

**Safety Data Sheet**

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

Section 1: Identification

Product Name PROGESTERONE USP WETTABLE POWDER (SOY)
Commercial Name Not available.
Product Use Pharmaceutical active used as hormone replacement therapy, oral contraceptive.
Restrictions On Use Not available.

Product Code 30-1017

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: Carcinogenicity Category 2 Reproductive toxicity Category 1
CFR 1910.1200

Signal Word DANGER

Hazard Statement(s) May cause cancer. May damage fertility. May damage the unborn child. May form combustible dust concentrations in air.

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 Progesterone
% By Weight 100
CAS# 57-83-0
Molecular Weight 314.47 g/mole
Chemical Formula C₂₁H₃₀O₂
Synonym(s) Pregn-4-ene-3,20-dione

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Progesterone USP Wettable (Powder)	57-83-0	100		Not available.

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

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Progestins: Single acute doses will seldom result in toxicity. Supportive treatment is adequate in most situations. For chronic toxicity, obtain a baseline CBC, hepatic and renal function tests, and treat symptomatically

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

None known

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.

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 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. 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. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	STEL 0.1 mg/m ³ TWA 12.5 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. General hygiene considerations: Wear appropriate thermal protective clothing, when necessary. Thermal hazards Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

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Section 9: Physical and Chemical Properties

Appearance	White to Creamy white. Crystalline powder.		
Odor	Odorless.		
Odor Threshold	Not available.		
Melting Point	260.6 - 267.8 °F (127 - 131 °	pH	Not available.
Freezing Point	Not available.	Vapor Pressure	0.0000004 kPa (77 °F (25 °C))
Boiling Point/Range	Not available.	Vapor Density	Not available.
Decomposition temperature	Not available.	Viscosity	Not available.
Partition Coefficient: n-octanol/water	3.87	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. Methanol: Soluble. Acetone: Soluble. Alcohol: Soluble. Dioxane: Soluble.		
Other	Chemical family Steroid. Molecular formula C21-H30-O2 Molecular weight 314.46 g/mol		

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. Alkaline metals. Peroxides.
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions

Section 11: Toxicological Information

RTECS TW0175000

Acute Toxicity

Oral LD50 Rat > 5000 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

Suspected of causing cancer

Reproductive Toxicity

May damage fertility or the unborn child. For progestins: Exposure during early pregnancy may lead to chromosomal abnormalities and congenital malformations, including genital abnormalities.

Routes of Entry

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Skin contact Based on information from therapeutic use, this material may cause: Endocrine effects. Ingestion Based on information from therapeutic use, this material may cause: Endocrine effects

Symptoms Related to Exposure

For progestins: Breast enlargement, pain, or tenderness. Hot flashes. Mood or mental changes. Headache. Gastrointestinal disturbances. Joint pain.

Potential Health Effects

Not available.

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.

Persistence and Degradability

Not available.

Bioaccumulative Potential

Octanol/water partition coefficient log Kow 3.87

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

Disposal of Container

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

Other Considerations

Not available.

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**

CERCLA/SARS 313 Emission reporting: Not listed California Proposition 65: Carcinogen initial date 1/1/88 Inventory - United States TSCA - Sect. 8(b): Present Australia (AICS): Present Standard for the Uniform Scheduling for drugs and poisons: Schedule 4 & schedule 5 EU EINECS/ELINCS List: 200-350-6

Other

Not available.

Section 16: Other Information

Pfizer Inc believes that the information contained in this SDS is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.