



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
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
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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 Repr.Cat.1;R60 Repr.Cat.1;R61	Carc. 1A,H350; 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 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.

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 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
Slovenia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/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
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³
	5 mg/m ³

Conjugated estrogens

Pfizer OEL TWA-8 Hr:	0.15µg/m ³
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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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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

Physical State:	Tablets	Color:	Blue, Green, or Maroon
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	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 Subcutaneous 7 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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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

Product Stewardship Hazard Communication

Prepared by: 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