SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

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: 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 Hazardous Products Regulations
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
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Version 6.1
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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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</td>
<td>Quartz</td>
</tr>
<tr>
<td></td>
<td>Progesterone</td>
</tr>
<tr>
<td></td>
<td>Bis(alpha, alpha-dimethylbenzyl) peroxide</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 delayed:
- May cause cancer by inhalation.
- 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

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 particulates)</td>
<td>0.025 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>0.1 mg/m³</td>
<td>CA ON 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 particulates)</td>
<td>0.025 mg/m³ (Silica)</td>
<td>CA AB 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</td>
<td>0.025 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>(Respirable particulate matter)</th>
<th>(Silica)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone 57-83-0 TWA 6 μg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Wipe limit 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**
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**
Self-contained breathing apparatus

**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

**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:
Acute oral toxicity : LD50 (Rat): > 22,500 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

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

**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:

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

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)

Progesterone:
Species: Mouse, female
Application Route: Subcutaneous
Exposure time: 104 weeks
Result: positive
Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies.

**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.

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
Effects on fetal development: Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive

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 concentra-
tions of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

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

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

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
## aquatic invertebrates

<table>
<thead>
<tr>
<th>Exposure time: 48 h</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

### 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 |

### 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

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
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

TDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Progesterone)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes (Progesterone)

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

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
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
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CA QC OEL: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA: 8-hour, time-weighted average
CA AB OEL / TWA: 8-hour Occupational exposure limit
CA BC OEL / TWA: 8-hour time weighted average
CA ON OEL / TWA: Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV: Time-weighted average exposure value

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


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 guideline 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...
SAFETY DATA SHEET

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

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