



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

Page 1 of 7

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

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

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

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

Hazardous

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

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Fluoxymesterone Tablets
Revision date: 15-Dec-2006

Page 2 of 7
Version: 1.1

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.

MATERIAL SAFETY DATA SHEET

Material Name: Fluoxymesterone Tablets
Revision date: 15-Dec-2006

Page 3 of 7
Version: 1.1

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) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Corn Starch

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ 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.

Analytical Method:

Analytical method available for fluoxymesterone. Contact Pfizer Inc for further information.

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:

MATERIAL SAFETY DATA SHEET

Material Name: Fluoxymesterone Tablets
Revision date: 15-Dec-2006

Page 4 of 7
Version: 1.1

Physical State: Tablets
Molecular Formula: Mixture
Color: Green or peach
Molecular Weight: Mixture

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

MATERIAL SAFETY DATA SHEET

Material Name: Fluoxymesterone Tablets
Revision date: 15-Dec-2006

Page 5 of 7
Version: 1.1

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

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:

MATERIAL SAFETY DATA SHEET

Material Name: Fluoxymesterone Tablets
Revision date: 15-Dec-2006

Page 6 of 7
Version: 1.1

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

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

Tragacanth

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-552-5

Lactose

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

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

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	220-491-7

Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9

Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

FD&C Blue No. 2

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	212-728-8

Sorbic acid

Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present

MATERIAL SAFETY DATA SHEET

Material Name: Fluoxymesterone Tablets
Revision date: 15-Dec-2006

Page 7 of 7
Version: 1.1

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