



## Section 1 - Identification of Chemical Product and Company

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**Substance:** Sterile suspension of proligestone 100 mg/mL injection  
**Trade Name:** **Covinan Progestagen For Subcutaneous Injection**  
**Product Code:** 21130  
**Recommended Use:** Oestrus control injection for use in horses, dogs and cats.  
**APVMA No:** 37221  
**Creation Date:** October, 2006  
**This Revision Date:** October, 2006

## Section 2 - Hazards Identification

### Statement of Hazardous Nature:

**This product is classified as:** Not classified as hazardous according to the criteria of ASCC.  
Not a Dangerous Good according to the Australian Dangerous Goods (ADG) Code.

**Risk Phrases:** Not Hazardous - No criteria found.

**Safety Phrases:** S25, S45. Avoid contact with eyes. In case of accident or if you feel unwell, contact a doctor or Poisons Information Centre immediately (show the label where possible).

**SUSDP Classification:** S4

**ADG Classification:** None allocated. Not a Dangerous Good under the ADG Code.

**UN Number:** None allocated

## Emergency Overview

**Physical Description & Colour:** Clear, colourless liquid.

**Odour:** No odour.

**Major Health Hazards:** no significant risk factors have been found for this product.

## Potential Health Effects

Proligestone has weakly progestogenic action. It is anti-oestrogenic but has no oestrogenic, androgenic, anti-gonadotrophic, anti-oestrogenic or anabolic action. It is slightly corticosteroid.

### 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. In addition product is unlikely to cause any discomfort in normal use.

**Long Term Exposure:** No data for health effects associated with long term skin exposure.

### Eye Contact:

**Short Term Exposure:** This product may be mildly irritating to eyes, but is unlikely to cause anything more than mild discomfort which should disappear once product is removed.

**Long Term Exposure:** No data for health effects associated with long term eye exposure.

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**Ingestion:**

**Short Term Exposure:** Significant oral exposure is considered to be unlikely. However, this product may be mildly irritating to mucous membranes but is unlikely to cause anything more than mild transient discomfort.

**Long Term Exposure:** No data for health effects associated with long term ingestion.

**Carcinogen Status:**

**ASCC:** No significant ingredient is classified as carcinogenic by ASCC.

**NTP:** No significant ingredient is classified as carcinogenic by NTP.

**IARC:** No significant ingredient is classified as carcinogenic by IARC.

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

Ingredients	CAS No	Conc, %	TWA (mg/m <sup>3</sup> )	STEL (mg/m <sup>3</sup> )
Proligestone	23873-85-0	10	not set	not set
Other non hazardous ingredients	various	5-10	not set	not set
Water	7732-18-5	to 100	not set	not set

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

The ASCC 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.

**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 11 26 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this MSDS 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 vaccine. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied.

Accidental self-injection may lead to fluid retention. This product has an action of 3-5 months duration in animals. It may have the same duration in humans so health monitoring is indicated for six months.

Treat any allergic reaction or any local irritancy symptomatically.

**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.

**Section 5 - Fire Fighting Measures**

**Fire and Explosion Hazards:** There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a fire. This will only occur after heating to dryness.

Fire decomposition products from this product are not expected to be hazardous or harmful.

**Extinguishing Media:** Not Combustible. Use extinguishing media suited to burning materials.

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

**Flash point:** Does not burn.  
**Upper Flammability Limit:** Does not burn.  
**Lower Flammability Limit:** Does not burn.  
**Autoignition temperature:** Not applicable - does not burn.  
**Flammability Class:** Does not burn.

### 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 vaccines. 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 MSDS 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:** This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Store in the closed original container in a dry, cool (below 25°C), well-ventilated area out of direct sunlight. Do not freeze. 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:  
Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Industrial Clothing: **AS2919**, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

ASCC Exposure Limits	TWA (mg/m <sup>3</sup> )	STEL (mg/m <sup>3</sup> )
Exposure limits have not been established by ASCC for any of the significant ingredients in this product.		

