

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 03.11.2024

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DuOtic

SECTION 1: Identification

Product identifier

Product name: DuOtic

Synonyms: Terbinafine and betamethasone acetate otic gel

Additional information: None

Recommended use of the product and restriction on use:

Relevant identified uses: VETERINARY USE: Corticosteroid and anti-infective ear get for dogs

Uses advised against: Not for human use.

Reasons why uses advised against: Veterinary product.

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:

National Poisons Centre, New Zealand

0800 764 766

SECTION 2: Hazards identification

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

Classified in accordance with the Hazardous Substances (Hazard Classification) Notice 2020.

HSNO Classification or Subclasses – Physical hazards: Not applicable

HSNO Classification or Subclasses – Health hazards:

Class	GHS Category	HSNO Category
Eye Irritation	Category 2	6.4A

HSNO Classification or Subclasses – Environmental hazards: Not applicable

GHS classification:

Eye irritation, category 2

Label elements

Hazard pictogram(s):



Signal word: Warning

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Hazard statements:

H319 Causes serious eye irritation

Precautionary statements:

P102 Keep out of reach of children.

P264 Wash thoroughly after handling.

P280 Wear eye protection/face protection.

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/attention.

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: 99569-11-6	Glycerol formal	35-45
CAS number: 9004-65-3	Hypromellose 2910	1-3
CAS number: 97281-48-6	Phospholipon 90H	0.1-1
CAS number: 91161-71-6	Terbinafine	0.833
CAS number: 112-80-1	Oleic acid	0.1-1
CAS number: 987-24-6	Betamethasone acetate	0.083

Additional information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret under the provisions of sections 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:

Immediately 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:

Skin contact may result in irritation and/or an allergic skin reaction. Symptoms may include redness, pain, burning, inflammation, rash, itching and dermatitis.

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:

Specific treatment:

Not determined or not applicable.

Notes for the doctor:

Treat symptomatically.

Workplace Facilities:

No additional information.

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 during fire-fighting:

Thermal decomposition may produce irritating/toxic fumes/gases.

Special protective equipment for firefighters:

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

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapours/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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Hazchem or Emergency Action Code:

Not Applicable.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapour, 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.

Methods and material for containment and cleaning up:

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).

Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage precautions

Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapour/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.

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

Storage conditions: Store at or below 77°F (25°C), with excursions up to 104°F (40°C).

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).

Safe packaging material

Suitable material:

Not determined or not applicable.

Unsuitable material:

Not determined or not applicable.

SECTION 8: Exposure controls and personal protection

Occupational Exposure limit values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
New Zealand	Hypromellose 2910	9004-65-3	8-Hour TWA: 10 mg/m ³

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Biological limit value:

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

Information on monitoring procedures:

Not determined or not applicable

Appropriate 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 protection 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).

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

Appearance	White to yellow Liquid (gel)
Odour	Not determined or not available
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 (closed cup)	> 194.0°F (>9 0.0°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	Not determined or not available.
Solubilities	Not determined or not available.

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Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-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

Reactivity:

Not reactive under recommended handling and storage conditions.

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:

Strong reducing agents, oxidizing agents, strong alkalis, strong acids

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: ≥3000 mg/kg
Phospholipon 90H	oral	LD50 Mouse: >10,000mg/kg
Terbinafine	oral	LD50 Rat: >4000 mg/kg
Oleic acid	oral	LD50 Rat: 25,000 mg/kg
	Inhalation ATE	LDC50 Rat: 0.5 mg/L (4 hr [Vapour])
Betamethasone acetate	oral	LD50 Rat: >2000 mg/kg

Skin corrosion/irritation

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

Product data: No data available.

Substance data:

Name	Result
Oleic acid	Causes skin irritation.

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Serious eye damage/irritation:

Assessment: Causes serious eye irritation.

Product data: No data available.

Substance data:

Name	Result
Propylene carbonate	Causes serious eye irritation.
Oleic acid	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.

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.

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.

Aspiration toxicity

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

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Product data: No data available.

Substance data: No data available.

Information on likely routes of exposure:

Eye contact

Symptoms related to the physical, chemical and toxicological characteristics:

Refer to Section 4 of this SDS.

Other information:

No data available.

SECTION 12: Ecological information

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	Fish LC50 Danio rerio: 2 mg/L (96 hr)
	Aquatic Invertebrates EC50 Daphnia magna: >1000 mg/L (48 hr)]
	Aquatic Plants EC50 Selenastrum capricornutum: >929 mg/L (72 hr [growth rate])
Terbinafine	Aquatic invertebrates EC50 Daphnia magna: 0.35 mg/L (48 hr) [mobility]
	Aquatic Plants EC50 Nitschia linearis: 2430 mg/L (120 hr [cell number])
Oleic acid	Fish LC50 Pimephales promelas: 205 mg/L (96 h)

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	Substance is readily biodegradable. 97% degradation in water, measured by DOC removal, after 14 days.
Terbinafine	The substance is not readily biodegradable. 4% degradation in water, measured by CO2 evolution, after 28 days.

Bioaccumulative potential

Product data: No data available.

Substance data:

Name	Result
Propylene carbonate	No bioaccumulation is expected based on the low log Kow (log Pow= -0.41) and the property of readily biodegradability of the substance.
Phospholipon 90H	Based on QSAR estimations, phosphatidylcholines, soya, hydrogenated is not readily biodegradable
Terbinafine	The substance has the potential to bioaccumulate (log Pow= > 3.3 at 37 °C).

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Mobility in soil

Product data: No data available.

Substance data:

Name	Result
Propylene carbonate	Substance is highly mobile in soil and adsorption to soil and sediment is not expected. Log Koc: 0.81
Phospholipon 90H	The substance is immobile, therefore, adsorption to soil is expected (Koc=1.615E+009 L/kg, MCI method).

Hazard to the ozone layer

Product data: No data available.

Substance data: No data available.

Other adverse effects: No data available.

SECTION 13: Disposal considerations

Disposal methods:

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

Contaminated packages:

Not determined or not applicable.

Disposal methods that should not be used:

No additional information.

SECTION 14: Transportation information

Road/Rail transport: (NZS 5433:2020)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

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

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

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International Maritime Dangerous Goods (IMDG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

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.

99569-11-5	Glycerol formal	Not Listed
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HSNO Classification or Subclasses:

Class	GHS Category	HSNO Category
Eye irritation	Category 2	6.4A

HSNO Group Standard Name:	HSNO Approval Number:
Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2017	HSR100757

HSNO Controls: Not determined.

Approved handler test certificate: Not determined.

Tracking: Not determined.

Controlled substance license requirements: Not applicable.

Agricultural Compounds and Veterinary Medicines Act 1997: Not applicable.

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

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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
2024-03-11	Version 1

End of Safety Data Sheet