Section 1 - Identification of The Material and Supplier

Ceva Animal Health Pty Ltd
11 Moores Rd
Glenorie NSW 2157
Phone: 02 9652 7000 (office hours)
Fax: 02 9652 7001
www.ceva.com.au

Chemical nature: Altrenogest, an Endocrine agent (hormone) in propylene glycol solution.

Trade Name: Readyserve Altrenogest Injection for Horses

Product Use: For the suppression of oestrus in normally cycling mares.

Creation Date: March, 2016

This version issued: August, 2016 and is valid for 5 years from this date.

Poisons Information Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification

Statement of Hazardous Nature

This product is classified as: Xn, Harmful. Hazardous according to the criteria of SWA.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

SUSMP Classification: S4

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

UN Number: None allocated

GHS Signal word: WARNING

Flammable liquids Category 4
Skin Sensitisation Category 1
Reproductive Toxicity Category 2

HAZARD STATEMENT:
H227: Combustible liquid.
H317: May cause an allergic skin reaction.
H361: Suspected of damaging fertility or the unborn child.

PREVENTION
P102: Keep out of reach of children.
P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P210: Keep away from heat, sparks, open flames and hot surfaces. - No smoking.
P261: Avoid breathing fumes, mists, vapours or spray.
P262: Do not get in eyes, on skin, or on clothing.
P272: Contaminated work clothing should not be allowed out of the workplace.
P281: Use personal protective equipment as required.

RESPONSE
P352: Wash with plenty of soap and water.
P363: Wash contaminated clothing before reuse.
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P303+P361+P353: IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water.
P308+P313: If exposed or concerned: Get medical advice.
P333+P313: If skin irritation or rash occurs: Get medical advice.
P370+P378: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

SAFETY DATA SHEET

Issued by: Ceva Animal Health Pty Ltd Phone: 02 9652 7000 (office hours)
Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)
**Product Name:** Readyserve Altrenogest Injection for Horses

This version issued: August, 2016

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**STORAGE**

- P405: Store locked up.
- P410: Protect from sunlight.
- P411: Store at temperatures not exceeding 30°C.
- P402+P404: Store in a dry place. Store in a closed container.

**DISPOSAL**

- P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

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**Emergency Overview**

**Physical Description & Colour:** A clear, viscous amber liquid free of particulate matter.

**Odour:** No data re odour.

**Major Health Hazards:** possible risk of harm to the unborn child. This is a physiologically active product and so contact should be minimised, especially if the user is taking a form of medication, as interactions can sometimes give unexpected and undesired results.

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**Section 3 - Composition/Information on Ingredients**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS No</th>
<th>Conc,%</th>
<th>TWA (mg/m³)</th>
<th>STEL (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altrenogest</td>
<td>850-52-2</td>
<td>50mg/mL</td>
<td>not set</td>
<td>not set</td>
</tr>
<tr>
<td>Other non hazardous ingredients</td>
<td>various</td>
<td>10-30</td>
<td>not set</td>
<td>not set</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>to 100</td>
<td>10</td>
<td>not set</td>
</tr>
</tbody>
</table>

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak "is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

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**Section 4 - First Aid Measures**

**General Information:**

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

**Self Injection:** Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed liquid. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied. Check your tetanus immunisation status.

**Inhalation:** First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

**Skin Contact:** Irritation is unlikely. However, if irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

**Eye Contact:** No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes. Take special care if exposed person is wearing contact lenses.

**Ingestion:** If product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

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**Section 5 - Fire Fighting Measures**

**Fire and Explosion Hazards:** The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

**Extinguishing Media:** In case of fire, use carbon dioxide, dry chemical, foam, water fog.

**Fire Fighting:** If a significant quantity of this product is involved in a fire, call the fire brigade.

**Flash point:** No data
Upper Flammability Limit: No data.
Lower Flammability Limit: No data.
Autoignition temperature: No data.
Flammability Class: No data.

Section 6 - Accidental Release Measures

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: Note that this product is GHS Flammable Class 4 and therefore, for Storage, meets the definition of Dangerous Goods. If you store large quantities (tonnes) of such products, we suggest that you consult your state's Dangerous Goods authority in order to clarify your obligations regarding their storage.

Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Some liquid preparations settle or separate on standing and may require stirring before use. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:


<table>
<thead>
<tr>
<th>SWA Exposure Limits</th>
<th>TWA (mg/m³)</th>
<th>STEL (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>10</td>
<td>not set</td>
</tr>
</tbody>
</table>

The ADI for Altrenogest is set at 0.0001mg/kg/day. The corresponding NOEL is set at 0.01mg/kg/day. ADI means Acceptable Daily Intake; NOEL means No-observable-effect-level. Data from Australian ADI List, June 2014.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that vapours and mists are minimised.

