Section 1: Identification

Material: Clobetasol Propionate Ointment USP, 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

Fire and Explosion
Expected to be non-combustible.

Health
Clobetasol propionate ointment, 0.05% is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

Environment
No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Ingredients
CAS
Clobetasol Propionate USP 25122-46-7

Section 4: First-Aid Measures

Ingestion
If swallowed, rinse mouth with water (only if the person is conscious).

Inhalation
Remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration.
Skin Contact
Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

Eye Contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

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 ointment can be absorbed in sufficient amounts to produce systemic effects.

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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.

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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

Handling
Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

Storage
Store at 20° to 25°C (68° to 77°F) excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

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

Physical Form
Clobetasol propionate ointment USP, 0.05% is a white to off white ointment and supplied in:
15-g tubes (NDC 43386-096-60)
30-g tubes (NDC 43386-096-61)
45-g tubes (NDC 43386-096-63)
60-g tubes (NDC 43386-096-62)

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate.

Studies in the rat following subcutaneous administration at dosage levels up to 50 mcg/kg/day revealed that the females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.
Clobetasol propionate was nonmutagenic in 3 different test systems: the Ames test, the *Saccharomyces cerevisiae* gene conversion assay, and the *E. coli* B WP2 fluctuation test.

### 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 Packaging Group : N/A
- DOT Label : N/A

### Section 15: Regulatory Information

**Section 15: Regulatory Information**

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.