

1. PRODUCT AND COMPANY INFORMATION

Distributed By: WG Critical Care, LLC.

120 Route 17 North

Suite 115

Paramus, NJ 07652 USA

Product Name: Nafcillin for Injection, USP

Active Ingredient/Primary

Component:

Nafcillin Sodium

Chemical Name: [Nafcillin is INN and BAN.]

 $\begin{tabular}{ll} (1) 4-Thia-1-azabicyclo [3.2.0] heptane-2-carboxylic acid, $6-[[(2-ethoxy-1-naphthalenyl]) carbonyl] amino]-3,3-dimethyl-7-oxo-, $$ $(2-ethoxy-1-naphthalenyl)$ are $(2-$

monosodium salt, monohydrate, [2S-(2a,5a,6b)]

(2) 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.

CAS Number: CAS 985-16-0 (Nafcillin Sodium Anhydrous)

Chemical Family: Antibiotic
Product Use: Pharmaceutical
Product Type: Prescription Drug

Container Information: Vials

Customer Service Phone Number: +1-888-493-0861

Emergency Phone Number: +1-866-562-4708 (Prosar)

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2. HAZARDS IDENTIFICATION

PRIMARY PHYSICAL AND HEALTH

HAZARDS:

May cause skin or eye irritation.

May cause allergic reaction.

ROUTES OF ENTRY: Inhalation, eye/skin contact, or ingestion.

SIGNS & SYMPTOMS OF

EXPOSURE:

Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Renal function effects (may include increased levels of creatinine, BUN, renal failure). Blood effects (may include anemia, neutropenia, thrombocytopenia,

bone marrow depression). Hypersensitivity (may include drug fever, rash, itching, or anaphylaxis). Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual

disturbances, headache, or coma).

CHEMICAL LISTED AS

CARCINOGEN:

NTP: NO

IARC: NO

OSHA: NO

3. COMPOSITION / INFORMATION ON INGREDIENTS				
<u>Ingredient</u>	Weight %	CAS No.		
Nafcillin Sodium (Anhydrous)	96	985-16-0		
Sodium Citrate	4	68-04-2		

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4. FIRST AID MEASURES

EYE EXPOSURE: Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 to 20 minutes, keeping eyelids open. Do not use an eye ointment. Seek immediate medical attention.

SKIN EXPOSURE: In case of contact, flush skin with plenty of water and mild soap for 15 to 20 minutes. Remove contaminated clothing and shoes. Get medical attention if irritation develops. **INGESTION:** Do NOT induce vomiting unless directed to do so by medical personnel. Do not attempt to give anything by mouth if the exposed subject is unconscious or semi-unconscious. If large quantities of this material are swallowed, call a physician immediately.

INHALATION: If inhaled, remove to fresh air. If breathing becomes difficult, call a physician immediately. If breathing has stopped, give artificial respiration and seek immediate medical attention.

NOTE TO PHYSICIAN: See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

FLASH POINT: Not determined

AUTO-IGNITION TEMPERATURE: Not available FLAMMABLE LIMITS IN AIR: Not available FLAMMABLE LIMITS: Not available

EXTINGUISHING MEDIA: Use alcohol resistant foam, carbon dioxide, water spray, or all-purpose dry

chemicals to extinguish.

UNUSUAL FIRE / EXPLOSION HAZARDS: 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.

6. ACCIDENTAL RELEASE MEASURE

SPILL: For small spills, add absorbent (soil may be used in the absence of other suitable materials) and scoop material and place in a sealed, liquid-proof container for disposal. Place spilled material in an appropriate container for disposal. After removal, flush spill area with soap and water to remove trace residue.

RELEASE TO AIR: No information is available.

RELEASE TO WATER: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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:** Store in the original containers at 20°C to 25°C (68°F to 77°F) [See USP controlled room temperature]. Keep the containers tightly closed. Do not freeze. Protect from light.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION: No personal respiratory protective equipment normally required with satisfactory ventilation. Normal precautions should be observed as for handling all chemical powders. Use protective mask, such as NIOSH approved respirator, if necessary.

EYE PROTECTION: Safety goggles recommended. Wear a face shield also when splash hazard exist.

VENTILATION: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, 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.

SKIN PROTECTION: Protective laboratory coat, apron, or disposable garment recommended.

OTHER PROTECTIVE EQUIPMENT: Consult with 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: Powder SPECIFIC GRAVITY: Not available APPEARANCE AND ODOR: White to EVAPORATION RATE: Not available

vellowish-white

BOILING POINT: 100°C **MELTING POINT:** Not available

10. STABILITY AND REACTIVITY

STABILITY: Stable under recommended storage conditions.

INCOMPATIBILITY (MATERIALS TO AVOID): Oxidizing Agents

HAZARDOUS POLYMERIZATION: No

HAZARDOUS DECOMPISITION: When heated to decomposition, the material emits very toxic fumes

of NO_X, NA₂O, and SO_X. Emits toxic fumes under fire conditions.

CONDITIONS TO AVOID: Avoid exposure to heat and moisture.

VAPOR PRESSURE: Not available **SOLUBILITY IN WATER:** Soluble **VAPOR DENSITY:** Not available **PH:** 6.0 to 8.5

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11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

COMPONENT	LD50s and LC50s
Nafcillin Sodium	Intravenous LD50 Mouse = 1 g/kg
	Intravenous LD50 Dog = 633 mg/kg
Sodium Citrate, anhydrous	None

^{*}Occasionally hypersensitivity reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and / or a history of sensitivity to multiple allergens.

12. ECOLOGICAL INFORMATION

Penicillins are easily biodegradable and chemically unstable in water. Observe local environmental regulations.

13. DISPOSAL CONSIDERATIONS

14. TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: Not Regulated

ICAO / IATA: Not Regulated

IMO: Not Regulated

WASTE DISPOSAL: Dispose of water in accordance with all applicable and local environmental

regulations.

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15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations

TSCA – No
CERCLA-No
SARA 302 – No
SARA 313 – No
OSHA Substance Specific - No

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.

WG Critical Care	, LLC.
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