



SECTION 1: IDENTIFICATION	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Dermcare Malaseb® Medicated Shampoo
<b>Synonyms:</b>	Not Available
<b>Proper Shipping name:</b>	Not Available
<b>Other means of identification:</b>	APVMA approval number: 47682 Active constituents: 20g/L Chlorhexidine Gluconate, 20g/L Miconazole Nitrate
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	Topical keratolytic, antibacterial, antifungal, and antipruritic shampoo for dogs and cats. Dogs: For the treatment and control of seborrhoeic dermatitis associated with <i>Malassezia pachydermatis</i> and <i>Staphylococcus intermedius</i> . Cats: As an aid in the treatment of ringworm due to <i>Microsporum canis</i> in conjunction with griseofulvin.
<b>Uses advised against:</b>	Do not use in case of hypersensitivity to the active substances or to any of the excipients.  Dogs and cats: In order to prevent reoccurrence of the infection, appropriate control methods should be employed in the animal's environment (e.g. cleaning and disinfection of kennels, beds). Cats: Malaseb shampoo should only be used in conjunction with griseofulvin when treating for ringworm. Shampooing cats may initially increase the recovery of <i>M. canis</i> by brush culture techniques.
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name:</b>	Dermcare-VET Pty Ltd
<b>Address:</b>	7 Centenary Road Slacks Creek, Qld. 4127 Australia
<b>Telephone:</b>	+(07) 3387 9700
<b>Fax:</b>	Not available
<b>Email:</b>	dermcare@dermcare.com.au
<b>Distributor name (Canada):</b>	Dechra Veterinary Products
<b>Address:</b>	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3 Canada

<b>Telephone:</b>	+1 (855) 332-9334
<b>Website:</b>	www.dechra.ca
<b>Email:</b>	Not Available
<b>1.4 Emergency Telephone Numbers</b>	
<b>Dermcare-VET (AUS) :</b>	+(07) 3387 9700
<b>Dechra (CA) :</b>	+1 (855) 332-9334

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

<b>DSD Classification:</b>	Acute toxicity, oral Category 5 Sensitisation, skin Category 1 Serious eye damage/eye irritation Category 1 Sensitisation, respiratory Category 1
<b>DPD Classification:</b>	Not Available
<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	Not Available

### 2.2 Label Elements

<b>GHS Label Elements: (pictograms)</b>	
<b>Signal Word:</b>	DANGER

### Hazard Statement(s)

H303 May be harmful if swallowed  
 H317 May cause an allergic skin reaction  
 H318 Causes serious eye damage  
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

### Additional Statement(s)

None

### Precautionary Statement(s) Prevention:

<b>P261</b>	Avoid breathing vapour.
<b>P272</b>	Contaminated work clothing should not be allowed out of the workplace.
<b>P280</b>	Wear protective (non-latex) gloves and eye protection/face protection.

### Precautionary Statement(s) Response:

<b>P301 + P310</b>	IF SWALLOWED: immediately call a POISON CENTER/doctor
<b>P330</b>	Rinse mouth.



<b>Precautionary Statement(s) Storage:</b>	
<b>P405</b>	Store locked up
<b>Precautionary Statement(s) Disposal:</b>	
<b>P501</b>	Dispose of contents / packaging according to 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

#### Composition %w/w

Ingredient Name / Nature	0<1	1<10	>10	>20	>30	>40	>50	>60	>70	>80	>90
Chlorhexidine Gluconate											
Miconazole Nitrate											
Surfactants											

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

Consider your own safety first. For advice, contact a Poisons Information Centre (418 656-8090) or a doctor.

<b>Eye contact:</b>	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or a doctor/physician.
<b>Skin contact:</b>	Wash with plenty of water, if skin irritation or rash occurs get medical advice/attention. Take off contaminated clothing and wash it before reuse. Discontinue use if allergic reaction is suspected.
<b>Inhalation:</b>	Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or a doctor/physician.
<b>Ingestion:</b>	Do NOT induce vomiting. Rinse mouth with water and spit. Give a glass of water. Seek medical advice.

#### 4.2 Most important symptoms and effects, both acute and delayed

**Chlorhexidine Gluconate** has been reported as causative agent of contact dermatitis, hives (urticaria), shortness of breath (dyspnoea) and anaphylactic shock. **Miconazole Nitrate** by ingestion: anorexia, nausea, vomiting and diarrhoea. Local irritation reactions and potentially hyperlipidaemia, drowsiness, febrile reactions, hyponatraemia, acute psychosis, arthralgia and anaphylaxis. **Surfactants:** incidents involving oral exposure have resulted in irritation to the mouth/throat/nose, vomiting/nausea/abdominal pain, dizziness, and headache; incidents involving inhalation exposure resulted in respiratory irritation/burning, irritation to the mouth/throat/nose, coughing/choking, chest pain, disorientation, dizziness & shortness of breath. Irritation/burning, rash, itching and blistering noted during incidental dermal exposure. Hives and allergic contact dermatitis were also noted following dermal exposure. Incidental exposure of eyes resulted in irritation/burning, eye pain, conjunctivitis, eye, and eyelid swelling.

