

SAFETY DATA SHEET

According to HSNO Hazardous Substances (Safety Data Sheets) Notice 2017

Section 1. Identification of the material and the supplier

Product: Easotic

Product Use: For the treatment of otitis externa of bacterial,

fungal or inflammatory origin. For the treatment of disease

due to gentamicin susceptible bacteria, especially Staphylococcus intermedius, Streptococcus spp.,

Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, and miconazole susceptible fungi mainly Malassezia

pachydermatis.

Restriction of Use: Refer to Section 15

New Zealand Supplier: Virbac New Zealand Limited

Address: 26 – 30 Maui Street Pukete, Hamilton

Telephone: +64 7 849 6782

Customer Service Toll no: 0800 VIRBAC (0800 847 222) (Mon-Fri 8:30am to 4:30pm)

Emergency No: 0800 764 766 (National Poison Centre)

Date of SDS Preparation: 27 September 2021

Section 2. Hazards Identification

This substance is hazardous according to the EPA Hazardous Substances (Classification) Notice 2020.

EPA Approval No: Veterinary Medicines (Limited Pack Size, Finished dose) – HSR100757

Pictograms



Signal Word: Warning

GHS Classification and Category	Hazard Code	Hazard Statement
Reproductive toxicity Cat. 2	H361	Suspected of damaging fertility or the unborn child.
Effects on or via lactation	H362	May cause harm to breast-fed children.

Prevention Code	Prevention Statement
P103	Read label before use.
P201	Obtain special instructions before use.

Product Name: Easotic SDS Prepared by: Technical Compliance Consultants (NZ) Ltd Date of SDS: 27 September 2021 Tel: 64 9 475 5240 www.techcomp.co.nz

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P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust, fumes, gas, mist, vapours or spray.
P263	Avoid contact during pregnancy while nursing.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P281	Use personal protective equipment as required.

Response Code	Response Statement
P308 + P313	IF exposed or concerned: Get medical advice/ attention.

Storage Code	Storage Statement
P405	Store locked up.

Disposal Code	Disposal Statement
P501	Dispose of according to Local Regulations or Authorities

Section 3. Composition / Information on Hazardous Ingredients

Ingredients	Wt%	CAS NUMBER.
Hydrocortisone aceponate	<u>></u> 0.1-<0.5	74050-20-7
Gentamicin sulphate	<u>></u> 0.25-<0.5	1405-41-0
Miconazole nitrate	<u>></u> 1-<2	22832-87-7
Not triggering or non-hazardous ingredients	To bal	

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Section 4.	First Aid Measures

Routes of Exposure:

If in Eyes Rinse eyes cautiously with a large quantity of water for several minutes. If

irritation occurs and persists, seek medical advice.

If on Skin Wash off skin with water and soap. If skin irritation occurs and persists,

seek medical advice.

If Swallowed If product is swallowed or gets in mouth, wash mouth with water and give

some water to drink. If symptoms develop, or if in doubt contact a Poisons

Information Centre or a doctor.

If Inhaled Remove person to fresh air. Remove contaminated clothing and loosen

remaining clothing. Allow person to assume most comfortable position and keep warm. Keep at rest until fully recovered. Apply artificial respiration if not breathing. Get medical advice if breathing becomes

difficult.

Most important symptoms and effects, both acute and delayed

Symptoms: Suspected of damaging fertility or the unborn child. May cause harm to

breast-fed children.

Section 5. Fire Fighting Measures

Hazard Type	Non Flammable
Hazards from products	None known.
Suitable	Water spray or fog / foam / dry chemical powder / carbon dioxide.
Extinguishing media	

Precautions for firefighters and special protective	Breathing apparatus for fire only.
clothing HAZCHEM CODE	None allocated.

Section 6. Accidental Release Measures

Wear sufficient respiratory protection where necessary and protective clothing to minimize skin exposure. Evacuate all non-essential personnel.

Absorb with absorbent material and place in a container for disposal. Dispose of in compliance with local and/or national regulations as per Section 13.

Section 7. Handling and Storage

Precautions for Handling:

- Read label before use.
- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Avoid contact during pregnancy or while nursing.
- Do not breathe dust, fumes, gas, mist, vapours or spray.
- Avoid contact during pregnancy while nursing.
- Wash hands thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Use personal protective equipment as required.

Precautions for Storage:

- Store away from incompatible materials listed in Section 10.
- Store locked up.
- Store below 25°C in original container, tightly closed, in a cool dry place.
- Do not freeze.

Section 8 Exposure Controls / Personal Protection

WORKPLACE EXPOSURE STANDARDS (provided for guidance only)

TWA STEL
Substance ppm mg/m³ ppm mg/m³

No ingredients have exposure standards.

