



SECTION 1: IDENTIFICATION	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Malaseb® shampoo for dogs and cats
<b>Synonyms:</b>	Not Available
<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>	<p>Dogs: For the treatment and control of seborrhoeic dermatitis associated with <i>Malassezia pachydermatis</i> and <i>Staphylococcus intermedius</i>.</p> <p>Cats: As an aid in the treatment of ringworm due to <i>Microsporium canis</i> in conjunction with griseofulvin.</p>
<b>Uses advised against:</b>	<p>Do not use in case of hypersensitivity to the active substances or to any of the excipients.</p> <p>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).</p> <p>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.</p>
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name:</b>	Dechra Ltd
<b>Address:</b>	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
<b>Telephone:</b>	+44 (0) 1756 791311
<b>Fax:</b>	+44 (0) 1756 798604
<b>Email:</b>	Not available
<b>1.4 Emergency Telephone Numbers</b>	
	+44 (0) 1756 791311



**SECTION 2: HAZARDS IDENTIFICATION**

**2.1 Classification of the substance or mixture**

<b>DSD Classification:</b>	Not Available
<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>Signal Word:</b>	Not Available
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**Hazard Statement(s)**

Not Available

**Additional Statement(s)**

None

**Precautionary Statement(s) Prevention:**

<b>P264</b>	Wash hands thoroughly after handling. (Check chemwatch).
<b>P270</b>	Do not eat, drink or smoke when using this product.

**Precautionary Statement(s) Response:**

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

**Precautionary Statement(s) Storage:**

<b>P405</b>	Store locked up
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**Precautionary Statement(s) Disposal:**

<b>P501</b>	Dispose of contents / packaging according to local regulations
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**2.3 Other Hazard Information**

**SECTION 3: INFORMATION ON THE INGREDIENTS**

**3.1 Substances**

See section below for composition of mixtures

<b>3.2 Mixtures</b>			
<b>1.CAS No 2.EC Number 3.Index Number 4.REACH Number</b>	<b>% Weight</b>	<b>Name</b>	<b>Classification according to regulations (EC) No 1272/2008 [CLP] (EU)</b>
1. 18472-51-0 2. 242-354-0 3. Not Available 4. 01-2119946568-22-XXXX	2%	Chlorhexidine digluconate (equivalent to chlorhexidine 11.26 mg)	Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 2, Serious Eye Damage Category 1, Skin Sensitizer Category 1, Acute Aquatic Hazard Category 1, Chronic Aquatic Hazard Category 1; H302, H315, H318, H317, H410 <sup>1</sup>
1. 22832-87-7 2. 245-256-6 3. Not Available 4. Not Available	2%	Miconazole nitrate (equivalent to miconazole 17.37 mg)	Acute Toxicity (Oral) Category 4, Chronic Aquatic Hazard Category 2; H302, H411 <sup>1</sup>
<b>Legend:</b> 1. Classified by Chemwatch			

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Eye contact:</b>	This product can cause eye irritation. Avoid contact with the eyes. In case of accidental contact with eyes, rinse with plenty of water. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
<b>Skin contact:</b>	In case of accidental contact of the product with the skin rinse with fresh water. Remove contaminated clothing. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
<b>Inhalation:</b>	This product is highly unlikely to be inhaled. Remove person to fresh air.
<b>Ingestion:</b>	Wash out mouth thoroughly and drink 1-2 glasses of water in small sips. Seek medical advice in case of persistent discomfort.

### 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

TO THE MEDICAL PRACTITIONER: Bromide intoxication can be treated by administration of sodium chloride or a suitable chloruretic agent.

**SECTION 5: FIRE FIGHTING MEASURES**

<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	Select extinguishing media suitable for surrounding area.
<b>Unsuitable:</b>	None.
<b>5.2 Special hazards arising from the substance or mixture</b>	
<b>Fire incompatibility:</b>	None known
<b>5.3 Special protective actions for fire-fighters:</b>	
<b>Firefighting:</b>	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.
<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**

<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	
For information on protective equipment, see section 8.	
<b>6.2 Environmental Precautions</b>	
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.	
<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>	Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with absorbent material and transfer to suitable waste containers.



**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. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Do not store above 30°C. Do not refrigerate or freeze. Keep out of the reach and sight of children.

