



# MATERIAL SAFETY DATA SHEET

Revision date: 16-Jun-2011

Version: 1.0

Page 1 of 7

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

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### Material Name: Anastrozole Tablets

Trade Name:	Not applicable
Chemical Family:	Aromatase inhibitor
Intended Use:	Pharmaceutical product used as Antineoplastic

## 2. HAZARDS IDENTIFICATION

Appearance: White Tablets  
Signal Word: DANGER

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

Additional Hazard Information:  
Long Term:

Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system. Adverse effects associated with therapeutic use include hot flashes, inflammation of the liver, abnormal liver function tests, skin reaction, swelling of the face, loss of hair, joint pain, gastrointestinal disturbances, headache

Known Clinical Effects:

EU Classification

EU Indication of danger: Toxic to reproduction, Category 2

EU Hazard Symbols:



EU Risk Phrases:

R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
Hazardous Substance. Non-Hazardous Substance.

Australian Hazard Classification  
(NOHSC):

# MATERIAL SAFETY DATA SHEET

Material Name: Anastrozole Tablets  
Revision date: 16-Jun-2011

Page 2 of 7  
Version: 1.0

## 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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Anastrozole	120511-73-1	Not Listed	Repr.Cat.2;R60-61	1
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Povidone	9003-39-8	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:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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.

**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:** Formation of toxic gases is possible during heating or fire.

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

**Fire / Explosion Hazards:** Not applicable

## MATERIAL SAFETY DATA SHEET

Material Name: Anastrozole Tablets  
Revision date: 16-Jun-2011

Page 3 of 7  
Version: 1.0

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	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.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	Restrict access to work area. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.
<b>Storage Conditions:</b>	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state **Occupational Exposure Limits**.

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Anastrozole

Pfizer Occupational Exposure Band (OEB):	OEB 5 (control exposure to <1ug/m <sup>3</sup> )
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<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

# MATERIAL SAFETY DATA SHEET

Material Name: Anastrozole Tablets  
Revision date: 16-Jun-2011

Page 4 of 7  
Version: 1.0

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Eyes:** Wear safety glasses or goggles if eye contact is possible.  
**Skin:** Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.  
**Respiratory protection:** If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Tablets	<b>Color:</b>	White
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

## 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this formulation. The remaining information describes the potential hazards of the individual ingredients.

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

#### **Povidone**

Rat Oral LD50 100 g/kg

#### **Magnesium stearate**

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

#### **Anastrozole**

Rat Oral LD50 > 100 mg/kg  
Rat IP LD50 > 50 mg/kg  
Dog Oral LD50 > 45 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)

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

#### **Anastrozole**

6 Month(s) Rat No route specified 1 mg/kg/day LOAEL Female reproductive system

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

#### **Anastrozole**

## MATERIAL SAFETY DATA SHEET

Material Name: Anastrozole Tablets  
Revision date: 16-Jun-2011

Page 5 of 7  
Version: 1.0

### 11. TOXICOLOGICAL INFORMATION

Fertility and Embryonic Development	Rat	Oral 0.02 mg/kg/day	LOAEL	Fetotoxicity, Fertility
Embryo / Fetal Development	Rat	Oral 1.0 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rabbit	Oral 0.2 mg/kg/day	NOAEL	Not Teratogenic

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

##### **Anastrozole**

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative

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

##### **Anastrozole**

2 Year(s)	Rat	Oral 25 mg/kg/day	LOAEL	Liver, Tumors, Thyroid, Female reproductive system
2 Year(s)	Mouse	Oral 5 mg/kg/day	LOAEL	Benign tumors

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

##### **Povidone**

IARC: Group 3

### 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

The following refers to all modes of transportation unless specified below.

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 2

# MATERIAL SAFETY DATA SHEET

Material Name: Anastrozole Tablets  
Revision date: 16-Jun-2011

Page 6 of 7  
Version: 1.0

## 15. REGULATORY INFORMATION

### EU Risk Phrases:

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.  
S57 - Use appropriate containment to avoid environmental contamination.

### OSHA Label:

DANGER

May damage fertility or the unborn child.

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

Class D, Division 2, Subdivision A



#### Sodium starch glycolate

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

#### Lactose NF, monohydrate

Australia (AICS):	Listed
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#### Povidone

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

#### Magnesium stearate

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

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

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

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients.

**Prepared by:** Product Stewardship Hazard Communications  
Pfizer Global Environment, Health, and Safety Operations

## MATERIAL SAFETY DATA SHEET

**Material Name: Anastrozole Tablets**  
**Revision date: 16-Jun-2011**

**Page 7 of 7**  
**Version: 1.0**

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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**