL) for paternal and maternal general toxicity based on decreased weight gain and for male reproductive toxicity based on increased weights of the seminal vesicles. The female reproductive NOEL was 12.5 mcg/kg/day (ratio of animal dose to proposed human dose of 0.03 on a mg/m<sup>2</sup>/day basis) based on reduction in the numbers of estrous cycles during the pre-cohabitation period and an increase in the number of nonviable embryos at higher doses.

## Section 12: Ecological Information

### Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

### Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

## Section 14: Transport Information

### Section 14: Transport Information

#### IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

#### IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

**DOT - Not Regulated**

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

**Section 15: Regulatory Information**

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This Section Contains Information relevant to compliance with other Federal and/or state laws.

**Section 16: Other Information**

**Section 16, Other information**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**Lupin** shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.