

	Sagent Pharmaceuticals, Inc.				
	Ampicillin and Sulbactam for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Feb. 16, 2015	SDS No.: SDS 027	SDS Version No.: 2.0	Form No.: R-SOP-009-F001	Page: 1 of 10

Section 1 - Identification

- (a) **Product Identifier:** Ampicillin and Sulbactam for Injection, USP
- (b) **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 Family:** Antibiotics
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:**
- HMIS Rating**
- | | |
|-----------------|---|
| Health Hazard | 2 |
| Flammability | 0 |
| Physical Hazard | 0 |
- NFPA Rating**
- | | |
|-------------------|---|
| Health Hazard | 2 |
| Fire Hazard | 0 |
| Reactivity Hazard | 0 |

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Signal Word:</u>	- WARNING
<u>Hazard Statements:</u> - May cause allergic skin reaction - May cause allergic or asthmatic symptoms or breathing difficulties if inhaled - May cause damage to liver through prolonged or repeated exposure	
<u>GHS Precautionary Statements:</u> - P260: Do not breathe dust/fume/gas/mist/vapors/spray - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. - If eye irritation persists, get medical attention. - Wash hands after handling. - Get medical attention if you feel unwell	

(d) Unknown Acute Toxicity: N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
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	Ampicillin Sodium	66.66% (w/w)	69-52-3	N/A
sodium (2S, 5R)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0] heptane-2-carboxylate 4,4-dioxide	Sulbactam Sodium	33.33% (w/w)	69388-84-7	N/A

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Section 4 - First Aid Measures

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

Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** 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) **Hazardous Combustion Products:** 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.
- (c) **Special Protective Equipment / Precautions:** Water spray, dry chemical, or carbon dioxide as appropriate to surroundings.

Section 6 - Accidental Release Measures

- Spill:** 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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Release to Air: 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.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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°-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

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
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)

(b) Engineering Controls

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

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(c) Individual Protection Measures

Respiratory Protection:	With satisfactory ventilation, respiratory protection is usually not required.
Eye Protection:	Safety glasses or goggles recommended.
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.

Section 9 - Physical and Chemical Properties

(a)	Appearance	White to off-white dry powder
(b)	Odor	No Odor
(c)	Odor Threshold	None
(d)	pH	8 – 10
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Approx to water
(i)	Flammability	Not flammable
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Approx to water
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

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Section 10 - Stability and Reactivity

(a)	Reactivity	Not available
(b)	Chemical Stability	Stable
(c)	Possibility of Hazardous Reactions	Hazardous polymerization does not occur
(d)	Conditions to Avoid	Avoid strong bases and strong acids.
(e)	Incompatible Materials	Strong oxidizing agents
(f)	Hazardous Decomposition Products	Carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides and other sulfur-containing compounds.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation, eye/skin contact, or ingestion.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	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.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Overdosage adverse reactions include neurological adverse reactions including convulsions. Ampicillin is reported to induce environmental or occupational asthma.

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(d) Acute Toxicity

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

(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	No applicable ecological information found.
(b)	Persistence and degradability	No applicable ecological information found.
(c)	Bioaccumulative potential	No applicable ecological information found.
(d)	Mobility in soil	No applicable ecological information found.
(e)	Other Adverse Effects	No applicable ecological information found.

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Section 13 - Disposal Considerations

Follow federal, state and local regulations.

Section 14 - Transport Information

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

DOT: Not regulated

ICAO/IATA: Not regulated

IMDG: Not regulated

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

California Proposition 65 – Not Listed

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

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that it is accurate. THIS 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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Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

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

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RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
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)