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Section 1 - Identification

- (a) **Product Identifier:** Ampicillin for Injection, USP
- (b) **Product Code:** 70860-112
70860-113
70860-114
70860-115
70860-118
- Common/Trade Name:** Ampicillin Sodium
- Chemical Name:** Monosodium salt of [2S-[2 α ,5 α ,6 β (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, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Respiratory Sensitization (Category 1)
Skin Sensitization (Category 1)

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	
GHS Signal Word:	Danger
GHS Hazard Statement:	May form combustible dust concentrations in air. H317 - May cause an allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
GHS Symbols:	

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GHS Precautionary Statements:	<p>P261 - Avoid breathing dust.</p> <p>P272 - Contaminated work clothing must not be allowed out of the workplace.</p> <p>P280 - Wear protective gloves, protective clothing, and eye protection.</p> <p>P284 - In case of inadequate ventilation wear respiratory protection.</p> <p>P302+P352 - If on skin: Wash with plenty of water.</p> <p>P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P321 - Specific treatment (see section 4 on this SDS).</p> <p>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.</p> <p>P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.</p> <p>P363 - Wash contaminated clothing before reuse.</p> <p>P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.</p>
Other Hazards	Exposure may aggravate pre-existing eye, skin, or respiratory conditions.


(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 salt of [2S-[2 α ,5 α ,6 β (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.

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- 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.
- (c) **Special Protective Equipment / Precautions:** Carbon oxides (CO_x), nitrogen oxides (NO_x), sodium oxides, sulfur oxides (SO_x) 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:** No special handling required under conditions of normal product use.
- Storage Conditions:** 20° to 25°C (68° to 77°F)

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Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

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

Notes:

OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit

ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.


(b) Engineering Controls

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Ensure all national/local regulations are observed.

(c) Individual Protection Measures

Respiratory Protection:	In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Eye Protection:	Chemical resistant goggles must be worn.
Skin Protection:	Wear chemically resistant protective gloves, materials and fabrics. Wash contaminated clothing before reuse.
Other Protective Equipment:	Protective Latex or Nitrile gloves. goggles. Insufficient ventilation: wear respiratory protection.
Additional Exposure Precautions:	When using, do not eat, drink or smoke.


Section 9 - Physical and Chemical Properties

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(a)	Appearance	Solid, white to off-white powder
(b)	Odor	No odor
(c)	Odor Threshold	Not available
(d)	pH	8 to 10
(e)	Melting Point:	195 - 203 °C (383 - 397.4 °F) decomposing
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Water: 500 g/l (Temperature: 20 °C)
(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	Hazardous reactions will not occur under normal conditions.
(b)	Chemical Stability	Stable under standard use and storage conditions.
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur.
(d)	Conditions to Avoid	Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).
(e)	Incompatible Materials	Strong acids, strong bases, strong oxidizers.
(f)	Hazardous Decomposition Products	Carbon oxides (CO, CO ₂). Nitrogen oxides. Sulfur oxides.

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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	May cause respiratory tract, eye and skin irritation. May cause allergic respiratory and skin reaction.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	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 ₅₀	Oral	Rat	5314 mg/kg
Ampicillin Sodium	LD ₅₀	Intraperitoneal	Rat	7400 mg/kg
Ampicillin Sodium	LD ₅₀	Subcutaneous	Rat	>5314 mg/kg

(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.

Section 13 - Disposal Considerations

Waste disposal of 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.

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Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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 – Not regulated
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 311/312: Immediate (acute) health hazard
 - Fire hazard
 - Sudden release of pressure hazard
- SARA 313 - Not on this list
- OSHA – Not on this list

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

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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
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
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

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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

Signature Manifest

Document Number: SDS023
Title: Ampicillin for Injection, USP

Revision: 02

All dates and times are in Eastern Standard Time.

Ampicillin SDS Revision

Change Request

Name/Signature	Title	Date	Meaning/Reason
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Quality	03 Jul 2018, 12:26:44 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	10 Jul 2018, 11:34:25 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	10 Jul 2018, 12:36:41 PM	Approved