

| SECTION 1: IDENTIFICATION         |  |  |  |  |  |
|-----------------------------------|--|--|--|--|--|
| 1.1 Product identifier            |  |  |  |  |  |
| Product name:                     | EpiKlean Ear Cleanser  |  |  |  |  |
| Synonyms:                         | None   |  |  |  |  |
| Proper Shipping name:             | Not applicable   |  |  |  |  |
| Other means of<br>identification: |  |  |  |  |  |
| 1.2 Relevant identified uses      | of the substances or mixture and uses advised against                          |  |  |  |  |
| Recommended uses:                 | Ear cleanser for dogs and cats   |  |  |  |  |
| Uses advised against:             | Not for human use.   |  |  |  |  |
| 1.3 Details of the supplier o     | f the substance or mixture   |  |  |  |  |
| Registered company name<br>(US):  | Dechra Veterinary Products LLC   |  |  |  |  |
| Address:                          | 7015 College Blvd<br>Suite 525<br>Overland Park<br>KS 66211<br>USA             |  |  |  |  |
| Telephone:                        | +1 (866) 933 2472  |  |  |  |  |
| Fax:                              | Not available  |  |  |  |  |
| Website:                          | www.dechra.com   |  |  |  |  |
| Email:                            | Not available  |  |  |  |  |
| Distributor name (Canada):        | Dechra Veterinary Products   |  |  |  |  |
|                                   | 1 Holiday Ave, East Tower, Suite 345<br>Pointe-Claire, QC<br>H9R 5N3<br>Canada |  |  |  |  |
| Telephone:                        | +1 (855) 332 9334  |  |  |  |  |
| Website:                          | www.dechra.ca  |  |  |  |  |
| Email:                            | Not Available  |  |  |  |  |
| 1.4 Emergency Telephone N         | lumbers  |  |  |  |  |
| Dechra (US):                      | +1 (866) 933 2472  |  |  |  |  |
| Dechra (CA):                      | +1 (855) 332 9334  |  |  |  |  |



| SECTION 2: HAZARDS IDEN   | ITIFICATION     |  |  |  |  |
|---|-----------------|--|--|--|--|
| 2.1 Classification of the substance or mixture                              |                 | Canadian WHMIS Symbol:                   |  |  |  |
| NFPA 704 Diamond  |                 | <b>(T)</b>                               |  |  |  |
| 2.2 Label Elements  |                 |  |  |  |  |
| Hazard Pictogram:   |                 |  |  |  |  |
| Signal Word:  | WARNING         |  |  |  |  |
| Hazard statement(s):  |                 |  |  |  |  |
| H319 Causes serious eye irrita  | ation           |  |  |  |  |
| Supplementary Statement(s   | ) EU:           |  |  |  |  |
|   | Not applicable  |  |  |  |  |
| Precautionary Statement(s) Prevention:                                      |                 |  |  |  |  |
|   | Not applicable. |  |  |  |  |
| Precautionary Statement(s) Response:  |                 |  |  |  |  |
|   | Not applicable. |  |  |  |  |
| Precautionary Statement(s) Storage:   |                 |  |  |  |  |
| Not applicable.   |                 |  |  |  |  |
| Precautionary Statement(s)  | Disposal:       |  |  |  |  |
|   | Not applicable. |  |  |  |  |
| <b>2.3 Other Hazard Information</b><br>The mixture does not contain a date. |                 | ery High Concern (SVHC) at the SDS print |  |  |  |



| SECTION 3: INFORMATION ON THE INGREDIENTS                   |                  |  |  |  |
|---|------------------|--|--|--|
| 3.1 Substances  |                  |  |  |  |
| See section below fo  | r composition    | of mixtures                                |  |  |
| 3.2 Mixtures  | 3.2 Mixtures     |  |  |  |
| 1.CAS No<br>2.EC Number<br>3.Index Number<br>4.REACH Number | % Weight         | Name                                       |  |  |
| 64-17-5   | 1-10             | Ethanol                                    |  |  |
| 57-55-6   | 1-10             | Propylene glycol                           |  |  |
| Other ingredients   | Not<br>indicated | Ingredients determined not to be hazardous |  |  |

