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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) **GHS Classification of substance or mixture:**
- | | |
|---------------|------|
| 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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GHS Symbols:	
GHS Precautionary Statements:	P261 - Avoid breathing dust/fume/gas/mist/vapors/spray P264 - Wash thoroughly after handling P271 - Use only outdoors or in a well-ventilated area P272 - Contaminated work clothing must not be allowed out of the workplace P280 - Wear protective gloves/protective clothing/eye protection/face protection P284 - [In case of inadequate ventilation] wear respiratory protection P302 + P352 - If on skin: Wash with plenty of water/... P304 + P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P312 - Call a poison center/doctor if you feel unwell P333+P313 - If skin irritation or rash occurs: Get medical advice/attention P337+P313 - If eye irritation persists: Get medical advice/attention P342 + P311 - If experiencing respiratory symptoms: Call a poison center/doctor/... P362 - Take off contaminated clothing and wash before reuse P362+P364 - Take off contaminated clothing and wash it before reuse P403+P233 - Store in a well-ventilated place. Keep container tightly closed P405 - Store locked up P501 - Dispose of contents/container in accordance with local/regional/national/international
Other Hazards	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

(a)	Appearance	white to off-white crystalline dry powder
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH (reconstituted)	6.0 – 8.5
(e)	Melting Point:	Not available
(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)	Freely soluble in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available

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(r)	Viscosity	Not available
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Section 10 - Stability and Reactivity

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

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Possibly skin, eyes, mouth
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Symptoms/injuries after inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Symptoms/injuries after skin contact: May cause an allergic skin reaction. Symptoms/injuries after eye contact: May cause eye irritation on direct contact. Symptoms/injuries after ingestion: Ingestion may cause irritation and malaise. May cause serious or fatal hypersensitivity (anaphylactic) reactions in some individuals.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	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 ₅₀	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

(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: 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.

(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

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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