SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

Version 3.3  Revision Date: 09.04.2021  SDS Number: 2183773-00008  Date of last issue: 10.10.2020
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: 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
Hazard pictograms:

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:
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>
</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 spills 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

<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>LT</td>
<td>8,5 mppcd / (% quartz+10) (Silica)</td>
<td>BR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LT (Respirable dust)</td>
<td>8 mg/m3 / (% quartz+2) (Silica)</td>
<td>BR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LT (Total dust)</td>
<td>24 mg/m3 / (% quartz+3)</td>
<td>BR OEL</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

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<table>
<thead>
<tr>
<th>(Silica)</th>
<th>TWA (Respirable particulate matter)</th>
<th>0.025 mg/m³ (Silica)</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>TWA</td>
<td>6 μg/m³ (OEB 4)</td>
</tr>
<tr>
<td>Further information: DSEN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wipe limit</td>
<td>60 μg/100 cm²</td>
<td>Internal</td>
<td></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**: Particulates type
- **Hand protection**: Chemical-resistant gloves

**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.
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 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

**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

**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:**

**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
SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

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

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

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

**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

**Persistence and degradability**
No data available

**Bioaccumulative potential**

**Components:**

**Progesterone:**
SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

Partition coefficient: n-octanol/water

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

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

International Regulations

The ingredients of this product are reported in the following inventories:
AICS: not determined
SECTION 16. OTHER INFORMATION

Further information

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

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...
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