SAFETY DATA SHEET



1. Identification

Product identifier Penicillin G Potassium

Other means of identification

Catalog number 1502508 CAS number 113-98-4

Synonyms Benzylpenicillin potassium

Chemical name Monopotassium (2S,5R,6R)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-

azabicyclo[3.2.0]heptane-2-carboxylate

Recommended use Specified quality tests and assay 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 RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Serious eye damage/eye irritation Category 2B

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. Causes eye irritation. May cause allergy or asthma symptoms

or breathing difficulties if inhaled.

Precautionary statement

Prevention Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Contaminated

work clothing must not be allowed out of the workplace. Wear protective gloves. 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. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Storage Not available.

Material name: Penicillin G Potassium usp sds us

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Penicillin G Potassium	Benzylpenicillin potassium	113-98-4	100

4. First-aid measures

Inhalation

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

Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Eye contact Ingestion

Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Treat symptomatically. Treatment of penicillin overdose may include the following: Perform gastric decontamination in cases of severe ingestion. Administer activated charcoal as a slurry. Manage anaphylaxis with establishment of patent airway, epinephrine, and diphenhydramine. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. Treat dysrhythmias with standard antiarrhythmic drugs, if necessary. Monitor fluid and electrolyte status and patients with severe vomiting and/or diarrhea. Monitor for renal and hematologic abnormalities. For coagulopathies, administer vitamin K. For moderate to severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis. Hemodialysis may aid in the removal of penicillins from the blood.

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

None known.

media

Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

Special protective equipment

Wear suitable protective equipment.

and precautions for firefighters

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. 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 Reference Standards, 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. 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 as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

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

Other

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.

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 reference standards. Procedures for any other uses or quantities should be determined after an appropriate

assessment.

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.
Odor Odorless.
Odor threshold Not available.
pH Not available.

Melting point/freezing point 417.2 - 422.6 °F (214 - 217 °C) (decomposes)

Initial boiling point and boiling

range

Not available.

Flash point

Evaporation rate

Flammability (solid, gas)

Not available.

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper Not available.

(%)

Material name: Penicillin G Potassium

USP SDS US

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure < 0.0000001 kPa at 25 °C

Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Very soluble.

Solubility (other) Chloroform: Practically insoluble.

Dextrose solutions: Very soluble.

Ethanol: Sparingly soluble. Ether: Practically insoluble.

Partition coefficient 1.83

(n-octanol/water)

Auto-ignition temperature

> 410 °F (> 210 °C)

Decomposition temperature Not available. **Viscosity** Not available.

Other information

Chemical family Aminopenicillanic acid derivative.

Molecular formula C16H17KN2O4S

Molecular weight 372.48

pH in aqueous solution 5 - 7.5 Solution: 6%

Specific gravity 0.4

10. Stability and reactivity

ReactivityThe 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.

Incompatible materials Acids. Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. SOx. NOx.

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 Causes eye irritation.

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

Product	Species	Test Results	
Penicillin G Potassium (C	CAS 113-98-4)		
Oral			
LD50	Rat	8900 mg/kg	
<u>Acute</u>			
Oral			
LD50	Mouse	6257 mg/kg	
	Rat	8900 mg/kg	

Skin corrosion/irritationBased on available data, the classification criteria are not met.

Serious eye damage/eye

irritation

Local effects

Eye irritation Result: Positive. Species: Rabbit Severity: Slight. Skin irritation Result: Negative. Species: Rabbit Causes eye irritation.

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.

Maximisation test Result: Sensitizing. Species: Guinea pig

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test

Result: Negative (+/- activation)

HGPRT assay (Chinese hamster ovary cells)

Result: Negative (+/- activation)

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

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.

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 The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this substance.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

1.83

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 instructionsDispose 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.

Material name: Penicillin G Potassium

1502508 Version #: 03 Revision date: 08-23-2019 Issue date: 11-26-2008

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

Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

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.

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 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

Classified hazard categories

Serious eye damage or eye irritation 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 2016 (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.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes

(PICCS)

Taiwan Chemical Substance Inventory (TCSI)

United States & Puerto Rico

Toxic Substances Control Act (TSCA) Inventory

Yes

Philippine Inventory of Chemicals and Chemical Substances

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

 Issue date
 11-26-2008

 Revision date
 08-23-2019

Version # 03

Philippines

Disclaimer USP Reference Standards are sold for chemical test and assay purposes only, and NOT for

human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained

herein.

Material name: Penicillin G Potassium usp sps us

Yes

^{*}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).