	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Ampicillin and Sulbactam for Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>Feb 09, 2010</b>	MSDS No.: <b>MSDS 027</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>1 of 8</b>

### Section 1 - Chemical Product and Company

**Distributor:**

Sagent Pharmaceuticals, Inc.  
1901 N. Roselle Rd, Suite 700  
Schaumburg, IL 60195  
847-908-1600

**Emergency Telephone:** 866-625-1618

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

**Product Code:** 25021-142  
25021-143  
25021-144

**Common/Trade Name:** Ampicillin Sodium / Sulbactam Sodium

**Chemical Name:** Ampicillin Sodium: monosodium (2S, 5R, 6R)-6-[(R)-2-amino-2-phenylacetamido]-3, 3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate.

Sulbactam Sodium: sodium (2S, 5R)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0] heptane-2-carboxylate 4,4-dioxide.

**Chemical Formula:** Ampicillin Sodium: C<sub>16</sub>H<sub>18</sub>N<sub>3</sub>NaO<sub>4</sub>S  
Sulbactam Sodium: C<sub>8</sub>H<sub>10</sub>NNaO<sub>5</sub>S

**Chemical Family:** Antibiotics


**Product Use:** Pharmaceutical

**Product Type:** Regulated Prescription Drug

**Container Information:** Vials

### Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	CAS No.
Ampicillin Sodium	66.66	69-52-3
Sulbactam Sodium	33.33	69388-84-7


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### Section 3 - Hazards Identification

<b>Routes of Entry:</b>	Inhalation, eye/skin contact, or ingestion.
<b>Signs &amp; Symptoms of Exposure:</b>	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.
<b>Chemical Listed as Carcinogen:</b>	<b>NTP: No IARC: No OSHA: No</b>
<b>Medical Conditions Generally Aggravated by Exposure:</b>	Previous allergic reaction to penicillins, penicillin derivatives, penicillamine, or cephalosporins. History of bleeding disorders, gastrointestinal disease, hepatic and renal function impairment.

### Section 4 - First Aid Measures

<b>Eye Exposure:</b>	Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
<b>Skin Exposure:</b>	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.
<b>Ingestion:</b>	Flush mouth out with water immediately. Seek medical attention.
<b>Inhalation:</b>	Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.
<b>Notes to Physician:</b>	See patient package insert in shipping carton for complete information.


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### Section 5 - Fire Fighting Measures

<b>Flash Point:</b>	Not established
<b>Auto-ignition Temperature:</b>	Not established
<b>Flammable Limits in Air:</b>	Lower %: Not established Upper %: Not established
<b>Flammable Limits:</b>	Not established
<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. Wear self-containing breathing apparatus and protective clothing.
<b>Special Fire Fighting Procedures:</b>	Water spray, dry chemical, or carbon dioxide as appropriate to surroundings.
<b>Unusual Fire/Explosion Hazards:</b>	Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides, and other sulfur-containing compounds. Ash remaining after thermal decomposition may contain cyanide compounds and should not come in contact with acidic condition.

### Section 6 - Accidental Release Measures

<b>Spill:</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.
<b>Release to Air:</b>	A system of local and/or general exhaust is recommended to keep employee exposure below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Use explosion-proof equipment.  This material must be handled in cool, well ventilated low humidity areas.
<b>Release to Water:</b>	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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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.

**Waste Disposal Method:** Follow federal, state and local regulations.

**Storage Conditions:** Store at 20°-25°C (68°-77°F), with excursions permitted between 15° and 30°C (59° and 86°F) prior to reconstitution. [See USP Controlled Room Temperature]. Follow instructions provided in packaging.

**Section 8 - Exposure Controls / Personal Protection**

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

**Eye Protection:** Safety glasses or goggles recommended.

**Ventilation:** Local exhaust ventilation is required unless used in a closed system.


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

**Other Protective Equipment:** Protective laboratory coat, apron, or disposable garment recommended.

**Additional Exposure Precautions:** No eating, drinking or smoking while handling this product. Use good personal hygiene.

**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 <sup>3</sup> (as free acid)


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### Section 9 - Physical and Chemical Properties

<b>Physical State:</b>	White to off-white dry powder	<b>Specific Gravity:</b>	Approx to water
<b>Appearance and Odor:</b>	White and Odorless	<b>Evaporation Rate:</b>	Approx to water
<b>Boiling Point:</b>	Not established	<b>Solubility in Water:</b>	Soluble in water
<b>Vapor Pressure:</b>	Not established	<b>pH:</b>	8-10 (Reconstituted Solution)
<b>Vapor Density:</b>	Not established	<b>Molecular Weight:</b>	Ampicillin Sodium -371.39 Sulbactam Sodium - 255.22

### Section 10 - Stability and Reactivity

<b>Stability:</b>	Stable
<b>Incompatibility (Materials to avoid):</b>	No known incompatibilities.
<b>Hazardous Decomposition:</b>	Carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides and other sulfur-containing compounds.
<b>Hazardous Polymerization:</b>	Does not occur.
<b>Conditions to Avoid:</b>	Avoid strong bases and strong acids.

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### Section 11 - Toxicological Information

#### Acute Toxicity

Component	Type	Route	Species	Dosage
Ampicillin Sodium	LD <sub>50</sub>	Oral	Rat	> 5314 mg/kg
Ampicillin Sodium	LD <sub>50</sub>	Subcutaneous	Rat	> 5314 mg/kg
Ampicillin Sodium	LD <sub>50</sub>	Intraperitoneal	Rat	7400 mg/kg
Ampicillin Sodium	LD <sub>50</sub>	Oral	Mouse	> 5314 mg/kg
Ampicillin Sodium	LD <sub>50</sub>	Subcutaneous	Mouse	> 5314 mg/kg
Ampicillin Sodium	LD <sub>50</sub>	Intraperitoneal	Mouse	5700 mg/kg
Sulbactam Sodium	LD <sub>50</sub>	Oral	Rat	> 4000 mg/kg
Sulbactam Sodium	LD <sub>50</sub>	Intravenous	Rat	4582 mg/kg
Sulbactam Sodium	LD <sub>50</sub>	Oral	Mouse	> 10,000 mg/kg
Sulbactam Sodium	LD <sub>50</sub>	Intravenous	Mouse	3604 mg/kg

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 - Ecological Information

No applicable ecological information found.

### Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.


### Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

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### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

#### **U.S. Regulations**

TSCA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*


OSHA Substance Specific - *No*

### Section 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.

For additional information contact:

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1901 N. Roselle Rd, Suite 700  
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**Glossary:** This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)