

SAFETY DATA SHEET

1. Identification

Product Identifier: Progesterone Capsule

Synonyms: Corpus luteum hormone

National Drug Code (NDC): 17478-766-10
17478-767-10

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.

Health Hazards: Harmful by ingestion Category 4

Symbol(s):



Signal Word:

Warning.

Hazard Statement(s):

H302 Harmful if swallowed.

H360U May damage the unborn child.

Precautionary Statement(s):

P201 Obtain special instructions before use.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301 IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell.
+
P312

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P330 Rinse mouth.

P501 Dispose of contents/container in accordance with all local and national regulations.

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Progesterone	57-83-0	Corpus luteum hormone	C ₂₁ H ₃₀ O ₂	314.47	10% or 20%

*The formula for Progesterone Capsules 100 mg contains Peanut Oil NF, Gelatin NF, Glycerin USP, Lecithin NF, Titanium Dioxide USP, D&C Yellow No. 10, and FD&C Red No. 40.

*The formula for Progesterone Capsules 200 mg contains Peanut Oil NF, Gelatin NF, Glycerin USP, Lecithin NF, and Titanium Dioxide USP.

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

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Protection of First-Aiders:	Use personal protective equipment (see section 8).
WARNING:	DO NOT USE if allergic to peanuts, having unusual vaginal bleeding and currently have or have had certain cancers.
Signs and Symptoms:	See package insert under Patient Information for more information.
Medical Conditions Aggravated by Exposure:	As with all pharmaceutical, hypersensitivity is possible.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Use water, carbon dioxide, dry chemical or foam as necessary.
Unsuitable Extinguishing Media:	Not determined.
<u>Specific Hazards Arising from the Chemical:</u>	
Hazardous Combustion Products:	Not determined.
Other Specific Hazards:	Not determined.
Special Protective Equipment/ Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Contain the source of the spill if it is safe to do so. If liquid has dried, collect spilled material by a method that controls dust generation. Clean spill area thoroughly.
Environmental Precautions:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Do not release to drains.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling:	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
Conditions for Safe Storage, Including Any Incompatibilities:	Store according to label and/or product insert information. Store away from oxidizing agents and acids.

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Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Progesterone	OEL: 1mg/m ³ , 8 Hour TWA

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Wear chemically compatible gloves when handling this compound. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color: White or creamy white, crystalline powder.
Odor: Odorless.
Odor Threshold: No data available.
pH: No data available.
Melting Point: 126°C – 131°C.
Freezing Point: No data available.
Boiling Point: No data available.
Flash Point: No data available.
Evaporation Rate: No data available.
Flammability (solid, gas): No data available.
Flammability Limit - Lower: No data available.
Flammability Limit - Upper: No data available.
Vapor Pressure: No data available.
Vapor Density: No data available.
Relative Density: No data available.

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Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	Keep away from heat and other sources of ignition, including electrostatic discharge.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Keep away from strong oxidizers.
Hazardous Decomposition Products:	Hazardous decomposition products formed under fire conditions – carbon oxides, nitrogen oxides, hydrogen chloride gas.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May be harmful if inhaled. May cause irritation to the respiratory system.
Ingestion:	Harmful if swallowed.
Skin Contact:	May cause skin irritation. May cause allergic response.
Eye Contact:	May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Progesterone	Rat	Oral	LD ₅₀	5,000 mg/kg
Progesterone	Rat	Intraperitoneal	LD ₅₀	327 mg/kg

Acute Toxicity – Dermal:

No data available.

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Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

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

12. **Ecological Information**

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. **Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

14. **Transport Information**

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. **Regulatory Information**

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.

New Jersey: Listed.

Pennsylvania: Listed.

California Proposition 65: Not listed.

16. **Other Information**

NFPA Rating:
Health Hazard: 3
Fire: 0
Reactivity Hazard: 0

HMS Classification:
Health Hazard: 3
Flammability: 0
Physical Hazard: 0

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