

## SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product (material) name: Auracol Ear & Skin Suspension For Dogs, Cats & Horses  
Other names: Auracol  
Recommended 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 Details: Pharmachem  
Unit 6, 70 Fison Ave West  
Eagle Farm QLD 4009  
Telephone: (07) 3868 0333  
Facsimile: (07) 3868 0344  
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Emergency Telephone: (07) 3630 1654

## SECTION 2 HAZARDS IDENTIFICATION

This product is not classified as dangerous goods under the Australian Dangerous Goods (ADG) Code, but is classified as hazardous according to the classification criteria of NOHSC:1008(2004), Approved Criteria For Classifying Hazardous Substances and the National Code of Practice for the Preparation of Material Safety Data Sheets 2<sup>nd</sup> Edition [NOHSC:2011(2003)]

### Health Hazard Information

Although this product contains active constituents and excipients that can be both harmful and toxic, only the concentrations of miconazole nitrate and the suspending medium present are above those listed for harmful and toxic substances in the above document.

The product may cause allergic or sensitivity reaction for individuals sensitive to one or more of the components

Primary Route(s) of Entry: Dermal, Ingestion.  
Signs and Symptoms of Exposure  
Overexposure Effects: May cause irritation, vomiting, diarrhoea, convulsions, heart rhythm disorders.  
Chronic Effects: Possible hypersensitization.  
Inhalation: None expected under normal conditions of use.  
Eyes: May cause irritation.  
Skin: May cause irritation.  
Ingestion: May cause vomiting, diarrhea, convulsions, heart rhythm disorders.  
Medical conditions potentially aggravated: Hypersensitivity to any of the ingredients.

### Miconazole Nitrate:

Risk Phrases: R22 Harmful if swallowed.  
R43 May cause sensitization by skin contact.  
Safety Phrases: S36/37 Wear suitable protective clothing and gloves.

### Mineral oil

Risk Phrases: R36 Irritating to eyes.  
R37 Irritating to respiratory system.  
R38 Irritating to skin.

### 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	8012-95-1	QS 1L

### SECTION 4 FIRST AID MEASURES

The following First Aid directions have been set by the Office of Chemical Safety (OCS) of the Commonwealth Department of Health and Aging:

If poisoning occurs, contact a doctor or Poisons Information Centre. Telephone 131126. (*FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals*)

However, the following additional information is provided for assistance in emergency circumstances while implementing the first aid directions above.

Eye and Mucous Membrane Contact:	Remove contact lens if worn. Flush with water for 15 minutes.
Skin Contact:	Should skin irritation, allergic reaction or rash occur, physically remove as much of the product as possible and thoroughly flush the area with water.
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

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

Emergency procedures:  
Slippery when wet. Contain spill using inert absorbent material. Collect and seal contained, absorbed material in chemical waste containers for disposal.

Methods and materials for containment and clean up  
Use absorbent material such as soil, sand or vermiculite. Wash area down with detergent and excess water. Do not allow wash water to enter sewers drains or waterways. Contain wash water as for spilled material.

## SECTION 7 HANDLING AND STORAGE

Precautions for safe handling  
Wash thoroughly after handling. Use normal hygiene to protect hands, eyes and skin.

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:	Safety glasses and gloves may be worn.

## 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

Health effects from the likely routes of exposure. Information on individual hazardous ingredients has been provided below where available

Miconazole nitrate:	
Oral (LD <sub>50</sub> ) (Rat):	920 mg/kg
Oral (LD <sub>50</sub> ) (Mouse):	578 mg/kg
Oral (LD <sub>50</sub> ) (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 (LD<sub>50</sub>) (Mouse): 1680 mg/kg  
Polymyxin B Sulphate:  
Oral (LD<sub>50</sub>) (Mouse): 790 mg (Base)/kg

Suspending medium:  
Oral (LD<sub>50</sub>) (Rat): 22000 mg/kg  
Irritation Data:  
Standard Draize: Rabbit: Skin = 100 mg/24H, mild  
Eye = 500 mg, moderate.

## 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:

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- 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.

Although all ingredients appear in the Australian Inventory of Chemical Substances (AICS), they have not been assessed by NICNAS (National Industrial Chemicals Notification and Assessment Scheme)

## SECTION 16 OTHER INFORMATION

MSDS version:	1
Date of Revision:	February 2011
Update of sections:	2,16

Date of last revision of the MSDS:

### **CONTACT POINT**

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References:

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, December 2009
2. Approved Criteria For Classifying Hazardous Substances, NOHSC:1008 (2004)
3. National Code of Practice for the Preparation of Material Safety Data Sheets 2<sup>nd</sup> Edition [NOHSC:2011 (2003)]
4. AICS (Australian Inventory of Chemical Substances), Safework Australia
5. APVMA Manual of Requirements and Guidelines for Agricultural Chemicals, Version 4.1, March 2008 Revision
6. ADI [Acceptable Daily Intake] List, Commonwealth Department of Health & Aged Care, TGA, March 2010
7. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) 7<sup>th</sup> Edition
8. Standard for the Uniform Scheduling of Drugs and Poisons, National Drugs and Poisons Schedule Committee
9. Hazardous Substances Information System, Last Updated – April 2009, Safework Australia

All information contained in this Material 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.