

SAFETY DATA SHEET**Piperacillin and Tazobactam, USP****1) PRODUCT AND COMPANY IDENTIFICATION**

Product Identifier:	Piperacillin and Tazobactam for Injection, USP
Common/Trade Name:	Piperacillin, Zosyn
Chemical Name:	Piperacillin: (2S, 5R, 6R)-6-[(R)-2-(4-ethyl-2,3-dioxo-1-piperazine-carboxamido)-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate Tazobactam: (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
Chemical Family:	Anti-Infective Agent
Product Use:	Pharmaceutical
Product Type:	Regulated Prescription Drug
Container Information:	Vials
Manufacturer:	Piramal Critical Care, Inc 268 Brodhead Road Bethlehem, PA, 18017
Emergency Telephone:	Customer Service: 610-974-9760 x 510 E-Mail: pcccustomerconnect@piramal.com 24 Hour Emergency: 484-895-5734
	CHEMTREC 1-800-424-9300 (For Transportation in US and Canada.

2) HAZARDS IDENTIFICATION

(a) Classification:	NFPA Rating	
	Health Hazard	2
	Fire Hazard	1
	Reactivity Hazard	0

US OSHA Classification: Possible Sensitizer, Target Organ Toxin, Possible Irritant

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	- Not available

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Potential Health Effects:</u>	
<ul style="list-style-type: none"> - Powders and solids are presumed to be combustible - May cause mechanical eye irritation - May cause skin irritation - Hypersensitivity reactions have been reported in patients receiving therapy with penicillins. Individuals with a history of penicillin hypersensitivity or a history 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 	
<u>GHS Precautionary Statements:</u>	
<ul style="list-style-type: none"> - P260: Do not breathe dust/fume/gas/mist/vapors/spray - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. - Get medical attention if you feel unwell 	

(d) Unknown Acute Toxicity N/A

3) COMPOSITION/INFORMATION ON INGREDIENTS

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(2S, 5R, 6R)-6-[(R)-2-(4-ethyl-2,3-dioxo-1-piperazine-carboxamido)-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate	Piperacillin sodium	2 - 4 g/vial	59703-84-3	N/A
(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	Tazobactam sodium	0.25 - 0.5 g/vial	89785-84-2	N/A

4) FIRST AID MEASURES

- Eye Exposure:** Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes.
- Skin Exposure:** Flush with copious amounts of water and soap for at least 15 minutes. Remove contaminated clothing and shoes.
- Ingestion:** Wash out mouth with water and administer fresh water provided that the person is conscious. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
- Injection:** See patient package insert in shipping carton for complete information.
- Inhalation:** Remove to fresh air. If breathing becomes difficult, call a physician. Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

5) FIRE FIGHTING MEASURES

- (a) **Extinguishing Media** Use water spray, foam, dry chemical or carbon dioxide. Do NOT use water jet.
- (b) **Hazardous Combustion Products:** Carbon oxides, nitrogen oxides and other noxious gases or vapors in case of incomplete combustion.
- (c) **Special Protective Equipment / Precautions:** 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 exposure, do not breathe fumes.

6) ACCIDENTAL RELEASE MEASURES

- Spill:** Switch off electrical equipment and any other sources of ignition. Evacuate area. Wear self-contained breathing apparatus, appropriate boots and heavy rubber gloves. Collect residues manually, wipe with a small quantity of ethanol, place in a bag and hold for waste disposal.
- Release to Air:** Avoid raising dust/mist. Ventilate area and wash spill site with water/detergent solution after material pick up is complete.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

7) HANDLING AND STORAGE

General Handling: Avoid inhalation, contact with eyes, skin and clothing. Avoid prolonged or repeat exposure.

Storage Conditions: Prior to Reconstitution: Store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.] Follow instructions provided in packaging.

8) EXPOSURE CONTROLS/PERSONAL PROTECTION**(a) Exposure Limits**

Compound	Issuer	Type	Exposure Limit
Piperacillin sodium	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Tazobactam sodium	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

(b) Engineering Controls

Ventilation: Mechanical exhaust.

(c) Individual Protection Measures

Respiratory Protection:	Protecting mask
Eye Protection:	Wear protective chemical safety goggles.
Skin Protection:	Wear protective suit.
Other Protective Equipment:	Compatible chemical-resistant gloves.
Additional Exposure Precautions:	Safety shower and eye bath required.

