SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

SECTION 1. IDENTIFICATION

Product name : Progesterone Formulation (Veterinary)

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Carcinogenicity (Inhalation) : Category 1A
Carcinogenicity : Category 2
Reproductive toxicity : Category 1A
Effects on or via lactation
Specific target organ toxicity - repeated exposure (Inhalation) : Category 1 (Lungs)

GHS label elements
Hazard pictograms : 

Signal Word : Danger

Hazard Statements : 
H350 May cause cancer by inhalation.
H351 Suspected of causing cancer.
H360FD May damage fertility. May damage the unborn child.
H362 May cause harm to breast-fed children.
H372 Causes damage to organs (Lungs) through prolonged or repeated exposure if inhaled.

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, fume, gas, mist, vapors or spray.
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 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
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quartz</td>
<td>14808-60-7</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Progesterone</td>
<td>57-83-0</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>Bis(alpha,alpha-dimethylbenzyl) peroxide</td>
<td>80-43-3</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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 : Flush eyes with water as a precaution.
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 : May cause cancer by inhalation.
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.
Causes damage to organs through prolonged or repeated exposure if inhaled.

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 (CO2)
Dry chemical

Unsuitable extinguishing media
None known.

Specific hazards during fire fighting
Exposure to combustion products may be a hazard to health.

Hazardous combustion products
Carbon oxides
Silicon oxides

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.
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.

SECTION 7. HANDLING AND STORAGE
SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

Technical measures

: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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, fume, gas, mist, vapors or spray.
  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.
  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:
  Strong oxidizing agents
  Self-reactive substances and mixtures
  Organic peroxides
  Explosives
  Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>Quartz</td>
<td>14808-60-7</td>
<td>TWA (Respirable dust)</td>
<td>0.05 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable)</td>
<td>10 mg/m³/ %SiO2+2</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable)</td>
<td>250 mppcf/ %SiO2+5</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>0.025 mg/m³ (Silica)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable dust)</td>
<td>0.05 mg/m³ (Silica)</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (respirable)</td>
<td>0.05 mg/m³</td>
<td>OSHA CARC</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWA (Dust)</td>
<td>20 Million particles per cubic foot (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Dust)</td>
<td>80 mg/m³</td>
<td>OSHA Z-3</td>
</tr>
</tbody>
</table>
Progesterone Formulation (Veterinary)

<table>
<thead>
<tr>
<th></th>
<th>%SiO2 (Silica)</th>
<th>TWA 6 mg/m³ (Silica)</th>
<th>NIOSH REL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>TWA 6 μg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>60 μg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Minimize workplace exposure concentrations. If sufficient ventilation is unavailable, use with local exhaust ventilation.

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 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: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection: Wear the following personal protective equipment: Safety glasses

Skin and body protection: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance: solid
Color: light green
Odor: No data available
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.1 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic: Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:
Quartz:
Acute oral toxicity: LD50 (Rat): > 22,500 mg/kg

Silicon dioxide:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Acute inhalation toxicity: LC50 (Rat): > 2.08 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

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

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity
Acute inhalation toxicity: LC50 (Rat): > 0.224 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Skin corrosion/irritation
Not classified based on available information.

Components:

Quartz:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Silicon dioxide:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Result: Skin irritation

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

Components:

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

Silicon dioxide:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

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

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Species: Rabbit
Result: Irritation to eyes, reversing within 7 days
Method: OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

**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

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
- Test Type: Local lymph node assay (LLNA)
- Routes of exposure: Skin contact
- Species: Mouse
- Method: OECD Test Guideline 429
- Result: negative

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

Components:

**Silicon dioxide:**
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
- Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Rat
  Application Route: Ingestion
  Result: negative

**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
**SAFETY DATA SHEET**

**Progesterone Formulation (Veterinary)**

Version 5.1  Revision Date: 04/04/2023  SDS Number: 2183757-00013  Date of last issue: 09/02/2022

Date of first issue: 11/15/2017

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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

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
- Genotoxicity in vitro:
  - Test Type: Chromosome aberration test in vitro
    - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
    - Method: OECD Test Guideline 476
    - Result: negative

**Carcinogenicity**

May cause cancer by inhalation. Suspected of causing cancer.

