

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**COMMON NAME:** LUTALYSE® Sterile Solution

**USE:** Veterinary product for intramuscular use in estrus synchronization, treatment of unobserved (silent) estrus and pyometra (chronic endometritis) in cattle; for abortion of feedlot and other non-lactating cattle and for parturition induction in swine. Not for human use.

**MANUFACTURER/SUPPLIER:**

PHARMACIA & UPJOHN  
7171 PORTAGE RD  
KALAMAZOO, MI 49001-0199

**TELEPHONE NUMBERS:**

(616) 833-5122 - (24 Hours, Emergency)  
(616) 833-7555 - (8:00 AM - 4:30 PM, EST Emergency)  
(800) 253-8600 - (8:00 AM - 4:30 PM, EST)

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**INGREDIENT 1**

**COMMON NAME:** Water.

**% BY WEIGHT:** 98.4% to 98.7%

**CAS NUMBER:** 7732-18-5

**EXPOSURE LIMIT(S):** Not established.

**INGREDIENT 2**

**COMMON NAME:** Benzyl Alcohol.

**% BY WEIGHT:** 0.9% to 1%

**CAS NUMBER:** 100-51-6

**EXPOSURE LIMIT(S):** Not established.

**INGREDIENT 3**

**COMMON NAME:** Dinoprost Tromethamine.

**CHEMICAL NAME:** Prosta-5,13-dien-1-oic acid, 9,11,15-trihydroxy-, (5Z,9,11,13E,15S)-,compd. with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)

**% BY WEIGHT:** 0.6% - 0.7%

**CAS NUMBER:** 38562-01-5

**EXPOSURE LIMIT(S):** PHARMACIA & UPJOHN

EXPOSURE LIMIT-TWA: 1 g/m<sup>3</sup>

PHARMACIA & UPJOHN EXPOSURE LIMIT-STEL:

10 g/m<sup>3</sup> Prostaglandin F2 alpha tromethamine salt

**EXPOSURE LIMIT(S) FOR THE MATERIAL:** Not established.

### 3. HAZARDS IDENTIFICATION/ PRIMARY ROUTE(S) OF EXPOSURE:

**PRIMARY ROUTE(S) OF EXPOSURE:** Skin contact, eye contact, inhalation, and ingestion.

**EFFECTS OF OVEREXPOSURE:** This product contains the potent and naturally occurring prostaglandin F2 alpha

(dinoprost) as the tromethamine salt. Dinoprost tromethamine stimulates smooth-muscle contraction. Inhalation of small quantities can induce dose-related respiratory effects including bronchoconstriction, wheezing, coughing, irritation, rapid breathing and anaphylaxis in some individuals. Asthmatic individuals may be more susceptible. Dinoprost has been administered orally to pregnant women to induce labor (30 mg to >100 mg). Overexposure to this material can cause uterine contractions, vaginal bleeding, uterine and urinary infections and other reproductive effects (including prevention or termination of pregnancy). Pregnant women should avoid all exposure. Gastrointestinal disturbances may also occur including abdominal cramping, diarrhea, vomiting and nausea. Other effects of overexposure may include increased pulse rate, elevated blood pressure, chills, fever and anorexia. Effects are dose related. Some more lipophilic prostaglandins have been shown to be readily absorbed through the skin. Significant absorption through intact skin of this material sufficient to produce pharmacologic activity is not anticipated from a short-term accidental exposure, but adequate studies have not been done. High doses of dinoprost lasting several weeks have also been shown in animal studies to induce bone proliferation. Chronic overexposure may also cause kidney, liver, ovarian and testicular damage.

**MEDICAL CONDITIONS AGGRAVATED BY**

**EXPOSURE:** Dinoprost tromethamine is contraindicated in persons with acute pelvic inflammatory disease or active heart, lung, kidney or liver disease or known hypersensitivity to this material. Caution should also be exercised for persons with a history of asthma, glaucoma, hypertension, epilepsy or cardiovascular disease.

### 4. FIRST AID MEASURES

**EYES:** Flush with water for 15 minutes. Hold eyelids open to assure complete contact with water.

**SKIN:** Wash with soap and water. Remove contaminated clothing.

**INHALATION:** Remove from exposure.

**INGESTION:** Contact a physician or poison control center.

**SELF-INJECTION:** Call a physician.

**NOTES TO PHYSICIAN:** The time of onset and duration of symptoms resulting from accidental overexposure is expected to be relatively rapid. The biological half-life of dinoprost tromethamine is no more than a few minutes.