| SECTION 4: FIRST AID MEASURES                                   |  |  |  |  |  |  |
|---|--|--|--|--|--|--|
| 4.1 Description of first aid                                    | 4.1 Description of first aid measures  |  |  |  |  |  |
| Eye contact:  | Accidental spillage on the eyes should be washed off with plenty<br>of water. If pain or irritation occurs, seek medical advice and<br>show the package leaflet or the label to the medical practitioner.  |  |  |  |  |  |
| Skin contact:   | Accidental spillage on the skin should be washed off with plenty<br>of water. If irritation occurs, seek medical advice and show the<br>package leaflet or the label to the medical practitioner.  |  |  |  |  |  |
| Inhalation:   | Inhalation is highly unlikely due to the nature of the product and<br>how it is packaged and administered.<br>If irritation or difficulty in breathing occurs, seek urgent medical<br>advice and show the package leaflet or the label to the medical<br>practitioner. Remove the patient from the contaminated area. Lay<br>the patient down, keep warm and rested. |  |  |  |  |  |
| Ingestion:  | Ingestion is highly unlikely due to the nature of the product and<br>how it is packaged and administered.<br>If swallowed, seek medical advice and show the package leaflet<br>or the label to the medical practitioner.<br>Remove material and give water to rinse out mouth, then provide<br>liquid slowly and as much as casualty can comfortably drink.          |  |  |  |  |  |
| 4.2 Most important symptoms and effects, both acute and delayed |  |  |  |  |  |  |
| Eye contact:  | May cause serious eye irritation.  |  |  |  |  |  |
| Skin contact:   | May cause any skin irritation.   |  |  |  |  |  |



| •  | May cause discomfort, nausea and vomiting if ingested in large quantities |  |
|--|---|--|
| See Section 11 for more detailed information                               |   |  |
| 4.3 Indication of immediate medical attention and special treatment needed |   |  |

Treat symptomatically.

| SECTION 5: FIRE FIGHTIN     | SECTION 5: FIRE FIGHTING MEASURES   |  |  |  |  |
|-----------------------------|---|--|--|--|--|
| 5.1 Extinguishing media     | 5.1 Extinguishing media   |  |  |  |  |
| Suitable:                   | Select extinguishing media suitable for surrounding area  |  |  |  |  |
| Unsuitable:                 | There is no restriction on the type of extinguisher which may be used   |  |  |  |  |
| 5.2 Special hazards arisin  | g from the substance or mixture   |  |  |  |  |
| Fire incompatibility:       | None known  |  |  |  |  |
| 5.3 Special protective acti | ons for fire-fighters:  |  |  |  |  |
| Firefighting:               | Use water delivered as a fine spray to control fire and cool<br>adjacent area.<br><b>Do not</b> approach containers suspected to be hot.<br>Cool fire exposed containers with water spray from a protected<br>location.<br>If safe to do so, remove containers from path of fire.<br>Equipment should be thoroughly decontaminated after use. |  |  |  |  |
| Fire / explosion hazard:    | Extremely high temperatures such as encountered in a fire may produce hazardous fumes.  |  |  |  |  |

| SECTION 6: ACCIDENTAL RELEASE MEASURES                                  |
|---|
| 6.1 Personal precautions, protective equipment and emergency procedures |

For information on protective equipment, see section 8

## 6.2 Environmental Precautions

See section 12

# 6.3 Methods and material for containment and cleaning up

Spills are unlikely due to the nature of the product and how it is packaged

| Minor Spills: | Small spills should be cleaned up and placed in a closed container for disposal.                                     |
|---------------|--|
|               | Large spills should be diked and contained and then absorbed with no reactive materials and place in disposal drums. |



| SECTION 7: HANDLING AND STORAGE                                  |  |  |  |  |
|--|--|--|--|--|
| 7.1 Precautions for safe handling                                |  |  |  |  |
| Safe Handling:   | Always wash hands with water after handling.<br>Observe manufacturer's storage and handling recommendations. |  |  |  |
| Other Information:   | Store at controlled room temperature of 20-25°C (68-77°F).<br>Keep out of the reach and sight of children.   |  |  |  |
| 7.2 Conditions for safe storage, including any incompatibilities |  |  |  |  |
| Suitable Container:  | 8 fl oz. bottle, 12 fl oz. bottle, 32 fl oz. bottle  |  |  |  |
| Storage incompatibility:   | No known incompatibilities.  |  |  |  |
| 7.3 Specific end uses  |  |  |  |  |
| Not available  |  |  |  |  |

## **SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

## 8.1 Control parameters

# DERIVED NO EFFECT LEVEL - DNEL (EU)

Not Available

## PREDICTED NO EFFECT LEVEL - PNEC (EU)

Not Available

## **OCCUPATIONAL EXPOSURE LIMITS (OEL)**

**INGREDIENT DATA** 

Not Available

## EMERGENCY LIMITS (EU/US):

| Ingredient               | Material<br>Name    |               | TEEL-1        | TEEL          | -2       | TEEL-3        |
|--------------------------|---------------------|---------------|---------------|---------------|----------|---------------|
| EpiKlean Ear<br>Cleanser | Not Avail           | able          | Not Available | Not A         | vailable | Not Available |
| Ethanol                  | Not Available       |               | Not Available | Not Available |          | Not Available |
| Propylene glycol         | Propylene<br>glycol |               | 30 mg/m3      | 330 mg/m3     |          | 2000mg/m3     |
| Ingredient               |                     | Original IDLH |               | Revised ID    | LH       |               |
| EpiKlean Ear Cleanser    |                     | Not Available |               | Not Available |          |               |



| Propylene glycol | Not Available | Not Available |
|------------------|---------------|---------------|
| Ethanol          | 3300 ppm      | Not Available |

| 8.2 Exposure controls                                 |   |  |  |
|---|---|--|--|
|   | The basic types of engineering controls are:<br>Process controls which involve changing the way a job<br>activity or process is done to reduce the particular risk. |  |  |
| Personal protection:                                  |   |  |  |
| Eye and face protection:                              | Safety glasses with side shields / chemical goggles   |  |  |
| Skin protection:                                      | See hand protection below   |  |  |
| Hands/ feet protection:                               | No special equipment needed when handling small quantities.<br>OTHERWISE: Wear chemical protective gloves   |  |  |
| Body protection:                                      | Wear appropriate clothing   |  |  |
| Other protection:                                     | No special equipment needed when handling small quantities  |  |  |
| Thermal hazards:                                      | Not applicable  |  |  |
| Respiratory protection:                               | Not applicable  |  |  |
| <b>8.3 Environmental exposure c</b><br>See Section 12 | ontrols   |  |  |



| SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES                                |
|--|
| 9.1 Information on basic physical and chemical properties                  |
| Appearance: Clear light blue liquid  |
| Container: 8 fl oz. bottle, 12 fl oz. bottle, 32 fl oz. bottle,            |
| Physical state: Liquid   |
| Odour: mild, characteristic apple odour                                    |
| Melting point / freezing point (degrees C): Not applicable                 |
| Initial boiling point and boiling range: Not available                     |
| Flash Point: Not applicable  |
| Evaporation rate Not applicable  |
| Flammability: Not available  |
| Upper/lower flammability or explosive limits: Not available                |
| Vapour pressure: Not applicable  |
| Specific Gravity: Not available  |
| Solubility in water and solvents (mg/l): Miscible in water                 |
| Auto ignition temperature (degrees C): Not available                       |
| Decomposition temperature (degrees C): Not available                       |
| Viscosity: (degrees C): Not available                                      |
| Explosive properties: Not available<br>Oxidising properties: Not available |
| Partition Coefficient: Not available                                       |
| Taste: Not applicable  |
| Surface tension: Not available   |
| Volatile component: Not available  |
| Gas group: Not applicable  |
| pH: 3.5-4.5  |
| VOC g/L: Not applicable  |
| 9.2 Other information  |
| Not Available  |

| SECTION 10: STABILITY AND REACTIVITY        |   |  |
|---|---|--|
| 10.1 Reactivity:                            | See Section 7.  |  |
| 10.2 Chemical stability:                    | Product is considered stable.<br>Hazardous polymerisation will not occur.   |  |
| 10.3 Possibility of<br>hazardous reactions: | The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur. |  |
| 10.4 Conditions to avoid:                   | Protect from light.   |  |
| 10.5 Incompatible materials:                | See section 7.  |  |
| 10.6 Hazardous<br>decomposition:            | See Section 5.  |  |



