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**SAFETY DATA SHEET**

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**Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY**

<b>Product Identifier:</b>	<b>VetACE 2.5 mg Tablets for Dogs and Cats VetACE 5 mg Tablets for Dogs and Cats VetACE 20 mg Tablets for Dogs</b>
<b>Product Code:</b>	503875 (2.5 mg x 28 tabs) 504045 (2.5 mg x 42 tabs) 503880 (5 mg x 28 tabs) 504060 (5 mg x 42 tabs) 503885 (20 mg x 28 tabs) 504055 (20 mg x 42 tabs)
<b>Recommended Use:</b>	For the treatment of heart failure in dogs due to mitral regurgitation (endocardiosis) and dilated cardiomyopathy, and both chronic renal insufficiency and hypertrophic cardiomyopathy in cats.
<b>Restrictions on Use:</b>	For animal treatment only.
<b>Company Identification:</b>	Jurox Pty Limited
<b>Address:</b>	85 Gardiner Street, Rutherford, NSW 2320, Australia
<b>Email:</b>	jenq@jurox.com.au
<b>Customer Centre:</b>	1800 023 312
<b>National Poisons Information Centre:</b>	13 1126 (Australia-wide)
<b>Emergency Telephone Number:</b>	1800 023 312 (9am – 5pm, Monday to Friday)

**Section 2: HAZARDS IDENTIFICATION**

**Hazard Classifications:** This product has been assessed according to GHS and is classified as non-hazardous.

**Signal word:** None.

**GHS Pictograms:** None.

**Precautionary statements:** None.

**Section 3: COMPOSITION / INFORMATION on INGREDIENTS**

INGREDIENT	CAS No.	CONTENT
Benazepril hydrochloride	86541-74-4	2.6% (2.5 mg and 5 mg tablets) 10.4% (20 mg tablets)
Ingredients not contributing to the hazards	-	To 100%

## Section 4: FIRST AID MEASURES

**General Information:** Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.

**Symptoms and Effects of Exposure:** The side effects of therapeutic use of benazepril include headache, cough, hypotension, dizziness, fatigue, nausea, angioedema (face, tongue and extremities) and dermatitis. The most significant sign of poisoning is likely to be marked hypotension.

**Inhalation:** First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

**Ingestion:** If swallowed do NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

**Skin:** If skin contact occurs, wash affected area thoroughly with plenty of soap and water. If skin irritation or rash occurs, get medical advice/attention.

**Eye:** If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. If eye irritation persists, get medical advice/attention.

**Recommended First Aid Facilities:** Ready access to running water and soap is required. Accessible eyewash is required.

**Advice to Doctor:** None.

## Section 5: FIRE FIGHTING MEASURES

**Flash Point:** No data. Not flammable. Not combustible.

**Hazardous Combustion Products:** If involved in a fire, may emit noxious and irritant fumes.

**Extinguishing Media:** There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

**Protective Equipment:** Protective gloves and breathing apparatus.

**HAZCHEM Code:** None specified.

## Section 6: ACCIDENTAL RELEASE MEASURES

**Spills and Disposal:** This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For small spills, clean up spilled product then wipe area and put empty container in garbage. Although no special protective clothing is normally necessary because of occasional minor contact with this product, it is good practice to wear impermeable gloves when handling chemical products. For large spills, exclude non-essential people from the area. Prevent spillage from entering drains or water courses and call emergency services.

**Protective Clothing:** For appropriate personal protective equipment see section 8.

**Environmental Precautions:** Prevent from entering drains, waterways or sewers. If spill does enter waterways contact local authority.

## Section 7: HANDLING AND STORAGE

**Handling:** Avoid contact with skin, eyes and inhalation of dusts. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

**Storage:** Keep out of reach of children. Store below 25°C (air conditioning), away from foodstuffs. Protect from heat and moisture. Unused half tablets should be returned to the open blister space and inserted back into the carton.

**Other Information:** Always read the label before use. See label for further information on handling and storage.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.**

**Exposure Limits:** An exposure limit for the mixture has not been established. No exposure standards for the ingredients are available.

The occupational toxicity risk is low from the tablet form. The occupational exposure standard for benazepril hydrochloride is 0.02 mg/m<sup>3</sup> (USA value).

**Engineering Controls:** No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that dusts are minimised.

### Personal Protective Equipment (PPE):

Eye protection: Protective glasses or goggles are recommended when bulk quantities of this product are being handled.

Skin protection: When handling bulk quantities, prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory protection: Not required for the normal use of this product.

