



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Osumnia® Ear Gel for Dogs
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:	Corticosteroid and anti-infective ear gel for dogs
Uses advised against:	Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name (EU):	Dechra Regulatory B.V.
Address:	Handelsweg 25 5531 AE Bladel The Netherlands
Telephone:	+31 (0)497 544 300
Fax:	+31 (0)497 544 302
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
Distributor 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-us.com
Email:	Not available
1.4 Emergency Telephone Numbers	
Dechra (US):	+1866-933-2472
Dechra (CA):	1 855 332-9334

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	Serious eye damage/ eye irritation Cat 2 Reproductive toxicity (fertility) Cat 2 Hazardous to aquatic environment Cat 1
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2.2 Label Elements



Signal Word: **WARNING**

Hazard statement(s):

H319 Causes serious eye irritation
 H361 Suspected of damaging fertility or the unborn child
 H410 Very toxic to aquatic life with long lasting effects

Precautionary Statement(s) Prevention:

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P264 Wash thoroughly after handling.
 P273 Avoid release to the environment
 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.
 P308 + P313 IF exposed or concerned: Get medical advice/attention.

Precautionary Statement(s) Storage:

P405 Store locked up



Precautionary Statement(s) Disposal:
P501 Dispose of contents/container in accordance with local/regional/national/international regulations
2.3 Other Hazard Information
None

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	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1.108-32-7 2.203-572-1 3.607-194-00-1 4.01-2119537232-48-XXXX 01-0000018257-67-XXXX	50-75	Propylene carbonate	Eye Irritation Category 2; H319 [2]
1.56-81-5 2.200-289-5 3.Not Available 4.01-2119471987-18-XXXX	25-50	Glycerol formal	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation); H315, H319, H335 [1]
1.73231-34-2 2.Not Available 3.Not Available 4.Not Available	<1	Florfenicol	Acute Aquatic Hazard Category 1, Specific target organ toxicity - repeated exposure Category 2, Reproductive Toxicity Category 2, Chronic Aquatic Hazard Category 1; H400, H373, H361, H410 [1]



1.91161-71-6 2.Not Available 3.Not Available 4.01-2119979838-10-XXXX	<1	Terbinafine	Eye Irritation Category 2, Reproductive Toxicity Category 2, Specific target organ toxicity – repeated exposure Category 2, Chronic Aquatic Hazard Category 1, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Skin Corrosion/Irritation Category 2; H319, H361fd, H373, H410, H335, H315 [1]
1.987-24-6 2.213-578-6 3.Not Available 4.Not Available	<0.1	Betamethasone acetate	Reproductive Toxicity Category 2; H361 [1]
1.128-37-0 2.204-881-4 3.Not Available 4.01-2119480433-40-XXXX	<=0.1	BHT	Acute Aquatic Hazard Category 1, Reproductive Toxicity Category 2, Carcinogenicity Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Eye Irritation Category 2, Chronic Aquatic Hazard Category 1, Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 2, Germ cell mutagenicity Category 2; H400, H361, H351, H335, H319, H410, H302, H315, H341 [1]
Legend:	1. Classified by Chemwatch; 2. Classification drawn from EC Directive 67/548/EEC - Annex I		

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	Accidental spillage on the eyes should be washed off immediately with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. If eye irritation persists, 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 soap and water. Remove contaminated clothes that are in direct contact with skin. 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:	If swallowed, do not induce vomiting. Remove material and give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. Get medical attention if symptoms occur.
4.2 Most important symptoms and effects, both acute and delayed	
Causes serious eye irritation. Suspected of damaging fertility or the unborn child	
4.3 Indication of immediate medical attention and special treatment needed	
Treat symptomatically.	

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Water fog. Foam. Dry chemical powder Carbon dioxide
Unsuitable:	Do not use water jet as an extinguisher, as this will spread the fire.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known.
5.3 Special protective actions for fire-fighters:	
Firefighting:	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. DO NOT approach containers suspected to be hot. Equipment should be thoroughly decontaminated after use.
Fire / explosion hazard:	Non-combustible. Not considered a significant fire risk, however containers may burn. Irritating and highly toxic gases may be generated from thermal decomposition or combustion.



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:	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Place in a suitable, labelled container for waste disposal.
Major Spills:	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent, by any means available, spillage from entering drains or water course.

SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Provide adequate ventilation. Avoid contact with eyes. Avoid prolonged exposure. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Other Information:	Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Single-use multi-layered aluminium and polyethylene tube with a polypropylene thermoplastic elastomer tip. Store at: 2 - 8 °C.
Storage incompatibility:	In the absence of incompatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.





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:						
Source	Ingredient	Material Name	TWA	STEL	Peak	Notes
Not Available						

EMERGENCY LIMITS:				
Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Propylene carbonate	Propylene carbonate, 1, 2-	34 mg/m3	370 mg/m3	2,200 mg/m3
glycerol	glycerol	45 mg/m3	180 mg/mg3	1,100 mg/m3
Ingredient	Original IDLH		Revised IDLH	
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: White to yellow, Liquid

Container: Single-use multi-layered aluminium and polyethylene tube with a polypropylene thermoplastic elastomer tip.