### 5. FIRE FIGHTING MEASURES

**FLASH POINT:** Nonflammable.

**LOWER EXPLOSION LIMIT (LEL):** Not applicable.

**UPPER EXPLOSION LIMIT (UEL):** Not applicable.

**EXTINGUISHING MEDIA:** Water, carbon dioxide or dry chemical.

# Pharmacia & Upjohn

Agent ID# 40645

## LUTALYSE® Sterile Solution MATERIAL SAFETY DATA SHEET

**FIRE FIGHTING PROCEDURES:** Wear self-contained breathing apparatus and full-body protective equipment.

**UNUSUAL FIRE OR EXPLOSION HAZARDS:** None known.

**HAZARDOUS COMBUSTION PRODUCTS:** Carbon monoxide. Carbon dioxide.

### 6. ACCIDENTAL RELEASE MEASURES

#### STEPS TO BE TAKEN IN CASE MATERIAL IS

**RELEASED OR SPILLED:** Wear appropriate personal protective equipment. Absorb spilled liquid on paper towels or other appropriate media. Wash spill site with dilute bleach when material pickup is complete. Dinoprost tromethamine can be inactivated in dilute bleach (1 hour).

### 7. HANDLING AND STORAGE

#### PRECAUTIONS FOR HANDLING AND STORAGE:

Harmful if swallowed, inhaled or absorbed through skin. Use protective equipment and good work practices to avoid exposure. Pregnant females should avoid all exposure. Wash thoroughly after handling. Launder contaminated clothing before reuse. Store in a cool dry place. Protect from light. Keep out of reach of children.

### 8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

**RESPIRATORY PROTECTION:** Approved respirator if there is opportunity for splash or mist or aerosol generation especially with large quantities.

**VENTILATION:** Local exhaust.

**PROTECTIVE GLOVES:** Rubber.

**EYE PROTECTION:** Safety glasses with side shields.

**OTHER PROTECTIVE EQUIPMENT:** Protective covering for exposed areas of skin.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**APPEARANCE/PHYSICAL STATE:** Clear liquid.

**FREEZING POINT:** 0°C (32°F)

**MOLECULAR WEIGHT:** Mixture. **pH:** 7.8 to 8.2

**SOLUBILITY IN WATER:** Soluble.

**SPECIFIC GRAVITY (WATER=1):** 0.996 to 1.004

**VOLATILITY:** 99.5%

### 10. STABILITY AND REACTIVITY

**STABILITY:** Stable.

**PHYSICAL CONDITIONS TO AVOID:** None.

**INCOMPATIBILITY WITH OTHER MATERIALS:** None.

**HAZARDOUS DECOMPOSITION PRODUCTS:** None.

**HAZARDOUS POLYMERIZATION:** Does not occur.

### 11. TOXICOLOGICAL INFORMATION

#### ACUTE STUDIES:

**DERMAL TOXICITY (RAT):** PGF2 alpha was relatively nontoxic when applied to abraded or intact skin. May slightly retard healing of abraded skin (7205/77/7263/005).

**SENSITIZATION:** No anaphylactic sensitizing potential was observed for dinoprost tromethamine in studies with the guinea pig.

**INTRAVENOUS LD50 (MOUSE):** 590 mg/kg (female); 679 mg/kg (male) (3102/71/7263/003) (dinoprost tromethamine).

**ORAL TOXICITY (HUMAN):** 30-mg orally of dinoprost tromethamine was the no observable effect dose in non-pregnant women and men. The no-effect dose in pregnant women is less (approximately 5 mg).

**ORAL LD50 (MOUSE):** 711 mg/kg (dinoprost tromethamine)

#### OTHER STUDIES:

**GENOTOXICITY:** Dinoprost tromethamine was negative in the Ames assay and DNA damage/ alkaline elution assay.

**REPRODUCTION/FERTILITY:** Treatment of pregnant rats with PGF2 alpha tromethamine salt at embryocidal dose levels (1 or 3 mg/kg/day) did not impair subsequent fertility or pregnancy.

**TERATOGENICITY:** Administration of 0.5 mg/kg/day dinoprost tromethamine subcutaneously to pregnant rats during organogenesis phase resulted in rib and vertebra defects, possibly due to decreased oxygen to the fetus as a result of uterine contractions or decreased uterine blood supply. Malformations observed in surviving fetuses of rabbits following subcutaneous administration suggest teratogenic activity in this species (5301/71/7263/024).

Many other studies showed no evidence of teratogenicity.

**CARCINOGENICITY:** Ingredient(s) are not listed as carcinogenic by IARC, NTP, or OSHA.

### 12. DISPOSAL CONSIDERATIONS

**WASTE DISPOSAL METHOD:** Dispose of by incineration in accordance with applicable international, national, state and/or local waste disposal regulations.

### 13. SHIPPING REGULATIONS

Not regulated for transportation by the United States Department of Transportation (DOT), International Maritime

Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.

## 14. OTHER INFORMATION

**PREPARED BY:** Environment & Safety.

**DISCLAIMER:** The MSDS information is believed to be correct but should only be used as a guide. Pharmacia & Upjohn disclaims any express or implied warranty as to the accuracy of the MSDS information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the information.

## 15. LABELING

This drug is subject to FDA labeling requirements; therefore, it is exempt from the labeling requirements of the OSHA Hazard Communication Standard.

NDC 0009-0327-03  
NDC 0009-0327-10

*June 23, 1997*