

SECTION 1: IDENTIFICATION

1.1 Product identifier

Product name:	Apex Benazepril Oral Solution
Synonyms:	Not Available
Proper Shipping name:	Not Available
Other means of identification:	None

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

Recommended uses:	For the treatment of heart failure due to mitral regurgitation (endocardiosis) and dilated cardiomyopathy. For the treatment of chronic kidney disease in dogs.
Uses advised against:	Not for human use.

1.3 Details of the supplier of the substance or mixture

Registered company name:	Apex Laboratories NZ Ltd
Address:	c/- RXVET Ltd PO Box 1604 Paraparaumu Beach, 5252
Telephone:	0800 473 838 (Business hours)
Fax:	04 974 7793
Email:	info@rxvet.co.nz
Website:	www.rxvet.co.nz

1.4 Emergency Telephone Numbers

	0800 764 766 (Poisons Information Centre)
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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not Applicable

2.2 Label Elements

Signal Word:	Not Applicable
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Hazard Statement(s)

Not Applicable

Additional Statement(s)

Not Applicable
Precautionary Statement(s) Prevention:
Not Applicable
Precautionary Statement(s) Response:
Not Applicable
Precautionary Statement(s) Storage:
Not Applicable
Precautionary Statement(s) Disposal:
Not Applicable
2.3 Other Hazard Information N/a

SECTION 3: INFORMATION ON THE INGREDIENTS
3.1 Substances
See section below for composition of mixtures

3.2 Mixtures			
Ingredient	CAS No	EC Number	Content
Benazepril Hydrochloride	86541-74-4	Not Available	0.5%
Other non-hazardous ingredients	N/a	N/a	N/a

SECTION 4: FIRST AID MEASURES	
4.1 Description of first aid measures	
Eye contact:	In case of accidental contact of the product with the eyes rinse abundantly with fresh water, removing any contact lenses. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
Skin contact:	In case of accidental contact of the product with the skin rinse abundantly with fresh water and non-abrasive soap. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.


Inhalation:	Generally not required due to the nature and packaging of the product. If concerned, remove to fresh air and seek medical advice if irritation occurs.
Ingestion:	In the case of accidental oral intake, wash out mouth with water. If concerned, seek medical advice and show the package leaflet to the medical practitioner.
4.2 Most important symptoms and effects, both acute and delayed	
See Section 11	
4.3 Indication of immediate medical attention and special treatment needed	
Not Available	

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Dry agent, water fog, mist or spray, carbon dioxide. As appropriate for surrounding area.
Unsuitable:	None.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Cool containers with water spray. Wear full breathing apparatus and self-contained breathing apparatus.
Fire / explosion hazard:	No known toxic hazards.
Hazchem code:	None allocated.

SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	
For information on protective equipment, see section 8.	
6.2 Environmental Precautions	
Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/surface or ground water.	
6.3 Methods and material for containment and cleaning up	
Minor Spills:	Spillage of the product is unlikely to be serious. However, avoid contact with skin and eyes.

Major Spills:	<p>For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.</p> <p>Control personal contact with the substance, by using protective equipment.</p> <p>Avoid contact with skin and eyes.</p> <p>Collect spillage into clean, dry, labelled containers and dispose after consulting appropriate authorities.</p>
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SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	<p>Wear suitable protection gloves and clothing when handling the product, keeping exposure to the product to a minimum.</p> <p>Wash hands after handling the product.</p> <p>Prohibit eating, drinking and smoking in storage and handling areas.</p> <p>Observe manufacturer's storage and handling recommendations.</p>
Other Information:	Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	<p>Store below 30°C (room temperature).</p> <p>Storage areas and containers should be clearly marked for drug holding, protected from light, freezing or physical damage and tightly sealed when not in use.</p>
Storage incompatibility:	Not available.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION	
8.1 Control parameters	
OCCUPATIONAL EXPOSURE LIMITS (OEL)	
INGREDIENT DATA:	
Not Available	
EMERGENCY LIMITS:	
Not Available	
8.2 Exposure controls	
Appropriate engineering controls:	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
Personal protection:	
Eye and face protection:	No special equipment needed when handling small quantities. OTHERWISE: Safety glasses with side shields / chemical goggles
Skin protection:	See hand protection below
Hands/ feet protection:	When opening the container and handling the product use disposable gloves.
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not applicable
Respiratory protection:	Not required under normal conditions of use.
8.3 Environmental exposure controls	
See Section 12	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Benazepril Hydrochloride: White or almost white, hygroscopic, crystalline powder
Physical state: Solution
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not available
Specific gravity/density: Not available
Solubility in water and solvents (mg/l): Benazepril Hydrochloride slightly soluble in water
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Molecular weight: Not available
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information
 Not Available

10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Product is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
10.3 Possibility of hazardous reactions:	Stable under normal temperatures and conditions.
10.4 Conditions to avoid:	No conditions to avoid other than extreme heat.
10.5 Incompatible materials:	No data available.

