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

Product Identifier

Material Name: Prempro Tablets

Trade Name: PREMPRO, PREMIA, PREMELLE
Synonyms: Conjugated Estrogens and Medroxyprogesterone Acetate Tablets
Chemical Family: Steroid

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

Intended Use: Pharmaceutical product used for hormone replacement therapy

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:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 1A
Carcinogenicity: Category 1A

Label Elements

Signal Word: Danger
Hazard Statements:
H350 - May cause cancer
H360FD - May damage fertility. May damage the unborn child.

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
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<tr>
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<td>7778-18-9</td>
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<tr>
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<td>Medroxyprogesterone acetate</td>
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<td>Sucrose</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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<td>Tricalcium Phosphate</td>
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<td>Methylcellulose</td>
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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 CLP/GHS abbreviations mentioned in this Section, see Section 16
4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.

Skin Contact: Wash off immediately with soap and plenty of 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: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting 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: 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.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
7. HANDLING AND STORAGE

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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.

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.

Calcium sulfate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Austria OEL - MAKs 5 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
France OEL - TWA 10 mg/m³
Germany - TRGS 900 - TWAs 6 mg/m³
Germany (DFG) - MAK 1.5 mg/m³
Hungary OEL - TWA 6 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 4 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 6 mg/m³
Slovenia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³

Conjugated estrogens

Pfizer OEL TWA-8 Hr: 0.15µg/m³

Magnesium stearate

Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Medroxyprogesterone acetate

Pfizer OEL TWA-8 Hr: 2 µg/m³, Skin

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³

4 mg/m³
SAFETY DATA SHEET

Material Name: Prempro Tablets
Revision date: 05-Feb-2018

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Version: 2.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>OEL - TWA</th>
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<tr>
<td>Russia OEL - TWA</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWA</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
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<tr>
<td></td>
<td>5 mg/m³</td>
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</tbody>
</table>

Polyethylene glycol
- Austria OEL - MAKs: 1000 mg/m³
- Germany - TRGS 900 - TWAs: 1000 mg/m³
- Germany (DFG) - MAK: 1000 mg/m³ average molecular weight 200-600
- Slovakia OEL - TWA: 1000 mg/m³
- Slovenia OEL - TWA: 1000 mg/m³
- Switzerland OEL - TWA: 1000 mg/m³

Sucrose
- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: 10 mg/m³
- Bulgaria OEL - TWA: 10.0 mg/m³
- Estonia OEL - TWA: 10 mg/m³
- France OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- Latvia OEL - TWA: 5 mg/m³
- Lithuania OEL - TWA: 10 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Slovakia OEL - TWA: 6 mg/m³
- Spain OEL - TWA: 10 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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Respiratory protection:** Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

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</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| Solvent Solubility:     | No data available.                   | Odor Threshold:   | No data available.              |
| Water Solubility:       | No data available.                   | Odor Threshold:   | No data available.              |
| pH:                     | No data available.                   | Odor Threshold:   | No data available.              |
| Melting/Freezing Point (°C): | No data available.            | Odor Threshold:   | No data available.              |
| Boiling Point (°C):     | No data available.                   | Odor Threshold:   | No data available.              |
| Partition Coefficient:  | (Method, pH, Endpoint, Value)        | Odor Threshold:   | No data available.              |
| Lactose NF, monohydrate | No data available.                   | Odor Threshold:   | No data available.              |
| Conjugated estrogens    | No data available.                   | Odor Threshold:   | No data available.              |
| Methylcellulose         | No data available.                   | Odor Threshold:   | No data available.              |
| Medroxyprogesterone acetate | No data available.             | Odor Threshold:   | No data available.              |
| Hydroxypropyl methylcellulose | No data available.     | Odor Threshold:   | No data available.              |
| Magnesium stearate      | No data available.                   | Odor Threshold:   | No data available.              |
| Polyethylene glycol     | No data available.                   | Odor Threshold:   | No data available.              |
| Hydroxypropyl cellulose | No data available.                   | Odor Threshold:   | No data available.              |
| Povidone                | No data available.                   | Odor Threshold:   | No data available.              |
| Calcium sulfate         | No data available.                   | Odor Threshold:   | No data available.              |
| Sucrose                 | No data available.                   | Odor Threshold:   | No data available.              |
| Glyceryl olate          | No data available.                   | Odor Threshold:   | No data available.              |
| Decomposition Temperature (°C): | No data available.          | Odor Threshold:   | No data available.              |
| Evaporation Rate (Gram/s): | No data available.                | Odor Threshold:   | No data available.              |
| Vapor Pressure (kPa):   | No data available.                   | Odor Threshold:   | No data available.              |
| Vapor Density (g/ml):   | No data available.                   | Odor Threshold:   | No data available.              |
| Relative Density:       | No data available.                   | Odor Threshold:   | No data available.              |
| Viscosity:              | No data available.                   | Odor Threshold:   | No data available.              |

| Flammability:           | Autoignition Temperature (Solid) (°C): | No data available |
| Flammability (Solids):  | No data available.                   | Odor Threshold:   | No data available.              |
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
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

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 reproductive system, the developing fetus. Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea).
Known Clinical Effects: Clinical use of this drug has caused effects on cardiovascular system, menstrual irregularities, lack of menstrual periods (amenorrhea), changes in cervical erosion and secretion, breast enlargement, breast pain, breast development in males (gynecomastia), nausea, vomiting, abdominal cramping, weight changes, fluid retention, changes in sexual desire (libido), loss of hair, mental depression.

