

SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product (material) name: Kleo Ear Cleaner
Other names: Kleo
Recommended use: An aid in the treatment of Otitis Externa in Dogs
Supplier Details: Pharmachem
Unit 6, 70 Fison Ave West
Eagle Farm QLD 4009
Telephone: (07) 3868 0333
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Contact Person: Mr Gray Boston
Emergency Telephone: (07) 3630 1654

SECTION 2 HAZARDS IDENTIFICATION

This product is not dangerous goods under the Australian Dangerous Goods (ADG) Code, and is classified as not 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 2nd Edition [NOHSC:2011(2003)]

Dangerous Goods Information:

Although this material contains isopropyl alcohol which is Class 3 dangerous goods, it also contains more than 90% W/W water and is therefore excluded from Class 3 of the ADG Code.

Health Hazard Information

Although this product contains substances that are classified as hazardous in their concentrated forms, the concentrations of these materials in this product are below the concentration cut off points that would make this product a hazardous material. However, the following health hazard information for individual ingredients is provided for information:

Menthol - May irritate the eyes. May be harmful if ingested in quantity. May be harmful if inhaled.

Chlorothymol - Harmful if swallowed. Irritant.

Risk Phrases:

R22 Harmful if swallowed. R36 Irritating to eyes.
R37 Irritating to respiratory system. R38 Irritating to skin.

Boric acid

Safety Phrases:

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36 Wear suitable protective clothing.
S37 Wear suitable gloves.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label whenever possible.)

Isopropanol - May be harmful by inhalation, ingestion or skin absorption. May act as an irritant.

Risk Phrases:

R11 Highly flammable. R36 Irritating to eyes.
R37 Irritating to respiratory system.

Safety Phrases:

S7 Keep container tightly closed. S16 Keep away from sources of ignition.
S24 Avoid contact with skin. S25 Avoid contact with eyes.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Cas No.	Proportion (% W/V)
Boric Acid	10043-35-3	2.37
Menthol	2216-51-5	0.91
Chlorothymol	89-68-9	0.1
Isopropanol	67-63-0	< 3%
Proprietary non-hazardous ingredients		< 3%
Demineralised Water		QS 100%

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 Poison Information Centre (Telephone Australia – 13 11 26; New Zealand – 0800 764 766) (*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.

Eyes:	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:	Not applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Emergency procedures:
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:

The following Safety Directions have been set by the Australian Pesticides & Veterinary Medicines Authority as part of the assessment of this product for registration:

Will irritate the eyes and skin. Avoid contact with eyes and skin and when using the product. Wear elbow length rubber gloves. Wash hands after use. After each day's use, wash gloves.

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 100mL 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 should be worn.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Colourless liquid
pH	4.7 - 5.0
Specific Gravity	0.95 - 1.0
Viscosity	350 - 600 cp
Effect of freezing	Nil

SECTION 10 STABILITY AND REACTIVITY

Chemical stability:	Stable
Conditions to avoid:	Keep away from heat, flame and incompatibles.
Incompatible materials:	Strong oxidising agents, acids and bases, potassium, acid anhydrides, alkali metals, halogens and aluminium.
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

Chlorothymol	Harmful if swallowed. Irritant.
Oral (LD ₅₀) (Rat):	5000 mg/kg
Menthol	May irritate the eyes. May be harmful if ingested in quantity. May be harmful if inhaled.

Oral (LD₅₀) (Rat): 2900 mg/kg
Oral (LD₅₀) (Mouse): 3100 mg/kg

Boric acid
Oral (LD₅₀) (Rat): 2660 mg/kg
Oral (LD₅₀) (Mouse): 3450 mg/kg
Oral (LDLO) (Man): 429 mg/kg
Oral (LDLO) (WMN): 200 mg/kg
Subcutaneous (LD₅₀) (Mouse): 3450 mg/kg
Intravenous (LD₅₀) (Mouse): 1240 mg/kg
Inhalation (LCLO) (Rat): 28 mg/m³/4h mg/kg

Isopropanol May be harmful by inhalation, ingestion or skin absorption. May act as an irritant.

Oral (LD₅₀) (Rat): 5045 mg/kg
Oral (LD₅₀) (Mouse): 3600 mg/kg
Skin (LD₅₀) (Rabbit): 12800 mg/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

Although this material contains the Class 3 dangerous goods, isopropanol, it is excluded from the ADG Code because it is a water miscible solution containing more than 90% W/W water. This material is therefore not subject to dangerous goods regulation in Australia.

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)

Kleo Ear Cleaner is a Schedule 5 poison in accordance with the Poisons Standard published by the Department of Health and Aging, Therapeutic Goods Administration.

SECTION 16 OTHER INFORMATION

MSDS version:	1
Date of Revision:	Not applicable
Update of sections:	Not applicable

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 2nd 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) 7th Edition
8. The Poisons Standard (as updated), 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.