Safety Data Sheet

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

Section 1: Identification

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

Product Code 30-1046

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 GHS Classsification: Reproductive Toxicity: Category 1B Carcinogenicity: Category 1B Combustible dust

Signal Word DANGER

Hazard Statement(s) Suspected of causing cancer. May damage fertility or the unborn child.

Pictogram(s) or Symbol(s)

Precautionary Statement(s):

Prevention P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood P281 - Use personal protective equipment as required
Response P308 + P313 - IF exposed or concerned: Get medical attention/advice
Storage P405 - Store locked up
Disposal Not available.

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	57-83-0	100		

Section 4: First-Aid Measures

Inhalation Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Skin Contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Eye Contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Ingestion Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Symptoms/Effects

Acute Not available

Delayed Not available

Immediate Medical Attention

N/A

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Dry chemical, CO2, alcohol-resistant foam or water spray.

Unsuitable Extinguishing Media

Not available.

Products of Combustion

Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

Firefighters Special Equipment and Precautions

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: Accidental Release Measures

Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment. Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Contain the source of the spill if it is safe to do so. Collect spilled material by a method that control dust generation. Clean spill area thoroughly. Avoid use of a filtered vacuum to clean spills of dry solids, due to the potential for electrostatic discharge and the strong dust explosion potential and very high sensitivity to ignition. Clean contaminated objects and areas thoroughly observing environmental regulations.

Section 7: Handling and Storage

Handling: All conductive elements of the system that contact the dry substance should be properly bonded and grounded and equipped with proper explosion relief or suppression systems. This material should not be flowed through nonconductive ducts or pipes because of the potential for electrostatic discharge ignition. Restricting the use of high resistivity materials, such as plastics, should be considered. Avoid open handling,. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye and clothing. When handling, use appropriate personal protective equpment. Wash hands and any exposed skin after removal of PPE. Release to the enviorment should be avoided. Review and implement appropriate technical and procedureal waste water and waste disposal measure to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmostphere should be contolled with dust collectors, HEPA filtration systems or other equivilent controls. Storage: Preserve in tighly closed containers. Protect from light.

Section 8: Exposure Controls/Personal Protection

Exposure Limits OEL TWA-8 Hr: 20mcg/m^3 skin

Engineering Controls Engineering controls should be used as the primary means to control exposures. Use process containment, local exaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protection	Eye/face protection: Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equvilant). Hand protection: Wear 2 layers of impervious disposable gloves (e.g., Nitrile, etc.) to prevent skin contact. (Protective gloces must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.). Skin and body protection: Wear impervious protective clothing to prevent skin contact - consider use of disposable clothing where appropriate. (Protective cltohing must meet the standards in accordance with EN 13982, ANSI 103 or international equivalent). Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g., particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN 136, EN 143, ASTM F2704-10 or international equivalent.)

Section 9: Physical and Chemical Properties

Appearance	White to creamy-white crystalline powder
Odor	Odorless.
Odor Threshold	Not available.

Melting Point	126-131°C	**pH**	Not available.
Freezing Point	Not available.	**Vapor Pressure**	Not available.
Boiling Point/Range	Not available.	**Vapor Density**	Not available.
Decomposition temperature	Not available.	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	Not available	**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)	7.31 mg/L (20 C) (pH 7) in water. soluble alochol Acetone Dioxane Cholorform Diethylether
Other	N/A

Section 10: Stability and Reactivity

Reactivity	Not available.
Chemical Stability	Stable under normal conditions.
Hazardous Polymerization	Will not occur.
Conditions to Avoid	Exposure to light. Keep away from heat and other sources of ignition, including electrostatic discharge.
Incompatible Materials	Keep away from strong oxidizers.
Hazardous Decomposition Products	None

Section 11: Toxicological Information

RTECS TW0175000

Acute Toxicity

May cause adverse reproductive effects and birth defects (teratogenic). May affect genetic material. May cause cancer (tumorigenic) based on animal data. Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: Dust may cause eye irritation. Inhalation: Dust may cause respiratory tract irritation. Ingestion: May cause gastrointestinal tract irritation including diarrhea and nausea. May affect behavior, liver, and metabolism. Rat Oral LD 50 > 5000 mg/kg Rat Sub-tenon injection (eye) LD50 327 mg/kg

Skin Corrosion/Irritation

Not available.

