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## 1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

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### 1.1 Product identifier

**Product name** OSURNIA EAR GEL FOR DOGS  
**Synonyms** OSURNIA

### 1.2 Uses and uses advised against

**Uses** VETERINARY APPLICATIONS • VETERINARY USE

### 1.3 Details of the supplier of the product

**Supplier name** DECHRA VETERINARY PRODUCTS (AUSTRALIA) PTY LTD  
**Address** 2 Cal Close, Somersby, NSW, 2250, AUSTRALIA  
**Telephone** 1300 015 825; (02) 4372 1661  
**Fax** (02) 4372 1668  
**Email** [info.au@dechra.com](mailto:info.au@dechra.com)  
**Website** <http://www.dechra.com.au/>

### 1.4 Emergency telephone numbers

**Emergency** 13 11 26 (Poisons Information Centre)

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## 2. HAZARDS IDENTIFICATION

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### 2.1 Classification of the substance or mixture

CLASSIFIED AS HAZARDOUS ACCORDING TO SAFE WORK AUSTRALIA CRITERIA

#### Physical Hazards

Not classified as a Physical Hazard

#### Health Hazards

Serious Eye Damage / Eye Irritation: Category 2A

#### Environmental Hazards

Aquatic Toxicity (Acute): Category 1  
Aquatic Toxicity (Chronic): Category 2

### 2.2 GHS Label elements

**Signal word** WARNING

#### Pictograms



#### Hazard statements

H319 Causes serious eye irritation.  
H400 Very toxic to aquatic life.  
H411 Toxic to aquatic life with long lasting effects.

#### Prevention statements

P264 Wash thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.

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### Response statements

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P332 + P337 + P313 If skin or eye irritation occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/attention.  
P391 Collect spillage.

### Storage statements

None allocated.

### Disposal statements

P501 Dispose of contents/container in accordance with relevant regulations.

### 2.3 Other hazards

No information provided.

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## 3. COMPOSITION/ INFORMATION ON INGREDIENTS

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### 3.1 Substances / Mixtures

Ingredient	CAS Number	EC Number	Content
PROPYLENE CARBONATE	108-32-7	203-572-1	50 to 75%
GLYCEROL FORMOL	4740-78-7, 5464-28-8	-	25 to 50%
FLORFENICOL	73231-34-2	642-986-0	<1%
TERBINAFINE	91161-71-6	618-706-8	<1%
2,6-DI-TERT-BUTYL-P-CRESOL (BHT)	128-37-0	204-881-4	<=0.1%
BETAMETHASONE ACETATE	987-24-6	213-578-6	<0.1%

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## 4. FIRST AID MEASURES

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### 4.1 Description of first aid measures

**Eye** If in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, a doctor, or for at least 15 minutes.

**Inhalation** If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.

**Skin** If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by a Poisons Information Centre or a doctor.

**Ingestion** For advice, contact a Poisons Information Centre on 13 11 26 (Australia Wide) or a doctor (at once). If swallowed, do not induce vomiting. Rinse mouth with water.

**First aid facilities** Eye wash facilities should be available.

### 4.2 Most important symptoms and effects, both acute and delayed

This product is used in veterinary applications. Due to the nature of use, adverse health effects are not anticipated with normal use. Refer to medical doctor/specialist for advice regarding adverse side effects.

### 4.3 Immediate medical attention and special treatment needed

Treat symptomatically.

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## 5. FIRE FIGHTING MEASURES

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### 5.1 Extinguishing media

Dry agent, carbon dioxide or water fog. Prevent contamination of drains and waterways. Do not use water jets.

### 5.2 Special hazards arising from the substance or mixture

Combustible. May evolve carbon oxides and hydrocarbons when heated to decomposition.

### 5.3 Advice for firefighters

Evacuate area and contact emergency services. Toxic gases may be evolved in a fire situation. Remain upwind and notify those downwind of hazard. Wear full protective equipment including Self Contained Breathing Apparatus (SCBA) when combating fire. Use waterfog to cool intact containers and nearby storage areas.

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### 5.4 Hazchem code

- 3Z
- 3 Alcohol Resistant Foam is the preferred firefighting medium but, if it is not available, normal foam can be used.
- Z Wear full fire kit and breathing apparatus. Contain spill and run-off.

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## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

Wear Personal Protective Equipment (PPE) as detailed in section 8 of the SDS.

### 6.2 Environmental precautions

Prevent product from entering drains and waterways.

### 6.3 Methods of cleaning up

Contain spillage, then cover / absorb spill with non-combustible absorbent material (vermiculite, sand, or similar), collect and place in suitable containers for disposal.

### 6.4 Reference to other sections

See Sections 8 and 13 for exposure controls and disposal.

