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

Material Name: Estradiol Cypionate Injection, USP

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
ChemSafe (24 hours): +44 (0)208 762 8322

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Appearance: Clear pale yellow liquid
Signal Word: DANGER

Statement of Hazard: May cause cancer.
May damage fertility or the unborn child.

Additional Hazard Information:

Long Term: 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). Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system the developing fetus. Known Clinical Effects: Clinical use of this drug has caused nausea, vomiting, abdominal cramping, weight changes, fluid retention, changes in sexual desire (libido), breast development in males (gynecomastia), loss of hair, mental depression, menstrual irregularities, lack of menstrual periods (amenorrhea), changes in cervical erosion and secretion, breast enlargement, breast pain.

EU Classification

EU Indication of danger: Carcinogenic: Category 1
Toxic to reproduction: Category 1

EU Hazard Symbols:

EU Risk Phrases:

R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorobutanol</td>
<td>57-15-8</td>
<td>200-317-6</td>
<td>Xn;R22</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Estradiol Cypionate</td>
<td>313-06-4</td>
<td>206-237-8</td>
<td>Not Listed</td>
<td>0.5</td>
</tr>
</tbody>
</table>

**Additional Information:**

* Proprietary

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 immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove clothing and wash affected skin with soap and 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.

5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Carbon dioxide, carbon monoxide

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

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 contact with eyes, skin and clothing. 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.

Storage Conditions: Store as directed by product packaging. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estradiol Cypionate
Pfizer OEL TWA-8 Hr: 0.2 µg/m³, Skin
The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Engineering Controls: Local exhaust ventilation (LEV) should be used to control airborne levels.
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: Rubber gloves
Eyes: Not required under normal conditions of use. Glasses or goggles are recommended if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. 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: Liquid
Molecular Formula: Mixture
Solubility: Insoluble: Water

Color: Light yellow - Pale yellow
Molecular Weight: Mixture

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.
10. STABILITY AND REACTIVITY

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information in this section describes the hazards of various forms of the active ingredient.

Acute Toxicity: (Species, Route, End Point, Dose)

**Estradiol Cypionate**
- Mouse Subcutaneous LD 50 > 1000 mg/kg

**Chlorobutanol**
- Rat Oral LD50 510 mg/kg

**Cottonseed Oil**
- Rat Oral LD50 > 90 ml/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)

**Chlorobutanol**
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

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

**Estradiol**
- 90 Day(s) Rat Oral 0.003 mg/kg/day NOAEL Blood, Female reproductive system, Male reproductive system, Endocrine system, Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

**Estradiol**
- Reproductive & Fertility-Females Rat Oral 0.003 mg/kg/day LOAEL Reproductive toxicity
- Embryo / Fetal Development Rat Intramuscular 30 mg/kg/day LOAEL Fetotoxicity

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

**Estradiol**
- Sister Chromatid Exchange Human Lymphocytes Positive
- Micronucleus Human Positive
- Chromosome Aberration Human Negative
- In Vivo Direct DNA Damage Hamster Positive
- In Vivo Micronucleus Rodent Bone Marrow Negative

**Estradiol Cypionate**
- Direct DNA Interaction Negative
- In Vitro Micronucleus Human Lymphocytes Negative
- In Vitro Micronucleus Mouse Lymphoma Negative
- Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative

**Chlorobutanol**

PZ01151
11. TOXICOLOGICAL INFORMATION

In Vitro Bacterial Mutagenicity (Ames)  Salmonella  Positive
In Vitro Micronucleus  Mouse Bone Marrow  Negative

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

Estradiol
2 Year(s)  Female Mouse  Oral  0.1 mg/kg  LOEL  Tumors, Mammary gland, Female reproductive system

Carcinogen Status:  See below

Estradiol
IARC:  Group 1
NTP:  Listed
OSHA:  Present

12. ECOLOGICAL INFORMATION

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

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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol:  T
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.

EU Safety Phrases:  S53 - Avoid exposure - obtain special instructions before use.
                   S24/25 - Avoid contact with eyes and skin.
### 15. REGULATORY INFORMATION

**OSHA Label:**
DANGER
May cause cancer.
May damage fertility or the unborn child.

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
Class D, Division 2, Subdivision A

**Chlorobutanol**
- Inventory - United States TSCA - Sect. 8(b):
  - Listed
- Australia (AICS):
  - Listed
- Standard for the Uniform Scheduling for Drugs and Poisons:
  - Schedule 2
- EU EINECS/ELINCS List
  - 200-317-6

**Estradiol Cypionate**
- Inventory - United States TSCA - Sect. 8(b):
  - Listed
- Australia (AICS):
  - Listed
- EU EINECS/ELINCS List
  - 206-237-8

**Cottonseed Oil**
- Inventory - United States TSCA - Sect. 8(b):
  - Listed
- Australia (AICS):
  - Listed
- EU EINECS/ELINCS List
  - 232-280-7

### 16. OTHER INFORMATION

**Text of R phrases mentioned in Section 3**

- R22 - Harmful if swallowed.

**Data Sources:**
Publicly available toxicity information.

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

**Prepared by:**
Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet