

**Safety Data Sheet**

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

Section 1: Identification

Product Name Prednisolone Sodium Phosphate USP
Commercial Name Not available.
Product Use Active pharmaceutical ingredient
Restrictions On Use Any use apart from the active pharmaceutical ingredient
Product Code 30-1550
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: Reproductive toxicity, category 2 Specific target organ toxicity, repeated exposure Category 1 (endocrine system)
CFR 1910.1200
Signal Word WARNING
Hazard Statement(s) Suspected of damaging 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. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. 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 Prednisolone sodium phosphate
% By Weight 100
CAS# 125-02-0
Molecular Weight 484.4 g/mole
Chemical Formula C₂₁H₂₇O₈Na₂P
Synonym(s) (11beta)-11,17,21-Trihydroxypregna 1,4-diene-3,20-dione sodium phosphate

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Prednisolone sodium phosphate	125-02-0	100	Not available.	Not available.

Section 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.
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	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. Endocrine system effects.
Delayed	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. Endocrine system effects.

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Treatment of corticosteroid overdose may include the following: Toxicity is low after acute ingestion. Gastrointestinal decontamination is generally not necessary.

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. Cool containers exposed to flames with water until well after the fire is out.

Section 6: Accidental Release Measures

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. 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. 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 65 micrograms/m ³
Engineering Controls	No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). 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.

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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: Consider double gloves. 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 disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. 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: Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover 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: Handle in accordance with good industrial hygiene and safety practice. Pharmacological effects may be seen with occupational exposure. 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 yellow. solid. (Powdered solid.)		
Odor	Odorless. Faint odor		
Odor Threshold	Not available		
Melting Point	Not available	pH	in aqueous solution 7.5 - 10.5 Sol
Freezing Point	Not available	Vapor Pressure	< 0.0000001 kPa at 25 °C
Boiling Point/Range	Not applicable	Vapor Density	Not available.
Decomposition temperature	No experimental data	Viscosity	Not available.
Partition Coefficient: n-octanol/water	No experimental data	Evaporation Rate	Not applicable
Flash Point	Not applicable	Autoignition temperature	No experimental data
Flammability	Not applicable	Flammability or Explosive Limits:	
		Lower	Not applicable
		Upper	Not applicable
Solubility(ies)	Freely soluble in water.		
Other	Acetone: Very slightly soluble. Alcohol: Slightly soluble. Chloroform: Slightly soluble. Dioxane: Very slightly soluble. Methanol: Soluble Chemical family Corticosteroid. Molecular formula C ₂₁ H ₂₇ O ₈ P . 2Na Molecular weight 484.39		

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	Contact with incompatible materials.
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition Products	POx, NaOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information**RTECS** TU4153300**Acute Toxicity**

Oral: LD50 Mouse > 2000 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.

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Routes of Entry

Ingestion.

Symptoms Related to Exposure

Corticosteroids: Fluid and electrolyte imbalance. Adrenal suppression. Immunosuppression. Cushing's syndrome. High blood pressure. Gastrointestinal disturbances. Headache. Lightheadedness. Weakness. Visual disturbances. Mood or mental status changes. Infection. Thinning skin. Swelling. Bruising. Bone fractures. Back pain. Joint pain. Tremors. Menstrual irregularities. Impotence.

Potential Health Effects

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Target Organ(s) Causes damage to organs (endocrine system) through prolonged or repeated exposure.**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.

Persistence and Degradability

Not available

Bioaccumulative Potential

Not available

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.

Disposal of Container

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner

Other Considerations

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Section 14: Transport Information**DOT Classification**

Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

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 toxicity Specific target organ toxicity (single or repeated exposure) Classified 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 Prednisolone Sodium Phosphate, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov. WARNING: California Proposition 65 - CRT: Listed date/Developmental toxin Prednisolone Sodium Phosphate (CAS 125-02-0) Listed: August 20, 1999

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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

This MSDS has been prepared by Newchem using information currently available from sources considered reliable, such as, EDQM. Newch has not independently verified the information. The accuracy of the information cannot therefore be guaranteed, nor can it be considered an expression of opinion of the product by Newchem, The information not constitute a guarantee for any of the specific product features and shall not establish a legal or contractual relationship. Use of the product outside the regulations of Newchem is not permitted.