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
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Omnicef Powder for Oral Suspension

Trade Name: OMNICEF®
Chemical Family: Cephalosporin antibiotic
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Cream/yellow powder
Signal Word: WARNING

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

Additional Hazard Information:
Short Term: If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects:
The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. 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. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

EU Indication of danger: Harmful

EU Hazard Symbols: Xn

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

2. HAZARDS IDENTIFICATION

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11. This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefdinir</td>
<td>91832-40-5</td>
<td>Not listed</td>
<td>Xn;R42/43</td>
<td>4-8</td>
</tr>
<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Xanthan gum</td>
<td>11138-66-2</td>
<td>234-394-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Guar gum</td>
<td>9000-30-0</td>
<td>232-536-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Citric acid, anhydrous</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium citrate</td>
<td>68-04-2</td>
<td>200-675-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Flavoring agents</td>
<td>Not assigned</td>
<td>Not listed</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.

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.

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: 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: Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

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.

Silicon dioxide, NF

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>2 mg/m³ TWA</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>Listed</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>4 mg/m³ TWA</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>4 mg/m³ MAK</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>2.4 mg/m³ TWA</td>
</tr>
<tr>
<td></td>
<td>6 mg/m³ TWA</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf TWA</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>Listed</td>
</tr>
</tbody>
</table>

Magnesium stearate

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

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³ LLV</td>
</tr>
</tbody>
</table>

Sucrose

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>OSHA - Final PELs - TWAs:</td>
<td>15 mg/m³ TWA total</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³ TWA</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>Listed</td>
</tr>
</tbody>
</table>

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

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.

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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Powder</th>
<th>Color:</th>
<th>Cream/yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

- **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)**
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)

Citric acid, anhydrous
- Eye Irritation: Rabbit, Severe
- Skin Irritation: Rabbit, Mild

Cefdinir
- Eye Irritation: Rabbit, Non-irritating
- Skin Irritation: Rabbit, Minimal
- Antigenicity: Active anaphylaxis: Guinea Pig, Negative

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

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

Cefdinir
- 26 Week(s), Rat, Oral: NOAEL 800 mg/kg/day Gastrointestinal System
- 26 Week(s), Dog, Oral: NOAEL None identified

PD012
Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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

Cefdinir
Reproductive & Fertility  Rat  Oral  1000 mg/kg/day  LOEL  Maternal toxicity
Embryo / Fetal Development  Rat  Oral  100 mg/kg/day  LOEL  Maternal Toxicity, Fetotoxicity, Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  10 mg/kg/day  LOEL  Maternal Toxicity, Not Teratogenic
Peri-/Postnatal Development  Rat  Oral  32 mg/kg/day  LOEL  Maternal Toxicity, Developmental toxicity

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

Cefdinir
Bacterial Mutagenicity (Ames)  Salmonella , E. coli  Negative
Chromosome Aberration  Negative
In Vivo Micronucleus  Mouse  Negative

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

Silicon dioxide, NF
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:  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

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.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
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

Silicon dioxide, NF
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 231-545-4
EEC No. 418-260-2

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

Xanthan gum
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS/ELINCS List 234-394-2

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

Guar gum
Inventory - United States TSCA - Sect. 8(b) XU
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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

Data Sources:
Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision:
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

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

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