

# MATERIAL SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

**Material** Cefadroxil for Oral Suspension USP  
250 mg/5 mL and 500 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	Quantity
Cefadroxil monohydrate equivalent to Cefadroxil	50370-12-2	250 mg/5 mL; 500 mg/5 mL
Non-hazardous ingredients	-----	q.s.

## 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

<b>Ingestion</b>	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.
<b>Inhalation</b>	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Flush eyes with plenty of water. Get medical attention.

### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	<p>Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.</p> <p>A study of children under six years of age suggested that ingestion of less than 250 mg/kg of cephalosporins is not associated with significant outcomes. No action is required other than general support and observation. For amounts greater than 250 mg/kg, induce gastric emptying.</p> <p>In five anuric patients, it was demonstrated that an average of 63% of a 1 g oral dose is extracted from the body during a 6–8 hour hemodialysis session.</p>
<b>Antidotes</b>	No specific antidote exists.

## 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

- 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 at 25°C (77°F); excursions permitted to 15°-30° C (59°-86° F); [see USP Controlled Room Temperature].After reconstitution: store in refrigerator.

## 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**                 Light orange coloured powder.

## 10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

## 11. TOXICOLOGICAL INFORMATION

The following adverse events and altered laboratory tests have been reported for cephalosporin-class antibiotics in general:

Toxic epidermal necrolysis, abdominal pain, superinfection, renal dysfunction, toxic nephropathy, aplastic anemia, hemolytic anemia, hemorrhage, prolonged prothrombin time, positive Coombs' test, increased BUN, increased creatinine, elevated alkaline phosphatase, elevated aspartate aminotransferase (AST), elevated alanine aminotransferase (ALT), elevated bilirubin, elevated LDH, eosinophilia, pancytopenia, neutropenia.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced.

If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

<b>Oral Toxicity:</b>	Not expected to be toxic following ingestion.
<b>Inhalation Toxicity:</b>	Can produce respiratory irritation. Adverse effects might occur following inhalation.
<b>Skin Effects:</b>	Irritation might occur following direct contact.
<b>Eye Effects:</b>	Irritation might occur following direct contact with eyes.
<b>Gastrointestinal Reactions:</b>	<i>Clostridium difficile</i> associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cefadroxil monohydrate, and may range in severity from mild diarrhea to fatal colitis. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.
<b>Hypersensitivity Reactions:</b>	Before therapy with cefadroxil is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefadroxil, other cephalosporins, penicillins, or other drugs. If cefadroxil is to be given to penicillin-sensitive patients, caution should be exercised because cross-hypersensitivity 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 cefadroxil occurs, the drug should be discontinued. 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.
<b>Genetic Toxicity:</b>	Not expected to be genotoxic based on animal studies.
<b>Carcinogenicity:</b>	Not expected to be carcinogenic based on animal studies.
<b>Reproductive Effects:</b>	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.
<b>Pharmacological Effects:</b>	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.