

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 02.21.2019

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Revision date: 06.07.2024

PMP Ear Suspension for Dogs and Cats

SECTION 1: Identification

Product identifier

Product name: PMP Ear Suspension for Dogs and Cats

Recommended use of the product and restriction on use:

Relevant identified uses: VETERINARY USE: 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.

Uses advised against: Not for human use.

Reasons why uses advised against: Veterinary product.

Manufacturer or supplier details

Supplier:

Dechra Veterinary Products NZ Limited

PO Box 1604,

Paraparaumu Beach, 5252

New Zealand

Phone: 0800 479 838

Email: info.nz@dechra.com

Website: <http://www.dechra.co.nz/>

Emergency telephone number:

National Poisons Centre, New Zealand

0800 764 766

SECTION 2: Hazards identification

Not Classified as a Dangerous Good according to NZS 5433:2012 Transport of Dangerous Goods on Land.

Classified in accordance with the relevant criteria of the HSNO Act 1996, the Hazardous Substances (Classification) Notice 2017 and the Hazardous Substances (Minimum Degrees of Hazard) Notice 2017, New Zealand.

HSNO Classification or Subclasses – Physical hazards: Not applicable

HSNO Classification or Subclasses – Health hazards:

Class	GHS Category	HSNO Category
Acute toxicity (oral)	Category 4	6.1D (Oral)
Skin sensitization	Category 1	6.5B
Reproductive toxicity	Category 1A	6.8A

HSNO Classification or Subclasses – Environmental hazards: Not applicable

GHS classification:

Acute toxicity (oral), category 4

Skin sensitization, category 1

Reproductive toxicity, category 1A

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Label elements

Hazard pictogram(s):



Signal word: Danger

Hazard statements:

- H317 May cause an allergic skin reaction
- H360 May damage fertility or the unborn child
- H302 Harmful if swallowed

Precautionary statements:

- P201 Obtain special instructions before use
- P202 Do not handle until all safety precautions have been read and understood
- P280 Wear protective gloves, protective clothing and eye protection
- P261 Do not breathe mist, vapours or spray
- P270 Do not eat, drink or smoke when using this product
- P264 Wash any exposed skin thoroughly after handling
- P272 Contaminated work clothing should not be allowed out of the workplace
- P302+P352 IF ON SKIN: Wash with plenty of soap and water
- P363 Wash contaminated clothing before reuse
- P333+P313 If skin irritation or rash occurs: Get medical advice or attention
- P321 Specific treatment (see Sections 4-8 of this SDS and any supplemental information on the product label).
- P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
- P330 Rinse mouth
- P308+P313 If exposed or concerned: Get medical advice and attention
- P405 Store locked up
- P501 Dispose of contents and container in accordance with local regulations

Hazards not otherwise classified:

None.

SECTION 3: Composition/information on ingredients

Mixture:

Identification	Name	Weight %
CAS number: 22832-87-7	Miconazole nitrate	28
CAS number: 7631-86-9	Silica colloidal anhydrous	15-25
CAS number: 52-21-1	Prednisolone acetate	6
CAS number: 1405-20-5	Polymyxin B, sulfate	0.85

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Additional information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret under the provisions of sections 55 (7) of the HSNO Act.

SECTION 4: First-aid measures

For advice, contact a Poisons Information Center (e.g. phone Australia 131 126, New Zealand 0800 764 766) or a doctor.

Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance. Take precautions to ensure your own safety before attempting rescue. Wear appropriate safety eyewear, gloves, protective clothing and respiratory protection to prevent exposure. See Section 8 of this SDS for personal protective equipment recommendations. Do not use the mouth to mouth method if victim has ingested or inhaled the product. Give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper device.

After inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. Keep person at rest. If breathing is difficult, administer oxygen. If breathing has stopped, provide artificial respiration. If experiencing respiratory symptoms, seek medical advice/attention.

After skin contact:

Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

After eye contact:

Rinse eyes with plenty of water for several minutes. Remove contact lenses, if present and easy to do so. Protect unexposed eye. If symptoms develop or persist, seek medical advice/attention.

After swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most important symptoms and effects, both acute and delayed:

Acute symptoms and effects:

Dermal exposure may cause an allergic skin reaction. Symptoms may include irritation, redness, pain, rash, inflammation, itching, burning and dermatitis.

