# SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

## Progesterone Formulation

**Version** 1.2  
**Revision Date:** 2021/04/09  
**SDS Number:** 5155471-00003  
**Date of last issue:** 2020/10/10  
**Date of first issue:** 2019/10/17

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product name:** Progesterone Formulation

**Manufacturer or supplier’s details**

<table>
<thead>
<tr>
<th>Company</th>
<th>Organon &amp; Co.</th>
</tr>
</thead>
</table>
| Address          | 30 Hudson Street, 33rd floor  
|                  | Jersey City, New Jersey, U.S.A 07302 |
| Telephone        | 551-430-6000  
| Emergency telephone number | 215-631-6999  
| E-mail address   | EHSSTEWARD@organon.com  |

**Recommended use of the chemical and restrictions on use**

| Recommended use | Pharmaceutical |

## 2. HAZARDS IDENTIFICATION

### Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Crystalline powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
</tbody>
</table>

Suspected of causing cancer. May damage fertility or the unborn child. May cause harm to breast-fed children.

### GHS Classification

<table>
<thead>
<tr>
<th>Carcinogenicity</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity</td>
<td>Category 1A</td>
</tr>
</tbody>
</table>

### Effects on or via lactation

### GHS label elements

**Hazard pictograms**

![Hazard pictogram]

**Signal word**  
Danger

**Hazard statements**

H351 Suspected of causing cancer.  
H360 May damage fertility or the unborn child.  
H362 May cause harm to breast-fed children.

**Precautionary statements**

**Prevention:**

P201 Obtain special instructions before use.
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P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy/ while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
Suspected of causing cancer. May damage fertility or the unborn child. May cause harm to breast-fed children.

Environmental hazards
Not classified based on available information.

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 27.777 %

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture if dispersed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>27.777</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>0.4475</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Suspected of causing cancer. May damage fertility or the unborn child. May cause harm to breast-fed children. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Do not use a solid water stream as it may scatter and spread fire. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>2021/04/09</td>
<td>5155471-00003</td>
<td>2020/10/10</td>
<td>2019/10/17</td>
</tr>
</tbody>
</table>

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling
Technical measures:
Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
Avoid contact during pregnancy and while nursing. Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
Oxidizing agents

Storage
Conditions for safe storage:
Keep in properly labelled containers.
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Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents

Packaging material:
Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>TWA</td>
<td>6 μg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: DSEN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>60 μg/100 cm2</td>
<td>Internal</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>PC-TWA (Total dust)</td>
<td>8 mg/m3</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: G2B - Possibly carcinogenic to humans</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m3 (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

These substance(s) are inextricably bound in the product and therefore do not contribute to a dust inhalation hazard.
Titanium dioxide

Engineering measures:
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted.
Use closed processing systems or containment technologies.

Personal protective equipment
Respiratory protection:
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Combined particulates and organic vapour type
Eye/face protection:
Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection:
Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Hand protection

Use appropriate degowning techniques to remove potentially contaminated clothing.

Material

Chemical-resistant gloves

Remarks

Consider double gloving.

Hygiene measures

If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Crystalline powder

Colour

White to off-white

Odour

Odourless

Odour Threshold

No data available

pH

No data available

Melting point/freezing point

126 °C

Initial boiling point and boiling range

No data available

Flash point

Not applicable

Evaporation rate

Not applicable

Flammability (solid, gas)

No data available

Upper explosion limit / Upper flammability limit

No data available

Lower explosion limit / Lower flammability limit

No data available

Vapour pressure

Not applicable

Relative vapour density

Not applicable

Relative density

No data available

Density

No data available
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Solubility(ies)
Water solubility : practically insoluble

Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available
Particle size : No data available

10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac-
tions : Dust can form an explosive mixture in air. Can react with strong oxidizing agents.

Conditions to avoid : Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION
Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Progesterone:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Titanium dioxide:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Titanium dioxide:**
Species: Rabbit
Result: No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Titanium dioxide:**
Species: Rabbit
Result: No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Titanium dioxide:**
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Progesterone:**
Genotoxicity in vitro: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Method: OECD Test Guideline 482
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Monkey
### Application Route
- Progesterone: Subcutaneous Result: negative
- Titanium dioxide: Subcutaneous Result: negative

### Genotoxicity in vitro
- Progesterone: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
- Titanium dioxide: Test Type: In vivo micronucleus test Species: Mouse Result: negative

### Genotoxicity in vivo
- Progesterone: Test Type: In vivo micronucleus test Species: Mouse Result: negative
- Titanium dioxide: Test Type: In vivo micronucleus test Species: Mouse Result: negative

### Carcinogenicity
- Suspected of causing cancer.

### Components:

#### Progesterone:
- Species: Mouse
- Application Route: Subcutaneous
- Exposure time: 19 weeks
- Result: positive

#### Titanium dioxide:
- Species: Rat
- Application Route: Inhalation (dust/mist/fume)
- Exposure time: 2 Years
- Method: OECD Test Guideline 453
- Result: positive
- Remarks: The mechanism or mode of action may not be relevant in humans.

