

# MATERIAL SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

**Material** Cefuroxime Axetil Tablets USP  
250 mg and 500 mg.

**Manufacturer** Lupin Limited  
Mandideep 462 046  
INDIA.

**Distributor** Lupin Pharmaceuticals, Inc.  
Harborplace Tower, 21<sup>st</sup> 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 USP	64544-07-6	250 mg and 500 mg

## 3. HAZARDOUS IDENTIFICATION

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

**Health** Cefuroxime axetil tablets are contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

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

## 4. FIRST AID MEASURES

**Ingestion** If conscious, give water to drink and 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

**OVERDOSAGE** Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

## 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 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.

**Storage** Store the tablets at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature].

Replace cap securely after each opening.

## 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

Cefuroxime axetil tablets USP, 250 mg of cefuroxime (as cefuroxime axetil), are white to off-white capsule-shaped film-coated tablets with "LUPIN" debossed on one side and "302" on the other side, supplied in bottles of 20 and 60.

20s Bottle	NDC 68180-302-20
60s Bottle	NDC 68180-302-60

Cefuroxime axetil tablets USP, 500 mg of cefuroxime (as cefuroxime axetil), are white to off-white capsule-shaped film-coated tablets with "LUPIN" debossed on one side and "303" on the other side, supplied in bottles of 20 and 60.

20s Bottle	NDC 68180-303-20
60s Bottle	NDC 68180-303-60

## 10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

## 11. TOXICOLOGICAL INFORMATION

### Carcinogenesis, Mutagenesis, Impairment of Fertility

Although lifetime studies in animals have not been performed to evaluate carcinogenic activity, no mutagenic activity was found for cefuroxime axetil in a battery of bacterial mutation tests. Positive results were obtained in an *in vitro* chromosome aberration assay, however, negative results were found in an *in vivo* micronucleus test at doses up to 1.5 g/kg. Reproduction studies in rats at doses up to 1000 mg/kg/day (9 times the recommended maximum human dose based on mg/m<sup>2</sup>) have revealed no impairment of fertility.

## 12. ECOLOGICAL INFORMATION

No information available

### 13. DISPOSAL CONSIDERATION

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

### 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

### 15. REGULATORY INFORMATION

No information available.

### 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.