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 is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

**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, PVC.

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

### Section 9 - Physical and Chemical Properties

**Physical Description & Colour:** Clear, colourless liquid.  
**Odour:** No odour.  
**Boiling Point:** Approximately 100°C at 100kPa.  
**Freezing/Melting Point:** Approximately 0°C.  
**Volatiles:** Water component.

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<b>Vapour Pressure:</b>	2.37 kPa at 20°C (water vapour pressure).
<b>Vapour Density:</b>	No data.
<b>Specific Gravity:</b>	1.035 at 25°C
<b>Water Solubility:</b>	Completely soluble in water.
<b>pH:</b>	5.8-7.7
<b>Volatility:</b>	No data.
<b>Odour Threshold:</b>	No data.
<b>Evaporation Rate:</b>	No data.
<b>Coeff Oil/water Distribution:</b>	No data
<b>Autoignition temp:</b>	Not applicable - does not burn.

### 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:** Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

**Incompatibilities:** acids, bases, oxidising agents.

**Fire Decomposition:** Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a fire. This will only occur after heating to dryness. Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Water. 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

**Proligestone** - in LD<sub>50</sub> studies in mice the highest doses tested 2000mg/kg I.P and 1000mg/kg S.C were not lethal. Daily S.C administration to rates at 50mg/kg and to dogs at 25mg/kg over a period of three months revealed no toxic effects. Teratological studies in rabbits and rates revealed no teratological effect or rabbit and rat embryogenesis.

The following is recorded as general properties of Progestagens and may or may not apply to Proligestone in humans.

**Side Effects:** of progestagens include gastrointestinal disturbances, acne, fluid retention, weight gain, allergic skin rashes or urticaria, mental depression, breast changes, libido changes, altered liver function and rarely, jaundice.

**Precautions:** mentioned are caution in humans with cardiovascular, renal or hepatic impairment, diabetes mellitus, asthma, epilepsy, migraine or other conditions which may be aggravated by fluid retention. There is a warning about use in humans suffering a history of mental depression.

### Classification of Hazardous Ingredients

#### Ingredient

#### Risk Phrases

No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.

### Section 12 - Ecological Information

This product is biodegradable. It will not accumulate in the soil or water or cause long term problems.

### Section 13 - Disposal Considerations

**Disposal:** There are many pieces of legislation covering waste disposal and they differ in each state and territory, so each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. The Hierarchy of Controls seems to be common - the user should investigate: Reduce, Reuse, and Recycle and only if all else fails should disposal be considered. Note that properties of a product may change in use, so that the following suggestions may not always be appropriate. The following may help you in properly addressing this matter for this product. Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container.

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## Section 14 - Transport Information

**ADG Code:** This product is not classified as a Dangerous Good. 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 ingredients: Proligestone, are mentioned in the SUSDP.

## Section 16 - Other Information

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

### Acronyms:

<b>ADG Code</b>	Australian Code for the Transport of Dangerous Goods by Road and Rail
<b>AICS</b>	Australian Inventory of Chemical Substances
<b>ASCC</b>	Office of the Australian Safety and Compensation Council
<b>CAS Number</b>	Chemical Abstracts Service Registry Number
<b>Hazchem Code</b>	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
<b>IARC</b>	International Agency for Research on Cancer
<b>NOS</b>	Not otherwise specified
<b>NTP</b>	National Toxicology Program (USA)
<b>R-Phrase</b>	Risk Phrase
<b>SUSDP</b>	Standard for the Uniform Scheduling of Drugs & Poisons
<b>UN Number</b>	United Nations Number

THIS MSDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS MSDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS. OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This MSDS is prepared in accord with the ASCC document "National Code of Practice for the Preparation of Material Safety Data Sheets" 2nd Edition [NOHSC:2011(2003)]

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