

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## PROGESTERONUM

EN

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### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name: Progesterone  
Progesteronum  
Progesteron  
Progestérone  
Progesteron

N° CAS: 57-83-0

N° EC: 200-350-6

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

#### 1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV  
Oostmalsebaan 1c (unit 5)  
2960 Sint-Lenaarts  
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Carc. 2 H351

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H351 Suspected of causing cancer.

Precautionary statements:

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.

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P308+P313

IF exposed: Call a POISON CENTER or doctor/physician.

Additional applicable label elements:



### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Progesterone
IUPAC name:	(8S,9S,10R,13S,14S,17S)-17-acetyl-10,13-dimethyl-1,2,6,7,8,9,11,12,14,15,16,17-dodecahydrocyclopenta[a]phenanthren-3-one
Synonyms:	Agolutin Luteohormone Crinone
N° CAS:	57-83-0
N° EC:	200-350-6
Molecular Formula:	C <sub>21</sub> H <sub>30</sub> O <sub>2</sub>
Content:	97.0 per cent to 102.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
After skin contact:	Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.
After eye contact:	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.
After ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

### 4.2 Most important symptoms and effects, both acute and delayed

Potential Acute Health effects: Hazardous in case of ingestion, of inhalation. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant).

Potential Chronic Health Effects: CARCINOGENIC EFFECTS: Classified 2B (Possible for human) by IARC. Classified 2 (Some evidence) by NTP. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Classified POSSIBLE for human. DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female, Reproductive system/toxin/male (possible).

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The substance is toxic to the reproductive system. Repeated or prolonged exposure to the substance can produce target organs damage.

### 4.3 Indication of any immediate medical attention and special treatment needed

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:

SMALL FIRE: Use DRY chemical powder.

LARGE FIRE: Use water spray, fog or foam.

Unsuitable extinguishing media:

Do not use water jet.

### 5.2 Special hazards arising from the substance/mixture

#### Flammability of the Product

May be combustible at high temperature.

#### Flash Points

CLOSED CUP: Higher than 93.3 °C (200 °F).

#### Products of Combustion

These products are carbon oxides (CO, CO<sub>2</sub>).

#### Fire Hazards in Presence of Various Substances

Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

#### Special Remarks on Fire Hazards

As with most organic solids, fire is possible at elevated temperatures.

#### Special Remarks on Explosion Hazards

Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

### 5.3 Advice for firefighters

Surrounding fires:

Not available.

Protection against fire:

Not available.

Hazardous combustion products:

Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### **For non-emergency personnel**

Not available.

#### **For emergency responders**

Not available.

### 6.2 Environmental precautions

Not available.

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

Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

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Large Spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

### 6.4 Reference to other sections

Not available.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Keep away from heat. Keep away from sources of ignition. Do not breathe dust. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If you feel unwell, seek medical attention and show the label when possible. Keep away from incompatibles such as oxidising agents.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

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

Storage:	Store in light-resistant containers.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed- Keep container in a cool, well-ventilated area. Do not store above 25 °C (77 °F). Sensitive to light.
Storage – away from:	Store protected from light.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

#### Individual protection measures

Eye/face protection:	Safety glasses. In case of a large spill: Splash goggles.
Skin protection:	Lab coat. In case of a large spill: Full suit. Boots.
Hand protection:	Gloves. In case of a large spill: Gloves.
Respiratory protection:	Dust respirator. Be sure to use an approved/certified respirator or equivalent.

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In case of a large spill: Dust respirator. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Thermal hazards: Not determined.

### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder or colourless crystals.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not applicable.
Melting/freezing point:	129.5 °C (265.1 °F)
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not applicable.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in anhydrous ethanol, sparingly soluble in acetone and in fatty oils.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Specific gravity: 1.17 (water = 1)

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

May decompose on exposure to light.

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### 10.2 Chemical stability

The product is stable.

Polymerisation: Will not occur.

### 10.3 Possibility of hazardous reactions

Corrosivity: Non-corrosive in presence of glass.

### 10.4 Conditions to avoid

Conditions of instability: light, incompatible materials.

### 10.5 Incompatible materials

Reactive with oxidising agents.

### 10.6 Hazardous decomposition products

Not available.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity: Not available.

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Classified 2B (possible for human) by IARC. Classified 2 (some evidence) by NTP.  
Special remarks on chronic effects on humans: May cause cancer (tumorigenic) based on animal data.

Reproductive toxicity: Teratogenic effects: Classified possible for human.  
Developmental toxicity: Classified Reproductive system/toxin/female, reproductive system/toxin/male (possible). Causes damage to the following organs: the reproductive system.  
Special remarks on chronic effects on humans: May cause adverse reproductive effects and birth defects (teratogenic). May affect genetic material.

Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: Not available.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Dust may cause eye irritation.

Skin contact: May cause skin irritation.

Inhalation: Hazardous in case of inhalation. Dust may cause respiratory tract irritation.

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Ingestion:	Hazardous in case of ingestion. May cause gastrointestinal tract irritation including diarrhoea and nausea. May affect behaviour, liver, and metabolism.
Aspiration:	Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Not available.

#### 12.2 Persistence and degradability

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The product itself and its products of degradation are not toxic.

#### 12.3 Bioaccumulative potential

Not available.

#### 12.4 Mobility in soil

Not available.

#### 12.5 Results of PBT and vPvB assessment

Not available.

#### 12.6 Other adverse effects

Not available.

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.5 Environmental hazards

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ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.6 Special precautions for user

Not applicable.

### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not applicable.

### 14.8 Additional transport information

DOT Classification: Not a DOT controlled material (United States).

## SECTION 15: REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Harmful

Risk phrases:

Not available.

Safety phrases:

S53 Avoid exposure – obtain special instructions before use.

### 15.2 Chemical safety assessment

Not available.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>



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### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department

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