



# SAFETY DATA SHEET

## 1. Identification

Product identifier	Amoxicillin Related Compound J	
Other means of identification		
Catalog number	1031605	
Recommended use	For analytical laboratory use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statement	
Prevention	Avoid breathing dust/fume/gas/mist/vapors/spray. Wear protective gloves. Contaminated work clothing must not be allowed out of the workplace. In case of inadequate ventilation wear respiratory protection.
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.
Storage	Not available.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.
Supplemental information	Pharmacologically active material.

### 3. Composition/information on ingredients

#### Mixture

Chemical name	Common name and synonyms	CAS number	%
Amoxicillin Related Compound J		2088960-43-2	8
Related Impurities		No Data	4
Amoxicillin	Amoxicillin trihydrate	61336-70-7	~ 87

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

### 4. First-aid measures

#### Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist. Do not use mouth-to-mouth method if the substance is inhaled. Oxygen or artificial respiration if needed. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

#### Skin contact

Wash off with soap and water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. For minor skin contact, avoid spreading material on unaffected skin.

#### Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

#### Ingestion

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

#### Most important symptoms/effects, acute and delayed

Hypersensitivity reactions. Pharmacologically active material. Occupational exposure may cause physiological effects.

#### Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

#### General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

#### Suitable extinguishing media

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

#### Unsuitable extinguishing media

None known.

#### Specific hazards arising from the chemical

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

#### Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

#### Fire fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

#### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

#### General fire hazards

No unusual fire or explosion hazards noted.

### 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

#### Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

#### Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

### Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

#### Industrial Use Components

#### Type

#### Value

Amoxicillin (CAS 61336-70-7)

STEL

0.1 mg/m3

TWA

0.2 mg/m3

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of USP materials.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Powder.

#### Color

White. Yellow.

### Odor

Not available.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

Not available.

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
<b>Upper/lower flammability or explosive limits</b>	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
<b>Solubility(ies)</b>	
Solubility (water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

## 10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Minimize dust generation and accumulation.
Incompatible materials	Oxidizing agents. Strong acids.
Hazardous decomposition products	NOx, SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical and toxicological characteristics	Penicillins: Skin rash. Red, scaly skin. Hives. Itching. Wheezing. Difficulty breathing. Fever. Swelling of face. Joint pain. Headache. Sore mouth or tongue. White patches in mouth or tongue. Vaginal itching. Vaginal discharge. Gastrointestinal disturbances. Drop in blood pressure. Superinfections. Pseudomembranous colitis.

### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
Amoxicillin (CAS 61336-70-7)		
<u>Acute</u>		
<b>Dermal</b>		
LD50	Rat	> 2000 mg/kg
<b>Oral</b>		
LD50	Mouse	> 25 g/kg
	Rat	> 15 g/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	

## Local effects

Amoxicillin

Eye irritation test

Result: Negative.

Species: Rabbit

Skin irritation test

Result: Negative.

Species: Rabbit

## Respiratory or skin sensitization

### Respiratory sensitization

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

Exposure to penicillins may cause serious hypersensitivity reactions, including anaphylactic shock and acute bronchial obstruction.

### Skin sensitization

May cause an allergic skin reaction.

Exposure to penicillins may cause hypersensitivity reactions that can range from harmless skin reactions to severe, life-threatening reactions.

## Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

## Carcinogenicity

Knowledge about carcinogenicity is incomplete.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

## Reproductive toxicity

Knowledge about health hazard is incomplete.

Penicillins are widely used in pregnant women and problems have not been documented.

Reproductive studies in animals have shown no evidence of impaired fertility or harm to the fetus.

### Reproductivity

Amoxicillin

2800 mg/day Reproductivity / Developmental, administered orally during gestation.

Result: Musculoskeletal abnormalities.

Species: Rat

9100 mg/kg Reproductivity / Developmental, administered orally during gestation.

Result: Fetotoxicity.

Species: Mouse

Epidemiological study

Result: No association between maternal therapeutic use of this material and birth defects.

Species: Human

Reproductivity / Developmental, doses up to ten times the human dose.

Result: Negative: No evidence of impaired fertility or fetal harm.

Species: Rodent

## Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

## Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

## Aspiration hazard

Based on available data, the classification criteria are not met.

## Further information

Pharmacologically active material. Occupational exposure may cause physiological effects.

## 12. Ecological information

### Ecotoxicity

Components		Species	Test Results
Amoxicillin (CAS 61336-70-7)			
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	1610 mg/l, 48 hours (static)
Fish	EC50	Oncorhynchus mykiss	> 950 mg/l, 96 hours (static)

## Persistence and degradability

No data is available on the degradability of any ingredients in the mixture.

## Bioaccumulative potential

Material name: Amoxicillin Related Compound J

1031605 Version #: 06 Revision date: 09-14-2022 Issue date: 09-14-2022

USP SDS US

5 / 7

**Octanol/water partition coefficient log Kow**

Amoxicillin

0.87, = Log Pow

**Mobility in soil**

No data available.

**Other adverse effects**

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

**13. Disposal considerations****Disposal instructions**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

**Local disposal regulations**

Dispose in accordance with all applicable regulations.

**Hazardous waste code**

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products**

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging**

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information****DOT**

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable.

**General information**

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

**15. Regulatory information****US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**Toxic Substances Control Act (TSCA)****TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical**

Yes

**Classified hazard categories**

Respiratory or skin sensitization

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

## US state regulations

### California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

Issue date	09-14-2022
Revision date	09-14-2022
Version #	06
Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
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