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**SAFETY DATA SHEET**

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**Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY**

<b>Product Name:</b>	<b>Tardak Androgen Inhibitive Suspension</b>
<b>Product Identifier:</b>	10 mg/mL Delmadinone Acetae (equivalent to 8.7 mg/mL Delmadinone)
<b>Product Code:</b>	60990 (10 mL)
<b>Recommended Use:</b>	An androgen inhibitive suspension for the modification of hypersexuality in the male dog and the treatment of canine prostate hypertrophy and circum-anal tumours.
<b>Restrictions on Use:</b>	For animal treatment only.
<b>Company Identification:</b>	Jurox Pty Limited
<b>Address:</b>	85 Gardiner Street Rutherford NSW 2320 Australia
<b>Customer Centre:</b>	1800 023 312
<b>Email:</b>	<a href="mailto:customerservice@jurox.com.au">customerservice@jurox.com.au</a>
<b>National Poisons Information Centre:</b>	131126 (Australia-wide) (24 hours)
<b>Emergency Telephone Number:</b>	1800 023 312 (Monday – Friday, 9a.m. – 5p.m.) (24 hours)

**Section 2: HAZARDS IDENTIFICATION**

This product has been assessed according to GHS criteria and is classified as non-hazardous.

**Signal word:** None.

**GHS Pictograms:** None.

**Precautionary statements:** None.

**Section 3: COMPOSITION / INFORMATION on INGREDIENTS**

INGREDIENT	CAS No.	CONTENT
Delmadinone acetate	13698-49-2	1.0%
Other ingredients not contributing to the hazards	-	> 90.0%

**Section 4: FIRST AID MEASURES**

**General Information:** Consult the National Poisons Centre on 131126 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 this SDS, product container or label at hand.

**Symptoms and Effects of Exposure:** Tardak contains a progestogen. Repeated intake of progestogens may produce headache, nausea and vomiting.

**Inhalation:** Unlikely to present an inhalation hazard under normal conditions of use. If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen and seek medical assistance immediately.

**Ingestion:** May result in headache, nausea and vomiting. Rapidly absorbed from the gastrointestinal tract. If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. For advice, contact a doctor or the National Poisons Centre on 131126.

**Skin:** Non-irritant. May lead to skin sensitisation. Readily absorbed through the skin. If skin contact occurs: Immediately remove all contaminated clothing, including footwear, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention.

**Eye:** If eye contact occurs: Immediately flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Continue flushing for at least 20 minutes. If eye irritation persists, get medical advice/attention.

**Injection:** Treat as for needle stick injury. Wash area well and disinfect. If other symptoms become evident, seek medical advice.

**Recommended First Aid Facilities:** Ready access to running water and soap is required. Accessible eyewash is required.

**Advice to Doctor:** Tardak Suspension is a potent anti-androgen. Treat symptomatically.

## Section 5: FIRE FIGHTING MEASURES

**Flash Point:** Not flammable.

**Hazardous Combustion Products:** If involved in a fire, may emit noxious and irritant 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. Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances. In such an event consider: foam, dry chemical powder and carbon dioxide.

**Protective Equipment:** Gas-tight chemical resistant suit, protective gloves and breathing apparatus.

**HAZCHEM Code:** None specified.

## Section 6: ACCIDENTAL RELEASE MEASURES

**Spills and Disposal:** Exclude non-essential people from the area. Wear gloves and appropriate protective clothing. For small spills, clean up spilled product then wipe area and put empty container in garbage. For large spills, contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

**Protective Clothing:** For appropriate personal protective equipment see section 8.

**Environmental Precautions:** Prevent from entering drains, waterways or sewers. If spill does enter waterways contact local authority.

**Section 7: HANDLING AND STORAGE**

**Handling:** Avoid contact with skin, eyes and inhalation of vapours. Take care to avoid accidental self-injection. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

**Storage:** Tardak Suspension is 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 foodstuffs. Store below 25°C (air temperature). Protect from light. 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 or its ingredients. Do not handle until all safety precautions have been read and understood.

**Engineering Controls:** Use only in a well-ventilated area. Make sure that the work environment remains clean and that vapours and mists are minimised.

**Personal Protective Equipment (PPE):**

Eye protection: Protective glasses or goggles are recommended when this product is being used.

Skin protection: When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory protection: Not required for the normal use of this product.

**Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

<b>Appearance:</b>	White aqueous suspension.	<b>Upper / Lower Flammability Limits:</b>	Not available.
<b>Odour:</b>	Not available.	<b>Vapour Pressure:</b>	Not available.
<b>Odour Threshold:</b>	Not available.	<b>Vapour Density:</b>	Not available.
<b>pH:</b>	5.0-7.0.	<b>Relative Density / Specific Gravity:</b>	Approx 1.010 -1.014.
<b>Melting Point / Freezing Point:</b>	Not applicable.	<b>Solubility:</b>	Miscible with water.
<b>Boiling Point and Boiling Range:</b>	Not available.	<b>Partition Coefficient (n-octanol/water):</b>	Not available.
<b>Flash Point:</b>	Not flammable.	<b>Auto-Ignition Temperature:</b>	Not applicable.
<b>Evaporation Rate:</b>	Not available.	<b>Decomposition Temperature:</b>	Not applicable.
<b>Flammability:</b>	Not flammable.	<b>Viscosity:</b>	Not available.

