



# SAFETY DATA SHEET

Revision date: 01-Apr-2015

Version: 4.0

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

### Product Identifier

**Material Name:** Premarin (Conjugated Estrogens) Tablets

**Trade Name:** PREMARIN  
**Synonyms:** Conjugated Estrogens 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

**Emergency telephone number:**  
**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:** 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

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**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
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

| Ingredient           | CAS Number | EU EINECS/ELINCS List | EU Classification                                  | GHS Classification                | %   |
|----------------------|------------|-----------------------|----------------------------------------------------|-----------------------------------|-----|
| Conjugated estrogens | 12126-59-9 | 235-199-5             | Carc.Cat.1;R45<br>Repr.Cat.1;R60<br>Repr.Cat.1;R61 | Carc. 1A,H350;<br>Repr. 1A,H360FD | 0.5 |

| Ingredient                  | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|-----------------------------|------------|-----------------------|-------------------|--------------------|---|
| Calcium sulfate             | 7778-18-9  | 231-900-3             | Not Listed        | Not Listed         | * |
| CELLULOSE (FIBRE DE PAPIER) | 9004-34-6  | 232-674-9             | Not Listed        | Not Listed         | * |
| Lactose NF, monohydrate     | 64044-51-5 | Not Listed            | Not Listed        | Not Listed         | * |
| Methylcellulose             | 9004-67-5  | Not Listed            | Not Listed        | Not Listed         | * |
| Sucrose                     | 57-50-1    | 200-334-9             | 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 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.

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**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 CO<sub>2</sub>, 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.

**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

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/m <sup>3</sup>   |
| Australia TWA                     | 10 mg/m <sup>3</sup>   |
| Austria OEL - MAKs                | 5 mg/m <sup>3</sup>    |
| Belgium OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                | 10.0 mg/m <sup>3</sup> |
| France OEL - TWA                  | 10 mg/m <sup>3</sup>   |
| Germany - TRGS 900 - TWAs         | 6 mg/m <sup>3</sup>    |
| Germany (DFG) - MAK               | 1.5 mg/m <sup>3</sup>  |
|                                   | 4 mg/m <sup>3</sup>    |
| Hungary OEL - TWA                 | 6 mg/m <sup>3</sup>    |
| Ireland OEL - TWAs                | 10 mg/m <sup>3</sup>   |
| Latvia OEL - TWA                  | 4 mg/m <sup>3</sup>    |
| OSHA - Final PELs - TWAs:         | 15 mg/m <sup>3</sup>   |
| Portugal OEL - TWA                | 10 mg/m <sup>3</sup>   |
| Slovakia OEL - TWA                | 6 mg/m <sup>3</sup>    |
| Slovenia OEL - TWA                | 6 mg/m <sup>3</sup>    |
| Spain OEL - TWA                   | 10 mg/m <sup>3</sup>   |
| Switzerland OEL - TWAs            | 3 mg/m <sup>3</sup>    |

#### CELLULOSE (FIBRE DE PAPIER)

|                                   |                      |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m <sup>3</sup> |
| Australia TWA                     | 10 mg/m <sup>3</sup> |
| Belgium OEL - TWA                 | 10 mg/m <sup>3</sup> |
| Estonia OEL - TWA                 | 10 mg/m <sup>3</sup> |
| France OEL - TWA                  | 10 mg/m <sup>3</sup> |
| Ireland OEL - TWAs                | 10 mg/m <sup>3</sup> |
|                                   | 4 mg/m <sup>3</sup>  |
| Latvia OEL - TWA                  | 2 mg/m <sup>3</sup>  |
| OSHA - Final PELs - TWAs:         | 15 mg/m <sup>3</sup> |
| Portugal OEL - TWA                | 10 mg/m <sup>3</sup> |
| Romania OEL - TWA                 | 10 mg/m <sup>3</sup> |
| Russia OEL - TWA                  | 6 mg/m <sup>3</sup>  |
| Spain OEL - TWA                   | 10 mg/m <sup>3</sup> |
| Switzerland OEL - TWAs            | 3 mg/m <sup>3</sup>  |
| Vietnam OEL - TWAs                | 10 mg/m <sup>3</sup> |
|                                   | 5 mg/m <sup>3</sup>  |

