# **LUPIN LIMITED**

## **SAFETY DATA SHEET**

## **Section 1: Identification**

Section 1, Identification

Material Desoximetasone Ointment USP 0.25%

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

**Fire and Explosion** Expected to be non-combustible.

**Health** Desoximetasone ointment, 0.25% is 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

IngredientsCASDesoximetasone382-67-2

## **Section 4: First-Aid Measures**

Section 4, First-aid measures

**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

**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.

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## 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, 0.25% is supplied as follows:

15 gram tubes NDC 68180-946-01 30 gram tubes NDC 68180-946-02 60 gram tubes NDC 68180-946-04 100 gram tubes NDC 68180-946-06

## **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

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.

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# **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/AIMDG UN/ID No:N/AIMDG Hazard Class:N/AIMDG Flash Point:N/AIMDG 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.

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# 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.

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