

# **MATERIAL SAFETY DATA SHEET**

## **1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY**

**Material** Cefprozil For Oral Suspension USP  
125 mg/5 mL and 250 mg/5 mL

**Manufacturer** Lupin Limited  
Mumbai 400 098  
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**

Cefprozil USP 92665-29-7

## **3. HAZARD IDENTIFICATION**

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

**Health** Cefprozil is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

**BEFORE THERAPY WITH CEFPROZIL IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEFPROZIL, CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-SENSITIVITY AMONG  $\beta$ -LACTAM ANTIBIOTICS HAS BEEN CLEARLY DOCUMENTED AND MAY OCCUR IN UP TO 10% OF PATIENTS WITH A HISTORY OF PENICILLIN ALLERGY. IF AN ALLERGIC REACTION TO CEFPROZIL OCCURS, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE**

AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, INTRAVENOUS FLUIDS, INTRAVENOUS ANTIHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED.

*Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cefprozil, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

*C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

#### 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**

Single 5000 mg/kg oral doses of cefprozil caused no mortality or signs of toxicity in adult, weanling, or neonatal rats, or adult mice. A single oral dose of 3000 mg/kg caused diarrhea and loss of appetite in cynomolgus monkeys, but no mortality.

Cefprozil is eliminated primarily by the kidneys. In case of severe overdosage, especially in patients with compromised renal function, hemodialysis will aid in the removal of cefprozil from the body.

## **5. FIRE FIGHTING MEASURES**

<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
<b>Extinguishing Media</b>	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

## **6. ACCIDENTAL RELEASE MEASURES**

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labeled container for recovery or disposal.

## **7. HANDLING AND STORAGE**

<b>Handling</b>	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.
<b>Storage</b>	Store dry powder at 20°- 25°C (68°-77°F) [See USP Controlled Room Temperature].  Store constituted suspension in refrigerator. Discard after 14 days. Preserve in tight containers.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

## 9. PHYSICAL AND CHEMICALS PROPERTIES

### Physical Form

Cefprozil for oral suspension, USP is a pink coloured powder, forming pink coloured suspension with characteristic odour on constitution.

Cefprozil for Oral Suspension, USP 125 mg/5 mL is available as follows:

50 mL Bottle	NDC 68180-401-01
75 mL Bottle	NDC 68180-401-02
100 mL Bottle	NDC 68180-401-03

Cefprozil for Oral Suspension, USP 250 mg/5 mL is available as follows:

50 mL Bottle	NDC 68180-402-01
75 mL Bottle	NDC 68180-402-02
100 mL Bottle	NDC 68180-402-03

All powder formulations for oral suspension contain cefprozil in a bubble-gum flavored mixture.

### Reconstitution Directions for Oral Suspension:

Prepare the suspension at the time of dispensing; for ease in preparation, add water in two portions and shake well after each aliquot.

### Total Amount of Water Required for Reconstitution

Bottle Size	Final Concentration 125 mg/5 mL	Final Concentration 250 mg/5 mL
50 mL	36 mL	36 mL
75 mL	53 mL	53 mL
100 mL	70 mL	70 mL

## 10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

## 11. TOXICOLOGICAL INFORMATION

### Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term *in vivo* studies have not been performed to evaluate the carcinogenic potential of cefprozil.

Cefprozil was not found to be mutagenic in either the Ames *Salmonella* or *E. coli* WP2 urvA reversion assays or the Chinese hamster ovary cell HGPRT forward gene mutation assay and it did not induce chromosomal abnormalities in Chinese hamster ovary cells or unscheduled DNA synthesis in rat hepatocytes *in vitro*. Chromosomal aberrations were not observed in bone marrow cells from rats dosed orally with over 30 times the highest recommended human dose based upon mg/m<sup>2</sup>. Impairment of fertility was not observed in male or female rats given oral doses of cefprozil up to 18.5 times the highest recommended human dose based upon mg/m<sup>2</sup>.

## 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.