



Piperacillin Sodium

Preparation Date 03-Jul-2007

Revision Date 03-Jul-2007

Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Piperacillin Sodium
Common Name Piperacillin Sodium
Chemical Name (2S, 5R, 6R)-6-[(R)-2-(4-ethyl-2,3-dioxo-1-piperazinecarboxamido)-2-phenylacetamido]-3, -3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate
Synonyms Piperacillin Sodium, Piperacil
Product Use Active pharmaceutical ingredient
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 is 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

Eyes May cause mechanical eye irritation.
Skin Not available
Inhalation Not available
Ingestion Not available
Other 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.

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

| Common Name | CAS-No | Composition |
|---------------------|------------|-------------|
| Piperacillin sodium | 59703-84-3 | 100% |

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. |
| 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 | |
| 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. Dust can form an explosive mixture in air. Take precautionary measures against static discharges. Keep away from open flames, hot surfaces and sources of ignition. When processing, use electrical classified equipment. |
| Storage | No special safety precautions required. Keep container tightly closed. |

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|--|
| Common Name Piperacillin sodium | Exposure Guideline 3000 mcg/m ³ |
| Risk Based Exposure Control Classification | 2 |
| 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 protective garment. |
| 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

| | | | |
|--|---|-------------------------|------------------|
| Appearance | Pharmaceutical powder | Physical State | Solid |
| Color | White to off-white | Odor | Not available |
| Odor Threshold | Not available | | |
| Molecular Formula | C ₂₃ H ₂₆ N ₅ NaO ₇ S | Molecular Weight | 539.54 |
| pH | Not available | | |
| Specific Gravity | Not applicable | Water Solubility | Soluble in water |
| Solubility | Not applicable | Evaporation Rate | Not applicable |
| Partition Coefficient (n-octanol/water) | < -2.0 | Vapor Density | Not applicable |
| Vapor Pressure | Not applicable | | |

| | | | |
|-----------------------------------|-----------------------------|---------------------------------|----------------|
| Boiling Point | Not applicable | Autoignition Temperature | Not applicable |
| Flash Point | Not applicable | Method | None |
| Melting Point | 155°C | | |
| Flammability Limits in Air | Upper Not applicable | Lower Not applicable | |
| Explosion Limits | Upper Not applicable | Lower Not applicable | |

10. STABILITY AND REACTIVITY

| | |
|---|-----------------------------|
| Chemical Stability | Stable at room temperature. |
| Conditions to Avoid | No data available |
| Materials to Avoid | Oxidizing materials. |
| Hazardous Decomposition Products | None under normal use. |
| Possibility of Hazardous Reactions | None under normal use. |

11. TOXICOLOGICAL INFORMATION

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 |

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 | Non-mutagenic in the mouse micronucleus assay. Positive in mouse lymphoma cells assay. Negative in <i>in vivo</i> assays in mice. |
| 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

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

Pipracil MSDS

Zosyn MSDS

OEG Rationale June 1985

Revision Summary

Changes to Section 2 due to changes in Pipracil Package Insert.

Disclaimer:

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End of MSDS