

# SAFETY DATA SHEET



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

### Product identifier

## ARIMIDEX TABLETS

**Details of the supplier of the safety data sheet** : ASTRAZENECA PTY LTD  
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### Alternative Names

Anastrozole tablets (1mg)

CAS No. : Not applicable  
 Use : Treatment of advanced breast cancer in postmenopausal women

## 2. HAZARDS IDENTIFICATION

### Classification of the substance or mixture

| Classification UN GHS                              |          |   |
|--|----------|---|
| Hazard class                                       | Category | Hazard statements                                 |
| Carcinogenicity                                    | 2        | H351  |
| Reproductive toxicity                              | 1B       | H360  |
| Specific target organ toxicity - repeated exposure | 2        | H373  |
| Chronic aquatic toxicity                           | 2        | H411<br># Refer to Section 16 'Other Information' |

| Label elements               |  |
|------------------------------|--|
| <b>Signal word</b><br>Danger |  |
| <b>Hazard statements</b>     |  |
| H351                         | : Suspected of causing cancer.                                       |
| H360                         | : May damage fertility. Suspected of damaging the unborn child.      |
| H373                         | : May cause damage to organs through prolonged or repeated exposure. |
| H411                         | : Toxic to aquatic life with long lasting effects.                   |

**Precautionary statements**

|             |   |
|-------------|---|
| P201        | Obtain special instructions before use.                             |
| P273        | Avoid release to the environment.                                   |
| P281        | Use personal protective equipment as required.                      |
| P308 + P313 | : IF exposed or concerned: Get medical advice/ attention.           |
| P501        | : Dispose of contents/ container to an approved incineration plant. |

**Other hazards**

See Section 11.

**3. COMPOSITION/INFORMATION ON INGREDIENTS****Mixture:**

| Component   | %  | CAS No.         |                            |  |
|-------------|--|-----------------|----------------------------|--|
| Anastrozole | 1  | 120511-73-1     |                            |  |
|             | <b>Hazard class #</b>                              | <b>Category</b> | <b>Hazard statements #</b> |  |
|             | Acute toxicity                                     | 3               | H301                       |  |
|             | Acute toxicity                                     | 3               | H331                       |  |
|             | Carcinogenicity                                    | 2               | H351                       |  |
|             | Specific target organ toxicity - repeated exposure | 1               | H372                       |  |
|             | Reproductive toxicity                              | 1B              | H360                       |  |
|             | Acute aquatic toxicity                             | 3               | H402                       |  |
|             | Chronic aquatic toxicity                           | 1               | H410                       |  |

# Refer to Section 16 'Other Information'

**4. FIRST-AID MEASURES****Description of first aid measures**

|              |   |  |
|--------------|---|--|
| Inhalation   | : | Remove patient from exposure, keep warm and at rest. Obtain medical attention.   |
| Skin Contact | : | Remove contaminated clothing. Wash skin immediately with water. Obtain medical attention.                                    |
| Eye Contact  | : | Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention. |
| Ingestion    | : | Wash out mouth with water. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.                          |

**Most important symptoms and effects, both acute and delayed**

Refer to sections 2 and 11

**Indication of any immediate medical attention and special treatment needed**

Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

**5. FIRE-FIGHTING MEASURES**

|                                  |   |  |
|----------------------------------|---|--|
| Extinguishing Media (suitable)   | : | water spray, foam, dry powder or CO <sub>2</sub> . |
| Extinguishing Media (unsuitable) | : | -  |

- Special hazards arising from the substance or mixture : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective actions for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

## 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages. See Section 8.
- Environmental Precautions : Prevent entry into drains, sewers or watercourses. Collect spillage.
- Methods and material for containment and cleaning up : Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13.

## 7. HANDLING AND STORAGE

- Precautions for safe handling : Avoid contact with skin and eyes. Wash hands after use. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.
- Conditions for safe storage, including any incompatibilities : Keep container tightly closed.
- Specific end use(s) : Storage temperature : < 30 °C  
Not applicable, refer to Section 1

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

### Occupational Exposure Limit Value

| Components  | Value        | Control parameters | Comments |
|-------------|--------------|--------------------|----------|
| Anastrozole | 0,0001 mg/m3 | LTEL 8hr TWA       | COM, HYG |

### Exposure Controls

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment. Prevent entry into drains, sewers or watercourses. See Section 6 for environmental precautions.

### Occupational exposure controls

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

### Respiratory protection

Use an air fed hood for occasional exposures or for repeated exposures use a self-contained breathing apparatus if the risk assessment does not support the selection of other protection.

NIOSH approved respiratory protection device consistent with the work place risk assessment.

Consult a qualified safety and health professional for additional guidance, as needed.

**Skin protection**

Use impervious clothing to protect against direct contact with the product or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

**Eye protection**

Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

**9. PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

Form : film-coated tablets

**Other information**

**No other data available**

**10. STABILITY AND REACTIVITY**

Reactivity : No known reactivity hazard under normal conditions.  
 Chemical stability : Stable under normal conditions.  
 Possibility of hazardous reactions : None known.  
 Conditions to avoid : No conditions producing hazardous situations known.  
 Incompatible materials : None known.  
 Hazardous decomposition products : No hazardous decomposition products are known.

