

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 22.05.2019

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ALTRENO ORAL

SECTION 1: Identification

Product identifier

Product name: ALTRENO ORAL

Synonyms: ALTRENOGEST

Recommended use of the product and restriction on use:

Relevant identified uses: VETERINARY USE: Oral progestagen for horses.

Uses advised against: Not for human use.

Reasons why uses advised against: Veterinary product.

Manufacturer or supplier details

Supplier:

Dechra Veterinary Products NZ Limited

PO Box 1604,

Paraparaumu Beach, 5252

New Zealand

Phone: 0800 479 838

Email: info.nz@dechra.com

Website: <http://www.dechra.co.nz/>

Emergency telephone number:

New Zealand

National Poisons Centre

0800 764 766

SECTION 2: Hazards identification

Not Classified as a Dangerous Good according to NZS 5433:2012 Transport of Dangerous Goods on Land.

Classified in accordance with the relevant criteria of the HSNO Act 1996, the Hazardous Substances (Classification) Notice 2017 and the Hazardous Substances (Minimum Degrees of Hazard) Notice 2017, New Zealand.

HSNO Classification or Subclasses – Physical hazards: Not applicable

HSNO Classification or Subclasses – Health hazards:

| Class | GHS Category | HSNO Category |
|------------------------|--------------|---------------|
| Chronic aquatic hazard | Category 1 | 9.1A |

HSNO Classification or Subclasses – Environmental hazards: Not applicable

GHS classification:

Chronic aquatic hazard, category 1

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Label elements

Hazard pictogram(s):



Signal word: Warning

Hazard statements:

H410 Very toxic to aquatic life with long lasting effects

Precautionary statements:

P273 Avoid release to the environment

P391 Collect spillage

P501 Dispose of contents and container in accordance with local regulations

Hazards not otherwise classified:

None.

SECTION 3: Composition/information on ingredients

Mixture:

| Identification | Name | Weight % |
|-------------------------|----------------|----------|
| CAS number: 100-51-6 | Benzyl Alcohol | <5 |
| CAS number: 850-52-2 | Altrenogest | 0.22 |
| CAS number: 128-37-0 | BHT | <0.1 |

Additional information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret under the provisions of sections 55 (7) of the HSNO Act.

SECTION 4: First-aid measures

For advice, contact a Poisons Information Center (e.g. phone Australia 131 126, New Zealand 0800 764 766) or a doctor.

Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

After inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. If respiratory symptoms develop or persist, seek medical advice/attention.

After skin contact:

Wash affected area with plenty of soap and water. Remove contaminated clothing and launder before reuse. If skin irritation develops or persists, seek medical advice/attention.

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After eye contact:

Immediately rinse eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 15 minutes. If eye irritation develops or persists, seek medical advice/attention.

After swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most important symptoms and effects, both acute and delayed:

Acute symptoms and effects:

No significant acute effects/symptoms.

Delayed symptoms and effects:

No significant acute effects/symptoms.

Immediate medical attention and special treatment:

Specific treatment:

Not determined or not applicable.

Notes for the doctor:

Treat symptomatically.

Workplace Facilities:

No additional information.

SECTION 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media:

Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media:

Do not use water jet.

Specific hazards during fire-fighting:

May evolve carbon oxides and hydrocarbons when heated to decomposition.

Special protective equipment for firefighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts.

Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers.

Avoid unnecessary run-off of extinguishing media which may cause pollution.

Hazchem or Emergency Action Code:

Not Applicable.

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SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain spillage, then cover/absorb spill with non-combustible absorbent material (vermiculite, sand, or similar), collect and place in suitable containers for disposal. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage precautions

Precautions for safe handling:

Carefully read the product label before use. Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Conditions for safe storage, including any incompatibilities:

Keep out of reach of children. Store in a cool (below 25°C), dry, well-ventilated location in an HDPE container out of direct sunlight. Keep away from food and beverages. Storage areas and containers should be clearly marked for drug holding. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

Safe packaging material

Suitable material:

Not determined or not applicable.

Unsuitable material:

Not determined or not applicable.

SECTION 8: Exposure controls and personal protection

Occupational Exposure limit values:

No occupational exposure limits noted for the ingredient(s).

Biological limit value:

No biological exposure limits noted for the ingredient(s).

