1. PRODUCT AND COMPANY IDENTIFICATION

- **Product Name**: Omegacin Injectable
- **Common Name**: Not available
- **Chemical Name**: Not applicable
- **Synonyms**: Biapenem, CL-186815, L-627, LJC-10627
- **Product Use**: Pharmaceutical product
- **Classification**: Beta-lactam Antibiotic
- **Supplier**: Wyeth
  
P.O. Box 8299
  Philadelphia, PA 19101 USA.
  Telephone: 1-610-688-4400

**Emergency Telephone Number**

Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

**Emergency Overview**

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Physical State</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical powder</td>
<td>Solid</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**Potential Physical Hazards**

Powders and solids are presumed to be combustible.

**Potential Health Effects**

<table>
<thead>
<tr>
<th>Eyes</th>
<th>May cause eye irritation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>May cause skin irritation.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>May cause irritation of respiratory tract.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Not available</td>
</tr>
<tr>
<td>Other</td>
<td>Hypersensitivity (anaphylactic/anaphylactoid) reactions (including shock) have been reported in patients receiving therapy with penicillins. Individuals with a history of penicillin hypersensitivity or a history of sensitivity to multiple allergens should avoid contact. The most common effects may include pseudomembranous colitis, bleeding disorders, neuromuscular excitability, convulsions, joint pain, fever, hives or itching, liver toxicity, inflammation of the kidney, skin rash, decrease in the number of white blood cells, mental disturbances, and seizures.</td>
</tr>
</tbody>
</table>

May cause harm to breastfed babies.

**Therapeutic Target Organ(s)**

None.

Not listed by OSHA, NTP or IARC.

**Potential Environmental Effects**

There is no known ecological information for this product.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biapenem</td>
<td>120410-24-4</td>
<td>300 mg/vial</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Remainder</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

Eye Contact
In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

Skin Contact
Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Inhalation
Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

Ingestion
If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties
Presumed to be a combustible particulate solid.

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

Unsuitable Extinguishing Media
Do NOT use water jet.

Fire Fighting
Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products
Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters
In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions
Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions
Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

Methods for Containment
Not available

Methods for Cleaning up
Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.
7. HANDLING AND STORAGE

Handling
For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage
No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name | Exposure Guideline
--- | ---
Biapenem | 3000 mcg/m³

Engineering Controls
Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

<table>
<thead>
<tr>
<th>Eye/face Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide eye protection based on risk assessment.</td>
</tr>
<tr>
<td>Skin Protection</td>
</tr>
<tr>
<td>Wear nitrile or latex gloves. Wear protective garment.</td>
</tr>
<tr>
<td>Respiratory Protection</td>
</tr>
<tr>
<td>Base respirator selection on a risk assessment.</td>
</tr>
</tbody>
</table>

General Hygiene Considerations
When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.

Other
Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical powder</td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>4.8 - 5.3</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient (n-octanol/water)</td>
<td>Not available</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Explosion Limits</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition Temperature Method</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper</td>
<td>Lower Not applicable</td>
</tr>
<tr>
<td>Lower</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Chemical Stability
Stable at room temperature.

Conditions to Avoid
No data available

Materials to Avoid
No materials to be especially mentioned.

Hazardous Decomposition Products
None under normal use.

Possibility of Hazardous Reactions
None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Biapenem

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 Oral</td>
<td>&gt;2000 mg/kg rats (IV)</td>
</tr>
<tr>
<td>Acute Dermal Irritation</td>
<td>No data available</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>No data available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Not a dermal sensitizer in guinea pigs.</td>
</tr>
</tbody>
</table>

Multiple Dose Toxicity

Biapenem

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Toxicologic Effect</td>
<td>The no toxicological effect level (NTEL) in rat studies was 300 mg/kg/day and in the dog studies 20 mg/kg/day. In dogs, death due to intestinal toxicity, emesis, salivation, mucous feces, immobilization, paleness, hypothermia, slight reduction of body weight and food consumption, red discoloration of the large intestine, and slight histopathological change of renal tubules were observed. The changes, including signs of toxicity, were reversible in rats and dogs, except for cecum enlargement of rats.</td>
</tr>
</tbody>
</table>

Maximum Tolerated Dose (MTD), Oral

Biapenem

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Genetic Toxicity</td>
<td>No evidence of mutagenicity was observed in a battery of in vitro and in vivo assays.</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
<td>Studies in rats were found to have no effect on fertility.</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>No morphological anomalies were observed in segment II studies in rats and rabbits.</td>
</tr>
</tbody>
</table>

Biapenem

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organ(s) of Toxicity</td>
<td>No data available</td>
</tr>
</tbody>
</table>
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information  Not available
Ecotoxicity  Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method  Dispose of in accordance with local and national regulations. Waste is inactivated by treatment with sodium hypochlorite solution.

14. TRANSPORT INFORMATION

Transport Information  This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT)  Not regulated
Canadian Transport of Dangerous Goods (TDG)  Not regulated
International Civil Aviation Organization (ICAO)  Not regulated
International Air Transport Association (IATA)  Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)  Not regulated
Transport of Dangerous Goods by Rail (RID)  Not regulated
Transport of Dangerous Goods by Road (ADR)  Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)  Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status
This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard  No
Chronic Health Hazard  No
Fire Hazard  No
Sudden Release of Pressure Hazard  No
Reactive Hazard  No
This product does not contain any HAPs.

State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

Canada
Not classified

WHMIS Hazard Class
Non-controlled

European Union
In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By  
Wyeth Department of Environment, Health & Safety

Format  
This MSDS was prepared in accordance with ANSI Z400.1-2004.

List of References  
See Patient Package Insert for more information.

Revision Summary  
Administrative

Disclaimer:
The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS