


Safety Data Sheet



1. Identification

Product Identifier	Progesterone
Other means of identification	
Internal item number	82393-0101 82393-0102 82393-0103
CAS number	57-83-0
Chemical name	Pregn-4-ene-3,20-dione
Relevant use and restrictions: No further information available.	
Application of substance: Active pharmaceutical ingredient.	
Manufacturer/Supplier information	
Company name	Pharma Source Direct
Address	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112
Website	www.pharmasd.com
Emergency phone number	Infotrac: 1-800-535-5053

2. Hazard(s) Identification

Physical hazards	Not classified	
Health hazards	Carcinogenicity	Category 2
	Reproductive toxicity	Category 1
Environmental hazards	Not classified	
OSHA defined hazards	Not classified	
Label elements		

Signal word	Danger
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.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/ international regulations.

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Hazards not otherwise classified (HNOC)

None known.

Supplemental information

Potent pharmacologically active material.

3. Composition/Information on Ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Progesterone	Corpus luteum hormone	57-83-0	100

4. First-aid Measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Reproductive system effects. Endocrine system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	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.
General Information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

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.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.

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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

For waste disposal, see section 13 of the SDS. 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.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

Precautions for safe handling

As a general rule, 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

Occupational exposure limits

Exposure limit values

Industrial Use

Material	Type	Value
Progesterone (CAS 57-83-0)	STEL	0.1 mg/m ³
	TWA	12.5 micrograms/m ³

Biological limit values

No biological exposure limits noted for the ingredient(s)

Appropriate 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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Individual protection measures, such as personal protective equipment

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. Chose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Procedures for any use or quantity should be determined after an appropriate assessment.

9. Physical and Chemical Properties

Appearance

Appearance descriptions are general information and not specific to any lot.

Physical state

Solid.

Form

Crystalline powder.

Color

White.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

260.6 – 267.8 °F (127 - 131 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

0.0000004 kPa at 25 °C

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Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Insoluble.
Solubility (other)	Dioxane: Soluble. Acetone: Soluble. Alcohol: Soluble.
Partition coefficient (n-octanol/water)	3.87
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Steroid
Molecular formula	C21-H30-O2
Molecular weight	314.47 g/mol
Specific gravity	1.17 at 23 °C

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. Gastrointestinal disturbances. Joint pain.

Information on toxicological effects

Acute toxicity	Not known.
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Product	Species	Test Results
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Acute

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Oral LD50	Rat > 5000 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.
Respiratory or skin sensitization	
Respiratory sensitization	Knowledge about health hazard is incomplete.
Skin sensitization	Knowledge about health hazard is incomplete.
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.
Mutagenicity	
Chromosomal aberration	
Result: Negative.	
Dominant lethal test	
Result: Negative.	
Species: Mouse	
Micronucleus test	
Result: Positive.	
Mutagenicity: Human sperm morphology	
Result: Positive.	
Mutagenicity: Sister chromatid exchange	
Result: Negative.	
Carcinogenicity	Suspected of causing cancer.
0.059 - 0.9 mg/day Carcinogenicity	
Result: Increased incidence of ovarian granulosa cell tumors.	
Species: Mouse	
Test Duration: 18 months	
Carcinogenicity	
Result: Earlier onset of breast carcinomas and higher incidence	
in mice with tumor virus.	
Species: Mouse	
Test Duration: 104 weeks	
IARC Monographs. Overall Evaluation of Carcinogenicity	
Progesterone (CAS 57-83-0)	2B Possibly carcinogenic to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not regulated.	
US. National Toxicology Program (NTP) Report on Carcinogens	
Progesterone (CAS 57-83-0)	Reasonably Anticipated to be a Human Carcinogen.
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.
Reproductivity	

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0.25 - 0.5 mg Gestational study
Result: Reproductive abnormalities in offspring.
Species: Mouse
30 mg/kg Gestational study
Result: Reproductive abnormalities in offspring.
Species: Rabbit
5 mg/kg Developmental
Result: Reduced birth weights, increased incidence of resorptions, and developmental defects.
Species: Rat

Specific target organ toxicity - single exposure	May cause drowsiness and dizziness.
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	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological Information

Ecotoxicity	Knowledge about health hazard is incomplete.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	
Octanol/water partition coefficient log K_{ow}	
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 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	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information

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DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

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.

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 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

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.

Safe Drinking Water Act (SDWA)

Not regulated.

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US state regulations

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

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/Female reproductive 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

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Phillipines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Unites States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other Information

Disclaimer

The information in this SDS has been compiled from sources considered dependable, but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product in regards to handling, storage, and/or disposal.

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