10.6 Hazardous decomposition:	No known decomposition products.
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SECTION 11: TOXICOLOGICAL INFORMATION

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone New Zealand 0800 764 766

Inhalation:	Not expected to irritate the respiratory system.	
Ingestion:	Not expected to be toxic when ingested.	
Skin contact:	May irritate the skin in some persons.	
Eye contact:	May irritate the eyes in some persons.	
Chronic:	Repeated exposure may cause allergic reactions.	
Benazepril Hydrochloride:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : >5000 mg/kg	Not Available

Skin corrosion/irritation:

May irritate the skin.

Serious eye damage/irritation:

Not expected to cause serious eye damage/irritation.

Respiratory or skin sensitization:

Not expected to be a skin sensitizer.

Germ cell mutagenicity:

Not expected to be mutagenic.

Carcinogenicity:

Not expected to be carcinogenic.

Reproductive toxicity:

Not expected to have reproductive toxicity.

STOT – single exposure:

Not available

STOT–repeated exposure:

Not available

Aspiration hazard:

Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in Soil

No data available

12.5 Other adverse effects

Not Available

SECTION 13: DISPOSAL CONSIDERATIONS
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13.1 Waste treatment methods

Product / packaging disposal:	<p>Empty containers may be recycled or sent to a commercial waste disposal site. Unused product should be suitable for landfill; however, contact the relevant local Waste Disposal Authority.</p> <p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p>
Waste Treatment Options:	Do not dispose into sewers or waterways
Sewage Disposal Options:	Do not dispose into sewers or waterways

SECTION 14: TRANSPORT INFORMATION
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Labels required:	None
Marine pollutant:	NO
Hazchem:	N/a

Land transport (ADG):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a
Air transport (IATA / ICAO):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a

	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
Sea transport (IMDG / IMO):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

Agricultural Compounds & Veterinary Medicines Approval No.: A011430

EPA Approval No.: HSR100757

Poison Schedule	Classified as a Schedule 4 (S4) Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
Classifications	Safework Australia criteria is based on the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals. The classifications and phrases listed below are based on the Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008(2004)].
Hazard codes	Not Applicable
Risk phrases	Not Applicable
Safety phrases	Not Applicable
Inventory listing(s)	NEW ZEALAND: NZIoC (New Zealand Inventory of Chemicals) All components are listed on NZIoC, or are exempt.

SECTION 16: OTHER INFORMATION

WORKPLACE CONTROLS AND PRACTICES:

Unless a less toxic chemical can be substituted for a hazardous substance, ENGINEERING CONTROLS are the most effective way of reducing exposure.

The best protection is to enclose operations and/or provide local exhaust ventilation at the site of chemical release. Isolating operations can also reduce exposure. Using respirators or protective equipment is less effective than the controls mentioned above, but is sometimes necessary.

PERSONAL PROTECTIVE EQUIPMENT GUIDELINES:

The recommendation for protective equipment contained within this report is provided as a guide only. Factors such as form of product, method of application, working environment, quantity used, product concentration and the availability of engineering controls should be considered before final selection of personal protective equipment is made.

HEALTH EFFECTS FROM EXPOSURE:

It should be noted that the effects from exposure to this product will depend on several factors including: form of product; frequency and duration of use; quantity used; effectiveness of control measures; protective equipment used and method of application. Given that it is impractical to prepare a report which would encompass all possible scenarios, it is anticipated that users will assess the risks and apply control methods where appropriate.

ABBREVIATIONS:

ACGIH: American Conference of Governmental Industrial Hygienists

CAS #: Chemical Abstract Service number - used to uniquely identify chemical compounds

CNS: Central Nervous System

EC No.: EC No - European Community Number

EMS: Emergency Schedules (Emergency Procedures for Ships Carrying Dangerous Goods)

GHS: Globally Harmonized System

GTEPG: Group Text Emergency Procedure Guide

IARC: International Agency for Research on Cancer

LC50: Lethal Concentration, 50% / Median Lethal Concentration

LD50: Lethal Dose, 50% / Median Lethal Dose

mg/m³: Milligrams per Cubic Metre

OEL: Occupational Exposure Limit

pH: relates to hydrogen ion concentration using a scale of 0 (high acidic) to 14 (highly alkaline).

ppm: Parts Per Million

STEL: Short-Term Exposure Limit

STOT-RE: Specific target organ toxicity (repeated exposure)

STOT-SE: Specific target organ toxicity (single exposure)

SUSMP: Standard for the Uniform Scheduling of Medicines and Poisons

SWA: Safe Work Australia

TLV: Threshold Limit Value

TWA: Time Weighted Average

This SDS summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user must review this SDS in the context of how the product will be handled and used in the workplace. Apex Laboratories Pty Ltd make no representation of merchantability, fitness for a particular purpose or application, or of any other nature with respect to the information or the product to which the information refers ("the product").

The information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability prior to use of the product. The physical data shown herein are typical values based on material tested. These values should not be construed as guaranteed analysis of any specific lot or as guaranteed specification for the product or specific lots hereof.