

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Doxycycline Injection 100 Mg/Vial
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.

Section 3: Composition/Information on Ingredients

Drug Substance:

Name	CAS No.
Doxycycline hyclate	24390-14-5
Ascorbic Acid	50-81-7

* 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	Avoid generating dust /flash, Avoid all contact with skin, eyes, or clothing. Do not breathe dust. Personnel involved in clean-up should wear appropriate personal protective equipment . Minimize exposure.
Environmental precautions	Prevent entry to sewers and public waters.
Methods and material for containment	For Containment : Avoid generation of dust during clean-up of spills. Use only non-sparking tools.
Method for Cleaning Up	For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Section 7: Handling and Storage

Precautions for safe handling	Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Hygiene Measures : This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.
Suitable Storage	Store in a dry and well-ventilated place. Protect from heat and direct sunlight. Controlled Room – between 20 and 25 C.

Section 8: Exposure Controls/Personal Protection

Protective Measures	Not generally required. The use of personal protective equipment may be necessary as conditions warrant. Dust formation: dust mask. Gloves. Protective clothing. Protective goggles.
Respiratory Protection	NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.
Hygiene Measures	This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.
Hands Protection	Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
Eyes	In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.
Skin & Body Protection	In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Section 9: Physical and Chemical Properties

HOW SUPPLIED	Doxycycline for Injection 100 Mg/Vial. Doxycycline for injection, USP is available as a lyophilized cake or powder packed in amber colored tubular glass vial with rubber stopper and orange aluminium flip-off seal containing doxycycline hyclate equivalent to 100 mg of doxycycline with 480 mg of ascorbic acid; packages of 10 (70748-338-10).
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Section 10: Stability and Reactivity

Reactivity	Hazardous reactions will not occur under normal conditions.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization will not occur.
Condition to avoid Incompatible Material	Direct sunlight. Extremely high or low temperatures. Avoid creating or spreading dust.

Section 11: Toxicological Information

Acute Toxicity	: Not classified
Skin Corrosion/Skin Irritation	: Causes Irritation
Serious eye damage/ Eye Irritation	: Causes Serious eye irritation
Respiratory/ Skin Sensitization	: Not Classified.
Germ Cell Mutagenicity	: Not Classified.
Teratogenicity	: Not available
Carcinogenicity	: Not Classified.
Specific Target Organ Toxicity	: Not Classified.
Aspiration Hazard	: Not classified.

Section 12: Ecological Information

No information available.

Section 13: Disposal Considerations

Sewage disposal recommendations:	Do not dispose of waste into sewer.
Waste disposal recommendations:	Dispose of waste material in accordance with Rules all local, regional.

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

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.