

SAFETY DATA SHEET**Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY**

Product Name:	Ovarid Tablets
Product Code:	60910 (5mg tablets), 60900 (20mg tablets)
Recommended Use:	For the postponement or prevention of oestrus and the treatment of false pregnancy and oestrogen-dependent mammary tumours in bitches. For oestrus control and for the treatment of miliary eczema and eosinophilic granuloma (rodent ulcer) in cats. For the treatment of behavioural abnormalities, such as hypersexuality in male dogs and urine spraying cats.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street Rutherford NSW 2320 Australia
Email:	customerservice@jurox.com.au
Customer Centre:	1800 023 312
National Poisons Information Centre:	13 1126 (Australia-wide)
Emergency Telephone Number:	1800 023 312 (Monday – Friday, 9a.m. – 5p.m.)

Section 2: HAZARDS IDENTIFICATION

Hazard Classifications: Considered a Hazardous Substance according to the criteria of GHS.
Not considered a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

GHS Hazard Classification:*

GHS Category	Hazard code	Hazard Statement
Carcinogenicity Category 2	H351	Suspected of causing cancer.
Reproductive Toxicity Category 1B, Lactation Effects	H360 H362	May damage fertility or the unborn child. May cause harm to breast-fed children.
Acute Aquatic Hazard Category 3, Chronic Aquatic Hazard Category 3	H412 H412	Harmful to aquatic life with long lasting effects. Harmful to aquatic life with long lasting effects.

GHS Pictogram:

Health hazard

Signal Word:* DANGER**Precautionary Statements:*****Prevention**

- P201 Obtain special instructions before use.
- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P263 Avoid contact during pregnancy/while nursing.
- P281 Use personal protective equipment as required.
- P270 Do not eat, drink or smoke when using this product.
- P273 Avoid release to the environment.

Response

- P308+P313 IF exposed or concerned: Get medical advice/attention.

Storage

P405 Store locked up.

Disposal

P501 Dispose of contents/container in accordance with local/national regulations.

* N.B.: These statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Megestrol acetate	595-33-5	1.7% (5mg tablet) 4.4% (20mg tablet)
Other non-hazardous components		10 - <30%
Dried yeast		>60%

Section 4: FIRST AID MEASURES

- General information:** Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have product container or label at hand.
- Inhalation:** If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually not necessary.
- Ingestion:** If swallowed, immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.
- Skin:** If skin contact occurs, immediately remove all contaminated clothing, including footwear. Wash affected area thoroughly with plenty of soap and water. If skin irritation or rash occurs, get medical advice/attention.
- Eye:** If eye contact occurs, rinse cautiously with water for at least 20 minutes. If eye irritation persists, get medical advice/attention.
- Advice to Doctor:** Contains Megestrol acetate which is a progestational agent. Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

- Flash Point:** Not flammable.
- Hazardous Combustion Products:** If involved in a fire, may emit noxious fumes. Non-combustible – not considered to be a significant fire risk.
- Extinguishing Media:** There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.
- Protective Equipment:** Protective gloves and boots and breathing apparatus.
- Special Hazards:** **Fire Incompatibility:** Avoid contamination with oxidising agents.
- HAZCHEM:** None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

- Spills and Disposal:** Avoid generating dust. Wear appropriate protective clothing. Exclude non-essential people from the area. Contain spill and sweep or vacuum up and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely.
- Protective Clothing:** For appropriate personal protective equipment see section 8.
- Environmental Precautions:** If contamination of drains and waterways occurs, advise Emergency Services.

Section 7: HANDLING AND STORAGE

- Handling:** Avoid all personal contact, including inhalation. Use personal protective equipment as required.
- Storage:** Ovarid Tablets are a Scheduled Poison (S4) and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Store in original container, away from food stuffs. Store below 30°C (room temperature) in a dry place. Keep out of reach of children.
- Other Information:** Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

