

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

Version
5.0

Revision Date:
14.04.2025

SDS Number:
5842519-00014

Date of last issue: 04.12.2024
Date of first issue: 08.05.2020

SECTION 1. IDENTIFICATION

Product identifier : Altrenogest (0.22%) Formulation (NZ)

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

Skin sensitization : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements :

Prevention:
P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves.

Response:

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 5.0 | Revision Date: 14.04.2025 | SDS Number: 5842519-00014 | Date of last issue: 04.12.2024 Date of first issue: 08.05.2020 |
|----------------|------------------------------|------------------------------|---|

P302 + P352 IF ON SKIN: Wash with plenty of water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|----------------|----------|--|-----------------------|
| Benzyl alcohol | 100-51-6 | Acute Tox. (Oral), 4 Eye Irrit., 2A Skin Sens., 1B | >= 1 - < 5 |
| Altrenogest | 850-52-2 | Acute Tox. (Oral), 3 Repr., 1B STOT RE, (Oral)(Immune system, Adrenal gland), 2 Aquatic Chronic, 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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. 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 cause an allergic skin reaction. |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection, |

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5842519-00014 Date of last issue: 04.12.2024 Date of first issue: 08.05.2020

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during 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.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

| | | | | |
|-------------|---------------------------|---------------------------|--------------------------------|---------------------------------|
| Version 5.0 | Revision Date: 14.04.2025 | SDS Number: 5842519-00014 | Date of last issue: 04.12.2024 | Date of first issue: 08.05.2020 |
|-------------|---------------------------|---------------------------|--------------------------------|---------------------------------|

employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Avoid breathing mist or vapors.
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.
Contaminated work clothing should not be allowed out of the workplace.
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.
Keep in a cool, well-ventilated place.
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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---------------------------|----------|-------------------------------|--|----------|
| Altrenogest | 850-52-2 | TWA | 1 µg/m3 (OEB 4) | Internal |
| Further information: Skin | | | | |

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5842519-00014 Date of last issue: 04.12.2024 Date of first issue: 08.05.2020

| | | | | |
|----|--|------------|---------------------------|----------|
| II | | Wipe limit | 10 µg/100 cm ² | Internal |
|----|--|------------|---------------------------|----------|

Engineering measures

: The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable. 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 : 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

Physical state : liquid

Color : No data available

Odor : odorless

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5842519-00014 Date of last issue: 04.12.2024
Date of first issue: 08.05.2020

| | |
|--|--|
| 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 |
| 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 characteristics | |
| Particle size | : No data available |

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5842519-00014 Date of last issue: 04.12.2024
Date of first issue: 08.05.2020

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Components:

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.200 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5,4 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

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

Altrenogest (0.22%) Formulation (NZ)Version
5.0Revision Date:
14.04.2025SDS Number:
5842519-00014Date of last issue: 04.12.2024
Date of first issue: 08.05.2020**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**

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:**Benzyl alcohol:**

| | | |
|--------------------|---|--|
| Test Type | : | Human repeat insult patch test (HRIPT) |
| Routes of exposure | : | Skin contact |
| Species | : | Humans |
| Result | : | positive |
| Assessment | : | Probability or evidence of low to moderate skin sensitization rate in humans |

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 synthesis in mammalian cells (in vitro) Result: negative |

Altrenogest (0.22%) Formulation (NZ)

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5842519-00014 Date of last issue: 04.12.2024
Date of first issue: 08.05.2020

II**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 |
| 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 - 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.

Altrenogest (0.22%) Formulation (NZ)

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 5.0 | Revision Date: 14.04.2025 | SDS Number: 5842519-00014 | Date of last issue: 04.12.2024 Date of first issue: 08.05.2020 |
|----------------|------------------------------|------------------------------|---|

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:

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|-------------------|---|--|
| 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.

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5842519-00014 Date of last issue: 04.12.2024
Date of first issue: 08.05.2020

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/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| | : NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |

Altrenogest:

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|-------------------------------------|--|
| 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

Components:

Benzyl alcohol:

| | |
|------------------|--|
| Biodegradability | : Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d |
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SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5842519-00014 Date of last issue: 04.12.2024
Date of first issue: 08.05.2020

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1,05

Altrenogest:

Partition coefficient: n-octanol/water : log Pow: 3,78

Mobility in soil

Components:

Altrenogest:

Distribution among environmental compartments : log Koc: 3,3

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
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) : 964

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

Version 5.0 Revision Date: 14.04.2025 SDS Number: 5842519-00014 Date of last issue: 04.12.2024
Date of first issue: 08.05.2020

ger aircraft)

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

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

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 - (LINACH) : Not applicable

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

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 5.0 | Revision Date: 14.04.2025 | SDS Number: 5842519-00014 | Date of last issue: 04.12.2024 Date of first issue: 08.05.2020 |
|----------------|------------------------------|------------------------------|---|

Revision Date : 14.04.2025
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 Agency, <http://echa.europa.eu/>

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 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 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.

SAFETY DATA SHEET



Altrenogest (0.22%) Formulation (NZ)

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Date of last issue: 04.12.2024
Date of first issue: 08.05.2020

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