

# SAFETY DATA SHEET



|                                  |                         |                             |                          |
|----------------------------------|-------------------------|-----------------------------|--------------------------|
| Title: ROPEL LIQUID TESTOSTERONE |                         | Document: SDS-AU093         |                          |
|                                  |                         | Rev: 2.2                    | PAGE 1 OF 10             |
| Status: Current                  | Issue Date: 18-Jun-2024 | Effective Date: 18-Jun-2024 | Review Date: 09-Aug-2027 |

## Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

|   |  |
|---|--|
| <b>Product Name:</b>                        | <b>Ropel Liquid Testosterone</b>   |
| <b>Product Identifier:</b>                  | Oily solution for injection containing 75 mg/mL testosterone enanthate.                      |
| <b>Recommended Use:</b>                     | For the prevention and treatment of external preputial ulceration and sheath rot in wethers. |
| <b>Restrictions on Use:</b>                 | For animal treatment only.   |
| <b>Company Identification:</b>              | Zoetis Australia Pty Ltd<br>ABN: 94 156 476 425  |
| <b>Address:</b>                             | Level 6, 5 Rider Boulevard<br>Rhodes NSW 2138<br>Australia                                   |
| <b>Telephone:</b>                           | 1800 814 883   |
| <b>Fax:</b>                                 | (02) 8876 0444   |
| <b>Email:</b>                               | productsupport@zoetis.com  |
| <b>National Poisons Information Centre:</b> | 13 11 26 (24 hours)  |
| <b>Police, Fire Brigade, Ambulance:</b>     | Dial 000   |
| <b>Emergency Telephone Number:</b>          | 1800 814 883 (all hours)   |

## Section 2: HAZARDS IDENTIFICATION

**Hazard Classifications:** This product has been assessed according to GHS and is classified as follows:

| GHS Category  | Hazard code | Hazard Statement                                 |
|---|-------------|--|
| Skin Corrosion / Irritation Category 2                  | H315        | Causes skin irritation.                          |
| Eye Damage / Irritation Category 2A                     | H319        | Causes serious eye irritation.                   |
| Skin Sensitizer Category 1                              | H317        | May cause an allergic skin reaction.             |
| Carcinogen Category 2                                   | H351        | Suspected of causing cancer.                     |
| Reproductive Toxicity Category 1B                       | H360        | May damage fertility or the unborn child.        |
| Specific Target Organ Toxicity Category 3 (Respiratory) | H335        | May cause respiratory irritation                 |
| Chronic Aquatic Environmental Hazard Category 2         | H411        | Toxic to aquatic life with long lasting effects. |

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**Signal word: DANGER**

## GHS Pictograms:



Exclamation Mark



Health Hazard



Aquatic pollutant

## Precautionary statements:

### General

- P101 If medical advice is needed, have product container or label at hand.  
P102 Keep out of reach of children.

### Prevention

- P202 Do not handle until all safety precautions have been read and understood.  
P261 Avoid breathing vapours.  
P264 Wash hands thoroughly after handling.  
P271 Use only outdoors or in a well-ventilated area.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves, eye protection and face protection.

### Response

- P302+P352 IF ON SKIN: wash with plenty of soap and water.  
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
P312 Call a POISON CENTRE/doctor if you feel unwell.  
P332+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.  
P362+P364 Take off contaminated clothing and wash it before reuse.  
P391 Collect spillage.

### Storage

- P403 Store in a well-ventilated place. Keep container tightly closed.  
P405 Store locked up.

### Disposal

- P501 Dispose of unused product in accordance with local regulations. Dispose of empty container by wrapping with paper and placing in garbage.

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N.B.: The above 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.

**Other hazards:** Slippery when spilt.

## Section 3: COMPOSITION / INFORMATION on INGREDIENTS

| INGREDIENT                                  | CAS No.   | CONTENT |
|---|-----------|---------|
| Sesame oil                                  | 8008-74-0 | >50%    |
| Testosterone enanthate                      | 315-37-7  | 7.5%    |
| Benzyl alcohol                              | 100-51-6  | <5%     |
| Ingredients not contributing to the hazards |           | -       |

## Section 4: FIRST AID MEASURES

**General Information:** Consult the National Poisons Centre on 13 11 26 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:** None known.

**Inhalation:** If fumes, aerosols or combustion products are inhaled remove from patient from contaminated area. Other measures are usually not necessary. 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:** If swallowed do NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully.

**Skin:** If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of rash or irritation.

**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. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

**Injection:** Treat as for needle stick injury. Wash the wound thoroughly with soap and water or use a waterless cleaner or antiseptic if water is unavailable. Apply a dressing as necessary, and apply pressure through the dressing if bleeding is occurring. Do not squeeze or rub the injury site. Dispose of the needle in a suitable sharps container and seek medical advice/attention immediately.

