

Safety Data Sheet

According to Hazardous Substances (Safety Data Sheets) Notice 2017 and Amendments under New Zealand, Hazardous Substances and New Organisms Act 1996 and Amendments.

Initial preparation date: 14.10.2020

Revision date: 22.08.2025

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OSURNIA ear gel for dogs

SECTION 1: Identification

Product identifier

Product name: OSURNIA ear gel for dogs

Synonyms: OSURNIA

Recommended use and restriction on use:

Recommended use: VETERINARY USE: For the treatment of acute otitis externa and acute exacerbation of recurrent otitis externa.

Restrictions on use: Not for human use.

Manufacturer or supplier details

Supplier

Dechra Veterinary Products NZ Limited

PO Box 1604,

Paraparaumu Beach, 5252

New Zealand

Phone: 0800 479 838

Email: info.nz@dechra.com

Website: <http://www.dechra.co.nz/>

Emergency telephone number:

New Zealand

National Poisons Centre

0800 764 766

SECTION 2: Hazard identification

Not Classified as a Dangerous Good according to NZS 5433:2020 Transport of Dangerous Goods on Land.

Classification in accordance with the Hazardous Substances (Hazard Classification) Notice 2020 and GHS Revision 7:

Hazard classification:

Eye irritation, category 2

Chronic aquatic hazard, category 1

Label elements

Hazard pictogram(s):



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Signal word: Warning

Hazard statements:

H319 Causes serious eye irritation

H410 Very toxic to aquatic life with long lasting effects

Precautionary statements:

P264 Wash skin thoroughly after handling

P280 Wear eye protection/face protection

P273 Avoid release to the environment

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337+P313 If eye irritation persists: Get medical advice or attention

P391 Collect spillage

P501 Dispose of contents and container in accordance with local regulations

Hazards not otherwise classified:

None.

SECTION 3: Composition/information on ingredients

Mixture:

Identification	Name	Weight %
CAS number: 108-32-7	Propylene carbonate	45-55
CAS number: 91161-71-6	Terbinafine	0.8
CAS number: 73231-34-2	Florfenicol	0.8
CAS number: 987-24-6	Betamethasone acetate	0.1

Additional information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret under the provisions of section 55 (7) of the HSNO Act.

SECTION 4: First-aid measures

For advice, contact a Poisons Information Center (e.g. phone Australia 131 126, New Zealand 0800 764 766) or a doctor.

Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

After inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. Keep person at rest. If breathing is difficult, administer oxygen. If breathing has stopped, provide artificial respiration. If experiencing respiratory symptoms, seek medical advice/attention.

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After skin contact:

Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

After eye contact:

Rinse eyes with plenty of gently flowing lukewarm water for 15 minutes. Remove contact lenses if present and easy to do so. Protect unexposed eye. If symptoms develop or persist, seek medical advice/attention.

After swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most important symptoms and effects, both acute and delayed:

Acute symptoms and effects:

Eye contact may result in irritation, redness, pain, inflammation, itching, burning and tearing.

Delayed symptoms and effects:

Effects are dependent on exposure (dose, concentration, contact time).

Immediate medical attention and special treatment:

Immediate medical attention:

Not determined or not applicable.

Special treatment:

Not determined or not applicable.

Notes for the doctor:

Treat symptomatically.

SECTION 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media:

Water mist/fog, carbon dioxide, dry chemical or alcohol resistant foam.

Unsuitable extinguishing media:

Do not use water jet.

Specific hazards arising from the chemical:

Thermal decomposition may produce irritating/toxic fumes/gases.

Special protective equipment and precautions for firefighters:

Protective equipment:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

Precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

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SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Advice on how to contain and clean up a spill or release:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

SECTION 7: Handling and storage

Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Conditions for safe storage, including any incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

Storage conditions: Store between 2°C and 8°C (refrigerate).

Storage container: Plastic tube inside carton.

SECTION 8: Exposure controls/personal protection

Occupational Exposure limit values:

No occupational exposure limits noted for the ingredient(s).

Biological limit values:

No biological exposure limits noted for the ingredient(s).

Engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protective equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

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Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	White to yellow gel
Odour	Slight odour
Odour threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point	>90 °C
Flammability (solid, gas)	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapour pressure	Not determined or not available.
Vapour density	Not determined or not available.
Relative density	1.2 (Water=1)
Solubility(ies)	Not determined or not available.
Partition coefficient: n-octanol/water	Not determined or not available.
Auto-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Particle characteristics	Not determined or not available.

Other information: No additional information.

SECTION 10: Stability and reactivity

Chemical reactivity:

Not reactive under recommended handling and storage conditions.

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Chemical stability:

Stable under recommended handling and storage conditions.

Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to avoid:

Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

Incompatible materials:

None known.

Hazardous decomposition products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity:

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Route	Result
Propylene carbonate	oral	LD50 Rat: >5000 mg/kg
	dermal	LD50 Rabbit: >=2000 mg/kg
Terbinafine	oral	LD50 Rat: >4000 mg/kg
Betamethasone acetate	Inhalation	LC50 Rat: 0.5 mg/L (4hr [Vapour])

Skin corrosion/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Serious eye damage/irritation

Assessment:

Causes serious eye irritation.

Product data: No data available.

Substance data:

Name	Result
Propylene carbonate	Causes serious eye irritation.