**11. TOXICOLOGICAL INFORMATION**

This health hazard assessment is based on a consideration of the composition of this product.

Inhalation : May cause effects as described under single exposure.(STOT)

Skin Contact : May cause skin rashes and dermatitis.

Eye Contact : Unlikely to cause eye irritation.

Ingestion : Low acute oral toxicity.

Specific Target Organ Toxicity (STOT) : **Single exposure**  
 Exposure routes: Oral  
 Ingestion may lead to hot flushes, abdominal pain, nausea, fatigue, headache and effect the nervous system.

**Repeated exposure**  
 Exposure routes: Oral  
 Target Organs: Liver, kidney, Testes, ovaries  
 Causes damage to organs through prolonged or repeated exposure. These effects are derived from studies in animals.  
 Effects derived from human findings:., May cause headache, nausea, vomiting, diarrhoea and skin rash., Can cause lowered estrogen levels resulting in:., bone and muscle pain, hot flushes, high cholesterol levels, anorexia, somnolence

Sensitisation : May cause an allergic reaction in rare cases.

- Carcinogenicity : Suspected of causing cancer.
- Mutagenicity : The substance is not considered to be genotoxic.
- Reproductive toxicity : May damage fertility. Suspected of damaging the unborn child.

## 12. ECOLOGICAL INFORMATION

No information on this formulation. The following information refers to active ingredient :

- Toxicity : NOEC Pseudokirchneriella subcapitata (green algae) 96 H growth rate 31,3 mg/l  
 NOEC Pseudokirchneriella subcapitata (green algae) 14 d growth rate 27 mg/l  
 NOEC blue-green algae 48 H growth rate < 48 mg/l  
 NOEC blue-green algae 21 H growth rate 3 mg/l  
 NOEC Daphnia magna 21 d 3,2 mg/l  
 NOEC Daphnia magna 21 d 3,2 mg/l  
 LC50 Lepomis macrochirus (Bluegill sunfish) 96 H (static) 84 mg/l  
 LC50 Oncorhynchus mykiss (rainbow trout) 96 H (static) 75 mg/l  
 NOEC Pimephales promelas (fathead minnow) 104 Days (flow through) 0,01 mg/l
- Effect on Effluent Treatment : No information available.
- Persistence and degradability : Not rapidly degradable.
- Bioaccumulative potential : The substance has low potential for bioaccumulation.
- Mobility in soil : The mobility depends on soil type.  
 The substance has low mobility in soil (pH <5.8).  
 The substance has moderate mobility in soil (pH7.7).  
 Water solubility >= 1 mg/l.
- Other adverse effects : No information available.

## 13. DISPOSAL CONSIDERATIONS

- Waste treatment methods : Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal waste disposal is via incineration operated by an accredited disposal contractor.
- Contaminated Packaging : Empty container will retain product residue. Observe all hazard precautions.

## 14. TRANSPORT INFORMATION

RESTRICTED FOR TRANSPORT

### ICAO/IATA

- UN No. : 3077
- Proper Shipping Name : Environmentally hazardous substance, solid, n.o.s. (ANASTROZOLE)

Class : 9  
Packing Group : III  
Environmental hazards : Environmentally hazardous

**IMO/IMDG**

UN No. : 3077  
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(ANASTROZOLE)  
Class : 9  
Packing Group : III  
Marine Pollutant : Marine Pollutant

**ADR**

UN No. : 3077  
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(ANASTROZOLE)  
Class : 9  
Label(s) : 9  
Packing Group : III  
Environmental hazards : Environmentally hazardous

**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

This material and its container must be disposed of as hazardous waste.

In order to comply with legal duties it is necessary to consult local and national legislation.

**16. OTHER INFORMATION**

Hazard statements : H301 : Toxic if swallowed.  
H331 : Toxic if inhaled.  
H351 : Suspected of causing cancer.  
H360 : May damage fertility. Suspected of damaging the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure.  
H373 : May cause damage to organs through prolonged or repeated exposure.  
H402 : Harmful to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.  
H411 : Toxic to aquatic life with long lasting effects.

The following sections contain revisions or new statements :

New significant SHE information:

14. New classification

Minor changes: 5, 6, 8, 13, 15

**GLOSSARY**

|       |   |   |
|-------|---|---|
| COM   | : | In-house occupational exposure limit  |
| LTEL  | : | Long-term exposure limit (8 hour TWA (time-weighted average))                   |
| STEL  | : | Short-term exposure limit (15-minute TWA (time-weighted average))               |
| TLV   | : | Threshold Limit Value (ACGIH)   |
| TLV-C | : | Threshold Limit Value - Ceiling limit (ACGIH)                                   |
| HYG   | : | An in-house analytical method for occupational exposure monitoring is available |
| Sk    | : | Can be absorbed through skin, thus contributing to systemic effects             |
| Sen   | : | Capable of causing respiratory sensitisation                                    |

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.