

SAFETY DATA SHEET



1. Identification

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| Product identifier | Lutalyse Sterile Solution |
| 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 | Veterinary product used for estrus synchronization |
| Recommended restrictions | Not for human use |
| Manufacturer/Importer/Supplier/Distributor information | |
| Company Name (US) | Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA) |
| Rocky Mountain Poison and Drug Center | 1-866-531-8896 |
| Product Support/Technical Services | 1-800-366-5288 |
| Emergency telephone numbers | CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887 |
| Company Name (EU) | Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium |
| Emergency telephone number | International CHEMTREC (24 hours): +1-703-527-3887 |
| Contact E-Mail | VMIPSrecords@zoetis.com |

2. Hazard(s) identification

| | | |
|------------------------------|-----------------------|-------------|
| Physical hazards | Not classified. | |
| Health hazards | Reproductive toxicity | Category 1B |
| Environmental hazards | Not classified. | |
| OSHA defined hazards | Not classified. | |

Label elements



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|--|--|
| Signal word | Danger |
| Hazard statement | May damage fertility or the unborn child. |
| Precautionary statement | |
| Prevention | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. |
| 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. |
| Hazard(s) not otherwise classified (HNOC) | 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

Mixtures

| Chemical name | Common name and synonyms | CAS number | % |
|------------------------|--------------------------|------------|---------|
| Benzyl Alcohol | | 100-51-6 | <5 |
| Dinoprost Tromethamine | | 38562-01-5 | 5 mg/ml |
| Water | | 7732-18-5 | |

Composition comments In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Inhalation

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

Ingestion

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed

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 diarrhea. Breathing mist or vapour may worsen asthma symptoms.

Indication of immediate medical attention and special treatment needed

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

General information

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.

5. Fire-fighting measures

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 firefighters

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.

Specific methods

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

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained.

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. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions**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 vapors 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. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis**Components****Type****Value**

Dinoprost Tromethamine
(CAS 38562-01-5)

TWA

1 µg/m³

US. Workplace Environmental Exposure Level (WEEL) Guides**Components****Type****Value**

Benzyl Alcohol (CAS
100-51-6)

TWA

44.2 mg/m³

10 ppm

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.

Control banding approach

Not available.

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, such as personal protective equipment**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 vapor 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.

General hygiene considerations 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.

Color Clear.

Odor Not available.

Odor threshold Not available.

pH 7.8 - 8.2

Melting point/freezing point 32 °F (0 °C)

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.

Vapor pressure Not available.

Vapor 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 information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

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.

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| Conditions to avoid | Contact with incompatible materials. Keep away from heat, spark, open flames and other sources of ignition. |
| Incompatible materials | Strong oxidizing 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 likely routes of exposure

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| Inhalation | May be harmful if inhaled. 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 be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure. | |

Symptoms related to the physical, chemical and toxicological characteristics

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 diarrhea. Breathing mist or vapour may worsen asthma symptoms.

Information on toxicological effects

Acute toxicity May be harmful in contact with skin. May be absorbed through the skin and cause systemic effects. May be harmful if inhaled. May be harmful if swallowed.

| 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 |
| Dinoprost Tromethamine (CAS 38562-01-5) | | |
| Acute | | |
| Intravenous | | |
| LD50 | Mouse | 331 mg/kg |
| Oral | | |
| LD50 | Mouse | 711 mg/kg |
| | Rat | 665 mg/kg |

| Components | Species | Test Results |
|---|--|--|
| 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/eye 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 sensitization | | |
| Respiratory sensitization | Not a respiratory sensitizer. | |
| Skin sensitization | This product is not expected to cause skin sensitization. | |
| Skin sensitization 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. | |
| IARC Monographs. Overall Evaluation of Carcinogenicity | Not listed. | |
| OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) | Not regulated. | |
| US. National Toxicology Program (NTP) Report on Carcinogens | Not listed. | |
| 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

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| Specific target organ toxicity - single exposure | Due to partial or complete lack of data the classification is not possible. May cause irritation to the respiratory system. |
| Specific target organ toxicity - repeated exposure | Not classified. |
| Aspiration hazard | Not an aspiration hazard. |
| Chronic effects | Prolonged inhalation may be harmful. |
| Further 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

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| 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. |
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| Components | Species | Test Results |
|-------------------------------|---------|--|
| Benzyl Alcohol (CAS 100-51-6) | EC50 | Daphnia magna (Water Flea) |
| | | 230 mg/L, 48 Hours |
| | | 66 mg/L, 21 Day(s) Reproduction |
| | | Pseudokirchneriella subcapitata (Green Alga) |
| | | 500 mg/L, 72 Hours |
| | LC50 | Pimephales promelas (Fathead Minnow) |
| | | 460 mg/L, 96 Hours |
| Aquatic | | |
| Fish | LC50 | Bluegill (Lepomis macrochirus) |
| | | 10 mg/l, 96 hours |

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| Persistence and degradability | No data is available on the degradability of this product. |
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| Bioaccumulative potential | No data available. |
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Partition coefficient n-octanol / water (log Kow)

Dinoprost Tromethamine -0.46, Predicted Log D @ pH 7.4

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| Mobility in soil | No data available. |
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| 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. |
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13. Disposal considerations

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| Disposal instructions | Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. |
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| Local disposal regulations | Dispose in accordance with all applicable regulations. |
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| Hazardous waste code | None known. |
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| Waste from residues / unused products | 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 (see: Disposal instructions). |
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| Contaminated packaging | Since emptied containers may retain product residue, follow label warnings even after container is emptied. |
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14. Transport information

DOT

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

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|----------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | Yes |
| 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 |

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|---|------------------------|
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| 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, including date of preparation or last revision

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|-----------------------------|--|
| Issue date | 12-16-2014 |
| Revision date | 06-03-2017 |
| Version # | 03 |
| 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 | This document has undergone significant changes and should be reviewed in its entirety. |