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

Conjugated estrogens
   Rat  IP  LD50  325 mg/kg
   Mouse  IV  LD50  1740mg/kg
   Rat  Oral  LD50  > 5000mg/kg

Medroxyprogesterone acetate
   Rat  Oral  LD50  > 6,400 mg/kg
   Mouse  Para-periosteal  LD50  376mg/kg
   Rat  Intraperitoneal  LD50  > 400mg/kg
   Rat  Subcutaneous  LD50  > 8000mg/kg

Hydroxypropyl methylcellulose
   Rat  Oral  LD50  > 10,000 mg/kg

Magnesium stearate
   Rat  Oral  LD50  > 2000 mg/kg
   Rat  Inhalation  LC50  > 2000 mg/m³
### 11. TOXICOLOGICAL INFORMATION

**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)

- **Conjugated estrogens**
  - Eye Irritation: Rabbit, Severe

- **Medroxyprogesterone acetate**
  - Eye Irritation: Rabbit, Non-irritating
  - Skin Irritation: Rabbit, Mild

- **Polyethylene glycol**
  - Eye Irritation: Rabbit, Mild
  - Skin Irritation: Rabbit, Mild

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

- **Medroxyprogesterone acetate**
  - 10 Year(s): Monkey, Intramuscular 3 mg/kg, LOAEL, Reproductive system
  - 18 Month(s): Mouse, Intramuscular 200 mg/kg, NOAEL, None identified
  - 24 Month(s): Rat, Intramuscular 200 mg/kg, NOAEL, None identified

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

- **Conjugated estrogens**
  - Embryo / Fetal Development: Rat, Subcutaneous 7 mg/kg/day, LOAEL, Embryotoxicity, Fetotoxicity

- **Medroxyprogesterone acetate**
  - Embryo / Fetal Development: Rat, Intramuscular 3 mg/kg, LOAEL, Embryotoxicity, Not teratogenic
  - Embryo / Fetal Development: Monkey, Intramuscular 25 mg/kg, LOAEL, Developmental toxicity
  - Embryo / Fetal Development: Rabbit, Intramuscular 1 mg/kg, LOAEL, Developmental toxicity
  - Embryo / Fetal Development: Rat, Subcutaneous 1 mg/kg, LOAEL, Developmental toxicity

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

- **Medroxyprogesterone acetate**
  - Bacterial Mutagenicity (Ames): *Salmonella* Negative
  - Micronucleus: Mouse Negative
  - Chromosome Aberration: Rodent germ cell Positive
  - Sister Chromatid Exchange: Rodent Lymphocytes Positive

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
11. TOXICOLOGICAL INFORMATION

Medroxyprogesterone acetate
18 Month(s) Mouse Intramuscular 200 mg/kg/month Not carcinogenic
24 Month(s) Rat Intramuscular 200 mg/kg/month Not carcinogenic
18 Month(s) Dog Intramuscular 0.2 mg/kg LOEL Benign tumors
40 Month(s) Dog Intramuscular 0.3 mg/kg NOAEL Tumors, Mammary gland

Carcinogen Status: See below

Conjugated estrogens
IARC: Group 1
NTP: Listed

Medroxyprogesterone acetate
IARC: Group 2B (Possibly Carcinogenic to Humans)

Povidone
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

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

**Calcium sulfate**
- 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: 231-900-3

**Povidone**
- 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: Not Listed

**Tricalcium Phosphate**
- 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: 231-840-8

**Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion - NF**
- 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: Not Listed

**Glyceryl oleate**
- 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: 247-038-6

**Conjugated estrogens**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Carcinogen, initial date 2/27/87; developmental, initial date 4/1/90
- EU EINECS/ELINCS List: 235-199-5

**Hydroxypropyl cellulose**
- CERCLA/SARA 313 Emission reporting: Not Listed
## 15. REGULATORY INFORMATION

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<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
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<tr>
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<td>Not Listed</td>
<td>California Proposition 65</td>
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15. REGULATORY INFORMATION

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Sucrose

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16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

- Carcinogenicity-Cat.1A; H350 - May cause cancer
- Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 05-Feb-2018

Prepared by: Product Stewardship Hazard Communication

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