#### 4.3 Indication of immediate medical attention and special treatment needed

Treat symptomatically

### SECTION 5: FIRE FIGHTING MEASURES

#### 5.1 Extinguishing media

<b>Suitable:</b>	Select extinguishing media suitable for surrounding area.
<b>Unsuitable:</b>	None.

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

On burning will emit toxic fumes, including those of oxides of carbon.

<b>Fire incompatibility:</b>	None known
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#### 5.3 Special protective actions for fire-fighters:

<b>Firefighting:</b>	Wear full breathing apparatus and self-contained breathing apparatus if risk of exposure to vapour or products of combustion. Cool containers with water spray.
<b>Fire / explosion hazard:</b>	The product is not directly flammable. Avoid inhalation of vapour and flue gases – seek fresh air

### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

Do not use if you are allergic to any of the ingredients. Avoid breathing vapour or mist. Wear protective (non-latex) gloves and eye protection. Contaminated work clothing should not be allowed out of the workplace. Rinse all skin thoroughly clean under running water after use.

#### 6.2 Environmental Precautions

Avoid discharging large quantities to drain or open waterways  
 Inform respective authorities in case of seepage into water course or sewage system.



<b>6.3 Methods and material for containment and cleaning up</b>	
<b>Minor Spills:</b>	Wipe up minor spills with a cloth. Rinse with water.
<b>Major Spills:</b>	Will cause hard surfaces to become slippery. Do NOT apply high-pressure water as this may cause excessive foaming. Collect excess material into disposable absorbent materials, dispose as solid waste, then dilute excess with water and wipe up residual materials.  Avoid breathing vapours and contact with skin and eyes. 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>	Ringworm in the cat is infectious to humans and so it is advisable to wear gloves and have arms covered during clipping and shampooing of infected cats. Avoid excessive handling and stroking of treated animals immediately following treatment. When shampooing a cat, in order to avoid prolonged contact with the shampoo, wash and dry hands gently. Do not scrub. When handling, <b>DO NOT</b> eat, drink or smoke. Prepare the work area; ensure adequate ventilation and a slip resistant workspace. Protect your eyes and skin from avoidable contact with solution. Read safety directions before opening or using.
<b>Other Information:</b>	Do not store above 30°C. Do not refrigerate or freeze. Keep out of the reach and sight of children. Wash hands and contaminated skin and clothing thoroughly clear under running water after use. Pat skin dry. If irritation occurs discontinue future contact.

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

<b>Suitable Container:</b>	Maintain in original, sealed container
<b>Storage incompatibility:</b>	Avoid mixing with other chemicals or treatments. Control cross contamination and sources of microbial spoilage, take care not to allow contaminated water or substances to enter the container.

### 7.3 Specific end uses

Not available
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SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION				
<b>8.1 Control parameters</b>				
<b>DERIVED NO EFFECT LEVEL - DNEL (EU)</b>				
Not Available				
<b>PREDICTED NO EFFECT LEVEL - PNEC (EU)</b>				
Not Available				
<b>OCCUPATIONAL EXPOSURE LIMITS (OEL)</b>				
<b>INGREDIENT DATA:</b>				
If symptoms of rash or breathing difficulties occur after exposure, discontinue use and seek medical advice, show this SDS.				
Adopt good industrial hygiene practice.				
<b>EMERGENCY LIMITS:</b>				
Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Ingredient	Original IDLH		Revised IDLH	
Not Available				
<b>8.2 Exposure controls</b>				
<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. Ensure supply of running water and adequate ventilation.			
<b>Personal protection:</b>	 			
<b>Eye and face protection:</b>	Safety glasses with side shields / chemical goggles			
<b>Skin protection:</b>	See hand protection below			
<b>Hands/ feet protection:</b>	Wear chemical protective gloves			
<b>Body protection:</b>	Wear appropriate clothing			
<b>Other protection:</b>	Additional controls or PPE may be merited by individual circumstances.			
<b>Thermal hazards:</b>	Not applicable			
<b>Respiratory protection:</b>	Not applicable			
<b>8.3 Environmental exposure controls</b>				
See Section 12				

