

**Altrenogest Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 05/13/2020  
5.1                10/10/2020                641680-00015            Date of first issue: 05/02/2016

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**SECTION 1. IDENTIFICATION**

Product name                                : Altrenogest Formulation

**Manufacturer or supplier's details**

Company name of supplier                : Merck & Co., Inc  
Address                                        : 2000 Galloping Hill Road  
    Kenilworth - New Jersey - U.S.A. 07033  
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

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**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                            :



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.

**Other hazards**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

## Altrenogest Formulation

Version 5.1      Revision Date: 10/10/2020      SDS Number: 641680-00015      Date of last issue: 05/13/2020  
 Date of first issue: 05/02/2016

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Altrenogest	850-52-2	>= 0.1 - < 1

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 (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : 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.

## Altrenogest Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/13/2020
5.1	10/10/2020	641680-00015	Date of first issue: 05/02/2016

---

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

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### 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.

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### 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.

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  
Organic peroxides

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## Altrenogest Formulation

Version 5.1      Revision Date: 10/10/2020      SDS Number: 641680-00015      Date of last issue: 05/13/2020  
 Date of first issue: 05/02/2016

Explosives

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Altrenogest	850-52-2	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm <sup>2</sup>	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** : 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** : 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.

**Hygiene measures** : If exposure to chemical is likely during typical use, provide

**Altrenogest Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 05/13/2020
5.1	10/10/2020	641680-00015	Date of first issue: 05/02/2016

---

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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor 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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
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

**Altrenogest Formulation**

Version 5.1      Revision Date: 10/10/2020      SDS Number: 641680-00015      Date of last issue: 05/13/2020  
Date of first issue: 05/02/2016

---

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

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**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.

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**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.

**Altrenogest Formulation**

Version 5.1      Revision Date: 10/10/2020      SDS Number: 641680-00015      Date of last issue: 05/13/2020  
Date of first issue: 05/02/2016

---

**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

**Altrenogest Formulation**

Version 5.1      Revision Date: 10/10/2020      SDS Number: 641680-00015      Date of last issue: 05/13/2020  
Date of first issue: 05/02/2016

---

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Components:****Altrenogest:**

Routes of exposure : Oral  
Target Organs : Immune system, Adrenal gland  
Assessment : May cause damage to organs through prolonged or repeated exposure.

Routes of exposure : 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 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.



**Altrenogest Formulation**

Version 5.1      Revision Date: 10/10/2020      SDS Number: 641680-00015      Date of last issue: 05/13/2020  
Date of first issue: 05/02/2016

---

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

**IATA-DGR**

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.

**Domestic regulation****49 CFR**

UN/ID/NA number : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Altrenogest)  
Class : 9  
Packing group : III  
Labels : CLASS 9  
ERG Code : 171  
Marine pollutant : yes(Altrenogest)  
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.

**Altrenogest Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 05/13/2020  
5.1                10/10/2020                641680-00015            Date of first issue: 05/02/2016

---

**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

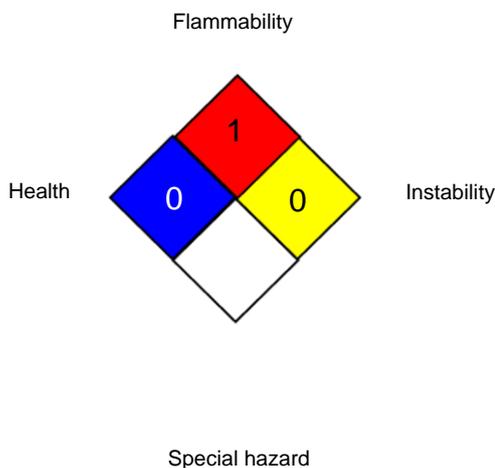
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**SECTION 16. OTHER INFORMATION****Further information**

## Altrenogest Formulation

Version  
5.1Revision Date:  
10/10/2020SDS Number:  
641680-00015Date of last issue: 05/13/2020  
Date of first issue: 05/02/2016

### NFPA 704:



### HMIS® IV:

<b>HEALTH</b>	*	<b>0</b>
<b>FLAMMABILITY</b>		<b>1</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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

AICC - 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; 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; 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; 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

## Altrenogest Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/13/2020
5.1	10/10/2020	641680-00015	Date of first issue: 05/02/2016

---

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 10/10/2020

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