Respiratory or skin sensitization:

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

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Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Species	Result
Betamethasone acetate		Suspected of causing cancer.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Reproductive toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Betamethasone acetate	May damage fertility or the unborn child.
Florfenicol	Suspected of damaging fertility or the unborn child.

Specific target organ toxicity (single exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Specific target organ toxicity (repeated exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Betamethasone acetate	Causes damage to the pituitary gland through prolonged or repeated exposure.
Florfenicol	Causes damage to organs through prolonged or repeated exposure.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Information on likely routes of exposure:

Inhalation; Ingestion; Skin contact; Eye contact.

Symptoms related to the physical, chemical and toxicological characteristics:

Refer to Section 4 of this SDS.

Other information:

No data available.

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SECTION 12: Ecological information

Ecotoxicity

Aquatic

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Propylene carbonate	Aquatic Invertebrates LC50 <i>Cyprinus carpio</i> : >1000 mg/L (48 hr [mortality])
	Aquatic Plants EC50 <i>Desmodesmus subspicatus</i> : >900 mg/L (72 hr [growth rate & biomass])
	Aquatic Invertebrates EC50 <i>Daphnia magna</i> : >1000 mg/L (48 hr [mobility])
Terbinafine	Aquatic Invertebrates EC50 <i>Daphnia magna</i> : 0.35 mg/L (48 hr [mobility])
	Aquatic Plants EC50 <i>Raphidocelis subcapitata</i> : 0.029 mg/L (72 hr [growth rate])

Chronic (long-term) toxicity

Assessment:

Very toxic to aquatic life with long lasting effects.

Product data: No data available.

Substance data: No data available.

Terrestrial

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Persistence and degradability

Product data: No data available.

Substance data:

Name	Result
Propylene carbonate	The substance is readily biodegradable. 87.7% degradation in water, measured by CO ₂ evolution, after 29 days.
Terbinafine	The substance is not readily biodegradable. 4% degradation in water, measured by CO ₂ evolution, after 28 days.

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Bioaccumulative potential

Product data: No data available.

Substance data:

Name	Result
Propylene carbonate	The substance is not expected to bioaccumulate (log Pow: -0.41).
Terbinafine	The substance has the potential to bioaccumulate (log Pow: > 3.3 at 37 °C).

Mobility in soil

Product data: No data available.

Substance data:

Name	Result
Propylene carbonate	The substance is highly mobile, therefore, adsorption to soil and sediment is not expected (log Koc: 0.81 at 20 °C, QSAR substance data).

Other adverse effects: No additional information.

SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities. Dispose of in accordance with all applicable local, regional, state and federal regulations.

Special precautions to be taken during disposal:

No additional information.

Disposal methods that should not be used:

No additional information.

SECTION 14: Transportation information

Road/Rail transport: (NZS 5433)

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone acetate, Florfenicol)
UN transport hazard class(es)	9 
Packing group	III
Environmental hazards	Marine Pollutant Betamethasone acetate & Florfenicol
Special precautions for user	None

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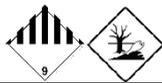
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International Air Transport Association Dangerous Goods Regulations (IATA-ICAO)

UN number	3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Betamethasone acetate, Florfenicol)
UN transport hazard class(es)	9 
Packing group	III
Environmental hazards	Marine Pollutant Betamethasone acetate & Florfenicol
Special precautions for user	None
ERG code	9L
Excepted quantities	E1
Passenger and cargo	450 L
Cargo aircraft only	450 L
Limited quantity	30 kg G

International Maritime Dangerous Goods (IMDG)

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone acetate, Florfenicol)
UN transport hazard class(es)	9 
Packing group	III
Environmental hazards	Marine Pollutant Betamethasone acetate & Florfenicol
Special precautions for user	None
EMS number	F-A, S-F
Stowage category	Category A
Excepted quantities	E1
Limited quantity	5 L

Transport in bulk according to Annex II of MARPOL and the IBC Code: Not Applicable

SECTION 15: Regulatory information

New Zealand Inventory of Chemicals (NZIoC): All ingredients are listed or exempt.

HSNO approval number: HSR100757.

Group standard title: Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2020.

HSNO Controls: Not determined.

Approved handler test certificate: Not determined.

Tracking: Not determined.

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Controlled substance license requirements: Not applicable.

Agricultural Compounds and Veterinary Medicines Act 1997:

ACVM number	ACVM No A011416
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Montreal Protocol (Ozone Depleting Substances): None of the ingredients are listed.

Stockholm Convention (Persistent Organic Pollutants): None of the ingredients are listed.

Rotterdam Convention (Prior Informed Consent): None of the ingredients are listed.

Basel Convention (Hazardous Waste): None of the ingredients are listed.

SECTION 16: Other information

Abbreviations and Acronyms:

ATE	Acute Toxicity Estimate
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
EC50	Effective Concentration of 50%
GHS	Globally Harmonized System
HSNO	Hazardous Substances and New Organisms
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%
MARPOL	International Convention for the Prevention of Pollution from Ships
NZIoC	New Zealand Inventory of Chemicals
TWA	Time Weighted Average
UN	United Nations
VOC	Volatile Organic Compounds

Disclaimer:

The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

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Revision Notes:

Revision Date	Notes
22-08-2025	Version 3 ; Supersedes Version 2 (20.06.2025)

End of Safety Data Sheet