

# Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

Holder Address: Gedian Economic Development District, E-Zhou, Hubei Province, P.R. China

TEL: +86-711-3811610 FAX: +86-711-3811590

Http://www.steroid-chem.com, E-mail: gdq@renfu.com.cn

## Material Safety Data Sheet



### 1. Identification of the substance/preparation

**Name of product:** Progesterone

**Manufacturer:** Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

**Address:** Gedian Development Zone, E-Zhou 436070, Hubei, China

**Company code:** HTT

**TEL:** +86-711-3811610 **FAX:** +86-711-3811590

### 2. Hazards identification

#### Health hazards

Carcinogenicity Category 2

Reproductive toxicity Category 1

#### Hazard statement

Suspected of causing cancer. May damage fertility or the unborn child.

#### Precautionary statement

**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.

### 3. Composition/information on ingredients

Molecular formula:  $C_{21}H_{30}O_2$  CAS: 57-83-0

### 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.

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## 5. Fire-fighting measures

### Suitable extinguishing media

Water. Foam. Dry chemical or CO<sub>2</sub>. Use fire-extinguishing media appropriate for surrounding materials.

### Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

### Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

### Fire fighting equipment/instructions

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.

### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

### General fire hazards

No unusual fire or explosion hazards noted.

## 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.

## 7. Handling and storage

### Precautions for safe handling

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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.

## Conditions for safe storage, including any incompatibilities:

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

Progesterone exposure limit values: 12.5 micrograms/m<sup>3</sup>

### Appropriate engineering controls

No open handling. 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:** 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.

**Hand:** 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.

**Skin:** 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:** 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

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Wear appropriate thermal protective clothing, when necessary.

## 9. Physical and chemical properties

Appearance: White crystalline powder.

Odor: Odorless.

Melting point: 260.6 – 267.8 °F (127 - 131 °C)

Vapor pressure: 0.0000004 kPa at 22°C

Solubility: Soluble in methanol, acetone, alcohol and dioxane. Practically insoluble in water.

Partition coefficient (n-octanol/water): 3.87

## 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.

### Possibility of hazardous reactions

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.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation:** Knowledge about health hazard is incomplete.

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

**Eye contact:** Knowledge about health hazard is incomplete.

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

**Symptoms related to the physical, chemical, and toxicological characteristics:** For progestins: Breast enlargement, pain, or tenderness. Hot flashes. Mood or mental changes. Headache.

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Gastrointestinal disturbances. Joint pain.

## Information on toxicological effects

**Acute toxicity:** LD50 > 5000 mg/kg (Rat)

**Skin corrosion/irritation:** Knowledge about health hazard is incomplete.

**Serious eye damage/eye irritation:** Knowledge about health hazard is incomplete.

**Germ cell mutagenicity:** Based on available data, the classification criteria are not met.

**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.

**Specific target organ toxicity - single exposure:** Knowledge about health hazard is incomplete.

**Specific target organ toxicity - repeated exposure:** Knowledge about health hazard is incomplete.

**Aspiration hazard:** Based on available data, the classification criteria are not met.

**Further information:** Pharmacologically active material. Occupational exposure may cause physiological effects.

## 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:** No data is available on the degradability of this product.

**Bioaccumulative potential:** Octanol/water partition coefficient log Kow: 3.87

**Mobility in soil:** No data available.

**Other adverse effects:** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal Considerations

### Disposal instructions

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

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for hazardous waste.

## Local disposal regulations

Dispose in accordance with all applicable regulations.

## Hazardous waste code

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

## Waste from residues / unused products

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 (see: Disposal instructions).

## Contaminated packaging

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.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

### US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance: Not listed.

SARA 311/312 Hazardous chemical: Yes

SARA 313 (TRI reporting): Not regulated.

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## US state regulations

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Progesterone (CAS 57-83-0) Listed: January 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Progesterone (CAS 57-83-0) Listed: April 1, 1990

US - California Proposition 65 - CRT: Listed date/Male reproductive toxin

Progesterone (CAS 57-83-0) Listed: April 1, 1990

## 16. Other information

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