



SAFETY DATA SHEET

Revision date: 04-Apr-2015

Version: 1.6

Page 1 of 8

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

Product Identifier

Material Name: Dinoprostone Endocervical Gel

Trade Name: PREPIDIL; PROSTIN E2; MINPROSTIN

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used for smooth muscle stimulation

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

No data available

Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

SAFETY DATA SHEET

Material Name: Dinoprostone Endocervical Gel
Revision date: 04-Apr-2015

Page 2 of 8
Version: 1.6

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Dinoprostone	363-24-6	206-656-6	Xn;R22 Repr.Cat.1;R61	Acute tox. 4 (H302) Repr.1A (H360FD)	<0.1
Silica gel, amorphous	112926-00-8	Not Listed	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Triacetin	102-76-1	203-051-9	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Carbon monoxide and carbon dioxide

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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

SAFETY DATA SHEET

Material Name: Dinoprostone Endocervical Gel
Revision date: 04-Apr-2015

Page 3 of 8
Version: 1.6

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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

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

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Dinoprostone

Pfizer OEL TWA-8 Hr: 0.5 µg/m³, Skin

Silica gel, amorphous

Australia TWA	10 mg/m ³
Austria OEL - MAKs	4 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Finland OEL - TWA	5 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf Listed
Poland OEL - TWA	10.0 mg/m ³
	2 mg/m ³
Switzerland OEL -TWAs	4 mg/m ³

Analytical Method:

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

Exposure Controls

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.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

SAFETY DATA SHEET

Material Name: Dinoprostone Endocervical Gel
Revision date: 04-Apr-2015

Page 4 of 8
Version: 1.6

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Silica gel, amorphous

No data available

Triacetin

No data available

Dinoprostone

Predicted 7.4 Log D 0.356

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable at normal conditions

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

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

Hazardous Decomposition Products: No data available

SAFETY DATA SHEET

Material Name: Dinoprostone Endocervical Gel
Revision date: 04-Apr-2015

Page 5 of 8
Version: 1.6

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

The information included in this section describes the potential hazards of the individual ingredients.

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.

Acute Toxicity: (Species, Route, End Point, Dose)

Triacetin

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

Dinoprostone

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

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

Dinoprostone

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 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.

Silica gel, amorphous

IARC:

Group 3 (Not Classifiable)

SAFETY DATA SHEET

Material Name: Dinoprostone Endocervical Gel
Revision date: 04-Apr-2015

Page 6 of 8
Version: 1.6

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)

Dinoprostone
Predicted 7.4 Log D 0.356

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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.

SAFETY DATA SHEET

Material Name: Dinoprostone Endocervical Gel
Revision date: 04-Apr-2015

Page 7 of 8
Version: 1.6

15. REGULATORY INFORMATION

Dinoprostone

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	206-656-6

Triacetin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-051-9

Silica gel, amorphous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.

Toxic to reproduction: Category 1
Xn - Harmful

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage.

Revision date: 04-Apr-2015

Product Stewardship Hazard Communication

Prepared by: 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.

SAFETY DATA SHEET

Material Name: Dinoprostone Endocervical Gel
Revision date: 04-Apr-2015

Page 8 of 8
Version: 1.6

End of Safety Data Sheet