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

**Advice to Doctor:** Treat symptomatically.

## Section 5: FIRE FIGHTING MEASURES

**Flash Point:** >200°C for sesame oil.

**Hazardous Combustion Products:** If involved in a fire, may emit poisonous and corrosive fumes.

**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.

**HAZCHEM Code:** Not specified.

## Section 6: ACCIDENTAL RELEASE MEASURES

**Spills and Disposal:** Slippery when spilt. Wear gloves and appropriate protective clothing. Avoid breathing vapours and contact with skin and eyes. Clean up all spills immediately. For small spills, clean up spilled product then wipe area and put empty container in garbage. For large spills, exclude non-essential people from the area. Contain and absorb spill with sand, earth, inert material or vermiculite. 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:** This product is a Scheduled Poison (S4) and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Handle this product to avoid exposure, taking all recommended precautions. Avoid accidental self-injection. Avoid contact with skin, eyes and inhalation of vapours. Use in a well-ventilated area. Do not allow clothing wet with material to stay in contact with skin. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

**Storage:** Keep out of reach of children. Store below 25°C (air conditioning). Protect from light. Store in a cool, dry, well-ventilated area. Store in original containers, securely sealed, away from foodstuffs. Store locked up and protect containers against physical damage. DO NOT re-use the container.

**Other Information:** Avoid contact with incompatible substances as listed in Section 10. Always read the label before use.

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## 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. Known exposure limits for ingredients are as follows:

| INGREDIENT             | TEEL-1        | TEEL-2        | TEEL-3        |
|------------------------|---------------|---------------|---------------|
| Sesame oil             | Not available | Not available | Not available |
| Testosterone enanthate | Not available | Not available | Not available |
| Benzyl alcohol         | 30 ppm        | 52 ppm        | 740 ppm       |

**Engineering Controls:** Handle in a well-ventilated area. Ensure that the work environment remains clean.

### Personal Protective Equipment (PPE):

Eye protection: Safety glasses with side shields or chemical goggles are recommended when handling bulk quantities of this product.

Skin protection: When handling bulk quantities, prevent skin contact by wearing chemical protective gloves e.g. PVC. Wear safety gumboots, e.g. rubber.

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

Other: When handling bulk quantities of this product, overalls, PVC apron, barrier cream, skin cleansing cream and eye wash unit may be required.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

|                                   |                    |                                   |                |
|-----------------------------------|--------------------|-----------------------------------|----------------|
| <b>Appearance:</b>                | Pale yellow liquid | <b>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>                        | No data            | <b>Relative density:</b>          | Not applicable |
| <b>Melting Point:</b>             | Not applicable     | <b>Specific Gravity:</b>          | Approx. 0.90   |
| <b>Boiling Point:</b>             | Not available      | <b>Solubility in Water:</b>       | Insoluble      |
| <b>Flash Point:</b>               | >200°C             | <b>Partition coefficient:</b>     | Not available  |
| <b>Evaporation Rate:</b>          | Not available      | <b>Auto-ignition temperature:</b> | Not available  |
| <b>Flammability:</b>              | Not flammable      | <b>Decomposition temperature:</b> | Not available  |
| <b>Upper flammability limits:</b> | Not available      | <b>Viscosity:</b>                 | Not available  |

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## Section 10: STABILITY AND REACTIVITY

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

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

**Conditions to Avoid:** Extreme temperatures.

**Incompatible Materials:** Oxidising agents.

**Hazardous Decomposition Products:** Combustion products include carbon dioxide, nitrogen oxides, silicon dioxide and other pyrolysis products typical of burning organic material.

## 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.

Sesame Oil: No data.

Testosterone Enanthate: Oral LD<sub>50</sub>: >1000 mg/kg (rat).

Benzyl Alcohol: Oral LD<sub>50</sub>: 1230 mg/kg (rat).

**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. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Sesame Oil: No data.

Testosterone Enanthate: No data.

Benzyl Alcohol: Inhalation LC<sub>50</sub>: >4.178 mg/L4h (rat).

**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. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Entry into the bloodstream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

Sesame Oil: Dermal LD<sub>50</sub>: >2000 mg/kg (rabbit).

Testosterone Enanthate: No data.

Benzyl Alcohol: Dermal LD<sub>50</sub>: 2000 mg/kg (rabbit).

**Injection:** No data for the mixture is available. Effects will vary in severity according to the quantity involved, from localised site reaction (pain, redness, swelling) to acute allergic reaction.

Sesame Oil: Intraperitoneal LD<sub>50</sub>: >50000 mg/kg (mouse).

Testosterone Enanthate: Intraperitoneal LD<sub>50</sub>: 1770 mg/kg (mouse).

Benzyl Alcohol: Intraperitoneal LD<sub>50</sub>: 400 mg/kg (rat).

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**Skin Corrosion / Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Corrosion/Irritation Category 2**.

**Serious Eye Damage / Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Eye Irritant Category 2A**.

**Respiratory or Skin Sensitisation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Sensitisation Category 1**.

**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 classified as **Carcinogen Category 2**. There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment. High doses of androgens over prolonged periods may produce liver tumours and hasten growth of cancer of the prostate.