## Section 10: STABILITY AND REACTIVITY

**Reactivity:** This product is unlikely to react or polymerise under normal storage conditions.

**Chemical Stability:** When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

**Conditions to Avoid:** Protect this product from light.

**Incompatible Materials:** Oxidising agents.

**Hazardous Decomposition Products:** Decomposes on heating and may produce toxic fumes of carbon dioxide, hydrogen chloride and phosgene.

## Section 11: TOXICOLOGICAL INFORMATION

### Acute Toxicity:

**Ingestion:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route. However, Repeated intake of progestogens may produce headache, nausea, vomiting, diarrhoea, inflammation of the mouth cavity with ulcers, swelling, weight change, fever, fatigue, increased or decreased sleep, mental depression, allergic rashes including hives and itching, acne, sensitivity to light, pigmented skin, hair loss, excessive hair growth, clotting and vein inflammation, obstructive jaundice, and precipitation of porphyria.

**Inhalation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route.

**Dermal:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

**Injection:** Effects may vary in severity according to the quantity involved, from localised site reaction (pain, redness, swelling) to acute systemic reaction.

**Aspiration Hazard:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard.

**Respiratory Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a respiratory irritant.

**Skin Corrosion / Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin irritant. However, may cause an allergic skin reaction in some persons.

**Serious Eye Damage / Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant. Although the liquid 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 considered to be a skin sensitiser or respiratory sensitiser. However, there is a limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

**Germ Cell Mutagenicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

**Carcinogenicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic. However, there is a limited evidence that progestogens are possibly carcinogenic to humans (Group 2B) Supplement 7: (1987) (p.289) [IARC].

**Reproductive Toxicity:** No data for the mixture is available. Not considered to affect reproduction, based on data for the ingredients. However, some progestogens have been associated with an increase in congenital abnormalities.

**Specific Target Organ Toxicity (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.

**Specific Target Organ Toxicity (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 repeat exposure. But repeated intake of progestogens may produce headache, nausea, vomiting, diarrhoea, inflammation of the mouth cavity with ulcers, swelling, weight change, fever, fatigue, increased or decreased sleep, mental depression, allergic rashes including hives and itching, acne, sensitivity to light, pigmented skin, hair loss, excessive hair growth, clotting and vein inflammation, obstructive jaundice, precipitation of porphyria and liver abnormalities.

**Narcotic Effects:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be narcotic.

### Section 12: ECOLOGICAL INFORMATION

**Ecotoxicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be toxic to the environment.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Delmadinone acetate	No data	No data	No data	No data

### Section 13: DISPOSAL INFORMATION

**Product Disposal:** Dispose of product only by using according to label or at an approved landfill.

**Container Disposal:** Dispose of empty container by wrapping with paper and placing in garbage.

### Section 14: TRANSPORT INFORMATION

**Dangerous Goods Classification:** Not considered a Dangerous Good for land, sea and air transport.

### Section 15: REGULATORY INFORMATION

**Poisons Schedule:** S4

**APVMA Registration No:** 36250

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

**Section 16: OTHER INFORMATION****Legend:**

<b>AICS</b>	Australian Inventory of Chemical Substances.
<b>APVMA</b>	Australian Pesticides and Veterinary Medicines Authority.
<b>CAS No.</b>	Chemical Abstracts Service Registry Number.
<b>EPA</b>	Environmental Protection Authority.
<b>GHS</b>	Globally Harmonized System of Classification and Labelling of Chemicals.
<b>Hazchem Code</b>	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
<b>HCIS</b>	Hazardous Chemical Information System.
<b>LD<sub>50</sub></b>	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
<b>NICNAS</b>	National Industrial Chemicals Notification and Assessment Scheme.
<b>PPE</b>	Personal Protective Equipment.
<b>PVC</b>	Polyvinyl chloride.
<b>SDS</b>	Safety Data Sheet.
<b>STOT</b>	Specific Target Organ Toxicity.
<b>SUSMP</b>	Standard for the Uniform Scheduling of Medicines and Poisons.

**References:**

ChemID Plus

<https://chem.nlm.nih.gov/chemidplus/>

HCIS (Hazardous Chemical Information System)

<http://hcis.safeworkaustralia.gov.au/HazardousChemical>

EPA New Zealand Chemical Classification and Information Database (CCID)

<https://www.epa.govt.nz/database-search/chemical-classification-and-information-database-ccid>

HSDB (Hazardous Substances Data Bank)

<https://toxnet.nlm.nih.gov>**This version issued:** 22 May 2018 and is valid for 5 years from this date.**Supersedes:** This SDS supersedes the version issued on 27 July 2017.**Revision History:**

Date of Revision	Reason
27 July 2017	Updates to section 1, 2, 3, 4, 5, 7, 10, 11, 12, 13 & 15; Updates to Legend and addition of Revision History in Section 16.
22 May 2018	Updates to section 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 13, 14 and Revision History in section 16.

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**END OF SDS**