# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

078880028

N/A

MATERIAL SAFETY DATA SHEET

MSDS#

3510-471

Identity: Easotic®

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Section I

Supplier Information:

**Emergency Telephone Number** 

Name:

VIRBAC CORP.

Virbac AH Inc.

Address:

P.O. BOX 162059

City: State: FORT WORTH TX 76161

Other emergencies: **POISON CONTROL CENTER or 911** 

Telephone Number for Information Contact Virbac: 800/338-3659

Transportation: Chemtrec 800-424-9300

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** 

Gentamicin Sulfate

Hydrocortisone Aceponate Miconazole nitrate

Not Applicable Not Applicable Not Applicable

Not Applicable Not Applicable

Not Applicable Not Applicable Not Applicable

74050-20-7 22832-87-7 1405-41-0

1.11 mg/mL 15.1 mg/mL 1505 IU/mL

**Inactive Ingredients** 

Paraffin

Not Applicable

Not Applicable

Not Applicable

Not Applicable

Section III - Physical/Chemical Characteristics

**Boiling Point:** 

Specific Gravity ( $H_2O = 1$ ): Vapor Pressure (mm Hg): Melting Point:

Vapor Density (AIR = 1): Evaporation Rate (Butyl Acetate = 1):

Solubility in Water: Appearance and Odor: Not Applicable

Not Applicable Not Applicable Not Applicable

Not Applicable Not Applicable

Not Applicable White Suspension

Section IV - Fire and Explosion Hazard Data

Flash Point (Method Used):

Flammable Limits:

Not Applicable 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:

Unusual Fire and Explosion Hazards:

Not applicable Not applicable

Section V - Reactivity Data

Stability Incompatibility STABLE

(Materials to Avoid): None Known

Hazardous Decomposition or Byproducts:

In case of fire, exposure to decomposition products may be dangerous. Do not breathe fumes.

WILL NOT OCCUR

Conditions to Avoid:

Hazardous Polymerization

Temperatures above 86°F (30°C).

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Section VI - Health Hazard Data

Routes of Entry:

Inhalation? YES

Skin? YES

Indestion? 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.

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:

Other Precautions:

Not applicable

Ventilation

Local Exhaust:

Special:

Not Applicable Not Applicable

Mechanical (General):

Not Applicable

Protective Gloves:

Waterproof gloves, preferably elbow length for prolonged or repeated

Eye Protection:

Other Protective Clothing or Equipment:

NIOSH approved safety glasses or goggles.

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

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### 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.

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### 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

Hq No data available No data available **Specific Gravity** Boiling Range/Point (°C/F) No data available No data available Melting Point (°C/F) Flash Point (PMCC) (°C/F) Not flammable No data available **Explosion Limits (%) 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.

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#### 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)

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### 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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