| SECTION 11: TOXICOLOGICAL INFORMATION |  |  |  |
|---------------------------------------|--|--|--|
| Inhalation:                           | Not expected to cause any irritation of the respiratory tract  |  |  |
| Ingestion:                            | May cause discomfort, nausea and vomiting if ingested in large quantities  |  |  |
| Skin contact:                         | May cause skin irritation  |  |  |
| Eye contact:                          | Can cause burning and irritation to eyes with attendant tearing and redness  |  |  |
| Chronic:                              | Long term exposure is not thought to produce chronic effects   |  |  |
| EpiKlean Ear<br>Cleanser:             | Toxicity   | Irritation   |  |
|                                       | Not available  | Not available  |  |
| Ethanol                               | Toxicity   | Irritation   |  |
|                                       | Inhalation (rat) LC50: 124.7<br>mg/l/4H [2]<br>Oral (rat) LD50: 1501 mg/kg [2]   | Eye (rabbit): 500mg SEVERE<br>Skin (rabbit): 400mg (open) - mild |  |
| Propylene glycol                      | Toxicity   | Irritation   |  |
|                                       | Dermal (rabbit) LD50: 11890<br>mg/kg [2]<br>Inhalation (rat) LC50: > 44.9<br>mg/l/4H [2]<br>Oral (rat) LD50: 20000 mg/kg [2] | Eye (rabbit): 100 mg – mild<br>Skin (human): 500 mg/ 7 days mild |  |

1.\* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances

## Skin corrosion/irritation:

May cause any skin irritation.

Serious eye damage/irritation:

May cause eye irritation

Respiratory or skin sensitization:

Not expected to be a respiratory sensitization. Not a skin sensitizer.

Germ cell mutagenicity:

Not available

Carcinogenicity:

Not expected to be carcinogenic.

**Reproductive toxicity:** 

Not expected to cause reproductive effects



| STOT – single exposure: |
|-------------------------|
| Not available           |
| STOT–repeated exposure: |
| Not available           |
| Aspiration hazard:      |
| Not available           |

| SECTION 12: ECOLOGICAL INFORMATION |   |                           |   |   |                  |
|------------------------------------|---|---------------------------|---|---|------------------|
| 12.1 Toxicity                      |   |                           |   |   |                  |
| Ingredient                         | Endpoint  | Test<br>duration<br>(hr)  | Species   | Value   | Source           |
| EpiKlean Ear<br>Cleaner            | Not<br>available                                    | Not<br>available          | Not available   | Not available                                     | Not available    |
| Ethanol                            | LC50<br>EC50<br>EC50<br>NOEC                        | 96<br>48<br>96<br>2016    | Fish<br>Crustacea<br>Algae or other<br>aquatic plants<br>Fish | 11 mg/l<br>2 mg/kl<br>17.92 mg/l<br>0.000375 mg/l | 2<br>4<br>4<br>4 |
| Propylene glycol                   | LC50<br>EC50<br>EC50<br>NOEC                        | 96<br>48<br>96<br>168     | Fish<br>Crustacea<br>Algae or other<br>aquatic plants<br>Fish | >19 mg/l<br>43-500 mg/l<br>19 mg/l<br>11-530 mg/l | 2<br>2<br>2<br>2 |
| DO NOT discharge                   | e into sewer  | or waterwa                | ays.  |   |                  |
| 12.2 Persistence                   | and degrad  | ability                   |   |   |                  |
| Ingredient                         | Ingredient Persistence: Water/Soil Persistence: Air |                           |   |   | r                |
| Ethanol                            | LOW (Half   |                           | f-life = 2.17 days)   | LOW (Half-life = 5.08 days)                       |                  |
| Propylene glycol                   | l LOW   |                           |   | LOW   |                  |
| 12.3 Bioaccumula                   | 12.3 Bioaccumulative potential                      |                           |   |   |                  |
| Ingredient                         | Bioaccum  | Bioaccumulative Potential |   |   |                  |
| Ethanol                            | LOW (LogKOW = -0.31)                                |                           |   |   |                  |
| Propylene glycol                   | LOW (BCF=1)   |                           |   |   |                  |
| 12.4 Mobility in Se                | oil   |                           |   |   |                  |
| Ingredient                         | Mobility  |                           |   |   |                  |
| Ethanol                            | HIGH (KOC=1)  |                           |   |   |                  |

