

<b>SECTION 1: IDENTIFICATION</b>	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Cardisure® Flavoured Tablets (containing 1.25mg, 2.5mg, 5mg or 10mg pimobendan)
<b>Synonyms:</b>	Pimocard, Pimosure
<b>Proper Shipping name:</b>	Not Available
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid regurgitation) or dilated cardiomyopathy.
<b>Uses advised against:</b>	Not for human use.
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name:</b>	Apex Laboratories Pty Ltd
<b>Address:</b>	Apex Laboratories Pty Ltd ACN 614 716 700 2 Cal Close Somersby NSW 2250
<b>Telephone:</b>	1300 015 825 (Business hours: 08:30 – 17:30)
<b>Fax:</b>	+61 2 4372 1668
<b>Email:</b>	thetvet@apexlabs.com.au
<b>Website:</b>	www.apexlabs.com.au
<b>1.4 Emergency Telephone Numbers</b>	
	13 11 26 (Poisons Information Centre)

<b>SECTION 2: HAZARDS IDENTIFICATION</b>	
<b>2.1 Classification of the substance or mixture</b>	
<b>GHS classification(s):</b>	Specific target organ toxicity - single exposure - Category 3 (respiratory tract irritation)
Please note that respiratory irritation is unlikely to occur due to physical form of the product and how it is packaged	
<b>2.2 Label Elements</b>	
<b>Signal Word:</b>	<b>WARNING</b>

<b>Hazard statement(s):</b>	
<b>H335</b>	May cause respiratory irritation
<b>Precautionary Statement(s) Prevention:</b>	
<b>P261</b>	Avoid breathing dust/fumes.
<b>Precautionary Statement(s) Response:</b>	
<b>P312</b>	Call a POISON CENTER or doctor/physician if you feel unwell.
<b>P304+P340</b>	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
<b>Precautionary Statement(s) Storage:</b>	
<b>P405</b>	Store locked up.
<b>Precautionary Statement(s) Disposal:</b>	
<b>P501</b>	Dispose of contents/container in accordance with local regulations.
<b>2.3 Other Hazard Information</b>	

### 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
Pimobendan	74150-27-9	NA	0.6%
Other ingredients	N/a	NA	To 100%

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

<b>Eye contact:</b>	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
<b>Skin contact:</b>	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
<b>Inhalation:</b>	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered.

	If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
<b>Ingestion:</b>	If swallowed, seek medical advice immediately and show the package leaflet or the label 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**

Advice to medical practitioners: accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.

**SECTION 5: FIRE FIGHTING MEASURES**

**5.1 Extinguishing media**

<b>Suitable:</b>	Select extinguishing media suitable for surrounding area .
<b>Unsuitable:</b>	There is no restriction on the type of extinguisher which may be used.

**5.2 Special hazards arising from the substance or mixture**

<b>Fire incompatibility:</b>	Alert Fire Brigade and tell them location and nature of hazard. Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.
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**5.3 Special protective actions for fire-fighters:**

<b>Firefighting:</b>	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses
<b>Fire / explosion hazard:</b>	Solid which exhibits difficult combustion or is difficult to ignite. Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire  A dust explosion may release large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.  Combustion products include: <ul style="list-style-type: none"> <li>• Carbon monoxide (CO)</li> </ul>

	<ul style="list-style-type: none"> <li>• Carbon dioxide (CO<sub>2</sub>)</li> <li>• Other pyrolysis products typical of burning organic material.</li> </ul> <p>May emit poisonous fumes.</p>
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## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

See section 8

### 6.2 Environmental Precautions

See section 12

### 6.3 Methods and material for containment and cleaning up

Spills are unlikely due to the nature of the product and how it is packaged

<b>Minor Spills:</b>	Remove all ignition sources Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Collect spillage and place into a suitable disposal container.
<b>Major Spills:</b>	Alert Fire Brigade and tell them location and nature of the hazard. Control personal contact with the substance, by using protective equipment.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

<b>Safe Handling:</b>	Wear suitable protection gloves and clothing when handling the product. When handling, <b>DO NOT</b> eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Store below 25°C (air conditioning). Protect from light. Discard unused material. Keep out of the reach and sight of children.

### 7.2 Conditions for safe storage, including any incompatibilities

<b>Suitable Container:</b>	Check that containers are clearly labelled. Return any divided tablet to the opened blister and use within 3 days.
<b>Storage incompatibility:</b>	Avoid reaction with oxidising agents.

