

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Vetmedin Capsules for Dogs
Product code:	A009130 (1.25 mg), A007867 (2.5 mg), A007868 (5 mg)
Recommended use:	Vetmedin capsules are indicated for the treatment of canine congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency (mitral and/or tricuspid regurgitation).
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 263 1400
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
Date of issue:	17 May 2018
Date of review:	7 February 2020

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:	Solid		
	Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilatative properties.		
	1.25 mg capsule contains 1.25 mg pimobendan		
	2.5 mg capsule contains 2.5 mg pimobendan		
	5 mg capsule contains 5 mg pimobendan		
Product components:			
Name	CAS	Proportion	
Pimobendan (3(2H)-Pyridazinone, 4,5-dihydro-6-[2-(4-methoxyphenyl)-1H-benzimidazol-5-yl]-5-methyl-)	74150-27-9	≤2%	
Ingredients determined not to be hazardous	N/A	Balance	

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.3B, 6.9B, 8.3A
Priority and secondary identifiers:	DANGER
Risk and safety phrases:	6.3B Substance that is mildly irritating to the skin 6.9B (Single exposure) - Substance that is harmful to human target organs or systems 6.9B (Repeated exposure) - Substance that is harmful to human target organs or systems 8.3A Substance that is corrosive to ocular tissue
	Hazard Statement(s) H316 Causes mild skin irritation. H318 Causes serious eye damage. H371 May cause damage to organs by oral. H373 May cause damage to organs through prolonged or repeated exposure by oral.
	Precautionary statement – Prevention P102 Keep out of reach of children.

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P103 Read label before use.
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P264 Wash contaminated skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement – Response

P101 If medical advice is needed, have product container or label at hand.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P309+P311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

P310 Immediately call a POISON CENTER or doctor/physician.

P314 Get medical advice/attention if you feel unwell.

P332+P313 If skin irritation occurs: Get medical advice/attention.

Precautionary statement – Storage

P405 Store locked up.

Precautionary statement – Disposal

P501 In the case of a substance that is in compliance with a HSNO approval other than a Part 6A (Group Standards) approval, a label must provide a description of one or more appropriate and achievable methods for the disposal of a substance in accordance with the Hazardous Substances (Disposal) Regulations 2001. This may also include any method of disposal that must be avoided. See Section 13 for disposal details.

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:

For advice, contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately.

Ingestion: If swallowed, seek medical attention. Do NOT induce vomiting. Wash out mouth thoroughly with water.

Eyes: If in eyes, hold eyelids apart and flush the eyes continuously with running water. Remove contact lenses. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. Seek immediate medical attention.

Skin: Remove all contaminated clothing immediately. Wash affected area thoroughly with soap and water. Wash contaminated clothing before reuse or discard. Seek medical attention.

Inhalation: If inhaled, remove affected person from contaminated area to fresh air. Keep at rest until recovered. If symptoms develop and/or persist, seek medical attention.

Workplace facilities:

No special facilities required.

Required instructions:

Observe good work practices and avoid skin contact. Wash hands and exposed skin before meals and after use. Do not eat or drink while using. Launder protective clothing separately from other clothing, and before each reuse.

Notes for medical personnel:

Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:

Combustible

Fire hazard properties:

Combustible. This product will burn if exposed to fire. Under fire conditions this product may emit toxic and/or irritating fumes, smoke and gases including carbon monoxide, carbon dioxide and oxides of nitrogen.

Extinguishing media and methods:

Use appropriate fire extinguisher for surrounding environment.

