1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Zosyn
Common Name: Not available
Chemical Name: Not applicable
Synonyms: Zosyn with EDTA, Zosyn without EDTA, Tazocin, Pipracillin, Tazobactam
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: Odorless

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

Potential Health Effects

<table>
<thead>
<tr>
<th>Eyes</th>
<th>May cause mechanical 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></td>
</tr>
</tbody>
</table>

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 diarrhea, headache, constipation, nausea, insomnia, rash, vomiting, dyspepsia, pruritus, stool changes, fever, agitation, pain, moniliasis, hypertension, dizziness, abdominal pain, chest pain, edema, anxiety, rhinitis, and dyspnea.

May cause harm to breastfed babies.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s): None

Potential Environmental Effects
See Section 12.
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 g/vial</td>
</tr>
<tr>
<td>Tazobactam Sodium</td>
<td>89785-84-2</td>
<td>0.25 - 0.5 g/vial</td>
</tr>
<tr>
<td>EDTA Disodium Dihydrate</td>
<td>6381-92-6</td>
<td>0 - 1 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.

Aggravated Medical Conditions

Allergy to penicillins.

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
- Piperacillin sodium
- Tazobactam Sodium
- EDTA Disodium Dihydrate

Exposure Guideline
- Piperacillin sodium: 3000 mcg/m³
- Tazobactam Sodium: 750 mcg/m³
- EDTA Disodium Dihydrate: Not assigned

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
- **Eye/face Protection**: Provide eye protection based on risk assessment.
- **Skin Protection**: Wear nitrile or latex gloves. Wear suitable protective equipment.
- **Respiratory Protection**: Base respirator selection on a risk assessment.
- **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><strong>Appearance</strong></td>
<td>Pharmaceutical powder</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>White to off-white</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Specific Gravity</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Solubility</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Partition Coefficient</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Boiling Point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Flammability Limits in Air</strong></td>
<td>Upper: Not applicable</td>
</tr>
<tr>
<td><strong>Explosion Limits</strong></td>
<td>Upper: Not applicable</td>
</tr>
<tr>
<td><strong>Water Solubility</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Evaporation Rate</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Vapor Pressure</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Autoignition Temperature</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>None</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

Piperacillin sodium
- LD50 Oral
  - 10 mg/kg rats
  - 10 mg/kg mice
- Acute Dermal Irritation: Not available
- Primary Eye Irritation: Not available
- Sensitization: Not available

Tazobactam Sodium
- LD50 Oral: >5000 mg/kg mice
- Acute Dermal Irritation: Not applicable
- Primary Eye Irritation: Not applicable
- Sensitization: Not applicable

EDTA Disodium Dihydrate
- LD50 Oral: >2000 mg/kg rats
- Maximum Tolerated Dose (MTD): Not available
- Primary Eye Irritation: Not applicable
- Sensitization: Not applicable

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.

Tazobactam Sodium
- No Toxicologic Effect
- Dose/Species/Study Length: Not available

EDTA Disodium Dihydrate
- No Toxicologic Effect
- Dose/Species/Study Length: Not available
## Maximum Tolerated Dose (MTD), Oral

### Piperacillin sodium
- **Carcinogenicity**: Long-term animal toxicity studies to evaluate the carcinogenic potential have not been conducted.
- **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.

### Tazobactam Sodium
- **Carcinogenicity**: Long-term animal toxicity studies to evaluate the carcinogenic potential have not been conducted.
- **Genetic Toxicity**: Mutagenic potential was assessed in 5 *in vitro* and 1 *in vivo* assay; positive results occurred in one assay (forward mutation assay using mouse lymphoma cells). However, the results were negative when the combination of Piperacillin Sodium and Tazobactum Sodium was assessed in a similar battery of tests.
- **Reproductive Toxicity**: Studies in mice and rats have shown no evidence of impaired fertility.
- **Developmental Toxicity**: Animal reproduction studies have not been conducted.

### EDTA Disodium Dihydrate
- **Carcinogenicity**: Long-term animal toxicity studies to evaluate the carcinogenic potential have not been conducted.
- **Genetic Toxicity**: No studies to assess the mutagenic potential have been performed.
- **Reproductive Toxicity**: See Developmental Toxicity.
- **Developmental Toxicity**: Studies in rats resulted in an impairment of fertility and fetal developmental effects. Since these effects were prevented by simultaneous supplementation of dietary zinc, they may have been caused by zinc deficiency.

### Target Organ(s) of Toxicity
- **Piperacillin sodium**: No data available
- **Tazobactam Sodium**: No data available
- **EDTA Disodium Dihydrate**: No data available
## 12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

### Chemical Fate Information

**Piperacillin sodium**
- Mobility: Not available
- Biodegradability: Not available
- Stability in Water: Not available
- Bioaccumulation: Not available

**Tazobactam Sodium**
- Mobility: Not available
- Biodegradability: Not readily biodegradable.
- Stability in Water: Stable at pH 7 and below. At pH 9, half life = 29h.
- Bioaccumulation: Not available

**EDTA Disodium Dihydrate**
- Mobility: Not available
- Biodegradability: Not available
- Stability in Water: Not available
- Bioaccumulation: Not available

### Ecotoxicity

**Piperacillin sodium**
- Microorganisms: Not available
- Algae: Not available
- Daphnia: Not available
- Fish: Not available

**Tazobactam Sodium**
- Microorganisms: Minimum inhibitory concentration (MIC) > 1000 mg/l for 3 test species. Pseudomonas MIC = 250 mg/l.
- Algae: Not available
- Daphnia: LC50/48h/daphnia > 8.5 mg/l, NOEC = 8.5 mg/l
- Fish: Not available

**EDTA Disodium Dihydrate**
- Microorganisms: Not available
- Algae: Not available
- Daphnia: Not available
- Fish: 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.

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End of MSDS