9) PHYSICAL AND CHEMICAL PROPERTIES

(a)	Appearance	Solid white to off-white
(b)	Odor	No Odor
(c)	Odor Threshold	None
(d)	pH	Not available
(e)	Melting Point:	155 °C
(f)	Initial Boiling Point:	Not applicable
(g)	Flash Point	Not established
(h)	Evaporation Rate:	Not applicable
(i)	Flammability	Presumed to be a combustible particulate solid.
(j)	Upper Lower Flammability or Explosion Limits	Not established
(k)	Vapor Pressure:	Not applicable
(l)	Vapor Density:	Not applicable
(m)	Relative Density	Not available
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not established
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

10) STABILITY AND REACTIVITY

(a)	Reactivity	Stable at normal temperatures and pressure
(b)	Chemical Stability	Stable under recommended conditions of use.
(c)	Possibility of Hazardous Reactions	Hazardous polymerization is not anticipated to occur with this product
(d)	Conditions to Avoid	Strong oxidizers and strong bases
(e)	Incompatible Materials	No materials to be especially mentioned
(f)	Hazardous Decomposition Products	During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x), nitrogen oxides (NO _x), or sulfur oxides (SO _x)

11) TOXICOLOGICAL INFORMATION

(a)	Likely Routes of Exposure	Eyes, skin, inhalation and ingestion
(b)	Symptoms related to the physical, chemical and toxicological characteristics	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.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Exposure may result in blood and lymphatic system disorder, leading to infections. Symptoms such as skin rash, diarrhea, nausea, vomiting or rash are commonly observed. Material crosses the placenta and is excreted in human milk. May be harmful to pregnant women and their babies. May be harmful to breastfed babies.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Piperacillin sodium	LD ₅₀	Oral	Rat	>10 g/kg
Piperacillin sodium	LD ₅₀	Oral	Mice	>10 g/kg
Piperacillin sodium	LD ₅₀	Intravenous	Rat	2260 mg/kg
Piperacillin sodium	TD _{Lo}	Intravenous	Woman	2180 mg/kg/6 days
Piperacillin sodium	TD _{Lo}	Intramuscular	Woman	960 mg/kg/3 days
Piperacillin sodium	LD ₅₀	Intraperitoneal	Mouse	9770 mg/kg
Piperacillin sodium	LD ₅₀	Subcutaneous	Mouse	>10 g/kg
Piperacillin sodium	LD ₅₀	Intravenous	Mouse	4900 mg/kg
Piperacillin sodium	LD ₅₀	Intravenous	Dog	>6 g/kg
Piperacillin sodium	LD ₅₀	Intravenous	Monkey	>4 g/kg
Tazobactam sodium	LD ₅₀	Oral	Mice	>5,000 mg/kg
Tazobactam sodium	LD ₅₀	Oral	Rat	>5,000 mg/kg
Tazobactam sodium	LD ₅₀	Intravenous	Mice	>5,000 mg/kg
Tazobactam sodium	LD ₅₀	Intravenous	Rat	>5,000 mg/kg

(e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

12) ECOLOGICAL INFORMATION

(a)	Ecotoxicity	Microorganism: Minimum inhibitory concentration (MIC) >1000 mg/l for 3 test species. Pseudomonas MIC=250 mg/l Daphnia: LC ₅₀ / 48h/daphnia >8.5 mg/l NOEC=8.5 mg/l
(b)	Persistence and degradability	Stable at pH 7 and below. At pH 9, half life = 29h
(c)	Bioaccumulative potential	Not available
(d)	Mobility in soil	Not available
(e)	Other Adverse Effects	Not available

13) DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

14) TRANSPORT INFORMATION

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

DOT: Not regulated

IATA/ICAO: Not regulated

IMDG: Not regulated

15) REGULATORY INFORMATION

U.S. Regulations:

TSCA - No

CERCLA - Not on this list

SARA 302 – Not on this list

SARA 311 - Not on this list

SARA 312 – Not on this list

SARA 313 – Not on this list

OSHA Substance Specific - No

16) OTHER INFORMATION

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SDS Updates:

05-20-2019 – New Document