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES	
<b>9.1 Information on basic physical and chemical properties</b>	
<p><b>Appearance:</b> Colourless to pale yellow transparent surfactant fluid.  <b>Container:</b> 250 ml and 500ml polyethylene bottle with a polypropylene screw cap.  <b>Physical state:</b> Liquid  <b>Odour:</b> Distinctive and characteristic  <b>Odour Threshold:</b> Not available  <b>pH (as supplied):</b> Not available  <b>Melting point / freezing point (degrees C):</b> ~ 0 °C  <b>Initial boiling point and boiling range:</b> ~ 100 °C  <b>Flash Point:</b> Not available  <b>Evaporation rate:</b> Not available  <b>Flammability:</b> Not available  <b>Upper/lower flammability or explosive limits:</b> Not available  <b>Vapour pressure:</b> Not available  <b>Relative Density (at degrees C):</b> 1.030 – 1.070 g/ml  <b>Solubility in water and solvents (mg/l):</b> Miscible in water  <b>Vapour density:</b> Not available  <b>Auto ignition temperature (degrees C):</b> Not available  <b>Decomposition temperature (degrees C):</b> Not available  <b>Viscosity: (degrees C):</b> 500 – 1,500 cPs  <b>Explosive properties:</b> Not available  <b>Oxidising properties:</b> Not available  <b>Partition Coefficient:</b> Not available  <b>Molecular weight:</b>  <b>Taste:</b> Not available  <b>Surface tension:</b> Not available  <b>Volative component:</b> Not available  <b>Gas group:</b> Not available  <b>pH as a solution:</b> 4.8 – 6.6 (10% solution)  <b>VOC g/L:</b> Not available</p>	
<b>9.2 Other information</b>	
Not Available	

10: REACTIVITY AND STABILITY	
<b>10.1 Reactivity:</b>	Miconazole nitrate may react with latex.
<b>10.2 Chemical stability:</b>	Formulated to be stable as supplied.
<b>10.3 Possibility of hazardous reactions:</b>	No data.
<b>10.4 Conditions to avoid:</b>	Avoid freezing, avoid strong light, do not store in damp areas or with strong chemicals.
<b>10.5 Incompatible materials:</b>	Oxidising products, anionic surfactants

<b>10.6 Hazardous decomposition:</b>	With prolonged storage, generally beyond product expiry date, Chlorhexidine Gluconate will degrade into p-chloroaniline (PCA), a category 2 carcinogen, accelerated by low pH and high temperatures. The breakdown product is readily absorbed by the skin and rapidly absorbed in the GI tract. It is then widely distributed throughout the body including to the muscle, fat, skin, blood, liver, spleen and kidneys.
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**SECTION 11: TOXICOLOGICAL INFORMATION**

<b>Inhalation:</b>	The product does not release hazardous vapours.	
<b>Ingestion:</b>	Ingestion may cause discomfort. May irritate mucous membranes in mouth and gastrointestinal tract.	
<b>Skin contact:</b>	Degreases and dries the skin.	
<b>Eye contact:</b>	Irritating to eyes. Causes a burning sensation and tearing.	
<b>Chronic:</b>	None known	
<b>Malaseb®:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not available	Not available
<b>Chlorhexidine digluconate:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	In a guideline-compliant study in Wistar rats, the LD50 values for Chlorhexidine Gluconate were 2,270mg/kg bw for males and 2,000mg/kg bw for females. Mortalities were noted six days after exposure. Psychomotor depression, ataxia, depressed respiratory tract, sporadic incidence of ptosis (drooping eyelid), chromodacryorrhoea (bloody tears), epistaxis (nasal bleeding) and diarrhoea were observed in treated rat.	May cause irritation to skin, eyes and respiratory tract.
<b>Miconazole nitrate</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	LD50 Guinea Pig 276mg/kg (CCID); Mouse 519mg/kg (CIDplus); Rat 550mg/kg (CIDplus); IN HUMANS: 125 – 250mg as tablets or gel 4 times daily. For the treatment of oral and intestinal candidiasis. After oral administration, Miconazole is incompletely absorbed from the gastrointestinal tract; peak plasma concentrations of about 1µg/mL have been achieved 4 hr after a dose of 1g. There is little absorption through skin or mucous membranes when Miconazole Nitrate is applied topically (Reynolds, 1989). Following intravaginal administration of Miconazole Nitrate, small amounts are absorbed (Briggs et al., 1986). Administration of a single dose of Miconazole Nitrate suppositories (100mg) to healthy subjects resulted in a total recovery from the urine and faeces of 0.85% (+0.43%) of the administered dose.	May cause irritation to skin, eyes and respiratory tract.



