

# Safety Data Sheet

acc. to OSHA HCS

SDS #372

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- **1.1 Product identifier**
- **Trade name:** Progesterone  
Progesteronum
- **Product Code:**  
105419  
100952
- **CAS Number:**  
57-83-0
- **EC number:**  
200-350-6
- **Application of the substance / the mixture** Pharma Active ingredients
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Inc  
2400 Pilot Knob Road  
St. Paul, MN 55120  
www.fagron.us  
QA@fagron.us
- **Information department:**  
Tel.: 800-423-6967  
Fax: 800-339-1596
- **1.4 Emergency telephone number:**  
Emergency Telephone:  
US: 1-800-535-5053  
International: 1-352-323-3500

Printing date 07/21/2017  
Reviewed on 07/21/2017

## 2 Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 Health hazard

Carc. 1B H350 May cause cancer.

Repr. 1B H360-H362 May damage fertility or the unborn child. May cause harm to breast-fed children.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** The substance is classified and labeled according to the CLP regulation.
- **Hazard pictograms** GHS08
- **Signal word** Danger
- **Hazard statements**  
H350 May cause cancer.  
H360-H362 May damage fertility or the unborn child. May cause harm to breast-fed children.
- **Precautionary statements**  
P263 Avoid contact during pregnancy/while nursing.  
P260 Do not breathe dusts or mists.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
P405 Store locked up.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**
- **HMIS-ratings (scale 0 - 4)**
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3 Composition/information on ingredients

- **3.1 Chemical characterization: Substances**
- **CAS No. Description**  
57-83-0 Progesterone  
Progesteronum
- **Identification number(s)**
- **EC number:** 200-350-6

## 4 First-aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Rinse out mouth and then drink plenty of water.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed** No further relevant information available.

## 5 Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
Carbon dioxide  
Fire-extinguishing powder  
Foam  
Water spray  
Use fire fighting measures that suit the environment.
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.  
Carbon monoxide (CO)  
During heating or in case of fire poisonous gases are produced.
- **5.3 Advice for firefighters**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.

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Mouth respiratory protective device.

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## 6 Accidental release measures

### · 6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Wear protective equipment. Keep unprotected persons away.

Mount respiratory protective device.

### · 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

### · 6.3 Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

### · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### · Protective Action Criteria for Chemicals

· PAC-1: Substance is not listed.

· PAC-2: Substance is not listed.

· PAC-3: Substance is not listed.

## 7 Handling and storage

### · 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

· Information about protection against explosions and fires: Keep respiratory protective device available.

### · 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

· Requirements to be met by storerooms and receptacles: No special requirements.

· Information about storage in one common storage facility: Not required.

· Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.

· 7.3 Specific end use(s) No further relevant information available.

## 8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see item 7.

### · 8.1 Control parameters

· Components with limit values that require monitoring at the workplace: Not required.

· Additional information: The lists that were valid during the creation were used as basis.

### · 8.2 Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

Clean skin thoroughly immediately after handling the product.

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Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Store protective clothing separately.

· **Breathing equipment:**

Suitable respiratory protective device recommended.  
Filter P3

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

## 9 Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Powder
Color:	White
Odor:	Recognizable
Odor threshold:	Not determined.

pH-value:	Not applicable.
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· **Change in condition**

Melting point/Melting range:	129-130 °C (264-266 °F)
Boiling point/Boiling range:	Undetermined.

Flash point:	Not applicable.
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· Flammability (solid, gaseous):	Product is not flammable.
· Ignition temperature:	
· Decomposition temperature:	Not determined.
· Auto igniting:	Not determined.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
· Bulk density at 20 °C (68 °F):	350-450 kg/m <sup>3</sup>
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 9.2 Other information	No further relevant information available.

## 10 Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** To avoid thermal decomposition do not overheat.
- **10.3 Possibility of hazardous reactions** Reacts with strong oxidizing agents.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

## 11 Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**

Oral LD50 > 5000 mg/kg (Rat)

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- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** Substance is not listed.
- **NTP (National Toxicology Program)** R
- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

## 12 Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** Easily biodegradable
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

## 13 Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:**  
Must be specially treated adhering to official regulations.  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- |                                       |      |
|---------------------------------------|------|
| · <b>14.1 UN-Number</b>               |      |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>    | Void |
| · <b>14.2 UN proper shipping name</b> |      |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>    | Void |

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· 14.3 Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· DOT, ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	Void

## 15 Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- National regulations:
- Additional classification according to Decree on Hazardous Materials:  
Carcinogenic hazardous material group I (extremely dangerous).  
Carcinogenic hazardous material group II (very dangerous).  
Carcinogenic hazardous material group III (dangerous).
- Information about limitation of use:  
Workers are not allowed to be exposed to this hazardous material. Exceptions can be made by the authorities in certain cases.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## 16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

- Relevant phrases  
R 40-60-61-64  
S 45-53
- Department issuing SDS:  
Fagron US  
Quality Assurance

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- **Contact:** QA@fagron.us
- **Date of preparation / last revision** 07/21/2017 / 17
- **Abbreviations and acronyms:**
  - RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
  - ICAO: International Civil Aviation Organisation
  - ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  - IMDG: International Maritime Code for Dangerous Goods
  - DOT: US Department of Transportation
  - IATA: International Air Transport Association
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - NFPA: National Fire Protection Association (USA)
  - HMIS: Hazardous Materials Identification System (USA)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - OSHA: Occupational Safety & Health
  - TLV: Threshold Limit Value
  - PEL: Permissible Exposure Limit
  - REL: Recommended Exposure Limit
  - Carc. 1B: Carcinogenicity – Category 1B
  - Repr. 1B: Reproductive toxicity – Category 1B
- **\* Data compared to the previous version altered.**

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