

# Altrenogest (0.4%) Formulation

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 6.0 06.07.2024 641681-00024 Date of first issue: 02.05.2016

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Altrenogest (0.4%) Formulation

Other means of identification : REGUMATE ORAL PROGESTAGEN FOR PIGS (45680)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

20 Spartan Road

1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person

responsible for the SDS

EHSDATASTEWARD@msd.com

# 1.4 Emergency telephone number

+1-908-423-6000

# **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B Long-term (chronic) aquatic hazard, Cat-

egory 1

H360: May damage fertility or the unborn child. H410: Very toxic to aquatic life with long lasting effects.

## 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)

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.



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Precautionary statements : Prevention:

P201 Obtain special instructions before use. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label: altrenogest

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## **SECTION 3: Composition/information on ingredients**

# 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Soya oil	8001-22-7 232-274-4	Aquatic Chronic 4; H413	>= 90 - <= 100
altrenogest	850-52-2 212-703-1	Acute Tox. 3; H301 Repr. 1B; H360 STOT RE 2; H373 (Immune system, Adrenal gland) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 100.000	>= 0,3 - < 1

For explanation of abbreviations see section 16.



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#### **SECTION 4: First aid measures**

## 4.1 Description of first aid measures

General advice In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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).

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.

#### 4.2 Most important symptoms and effects, both acute and delayed

Risks May damage fertility or the unborn child.

## 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

# **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

## 5.2 Special hazards arising from the substance or mixture

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

fighting



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Hazardous combustion prod- : Carbon oxides

## 5.3 Advice for firefighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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

Evacuate area.

#### **SECTION 6: Accidental release measures**

# 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

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

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

# 6.3 Methods and material for containment and cleaning up

Methods for 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 absor-

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## **SECTION 7: Handling and storage**

## 7.1 Precautions for safe handling

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 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 as-

sessment

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 contami-

nated 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.

# 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

**Explosives** 

7.3 Specific end use(s)

Specific use(s) : No data available

No data available

# **SECTION 8: Exposure controls/personal protection**

# 8.1 Control parameters

# **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis		
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		



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#### 8.2 Exposure controls

#### **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

Eye/face 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.

Hand protection

Material Chemical-resistant gloves

Remarks Consider double gloving.

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.

If adequate local exhaust ventilation is not available or expo-Respiratory protection

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Particulates type (P)

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Appearance liquid

Colour No data available Odour No data available Odour Threshold No data available

No data available рΗ

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

Flash point No data available

No data available Evaporation rate

Flammability (solid, gas) Not applicable

Upper explosion limit / Upper No data available



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flammability limit

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
Partition coefficient: n-

octanol/water

No data available

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.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

# **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

# 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents



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## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

# **SECTION 11: Toxicological information**

## 11.1 Information on toxicological effects

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: > 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 syn-

thesis in mammalian cells (in vitro)



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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

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 fertil-

ity, 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



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NOAEL : 0,06 mg/kg
Application Route : Oral
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 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**

### 12.1 Toxicity

#### **Components:**

#### altrenogest:

Toxicity to fish (Chronic tox- : NOEC: 0,0004 µg/l icity) Exposure time: 32 d

Species: Danio rerio (zebra fish)

Method: OECD Test Guideline 210

M-Factor (Chronic aquatic

toxicity)

: 100.000



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#### 12.2 Persistence and degradability

No data available

# 12.3 Bioaccumulative potential

#### **Components:**

Soya oil:

Partition coefficient: n- : log Pow: > 4

octanol/water Remarks: Calculation

altrenogest:

Partition coefficient: n-

octanol/water

: log Pow: 3,78

### 12.4 Mobility in soil

# Components:

altrenogest:

Distribution among environ- : log Koc: 3,3

mental compartments

#### 12.5 Results of PBT and vPvB assessment

**Product:** 

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

#### 12.6 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

: The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.



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# **SECTION 14: Transport information**

#### 14.1 UN number

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (altrenogest)

**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (altrenogest)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (altrenogest)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (altrenogest)

**IATA** : Environmentally hazardous substance, liquid, n.o.s.

(altrenogest)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

# 14.4 Packing group

**ADN** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)



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**RID** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

**RID** 

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## **SECTION 15: Regulatory information**

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



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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

#### **Full text of H-Statements**

H301 : Toxic if swallowed.

H360 : May damage fertility or the unborn child.

H373 : May cause damage to organs through prolonged or repeated

exposure if swallowed.

H410 : Very toxic to aquatic life with long lasting effects.
H413 : May cause long lasting harmful effects to aquatic life.

### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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 - (Quanti-



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tative) 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

#### **Further information**

Sources of key data used to compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Classification of the mixture: Classification procedure:

Repr. 1B H360 Calculation method Aquatic Chronic 1 H410 Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

ZA / EN