



MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

1501 East Woodfield Road **Emergency Telephone** **(800) 551-7176**
Suite 300 East
Schaumburg, IL 60173
(847) 969-2700

Product Identifier: Ampicillin and Sulbactam for Injection, USP
Chemical Name: Ampicillin Sodium and Sulbactam Sodium
Category: Anti-Infective

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Ampicillin Sodium	69-52-3	66%
Sulbactam Sodium	69388-84-7	44%

SECTION 3 - HAZARDS IDENTIFICATION

Route of Entry: Inhalation, eye/skin contact, or ingestion

Chemical Listing as Carcinogen

NTP: No

IARC: No

OSHA: No

Note: May cause allergic reaction in penicillin-sensitive individuals

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.

Skin: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention if pain, redness, or swelling persists.

Inhalation: Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

Ingestion: Flush mouth out with water immediately. Seek medical attention.

Contact Info: For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Data

Closed Cup Flash Point:	NE
Open Cup Flash Point:	NE
Fire Point:	NE
Autoignition:	NE
Lower Explosion Limit:	NE
Upper Explosion Limit:	NE
General Hazard:	When heated to decomposition, toxic fumes may be emitted.
Fire Fighting Instructions:	Water spray, dry chemical, or carbon dioxide as appropriate to surroundings.
Fire Fighting Equipment:	Wear self-containing breathing apparatus and protective clothing.
Hazardous Combustion Products:	Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides, and other sulfur-containing compounds.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Clean-Up:	Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Wipe up with damp cloth or handle spills with vacuuming or wet mopping. Avoid generation of airborne dust. Wipe surface area clean with soap and water.
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SECTION 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.
Storage Conditions:	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab hood.
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SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION...continued

Personal Protective Equipment

Eye Protection: Safety glasses or goggles recommended.

Hand Protection: Disposable latex gloves recommended.

Respiratory Protection: With satisfactory ventilation, respiratory protection is usually not required.

Skin Protection: Disposable garments if direct skin contact is anticipated.

Exposure Limits:

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Ampicillin Sodium	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Sulbactam Sodium	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
	---	TWA - 8 hours	3 mg/m ³ (as free acid)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical Form/Appearance: White to off-white dry powder

Boiling Point/Boiling Range: NE

Melting Point/Melting Range: 419°F (215°C)

Freezing Point: NE

Vapor Pressure : NE

Relative Vapor Density: NE

Percent Volatiles: Not applicable (N/A)

pH: 8-10 (Reconstituted solution)

Molecular Weight: Ampicillin Sodium - 371.39
Sulbactam Sodium - 255.22

Solvent Solubility: Soluble in water

Note: NA

SECTION 10 - STABILITY AND REACTIVITY

Stability:	Stable
Conditions to Avoid:	Strong bases and strong acids.
Hazardous Polymerization:	Does not occur.

SECTION 11 - TOXICOLOGY INFORMATION

Signs & Symptoms of Exposure & Overexposure: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions include: diarrhea, rash, itching, nausea, vomiting, candidiasis, fatigue, malaise, headache, chest pain, flatulence, abdominal distension, glossitis, urine retention, dysuria, edema, facial swelling, erythema, chills, tightness in throat, substernal pain, epistaxis, and mucosal bleeding. Overdosage adverse reactions include neurological adverse reactions including convulsions. Ampicillin is reported to induce environmental or occupational asthma.

Medical Conditions Aggravated by Accidental Exposure: Previous allergic reaction to penicillins, penicillin derivatives, penicillamine, or cephalosporins. History of bleeding disorders, gastrointestinal disease, hepatic and renal function impairment.

Acute Toxicity:

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Ampicillin Sodium	LD ₅₀	Oral	Rat	> 5314 mg/kg
	LD ₅₀	Oral	Mouse	> 5314 mg/kg
	LD ₅₀	SC	Rat	> 5314 mg/kg
	LD ₅₀	SC	Mouse	> 5314 mg/kg
	LD ₅₀	IP	Rat	7400 mg/kg
	LD ₅₀	IP	Mouse	5700 mg/kg
Sulbactam Sodium	LD ₅₀	Oral	Rat	> 4000 mg/kg
	LD ₅₀	Oral	Mouse	> 10,000 mg/kg
	LD ₅₀	IV	Rat	4582 mg/kg
	LD ₅₀	IV	Mouse	3604 mg/kg

Other: Sulbactam Sodium was not teratogenic in studies in mice, rats, and rabbits. Two reports in which high oral doses of ampicillin did not produce teratogenic effects in rats. A third report identified high doses of ampicillin associated with limb defects.

SECTION 12 - TRANSPORTATION INFORMATION

UN/NA Number:	NA
U.S. DOT Hazard Class:	NA

SECTION 12 - TRANSPORTATION INFORMATION...continued

Proper Shipping Name: NA

Shipping Label: NA

SECTION 13 - DISPOSAL INFORMATION

Disposal Procedure : Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

SECTION 14 - OTHER

Key to Abbreviations: ACGIH - American Conference of Governmental Industrial Hygienists
HEPA - High Efficiency Particulate Air
IARC - International Agency for Research on Cancer
NA - Not Applicable
NE - Not Established
NG - Not Given
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PEL - Permissible Exposure Limit
PPM - Parts Per Million
QS - Quantity Sufficient
RCRA - Resource Conservation and Recovery Act
STEL - Short Term Exposure Limit
TLV - Threshold Limit Value
USP - United States Pharmacopeia

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