



# MATERIAL SAFETY DATA SHEET

Revision date: 26-Jul-2013

Version: 1.3

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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

|                         |   |
|-------------------------|---|
| <b>Trade Name:</b>      | VANTIN  |
| <b>Chemical Family:</b> | Mixture   |
| <b>Intended Use:</b>    | Pharmaceutical product used as antibiotic agent |

## 2. HAZARDS IDENTIFICATION

**Appearance:** Orange tablets or Red tablets  
**Signal Word:** DANGER

**Statement of Hazard:** May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.  
May cause allergic skin reaction.

**Additional Hazard Information:**  
**Short Term:** 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. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may occur.

**Known Clinical Effects:**

**EU Indication of danger:** Harmful

**EU Hazard Symbols:**  
Xn



**EU Risk Phrases:**

R42/43 - May cause sensitization by inhalation and skin contact.  
Hazardous Substance. Non-Dangerous Goods.

**Australian Hazard Classification (NOHSC):**

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## 2. HAZARDS IDENTIFICATION

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

| Ingredient            | CAS Number | EU EINECS/ELINCS List | EU Classification | %                |
|-----------------------|------------|-----------------------|-------------------|------------------|
| Cefpodoxime Proxetil  | 87239-81-4 | Not Listed            | Xn;R42/43         | 100 or 200 mg*** |
| Sodium Lauryl Sulfate | 151-21-3   | 205-788-1             | Not Listed        | *                |
| Magnesium Stearate    | 557-04-0   | 209-150-3             | Not Listed        | *                |
| Titanium dioxide      | 13463-67-7 | 236-675-5             | Not Listed        | *                |

| Ingredient                         | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|------------------------------------|------------|-----------------------|-------------------|---|
| Carboxy methylcellulose calcium    | 9050-04-8  | Not Listed            | Not Listed        | * |
| Hydroxypropyl cellulose            | 9004-64-2  | Not Listed            | Not Listed        | * |
| Lactose Monohydrate                | 64044-51-5 | Not Listed            | Not Listed        | * |
| FD & C Red No. 40                  | 25956-17-6 | 247-368-0             | Not Listed        | * |
| Carnauba wax                       | 8015-86-9  | 232-399-4             | Not Listed        | * |
| D & C yellow No. 10                | 8004-92-0  | Not Listed            | Not Listed        | * |
| FD&C Yellow No. 6; (Sunset yellow) | 2783-94-0  | 220-491-7             | Not Listed        | * |
| Propylene glycol                   | 57-55-6    | 200-338-0             | Not Listed        | * |
| Hydroxypropyl methylcellulose      | 9004-65-3  | Not Listed            | Not Listed        | * |

### Additional Information:

\* Proprietary

\*\*\* per tablet/capsule/lozenge/suppository

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

## 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**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.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**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.

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### 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

### 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.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 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.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

|                             |  |
|-----------------------------|--|
| <b>Cefpodoxime Proxetil</b> |  |
| Pfizer OEL TWA-8 Hr:        | 100µg/m <sup>3</sup> , Sensitizer                        |
| <b>Propylene glycol</b>     |  |
| Australia TWA               | 150 ppm<br>474 mg/m <sup>3</sup><br>10 mg/m <sup>3</sup> |
| Ireland OEL - TWAs          | 150 ppm<br>470 mg/m <sup>3</sup><br>10 mg/m <sup>3</sup> |
| Latvia OEL - TWA            | 7 mg/m <sup>3</sup>                                      |
| Lithuania OEL - TWA         | 7 mg/m <sup>3</sup>                                      |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Magnesium Stearate

|                                   |                      |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m <sup>3</sup> |
| Lithuania OEL - TWA               | 5 mg/m <sup>3</sup>  |
| Sweden OEL - TWAs                 | 5 mg/m <sup>3</sup>  |

#### Titanium dioxide

|                                   |                        |
|-----------------------------------|------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m <sup>3</sup>   |
| Australia TWA                     | 10 mg/m <sup>3</sup>   |
| Austria OEL - MAKs                | 5 mg/m <sup>3</sup>    |
| Belgium OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                | 10.0 mg/m <sup>3</sup> |
| Denmark OEL - TWA                 | 6 mg/m <sup>3</sup>    |
| Estonia OEL - TWA                 | 5 mg/m <sup>3</sup>    |
| France OEL - TWA                  | 10 mg/m <sup>3</sup>   |
| Greece OEL - TWA                  | 10 mg/m <sup>3</sup>   |
|                                   | 5 mg/m <sup>3</sup>    |
| Ireland OEL - TWAs                | 10 mg/m <sup>3</sup>   |
|                                   | 4 mg/m <sup>3</sup>    |
| Latvia OEL - TWA                  | 10 mg/m <sup>3</sup>   |
| Lithuania OEL - TWA               | 5 mg/m <sup>3</sup>    |
| OSHA - Final PELs - TWAs:         | 15 mg/m <sup>3</sup>   |
| Poland OEL - TWA                  | 10.0 mg/m <sup>3</sup> |
| Portugal OEL - TWA                | 10 mg/m <sup>3</sup>   |
| Romania OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| Spain OEL - TWA                   | 10 mg/m <sup>3</sup>   |
| Sweden OEL - TWAs                 | 5 mg/m <sup>3</sup>    |

#### 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. Keep airborne contamination levels below the exposure limits listed above in this section.

#### Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

#### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

#### Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

#### Eyes:

Wear safety glasses or goggles if eye contact is possible.

#### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

#### 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Tablets

#### Color:

Orange or Red

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Polymerization:

Will not occur

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### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Not determined  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Propylene glycol**

Mouse Oral LD50 22,000 mg/kg  
Rat Oral LD50 20,000 mg/kg  
Rabbit Dermal LD50 20,800 mg/kg

##### **FD&C Yellow No. 6; (Sunset yellow)**

Rat Oral LD50 > 10,000 mg/kg  
Mouse Oral LD50 > 6,000 mg/kg

##### **Lactose Monohydrate**

Rat Oral LD 50 29700 mg/kg

##### **D & C yellow No. 10**

Rat Oral LD50 2000 mg/kg

##### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD50 50 mg/kg

##### **Sodium Lauryl Sulfate**

Rat Oral LD 50 1288 mg/kg  
Rat Sub-tenon injection (eye) LD 50 210 mg/kg

##### **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

##### **Hydroxypropyl methylcellulose**

Rat Oral LD50 > 10,000 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Propylene glycol**

Skin Irritation Rabbit Mild

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### 11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Mild

#### Cefpodoxime Proxetil

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit No effect

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Sodium Lauryl Sulfate

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

##### Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Cefpodoxime Proxetil

Reproductive & Fertility Rat Oral > 500 mg/kg/day NOAEL Fertility  
Reproductive & Fertility Rabbit Oral > 500 mg/kg/day NOAEL Fertility  
Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity  
Embryo / Fetal Development Rabbit Oral 30 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Lactose Monohydrate

*In Vitro* Bacterial Mutagenicity (Ames) Negative

##### Cefpodoxime Proxetil

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Chromosome Aberration Negative  
Unscheduled DNA Synthesis Negative  
*In Vivo* Micronucleus Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below :

#### FD&C Yellow No. 6; (Sunset yellow)

IARC: Group 3 (Not Classifiable)

#### Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)  
OSHA: Listed

### 12. ECOLOGICAL INFORMATION

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

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### 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.

### 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.

### 15. REGULATORY INFORMATION

**EU Symbol:** Xn  
**EU Indication of danger:** Harmful

**EU Risk Phrases:**  
R42/43 - May cause sensitization by inhalation and skin contact.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
S24 - Avoid contact with skin.  
S37 - Wear suitable gloves.

**OSHA Label:**  
DANGER  
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.  
May cause allergic skin reaction.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A  
Class D, Division 2, Subdivision B



Cefpodoxime Proxetil

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### 15. REGULATORY INFORMATION

|   |            |
|---|------------|
| California Proposition 65                                     | Not Listed |
| <b>Carboxy methylcellulose calcium</b>                        |            |
| California Proposition 65                                     | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                   | Present    |
| Australia (AICS):   | Present    |
| <b>Hydroxypropyl cellulose</b>                                |            |
| California Proposition 65                                     | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                   | Present    |
| Australia (AICS):   | Present    |
| <b>Sodium Lauryl Sulfate</b>                                  |            |
| California Proposition 65                                     | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                   | Present    |
| Australia (AICS):   | Present    |
| Standard for the Uniform Scheduling<br>for Drugs and Poisons: | Schedule 6 |
| EU EINECS/ELINCS List   | 205-788-1  |
| <b>Lactose Monohydrate</b>                                    |            |
| California Proposition 65                                     | Not Listed |
| Australia (AICS):   | Present    |
| <b>FD &amp; C Red No. 40</b>                                  |            |
| California Proposition 65                                     | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                   | Present    |
| Australia (AICS):   | Present    |
| EU EINECS/ELINCS List   | 247-368-0  |
| <b>Carnauba wax</b>   |            |
| California Proposition 65                                     | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                   | Present    |
| Australia (AICS):   | Present    |
| EU EINECS/ELINCS List   | 232-399-4  |
| <b>D &amp; C yellow No. 10</b>                                |            |
| California Proposition 65                                     | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                   | Present    |
| Australia (AICS):   | Present    |
| <b>FD&amp;C Yellow No. 6; (Sunset yellow)</b>                 |            |
| California Proposition 65                                     | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                   | Present    |
| Australia (AICS):   | Present    |
| EU EINECS/ELINCS List   | 220-491-7  |
| <b>Propylene glycol</b>                                       |            |
| California Proposition 65                                     | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                   | Present    |
| Australia (AICS):   | Present    |
| EU EINECS/ELINCS List   | 200-338-0  |



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## 15. REGULATORY INFORMATION

### Hydroxypropyl methylcellulose

|  |            |
|--|------------|
| California Proposition 65                                  | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                | Present    |
| Australia (AICS):  | Present    |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4 |

### Magnesium Stearate

|   |            |
|---|------------|
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| EU EINECS/ELINCS List                       | 209-150-3  |

### Titanium dioxide

|   |   |
|---|---|
| California Proposition 65                   | carcinogen initial date 9/2/11 airborne, unbound particles of respirable size |
| Inventory - United States TSCA - Sect. 8(b) | Present   |
| Australia (AICS):                           | Present   |
| EU EINECS/ELINCS List                       | 236-675-5   |

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R42/43 - May cause sensitization by inhalation and skin contact.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**