Section 1: Identification

Product name : Progesterone Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : 30 Hudson Street, 33nd 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

Section 2: Hazard identification

GHS Classification
Carcinogenicity : Category 2
Reproductive toxicity : Category 1A
Effects on or via lactation

GHS label elements
Hazard pictograms : 

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.
                           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.
                           P281 Use personal protective equipment as required.

Response:
Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
</tr>
</tbody>
</table>

Section 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.

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).
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Notes to physician : Treat symptomatically and supportively.

Section 5: Fire-fighting 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.

Section 6: Accidental release measures

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.
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Version 1.2  Revision Date: 09.04.2021  SDS Number: 5155502-00003  Date of last issue: 10.10.2020  Date of first issue: 17.10.2019

Section 7: Handling and storage

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.

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.

Conditions for safe storage: Keep in properly labelled containers. 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

Section 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>
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<tr>
<td>Further information: DSEN</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>60 μg/100 cm2</td>
<td>Internal</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>WES-TWA (Mist)</td>
<td>10 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>WES-TWA</td>
<td>10 mg/m3</td>
<td>NZ OEL</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
- **Hand protection**: Chemical-resistant gloves
- **Remarks**: Consider double gloving.

**Eye 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 faceshield 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. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Section 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
Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : 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 : No hazardous decomposition products are known.
Section 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

**Glycerine:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity: LD50 (Guinea pig): > 5,000 mg/kg

**Titanium dioxide:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation:
Not classified based on available information.

Components:

**Glycerine:**
- Species: Rabbit
- Result: No skin irritation

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

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

Components:

**Glycerine:**
- Species: Rabbit
- Result: No eye irritation
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

Chronic toxicity

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: Subcutaneous
Result: negative

Glycerine:
Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Titanium dioxide:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : 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

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

Glycerine:
Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

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 : 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.

Glycerine:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Glycerine:
Species: Rat
NOAEL: 0.167 mg/l
NOAEL: 0.622 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 13 Weeks

Species: Rat
NOAEL: 8,000 - 10,000 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

Species: Rabbit
NOAEL: 5,040 mg/kg
Application Route: Skin contact
Exposure time: 45 Weeks

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.

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**Section 12: Ecological information**

Ecotoxicity

**Components:**

**Progesterone:**

Ecotoxicology Assessment

Acute aquatic toxicity: Toxic effects cannot be excluded

Chronic aquatic toxicity: Toxic effects cannot be excluded

**Glycerine:**

- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
  Exposure time: 96 h

- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1,955 mg/l
  Exposure time: 48 h

- Toxicity to microorganisms: NOEC (Pseudomonas putida): > 10,000 mg/l
  Exposure time: 16 h
  Method: DIN 38 412 Part 8

**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

- Toxicity to microorganisms: EC50: > 1,000 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209

**Persistence and degradability**

**Components:**

**Glycerine:**

Biodegradability: Result: Readily biodegradable.
Biodegradation: 92%
Exposure time: 30 d
Bioaccumulative potential

**Components:**

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

**Glycerine:**
Partition coefficient: n-octanol/water: log Pow: -1.75

**Mobility in soil**
No data available

**Other adverse effects**
No data available

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**Section 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.

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**Section 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**

**NZS 5433**
Not regulated as a dangerous good

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**Section 15: Regulatory information**

Safety, health and environmental regulations/legislation specific for the substance or mixture
HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
IECSC : not determined
AICS : not determined
DSL : not determined

Section 16: Other information

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA, ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

All abbreviations are defined in the full text of other abbreviations section.
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### Progesterone Formulation

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NZ / EN