Hazchem code:

N/A

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Recommended protective clothing:	Fire fighters should wear full protective clothing and self-contained breathing apparatus operated in positive pressure mode. Fight fire from safe location.
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SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:	<p>Wear appropriate personal protective equipment and clothing. Avoid inhalation of dusts, and skin or eye contact.</p> <p>For a small spill: Sweep up material avoiding dust generation or dampen spilled material with water to avoid airborne dust, and then transfer material to a suitable labelled container for subsequent recycling or disposal. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations.</p> <p>For a large spill: Increase ventilation. Evacuate all unprotected personnel. If possible, contain the spill. Sweep up material avoiding dust generation or dampen spilled material with water to avoid airborne dust, then transfer material to a suitable container. Wash surfaces well with soap and water. Seal all wastes in labelled plastic containers for subsequent recycling or disposal. Dispose of waste according to the applicable local and national regulations. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations.</p>
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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Use as directed on label or package insert. Avoid generating dusts. Use in a well ventilated area. Exposure without protection should be prevented in order to lessen the possibility of disorders. Maintain high standards of personal hygiene i.e. Washing hands prior to eating, drinking, smoking or using toilet facilities.
Approved handlers:	Not required
Conditions for safe storage:	Store in a cool, dry, well-ventilated area, out of direct sunlight. Protect from light and moisture. Store in suitable, labelled containers. Keep containers closed when not in use. Store away from incompatible materials. Ensure that storage conditions comply with applicable local and national regulations.
Store site requirements:	Store below 25 °C. Keep the container tightly closed.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:	No exposure standards have been established for the mixture. However, over-exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels.
Application in the workplace:	Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.
Engineering controls:	None required, when used as intended. However, if there is risk of airborne exposure, use with good general ventilation. If dusts are produced, local exhaust ventilation should be used.
Personal protection:	<p>Respiratory Protection Industrial application: Use with good general ventilation. If engineering controls are not effective in controlling airborne exposure then an approved respirator with a replaceable dust/particulate/ mist filter should be used. Refer to relevant regulations for further information concerning respiratory protective requirements.¹</p> <p>Eye Protection Safety glasses with full face shield should be used. Eye protection devices should conform to relevant regulations.²</p> <p>Hand Protection</p>

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None required, when used as intended. However, where exposure to the contents is likely wear gloves of impervious material. Final choice of appropriate gloves will vary according to individual circumstances, i.e. methods of handling or according to risk assessments undertaken. Occupational protective gloves should conform to relevant regulations.³

Body Protection

Suitable protective workwear, e.g. cotton overalls buttoned at neck and wrist is recommended. Chemical resistant apron is recommended where large quantities are handled.

Other Information

No exposure standards have been established for this material. However, over-exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels. The exposure limits for particulates not otherwise classified are as follows: Particulates TWA 10 mg/m³ (inhalable) TWA 3 mg/m³ (respirable)

TWA (Time Weighted Average): The average airborne concentration of a particular substance when calculated over a normal eight- hour working day, for a five-day week.

References:

1. Reference should be made to Australian Standards AS/ NZS 1715, Selection, Use and Maintenance of Respiratory Protective Devices; and AS/NZS 1716, Respiratory Protective Devices, in order to make any necessary changes for individual circumstances.
2. Eye protection should conform with Australian/New Zealand Standard AS/NZS 1337 - Eye Protectors for Industrial Applications.
3. Reference should be made to AS/NZS 2161.1: Occupational protective gloves - Selection, use and maintenance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	<u>Formulation type</u> : Solid <u>Appearance</u> : White polypropylene tubes containing 100 capsules each <u>Specific gravity</u> : Not available <u>Boiling Point</u> : Not available <u>Vapour Pressure</u> : Not available <u>Solubility in Water</u> : Not available <u>Flammability</u> : Combustible
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SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable under normal conditions of use and storage.
Conditions to avoid:	Extremes of temperature and direct sunlight.
Material to avoid:	No specific materials to avoid.
Hazardous decomposition products:	Under fire conditions this product may emit toxic and/or irritating fumes, smoke and gases including carbon monoxide, carbon dioxide and oxides of nitrogen.
Hazardous polymerization:	Will not occur.
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:	Acute Toxicity - Oral LD50 (rat): 4120 mg/kg (value for the active ingredient) Acute Toxicity - Inhalation LC50 (rat): > 175.6 mg/kg (Estimated value for the active
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ingredient) Ingestion Ingestion of this product may irritate the gastric tract causing nausea and vomiting. Inhalation Inhalation of product dusts may cause irritation of the nose, throat and respiratory system. Skin Causes mild skin irritation. Skin contact will cause redness, itching and swelling. Repeated exposure may cause skin dryness and cracking and may lead to dermatitis. Eye Causes eye damage. Eye contact will cause stinging, blurring, tearing, severe pain and possible burns, necrosis, permanent damage and blindness. Respiratory sensitisation Not expected to be a respiratory sensitiser. Skin Sensitisation Not expected to be a skin sensitiser. Germ cell mutagenicity Not considered to be a mutagenic hazard. Carcinogenicity Not considered to be a carcinogenic hazard. Reproductive Toxicity Not considered to be toxic to reproduction. STOT-single exposure May cause damage to organs by oral. STOT-repeated exposure May cause damage to organs through prolonged or repeated exposure by oral. Aspiration Hazard Not expected to be an aspiration hazard.

