SAFETY DATA SHEET

Revision date: 07-Feb-2018  Version: 2.1  Page 1 of 8

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

Product Identifier

Material Name: PREMARIN (Conjugated Estrogens) for Injection
Trade Name: PREMARIN
Chemical Family: Steroid

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Global Supply  Pfizer Ltd
Pfizer Inc  Ramsgate Road
235 East 42nd Street  Sandwich, Kent
New York, NY  10017  CT13 9NJ
1-800-879-3477  United Kingdom

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 1A
Carcinogenicity: Category 1A

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger
Hazard Statements:
H350 - May cause cancer
H360 - May damage fertility or the unborn child
May form combustible dust concentrations in air

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
SAFETY DATA SHEET

Material Name: PREMARIN (Conjugated Estrogens) for Injection
Revision date: 07-Feb-2018

SAFETY DATA SHEET

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 Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjugated estrogens</td>
<td>12126-59-9</td>
<td>235-199-5</td>
<td>Carc.1A (H350)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.1A (H360FD)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, anhydrous</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Simethicone</td>
<td>8050-81-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium citrate</td>
<td>68-04-2</td>
<td>200-675-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</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 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.

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

PZ01892
SAFETY DATA SHEET

Material Name: PREMARIN (Conjugated Estrogens) for Injection
Revision date: 07-Feb-2018

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

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters
During all firefighting 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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Minimize dust generation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Conjugated estrogens

Pfizer OEL TWA-8 Hr: 0.15µg/m³

Simethicone

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000µg/m³ to 3000µg/m³)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

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

Material name: PREMARIN (Conjugated Estrogens) for Injection

Physical State: lyophilised cake
Odor: No data available.
Molecular Formula: 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
Lactose NF, anhydrous
No data available
Sodium citrate
No data available
Simethicone
No data available
Decomposition Temperature (°C): No data available.

PZ01892
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

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).

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

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
11. TOXICOLOGICAL INFORMATION

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.
SAFETY DATA SHEET

Material Name: PREMARIN (Conjugated Estrogens) for Injection
Revision date: 07-Feb-2018

Page 7 of 8
Version: 2.1

15. REGULATORY INFORMATION

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

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

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

Simethicone

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Sodium citrate

- 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: 200-675-3

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. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 07-Feb-2018

Prepared by: Product Stewardship Hazard Communication

Pfizer Global Environment, Health, and Safety Operations
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End of Safety Data Sheet