

SAFETY DATA SHEET



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

Product identifier

NOLVADEX TABLETS

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

Tamoxifen citrate tablets
 Nolvadex tablets (10, 20, 30, 40 mg)

CAS No. : Not applicable
 Use : 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

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification UN GHS		
Hazard class	Category	Hazard statements
Carcinogenicity	1B	H350
Reproductive toxicity	1A	H360
Specific target organ toxicity - repeated exposure	1	H372
Acute aquatic toxicity	1	H400
Chronic aquatic toxicity	1	H410
		# Refer to Section 16 'Other Information'

Label elements	
Signal word Danger	
Hazard statements	
H350	: May cause cancer.
H360	: May damage fertility. May damage the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.
H410	: Very toxic to aquatic life with long lasting effects.

Precautionary statements

P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust.
P273	Avoid release to the environment.
P308 + P313	: IF exposed or concerned: Get medical advice/ attention.
P391	: Collect spillage.
P501	: Dispose of contents/ container to an approved waste disposal plant.

Other hazards

See Section 11.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	%	CAS No.		
Tamoxifen citrate	8 - 17	54965-24-1		
	Hazard class #	Category	Hazard statements #	
	Acute toxicity	4	H302	
	Carcinogen	1B	H350	
	Reproductive toxicant	1A	H360FD	
	Specific target organ toxicity - repeated exposure	1	H372	
	Acute aquatic toxicity	1	H400	
	Chronic aquatic toxicity	1	H410	
Component	%	CAS No.		
Celluloses	3,4	-		
	Hazard class #	Category	Hazard statements #	
	-	-	-	

Refer to Section 16 'Other Information'

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

Inhalation	:	Remove patient from exposure. Obtain medical attention.
Skin Contact	:	Wash skin with soap and water. If symptoms (irritation or blistering) occur obtain medical attention.
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.
Ingestion	:	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 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 ₂ .
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. 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	:	Do not breathe dust. Avoid contact with skin and eyes. Wash hands thoroughly after handling. 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. Protect from light.
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
Tamoxifen citrate	0,01 mg/m ³	LTEL 8hr TWA	COM, HYG
Cellulose (Total Inhalable Dust)	10 mg/m ³	LTEL 8hr TWA	WEL
Cellulose (Total Inhalable Dust)	20 mg/m ³	STEL 15min	WEL
Cellulose (Respirable Dust)	4 mg/m ³	LTEL 8hr TWA	WEL

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. See Section 6 for environmental precautions.

Occupational exposure controls

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.

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.

Respiratory protection

Use an air fed hood if the risk assessment does not support the selection of other protection.

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
Colour : white

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 repeated exposure.(STOT)
- Skin Contact : May cause skin irritation in sensitive individuals.
- Eye Contact : No evidence of irritant effects from normal handling and use.
- Ingestion : Low acute oral toxicity.
- Specific Target Organ Toxicity (STOT) : **Single exposure**
No specific effects reported.
- Repeated exposure**
Exposure routes: Oral
Target Organs: Eyes, Liver
Causes damage to organs through prolonged or repeated exposure.
- Sensitisation : Unlikely to cause skin sensitisation.
- Carcinogenicity : May cause cancer.
- Mutagenicity : There is no evidence of genotoxic potential in in vitro and in vivo tests.
- Reproductive toxicity : May damage fertility. May damage the unborn child.

12. ECOLOGICAL INFORMATION

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

- Toxicity : EC50 green algae 96 H 0,0092 mg/l
NOEC green algae 14 d 0,0049 mg/l
NOEC blue-green algae 21 d 0,098 mg/l
EC50 nitrifying bacteria > 100 mg/l
EC50 bacteria, aerobic > 100 mg/l
EC50 Daphnia magna 48 H < 1,0 mg/l
NOEC Daphnia magna 21 d 0,043 mg/l
LC50 Rainbow trout 96 H 0,32 mg/l
(OECD 203)
NOEC Rainbow trout 96 H 0,27 mg/l
LC50 Bluegill Sunfish 96 H (flow through) 0,23 mg/l
(OECD 203)
NOEC Bluegill Sunfish 96 H < 0,093 mg/l
NOEC fathead minnow 284 d 0,00008 mg/l
- Effect on Effluent Treatment : This substance was not shown to be biodegradable under anaerobic conditions.
- Persistence and degradability : Not rapidly degradable.

Bioaccumulative potential : The substance has high potential for bioaccumulation.

Mobility in soil : The substance has low mobility in soil.
Water solubility \geq 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. Dispose of contents/ container to an approved incineration plant.

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. (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

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Hazard statements H302 : Harmful if swallowed.
 H350 : May cause cancer.
 H360 : May damage fertility. May damage the unborn child.
 H372 : Causes damage to organs through prolonged or repeated exposure.
 H400 : Very toxic to aquatic life.
 H410 : Very toxic to aquatic life with long lasting effects.

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.