

# Product Name: Ampicillin Sulbactam 2:1



## MATERIAL SAFETY DATA SHEET

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

<b>Distributor Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045
<b>Emergency Telephone Hospira, Inc. Sandoz GmbH</b>	CHEMTREC: 800-424-9300 224-212-2055 +43 5338 200 0
<b>Manufacturer Name and Address</b>	Sandoz GmbH Biochemiestrasse 10 A-6250 Kundl / Tirol Austria
<b>Product Name</b>	Ampicillin Sulbactam 2:1
<b>Synonyms</b>	Ampicillin-Sulbactam mixture (2:1); Sulbactam-Ampicillin mixture (1:2);  4-Thia-1-azabicyclo(3.2.0)heptane-2-carboxylic acid, 6- ((aminophenylacetyl)amino)-3,3- dimethyl-7-oxo, (2S-(2-alpha,5-alpha,6- beta(S*)))-, mixture with (2S-cis)-3,3-dimethyl-7-oxo- thia-1- azabicyclo(3.2.0)heptane-2-carboxylic acid 4,4-dioxide

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Ampicillin Sodium	Approx 60	69-52-3	XH84000000
Sulbactam Sodium	Approx 25	69388-84-7	NA

### 3. HAZARD INFORMATION

<b>Emergency Overview</b>	Dust may irritate eyes and skin. Low levels of exposure can prompt serious hypersensitivity reactions in allergic/sensitized individuals.
<b>Occupational Exposure Potential</b>	Primary routes of occupational exposures are via inhalation and eye/skin contact.
<b>Signs and Symptoms</b>	Irritation, diarrhea, rash, convulsion, hypersensitivity reactions.
<b>Medical Conditions Aggravated by Exposure</b>	Persons with asthma, sensitivity to multiple allergens or known sensitivity to penicillin, penicillin derivatives, penicillamine, or cephalosporins. History of bleeding disorders, gastrointestinal disease, hepatic and renal function impairment.

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**Target Organ Effects** Skin, eyes, respiratory and gastrointestinal tract.

### 4. FIRST AID MEASURES

<b>Eye Contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Skin Contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Ingestion</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

### 5. FIRE FIGHTING MEASURES

<b>Flammability</b>	No information identified
<b>Fire &amp; Explosion Hazard</b>	Not expected
<b>Extinguishing Media</b>	Use extinguishing media appropriate for primary cause of fire (water, carbon dioxide or dry chemical). Use water spray to cool fire exposed containers.
<b>Special Fire Fighting Procedures</b>	Wear protective clothing and NIOSH-approved self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Spill Cleanup and Disposal</b>	Collect spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.
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### 7. HANDLING AND STORAGE

<b>Handling</b>	When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the product. Take precautionary measures against static discharges.
<b>Storage</b>	Keep container tightly closed. Keep dry. Store in a cool place and protect from light.
<b>Special Precautions</b>	None identified

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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines		
Component	OSHA-PEL	ACGIH-TLV
Ampicillin Sodium	Non Established	Non Established
Sulbactam Sodium	Non Established	Non Established

<b>Respiratory Protection</b>	Wear a full face NIOSH-approved dust respirator or dust mask where airborne dust is present.
<b>Skin Protection</b>	Avoid contact with skin by wearing butyl rubber gloves.
<b>Eye Protection</b>	Eye protection is not required during expected product use conditions but may be warranted if eye contact is likely.
<b>Engineering Controls</b>	Engineering controls are not needed during normal product use conditions.

### 9. PHYSICAL/CHEMICAL PROPERTIES

<b>Appearance/Physical State</b>	Solid, white to off-white crystalline powder
<b>Odor</b>	Practically odorless
<b>Boiling Point</b>	NA
<b>Freezing Point</b>	NA
<b>Vapor Pressure</b>	NA
<b>Vapor Density (Air =1)</b>	NA
<b>Evaporation Rate</b>	NA
<b>Bulk Density</b>	Not identified
<b>Specific Gravity</b>	Not identified
<b>Solubility</b>	Soluble in water; sparingly soluble in acetone
<b>pH</b>	8.5 – 9.5 (100 g/L, 20 °C)

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability</b>	Stable
<b>Incompatibilities</b>	Strong acids and strong bases
<b>Hazardous Decomposition Products</b>	Carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides and other sulfur-containing compounds

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Hazardous Polymerization Does not occur

### 11. TOXICOLOGICAL INFORMATION

#### Acute Toxicity – Oral:

Ingredient(s)	Test Type	Value	Units	Species
Ampicillin Sodium	Oral LD <sub>50</sub>	>5314	mg/kg	Rat
Sulbactam Sodium	Oral LD <sub>50</sub>	>4000	mg/kg	Rat

**Mutagenicity** Ampicillin (trihydrate) was negative in the Ames bacterial cell mutagenicity test.

**Dermal Irritation** No studies identified

**Ocular Irritation** No studies identified

**Reproductive/Developmental Toxicity** Ampicillin did not cause birth defects in rats at doses comparable to human therapeutic doses.  
Sulbactam did not cause birth defects in rats at doses up to 500 mg/kg/day.

**Carcinogenicity** NTP: Not listed  
IARC: Ampicillin is listed as Group 3 (Not Classifiable – Monograph 50, 1990)  
OSHA: Not listed

### 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity/  
Environmental Fate** No studies identified

### 13. DISPOSAL CONSIDERATIONS

**Waste Disposal** Disposal should be performed in accordance with federal, state or local regulatory requirements.

**Container Handling and Disposal** Dispose of container and unused contents in accordance with federal, state and local regulations.

### 14. TRANSPORTATION INFORMATION

**DOT/IATA Status** Not regulated

### 15. REGULATORY INFORMATION

**TSCA Status** Not listed

**CERCLA Status** Not listed

**SARA Status** Not listed

**RCRA Status** Not listed

**PROP 65 (Calif.)** Not listed

**EC Label** Xn harmful

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R42/43: May cause sensitization by inhalation and skin contact  
S22: Do not breathe dust.  
S24/25: Avoid contact with skin and eyes  
S36: Wear suitable protective clothing

**16. OTHER INFORMATION**

Notes: ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value  
CAS: Chemical Abstracts Service Number  
CERCLA: US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act  
DOT: US Department of Transportation Regulations  
IATA : International Air Transport Association  
IARC: International Agency for Research on Cancer  
LD<sub>50</sub>: is the dosage producing 50% mortality  
NA: Not applicable/Not available  
NIOSH: National Institute for Occupational Safety and Health  
NTP: National Toxicology Program  
OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
Prop 65: California Proposition 65  
RCRA, US EPA, Resource Conservation and Recovery Act  
RTECS: registry of Toxic Effects of Chemical Substances  
SARA, Superfund Amendments and Reauthorization Act  
TSCA: Toxic Substance Control Act

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