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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Cefpodoxime Proxetil Tablets 100 mg and 200 mg

Trade Name: VANTIN  
Chemical Family: Mixture  
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefpodoxime Proxetil</td>
<td>87239-81-4</td>
<td>Not listed</td>
<td>100 or 200 mg***</td>
</tr>
<tr>
<td>Sodium Lauryl Sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>*</td>
</tr>
<tr>
<td>Carboxy methylcellulose calcium</td>
<td>9050-04-6</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Red No. 40</td>
<td>25956-17-6</td>
<td>247-368-0</td>
<td>*</td>
</tr>
<tr>
<td>D &amp; C yellow No. 10</td>
<td>8004-92-0</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Yellow No. 6; (Sunset yellow)</td>
<td>2783-94-0</td>
<td>220-491-7</td>
<td>*</td>
</tr>
<tr>
<td>Carnauba wax</td>
<td>8015-86-9</td>
<td>232-399-4</td>
<td>*</td>
</tr>
<tr>
<td>Hypromellose</td>
<td>9004-65-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:  * Proprietary  
*** per tablet/capsule/lozenge/suppository  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Orange tablets or Red tablets

Signal Word: WARNING

Statement of Hazard: May cause sensitization by inhalation and skin contact

Additional Hazard Information:
Material Name: Cefpodoxime Proxetil Tablets 100 mg and 200 mg
Revision date: 02-Jan-2007
Version: 1.1

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.

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Avoid generating airborne dust. Wash thoroughly after handling.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Cefpodoxime Proxetil
Pfizer OEL TWA-8 Hr: 0.1mg/m³, Sensitizer

Propylene glycol
Australia TWA 10 mg/m³ TWA
   = 150 ppm TWA
   = 474 mg/m³ TWA

Magnesium Stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA except stearates of toxic metals
Australia TWA 10 mg/m³ TWA

Titanium dioxide
OSHA - Final PELS - TWAs: 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

   Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
   Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
   Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
   Respiratory protection: Not required for the normal use of this product. 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
Molecular Formula: Mixture
Color: Orange or Red
Molecular Weight: Mixture
10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: Not determined
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Polymerization: Will not occur

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 LD50 29700 mg/kg

D & C yellow No. 10
Rat Oral LD50 2000 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Sodium Lauryl Sulfate
Rat Oral LD 50 1288 mg/kg
Rat Intraperitoneal LD 50 210 mg/kg

Cefpodoxime Proxetil
Mouse Oral LD 50 > 8000 mg/kg
Mouse Intraperitoneal LD 50 2535 mg/kg
Mouse Subcutaneous LD 50 > 10,000 mg/kg
Rat Intravenous LD 50 > 4000 mg/kg

Hypromellose
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
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)**

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

Carcinogen Status:  See below

**FD&C Yellow No. 6; (Sunset yellow)**
**IARC:**  Group 3

**Titanium dioxide**
**IARC:**  Group 2B
**OSHA:**  Present

### 12. ECOLOGICAL INFORMATION

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

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.
14. TRANSPORT INFORMATION
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: WARNING
May cause sensitization by inhalation and skin contact

Canada - WHMIS: Classifications

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

Carboxy methylcellulose calcium
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Hydroxypropyl cellulose
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Sodium Lauryl Sulfate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 205-788-1

Lactose Monohydrate
Australia (AICS): Present

Propylene glycol
MATERIAL SAFETY DATA SHEET

Material Name: Cefpodoxime Proxetil Tablets 100 mg and 200 mg

Revision date: 02-Jan-2007

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Version: 1.1

16. OTHER INFORMATION

Reasons for Revision:
Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

Prepared by:
Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet