

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Altrenogest (0.4%) Formulation (AU)

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 03.12.2024  |
| 6.1     | 14.04.2025     | 9372683-00014 | Date of first issue: 27.08.2021 |

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

#### 1.1 Product identifier

Trade name : Altrenogest (0.4%) Formulation (AU)

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-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Walton Manor, Walton  
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

|                                                |                                                             |
|------------------------------------------------|-------------------------------------------------------------|
| Reproductive toxicity, Category 1B             | H360: May damage fertility or the unborn child.             |
| Long-term (chronic) aquatic hazard, Category 1 | H410: Very toxic to aquatic life with long lasting effects. |

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

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Hazard pictograms :

Signal word : Danger

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

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ 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.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                                                             | Concentration<br>(% w/w) |
|---------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Soya oil      | 8001-22-7<br>232-274-4                                | Aquatic Chronic 4;<br>H413                                                                                                 | >= 90 - <= 100           |
| altrenogest   | 850-52-2<br>212-703-1                                 | Acute Tox. 3; H301<br>Repr. 1B; H360<br>STOT RE 2; H373<br>(Immune system,<br>Adrenal gland)<br>Aquatic Chronic 1;<br>H410 | >= 0.3 - < 1             |

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|                |                              |                              |                                                                   |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|
| Version<br>6.1 | Revision Date:<br>14.04.2025 | SDS Number:<br>9372683-00014 | Date of last issue: 03.12.2024<br>Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|

|  |  |                                                 |  |
|--|--|-------------------------------------------------|--|
|  |  | M-Factor (Chronic aquatic toxicity):<br>100,000 |  |
|--|--|-------------------------------------------------|--|

For explanation of abbreviations see section 16.

### 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 advice immediately.<br>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.<br>Get medical attention.                                                                                                                                                            |
| In case of skin contact    | : In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                                  |
| If swallowed               | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> ) |
|------------------------------|------------------------------------------------------------------------------|

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| 6.1     | 14.04.2025     | 9372683-00014 | Date of first issue: 27.08.2021 |

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Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products : 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 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.

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## 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 protective 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 barriers).  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 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 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 deter-

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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 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.<br>Do not breathe vapours or spray mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>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.<br>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:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|                 |   | No data available |

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### 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/m <sup>3</sup> (OEB 4) | Internal |
|             | Further information: Skin |                               |                             |          |
|             |                           | Wipe limit                    | 10 µg/100 cm <sup>2</sup>   | Internal |

#### 8.2 Exposure controls

##### 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

- 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.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

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---

|             |                                       |
|-------------|---------------------------------------|
| Filter type | Equipment should conform to BS EN 143 |
|             | : Particulates type (P)               |

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### 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 |
| 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 |
| Vapour pressure                                  | : No data available |
| Relative vapour density                          | : No data available |
| Relative density                                 | : No data available |
| Density                                          | : No data available |
| Solubility(ies)                                  |                     |
| Water solubility                                 | : No data available |
| Partition coefficient: n-octanol/water           | : No data available |
| Auto-ignition temperature                        | : No data available |
| Decomposition temperature                        | : No data available |
| Viscosity                                        |                     |
| Viscosity, kinematic                             | : No data available |
| Explosive properties                             | : Not explosive     |

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

### 9.2 Other information

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

### 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



# SAFETY DATA SHEET

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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)<br>Result: negative                                        |
|                       |   | Test Type: Chromosome aberration test in vitro<br>Result: negative                                            |
|                       |   | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>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<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 0.016 mg/kg body weight<br>Result: Effects on fertility, No effects on mating performance |
|                                    |   | Test Type: Fertility/early embryonic development<br>Species: Monkey, female<br>Application Route: Oral<br>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                                                                                          |

# SAFETY DATA SHEET

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UK REACH Regulations SI 2019/758



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---

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### altrenogest:

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

|                 |                   |
|-----------------|-------------------|
| Exposure routes | : Oral            |
| Target Organs   | : Pituitary gland |

### Repeated dose toxicity

### Components:

#### Soya oil:

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

#### altrenogest:

|                   |                                                                                      |
|-------------------|--------------------------------------------------------------------------------------|
| Species           | : Rat                                                                                |
| NOAEL             | : 0.06 mg/kg                                                                         |
| Application Route | : Oral                                                                               |
| Exposure time     | : 13 Weeks                                                                           |
| Target Organs     | : Immune system, male reproductive organs, female reproductive organs, Adrenal gland |
| Remarks           | : Effects on fertility                                                               |

|                   |                                                        |
|-------------------|--------------------------------------------------------|
| Species           | : Pig                                                  |
| NOAEL             | : 0.004 mg/kg                                          |
| Application Route | : Oral                                                 |
| Exposure time     | : 13 Weeks                                             |
| Target Organs     | : male reproductive organs, female reproductive organs |
| Remarks           | : Effects on fertility                                 |

