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

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

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

Material Name: Esterified Estrogens Tablets
Revision date: 30-Jan-2017
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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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
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<th>GHS Classification</th>
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<td>Stearic acid</td>
<td>57-11-4</td>
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</tbody>
</table>

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.
SAFETY DATA SHEET

Material Name: Esterified Estrogens Tablets
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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
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.)
### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
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</table>

### 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 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
11. TOXICOLOGICAL INFORMATION

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
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
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>EU EINECS/ELINCS List</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
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</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/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.

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.

Revision date: 30-Jan-2017
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