Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

DuOtic

SECTION 1: Identification

Product Identifier

Product Name: DuOtic

Synonyms: Terbinafine and betamethasone acetate otic gel

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:

United States

Dechra Veterinary Products
7015 College Blvd Suite 525
Overland Park, KS 66211
866-933-2472
support@dechra.com
www.dechra-us.com

Emergency Telephone Number:

United States

Dechra Veterinary Products
866-933-2472 (Normal business hours)

SECTION 2: Hazard(s) Identification

GHS Classification:

Eye irritation, category 2A

Label elements

Hazard Pictograms:

Signal Word: Warning

Hazard statements:

H319 Causes serious eye irritation

Precautionary Statements:

P102 Keep out of reach of children
P264 Wash thoroughly after handling.
P280 Wear protective gloves, protective clothing and eye 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

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 in accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200).

SECTION 4: First Aid Measures

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.

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

Specific Treatment:

Not determined or not applicable.

Notes for the Doctor:

Treat symptomatically.

SECTION 5: Firefighting 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/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.

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, 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.

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 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).
Container Type: Single-use multi-layered aluminium and polyethylene tube with a polypropylene thermoplastic elastomer tip.
Storage condition: Store at or below 77°F (25°C), with excursions up to 104°F (40°C).

SECTION 8: Exposure Controls/Personal Protection

Only those substances with limit values have been included below.

Occupational Exposure Limit Values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
OSHA	Hypromellose 2910	9004-65-3	8-Hour TWA-PEL: 15 mg/m³ (total dust [cellulose])
	Hypromellose 2910	9004-65-3	8-Hour TWA-PEL: 5 mg/m³ (respirable fraction [cellulose])
NIOSH	Hypromellose 2910	9004-65-3	REL-TWA: 10 mg/m³ (total dust [cellulose] - up to 10 hr)
	Hypromellose 2910	9004-65-3	REL-TWA: 5 mg/m³ (respirable dust [cellulose] - up to 10 hr)
ACGIH	Hypromellose 2910	9004-65-3	8-Hour TWA: 10 mg/m³
United States(California)	Hypromellose 2910	9004-65-3	8-Hour TWA-PEL: 10 mg/m³ (total dust - PNOR)
	Hypromellose 2910	9004-65-3	8-Hour TWA: 5 mg/m³ (respirable fraction - PNOR)

Biological Limit Values:

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

Information on Basic Physical and Chemical Properties

Appearance	White to yellow liquid gel
Odor	Not determined or not available.
Odor 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 (>90.0°C)
Evaporation rate	Not determined or not available.
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.
Vapor pressure	Not determined or not available.
Vapor density	Not determined or not available.
Density	Not determined or not available.
Relative density	Not determined or not available.
Solubilities	Not determined or not available.
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.
Dynamic viscosity	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Explosive properties	Not determined or not available.
Oxidizing properties	Not determined or not available.

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, strong 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
Terbinafine	oral	LD50 Rat: >4000 mg/kg
Betamethasone acetate	Inhalation ATE	LC50 Rat: 0.5 mg/L (4hr [Vapour])
Propylene carbonate	oral	LD50 Rat: >5000 mg/kg
	dermal	LD50 Rabbit: ≥ 2000 mg/kg
Phospholipon 90H	oral	LD50 Mouse: >10,000 mg/kg
Oleic Acid	oral	LD50 Rat: 25,000 mg/kg

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.

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):

Name	Classification
Betamethasone acetate	Not Applicable

National Toxicology Program (NTP):

Name	Classification
Betamethasone acetate	Not Applicable

OSHA Carcinogens: Not applicable

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 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:

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
Terbinafine	Aquatic Invertebrates EC50 Daphnia magna: 0.35 mg/L (48 hr [mobility])
	Aquatic Plants EC50 Pseudokirchneriella subcapitata: 0.029 mg/L (72 hr [growth rate])
Propylene carbonate	Aquatic Invertebrates EC50 Daphnia magna: >1000 mg/L (48 hr [immobilization])
	Aquatic Plants EC50 Desmodesmus subspicatus: >900 mg/L (72 hr [growth rate, biomass])
	Fish LC50 Cyprinus carpio: >1000 mg/L (96 hr)
Oleic Acid	Fish LC50 Pimephales promelas: 205 mg/L (96 hr)

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
Terbinafine	The substance is not readily biodegradable. 4% degradation in water, measured by CO2 evolution, after 28 days.
Propylene carbonate	The substance is readily biodegradable. 87.7% degradation in water, measured by CO2 evolution, after 29 days.

Bioaccumulative Potential

Product Data: No data available.

Substance Data:

Name	Result
Terbinafine	The substance has the potential to bioaccumulate (log Pow= > 3.3 at 37 °C).
Propylene carbonate	The substance is not expected to bioaccumulate (log Pow= -0.41).
Oleic Acid	The substance is not expected to bioaccumulate (BCF=10).

Mobility in Soil

Product Data: No data available.

Substance Data:

Name	Result
Propylene carbonate	The substance is highly mobile, therefore, adsorption to soil is not expected(log Koc= 0.81 at 20 °C, QSAR substance data).
Phospholipon 90H	The substance is immobile, therefore, adsorption to soil is expected (Koc=1.615E+009 L/kg, MCI method).

Results of PBT and vPvB assessment

Product Data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance Data:

PBT assessment:

Propylene carbonate	The substance is not PBT.
Phospholipon 90H	The substance is not PBT.

vPvB assessment:

Propylene carbonate	The substance is not vPvB.
Phospholipon 90H	The substance is not vPvB.

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.

SECTION 14: Transport Information

United States Transportation of Dangerous Goods (49 CFR DOT)

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 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

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

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

SECTION 15: Regulatory Information

United States Regulations

Inventory Listing (TSCA):

91161-71-6	Terbinafine	Not Listed

987-24-6	Betamethasone acetate	Not Listed
108-32-7	Propylene carbonate	Listed - Active
99569-11-6	Glycerol formal	Not Listed
97281-48-6	Phospholipon 90H	Not Listed
9004-65-3	Hypromellose 2910	Listed - Active
112-80-1	Oleic Acid	Listed - Active

Significant New Use Rule (TSCA Section 5): None of the ingredients are listed.

Export Notification under TSCA Section 12(b): None of the ingredients are listed.

SARA Section 302 Extremely Hazardous Substances: None of the ingredients are listed.

SARA Section 313 Toxic Chemicals: None of the ingredients are listed.

CERCLA: None of the ingredients are listed.

RCRA: None of the ingredients are listed.

Section 112(r) of the Clean Air Act (CAA): None of the ingredients are listed.

Massachusetts Right to Know: None of the ingredients are listed.

New Jersey Right to Know: None of the ingredients are listed.

New York Right to Know: None of the ingredients are listed.

Pennsylvania Right to Know:

112-80-1	Oleic Acid	Listed

California Proposition 65: None of the ingredients are listed.

Additional information: Not determined.

SECTION 16: Other Information

Abbreviations and Acronyms: None

Disclaimer:

This product has been classified in accordance with OSHA HCS 2012 guidelines. 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.

Initial Preparation Date: 02.13.2024

Revision Notes:

Revision Date	Notes
2024-02-13	Version 1

End of Safety Data Sheet