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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

#### ARIMIDEX TABLETS

Details of the supplier of the safety data sheet

: ASTRAZENECA PTY LTD      Emergency Telephone  
PO Box 131      +44 (0) 1235 239 670  
66 Talavera Rd, North Ryde  
NSW 2113  
AUSTRALIA  
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

#### Alternative Names

Anastrozole tablets (1mg)

CAS No. : Not applicable

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Treatment of advanced breast cancer in postmenopausal women

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## SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Kidney, Testes, ovaries)

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H351 Suspected of causing cancer.  
H360 May damage fertility or the unborn child.  
H373 May cause damage to organs (Liver, Kidney, Testes, ovaries) through prolonged or repeated exposure if swallowed.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read

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and understood.  
 P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
 P273 Avoid release to the environment.  
 P281 Use personal protective equipment as required.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/  
 attention.  
 P391 Collect spillage.

**Disposal:**

P501 Dispose of contents/ container to an approved waste  
 disposal plant.

**Other hazards which do not result in classification**

May cause skin rashes and dermatitis.  
 May cause an allergic reaction in rare cases.  
 See Section 11.  
 The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to  
 accumulate.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Anastrozole	120511-73-1	1

**SECTION 4. FIRST AID MEASURES**

If inhaled : Remove patient from exposure, keep warm and at rest.  
 Obtain medical attention.

In case of skin contact : Remove contaminated clothing.  
 Wash skin immediately with water.  
 Obtain medical attention.

In case of eye contact : Irrigate with eyewash solution or clean water, holding the  
 eyelids apart, for at least 10 minutes.  
 Obtain medical attention.

If swallowed : 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  
 Suspected of causing cancer.  
 May damage fertility or the unborn child.  
 May cause damage to organs through prolonged or repeated  
 exposure if swallowed.

Notes to physician : Symptomatic treatment and supportive therapy as indicated.  
 For further detail consult the prescribing information.

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**SECTION 5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : water spray, foam, dry powder or CO<sub>2</sub>.
- Unsuitable extinguishing media : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
- Specific hazards during firefighting : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective equipment for firefighters : 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.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.  
Avoid dispersal of dust in the air.  
See Section 8.
- Environmental precautions : Prevent entry into drains, sewers or watercourses.  
Collect spillage.
- Methods and materials 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.

**SECTION 7. HANDLING AND STORAGE**

- Advice on safe handling : Avoid contact with skin and eyes.  
Wash hands after use.  
Minimize dust generation and accumulation.  
The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.
- Conditions for safe storage : Keep container tightly closed.
- Recommended storage temperature : < 30 °C

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Anastrozole	120511-73-1	TWA	0.0001 mg/m <sup>3</sup>	COM; HYG

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**Engineering measures** : 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.

**Personal protective equipment**

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.

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.

Skin and body 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.

Protective measures : 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. All the information above 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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : film-coated tablets

Colour : white

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Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/range : No data available

Initial boiling point and boiling range : Not applicable

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Solubility(ies)  
Water solubility : No data available

Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : No data available

Oxidizing properties : Not applicable

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.

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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.

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## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1 Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

#### Components:

##### **Anastrozole:**

Acute oral toxicity	:	LD50 Oral (Rat): 100 - 250 mg/kg Assessment: The component/mixture is toxic after single ingestion.
Acute inhalation toxicity	:	Assessment: The component/mixture is toxic after short term inhalation.
Acute dermal toxicity	:	Remarks: No information available.

### 11.2 Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### **Anastrozole:**

Remarks	:	May cause skin rashes and dermatitis.
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### 11.3 Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### **Anastrozole:**

Remarks	:	Non-irritant to rabbit eyes. Unlikely to cause eye irritation in man.
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#### 11.4 Respiratory or skin sensitisation

##### **Skin sensitisation**

Not classified based on available information.

##### **Respiratory sensitisation**

Not classified based on available information.

##### **Components:**

##### **Anastrozole:**

Remarks : May cause an allergic reaction in rare cases.

