

Material Safety Data Sheet

Aurimic Ear Drops and cutaneous suspension for dogs and cats

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s): Aurimic Ear Drops and cutaneous suspension for dogs and cats
 Product code(s): XVD 310

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Veterinary medicinal product
 Uses advised against: Not for human use. Refer to the product information leaflet
 Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name: Animalcare Limited
 Address: 10 Great Northway
 York Business Park
 Nether Poppleton
 York
 YO26 6RB
 United Kingdom

1.4 Emergency telephone number

Daytime: +44 (0) 1904 487687

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008: This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008: This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms: Not applicable
 Signal word: Not applicable
 Hazard statements: Not applicable
 Precautionary statements: Not applicable
 Supplemental information: Not applicable

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC): None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

<i>Dangerous substances in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
Chlorphenaminhydrogenmaleat	[113-92-8]	1%
Miconazole nitrate	[22832-87-7]	< 2.5%
Prednisolone 21-acetate	[52-21-1]	< 0.5%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes:	Rinse opened eye for several minutes under running water
Skin:	After skin contact immediately wash with water and soap and rinse thoroughly
Ingestion:	After swallowing call for a doctor immediately
Inhalation:	Supply fresh air and be sure call for a doctor. In case of unconsciousness place patient stably in side position for transportation

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more information on health effects and symptoms

4.3 Indication of any immediate medical attention and special treatment needed

See patient package insert in shipping carton for complete information.

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
Unsuitable extinguishing media:	None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:	Not flammable or combustible
Hazardous combustion products:	Decomposition products may include the following materials: Carbon oxides (CO _x), nitrogen oxides (NO _x)

5.3 Advice for fire-fighters

Special protective equipment for firefighters:	Wear self-contained respiratory protective device
Further information:	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:	Refer to protective measures listed in sections 7 and 8
Advice for emergency responders:	If specialised clothing is required to deal with the spillage, take note of any information in section 8 on suitable and unsuitable materials

6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water of drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Small spills:	Wear recommended personal protective equipment (see section 8- Exposure controls/personal Protection). Use absorbent towels or brooms to clean up spill. Wipe surface area clean with soap and water
Large spills:	Dike spilled material or otherwise contain material to ensure runoff does not reach a waterway

6.4 Reference to other sections

See Section 1 for emergency contact information
See section 8 for personal protection
See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling:	Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols
Hygiene measures:	None identified

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:	Keep out of reach of children. Keep in the original packaging. Keep container tightly closed
Storage temperature:	No special requirements
Further information on storage conditions:	No special requirements

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. At this time, none of the constituents have known exposure limits

8.2 Exposure controls

Engineering measures:	Good general ventilation should be sufficient to control worker exposure to airborne contaminants
Individual protection measures:	
Hygiene measures:	Keep away from foodstuffs, beverages and feed Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work
Eye/face protection:	Goggles recommended during refilling
Skin/body protection:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent)
Hand protection:	The glove material has to be impermeable and resistant to the product/the substances/the preparation. Due to missing tests no recommendation to the glove material can be given for the product/the preparation/the chemical mixture.

	Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Respiratory protection:	In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device
Environmental exposure controls:	Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Suspension
Colour:	White
Odour:	Odourless
Odour threshold:	No data available
pH:	No data available
Density:	No data available
Melting point:	No data available
Boiling point:	No data available
Flash point:	> 110 °C
Evaporation rate:	No data available
Flammability:	No data available
Water solubility:	No data available
Partition coefficient:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Explosive properties:	No data available
Oxidizing properties:	The substance or mixture is not classified as oxidizing

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

None Known

10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	No data available
Chronic toxicity:	No data available
Skin irritation/sensitization:	No data available
Reproductive toxicity:	No data available
Carcinogenicity:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related carcinogenic/tumorigenic effects based on animal data
Mutagenicity:	No data available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

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