**Reproductive Toxicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is considered to be a **Reproductive Toxicant 1B**. Clinical use has caused effects on reproductive system, including prolonged erection (priapism), breast development in males (gynecomastia), loss of libido, decreased sperm count, impairment of male fertility, development of male characteristics (masculinization), development of male characteristics in the female foetus, impairment of female fertility.

**STOT: Single exposure:** No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Specific Target Organ Toxicant after single exposure Category 3 (Respiratory Irritation)**.

**STOT: Repeat exposure:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not thought to be a Specific Target Organ Toxicant after repeat exposure.

**Aspiration Hazard:** No data available.

**Narcotic Effects:** No data for the mixture is available. Based on available data for the ingredients, the mixture is considered to have mild narcotic effects due to the presence of benzyl alcohol and may cause drowsiness or dizziness.

## Section 12: ECOLOGICAL INFORMATION

**Ecotoxicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Chronic Aquatic Environmental Hazard Category 2**.

### Fish

|                |  |
|----------------|--|
| Sesame oil:    | No data.   |
| Testosterone:  | NOEC(ECx) 21h: < 0.001 mg/L.                             |
| Benzyl alcohol | NOEC(ECx) 336h: 5.1 mg/L; LC <sub>50</sub> 96h: 10 mg/L. |

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## Crustacea

Sesame oil: No data.  
Testosterone enanthate: No data.  
Benzyl alcohol: EC<sub>50</sub> 48h: 230 mg/L.

## Algae and other aquatic plants

Sesame oil: No data.  
Testosterone: EC<sub>50</sub> 72h: 0.5 mg/L.  
Benzyl alcohol: EC<sub>50</sub> 72h: 500 mg/L; EC<sub>50</sub> 96h: 76.8 mg/L.

| Ingredient             | Persistence:<br>Water/Soil | Persistence:<br>Air | Bioaccumulation           | Mobility              |
|------------------------|----------------------------|---------------------|---------------------------|-----------------------|
| Sesame oil             | No data                    | No data             | No data                   | No data               |
| Testosterone enanthate | HIGH                       | HIGH                | HIGH<br>(LogKOW = 6.7301) | LOW<br>(KOC = 280200) |
| Benzyl alcohol         | LOW                        | LOW                 | LOW<br>(LogKOW = 1.1)     | LOW<br>(KOC = 15.66)  |

## 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 the garbage.

## Section 14: TRANSPORT INFORMATION

**Dangerous Goods Classification:** Not classified as a Dangerous Good for land, sea or air transport.

## Section 15: REGULATORY INFORMATION

**Poison Schedule (Product):** Schedule 4

**APVMA No.:** 38228

**AICS:** All of the significant ingredients in this formulation are compliant with NICNAS regulations.

## Section 16: OTHER INFORMATION

This information is based on data believed by Zoetis Australia 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 Zoetis Australia 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:

**AICS** Australian Inventory of Chemical Substances.  
**APVMA** Australian Pesticides and Veterinary Medicines Authority.  
**CAS No.** Chemical Abstracts Service Registry Number.

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|                        |   |
|------------------------|---|
| <b>ECx</b>             | The effect concentration at which x% effect (mortality, inhibition of growth, reproduction, etc) is observed compared to the control group. It is usually obtained using an appropriate statistical method such as regression analysis.   |
| <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>KOC</b>             | Soil-Water Partition Coefficient. The ratio of a chemical's concentration that is adsorbed in the soil to the concentration of chemical in solution.  |
| <b>KOW</b>             | Octanol Water Partition Coefficient. The ratio of a compound's concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium.   |
| <b>LC<sub>50</sub></b> | The median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of animals.  |
| <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>NOEC</b>            | No observable effect concentration.   |
| <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.   |
| <b>TEELs</b>           | Temporary Emergency Exposure Limits. Guidelines designed to predict the response of members of the general public to different concentrations of a chemical during an emergency response incident.  |
| <b>TEEL-1</b>          | The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic, nonsensory effects. However, these effects are not disabling and are transient and reversible upon cessation of exposure. |
| <b>TEEL-2</b>          | The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting, adverse health effects or an impaired ability to escape.  |
| <b>TEEL-3</b>          | The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening adverse health effects or death.  |

## References:

ChemID Plus

Chemwatch

EPA New Zealand Chemical Classification and Information Database (CCID)

European Chemicals Agency (ECHA)

HSDB (Hazardous Substances Data Bank)

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## Revision History:

| Date of Revision | Reason  |
|------------------|---|
| 29 June 2012     | Updated the format as per the Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals, December 2011, published by Safe Work Australia. |
| 04 July 2017     | Five year update. New email address.  |
| 09 August 2022   | Routine 5-year review. Update to GHS 7. Updates to all sections including update to GHS classification.   |
| 01 March 2023    | Update of Customer Service and emergency telephone numbers to Zoetis numbers.   |
| 18 June 2024     | Minor revision to update the company details to Zoetis Australia. Minor formatting changes  |

**END OF SDS**