






SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	KlearOtic Ear Cleanser
Synonyms:	None
Proper Shipping name:	Environmentally hazardous substance – contains isopropyl myristate
Other means of identification:	None
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 of the substance or mixture	
Registered company name (US):	Dechra Veterinary Products LLC
Address:	7015 College Blvd Suite 525 Overland Park KS 66211 USA
Telephone:	+1 (866) 933 2472
Fax:	Not available
Website:	www.dechra.com
Email:	Not available
Distributor name (Canada):	Dechra Veterinary Products
Address:	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3 Canada
Telephone:	+1 (855) 332 9334
Website:	www.dechra.ca
Email:	Not Available
1.4 Emergency Telephone Numbers	
Dechra (US):	+1 (866) 933 2472
Dechra (CA):	+1 (855) 332 9334

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture NFPA 704 Diamond 	Canadian WHMIS Symbol: 
2.2 Label Elements	
Hazard Pictogram:	
Signal Word:	WARNING
Hazard statement(s):	
H315 Causes skin irritation H319 Causes serious eye irritation H411 Toxic to aquatic life with long lasting effects	
Precautionary Statement(s) Prevention:	
	P280 Wear protective gloves/ protective clothing / eye protection/ face protection
Precautionary Statement(s) Response:	
	P305+P351+P338 If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
Precautionary Statement(s) Storage:	
	P405 Store locked up
Precautionary Statement(s) Disposal:	
	P501 Dispose of contents / containers in accordance with local regulations
2.3 Other Hazard Information	
The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.	



SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

1. CAS No 2. EC Number 3. Index Number 4. REACH Number	% Weight	Name
8042-47-5	30-60	White mineral oil
110-27-0	10-30	Isopropyl myristate
111-01-3	10-30	Squalene
Other ingredients	Not indicated	Ingredients determined not to be hazardous

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
Ingestion:	Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. If swallowed, seek medical advice and show the package leaflet or the label to the medical practitioner. Remove material and give water to rinse out mouth, then provide 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.
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Skin contact:	May cause any skin irritation.
Ingestion:	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 FIGHTING MEASURES	
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 arising from the substance or mixture	
Fire incompatibility:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Use water delivered as a fine spray to control fire and cool adjacent area. Do not approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. 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.
Major Spills:	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. Observe manufacturer's storage and handling recommendations.
Other Information:	Store at controlled room temperature of 20-25°C (66-77°F). Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	4 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 Name	TEEL-1	TEEL-2	TEEL-3
KlearOtic Ear Cleanser	Not Available	Not Available	Not Available	Not Available
Isopropyl myristate	Myristic acid	81 mg/m ³	900 mg/m ³	5,400 mg/m ³
Squalene	Squalene	0.69 ppm	7.6 ppm	46 ppm
Ingredient		Original IDLH		Revised IDLH
KlearOtic Ear Cleanser		Not Available		Not Available

White mineral oil	2,500 mg/m ³	Not Available
Isopropyl myristate	Not Available	Not Available
Squalene	Not Available	Not Available

8.2 Exposure controls	
Appropriate engineering controls:	The basic types of engineering controls are: Process controls which involve changing the way a job 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. 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
8.3 Environmental exposure controls	
See Section 12	



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Clear colorless oily liquid
Container: 4 oz bottle
Physical state: Liquid
Odor: No discernable odor
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
Vapor pressure: Not applicable
Specific Gravity: Not available
Solubility in water and solvents (mg/l): Immiscible in water
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidizing properties: Not available
Partition Coefficient: Not available
Taste: Not applicable
Surface tension: Not available
Volatile component: Not available
Gas group: Not applicable
pH: Not available
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. Hazardous polymerization will not occur.
10.3 Possibility of hazardous reactions:	The product is not considered to be hazardous if used as per instructions. Hazardous polymerization will not occur.
10.4 Conditions to avoid:	Protect from light.
10.5 Incompatible materials:	See section 7.
10.6 Hazardous 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:	May cause eye irritation	
Chronic:	Long term exposure is not thought to produce chronic effects	
KlearOtic Ear Cleanser:	Toxicity	Irritation
	Not available	Not available
White mineral oil	Toxicity	Irritation
	Dermal (rabbit) LD50: >2000mg/kg [1] Oral (rat): LD50: >5000mg/kg [1]	Eye: no adverse effect observed [1] Skin: adverse effect observed (irritating) [1]
Isopropyl myristate	Toxicity	Irritation
	Dermal (rabbit) LD50: 5000 mg/kg [2] Oral (rat) LD50: >2000mg/kg [1]	Skin (human): 85 mg/3d-l-mild Skin (rabbit): 100 mg/24h-Severe
Squalene	Toxicity	Irritation
	Not available	Skin (guinea pig): 100 mg/24h-mod

