

Material Safety Data Sheet ANSI Format

Pipracil

Preparation Date 03-Jul-2007 Revision Date 03-Jul-2007 Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Pipracil
Common Name Not available
Chemical Name Not applicable

Synonyms Piperacillin Sodium, Pipracillin for Injection

Product UsePharmaceutical productClassificationAnti-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 powderPhysical StateSolidOdor 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.

Please see Patient Package Insert for further information.

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	2-4 mg/vial
Inactive Ingredients	Not applicable	Remainder

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

Suitable Extinguishing Media Unsuitable 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.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Exposure Guideline

3000 mcg/m³ Piperacillin sodium

Apply technical measures to comply with the occupational exposure guideline. Local exhaust **Engineering Controls**

ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

Considerations

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 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

White to off-white Odor Not available Color

Not available **Odor Threshold**

Not available pН

Not applicable **Specific Gravity Water Solubility** Not available Solubility Not applicable Not applicable **Evaporation Rate**

Partition Coefficient Not available Not applicable Vapor Density (n-octanol/water)

Vapor Pressure Not applicable

Boiling Point Autoignition Temperature Not applicable Not applicable

Method **Flash Point** Not applicable None **Melting Point** Not available

Flammability Limits Upper Not applicable Lower Not applicable

in Air

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 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 Not available Not available Not available

Multiple Dose Toxicity

Sensitization

Piperacillin sodium

No Toxicologic Effect Multiple doses used in reproduction studies carried out in mice and rats showed no evidence

Dose/Species/Study Length: of impaired fertility at half of the maximum recommended human daily dose.

Maximum Tolerated Dose (MTD), Oral

Acute Dermal Irritation Primary Eye Irritation

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 in vivo 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

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)

Canadian Transport of Dangerous Goods (TDG)

International Civil Aviation Organization (ICAO)

International Air Transport Association (IATA)

International Maritime Dangerous Goods (IMDG)/International

Not regulated

Not regulated

Not regulated

Maritime Organization (IMO)

Transport of Dangerous Goods by Rail (RID)

Transport of Dangerous Goods by Road (ADR)

Not regulated

Transportation of Dangerous Goods via Inland Waterways

Not regulated

(ADN)

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 HazardNoChronic Health HazardNoFire HazardNoSudden Release of Pressure HazardNoReactive HazardNo

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