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

**International CHEMTREC (24 hours): +1-703-527-3887**

### 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**
- **GHS - Classification**
  - Reproductive Toxicity: Category 1A
  - Carcinogenicity: Category 1A

- **EU Classification:**
  - EU Indication of danger: Carcinogenic: Category 1
  - Toxic to reproduction: Category 1

- **EU Risk Phrases:**
  - R45 - May cause cancer.
  - R60 - May impair fertility.
  - R61 - May cause harm to the unborn child.

**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**

**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

<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>
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</thead>
<tbody>
<tr>
<td>Calcium sulfate</td>
<td>7778-18-9</td>
<td>231-900-3</td>
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<td>235-199-5</td>
<td>Carc. Cat. 1; R45 Rep. Cat. 1; R60 Rep. Cat. 1; R61</td>
<td>Carc. 1A, H350; Rep. 1A, H360FD</td>
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<tr>
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<tr>
<td>Medroxyprogesterone acetate</td>
<td>71-58-9</td>
<td>200-757-9</td>
<td>Carc. Cat. 3; R40 Rep. Cat. 1; R60-61</td>
<td>Carc. 2 (H351) Rep. 1A (H360FD)</td>
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<tr>
<td>Microcrystalline cellulose</td>
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<tr>
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<td>Sucrose</td>
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<td>Not Listed</td>
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</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>
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<tr>
<td>Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion - NF</td>
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<tr>
<td>Glyceryl oleate</td>
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<td>247-038-6</td>
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</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:** 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 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:** 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.
**SAFETY DATA SHEET**

**Material Name:** Prempro Tablets  
**Revision date:** 23-Feb-2015  
**Version:** 2.0

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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.

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**7. HANDLING AND STORAGE**

**Precautions for Safe Handling**
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

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**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
  - 4 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**
- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **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**
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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).

Hands:
Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

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

Skin:
Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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Material Name: Prempro Tablets
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Version: 2.0

WP00068
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>
<th>Notes</th>
</tr>
</thead>
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<tr>
<td>Physical State</td>
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<tr>
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<tr>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
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</tbody>
</table>
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

Povidone
Rat Oral LD50 100 g/kg
11. TOXICOLOGICAL INFORMATION

Sucrose
Rat Oral LD 50 29,700 mg/kg

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

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

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
11. TOXICOLOGICAL INFORMATION

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
15. REGULATORY INFORMATION

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

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

Conjugated estrogens
CERCLA/SARA 313 Emission reporting Not Listed
carcinogen, initial date 2/27/87; developmental, initial date 4/1/90
California Proposition 65 carcinoma, 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
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List Not Listed

Hydroxypropyl methylcellulose
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List Not Listed

Magnesium stearate
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 209-150-3

Medroxyprogesterone acetate
CERCLA/SARA 313 Emission reporting Not Listed
carcinogen initial date 1/1/90
developmental toxicity initial date 4/1/90
California Proposition 65 Not Listed
carcinogen initial date 1/1/90
developmental toxicity initial date 4/1/90
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-757-9
15. REGULATORY INFORMATION

Methylcellulose
- 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

Microcrystalline cellulose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex XVII - Restrictions on Certain Dangerous Substances: Use restricted. See item 9(f). powder
- EU EINECS/ELINCS List: 232-674-9

Polyethylene glycol
- 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

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

Sucrose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 200-334-9

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
15. REGULATORY INFORMATION

| 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 |

16. OTHER INFORMATION

Text of R phrases and 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.

Carcinogenic: Category 1
Toxic to reproduction: Category 1

R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to 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 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 23-Feb-2015
Prepared by: Product Stewardship Hazard Communication

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End of Safety Data Sheet