SAFETY DATA SHEET

Progesterone Formulation (Veterinary)

Version 4.1  Revision Date: 2021/04/09  SDS Number: 2183763-00008  Date of last issue: 2020/10/10
Date of first issue: 2017/11/15

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Progesterone Formulation (Veterinary)

Supplier’s company name, address and phone number
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTWARD@msd.com
Emergency telephone number: +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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:
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.
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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 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.

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

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz</td>
<td>14808-60-7</td>
<td>&gt;= 30 - &lt; 40</td>
<td>1-548</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td></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.

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.

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 (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
7. HANDLING AND STORAGE

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.

Avoidance of contact : Oxidizing agents
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.

Storage

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>OEL-C (Respirable dust)</td>
<td>0.03 mg/m³ (Silica)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>0.025 mg/m³ (Silica)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: Group 1: carcinogenic to humans
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Comments:

Further information: DSEN

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:
- 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).

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>TWA</th>
<th>Wipe limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>6 μg/m³ (OEB 4)</td>
<td>60 μg/100 cm²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Internal</td>
<td>Internal</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical state: solid
- Colour: light green
- Odour: No data available
- Odour Threshold: No data available
- Melting point/freezing point: No data available
- Boiling point, initial boiling point and boiling range: No data available
- Flammability (solid, gas): Not classified as a flammability hazard
- Flammability (liquids): No data available
- Lower explosion limit and upper explosion limit / flammability limit: No data available
- Upper explosion limit / Upper flammability limit: No data available
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

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 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:
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

Aspiration toxicity
Not classified based on available information.

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
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Bioaccumulative potential

Components:

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

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

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.

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.
Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalline silica</td>
<td>165</td>
<td>&gt;=30 - &lt;40</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalline silica</td>
<td>165</td>
</tr>
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Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable
Vessel Safety Law  
Not regulated as a dangerous good

Aviation Law  
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law  
Bulk transportation : Not classified as noxious liquid substance  
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act  
Narcotic or Psychotropic Raw Material (Export / Import Permission)  
Not applicable  
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)  
Not applicable

Waste Disposal and Public Cleansing Law  
Industrial waste

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 / TWA : 8-hour, time-weighted average  
JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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
<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<tr>
<td>4.1</td>
<td>2021/04/09</td>
<td>2183763-00008</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Equipment of Ships carrying Dangerous Chemicals in Bulk; 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 Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; 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 Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

JP / EN