

# SAFETY DATA SHEET

Zoetis New Zealand Limited



## Section 1: Identification of the Substance and Supplier

<b>Trade Name:</b>	<b>LUTALYSE®</b>
<b>ACVM Registration No.:</b>	A003231
<b>Classification:</b>	Restricted Veterinary Medicine (RVM)
<b>Recommended Use:</b>	Injectable endocrine agent for control of oestrus and as an aid in control of reproduction dependent on a corpus luteum in cattle, horses and pigs.
<b>Company Details:</b>	Zoetis New Zealand Limited
<b>Address:</b>	Level 5, 8 Mahuhu Crescent Auckland Central Auckland 1010 New Zealand
<b>Telephone No.:</b>	0800 963 847 (Business Hours)
<b>Emergency Telephone No.:</b>	National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111
<b>Date of Preparation:</b>	30 June 2014

## Section 2: Hazards Identification

<b>Hazard Classification:</b>	6.8A, 6.9A
<b>Priority Identifier(s):</b>	WARNING – KEEP OUT OF REACH OF CHILDREN
<b>Secondary Identifier(s):</b>	6.8A May damage fertility or the unborn child from repeated oral exposure. 6.9A May cause target organ damage from repeated oral exposure at high doses.

## Section 3: Composition / Information on Ingredients

### Chemical Identity of Ingredients

Ingredient	CAS No.	Concentration
Dinoprost trometamol	38562-01-5	5.0 g/L
Benzyl alcohol USP	100-51-6	Proprietary
Other ingredients determined not to be hazardous.	-	-

This is a commercial product whose exact ratio of components may vary.  
Trace quantities of impurities are also likely.

## Section 4: First Aid Measures

<b>Necessary First Aid Measures:</b>	<p><b>For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately.</b> If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.</p> <p><b>Self-Injection:</b> Immediate medical advice should be sought on the management of <b>all</b> instances of accidental self-injection, particularly those near a joint or associated with bruising. Allow the wound to bleed freely and avoid squeezing the injection site to avoid spread of the product. Clean the wound thoroughly with soap and water, then keep it clean and dry.</p> <p><b>Ingestion:</b> DO NOT induce vomiting. If the patient is conscious wash mouth out with water. Do not give anything by mouth to an unconscious person. Seek medical advice immediately.</p> <p><b>Eye Contact:</b> Flush the eye(s) out with running water for at least 15 minutes. Removal of contact lenses should be done with caution within 5 minutes of exposure. If symptoms develop seek medical advice immediately.</p> <p><b>Skin Contact:</b> Remove any contaminated clothing and wash the affected area immediately with soap and water. If symptoms develop seek medical advice immediately.</p> <p><b>Inhalation:</b> Move the patient to fresh air. If symptoms develop seek medical advice immediately.</p>
<b>Poisoning Symptoms:</b>	May cause skin and/or eye irritation. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Repeat-dose studies in animals have shown the potential to cause adverse effects on the testes and harm to the developing foetus. Individuals sensitive to this chemical, or other materials in its chemical class, may develop allergic reactions.
<b>Workplace Facilities:</b>	No specific facilities required. Standard emergency equipment must be available.
<b>Hygiene Practices:</b>	Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
<b>Notes for Medical Personnel:</b>	Accidental self-injection may lead to an inflammatory response and deep injections, particularly those near a joint or associated with bruising should be treated medically or surgically. Treat respiratory distress resulting from accidental inhalation or injection of LUTALYSE in humans with a rapid acting bronchodilator such as isoprenaline or salbutamol by inhalation. Please see "chronic health effects".

