SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Progesterone Formulation (Veterinary)

Manufacturer or supplier's details
Company : MSD
Address : Rua Coronel Bento Soares, 530
           Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
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 in accordance with ABNT NBR 14725 Standard
Signal Word : Danger
Hazard Statements : H350 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:
SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

P201 Obtain special instructions before use.
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.

Additional Labeling
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz</td>
<td>14808-60-7</td>
<td>Carcinogenicity (Inhalation), Category 1A, Specific target organ toxicity - repeated exposure (Inhalation) (Lungs), Category 1</td>
<td>&gt;= 30 &lt; 50</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>Carcinogenicity, Category 2, Reproductive toxicity, Category 1A, Effects on or via lactation,</td>
<td>&gt;= 5 &lt; 10</td>
</tr>
<tr>
<td>Bis(alpha,alpha-dimethylbenzyl) peroxide</td>
<td>80-43-3</td>
<td>Organic peroxides, Type F, Skin irritation, Category 2, Eye irritation, Category 2B, Reproductive toxicity, Category 1B, Long-term (chronic) aquatic hazard, Category 2</td>
<td>&gt;= 0.3 &lt; 1</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 (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.

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.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters
Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
---|---|---|---|---|
Quartz | 14808-60-7 | LT | 8,5 mppcd / (% quartz+10) (Silica) | BR OEL |
 |  | LT (Respirable dust) | 8 mg/m³ / (% quartz+2) (Silica) | BR OEL |
 |  | LT (Total dust) | 24 mg/m³ / (% quartz+3) (Silica) | BR OEL |
Progesterone | 57-83-0 | TWA | 6 μg/m³ (OEB 4) | Internal |
 |  |  |  | Wipe limit | 60 μg/100 cm² |

### 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).

### 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**

<table>
<thead>
<tr>
<th>Component</th>
<th>Acute oral toxicity</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz:</td>
<td>LD50 (Rat): &gt; 22.500 mg/kg</td>
<td>OECD Test Guideline 401</td>
</tr>
<tr>
<td>Progesterone:</td>
<td>LD50 (Rat): &gt; 5.000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Bis(alpha,alpha-dimethylbenzyl) peroxide:</td>
<td>LD50 (Rat): &gt; 2.000 mg/kg</td>
<td>OECD Test Guideline 402</td>
</tr>
</tbody>
</table>

**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**

<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>
</tbody>
</table>
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

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:

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: 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
### 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  
  - 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:

- **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

- **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 concentrations 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.
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:
- Ecotoxicology Assessment
  Acute aquatic toxicity: Toxic effects cannot be excluded
  Chronic aquatic toxicity: Toxic effects cannot be excluded

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:

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

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
- Bioaccumulation: Species: Cyprinus carpio (Carp)
  - Bioconcentration factor (BCF): 137 - 1.470
  - Method: OECD Test Guideline 305C
- Partition coefficient: n-octanol/water: log Pow: 5.6

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**

- **ANTT**
  Not regulated as a dangerous good

**Special precautions for user**

Not applicable
SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH)

Group 1: Carcinogenic to humans
Quartz 14808-60-7

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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


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

Full text of other abbreviations

- ACeIH : USA. ACeIH Threshold Limit Values (TLV)
- BR OEL : Brazil. NR 15 - Unhealthy activities and operations
- ACeIH / TWA : 8-hour, time-weighted average
- BR OEL / LT : Up to 48 hours /week

AIIc - Australian Inventory of Industrial Chemicals; 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; 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; 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; LC50 - Lethal Con-
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BR / Z8