SAFETY DATA SHEET

1. Identification

Product identifier **LUTALYSE® Injectable Prostaglandin**

Other means of identification

Synonyms LUTALYSE * DINOLYTIC * Lutalyse® * Lutalyse® Injection * Dinoprost tromethamine sterile solution * Lutalyse/Dinolytic 5 mg/ml Sterile Injectable Solution * Lutalyse 5 * Dinolytic 5

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product used for estrus synchronization

Restrictions on use Not for human use

Details of manufacturer or importer

Company Name (AU) Zoetis Australia Pty Ltd
ABN 94 156 476 425
Level 6, 5 Rider Boulevard
Rhodes NSW 2138 AUSTRALIA

Tel 1800 814 883

Fax (02) 8876 0444

Email productsupport.au@zoetis.com

Emergency Phone 1800 814 883 (all hours)

Police and Fire Brigade Dial 000

If ineffective Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 1B
Environmental hazards	Not classified.	

Label elements, including precautionary statements

Hazard symbol(s)

Health hazard

Signal word Danger

Hazard statement(s) May damage fertility or the unborn child.

Precautionary statement(s)

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.

Response IF exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards which do not result in classification None known.

Supplemental information May cause eye irritation. May cause skin irritation. May be absorbed through the skin and cause systemic effects. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and/or bronchospasms.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Benzyl alcohol	100-51-6	<5
Dinoprost tromethamine	38562-01-5	5 mg/ml
Water	7732-18-5	

4. First-aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician or poison control centre immediately.

Skin contact In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately. Wash contaminated clothing before reuse.

Eye contact Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Call a physician or poison control centre immediately.

Ingestion Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

Personal protection for first-aid responders For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

Symptoms caused by exposure Inhalation may cause difficulty breathing, chest tightness, and respiratory irritation with coughing, wheezing, and sputum generation. Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause skin irritation. May cause redness and pain. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. May cause reproductive effects. Ingestion of large amounts may produce gastrointestinal disturbances including irritation, nausea, and diarrhoea. Breathing mist or vapour may worsen asthma symptoms.

Medical attention and special treatment Monitor respiratory, cardiac and reproductive systems. Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Hazchem code None.

General fire hazards No unusual fire or explosion hazards noted.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away.
For emergency responders	Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapour. Do not get in eyes, on skin, or on clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
Methods and materials for containment and cleaning up	Wear personal protective equipment. Ensure adequate ventilation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas. Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling	Do not handle until all safety precautions have been read and understood. Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and/or bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water. Use this product with adequate ventilation. Do not breathe vapours or spray mist. Do not get in eyes, on skin, on clothing. Avoid prolonged exposure. Avoid accidental injection. When using, do not eat, drink or smoke. Wear personal protective equipment. Observe good industrial hygiene practices. Wash thoroughly after handling. Avoid release to the environment.
Conditions for safe storage, including any incompatibilities	Use care in handling/storage. Store locked up. Keep away from heat, sparks and open flame. Store in a well-ventilated place. @ 15 - 25˚C (59 - 77˚F). Do not allow material to freeze. Keep out of the reach of children.

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components	Type	Value
Dinoprost tromethamine (CAS 38562-01-5)	TWA	1 µg/m³

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Benzyl alcohol (CAS 100-51-6)	TWA	22 mg/m3	Vapour and aerosol.
		5 ppm	Vapour and aerosol.

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines OEL Additional Information: Dinoprost Tromethamine 15 minute STEL (Short-Term Exposure Limit) = 4 µg/m3.

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash facilities and emergency shower must be available when handling this product.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. Impervious gloves.
Other	Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection.
Thermal hazards	Not applicable.
Hygiene measures	Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Liquid.
Colour	Clear.
Odour	Not available.
Odour threshold	Not available.
pH	5.5 - 7.5
Melting point/freezing point	0 °C (32 °F)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	100 %
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other physical and chemical parameters	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.
Specific gravity	0.996 - 1.004

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Keep away from heat, spark, open flames and other sources of ignition.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Nitrogen oxides (NOx). Carbon oxides.

