



MATERIAL SAFETY DATA SHEET

Revision date: 20-Dec-2006

Version: 1.0

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

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Pfizer Pharmaceuticals Group
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Ramsgate Road
Sandwich, Kent
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Emergency telephone number:
1-212-573-2222
Hours of Operation - 24 Hours

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

Material Name: Tamoxifen Citrate Tablets

Trade Name: KESSAR; DIEMON; ESTROXYN; TAMONE
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic, Antiestrogen

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Tamoxifen Citrate	54965-24-1	259-415-2	15 or 30 mg ***
Maize starch	9005-25-8	232-679-6	*
Magnesium Stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*
Povidone	9003-39-8	Not listed	*
Sodium starch glycolate	9063-38-1	Not listed	*

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: White tablets
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
May cause reproductive system effects
May cause harm to the unborn child.
Carcinogen
Possible mutagen

Additional Hazard Information:
Short Term: Harmful if swallowed (based on animal data) .
Long Term: Animal studies indicate that this material may cause adverse effects on the reproductive system, and the developing fetus.

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Known Clinical Effects: The use of antiestrogens is associated with increased risks of myocardial infarction, thromboembolism, stroke, cancer of the breast and endometrium, and gallbladder disease.

EU Indication of danger: Harmful
Carcinogenic: Category 1
Toxic to reproduction, Category 2
Mutagenic Category 3

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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: 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. 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: Emits toxic fumes of carbon monoxide, carbon dioxide and oxides of nitrogen.

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.

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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. Minimize dust generation and accumulation. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tamoxifen Citrate

Pfizer OEL TWA-8 Hr: 0.5 ug/m³

Maize 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

Magnesium 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: Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Wear protective clothing with long sleeves when working with large quantities. Wash hands and arms thoroughly after handling this material. Clean up spills immediately.
Respiratory protection: 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:	Tablets	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

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Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
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)

Lactose

Rat Oral LD50 > 10 g/kg

Tamoxifen Citrate

Rat Oral LD50 1190 mg/kg

Rat Intravenous LD50 62.5 mg/kg

Rat Intraperitoneal LD50 575 mg/kg

Mouse Oral LD50 3100 mg/kg

Mouse Intravenous LD50 62.5 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.

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

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Tamoxifen Citrate

7 Week(s) Rat Oral 147 mg/kg LOAEL Female reproductive system

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

Tamoxifen Citrate

Embryo / Fetal Development Rabbit Oral 0.5 mg/kg/day LOAEL Fetotoxicity

Embryo / Fetal Development Rabbit Oral 2 mg/kg/day NOAEL Not Teratogenic

Fertility & Early Embryonic Development-Females Rat Oral 0.04 mg/kg/day LOAEL Fertility, Fetotoxicity

Fertility & Early Embryonic Development - Females Rat Oral 0.16 mg/kg/day LOAEL Fertility, Fetotoxicity

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

Tamoxifen Citrate

In Vitro Unscheduled DNA Synthesis Rat Positive

In Vivo Direct DNA Interaction Mouse Positive

In Vitro Direct DNA Interaction Mouse Positive

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

Tamoxifen Citrate

6 Month(s) Rat Oral 45 mg/kg/day LOAEL Tumors, Liver

13-15 Month(s) Mouse Oral 5 mg/kg/day LOAEL Benign tumors, Reproductive System

2 Year(s) Rat Oral 5 mg/kg/day LOAEL Tumors, Liver

Carcinogen Status: See below

Povidone

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IARC: Group 3

Tamoxifen Citrate

IARC: Group 1 - Carcinogenic to Humans

OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been 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: Harmful
Carcinogenic: Category 1
Toxic to reproduction, Category 2
Mutagenic Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

EU Safety Phrases:
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING

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Canada - WHMIS: Classifications

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



Tamoxifen Citrate

California Proposition 65	Listed - Developmental Toxicity
Australia (AICS):	Present
EU EINECS List	259-415-2

Maize starch

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

Magnesium Stearate

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

Lactose

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

Povidone

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

Sodium starch glycolate

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

16. OTHER INFORMATION

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.

End of Safety Data Sheet