#### Carcinogenicity - Assessment
- Progesterone: Limited evidence of carcinogenicity in animal studies
- Titanium dioxide: Limited evidence of carcinogenicity in inhalation studies with animals.

### Reproductive toxicity
- May damage fertility or the unborn child.
- May cause harm to breast-fed children.

### Components:

#### Progesterone:
- Effects on fertility: Test Type: Fertility Species: Rat Application Route: Subcutaneous Result: positive
- Effects on foetal development: Test Type: Embryo-foetal development Species: Rat Application Route: Skin contact Result: positive
Reproductive toxicity - Assessment: Positive evidence of adverse effects on sexual function, fertility and/or development from human epidemiological studies. Studies indicating a hazard to babies during the lactation period.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Titanium dioxide:
Species: Rat
NOAEL: 24,000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days

Species: Rat
NOAEL: 10 mg/m3
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 yr

Aspiration toxicity
Not classified based on available information.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Progesterone:

Ecotoxicology Assessment
Acute aquatic toxicity: Toxic effects cannot be excluded
Chronic aquatic toxicity: Toxic effects cannot be excluded

Titanium dioxide:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
11. Toxicity to microorganisms
   EC50: > 1,000 mg/l
   Exposure time: 3 h
   Method: OECD Test Guideline 209

12. Persistence and degradability
   No data available

13. Bioaccumulative potential

Components:

Progesterone:
   Partition coefficient: n-octanol/water: Pow: 3.65

Mobility in soil
   No data available

Other adverse effects
   No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
   Waste from residues: Dispose of in accordance with local regulations.
   Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
   If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
   Not regulated as a dangerous good

IATA-DGR
   Not regulated as a dangerous good

IMDG-Code
   Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
   Not applicable for product as supplied.

National Regulations

GB 6944/12268
   Not regulated as a dangerous good

Special precautions for user
   Not applicable
15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet:

Date format: yyyy/mm/dd

Full text of other abbreviations:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>CN OEL</td>
<td>Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>CN OEL / PC-TWA</td>
<td>Permissible concentration - time weighted average</td>
</tr>
</tbody>
</table>

Abbreviations:
- AICL - Australian Inventory of Industrial Chemicals
- ANTT - National Agency for Transport by Land of Brazil
- ASTM - American Society for the Testing of Materials
- bw - Body weight
- CMR - Carcinogen, Mutagen or Reproductive Toxicant
- DIN - Standard of the German Institute for Standardisation
- DSL - Domestic Substances List (Canada)
- ECx - Concentration associated with x% response
- ELx - Loading rate associated with x% response
- EmS - Emergency Schedule
- ENCS - Existing and New Chemical Substances (Japan)
- ErCx - Concentration associated with x% growth rate response
- ERG - Emergency Response Guide
- GHS - Globally Harmonized System
- GLP - Good Laboratory Practice
- IARC - International Agency for Research on Cancer
- IATA - International Civil Aviation Organization
- IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- IECSC - Inventory of Existing Chemical Substances in China
- IMDG - International Maritime Dangerous Goods
- IMO - International Maritime Organization
- ISHL - Industrial Safety and Health Law (Japan)
- ISO - International Organisation for Standardization
- KECI - Korea Existing Chemicals Inventory
- LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)
- LC50 - Half maximal inhibitory concentration
- ICAO - International Civil Aviation Organization
- IECSC - Inventory of Existing Chemical Substances in China
- ACGIH - American Conference of Governmental Industrial Hygienists
- OEL - Occupational Exposure Limit
- OAEL - Overall Airborne Exposure Limit
- OEL - Occupational Exposure Limit
- OELR - Occupational Exposure Loading Rate
- NTP - National Toxicology Program
- NO(A)EC - No Observed (Adverse) Effect Concentration
- NO(A)EL - No Observed (Adverse) Effect Level
- NTP - National Toxicology Program
- NZIoC - New Zealand Inventory of Chemicals
- OECD - Organization for Economic Co-operation and Development
- OPPTS - Office of Chemical Safety and Pollution Prevention
- PBT - Persistent, Bioaccumu-
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Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

CN / EN