SAFETY DATA SHEET

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

Product Identifier

Material Name: Cefuroxime for Injection (Hospira, Inc.)

Trade Name: Not applicable

Chemical Family: Cephalosporin antibiotic

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger

Hazard Statements:
H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
May form combustible dust concentrations in air
Precautionary Statements:  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P272 - Contaminated work clothing must not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P285 - In case of inadequate ventilation wear respiratory protection  
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing  
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician  
P363 - Wash contaminated clothing before reuse  
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards  
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefuroxime axetil</td>
<td>64544-07-6</td>
<td>Not Listed</td>
<td>Resp. Sens. 1 (H334) Skin Sens. 1 (H317)</td>
<td>100</td>
</tr>
</tbody>
</table>

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

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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.

Most Important Symptoms and Effects, Both Acute and Delayed
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.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

Advice for Fire-Fighters
Wear approved positive pressure, self-contained breathing apparatus and full protective turnout gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
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.

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

Precautions for Safe Handling
Minimize dust generation and accumulation. Avoid breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Cefuroxime axetil

Pfizer Occupational Exposure Band (OEB):

OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

Exposure Controls

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Powder
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value) Cefuroxime axetil

Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available

Color: White to off-white
Odor Threshold: No data available.
Molecular Weight: Mixture

Material Name: Cefuroxime for Injection (Hospira, Inc.)
Revision date: 22-Mar-2017
Version: 1.0
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10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  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
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

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

Short Term: Inhalation of significant quantities of this substance could result in the health effects described in 'Known clinical effects'. Ingestion of this material can cause effects similar to those seen in clinical use including cholinergic crisis, characterized by severe nausea, vomiting, salivation, sweating, slow heart rate, low blood pressure, muscle weakness, respiratory depression.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Concomitant administration of aminoglycosides and cephalosporins has caused nephrotoxicity. 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.

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

Cefuroxime axetil
  Rat Oral LD50 > 10 g/kg
  Rat Sub-tenon injection (eye) LD50 950mg/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)

Cefuroxime axetil
  Eye Irritation Rabbit Slight
  Skin Irritation / Sensitization Hypersensitivity reactions, including cross reactions (with penicillins) and anaphylaxis, are common among the cephalosporins.
### 11. TOXICOLOGICAL INFORMATION

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefuroxime axetil</td>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>No route specified</td>
<td>1000 mg/kg/day</td>
<td>NOAEL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Reproductive &amp; Fertility</td>
<td>Mouse</td>
<td>No route specified</td>
<td>3200 mg/kg/day</td>
<td>NOAEL</td>
<td>Negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Study Type</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefuroxime axetil</td>
<td>In Vitro</td>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Not specified</td>
</tr>
<tr>
<td></td>
<td>In Vitro</td>
<td>Chromosome Aberration</td>
<td>Not specified</td>
</tr>
<tr>
<td></td>
<td>In Vivo</td>
<td>Micronucleus</td>
<td>Not specified</td>
</tr>
</tbody>
</table>

#### Carcinogen Status:

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

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

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

#### Toxicity:

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Daphnia magna</em> (Water Flea)</td>
<td>EC50</td>
<td>48 Hours</td>
<td>&gt; 1000 mg/L</td>
<td></td>
</tr>
<tr>
<td><em>Oncorhynchus mykiss</em> (Rainbow Trout)</td>
<td>EC50</td>
<td>96 Hours</td>
<td>&gt; 120 mg/L</td>
<td></td>
</tr>
<tr>
<td><em>Selenastrum capricornutum</em> (Green Alga)</td>
<td>IC50</td>
<td>72 Hours</td>
<td>&gt; 91 mg/L</td>
<td></td>
</tr>
<tr>
<td>Activated sludge</td>
<td>OECD IC50</td>
<td>3 Hours</td>
<td>&gt; 100 mg/L</td>
<td></td>
</tr>
</tbody>
</table>

#### Persistence and Degradability:

No data available

#### Bio-accumulative Potential:

No data available

#### Mobility in Soil:

No data available

### 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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Cefuroxime axetil

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Data Sources: Publicly available toxicity information.

Reasons for Revision: New data sheet.

Revision date: 22-Mar-2017


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