



MATERIAL SAFETY DATA SHEET

Revision date: 19-Dec-2011

Version: 1.2

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

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Material Name: Conjugated Estrogens Vaginal Cream (US)

Trade Name:	PREMARIN
Chemical Family:	Steroid
Intended Use:	Pharmaceutical product used for hormone replacement therapy

2. HAZARDS IDENTIFICATION

Appearance: White Cream

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term:	May cause eye and skin irritation (based on components)
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: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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2. HAZARDS IDENTIFICATION

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	0.0625
Cetyl alcohol	36653-82-4	253-149-0	Not Listed	*
Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Glyceryl monostearate	31566-31-1	250-705-4	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
White wax	8006-40-4	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Methyl stearate	112-61-8	Not Listed	Not Listed	*
Mineral oil, white	8042-47-5	232-455-8	Not Listed	*
Cetyl stearate	1190-63-2	Not Listed	Not Listed	*
Fatty acids, C16-18, esters with propylene glycol	91031-35-5	Not Listed	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.

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5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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 spill with absorbent material. 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: Avoid breathing mist or aerosols. 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.

Conjugated estrogens	
Pfizer OEL TWA-8 Hr:	0.15µg/m ³
Cetyl alcohol	
Germany - TRGS 900 - TWAs	20 ppm 200 mg/m ³
Benzyl Alcohol	
Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm 45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Glycerin, USP

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Czech Republic OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
Finland OEL - TWA 20 mg/m³
France OEL - TWA 10 mg/m³
Germany (DFG) - MAK 50 mg/m³ inhalable fraction
Greece OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Mineral oil, white

ACGIH Threshold Limit Value (TWA) 5 mg/m³
ACGIH Threshold Limit Value (STEL) 10 mg/m³ (oil mist)

Glyceryl monostearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Cream

Color:

White

Molecular Formula:

Mixture

Molecular Weight:

Mixture

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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)

Benzyl Alcohol

Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53 mg/kg
Rat Inhalation LC50 46 mg/m³

Cetyl alcohol

Rat Oral LD50 5000 mg/kg
Rabbit Dermal LD50 > 2,600 mg/kg
Mouse Oral LD50 3200 mg/kg

Glycerin, USP

Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1hr > 570 mg/m³
Rat Dermal LD 50 >21.9 g/kg

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

Glyceryl monostearate

Mouse IP LD50 200 mg/kg

Conjugated estrogens

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

Mineral oil, white

Rat Oral LD50 > 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)

Benzyl Alcohol

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate
Skin Irritation Guinea Pig Moderate

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11. TOXICOLOGICAL INFORMATION

Glycerin, USP

Eye Irritation Rabbit Mild

Sodium lauryl sulfate

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild Moderate

Skin Sensitization - GPMT Guinea Pig Negative

Skin Sensitization - LLNA Mouse Negative

Conjugated estrogens

Eye Irritation Rabbit Severe

Mineral oil, white

Skin Irritation Rabbit Slight

Eye Irritation Rabbit Slight

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

Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

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.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LD50 96 Hours 50 mg/L

Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L

Sodium lauryl sulfate

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 3.6 mg/L

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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 Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Conjugated estrogens

California Proposition 65
EU EINECS/ELINCS List

carcinogen, initial date 2/27/87; developmental. initial date 4/1/90
235-199-5

Cetyl alcohol

Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List

Present
Present
253-149-0

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15. REGULATORY INFORMATION

Benzyl Alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	205-788-1

Water, purified

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	231-791-2

Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex V - Exemptions from the obligations of Register:	Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5

Methyl stearate

Inventory - United States TSCA - Sect. 8(b)	Present
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Mineral oil, white

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-455-8

Cetyl stearate

Inventory - United States TSCA - Sect. 8(b)	Present
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Glyceryl monostearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	250-705-4

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

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

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