1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Pipracil  
Common Name: Not available  
Chemical Name: Not applicable  
Synonyms: Piperacillin Sodium, Pipracillin for Injection  
Product Use: Pharmaceutical product  
Classification: Anti-infective Agent  
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.

Appearance: Pharmaceutical powder  
Physical State: Solid  
Odor: Not available

Potential Physical Hazards:  
Powders and solids are presumed to be combustible.

Potential Health Effects:

<table>
<thead>
<tr>
<th>Component</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>May cause mechanical eye irritation.</td>
</tr>
<tr>
<td>Skin</td>
<td>Not available</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Not available</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 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, seizures and diarrhea.</td>
</tr>
<tr>
<td></td>
<td>May cause harm to breastfed babies.</td>
</tr>
<tr>
<td></td>
<td>Please see Patient Package Insert for further information.</td>
</tr>
</tbody>
</table>

Therapeutic Target Organ(s): None

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>Piperacillin sodium</td>
<td>59703-84-3</td>
<td>2-4 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 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.

**Aggravated Medical Conditions**
Allergy to penicillins.

**Notes to Physician**
Serious anaphylactic/anaphylactoid reactions (including shock) require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including incubation, should also be administered as indicated.

5. FIRE-FIGHTING MEASURES

**Flammable Properties**
Presumed to be a combustible particulate solid.

**Extinguishing Media**
- Use water spray, foam, dry chemical or carbon dioxide.
- 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
---|---
Piperacillin sodium | 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>
<th>Skin Protection</th>
<th>Respiratory Protection</th>
</tr>
</thead>
</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 to off-white</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Not available</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>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td>Upper</td>
</tr>
<tr>
<td>Explosion Limits</td>
<td>Upper</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>Not available</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition Temperature Method</td>
<td>None</td>
</tr>
<tr>
<td>Upper</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lower</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lower</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Revision Date 03-Jul-2007
### 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**

**Piperacillin sodium**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 Oral</td>
<td>10 mg/kg rats</td>
</tr>
<tr>
<td></td>
<td>10 mg/kg mice</td>
</tr>
<tr>
<td>Acute Dermal Irritation</td>
<td>Not available</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>Not available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**Multiple Dose Toxicity**

**Piperacillin sodium**

*No Toxicologic Effect*

**Dose/Species/Study Length:**

Multiple doses used in reproduction studies carried out in mice and rats showed no evidence of impaired fertility at half of the maximum recommended human daily dose.

**Maximum Tolerated Dose (MTD), Oral**

**Piperacillin sodium**

**Carcinogenicity**

Long-term animal toxicity studies to evaluate the carcinogenic potential have not been conducted.

**Genetic Toxicity**


**Reproductive Toxicity**

Studies in rats and mice have shown no evidence of impaired fertility or harm to the fetus.

**Developmental Toxicity**

No teratogenic effects were observed in mice and rats.

**Piperacillin sodium**

**Target Organ(s) of Toxicity**

No data available
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.

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
Changes to Section 2 due to change in Package Insert

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