



MATERIAL SAFETY DATA SHEET

Revision date: 31-Jul-2012

Version: 3.1

Page 1 of 8

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Premarin (Conjugated Estrogens) Tablets

| | |
|-------------------------|-------------------------------------------------------------|
| Trade Name: | PREMARIN |
| Synonyms: | Conjugated Estrogens Tablets |
| Chemical Family: | Steroid |
| Intended Use: | Pharmaceutical product used for hormone replacement therapy |

2. HAZARDS IDENTIFICATION

Appearance: Blue, Green or Maroon Tablets
Signal Word: DANGER

Statement of Hazard: May cause cancer.
May damage fertility or the unborn child.

Additional Hazard Information:
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

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

EU Hazard Symbols:



MATERIAL SAFETY DATA SHEET

Material Name: Premarin (Conjugated Estrogens) Tablets
Revision date: 31-Jul-2012

Page 2 of 8
Version: 3.1

2. HAZARDS IDENTIFICATION

EU Risk Phrases:

R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|----------------------|------------|-----------------------|----------------------------------------------------|-----|
| Conjugated estrogens | 12126-59-9 | 235-199-5 | Carc.Cat.1;R45 Repr.Cat.1;R60 Repr.Cat.1;R61 | 0.5 |

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

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Premarin (Conjugated Estrogens) Tablets
Revision date: 31-Jul-2012

Page 3 of 8
Version: 3.1

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

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: 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.

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: 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.

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.

Calcium sulfate

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

MATERIAL SAFETY DATA SHEET

Material Name: Premarin (Conjugated Estrogens) Tablets
Revision date: 31-Jul-2012

Page 4 of 8
Version: 3.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|--------------------|----------------------|
| Slovenia OEL - TWA | 6 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |

Conjugated estrogens

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

CELLULOSE (FIBRE DE PAPIER)

| | |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Estonia OEL - TWA | 10 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| Latvia OEL - TWA | 2 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |

Sucrose

| | |
|-----------------------------------|------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Bulgaria OEL - TWA | 10.0 mg/m ³ |
| Estonia OEL - TWA | 10 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| Latvia OEL - TWA | 5 mg/m ³ |
| Lithuania OEL - TWA | 10 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Slovakia OEL - TWA | 6 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |

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:

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.

MATERIAL SAFETY DATA SHEET

Material Name: Premarin (Conjugated Estrogens) Tablets
Revision date: 31-Jul-2012

Page 5 of 8
Version: 3.1

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|--------------------|---------|-------------------|------------------------|
| Physical State: | Tablets | Color: | Blue, Green, or Maroon |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |

10. STABILITY AND REACTIVITY

| | |
|-------------------------|--------------------------------------------------------------------|
| Chemical Stability: | Stable under normal conditions of use. |
| 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)

Conjugated estrogens

| | | | |
|-------|------|------|--------------|
| Rat | IP | LD50 | 325 mg/kg |
| Mouse | IV | LD50 | 1740 mg/kg |
| Rat | Oral | LD50 | > 5000 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 | > 5000 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 |
|----------------|--------|--------|

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

| | |
|--------------------|-----------|
| Carcinogen Status: | See below |
|--------------------|-----------|

Conjugated estrogens

| | |
|-------|---------|
| IARC: | Group 1 |
| NTP: | Listed |

MATERIAL SAFETY DATA SHEET

Material Name: Premarin (Conjugated Estrogens) Tablets
Revision date: 31-Jul-2012

Page 6 of 8
Version: 3.1

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 Symbol: T
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.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
May cause cancer.
May damage fertility or the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

MATERIAL SAFETY DATA SHEET

Material Name: Premarin (Conjugated Estrogens) Tablets
Revision date: 31-Jul-2012

Page 7 of 8
Version: 3.1

15. REGULATORY INFORMATION



Calcium sulfate

| | |
|---------------------------------------------|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 231-900-3 |

Conjugated estrogens

| | |
|---------------------------|----------------------------------------------------------------------|
| California Proposition 65 | carcinogen, initial date 2/27/87; developmental. initial date 4/1/90 |
| EU EINECS/ELINCS List | 235-199-5 |

CELLULOSE (FIBRE DE PAPIER)

| | |
|---------------------------------------------|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 232-674-9 |

Lactose NF, monohydrate

| | |
|-------------------|---------|
| Australia (AICS): | Present |
|-------------------|---------|

Methylcellulose

| | |
|---------------------------------------------|---------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |

Sucrose

| | |
|-----------------------------------------------------------------|-----------|
| 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 mentioned in Section 3

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.

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

MATERIAL SAFETY DATA SHEET

Material Name: Premarin (Conjugated Estrogens) Tablets
Revision date: 31-Jul-2012

Page 8 of 8
Version: 3.1
