
1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

1.1 Product identifier

Product name APEX PMP EAR SUSPENSION (NZ)
Synonyms APEX PMP EAR SUSPENSION FOR DOGS AND CATS

1.2 Uses and uses advised against

Uses TOPICAL TREATMENT
Topical treatment for dogs and cats of otitis externa and skin infections and inflammation caused by organisms sensitive to the antibiotic and antifungal in the preparation.

1.3 Details of the supplier of the product

Supplier name DECHRA VETERINARY PRODUCTS NZ LTD
Address PO Box 1604, Paraparaumu Beach, 5252, NEW ZEALAND
Telephone 0800 473 838
Email info.nz@dechra.com
Website <http://www.dechra.co.nz/>

1.4 Emergency telephone numbers

Emergency 0800 764 766 (National Poisons Centre NZ)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

HAZARDOUS ACCORDING TO NZ ENVIRONMENTAL PROTECTION AUTHORITY CRITERIA

Physical Hazards

Not classified as a Physical Hazard

Health Hazards

6.5B - Substances that are contact sensitisers
6.8B - Substances that are suspected human reproductive or developmental toxicants

Environmental Hazards

9.1C - Substances that are harmful in the aquatic environment

2.2 GHS Label elements

Signal word WARNING

Pictograms

**Hazard statements**

H317 May cause an allergic skin reaction.
H361 Suspected of damaging fertility or the unborn child.
H412 Harmful to aquatic life with long lasting effects.

PRODUCT NAME APEX PMP EAR SUSPENSION (NZ)**Prevention statements**

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Response statements

P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P308 + P313	IF exposed or concerned: Get medical advice/ attention.
P321	Specific treatment is advised - see first aid instructions.
P363	Wash contaminated clothing before reuse.

Storage statements

P405	Store locked up.
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Disposal statements

P501	Dispose of contents/container in accordance with relevant regulations.
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2.3 Other hazards

No information provided.

3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.1 Substances / Mixtures

Ingredient	CAS Number	EC Number	Content
MICONAZOLE NITRATE	22832-87-7	245-256-6	<10%
POLYMYXIN B SULPHATE	1405-20-5	215-774-7	<10%
PREDNISOLONE ACETATE	52-21-1	200-134-1	<10%
NON HAZARDOUS INGREDIENTS	Not Available	Not Available	Remainder

4. FIRST AID MEASURES

4.1 Description of first aid measures

Eye	If in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, a doctor, or for at least 15 minutes.
Inhalation	If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.
Skin	If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by a Poisons Information Centre or a doctor.
Ingestion	For advice, contact the National Poisons Centre on 0800 764 766 (0800 POISON) or +643 479 7248 or a doctor (at once).
First aid facilities	None allocated.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

4.3 Immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Use an extinguishing agent suitable for the surrounding fire.

5.2 Special hazards arising from the substance or mixture

Non flammable. May evolve carbon oxides and hydrocarbons when heated to decomposition.

5.3 Advice for firefighters

Treat as per requirements for surrounding fires. Evacuate area and contact emergency services. Remain upwind and notify those downwind of hazard. Wear full protective equipment including Self Contained Breathing Apparatus (SCBA) when combating fire. Use waterfog to cool intact containers and nearby storage areas.

5.4 Hazchem code

None allocated.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear Personal Protective Equipment (PPE) as detailed in section 8 of the SDS.

6.2 Environmental precautions

Prevent product from entering drains and waterways.

6.3 Methods of cleaning up

Contain spillage, then cover / absorb spill with non-combustible absorbent material (vermiculite, sand, or similar), collect and place in suitable containers for disposal.

6.4 Reference to other sections

See Sections 8 and 13 for exposure controls and disposal.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, well marked area, removed from incompatible substances, foodstuffs and other drugs. Storage areas and containers should be clearly marked for drug holding, protected from light, freezing or physical damage and tightly sealed when not in use. Keep out of reach of children. Store below 25°C.

7.3 Specific end uses

No information provided.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Exposure standards

No exposure standards have been entered for this product.

Biological limits

No biological limit values have been entered for this product.

8.2 Exposure controls

Engineering controls Avoid inhalation. Use in well ventilated areas.

PPE

Eye / Face	Wear splash-proof goggles.
Hands	Wear PVC or rubber gloves.
Body	Wear coveralls.
Respiratory	Where an inhalation risk exists, wear a Type A (Organic vapour) respirator.



9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	WHITE LIQUID
Odour	ODOURLESS
Flammability	NON FLAMMABLE
Flash point	NOT RELEVANT
Boiling point	NOT AVAILABLE
Melting point	NOT AVAILABLE
Evaporation rate	NOT AVAILABLE
pH	NOT AVAILABLE
Vapour density	NOT AVAILABLE
Specific gravity	0.84 to 0.89
Solubility (water)	NOT AVAILABLE
Vapour pressure	NOT AVAILABLE
Upper explosion limit	NOT RELEVANT
Lower explosion limit	NOT RELEVANT
Partition coefficient	NOT AVAILABLE
Autoignition temperature	NOT AVAILABLE
Decomposition temperature	NOT AVAILABLE
Viscosity	NOT AVAILABLE
Explosive properties	NOT AVAILABLE
Oxidising properties	NOT AVAILABLE
Odour threshold	NOT AVAILABLE

10. STABILITY AND REACTIVITY

10.1 Reactivity

Carefully review all information provided in sections 10.2 to 10.6.

