Section 1 - Identification

(a) Product Identifier: Nafcillin for Injection, USP

(b) Product Code: 25021-139, 25021-140, 25021-141

Common/Trade Name: Nafcillin for Injection

Chemical Name: monosodium (2*S*,5*R*,6*R*)-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

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: N/A

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	**(c) Description of Hazards:**
Signal Word:	N/A
Statement of Hazard:	N/A

(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 (2*S*,5*R*,6*R*)-6-(2-ethoxy-1-naphthamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate	Nafcillin Sodium	96%	7177-50-6	N/A
Sodium citrate	Sodium Citrate	4%	68-04-2	N/A

Section 4 - First Aid Measures

Eye Exposure: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Exposure: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Injection: See patient package insert in shipping carton for complete information.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediately medical attention.

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

(a) Extinguishing Media Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

(b) Hazardous Combustion Products: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

(c) Special Protective Equipment / Precautions: As in any fire, wear self-contained breathing apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Section 6 - Accidental Release Measures

Spill: Contain spills with an inert absorbent material such as soil, sand or oil dry. Place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

Release to Air: No information available.

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 vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Storage Conditions: Prior to reconstitution store powder at 20°-25°C (68°-77°F). Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Nafcillin Sodium	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Sodium Citrate Anhydrous	OSHA ACGIH -----	PEL TLV STEL	NE NE NE

(b) Engineering Controls

Ventilation: General ventilation is sufficient if this product is being used in a controlled medical setting (clinical, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

(c) Individual Protection Measures

Respiratory Protection:	No personal respiratory protective equipment normally required.
Eye Protection:	Chemical splash goggles. Wear a face shield also when splash hazards exist.
Skin Protection:	Protective laboratory coat, apron, or disposable garment recommended.
Other Protective Equipment:	Consult local procedures for selection, training, inspection and maintenance of the personal protective equipment.
Additional Exposure Precautions:	Wear appropriate protective gloves. Consult glove manufacturer data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

Section 9 - Physical and Chemical Properties

(a)	**Appearance**	Powder, white to yellow/white
(b)	**Odor**	No Odor
(c)	**Odor Threshold**	None
(d)	**pH**	6.0 – 8.5
(e)	**Melting Point:**	Not available
(f)	**Initial Boiling Point:**	100ºC (212ºF)
(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)**	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 available
(b)	**Chemical Stability**	Stable under recommended storage conditions
(c)	**Possibility of Hazardous Reactions**	Hazardous polymerization will not occur
(d)	**Conditions to Avoid**	Avoid exposure to heat and moisture.
(e)	**Incompatible Materials**	Oxidizing Agents
(f)	**Hazardous Decomposition Products**	When heated to decomposition, the material emits very toxic fumes of NOX, NA2O, and SOX. Emits toxic fumes under fire conditions.

Section 11 - Toxicological Information

(a)	**Likely Routes of Exposure**	Inhalation, ingestion, eye contact, skin absorption and injection
(b)	**Symptoms related to the physical, chemical and toxicological characteristics**	Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Renal function effects (may including increased levels of creatinine, BUN, renal failure). Blood effects (may include anemia, neutropenia (decreased number of neutrophils), thrombocytopenia (decreased number of platelets), bone marrow depression). Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual disturbances, headaches, coma).

(c)	**Delayed and immediate effects and also chronic effects from short and long term exposure**	Potential adverse reactions from prescribed doses and overdoses are described in the package insert. May cause sensitization by inhalation and skin contact.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Nafcillin Sodium	LD_{50}	Intravenous	Mouse	1 g/Kg
Nafcillin Sodium	LD_{50}	Intravenous	Dog	633 mg/Kg

(e) Hazardous Chemical Listings

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

Section 12 - Ecological Information

(a)	**Ecotoxicity**	Not available
(b)	**Persistence and degradability**	Not available
(c)	**Bioaccumulative potential**	Not available
(d)	**Mobility in soil**	Not available
(e)	**Other Adverse Effects**	Not available

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

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

(g)	**Special Precautions**	Not available

DOT: Not regulated
ICAO/IATA: Not regulated
IMDG: Not regulated

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
OSHA Substance Specific - 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
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
IMDG	International Maritime Dangerous Goods
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