

SECTION 1: IDENTIFICATION

1.1 Product identifier	
Product name:	Enrofloxacin 50mg and 150mg Tablets
Synonyms:	Not Available
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	Treatment of bacterial infections caused by organisms sensitive to enrofloxacin in dogs.
Uses advised against:	Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Apex Laboratories Pty Ltd
Address:	Apex Laboratories Pty Ltd ACN 614 716 700 2 Cal Close Somersby NSW 2250
Telephone:	1300 015 825 (Business hours: 08:30 – 17:30)
Fax:	+61 2 4372 1668
Email:	thetvet@apexlabs.com.au
Website:	www.apexlabs.com.au
1.4 Emergency Telephone Numbers	
	13 11 26 (Poisons Information Centre)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture	
GHS classification(s):	Acute toxicity oral: Category 4 Specific target organ systemic toxicity (repeated exposure): Category 2
2.2 Label Elements	
Signal Word:	WARNING
Hazard Statement(s)	
H302	Harmful if swallowed

H373	May cause damage to organs through prolonged or repeated exposure
Additional Statement(s)	
None	
Precautionary Statement(s) Prevention:	
P264	Wash hands thoroughly after handling
P270	Do not eat, drink or smoke when using this product
P260	Do not breathe dust
Precautionary Statement(s) Response:	
P301 + P312	If swallowed: Call a poison centre or doctor if you feel unwell
P330	Rinse mouth
Precautionary Statement(s) Storage:	
None	
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/packaging according to local regulations
2.3 Other Hazard Information	
N/a	

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

Ingredient	CAS No	EC Number	Content
Enrofloxacin	93106-60-6	NA	30 – 35%
Talc	14807-96-6	NA	< 2%
Other non-hazardous ingredients	NA	NA	To 100%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention if irritation persists.
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Skin contact:	Remove contaminated clothing immediately. Flush area with large amounts of soap and water. Seek medical attention if irritation or rash occurs.
Inhalation:	Generally not required due to the nature and packaging of the product. If concerned, remove to fresh air and seek medical advice if concerned.
Ingestion:	If swallowed, contact a Poisons Information Centre or doctor.
4.2 Most important symptoms and effects, both acute and delayed	
See Section 11	
4.3 Indication of immediate medical attention and special treatment needed	
Treat symptomatically.	

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable:	Dry agent, water, foam, carbon dioxide. As appropriate for surrounding area.
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5.2 Special protective actions for fire-fighters:

Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Cool containers with water spray. Wear full breathing apparatus and self-contained breathing apparatus.
Fire / explosion hazard:	May emit carbon dioxide, carbon monoxide, nitrogen oxides and sulfur dioxide under fire conditions.
Hazchem code:	None allocated.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For information on protective equipment, see section 8.

6.2 Environmental Precautions

Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Minor Spills:	Spillage of formulated product from marketed packaging is unlikely to be serious.
Major Spills:	In the event of a major spill, protect drains and water courses from contamination.

	Wear protective clothing (overalls, gloves, goggles and boots). Shovel spillage into clean, dry, labelled containers and dispose after consulting appropriate authorities. Avoid contact with skin and eyes.
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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	Always use good occupational work practices and observe recommendations on the label. Keep exposure to this product to a minimum. Prohibit eating, drinking and smoking in storage and handling areas. Wash hands after handling and remove contaminated clothing and any protective equipment before entering eating areas. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep out of the reach and sight of children.

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	Store below 30°C (room temperature) in original container. Storage areas and containers should be protected from light, freezing or physical damage and tightly sealed when not in use.
Storage incompatibility:	Not available.

7.3 Specific end uses

Not available

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

Talc	2.5 mg/m ³ (TWA)
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EMERGENCY LIMITS:

Not Available

8.2 Exposure controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
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Personal protection:	Not required when product used as directed.
Eye and face protection:	Eye protection is not normally necessary. If there is risk of significant dust formation wear protective goggles or glasses. Wash hands after handling and prior to touching eye and in particular handling contact lenses.
Skin protection:	Skin protection is not normally necessary, however it is good practice to avoid contact with chemicals by wearing suitable gloves when handling.
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not applicable
Respiratory protection:	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to build up then use of a suitable dust mask would be appropriate.
8.3 Environmental exposure controls See Section 12	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Off white to tan coloured, scored tablets
Physical state: Solid
Odour: Nonspecific odour
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not available
Specific gravity/density: Not available
Solubility in water and solvents (mg/l): Not available
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available

Molecular weight: Not applicable
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information

Not Available

SECTION 10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Mixture is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
10.3 Possibility of hazardous reactions:	No data available
10.4 Conditions to avoid:	No conditions to avoid other than extreme heat.
10.5 Incompatible materials:	No data available
10.6 Hazardous decomposition:	No known decomposition products

SECTION 11: TOXICOLOGICAL INFORMATION

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126

Inhalation:	No data for the mixture is available. The material is not thought to produce adverse health effects or irritation of the respiratory tract. Not normally a hazard due to the non-volatile nature of the product.
Ingestion:	No data for the mixture is available. The data available suggests that ingestion can lead to nausea, vomiting and diarrhoea. Headaches, dizziness and restlessness have also been reported to occur. Cartilage damage can occur in young growing animals and may have contributed to an arthropathy in an adolescent human.
Skin contact:	No data for the mixture is available. Not considered an irritant through normal use.
Eye contact:	Not normally a hazard due to the nature of the product. Although the material is not thought to be an irritant, direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness.
Acute toxicity:	
Enrofloxacin:	Oral (rabbit) LD ₅₀ : 500 mg/kg

