



**SAFETY DATA SHEET**  
**EASOTIC® (hydrocortisone aceponate,  
miconazole nitrate, gentamycin sulfate)**  
**Otic Suspension**

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**1. IDENTIFICATION**

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<b>Product Name</b>	EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamycin sulfate) Otic Suspension
<b>Recommended use of the chemical and restrictions on use</b>	
<b>Identified uses</b>	Auricular treatment for otitis in dogs
<b>Restrictions on Use</b>	Federal law restricts this drug to use by or on the order of a licensed veterinarian.
<b>Company Identification</b>	Virbac AH, Inc. P.O. Box 162059 Fort Worth, Texas 76161 (800) 338-3659
<b>Customer Information Number</b>	
<b>Emergency Telephone Number</b>	
<b>CHEMTREC Number</b>	(800) 424-9300
<b>Other Emergency Number:</b>	Human Toll-free 833-224-2009 Animal Toll-free 833-224-2013
<b>Issue Date</b>	February 25, 2020
<b>Supersedes Date</b>	February 8, 2016
<i>Safety Data Sheet prepared in accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)</i>	

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**2. HAZARDS IDENTIFICATION**

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**Hazard Classification**  
Toxic to Reproduction - Category 1B

**Label Elements**  
Hazard Symbols



Signal Word: Danger

**Hazard Statements**  
May damage fertility or the unborn child.

**Precautionary Statements**

**Prevention**

Obtain special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Wear eye protection, face protection, protective clothing and protective gloves.

**Response**

If exposed or concerned: Get medical advice/attention.

**Storage**

Store locked up.

**Disposal**

Dispose of contents/container in accordance with local regulation.



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**2. HAZARDS IDENTIFICATION**

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**Other Hazards**

None.

**Specific Concentration Limits**

The values listed below represent the percentages of ingredients of unknown toxicity.

Acute oral toxicity	< 10%
Acute dermal toxicity	< 10%
Acute inhalation toxicity	>90%
Acute aquatic toxicity	>90%

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**3. COMPOSITION/INFORMATION ON INGREDIENTS**

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**Synonyms:**

This product is a mixture.

<b>Component Name</b>	<b>CAS Number</b>	<b>Concentration</b>
Hydrocortisone Aceponate	74050-20-7	0.14% (1.11 mg/ml)
Miconazole Nitrate	22832-87-7	2.14% (17.4 mg/ml)
Gentamycin Sulfate	1405-41-0	0.37% (1.5 mg/ml)

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**4. FIRST AID MEASURES**

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**Description of necessary first-aid measures**

**Eyes**

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

**Skin**

Wash skin 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.

**Most important symptoms/effects, acute and delayed**

Aside from the information found under Description of necessary first aid measures (above) and Indication of immediate medical attention and special treatment needed, no additional symptoms and effects are anticipated.

**Indication of immediate medical attention and special treatment needed**

**Notes to Physicians**

Treat symptomatically.

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**5. FIRE - FIGHTING MEASURES**

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**Extinguishing Media**

Use extinguishing media appropriate for surrounding materials.



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**5. FIRE - FIGHTING MEASURES**

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**Unusual Fire and Explosion Hazards**

None known

**Protective Equipment for Fire-Fighting**

Wear full protective clothing and self-contained breathing apparatus.

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**6. ACCIDENTAL RELEASE MEASURES**

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**Personal precautions, protective equipment and emergency procedures**

Wear appropriate protective clothing.

**Environmental Precautions**

Prevent the material from entering drains or watercourses.

**Methods and materials for containment and cleaning up**

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

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**7. HANDLING AND STORAGE**

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**Precautions for safe handling**

Wear appropriate protective clothing. Avoid contact with skin, eyes and clothing. Wash and remove contaminated clothing before reuse. Wash hands thoroughly after handling and before eating, drinking or smoking.

**Conditions for safe storage**

Store in original container at room temperature 68-77°F (20-25°C). Store away from children and pets.

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**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**Control parameters**

Exposure limits are listed below, if they exist.

**Hydrocortisone Aceponate**

None established

**Miconazole Nitrate**

None established

**Gentamycin Sulfate**

None established

**Appropriate engineering controls**

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

**Individual protection measures**

**Respiratory Protection**

Not required under normal conditions of use.

**Skin Protection**

Gloves



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**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**Eye/Face Protection**

Safety glasses or goggles.

