LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	**Doxycycline Hyclate Tablets USP** 75 mg and 150 mg
Manufacturer	**Lupin Limited** Nagpur 441 108 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	Doxycycline hyclate is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.
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**
Doxycycline Hyclate USP	24390-14-5

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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	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

Fire and Explosion Hazards	Strong dust explosion characteristic. High sensitivity of a dust cloud to ignition, based on minimum ignition energy.
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Special Firefighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Clean-up Methods	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Avoid use of a filtered vacuum to clean spills of dry solids, due to the potential for electrostatic discharge and the strong dust explosion characteristic and high sensitivity to ignition.

Section 7: Handling and Storage

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Handling	If tablets or capsules are crushed and/or broken, Avoid breathing dust and avoid contact with eyes, skin and clothing. Use adequate ventilation.
Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Protect from light and moisture. Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

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 Hyclate Tablets USP, 75 mg are light-teal, round, biconvex, film-coated tablets debossed with “LU” on one side and “C80” on the other side. Each 75 mg tablet contains 86.6 mg of doxycycline hyclate equivalent to 75 mg of doxycycline.

Bottles of 30 tablets:	NDC 68180-653-06
Bottles of 60 tablets:	NDC 68180-653-07
Bottles of 90 tablets:	NDC 68180-653-09

Doxycycline Hyclate Tablets USP, 150 mg are mossy-green, capsule-shaped, biconvex, film-coated tablets scored on both sides. Each side of the functionally scored tablet has two parallel score line for splitting into 3 equal portions with “C” debossed on each portion of one side of the tablet, and plain on the other side. Each 150 mg tablet contains 173.2 mg of doxycycline hyclate equivalent to 150 mg of doxycycline.

Bottles of 30 tablets:	NDC 68180-654-06
Bottles of 60 tablets:	NDC 68180-654-07
Bottles of 90 tablets:	NDC 68180-654-09

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 hyclate have not been conducted.

However, a 2 year carcinogenicity study with doxycycline administered daily by oral gavage to adult rats (20, 75, 200 mg/kg/day) demonstrated an increase in uterine polyps in female rats at 200 mg/kg/day (10 times the maximum recommended daily adult dose of doxycycline hyclate based on body surface area comparison) with no change in tumor incidence in male rats at the same dose. A 2-year carcinogenicity study with doxycycline administered daily by oral gavage to adult male (maximum dose 150 mg/kg/day) and female (maximum dose 300 mg/kg/day) mice showed no changes in tumor incidence, at approximately 4 and 7 times the maximum recommended daily adult dose of doxycycline hyclate, based on a body surface area comparison, respectively.

Mutagenesis and fertility studies have not been conducted with doxycycline hyclate. Mutagenesis studies with doxycycline demonstrated no potential to cause genetic toxicity in an *in vitro* point mutation study with mammalian cells or in an *in vivo* micronucleus assay in CD-1 mice. However, data from an *in vitro* mammalian chromosomal aberration assay conducted in CHO cells suggest that doxycycline is a weak clastogen. Oral administration of doxycycline to Sprague-Dawley rats showed adverse effects on fertility and reproduction including increased time for mating, reduced sperm motility, velocity and concentration as well as increased pre and post implantation loss. Reduced sperm velocity was seen at the lowest dosage tested, 50 mg/kg/day which is 2.5 times the maximum recommended daily adult dose of doxycycline hyclate. Although doxycycline impairs the fertility of rats when administered at sufficient dosages, the effect of doxycycline hyclate on human fertility is unknown.

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

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.