<b>7.3 Specific end uses</b>
Not available

**SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

**8.1 Control parameters**

**OCCUPATIONAL EXPOSURE LIMITS (OEL)**

Not applicable

**EMERGENCY LIMITS:**

Not available

**8.2 Exposure controls**

<b>Appropriate engineering controls:</b>	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.
<b>Personal protection:</b>	Not required when product used as directed.
<b>Eye and face protection:</b>	No special equipment needed when handling small quantities. OTHERWISE: Wear safety glasses with side shields / chemical goggles
<b>Skin protection:</b>	See hand protection below
<b>Hands/ feet protection:</b>	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
<b>Body protection:</b>	Wear appropriate clothing
<b>Other protection:</b>	No special equipment needed when handling small quantities
<b>Thermal hazards:</b>	Not applicable
<b>Respiratory protection:</b>	Not applicable

**8.3 Environmental exposure controls**  
 See Section 12

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

**Appearance:** Tablets: light brown, round tablets, scored on one side and plain on the other side.  
 Pimobendan: White or slightly yellowish, hygroscopic powder  
**Physical state:** Solid  
**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 applicable  
**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  
**Solubility in water and solvents (mg/l), Pimobendan:**  
     **Water:** practically insoluble  
     **Acetone:** slightly soluble  
     **Methyl alcohol:** slightly soluble  
     **Dimethylformamide:** freely soluble  
**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:** 334.37  
**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

## SECTION 10: REACTIVITY AND STABILITY

<b>10.1 Reactivity:</b>	See Section 7
<b>10.2 Chemical stability:</b>	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
<b>10.3 Possibility of hazardous reactions:</b>	The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur.
<b>10.4 Conditions to avoid:</b>	See Section 7.
<b>10.5 Incompatible materials:</b>	See section 7.
<b>10.6 Hazardous decomposition:</b>	See Section 5.

**SECTION 11: TOXICOLOGICAL INFORMATION**

<b>Inhalation:</b>	This substance may cause respiratory irritation in some people. The reaction to this irritation can lead to further damage to the lungs.	
<b>Ingestion:</b>	Unintentional ingestion by the mouth of this substance may cause health damage. Polysaccharides (cellulose) are not easily absorbed from the digestive system, but may have a laxative effect. Accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.	
<b>Skin contact:</b>	This substance is not considered to cause irritation of the skin upon contact (in the classification according to EC directives based on animal models). Nevertheless, good hygiene requires that exposure is minimized. Open wounds, scratched or irritated skin should not be exposed to this material. Inflammation in the bloodstream through, for example, cut wounds, can cause bodily injury throughout the body with harmful effects. Inspect the skin for use of the material and ensure that any external injury is properly protected.	
<b>Eye contact:</b>	Although the substance according to EC directives is NOT classified as irritating, direct contact with the eyes may cause temporary discomfort, characterized by tearing eyes or redness of the connective tissue (such as when exposed to severe wind). Slight damage due to scratches can also occur.	
<b>Chronic:</b>	Long term exposure to compounds that irritate the respiratory system may cause airways such as difficulty breathing and related systemic problems. Accumulation of the substance in the body may occur and may cause some concern for occupational repeated or long term exposure. There is limited evidence that skin contact in some individuals will cause an allergic reaction to the general population.	
<b>Cardisure:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
<b>Pimobendan:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Oral (rat) LD <sub>50</sub> : 950 mg/kg <sup>1</sup>	Not available

1.\* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances

**Skin corrosion/ irritation:**

Not available
<b>Serious eye damage/ irritation:</b>
Not available
<b>Respiratory or skin sensitization:</b>
Not available
<b>Germ cell mutagenicity:</b>
Not available
<b>Carcinogenicity:</b>
Not available
<b>Reproductive toxicity:</b>
Not available
<b>STOT–single exposure:</b>
Not available
<b>STOT–repeated exposure:</b>
Not available
<b>Aspiration hazard:</b>
Not available

<b>SECTION 12: ECOLOGICAL INFORMATION</b>
<b>12.1 Toxicity</b>
Not available
<b>12.2 Persistence and degradability</b>
Not available
<b>12.3 Bioaccumulative potential</b>
Not available
<b>12.4 Mobility in Soil</b>
Not available

<b>SECTION 13: DISPOSAL CONSIDERATIONS</b>		
<b>13.1 Waste treatment methods</b>		
<table border="1"> <tr> <td><b>Product / packaging disposal:</b></td> <td>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.</td> </tr> </table>	<b>Product / packaging disposal:</b>	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.
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	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.
<b>Waste Treatment Options:</b>	Do not dispose into sewers or waterways
<b>Sewage Disposal Options:</b>	Do not dispose into sewers or waterways

<b>SECTION 14: TRANSPORT INFORMATION</b>	
<b>Labels required:</b>	
<b>Marine pollutant:</b>	NO
<b>Hazchem:</b>	Not Applicable
<b>Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Air transport (ICAO-ICAO): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Sea transport (IMDG-IMO): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	

<b>SECTION 15: REGULATORY INFORMATION</b>	
<b>15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture</b> Australian Pesticides & Veterinary Medicines Authority (APVMA) Approval No. 81942 (5mg); 81944 (10mg); 81946 (2.5mg); 81948 (1.25mg)	
<b>Poison Schedule</b>	Classified as Schedule 4 according to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
<b>Classifications</b>	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)].
<b>Hazard codes</b>	H335: May cause respiratory irritation
<b>Risk phrases</b>	R37: Irritating to respiratory system.
<b>Inventory listing(s)</b>	<b>AUSTRALIA: AICS (Australian Inventory of Chemical Substances)</b> All components are listed on AICS, 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/m<sup>3</sup>:** 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.