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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-212-573-2222</td>
<td>United Kingdom</td>
</tr>
<tr>
<td></td>
<td>+00 44 (0)1304 616161</td>
</tr>
</tbody>
</table>

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

**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Material Name:** Anastrozole Tablets

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

# 2. HAZARDS IDENTIFICATION

<table>
<thead>
<tr>
<th>Appearance:</th>
<th>White Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Word:</td>
<td>DANGER</td>
</tr>
</tbody>
</table>

**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.
- **Known Clinical Effects:** 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

**EU Classification**

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

**EU Hazard Symbols:**

- T

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

**Australian Hazard Classification (NOHSC):**
Hazardous Substance. Non-Hazardous Substance.
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastrozole</td>
<td>120511-73-1</td>
<td>Not Listed</td>
<td>Repr.Cat.2;R60-61</td>
<td>1</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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
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:** 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.

**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.

**Magnesium stearate**

<table>
<thead>
<tr>
<th></th>
<th>Threshold Limit Value (TWA)</th>
<th>Australia TWA</th>
<th>Belgium OEL - TWA</th>
<th>Ireland OEL - TWAs</th>
<th>Lithuania OEL - TWA</th>
<th>Portugal OEL - TWA</th>
<th>Spain OEL - TWA</th>
<th>Sweden OEL - TWAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACNIH TWA</td>
<td>10 mg/m³ TWA</td>
<td>10 mg/m³</td>
<td>Listed</td>
<td>Listed</td>
<td>Listed</td>
<td>Listed</td>
<td>Listed</td>
<td>Listed</td>
</tr>
</tbody>
</table>

**Anastrozole**

<table>
<thead>
<tr>
<th></th>
<th>Pfizer Occupational Exposure Band (OEB):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OEB 5 (control exposure to &lt;1ug/m³)</td>
</tr>
</tbody>
</table>

**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.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.
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

Physical State: Tablets  Color: White
Molecular Formula: Mixture  Molecular Weight: 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 mg/kg

Magnesium stearate
Rat  Oral  LD50  > 2000 mg/kg
Rat  Inhalation  LC50  > 2000 mg/m³

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

PZ01527
11. TOXICOLOGICAL INFORMATION

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

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

Anastrozole
- In Vitro Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
- In Vitro Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
- In Vitro Chromosome Aberration Human Lymphocytes Negative
- In Vivo 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
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

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
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