

## 1. PRODUCT AND COMPANY INFORMATION

**Distributed By:** WG Critical Care, LLC.  
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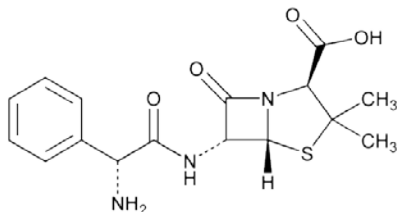
**Product Name:** **Ampicillin and Sulbactam for Injection, USP**

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

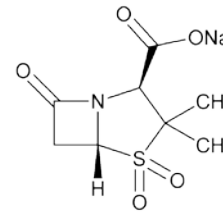
**Common / Trade Name:** Ampicillin and Sulbactam for Injection, USP

**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 $\alpha$ ,5 $\alpha$ ,6 $\beta$ (*S*<sup>\*</sup>)]]-; (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**

C<sub>16</sub>H<sub>19</sub>N<sub>3</sub>O<sub>4</sub>S

**Sulbactam**

C<sub>8</sub>H<sub>10</sub>NNaO<sub>5</sub>S

**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.)

<b>Chemical Family:</b>	<b><u>Ampicillin</u></b> Antibacterial	<b><u>Sulbactam</u></b> Inhibitor (b-lactamase); synergist (pen./ceph.)
<b>Product Use:</b>	Pharmaceutical	
<b>Product Type:</b>	Prescription Drug	
<b>Container Information:</b>	Vials	
<b>General Phone Number:</b>	+1-847-549-3200	
<b>Customer Service Phone Number:</b>	+1-888-493-0861	
<b>Emergency Phone Number:</b>	+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

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

#### 6. ACCIDENTAL RELEASE MEASURE

<b>SPILL:</b>	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.
<b>RELEASE TO AIR:</b>	Prevent release to drains and waterways. Prevent release to the environment.
<b>RELEASE TO WATER:</b>	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

#### 7. HANDLING AND STORAGE

<b>GENERAL HANDLING:</b>	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.
<b>STORAGE CONDITIONS:</b>	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

<b>RESPIRATORY PROTECTION:</b>	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.
<b>EYE PROTECTION:</b>	Safety glasses with side shields or goggles are recommended.
<b>VENTILATION:</b>	General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.
<b>SKIN PROTECTION:</b>	Protect with disposable garments if direct skin contact is anticipated.
<b>OTHER PROTECTIVE EQUIPMENT:</b>	Chemical resistant gloves.
<b>ADDITIONAL EXPOSURE PRECAUTIONS:</b>	Wash hands and face before breaks and immediately after handling product.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

## 10. STABILITY AND REACTIVITY

<b>STABILITY:</b>	Stable under recommended storage conditions
<b>INCOMPATIBILITY : (MATERIALS TO AVOID)</b>	Acids, bases, oxidizing agents
<b>HAZARDOUS POLYMERIZATION:</b>	Not available
<b>HAZARDOUS DECOMPOSITION:</b>	Not available
<b>CONDITIONS TO AVOID:</b>	Acids, bases, oxidizing agents WG Critical Care, LLC.

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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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