

## Section 1 - Identification of Chemical Product and Company

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**Substance:** Flugestone acetate is a synthetic progesterone.  
**Trade Name:** **Chrono-Gest® Vaginal Sponges**  
**Other Names:** This MSDS is intended for Chrono-Gest® CR Vaginal Sponges  
Note that the Active ingredient is also known as Cronolone "Synchro-Mate"  
**Product Code:** 55132 (CR)  
**Recommended Use:** Prescription only, intra-vaginal sponges for use in sheep and goats to induce oestrus synchronisation.  
**APVMA No:** 55132  
**Creation Date:** November, 2006  
**This Revision Date:** November, 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:** S20, S24. When using, do not eat or drink. Avoid contact with skin.

**SUSDP Classification:** S4

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

**UN Number:** None allocated

## Emergency Overview

**Physical Description & Colour:** Chrono-Gest® CR has 10, 25 or 50 sponges per bag.

**Odour:** No odour.

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

## Potential Health Effects

Progestagens can influence fertility in humans if taken in sufficiently high dosage. This is most unlikely to occur from normal usage of this product.

### 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:

## MATERIAL SAFETY DATA SHEET

**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.

#### 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:

**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> ) |
|---------------------------------|-----------|--------|--------------------------|---------------------------|
| Flugestone acetate              | 2529-45-5 | 20mg   | not set                  | not set                   |
| Other non hazardous ingredients | various   |        | 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.**

Any allergic reaction or any local irritancy should be treated 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.

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

**Extinguishing Media:** Preferred extinguishing media are 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:** Combustible solid.

**Upper Flammability Limit:** No data.

**Lower Flammability Limit:** No data.

**Autoignition temperature:** No data.

**Flammability Class:** Combustible solid.

### MATERIAL SAFETY DATA SHEET

### 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 impervious gloves when handling these products. 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 30°C) 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. 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.

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

### Section 9 - Physical and Chemical Properties

|   |   |
|---|---|
| <b>Physical Description &amp; Colour:</b> | Grey or white sponges; 25 per bag.                          |
| <b>Odour:</b>                             | No odour.   |
| <b>Boiling Point:</b>                     | Not applicable.   |
| <b>Freezing/Melting Point:</b>            | Not applicable.   |
| <b>Volatiles:</b>                         | No data.  |
| <b>Vapour Pressure:</b>                   | No data.  |
| <b>Vapour Density:</b>                    | No data.  |
| <b>Specific Gravity:</b>                  | Not applicable.   |
| <b>Water Solubility:</b>                  | Active ingredient is slightly soluble; sponge is insoluble. |

## MATERIAL SAFETY DATA SHEET

|                                      |                 |
|--------------------------------------|-----------------|
| <b>pH:</b>                           | Not applicable. |
| <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>            | No data.        |

### 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:** No particular Incompatibilities.

**Fire Decomposition:** Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. Oxides of sulfur (sulfur dioxide is a respiratory hazard) and other sulfur compounds. Most will have a foul odour. 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

#### Local Effects:

**Target Organs:** none known

### Classification of Hazardous Ingredients

#### Ingredient

#### Risk Phrases

No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations. Side effects are recorded from the therapeutic use of progestagens. These are profound and considerable (see Martindale) but are most unlikely to ever occur from the use of, or accidental absorption of, flugestone acetate. Nevertheless, gloves should be worn.

### Section 12 - Ecological Information

There is no data on ecological effects. It is not anticipated that this product will enter the environment as a consequence of normal use. Accidental spillage of large shipments could be a problem. Thus, disposal of large volumes into drainage sewerage systems of local councils should be avoided.

### 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. Special help is available for the disposal of Agricultural Chemicals. The product label will give general advice regarding disposal of small quantities, and how to cleanse containers. However, for help with the collection of unwanted rural chemicals, contact ChemClear 1800 008 182 <http://www.chemclear.com.au/> and for help with the disposal of empty drums, contact DrumMuster <http://www.drummuster.com.au/> where you will find contact details for your area.

### Section 14 - Transport Information

## MATERIAL SAFETY DATA SHEET

**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 ingredient: Flugestone acetate, (a progesterone) is mentioned in the SUSDP.

**This product has a withholding period - refer to restrictions on label.**

### 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)]