

# Ampicillin & Sulbactam for Injection

## Safety Data Sheet

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product name : Ampicillin & Sulbactam for Injection  
Other means of identification : NDC CODE: 55150-116-20, 55150-117-20, 55150-118-20( for 1.5g, 3g, 15g)

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Antibacterial/Beta lactam, Penicillins

#### 1.3. Details of the supplier of the safety data sheet

AuroMedics  
6 Wheeling Road  
Dayton, NJ 08810  
T 609-642-1136

#### 1.4. Emergency telephone number

Emergency number : 732-823-8084

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification (GHS-US)

Acute Tox. 4 (Oral) H302  
Resp. Sens. 1 H334  
Skin Sens. 1 H317

Full text of H-phrases: see section 16

#### 2.2. Label elements

##### GHS-US labeling

Hazard pictograms (GHS-US)



GHS07

GHS08

Signal word (GHS-US) : Danger

Hazard statements (GHS-US) : H302 - Harmful if swallowed  
H317 - May cause an allergic skin reaction  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements (GHS-US) : P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P264 - Wash ... thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P272 - Contaminated work clothing must not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P284 - [In case of inadequate ventilation] wear respiratory protection  
P301 + P312 - If swallowed: Call a poison center/doctor if you feel unwell  
P302 + P352 - If on skin: Wash with plenty of water  
P304 + P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing  
P330 - Rinse mouth  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention  
P342 + P311 - If experiencing respiratory symptoms: Call a poison center/doctor  
P362+P364 - Take off contaminated clothing and wash it before reuse  
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS-US)

Not applicable

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### SECTION 3: Composition/information on ingredients

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Sodium [2S-[2.alpha.,5.alpha.,6.beta.(S*)]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate	(CAS No) 69-52-3	60 - 70	Resp. Sens. 1, H334 Skin Sens. 1, H317
Sodium (2S-cis)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate 4,4-dioxide	(CAS No) 69388-84-7	30 - 40	Acute Tox. 4 (Oral), H302

Full text of H-phrases: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation	: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and monitor closely. Get medical attention immediately.
First-aid measures after skin contact	: Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Immediately flush with plenty of water for at least 15 minutes occasionally lifting upper and lower eyelids. If easy to do, remove contact lenses. Get medical attention if symptoms persist.
First-aid measures after ingestion	: DO NOT induce vomiting. If victim is fully conscious, give a cupful of water. Never give anything by mouth to an unconscious person. If vomiting occurs, keep head lower than the hips to help prevent aspiration. Call a physician or poison control center immediately.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/injuries after skin contact	: May cause an allergic skin reaction.
Symptoms/injuries after eye contact	: May cause eye irritation on direct contact.
Symptoms/injuries after ingestion	: Ingestion may cause irritation and malaise. May cause serious or fatal hypersensitivity (anaphylactic) reactions in some individuals.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
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#### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
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#### 5.3. Advice for firefighters

Protection during firefighting	: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
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### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No special measures required.
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##### 6.1.1. For non-emergency personnel

No additional information available

##### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

#### 6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
Methods for cleaning up	: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

#### 6.4. Reference to other sections

No additional information available

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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Wear protective clothing as described in Section 8 of this safety data sheet. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Use only with adequate ventilation. Wash thoroughly after handling. Minimize dust generation and accumulation.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at controlled room temperature at 20–25 °C (68–77°F). Store away from incompatible materials

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

**Sodium [2S-[2.alpha.,5.alpha.,6.beta.(S\*)]]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate (69-52-3)**

ACGIH Not applicable

OSHA Not applicable

**Sodium (2S-cis)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate 4,4-dioxide (69388-84-7)**

ACGIH Not applicable

OSHA Not applicable

#### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Wear protective gloves.

Eye protection : Wear safety glasses with side shields (or goggles).

Skin and body protection : Wear suitable working clothes.

Respiratory protection : If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134. Respirator type: Use high efficiency particulate respirator with appropriate filter.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Powder.

Color : White to off-white

Odor : Odorless.

Odor threshold : No data available

pH : No data available

Melting point : No data available

Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Relative evaporation rate (butyl acetate=1) : No data available

Flammability (solid, gas) : No data available

Explosion limits : No data available

Explosive properties : No data available

Oxidizing properties : No data available

Vapor pressure : No data available

Relative density : No data available

Relative vapor density at 20 °C : No data available

Solubility : No data available

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Log Pow	: No data available
Log Kow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

Heat. Water, moisture. Minimize dust generation and accumulation. Contact with incompatible materials.

### 10.5. Incompatible materials

Strong oxidizers.

### 10.6. Hazardous decomposition products

Carbon oxides. Nitrogen oxides. Sulfur oxides.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

Ampicillin & Sulbactam for Injection	
ATE US (oral)	1250.000 mg/kg body weight
Sodium [2S-[2.alpha.,5.alpha.,6.beta.(S*)]]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate (69-52-3)	
LD50 oral rat	> 5314 mg/kg
Sodium (2S-cis)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate 4,4-dioxide (69388-84-7)	
ATE US (oral)	500.000 mg/kg body weight

Skin corrosion/irritation	: Not classified pH: 6 - 8.5 (Aqueous solution)
Serious eye damage/irritation	: Not classified pH: 6 - 8.5 (Aqueous solution)
Respiratory or skin sensitization	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Sodium [2S-[2.alpha.,5.alpha.,6.beta.(S*)]]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate (69-52-3)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

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## Safety Data Sheet

### SECTION 12: Ecological information

#### 12.1. Toxicity

No additional information available

#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Other adverse effects

Effect on the global warming : No known ecological damage caused by this product.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Not a dangerous good as defined in transport regulations

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

No additional information available

#### 15.2. US State regulations

No additional information available

### SECTION 16: Other information

Full text of H-phrases::

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Sens. 1	Skin sensitization Category 1
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*