

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

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| Material | Desoximetasone Ointment USP 0.05% For topical use only. Not for oral, ophthalmic, or intravaginal use. |
| 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

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 |
|--------------------|------------|
| Desoximetasone | 382-67-2 |

Section 4: First-Aid Measures

Section 4, First-aid measures

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| Ingestion | If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention. |
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| Inhalation | Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance. |
| Skin Contact | Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs. |
| Eye Contact | Flush eyes with plenty of water. Get medical attention. |
| NOTES TO HEALTH PROFESSIONALS | |
| Medical Treatment | Individuals who have had allergic reactions to products containing the Desoximetasone component of this product or any other components of this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infections, skin atrophy, striae, and miliaria. |
| OVERDOSAGE | Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. |

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

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| 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 | 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

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| Personal Precautions | Wear protective clothing and equipment consistent with the degree of hazard. |
| Environmental Precautions | For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems. |
| Clean-up Methods | Collect and place it in a suitable, properly labeled container for recovery or disposal. |

Section 7: Handling and Storage

Section 7, Handling and storage

Handling

Avoid contact with eyes. Do not ingest. Handle in accordance with good industrial hygiene and safety practices. Follow all MSDS and label precautions.

Storage

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

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**HOW SUPPLIED**

Desoximetasone ointment USP, 0.05% is supplied as follows:

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|-----------------|------------------|
| 15 gram tubes: | NDC 68180-948-01 |
| 30 gram tubes: | NDC 68180-948-02 |
| 60 gram tubes: | NDC 68180-948-04 |
| 100 gram tubes: | NDC 68180-948-06 |

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, and Impairment of Fertility**Carcinogenesis, Mutagenesis, and Impairment of Fertility**

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

Desoximetasone was nonmutagenic in the Ames test.

Section 12: Ecological Information

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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

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|---------------------------|---|-----|
| 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

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|---------------------------|---|-----|
| 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

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|--------------------------|---|-----|
| 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

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.