

SAFETY DATA SHEET



Altrenogest (0.4%) Formulation (AU)

Version 3.1 Revision Date: 30.09.2023 SDS Number: 4458980-00006 Date of last issue: 04.04.2023
Date of first issue: 13.06.2019

SECTION 1: Identification of the hazardous chemical and of the supplier

Product identifier

Product name : Altrenogest (0.4%) Formulation (AU)
Chemical name :
CAS-No. : Not Assigned
Product code :

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

SECTION 2: Hazards identification

Classification of the hazardous chemical

Reproductive toxicity : Category 1B
Hazardous to the aquatic environment - chronic hazard : Category 1

Label elements

Hazard pictograms : 
Signal word : Danger
Hazard statements : H360 May damage fertility or the unborn child.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.

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P273 Avoid release to the environment.

P281 Use personal protective equipment as required.

Response:

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

P391 Collect spillage.

Storage:

P405 Store locked up.

Other hazards which do not result in classification

None known.

SECTION 3: Composition and information of the ingredients of the hazardous chemical

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Soya oil	8001-22-7	>= 60 -<= 100
altrenogest	850-52-2	>= 0.3 - < 1

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

Extinguishing media

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Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.

Physicochemical hazards arising from the chemical

Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides

Special protective equipment and precautions for fire-fighters

Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
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.
Hazchem Code	:	•3Z

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.

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3.1Revision Date:
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Date of first issue: 13.06.2019**SECTION 7: Handling and storage****Handling****Precautions for safe 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 : 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.

Storage**Conditions for safe storage, including any incompatibilities**

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 and personal protection**Control parameters**

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

Appropriate engineering controls

: 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.

Individual protection measures, such as personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

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	<p>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.</p>
Skin protection	<p>: 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.</p>
Hand protection	
Material	<p>: Chemical-resistant gloves</p>
Remarks	<p>: Consider double gloving.</p>
Respiratory protection	<p>: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</p>
Filter type	<p>: Particulates type</p>
Hygiene measures	<p>: 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.</p>

SECTION 9: Physical and chemical properties

Appearance	: liquid
Colour	: No data available
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

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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 : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

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.

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

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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.

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.

Reproductive toxicity

May damage fertility or the unborn child.

Components:

altrenogest:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat

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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:**

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

Exposure routes : Oral
Target Organs : Pituitary gland

Repeated dose toxicity**Components:****Soya oil:**

Species : Rat
NOAEL : 4,000 mg/kg
Application Route : Ingestion
Exposure time : 90 h

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

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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

M-Factor (Chronic aquatic toxicity) : 100,000

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Soya oil:

Partition coefficient: n-octanol/water : log Pow: > 4
Remarks: Calculation

altrenogest:

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

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Mobility in soil

Components:

altrenogest:

Distribution among environmental compartments : log Koc: 3.3

Other adverse effects

No data available

SECTION 13: Disposal information

Disposal methods

Waste from residues : Disposal of waste to be in accordance with the Environmental Quality (Scheduled Wastes) Regulations and other guidelines issuance by DOE and/or local authorities.
Do not dispose of waste into sewer.

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
Environmentally hazardous : yes

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.
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Class : 9
Packing group : III

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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.

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 specific for the hazardous chemical

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013.

Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000.

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16: Other information

Revision Date : 30.09.2023

Further information

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

Date format : dd.mm.yyyy

Full text of other abbreviations

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 Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory con-

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centration; 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; 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 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.

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