SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Canaural® ear drops, suspension
Synonyms:	Not Available
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	For the treatment of otitis externa including the ear mite, *Otodectes cynotis,* in the dog and cat.
Uses advised against:	• Do not use in animals with a perforated eardrum. • Do not use concomitantly with products known to be ototoxic. • Do not use in animals with known hypersensitivity to the active substances or to the excipient. • People with known hypersensitivity to any of the active substances or the excipient in the product should avoid contact with the veterinary medicinal product.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Ltd
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
Telephone:	+44 (0) 1756 791311
Fax:	+44 (0) 1756 798604
Email:	Not available
1.4 Emergency Telephone Numbers	
Telephone:	+44 (0) 1756 791311

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
DSD Classification (EU):	Not Available
DPD Classification (EU)[1]:	Not Available

Classification according to regulation (EC) No 1272/2008 [CLP] (EU)[1]:	No Data Available
2.2 Label Elements	
Signal Word:	
Hazard Statement(s)	
No Data Available	
Additional Statement(s)	
None	
Precautionary Statement(s) Prevention:	
P264	Wash hands thoroughly after handling. (Check chemwatch).
P270	Do not eat, drink or smoke when using this product.
Precautionary Statement(s) Response:	
P301 + P310	IF SWALLOWED: immediately call a POISON CENTER/doctor
P330	Rinse mouth.
Precautionary Statement(s) Storage:	
P405	Store locked up
Precautionary Statement(s) Disposal:	
P501	Dispose of contents / packaging according to local regulations
2.3 Other Hazard Information N/a	

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 in 1g suspension**	**Name**	**Classification according to regulations (EC) No 1272/2008 [CLP] (EU)**
1. 16391-75-6 2. Not Available 3. Not Available 4. Not Available	0.5	Diethanolamine fusidate	No data available
1. 28002-70-2	0.5	Framycetin	Skin Sensitizer Category 1,

2. 248-770-9 3. Not Available 4. Not Available		sulphate	Reproductive Toxicity 2, STOT - RE Category 2; H317, H361, H373[1]
1. 1400-61-9 2. 215-749-0 3. Not Available 4. Not Available	100,000 IU	Nystatin	Skin Sensitizer Category 1; H317[1]
1. 50-24-8 2. Not Available 3. Not Available 4. Not Available	0.25	Prednisolone	Acute toxicity category 4; H302[1]
Legend:	*1. Classified by Chemwatch*		

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	If the product comes into contact with the eyes, rinse immediately with plenty of water. Seek medical advice if irritation persists and show the package leaflet or the label to the medical practitioner.
Skin contact:	In case of accidental contact of the product with the skin, rinse with fresh water. Seek medical advice if irritation persists and show the package leaflet or the label to the medical practitioner.
Inhalation:	Due to physical form of this product, inhalation exposure is unlikely. However, if this product causes irritation, seek medical advice if irritation persists and show the package leaflet or the label to the medical practitioner.
Ingestion:	Wash out mouth thoroughly and drink 1-2 glasses of water in small sips. Seek medical advice in case of persistent discomfort, showing the package leaflet or the label to the medical practitioner.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11.

4.3 Indication of immediate medical attention and special treatment needed

Not available.

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Powder, foam, carbon dioxide or water mist.
Unsuitable:	Water stream.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known.
5.3 Special protective actions for fire-fighters:	
Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus. Use water or water mist to cool non-ignited stock. Avoid inhalation of vapour.
Fire / explosion hazard:	None known.

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	
Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/ surface or ground water.	
6.3 Methods and material for containment and cleaning up	
Minor Spills:	Flush residues and small spillages to waste with copious quantities of water. Control personal contact with the substance, by using protective equipment.
Major Spills:	Clean all spills immediately. Clear area of personnel and move upwind. Avoid breathing vapours and contact with skin and eyes. Large spills should be collected into an appropriate container for waste disposal.

SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	People with known hypersensitivity to any of the active substances or the excipient in the product should avoid contact with the veterinary medicinal product. Wear suitable protection gloves and clothing when handling the product. When handling, **DO NOT** eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Other Information:	Do not store above 25°C. Protect from direct sunlight. Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Shelf-life after first opening the immediate packaging: 3 months.
Storage incompatibility:	Unknown.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION				
8.1 Control parameters				
DERIVED NO EFFECT LEVEL - DNEL				
Not Available				
PREDICTED NO EFFECT LEVEL - PNEC				
Not Available				
OCCUPATIONAL EXPOSURE LIMITS (OEL)				
INGREDIENT DATA:				
Not Available				
EMERGENCY LIMITS:				
Ingredient	**Material Name**	**TEEL-1**	**TEEL-2**	**TEEL-3**
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: Canaural®**:** Yellow, oily suspension
Container: High density polyethylene squeeze dropper bottles, supplied in boxes of 1x15ml, 10x15ml, 1x25ml, 1x100ml. Not all pack sizes may be marketed.
Physical state: Suspension
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: In water – no flash point.
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not available
Solubility in water and solvents (mg/l): Not available
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Molecular weight: Not available
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information

Not Available

10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Product is considered stable. Hazardous polymerisation will not occur.
10.3 Possibility of 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:	See Section 7.
10.5 Incompatible materials:	See section 7.

