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

Material Name: Dinoprostone Endocervical Gel

| Trade Name: | PREPIDIL; PROSTIN E2; MINPROSTIN |
| 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


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.
3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Dinoprostone</td>
<td>363-24-6</td>
<td>206-656-6</td>
<td>Xn;R22</td>
<td>&lt;0.1</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat.1;R61</td>
<td></td>
</tr>
<tr>
<td>Silica gel, amorphous</td>
<td>112926-00-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

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

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: 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.

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.

Dinoprostone
- Pfizer OEL TWA-8 Hr: 0.5 µg/m³, Skin
- Silica gel, amorphous
  - Australia TWA: 10 mg/m³
  - Austria OEL - MAKs: 4 mg/m³
  - Belgium OEL - TWA: 10 mg/m³
  - Bulgaria OEL - TWA: 10.0 mg/m³
  - Finland OEL - TWA: 5 mg/m³
  - OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf Listed
  - Poland OEL - TWA: 10.0 mg/m³ 2 mg/m³


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
- Molecular Formula: Mixture
- Color: Colourless
- Molecular Weight: Mixture

Polymerization: Will not occur

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10. STABILITY AND REACTIVITY

Chemical 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 Para-periosteal 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)

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)

12. ECOLOGICAL INFORMATION

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

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.

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

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

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15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Australia (AICS):</th>
<th>Present</th>
</tr>
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<tbody>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>203-051-9</td>
</tr>
</tbody>
</table>

Silica gel, amorphous

| Australia (AICS): | Present |

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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.

Prepared by: Product Stewardship 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