SAFETY DATA SHEET

1. IDENTIFICATION

Material	**Cephalexin for Oral Suspension USP 125 mg/5 mL and 250 mg/5 mL**
Recommended Use	Rx Pharmaceutical for human use
Manufacturer	Alkem Laboratories Ltd. Mumbai - 400013, INDIA.
Distributor	Ascend Laboratories, LLC Parsippany, NJ 07054
Contact Phone Number	201-476-1977

2. HAZARD(S) IDENTIFICATION

Fire and Explosion	Expected to be non-combustible
Health	Cephalexin is 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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Active Ingredients	**CAS**	**Quantity**
Cephalexin USP	23325-78-2	125 mg/5 mL and 250 mg/5 mL

Inactive Ingredient:	CAS Number:	Inactive Ingredient:	CAS Number:
Sucrose	57-50-1	Xanthan Gum	11138-66-2
Methyl Cellulose	9009-67-5	Colloidal Silicon Dioxide	7631-86-9
Sodium Benzoate	532-32-1	Strawberry Flavor	N/A
FDC Red	25956-17-6		

4. FIRST-AID MEASURE

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

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. 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.

OVERDOSAGE

Signs and Symptoms:
Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhea, and hematuria. If other symptoms are present, it is probably secondary to an underlying disease state, an allergic reaction, or toxicity due to ingestion of a second medication.

Treatment
To obtain up-to-date information about the treatment of overdose, a good resource is your certified Regional Poison Control Center. Telephone Numbers of certified poison control centers are listed in the Physicians' Desk Reference (PDR). In managing overdosage, consider the Possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient.
Unless 5 to 10 times the normal dose of cephalexin has been ingested, gastrointestinal decontamination should not be necessary.
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.

The oral median lethal dose of cephalexin in rats is >5,000 mg/kg.

5. FIRE-FIGHTING MEASURE

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 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 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form

On reconstitution with water, gives light pink color homogeneous suspension, having characteristic odour.

Cephalexin for Oral Suspension USP is available in:

The 125 mg per 5 mL oral suspension* is available as follows:

100-mL Bottles	NDC 67877-544-88
200-mL Bottles	NDC 67877-544-68

The 250 mg per 5 mL oral suspension* is available as follows:

100-mL Bottles	NDC 67877-545-88
200-mL Bottles	NDC 67877-545-68

* After mixing, store in a refrigerator. May be kept for 14 days without significant loss of potency.

Shake well before using. Keep tightly closed.

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility

Lifetime studies in animals have not been performed to evaluate the carcinogenic potential of cephalexin. Tests to determine the mutagenic potential of cephalexin have not been performed. In male and female rats, fertility and reproductive performance were not affected by cephalexin oral doses up to 1.5 times the highest recommended human dose based upon mg/m^2.

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

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 Poin	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

15. REGULATORY INFORMATION

This Section Contains Information relevant to compliance with other Federal and/or state laws.

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.

Alkem Or Ascend shall not be held liable for any damage resulting from handling or from contact with the above product. Alkem Or Ascend reserves the right to revise this MSDS.