## Section 5: Fire-Fighting Measures

<b>Type of hazard:</b>	This product is not flammable, however, irritating and possibly toxic gases may be generated by thermal decomposition or combustion.
<b>Fire Hazard Properties:</b>	Fine particles (such as dusts or mists) may fuel fires/explosions.
<b>Regulatory Requirements:</b>	Not applicable.
<b>Extinguishing Media &amp; Methods:</b>	Use dry chemical, carbon dioxide or water to extinguish fires involving this product.
<b>Hazchem Code:</b>	Not allocated.
<b>Recommended Protective Clothing:</b>	During large-scale fire fighting operations wear approved positive pressure, self-contained breathing apparatus and full protective turn-out gear.

## Section 6: Accidental Release Measures

<b>Personal Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment to minimise exposure. This may include eye protection, chemically resistant gloves, boots and overalls.
<b>Environmental Precautions:</b>	Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services.
<b>Procedure for Spills:</b>	<ol style="list-style-type: none"><li>1. Non-essential personnel should be evacuated from the affected area.</li><li>2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.</li><li>3. Absorb the spill with an absorbent material (e.g. sand).</li><li>4. Collect the spilled material into labelled containers for disposal, minimising dust generation.</li><li>5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.</li></ol>
<b>Procedure for Disposal:</b>	Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container.

## Section 7: Handling and Storage

### Handling

<b>Precautions for Safe Handling:</b>	No special technical protective measures required. No special handling advice required.
<b>Regulatory Requirements:</b>	Not required.
<b>Handling Practices:</b>	Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
<b>Approved Handlers:</b>	Approved handlers are not required for this product.

### Storage

<b>Conditions for Safe Storage:</b>	Store below 30°C (Room Temperature). Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs.
<b>Store Site Requirements:</b>	No additional requirements.
<b>Packaging:</b>	Store in the original container, away from foodstuffs.

## Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

### Workplace Exposure Guidelines

<b>Workplace Exposure Standards:</b>	A time weighted average (TWA) concentration for an 8-hour day and a 5-day week has not been established by NOHSC Australia for any of the major ingredients in this product. There is a blanket limit of 10 mg/m <sup>3</sup> for dusts or mists when limits have not otherwise been established.
<b>Application in the Workplace:</b>	The nature of this product makes it unlikely that this level will be approached during normal handling.
<b>Exposure Standards Outside the Workplace:</b>	None set.
<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
<b>Personal Protection:</b>	<p>The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.</p> <p><b>Hands:</b> Impervious gloves are recommended if skin contact is possible and for bulk processing operations.</p> <p><b>Eyes:</b> It is always prudent to utilise protective eyewear.</p> <p><b>Skin:</b> When prolonged or frequently repeated contact could occur, utilise chemically protective clothing. Selection of specific items such as a face shield, gloves, boots, or overalls will depend on the situation.</p> <p><b>Respiratory:</b> Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.</p>
<b>General Hygiene:</b>	Change work clothes regularly. Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

### Section 9: Physical and Chemical Properties

<b>Appearance:</b>	Clear liquid
<b>Odour:</b>	No data available
<b>Density:</b>	0.996 – 1.004
<b>Melting Point:</b>	No data available
<b>Boiling Point:</b>	No data available
<b>pH:</b>	6.0 – 7.0
<b>Solubility in Water:</b>	Soluble
<b>Flashpoint:</b>	Not applicable. This product is not flammable
<b>Oxidising Properties:</b>	Not applicable. This product is not an oxidiser
<b>Corrosive Properties:</b>	Not applicable. This product is not corrosive
<b>Vapour Pressure:</b>	No data available

## Section 10: Stability and Reactivity

<b>Stability of the Substance:</b>	This product is stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Store as recommended. No special conditions to avoid.
<b>Material to Avoid:</b>	As a precautionary measure, keep away from strong oxidisers.
<b>Hazardous Decomposition Products:</b>	This product is unlikely to spontaneously decompose. No significant quantities of decomposition products are expected at temperatures normally achieved in a fire.
<b>Hazardous Polymerisation:</b>	This product is unlikely to spontaneously polymerise.
<b>Specific Data:</b>	No specific data available.