10.2 Chemical stability

Stable under recommended conditions of storage.

10.3 Possibility of hazardous reactions

Polymerization is not expected to occur.

10.4 Conditions to avoid

Avoid heat, sparks, open flames and other ignition sources.

10.5 Incompatible materials

Incompatible with oxidising agents (e.g. hypochlorites), acids (e.g. nitric acid) and alkalis (e.g. sodium hydroxide).

10.6 Hazardous decomposition products

May evolve carbon oxides and hydrocarbons when heated to decomposition.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity May be harmful if swallowed in large quantities. This product is used in veterinary applications. Refer to specialist for advice regarding adverse side effects.

Information available for the ingredients:

Ingredient	Oral LD50	Dermal LD50	Inhalation LC50
MICONAZOLE NITRATE	578 mg/kg (mouse)	--	--
POLYMYXIN B SULPHATE	790 mg(base)/kg (mouse)	--	--

Skin Contact may result in irritation, redness, pain and rash.

Eye Contact may result in irritation, lacrimation, pain and redness.

Sensitisation May cause an allergic skin reaction. This product is not classified as a respiratory sensitiser.

Mutagenicity Not classified as a mutagen.

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Carcinogenicity	Not classified as a carcinogen.
Reproductive	Contains ingredients that have had some effect on reproductive performance in animal studies. Miconazole has not shown teratogenic effects but is embryotoxic following high oral doses. Studies in mice, rabbits, hamsters and rats showed that prednisolone caused malformations including cleft palate when administered parenterally. The teratogenic potential was much less when prednisolone was administered orally.
STOT - single exposure	Not classified as causing organ damage from single exposure. However, high level exposure may result in headache, nausea and respiratory tract irritation.
STOT - repeated exposure	Not classified as causing organ damage from repeated exposure.
Aspiration	Not classified as causing aspiration.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Harmful to aquatic life with long lasting effects.

12.2 Persistence and degradability

No information provided.

12.3 Bioaccumulative potential

No information provided.

12.4 Mobility in soil

No information provided.

12.5 Other adverse effects

No information provided.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal	Return to manufacturer/supplier where possible. For small amounts, bury in approved landfill site. Contact the manufacturer/supplier for additional information (if required).
Legislation	Dispose of in accordance with relevant local legislation.

14. TRANSPORT INFORMATION

NOT CLASSIFIED AS A DANGEROUS GOOD ACCORDING TO LAND TRANSPORT RULE: DANGEROUS GOODS 2005; NZS 5433:2012, UN, IMDG OR IATA

	LAND TRANSPORT (NZS 5433)	SEA TRANSPORT (IMDG / IMO)	AIR TRANSPORT (IATA / ICAO)
14.1 UN Number	None allocated.	None allocated.	None allocated.
14.2 Proper Shipping Name	None allocated.	None allocated.	None allocated.
14.3 Transport hazard class	None allocated.	None allocated.	None allocated.
14.4 Packing Group	None allocated.	None allocated.	None allocated.

14.5 Environmental hazards

No information provided.

14.6 Special precautions for user

Hazchem code	None allocated.
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15. REGULATORY INFORMATION

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

Approval code	HSR100757
Group standard	Veterinary Medicine (Limited Pack Size, Finished Dose) Group Standard 2012

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Inventory listings NEW ZEALAND: NZIoC (New Zealand Inventory of Chemicals)
All components are listed on the NZIoC inventory, or are exempt.

16. OTHER INFORMATION

Additional 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.

RESPIRATORS: In general the use of respirators should be limited and engineering controls employed to avoid exposure. If respiratory equipment must be worn ensure correct respirator selection and training is undertaken. Remember that some respirators may be extremely uncomfortable when used for long periods. The use of air powered or air supplied respirators should be considered where prolonged or repeated use is 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
	CCID	Chemical Classification and Information Database (HSNO)
	CNS	Central Nervous System
	EC No.	EC No - European Community Number
	EMS	Emergency Schedules (Emergency Procedures for Ships Carrying Dangerous Goods)
	EPA	Environmental Protection Authority [New Zealand]
	GHS	Globally Harmonized System
	HSNO	Hazardous Substances and New Organisms
	IARC	International Agency for Research on Cancer
	LC50	Lethal Concentration, 50% / Median Lethal Concentration
	LD50	Lethal Dose, 50% / Median Lethal Dose
	mg/m ³	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)
	TLV	Threshold Limit Value
	TWA	Time Weighted Average

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Report status

This document has been compiled by RMT on behalf of the manufacturer, importer or supplier of the product and serves as their Safety Data Sheet ('SDS').

It is based on information concerning the product which has been provided to RMT by the manufacturer, importer or supplier or obtained from third party sources and is believed to represent the current state of knowledge as to the appropriate safety and handling precautions for the product at the time of issue. Further clarification regarding any aspect of the product should be obtained directly from the manufacturer, importer or supplier.

While RMT has taken all due care to include accurate and up-to-date information in this SDS, it does not provide any warranty as to accuracy or completeness. As far as lawfully possible, RMT accepts no liability for any loss, injury or damage (including consequential loss) which may be suffered or incurred by any person as a consequence of their reliance on the information contained in this SDS.

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