SECTION 12: ENVIRONMENTAL INFORMATION	
Potential environmental interactions:	No ecological data available for this material.
Data organisation :	Persistence and degradability Not available Mobility Not available Bioaccumulative Potential Not available Other Adverse Effects Not available
Environmental risk and safety phrases:	Prevent this material entering waterways, drains and sewers.

SECTION 13: DISPOSAL CONSIDERATIONS	
Disposal information :	The disposal of the spilled or waste material must be done in accordance with applicable local and national regulations. <u>Product Disposal:</u> Product wastes are controlled wastes and should be disposed of in accordance with all applicable local and national regulations. The product should be rendered non-hazardous before being sent to a licensed landfill facility. In this specific case the product is a combustible substance and therefore can be sent to an approved high temperature incineration plant for disposal.

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	<p>Personal protective clothing and equipment as specified in Section 8 of this SDS must be worn during handling and disposal of this product. The ventilation requirements as specified in the same section must also be followed, and the precautions given in Section 7 of this SDS regarding handling must also be followed. Do not dispose into the sewerage system. Do not discharge into drains or watercourses or dispose where ground or surface waters may be affected.</p> <p>In New Zealand, the disposal agency or contractor must comply with the New Zealand Hazardous Substances (Disposal) Regulations 2001. Further details regarding disposal can be obtained on the EPA New Zealand website under specific group standards.</p> <p><u>Container Disposal:</u> The container or packaging must be cleaned and rendered incapable of holding any substance. It can then be disposed of in a manner consistent with that of the substance it contained. In this instance the packaging can be disposed through a commercial waste collection service. Alternatively, the container or packaging can be recycled if the hazardous residues have been thoroughly cleaned or rendered non-hazardous. In New Zealand, the packaging (that may or may not hold any residual substance) that is lawfully disposed of by householders or other consumers through a public or commercial waste collection service is a means of compliance with regulations.</p>
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	Not classified as dangerous for rail, road, air or sea transport.
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No. A009130 (1.25 mg capsules), A007867 (2.5 mg capsules), A007868 (5 mg capsules). See www.foodsafety.govt.nz for registration conditions
	Restricted Veterinary Medicine For use only under the authority or prescription of a veterinarian.
	Approved pursuant to the HSNO Act, Approval Code HSR002302 See www.epa.govt.nz for approval conditions
HSNO and ACVM controls:	Refer to Section 3

SECTION 16: OTHER INFORMATION

Additional information:	For product information visit the Boehringer Ingelheim website www.boehringer-ingelheim.co.nz While the information set forth is believed to be accurate as of the date hereof, BOEHRINGER INGELHEIM makes no warranty with respect hereto and disclaims all liability from reliance thereon.
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