

## SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

GHS Product identifier: Kleo Ear Cleaner  
Other means of identification: Kleo  
Recommended use of the product and restrictions on use: An aid in the treatment of Otitis Externa in Dogs  
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 not classified as a hazardous substance or mixture under the classification criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition.

### GHS label elements, including precautionary statements:

Pictogram: Not required  
Signal word: Not required  
Hazard statements: None  
Precautionary statements:  
Prevention: None  
Response: None

Other Hazards: None known

## 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

### Routes of Exposure:

Exposure to Kleo may occur through inhalation, 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 Kleo. Information on individual ingredients has been provided where available.

### Signs and symptoms of exposure:

Oral:	Not known
Eyes:	Not known
Skin:	Not known
Inhalation:	Not applicable
Sensitizing:	Not known

### Summary of Toxicology:

Chlorothymol                      Harmful if swallowed. Irritant.  
 Oral (LD<sub>50</sub>) (Rat):                      5000 mg/kg

Menthol                              May irritate the eyes. May be harmful if ingested in quantity. May be harmful if inhaled.  
 Oral (LD<sub>50</sub>) (Rat):                      2900 mg/kg  
 Oral (LD<sub>50</sub>) (Mouse):                      3100 mg/kg

### Boric acid

Oral (LD <sub>50</sub> ) (Rat):	2660 mg/kg
Oral (LD <sub>50</sub> ) (Mouse):	3450 mg/kg
Oral (LDLO) (Man):	429 mg/kg
Oral (LDLO) (WMN):	200 mg/kg
Subcutaneous (LD <sub>50</sub> ) (Mouse):	3450 mg/kg
Intravenous (LD <sub>50</sub> ) (Mouse):	1240 mg/kg
Inhalation (LCLO) (Rat):	28 mg/m <sup>3</sup> /4h mg/kg

Isopropanol                      May be harmful by inhalation, ingestion or skin absorption. May act as an irritant.  
 Oral (LD<sub>50</sub>) (Rat):                      5045 mg/kg  
 Oral (LD<sub>50</sub>) (Mouse):                      3600 mg/kg  
 Skin (LD<sub>50</sub>) (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:	2
Date of Revision:	April 2016
Update of sections:	Update to GHS

### **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, (as updated)
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, (as updated)
6. ADI [Acceptable Daily Intake] List, Commonwealth Department of Health & Aged Care, TGA, (as updated)
7. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) 7<sup>th</sup> Edition
8. The Poisons Standard (as updated), National Drugs and Poisons Schedule Committee
9. Hazardous Substances Information System, Safework Australia (as updated)
10. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition, United Nations, New York and Geneva, 2009

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.