

SAFETY DATA SHEETS

This SDS packet was issued with item:

078880028

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

078951932

Identity: Easotic®

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Section I

Supplier Information:	Emergency Telephone Number
Name: VIRBAC CORP. Virbac AH Inc.	Transportation: Chemtrec 800-424-9300 Other emergencies:
Address: P. O. BOX 162059	POISON CONTROL CENTER or 911
City: FORT WORTH	Telephone Number for Information
State: TX 76161	Contact Virbac: 800/338-3659

Section II - Hazardous Ingredients/Identity Information

Hazardous Components	OSHA PEL	ACGIH TLV	STEL	CAS #	% (opt.)
Do not use in case of hypersensitivity to the active substance or to any of the excipients; to corticosteroids; to other azole antifungal agents and other aminoglycosides.					

(Special Chemical Identification; Common Name)

Active Ingredients

Hydrocortisone Aceponate	Not Applicable	Not Applicable	Not Applicable	74050-20-7	1.11 mg/mL
Miconazole nitrate	Not Applicable	Not Applicable	Not Applicable	22832-87-7	15.1 mg/mL
Gentamicin Sulfate	Not Applicable	Not Applicable	Not Applicable	1405-41-0	1505 IU/mL

Inactive Ingredients

Paraffin	Not Applicable	Not Applicable	Not Applicable		
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Section III - Physical/Chemical Characteristics

Boiling Point:	Not Applicable
Specific Gravity (H ₂ O = 1):	Not Applicable
Vapor Pressure (mm Hg):	Not Applicable
Melting Point:	Not Applicable
Vapor Density (AIR = 1):	Not Applicable
Evaporation Rate (Butyl Acetate = 1):	Not Applicable
Solubility in Water:	Not Applicable
Appearance and Odor:	White Suspension

Section IV - Fire and Explosion Hazard Data

Flash Point (Method Used):	Not Applicable
Flammable Limits:	LEL: Not Applicable UEL: Not Applicable
Extinguishing Media:	Water spray, dry chemical, carbon dioxide, or foam suitable for the surrounding fire and materials.
Special Firefighting Procedures:	Not applicable
Unusual Fire and Explosion Hazards:	Not applicable

Section V - Reactivity Data

Stability	STABLE
Incompatibility	(Materials to Avoid): None Known
Hazardous Decomposition or Byproducts:	In case of fire, exposure to decomposition products may be dangerous. Do not breathe fumes.
Hazardous Polymerization	WILL NOT OCCUR
Conditions to Avoid:	Temperatures above 86°F (30°C).

Identity: Easotic®

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Section VI - Health Hazard Data

Routes of Entry:	Inhalation? YES	Skin? YES	Ingestion? YES
Health Hazards (Acute and Chronic):	If hypersensitivity to any of the components occur, discontinue use and seek medical attention. Possible irritation of the skin or eyes or ears. If sufficient quantity is ingested, it may cause the following adverse effects: suppression of adrenal gland secretion, Cushing's Syndrome, water retention, electrolyte imbalance, and hyperglycemia.		
Carcinogenicity:	NTP? NO	IARC Monographs? NO	OSHA Regulated? NO
Signs and Symptoms of Exposure:	Slightly Irritating to eyes and skin following contact.		
Medical Conditions Generally Aggravated by Exposure:	Hypersensitivity reaction.		
Emergency and First Aid Procedures			
INGESTED:	Immediately call a physician or the Poison Control Center. Do not induce vomiting. Never give anything by mouth to an unconscious person.		
SKIN CONTACT:	If irritation develops, discontinue use or wear rubber gloves. Wash affected area with soap and water. If irritation persists, contact a physician.		
EYE CONTACT:	Hold eye open and rinse slowly with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes. Call a Poison Control Center or doctor for treatment advice.		
INHALATION:	Not Applicable		

Section VII - Precautions for Safe Handling and Use

Do not use in case of hypersensitivity to the active substance or to any of the excipients, to corticosteroids, to other azole antifungal agents and other aminoglycosides.

Steps to be Taken in Case Material is Released or Spilled:	Dike and contain spill. Do not allow to enter drains or water courses. Clean with inert absorbent material and collect for disposal.
Waste Disposal Method:	Wrap container and dispose of in accordance with all applicable federal, state, and local laws.
Precautions to be Taken in Handling or Storage:	Avoid contact if allergic reaction to gentamicin, miconazole nitrate, or hydrocortisone.
Other Precautions:	Store in a tightly closed container, in a cool dry area. Keep out of the reach and sight of children. For animal use only. For topical use only. Avoid contact with eyes.