Information on monitoring procedures:

Not determined or not applicable

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Appropriate engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protection equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and chemical properties

| | |
|------------------------------------------------|----------------------------------|
| Physical state | Clear yellow liquid |
| Odour | Slight benzyl alcohol odour |
| Odour threshold | Not determined or not available. |
| pH | Not determined or not available. |
| Melting point/freezing point | Not determined or not available. |
| Initial boiling point/range | Not determined or not available. |
| Flash point (closed cup) | Not determined or not available. |
| Flammability (solid, gas) | Non flammable |
| Upper flammability/explosive limit | Not determined or not available. |
| Lower flammability/explosive limit | Not determined or not available. |
| Vapour pressure | Not determined or not available. |
| Vapour density | Not determined or not available. |
| Relative density | 0.92 to 0.96 |
| Solubilities | Slightly soluble in water. |
| Partition coefficient (n-octanol/water) | Not determined or not available. |
| Auto/Self-ignition temperature | Not determined or not available. |

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| | |
|----------------------------------|----------------------------------|
| Decomposition temperature | Not determined or not available. |
| Kinematic viscosity | Not determined or not available. |
| Particle characteristics | Not determined or not available. |

Other information: No additional information.

SECTION 10: Stability and reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Chemical stability:

Stable under recommended handling and storage conditions.

Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to avoid:

Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

Incompatible materials:

Oxidising agents (e.g. hypochlorites), acids (e.g. nitric acid) and alkalis (e.g. sodium hydroxide).

Hazardous decomposition products:

May evolve carbon oxides and hydrocarbons when heated to decomposition.

SECTION 11: Toxicological information

Acute toxicity:

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

| Name | Route | Result |
|----------------|------------|----------------------------------------|
| BHT | oral | LD50 Rat: > 6000 mg/kg |
| | dermal | LD50 Rat: > 2000 mg/kg |
| Benzyl Alcohol | oral | LD50 Rat: 1620 mg/kg |
| | inhalation | LC50 Rat: >4.178 mg/L (4 hr [aerosol]) |
| | dermal | LD50 Rabbit: >2000 mg/kg |
| Altrenogest | Oral ATE | LD50 Rat: 100 mg/kg |

Skin corrosion/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Serious eye damage/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

| Name | Result |
|----------------|--------------------------------|
| Benzyl Alcohol | Causes serious eye irritation. |

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Respiratory or skin sensitization:

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Reproductive toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

| Name | Result |
|-------------|-------------------------------------------|
| Altrenogest | May damage fertility or the unborn child. |

Specific target organ toxicity (single exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Specific target organ toxicity (repeated exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

| Name | Result |
|-------------|--------------------------------------------------------------------|
| Altrenogest | May cause damage to organs through prolonged or repeated exposure. |

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Information on likely routes of exposure:

No data available.

Symptoms related to the physical, chemical and toxicological characteristics:

No data available.

Other information:

No data available.

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SECTION 12: Ecological information

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

| Name | Result |
|----------------|------------------------------------------------------------------------------|
| BHT | Aquatic Invertebrates EC50 Daphnia magna: 0.48 mg/L (48 hr [mobility]) |
| | Fish LC50 Fish: 0.199 mg/L (96 hr [QSAR substance data]) |
| | Aquatic Plants EC50 Desmodium subspicatus: >0.4 mg/L (72 hr [growth rate]) |
| Benzyl Alcohol | Fish LC50 Pimephales promelas: 460 mg/L (96 hr) |
| | Aquatic Invertebrates EC50 Daphnia magna: 230 mg/L (48 hr [mobility]) |
| | Aquatic Plants EC50 Raphidocelis subcapitata: 770 mg/L (72 hr [growth rate]) |

Chronic (long-term) toxicity

Assessment:

Very toxic to aquatic life with long lasting effects.

Product data: No data available.

Substance data:

| Name | Result |
|----------------|--------------------------------------------------------------------------------|
| BHT | Fish NOEC Oryzias latipes: 0.053 mg/L (30 d) |
| | Aquatic Invertebrates NOEC Daphnia magna: 0.069 mg/L (21 d [reproduction]) |
| Benzyl Alcohol | Fish NOEC Freshwater fish: 48.897 mg/L (30 d [mortality, QSAR substance data]) |
| | Aquatic Invertebrates NOEC Daphnia magna: 51 mg/L (21 d [reproduction]) |

Persistence and degradability

Product data: No data available.

Substance data:

| Name | Result |
|----------------|------------------------------------------------------------------------------------------------------------------|
| BHT | The substance is not readily biodegradable. 4.7% degradation in water, measured by radiochem, after 28 days. |
| Benzyl Alcohol | The substance is readily biodegradable. 92 - 96% degradation in water, measured by O2 consumption after 14 days. |

Bioaccumulative potential

Product data: No data available.