- Exposure Limits:** No exposure limits have been assigned for this product. Do not handle until all safety precautions have been read and understood.
- Protective Equipment:** Safety glasses with eye side shields or chemical goggles. Chemical protective gloves, e.g. PVC. Safety footwear or safety gumboots, e.g. rubber.
- Engineering Controls:** Handle in a well ventilated area.
- Hygiene Precautions:** Do not drink, eat or smoke when handling this product. Wash hands after use.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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|-----------------------------------|-------------------------------------------------------------------------------------|-----------------------------------|---------------------------------|
| Appearance: | Buff-coloured, slightly speckled uncoated biconvex tablet, half-scored on one side. | Lower flammability limits: | Not applicable. |
| Odour: | No data. | Vapour Pressure: | Not applicable. |
| Odour threshold: | No data. | Vapour density: | Not applicable. |
| pH: | Not applicable. | Relative density: | No data. |
| Melting Point: | No data. | Specific Gravity: | Not applicable. |
| Boiling Point: | Not applicable. | Solubility in Water: | Partly soluble (disintegrates). |
| Flash Point: | Not flammable. | Partition coefficient: | Not applicable. |
| Evaporation Rate: | Not applicable. | Auto-ignition temperature: | No data. |
| Flammability: | Not applicable. | Decomposition temperature: | Not applicable. |
| Upper flammability limits: | Not applicable. | Viscosity: | Not applicable. |

Section 10: STABILITY AND REACTIVITY

- Stability:** When stored appropriately this product should show no significant degradation within the expiry period shown on the labelling.
- Hazardous Polymerisation:** Not known to occur.
- Materials to Avoid:** None known.

Section 11: TOXICOLOGICAL INFORMATION

- Acute toxicity:** **Inhalation:** Not normally a hazard due to the non-volatile nature of the product.
- Ingestion:** The material has **NOT** been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. May cause nausea, vomiting and diarrhoea. Readily absorbed from the gastro-intestinal tract. May lead to oedema, headache and depression.
- Skin Irritation/ Corrosion:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be skin corrosive or irritant.
- Serious Eye Damage / Irritation:** Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
- Respiratory or Skin Sensitisation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as a skin sensitiser or a respiratory sensitiser.
- Chronic Effects:** Due to the presence of Megestrol acetate, prolonged or repeated exposure may lead to weight gain, acne, oedema, gastro-intestinal side effects, depression and alteration of liver function.
- Reproductive Toxicity:** Studies in animals and or humans have demonstrated positive evidence that exposure to Megestrol acetate during pregnancy can lead to foetal abnormalities.
- Mutagenicity:** Not known to be mutagenic.
- Carcinogenicity:** Based on available data for the ingredients, the mixture is classified as Carcinogenic Category 2 – Suspected of causing cancer.
- STOT-Single Exposure:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure.
- STOT – Repeated Exposure:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after repeated exposure, but long term exposure to Megestrol acetate may cause physical defects in the developing embryo (teratogenesis). Diabetes mellitus, skin tumours, paternal effects, maternal effects, effects on fertility, specific developmental abnormalities (urogenital system) recorded.
- Aspiration Hazard:** No available data.

Section 12: ECOLOGICAL INFORMATION

- Ecotoxicity:** The mixture is classified as Harmful to aquatic life with long lasting effects - Acute Aquatic Hazard Category 3 & Chronic Aquatic Hazard Category 3. DO NOT discharge into sewer or waterways. Megestrol is toxic to aquatic organisms.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Megestrol	High	High	Medium	Low

Section 13: DISPOSAL INFORMATION

- Product Disposal:** Dispose of product only by using according to APVMA approved label or by approved waste collection.
- Container Disposal:** Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

- Dangerous Goods Classification:** Not classified as a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.
- HAZCHEM Code:** None specified.

Section 15: REGULATORY INFORMATION

Poisons Schedule: S4

APVMA Registration No: 36150 (Ovarid 20mg Tablets); 36149 (Ovarid 5mg Tablets).

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

Section 16: OTHER INFORMATION

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein does so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

Legend:

ADG	Australian Code for the Transport of Dangerous Goods by Road & Rail, 7 th Edition.
AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
CAS No.	Chemical Abstracts Service Registry Number.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
LD₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
PPE	Personal Protective Equipment.
PVC	Polyvinyl Chloride.
SDS	Safety Data Sheet.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.

References

ChemID PlusLite, <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>, entry for Megestrol acetate (RN: 595-33-5).

Environmental Protection Authority, HSNO Chemical Classification and Information Database (CCID), entry for Megestrol Acetate. <http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx>.

HSDB <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB> entry for MEGESTROL (CASRN: 3562-63-8).

This version issued: 18 October 2017 and is valid for 5 years from this date.

Supersedes: This SDS supersedes the version issued on 14 July 2017.

Revision History:

Date of Revision	Reason
18 October 2017	Addition of APVMA Registration No for Ovarid 5mg Tablets in Section 15.

END OF SDS