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### Section 1 - Identification

- (a) **Product Identifier:** Nafcillin for Injection, USP
- (b) **Product Code:** 70860-116  
70860-117  
70860-119
- Common/Trade Name:** Nafcillin for Injection
- Chemical Name:** Monosodium (2S,5R,6R)-6-(2-ethoxy-1-naphthamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0]heptane-2-carboxylate monohydrate
- Chemical Family:** Antibiotic
- (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) <b>GHS Classification of substance or mixture:</b> | Skin Irrit. 2 | H315 |
|  | Eye Irrit. 2A | H319 |
|  | Resp. Sens. 1 | H334 |
|  | Skin Sens. 1  | H317 |
|  | STOT SE 3     | H335 |

**(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):**

**GHS Signal Word:** Danger


**GHS Hazard Statement:**

H315 - Causes skin irritation  
H317 - May cause an allergic skin reaction  
H319 - Causes serious eye irritation  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H335 - May cause respiratory irritation

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<b>GHS Symbols:</b>	
<b>GHS Precautionary Statements:</b>	<p>P261 - Avoid breathing dust/fume/gas/mist/vapors/spray</p> <p>P264 - Wash thoroughly after handling</p> <p>P271 - Use only outdoors or in a well-ventilated area</p> <p>P272 - Contaminated work clothing must not be allowed out of the workplace</p> <p>P280 - Wear protective gloves/protective clothing/eye protection/face 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 comfortable for breathing</p> <p>P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</p> <p>P312 - Call a poison center/doctor if you feel unwell</p> <p>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention</p> <p>P337+P313 - If eye irritation persists: Get medical advice/attention</p> <p>P342 + P311 - If experiencing respiratory symptoms: Call a poison center/doctor/...</p> <p>P362 - Take off contaminated clothing and wash before reuse</p> <p>P362+P364 - Take off contaminated clothing and wash it before reuse</p> <p>P403+P233 - Store in a well-ventilated place. Keep container tightly closed</p> <p>P405 - Store locked up</p> <p>P501 - Dispose of contents/container in accordance with local/regional/national/international</p>
<b>Other Hazards</b>	No additional information available.

**(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
Nafcillin sodium	Nafcillin Sodium	96%	7177-50-6	N/A
Sodium Citrate*	Sodium Citrate	4%	6132-04-3	N/A


\* Used as a buffering agent.

### Section 4 – First Aid Measures

- Eye Exposure:** Immediately flush with plenty of water for at least 15 minutes occasionally lifting upper and lower eyelids. If easy to do, remove contact lenses. Get medical attention if symptoms persist.
- Skin Exposure:** Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash contaminated clothing before reuse.
- Ingestion:** DO NOT induce vomiting. If victim is fully conscious, give a cupful of water. Never give anything by mouth to an unconscious person. If vomiting occurs, keep head lower than the hips to help prevent aspiration. Call a physician or poison control center immediately.
- Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and monitor closely. Get medical attention immediately.

### Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** As with any fire, use extinguishing media appropriate for primary cause of fire.
- (b) **Hazardous Combustion Products:** None determined

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- (c) **Special Protective Equipment / Precautions:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

### Section 6 - Accidental Release Measures

- Spill:** Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation
- Release to Air:** Not available.
- Release to Water:** Prevent entry to sewers and public waters. Refer to the local water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.

### Section 7 - Handling and Storage

**General Handling:** Wear protective clothing as described in Section 8 of this safety data sheet. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Use only with adequate ventilation. Wash thoroughly after handling. Minimize dust generation and accumulation.

**Storage Conditions:** Store dry powder at 20° to 25°C (68° to 77°F).

### Section 8 - Exposure Controls / Personal Protection

#### (a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Nafcillin Sodium	OSHA	PEL	NE
	ACGIH	TLV	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

Appropriate engineering controls      Local exhaust and general ventilation must be adequate to meet exposure standards.


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**(c) Individual Protection Measures**

Respiratory Protection:	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134. Respirator type: Use high efficiency particulate respirator with appropriate filter
Eye Protection:	Wear safety glasses with side shields (or goggles).
Skin Protection:	Wear suitable working clothes.
Other Protective Equipment:	Protective gloves
Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product.

**Section 9 - Physical and Chemical Properties**

<b>(a) Appearance</b>	white to off-white crystalline dry powder
<b>(b) Odor</b>	Not available
<b>(c) Odor Threshold</b>	Not available
<b>(d) pH (reconstituted)</b>	6.0 – 8.5
<b>(e) Melting Point:</b>	Not available
<b>(f) Initial Boiling Point:</b>	Not available
<b>(g) Flash Point</b>	Not available
<b>(h) Evaporation Rate:</b>	Not available
<b>(i) Flammability</b>	Not available
<b>(j) Upper Lower Flammability or Explosion Limits</b>	Not available
<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>	Freely soluble in water
<b>(o) Partition Coefficient: n-octanol/water</b>	Not available
<b>(p) Auto-ignition Temperature</b>	Not available
<b>(q) Decomposition Temperature</b>	Not available

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<b>(r)</b>	<b>Viscosity</b>	Not available
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**Section 10 - Stability and Reactivity**

<b>(a)</b>	<b>Reactivity</b>	Not determined
<b>(b)</b>	<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>(c)</b>	<b>Possibility of Hazardous Reactions</b>	Will not occur
<b>(d)</b>	<b>Conditions to Avoid</b>	Heat, water, moisture. Minimize dust generation and accumulation. Contact with incompatible materials.
<b>(e)</b>	<b>Incompatible Materials</b>	Strong oxidizers.
<b>(f)</b>	<b>Hazardous Decomposition Products</b>	Carbon oxides. Nitrogen oxides. Sulfur oxides.

**Section 11 - Toxicological Information**

<b>(a)</b>	<b>Likely Routes of Exposure</b>	Possibly skin, eyes, mouth
<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	<p>Symptoms/injuries after inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p> <p>Symptoms/injuries after skin contact: May cause an allergic skin reaction.</p> <p>Symptoms/injuries after eye contact: May cause eye irritation on direct contact.</p> <p>Symptoms/injuries after ingestion: Ingestion may cause irritation and malaise. May cause serious or fatal hypersensitivity (anaphylactic) reactions in some individuals.</p>
<b>(c)</b>	<b>Delayed and immediate effects and chronic effects from short and long term exposure</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. May cause respiratory irritation.

**(d) Acute Toxicity**  
Not classified.

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Component	Type	Route	Species	Dosage
Nafcillin Sodium	LD <sub>50</sub>	Intravenous	Mouse Dog	1 g/Kg 633 mg/Kg

**(e) Hazardous Chemical Listings**

NTP: Not Listed      IARC: Not Listed      OSHA: Not Listed

**Section 12 - Ecological Information**

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


**Section 13 - Disposal Considerations**

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

**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.

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

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### 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: Not on this list
- 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 contact:

Athenex Pharmaceutical Division  
 10 N. Martingale Road, Suite 230  
 Schaumburg, IL 60173  
 847-886-9515

**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



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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
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:** SDS026  
**Title:** Nafcillin for Injection, USP

**Revision:** 01

All dates and times are in Eastern Standard Time.

### Nafcillin for Injection, USP

#### Change Request

Name/Signature	Title	Date	Meaning/Reason
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Quality	20 Jul 2018, 12:01:39 PM	Approved

#### Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	20 Jul 2018, 04:42:00 PM	Approved

#### Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	20 Jul 2018, 05:24:06 PM	Approved