1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: LUTALYSE® Sterile Solution
SYNONYMS: 474550 - EDP Number, 474554 - EDP Number
MOLECULAR FORMULA: Mixture
CHEMICAL FAMILY: Prostaglandin
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 CO., A SUBSIDIARY OF PHARMACIA CORP.
7171 PORTAGE RD
KALAMAZOO, MI 49001-0199
TELEPHONE NUMBERS:
(616) 833-5122-(24 Hours)
(616) 833-7555 - (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-l-oic acid, 9,11,15-trihydroxy-, (5Z,9a,11a,13£,15S)-, compd. with 2-amino-2-(hydroxy-methyl)-1,3-propanediol
% BY WEIGHT: 0.6% - 0.7%
CAS NUMBER: 38562-01-5
EXPOSURE LIMIT(S): PHARMACIA & UPJOHN
PHARMACIA & UPJOHN EXPOSURE LIMIT-TWA: 1 ug/m³
PHARMACIA & UPJOHN EXPOSURE LIMIT-STEL: 10 ug/m³ (Prostaglandin F2 alpha tromethamine salt)
EXPOSURE LIMIT(S) FOR THE MATERIAL: Not established.

3. HAZARDS IDENTIFICATION

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

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: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
SKIN: Wash off with soap and water. Take off all contaminated clothing immediately.
INHALATION: Move to fresh air.
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.
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. When material pickup is complete, wash spill site with neutral chlorine (sodium dichloro-triazine-trione: commercial names - Diklor or "Spa bleach") for at least one minute. Optimum concentration of the chlorine solution is 1% wt/volume (1 gram/100 ml water).

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%
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

REVIEWED BY: Environment & Safety.

DISCLAIMER: The information contained in the MSDS is believed to be correct as of its date of issuance. BY MAKING THE MSDS AVAILABLE, PHARMACIA & UPJOHN CO. DOES NOT MAKE ANY EXPRESS OR IMPLIED WARRANTY (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) REGARDING THE MSDS, ITS ACCURACY OR THE PRODUCT TO WHICH IT RELATES. Anyone using this information agrees that Pharmacia & Upjohn shall not be held liable (based on its negligence or otherwise) for any personal injury or other damage relating to, or arising from such use, including direct, incidental, or consequential damage and such user agrees to indemnify Pharmacia & Upjohn for any claims arising out of its use.

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

July 31, 2001