**Body Protection**

Protective clothing.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

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**Appearance**

	<b>Physical State</b>	Liquid (suspension)
	<b>Color</b>	Opaque white
<b>Odor</b>		None
<b>Odor Threshold</b>		No data available
<b>pH</b>		No data available
<b>Specific Gravity</b>		No data available
<b>Boiling Range/Point (°C/F)</b>		No data available
<b>Melting Point (°C/F)</b>		No data available
<b>Flash Point (PMCC) (°C/F)</b>		Not flammable
<b>Vapor Pressure</b>		No data available
<b>Evaporation Rate (BuAc=1)</b>		No data available
<b>Solubility in Water</b>		Insoluble
<b>Vapor Density (Air = 1)</b>		No data available
<b>VOC</b>		No data available
<b>Partition coefficient (n-octanol/water)</b>		Not applicable
<b>Viscosity</b>		Not applicable
<b>Auto-ignition Temperature</b>		No data available
<b>Decomposition Temperature</b>		No data available
<b>Upper explosive limit</b>		No data available
<b>Lower explosive limit</b>		No data available
<b>Flammability (solid, gas)</b>		No data available

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**10. STABILITY AND REACTIVITY**

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**Reactivity**

Data is not available

**Chemical Stability**

Stable under normal conditions.

**Possibility of hazardous reactions**

Hazardous polymerization will not occur.

**Conditions to Avoid**

Heat - high temperatures

**Incompatible Materials**

Strong oxidizers



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**10. STABILITY AND REACTIVITY**

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**Hazardous Decomposition Products**

Oxides of carbon – oxides of nitrogen – hydrogen chloride gas

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**11. TOXICOLOGICAL INFORMATION**

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**Acute Toxicity**

EASOTIC

Oral LD50 (rat) >5000 mg/kg

Dermal LD50 (rat) >2000 mg/kg

No mortality was seen in the rat.

**Specific Target Organ Toxicity (STOT) – single exposure**

EASOTIC: Available data indicates this product is not expected to cause target organ effects after a single exposure under normal conditions of use.

**Specific Target Organ Toxicity (STOT) – repeat exposure**

EASOTIC: Available data indicates this product is not expected to cause target organ effects after a repeat exposure under normal conditions of use.

**Serious Eye damage/Irritation**

EASOTIC: Ocular irritation studies in the rabbit demonstrated the product to be weakly irritating to the eyes.

**Skin Corrosion/Irritation**

EASOTIC: Dermal irritation studies in the rabbit demonstrated the product to be a non-irritant to the skin.

**Respiratory or Skin Sensitization**

EASOTIC: In the Buehler test (guinea pigs) the results demonstrate a lack of sensitisation resulting from application of the suspension of HCA, miconazole and gentamicin.

**Carcinogenicity**

Not considered carcinogenic by NTP, IARC, and OSHA.

**Germ Cell Mutagenicity**

Gentamicin: Not considered to be a mutagenic compound based on animal studies.

Miconazole: Miconazole has been used in both veterinary and human medicine, and as transcutaneous absorption of the substance has been shown to be very low, miconazole present in EASOTIC does not represent a mutagenic concern for the target animal or for the pet owner.

Hydrocortisone Aceponate: No evidence of mutagenicity was seen in the genetic mutation, chromosomal aberration and micronucleus test.

**Reproductive Toxicity**

Miconazole: In the rat reproductive study miconazole had no impact on fertility, gestation period, perinatal or postnatal performance. In both the rat and the rabbit miconazole has no teratogenic effects on foetuses or offspring. In both species malformations observed at the highest dose group of 100 mg/kg b.w. were associated with maternal toxicity.



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**Reproductive Toxicity**

Gentamicin: No evidence of reproductive toxicity was observed in rats after administration by the intramuscular route at doses up to 15 mg/kg b.w. In three studies performed with administration by the intramuscular route (rats) or subcutaneous route (mice), gentamicin was embryotoxic but without teratogenic potency. Consequently, this drug is contraindicated for use in pregnant women.

Hydrocortisone: In summary, embryotoxic and teratogenic effects of HCA including skeletal changes, reduction in foetal and placental weight and elevated post-implantation losses, were seen in rats and rabbits at higher doses.

**Aspiration Hazard**

Not an aspiration hazard.

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**12. ECOLOGICAL INFORMATION**

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**Ecotoxicity**

No relevant studies identified.

**Mobility in soil**

No relevant studies identified.

**Persistence/Degradability**

No relevant studies identified.

**Bioaccumulative Potential**

No relevant studies identified.

**Other adverse effects**

No relevant studies identified.

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**13. DISPOSAL CONSIDERATIONS**

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**Disposal Methods**

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

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**14. TRANSPORT INFORMATION**

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Contact supplier for transport information.

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**15. REGULATORY INFORMATION**

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**United States TSCA Inventory**

This product is a drug and is exempted from the US EPA Toxic Substance Control Act.

**Canada DSL Inventory**

This product is a drug and is exempted from the Canadian Environmental Protection Act.

**SARA Title III Sect. 311/312 Categorization**

Reproductive Toxicity



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**15. REGULATORY INFORMATION**

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**SARA Title III Sect. 313**

The following chemicals are listed in Section 313 at or above de minimis concentrations: None.

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**16. OTHER INFORMATION**

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**Legend**

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

Revision Date: February 25, 2020

Replaces: February 8, 2016

Changes made: Updates to emergency phone numbers and Sections 3 and 15.

**Information Source and References**

This SDS is prepared by Hazard Communication Specialists based on information provided by internal company references.

**Prepared By:** EnviroNet LLC.

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