

SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

GHS Product identifier: Auracol Ear & Skin Suspension For Dogs, Cats & Horses
Other means of identification: Auracol
Recommended use of the product and restrictions on use: For the treatment of otitis externa and skin infections caused by fungi, yeasts, Gram-negative and Gram-positive bacteria in dogs, cats and horses
Supplier's Details: Pharmachem Australia Pty Ltd
 Unit 6, 70 Fison Ave West
 Eagle Farm QLD 4009
 Telephone: (07) 3868 0333

Emergency phone number: 13 11 26 (Poisons Information Hotline)

SECTION 2 HAZARDS IDENTIFICATION

Classification of Product:
 This product is classified as a health hazard in accordance with the following classification criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition.

Health hazards:	Acute toxicity, oral	Category 4
	Sensitization, skin	Category 1
	Eye irritant	Category 2

GHS label elements, including precautionary statements:
Pictogram:



Signal word: Warning
Hazard statements: Harmful if swallowed. May cause an allergic skin reaction.
 Causes serious eye irritation.
Precautionary statements:
Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace.
 Wear protective gloves/ eye protection/ face protection.
Response:
If swallowed:
 Call a poison center/doctor/medical professional/ if you feel unwell. Rinse mouth.
If on skin:
 Wash with plenty of water/soap. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
If in eyes:
 Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/ attention.

Other Health Hazards: None known

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENTS	Cas No.	Proportion
Miconazole Nitrate	22382-87-7	23 g/L
Prednisolone Acetate	52-21-1	5 g/L
Polymyxin B Sulphate	1405-20-5	0.696 g/L
Proprietary suspending medium	Not applicable	QS 1L

SECTION 4 FIRST AID MEASURES

The following First Aid directions have been derived from the FAISD Handbook published by the Australian Pesticides and Veterinary Medicines Authority (APVMA). These directions have been developed on the basis of advice provided by the Office of Chemical Safety (OCS) of the Commonwealth Department of Health:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.

The following information is provided from the GHS for further assistance, if necessary, while implementing the First Aid measures above.

Eye and Mucous Membrane Contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Skin Contact:	Should skin irritation, allergic reaction or rash occur, physically remove as much of the product as possible and wash with plenty of water/soap.
Ingestion:	Do not induce vomiting as aspiration of the product might occur. Drink large amounts of water.
Inhalation:	Not expected under normal usage conditions. However, the following actions can be taken if necessary. Remove to fresh air. If breathing is difficult, give oxygen. If breathing has stopped, give artificial respiration.

SECTION 5 FIRE FIGHTING MEASURES

This material is supplied to end users in 30mL squeeze bottles with application nozzles, so involvement in fire situations will be limited. Where larger quantities are kept by wholesaler / retailers, the total amounts will be less than 5L. In general, fire fighting procedures for the surrounding fire would apply.

Suitable extinguishing media:	Alcohol foam, dry chemical, carbon dioxide and water spray.
Hazards from combustion products:	May emit toxic fumes.
Special protective precautions and equipment for fire fighters:	Use precautions and equipment suitable for the surrounding fire.
Hazchem Code:	None allocated

SECTION 6 ACCIDENTAL RELEASE MEASURES

This material is supplied to end users in 30mL squeeze bottles with application nozzles, so accidental release will be limited. Where larger quantities are kept by wholesaler / retailers, the total amounts will be less than 5L.

Emergency procedures:

Slippery when wet. Wear eye protection and protective gloves when cleaning up spills. Absorb spills with inert absorbent materials including absorbent cloth or wipes. Collect and seal absorbed material in chemically resistant containers for disposal.

Methods and materials for containment and clean up

Use absorbent material such as inert cloths or wipes, soil, sand or vermiculite. Wash area down with detergent and excess water. Do not allow wash water to enter sewers, drains or waterways. Absorb wash water as for spilled material.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling:

Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves, eye protection and face protection.

Conditions for safe storage, including any incompatibilities:

Store below 25°C (Air Conditioning) away from heat, light, oxidants and bases. Keep container closed when not in use.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

This material is supplied to end users in 30mL squeeze bottles with application nozzles, so exposure will be limited by quantity for these users. Where larger quantities are kept by wholesaler / retailers, the total amounts will be less than 5L.

National exposure standards:	None allocated
Biological limit values:	None set
Engineering controls:	Use with adequate ventilation
Personal protective equipment:	Use safety glasses and gloves.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White, slightly viscous liquid suspension
Odour:	Paraffin Oil Odour
Specific Gravity:	0.83 – 0.87
Viscosity:	160 – 190 cP

SECTION 10 STABILITY AND REACTIVITY

Chemical stability:	Stable
Conditions to avoid:	Keep away from heat, flame and incompatibles.
Incompatible materials:	Strong oxidising agents and bases
Hazardous decomposition products:	Oxides of nitrogen, carbon dioxide and carbon monoxide may be produced under fire conditions.
Hazardous reactions:	Hazardous polymerisation will not occur

SECTION 11 TOXICOLOGICAL INFORMATION

Routes of Exposure:

Exposure to Auracol can occur through ingestion and eye or skin contact. The major routes of exposure are expected to be eye and skin contact. There are no toxicology data available for Auracol. Information on individual ingredients has been provided where available.