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## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

### 7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, well marked area, removed from incompatible substances, foodstuffs and other drugs. Storage areas and containers should be clearly marked for drug holding, protected from light, freezing or physical damage and tightly sealed when not in use. Keep out of reach of children. Store between 2°C and 8°C.

### 7.3 Specific end uses

No information provided.

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters

#### Exposure standards

Ingredient	Reference	TWA		STEL	
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>
2,6-Di-tert-butyl-p-cresol	SWA [AUS]	--	10	--	--

#### Biological limits

No biological limit values have been entered for this product.

### 8.2 Exposure controls

**Engineering controls** Avoid inhalation. Use in well ventilated areas.

#### PPE

- Eye / Face** Wear splash-proof goggles.
- Hands** Wear PVC or rubber gloves.
- Body** Wear coveralls.
- Respiratory** Where an inhalation risk exists, wear a Type A (Organic vapour) respirator.



## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance	WHITE TO YELLOW GEL
Odour	SLIGHT ODOUR
Flammability	COMBUSTIBLE
Flash point	> 90°C
Boiling point	NOT AVAILABLE
Melting point	NOT AVAILABLE
Evaporation rate	NOT AVAILABLE
pH	NOT AVAILABLE
Vapour density	NOT AVAILABLE
Specific gravity	NOT AVAILABLE
Solubility (water)	NOT AVAILABLE
Vapour pressure	NOT AVAILABLE
Upper explosion limit	NOT AVAILABLE
Lower explosion limit	NOT AVAILABLE
Partition coefficient	NOT AVAILABLE
Autoignition temperature	NOT AVAILABLE
Decomposition temperature	NOT AVAILABLE
Viscosity	NOT AVAILABLE
Explosive properties	NOT EXPLOSIVE
Oxidising properties	NON OXIDISING
Odour threshold	NOT AVAILABLE

### 9.2 Other information

Density	1.20 g/cm <sup>3</sup>
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## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

Carefully review all information provided in sections 10.2 to 10.6.

### 10.2 Chemical stability

Stable under recommended conditions of storage.

### 10.3 Possibility of hazardous reactions

Polymerization is not expected to occur.

### 10.4 Conditions to avoid

Avoid heat, sparks, open flames and other ignition sources.

### 10.5 Incompatible materials

Incompatible with oxidising agents (e.g. hypochlorites), heat and ignition sources.

### 10.6 Hazardous decomposition products

May evolve carbon oxides and hydrocarbons when heated to decomposition.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

**Acute toxicity** This product is used in veterinary applications. Use safe work practices to avoid eye contact, prolonged skin contact and ingestion. Refer to medical doctor/specialist for advice regarding adverse side effects.

**Information available for the ingredients:**

Ingredient	Oral LD50	Dermal LD50	Inhalation LC50
PROPYLENE CARBONATE	20.7 g/kg (mouse)	> 20 mL/kg (rabbit)	--
2,6-DI-TERT-BUTYL-P-CRESOL (BHT)	> 6000 mg/kg (rat)	> 2000 mg/kg (rat)	--

**Skin** Contact may result in irritation, redness, pain and rash.

**Eye** Contact may result in irritation, lacrimation, pain and redness.

**Sensitisation** Not classified as causing skin or respiratory sensitisation.

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<b>Mutagenicity</b>	Not classified as a mutagen.
<b>Carcinogenicity</b>	Not classified as a carcinogen.
<b>Reproductive</b>	Not classified as a reproductive toxin.
<b>STOT - single exposure</b>	Not classified as causing organ damage from single exposure. However, high level exposure may result in headache, nausea and respiratory tract irritation.
<b>STOT - repeated exposure</b>	Not classified as causing organ damage from repeated exposure.
<b>Aspiration</b>	Not classified as causing aspiration.

**12. ECOLOGICAL INFORMATION****12.1 Toxicity**

Very toxic to aquatic life. Toxic to aquatic life with long lasting effects. LC50 (BHT) = 0.199 mg/L/96h (Fish).

**12.2 Persistence and degradability**

No data is available on the degradability of this product.

**12.3 Bioaccumulative potential**

No data available for this product.

**12.4 Mobility in soil**

No data available for this product.

**12.5 Other adverse effects**

No information provided.

**13. DISPOSAL CONSIDERATIONS****13.1 Waste treatment methods**

<b>Waste disposal</b>	Return to manufacturer/supplier where possible. For small amounts, bury in approved landfill site. Contact the manufacturer/supplier for additional information (if required).
<b>Legislation</b>	Dispose of in accordance with relevant local legislation.

