



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
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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 Oral Tablets

Trade Name: PROSTIN(R) 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	0.5 mg ***
Maize starch	9005-25-8	232-679-6	*
Silica colloidal, Ph. Eur.	112945-52-5	Not listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium Stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Lactose Monohydrate	64044-51-5	Not listed	*

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White tablet
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
Causes eye irritation.
Causes skin irritation.
May damage fertility or the unborn child.

Additional Hazard Information:

Short Term: May cause irritation of respiratory tract. 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.

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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.

EU Indication of danger: Harmful
Irritant
Toxic to reproduction: Category 1

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.
R36/37/38 - Irritating to eyes, respiratory system and skin.
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: Not applicable

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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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:

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

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

Maize starch

OSHA - Final PELs - TWAs:

= 15 mg/m³ TWA total

= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)

= 10 mg/m³ TWA

Australia TWA

= 10 mg/m³ TWA

Microcrystalline cellulose

OSHA - Final PELs - TWAs:

= 15 mg/m³ TWA total

= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)

= 10 mg/m³ TWA

Australia TWA

= 10 mg/m³ TWA

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)

= 10 mg/m³ TWA except stearates of toxic metals

Australia TWA

= 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

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:

Not required for the normal use of this product. Wear protective gloves when working with large quantities.

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:

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Physical State: Tablets
Color: White
Molecular Formula: Mixture
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
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)

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

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

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOEL Liver

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

Dinoprostone

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

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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.

Silica colloidal, Ph. Eur.

IARC: Group 3

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Harmful
Irritant
Toxic to reproduction: Category 1

EU Risk Phrases:

R22 - Harmful if swallowed.
R36/37/38 - Irritating to eyes, respiratory system and skin.
R60 - May impair fertility.

EU Safety Phrases:

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S53 - Avoid exposure - obtain special instructions before use.

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OSHA Label:

WARNING

May be harmful if swallowed.

Causes eye irritation.

Causes skin irritation.

May damage fertility or the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Dinoprostone

Standard for the Uniform Scheduling
for Drugs and Poisons:

Schedule 4

EU EINECS List

206-656-6

Maize starch

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

XU

Australia (AICS):

Present

EU EINECS List

232-679-6

Silica colloidal, Ph. Eur.

Australia (AICS):

Present

Lactose Monohydrate

Australia (AICS):

Present

Microcrystalline cellulose

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

XU

Australia (AICS):

Present

EU EINECS List

232-674-9

Magnesium Stearate

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

Present

Australia (AICS):

Present

EU EINECS List

209-150-3

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 5 - Fire Fighting Measures. 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.

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End of Safety Data Sheet