Section VIII - Control Measures

Respiratory Protection:	Not applicable	
Ventilation	Local Exhaust:	Not Applicable
	Special:	Not Applicable
	Mechanical (General):	Not Applicable
Protective Gloves:	Waterproof gloves, preferably elbow length for prolonged or repeated exposure	
Eye Protection:	NIOSH approved safety glasses or goggles.	
Other Protective Clothing or Equipment:	Protective clothing, i.e., and waterproof aprons should be worn by persons, who repeatedly use or are exposed to this product in grooming operations.	
Work/Hygienic Practices:	Wash hands after using.	

Section IX - Additional Information

Easotic is a registered trademark of Virbac SA.

Disclaimer of Expressed and Implied Warranties: This information is provided in good faith but without express or implied warranty. Buyer assumes all responsibility for safety and use not in accordance with label instructions.

Prepared by Regulatory Affairs Department

New MSDS Dated: July 2, 2009

Supersedes MSDS Date: Not Applicable



MATERIAL SAFETY DATA SHEET
EASOTIC[®] Otic Suspension
Product Number: 09360

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATIONS AND OF THE COMPANY UNDERTAKING

Product Name EASOTIC[®] Otic Suspension
Product Description Auricular treatment for otitis in dogs
Manufacturer/Supplier Virbac AH, Inc.
Address P.O. Box 162059
Fort Worth, Texas 76161
Phone Number (800) 338-3659 for Technical Support
Chemtrec Number (24 hour) (800) 424-9300
Emergency Number: (800) 338-3659 for Human and Animal Medical Emergencies
MSDS Revision Date: November 18, 2011
Supersedes MSDS Dated: October 29, 2011

Material Safety Data Sheet in compliance with OSHA's Hazcom Standard (29 CFR 1910.1200)

2. HAZARDS IDENTIFICATION

Emergency Overview

CAUTION!

Avoid contact with eyes and skin.
Harmful if swallowed.
Keep out of reach of children.
Read entire label before each use.

Routes of Entry

Eye - Skin - Ingestion

Carcinogenic Status

Not considered carcinogenic by NTP, IARC, and OSHA.

Target Organs

Eyes - Skin - Central Nervous System - Blood - Reproductive System

Health Effects - Eyes

Contact with eyes can cause irritation.

Health Effects - Skin

Contact with skin may cause slight irritation and skin sensitization.

Health Effects - Ingestion

Harmful if swallowed. Prolonged, repeated ingestion can cause adverse effects to the central nervous system, blood and reproductive system.

Health Effects - Inhalation

No adverse effects are expected during normal conditions of use.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component Name	CAS Number	Concentration
Hydrocortisone Aceponate	74050-20-7	0.14% (1.11 mg/ml)
Miconazole Nitrate	22832-87-7	2.14% (15.1 mg/ml)
Gentamycin Sulfate	1405-41-0	0.37% (1505 IU/ml)
Paraffin	8002-74-2	NA



4. FIRST AID MEASURES

Eyes

Immediately flood the eye with plenty of water for at least 15-20 minutes, holding the eye open. Obtain medical attention if soreness or redness persists.

Skin

If irritation develops wash skin thoroughly with soap and water. Obtain medical attention if redness or soreness persists.

Ingestion

Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Inhalation

Remove person to fresh air. Seek medical attention if symptoms persist.

Advice to Physicians

Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

5. FIRE - FIGHTING MEASURES

Extinguishing Media

Use extinguishing media appropriate for surrounding materials.

Unusual Fire and Explosion Hazards

Can release hazardous vapors during a fire.

Protective Equipment for Fire-Fighting

Wear full protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Wear appropriate protective clothing. Wipe up and transfer into suitable containers for recovery or disposal. Prevent the material from entering drains or watercourses.

7. HANDLING AND STORAGE

Store in original container in a cool, dry place. Store away from children and pets. Do not store near foodstuffs. Do not contaminate water, food or feed by storage. Wear appropriate protective clothing. Avoid contact with eyes. Wash hands thoroughly after handling and before eating, drinking or smoking.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Standards

Exposure limits are listed below, if they exist.

Hydrocortisone Aceponate

None established

Miconazole Nitrate

None established

Gentamycin Sulfate

None established

Paraffin Wax Fume

ACGIH: TLV 2 mg/m³ TWA

Engineering Control Measures

No specific measures necessary. Good general room ventilation is expected to be adequate to control airborne levels.



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection

Not required under normal conditions of use.

Hand Protection

Chemical resistant gloves.

Eye Protection

Safety glasses or goggles.

Body Protection

Waterproof apron.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Liquid (Suspension)
Color	Opaque White
Odor	None
pH	No data available
Specific Gravity	No data available
Boiling Range/Point (°C/F)	No data available
Melting Point (°C/F)	No data available
Flash Point (PMCC) (°C/F)	Not flammable
Explosion Limits (%)	No data available
Vapor Pressure	No data available
Density	No data available
Solubility in Water	Insoluble
Vapor Density (Air = 1)	No data available

10. STABILITY AND REACTIVITY

Stability

Stable under normal conditions.

Conditions to Avoid

Heat - high temperatures

Materials to Avoid

Strong oxidizers

Hazardous Polymerization

Will not occur.

Hazardous Decomposition Products

Oxides of carbon – oxides of nitrogen – hydrogen chloride gas

11. TOXICOLOGICAL INFORMATION

See product packaging for additional information.

Acute Toxicity

Hydrocortisone Aceponate: Oral LD50 (rat) 2200 mg/kg

Miconazole Nitrate: Oral LD50 (rat) 640 mg/kg

Specific Target Organ Systemic Toxicity (single and repeat)

Miconazole Nitrate: May affect the central nervous system (drowsiness and headache). Prolonged or repeated ingestion may cause changes in blood cell count.

Gentamycin Sulfate: In humans receiving systemic Gentamycin therapy, ototoxicity and nephrotoxicity have occurred.



11. TOXICOLOGICAL INFORMATION

Serious Eye damage/Eye Irritation

No relevant studies identified.

Skin Corrosion/Irritation

No relevant studies identified.

Respiratory or Skin Sensitization

Miconazole Nitrate: Local sensitivity reactions have been reported in humans.

Gentamycin sulfate: May cause allergic skin and respiratory reactions and photosensitivity.

Carcinogenicity

Not considered carcinogenic by NTP, IARC, and OSHA.

Germ Cell Mutagenicity

No relevant studies identified.

Toxicity to Reproduction

Miconazole Nitrate: May cause adverse reproductive effects based on animal oral toxicity studies at doses equal or above 80 mg/kg/day.

12. ECOLOGICAL INFORMATION

Mobility

No relevant studies identified.

Persistence/Degradability

No relevant studies identified.

Bio-accumulation

No relevant studies identified.

Ecotoxicity

No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with all applicable local and national regulations.

14. TRANSPORT INFORMATION

Contact supplier for transport information.

15. REGULATORY INFORMATION

US REGULATIONS (Federal, State) and INTERNATIONAL CHEMICAL REGISTRATION LAWS**TSCA Listing**

This product contains ingredients that are listed on or exempt from listing on the EPA Toxic Substance Control Act Chemical Substance (TSCA) Inventory.

DSL (Canadian) Listing

This product contains ingredients that are not listed on the Domestic Substance List (DSL).

WHMIS Classification

D.2.A

This product was classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations and the MSDS contains all the information required by these regulations.

MA Right To Know Law

This product contains the following chemicals on the Massachusetts Right to Know Law: None

PA Right To Know Law

This product contains the following chemicals on the Pennsylvania Hazardous Substance List: Paraffin (8042-47-5)



15. REGULATORY INFORMATION

NJ Right To Know Law

This product contains the following chemicals on the New Jersey Workplace Hazardous Substance List: Paraffin (8042-47-5)

California Proposition 65

This product contains the following materials which the State of California has found to cause cancer, birth defects or other reproductive harm: None

SARA Title III Sect. 311/312 Categorization

Immediate (acute) Delayed (chronic)

SARA Title III Sect. 313

This product contains the following chemicals that are listed in Section 313 at or above de minimis concentrations: None

16. OTHER INFORMATION

NFPA Ratings

NFPA Code for Flammability - 0

NFPA Code for Health - 1

NFPA Code for Reactivity - 0

NFPA Code for Special Hazards – 0

HMIS Ratings

HMIS Code for Flammability - 0

HMIS Code for Health – 1*

HMIS Code for Reactivity - 0

HMIS Code for Personal Protection - See Section 8

Abbreviations

ACGIH: American Conference of Governmental Industrial Hygienists

BOD: Biological Oxygen Demand

CAS#: Chemical Abstracts Service Number

FIFRA: Federal Insecticide, Fungicide and Rodenticide Act

IARC: International Agency for Research on Cancer

LC50: Lethal Concentration 50%

LD50: Lethal Dose 50%

N/A: Denotes no applicable information found or available

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Administration

PEL: Permissible Exposure Limit

STEL: Short Term Exposure Limit

TLV: Threshold Limit Value

TSCA: Toxic Substance Control Act

For further information call: (800) 338-3659

Prepared By: EnviroNet LLC

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