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Tazobactam Sodium

Preparation Date 05-Feb-2007

Revision Date 26-Jan-2010\*\*\*

Revision Number 3\*\*\*

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

<b>Product Name</b>	Tazobactam Sodium
<b>Common Name</b>	Tazobactam Sodium
<b>Chemical Name</b>	(2S, 3S, 5R)-3-methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo-[3.2.0]heptane-2-carboxylate-4,4-dioxide
<b>Synonyms</b>	Not available
<b>Product Use</b>	Active pharmaceutical ingredient
<b>Classification</b>	Anti-infective Agent
<b>Supplier</b>	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
<b>Contact E-Mail:</b>	pfizer-MSDS@pfizer.com
<b>Emergency Telephone Number</b>	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.

<b>Appearance</b> Pharmaceutical powder	<b>Physical State</b> Solid	<b>Odor</b> Not available
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#### 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**

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 pseudomembranous colitis, 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.

**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	EC No.	Composition	Classification
Tazobactam Sodium	89785-84-2	Not Applicable	100%	R 36/37/38, S 13/24/25/39

### 4. FIRST AID MEASURES

<b>Eye Contact</b>	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
<b>Skin Contact</b>	Wash off with soap and plenty of water
<b>Inhalation</b>	Artificial respiration and/or oxygen may be necessary
<b>Ingestion</b>	Immediate medical attention is required
<b>Aggravated Medical Conditions</b>	Allergy to penicillins.
<b>Notes to Physician</b>	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

<b>Flammable Properties</b>	Not flammable
<b>Extinguishing Media</b>	
<b>Suitable Extinguishing Media</b>	Use water spray, foam, dry chemical or carbon dioxide.
<b>Unsuitable Extinguishing Media</b>	Do NOT use water jet.
<b>Fire Fighting</b>	Evacuate area and fight fire from a safe distance
<b>Hazardous Combustion Products</b>	Carbon oxides, nitrogen oxides.
<b>Protective Equipment and Precautions for Firefighters</b>	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Safety glasses or goggles when splash potential exists
<b>Environmental Precautions</b>	Local authorities should be advised if a significant spill cannot be contained
<b>Methods for Containment</b>	Not available
<b>Methods for Cleaning up</b>	Take up mechanically and collect in suitable container for disposal

## 7. HANDLING AND STORAGE

<b>Handling</b>	Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.***
<b>Storage</b>	No special safety precautions required

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>OEB Statement</b>	The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.***
<b>Tazobactam Sodium Pfizer Occupational Exposure Band (OEB):</b>	OEB1 (control exposure to the range of >1000ug/m <sup>3</sup> to < 3000ug/m <sup>3</sup> )***
<b>Engineering Controls</b>	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range. All operations should be fully enclosed. No air recirculation permitted.***
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Wear safety glasses as minimum protection.***
<b>Skin Protection</b>	Wear impervious gloves as minimum protection. Wear impervious protective clothing when handling this compound.***
<b>Respiratory Protection</b>	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.***
<b>General Hygiene Considerations</b>	Consult a health and safety professional for specific PPE, respirator and risk assessment guidance
<b>Other</b>	Limit access to only personnel trained in the safe handling of this material

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Pharmaceutical powder	<b>Physical State</b>	Solid
<b>Color</b>	White to off-white	<b>Odor</b>	Not available
<b>Odor Threshold</b>	Not available		
<b>Molecular Formula</b>	C <sub>10</sub> H <sub>11</sub> N <sub>4</sub> NaO <sub>5</sub> S	<b>Molecular Weight</b>	322.3
<b>pH</b>	Not applicable		
<b>Specific Gravity</b>	Not applicable	<b>Water Solubility</b>	17 mg/ml
<b>Solubility</b>	Not applicable	<b>Evaporation Rate</b>	Not applicable
<b>Partition Coefficient (n-octanol/water)</b>	< -2.0	<b>Vapor Pressure</b>	Not applicable

<b>Boiling Point</b>	Not applicable	<b>Autoignition Temperature</b>	Not applicable
<b>Flash Point</b>	Not applicable	<b>Melting Point</b>	180°C
<b>Flammability Limits in Air</b>	<b>Upper</b> Not applicable	<b>Lower</b> Not applicable	
<b>Upper</b> Not applicable	<b>Lower</b> Not applicable		

## 10. STABILITY AND REACTIVITY

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

## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity

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

### Multiple Dose Toxicity \*\*\*

<b>Tazobactam Sodium</b>	
<b>No Toxicologic Effect</b>	Not available
<b>Dose/Species/Study Length:</b>	

### Maximum Tolerated Dose (MTD), Oral

<b>Tazobactam Sodium</b>	
<b>Carcinogenicity</b>	Long-term animal toxicity studies to evaluate the carcinogenic potential have not been conducted.
<b>Genetic Toxicity</b>	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.
<b>Reproductive Toxicity</b>	Studies in mice and rats have shown no evidence of impaired fertility.
<b>Developmental Toxicity</b>	Animal reproduction studies have not been conducted.

<b>Tazobactam Sodium</b>	
<b>Target Organ(s) of Toxicity</b>	No data available

## 12. ECOLOGICAL INFORMATION

### Chemical Fate Information

**Tazobactam Sodium**

<b>Mobility</b>	Not available
<b>Biodegradability</b>	Not readily biodegradable.
<b>Stability in Water</b>	Stable at pH 7 and below. At pH 9, half life = 29h.
<b>Bioaccumulation</b>	Not available

**Ecotoxicity****Tazobactam Sodium**

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

**13. DISPOSAL CONSIDERATIONS****Waste Disposal Method**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. \*\*\*

**14. TRANSPORT INFORMATION****Transport Information**

This material is not regulated for transportation as a hazardous material/dangerous goods.\*\*\*

**15. REGULATORY INFORMATION**

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

**16. OTHER INFORMATION**

<b>Prepared By</b>	Wyeth Department of Environment, Health & Safety
<b>Format</b>	This MSDS was prepared in accordance with Directive 2001/58/EC.
<b>List of References</b>	Zosyn MSDS, OEG Rationale June 2000.
<b>Revision Summary</b>	Changes to Section 8, 14*****

## Disclaimer:

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**End of MSDS**