

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

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| Material | Desoximetasone Topical Spray, 0.25% |
| 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 | 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

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|--------------------|------------|
| Ingredients | CAS |
| Desoximetasone USP | 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

Desoximetasone topical spray, 0.25% 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

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**

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 controlled room temperature between 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Spray is flammable; avoid heat, flame or smoking when using this product.

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 topical spray, 0.25% is a clear, colorless liquid supplied in white, opaque bottles with white, opaque screw caps in the following sizes:

- 30 mL (NDC 68180-944-11)
- 50 mL (NDC 68180-944-22)
- 100 mL (NDC 68180-944-33)

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

Long-term animal studies have not been performed to evaluate the carcinogenic potential of desoximetasone topical spray, 0.25%.

In a 13-week repeat-dose toxicity study in rats, topical administration of desoximetasone spray at concentrations of 0.001, 0.005 and 0.02% BID (which corresponds to dose levels of 0.01, 0.05, or 0.2 mg/kg/dose BID,

respectively) resulted in a toxicity profile consistent with long-term exposure to corticosteroids, including adrenal atrophy and histopathological changes in several organ systems indicative of severe immune suppression. A no observable adverse effect level (NOAEL) could not be determined in this study. Although the clinical relevance of the findings in animals to humans is not clear, sustained glucocorticoid-related immune suppression may increase the risk of infection and possibly the risk for carcinogenesis.

Desoximetasone revealed no evidence of mutagenic or clastogenic potential based on the results of two *in vitro* genotoxicity tests (Ames assay and Chinese hamster ovary cell chromosome aberration assay) and one *in vivo* genotoxicity test (mouse bone marrow micronucleus assay).

No evidence of impairment of male or female fertility was observed at subcutaneous desoximetasone doses up to 0.1 mg/kg/day (0.6 mg/m²/day) in Sprague-Dawley rats.

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

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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

| | | |
|---------------------------|---|-----|
| 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.