Eye Protection: Eye protection such as protective glasses or goggles is recommended when this product is being used.

Skin Protection: The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products and that you wear suitable gloves (preferably elbow-length) when skin contact is likely.

Protective Material Types: We suggest that protective clothing be made from the following materials: rubber, butyl rubber.

Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

Section 9 - Physical and Chemical Properties:

Physical Description & colour: A clear, viscous amber liquid free of particulate matter.
Odour: No data re odour.
Boiling Point: Not available.
Freezing/Melting Point: No specific data. Liquid at normal temperatures.
Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: acids, bases, oxidising agents.

Fire Decomposition: Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Local Effects:
Target Organs: There is no data to hand indicating any particular target organs.

Classification of Hazardous Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Risk Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.</td>
<td></td>
</tr>
</tbody>
</table>

Some progestogens when given during pregnancy have been reported to cause virilisation (masculinisation) of a female foetus. This appears to have been associated with those progestogens with more pronounced androgenic activity such as norethisterone; the natural progestogenic hormone progesterone and its derivatives such as dydrogesterone and medroxyprogesterone do not appear to have been associated with such effects.

A large study compared a contraceptive progesterone-releasing vaginal ring and a copper IUD for 1 year in breast-feeding women. There was little difference in infant weight gain during the study, although at 12 months the infants of mothers using IUD were breast-fed less frequently, receiving more supplementary feeding, and were heavier. There was no effect of progesterone on lactation or infant growth. Further smaller studies have also found no adverse effect on lactation or infant growth. The American Academy of Pediatrics has found no reports of adverse effects in breast-fed infants of mothers given progesterone, and therefore considers it to be usually compatible with breast feeding.

Signs and symptoms of exposure to Altrenogest:

May cause gastrointestinal disturbances, changes in appetite or weight, fluid retention, oedema, acne, chloasma, (melasma), allergic skin rashes, urticaria, mental depression, breast changes including discomfort or occasionally gynaecomastia, changes in libido, hair loss, hirsutism, fatigue, drowsiness or insomnia, fever, headache, premenstrual syndrome-like symptoms, and altered menstrual cycles or irregular menstrual bleeding.

Anaphylaxis or anaphylactoid reactions may occur, and rarely alterations in liver-function tests and jaundice.

Potential Health Effects

The following people should not handle this product:
1. Women who are or suspect that they are pregnant
2. Anyone with thrombophlebitis or thromboembolic disorders or with a history of these events
3. Anyone having cerebrovascular or coronary artery disease
4. Women with known or suspected carcinoma of the breast
5. People with known or suspected oestrogen-dependent neoplasia

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6. Women with undiagnosed vaginal bleeding
7. People with benign or malignant tumours which developed during the use of oral contraceptives or other oestrogen containing products

Altrenogest can be absorbed after skin contact and absorption can be enhanced if the drug is covered by occlusive materials (e.g., under latex gloves, etc.).

Inhalation:
Short Term Exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.
Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:
Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. However product may be mildly irritating, but is unlikely to cause anything more than mild discomfort which should disappear once contact ceases.
Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:
Short Term Exposure: This product may be irritating to eyes, but is unlikely to cause anything more than mild transient discomfort.
Long Term Exposure: No data for health effects associated with long term eye exposure.

Ingestion:
Short Term Exposure: Significant oral exposure is considered to be unlikely. However, this product may be irritating to mucous membranes but is unlikely to cause anything more than transient discomfort.
Long Term Exposure: No data for health effects associated with long term ingestion.

Carcinogen Status:
SWA: No significant ingredient is classified as carcinogenic by SWA.
NTP: No significant ingredient is classified as carcinogenic by NTP.
IARC: No significant ingredient is classified as carcinogenic by IARC.

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### Section 12 - Ecological Information

Insufficient data to be sure of status. Expected to not be an environmental hazard.

### Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

### Section 14 - Transport Information

UN Number: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

### Section 15 - Regulatory Information

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Altrenogest, is mentioned in the SUSMP.

### Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

**Acronyms:**
- ADG Code: Australian Code for the Transport of Dangerous Goods by Road and Rail (7th edition)
- AICS: Australian Inventory of Chemical Substances
- SWA: Safe Work Australia, formerly ASCC and NOHSC
- CAS number: Chemical Abstracts Service Registry Number
- Hazchem Code: Emergency action code of numbers and letters that provide information to emergency services especially firefighters
- IARC: International Agency for Research on Cancer

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Issued by: Ceva Animal Health Pty Ltd Phone: 02 9652 7000 (office hours)
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Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document “Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice” (December 2011)
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http://www.kilford.com.au/ Phone (02)9251 4532