

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

|                     |  |
|---------------------|--|
| <b>Material</b>     | <b>Doxycycline for Oral Suspension USP, 25 mg/5 mL</b>   |
| <b>Manufacturer</b> | <b>Lupin Limited</b><br>Goa - 403722<br>India  |
| <b>Distributor</b>  | Lupin Pharmaceuticals, Inc.<br>111 South Calvert Street,<br>Harborplace Tower, 21st Floor,<br>Baltimore, Maryland 21202<br>United States<br>Tel. 001-410-576-2000<br>Fax. 001-410-576-2221 |

### Section 2: Hazard(s) Identification

#### Section 2, Hazard(s) identification

|                           |   |
|---------------------------|---|
| <b>Fire and Explosion</b> | Expected to be non-combustible.   |
| <b>Health</b>             | This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.      |
| <b>Environment</b>        | 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

| <b>Ingredients</b> | <b>CAS</b> |
|--------------------|------------|
| Doxycycline USP    | 17086-28-1 |

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

|                  |  |
|------------------|--|
| <b>Ingestion</b> | 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. |
|------------------|--|

|                                      |   |
|--------------------------------------|---|
| <b>Inhalation</b>                    | Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.   |
| <b>Skin Contact</b>                  | 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.  |
| <b>Eye Contact</b>                   | Flush eyes with plenty of water. Get medical attention.   |
| <b>NOTES TO HEALTH PROFESSIONALS</b> |   |
| <b>Medical Treatment</b>             | 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. |
| <b>OVERDOSAGE</b>                    | In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Dialysis does not alter serum half-life and thus would not be of benefit in treating cases of overdosage.   |

## Section 5: Fire-Fighting Measures

### Section 5, Fire-fighting measures

|  |   |
|--|---|
| <b>Fire and Explosion Hazards</b>      | Assume that this product is capable of sustaining combustion.   |
| <b>Extinguishing Media</b>             | Water spray, carbon dioxide, dry chemical powder or appropriate foam.   |
| <b>Special Firefighting Procedures</b> | For single units (packages): No special requirements needed.<br><br>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. |
| <b>Hazardous Combustion Products</b>   | Hazardous combustion or decomposition products are expected when the product is exposed to fire.  |

## Section 6: Accidental Release Measures

### Section 6, Accidental release measures

|                                  |   |
|----------------------------------|---|
| <b>Personal Precautions</b>      | Wear protective clothing and equipment consistent with the degree of hazard.                            |
| <b>Environmental Precautions</b> | For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems. |
| <b>Clean-up Methods</b>          | 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

No special control measures required for the normal handling of this product.  
Normal room ventilation is expected to be adequate for routine handling of this product.

#### Storage

Doxycycline for Oral Suspension USP is to be stored at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature] and dispensed in tight, light-resistant containers (USP).

## 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

Doxycycline for Oral Suspension USP (doxycycline monohydrate) is available as a raspberry-flavored, dry powder for oral suspension. When reconstituted, each teaspoonful (5 mL) contains doxycycline monohydrate equivalent to 25 mg of doxycycline:

60 mL bottles (NDC 68180-657-01)

## 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 studies in animals to evaluate carcinogenic potential of doxycycline have not been conducted. However, there has been evidence of oncogenic activity in rats in studies with the related antibacterial drugs, oxytetracycline (adrenal and pituitary tumors), and minocycline (thyroid tumors).

Likewise, although mutagenicity studies of doxycycline have not been conducted, positive results in *in vitro* mammalian cell assays have been

reported for related antibacterial drugs (tetracycline, oxytetracycline).

Doxycycline administered orally at dosage levels as high as 250 mg/kg/day had no apparent effect on the fertility of female rats. Effect on male fertility has not been studied.

## 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 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 MSDS.