

# Cefpodoxime Proxetil Tablets

Safety Data Sheet



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Version:.00

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Name:** Cefpodoxime Proxetil Tablets 100 mg and 200 mg

### 1.2. Intended Use of the Product

Cefpodoxime Proxetil Tablets are indicated for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G,  $\beta$  hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

### 1.3. Name, Address of the Responsible Party

Felix Pharmaceuticals Private Limited,  
25-28 North Wall Quay Dublin 1, Ireland

### 1.4. Emergency Telephone Number

**Emergency Number:** Contact Felix Pharmaceuticals Private Limited at 1-833-571-1525.

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. 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.). Cefpodoxime proxetil is a prodrug; its active metabolite is cefpodoxime. All doses of Cefpodoxime Proxetil Tablets are expressed in terms of the active cefpodoxime moiety. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).

### 2.2. Label Elements



### 2.3. Other Hazards

No additional information available

### 2.4. Unknown Acute Toxicity (GHS-US)

Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Ingredient Name

Cefpodoxime proxetil

### 3.2. Chemical Formula:

(+/-)-1-Hydroxyethyl(+)-(6R,7R)-7-[2-(2-amino-4-thiazolyl)glyoxylamido]-3-methoxymethyl)-8-oxo-5-thia-1-azabicyclo [4.2.0] oct-2-ene-2-carboxylate, 7<sup>2</sup>-(Z)-(O-methyloxime), isopropyl carbonate (ester).

### 3.3. Mixture

Component	Approximate Quantity	CAS number
Cefpodoxime proxetil	100/200 mg	87239-81-4
Non-hazardous Ingredients	q.s	Not Applicable

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First Aid Measures

**First-aid Measures General:** Wash contaminated clothing before reuse. Seek medical advice/attention.

**First-aid Measures After Inhalation:** If experiencing respiratory symptoms. Seek medical attention immediately.

**First-aid Measures After Skin Contact:** Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.

**First-aid Measures After Eye Contact:** Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

**First-aid Measures After Ingestion:** Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control centre. Get medical advice/attention if you feel unwell.

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## 4.2. Most important symptoms and effects, both acute and delayed

**Symptoms/Injuries After Inhalation:** May cause allergic respiratory reaction.

**Symptoms/Injuries After Skin Contact:** Mild skin irritation. May cause an allergic skin reaction.

**Symptoms/Injuries After Eye Contact:** Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort.

**Symptoms/Injuries After Ingestion:** May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhoea, nausea, and abdominal pain.

**Chronic Symptoms:** Dermatitis. Rash. Difficulty in breathing.

## 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. 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.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**Unsuitable Extinguishing Media:** Do not use water jet as an extinguisher, as this will spread the fire.

### 5.2. Special Hazards Arising from the Substance or Mixture

**Fire Hazard:** No unusual fire or explosion hazards noted.

**Explosion Hazard:** No unusual fire or explosion hazards noted.

**Reactivity:** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Special Fire Fighting Procedure:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Firefighting Instructions:** Use water spray to cool unopened containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid unnecessary contact with skin, eyes and clothing.

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Wear appropriate protective equipment and clothing during clean-up.

**Emergency Procedures:** Keep unnecessary personnel away. Ensure adequate ventilation.

#### 6.1.2. For Emergency Responders

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Local authorities should be advised if significant spillages cannot be contained.

### 6.2. Environmental Precautions

Avoid discharge into drains, water courses or onto the ground.

### 6.3. Methods and Material for Containment and Cleaning Up

**For Containment:** Never return spills in original containers for re-use.

**Methods for Cleaning Up:** Ensure adequate ventilation. Remove sources of ignition.

**Large Spills:** Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

**Small Spills:** Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

### 6.4. Reference to Other Sections

For waste disposal, see section 13 of the SDS, and for personal protection, see section 8 of the SDS.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Hygiene Measures:** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

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## 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (between 59° and 86°F) [see USP Controlled Room Temperature]. Dispense in tight, light-resistant container. Replace cap securely after each opening.

**Incompatible Products:** Strong oxidizing agents.

## 7.3. Specific End Use(s)

No data available.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

### 8.2. Exposure Controls

- |                                  |   |   |
|----------------------------------|---|---|
| Appropriate Engineering Controls | : | Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rate should be based on the following conditions.                                |
| Personal Protective Equipment    | : | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).   |
| Hand Protection                  | : | Wear impervious gloves if skin contact is possible.   |
| Eye Protection                   | : | If contact is likely, safety glasses with side shields are recommended.   |
| Skin and Body Protection         | : | Wear suitable protective clothing.  |
| Respiratory Protection           | : | No protection equipment is needed under normal use conditions. If exposure limits are exceeded, use a respirator with a protection factor sufficient to control exposure. |

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	:	Solid
Appearance	:	Red-colored, oval-shaped, film-coated, scored tablet
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Evaporation Rate	:	No data available
Melting Point	:	No data available
Freezing Point	:	No data available
Boiling Point	:	No data available
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapor Pressure	:	No data available
Relative Vapor Density at 20 °C	:	No data available
Relative Density	:	No data available
Solubility	:	No data available
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity	:	No data available

### 9.2. Other Information: No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- |  |   |   |
|--|---|---|
| 10.1. Reactivity                         | : | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| 10.2. Chemical Stability                 | : | Material is stable under normal conditions.   |
| 10.3. Possibility of Hazardous Reactions | : | No dangerous reaction known under conditions of normal use.                                   |
| 10.4. Conditions to Avoid                | : | Heat, flames and sparks. Contact with incompatible materials.                                 |
| 10.5. Incompatible Materials             | : | Strong oxidizing agents.  |

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- 10.6. Hazardous Decomposition Products** : Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. Acute Toxicity** : **Intravenous** LD50 (Rat) >4000 mg/kg  
**Oral** LD50 (Mouse) >8000 mg/kg  
**Other** LD50 (Mouse) 2535 mg/kg  
**Subcutaneous** LD50 (Mouse) >10000 mg/kg
- 11.2. Local Effects** : Not Classified
- 11.3. Reproductive Effects** : Not Classified
- 11.4. Mutagenicity** : Not Classified

## SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Toxicity** : Avoid release to the environment. The product is not classified as environmentally hazardous.
- 12.2. Persistence and Degradability** : No additional information available.
- 12.3. Bio accumulative Potential** : No additional information available
- 12.4. Mobility in Soil** : No additional information available
- 12.5. Other Adverse Effects** : No other adverse environmental effects

## SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods**
- Waste Disposal Recommendations** : Dispose of waste material in accordance with all local, regional, national, and international regulations.

## SECTION 14: TRANSPORT INFORMATION

- 14.1.** Transport according to all local, state and federal regulation

## SECTION 15: REGULATORY INFORMATION

- 15.1.** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

- 16.1. Previous Version** : **Effective Date**  
Nil : Nil

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. To the best of Felix's knowledge, the information contained here is accurate. However, neither the above-named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All material may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist