

Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	24.08.2017	20769	Date of first issue: 24.08.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**1.1 Product identifier****TENORMINTABLETS**Details of the supplier of the
safety data sheet

: ASTRAZENECA PTY LTD
PO Box 131
Alma Road, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

Emergency Telephone
+44 (0) 1235 239 670

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

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.

Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	24.08.2017	20769	Date of first issue: 24.08.2017

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

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Atenolol	29122-68-7	≥ 20 - < 30
Magnesium stearate	557-04-0	≥ 1 - < 10
Celluloses	9004-34-6	≥ 1 - < 10

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 CO₂.
- Unsuitable extinguishing media : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

SAFETY DATA SHEET



Version 4.0 Revision Date: 24.08.2017 SDS Number: 20769 Date of last issue: -
Date of first issue: 24.08.2017

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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.
See Section 8.
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 ³	COM; HYG
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
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

Engineering measures : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate

Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	24.08.2017	20769	Date of first issue: 24.08.2017

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
- Odour Threshold : No data available
- pH : No data available

SAFETY DATA SHEET



Version 4.0	Revision Date: 24.08.2017	SDS Number: 20769	Date of last issue: - Date of first issue: 24.08.2017
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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	: No data available
Lower explosion 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

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.

Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	24.08.2017	20769	Date of first issue: 24.08.2017

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:**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.

11.1.2 Skin corrosion/irritation

Not classified based on available information.

Components:**Atenolol:**

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

11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:**Atenolol:**

Remarks: Unlikely to cause eye irritation.

11.1.4 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.

11.1.5 Germ cell mutagenicity

Not classified based on available information.

Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	24.08.2017	20769	Date of first issue: 24.08.2017

Components:**Atenolol:**

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

11.1.6 Carcinogenicity

Not classified based on available information.

Components:**Atenolol:**

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

11.1.7 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

11.1.8 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.

11.1.9 STOT - repeated exposure

Not classified based on available information.

Components:**Atenolol:**

Exposure routes: Inhalation, Oral

Remarks: Atenolol reduces heart rate and lowers blood pressure.

11.1.10 Aspiration toxicity

Not classified based on available information.

Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	24.08.2017	20769	Date of first issue: 24.08.2017

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
Remarks: (OECD 203) |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (<i>Ceriodaphnia dubia</i> (water flea)): 33.4 mg/l
Exposure time: 48 H
Remarks: (EPA 600/4-90/027)

EC50 (<i>Daphnia magna</i> (Water flea)): 180 mg/l
Exposure time: 48 H
Remarks: (OECD 202) |
| Toxicity to algae | : | EC50 (green algae): 110 mg/l
Exposure time: 96 H
Test Type: growth rate
Remarks: (OECD 201)

NOEC (green algae): 10 mg/l
Exposure time: 96 H
Test Type: growth rate
Remarks: (OECD 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 bacteria | : | EC50 (nitrifying bacteria): > 100 mg/l

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

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

Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	24.08.2017	20769	Date of first issue: 24.08.2017

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 ≥ 1 mg/l.
The substance has moderate mobility in soil.

Distribution among environmental compartments : Remarks: No data 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.
Normal disposal is via incineration operated by an accredited disposal contractor.

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

SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	24.08.2017	20769	Date of first issue: 24.08.2017

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.

Atenolol 29122-68-7

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; 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

Version	Revision Date:	SDS Number:	Date of last issue: -
4.0	24.08.2017	20769	Date of first issue: 24.08.2017

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

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, 3. New classification, 12. New classification, 12. Ecological information, Minor changes:, 2, 5, 6, 8, 12

Date format : dd.mm.yyyy

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