### Section 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Round, concave, half-scored, tan/grey film coated (2.5 mg) tablets	<b>Evaporation Rate:</b>	Not applicable
	Round, concave, half-scored, yellow film coated (5 mg) tablets	<b>Upper / Lower Flammability or Explosive Limits:</b>	Not available
	Round, concave, half-scored, red film coated (20 mg) tablets	<b>Vapour Pressure:</b>	Not applicable
<b>Odour:</b>	Not available	<b>Vapour Density:</b>	Not applicable
		<b>Relative Density:</b>	Not applicable
<b>Odour Threshold:</b>	Not available	<b>Solubility in Water:</b>	Disintegrates in water
<b>pH:</b>	Not applicable	<b>Partition coefficient</b>	Not available
<b>Melting Point / Freezing point:</b>	Not available	<b>Auto-Ignition Temperature:</b>	Not available
<b>Initial Boiling Point and Boiling Range:</b>	Not applicable	<b>Decomposition Temperature:</b>	Not applicable
<b>Flashpoint:</b>	Not available	<b>Viscosity:</b>	Not applicable

### Section 10: STABILITY AND REACTIVITY

**Reactivity:** This product is unlikely to react or polymerise under normal storage conditions.

**Stability:** When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

**Conditions to Avoid:** Elevated temperatures and/or direct sunlight.

**Incompatible Materials:** Oxidising agents.

**Hazardous Decomposition Products:** No data available.

### Section 11: TOXICOLOGICAL INFORMATION

**Signs & Symptoms of Exposure:** No data.

**Medical Conditions Generally Aggravated by Exposure:** None known.

**Acute Toxicity:**

**Ingestion:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route.

Benazepril hydrochloride: Oral LD<sub>50</sub>: 4019 mg/kg (mouse), 5000 mg/kg (rat).

**Inhalation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route.

**Dermal:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

**Skin Corrosion / Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be skin corrosive or irritant.

**Serious Eye Damage / Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant.

**Respiratory or Skin Sensitisation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin sensitiser or a respiratory sensitiser.

**Germ Cell Mutagenicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

**Carcinogenicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

**Reproductive Toxicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant. At doses of 50 – 500 mg / kg / day, benazepril had no effect on the reproductive performance of male and female rats.

**STOT: Single exposure:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure.

**STOT: Repeat exposure:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after repeat exposure. Benazepril hydrochloride has been shown to be an effective and well tolerated oral agent in human patients for the chronic treatment of advanced congestive heart failure. Ref: Mirvis, D.M. *et al.* Am. J. Med Sci. 1990; 300 (6): 354 – 60.

**Aspiration hazard:** No data available.

## Section 12: ECOLOGICAL INFORMATION

**Ecotoxicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be toxic to the environment.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation potential	Mobility
Benazepril hydrochloride	No data	No data	No data	No data

## Section 13: DISPOSAL INFORMATION

**Product Disposal:** Dispose of product only by using according to label or at an approved landfill.

**Container Disposal:** Dispose of container by wrapping with paper and putting in garbage.

## Section 14: TRANSPORT INFORMATION

**Dangerous Goods Classification:** Not classed as a Dangerous Good for transport purposes by road, sea or air.

## Section 15: REGULATORY INFORMATION

**Poison Schedule (SUSMP):** S4.

**APVMA Registration No:** 61589 (VetACE 2.5 mg); 61920 (VetACE 5 mg); 61583 (VetACE 20 mg).

**AICS:** All of the significant ingredients in this formulation are compliant with NICNAS regulations.

**Section 16: OTHER INFORMATION**

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein does so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

**Legend:**

<b>AICS</b>	Australian Inventory of Chemical Substances.
<b>APVMA</b>	Australian Pesticides and Veterinary Medicines Authority.
<b>CAS No.</b>	Chemical Abstracts Service Registry Number.
<b>GHS</b>	Globally Harmonized System of Classification and Labelling of Chemicals.
<b>Hazchem Code</b>	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
<b>LD<sub>50</sub></b>	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
<b>NICNAS</b>	National Industrial Chemicals Notification and Assessment Scheme.
<b>PPE</b>	Personal Protective Equipment.
<b>PVC</b>	Polyvinyl Chloride.
<b>SDS</b>	Safety Data Sheet.
<b>STOT</b>	Specific Target Organ Toxicity.
<b>SUSMP</b>	Standard for the Uniform Scheduling of Medicines and Poisons.

**References:**

ChemID Plus

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

**This version issued:** 12 July 2016 and is valid for 5 years from this date.

**Supersedes:** This SDS supersedes the version issued on 7 November 2011.

**Revision History:**

Date of Revision	Reason
12 July 2016	Reclassification of substance to GHS classification and update of SDS to comply with SWA Code of Practice.

**END OF SDS**