11. Toxicological information

Information on possible routes of exposure

Inhalation	Prolonged inhalation may be harmful. Breathing mist or vapour may worsen asthma symptoms.
Skin contact	Prolonged skin contact may cause temporary irritation. May be absorbed through the skin and cause systemic effects.
Benzyl alcohol	Species: Guinea Pig Severity: Moderate Species: Rabbit Severity: Minimal
Dinoprost tromethamine	Species: Rat Severity: No effect
Eye contact	Direct contact with eyes may cause temporary irritation.
Benzyl alcohol	Species: Rabbit Severity: Severe
Dinoprost tromethamine	Species: Rabbit Severity: Severe
Ingestion	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to exposure	Inhalation may cause difficulty breathing, chest tightness, and respiratory irritation with coughing, wheezing, and sputum generation. May cause eye irritation. Exposure may cause temporary irritation, redness, or discomfort. Prolonged skin contact may cause temporary irritation. May cause redness and pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy. Ingestion of large amounts may produce gastrointestinal disturbances including irritation, nausea, and diarrhoea. Breathing mist or vapour may worsen asthma symptoms.
Acute toxicity	Not acutely toxic

Components	**Species**	**Test Results**
Benzyl alcohol (CAS 100-51-6)		
Acute		
Dermal		
LD50	Rabbit	2000 mg/kg
Inhalation		
LC50	Rat	> 4.178 mg/l
		1000 mg/l, 8 Hours
Oral		
LD50	Mouse	1580 mg/kg
	Rat	1230 mg/kg

Components	Species	Test Results
Dinoprost tromethamine (CAS 38562-01-5)		
Acute		
Intravenous		
LD50	Mouse	331 mg/kg
Oral		
LD50	Mouse	711 mg/kg
	Rat	665 mg/kg
Other		
LD50	Rat	101 mg/kg (Para-periosteal)
Chronic		
Intraperitoneal		
LOAEL	Rat	32.8 mg/kg, 6 months (Target organ(s): Male reproductive system)

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Dinoprost tromethamine	Species: Rat Severity: No effect

Serious eye damage/irritation Direct contact with eyes may cause temporary irritation.

Eye contact

Benzyl alcohol	Species: Rabbit Severity: Severe
Dinoprost tromethamine	Species: Rabbit Severity: Severe

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitizer.

Skin sensitisation This product is not expected to cause skin sensitisation.

Skin Sensitisation

Dinoprost tromethamine	GPMT Species: Guinea Pig Severity: Negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Dinoprost tromethamine	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella Direct DNA Interaction Result: Negative

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity May damage fertility or the unborn child. Repeat-dose studies in animals have shown a potential to cause adverse effects on testes and developing fetus.

Developmental effects

Dinoprost tromethamine	0.5 mg/kg/day Embryo / Fetal Development, teratogenic Result: LOAEL Species: Rat Organ: Subcutaneous 1 - 3 mg/kg/day Embryo / Fetal Development, Fetotoxicity Result: LOAEL Species: Rat

Reproductivity

Dinoprost tromethamine	1 - 3 mg/kg/day Reproductive & Fertility, Fertility Result: NOAEL Species: Rat

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Other information Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and/or bronchospasms.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components		Species	Test Results
Benzyl alcohol (CAS 100-51-6)			
Aquatic			
Algae	EC50	Pseudokirchneriella subcapitata (Green Alga)	500 mg/l, 72 Hours
Crustacea	EC50	Daphnia magna (Water Flea)	230 mg/l, 48 Hours
			66 mg/l, 21 day(s) Toxicity for reproduction
Fish	LC50	Pimephales promelas (Fathead Minnow)	460 mg/l, 96 Hours
Acute			
Fish	LC50	Bluegill (Lepomis macrochirus)	10 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Biodegradability

Percent Degradation (Aerobic Biodegradation)

Benzyl alcohol	92 - 96 % Test Duration: 28 days

Bioaccumulative potential See below

Partition coefficient n-octanol / water (log Kow)

Benzyl alcohol	1.1
Dinoprost tromethamine	-0.46, Predicted Log D @ pH 7.4

Mobility in soil No data available for this product.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal methods Avoid release to the environment. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

ADG

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

Safety, health and environmental regulations

National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No. 38700

Poison Schedule (Product) - Schedule 4

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Benzyl alcohol (CAS 100-51-6)	10000 - 99999 TONNES See the regulation for additional information.
Water (CAS 7732-18-5)	1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Resricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 06-December-2016

Revision date	13-December-2021
Disclaimer	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	Composition/information on ingredients: Component information Physical & Chemical Properties: Multiple Properties Toxicological information: Ingestion Toxicological information: Inhalation Toxicological information: Specific target organ toxicity - repeated exposure Toxicological information: Specific target organ toxicity - single exposure GHS: Classification