Workplace Exposure Standard – Time Weighted Average (WES-TWA). The time-weighted average exposure standard designed to protect the worker from the effects of long-term exposure. Workplace Exposure Standard – Short-Term Exposure Limit (WESSTEL). The 15-minute average exposure standard. Applies to any 15- Minute period in the working day and is designed to protect the worker against adverse effects of irritation, chronic or irreversible tissue change, or narcosis that may increase the likelihood of accidents. The WES-STEL is not an alternative to the WES-TWA; both the short-term and time-weighted average exposures apply. Workplace Exposure Standards and Biological Exposure Indices NOV 2020 12TH EDITION.

Engineering Controls

None required.

Personal Protection Equipment



Eyes	Not required.
Skin	When handing bulk quantities, wear suitable gloves and protective gear.
Respiratory	Not required.

Hygiene	Wash hands thoroughly with soap and water after handing.
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Section 9 Physical and Chemical Properties

Appearance	White suspension
Odour	Not available
Odour Threshold	Not available
pH	Not available
Boiling Point	Not available
Melting Point	Not available
Freezing Point	Not available
Flash Point	Not available
Flammability	Not available
Combustibility	Not available
Upper and Lower	Not available
Explosive Limits	
Vapour Pressure	Not available
Vapour Density	Not available
Specific Gravity	0.850 - 0.890 g/L
Water Solubility	Soluble
Partition Coefficient:	Not available
Auto-ignition	Not available
Temperature	
Decomposition	Not available
Temperature	
Kinematic Viscosity	Not available
Particle Characteristics	Not available

Section 10. Stability and Reactivity

Stability of Substance	This product is stable under normal storage conditions.	
Possibility of hazardous	Not available	
reactions		
Conditions to Avoid	Avoid contact during pregnancy or while nursing.	
Incompatible Materials	None known.	
Hazardous Decomposition	None know.	
Products		

Section 11 Toxicological Information

Acute Effects:

Swallowed	Not applicable.	
Dermal	Not applicable.	
Inhalation	Not applicable.	
Eye	Not applicable.	
Skin	Not applicable.	

Chronic Effects:

Carcinogenicity	Not applicable.	
Reproductive	Suspected of damaging fertility or the unborn child.	
Toxicity	May cause harm to breast-fed children.	
Germ Cell	Not applicable.	
Mutagenicity		
Aspiration	Not applicable.	
STOT/SE	Not applicable.	
STOT/RE	Not applicable.	

Section 12. Ecotoxicological Information

This product is not hazardous to the environment.

Product:	
Persistence and degradability	No data available
Bioaccumulation	No data available
Mobility in Soil	No data available
Other adverse effects	No data available

Section 13. Disposal Considerations

Disposal Method:

Dispose of empty container by wrapping with paper and placing in the garbage, in accordance with the Local Regulations.

Precautions or methods to avoid: None known.

Section 14 Transport Information

This product is NOT classified as a Dangerous Good for transport in NZ; NZS 5433:2012

Section 15 Regulatory Information

This substance is classified hazardous according to the EPA Hazardous Substances (Classification) Notice 2020

EPA Approval Code: Veterinary Medicines (Limited Pack Size, Finished dose) -

HSR100757

GHS Classification:

Reproductive toxicity Cat. 2 Effects on or via lactation

HSW (HS) Regulations 2017 and EPA Notices	Trigger Quantity
Certified Handler	Not required
Location Certificate	Not required
Tracking Trigger Quantities	Not required
Signage Trigger Quantities	Not required
Emergency Response Plan	Not required
Secondary Containment	Not required
Restriction of Use	Only use for the intended purpose.
ACVM Approval No	A010305
See <u>www.foodsafety.govt.nz</u> for registration	
Conditions	

Section 16 Other Information

Glossary

Cat Category

EC50Median effective concentration.EELEnvironmental Exposure Limit.EPAEnvironmental Protection Authority

HSNO Hazardous Substances and New Organisms.

HSW Health and Safety at Work.

LC₅₀ Lethal concentration that will kill 50% of the test organisms

inhaling or ingesting it.

LD₅₀ Lethal dose to kill 50% of test animals/organisms.

LEL Lower explosive level.

OSHA American Occupational Safety and Health Administration.

TEL Tolerable Exposure Limit.

TLV Threshold Limit Value-an exposure limit set by responsible

authority.

UEL Upper Explosive Level WES Workplace Exposure Limit

References:

1. EPA Hazardous Substances (Safety Data Sheets) Notice 2017

- 2. Workplace Exposure Standards and Biological Exposure Indices Nov 2020 edition.
- 3. Assigning a hazardous substance to a HSNO Approval (Aug 2013).
- 4. Transport of Dangerous goods on land NZS 5433:2012
- 5. HSW (Hazardous Substances) Regulations 2017

Disclaimer

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Please contact the New Zealand distributor, if further information is required.

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