Substance data:

| Name | Result |
|----------------|-------------------------------------------------------------------------------------------------------------------|
| BHT | The substance has the potential to bioaccumulate significantly (BCF: 1277 dimensionless, basis: whole body w.w.). |
| Benzyl Alcohol | The substance is not expected to bioaccumulate (log Pow= 1 at 20 °C and BCF= 1. 1.371 L/kg- QSAR data). |

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Mobility in soil

Product data: No data available.

Substance data:

| Name | Result |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| BHT | The substance is hardly mobile, therefore, there is a high potential for adsorption to soil and sediment (log Koc: 4.362, QSAR substance data). |
| Benzyl Alcohol | The substance is mobile, therefore, adsorption to soil is not expected (log Koc= 1.332 L/kg, QSAR substance data). |

Hazard to the ozone layer

Product data: No data available.

Substance data: No data available.

Other adverse effects: No data available.

SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory agencies. Dispose of in accordance with all applicable local, regional, state and federal regulations.

Contaminated packages:


Not determined or not applicable.

Disposal methods that should not be used:


No additional information.

SECTION 14: Transportation information

Road/Rail transport: (NZS 5433:1999)

| | |
|-------------------------------|-----------------------------------------------------------------------------------------|
| UN number | 3082 |
| UN proper shipping name | Environmentally hazardous substance, liquid, n.o.s. (Alrenogest) |
| UN transport hazard class(es) | 9  |
| Packing group | III |
| Environmental hazards | None |
| Special precautions for user | None |

International Air Transport Association Dangerous Goods Regulations (IATA-ICAO)

| | |
|-------------------------------|-----------------------------------------------------------------------------------------|
| UN number | 3082 |
| UN proper shipping name | Environmentally hazardous substance, liquid, n.o.s. (Alrenogest) |
| UN transport hazard class(es) | 9  |
| Packing group | III |
| Environmental hazards | None |
| Special precautions for user | None |

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International Maritime Dangerous Goods (IMDG)

| | |
|-------------------------------|---------------------------------------------------------------------------------------|
| UN number | 3082 |
| UN proper shipping name | Environmentally hazardous substance, liquid, n.o.s. (Alrenogest) |
| UN transport hazard class(es) | 9  |
| Packing group | III |
| Environmental hazards | None |
| Special precautions for user | None |

Transport in bulk according to Annex II of MARPOL and the IBC Code: Not Applicable

SECTION 15: Regulatory information

New Zealand Inventory of Chemicals (NZIoC): All of the ingredients are listed or exempt.

HSNO Classification or Subclasses:

| Class | GHS Category | HSNO Category |
|------------------------|--------------|---------------|
| Chronic aquatic hazard | category 1 | 9.1A |

| | |
|------------------------------------------|------------------------------|
| HSNO Substance Name: | HSNO Approval Number: |
| Liquid containing 0.15-0.25% altrenogest | HSR002244 |

HSNO Controls: Not determined.

Approved handler test certificate: Not determined.

Tracking: Not determined.

Controlled substance license requirements: Not applicable.

Agricultural Compounds and Veterinary Medicines Act 1997:

| | |
|-------------|--------|
| ACVM number | A10544 |
|-------------|--------|

Montreal Protocol (Ozone Depleting Substances): None of the ingredients are listed.

Stockholm Convention (Persistent Organic Pollutants): None of the ingredients are listed.

Rotterdam Convention (Prior Informed Consent): None of the ingredients are listed.

Basel Convention (Hazardous Waste): None of the ingredients are listed.

SECTION 16: Other information

Abbreviations and Acronyms:

| | |
|------|----------------------------------------|
| ATE | Acute Toxicity Estimate |
| BCF | Bioconcentration Factor |
| CAS | Chemical Abstracts Service |
| EC50 | Effective Concentration of 50% |
| GHS | Globally Harmonized System |
| HSNO | Hazardous Substances and New Organisms |

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| | |
|---------------|---------------------------------------------------------------------|
| IARC | International Agency for Research on Cancer |
| IATA | International Air Transport Association |
| IBC | Intermediate Bulk Container |
| ICAO | International Civil Aviation Organization |
| IMDG | International Maritime Dangerous Goods |
| LC50 | Lethal Concentration 50% |
| LD50 | Lethal Dose 50% |
| MARPOL | International Convention for the Prevention of Pollution from Ships |
| NZIoC | New Zealand Inventory of Chemicals |
| TWA | Time Weighted Average |
| UN | United Nations |
| VOC | Volatile Organic Compounds |

Disclaimer:

The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

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Revision Notes:

| Revision Date | Notes |
|---------------|-----------------------------------------------|
| 15-08-2024 | Version 2; Supersedes (Version 1: 22.05.2019) |

End of Safety Data Sheet