

# Altrenogest (0.22%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 25.03.2024

 2.9
 23.07.2024
 5842519-00011
 Date of first issue: 08.05.2020

## **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Altrenogest (0.22%) Formulation

Other means of identification : REGUMATE (A004536)

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.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 ABNT NBR 14725 Standard

Long-term (chronic) aquatic

hazard

: Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:

P273 Avoid release to the environment.

Response:

P391 Collect spillage.

Other hazards which do not result in classification

None known.



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

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)	
Benzyl alcohol	100-51-6	Acute toxicity (Oral), Category 4 Acute toxicity (Inhala- tion), Category 4 Eye irritation, Category 2A	>= 1 -< 5	
Altrenogest	850-52-2	Acute toxicity (Oral), Category 3 Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Oral) (Immune system, Adrenal gland), Category 2 Long-term (chronic) aquatic hazard, Category 1	>= 0,1 -< 0,25	

#### **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.

Flush eyes with water as a precaution.
 Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

None known.

Protection of first-aiders

In case of eye contact

: 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.



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#### **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 fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec-:

tive equipment and emer-

gency 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



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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.

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 labeled containers.

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 Gases

# **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

0	0.40.11	17-1 - 1	0 ( )	D '-		
Components	CAS-No.	Value type	Control parame-	Basis		
		(Form of	ters / Permissible			
		exposure)	concentration			
Altrenogest	850-52-2	TWA	1 μg/m3 (OEB 4)	Internal		
	Further inform	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.



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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

Combined particulates and organic vapor 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**

Appearance : liquid

Color : No data available

Odor : odorless

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



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Relative vapor density No data available

Relative density No data available

No data available Density

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

No data available Viscosity, kinematic

Explosive properties Not explosive

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

Molecular weight No data available

Particle characteristics

Particle size No data available

# **SECTION 10. STABILITY AND REACTIVITY**

: Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions. Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

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: Inhalation Skin contact exposure

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



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Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

**Components:** 

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Altrenogest:

Acute oral toxicity : LD50 (Rat): 177 mg/kg

LD50 (Dog): 400 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

**Components:** 

Benzyl alcohol:

Test Type : Maximization Test Routes of exposure : Skin contact



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Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

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 syn-

thesis in mammalian cells (in vitro)

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials



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Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse

Application Route: Ingestion

Result: negative

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 - As-

sessment

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:

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:**

# Benzyl alcohol:

Species : Rat NOAEL : 1,072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

Altrenogest:

Species : Rat

NOAEL : 0,06 mg/kg

Application Route : Oral



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Exposure time : 13 Weeks

Target Organs : Immune system, male reproductive organs, female reproduc-

tive 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.

## **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:

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/i

Exposure time: 72 h

Method: OECD Test Guideline 201



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NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

ic toxicity)

NOEC (Daphnia magna (Water flea)): 51 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Altrenogest:

Toxicity to fish (Chronic tox-

icity)

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

**Components:** 

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 % Exposure time: 14 d

**Bioaccumulative potential** 

**Components:** 

Benzyl alcohol:

Partition coefficient: n-

log Pow: 1,05

octanol/water

Altrenogest:

Partition coefficient: n-

--

log Pow: 3,78

octanol/water

Mobility in soil

**Components:** 

Altrenogest:

Distribution among environ-

mental compartments

: log Koc: 3,3

Other adverse effects

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.



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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)

Packing instruction (passen- : 964

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

(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**

**ANTT** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(altrenogest)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90



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#### 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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal

Police

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 23.07.2024 Date format : dd.mm.yyyy

**Further information** 

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 Agen-

cy, http://echa.europa.eu/

## 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 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



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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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