<b>Ethoxylated alcohol</b> <b>CAS 68439-50-9</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	LD50 (Rat, male): 1,376.3mg/kg, LD50 (Rat, female): 1,788.9mg/kg.	Extremely corrosive to skin and eye
<b>Skin corrosion/ irritation:</b>		
May cause a slight irritation to the skin.		
<b>Serious eye damage/ irritation:</b>		
Will cause eye irritation if in contact.		
<b>Respiratory or skin sensitization:</b>		
May cause sensitization by skin contact. Symptoms include reddening, swelling, blistering and ulceration – often slowly developing.		
<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		



SECTION 12: ECOLOGICAL INFORMATION		
<b>12.1 Toxicity</b>		
Toxic to aquatic life. <b>DO NOT discharge into sewer or waterways.</b>		
<b>12.2 Persistence and degradability</b>		
<b>Ingredient</b>	<b>Persistence: Water/Soil</b>	<b>Persistence: Air</b>
Some surfactants are biodegradable, however actives are not.		
<b>12.3 Bioaccumulative potential</b>		
<b>Ingredient</b>	<b>Bioaccumulative potential</b>	
Not Available		
<b>12.4 Mobility in Soil</b>		
<b>Ingredient</b>	<b>Mobility</b>	
Not Available		
<b>12.5 Results of PBT and vPvB assessment</b>		
Not Available		
<b>12.6 Other adverse effects</b>		
Not Available		
SECTION 13: DISPOSAL CONSIDERATIONS		
<b>13.1 Waste treatment methods</b>		
<b>Product / packaging disposal:</b>	<p>Collect spills and waste in closed, leak-proof containers for disposal. 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> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Products Regulations (Canada, 2015).</p> <p>Wrap bottle in paper and dispose of as permitted by local jurisdiction. Avoid excessive use; do not let large volumes run to waterways.</p>	
<b>Waste Treatment Options:</b>	Not Available	
<b>Sewage Disposal Options:</b>	Not Available	



<b>SECTION 14: TRANSPORT INFORMATION</b>	
<b>Labels required:</b> None	
<b>Marine pollutant:</b>	NO
<b>Hazchem:</b>	Not applicable
<b>Land transport (EU: ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:</b> Not applicable	
<b>Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:</b> Not applicable	
<b>Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:</b> Not applicable	
<b>Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:</b> Not applicable	

<b>SECTION 15: REGULATORY INFORMATION</b>	
<b>15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture</b>	
This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable:- 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC	
<b>Classification</b>	
<b>Montreal Protocol:</b>	Not applicable
<b>Stockholm Protocol:</b>	Not included
<b>Rotterdam Protocol:</b>	Not included
<b>Basel Convention:</b>	Not included
<b>MARPOL:</b>	Not included
<b>SUSMP</b>	S6 Poison.
<b>Prohibitions / licensing restrictions</b>	As per S6 poison.
<b>APVMA</b>	APVMA approval number: 47682
<b>NICNAS</b>	Several ingredients have been classified and reviewed at IMAP T2, relevant findings are included herein.



SECTION 16: OTHER INFORMATION	
<b>16.1 Consumer and General Usage Information</b>	
<b>Directions for use</b>	Use as directed on the label. Apply to wet animal at several points and massage into coat. Leave solution on the animal for 10 minutes then rinse off thoroughly with clean water. Do not leave animal unsupervised during 10 minute contact time.
<b>Directions for removal</b>	Rinse thoroughly clean under running water.
<p>The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.</p> <p>References            Preparation of Safety Data Sheets for Hazardous Chemicals Code of Practice February 2016. ISBN 978-0-642-33311-7.            GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS) Fourth revised edition.            Hazardous Substances Data Bank (HSDB) <a href="https://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB">https://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB</a> Suppliers' SDS; RTECS Toxicity Database; IRAC; CDC NIOSH, HSIS</p> <p>The information provided in this Safety Data Sheet has been compiled by Dechra Ltd using a number of different sources, and is correct to the best of its knowledge, information and belief as at the date of its publication. However, Dechra Ltd makes no warranties, express or implied, in relation to the information set out in this Safety Data Sheet, including, without limitation, as to its accuracy or completeness.</p> <p>The information provided is not a quality specification, and is prepared by way of guidance as to the safe handling, use, processing, storage, transportation, disposal and release of the relevant products referred to. The user is responsible for determining whether or not the product is fit for any particular purpose and/or suitable for the user's proposed method of use and application.</p> <p>® MALASEB is a registered trade mark of Dermcare-Vet Pty Ltd.</p> <p>Copyright, 2020, Dechra Ltd. All rights reserved.</p> <p>Copying and/or downloading of this information for the purpose of properly utilizing Dechra Ltd products is permitted provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Dechra Ltd, and (2) neither the copy nor the original is resold or otherwise distributed for the purposes of making a profit thereon.</p>	