



MATERIAL SAFETY DATA SHEET

Revision date: 05-Nov-2012

Version: 2.2

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288
Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Lutalyse Sterile Solution

| | |
|-----------------------------|--|
| Trade Name: | LUTALYSE; DINOLYTIC |
| Synonyms: | Dinoprost tromethamine sterile solution |
| Chemical Family: | Mixture |
| Intended Use: | Veterinary product used for estrus synchronization |
| Restrictions on Use: | Not for human use |

2. HAZARDS IDENTIFICATION

Appearance: Clear liquid
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.

Short Term: May cause eye and skin irritation (based on components) . May be absorbed through the skin and cause systemic effects. May be harmful if swallowed. (based on animal data) . 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.

EU Indication of danger: Toxic to reproduction, Category 2

EU Hazard Symbols:



EU Risk Phrases:

R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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 | % |
|------------------------|------------|-----------------------|------------------------------------|---------|
| Dinoprost Tromethamine | 38562-01-5 | 254-002-3 | Repr.Cat.2;R61 Xn;R22 Xi;R36 | 0.6-0.7 |
| Benzyl Alcohol | 100-51-6 | 202-859-9 | Xn;R20/22 | 0.9-1.0 |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|------------|------------|-----------------------|-------------------|---|
| Water | 7732-18-5 | 231-791-2 | Not Listed | * |

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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6. ACCIDENTAL RELEASE MEASURES

| | |
|---|--|
| Health and Safety Precautions: | Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. |
| 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. |
| Measures for Environmental Protections: | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. |
| 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

| | |
|----------------------------|---|
| General Handling: | Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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. |
| Storage Conditions: | Store as directed by product packaging. |

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

| | |
|-------------------------------|-----------------------|
| Dinoprost Tromethamine | |
| Pfizer OEL TWA-8 Hr: | 1 µg/m ³ |
| Benzyl Alcohol | |
| Bulgaria OEL - TWA | 5.0 mg/m ³ |
| Czech Republic OEL - TWA | 40 mg/m ³ |
| Finland OEL - TWA | 10 ppm |
| | 45 mg/m ³ |
| Latvia OEL - TWA | 5 mg/m ³ |
| Lithuania OEL - TWA | 5 mg/m ³ |
| Poland OEL - TWA | 240 mg/m ³ |

| | |
|---|--|
| 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. |
| Environmental Exposure Controls: | Refer to specific Member State legislation for requirements under Community environmental legislation. |
| 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. |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

| | | | |
|-------------------------------------|----------------|--------------------------|---------|
| Physical State: | Liquid | Color: | Clear |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| Solubility: | Soluble: Water | | |
| pH: | 7.8-8.2 | | |
| Melting/Freezing Point (°C): | 0 | | |
| Specific Gravity: | 0.996-1.004 | | |

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Dinoprost Tromethamine

| | | | |
|-------|-----------------|-------|-----------|
| Rat | Oral | LD 50 | 665 mg/kg |
| Rat | Para-periosteal | LD 50 | 101 mg/kg |
| Mouse | Oral | LD 50 | 711 mg/kg |
| Mouse | Intravenous | LD 50 | 331 mg/kg |

Benzyl Alcohol

| | | | |
|-----|-----------------|------|----------------------|
| Rat | Oral | LD50 | 1230 mg/kg |
| Rat | Para-periosteal | LD50 | 53 mg/kg |
| Rat | Inhalation | LC50 | 46 mg/m ³ |

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

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 | Moderate |
| Skin Irritation | Guinea Pig | Moderate |

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11. TOXICOLOGICAL INFORMATION

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

Dinoprost Tromethamine

6 Month(s) Rat Intraperitoneal 32.8 mg/kg LOEL 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 NOEL Fertility
Embryo / Fetal Development Rat Subcutaneous 0.5 mg/kg/day LOEL Teratogenic
Embryo / Fetal Development Rat 1-3 mg/kg/day LOEL 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.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

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.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction, Category 2

EU Risk Phrases:

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15. REGULATORY INFORMATION

R61 - May cause harm to the unborn child.

EU Safety Phrases:

S23 - Do not breathe gas/fumes/vapour/spray.
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:

DANGER

May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B



Dinoprost Tromethamine

| | |
|-----------------------|-----------|
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 254-002-3 |

Benzyl Alcohol

| | |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 202-859-9 |

Water

| | |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 231-791-2 |

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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:

Pfizer proprietary drug development information. Publicly available toxicity information.

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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 7 - Handling and Storage.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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.

End of Safety Data Sheet