

1. PRODUCT AND COMPANY INFORMATION

Distributed By: WG Critical Care, LLC.
120 Route 17 North
Suite 115
Paramus, NJ 07652 USA

Product Name: Piperacillin and Tazobactam for Injection

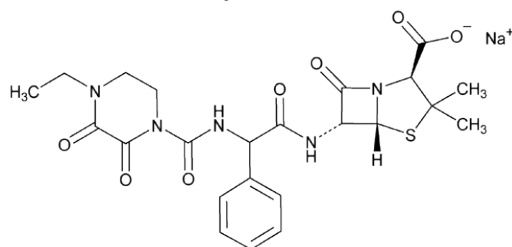
Product Code:

2.25g Vial:	44567-801-10
3.375g Vial:	44567-802-10
3.375g Vial:	44567-882-10
4.5g Vial:	44567-803-10
40.5g Vial:	44567-804-01

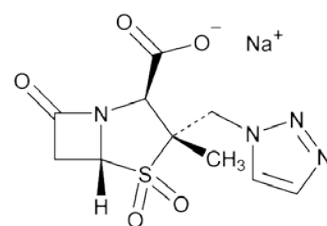
Common / Trade Name: Piperacillin and Tazobactam for Injection

Structure:

Piperacillin Sodium



Tazobactam Sodium



Chemical Name:

Piperacillin Sodium

(1) 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[[(4-ethyl-2,3-dioxo-1-piperazinyl)carbonyl]amino]phenylacetamido]-3,3-dimethyl-7-oxo-, monosodium salt, [2*S*-[2*a*,5*a*,6*b*(*S*^{*})]];

(2) Sodium (2*S*,5*R*,6*R*)-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

Tazobactam Sodium

(1) 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3-methyl-7-oxo-3-(1*H*-1,2,3-triazol-1-ylmethyl)-, 4,4-dioxide, sodium salt, [2*S*-(2*α*,3*β*,5*α*)]-;

(2) Sodium (2*S*,3*S*,5*R*)-3-methyl-7-oxo-3-(1*H*-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate, 4,4-dioxide

Molecular Formula:

Piperacillin Sodium

C₂₃H₂₆N₅NaO₇ MW:539.54

Tazobactam Sodium

C₁₀H₁₁N₄NaO₅S MW:322.27

UNII Code:

Piperacillin Sodium

UNII-M98T69Q7HP

Tazobactam Sodium

UNII-UXA545ABTT

CAS Number:

Piperacillin Sodium

59703-84-3

Tazobactam Sodium

89785-84-2

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1. PRODUCT AND COMPANY INFORMATION (CONT.)

Chemical Family:	<u>Piperacillin Sodium</u> <i>Antibacterial</i>	<u>Tazobactam Sodium</u> <i>Inhibitor (beta-lactamase)</i>
Product Use:	Pharmaceutical	
Product Type:	Prescription Drug	
Container Information:	Vials	
General Phone Number:	+1-224-544-5632	
Customer Service Phone Number:	+1-888-493-0861	
Emergency Phone Number:	+1-866-562-4708 (Prosar)	

2. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
Piperacillin Sodium, USP	80-88%	59703-84-3
Tazobactam Sodium	12-20%	89785-84-2
Sodium Bicarbonate, USP	2.5-5%	144-55-8

3. HAZARDS IDENTIFICATION

PRIMARY PHYSICAL AND HEALTH HAZARDS: May cause respiratory tract, eye, and skin irritation. May cause allergic respiratory and skin reaction

ROUTES OF ENTRY: Inhalation, injection, eye/skin contact and/or ingestion

SIGNS & SYMPTOMS OF EXPOSURE: May cause sensitization by inhalation and skin contact. Irritating to eyes, respiratory system, and skin. May cause allergic reaction in penicillin-sensitive individuals.

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.