## Section 11: Toxicological Information

### HSNO Classifications

- 6.8A** May damage fertility or the unborn child from repeated oral exposure.
- 6.9A** May cause target organ damage from repeated oral exposure to high doses.

### Acute Effects

<b>Acute Toxicity:</b>	(Species, Route, End Point, Dose): Dinoprost trometamol: <ul style="list-style-type: none"><li>• Oral LD<sub>50</sub> (Rat): 665 mg/kg</li><li>• Intravenous LD<sub>50</sub> (Rat): 101 mg/kg</li><li>• Oral LD<sub>50</sub> (Mouse): 711 mg/kg</li><li>• Intravenous LD<sub>50</sub> (Mouse): 331 mg/kg</li></ul> Benzyl alcohol: <ul style="list-style-type: none"><li>• Oral LD<sub>50</sub> (Rat): 1.23 g/kg</li><li>• Intravenous LD<sub>50</sub> (Rat): 53 mg/kg</li></ul>
<b>Skin Contact:</b>	(Study Type, Species, Severity): Dinoprost trometamol: <ul style="list-style-type: none"><li>• Skin Irritation Rat No effect</li><li>• Skin Sensitization - GPMT Guinea Pig Negative</li></ul> Benzyl alcohol: <ul style="list-style-type: none"><li>• Skin Irritation Rabbit Moderate</li><li>• Skin Irritation Guinea Pig Moderate</li></ul>
<b>Eye Contact:</b>	(Study Type, Species, Severity): Dinoprost trometamol: <ul style="list-style-type: none"><li>• Eye Irritation Rabbit Severe</li></ul> Benzyl alcohol: <ul style="list-style-type: none"><li>• Eye Irritation Rabbit Severe</li></ul>

### Chronic / Long Term Effects

<b>Repeated Dose Toxicity:</b>	(Duration, Species, Route, Dose, End Point, Target Organ): Dinoprost trometamol: <ul style="list-style-type: none"><li>• 6 Month(s) Rat Intraperitoneal 32.8 mg/kg LOAEL Male reproductive system</li></ul>
<b>Reproduction &amp; Developmental Toxicity:</b>	(Study Type, Species, Route, Dose, End Point, Effect(s)): Dinoprost trometamol: <ul style="list-style-type: none"><li>• Reproductive &amp; Fertility Rat 1-3 mg/kg/day NOAEL Fertility</li><li>• Embryo / Foetal Development Rat Subcutaneous 0.5 mg/kg/day LOAEL Teratogenic</li><li>• Embryo / Foetal Development Rat 1-3 mg/kg/day LOAEL Fetotoxicity</li></ul>
<b>Genotoxicity:</b>	(Study Type, Cell Type/Organism, Result): Dinoprost trometamol: <ul style="list-style-type: none"><li>• Bacterial Mutagenicity (Ames) <i>Salmonella</i> Negative</li><li>• Direct DNA Interaction Negative</li></ul>
<b>Carcinogenicity:</b>	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### Section 12: Ecotoxicity Information

#### HSNO Classifications

Not applicable. This product is not classified as ecotoxic.

The environmental characteristics of this material have not been fully evaluated.  
Avoid contamination of any water supply with product or empty container.

#### Ecotoxicity Effects

<b>Toxicity to Birds:</b>	Not applicable
<b>Acute Toxicity to Fish:</b>	Not applicable
<b>Toxicity to Algae:</b>	Not applicable
<b>Toxicity to Aquatic Invertebrates:</b>	Not applicable
<b>Toxicity to Soil Dwelling Organisms:</b>	Not applicable
<b>Acute Toxicity to Bees:</b>	Not applicable

#### Environmental Fate

No information available.

### Section 13: Disposal Considerations

<b>Product Disposal:</b>	Preferably dispose of product by use in accordance with label directions. Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with product.
<b>Container Disposal:</b>	Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with empty container. Used needles and syringes should immediately be placed in a designated and appropriately labelled "sharps" container.