Physical state: Gel

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: > 194.0°F (>90.0°C)

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 explosive

Oxidising properties: Not oxidizing

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 material is not thought to produce adverse health effects or irritation of the respiratory tract.
Ingestion:	Ingestion may result in nausea, abdominal irritation, pain and vomiting. In the case of accidental and if symptoms occur, get medical attention.
Skin contact:	Not expected to be an irritant
Eye contact:	May cause eye irritation
Chronic:	Suspected of damaging fertility or the unborn child

Osumnia Ear Gel for Dogs:	Acute toxicity	Irritation
	Dermal (rat) LD50: >2020 mg/kg Oral (rat) LD50: >2000 mg/kg	Not Available
Glycerol:	Acute toxicity	Irritation
	Oral (rat) LD50:> 10000 mg/kg ²	Not available
BHT:	Acute toxicity	Irritation
	Dermal (rat) LD50: >6000 mg/kg Oral (rat) LD50:> 2000 mg/kg	Not available



Terbinafine:	Acute toxicity	Irritation	
	Oral (rat) LD50:> 4000 mg/kg ²	Not available	
Florfenicol:	Acute toxicity	Irritation	
	Oral (mouse) LD50: >2000 mg/kg Oral (rat) LD50: >2000 mg/kg Oral NOEL: Dog – 1 mg/kg Oral NOEL: Rat – 1 mg/kg adverse effects on the male reproductive system	Not available	
Propylene carbonate:	Acute toxicity	Irritation	
	Dermal (rat) LD50: >2000 mg/kg Oral (rat) LD50: >5000 mg/kg	Eye irritation observed ¹	Not irritating to skin ¹
1.* Value obtained from Europe ECHA Registered Substances – acute toxicity. 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:			
Moderate eye irritation (rabbit)			
Respiratory or skin sensitization:			
Not Available			
Germ cell mutagenicity:			
Not Available			
Carcinogenicity:			
Not Available			
Reproductive toxicity:			
Suspected of damaging fertility or the unborn child			
STOT – single exposure:			
Not Available			
STOT–repeated exposure:			
Not Available			
Aspiration hazard:			
Not Available			
i) Germ cell mutagenicity:	Not available	j) Aspiration hazard:	Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
BHT	EC50	96	Algae or other aquatic plants	0.758mg/L	1
	EC50	48	Crustacea	0.48 mg/L	1
	LC50	96	Fish	0.199 mg/L	1
	NOEC	48	Crustacea	0.15 mg/L	1
Florfenicol	EC50	72	Algae or other aquatic plants	3.83mg/L	1
	NOEC	72	Algae or other aquatic plants	0.32 mg/l	1
	EC50	48	Crustacea	84.5 mg/l	1
	NOEC	96	Crustacea	>900 mg/l	1
	LC50	96	Fish	>900 mg/l	1
Propylene carbonate	EC50	48	Crustacea	>1000mg/L	1
		96	Fish	>1000mg/L	1
Terbinafine	EC50	-	Algae or other aquatic plants	0.029mg/L	1
	EC50	48	Crustacea	0.35mg/L	1
	NOEC	32 days	Fish	0.047 mg/L	1

Legend: 1. Elanco Osurnia SDS

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No data available	No data available

12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
Florfenicol	(LogKOW = 0.37)
Propylen carbonate	(LogKOW = -0.41)

12.4 Mobility in Soil

Ingredient	Mobility
	No data 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 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>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:	NO	
Hazchem:	Not Applicable	
Land transport (EU: ADR / US: DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	UN3082	
14.2 UN Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TERBINAFINE, Florfenicol)	
14.3 Transport hazard class(es)	Class	9
	Sub risk	-
	Label(s)	9
	Hazard No.	90
	Tunnel restriction code	E
14.4 Packing group	III	
14.5 Environmental hazards	Yes	
14.6 Special precautions for user	Special provisions	Not available
	Limited quantity	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not established	



Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	UN3082	
14.2 UN Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TERBINAFINE, Florfenicol)	
14.3 Transport hazard class(es)	Class	9
	Sub risk	-
14.4 Packing group	III	
14.5 Environmental hazards	Yes. ERG code: 9L	
14.6 Special precautions for user	Special provisions	Not available
	Cargo only packing instructions	Allowed with restrictions
	Cargo only maximum qty/pack	Allowed with restrictions
	Passenger and cargo packaging instructions	Allowed with restrictions
	Passenger and cargo maximum qty/pack	Allowed with restrictions
	Passenger and cargo limited quantity packing instructions	Allowed with restrictions
	Passenger and cargo limited maximum qty/pack	Allowed with restrictions
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not established	



Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	UN 3082	
14.2 UN Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TERBINAFINE, Florfenicol)	
14.3 Transport hazard class(es)	Class	9
	Sub risk	-
14.4 Packing group	N/a	
14.5 Environmental hazards	Marine pollutant: Yes EmS: F-A, S-F	
14.6 Special precautions for user	EMS Number	Not available
	Special provisions	Not available
	Limited quantities	Not available
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not established	



Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	UN3082	
14.2 UN Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TERBINAFINE, Florfenicol)	
14.3 Transport hazard class(es)	Class	9
	Sub risk	-
	Label(s)	9
14.4 Packing group	III	
14.5 Environmental hazard	Yes.	
14.6 Special precautions for user	Classification Code	Not available
	Special provisions	Not available
	Limited quantity	Not available
	Equipment required	Not available
	Fire cones number	Not available
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not established	

SECTION 15: REGULATORY INFORMATION

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

- European EC Inventory

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Commission Regulation (EU) 2015/830, Regulation (EC) No 1272/2008 and their amendments

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Not available	Not available	Not Available	Not Available



Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
Not available	Not available	Not available	Not available

National Inventory	Status
Australia – AICS	N
Canada – DSL	N
Canada – NDSL	N
China – IECSC	N
Europe - EINEC / ELINCS / NLP	N
Japan – ENCS	N
Korea – KECI	N
New Zealand – NZIoC	Y
Philippines – PICCS	N
USA – TSCA	N
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, OSHA and ECHA.

Full text Risk and Hazard codes:

H319	Causes serious eye irritation
H361	Suspected of damaging fertility or the unborn child
H410	Very toxic to aquatic life with long lasting effects

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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