



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

Page 1 of 6

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

Pfizer Inc
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Pfizer Ltd
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Sandwich, Kent
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Dinoprostone Solution for Infusion

Trade Name: PROSTINE E2
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for smooth muscle stimulation

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Dinoprostone	363-24-6	206-656-6	1
Ethanol	64-17-5	200-578-6	99

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

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution with a characteristic alcohol odor
Signal Word: WARNING

Statement of Hazard: Highly flammable liquid and vapor.
May be harmful if swallowed.
Causes eye irritation.
Causes skin irritation.
May damage fertility or the unborn child.
May cause damage to liver, central nervous system through prolonged or repeated exposure.

Additional Hazard Information:

Short Term: May cause irritation of respiratory tract. Breathing high vapor concentrations may cause central nervous system (CNS) depression resulting in dizziness, light-headedness, headache, nausea, and loss of coordination. Continued inhalation may result in unconsciousness and death. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus. Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and congenital malformations.

Known Clinical Effects: Clinical use of this drug has caused hot flashes diarrhea nausea vomiting May cause low blood pressure and dizziness. Uterine contractions, vaginal bleeding, and prevention/termination of pregnancy have been seen in women taking this drug.

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprostone Solution for Infusion
Revision date: 15-Dec-2006

Page 2 of 6
Version: 1.1

EU Indication of danger: F - Highly flammable
Toxic to reproduction: Category 1

EU Hazard Symbols:



EU Risk Phrases: R11 - Highly flammable.
R60 - May impair fertility.

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.

4. FIRST AID MEASURES

Eye Contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Carbon monoxide and carbon dioxide

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

Fire / Explosion Hazards: Highly flammable. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment. Ground and bond containers when transferring material.

Measures for Cleaning / Collecting: Contain the source of the spill or leak. Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.

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

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprostone Solution for Infusion
Revision date: 15-Dec-2006

Page 3 of 6
Version: 1.1

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: Flammable liquid and vapor- keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after handling. Keep containers closed when not in use. Avoid breathing vapor or mist.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Dinoprostone

Pfizer OEL TWA-8 Hr: 0.5 ug/m³, Skin
Pfizer STEL 2ug/m³, Skin

Ethanol

OSHA - Final PELs - TWAs: = 1000 ppm TWA
= 1900 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA
Australia TWA = 1880 mg/m³ TWA

Analytical Method: Analytical method available for Dinoprostone. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Not required for the normal use of this product. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. 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, colorless
Molecular Formula: Mixture **Molecular Weight:** Mixture

Boiling Point (°C): 78.3 based on lowest component boiling point: Ethanol
Vapor Pressure (kPa): 5.9 (20 °C)
Vapor Density (g/ml): 1.59 (Ethanol)

Flash Point (Liquid) (°C): 12.8 Closed cup (Ethanol)
Upper Explosive Limits (Liquid) (% by Vol.): 19
Lower Explosive Limits (Liquid) (% by Vol.): 3.3

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprostone Solution for Infusion
Revision date: 15-Dec-2006

Page 4 of 6
Version: 1.1

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition.
Incompatible Materials: Acids, Bases, Strong oxidising agents.
Polymerization: Will not occur

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)

Ethanol

Mouse Oral LD50 3,450 g/m³
Rat Oral LD50 7,060 mg/kg
Mouse Inhalation LC50 4h 39 g/m³
Rat Inhalation LC50 10h 20,000 ppm

Dinoprostone

Rat Oral LD 50 500 mg/kg
Rat Intravenous LD 50 59.5 mg/kg
Rat Subcutaneous LD 50 31.6 mg/kg
Mouse Oral LD 50 750 mg/kg
Mouse Intravenous LD 50 23.2 mg/kg

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

Ethanol

Eye Irritation Rabbit Severe

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

Dinoprostone

Embryo / Fetal Development Mouse Oral 6 mg/kg LOAEL Fetotoxicity
Embryo / Fetal Development Rat Oral 6 mg/kg LOAEL Fetotoxicity
Embryo / Fetal Development Rat Intraperitoneal 12.5 mg/kg/day LOEL Teratogenic

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

Dinoprostone

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Direct DNA Damage Negative
Micronucleus 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.

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprostone Solution for Infusion
Revision date: 15-Dec-2006

Page 5 of 6
Version: 1.1

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

Ethanol

Fingerling Trout	NPDES	LC50	24 Hours	11,200 mg/L
Rainbow Trout	NPDES	LC50	96 Hours	12,900 mg/L
Fathead minnow	NPDES	LC50	96 Hours	14,200 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

This material is regulated for transportation as a hazardous material/dangerous good. The following refers to all categories of classifications unless specified below.

Proper shipping name:	Ethanol solution
UN / ID No:	UN 1170
Hazard class:	3
Packing group:	II

15. REGULATORY INFORMATION

EU Symbol:	F , T
EU Indication of danger:	F - Highly flammable Toxic to reproduction: Category 1

EU Risk Phrases:

R11 - Highly flammable.
R60 - May impair fertility.

EU Safety Phrases:

S 7 - Keep container tightly closed.
S16 - Keep away from sources of ignition - No smoking.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

WARNING

Highly flammable liquid and vapor.

May be harmful if swallowed.

Causes eye irritation.

Causes skin irritation.

May damage fertility or the unborn child.

May cause damage to liver, central nervous system through prolonged or repeated exposure.

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprostone Solution for Infusion
Revision date: 15-Dec-2006

Page 6 of 6
Version: 1.1

Canada - WHMIS: Classifications

WHMIS hazard class:

Class B, Division 2

Class D, Division 2, Subdivision A



Dinoprostone

Standard for the Uniform Scheduling
for Drugs and Poisons:
EU EINECS List

Schedule 4

206-656-6

Ethanol

California Proposition 65

developmental toxicity, initial date 10/1/87 (when in alcoholic
beverages)

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS List

200-578-6

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by:

Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet