SECTION 1. IDENTIFICATION

Product name: Progesterone Formulation (Veterinary)
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Carcinogenicity (Inhalation): Category 1A
Carcinogenicity: Category 2
Reproductive toxicity: Category 1A
Effects on or via lactation: Category 1 (Lungs)

Specific target organ systemic toxicity - repeated exposure (Inhalation): Category 1 (Lungs)

GHS label elements
Hazard pictograms: 
Signal Word: Danger
Hazard Statements: 
H350i May cause cancer by inhalation.
H351 Suspected of causing cancer.
H360 May damage fertility or 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/ 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/ 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.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz</td>
<td>14808-60-7</td>
<td></td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td></td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td></td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range 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 and effects, both acute and: May cause cancer by inhalation.
Suspected of causing cancer.
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 and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- 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

Technical measures:
- See Engineering measures under EXPOSURE
Local/Total ventilation: Use with local exhaust ventilation.
Advice on safe handling:
- Do not get on skin or clothing.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- 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
  - Organic peroxides
  - Explosives
  - Gases

**SECTON 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 fraction)</td>
<td>0.1 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulates)</td>
<td>0.025 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (respirable dust)</td>
<td>0.1 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>0.025 mg/m³ (Silica)</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>0.025 mg/m³ (Silica)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWAEV (respirable dust)</td>
<td>6 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>1.5 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total)</td>
<td>4 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>TWA (Respirable)</td>
<td>5 μg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information:</td>
<td>DSEN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>50 μg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Engineering measures**: Minimize workplace exposure concentrations.
Use with local exhaust ventilation.

**Personal protective equipment**

**Respiratory protection**
- Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.
- Filter type: Particulates type

**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**
- Ensure that eye flushing systems and safety showers are located 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 information available.

**Odor Threshold**
- No data available

**pH**
- No data available

**Melting point/freezing point**
- No data available

**Initial boiling point and boiling range**
- No data available

**Flash point**
- Not applicable

**Evaporation rate**
- Not applicable

**Flammability (solid, gas)**
- Not classified as a flammability hazard

**Flammability (liquids)**
- 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: 1.1 g/cm³

Solubility(ies)
  Water solubility: soluble

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: Not applicable
Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

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:
### SAFETY DATA SHEET

**Progesterone Formulation (Veterinary)**

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<thead>
<tr>
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</tbody>
</table>

#### Acute oral toxicity
- **Silicon dioxide:**
  - LD50 (Rat): > 22,500 mg/kg
- **Progesterone:**
  - LD50 (Rat): > 5,000 mg/kg

#### Acute inhalation toxicity
- **Silicon dioxide:**
  - 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
- **Silicon dioxide:**
  - LD50 (Rabbit): > 5,000 mg/kg

#### 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

#### 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
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

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: 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

Carcinogenicity
May cause cancer by inhalation. Suspected of causing cancer.

Components:

Quartz:

Silicon dioxide:
Species: Rat Application Route: Ingestion
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</table>

| Exposure time | : 103 weeks |
| Result        | : negative  |

**Progesterone:**

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

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

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

**Components:**

**Silicon dioxide:**

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

**Progesterone:**

- **Effects on fertility**: Test Type: Fertility
  - Species: Rat
  - Application Route: Subcutaneous
  - Result: positive

- **Effects on fetal development**: Test Type: Embryo-fetal 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**
- 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.
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

Aspiration toxicity
Not classified based on available information.

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: 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
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</table>

**Ecotoxicology Assessment**

- **Acute aquatic toxicity**: Toxic effects cannot be excluded
- **Chronic aquatic toxicity**: Toxic effects cannot be excluded

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Components**

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

**Domestic regulation**

- **TDG**: Not regulated as a dangerous good
SECTION 15. REGULATORY INFORMATION

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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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; CPR - Controlled Products Regulations; 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 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; IECS - Inventory of Existing Chemicals 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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 concern-
SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

Version 2.0  Revision Date: 10/16/2018  SDS Number: 2183772-00003  Date of last issue: 03/26/2018

Date of first issue: 11/15/2017

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

Revision Date: 10/16/2018

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

CA / Z8