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| Propylene glycol H | IIGH (KOC=1) |
|--------------------|--------------|
|--------------------|--------------|

#### **12.5 Results of PBT and vPvB assessment** Not Available

## 12.6 Other adverse effects

Not Available

## SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

|                             | Any unused veterinary medicinal product or waste material derived from<br>such veterinary medicinal products should be disposed of in accordance<br>with national requirements.  |
|-----------------------------|--|
|                             | Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area.  |
|                             | Recycle wherever possible or consult manufacturer for recycling options.<br>Consult State Land Waste Management Authority for disposal.<br>Bury residue in an authorized landfill.<br>Recycle containers if possible, or dispose of in an authorized landfill. |
|                             | Shelf life considerations should also be applied in making decisions of<br>this type. Note that properties of a material may change in use, and<br>recycling or reuse may not always be appropriate. Where in doubt<br>contact the responsible authority.      |
|                             | Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.   |
| Waste Treatment<br>Options: |  |
| Sewage Disposal<br>Options: |  |



## SECTION 14: TRANSPORT INFORMATION

Labels required:

Marine pollutant: NO

Land transport (US: DOT / TDG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code: Not applicable

## **SECTION 15: REGULATORY INFORMATION**

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

#### ETHANOL IS FOUND IN THE FOLLOWING REGULATORY LISTS:

USA: GESAMP/EHS / IMO IBC / IMO MARPOL / US ATSDR / TEELs / TLV / US DOT / TSCA / TERA / WEEL / REL / TSCA Canada: OELs / DSL / WHMIS GHS / IMO IBC / IMO MARPOL . IATA / IMDG Code

## **PROPYLENE GLYCOL IS FOUND IN THE FOLLOWING REGULATORY LISTS:** USA: GESAMP/EHS / IMO IBC / IMO MARPOL / US ATSDR / TEELs / US DOT / TSCA /

TERA / WEEL

Canada: DSL / WHMIS GHS / GESAMP/EHS / IMO IBC / IMO MARPOL

## FEDERAL REGULATIONS:

## Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 Hazard Categories

| Immediate (acute) health hazard | NO |
|---------------------------------|----|
| Delayed (chronic) health hazard | NO |
| Fire hazard                     | NO |
| Pressure hazard                 | NO |
| Reactivity hazard               | NO |

#### US. EPA Cercla Hazardous Substances and Reportable Quantities (40 CFR 302.4) None reported

STATE REGULATIONS:

## **US. CALIFORNIA PROPOSITION 65**

None reported

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| National Inventory               | Status  |
|----------------------------------|---|
| Australia - AICS                 | Yes   |
| Canada - DSL                     | Yes   |
| Canada - NDSL                    | No (propylene glycol)   |
| China - IECSC                    | Yes   |
| Europe - EINEC / ELINCS /<br>NLP | Yes   |
| Japan - ENCS                     | Yes   |
| Korea - KECI                     | Yes   |
| New Zealand - NZIoC              | Yes   |
| Philippines - PICCS              | Yes   |
| USA - TSCA                       | Yes   |
| Taiwan – TCSI                    | Yes   |
| Mexico – INSQ                    | Yes   |
| Vietnam – NCI                    | Yes   |
| Russia – ARIPS                   | Yes   |
| Legend:                          | Y = All ingredients are on the inventory<br>N = Not determined or one or more ingredients are not<br>on the inventory and are not exempt from listing (see<br>specific ingredients in brackets) |



# SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS, WHMIS and OSHA.

## **Definitions and abbreviations**

PC-TWA: Permissible Concentration-Time Weighted Average PC-STEL: Permissible Concentration-Short Term Exposure Limit STEL: Short Term Exposure Limit TEEL: Temporary Emergency Exposure Limit IDLH: Immediately Dangerous to Life or Health Concentrations

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