



Zosyn

Preparation Date 30-Nov-2006

Revision Date 24-Apr-2007

Revision Number 1

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

Eyes

May cause mechanical eye irritation.

Skin

May cause skin irritation.

Inhalation

May cause irritation of respiratory tract.

Ingestion

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

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects

See Section 12.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Piperacillin sodium	59703-84-3	2 - 4 g/vial
Tazobactam Sodium	89785-84-2	0.25 - 0.5 g/vial
EDTA Disodium Dihydrate	6381-92-6	0 - 1 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 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	Exposure Guideline
Piperacillin sodium	3000 mcg/m ³
Tazobactam Sodium	750 mcg/m ³
EDTA Disodium Dihydrate	None 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

Appearance	Pharmaceutical powder	Physical State	Solid
Color	White to off-white	Odor	Odorless
Odor Threshold	Not available		
pH	Not applicable		
Specific Gravity	Not applicable	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not applicable
Boiling Point	Not applicable	Autoignition Temperature Method	Not applicable
Flash Point	Not available		None
Melting Point	Not available		
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	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
Acute Dermal Irritation	Not applicable
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.
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.

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 <i>in vitro</i> and 1 <i>in vivo</i> 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 Tazobactam 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.

Piperacillin sodium

Target Organ(s) of Toxicity No data available

Tazobactam Sodium

Target Organ(s) of Toxicity No data available

EDTA Disodium Dihydrate

Target Organ(s) of Toxicity 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.

Disclaimer:

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End of MSDS