

Version 6.0 Revision Date: 16.08.2018 SDS Number: 13224 Date of last issue: 16.08.2018
 Date of first issue: 19.01.2018

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

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)
 Chronic aquatic toxicity : 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 and understood.

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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.

Hazardous components which must be listed on the label:

Anastrozole

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

Hazardous 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.

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

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : water spray, foam, dry powder or CO₂.

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	Control parameters /	Basis
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		exposure)	Permissible concentration	
Anastrozole	120511-73-1	TWA	0.0001 mg/m ³	COM; HYG

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.

NIOSH approved respiratory protection device consistent with the work place risk assessment.
 Consult a qualified safety and health professional for additional guidance, as needed.

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

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

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Oxidizing properties : Not applicable

SECTION 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.

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.

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

11.6 Carcinogenicity

Suspected of causing cancer.

Components:

Anastrozole:

Carcinogenicity - : Limited evidence of carcinogenicity in animal studies, Studies
Assessment 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 - : Clear evidence of adverse effects on sexual function and
Assessment 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.

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11.8 STOT - single exposure

Not classified based on available information.

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

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

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LC50 (Oncorhynchus mykiss (rainbow trout)): 75 mg/l
Exposure time: 96 H
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 : 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).

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Water solubility ≥ 1 mg/l.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

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.

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)

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Class : 9
Label(s) : 9
Packing Group : III
Environmental hazards : Environmentally hazardous

SECTION 15. REGULATORY INFORMATION

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

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:

REACH : Not listed
DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
Anastrozole 120511-73-1
AICS : Not listed
ENCS : Not listed
ISHL : Not listed
IECSC : Not listed
TCSI : Not listed
TSCA : Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

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; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; 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);

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ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; 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; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; 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; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (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; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); 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

Further information

Revision Date	:	16.08.2018
Other information	:	New significant SHE information:, 14. Transport information, Minor changes:, 6, 12
Date format	:	dd.mm.yyyy

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