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 duration (hr)	Species	Value	Source
KlearOtic Ear Cleaner	Not available	Not available	Not available	Not available	Not available
White mineral oil	LC50	96	Fish	1.13 mg/l	2
	EC50	48	Crustacea	2 mg/l	2
	EC50	72	Algae or other aquatic plants	1.714 mg/l	2
Isopropyl myristate	LC50	96	Fish	0.070 mg/l	3
	EC50	48	Crustacea	>0.05 mg/l	2
	EC50	96	Algae or other aquatic plants	0.007 mg/l	3
	NOEC	384	Crustacea	0.1 mg/l	1
Squalene	NOEC	72	Algae or other aquatic plants	>100 mg/l	2

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Isopropyl myristate	LOW	LOW
squalene	HIGH	HIGH

12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
Isopropyl myristate	LOW (LogKOW = 7.175)



squalene	LOW (LogKOW = 14.6334)
12.4 Mobility in Soil	
Ingredient	Mobility
Isopropyl myristate	LOW (KOC – 15390)
squalene	LOW (KOC = 149400000)
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	
Product / packaging disposal:	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area.</p> <p>Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill.</p> <p>Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Products Regulations (Canada, 2015).</p>
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available

SECTION 14: TRANSPORT INFORMATION

Labels required:	 	Marine pollutant
Marine pollutant:	NO	

Land transport (EU: ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1 UN Number	3082	
14.2 UN Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s (contains isopropyl myristate)	
14.3 Transport hazard class(es)	Class	9
	Subrisk	Not applicable
14.4 Packing group	III	
14.5 Environmental hazards	Environmentally hazardous	

14.6 Special precautions for user	Hazard label	9
	Special provisions	8, 146, 173, 335, IB3, T4, TP1, TP29

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

14.1 UN Number	3082	
14.2 UN Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s (contains isopropyl myristate)	
14.3 Transport hazard class(es)	ICAO/IATA Class	9
	ICAO / IATA Sub risk	N/A
	ERG Code	9L
14.4 Packing group	III	
14.5 Environmental hazards	Environmentally hazardous	



14.6 Special precautions for user	Special provisions	A97 A158 A197
	Cargo only packing instructions	964
	Cargo only maximum qty/pack	450 L
	Passenger and cargo packaging instructions	964
	Passenger and cargo maximum qty/pack	450 L
	Passenger and cargo limited quantity packing instructions	Y964
	Passenger and cargo limited maximum qty/pack	30 kg G

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	3082	
14.2 UN Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s (contains isopropyl myristate)	
14.3 Transport hazard class(es)	IMDG Class	9
	IMDG Sub risk	N/A
14.4 Packing group	III	
14.5 Environmental hazards	Marine pollutant	
14.6 Special precautions for user	EMS Number	F-A, S-F
	Special provisions	274 335 969
	Limited quantities	5 L

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/A
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Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS				
14.1 UN Number	Not applicable			
14.2 UN Proper Shipping Name	Not applicable			
14.3 Transport hazard class(es)	Not applicable	Not applicable		
14.4 Packing group	N/A			
14.5 Environmental hazard	N/A			
14.6 Special precautions for user	Classification Code		N/A	
	Special provisions		N/A	
	Limited quantity		N/A	
	Equipment required		N/A	
	Fire cones number		N/A	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Source	Product Name	Pollution Category	Ship Type
		Benzyl alcohol	Y	3

SECTION 15: REGULATORY INFORMATION

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

WHITE MINERAL OIL IS FOUND IN THE FOLLOWING REGULATORY LISTS:
 USA: IMO/ IARC / FOSFA / TLV/ WEELs / NTP / RELs/ PELs/ USPS/ TSCA
 Canada: OELs / DSL / WHMIS GHS / IMO / IARC / FOSFA

ISOPROPYL MYRISTATE IS FOUND IN THE FOLLOWING REGULATORY LISTS:
 USA: GESAMP/EHS / IMO IBC / IMO MARPOL / IATA / IMDG Code / DOT. TEELs / USPS / TSCA
 Canada: DSL / GESAMP/EHS / IMO IBC / IMO MARPOL / IATA / IMDG Code

SQUALENE IS FOUND IN THE FOLLOWING REGULATORY LISTS:
 USA: TEELs / TSCA
 Canada: DSL



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	

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



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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