CHEMICAL LISTED AS CARCINOGEN: NTP: NO IARC: NO OSHA: NO

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4. FIRST AID MEASURES

EYE EXPOSURE:	Immediately rinse eyes with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Seek medical advice.
SKIN EXPOSURE:	Remove contaminated clothing immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
INGESTION:	Never attempt to induce vomiting. Flush mouth out with water immediately. Seek medical attention.
INHALATION:	Use appropriate personal protective equipment. Move to fresh air and monitor breathing. If breathing becomes difficult, maintain ventilation, give oxygen as appropriate, and seek medical attention.
NOTE TO PHYSICIAN:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

FLASH POINT:	Not Established
AUTO-IGNITION TEMPERATURE:	Not Established
FLAMMABLE LIMITS IN AIR:	Lower %: Not Established Upper %: Not Established
FLAMMABLE LIMITS:	Not Established
EXTINGUISHING MEDIA:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
UNUSUAL FIRE / EXPLOSION HAZARDS:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen, and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

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6. ACCIDENTAL RELEASE MEASURE

SPILL:	Contain and collect spillage and place in container for disposal according to local regulations (See Section 13). Wipe surface area clean with soap and water. Avoid contact with strong oxidizing agents.
RELEASE TO AIR:	Prevent release to drains and waterways. Prevent release to the environment.
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:	When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product. Keep away from sources of ignition.
STORAGE CONDITIONS:	Store at controlled room temperature between 20° – 25°C in the original packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION:	If respiratory protection is used, the type of protection will depend upon air concentration present, required protection factor as well as hazards, physical properties of substance.
EYE PROTECTION:	Safety glasses with side shields or goggles are recommended.
VENTILATION:	General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.
SKIN PROTECTION:	Protect with disposable garments if direct skin contact is anticipated.
OTHER PROTECTIVE EQUIPMENT:	Chemical resistant gloves.
ADDITIONAL EXPOSURE PRECAUTIONS:	Wash hands and face before breaks and immediately after handling product.

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9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Cryodessicated Powder	SPECIFIC GRAVITY:	H 0.6 (BULK)
APPEARANCE AND ODOR:	White to off white	EVAPORATION RATE:	Not Available
BOILING POINT:	Not Available	MELTING POINT:	205° C
VAPOR PRESSURE:	Not Available	SOLUBILITY:	Soluble in dimethylformamide
VAPOR DENSITY:	Not Available	pH:	4.5-7 (1g Piperacillin Sodium / 5ml Solution)
PERCENT VOLATILE:	5%	EXPLOSIVE PROPERTIES:	Not Available

10. STABILITY AND REACTIVITY

STABILITY:	Stable under normal conditions
INCOMPATIBILITY: (MATERIALS TO AVOID)	Not Available
HAZARDOUS POLYMERIZATION:	No hazardous polymerizations
HAZARDOUS DECOMPOSITION:	Decomposition products of this compound may include potentially hazardous byproducts, acrid and toxic fumes.
CONDITIONS TO AVOID:	No conditions contributing to instability are known to exist. Avoid contact with strong oxidizing agents

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11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Piperacillin Sodium	LD ₅₀	Oral	Rat	10g/kg
Piperacillin Sodium	LD ₅₀	Intraperitoneal	Rat	7600 mg/kg
Piperacillin Sodium	LD ₅₀	Subcutaneous	Rat	8800 mg/kg
Tazobactam Sodium	LD ₅₀	Oral	Mice	5000mg/kg
Sodium Bicarbonate	LD ₅₀	Oral	Mice	3360mg/kg

*Occasionally hypersensitivity reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and / or a history of sensitivity to multiple allergens.

12. ECOLOGICAL INFORMATION

No applicable information found.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations

14. TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: Not Regulated

ICAO / IATA: Not Regulated

IMO: Not Regulated

15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations

TSCA – No

CERCLA-No

SARA 313 – No

OSHA Substance Specific - No

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16. OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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