SECTION 1. PRODUCT AND COMPANY INFORMATION

Product Name: Ceftriaxone for Injection, USP
Supplier: West-Ward Injectables Inc.
200 Industrial Way West,
Eatontown, NJ 07724
Phone (732 542 1191)
Fax (732 720 6220)

Technical Phone: (800 631 2174)

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

CAS Number Description Amount
104376-79-6 Ceftriaxone Sodium 250mg, 500mg, 1g, 2g, 10g vials

Category: Anti-Infective

SECTION 3. HAZARDS IDENTIFICATION, EMERGENCY OVERVIEW

Route of Entry: Inhalation, eye/skin contact, or ingestion

Chemical List as
Carcinogen:
    NTP: No
    IARC: No
    OSHA: No

Note: May cause hypersensitivity reactions to individuals sensitive to cephalosporins, penicillins, or other drugs.

SECTION 4. FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention

Skin: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Seek medical attention as needed.

Inhalation: Move exposed subject to fresh air immediately. Give artificial and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

Ingestion: Flush mouth with water immediately. Seek medical attention
SECTION 5. FIRE AND EXPLOSION DATA

Fire and explosion Data

- Closed Cup Flash Point: N/A
- Open Cup Flash Point: N/A
- Fire Point: N/A
- Autoignition: N/A
- Lower Explosion Limit: N/A
- General Hazard: When heated to decomposition it emits very toxic fumes of NO\textsubscript{x} and SO\textsubscript{x}.

Fire Fighting Instructions: Wear self-containing breathing apparatus and protective clothing.

Hazardous Combustion Products: Toxic and corrosive fumes of NO\textsubscript{x} and SO\textsubscript{x}.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Clean Up: Wear recommended personal protective equipment. Use appropriate absorbent material to clean affected area. Wipe area with soap and water. Dispose of materials according to the applicable federal, state and/or local regulations.

SECTION 7. HANDLING AND STORAGE

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with product.

Storage Conditions: Store at controlled room temperature 20\textdegree{} - 25\textdegree{}C (68\textdegree{} - 77\textdegree{}F). Protect from light and excessive heat. [see USP Controlled Room Temperature].

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: General room ventilation is usually satisfactory. Use Local exhaust ventilation if necessary.

Personal Protective Equipment

- Eye protection: Safety glasses or goggles recommended.
- Hand protection: Latex rubber gloves recommended.
- Respiratory Protection: With satisfactory ventilation, respirators are not required.
- Skin Protection: Disposable garments if direct skin contact is anticipated.

Exposure Limits:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Sodium</td>
<td>OSHA</td>
<td>PEL</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td>TLV</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>0.06 mg/m\textsuperscript{3} (4 x 30 min)</td>
</tr>
</tbody>
</table>
SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Form/ Appearance</td>
<td>White to yellowish-orange crystalline powder.</td>
</tr>
<tr>
<td>Boiling Point/ Boiling Range</td>
<td>N/A</td>
</tr>
<tr>
<td>Melting Point/ Melting Range</td>
<td>&gt; 155°C with decomposition.</td>
</tr>
<tr>
<td>Freezing Point</td>
<td>N/A</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>N/A</td>
</tr>
<tr>
<td>Relative Vapor Density</td>
<td>N/A</td>
</tr>
<tr>
<td>Percent Volatiles</td>
<td>N/A</td>
</tr>
<tr>
<td>pH</td>
<td>6.7 in 1% aqueous solution</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>661.59</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>470,000 mg/L in water (22°C)</td>
</tr>
<tr>
<td></td>
<td>32,000 mg/L in methanol (22°C)</td>
</tr>
<tr>
<td></td>
<td>200 mg/L in acetone (22°C)</td>
</tr>
</tbody>
</table>

SECTION 10. STABILITY AND REACTIVITY DATA.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability</td>
<td>Stable</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Avoid storage next to strong oxiders. Conserve in containers hermetically closed as foresee from USP.</td>
</tr>
<tr>
<td>Hazardous Polymerization</td>
<td>Will not occur</td>
</tr>
</tbody>
</table>

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Sodium</td>
<td>LD50</td>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 10,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50</td>
<td>Oral</td>
<td>Mouse</td>
<td>&gt; 10,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50</td>
<td>IV</td>
<td>Several</td>
<td>&gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

Other:

IMMEDIATE EFFECTS:
Eye, skin, mucous membrane and respiratory irritation may occur.

DELAYED EFFECTS:
Hypersensitivity reactions ranging from mild to life-threatening may occur in individuals allergic to the cephalosporin and penicillin groups.

Not mutagenic (OECD No. 474 Micronucleus Test)
Not mutagenic (Ames Test)

SECTION 12. ECOLOGICAL INFORMATION

Information is currently not available on the environmental impact of Ceftriaxone. Handle in a manner to prevent spills or releases to the environment.

SECTION 13. DISPOSAL CONSIDERATIONS

Dispose of by incineration at an approved / permitted incinerator. Review local, state, and federal regulations for your regulatory area.
SECTION 14. TRANSPORT INFORMATION

UN/NA Number:  N/A
US DOT Hazard Class:  N/A
Proper Shipping Name:  N/A
Shipping Label:  N/A

SECTION 15. REGULATORY INFORMATION

U.S. Regulatory Information:  not regulated.

SECTION 16. OTHER INFORMATION

This documented has been generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. We do not assume any responsibility and expressly disclaim any liability for any loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.