

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

## Progesterone Formulation

Version 3.1      Revision Date: 09/30/2023      SDS Number: 5155504-00010      Date of last issue: 04/04/2023  
Date of first issue: 10/17/2019

### SECTION 1. IDENTIFICATION

Product name : Progesterone Formulation

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302  
Telephone : 1-551-430-6000  
Emergency telephone : 1-215-631-6999  
E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Carcinogenicity : Category 2

Reproductive toxicity : Category 1A

Effects on or via lactation

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : May form combustible dust concentrations in air.  
H351 Suspected of causing cancer.  
H360FD May damage fertility. May damage 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 and 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version 3.1      Revision Date: 09/30/2023      SDS Number: 5155504-00010      Date of last issue: 04/04/2023  
Date of first issue: 10/17/2019

and face protection.

**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Sunflower oil	8001-21-6	41.387
Progesterone	57-83-0	27.777
Glycerine	56-81-5	8.337
Titanium dioxide	13463-67-7	0.4475

### 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. May damage 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

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.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : 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 (NO<sub>x</sub>)

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 fire-fighters : 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 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.
- Conditions for safe storage : Keep in properly labeled 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:  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

- inert or nuisance dust 50 Million particles per cubic foot  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3
- 15 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3
- 5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable fraction)

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version 3.1      Revision Date: 09/30/2023      SDS Number: 5155504-00010      Date of last issue: 04/04/2023  
Date of first issue: 10/17/2019

Basis: OSHA Z-3

15 Million particles per cubic foot  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

Dust, nuisance dust and particulates

10 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sunflower oil	8001-21-6	TWA (mist - total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (mist - respirable)	5 mg/m <sup>3</sup>	NIOSH REL
Progesterone	57-83-0	TWA	6 µg/m <sup>3</sup> (OEB 4)	Internal
		Wipe limit	60 µg/100 cm <sup>2</sup>	Internal
Titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Respirable particulate matter)	2.5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH

**This substance(s) is not bioavailable and therefore does 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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : 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.

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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Crystalline powder

Color : white to off-white

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : 259 °F / 126 °C

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : Not applicable

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

---

Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	practically insoluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition 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

---

### 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.
Conditions to avoid	:	Avoid dust formation.
Incompatible materials	:	None.
Hazardous decomposition products	:	No hazardous decomposition products are known.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Sunflower oil:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 401  
Remarks: Based on data from similar materials

##### Progesterone:

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

##### 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:

##### Sunflower oil:

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

##### Progesterone:

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

---

### 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:

#### Sunflower oil:

Species : Rabbit  
Result : No eye irritation  
Remarks : Based on data from similar materials

#### Progesterone:

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

### Glycerine:

Species : Rabbit  
Result : No eye irritation

### Titanium dioxide:

Species : Rabbit  
Result : No eye irritation

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Sunflower oil:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

---

### Progesterone:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Rabbit  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

### Titanium dioxide:

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Sunflower oil:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

#### Progesterone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

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

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### Glycerine:

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

---

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, female  
Application Route : Subcutaneous  
Exposure time : 104 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.  
This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

ment animals.

**IARC** Group 2B: Possibly carcinogenic to humans  
Titanium dioxide 13463-67-7

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** Reasonably anticipated to be a human carcinogen  
Progesterone 57-83-0

### Reproductive toxicity

May damage fertility. May damage the unborn child.  
May cause harm to breast-fed children.

### Components:

#### **Progesterone:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Subcutaneous  
Result: positive

Effects on fetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Subcutaneous  
Result: positive

Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies., Clear evidence of adverse effects on development, based on animal experiments., 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 fetal development : Test Type: Embryo-fetal 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version 3.1      Revision Date: 09/30/2023      SDS Number: 5155504-00010      Date of last issue: 04/04/2023  
Date of first issue: 10/17/2019

---

### Repeated dose toxicity

#### Components:

##### **Glycerine:**

Species : Rat  
NOAEL : 0.167 mg/l  
LOAEL : 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 y

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/m<sup>3</sup>  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 y

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### **Progesterone:**

General Information : Target Organs: Endocrine system  
Symptoms: Effects on fertility.

