SAFETY DATA SHEETS

This SDS packet was issued with item:

078948651

N/A

SAFETY DATA SHEET

ALKEM

Cefpodoxime Proxetil Tablets, USP
100 mg and 200 mg

1. IDENTIFICATION

Material	Cefpodoxime Proxetil Tablets,USP 100 mg and 200 mg
Recommended Use	Rx Pharmaceutical for human use
Manufacturer	Alkem Laboratories Ltd. Mumbai - 400013, INDIA.
Distributor	Amici Pharmaceuticals, LLC Melville, NY 11747
Emergency Phone Number	001-201-476-1977

2. HAZARD(S) IDENTIFICATION

3.1 Classification of the substance or Mixture

Classification (GHS-US)

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii)

3.2 Label Elements

No labeling is required as defined in the 29 CFR 1910.1200(b)(5)(iii)

3.3 Other Hazards

No additional information available.

3.4 Unknown Acute Toxicity (GHS-US)

No data available

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Environment

Prevent entry to sewers and public waters.

3. COMPOSITION

Ingredients	CAS No.
Cefpodoxime Proxetil USP	87239-81-4
Lactose Monohydrate (200M)	64044-51-5
Carboxymethyl Cellulose calcium	9050-04-8
Sodium Lauryl Sulfate	151-21-3
Crospovidone	9003-39-8
Colloidal Silicon Dioxide	7631-86-9
L-HPC (LH-21)	9004-64-2
Magnesium Stearate	557-04-0
Hypromellose	9004-65-3
Titanium Dioxide	13463-67-7
Polyethylene Glycol	25322-68-3
FD&C Yellow #6/sunset yellow FCF Aluminium lake	2783-94-0
FD&C Yellow #5/ Tartrazine Aluminium lake	12225-21-7
Iron oxied red	1309-37-1

4. FIRST-AID M EASURE

Ingestion Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention

Inhalation The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact	The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. 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	Limited data are available related to overdosage in humans. In acute rodent toxicity studies, a single 5 g/kg oral dose produced no adverse effects. In the event of serious toxic reaction from overdosage, hemodialysis or peritoneal dialysis may aid in the removal of cefpodoxime from the body, particularly if renal function is compromised. The toxic symptoms following an overdose of beta-lactam antibiotics may include nausea, vomiting, epigastric distress, and diarrhea.

5. FIRE-FIGHTING MEASURE

Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Unsuitable Extinguishing Media	Do not use a heavy water stream. Use of heavy stream of water may spread fire.
Special Firefighting Procedures	Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers. Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Avoid contact with skin, eyes and clothing. Avoid generating dust.
For Non-emergency Personnel: Use appropriate personal protection equipment (PPE).

Environmental Precautions

Prevent entry to sewers and public waters.

Clean-up

Clean up spills immediately and dispose of waste safely. Avoid actions that cause dust to become airborne during clean-up such as dry sweeping or using compressed air. Use HEPA vacuum or thoroughly wet with water to clean-up dust.
Use personal protection equipment (PPE).Contact competent authorities after a spill.

7. HANDLING AN D STORAGE

Handling

Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures.
Avoid contact with eyes, skin and clothing.
Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Storage conditions

Store 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

The use of personal protective equipment may be necessary as conditions warrant. Gloves. Safety glasses. Dust formation: dust mask

9. PHYSICAL AND CHEMICAL PROPERTIES

Strength	Description	Packs	NDC No
100 mg	Orange colored, oval shaped, film coated tablets debossed with "A55" on one side and plain on other side.		
		Bottles of 100	69292-514-01
		Bottles of 500	69292-514-50
200 mg	Orange colored, capsule shaped, film coated tablets debossed with "A57" on one side and plain on other side.		
		Bottles of 100	69292-516-01
		Bottles of 500	69292-516-50

10. STABILITY AND REACTIVITY

Stability Stable under recommended handling and storage conditions

Reactivity:. Hazardous reactions will not occur under normal conditions

11. TOXICOLOGICAL INFORMATION

Single dose toxicity

- In clinical trials using multiple doses of cefpodoxime proxetil filmcoated tablets, 4696 patients were treated with the recommended dosages of cefpodoxime (100 to 400 mg Q 12 hours). There were no deaths or permanent disabilities thought related to drug toxicity. One-hundred twenty-nine (2.7%) patients discontinued medication due to adverse events thought possibly or probably related to drug toxicity.

Genotoxicity

- Mutagenesis studies of cefpodoxime, including the Ames test both with and without metabolic activation, the chromosome aberration test, the unscheduled DNA synthesis assay, mitotic recombination and gene conversion,the forward gene mutation assay and the in

vivo micronucleus test, were all negative.

Carcinogenicity - Long-term animal carcinogenesis studies of cefpodoxime proxetil have not been performed

Reproduction Toxicity - No untoward effects on fertility or reproduction were noted when 100 mg/kg/day or less (2 times the human dose based on mg/m2) was administered orally to rats

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATION

Disposal Procedures - Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

IATA/ICAO - Not	: N/A
Regulated	: N/A
IATA Proper shipping Name	: N/A
IATA UN/ID No	: N/A
IATA Hazard Class	: N/A
IATA Packaging Group	
IATA Label	
IMDG - Not Regulated	: N/A
IMDG Proper shipping Name	: N/A
IMDG UN/ID No	: N/A
IMDG Hazard Class	: N/A
IMDG Flash Point	: N/A
IMDG Label	
DOT - Not Regulated	: N/A
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	

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

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.

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