SAFETY DATA SHEET

Altrenogest Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Altrenogest Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 91-105 Harpin Street
Bendigo 3550, Victoria Australia
Telephone : 908-740-4000
Emergency telephone number : 1 800 033 461
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 1 800 817 414

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity : Category 1B

GHS label elements
Hazard pictograms :

Signal word : Danger
Hazard statements : H360 May damage fertility or 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.
P281 Use personal protective equipment as required.
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
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>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>altrenogest</td>
<td>850-52-2</td>
<td>&gt;= 0.3 &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 damage fertility or 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. 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
### SECTION 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental precautions</td>
<td>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.</td>
</tr>
<tr>
<td>Methods and materials for containment and cleaning up</td>
<td>Soak up with inert absorbent material. For large spills, provide dyeing or other appropriate containment to keep material from spreading. If dyed 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.</td>
</tr>
</tbody>
</table>

### 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 vapours or spray mist. 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 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.
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>altrenogest</td>
<td>850-52-2</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
Wipe limit 10 µg/100 cm² Internal

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:
Material: Chemical-resistant gloves
Remarks: 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Altrenogest Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>10.10.2020</td>
<td>641662-00013</td>
<td>13.05.2020</td>
<td>02.05.2016</td>
</tr>
</tbody>
</table>

- Viscosity, kinematic: No data available
- Explosive properties: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.
- Molecular weight: No data available
- Particle size: No data available

**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:**

**altrenogest:**

**Acute oral toxicity**
- LD50 (Rat): 177 mg/kg
- LD50 (Dog): 400 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.

**Components:**

**altrenogest:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
May damage fertility or the unborn child.

**Components:**

**altrenogest:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>Fertility: NOAEL: 0.016 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td>Result: Effects on fertility, No effects on mating performance</td>
</tr>
<tr>
<td></td>
<td>Test Type: Fertility/early embryonic development</td>
</tr>
<tr>
<td></td>
<td>Species: Monkey, female</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>Fertility: NOAEL: 0.004 mg/kg body weight</td>
</tr>
</tbody>
</table>

Reproductive toxicity - Assessment: Clear evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments

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

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

**Components:**

**altrenogest:**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Immune system, Adrenal gland</td>
</tr>
</tbody>
</table>
Assessment: May cause damage to organs through prolonged or repeated exposure.

Exposure routes: Oral
Target Organs: Pituitary gland

Repeated dose toxicity

Components:

altrenogest:
Species: Rat
NOAEL: 0.06 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Immune system, male reproductive organs, female reproductive organs, Adrenal gland
Remarks: Effects on fertility

Species: Pig
NOAEL: 0.004 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: male reproductive organs, female reproductive organs
Remarks: Effects on fertility

Species: Pig
NOAEL: 0.002 mg/kg
Application Route: Oral
Exposure time: 1 yr
Target Organs: male reproductive organs, Pituitary gland
Remarks: Effects on fertility

Species: Horse
LOAEL: 220 mg/kg
Application Route: Oral
Exposure time: 86 Days
Remarks: No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

altrenogest:
Inhalation: Symptoms: respiratory tract irritation
Skin contact: Symptoms: Skin irritation
Eye contact: Symptoms: Eye irritation
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

altrenogest:
Toxicity to fish (Chronic toxicity):
NOEC (Danio rerio (zebra fish)): 0.0004 µg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Persistence and degradability
No data available

Bioaccumulative potential

Components:

altrenogest:
Partition coefficient: n-octanol/water:
log Pow: 3.78

Mobility in soil

Components:

altrenogest:
Distribution among environmental compartments:
log Koc: 3.3

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:
UN 3082
Proper shipping name:
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest)
Class:
9
Packing group:
III
Labels:
9

IATA-DGR
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UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (altrenogest)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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

National Regulations

ADG
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest)
Class: 9
Packing group: III
Labels: 9
Hazchem Code: •3Z

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements: There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.
The components of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

**SECTION 16. OTHER INFORMATION**

Further information

- Revision Date: 10.10.2020
- Date format: dd.mm.yyyy

Full text of other abbreviations

- AIIIC - 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
- PBT - Persistent, Bioaccumulative and Toxic substance
- PICCS - Philippines Inventory of Chemicals and Chemical Substances
- (Q)SAR - (Quantitative) Structure Activity Relationship
- 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.