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

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):


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

PZ00258
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dinoprostone</td>
<td>363-24-6</td>
<td>206-656-6</td>
<td>Xn;R22</td>
<td>Acute tox. 4 (H302)</td>
<td>&lt;0.1</td>
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<tr>
<td>Silica gel, amorphous</td>
<td>112926-00-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triacetin</td>
<td>102-76-1</td>
<td>203-051-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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: None known

Aggravated by Exposure: None

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.
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/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
Switzerland OEL -TWAs: 4 mg/m³


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).
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Gel</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
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<tr>
<td>Water Solubility</td>
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<tr>
<td>pH</td>
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<td>Melting/Freezing Point (°C)</td>
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<tr>
<td>Boiling Point (°C)</td>
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<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<tr>
<td>Silica gel, amorphous</td>
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<tr>
<td>Triacetin</td>
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<tr>
<td>Dinoprostone</td>
<td>Predicted 7.4 Log D 0.356</td>
</tr>
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<td>Decomposition Temperature (°C):</td>
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<td>Evaporation Rate (Gram/s)</td>
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<td>Vapor Pressure (kPa)</td>
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<td>Vapor Density (g/ml)</td>
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<td>Relative Density</td>
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<td>Viscosity</td>
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<td>Flammability</td>
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<td>Autoignition Temperature (Solid) (°C):</td>
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<tr>
<td>Flammability (Solids)</td>
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<td>Flash Point (Liquid) (°C):</td>
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<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
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<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
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</tr>
<tr>
<td>Polymerization</td>
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</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
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<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable at normal conditions</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
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<tr>
<td>Oxidizing Properties</td>
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<tr>
<td>Conditions to Avoid</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
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</tr>
</tbody>
</table>
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 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.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

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.
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
Prepared by: Product Stewardship Hazard Communication

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