SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Altrenogest (0.4%) Formulation

Version: 5.9   Revision Date: 09/30/2023   SDS Number: 641680-00023   Date of last issue: 04/04/2023
Date of first issue: 05/02/2016

SECTION 1. IDENTIFICATION

Product name: Altrenogest (0.4%) Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Reproductive toxicity: Category 1B

GHS label elements
Hazard pictograms: ![Hazard Pictogram]

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.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

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

Storage: P405 Store locked up.

Disposal: P501 Dispose of contents and container to an approved waste disposal plant.
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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Altrenogest</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>Altrenogest</td>
<td>850-52-2</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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. FIRE-FIGHTING 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
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.
- 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 diking or other appropriate containment to keep material from spreading. If diked 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 vapors 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.
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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
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

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:
- General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
- Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
- Material: Chemical-resistant gloves
- Remarks: Consider double gloving.

Eye protection
- Material: Wear safety glasses with side shields or goggles.
- Remarks: 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
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.

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.

**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>
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<tr>
<td>Color</td>
<td>No data available</td>
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<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor 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>
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<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>
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<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
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<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>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition 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.
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
Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact
Acute toxicity
Not classified based on available information.
Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 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 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:
    - Altrenogest:
      - Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
        - Result: negative
      - Test Type: Chromosome aberration test in vitro
        - Result: negative
      - Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
        - Result: negative
  - Carcinogenicity: Not classified based on available information.
    - IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
    - OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.
    - NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
  - Reproductive toxicity: May damage fertility or the unborn child.
  - Components:
    - Altrenogest:
Effects on fertility:

- Test Type: Two-generation reproduction toxicity study
- Species: Rat
- Application Route: Oral
- Fertility: NOAEL: 0.016 mg/kg body weight
- Result: Effects on fertility, no effects on mating performance.

- Test Type: Fertility/early embryonic development
- Species: Monkey, female
- Application Route: Oral
- Fertility: NOAEL: 0.004 mg/kg body weight

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

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Pituitary gland</td>
</tr>
</tbody>
</table>

**Repeated dose toxicity**

**Components:**

**Altrenogest:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.06 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Immune system, male reproductive organs, female reproductive organs, Adrenal gland</td>
</tr>
<tr>
<td>Remarks</td>
<td>Effects on fertility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.004 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>male reproductive organs, female reproductive organs</td>
</tr>
<tr>
<td>Remarks</td>
<td>Effects on fertility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.002 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
</tbody>
</table>
Altrenogest (0.4%) Formulation

Exposure time: 1 y
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

<table>
<thead>
<tr>
<th>Disposal methods</th>
<th>Disposal of in accordance with local regulations. Do not dispose of waste into sewer. Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste from residues</td>
<td></td>
</tr>
<tr>
<td>Contaminated packaging</td>
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</table>

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

**UNRTDG**

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN 3082</th>
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</thead>
<tbody>
<tr>
<td>Proper shipping name</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest)</td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>9</td>
</tr>
<tr>
<td>Environmentally hazardous</td>
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</table>

**IATA-DGR**

<table>
<thead>
<tr>
<th>UN/ID No.</th>
<th>UN 3082</th>
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<tbody>
<tr>
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<td>Environmentally hazardous substance, liquid, n.o.s. (Altrenogest)</td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
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<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>Miscellaneous</td>
</tr>
<tr>
<td>Packing instruction (cargo aircraft)</td>
<td>964</td>
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<tr>
<td>Packing instruction (passenger aircraft)</td>
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<tr>
<td>Environmentally hazardous</td>
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**IMDG-Code**

<table>
<thead>
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<th>UN 3082</th>
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<tbody>
<tr>
<td>Proper shipping name</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Altrenogest)</td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
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<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>9</td>
</tr>
<tr>
<td>EmS Code</td>
<td>F-A, S-F</td>
</tr>
<tr>
<td>Marine pollutant</td>
<td>yes</td>
</tr>
</tbody>
</table>

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

#### Domestic regulation

**49 CFR**

<table>
<thead>
<tr>
<th>UN/ID/NA number</th>
<th>UN 3082</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper shipping name</td>
<td>Environmentally hazardous substance, liquid, n.o.s.</td>
</tr>
</tbody>
</table>
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Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes(Alrenogest)
Remarks : Above applies only to containers over 119 gallons or 450 liters.

Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity
SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations
Pennsylvania Right To Know
Soya oil 8001-22-7

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

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET
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Version 5.9 Revision Date: 09/30/2023 SDS Number: 641680-00023 Date of last issue: 04/04/2023
Date of first issue: 05/02/2016

NFPA 704:

Flammability Instability Special hazard

Health 0 1 0

HMIS® IV:

HEALTH FLAMMABILITY PHYSICAL HAZARD

* 0 1 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; IECS - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act
Altrenogest (0.4%) Formulation

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/30/2023

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.

US / Z8