

SAFETY DATA SHEET



Ampicillin and Sulbactam, USP

1) PRODUCT AND COMPANY IDENTIFICATION

Product Identifier:	Ampicillin and Sulbactam for Injection, USP
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
Product Use:	Pharmaceutical
Product Type:	Regulated Prescription Drug
Container Information:	Vials
Manufacturer:	Piramal Critical Care, Inc 268 Brodhead Road Bethlehem, PA, 18017
Important Phone Numbers:	Customer Service: 610-974-9760 x 510 E-Mail: pccustomerconnect@piramal.com 24 Hour Emergency: 484-895-5734 CHEMTREC 1-800-424-9300 (For Transportation in US and Canada)

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	

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	- WARNING
Hazard Statements:	
<ul style="list-style-type: none"> - 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 	
GHS Precautionary Statements:	
<ul style="list-style-type: none"> - 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

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

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

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.

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.

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.

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.

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.

(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.

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

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.

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.

(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

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.

13) DISPOSAL CONSIDERATIONS

Follow federal, state and local regulations.

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

15) REGULATORY INFORMATION**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

16) OTHER INFORMATION

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SDS Updates:

04-15-2019 – New Document