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

# SAFETY DATA SHEET

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|                   |   |                                              |
|-------------------|---|----------------------------------------------|
| 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 toxicity) | : | NOEC: 0.0004 µg/l<br>Exposure time: 32 d<br>Species: Danio rerio (zebra fish)<br>Method: OECD Test Guideline 210 |
|-------------------------------------|---|------------------------------------------------------------------------------------------------------------------|

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

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

##### Soya oil:

|                                        |   |                                      |
|----------------------------------------|---|--------------------------------------|
| Partition coefficient: n-octanol/water | : | log Pow: > 4<br>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 |
|-----------------------------|---|--------------|

# SAFETY DATA SHEET

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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 potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|                        |                                                                                                                                                                                                                                                                                                                      |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.                                                                                                                                                        |

## 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.<br>(altrenogest) |
| ADR | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(altrenogest) |
| RID | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,                         |

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|             |                                                                           |
|-------------|---------------------------------------------------------------------------|
|             | N.O.S.<br>(altrenogest)                                                   |
| <b>IMDG</b> | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(altrenogest) |
| <b>IATA</b> | : Environmentally hazardous substance, liquid, n.o.s.<br>(altrenogest)    |

### 14.3 Transport hazard class(es)

|             | Class | Subsidiary risks |
|-------------|-------|------------------|
| <b>ADN</b>  | : 9   |                  |
| <b>ADR</b>  | : 9   |                  |
| <b>RID</b>  | : 9   |                  |
| <b>IMDG</b> | : 9   |                  |
| <b>IATA</b> | : 9   |                  |

### 14.4 Packing group

|                                          |                 |
|------------------------------------------|-----------------|
| <b>ADN</b>                               |                 |
| Packing group                            | : III           |
| Classification Code                      | : M6            |
| Hazard Identification Number             | : 90            |
| Labels                                   | : 9             |
| <b>ADR</b>                               |                 |
| Packing group                            | : III           |
| Classification Code                      | : M6            |
| Hazard Identification Number             | : 90            |
| Labels                                   | : 9             |
| Tunnel restriction code                  | : (-)           |
| <b>RID</b>                               |                 |
| Packing group                            | : III           |
| Classification Code                      | : M6            |
| Hazard Identification Number             | : 90            |
| Labels                                   | : 9             |
| <b>IMDG</b>                              |                 |
| Packing group                            | : III           |
| Labels                                   | : 9             |
| EmS Code                                 | : F-A, S-F      |
| <b>IATA (Cargo)</b>                      |                 |
| Packing instruction (cargo aircraft)     | : 964           |
| Packing instruction (LQ)                 | : Y964          |
| Packing group                            | : III           |
| Labels                                   | : Miscellaneous |
| <b>IATA (Passenger)</b>                  |                 |
| Packing instruction (passenger aircraft) | : 964           |

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Altrenogest (0.4%) Formulation (AU)

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 03.12.2024  |
| 6.1     | 14.04.2025     | 9372683-00014 | Date of first issue: 27.08.2021 |

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

Relevant EU provisions transposed through retained EU law

|                                                                                                              |   |                                                                                                                                                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| UK REACH List of restrictions (Annex 17)                                                                     | : | Conditions of restriction for the following entries should be considered:<br>Number on list 3                                                                                                                                                                                                                   |
|                                                                                                              |   | Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not. |
| UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation                          | : | Not applicable                                                                                                                                                                                                                                                                                                  |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit- | : | Not applicable                                                                                                                                                                                                                                                                                                  |

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Altrenogest (0.4%) Formulation (AU)

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 03.12.2024  |
| 6.1     | 14.04.2025     | 9372683-00014 | Date of first issue: 27.08.2021 |

ain)

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)

|    |                       |                     |                     |
|----|-----------------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|-----------------------|---------------------|---------------------|

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

### 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Altrenogest (0.4%) Formulation (AU)

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 03.12.2024  |
| 6.1     | 14.04.2025     | 9372683-00014 | Date of first issue: 27.08.2021 |

Road; AIIIC - 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 - (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; 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 Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

|                   |      |
|-------------------|------|
| Repr. 1B          | H360 |
| Aquatic Chronic 1 | H410 |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |

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

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