SAFETY DATA SHEETS

This SDS packet was issued with item:

078944729

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078922403 078922404 078944380 078944714 078945115

Issue Date: 06/2020

Version No: 1 Page 1 of 18



SECTION 1: IDENTIFICATIO	N	
1.1 Product identifier		
Product name:	Osurnia 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 aga		
Recommended uses:	Corticosteroid and anti-infective ear gel for dogs	
Uses advised against:	Not for human use.	
1.3 Details of the supplier of	f 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	

Product Name: Osurnia Ear Gel for Dogs

Issue Date: 06/2020

Version No: 1 Page 2 of 18



Fax:	Not available		
Website:	www.dechra-us.com		
Email:	Not available		
1.4 Emergency Telephone Numbers			
Dechra (US):	+1866-933-2472		
Dechra (EU):	+31 (0)497 544 300		

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No Reproductive toxicity (fertility) Cat 2
1272/2008 [CLP] (EU)¹: Hazardous to aquatic environment Cat 1

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

Product Name: Osurnia Ear Gel for Dogs

Issue Date: 06/2020

Version No: 1 Page 3 of 18



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]

Issue Date: 06/2020

Version No: 1 Page 4 of 18



	1		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	ВНТ	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.			

Issue Date: 06/2020

Version No: 1 Page 5 of 18



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 FIGHTIN	IG MEASURES			
5.1 Extinguishing media				
Suitable:	Water fog. Foam. Dry chemical powder Carbon dioxide			
Unsuitable:	ble: 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.			

Product Name: Osurnia Ear Gel for Dogs

course.

Issue Date: 06/2020

Version No: 1 Page 6 of 18



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 sect	ion 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				

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 sto	orage, 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.				

Product Name: Osurnia Ear Gel for Dogs

Issue Date: 06/2020

Version No: 1 Page 7 of 18



7.3 Specific end use

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 D	ATA:					
Source	Ingredient	Material Name	TWA	STEL	Peak	Notes
Not Available						

EMERGENCY LIMITS:						
Ingredient Materia			al TEEL-1		2	TEEL-3
Propylene carbonate	Propylene carbonate, 1, 2-		34 mg/m3	370 r	mg/m3	2,200 mg/m3
glycerol	glycero	ol	45 mg/m3	180 r	ng/mg3	1,100 mg/m3
Ingredient			Original IDLH		Revised IDLH	
Not Available						
8.2 Exposure controls	5					
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			

Product Name: Osurnia Ear Gel for Dogs

Issue Date: 06/2020

Version No: 1 Page 8 of 18



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 oxidising 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

Product Name: Osurnia Ear Gel for Dogs

Issue Date: 06/2020

Version No: 1 Page 9 of 18



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		

Osurnia 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

Issue Date: 06/2020

Version No: 1 Page 10 of 18



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 ob Not irritating to			
	Europe ECHA Registered Substance urer's SDS. Unless otherwise specific of chemical Substances				
Skin corrosion/ irritation	on:				
Not Available					
Serious eye damage/ ir	ritation:				
Moderate eye irritation (rabbit)					
Respiratory or skin ser	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:					

Issue Date: 06/2020

Version No: 1 Page 11 of 18



SECTION 12: E	COLOGICAL	NFORMA	ΓΙΟΝ		
12.1 Toxicity					
Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
ВНТ	EC50 EC50 LC50	96 48 96	Algae or other aquatic plants Crustacea Fish	0.758mg/L 0.48 mg/L 0.199 mg/L	1 1 1
	NOEC	48	Crustacea	0.15 mg/L	1
Florfenical	EC50 NOEC EC50 NOEC LC50	72 72 48 96 96	Algae or other aquatic plants Algae or other aquatic plants Crustacea Crustacea Fish	3.83mg/L 0.32 mg/l 84.5 mg/l >900 mg/l >900 mg/l	1 1 1 1
Propylene carbonate	EC50	48 96	Crustacea Fish	>1000mg/L >1000mg/L	1 1
Terbinafine	EC50 EC50 NOEC	- 48 32 days	Algae or other aquatic plants Crustacea Fish	0.029mg/L 0.35mg/L 0.047 mg/L	1 1 1
		Legend:	1. Elanco Osurni	ia SDS	
DO NOT discha	rge into sewer	or waterwa	ays.		
12.2 Persisten	ce and degrad	lability			
Ingredient		Persisten	ce: Water/Soil	Persistence: A	ir
		No data a	vailable	No data availab	ole
12.3 Bioaccum	nulative poten	tial			
Ingredient	Bioaccum	Bioaccumulative Potential			
Florfenical	(LogKOW	(LogKOW = 0.37			
Propyelen carbonate	(LogKOW	(LogKOW = -0.41)			
12.4 Mobility in	Soil				
Ingredient	Mobility				
	No data available				

Product Name: Osurnia Ear Gel for Dogs

Sewage Disposal Options: Not Available

Issue Date: 06/2020

Version No: 1 Page 12 of 18



12.5 Results of PB Not available	T and vPvB assessment
12.6 Other adverse Not available	effects
SECTION 13: DISP	POSAL CONSIDERATIONS
13.1 Waste treatm	ent methods
packaging	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance 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:	

Issue Date: 06/2020

Version No: 1 Page 13 of 18



SECTION 14: TRANSPORT INFORMATION			
Labels required:			
Marine pollutant:	NO		
Hazchem:	Not Applicable		
Land transport (EU: DANGEROUS GOOD		REGULATED FOR TRANSPORT OF	
14.1 UN Number	UN3082		
	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TERBINAFINE, Florfenicol)		
14.3 Transport	Class	9	
hazard class(es)	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 Special provisions Not available precautions for		Not available	
user	Limited quantity	N/a	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not established		

Issue Date: 06/2020

Version No: 1 Page 14 of 18



Air transport (ICAO-I	ATA / DGR)· NOT REG	III ATED FOR TRANSPORT OF		
	Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS			
14.1 UN Number	UN3082			
	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TERBINAFINE, Florfenicol)			
14.3 Transport	Class	9		
hazard class(es)	Sub risk	-		
14.4 Packing group	III			
14.5 Environmental hazards	Yes. ERG code: 9L			
-	Special provisions	Not available		
precautions for user	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	Not established			
the IBC Code				

Issue Date: 06/2020

Version No: 1 Page 15 of 18



Sea transport (IMDG DANGEROUS GOOD		OT REGULATED FOR TRANSPORT OF	
14.1 UN Number	UN 3082		
	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TERBINAFINE, Florfenicol)		
14.3 Transport	Class	9	
hazard class(es)	Sub risk -		
14.4 Packing group	N/a		
	Marine pollutant: Yes EmS: F-A, S-F		
I =	EMS Number	Not available	
precautions for user	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		

Product Name: Osurnia Ear Gel for Dogs

Issue Date: 06/2020

Version No: 1 Page 16 of 18



Inland waterways tra DANGEROUS GOOD		EGULATED	FOR TRANSPORT OF	
14.1 UN Number	UN3082			
-	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TERBINAFINE, Florfenicol)			
14.3 Transport	Class	9		
hazard class(es)	Sub risk	-		
	Label(s) 9			
14.4 Packing group	III			
14.5 Environmental hazard	Yes.			
	Classification Code		Not available	
precautions for user	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				

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

Issue Date: 06/2020

Version No: 1 Page 17 of 18



Harmonization (C&L Inventory)		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	Υ	
Philippines – PICCS	N	
USA – TSCA	N	
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)	

Product Name: Osurnia Ear Gel for Dogs

Issue Date: 06/2020

Version No: 1 Page 18 of 18



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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