Section 1: Identification

Product name: Proligestone Formulation

Manufacturer or supplier's details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

Section 2: Hazard identification

GHS Classification
Carcinogenicity: Category 2
Reproductive toxicity: Category 1B

GHS label elements
Hazard pictograms: ☢️
Signal word: Danger
Hazard statements: H351 Suspected of causing cancer.
H360D May damage the unborn child.

Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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.

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proligestone</td>
<td>23873-85-0</td>
<td>&gt;= 1 - &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: Suspected of causing cancer. May damage the unborn child.

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)

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides  
Metal 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.  

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. Prevent spreading over a wide area (e.g. by containment or oil barriers). 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: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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: Do not get on skin or clothing. Do not breathe mist or vapours. 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
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. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

Section 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>Proligestone</td>
<td>23873-85-0</td>
<td>TWA</td>
<td>5 ug/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>50 ug/100cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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

Material: Consider double gloving.

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance: suspension

Colour: white to off-white

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: No data available

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

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: No data available

Relative vapour density: No data available

Relative density: No data available

Density: 1.035 g/cm³

Solubility(ies)

Water solubility: soluble

Solubility in other solvents: No data available

Partition coefficient: n-octanol/water: Not applicable

Auto-ignition temperature: No data available
Decomposition temperature  :  No data available

Viscosity
  Viscosity, kinematic  :  No data available

Explosive properties  :  Not explosive

Oxidizing properties  :  The substance or mixture is not classified as oxidizing.

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

Exposure routes
  Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity  :  Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

Components:

Proligestone:
Acute oral toxicity  :  LD50 (Mouse): 1,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Suspected of causing cancer.

**Components:**

Proligestone:

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

Reproductive toxicity
May damage the unborn child.

**Components:**

Proligestone:

Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 10 mg/kg body weight
Result: No effects on fertility

Test Type: Fertility
Species: Rabbit
Application Route: Subcutaneous
Fertility: LOAEL: 10 mg/kg body weight
Result: Postimplantation loss.

Reproductive toxicity - Assessment: May damage the unborn child. Suspected of damaging fertility.

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Not classified based on available information.

**Components:**

Proligestone:

Target Organs: Adrenal gland, Ovary, Uterus (including cervix)
Assessment: May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Proligestone:**

- **Species:** Dog
- **LOAEL:** 25 mg/kg
- **Application Route:** Subcutaneous
- **Exposure time:** 90 d
- **Target Organs:** Adrenal gland, Uterus (including cervix), Ovary

- **Species:** Rat
- **LOAEL:** 50 mg/kg
- **Application Route:** Subcutaneous
- **Exposure time:** 90 d
- **Target Organs:** Adrenal gland, Uterus (including cervix), Ovary

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

**Components:**

**Proligestone:**

General Information: Remarks: May cause cancer based on animal data.

Inhalation: Symptoms: Jaundice, Headache, Dizziness, menstrual irregularities, changes in libido, bleeding, breast changes

Section 12: Ecological information

Ecotoxicity

**Components:**

**Proligestone:**

- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): > 0.5 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: No toxicity at the limit of solubility

- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 0.5 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: No toxicity at the limit of solubility

- **Toxicity to algae/aquatic plants:** EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

  NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

Persistence and degradability

Components:

Proligestone:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential
No data available

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
UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
IATA-DGR
SAFETY DATA SHEET

Proligestone Formulation

Version: 2.5 Revision Date: 27.08.2021 SDS Number: 3068523-00007 Date of last issue: 10.10.2020

Date of first issue: 07.08.2018

UN/ID No.: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
Packing instruction (cargo aircraft): Not applicable
Packing instruction (passenger aircraft): Not applicable

IMDG-Code
UN number: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
EmS Code: Not applicable
Marine pollutant: Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
UN number: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
Hazchem Code: Not applicable

Special precautions for user
Not applicable

Section 15: Regulatory information

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC : not determined

Section 16: Other information

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations

ALLI - 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 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; PB2 - 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; TECI - Thailand Existing Chemicals Inventory; 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
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NZ / EN