Acute oral exposure may lead to dizziness, drowsiness, headache, breathing difficulties, nausea, vomiting, abdominal pain, and lowering of consciousness. Adverse effects are dependent on exposure (dose, concentration, contact time).

Delayed symptoms and effects:

Effects are dependent on exposure (dose, concentration, contact time).

Long term exposure may affect fertility. Symptoms include, but are not limited to: menstrual problems, altered sexual behavior/fertility/ and pregnancy outcome. Long term exposure may also affect development of the unborn child. Symptoms include, but are not limited to: intrauterine growth retardation, pre-term birth, birth defects and postnatal death.

Symptoms of exposure may be delayed.

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Immediate medical attention and special treatment:

Specific treatment:

Not determined or not applicable.

Notes for the doctor:

Treat symptomatically.

Workplace Facilities:

No additional information.

SECTION 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media:

Water mist/fog, carbon dioxide, dry chemical or alcohol-resistant foam.

Unsuitable extinguishing media:

Do not use water jet.

Specific hazards during fire-fighting:

Thermal decomposition may produce irritating/toxic fumes/gases like carbon oxides and hydrocarbons.

Special protective equipment for firefighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

Hazchem or Emergency Action Code:

Not Applicable.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Do not get on skin, eyes or on clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling. Remove contaminated clothing and laundry before reuse.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up:

Harmful if swallowed. Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Avoid breathing dust, mist, fumes, vapors or spray. Stop leak if you can do it without risk. Contain spillage, then cover or absorb spill with non-combustible absorbent material (vermiculite, sand, or similar) and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

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SECTION 7: Handling and storage precautions

Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Container Type: HDPE bottle.

Storage conditions: Store below 25°C. Protect from light.

Conditions for safe storage, including any incompatibilities:

Store below 25°C in a cool, dry, well-ventilated location out of direct sunlight in an HDPE bottle. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed out of reach of children. Store away from incompatible materials (See Section 10).

Safe packaging material

Suitable material:

Not determined or not applicable.

Unsuitable material:

Not determined or not applicable.

SECTION 8: Exposure controls and personal protection

Occupational Exposure limit values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
New Zealand	Silica colloidal anhydrous	7631-86-9	TWA: 2 mg/m ³ (Silica, Amorphous: Fumed silica)
	Silica colloidal anhydrous	7631-86-9	TWA: 10 mg/m ³ (Nuisance dusts, inhalable dust)

Biological limit value:

No biological exposure limits noted for the ingredient(s).

Information on monitoring procedures:

Not determined or not applicable

Appropriate engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protection equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

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Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and chemical properties

Appearance	White suspension liquid
Odour	Odourless
Odour threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Flammability (solid, gas)	Non flammable
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapour pressure	Not determined or not available.
Vapour density	Not determined or not available.
Relative density	0.84 - 0.89
Solubilities	Not determined or not available.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Particle characteristics	Not determined or not available.

Other information: No additional information.

SECTION 10: Stability and reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Chemical stability:

Stable under recommended handling and storage conditions.

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Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to avoid:

Extreme heat, open flames, hot surfaces, sparks, ignition sources, and incompatible materials.

Incompatible materials:

Oxidising agents (e.g. hypochlorites), acids (e.g. nitric acid) and alkalis (e.g. sodium hydroxide).

Hazardous decomposition products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

May evolve carbon oxides and hydrocarbons when heated to decomposition.

SECTION 11: Toxicological information

Acute toxicity:

Assessment:

Harmful if swallowed.

Product data:

Route	Result
Oral ATE	LD50 Rat: 1044.93 mg/kg

Substance data:

Name	Route	Result
Miconazole nitrate	Oral ATE	LD50 Rat: 500 mg/kg
Prednisolone acetate	oral	LD50 Rat: 240 mg/kg
Polymyxin B, sulfate	Oral ATE	LD50 Rat: 500 mg/kg
Silica colloidal anhydrous	oral	LD50 Rat: > 5000 mg/kg
	dermal	LD50 Rabbit: > 2000 mg/kg
	inhalation	LC50 rat: > 5.01 mg/L (4hr [aerosol])

Skin corrosion/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Serious eye damage/irritation:

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Respiratory or skin sensitization:

Assessment:

May cause an allergic skin reaction.

