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### Section 1 - Identification

- (a) **Product Identifier:** Ampicillin for Injection, USP
- (b) **Product Code:** 25021-134, 25021-135, 25021-136, 25021-137, 25021-138
- Common/Trade Name:** Ampicillin Sodium
- Chemical Name:** Monosodium salt of [2S-[2 $\alpha$ , 5 $\alpha$ , 6 $\beta$ (S\*)]]-6-[(aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid
- Chemical Family:** Anti-Infective
- (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:** GHS Ratings  
Respiratory Sensitization (Category 1)  
Skin Sensitization (Category 1)


HMIS Rating

Health Hazard	3
Flammability	0
Physical Hazard	0


NFPA Rating

Health Hazard	3
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:
	<ul style="list-style-type: none"> <li>- <u>Signal Word:</u> Danger</li> </ul>
<u>Hazard Statements:</u> H315 H317 H334	<ul style="list-style-type: none"> <li>- Causes Skin Irritation</li> <li>- May cause an allergic skin reaction</li> <li>- May cause allergy or asthma symptoms or breathing difficulties if inhaled</li> </ul>
<u>Precautionary Statements:</u> P261 P272  P280 P285  P302 + P352 P304 + P341  P321  P333 + P313  P342 + P311  P363 P501	<ul style="list-style-type: none"> <li>- Avoid breathing dust/fume/gas/mist/vapours/spray</li> <li>- Contaminated work clothing should not be allowed out of the workplace</li> <li>- Wear protective gloves</li> <li>- In case of inadequate ventilation wear respiratory protection</li> <li>- IF ON SKIN: Wash with plenty of soap and water</li> <li>- IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing</li> <li>- Specific treatment (see supplemental first aid instructions on this label)</li> <li>- If skin irritation or rash occurs: Get medical advice/attention</li> <li>- If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician</li> <li>- Wash contaminated clothes before reuse</li> <li>- Dispose of contents/container to an approved waste disposal plant</li> </ul>

**(d) Unknown Acute Toxicity:** N/A

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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 salt of [2S-[2 $\alpha$ , 5 $\alpha$ , 6 $\beta$ (S*)]]-6-[(aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid	Ampicillin Sodium	100%	69-52-3	N/A

### Section 4 - First Aid Measures

- Eye Exposure:** Immediately rinse eyes with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Seek medical advice.
- Skin Exposure:** Remove contaminated clothing immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
- Ingestion:** Never attempt to induce vomiting. Flush mouth out with water immediately. Seek medical attention.
- Injection:** In case of accidental injection, wash and disinfect area, set medical attention.
- Inhalation:** Use appropriate personal protective equipment. Move to fresh air and monitor breathing. If breathing becomes difficult, maintain ventilation, give oxygen as appropriate and seek medical attention.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

### Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Water, carbon dioxide, dry chemical powder, polymer foam. Water is recommended for fires involving packaging.
- (b) **Hazardous Combustion Products:** Dust clouds are potentially sensitive to ignition from electrostatic discharge especially if finely divided.

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- (c) **Special Protective Equipment / Precautions:** Carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), sodium oxides, sulfur oxides (SO<sub>x</sub>) may be emitted upon thermal decomposition.

### Section 6 - Accidental Release Measures

- Spill:** Contain and collect spillage and place in container for disposal according to local regulations (See Section 13). Wipe surface area clean with soap and water. Avoid contact with strong oxidizing agents.
- Release to Air:** Prevent release to drains and waterways. Prevent release to the environment.
- 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. Keep away from sources of ignition.
- Storage Conditions:** Store at controlled room temperature between 20 to 25°C (68 to 77°F) in the original container. Keep tightly closed.


### Section 8 - Exposure Controls / Personal Protection

**(a) Exposure Limits**

Compound	Issuer	Type	Exposure Limit
Ampicillin Sodium	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

**(b) Engineering Controls**

- Ventilation:** General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.


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**(c) Individual Protection Measures**

Respiratory Protection:	If respiratory protection is used, the type of protection will depend upon air concentration present, required protection factor as well as hazards, physical properties of substance present.
Eye Protection:	Safety glasses with side shields or goggles are recommended.
Skin Protection:	Protect with disposable garments if direct skin contact is anticipated.
Other Protective Equipment:	Chemical resistant gloves.
Additional Exposure Precautions:	Wash hands and face before breaks and immediately after handling the product.

**Section 9 - Physical and Chemical Properties**

<b>(a) Appearance</b>	White to off-white powder
<b>(b) Odor</b>	Not established
<b>(c) Odor Threshold</b>	None
<b>(d) pH</b>	8.0-10.0
<b>(e) Melting Point:</b>	205 °C
<b>(f) Initial Boiling Point:</b>	Not available
<b>(g) Flash Point</b>	Not established
<b>(h) Evaporation Rate:</b>	Not available
<b>(i) Flammability</b>	Not available
<b>(j) Upper Lower Flammability or Explosion Limits</b>	Not established
<b>(k) Vapor Pressure:</b>	Not available
<b>(l) Vapor Density:</b>	Not available
<b>(m) Relative Density</b>	Not available
<b>(n) Solubility(ies)</b>	Soluble in water
<b>(o) Partition Coefficient: n-octanol/water</b>	N/A
<b>(p) Auto-ignition Temperature</b>	Not established
<b>(q) Decomposition Temperature</b>	N/A
<b>(r) Viscosity</b>	N/A

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### Section 10 - Stability and Reactivity

(a)	<b>Reactivity</b>	Stable under normal conditions.
(b)	<b>Chemical Stability</b>	No hazardous polymerizations.
(c)	<b>Possibility of Hazardous Reactions</b>	See Section 10f
(d)	<b>Conditions to Avoid</b>	No conditions contributing to instability are known to exist. Avoid contact with strong oxidizing agents.
(e)	<b>Incompatible Materials</b>	Not available.
(f)	<b>Hazardous Decomposition Products</b>	Formed under fire conditions: Carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ), sodium oxides, sulfur oxides (SO <sub>x</sub> ).

### Section 11 - Toxicological Information

(a)	<b>Likely Routes of Exposure</b>	Inhalation, eye/skin contact, or ingestion
(b)	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	May cause respiratory tract, eye and skin irritation. May cause allergic respiratory and skin reaction.
(c)	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	May cause sensitization by inhalation and skin contact. Irritating to eyes, respiratory system and skin. May cause allergic reaction in penicillin-sensitive individuals.

#### (d) Acute Toxicity


Component	Type	Route	Species	Dosage
Ampicillin Sodium	LD <sub>50</sub>	Oral	Rat	5314 mg/kg
Ampicillin Sodium	LD <sub>50</sub>	Intraperitoneal	Rat	7400 mg/kg
Ampicillin Sodium	LD <sub>50</sub>	Subcutaneous	Rat	>5314 mg/kg

#### (e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

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**Section 12 - Ecological Information**

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

**Section 13 - Disposal Considerations**

**Product**

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

**Contaminated packaging**

Dispose of as unused product.


**Section 14 - Transport Information**

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

**DOT:** Not dangerous goods

**ICAO/IATA:** Not dangerous goods

**IMO:** Not dangerous goods

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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
- SARA 311/312: Acute Health Hazard
- OSHA Substance Specific - No
- Massachusetts Right to Know Components – No
- Pennsylvania Right to Know Components – Yes
- New Jersey Right to Know Components – Yes
- California Prop 65 Components – 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 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:

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


**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
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute



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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
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 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
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

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UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System