



MATERIAL SAFETY DATA SHEET

Revision date: 05-Feb-2010

Version: 1.2

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Material Name: Dinoprostone Vaginal Gel

Trade Name:	PROSTIN E2; PREPIDIL GEL; PROSTIN
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used for smooth muscle stimulation

2. HAZARDS IDENTIFICATION

Appearance:	Colorless gel
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.
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. Symptoms reported after accidental human exposure have included respiratory system, skin, and eye irritation.
EU Indication of danger:	Not classified

Australian Hazard Classification (NOHSC):	Non-Hazardous Substance. Non-Dangerous Goods.
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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.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Silica gel, amorphous	112926-00-8	Not listed	Not Listed	*
Dinoprostone	363-24-6	206-656-6	Xn;R22 Repr.Cat.1;R61	<0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Triacetin	102-76-1	203-051-9	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: 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: Fine particles (such as dust and mists) may fuel fires/explosions.

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: Clean spill area thoroughly. Use absorbent material to wipe up spill and place in a sealed container for disposal.

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

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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 hands and any exposed skin after removal of PPE. 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.

Silica gel, amorphous

Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Finland OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	- (80)/(% SiO ₂) mg/m ³ TWA TWA-20 mppcf
Poland OEL - TWA	Listed
Spain OEL - TWA	Listed

Dinoprostone

Pfizer OEL TWA-8 Hr: 0.5 µg/m³, Skin

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. 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: Wear impervious gloves if skin contact is possible.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Wear protective clothing when working with large quantities.

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:	Gel	Color:	Colourless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: Will not occur

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10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
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)

Triacetin

Rat Oral LD 50 3000 mg/kg
Mouse Oral LD 50 1100 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

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

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Skin Sensitization - GPMT Guinea Pig Negative

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

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 gel, amorphous

IARC: Group 3

12. ECOLOGICAL INFORMATION

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

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13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Triacetin

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	203-051-9

Silica gel, amorphous
Australia (AICS):

Listed

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15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	206-656-6

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R61 - May cause harm to the unborn child.

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on
Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and
Storage. Updated Section 11 - Toxicology Information.

Prepared by:

Toxicology and 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