Product data: No data available.

Substance data:

Name	Result
Miconazole nitrate	May cause an allergic skin reaction.

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Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC):

Name	Result
Silica colloidal anhydrous	Group 3

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Reproductive toxicity

Assessment:

May damage fertility or the unborn child.

Product data: No data available.

Substance data:

Name	Result
Prednisolone acetate	May damage fertility or the unborn child.

Specific target organ toxicity (single exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Specific target organ toxicity (repeated exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Prednisolone acetate	May cause damage to organs through prolonged or repeated exposure.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Information on likely routes of exposure:

Oral, skin and eye contact.

Symptoms related to the physical, chemical and toxicological characteristics:

See section 4 of this SDS.

Other information:

No data available.

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SECTION 12: Ecological information

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Silica colloidal anhydrous	Fish LC50 Pimephales promelas: > 5000 mg/L (96 hr)
	Aquatic Invertebrates EC50 Daphnia magna: > 5000 mg/L (48 hr [mobility])
	Aquatic Plants EC50 Desmodemus subspicatus: >173.1 mg/L (72 hr [yield & growth rate])

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Silica colloidal anhydrous	Aquatic Invertebrates NOEC Daphnia magna: 68 mg/L (21 d [mortality])
	Fish NOEC Fish species: 57.001 mg/L (30 d [mortality-no toxicity at the limit of solubility, QSAR substance data])

Persistence and degradability

Product data: No data available.

Substance data:

Name	Result
Silica colloidal anhydrous	Persistence assessment based on biodegradability is not relevant for inorganic compounds such as this substance.

Bioaccumulative potential

Product data: No data available.

Substance data:

Name	Result
Silica colloidal anhydrous	Bioaccumulation assessment using a classic BCF assessment is not considered relevant for inorganic compounds such as this substance.

Mobility in soil

Product data: No data available.

Substance data:

Name	Result
Silica colloidal anhydrous	Mobility in soil assessment based on KOC/Kd values are not relevant for inorganic compounds such as this substance.

Hazard to the ozone layer

Product data: No data available.

Substance data: No data available.

Other adverse effects: No data available.

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SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory agencies. Dispose of in accordance with all applicable local, regional, state and federal regulations.

Contaminated packages:

Not determined or not applicable.

Disposal methods that should not be used:

No additional information.

SECTION 14: Transportation information

Road/Rail transport: (NZS 5433:1999)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Air Transport Association Dangerous Goods Regulations (IATA-ICAO)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Maritime Dangerous Goods (IMDG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

Transport in bulk according to Annex II of MARPOL and the IBC Code: Not Applicable

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SECTION 15: Regulatory information

New Zealand Inventory of Chemicals (NZIoC): All Ingredients are listed.

HSNO Classification or Subclasses:

Class	GHS Category	HSNO Category
Acute toxicity (oral)	Category 4	6.1D (Oral)
Skin sensitization	Category 1	6.5B
Reproductive toxicity	Category 1A	6.8A

HSNO Group Standard Name:	HSNO Approval Number:
Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2017	HSR100757

HSNO Controls: Not determined.

Approved handler test certificate: Not determined.

Tracking: Not determined.

Controlled substance license requirements: Not applicable.

Agricultural Compounds and Veterinary Medicines Act 1997:

ACVM number	
A011130	

Montreal Protocol (Ozone Depleting Substances): None of the ingredients are listed.

Stockholm Convention (Persistent Organic Pollutants): None of the ingredients are listed.

Rotterdam Convention (Prior Informed Consent): None of the ingredients are listed.

Basel Convention (Hazardous Waste): None of the ingredients are listed.

SECTION 16: Other information

Abbreviations and Acronyms:

ATE	Acute Toxicity Estimate
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
EC50	Effective Concentration of 50%
GHS	Globally Harmonized System
HSNO	Hazardous Substances and New Organisms
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%
MARPOL	International Convention for the Prevention of Pollution from Ships
NZIoC	New Zealand Inventory of Chemicals
TWA	Time Weighted Average
UN	United Nations
VOC	Volatile Organic Compounds

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Disclaimer:

The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

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Revision Notes:

Revision Date	Notes
2024-06-07	Version 2; Supersedes (Version 1: 02.21.2019)

End of Safety Data Sheet