#### Conjugated estrogens

|                      |                       |
|----------------------|-----------------------|
| Pfizer OEL TWA-8 Hr: | 0.15µg/m <sup>3</sup> |
|----------------------|-----------------------|

#### Sucrose

|                                   |                        |
|-----------------------------------|------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m <sup>3</sup>   |
| Australia TWA                     | 10 mg/m <sup>3</sup>   |
| Belgium OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                | 10.0 mg/m <sup>3</sup> |
| Estonia OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| France OEL - TWA                  | 10 mg/m <sup>3</sup>   |
| Ireland OEL - TWAs                | 10 mg/m <sup>3</sup>   |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                           |                      |
|---------------------------|----------------------|
| Latvia OEL - TWA          | 5 mg/m <sup>3</sup>  |
| Lithuania OEL - TWA       | 10 mg/m <sup>3</sup> |
| OSHA - Final PELs - TWAs: | 15 mg/m <sup>3</sup> |
| Portugal OEL - TWA        | 10 mg/m <sup>3</sup> |
| Slovakia OEL - TWA        | 6 mg/m <sup>3</sup>  |
| Spain OEL - TWA           | 10 mg/m <sup>3</sup> |

#### 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.

**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

|                           |                    |                          |                        |
|---------------------------|--------------------|--------------------------|------------------------|
| <b>Physical State:</b>    | Tablets            | <b>Color:</b>            | Blue, Green, or Maroon |
| <b>Odor:</b>              | No data available. | <b>Odor Threshold:</b>   | No data available.     |
| <b>Molecular Formula:</b> | Mixture            | <b>Molecular Weight:</b> | 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)**

**Lactose NF, monohydrate**

No data available

**Conjugated estrogens**

No data available

**Sucrose**

No data available

**Calcium sulfate**

No data available

**CELLULOSE (FIBRE DE PAPIER)**

No data available

**Methylcellulose**

No data available

**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

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### 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 |

## 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 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 |

#### Sucrose

|     |      |       |              |
|-----|------|-------|--------------|
| Rat | Oral | LD 50 | 29,700 mg/kg |
|-----|------|-------|--------------|

#### CELLULOSE (FIBRE DE PAPIER)

|        |            |       |                     |
|--------|------------|-------|---------------------|
| Rabbit | Dermal     | LD 50 | > 2000 mg/kg        |
| Rat    | Inhalation | LC 50 | > 5.05 mg/L/4 hours |
| Rat    | Oral       | LD 50 | > 5000mg/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)

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### 11. TOXICOLOGICAL INFORMATION

#### Conjugated estrogens

Eye Irritation   Rabbit   Severe

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

#### Conjugated estrogens

Embryo / Fetal Development   Rat   Subcutaneous7 mg/kg/day   LOAEL   Embryotoxicity, Fetotoxicity

#### Carcinogen Status:

See below

#### Conjugated estrogens

IARC:

Group 1

NTP:

Listed

### 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.

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### 15. REGULATORY INFORMATION

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

##### 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  |

##### CELLULOSE (FIBRE DE PAPIER)

|                                                                    |                                       |
|--------------------------------------------------------------------|---------------------------------------|
| 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                             |

##### 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                                                            |

##### Lactose NF, monohydrate

|                                                                 |            |
|-----------------------------------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting                              | Not Listed |
| California Proposition 65                                       | Not Listed |
| Australia (AICS):                                               | Present    |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present    |
| EU EINECS/ELINCS List                                           | Not Listed |

##### 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 |

##### Sucrose

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### 15. REGULATORY INFORMATION

|                                                                 |            |
|-----------------------------------------------------------------|------------|
| 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  |

### 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 16 - Other Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Revision date:** 01-Apr-2015

**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**