

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
Unit 6, 70 Fison Ave West
Eagle Farm QLD 4009
Telephone: (07) 3868 0333
Facsimile: (07) 3868 0344
Contact Person: Mr Gray Boston
Emergency phone number: (07) 3630 1654

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), Third Revised Edition.

Health hazards: Miconazole Nitrate:
Acute toxicity, oral Category 4
Sensitization, skin Category 1
Mineral Oil:
Eye irritant Category 2

Miconazole Nitrate:
GHS label elements, including precautionary statements:
Pictogram:



Signal word: Warning
Hazard statements: Harmful if swallowed. May cause an allergic skin reaction.
Precautionary statement
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.
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.

Mineral Oil:
GHS Label elements, including precautionary statements
Pictogram:



Signal word: Warning
Hazard statement: Causes serious eye irritation.
Precautionary statement(s)
Prevention: Wash skin thoroughly after handling.
Wear protective gloves/ eye protection/ face protection.
Response: 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	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.

PHARMACHEM

Date of Issue: April 2014

SAFETY DATA SHEET

AURACOL SUSPENSION

Page 2 of 6

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

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

Mineral oil:

Oral (LD₅₀) (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:

- 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:	2
Date of Revision:	April 2014
Update of sections:	2, 11

CONTACT POINT

Mr Gray Boston, General Manager
B/Hrs Phone (07) 3868 0333 A/Hrs (07) 3630 1654

References:

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, March 2005
2. Approved Criteria For Classifying Hazardous Substances, NOHSC:1008 (2004)
3. National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC:2011 (2003)]

4. AICS (Australian Inventory of Chemical Substances)
5. APVMA Manual of Requirements and Guidelines for Agricultural Chemicals, October 2005
6. ADI [Acceptable Daily Intake] List, Commonwealth Department of Health & Aged Care, TGA, August 2001
7. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) 6th Edition
8. Hazardous Substances Information System, Version 1.2.2 (September 2004), Last Updated – November 2005, NOHSC

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.