Safety Data Sheet

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

Section 1: Identification

Product Name Prednisolone USP Micronized Anhydrous
Commercial Name Not available.
Product Use Pharmaceutical active used as anti-inflammatory
Restrictions On Use Not available.

Product Code 30-1148

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 Specific target organ toxicity, repeated exposure Cateogry 1 (endocrine system)

Signal Word WARNING

Hazard Statement(s) Harmful if inhaled. Harmful in contact with skin. Harmful if swallowed. Causes serious eye irritation. May cause respiratory irritation.

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
% By Weight 100
CAS# 50-24-8
Molecular Weight 360.44 g/mole
Chemical Formula C21H28O5
Synonym(s) (11beta)-11,17,21-Trihydroxypregna-1,4-diene-3,20-dione

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Prednisolone	50-24-8	100	Not available.	ORAL (LD50):Acute: 1680mg/kg [Mouse].

Section 4: First-Aid Measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin Contact	Wash off with soap and water. Get medical attention if irritation develops and persists
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Symptoms/Effects	
Acute	Fluid and electrolyte disturbances. Mood or mental changes. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Delayed	Fluid and electrolyte disturbances. Mood or mental changes. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological 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

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.

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.

Section 6: Accidental Release Measures

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. 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. 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. 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 4 micrograms/m3
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.

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 consideration: 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 to Off-white solid. (Solid crystalline powder.)
Odor	Odorless
Odor Threshold	Not available.

Melting Point	455 °F (235 °C)	**pH**	Not available.
Freezing Point	Not available.	**Vapor Pressure**	< 0.0000001 kPa at 25 °C
Boiling Point/Range	Not available.	**Vapor Density**	Not available.
Decomposition temperature	Not available.	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	1.62	**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)	Very slightly soluble
Other	Acetone: Sparingly soluble. Alcohol: Sparingly soluble. Chloroform: Slightly soluble. Dioxane: Soluble. Methanol: Soluble. Chemical family Corticosteroid. Dust explosion properties Minimum ignition energy (MIE) - dust cloud 3 - 10 mJ Molecular formula C21-H28-O5 Molecular weight 360.44 g/mol Surface tension 60.7 mN/m

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

Section 11: Toxicological Information

RTECS TU4152000

Acute Toxicity
Oral: LD50 Mouse 1680 mg/kg, Rat 3857 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. Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in the incidence of cleft palate was seen in some human studies. Infants born to mothers who received substantial doses of corticosteroids during pregnancy should be observed for signs of hypoadrenalism.

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. Aquatic Acute: Fish Ide, silver or golden orfe (Leuciscus idus) > 500 mg/l, 96 hours

Persistance and Degradability

Readily biodegradable

Bioaccumulative Potential

log Kow 1.62

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

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 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 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 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.

Other

WHMIS CLASS D-2A: Material causing other toxic (Canada) effects (VERY TOXIC).;DSCL (EEC) R36- Irritating to eyes.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.;Splash goggles.

Section 16: Other Information

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection, Updated Section 13 - Disposal Considerations. Prepared by: Toxicology and Hazard Communication Pfizer Global Environment, Health, and Safety Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.