

Safety Data Sheet

According to Australian Work Health and Safety Regulations 2021 and the GHS Revision 7

Initial preparation date: 02.20.2019

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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:

Australia

Dechra Veterinary Products (Australia) Pty Ltd

2 Cal Close

Somersby, NSW 2250

1300 015 825

info.au@dechra.com

<http://www.dechra.com.au/>

Emergency telephone number:

Australia

Poisons Information Centre

13 11 26 (24 hours, 7 days a week)

SECTION 2: Hazard(s) identification

Classification in accordance with Australian Work Health and Safety Regulations and the GHS Revision 7:

Acute toxicity (oral), category 4

Skin sensitization, category 1

Reproductive toxicity, category 1A

Label elements

Hazard pictograms:



Signal Word: Danger

Hazard statements:

H317 May cause an allergic skin reaction

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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 and information on ingredients

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

Additional Information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with the Australian Work Health and Safety Regulations 2021.

SECTION 4: First aid measures

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

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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.

Immediate medical attention and special treatment

Specific treatment:

Not determined or not applicable.

Notes for the doctor:

Treat symptomatically.

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.

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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.

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 launder 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.

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.

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).

SECTION 8: Exposure controls and personal protection

Only those substances with limit values have been included below.

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Occupational Exposure limit values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
Australia	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 values:

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).

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

Information on basic physical and chemical properties

Physical state	Suspension liquid
Colour	White
Odour	Odourless
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.

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Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Flammability (solid, gas)	Non flammable
Lower flammability/explosive limit	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.
Relative density	0.84 - 0.89
Relative vapor density	Not determined or not available.
Density	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.
Solubilities	Not determined or not available.

SECTION 10: Stability and reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Chemical stability:

Stable under recommended handling and storage conditions.

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: Hazard 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

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Name	Route	Result
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.

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	Classification
Silica colloidal anhydrous	Group 3

National Toxicology Program (NTP): None of the ingredients are listed.

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.

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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.

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:

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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.

Results of PBT and vPvB assessment

Product data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance data:

PBT assessment:

Silica colloidal anhydrous	PBT assessment does not apply to inorganic compounds such as this substance.
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vPvB assessment:

Silica colloidal anhydrous	vPvB assessment does not apply to inorganic compounds such as this substance.
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Other adverse effects: No data available.

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.

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SECTION 14: Transport information

Australian Dangerous Goods (ADG)

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

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

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 MARPOL73/78 and the IBC Code

Bulk Name	None
Ship type	None
Pollution category	None

SECTION 15: Regulatory information

Australia regulations

Australian Inventory of Chemical Substances (AICS):

22832-87-7	Miconazole nitrate	Not Listed
52-21-1	Prednisolone acetate	Not Listed
1405-20-5	Polymyxin B, sulfate	Not Listed

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7631-86-9	Silica colloidal anhydrous	Listed
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Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP):

Ingredient Name	CAS	Schedules
Miconazole nitrate	22832-87-7	Not Applicable
Prednisolone acetate	52-21-1	Not Applicable
Polymyxin B, sulfate	1405-20-5	4
Silica colloidal anhydrous	7631-86-9	Not Applicable

Additional information:

APVMA No. 62596 Poison Schedule: S4

SECTION 16: Other information

Abbreviations and Acronyms: None

Disclaimer:

This SDS was authored in accordance with the Australian Work Health and Safety Regulations 2021 and the GHS Revision 7 and supplemented by the Australian Code of Practice on the Preparation of Safety Data Sheets for Hazardous Chemicals. 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
2024-05-31	Version 2; Supersedes (Version 1: 02.20.2019)

End of Safety Data Sheet