MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material **Suprax®**
Cefixime for Oral Suspension, USP
100 mg/5 mL

Manufacturer Lupin Limited
Mumbai 400 098 INDIA

Distributor Lupin Pharmaceuticals, Inc.
Harborplace Tower, 21st Floor
111, South Calvert Street
Baltimore, MD 21202
United States
Tel. 001-410-576-2000
Fax. 001-410-576-2221

2. COMPOSITION / INFORMATION ON INGREDIENTS

Label Claim: When reconstituted, each teaspoonful (5 mL) contains 100 mg of cefixime as the trihydrate

Ingredients	**CAS**	**Quantity (% w/w)**
Cefixime (as trihydrate)	79350-37-1	4.82
Non-hazardous ingredients	----------	95.18

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 sensitisation 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 — Physical form suggests that risk of inhalation exposure is negligible.

Skin Contact — Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs.

Eye contact — Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention if required.

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. Medical treatment in cases of overexposure should be treated as an overdose of a cephalosporin antibiotic. Gastric lavage may be indicated; otherwise no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.

Antidotes — No specific antidote exists.

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 — Hazardous combustion or decomposition products are expected when the product is exposed to fire.

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 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 Store drug powder at 20-25° C (68 – 77°F) [See USP Controlled Room Temperature]. The reconstituted product may be stored at room temperature or under refrigeration.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL & CHEMICAL PROPERTIES

Physical Form Powder (Granules).

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity: Not expected to be toxic following ingestion.

Inhalation Toxicity: Can produce respiratory irritation. Adverse effects might occur following inhalation.

Skin Effects: Irritation might occur following direct contact.

Eye Effects: Irritation might occur following direct contact with eyes.

Gastrointestinal Reactions: Diarrhea, loose or frequent stools, abdominal pain, nausea, dyspepsia and flatulence.

Hypersensitivity Reactions: Incidence rates below 2% reported.

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.

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

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.