##### **Chronic toxicity**

#### 11.5 Germ cell mutagenicity

Not classified based on available information.

##### **Components:**

##### **Anastrozole:**

Germ cell mutagenicity - Assessment : The substance is not considered to be genotoxic.

#### 11.6 Carcinogenicity

Suspected of causing cancer.

##### **Components:**

##### **Anastrozole:**

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies, Studies in animals have shown that repeated doses produce cancer in rats and mice.

#### 11.7 Reproductive toxicity

May damage fertility or the unborn child.

##### **Components:**

##### **Anastrozole:**

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments., Studies in animals have shown that repeated doses produce adverse reproductive effects., A study in animals has shown that repeated doses produce embryo/foetotoxic effects in the absence of maternal toxicity.

#### 11.8 STOT - single exposure

Not classified based on available information.

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**Components:****Anastrozole:**

Remarks : No specific effects reported.

**11.9 STOT - repeated exposure**

May cause damage to organs (Liver, Kidney, Testes, ovaries) through prolonged or repeated exposure if swallowed.

**Components:****Anastrozole:**

Exposure routes : Oral  
Target Organs : Liver, Kidney, Testes, ovaries  
Assessment : Causes damage to organs through prolonged or repeated exposure.  
Remarks : These effects are derived from studies in animals.  
Remarks : 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

**11.10 Aspiration toxicity**

Not classified based on available information.

**Components:****Anastrozole:**

No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Product:****Ecotoxicology Assessment**

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

**Components:****Anastrozole:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 84 mg/l  
Exposure time: 96 h  
Test Type: static test  
  
LC50 (Oncorhynchus mykiss (rainbow trout)): 75 mg/l  
Exposure time: 96 h

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Test Type: static test

- Toxicity to daphnia and other aquatic invertebrates : NOEC (Daphnia magna (Water flea)): 3.2 mg/l  
Exposure time: 21 d
- Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 31.3 mg/l  
Exposure time: 96 h  
Test Type: growth rate
- NOEC (Pseudokirchneriella subcapitata (green algae)): 27 mg/l  
Exposure time: 14 d  
Test Type: growth rate
- NOEC (blue-green algae): 3 mg/l  
Exposure time: 21 h  
Test Type: growth rate
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.01 mg/l  
Exposure time: 104 d
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 3.2 mg/l  
Exposure time: 21 d
- M-Factor (Chronic aquatic toxicity) : 10

### Persistence and degradability

#### Components:

##### **Anastrozole:**

Biodegradability : Result: not rapidly degradable

### Bioaccumulative potential

#### Components:

##### **Anastrozole:**

Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

### Mobility in soil

#### Components:

##### **Anastrozole:**

Mobility : Remarks: 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.

Distribution among environmental compartments : Remarks: No information available.

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## Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

- Waste from residues : 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.  
Dispose of contents/ container to an approved incineration plant.
- Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.
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## SECTION 14. TRANSPORT INFORMATION

### 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

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Environmental hazards : Environmentally hazardous

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## SECTION 15. REGULATORY INFORMATION

### **Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

### **The components of this product are reported in the following inventories:**

TCSI : Not listed

TSCA : Substance(s) not listed on TSCA inventory

AICS : Not listed

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
Anastrozole

ENCS : Not listed

ISHL : Not listed

KECI : Not listed

IECSC : Not listed

CHINV : Not in compliance with the inventory

REACH : Not in compliance with the inventory

TRINV : Not in compliance with the inventory

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## SECTION 16. OTHER INFORMATION

### **Further information**

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Other information : Minor changes:

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Date format : dd.mm.yyyy

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM - In-house occupational exposure limit; CPR - Controlled Products Regulations; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HYG - Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; Sen - Capable of causing respiratory sensitization; Sk - Can be absorbed through skin, thus contributing to systemic effects; STEL - Short-term exposure limit 15-minutes time-weighted average; TLV - Threshold Limit Value (ACGIH); TLV-C - Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA - Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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