SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Progesterone Formulation (Veterinary)

Version 3.3 Revision Date: 09.04.2021 SDS Number: 2190087-00008 Date of last issue: 10.10.2020 Date of first issue: 15.11.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Progesterone Formulation (Veterinary)

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Walton Manor, Walton MK7 7AJ Milton Keynes - United Kingdom
Telephone: +1-908-740-4000
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Carcinogenicity, Category 1A H350i: May cause cancer by inhalation.
Carcinogenicity, Category 2 H351: Suspected of causing cancer.
Reproductive toxicity, Category 1A H360: May damage fertility or the unborn child.
Effects on or via lactation H362: May cause harm to breast-fed children.
Specific target organ toxicity - repeated exposure, Category 1 H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
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 through prolonged or repeated exposure.
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
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/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:
Quartz
Progesterone

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

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
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</thead>
<tbody>
<tr>
<td>Quartz</td>
<td>14808-60-7</td>
<td>238-878-4</td>
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<td></td>
<td>Carc. 1A; H350i STOT RE 1; H372 (Lungs)</td>
<td>&gt;= 30 - &lt; 50</td>
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<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>200-350-6</td>
<td></td>
<td></td>
<td>Carc. 2; H351 Repr. 1A; H360 Lact.H362</td>
<td>&gt;= 1 - &lt; 10</td>
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</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks

: 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment

: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting

: Exposure to combustion products may be a hazard to health.

Hazardous combustion products

: Carbon oxides
Silicon oxides
5.3 Advice for firefighters

- **Special protective equipment for firefighters**: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

- **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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- **Personal precautions**: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- **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.

6.3 Methods and material for containment and cleaning up

- **Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- **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, vapours 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)
Specific use(s):
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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</thead>
<tbody>
<tr>
<td>Quartz</td>
<td>14808-60-7</td>
<td>TWA (Respirable dust)</td>
<td>0.1 mg/m³</td>
<td>2004/37/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>0.1 mg/m³ (Silica)</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWA (Inhalable dust)</td>
<td>6 mg/m³ (Silica)</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable dust)</td>
<td>2.4 mg/m³ (Silica)</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>TWA</td>
<td>6 μg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>60 μg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:
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according to Regulation (EC) No. 1907/2006

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Substance name | End Use | Exposure routes | Potential health effects | Value
--- | --- | --- | --- | ---
Silicon dioxide | Workers | Inhalation | Long-term systemic effects | 4 mg/m³

8.2 Exposure controls

**Engineering measures**
Minimize workplace exposure concentrations.
If sufficient ventilation is unavailable, use with local exhaust ventilation.

**Personal protective equipment**

**Eye protection**
Wear the following personal protective equipment:
- Safety glasses
- Equipment should conform to BS EN 166

**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.**

**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).

**Respiratory protection**
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Equipment should conform to BS EN 143

**Filter type**
- Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- **Appearance**: solid
- **Colour**: light green
- **Odour**: No data 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.

9.2 Other information
Molecular weight : Not applicable

Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
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10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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
Method: OECD Test Guideline 405
Result: No eye irritation
Remarks: Based on data from similar materials
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:

**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

  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:**
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**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 through prolonged or repeated exposure.

**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

**Aspiration toxicity**
Not classified based on available information.

**SECTION 12: Ecological information**

**12.1 Toxicity**

**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: EC50 (Daphnia magna (Water flea)): 731 mg/l
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aquatic invertebrates
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

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:
Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
   Not regulated as a dangerous good

14.2 UN proper shipping name
   Not regulated as a dangerous good

14.3 Transport hazard class(es)
   Not regulated as a dangerous good

14.4 Packing group
   Not regulated as a dangerous good

14.5 Environmental hazards
   Not regulated as a dangerous good

14.6 Special precautions for user
   Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
   Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

   REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
   REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
   REACH - List of substances subject to authorisation (Annex XIV): Not applicable
   Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
   Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
   Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Other regulations:
   Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
   Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS: not determined
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DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other 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 H-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 through prolonged or repeated exposure if inhaled.

Full text of other abbreviations

Carc. : Carcinogenicity
Lact. : Effects on or via lactation
Repr. : Reproductive toxicity
STOT RE 2004/37/EC : Specific target organ toxicity - repeated exposure
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
2004/37/EC / TWA : Long term exposure limit
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Speci-
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Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
<th>Carc. 1A</th>
<th>H350i</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculation method</td>
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<tr>
<td>Carc. 2</td>
<td>H351</td>
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<td>Calculation method</td>
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<td>Repr. 1A</td>
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<tr>
<td>Lact.</td>
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<td>Calculation method</td>
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<tr>
<td>STOT RE 1</td>
<td>H372</td>
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<tr>
<td>Calculation method</td>
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</tbody>
</table>

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.

GB / EN