**14. TRANSPORT INFORMATION**

CLASSIFIED AS A DANGEROUS GOOD BY THE CRITERIA OF THE ADG CODE



	LAND TRANSPORT (ADG)	SEA TRANSPORT (IMDG / IMO)	AIR TRANSPORT (IATA / ICAO)
<b>14.1 UN Number</b>	3082	3082	3082
<b>14.2 Proper Shipping Name</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains terbinafine, florfenicol)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains terbinafine, florfenicol)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains terbinafine, florfenicol)
<b>14.3 Transport hazard class</b>	9	9	9
<b>14.4 Packing Group</b>	III	III	III

**14.5 Environmental hazards**

Marine Pollutant.

**14.6 Special precautions for user**

<b>Hazchem code</b>	●3Z
<b>GTEPG</b>	9C1
<b>EmS</b>	F-A, S-F

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**Other information** The environmentally hazardous substance mark is not required when transported in packages of less than 5 kg/L (UN Model Regulations: Special Provision 375; IATA: Special Provision A197; IMDG: Special Provision 969) or less than 500 kg/L by Australian Road and Rail.

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## 15. REGULATORY INFORMATION

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

**Poison schedule** Classified as a Schedule 4 (S4) Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

**APVMA Numbers** 69931

**Classifications** Safework Australia criteria is based on the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals.

**Inventory listings** **AUSTRALIA: AIIC (Australian Inventory of Industrial Chemicals)**  
All components are listed on AIIC, or are exempt.  
**NEW ZEALAND: NZIoC (New Zealand Inventory of Chemicals)**  
All components are listed on the NZIoC inventory, or are exempt.

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## 16. OTHER INFORMATION

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**Additional information** **WORKPLACE CONTROLS AND PRACTICES:** Unless a less toxic chemical can be substituted for a hazardous substance, **ENGINEERING CONTROLS** are the most effective way of reducing exposure. The best protection is to enclose operations and/or provide local exhaust ventilation at the site of chemical release. Isolating operations can also reduce exposure. Using respirators or protective equipment is less effective than the controls mentioned above, but is sometimes necessary.

**RESPIRATORS:** In general the use of respirators should be limited and engineering controls employed to avoid exposure. If respiratory equipment must be worn ensure correct respirator selection and training is undertaken. Remember that some respirators may be extremely uncomfortable when used for long periods. The use of air powered or air supplied respirators should be considered where prolonged or repeated use is necessary.

**PERSONAL PROTECTIVE EQUIPMENT GUIDELINES:**  
The recommendation for protective equipment contained within this report is provided as a guide only. Factors such as form of product, method of application, working environment, quantity used, product concentration and the availability of engineering controls should be considered before final selection of personal protective equipment is made.

**HEALTH EFFECTS FROM EXPOSURE:**  
It should be noted that the effects from exposure to this product will depend on several factors including: form of product; frequency and duration of use; quantity used; effectiveness of control measures; protective equipment used and method of application. Given that it is impractical to prepare a report which would encompass all possible scenarios, it is anticipated that users will assess the risks and apply control methods where appropriate.

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**Abbreviations**

ACGIH	American Conference of Governmental Industrial Hygienists
CAS #	Chemical Abstract Service number - used to uniquely identify chemical compounds
CNS	Central Nervous System
EC No.	EC No - European Community Number
EMS	Emergency Schedules (Emergency Procedures for Ships Carrying Dangerous Goods)
GHS	Globally Harmonized System
GTEPG	Group Text Emergency Procedure Guide
IARC	International Agency for Research on Cancer
LC50	Lethal Concentration, 50% / Median Lethal Concentration
LD50	Lethal Dose, 50% / Median Lethal Dose
mg/m <sup>3</sup>	Milligrams per Cubic Metre
OEL	Occupational Exposure Limit
pH	relates to hydrogen ion concentration using a scale of 0 (high acidic) to 14 (highly alkaline).
ppm	Parts Per Million
STEL	Short-Term Exposure Limit
STOT-RE	Specific target organ toxicity (repeated exposure)
STOT-SE	Specific target organ toxicity (single exposure)
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
SWA	Safe Work Australia
TLV	Threshold Limit Value
TWA	Time Weighted Average

**Report status**

This document has been compiled by RMT on behalf of the manufacturer, importer or supplier of the product and serves as their Safety Data Sheet ('SDS').

It is based on information concerning the product which has been provided to RMT by the manufacturer, importer or supplier or obtained from third party sources and is believed to represent the current state of knowledge as to the appropriate safety and handling precautions for the product at the time of issue. Further clarification regarding any aspect of the product should be obtained directly from the manufacturer, importer or supplier.

While RMT has taken all due care to include accurate and up-to-date information in this SDS, it does not provide any warranty as to accuracy or completeness. As far as lawfully possible, RMT accepts no liability for any loss, injury or damage (including consequential loss) which may be suffered or incurred by any person as a consequence of their reliance on the information contained in this SDS.

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