

# MATERIAL SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

**Material** Cephalexin for Oral Suspension, USP  
125 mg/5 mL or 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  
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## 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS	Quantity
Cephalexin	23325-78-2	125 mg/5 mL or 250 mg/5 mL after reconstitution
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>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Contact</b>	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs.
<b>Eye contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention if required.
<b>Health Hazard acute &amp; Chronic</b>	This item may cause hypersensitivity (Rash, Hives) or anaphylaxis. May cause blood, liver or kidney dysfunction.

### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	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. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Safeguard the patient's airway when employing gastric emptying or charcoal. Forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion have not been established as beneficial for an overdose of cephalexin; however, it would be extremely unlikely that one of these procedures would be indicated. 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.
<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, dry chemical, carbon dioxide, foam.
<b>Special Firefighting Procedures</b>	Use a self contained breathing apparatus and full protective equipment.
<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 control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
<b>Storage</b>	Prior to mixing store at 20° to 25° C (68° to 77°F) [See USP Controlled Room Temperature]. After mixing, store in a refrigerator. Keep tightly closed.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

## 9. PHYSICAL & CHEMICAL PROPERTIES

<b>Physical Form</b>	Pink coloured powder (Granules)
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## 10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

## 11. TOXICOLOGICAL INFORMATION

<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>	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.
<b>Hypersensitivity Reactions:</b>	Allergic reaction in the form of rash, urticara, 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.
<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.