



# MATERIAL SAFETY DATA SHEET

Revision date: 26-Nov-2007

Version: 1.0

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
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**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**ChemSafe (24 hours): +44 (0)208 762 8322**

### Material Name: Estropipate tablets

<b>Trade Name:</b>	OGEN; OGENEST; HARMOGEN; GENORAL
<b>Synonyms:</b>	Estrone Piperazine Sulfate
<b>Chemical Family:</b>	Synthetic estrogen
<b>Intended Use:</b>	Pharmaceutical product used for hormone replacement therapy

## 2. HAZARDS IDENTIFICATION

**Appearance:** Yellow, Peach, or Blue Tablets, varying in color depending on strength  
**Signal Word:** WARNING

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

**Additional Hazard Information:**  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on 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 estrogens has resulted in breast changes (enlargement, tenderness, and secretion), along with effects on the genitourinary (changes in vaginal bleeding), and GI systems. Effects on the skin, eyes, and CNS have also been reported. Clinical use has caused clotting abnormalities which may lead to stroke, heart attack, and pulmonary embolism.

**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.

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## Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

## 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	Classification	%
Estropipate	7280-37-7	230-696-3	Carc. Cat.1;R45 Repr. Cat.1;60-61	0.3-1.5
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	*
FD&C Blue No. 2	860-22-0	212-728-8	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lactose Monohydrate	64044-51-5	Not listed	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	Not Listed	*
Dibasic Potassium Phosphate	7758-11-4	231-834-5	Not Listed	*
Tromethamine	77-86-1	201-064-4	Not Listed	*
Sodium starch glycolate	9063-38-1	Not listed	Not Listed	*
Hydrogenated vegetable oil	68334-00-9	269-804-9	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	Not Listed	*
Quinoline yellow E104	8004-92-0	Not listed	Not Listed	*

## 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:** Immediately flush eyes with water 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. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

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**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.

### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

**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 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.

**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:** 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 thoroughly after handling.

**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.

#### Estropipate

Pfizer OEL TWA-8 Hr: 1  $\mu\text{g}/\text{m}^3$

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 $\text{mg}/\text{m}^3$ TWA	except stearates of toxic metals
Australia TWA	= 10 $\text{mg}/\text{m}^3$ TWA	
Belgium OEL - TWA	= 10 $\text{mg}/\text{m}^3$ TWA	
Ireland OEL - TWAs	= 10 $\text{mg}/\text{m}^3$ TWA	except lead stearate
Lithuania OEL - TWA	= 3 $\text{mg}/\text{m}^3$ IPRV	
Portugal OEL - TWA	= 10 $\text{mg}/\text{m}^3$ TWA	does not include stearates of toxic metals
Spain OEL - TWA	= 10 $\text{mg}/\text{m}^3$ VLA-ED	not including stearates of toxic metals
Sweden OEL - TWAs	= 5 $\text{mg}/\text{m}^3$ LLV	

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## Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA
Australia TWA	= 10 mg/m <sup>3</sup> TWA
Belgium OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Estonia OEL - TWA	= 10 mg/m <sup>3</sup> TWA
France OEL - TWA	= 10 mg/m <sup>3</sup> VME
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA = 4 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	= 2 mg/m <sup>3</sup> TWA
OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA total = 5 mg/m <sup>3</sup> TWA
Portugal OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Romania OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Spain OEL - TWA	= 10 mg/m <sup>3</sup> VLA-ED

## Colloidal silicon dioxide

Australia TWA	= 2 mg/m <sup>3</sup> TWA
Austria OEL - MAKs	= 4 mg/m <sup>3</sup> MAK
Czech Republic OEL - TWA	= 0.1 mg/m <sup>3</sup> TWA = 4.0 mg/m <sup>3</sup> TWA
Estonia OEL - TWA	= 2 mg/m <sup>3</sup> TWA
Germany - TRGS 900 - TWAs	= 4 mg/m <sup>3</sup> TWA
Ireland OEL - TWAs	= 2.4 mg/m <sup>3</sup> TWA = 6 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	= 1 mg/m <sup>3</sup> TWA containing more than 70% SiO <sub>2</sub> (quartz) = 2 mg/m <sup>3</sup> TWA containing 10-70% SiO <sub>2</sub> (granite, mica) = 4 mg/m <sup>3</sup> TWA containing 2-10% SiO <sub>2</sub> (copper sulfate ores)
OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(% SiO <sub>2</sub> ) mg/m <sup>3</sup> TWA = 20 mppcf TWA
Slovakia OEL - TWA	= 4.0 mg/m <sup>3</sup> TWA
Slovenia OEL - TWA	= 4 mg/m <sup>3</sup> TWA

**Analytical Method:** Analytical method available for estropipate. Contact Pfizer Inc for further information.

**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:

<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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:

<b>Physical State:</b>	Tablets	<b>Color:</b>	Yellow, Peach, or Blue
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

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### 10. STABILITY AND REACTIVITY

**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)

##### **Tromethamine**

Rat Oral LD50 5900 mg/kg

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### **Lactose Monohydrate**

Rat Oral LD 50 29700 mg/kg

##### **Lactose**

Rat Oral LD50 > 10 g/kg

##### **Microcrystalline cellulose**

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### **FD&C Yellow No. 6; (Sunset yellow)**

Rat Oral LD50 > 10,000 mg/kg  
Mouse Oral LD50 > 6,000 mg/kg

##### **FD&C Blue No. 2**

Rat Oral LD50 2 g/kg  
Mouse Oral LD50 2500 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)

##### **Microcrystalline cellulose**

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

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

##### **Estropipate**

30 Day(s) Dog Vaginal 10 mg/day LOAEL Female reproductive system  
2 Year(s) Dog Oral 0.1-1 mg/kg/day LOAEL Male reproductive system  
2 Year(s) Rat Oral 0.1-1.0 mg/kg LOAEL Male reproductive system



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## 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:**  
S22 - Do not breathe dust.  
S36/37 - Wear suitable protective clothing and gloves.  
S53 - Avoid exposure - obtain special instructions before use.

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

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
D2a very toxic materials



### **Estropipate**

<b>California Proposition 65</b>	Listed - Cancer Listed - Developmental Toxicity
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	230-696-3

### **Lactose Monohydrate**

<b>Australia (AICS):</b>	Present
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### **Lactose**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	200-559-2

### **Magnesium stearate**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	209-150-3

### **Hydroxypropyl cellulose**

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<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>Dibasic Potassium Phosphate</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	231-834-5
<b>Tromethamine</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	201-064-4
<b>Sodium starch glycolate</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>Microcrystalline cellulose</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	232-674-9
<b>Colloidal silicon dioxide</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	231-545-4 EEC No. 418-260-2
<b>Hydrogenated vegetable oil</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	269-804-9
<b>Water, purified</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	231-791-2
<b>FD&amp;C Yellow No. 6; (Sunset yellow)</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	220-491-7
<b>Quinoline yellow E104</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>FD&amp;C Blue No. 2</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	212-728-8



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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.

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

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**