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

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

Pfizer Ltd
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Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
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Material Name: Cefpodoxime Proxetil Oral Suspension

Trade Name: Vantin (R) Oral Suspension
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
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<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>*</td>
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<tr>
<td>Cefpodoxime Proxetil</td>
<td>87239-81-4</td>
<td>Not listed</td>
<td>1-2</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
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<tr>
<td>Propylene glycol alginate</td>
<td>9005-37-2</td>
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<td>*</td>
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<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td>*</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</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>Hydrogenated vegetable oil</td>
<td>68334-00-9</td>
<td>269-804-9</td>
<td>*</td>
</tr>
<tr>
<td>Maltodextrin</td>
<td>9050-36-6</td>
<td>232-940-4</td>
<td>*</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Butylated hydroxyanisole</td>
<td>25013-16-5</td>
<td>246-563-8</td>
<td>*</td>
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<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
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<tr>
<td>Flavoring agents</td>
<td>Not assigned</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium Citrate, Anhydrous</td>
<td>6132-04-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Carrageenan</td>
<td>9000-07-1</td>
<td>232-524-2</td>
<td>*</td>
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</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White to off-white powder
Signal Word: WARNING
Statement of Hazard: May cause sensitization by inhalation and skin contact

Additional Hazard Information:

Short Term: The active ingredient is not acutely toxic. Not expected to cause skin irritation. 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.

Known Clinical Effects: Hypersensitivity reactions may also occur in susceptible individuals. Serious allergic reactions, including anaphylaxis, have been reported. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

EU Indication of danger: Xn - Harmful

EU Hazard Symbols: [Image]

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

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.

4. FIRST AID MEASURES

Eye Contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing. If irritation occurs or persists, get 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: Emits toxic fumes of carbon monoxide, carbon dioxide and oxides of nitrogen.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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: Avoid contact with eyes, skin and clothing. Avoid breathing dust. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sucrose

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

Microcrystalline cellulose

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

Starch

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

Colloidal silicon dioxide

- OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO2) mg/m³ TWA = 20 mppcf TWA
- Australia TWA = 2 mg/m³ TWA

Cefpodoxime Proxetil

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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. In dusty conditions use an approved dust mask or more protection as needed.

9. PHYSICAL AND CHEMICAL PROPERTIES:

| Physical State: | Powder |
| Solubility: | Soluble: Water |

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
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)

Cefpodoxime Proxetil
- Mouse Oral LD50 > 8000 mg/kg
- Mouse Intraperitoneal LD50 2535 mg/kg
- Mouse Subcutaneous LD50 > 10,000 mg/kg
- Rat Oral LD50 > 4000 mg/kg
- Rat Intravenous LD50 > 4000 mg/kg

Sucrose
- Rat Oral LD50 29.7 g/kg

Butylated hydroxyanisole
- Rat Oral LD50 2000 mg/kg
- Mouse Oral LD50 1100 mg/kg
- Rat Intraperitoneal LD50 881 mg/kg

Carboxymethylcellulose sodium
- Mouse Oral LD50 > 27,000 mg/kg
- Rat Oral LD50 27,000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

Microcrystalline cellulose
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

Citric acid
- Rat Oral LD50 3000 mg/kg

Lactose
- Rat Oral LD50 > 10 g/kg
Sodium benzoate
Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600 mg/kg

Starch
Mouse IP LD50 6600 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)
Cefpodoxime Proxetil
Eye Irritation Rabbit Minimal
Skin Irritation Rabbit No effect

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Citric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

Butylated hydroxyanisole
12 Day(s) Rat Oral 3300 mg/kg LOAEL Liver, Blood

Carboxymethylcellulose sodium
13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

Sodium benzoate
10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

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

Butylated hydroxyanisole
Embryo / Fetal Development Rat Oral 30 g/kg LOEL Teratogenic

Sodium benzoate
Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

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

Cefpodoxime Proxetil
Bacterial Mutagenicity (Ames) Salmonella Negative
Chromosome Aberration Negative
Unscheduled DNA Synthesis Negative
Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Butylated hydroxyanisole**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>728 g/kg/day</td>
<td>Gastrointestinal system, Tumors</td>
<td></td>
</tr>
<tr>
<td>Two Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>874 g/kg/day</td>
<td>Gastrointestinal system, Endocrine system, Tumors</td>
<td></td>
</tr>
</tbody>
</table>

Carcinogen Status: See below

**Butylated hydroxyanisole**

- IARC: Group 2B
- NTP: Reasonably Anticipated To Be A Carcinogen
- OSHA: Present

**Carrageenan**

- IARC: Group 2B (Carrageenan, degraded)
- OSHA: Present

**In Vitro**

- Bacterial Mutagenicity (Ames): Salmonella Negative

**Colloidal silicon dioxide**

- IARC: Group 3

### 12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been 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 Indication of danger:** Xn - 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

Sucrose
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 200-334-9

Propylene glycol alginate
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Lactose
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 200-559-2

Citric acid
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 201-069-1

Microcrystalline cellulose
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS List 232-674-9

Sodium benzoate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 208-534-8

Starch
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS List 232-679-6
16. OTHER INFORMATION

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet