

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material Ceftriaxone for Injection USP 250 mg, 500 mg, 1 g and 2 g
Ceftriaxone for Injection USP 10 g/vial (Pharmacy Bulk Package)

Manufacturer Lupin Limited
Mumbai 400 098 INDIA

Distributor Lupin Pharmaceuticals, Inc.
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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS	Quantity
Ceftriaxone sodium USP equivalent to Ceftriaxone	73384-59-5	250 mg, 500 mg, 1 g, 2 g, 10 g/ vial

3. HAZARDOUS IDENTIFICATION

Fire and Explosion Assume that this product is capable of sustaining combustion.

Health Exposure might occur via skin; eyes; ingestion; inhalation.
May cause allergic reaction by inhalation or skin contact.

Environment No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST AID MEASURES

Ingestion	Never attempt to 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.
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 & Antidote	<ul style="list-style-type: none">-Treat symptomatically.-In case of strong sensitization against Cephalosporin, anaphylaxis and asthma are possible.Weak cases:<ul style="list-style-type: none">-Antihistaminic I.V.-In case of asthma topical steroids and inhalative β-Mimeticasevere cases:<ul style="list-style-type: none">-Adrenalin 0.3 – 0.5 mg i.v.-Antihistaminica i.v.-High dosage of steroids i.v.-in case of asthma additional inhalation with topical steroids and β-Mimetica.
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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	Formation of toxic and corrosive combustion gases (nitrogen oxides, sulfur oxides) possible.

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.

7. HANDLING AND STORAGE

- Handling** Processing only in closed rooms with reduced pressure and high efficiency particulate air filter (HEPA filter; GMP). Avoid dust formation; high dust explosion hazard; local exhaust ventilation is necessary; take precautionary measures against electrostatic charging.
- Storage** Ceftriaxone for injection sterile powder should be stored at 20° to 25°C (68° to 77°F).

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection is recommended as a precaution to minimize exposure. In case of open handling or accidental release: particle mask or respirator with independent air supply should be used. Wear appropriate clothing to avoid skin contact. Allergic persons should possibly be excluded from any occupational exposure to Ceftriaxone (evaluation of aptitude by physician).

9. PHYSICAL & CHEMICAL PROPERTIES

- Physical Form** White to yellowish powder.

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity:	Not expected to be toxic following ingestion.
Inhalation Toxicity:	Can cause allergic reaction.
Skin Effects:	Irritation might occur following direct contact.
Eye Effects:	Irritation might occur following direct contact with eyes.
Gastrointestinal Reactions:	Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps and loss of appetite.
Hypersensitivity Reactions:	Rash may occur. Conditions aggravated: Hypersensitivity to penicillin and other antibiotics.
Genetic Toxicity:	Not expected to be genotoxic based on animal studies.
Carcinogenicity:	Not expected to be carcinogenic based on animal studies.
Reproductive Effects:	Not expected to produce adverse effects on fertility or development based on animal studies. No adequate and well-controlled studies in pregnant women. No studies during labor and delivery. Should be used during pregnancy only if clearly needed. Since this material has been shown to be excreted in breast milk, nursing mothers should exercise caution regarding exposure.
Pharmacological Effects:	This material is an antibiotic; a cephalosporin. It is an agent intended for the treatment of bacterial infections.

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATION

Small amounts (up to approx. 100 g): Dissolve in water and decompose with sodium hydroxide or prolonged boiling. Afterwards the solution can be drained. Large amounts: Incinerate in an approved facility. Follow all federal state and local environmental regulations.

14. TRANSPORT INFORMATION

The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, or ground transport purposes.

15. REGULATORY INFORMATION

No information found.

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.