

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

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Material	Fluocinonide 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

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Fire and Explosion	Expected to be non-combustible.
Health	Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.
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
Fluocinonide USP	356-12-7

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
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Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye Contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

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 corticosteroids can be absorbed in sufficient amounts 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	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Firefighting Procedures	As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.
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

Store at 20° to 25°C (68°to 77°F). Avoid temperature over 30°C (86°F).

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**

Fluocinonide Ointment, 0.05% is supplied in
15 g Tube - NDC 43386-095-60
30 g Tube - NDC 43386-095-62
60 g Tube - NDC 43386-095-61

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**

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

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

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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.