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

Material Name: Fluoxymesterone Tablets

Trade Name: Halotestin®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for hormone replacement therapy, breast cancer.

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxymesterone</td>
<td>76-43-7</td>
<td>200-961-8</td>
<td>2mg, 5mg, or 10mg ***</td>
<td></td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Calcium stearate</td>
<td>1592-23-0</td>
<td>216-472-8</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tragacanth</td>
<td>9000-65-1</td>
<td>232-552-5</td>
<td>*</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Yellow No. 6; (Sunset yellow)</td>
<td>2783-94-0</td>
<td>220-491-7</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Blue No. 2</td>
<td>860-22-0</td>
<td>212-728-8</td>
<td>*</td>
</tr>
<tr>
<td>Sorbic acid</td>
<td>110-44-1</td>
<td>203-768-7</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Yellow No. 5</td>
<td>1934-21-0</td>
<td>217-699-5</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Green or peach tablet
Signal Word: DANGER

Statement of Hazard:
May damage fertility or the unborn child.
Suspected of causing genetic defects.
Suspected of causing cancer.

Additional Hazard Information:
Long Term: Due to its pharmacological action, exposure to this compound may produce adverse effects on fetal development.
Known Clinical Effects: Clinical use has resulted in liver effects. Symptoms may include jaundice, liver function test abnormalities, and hepatitis. Clinical use of this drug has resulted in the development of male characteristics in females. Clinical use of this drug has caused development of male characteristics in the female fetus, breast changes in men (tenderness, enlargement, secretion).

EU Indication of danger: Toxic to reproduction: Category 1
Carcinogenic: Category 2

EU Hazard Symbols:

EU Risk Phrases: R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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.

4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
Skin Contact: Wash skin with soap and water. If skin irritation persists, call a physician.
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 monoxide, carbon dioxide, nitrogen oxides and fluorine-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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Fluoxymesterone

Pfizer OEL TWA-8 Hr: 5 ug/m³

Sucrose

OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)

Australia TWA = 10 mg/m³ TWA

Calcium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals

Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles 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:
10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Polymerization: Will not occur

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)

Lactose
Rat  Oral  LD50  > 10  g/kg

Sucrose
Rat  Oral  LD50  29.7  g/kg

Sorbic acid
Rat  Oral  LD50  7360 mg/kg
Mouse  Oral  LD50  3200 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

Fluoxymesterone
Mouse  Intraperitoneal  LD 50  2350 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.

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

Fluoxymesterone
Embryo / Fetal Development  Rat  No route specified  10  mg/kg/day  LOEL  Developmental toxicity

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

FD&C Blue No. 2
Bacterial Mutagenicity (Ames)  Salmonella  Negative

Fluoxymesterone
**12. ECOLOGICAL INFORMATION**

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

**13. DISPOSAL CONSIDERATIONS**

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

**14. TRANSPORT INFORMATION**

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

**15. REGULATORY INFORMATION**

**EU Symbol:** T

**EU Indication of danger:**
- Toxic to reproduction: Category 1
- Carcinogenic: Category 2

**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.
- S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

**OSHA Label:**

Bacterial Mutagenicity (Ames) Negative

Chromosome Aberration Human Lymphocytes Positive

Sister Chromatid Exchange Human Lymphocytes Positive

Sister Chromatid Exchange Mouse Bone Marrow Positive

Carcinogen Status: See below

FD&C Yellow No. 6; (Sunset yellow)
- IARC: Group 3

Fluoxymesterone
- IARC: Group 2A
- OSHA: Present

IARC:
- Fluoxymesterone: Group 2A
- FD&C Yellow No. 6; (Sunset yellow): Group 3
DANGER
May damage fertility or the unborn child.
Suspected of causing genetic defects.
Suspected of causing cancer.

Canada - WHMIS: Classifications

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

### Fluoxymesterone

<table>
<thead>
<tr>
<th>California Proposition 65</th>
<th>developmental toxicity, initial date 4/1/90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Enforcement Administration:</td>
<td>Schedule III</td>
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<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 4</td>
</tr>
<tr>
<td>EU EINECS List</td>
<td>200-961-8</td>
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</table>

### Tragacanth

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>XU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS List</td>
<td>232-552-5</td>
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</table>

### Lactose

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
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</thead>
<tbody>
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<td>Australia (AICS):</td>
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<td>EU EINECS List</td>
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### FD&C Yellow No. 6; (Sunset yellow)

<table>
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<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
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<tbody>
<tr>
<td>Australia (AICS):</td>
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<tr>
<td>EU EINECS List</td>
<td>220-491-7</td>
</tr>
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### Sucrose

<table>
<thead>
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<th>Inventory - United States TSCA - Sect. 8(b)</th>
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</thead>
<tbody>
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<td>Australia (AICS):</td>
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<td>EU EINECS List</td>
<td>200-334-9</td>
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### Corn Starch

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
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</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
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</tr>
<tr>
<td>EU EINECS List</td>
<td>232-679-6</td>
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</tbody>
</table>

### FD&C Blue No. 2

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS List</td>
<td>212-728-8</td>
</tr>
</tbody>
</table>

### Sorbic acid

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
</tbody>
</table>
EU EINECS List 203-768-7

**FD & C Yellow No. 5**

| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS):                   | Present |
| EU EINECS List                      | 217-699-5 |

**Calcium stearate**

| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS):                   | Present |
| EU EINECS List                      | 216-472-8 |

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

**Prepared by:** Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet