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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

NOLVADEX TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD Emergency Telephone
 PO Box 131 +44 (0) 1235 239 670
 Alma Road, North Ryde
 NSW 2113
 AUSTRALIA
 +61 2 9978 3500
 SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

Tamoxifen citrate tablets
 Nolvadex tablets (10, 20, 30, 40 mg)
 CAS No. : Not applicable

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



Use of the Substance/Mixture : 1. Treatment of breast cancer 2. Reduction of breast cancer incidence in high risk women 3. Treatment of anovulatory infertility 4. Treatment of endometrial cancer

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Carcinogenicity : Category 1A
 Reproductive toxicity : Category 1A
 Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Eyes, Liver, Reproductive organs)
 Acute aquatic toxicity : Category 1
 Chronic aquatic toxicity : Category 1

GHS label elements

Hazard pictograms :  

Signal word : Danger

Hazard statements : H350 May cause cancer.
 H360 May damage fertility or the unborn child.
 H372 Causes damage to organs (Eyes, Liver, Reproductive organs) through prolonged or repeated exposure if swallowed.
 H410 Very toxic to aquatic life with long lasting effects.

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Precautionary statements : **Prevention:**
 P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
 P264 Wash skin thoroughly after handling.
 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 irritation.

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)
Tamoxifen citrate	54965-24-1	>= 10 - < 20
Celluloses	9004-34-6	>= 1 - < 10
Magnesium stearate	557-04-0	>= 1 - < 10

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure.
Obtain medical attention.

In case of skin contact : Wash skin with soap and water.
If symptoms (irritation or blistering) occur 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 ill effects remain.

If swallowed : Wash out mouth with water and give 200-300ml of water to drink.
Obtain medical attention.
Do NOT induce vomiting as a First-Aid measure.

Most important symptoms : Refer to sections 2 and 11

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and effects, both acute and delayed : May cause cancer.
May damage fertility or the unborn child.
Causes 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.

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.

Environmental precautions : Prevent entry into drains.
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.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Do not breathe dust.
Avoid contact with skin and eyes.
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.
Protect from light.

Recommended storage temperature : < 30 °C

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Tamoxifen citrate	54965-24-1	TWA	0.003 mg/m ³	COM; HYG
Celluloses	9004-34-6	TWA	10 mg/m ³	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m ³	ACGIH
Magnesium stearate	557-04-0	TWA	10 mg/m ³	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m ³	ACGIH

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 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.

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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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	film-coated tablets
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	Not applicable
Melting point/range	:	Not applicable
Initial boiling point and boiling range	:	Not applicable
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Upper explosion limit	:	No data available
Lower explosion 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		

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Viscosity, dynamic : Not applicable
Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
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

11.1.1 Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Remarks: Low acute oral toxicity.

Components:

Tamoxifen citrate:

Acute oral toxicity : LD50 Oral (Rat): 2,000 mg/kg

Acute inhalation toxicity : Remarks: No information available on acute toxicity.
May cause effects as described under repeated exposure.(STOT)

Acute dermal toxicity : Remarks: No information available.

11.1.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Tamoxifen citrate:

Remarks: May cause skin irritation.

11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

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Components:**Tamoxifen citrate:**

Remarks: No evidence of irritant effects from normal handling and use.

11.1.4 Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Tamoxifen citrate:**

Remarks: It is not a skin sensitiser in vivo.
Unlikely to cause skin sensitisation.

11.1.5 Germ cell mutagenicity

Not classified based on available information.

Components:**Tamoxifen citrate:**

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

11.1.6 Carcinogenicity

May cause cancer.

Components:**Tamoxifen citrate:**

Carcinogenicity - Assessment : Human carcinogen., Epidemiological studies have shown that repeated exposures are associated with increased incidence of endometrial cancer., Evidence of carcinogenicity in animal studies.

11.1.7 Reproductive toxicity

May damage fertility or the unborn child.

Components:**Tamoxifen citrate:**

Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies., Positive evidence of adverse effects on development from human epidemiological studies.

11.1.8 STOT - single exposure

Not classified based on available information.

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Components:**Tamoxifen citrate:**

Remarks: No specific effects reported.

11.1.9 STOT - repeated exposure

Causes damage to organs (Eyes, Liver, Reproductive organs) through prolonged or repeated exposure if swallowed.

Components:**Tamoxifen citrate:**

Exposure routes: Oral

Target Organs: Eyes, Liver, Reproductive organs

Assessment: Causes damage to organs through prolonged or repeated exposure.

11.1.10 Aspiration toxicity

Not classified based on available information.

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

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.
Remarks: No information on this formulation.
The following information refers to active ingredient:

Components:**Tamoxifen citrate:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.32 mg/l
Exposure time: 96 H

Remarks: (OECD 203)

NOEC (Oncorhynchus mykiss (rainbow trout)): 0.27 mg/l
Exposure time: 96 H

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.23 mg/l
Exposure time: 96 H
Test Type: flow-through test

Remarks: (OECD 203)

Toxicity to algae : ErC50 (green algae): 0.0092 mg/l
Exposure time: 96 H

NOEC (green algae): 0.0049 mg/l
Exposure time: 14 d

NOEC (blue-green algae): 0.098 mg/l

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Exposure time: 21 d

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.00008 mg/l
Exposure time: 284 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.043 mg/l
Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 1,000

Toxicity to bacteria : Remarks: This substance was not shown to be biodegradable under anaerobic conditions.

Persistence and degradability

Components:

Tamoxifen citrate:

Biodegradability : Result: not rapidly degradable
Remarks: BOD (28 d) 0 % (OECD 301C).
BOD/COD (28 d) 10 % (OECD 301F).

Bioaccumulative potential

Components:

Tamoxifen citrate:

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

Mobility in soil

Components:

Tamoxifen citrate:

Mobility : Remarks: The substance has low mobility in soil.
Water solubility \geq 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

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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. (TAMOXIFEN CITRATE)
Class : 9
Packing Group : III
Environmental hazards : Environmentally hazardous

IMO/IMDG

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

ADR

UN No. : 3077
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (TAMOXIFEN CITRATE)
Class : 9
Label(s) : 9
Packing Group : III
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.

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.

Tamoxifen citrate 54965-24-1

AICS : On the inventory, or in compliance with the inventory

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; 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,

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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

Further information

Other information : The Safety Data Sheet has been updated to the SAP EH&S Standard template., This update affects all Sections of the Safety Data Sheet., New significant SHE information:., 2. New classification, 11. Carcinogenicity, Minor changes:., 3, 11, 12

Date format : dd.mm.yyyy

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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