Serious Eye Damage/Irritation

Not available.

Respiratory or Skin Sensitization

Not available.

Germ Cell Mutagenicity

Progesterone: Bacterial Mutagenicity (Ames). In Vivo Dominant Lethal Assay. In Vivo Chromosome Aberration. In Vitro Chromosome Aberration. In Vitro Chromosome Aberration

Carcinogenicity

Progesterone: 2 Year(s) Rabbit Intramuscular 13 mg/kg NOEL Not carcinogenic. 18 Month(s) Mouse Subcutaneous 0.059 mg /day LOEL Malignant tumors, Female reproductive system, Mammary gland. 40 Week(s) Rat Subcutaneous 200 mg/kg/day LOEL Malignant tumors, Liver 19 Week(s) Female Mouse Subcutaneous 25 mg/kg (5 days /week) LOEL Tumors, Mammary gland

Reproductive Toxicity
Progesterone: Embryo / Fetal Development Rat No route specified Dose not specified Not Teratogenic - Embryo / Fetal Development Monkey No route specified Dose not specified Not Teratogenic

Routes of Entry
Not available.

Symptoms Related to Exposure
Not available.

Potential Health Effects
Not available.

Target Organ(s) Not available.

Section 12: Ecological Information

Ecotoxicity
May persist in the aquatic environment. Releases to the environment should be avoided.

Persistance and Degradability
Not available.

Bioaccumulative Potential
Predicted 7.4 Log D 4.04

Mobility in Soil
Not available.

Other Adverse Effects
Not available.

Section 13: Disposal Considerations

Waste Disposal
Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known enviromental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prvent occupational expsorue and environmental release. It is recommended that water minimization be practiced. The best available technology should be utilzed to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Disposal of Container
Not available.

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

EUROPEAN INFORMATION TOXIC R 46 MAY CAUSE HERITABLE GENETIC DAMAGE. R 60 MAY IMPAIR FERTILITY. R 63 POSSIBLE RISK OF HARM TO THE UNBORN CHILD. S 45 IN CASE OF ACCIDENT OR IF YOU FEEL UNWELL, SEEK MEDICAL ADVICE IMMEDIATELY (SHOW THE LABEL WHERE POSSIBLE). S 36/37/39 WEAR SUITABLE PROTECTIVE CLOTHING, GLOVES AND EYE/FACE PROTECTION. S 3/7/9 KEEP CONTAINER TIGHTLY CLOSED IN A COOL WELL-VENTILATED PLACE. S 22 DO NOT BREATHE DUST. REVIEWS, STANDARDS, AND REGULATIONS OEL=MAK IARC CANCER REVIEW:ANIMAL SUFFICIENT EVIDENCE IMSUDL 7,296,1987 NOHS 1974: HZD 84510; NIS 2; TNF 134; NOS 9; TNE 22963 NOES 1983: HZD 84510; NIS 2; TNF 55; NOS 2; TNE 287; TFE 55 EPA GENETOX PROGRAM 1988, POSITIVE: CARCINOGENICITY-MOUSE/RAT EPA GENETOX PROGRAM 1988, POSITIVE: CELL TRANSFORM.-RLV F344 RAT EMBRYO EPA GENETOX PROGRAM 1988, POSITIVE: SPERM MORPHOLOGY-HUMAN EPA GENETOX PROGRAM 1988, NEGATIVE: CELL TRANSFORM.-BALB/C-3T3; SHE-CLONAL ASSAY EPA GENETOX PROGRAM 1988, NEGATIVE: SPERM MORPHOLOGY-MOUSE EPA GENETOX PROGRAM 1988, INCONCLUSIVE: E COLI POLA WITHOUT S9 EPA TSCA SECTION 8(B) CHEMICAL INVENTORY NTP 9TH REPORT ON CARCINOGENS,2000:REASONABLY ANTICIPATED TO BE HUMAN CARCINOGEN U.S. INFORMATION CALIFORNIA PROPOSITION 65: THIS PRODUCT IS OR CONTAINS CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER.

Other
N/A

Section 16: Other Information

N/A