Signs and symptoms of exposure:

Oral:	miconazole nitrate: vomiting, diarrhoea, rarely heart rhythm disorders, convulsions (fits, muscle spasms)
Eyes:	Not known
Skin:	Not known
Inhalation:	Not applicable
Sensitizing:	Not known

Summary of Toxicology:

Miconazole nitrate:

Oral (LD₅₀) (Rat): 920 mg/kg
Oral (LD₅₀) (Mouse): 578 mg/kg
Oral (LD₅₀) (Guinea pig): 276 mg/kg

Dermal: There are no reports of miconazole being absorbed from intact skin.
Reproductive: Animal studies in rats and rabbits involving the oral route of administration of miconazole, have revealed evidence of reproductive toxicity at doses of 270 mg/kg.

Other Information: Acute miconazole toxicity studies in dogs, guinea pigs, mice and rats, via the oral, subcutaneous, intraperitoneal and intravenous routes of administration demonstrated evidence of ataxia and stomach ulceration in doses > 5g/kg

Prednisolone acetate:

Oral (LD₅₀) (Mouse): 1680 mg/kg

Polymyxin B Sulphate:

Oral (LD₅₀) (Mouse): 790 mg (Base)/kg

SECTION 12 ECOLOGICAL INFORMATION

No ecological information available. As a precaution, prevent from entering sewers, drains, streams or other waterways.

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal methods and containers:

The following disposal directions for containers have been approved by the APVMA:

Dispose of empty container by wrapping with paper and putting in garbage.

In addition, do not burn empty containers or unused product. Unused product may be disposed of in local municipal landfill.

Special precautions for landfill or incineration:

Seek advice from local government authority before disposing of unused product in municipal landfill.

SECTION 14 TRANSPORT INFORMATION

Not defined as Dangerous Goods by the Australian Code for the Transport of Dangerous Goods by Road and Rail

SECTION 15 REGULATORY INFORMATION

This product has been registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). In granting registration to any product, the APVMA has exercised its legislative responsibility to ensure that the product is suitably formulated and properly labelled and, when used according to instructions is:

- safe to the host, the user, consumers and the environment;
- efficacious (that is, the product does the job it claims it shall do); and
- not unduly prejudicial to trade.

The APVMA uses the services of a number of Australian and State government agencies as advisers to help with some of these evaluations of applications for registration of agricultural and veterinary chemical products. These include:

- the Office of Chemical Safety (OCS) of the Commonwealth Department of Health and Ageing which:
 - evaluates and reports on toxicology and metabolism studies; proposes first aid and safety directions; determines poison schedule classifications; and establishes acceptable daily intakes (ADIs) and acute reference doses (ARfD); and
 - evaluates the occupational health and safety aspects of an application and recommends safety directions and occupational controls on use and advises on a Material Safety Data Sheet (MSDS);
- the Commonwealth Department of the Environment and Heritage (DEH) which evaluates environmental data and recommends appropriate use controls and instructions for the product that will protect the environment; and
- State and Territory departments responsible for agricultural and primary industries which evaluate and reports on efficacy and target crop or animal safety data for new agricultural chemicals and new uses of registered products. In some cases, the APVMA contracts this work out to other agencies such as universities, the CSIRO or to other experts.

Auracol is a Schedule 4 poison under the SUSMP and is therefore available only by prescription.

Auracol is not regulated under the AICIS (Australian Industrial Chemicals Introduction Scheme),

SECTION 16 OTHER INFORMATION

References:

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, (as updated), APVMA (Australian Pesticides and Veterinary Medicines Authority), <https://apvma.gov.au/node/26586>
2. Code of Practice – Preparation of safety data sheets for hazardous chemicals, Safe Work Australia, May 2018, <https://www.safeworkaustralia.gov.au/doc/model-code-practice-preparation-safety-data-sheets-hazardous-chemicals>
3. Australian Inventory of Industrial Chemicals (as updated), AICIS (Australian Industrial Chemicals Introduction Scheme), Australian Government Department of Health, <https://www.industrialchemicals.gov.au/search-inventory>
4. APVMA Registrations and Permits, <https://apvma.gov.au/node/1060>
5. ADI [Acceptable Daily Intake] List (as updated), Commonwealth Department of Health, TGA (Therapeutic Goods Administration), <https://apvma.gov.au/sites/default/files/publication/74511-acceptable-daily-intakes-adi-for-agricultural-and-veterinary-chemicals-used-in-food-producing-crops-or-animals-edition-4-2020.pdf>
6. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code), Edition 7.7, 2020, https://www.ntc.gov.au/sites/default/files/assets/files/ADG%20Code%207.7_0.pdf
7. SUSMP (Standard for the Uniform Scheduling of Medicines and Poisons) (as updated), Chemicals and Medicines Scheduling Secretariat (MD122), Scheduling and Committee Governance, TGA, Commonwealth Department of Health, <https://www.tga.gov.au/publication/poisons-standard-susmp>
8. Hazardous Chemical Information System (HCIS), Safework Australia (as updated), <http://hcis.safeworkaustralia.gov.au/>
9. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition, United Nations, New York and Geneva, 2019, <https://unece.org/ghs-rev8-2019>
10. NIOSH Pocket Guide to Chemical Hazards
11. Chemical Classification and Information Database (CCID) (as updated), New Zealand Environmental Protection Authority, <http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx>

All information contained in this Safety Data Sheet is as accurate and up to date as possible. Since Pharmachem cannot anticipate or control the conditions under which this information may be used, each user should review the information in the specific context of the intended application. Pharmachem will not be responsible for damages of any nature resulting from use of or reliance upon the information. No expressed or implied warranties are given other than those implied as mandatory by Commonwealth State or Territory legislation.