Version	Revision Date:	SDS Number:	Date of last issue: 18.01.2018
4.0	28.05.2019	12310	Date of first issue: 18.01.2018

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

ZESTRIL TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
Lisinopril dihydrate tablets
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 essential hypertension and renovascular hypertension.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H360 May damage fertility or the unborn child.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P281 Use personal protective equipment as required.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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 skin and eye 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

Components

Chemical name	CAS-No.	Concentration (% w/w)
Lisinopril dihydrate	83915-83-7	2.5 -9.7

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest.
Obtain medical attention if ill effects occur.

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 occur.

If swallowed : Wash out mouth with water and give 200-300ml of water to drink.
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
May damage fertility or the unborn child.

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.

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.
Methods and materials for containment and cleaning up	:	Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water. 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	:	Protect from light.
Recommended storage temperature	:	< 30 °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
Lisinopril dihydrate	83915-83-7	TWA	0.1 mg/m3	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.

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	:	uncoated tablets
Colour	:	2,5 mg: white; 5, 10, 20, 30 mg: pink; 40 mg: yellow
Odour	:	No data available
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
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
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	:	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	:	Incompatible materials: oxidising agents
Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	Oxidizing agents
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	:	Remarks: Low acute oral toxicity.

Components:

Lisinopril dihydrate:

Acute oral toxicity	:	LD50 Oral (Rat): > 20 g/kg
Acute inhalation toxicity	:	Remarks: May cause effects as described under repeated exposure.(STOT)
Acute dermal toxicity	:	Remarks: No information available.

11.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Lisinopril dihydrate:

Remarks : May cause skin irritation.
Cases of contact dermatitis have been reported.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Lisinopril dihydrate:

Result : 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:

Lisinopril dihydrate:

Remarks : It is not a skin sensitiser in animal tests.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Lisinopril dihydrate:

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

11.6 Carcinogenicity

Not classified based on available information.

Components:

Lisinopril dihydrate:

Carcinogenicity - Assessment : Studies in animals have shown that repeated doses do not produce carcinogenic effects.

11.7 Reproductive toxicity

May damage fertility or the unborn child.

Components:

Lisinopril dihydrate:

Reproductive toxicity - : Clear evidence of adverse effects on development, based on

Assessment animal experiments.

11.8 STOT - single exposure

Not classified based on available information.

Product:

Exposure routes : Oral
Remarks : May cause lowering of blood pressure.

Components:

Lisinopril dihydrate:

Remarks : May cause effects as described under repeated exposure.(STOT)

11.9 STOT - repeated exposure

Not classified based on available information.

Components:

Lisinopril dihydrate:

Exposure routes : Inhalation, Oral
Target Organs : Kidney
Remarks : Repeated exposure to high levels may cause effect on the kidneys.
May produce dizziness, headache, fatigue, diarrhoea and characteristic cough.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Lisinopril dihydrate:

No information available.

Further information

Product:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Lisinopril dihydrate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 1,060 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: 84/449/E EC C1

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,060 mg/l
Exposure time: 96 h
Method: 84/449/E EC C1

Toxicity to daphnia and other aquatic invertebrates : NOEC (Daphnia magna (Water flea)): > 120 mg/l
Exposure time: 48 h
Test Type: Immobilization
Method: OECD Test Guideline 202

Toxicity to algae : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 120 mg/l
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 120 mg/l
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201

Toxicity to microorganisms : Remarks: There is no evidence of inhibition to the aerobic treatment process at a concentration of 100 mg/l.
There is no evidence of inhibition to the anaerobic treatment process at a concentration (% on dry solids) of 529 mg/l

Persistence and degradability

Components:

Lisinopril dihydrate:

Biodegradability : Remarks: The substance shows no evidence for biodegradability in water.

Bioaccumulative potential

Components:

Lisinopril dihydrate:

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

Mobility in soil

Components:

Lisinopril dihydrate:

Mobility : Remarks: The substance is soluble in water.

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

Not classified as dangerous in the meaning of transport regulations.

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. Lisinopril dihydrate
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

SECTION 16. OTHER INFORMATION

Further information

Revision Date	:	28.05.2019
Other information	:	Full Review - minor changes 6 11 12 15
Date format	:	dd.mm.yyyy

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, 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 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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