SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

Version 1.2  Revision Date: 10/16/2018  SDS Number: 2183775-00003  Date of last issue: 26.03.2018  Date of first issue: 15.11.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Progesterone Formulation (Veterinary)

Manufacturer or supplier’s details
Company: MSD
Address: 26 Talavera Road, Talavera Corp Centre, Macquarie Park New South Wales, 2113 Australia
Telephone: (61)-02-8988-8000
Emergency telephone number: (61)-02-8988-8000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
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: 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/ vapours/ spray.
- P263 Avoid contact during pregnancy/ while nursing.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P281 Use personal protective equipment as required.

**Response:**
- 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 which do not result in classification
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<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>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

### SECTION 4. FIRST AID MEASURES

**General advice:**
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

**If inhaled:**
- If inhaled, remove to fresh air.
- Get medical attention.

**In case of skin contact:**
- In case of contact, immediately flush skin with soap and plenty of water.
- Remove contaminated clothing and shoes.
- Get medical attention.
- Wash clothing before reuse.
- Thoroughly clean shoes before reuse.

**In case of eye contact:**
- 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 or 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.

Notes to physician:
- Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- None known.

Specific hazards during firefighting:
- 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 firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice 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 CONTROLS/PERSONAL PROTECTION section.

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.

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.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz</td>
<td>14808-60-7</td>
<td>TWA (Respirable dust)</td>
<td>0.1 mg/m3</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>0.025 mg/m3 (Silica)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWA (Respirable dust)</td>
<td>2 mg/m3</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica

<table>
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<th>Value type</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>TWA</td>
<td>5 μg/m3 (OEB 4)</td>
<td>Internal</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 and quantity of the hazardous substance and 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).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solid
Colour: light green
Odour: No information available.
Odour 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
Vapour pressure: Not applicable
Relative vapour 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

Auto-ignition 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

Exposure routes
- 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 inhala-
### Progesterone Formulation (Veterinary)

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</tbody>
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#### Acute dermal toxicity

Progesterone:
- **LD50 (Rabbit):** > 5,000 mg/kg

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz</td>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
<td></td>
</tr>
</tbody>
</table>

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz</td>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

#### Respiratory or skin sensitisation

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

#### Chronic toxicity

**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:

Species: Humans
Application Route: Inhalation (dust/mist/fume)
Result: positive
Remarks: IARC: (International Agency for Research on Cancer)

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

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

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Skin contact
Result: positive

Reproductive toxicity - Assessment: Positive evidence of adverse effects on sexual function, fertility and/or development from human epidemiological studies., Studies indicating a hazard to babies during the lactation period

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:
Exposure routes: 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

Progesterone:

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

Components:

Progestrone:
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.

National Regulations

ADG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Prohibition/Licensing Requirements: Quartz
Refer to model WHS Act and Regulations for prohibition, authorisation and restricted use.
The components of this product are reported in the following inventories:

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

**SECTION 16. OTHER INFORMATION**

**Further information**

- **Revision Date**: 10/16/2018
- **Date format**: dd.mm.yyyy

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **AU OEL**: Australia. Workplace Exposure Standards for Airborne Contaminants.
- **ACGIH / TWA**: 8-hour, time-weighted average
- **AU OEL / TWA**: Exposure standard - time weighted average

- 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; LC50 - 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; LD50 - Lethal Dose to 50% of a test population; LC50 - Lethal Concentration to 50% of a test population; NOELR - No Observable Effect Loading Rate; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Con-
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.