

1. PRODUCT AND COMPANY INFORMATION

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

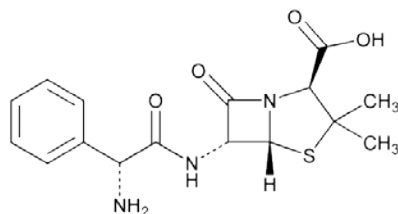
Product Name: **Ampicillin and Sulbactam for Injection, USP**

Product Code: 1.5mg Vial: 44567-210-10
3mg Vial: 44567-211-10
15g Vial: 44567-212-01

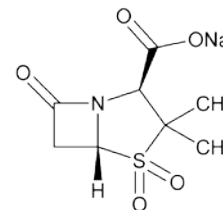
Common / Trade Name: Ampicillin and Sulbactam for Injection, USP

Structure:

Ampicillin



Sulbactam



Chemical Name:

Ampicillin

(1) 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[(aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-, [2*S*-[2 α ,5 α ,6 β (*S*^{*})]]-; (2) (2*S*,5*R*,6*R*)-6-[(*R*)-2-Amino-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid

Sulbactam

(1) 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-, 4,4-dioxide, sodium salt, (2*S*-*cis*)-; (2) Sodium (2*S*,5*R*)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate 4,4-dioxide

Molecular Formula:

Ampicillin

C₁₆H₁₉N₃O₄S

Sulbactam

C₈H₁₀NNaO₅S

UNII Code:

Ampicillin

7C782967RD

Sulbactam

DKQ4T82YE6

CAS Number:

Ampicillin

69-53-4

Sulbactam

69388-84-7

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1. PRODUCT AND COMPANY INFORMATION (CONT.)

Chemical Family:	<u>Ampicillin</u> Antibacterial	<u>Sulbactam</u> Inhibitor (b-lactamase); synergist (pen./ceph.)
Product Use:	Pharmaceutical	
Product Type:	Prescription Drug	
Container Information:	Vials	
General Phone Number:	+1-847-549-3200	
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 Number</u>
Ampicillin Sodium	66-67	69-52-3
Sulbactam Sodium	33-34	69388-84-7

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: Ingestion. Eye contact. Inhalation.

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3. HAZARDS IDENTIFICATION (CONT.)

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

4. FIRST AID MEASURES

EYE EXPOSURE: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

SKIN EXPOSURE: Wash contaminated skin with soap and water. Get medical attention if irritation develops.

INGESTION: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

INHALATION: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

NOTE TO PHYSICIAN: See patient package insert in shipping carton for complete information.

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5. FIRE FIGHTING MEASURES

FLASH POINT:	Not Established
AUTO-IGNITION TEMPERATURE:	Not Established
FLAMMABLE LIMITS IN AIR:	Not Established
FLAMMABLE LIMITS:	Not Established
EXTINGUISHING MEDIA:	Use foam or all-purpose dry chemicals
UNUSUAL FIRE / EXPLOSION HAZARDS:	No data available

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:	Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).

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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.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Crystalline Form	SPECIFIC GRAVITY:	Not Available
APPEARANCE AND ODOR:	Powder	EVAPORATION RATE:	Not Available
BOILING POINT:	Not Available	MELTING POINT:	Not available
VAPOR PRESSURE:	Not Available	SOLUBILITY:	Soluble in water
VAPOR DENSITY:	Not Available	pH:	8.0-10.0
Percent Volatile:	Not Available	Explosive Properties:	Not Available

10. STABILITY AND REACTIVITY

STABILITY: Stable under recommended storage conditions

INCOMPATIBILITY : (MATERIALS TO AVOID) Acids, bases, oxidizing agents

HAZARDOUS POLYMERIZATION: Not available

HAZARDOUS DECOMPISITION: Not available

CONDITIONS TO AVOID: Acids, bases, oxidizing agents
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11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Ampicillin	LD50	Oral	Rat	5314mg/kg
Sulbactam	--	--	--	--

12. ECOLOGICAL INFORMATION

No applicable information found.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local 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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