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

<b>Suitable Container:</b>	Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Shelf-life after first opening the immediate packaging: 3 months.
<b>Storage incompatibility:</b>	Unknown.

**7.3 Specific end uses**

Not available

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

**8.1 Control parameters**

**DERIVED NO EFFECT LEVEL - DNEL (EU)**

Not Available

**PREDICTED NO EFFECT LEVEL - PNEC (EU)**

Not Available


**OCCUPATIONAL EXPOSURE LIMITS (OEL)**

**INGREDIENT DATA:**

Not Available

**EMERGENCY LIMITS:**

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
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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.	
<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>	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	
<b>8.3 Environmental exposure controls</b>		
See Section 12		

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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

**Appearance:** A clear to slightly unclear, light yellow to light brown liquid.  
**Container:** 250 ml polyethylene bottle with a polypropylene screw cap.  
**Physical state:** Liquid  
**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  
**Solubility in water and solvents (mg/l):** Miscible  
**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:**  
**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**

<b>10.1 Reactivity:</b>	See Section 7
<b>10.2 Chemical stability:</b>	Product is considered stable.
<b>10.3 Possibility of hazardous reactions:</b>	Stable under normal temperatures and conditions.
<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.
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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>
	Data Not Available	Data Not Available
<b>Chlorhexidine digluconate:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Data Not Available	Data Not Available
<b>Miconazole nitrate</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Data Not Available	Data Not Available
<b>Skin corrosion/ irritation:</b>		
Not Available		
<b>Serious eye damage/ irritation:</b>		
Not available		
<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>		





**SECTION 11: TOXICOLOGICAL INFORMATION**

Not available
<b>STOT–repeated exposure:</b>
Not available
<b>Aspiration hazard:</b>
Not available

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1 Toxicity**

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Chlorhexidine gluconate	BCF	24	Algae or other aquatic plants	0.05mg/L	1

Legend: *Extracted from 1. US EPA, Ecotox database - Aquatic Toxicity Data*

**DO NOT discharge into sewer or waterways.**

**12.2 Persistence and degradability**

Ingredient	Persistence: Water/Soil	Persistence: Air
Not Available		

**12.3 Bioaccumulative potential**

Ingredient	Bioaccumulative potential
Not Available	

**12.4 Mobility in Soil**

Ingredient	Mobility
Not Available	

**12.5 Results of PBT and vPvB assessment**

Not Available

**12.6 Other adverse effects**

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 Substances (Disposal) Regulations 2001.</p>
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

**SECTION 14: TRANSPORT INFORMATION**

<b>Labels required:</b>	None	
<b>Marine pollutant:</b>	NO	
<b>Hazchem:</b>	Not Applicable	
<b>Land transport (ADR):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	Class	N/a
	Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	

<b>14.6 Special precautions for user</b>	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Air transport (ICAO-IATA / DGR):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	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

<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Sea transport (IMDG-Code / GGVSee):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	IMDG Class	N/a
	IMDG Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Inland waterways transport (ADN):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	N/a	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazard</b>	N/a	
<b>14.6 Special precautions for user</b>	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a

<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a
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## SECTION 15: REGULATORY INFORMATION

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

#### MICONAZOLE NITRATE (22832-87-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs Inventory of Chemical Substances ECICS (English)
- European Union – European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

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

### 15.2 Chemical Safety Assessment

#### ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Miconazole Nitrate	22832-87-7	Not Available	Not Available
Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4, Skin Sens. 1	GHS07, Wng	H302, H317
2	Acute Tox. 4, Skin Sens. 1, Eye Irrit. 2, Aquatic Acute 1, Aquatic Chronic 1, Muta. 2, Repr. 2, Aquatic Chronic 2	GHS09, Dgr, GHS08	H302, H317, H319, H410, H400, H341, H361, H312, H332, H373
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (miconazole nitrate)
China - IECSC	N (miconazole nitrate)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (miconazole nitrate)



Korea - KECI	N (miconazole nitrate)
New Zealand - NZIoC	Y
Philippines - PICCS	N (miconazole nitrate)
USA - TSCA	N (miconazole nitrate)
<b>Legend:</b>	<i>Y = All ingredients are on the inventory        N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i>

### SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

#### Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit.
- IDLH: Immediately Dangerous to Life or Health Concentrations

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