SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Progesterone Formulation (Veterinary)

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

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.
- 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.

**Additional Labelling**

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 6.609 %

**Other hazards which do not result in classification**

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 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>

### 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.
3. IN CASE OF SHELL CONTACT
   : Flush eyes with water as a precaution.
   Get medical attention if irritation develops and persists.

4. IF SWALLOWED
   : If swallowed, DO NOT induce vomiting.
   Get medical attention.
   Rinse mouth thoroughly with water.

5. 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.

6. 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.

7. Notes to physician
   : Treat symptomatically and supportively.

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.

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

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.

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

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>NAB (Respirable)</td>
<td>0.1 mg/m3</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>NAB</td>
<td>10 mg/m3</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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
Filter type: Particulates type
Hand protection: 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).

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.

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
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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

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.

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
SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

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 oral toxicity: LD50 (Rat): > 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 sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
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:
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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

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:**

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

**Mobility in soil**
No data available

**Other adverse effects**
No data available

### 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.

### 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.

### 15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered: Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use: Not applicable

Prohibited substances: Not applicable

Restricted substances: Not applicable

**Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials**

Types of Hazardous Materials governed by Import Regulations: Not applicable

Types of Hazardous Materials of which the Distribution and Supervision is Regulated: Not applicable

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

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

16. OTHER INFORMATION

**Further information**


Date format: yyyy/mm/dd

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **ID OEL**: Indonesia. Occupational Exposure Limits
- **ACGIH / TWA**: 8-hour, time-weighted average
- **ID OEL / NAB**: Long term exposure limit

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;
ID / EN