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Section 1 - Identification

- (a) **Product Identifier:** Ampicillin and Sulbactam for Injection, USP
- (b) **Product Code:** 83634-108; 83634-109; 83634-110
- Common/Trade Name:** UNASYN®
- 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:** Antibiotic Agent
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229

Section 2 - Hazards Identification

- (a) **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

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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
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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/v)	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/v)	69388-84-7	N/A

Section 4 – First Aid Measures

Eye Exposure:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
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:	Wash out mouth with water immediately. Seek medical attention.
Inhalation:	Remove to fresh air and keep patient at rest. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

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.

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

Section 6 - Accidental Release Measures

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	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.
Measures for Environmental Protections:	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.
Additional Considerations for Large Spills:	<p>This material must be handled in cool, well-ventilated low humidity areas.</p> <p>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.</p>


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 as directed by product 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)

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(b) Engineering Controls

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

(c) Individual Protection Measures


Personal Protective Equipment:	Protective laboratory coat, apron, or disposable garment recommended.
Eye Protection:	Safety glasses or goggles recommended.
Skin Protection:	Disposable garments if direct skin contact is anticipated.
Respiratory Protection:	With satisfactory ventilation, respiratory protection is usually not required.

Section 9 - Physical and Chemical Properties

(a)	Appearance	White dry powder
(b)	Odor	Odorless
(c)	Odor Threshold	Not available
(d)	pH	8.0 to 10.0
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point (Liquid) (°C)	Not determined
(h)	Evaporation Rate:	Not determined
(i)	Flammability	Not flammable
(j)	Upper Lower Flammability or Explosion Limits	Not determined
(k)	Vapor Pressure (kPa):	Not determined
(l)	Vapor Density:	Not determined
(m)	Relative Density	Not determined
(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

Section 10 - Stability and Reactivity

(a)	Reactivity	Not determined
(b)	Chemical Stability	Stable under standard use and storage conditions.

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(c)	Possibility of Hazardous Reactions	Not determined
(d)	Conditions to Avoid	Avoid strong bases and strong acids
(e)	Incompatible Materials	As a precautionary measure, keep away from strong oxidizers.
(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 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
Ampicillin Sodium	LD ₅₀	Oral	Rat	>4000 mg/kg
Ampicillin Sodium	LD ₅₀	Intravenous	Rat	4582 mg/kg
Ampicillin Sodium	LD ₅₀	Oral	Mouse	>10,000 mg/kg
Ampicillin Sodium	LD ₅₀	Intravenous	Mouse	3604 mg/kg

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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.

(c) Hazardous Chemical Listings

NTP: Not listed.
IARC: Not listed.
OSHA: Not listed.
NIOSH: Not listed.

Section 12 - Ecological Information

(a)	Ecotoxicity	N/A
(b)	Persistence and degradability	N/A
(c)	Bioaccumulative potential	N/A
(d)	Mobility in soil	N/A
(e)	Other Adverse Effects	N/A

Section 13 - Disposal Considerations

Waste Disposal: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

Section 14 - Transport Information


Not regulated for transport under USDOT, UN, ICAO/IATA, or IMDG regulations.

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy 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.

US Regulations

TSCA	No
CERCLA	Not Listed
SARA 302/313	Not Listed
OSHA Substance Specific	No
California Proposition 65	Not Listed

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Section 16 - Other Information


As of the date of effectiveness, 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 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:

Avenacy
10 N. Martingale Road, Suite 225
Schaumburg, IL 60173
847-773-4901

Glossary: This glossary contains definitions of general terms used in Safety Data Sheets. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
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

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NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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
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)
WHMIS	Workplace Hazardous Materials Information System