

# SAFETY DATA SHEET



Revision date: 11-Mar-2015

Version: 3.2

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Lutalyse Sterile Solution

**Trade Name:** LUTALYSE; DINOLYTIC

**Synonyms:** Dinoprost tromethamine sterile solution; Lutalyse/Dinolytic 5 mg/ml Sterile Injectable Solution; Lutalyse 5; Dinolytic 5

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product used for estrus synchronization

**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
CHEMTREC (24 hours): 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Clear liquid

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 1B

#### EU Classification:

EU Indication of danger: Toxic to reproduction, Category 2

EU Symbol: T

EU Risk Phrases:  
R61 - May cause harm to the unborn child.

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H360D - May damage the unborn child

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**Precautionary Statements:** P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

**Short Term:** May cause eye and skin irritation (based on components) . Signs and symptoms might include redness, swelling, blurred vision or pain. Signs and symptoms might include skin rash, itching, redness or swelling. May be absorbed through the skin and cause systemic effects. May be harmful if swallowed. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on testes the developing fetus.

**Known Clinical Effects:** Common adverse effects include gastrointestinal disturbances nausea vomiting diarrhea Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

### Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Dinoprost Tromethamine	38562-01-5	254-002-3	Repr.Cat.2;R61 Xn;R22 Xi;R36	Acute tox. 4 (H302) Eye Irrit. 2A (H319) Repr. 1B (H360D)	0.6-0.7
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox.4 (H302) Acute Tox.4 (H332)	0.9-1.0

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

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### 4. FIRST AID MEASURES

#### Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- Fire / Explosion Hazards:** Not flammable.

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Additional Information:** This product is a nonflammable aqueous solution.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

- Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

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### 7. HANDLING AND STORAGE

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Veterinary product used for estrus synchronization

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Dinoprost Tromethamine

Zoetis OEL TWA 8-hr 1 µg/m<sup>3</sup>

#### Benzyl Alcohol

Bulgaria OEL - TWA 5.0 mg/m<sup>3</sup>

Czech Republic OEL - TWA 40 mg/m<sup>3</sup>

Finland OEL - TWA 10 ppm

45 mg/m<sup>3</sup>

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Poland OEL - TWA 240 mg/m<sup>3</sup>

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Clear
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>Solubility:</b>	Soluble: Water		
<b>pH:</b>	7.8-8.2		
<b>Melting/Freezing Point (°C):</b>	0		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Boiling Point (°C):** No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Dinoprost Tromethamine**

Predicted 7.4 Log D -0.46

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Specific Gravity:** 0.996-1.004

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.  
Routes of exposure: eye contact , skin contact

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Dinoprost Tromethamine**

Rat Oral LD 50 665 mg/kg

Rat Para-periosteal LD 50 101mg/kg

Mouse Oral LD 50 711mg/kg

Mouse Intravenous LD 50 331mg/kg

**Benzyl Alcohol**

Rat Oral LD50 1230 mg/kg

Rat Para-periosteal LD50 53mg/kg

Rat Inhalation LC50 >4.178mg/L

**Irritation / Sensitization: (Study Type, Species, Severity)**

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### 11. TOXICOLOGICAL INFORMATION

#### Dinoprost Tromethamine

Eye Irritation Rabbit Severe  
Skin Irritation Rat No effect  
Skin Sensitization - GPMT Guinea Pig Negative

#### Benzyl Alcohol

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Minimal  
Skin Irritation Guinea Pig Moderate

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Dinoprost Tromethamine

6 Month(s) Rat Intraperitoneal 32.8 mg/kg LOAEL Male reproductive system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Dinoprost Tromethamine

Reproductive & Fertility Rat 1-3 mg/kg/day NOAEL Fertility  
Embryo / Fetal Development Rat Subcutaneous 0.5 mg/kg/day LOAEL Teratogenic  
Embryo / Fetal Development Rat 1-3 mg/kg/day LOAEL Fetotoxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Dinoprost Tromethamine

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Direct DNA Interaction Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Product Level Toxicity Data

Acute Toxicity Estimate (ATE),  
oral

>5000 mg/kg

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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Benzyl Alcohol**

<i>Pimephales promelas</i> (Fathead Minnow)	EPA	LC50	96 Hours	460 mg/L
<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	230 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD	EC50	72 Hours	500 mg/L

**Benzyl Alcohol**

<i>Daphnia magna</i> (Water Flea)	OECD	21 Day(s)	EC50 66 mg/L	Reproduction
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**Persistence and Degradability:** No data available

**Benzyl Alcohol**

OECD	Activated sludge	Ready	92% After	14 Day(s)	Ready
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**Bio-accumulative Potential:** No data available

**Dinoprost Tromethamine**

Predicted	7.4	Log D	-0.46
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**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Should not be released into the environment. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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### 15. REGULATORY INFORMATION

#### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class D, Division 2, Subdivision A

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



##### Dinoprost Tromethamine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	254-002-3

##### Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation  
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Toxic to Reproduction: Category 2

Xn - Harmful

Xi - Irritant

R22 - Harmful if swallowed.

R36 - Irritating to eyes.

R61 - May cause harm to the unborn child.

R20/22 - Harmful by inhalation and if swallowed.

#### Data Sources:

The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.



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**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.  
Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.  
Updated Section 11 - Toxicology Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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**End of Safety Data Sheet**