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

Pfizer Inc
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Cefdinir Capsules

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

2. HAZARDS IDENTIFICATION

Appearance: Red and blue capsules
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<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>300 mg***</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>EEC No. 418-260-2</td>
<td>*</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>
<td></td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>D&amp;C red #28</td>
<td>18472-87-21</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>PEG-40 Stearate</td>
<td>9004-99-3</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>FD &amp; C Red No. 40</td>
<td>25956-17-6</td>
<td>247-368-0</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Sodium Lauryl Sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>FD &amp; C Blue No. 1</td>
<td>3844-45-9</td>
<td>223-339-8</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Carboxy methylcellulose calcium</td>
<td>9050-04-8</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</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: 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).

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Titanium dioxide

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Austria OEL - MAKs Listed
Belgium OEL - TWA Listed
Bulgaria OEL - TWA Listed
Denmark OEL - TWA Listed
Estonia OEL - TWA Listed
France OEL - TWA Listed
Germany (DFG) - MAK = 1.5 mg/m³ MAK
Greece OEL - TWA Listed
Ireland OEL - TWA = 10 mg/m³ TWA
= 4 mg/m³ TWA
Latvia OEL - TWA Listed
Lithuania OEL - TWA Listed
Netherlands OEL - TWA Listed
OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
Poland OEL - TWA Listed
Portugal OEL - TWA Listed
Romania OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs = 5 mg/m³ LLV

Silicon dioxide, NF

Australia TWA = 2 mg/m³ TWA
Austria OEL - MAKs Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Germany - TRGS 900 - TWAs = 4 mg/m³ TWA
Germany (DFG) - MAK = 4 mg/m³ MAK
Ireland OEL - TWAs = 2.4 mg/m³ TWA
= 6 mg/m³ TWA
Latvia OEL - TWA Listed
OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO2) mg/m³ TWA
= 20 mppcf TWA
Slovenia OEL - TWA Listed

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA Listed
Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
Lithuania OEL - TWA Listed
Portugal OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs = 5 mg/m³ LLV

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:

| Physical State: | Capsule |
| Color: | Red and blue |

| Molecular Formula: | Mixture |
| Molecular Weight: | Mixture |

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)
MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Sodium Lauryl Sulfate
Rat Oral LD50 1288 mg/kg
Rat Intraperitoneal LD50 210 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Silicon dioxide, NF
Rat Oral LD50 10 g/kg

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

PEG-40 Stearate
Rat Oral LD50 > 20,000 mg/kg

Cefdinir
Dog Oral LD50 > 3200 mg/kg
Mouse Oral LD50 > 5600 mg/kg
Rat Oral LD50 > 5600 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)

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

Cefdinir
26 Week(s) Rat Oral 320 mg/kg/day LOAEL Gastrointestinal System
26 Week(s) Dog Oral 800 mg/kg/day NOAEL None identified

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

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.

FD & C Blue No. 1
IARC: Group 3 (Not Classifiable)

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

Titanium dioxide
IARC: Group 2B (Possibly Carcinogenic to Humans)
OSHA: Present

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

Gelatin
  Inventory - United States TSCA - Sect. 8(b) XU
  Australia (AICS): Present
  EU EINECS/ELINCS List 232-554-6

PEG-40 Stearate
  Inventory - United States TSCA - Sect. 8(b) XU
  Australia (AICS): Present

FD & C Red No. 40
  Inventory - United States TSCA - Sect. 8(b) Present
  Australia (AICS): Present
  EU EINECS/ELINCS List 247-368-0

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

Titanium dioxide
  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.

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