

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations
Date of Issue: 04/14/2025

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Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier Product Form: Substance

Product Name: Ampicillin for Injection, USP

CAS-No.: 69-52-3

1.2 Recommended Use and Restrictions on Use Use of the Substance/Mixture: Penicillin Antibiotic Restrictions on use: No additional information available

1.3. Name, Address, and Telephone of the Responsible Party

WG Critical Care, LLC.

120 Route 17 North, Suite 115 Paramus, NJ 07652 USA + 1-888-493-0861

wgccquality@wgcriticalcare.com www.wgcriticalcare.com

1.4. Emergency Telephone Number

Emergency Number : +1-866-562-4708 (ProPharma)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Respiratory sensitization, Category 1 H334
Skin sensitization, Category 1 H317
Combustible dust

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

Hazard Statements (GHS-US)

: Danger

: May form combustible dust concentrations in air [if small particles are generated during further processing, handling or by other means].

H317 - May cause an allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing dust.

P272 - Contaminated work clothing must not be allowed out of the workplace.

P280 - Wear eye protection, protective gloves and clothing. P284 - In case of inadequate ventilation wear dust mask. P302+P352 - If on skin: Wash with plenty of soap and water.

P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P321 - Specific treatment (see Section 4 of this Safety Data Sheet on this label). P333+P313 - If skin irritation or rash occurs: Get medical advice or attention. P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.

P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Proper grounding procedures to avoid static electricity should be followed. Prevent dust accumulation (to minimize explosion hazard). Avoid generating dust.

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2.3 Hazards associated with known or reasonably anticipated uses

This product is a pharmaceutical product designed for administration to a patient by a qualified medical professional. No other uses are anticipated. A Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information.

2.4. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.5. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Name : Ampicillin for Injection, USP

CAS-No. :69-52-3

Name	Synonyms	Product Identifier	%	GHS US classification
Ampicillin sodium	Ampicillin sodium / Ampicillin sodium salt / Binotal sodium / Domicillin / Polycillin-N / Sodium amipicillin / Sodium binotal / Sodium P-50 / 4-Thia-1-azabicyclo(3.2.0) heptane-2-carboxylic acid, 6-(2-amino-2-phenylacetamido)- 3,3-dimethyl-7-oxo-, sodium salt, D-(-)- / 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6- [(aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-, monosodium salt, [2S-[2.alpha.,5.alpha.,6.beta.(S*)]]- / 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-(2-amino-2-phenylacetamido)- 3,3-dimethyl-7-oxo-, sodium salt, d-(-)- / Sodium ampicillin / 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[(2R)-aminophenylacetyl]amino]-3,3-dimethyl-7-oxo-, monosodium salt, (2S,5R,6R)- / 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[(2R)-2-amino-2-phenylacetyl]amino]-3,3-dimethyl-7-oxo-, sodium salt (1:1), (2S,5R,6R)- / 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[(aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-, monosodium salt, [2S-[2.alpha.,5.alpha.,6.beta.(S*)]]- / Sodium (2S,5R,6R)-6-[(R)-2-amino-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate / Sodium [2S-[2.alpha.,5.alpha.,6.beta.(S*)]]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate / Sodium [2S-[2.alpha.,5.alpha.,6.beta.(S*)]]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate	(CAS-No.) 69-52-3	97 – 100	Resp. Sens. 1, H334 Skin Sens. 1, H317 Combustible Dust

Full text of H-phrases: see section 16

3.2. Mixture

Not applicable

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

First-aid Measures After Inhalation: Using proper respiratory protection, immediately move the exposed person to fresh air. Encourage exposed person to cough, spit out, and blow nose to remove dust. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Wash affected area with soap and water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

First-aid Measures After Eye Contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for at least 15 minutes. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin sensitization.

Symptoms/Injuries After Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: Eye contact with dust may cause mechanical irritation.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Inhalation may cause allergic respiratory reaction with asthma-like symptoms and difficulty breathing. Repeated and prolonged exposure may cause an allergic skin reaction.

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4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand. Treat needlestick exposures symptomatically to include monitoring for anaphylaxis.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical. **Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures. Product is not a dust as supplied; however, product dusts may be combustible.

Explosion Hazard: Product is not explosive. Product is not a dust as supplied; however, product dusts may be combustible.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. **Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Oxides of carbon, nitrogen, sulfur and sodium.

Other Information: No additional information available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe dust. Do not get in eyes, on skin, or on clothing. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Eliminate ignition sources first, then ventilate the area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. **Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Vacuum clean-up is preferred. If sweeping is required use water mist as a dust suppressant. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms during use. Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing dust. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with established protocols.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: Do not freeze reconstituted liquid!

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Specific End Use(s) 7.3.

Penicillin Antibiotic

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. **Control Parameters**

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

8.2. **Exposure Controls**

Appropriate Engineering Controls : Suitable eye/body wash equipment should be available in the vicinity of any

potential exposure. Ensure adequate ventilation, especially in confined areas.

Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Protective clothing. Protective goggles or glasses. Insufficient ventilation:

wear respiratory protection.









Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eve and Face Protection Skin and Body Protection : Chemical goggles or safety glasses. : Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient

atmosphere, or where exposure levels are not known wear approved respiratory protection.

Thermal Hazard Protection : Not applicable.

