Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Spironolactone USP Micronized
Commercial Name Not available.
Product Use Not available.
Restrictions On Use Not available.

Product Code 30-1377

Company
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Reproductive toxicity Category 2

Signal Word WARNING

Hazard Statement(s) Suspected of damaging fertility or the unborn child.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
Response If exposed or concerned: Get medical advice/attention.
Storage Store locked up.
Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Spironolactone
% By Weight 100
CAS# 52-01-7
Molecular Weight 416.59 g/mole
Chemical Formula C24H32O4S
Synonym(s) 7-(Acetylthio)-17-hydroxy-3-oxopregn-4-ene-21-carboxylic acid gamma-lactone

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Spironolactone	52-01-7	100	Not available.	Not available.

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Section 4: First-Aid Measures

Inhalation	Move to fresh air. Get medical attention if symptoms occur.
Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
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.
Symptoms/Effects	
Acute	Pharmacologically active material. Occupational exposure may cause physiological effects
Delayed	Pharmacologically active material. Occupational exposure may cause physiological effects

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Administer activated charcoal as a slurry. Monitor serum potassium levels. For severe hyperkalemia, administer intravenous calcium chloride, sodium bicarbonate, and insulin/dextrose; administer sodium polystyrene sulfonate by nasogastric tube or rectal enema, as needed. Monitor ECG

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

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

Unsuitable Extinguishing Media

Not available.

Products of Combustion

No unusual fire or explosion hazards noted.

Firefighters Special Equipment and Precautions

Wear suitable protective equipment. 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. Use standard firefighting procedures and consider the hazards of other involved materials.

Section 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.

Section 7: Handling and Storage

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. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	TWA 90 micrograms/m3
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.

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

Section 9: Physical and Chemical Properties

Appearance	White Light cream powder. Solid.
Odor	Very faint. Mercaptan
Odor Threshold	Not available.

Melting Point	273.2 - 275 °F (134 - 135 °C)	**pH**	Not available.
Freezing Point	Not available.	**Vapor Pressure**	< 0.0000001 kPa at 25 °C
Boiling Point/Range	Not avaialable	**Vapor Density**	Not available.
Decomposition temperature	Not available.	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	2.78	**Evaporation Rate**	Not available.
Flash Point	Not available.	**Autoignition temperature**	Not available.
Flammability	Not available.	**Flammability or Explosive Limits:**	
		Lower	Not available.
		Upper	Not available.

Solubility(ies)	Practically insoluble in water.
Other	Fixed oils: Slightly soluble. Methanol: Slightly soluble. Alcohol: Soluble. Ethyl acetate: Soluble. Chloroform: Freely soluble. Benzene: Freely soluble Chemical family Synthetic steroid. Molecular formula C24H32O4S Molecular weight 416.57

Section 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
Hazardous Polymerization	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	Not available.
Incompatible Materials	Strong oxidizing agent.
Hazardous Decomposition Products	SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

RTECS TU4725000

Acute Toxicity
Oral LD50 Rat > 1000 mg/kg

Skin Corrosion/Irritation
Not available.

Serious Eye Damage/Irritation
Not available.

Respiratory or Skin Sensitization
Not available

Germ Cell Mutagenicity
Not available.

Carcinogenicity
Not available.

Reproductive Toxicity
Suspected of damaging fertility or the unborn child.

Routes of Entry
Not available.

Symptoms Related to Exposure
Increased urination. Confusion. Irregular heartbeat. Numbness, pain, tingling, or weakness in hands or feet. Difficulty breathing. Tiredness. Weakness. Lower back or side pain. Clumsiness. Headache. Dizziness. Nausea. Vomiting. Cramps. Diarrhea. Drowsiness. Dry mouth. Sweating.

Potential Health Effects
Not avialable

Target Organ(s) Not available.

Section 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.

Persistance and Degradability
Not available.

Bioaccumulative Potential
Octanol/water partition coefficient log Kow 2.78

Mobility in Soil
Not available.

Other Adverse Effects
Not available.

Section 13: Disposal Considerations

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

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

Other Considerations
Not available.

Section 14: Transport Information

DOT Classification
DOT Not regulated as dangerous goods

Section 15: Regulatory Information

Regulations
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. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Reproductive toxicityClassified hazard categories 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. Not regulated.Safe Drinking Water Act (SDWA) US state regulations California Proposition 65 This product can expose you to Spironolactone, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov. WARNING: California Proposition 65 - CRT: Listed date/Carcinogenic substance Spironolactone (CAS 52-01-7) Listed: May 1, 1997

Other
WHMIS Not controlled under WHMIS (Canada). (Canada);DSCL (EEC) R36/38- Irritating to eyes and skin.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent.;Splash goggles.

Section 16: Other Information

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.