

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Doxycycline Capsules 40 mg
Manufacturer	Lupin Limited Nagpur - 441108 Maharashtra, 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
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Fire and Explosion	Expected to be non-combustible.
Health	This drug 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. Avoid release to the environment.

Section 3: Composition/Information on Ingredients

Drug Substance:

Name	CAS No.
Sugar Spheres NF	92004-84-7
Hydroxypropyl Methyl Cellulose NF	9004-65-3
Iso Propyl Alcohol USP	67-63-0.
Methylene Chloride NF	75-09-2.
Doxycycline USP	17086-28-1
Methacrylic acid Copolymer NF	25086-15-1
Triethyl Citrate	77-93-0

* The exact percentage composition of this mixture has been withheld as a trade secret.

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. If not breathing, give artificial respiration. 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
Overdosage	In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures.

Section 5: Fire-Fighting Measures

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Suitable extinguishing media	Use water spray, Use carbon dioxide, dry chemical, or foam.
Advise for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Hazardous combustion products	May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.
Environmental precautions	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.
Disposal Methods	Dispose of in accordance with local, state, and national regulations.

Section 7: Handling and Storage

Precautions for safe handling	No special precautions are necessary when handling packed product. In case of accident, avoid breathing dust from crushed tablets. Avoid contact with skin and eyes. Wash hands after use.
Suitable 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.

Section 8: Exposure Controls/Personal Protection

Hygiene Measures	Wash skin thoroughly with soap and water.
Hands Protection	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes	Wear safety glasses or goggles if eye contact is possible.
Skin & Body Protection	Additional body garments should be used based upon the task being performed (e.g., sleeveless, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate disgowning techniques to remove potentially contaminated clothing.

Section 9: Physical and Chemical Properties

HOW SUPPLIED	Size '2' hard gelatin capsules with beige Opaque Cap and beige opaque body , imprinted with "LU" on cap and "D09" on body in black ink containing creamish white to yellowish brown colored pellets." Doxycycline Capsule 40 mg
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Section 10: Stability and Reactivity

Stability	Stable under recommended storage condition.
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Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate the carcinogenic potential of doxycycline have not been conducted. However, there has been evidence of oncogenic activity in rats in studies with related antibacterial, 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 (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

No information available.

Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

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

No information available.

Section 16: Other Information

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.