



SAFETY DATA SHEET

Revision date: 30-Jan-2017

Version: 1.1

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

Product Identifier

Material Name: Esterified Estrogens Tablets

Trade Name: MENEST
Synonyms: Esterified 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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A
Carcinogenicity: Category 1A

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 An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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	GHS Classification	%
Conjugated estrogens	12126-59-9	235-199-5	Carc.1A (H350) Repr.1A (H360FD)	0.5
Estrogens, esterified	308064-84-8	Not Listed	Carc.1A (H350) Repr.1A (H360FD)	<1.0
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Methylcellulose	9004-67-5	Not Listed	Not Listed	*
Sodium bicarbonate	144-55-8	205-633-8	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Shellac	9000-59-3	232-549-9	Not Listed	*
Lactose NF, anhydrous	63-42-3	200-559-2	Not Listed	*
Stearic acid	57-11-4	200-313-4	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 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.

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Medical Conditions None known
Aggravated by Exposure:

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.

Conjugated estrogens

Manufacturer OEL: 0.15ug/m³

Sodium bicarbonate

Czech Republic OEL - TWA 5 mg/m³

Latvia OEL - TWA 5 mg/m³

Corn Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m³

Australia TWA 10 mg/m³

Belgium OEL - TWA 10 mg/m³

Bulgaria OEL - TWA 10.0 mg/m³

Czech Republic OEL - TWA 4.0 mg/m³

Greece OEL - TWA 10 mg/m³

5 mg/m³

Ireland OEL - TWAs 10 mg/m³

4 mg/m³

OSHA - Final PELs - TWAs: 15 mg/m³

Portugal OEL - TWA 10 mg/m³

Slovakia OEL - TWA 4 mg/m³

Spain OEL - TWA 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³

Lithuania OEL - TWA 5 mg/m³

Sweden OEL - TWAs 5 mg/m³

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	Color:	Various
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)

Conjugated estrogens

No data available

Methylcellulose

No data available

Lactose NF, anhydrous

No data available

Sodium bicarbonate

No data available

Shellac

No data available

Magnesium stearate

No data available

Stearic acid

No data available

Corn Starch

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

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

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11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

The following information is from a related compound and is presumed to be predictive of the effects produced by this material. The remaining information 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

Sodium bicarbonate

Rat Oral LD50 4220 mg/kg
Mouse Oral LD50 3360mg/kg
Rat Inhalation LC50 > 900mg/m³

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Stearic acid

Rat Oral LD50 > 4640 mg/kg
Rabbit Dermal LD50 > 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)

Conjugated estrogens

Eye Irritation Rabbit Severe

Sodium bicarbonate

Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Slight

Stearic acid

Skin Irritation Rabbit Moderate

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11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Stearic acid

30 Week(s) Rat Oral 300 ppm LOAEL Adipose tissue

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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Stearic acid

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

Unscheduled DNA Synthesis *E. coli* Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Stearic acid

26 Week(s) Rat Subcutaneous 0.5 mg/kg/week NOAEL Not carcinogenic

52 Week(s) Mouse Subcutaneous 0.05 mg/kg/week LOAEL Tumors

Carcinogen Status: See below

Conjugated estrogens

IARC: Group 1

NTP: Listed

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.

Toxicity:

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

Sodium bicarbonate

Daphnia magna (Water Flea) EC50 48 Hours 2350 mg/L

Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 8250 mg/L

Gambusia affinis (Mosquitofish) LC50 96 Hours 7550 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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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

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



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

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

Estrogens, esterified

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed
Sodium bicarbonate	
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	205-633-8
Corn Starch	
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	232-679-6
Shellac	
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	232-549-9
Lactose NF, anhydrous	
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	200-559-2
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
Stearic acid	
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	200-313-4

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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Carcinogenicity-Cat.1A; H350 - May cause cancer
Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage 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 8 - Exposure Controls / Personal Protection.

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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