Environmental Exposure Controls : Avoid unnecessary release into the environment.

Other Information When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties 9.1.

Physical State : Solid

Color : White to off-white solid, crystalline powder

Odor : No data available

pН : 8 – 10 [When reconstituted] **Melting Point** : 195 - 215 °C (383 - 419 °F) **Freezing Point** : 195 - 215 °C (383 - 419 °F)

Boiling Point : No data available **Flash Point** : No data available **Auto-ignition Temperature** : 440 °C (824 °F)

Decomposition Temperature : Stable to 150 °C (302 °F); Decomposition at 224 °C (435 °F)

Flammability (solid, gas) : No data available : No data available **Vapor Pressure** Relative Vapor Density at 20°C No data available **Relative Density** : No data available

: 0.45 g/cm³ [at 20 °C (68 °F)] Density

Solubility : Water: Very soluble **Partition Coefficient: N-Octanol/Water** : No data available : No data available Viscosity, Kinematic **Particle Size** No data available **Particle Size Distribution** : No data available **Particle Shape** : No data available : No data available **Particle Aspect Ratio Particle Aggregation State** : No data available : No data available **Particle Agglomeration State**

Particle Specific Surface Area : No data available **Particle Dustiness** : No data available **Explosible Concentration Range** : 125 - 250 g/m³

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Minimum Ignition Energy : >1000 mJ

Gas Formation Volume : 10 L/kg [Temp: 350 °C (662 °F)]

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions, Including those Associated with Foreseeable Emergencies

Hazardous polymerization will not occur. Product is not a dust as supplied; however, product dusts may be combustible. Under fire conditions, thermal decomposition products include the following: Oxides of carbon, nitrogen, sulfur and sodium.

10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials. Avoid creating or spreading dust.

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Oxides of carbon, nitrogen, sulfur and sodium.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Likely Routes of Exposure: Dermal, Ingestion, Inhalation, Eye contact

Acute Toxicity (Oral): Not classified.
Acute Toxicity (Dermal): Not classified.
Acute Toxicity (Inhalation): Not classified.

Ampicillin Sodium (69-52-3)		
LD50 Oral Rat	> 5314 mg/kg (Source: NLM_CIP)	

Skin Corrosion/Irritation: Not classified.

pH: 8 – 10 [When reconstituted]

Serious Eye Damage/Irritation: Not classified.

pH: 8 - 10 [When reconstituted]

Respiratory or Skin Sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an

allergic skin reaction.

Germ Cell Mutagenicity: Not classified. **Carcinogenicity:** Not classified.

Ampicillin Sodium (69-52-3)	
IARC group	3

Reproductive Toxicity: Not classified.

Specific Target Organ Toxicity (Single Exposure): Not classified.

Specific Target Organ Toxicity (Repeated Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: Eye contact with dust may cause mechanical irritation.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Inhalation may cause allergic respiratory reaction with asthma-like symptoms and difficulty breathing. Repeated and prolonged exposure may cause an allergic skin reaction.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability

Ampicillin for Injection, USP (69-52-3)	
Persistence and Degradability	Expected to be biodegradable.

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12.3. **Bioaccumulative Potential**

Ampicillin for Injection, USP (69-52-3)	
Bioaccumulative Potential	Not expected to bioaccumulate.

Mobility in Soil 12 /

12.41 Wooling in Son	
Ampicillin for Injection, USP (69-52-3)	
Ecology - Soil	Adsorption to solid soil phase is not expected. Leaches if exposed to water.

12.5. **Other Adverse Effects**

Other Adverse Effects : None known.

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Treatment Methods

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product. Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

In Accordance with IMDG 14.2.

Not regulated for transport

In Accordance with IATA

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

US Federal Regulations 15.1.

Ampicillin for Injection, USP (69-52-3)	
SARA Section 311/312 Hazard Classes	Health hazard - Respiratory or skin sensitization
	Physical hazard - Combustible dust

15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 04/14/2025

Other Information This document has been prepared in accordance with the SDS requirements of the

OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of

Health and Human Services) AU WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency) EC_RAR: European Commission Renewal Assessment Report

EC_SCOEL: European Commission Scientific Committee on Occupational

Exposure Limits

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals

Reports

ECHA_API: European Chemicals Agency API ECHA_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority

FOOD_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer

IDLH: National Institute for Occupational Health and Safety Immediately

Dangerous to Life or Health Value Profiles

IUCLID: International Uniform Chemical Information Database

JAPAN_GHS: Japan GHS Basis for Classification Data

JP_J-CHECK: Japan J-Check

KR_NIER: South Korea National Institute of Environmental Research

Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment

Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S.

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EPA: U.S. Environmental Protection Agency

EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)

EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)

EPA_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)

EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)

EU_CLH: European Union Harmonised Classification and Labelling Proposal

EU RAR: European Union Risk Assessment Report

Department of Health and Human Services)

NLM_CIP: National Library of Medicine ChemID plus database

NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank

NLM_PUBMED: National Library of Medicine PubMed database

NTP: National Toxicology Program

NZ_CCID: New Zealand Chemical Classification and Information Database OECD_EHSP: Environment, Health, and Safety Publication (Organisation for

Economic Co-operation and Development)

OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-

operation and Development)

WHO: World Health Organization

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)

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