



SAFETY DATA SHEET

Product Name: Dermotic Ear & Skin Suspension

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This revision issued: April, 2015

Section 1 - Identification of The Material and Supplier

Troy Laboratories Australia Pty. Ltd ABN: 21 000 283 769 Tel: (02) 8808 3600 (office hours)
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Glendenning NSW 2761

Chemical nature: Multipurpose preparation - includes antibiotic and fungal ingredients.
Trade Name: Dermotic Ear & Skin Suspension
APVMA Code: 53950
Product Use: For the treatment of certain skin infections in horses, cats and dogs as indicated on the product label.
Creation Date: June, 2005
This version issued: April, 2015 and is valid for 5 years from this date.
Poisons Information Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification

Statement of Hazardous Nature

This product is classified as: Not classified as hazardous according to the criteria of SWA Australia.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA and IMDG/IMSBC criteria.

Risk Phrases: Not Hazardous - No criteria found.

Safety Phrases: Not Hazardous - No criteria found.

SUSMP Classification: S4

ADG Classification: None allocated. Not a Dangerous Good under the ADG Code.

UN Number: None allocated

GHS Signal word: NONE. Not hazardous.

PREVENTION

P102: Keep out of reach of children.

P262: Do not get in eyes, on skin, or on clothing.

P281: Use personal protective equipment as required.

RESPONSE

P337: If eye irritation persists: seek medical attention.

P352: Wash with plenty of soap and water.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P370+P378: Not combustible. Use extinguishing media suited to burning materials.

STORAGE

P403+P235: Store in a well-ventilated place. Keep cool.

DISPOSAL

P501: Dispose of contents and containers as specified on the registered label.

Emergency Overview

Physical Description & Colour: Thick white oily suspension.

Odour: Mild odour.

Major Health Hazards: no significant risk factors have been found for this product.

Potential Health Effects

One of the ingredients is an antibiotic. Any person with a history of allergies to this class of substances should avoid all contact with this product as it may cause sensitisation.

Inhalation

Short Term Exposure: Significant inhalation exposure is considered to be unlikely. Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:

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Phone: 02 8808 3600 (office hours)

Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)

Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. In addition product is unlikely to cause any discomfort in normal use.

Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:

Short Term Exposure: Exposure via eyes is considered to be unlikely. This product may be mildly irritating to eyes, but is unlikely to cause anything more than mild discomfort which should disappear once product is removed.

Long Term Exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short Term Exposure: Significant oral exposure is considered to be unlikely. This product is unlikely to cause any irritation problems in the short or long term.

Long Term Exposure: No data for health effects associated with long term ingestion.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA.

NTP: No significant ingredient is classified as carcinogenic by NTP.

IARC: No significant ingredient is classified as carcinogenic by IARC.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m ³)	STEL (mg/m ³)
Miconazole nitrate	22832-87-8	23mg/mL	not set	not set
Prednisolone acetate	52-21-1	5mg/mL	not set	not set
Polymyxin B sulfate	1405-20-5	0.695mg/mL	not set	not set
Other non hazardous ingredients		to 100	not set	not set

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that should not be exceeded for more than 15 minutes and should not be repeated for more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 - First Aid Measures

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Inhalation: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Skin Contact: Irritation is unlikely. However, if irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

Eye Contact: No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes.

Ingestion: 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.

Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: This product is classified as a C2 combustible product. There is no risk of an explosion from this product under normal circumstances if it is involved in a fire. Violent steam generation or eruption may occur upon application of direct water stream on hot liquids.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

Extinguishing Media: Preferred extinguishing media are carbon dioxide, dry chemical, foam, water fog.

Fire Fighting: If a significant quantity of this product is involved in a fire, call the fire brigade.

Flash point: Major Ingredient Flashes About 180°C

Upper Flammability Limit: No data.

Lower Flammability Limit: No data.

Autoignition temperature: No data.

Flammability Class: C2

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Section 6 - Accidental Release Measures

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling chemical products. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: Note that this product is combustible and therefore, for Storage, meets the definition of Dangerous Goods in some states. If you store large quantities (tonnes) of such products, we suggest that you consult your state's Dangerous Goods authority in order to clarify your obligations regarding their storage.

Store packages of this product in a cool place. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Some liquid preparations settle or separate on standing and may require shaking before use. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits **TWA (mg/m³)** **STEL (mg/m³)**

Exposure limits have not been established by SWA for any of the known significant ingredients in this product.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that vapours and mists are minimised.

Eye Protection: Eye protection is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

Skin Protection: The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products, especially when they contain antibiotics and that you wear suitable gloves (preferably elbow-length) when skin contact is likely.

Protective Material Types: There is no specific recommendation for any particular protective material type.

Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Section 9 - Physical and Chemical Properties:

Physical Description & colour:	Thick white oily suspension.
Odour:	Mild odour.
Boiling Point:	Not available.
Freezing/Melting Point:	No specific data. Liquid at normal temperatures.
Volatiles:	No specific data. Expected to be low at 100°C.
Vapour Pressure:	No data.
Vapour Density:	No data.
Specific Gravity:	No data. Expected to be about 0.9
Water Solubility:	Negligible.
pH:	No data.
Volatility:	No data.
Odour Threshold:	No data.
Evaporation Rate:	No data.
Coeff Oil/water Distribution:	No data
Autoignition temp:	No data.

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Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: This product should be kept in a cool place, preferably below 25°C. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: strong acids, strong bases, strong oxidising agents.

Fire Decomposition: Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Water. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Local Effects:

Target Organs: none known

Classification of Hazardous Ingredients

Ingredient

Risk Phrases

No ingredient mentioned in the HSIS database is present in this product at hazardous concentrations.

Section 12 - Ecological Information

This product is biodegradable. It will not accumulate in the soil or water or cause long term problems.

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 14 - Transport Information

UN Number: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this product are compliant with NICNAS regulations. The following ingredients: Miconazole, Polymyxin, Prednisolone are mentioned in the SUSMP.

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail, 7th Edition
AICS	Australian Inventory of Chemical Substances
CAS Number	Chemical Abstracts Service Registry Number
IARC	International Agency for Research on Cancer
SWA	Safe Work Australia, formerly ASCC and NOHSC
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS. OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

SAFETY DATA SHEET

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)
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