---

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Sunflower oil:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

---

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

## Progesterone Formulation

Version 3.1      Revision Date: 09/30/2023      SDS Number: 5155504-00010      Date of last issue: 04/04/2023  
Date of first issue: 10/17/2019

---

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 32 mg/l  
Exposure time: 48 h  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

Toxicity to microorganisms : EC10 (Pseudomonas putida): 883 mg/l  
Exposure time: 18 h  
Remarks: Based on data from similar materials

### Progesterone:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 1 - 10 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.000010 mg/l  
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.1 mg/l  
Exposure time: 26 d

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

---

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

### Persistence and degradability

#### Components:

##### **Progesterone:**

Biodegradability : Result: Readily biodegradable.  
Remarks: Based on data from similar materials

##### **Glycerine:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 %  
Exposure time: 30 d  
Method: OECD Test Guideline 301D

### Bioaccumulative potential

#### Components:

##### **Progesterone:**

Partition coefficient: n-octanol/water : Pow: 3.65  
Method: OECD Test Guideline 117

##### **Glycerine:**

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

#### **Mobility in soil**

No data available

#### **Other adverse effects**

No data available

---

## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.

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.

---

## SECTION 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

UN number : UN 3077

---

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version 3.1      Revision Date: 09/30/2023      SDS Number: 5155504-00010      Date of last issue: 04/04/2023  
Date of first issue: 10/17/2019

---

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Progesterone)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Progesterone)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Progesterone)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

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

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

UN/ID/NA number : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Progesterone)  
Class : 9  
Packing group : III  
Labels : CLASS 9  
ERG Code : 171  
Marine pollutant : yes(Progesterone)  
Remarks : Above applies only to containers over 119 gallons or 450 liters.  
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### SECTION 15. REGULATORY INFORMATION

#### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Combustible dust  
Carcinogenicity  
Reproductive toxicity

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### US State Regulations

##### Pennsylvania Right To Know

Sunflower oil	8001-21-6
Progesterone	57-83-0
Gelatins	9000-70-8
Glycerine	56-81-5

##### California Prop. 65

WARNING: This product can expose you to chemicals including Progesterone, which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

##### California List of Hazardous Substances

Progesterone	57-83-0
--------------	---------

##### California Permissible Exposure Limits for Chemical Contaminants

Sunflower oil	8001-21-6
Glycerine	56-81-5

#### The ingredients of this product are reported in the following inventories:

IECSC	: not determined
AICS	: not determined
DSL	: not determined

### SECTION 16. OTHER INFORMATION

#### Further information

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

## Progesterone Formulation

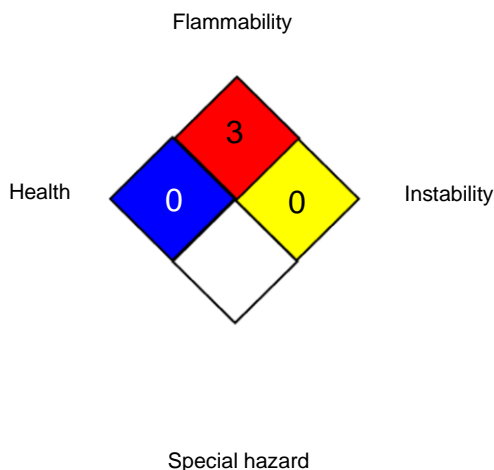
Version  
3.1

Revision Date:  
09/30/2023

SDS Number:  
5155504-00010

Date of last issue: 04/04/2023  
Date of first issue: 10/17/2019

### NFPA 704:



### HMIS® IV:

HEALTH	*	4
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CAL PEL	:	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
CAL PEL / PEL	:	Permissible exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Pre-

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

## Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	5155504-00010	Date of first issue: 10/17/2019

---

vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/30/2023

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.

US / Z8