Irritation:	
Enrofloxacin:	Not available
Chronic toxicity:	
Enrofloxacin:	Not available
Respiratory or skin sensitization:	
Enrofloxacin:	Not available
Mutagenicity:	
Enrofloxacin:	Not available
Carcinogenicity:	
Enrofloxacin:	Not available
Reproductive toxicity:	
Enrofloxacin:	Not available
STOT – single exposure:	
Not available	
STOT–repeated exposure:	
Enrofloxacin	Quinolones may affect the eye as a potential target organ. In humans, alteration of the lens or melanin-containing eye tissues have been reported. Retinal toxicity has been reported in cats.
Aspiration hazard:	
Not available	

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Enrofloxacin:	Aquatic invertebrates: EC ₅₀ (48h) = 14.3 mg/L (<i>Penaeus vannamei</i>) Algae: EC ₅₀ = 49 µg/L (<i>M. aeruginosa</i>) Algae: EC ₅₀ = 3100 µh/L (<i>P. subcapitata</i>)
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12.2 Persistence and degradability

Enrofloxacin:	Not available
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12.3 Bioaccumulative potential

Enrofloxacin:	Not available
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12.4 Mobility in Soil

Enrofloxacin:	Not available
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12.5 Other adverse effects
Not available

SECTION 13: DISPOSAL CONSIDERATIONS
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13.1 Waste treatment methods	
Product / packaging disposal:	<p>Empty containers may be recycled or sent to a commercial waste disposal site. Unused product should be suitable for landfill however contact the relevant local Waste Disposal Authority.</p> <p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p>
Waste Treatment Options:	Do not dispose into sewers or waterways
Sewage Disposal Options:	Do not dispose into sewers or waterways

SECTION 14: TRANSPORT INFORMATION
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Labels required:	None	
Marine pollutant:	NO	
Hazchem:	N/a	
Land transport (ADG):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	

14.6 Special precautions for user	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a
Air transport (IATA / ICAO):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
Sea transport (IMDG / IMO):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
	IMDG Class	N/a

14.3 Transport hazard class(es)	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a

SECTION 15: REGULATORY INFORMATION

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

Australian Pesticides & Veterinary Medicines Authority (APVMA) Approval No.: 60497 (150mg); 59484 (50mg)

Poison Schedule	Classified as Schedule 4 according to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
Classifications	Safework Australia criteria is based on the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals. The classifications and phrases listed below are based on the Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008(2004)].
Hazard codes	H302: Harmful if swallowed. H373: May cause damage to organs through prolonged or repeated exposure.
Risk phrases	R22: Harmful if swallowed. R48: Danger of serious damage to health by prolonged exposure.
Inventory listing(s)	AUSTRALIA: AICS (Australian Inventory of Chemical Substances) All components are listed on AICS, or are exempt.

SECTION 16: OTHER INFORMATION

WORKPLACE CONTROLS AND PRACTICES:

Unless a less toxic chemical can be substituted for a hazardous substance, ENGINEERING CONTROLS are the most effective way of reducing exposure. The best protection is to enclose operations and/or provide local exhaust ventilation at the site of chemical release. Isolating operations can also reduce exposure. Using respirators or protective equipment is less effective than the controls mentioned above, but is sometimes necessary.

PERSONAL PROTECTIVE EQUIPMENT GUIDELINES:

The recommendation for protective equipment contained within this report is provided as a guide only. Factors such as form of product, method of application, working environment, quantity used, product concentration and the availability of engineering controls should be considered before final selection of personal protective equipment is made.

HEALTH EFFECTS FROM EXPOSURE:

It should be noted that the effects from exposure to this product will depend on several factors including: form of product; frequency and duration of use; quantity used; effectiveness of control measures; protective equipment used and method of application. Given that it is impractical to prepare a report which would encompass all possible scenarios, it is anticipated that users will assess the risks and apply control methods where appropriate.

ABBREVIATIONS:

ACGIH: American Conference of Governmental Industrial Hygienists

CAS #: Chemical Abstract Service number - used to uniquely identify chemical compounds

CNS: Central Nervous System

EC No.: EC No - European Community Number

EMS: Emergency Schedules (Emergency Procedures for Ships Carrying Dangerous Goods)

GHS: Globally Harmonized System

GTEPG: Group Text Emergency Procedure Guide

IARC: International Agency for Research on Cancer

LC50: Lethal Concentration, 50% / Median Lethal Concentration

LD50: Lethal Dose, 50% / Median Lethal Dose

mg/m³: Milligrams per Cubic Metre

OEL: Occupational Exposure Limit

pH: relates to hydrogen ion concentration using a scale of 0 (high acidic) to 14 (highly alkaline).

ppm: Parts Per Million

STEL: Short-Term Exposure Limit

STOT-RE: Specific target organ toxicity (repeated exposure)

STOT-SE: Specific target organ toxicity (single exposure)

SUSMP: Standard for the Uniform Scheduling of Medicines and Poisons

SWA: Safe Work Australia

TLV: Threshold Limit Value

TWA: Time Weighted Average

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. Apex Laboratories Pty Ltd make no representation of merchantability, fitness for a particular purpose or application, or of any other nature with respect to the information or the product to which the information refers ("the product").

The information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability prior to use of the product.

The physical data shown herein are typical values based on material tested. These values should not be construed as guaranteed analysis of any specific lot or as guaranteed specification for the product or specific lots hereof.