MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material **Cefuroxime Axetil Tablets, USP**
250 mg or 500 mg

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

Ingredients	CAS	Quantity
Cefuroxime axetil	64544-07-6	250 mg/Tablet or 500 mg/Tablet
Non-hazardous ingredients	----------	q.s.

3. HAZARDOUS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health Exposure might occur via skin; eyes; ingestion.
May produce allergic skin reactions.
Respiratory allergen.
Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); nausea; vomiting; diarrhea.
Health effects information is based on hazards of components.

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. If the exposed subject is fully conscious, give plenty of water to drink. 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, which may be immediate or delayed.
Eye contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

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. 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.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product. Ocular symptoms may be indicative of allergic reaction. Pulmonary symptoms may indicate allergic reaction or asthma. This material may cause or aggravate allergy to cephalosporin antibiotics.
Antidotes	No specific antidote exists.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
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. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal 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.
Decontamination Procedure	No specific decontamination or detoxification procedures have been identified for this product. Water can be used for clean-up and decontamination operations.

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.
General Requirements	Avoid breaking or crushing tablets.
Storage	Store at 20° to 25°C (68° to 77° F) [See USP Controlled Room Temperature].

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	Wear approved safety glasses with side shields if eye contact is possible.
Respirators	If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present.
Other Equipment or Procedures	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL & CHEMICAL PROPERTIES

Physical Form Tablet.

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.

Target Organ Effects No specific target organ effects have been identified.

Sensitization Allergic skin reactions might occur following dermal exposure. Assessment based upon effects of structurally similar substances.

Gastrointestinal Reactions: Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. The most frequent side effect has been diarrhea. It was very rarely severe enough to warrant cessation of therapy. Dyspepsia, gastritis, and abdominal pain have also occurred. As with some penicillins and some other cephalosporins, transient hepatitis and chloestatic jaundice have been reported rarely.

Hypersensitivity Reactions: Allergic reaction in the form of rash, urticaria, angioedema, and rarely, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis have been observed. These reactions usually subsided upon discontinuation of the drug. In some of these reactions, supportive therapy may be necessary. Anaphylaxis has also been reported.

Genetic Toxicity: Not expected to be genotoxic under occupational exposure conditions. Assessment based upon effects of structurally similar substances

Carcinogenicity: Not expected to produce cancer in humans under occupational exposure conditions.

Reproductive Effects: Not expected to produce adverse effects on fertility or development under occupational exposure conditions. No adverse effects have been reported following extensive use or exposure in humans.

Pharmacological Effects: This material is an antibiotic; a cephalosporin. It is an agent intended for the treatment of bacterial infections.

12. ECOLOGICAL INFORMATION

*** Summary** This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

*** Activated Sludge Respiration** This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.
IC50: > 100 mg/l, 3 Hours, Activated sludge

*** Microbial Growth Inhibition** This material contains an active pharmaceutical ingredient that is toxic to these microorganisms.
Minimum Inhibition Concentration:

0.2 mg/l, , Azotobacter beijerinckii
0.2 mg/l, , Nostoc commune
> 1 mg/l, , Pseudomonas aeruginosa
> 1 mg/l, , Trichoderma harzianum
> 1 mg/l, , Aspergillus niger

*** Algal** This material contains an active pharmaceutical ingredient that is not toxic to algae.

IC50: > 91 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test
NOEL: 91 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test

*** Daphnid** This material contains an active pharmaceutical ingredient that is not toxic to daphids.

EC50: > 1000 mg/l, 48 Hours, Daphnia magna, Static test
NOEL: > 1000 mg/l, 48 Hours, Daphnia magna, Static test

*** Fish**

This material contains an active pharmaceutical ingredient that is not toxic to fish.
Adult Oncorhyncus mykiss, rainbow trout
EC50: > 120 mg/l, 96 Hours, Static test
Adult Oncorhyncus mykiss, rainbow trout
NOEL: 120 mg/l, 96 Hours, Static test

MOBILITY

*** Solubility**

This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

*** Volatility**

This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance. This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant Estimated at 25° C

*** Adsorption**

This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment. This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

Soil Sediment Sorption (log Koc): 1.09 to 1.19

*** Partitioning**

This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

*** Hydrolysis**

This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism.

Half-Life, Neutral: 30.2 Hours
Half-Life, Basic: 1.05 Hours
Half-Life, Acidic: 299 Hours

*** Photolysis**

This material contains an active pharmaceutical ingredient that is likely to undergo photo degradation.
UV/Visible Spectrum: 290 nm

*** Biodegradation**

This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Ready
Percent Degradation: 42 %, 64 days, Modified Sturm test.
Percent Degradation: 28 %, 28 days, Modified Sturm test.

Aerobic - Inherent
Percent Degradation: 74 %, < 1 day, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Aerobic - Soil
Percent Degradation: 42.8 to 80 %, 64 days

*** BIOACCUMULATION** This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

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

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

US OSHA Standard (29 CFR Part 1910.1200)
Classification This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations
TSCA Status Exempt
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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.