**Components:**

**Quartz:**
- Species: Humans
- Application Route: inhalation (dust/mist/fume)
- Result: positive

**Carcinogenicity - Assessment:**
- Positive evidence from human epidemiological studies (inhalation)

**Silicon dioxide:**
- Species: Rat
- Application Route: Ingestion
- Exposure time: 103 weeks
- Result: negative

**Progesterone:**
- Species: Mouse, female
- Application Route: Subcutaneous
- Exposure time: 104 weeks
- Result: positive

**Carcinogenicity - Assessment:**
- Limited evidence of carcinogenicity in animal studies

**IARC**
- Group 1: Carcinogenic to humans
### Quartz (Silica dust, crystalline)

Quartz 14808-60-7

<table>
<thead>
<tr>
<th>OSHA</th>
<th>OSHA specifically regulated carcinogen</th>
<th>14808-60-7</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quartz (crystalline silica)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NTP</th>
<th>Reasonably anticipated to be a human carcinogen</th>
<th>14808-60-7</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Progesterone 57-83-0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Known to be human carcinogen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quartz (Silica, Crystalline (Respirable Size))</td>
<td></td>
</tr>
</tbody>
</table>

### Reproductive toxicity

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

### Components:

#### Silicon dioxide:

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

#### Progesterone:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Subcutaneous</td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Subcutaneous</td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
</tbody>
</table>

#### Bis(alpha,alpha-dimethylbenzyl) peroxide:

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 414</td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
</tbody>
</table>

| 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 |

| Reproductive toxicity - Assessment | Clear evidence of adverse effects on development, based on animal experiments. |
STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs (Lungs) through prolonged or repeated exposure if inhaled.

Components:

Quartz:
Routes of exposure : inhalation (dust/mist/fume)
Target Organs : Lungs
Assessment : Shown to produce significant health effects in animals at concentrations of 0.02 mg/l/6h/d or less.

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Routes of exposure : Ingestion
Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

Quartz:
Species : Humans
LOAEL : 0.053 mg/m³
Application Route : Inhalation

Silicon dioxide:
Species : Rat
NOAEL : 1.3 mg/m³
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Species : Rat
NOAEL : 60 mg/kg
LOAEL : 200 mg/kg
Application Route : Ingestion
Exposure time : 28 Days
Method : OECD Test Guideline 407

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:

Quartz:
- Toxicity to fish: LC50 (Danio rerio (zebra fish)): 508 mg/l
  Exposure time: 96 h
  Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 731 mg/l
  Exposure time: 48 h
  Remarks: Based on data from similar materials

Silicon dioxide:
- Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
  Exposure time: 24 h
  Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials
- NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  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: NOEC (Daphnia magna (Water flea)): 0.1 mg/l
aquatic invertebrates (Chronic toxicity)

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 0.397 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 20 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.177 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms: NOEC: > 1,000 mg/l
Exposure time: 30 min
Remarks: No toxicity at the limit of solubility.

**Persistence and degradability**

**Components:**

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

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 20.2 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

**Bioaccumulative potential**

**Components:**

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

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 137 - 1,470
Method: OECD Test Guideline 305C
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
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Progesterone)
Class: 9
Packing group: III
Labels: 9

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: 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 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: Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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
Siloxanes and Silicones, dimethyl, methylvinyl, vinyl group-terminated 68083-18-1
Quartz 14808-60-7
Silicon dioxide 7631-86-9
Progesterone 57-83-0

California Prop. 65
WARNING: This product can expose you to chemicals including Quartz, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.
California List of Hazardous Substances
- Silicon dioxide: 7631-86-9
- Progesterone: 57-83-0

California Permissible Exposure Limits for Chemical Contaminants
- Quartz: 14808-60-7
- Silicon dioxide: 7631-86-9

California Regulated Carcinogens
- Quartz: 14808-60-7

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:
- Flammability: 1
- Health: 0
- Instability: 0
- Special hazard

HMIS® IV:
- HEALTH: * 4
- FLAMMABILITY: 1
- 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)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA CARC: OSHA Specifically Regulated Chemicals/Carcinogens
- 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
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

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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 Toxican; 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; IC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - 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 Prevention 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(A)EL - No Observed (Adverse) Effect Concentration/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; 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; 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


Revision Date: 04/04/2023

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.