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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

## TENORMINTABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD      EmergencyTelephone  
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

Atenolol tablets  
Tenormin 25 mg, 50 mg and 100 mg tablets  
CAS No. : Not applicable

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

Use of the Substance/Mixture : management of hypertension, angina pectoris and dysrhythmias

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## SECTION 2. HAZARDS IDENTIFICATION

### GHS Classification

Reproductive toxicity : Category 1A

Effects on or via lactation

### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360 May damage fertility or the unborn child.  
H362 May cause harm to breast-fed children.

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 or mist.  
P264 Wash skin thoroughly after handling.  
P281 Use personal protective equipment as required.  
  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/attention.

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**Disposal:**

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

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

May cause lowering of blood pressure.

May cause increased difficulty in treating anaphylactic reactions to allergens or cause more severe reactions to allergens.

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)
Atenolol	29122-68-7	$\geq 23$ - $\leq 24$
Magnesium stearate	557-04-0	$\geq 2.3$ - $\leq 2.4$
Celluloses	9004-34-6	$\geq 1.4$ - $\leq 1.8$

**SECTION 4. FIRST AID MEASURES**

- If inhaled : Remove patient from exposure.  
Obtain medical attention if ill effects occur.
- In case of skin contact : Wash skin with soap and water.
- 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 if ill effects occur.  
Do NOT induce vomiting as a First-Aid measure.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11  
May damage fertility or the unborn child.  
May cause harm to breast-fed children.
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.  
For further information consult the prescribing information.

**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 : If involved in a fire, it may burn and emit noxious and toxic

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firefighting    fumes.

Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

## 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, sewers or watercourses.

Methods and materials for containment and cleaning up : Avoid dust generation.  
Transfer spilled tablets to a suitable container for disposal.  
Wash the spillage area with water.

## 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.  
Keep away from moisture.  
Protect from light.

Recommended storage temperature : < 25 °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
Atenolol	29122-68-7	TWA	0.5 mg/m <sup>3</sup>	COM; HYG
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA (Inhalable fraction)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable fraction)	3 mg/m <sup>3</sup>	ACGIH
Celluloses	9004-34-6	TWA	10 mg/m <sup>3</sup>	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			

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		TWA	10 mg/m3	ACGIH
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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.

### 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.

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, or, orange  
Odour : No data available

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Odour Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
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 : No data available

Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

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## 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.

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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 : Remarks: Low acute oral toxicity.

**Components:**

**Atenolol:**

Acute oral toxicity : No evident toxicity in rats at a dose of: 3,000 mg/kg

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

Acute dermal toxicity : Remarks: No information available.

### 11.2 Skin corrosion/irritation

Not classified based on available information.

**Components:**

**Atenolol:**

Remarks : Repeated and/or prolonged contact may cause irritation.

### 11.3 Serious eye damage/eye irritation

Not classified based on available information.

**Components:**

**Atenolol:**

Remarks : Unlikely to cause eye irritation.

### 11.4 Respiratory or skin sensitisation

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Atenolol:**

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

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## Chronic toxicity

### 11.5 Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### **Atenolol:**

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

### 11.6 Carcinogenicity

Not classified based on available information.

#### Components:

##### **Atenolol:**

Carcinogenicity - Assessment : No evidence of carcinogenicity in animal studies.

### 11.7 Reproductive toxicity

May damage fertility or the unborn child.  
May cause harm to breast-fed children.

#### Components:

##### **Atenolol:**

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies., Foetal and neonatal toxicity in babies born to women receiving treatment during pregnancy has been reported., Studies in animals have shown that high doses produce embryo/foetotoxic effects.  
Effects on or via lactation

### 11.8 STOT - single exposure

Not classified based on available information.

#### Components:

##### **Atenolol:**

Exposure routes : Inhalation, Oral  
Remarks : Atenolol reduces heart rate and lowers blood pressure.  
May cause dizziness, fatigue, coldness of the fingers and toes, and difficulty in breathing.

### 11.9 STOT - repeated exposure

Not classified based on available information.

#### Components:

##### **Atenolol:**

Exposure routes : Inhalation, Oral  
Remarks : Atenolol reduces heart rate and lowers blood pressure.

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**11.10 Aspiration toxicity**

Not classified based on available information.

**Components:****Atenolol:**

No information available.

**Further information****Product:**

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

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Atenolol:**

Toxicity to fish	:	LC50 ( <i>Oryzias latipes</i> (Japanese medaka)): 1,800 mg/l Exposure time: 96 H Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Ceriodaphnia dubia</i> (water flea)): 33.4 mg/l Exposure time: 48 H Method: (EPA 600/4-90/027)
		EC50 ( <i>Daphnia magna</i> (Water flea)): 180 mg/l Exposure time: 48 H Method: OECD Test Guideline 202
Toxicity to algae	:	EC50 (green algae): 110 mg/l Exposure time: 96 H Test Type: growth rate Method: OECD Test Guideline 201
		NOEC (green algae): 10 mg/l Exposure time: 96 H Test Type: growth rate Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC ( <i>Pimephales promelas</i> (fathead minnow)): 3.2 mg/l Exposure time: 28 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC ( <i>Daphnia magna</i> (Water flea)): 8.87 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50 (nitrifying bacteria): > 100 mg/l  EC50 (bacteria, anaerobic): > 100 mg/l



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EC50 (bacteria, aerobic): > 100 mg/l

Remarks: There is no evidence of inhibition to the aerobic treatment process at a concentration of > 100 mg/l.

#### **Persistence and degradability**

##### **Components:**

##### **Atenolol:**

Biodegradability : Result: not rapidly degradable  
Biodegradation: 6 %  
Exposure time: 5 d  
Remarks: Biological oxygen demand (BOD5/COD):

#### **Bioaccumulative potential**

##### **Components:**

##### **Atenolol:**

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

#### **Mobility in soil**

##### **Components:**

##### **Atenolol:**

Mobility : Remarks: Water solubility  $\geq 1$  mg/l.  
The substance has moderate mobility in soil.

Distribution among environmental compartments : Remarks: No data available

#### **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.  
Normal disposal is via incineration operated by an accredited disposal contractor.

Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.

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## SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

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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:**

REACH : Not in compliance with the inventory

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

Atenolol

AICS : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Not On TSCA Inventory

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## SECTION 16. OTHER INFORMATION

### **Further information**

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Other information : New significant SHE information:  
8. New Occupational Exposure Limit Value  
Minor changes:  
3  
15  
16

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average  
AU OEL / TWA : Exposure standard - time weighted average

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

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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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