10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION		
Inhalation:	The product does not release hazardous vapours.	
Ingestion:	Ingestion may cause discomfort.	
Skin contact:	The product may produce slight skin irritation in some persons**.**	
Eye contact:	The product may produce eye irritation in some persons**.**	
Chronic:	None known.	
Canaural®:	**Acute toxicity**	**Irritation**
	Not Available	Not Available
Framycetin sulphate:	**Acute toxicity**	**Irritation**
	Not Available	Skin: slight
Nystatin:	**Acute toxicity**	**Irritation**
	Oral (rat) LD_{50}: 10000 mg/kgd[2]	Not Available
Prednisolone:	**Acute toxicity**	**Irritation**
	Oral (rat) LD_{50}: 3857 mg/kg[1]	Not Available
1. *Value obtained from Europe ECHA registered substances* 2. **Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances*		
Skin corrosion/ irritation:		
Not Available		
Serious eye damage/ irritation:		
Not available		
Respiratory or skin sensitization:		
The product contains small amounts of Neomycin B sulphate. Persons with a known allergy may exhibit an allergic response to the product.		
Germ cell mutagenicity:		
Not available		
Carcinogenicity:		

SECTION 11: TOXICOLOGICAL INFORMATION
Not available
Reproductive toxicity:
Not available
STOT – single exposure:
Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity
Not Available
DO NOT discharge into sewer or waterways.
12.2 Persistence and degradability
Not Available
12.3 Bioaccumulative potential
Not Available
12.4 Mobility in Soil
Not Available
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	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance

disposal:	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. Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available

SECTION 14: TRANSPORT INFORMATION		
Labels required:	None	
Marine pollutant:	NO	
Hazchem:	Not Applicable	
Land transport (ADR):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Air transport (ICAO-IATA / DGR):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	

14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	

Inland waterways transport (ADN):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a	N/a
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	N/a	

SECTION 15: REGULATORY INFORMATION

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

FRAMYCETIN SULFATE (28002-70-2) IS FOUND ON THE FOLLOWING REGULATORY LISTS:
• European Customs Inventory of Chemical Substances ECICS (English) • European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)
NYSTATIN (1400-61-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS:
• European Customs Inventory of Chemical Substances ECICS (English) • European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)
PREDNISOLONE (50-24-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS:
• European Customs Inventory of Chemical Substances ECICS (English) • European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

15.2 Chemical Safety Assessment
ECHA SUMMARY

Ingredient	**CAS number**	**Index Number**	**ECHA Dossier**
Framycetin sulfate	28002-70-2	Not Available	Not Available
Harmonization (C&L Inventory)	**Hazard Class and Category Code(s)**	**Pictograms Signal Word Code(s)**	**Hazard Statement Code(s)**
2	Acute Tox. 4, Repr. 2	GHS07, Wng	H312, H332, H361
1	Repr. 2, STOT RE 2	GHS08, Wng	H361, H373
2	Repr. 2, STOT RE 2, Skin Sens. 1, Resp. Sens. 1, Acute Tox. 4, Skin Irrit. 2	GHS08, Dgr	H361, H373, H317, H334, H302, H315, H332
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	**CAS number**	**Index Number**	**ECHA Dossier**
Nystatin	1400-61-9	Not Available	Not Available
Harmonization (C&L Inventory)	**Hazard Class and Category Code(s)**	**Pictograms Signal Word Code(s)**	**Hazard Statement Code(s)**
2	STOT SE 3, STOT RE 1, Acute Tox. 1	Dgr, GHS08	H335, H372, H300

Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

Ingredient	**CAS number**	**Index Number**	**ECHA Dossier**
Prednisolone	50-24-8	Not Available	01-2119560581-40-XXXX
Harmonization (C&L Inventory)	**Hazard Class and Category Code(s)**	**Pictograms Signal Word Code(s)**	**Hazard Statement Code(s)**
1	Acute Tox. 4	GHS07, Wng	H302, H312, H332
2	Repr. 1B, Acute Tox. 4, Repr. 1A, STOT RE 2, Repr. 2, Muta. 2, Carc. 1B, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3	GHS08, Dgr	H302, H312, H332, H360Df, H341, H350, H373, H315, H319, H335, H400
1	Repr. 1A, STOT RE 2	GHS08, Dgr	H360, H373
2	Repr. 1A, STOT RE 2	GHS08, Dgr	H360, H373
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (framycetin sulfate, nystatin, prednisolone)
China - IECSC	N (framycetin sulfate, nystatin)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (framycetin sulfate)
Korea - KECI	N (framycetin sulfate, nystatin))
New Zealand - NZIoC	Y
Philippines - PICCS	N (framycetin sulfate, nystatin))
USA - TSCA	N (framycetin sulfate, nystatin))
Legend:	*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)*

SECTION 16: OTHER INFORMATION

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

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:
EN 166 Personal eye-protection
EN 340 Protective clothing
EN 374 Protective gloves against chemicals and micro-organisms
EN 13832 Footwear protecting against chemicals
EN 133 Respiratory protective devices

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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