

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

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Material	Clobetasol Propionate Topical Spray, 0.05%
Manufacturer	Lupin Limited Pithampur (M.P.) - 454 775 INDIA
Distributor	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

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Fire and Explosion	Expected to be non-combustible.
Health	None.
Environment	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

Ingredients	CAS
Clobetasol Propionate USP	25122-46-7

Section 4: First-Aid Measures

Section 4, First-aid measures

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

Skin Contact

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Eye Contact

Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

NOTES TO HEALTH PROFESSIONALS**Medical Treatment**

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.

OVERDOSAGE

Topically applied clobetasol propionate spray, 0.05% can be absorbed in sufficient amount to produce systemic effects.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures**Fire and Explosion Hazards**

Assume that this product is capable of sustaining combustion.

Extinguishing Media

Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.

Special Firefighting Procedures

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.

Hazardous Combustion Products

Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures**Personal Precautions**

Avoid excessive contact and contact with eyes. Wear safety goggles or shield.

Environmental Precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods

This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

Section 7: Handling and Storage

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Handling

No special control measures required for the normal handling of this product.

Storage

Keep tightly closed. Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Do not freeze, refrigerate or store above 30°C. Spray is flammable; avoid heat, flame or smoking when using this product. Keep out of reach of children.

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 Spray, 0.05% is a clear, colorless liquid packed in white HDPE bottle with a white polypropylene cap and clean peel induction heat seal liner, available in the following sizes:

2 fl oz/59 mL NDC 68180-551-11

4.25 fl oz/125 mL NDC 68180-551-22

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/m²/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 with fluid. The female reproductive NOEL was 12.5 mcg/kg/day (ratio of animal dose to proposed human dose of 0.03 on a mg/m²/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

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No relevant studies identified.

Section 13: Disposal Considerations

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

Section 14: Transport Information

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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.