

Safety Data Sheet

Cefpodoxime Proxetil Tablets 100 mg and 200 mg

SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	Cefpodoxime Proxetil Tablets 100 mg and 200 mg
Manufacturer	Orchid Healthcare (A Division of Orchid Pharma Ltd.) Plot No. B5(Part) and B6(Part), SIPCOT Industrial Park, Irungattukottai, Sriperumbudur, Kancheepuram District - 602 105, India

SECTION 2 - HAZARDS IDENTIFICATION

Label elements	May cause allergy or asthma symptoms or breathing difficulties if inhaled May cause allergic skin reaction.
Hazard(s) not otherwise classified (HNOC)	Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Strength and Label Claim		
Strength	Label claim	
100 mg	Each 248 mg of film coated tablet contains 100 mg Cefpodoxime Proxetil USP equivalent to Cefpodoxime	
200 mg	Each 496 mg of film coated tablet contains 200 mg Cefpodoxime Proxetil USP equivalent to Cefpodoxime	
Chemical Name and Composition		
Ingredients	CAS #	Quantity (% w/w)
Cefpodoxime Proxetil	87239-81-4	260.88
Non Hazardous excipients (For 200 mg Strength)	..	219.12

SECTION 4 - FIRST AID MEASURES

Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Symptoms and Effects of Exposure	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information..
Indication of immediate medical attention and special treatment needed	None

SECTION 5 - FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures	During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.
Fire / Explosion Hazards	Not applicable

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure
Measures for Cleaning / Collecting	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

SECTION 7 - HANDLING AND STORAGE

General Handling:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store as directed by product packaging.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

<p>Control Parameters Refer to available public information for specific member state Occupational Exposure Limits.</p> <p>Cefpodoxime Proxetil Zoetis OEL TWA 8-hr - 100µg/m³ Sensitizer</p> <p>Magnesium Stearate ACGIH Threshold Limit Value (TWA) 10 mg/m³</p> <p>Exposure Controls Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.</p> <p>Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).</p> <p>Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.</p> <p>Eyes: Wear safety glasses or goggles if eye contact is possible.</p> <p>Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.</p> <p>Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL</p>

SECTION 9- PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Solid
Form	Tablet
Strength	Description
100 mg	Orange coloured film coated, elliptical shaped tablets plain on one side and “522” on the other side.
200 mg	Wine red coloured film coated, elliptical shaped tablets plain on one side and “523” on the other side.
Molecular Formula	Mixture
Molecular Weight	Mixture
Odour	Not available
Odour threshold	Not available
pH	Not available
Melting point/Freezing point	Not available
Flash point	Not available
Evaporation rate	Not available
Flammability	Not available
Vapour pressure	Not available
Vapour density	Not available
Partition coefficient	Not available
Solvent Solubility	Not available
Water Solubility	Not available
Auto ignition temperature	Not available
Decomposition temperature	Not available
Polymerisation	Will not occur

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid	Not determined
Chemical stability	Material is stable under normal conditions
Incompatible materials	As a precautionary measure, keep away from strong oxidizers

SECTION 11 - TOXICOLOGICAL INFORMATION

General Information	The information included in this section describes the potential hazards of the individual ingredients.
Cefpodoxime Proxetil Mouse Oral LD 50 > 8000 mg/kg Mouse Sub-tenon injection (eye) LD 50 2535 mg/kg Mouse Subcutaneous LD 50 > 10,000 mg/kg Rat Intravenous LD 50 > 4000 mg/kg Cefpodoxime Proxetil Eye Irritation Rabbit Minimal Skin Irritation Rabbit No effect Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.	

SECTION 12 - ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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SECTION 14 - TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below. Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
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SECTION 15 - REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

Cefpodoxime Proxetil

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List Not Listed

SECTION 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.

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