Dechra

SAFETY DATA SHEET

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

1.1 Product identifier

Product name **ENROFLOXACIN 50MG AND 150MG TABLETS (NZ)**

Synonyms ENROFLOXACIN TABLETS

1.2 Uses and uses advised against

Uses VETERINARY USE

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 product

Supplier name **DECHRA VETERINARY PRODUCTS NZ LTD**

Address PO Box 1604, Paraparaumu Beach, 5252, NEW ZEALAND

Telephone 0800 473 838

Email info.nz@dechra.com

Website http://www.dechra.co.nz/

1.4 Emergency telephone numbers

Emergency 0800 764 766 (National Poisons Centre NZ)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

HAZARDOUS ACCORDING TO NZ ENVIRONMENTAL PROTECTION AUTHORITY CRITERIA

Physical Hazards

Not classified as a Physical Hazard

Health Hazards

Acute Toxicity: Oral: Category 4
Specific Target Organ Toxicity (Repeated Exposure): Category 2

Environmental Hazards

Aquatic Toxicity (Chronic): Category 3

2.2 GHS Label elements

Signal word **WARNING**

Pictograms

Hazard statements

H302 Harmful if swallowed.
H373 May cause damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Prevention statements

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.

Response statements

P301 + P312	IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
P314	Get medical advice/attention if you feel unwell.
P330	Rinse mouth.

Storage statements

None allocated.

Disposal statements

P501	Dispose of contents/container in accordance with relevant regulations.

2.3 Other hazards

No information provided.

3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.1 Substances / Mixtures

Ingredient	CAS Number	EC Number	Content
ENROFLOXACIN	93106-60-6	618-911-2	30 to 35%
TALC	14807-96-6	238-877-9	<2%
NON HAZARDOUS INGREDIENTS	Not Available	Not Available	Remainder

4. FIRST AID MEASURES

4.1 Description of first aid measures

Eye If in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, a doctor, or for at least 15 minutes.

Inhalation If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.

Skin If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by a Poisons Information Centre or a doctor.

Ingestion For advice, contact the National Poisons Centre on 0800 764 766 (0800 POISON) or +643 479 7248 or a doctor (at once). If swallowed, do not induce vomiting.

First aid facilities None allocated.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

4.3 Immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Use an extinguishing agent suitable for the surrounding fire.

5.2 Special hazards arising from the substance or mixture

Non flammable. May evolve carbon oxides, sulphur oxides and nitrogen oxides when heated to decomposition.

5.3 Advice for firefighters

Treat as per requirements for surrounding fires. Evacuate area and contact emergency services. Remain upwind and notify those downwind of hazard. Wear full protective equipment including Self Contained Breathing Apparatus (SCBA) when combating fire. Use waterfog to cool intact containers and nearby storage areas.

5.4 Hazchem code

None allocated.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Wear Personal Protective Equipment (PPE) as detailed in section 8 of the SDS.

6.2 Environmental precautions
Prevent product from entering drains and waterways.

6.3 Methods of cleaning up
If spilt, collect and reuse where possible.

6.4 Reference to other sections
See Sections 8 and 13 for exposure controls and disposal.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

7.2 Conditions for safe storage, including any incompatibilities
Store in a cool, dry, well marked area, removed from foodstuffs and other drugs. Storage areas and containers should be clearly marked for drug holding, protected from light, freezing or physical damage and tightly sealed when not in use. Keep out of reach of children. Store below 30°C.

7.3 Specific end uses
No information provided.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters
Exposure standards

Ingredient	Reference	TWA		STEL	
		ppm	mg/m³	ppm	mg/m³
Talc (no asbestos fibres)	WES [NZ]	--	2	--	--

Biological limits
No biological limit values have been entered for this product.

8.2 Exposure controls
Engineering controls Avoid inhalation. Use in well ventilated areas. Maintain dust levels below the recommended exposure standard.

PPE

Eye / Face	Not required under normal conditions of use.
Hands	Individuals with sensitive skin should consider wearing latex gloves.
Body	Not required under normal conditions of use.
Respiratory	Not required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	OFF-WHITE TO TAN COLOURED TABLET
Odour	ODOURLESS
Flammability	NON FLAMMABLE
Flash point	NOT RELEVANT
Boiling point	NOT AVAILABLE
Melting point	NOT AVAILABLE
Evaporation rate	NOT AVAILABLE
pH	NOT AVAILABLE
Vapour density	NOT AVAILABLE

9.1 Information on basic physical and chemical properties

Relative density	NOT AVAILABLE
Solubility (water)	NOT AVAILABLE
Vapour pressure	NOT AVAILABLE
Upper explosion limit	NOT RELEVANT
Lower explosion limit	NOT RELEVANT
Partition coefficient	NOT AVAILABLE
Autoignition temperature	NOT AVAILABLE
Decomposition temperature	NOT AVAILABLE
Viscosity	NOT AVAILABLE
Explosive properties	NOT AVAILABLE
Oxidising properties	NOT AVAILABLE
Odour threshold	NOT AVAILABLE

10. STABILITY AND REACTIVITY

10.1 Reactivity

Carefully review all information provided in sections 10.2 to 10.6.

10.2 Chemical stability

Stable under recommended conditions of storage.

10.3 Possibility of hazardous reactions

Polymerization will not occur.

10.4 Conditions to avoid

Avoid contact with incompatible substances.

10.5 Incompatible materials

Compatible with most commonly used materials.

10.6 Hazardous decomposition products

May evolve carbon oxides and hydrocarbons when heated to decomposition.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity Harmful if swallowed. This product is used in veterinary applications. Use safe work practices to avoid eye contact, prolonged skin contact and ingestion. Refer to medical doctor/specialist for advice regarding adverse side effects.

Information available for the ingredients:

Ingredient	Oral LD50	Dermal LD50	Inhalation LC50
ENROFLOXACIN	4336 mg/kg (mouse)	--	--
TALC	> 5000 mg/kg (rat)	--	--

Skin Contact may result in irritation, redness and rash.

Eye Contact may result in irritation, lacrimation, pain, redness and conjunctivitis.

Sensitisation Not classified as causing skin or respiratory sensitisation.

Mutagenicity Not classified as a mutagen.

Carcinogenicity Not classified as a carcinogen.

Reproductive Not classified as a reproductive toxin.

STOT - single exposure Over exposure may result in irritation of the nose and throat, with coughing.

STOT - repeated exposure May cause damage to organs through prolonged or repeated exposure.

Aspiration Not classified as causing aspiration.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
Harmful to aquatic life with long lasting effects.

12.2 Persistence and degradability
No information provided.

12.3 Bioaccumulative potential
No information provided.

12.4 Mobility in soil
No information provided.

12.5 Other adverse effects
No information provided.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal For small quantities, collect and place in sealable containers. Dispose of, as with other clinical waste, by high temperature incineration (recommended > 1100°C). Burial to landfill may be acceptable, but only at an approved and licensed waste disposal site.

Legislation Dispose of in accordance with relevant local legislation.

14. TRANSPORT INFORMATION

NOT CLASSIFIED AS A DANGEROUS GOOD ACCORDING TO LAND TRANSPORT RULE: DANGEROUS GOODS 2005; NZS 5433:2012, UN, IMDG OR IATA

	LAND TRANSPORT (NZS 5433)	SEA TRANSPORT (IMDG / IMO)	AIR TRANSPORT (IATA / ICAO)
14.1 UN Number	None allocated.	None allocated.	None allocated.
14.2 Proper Shipping Name	None allocated.	None allocated.	None allocated.
14.3 Transport hazard class	None allocated.	None allocated.	None allocated.
14.4 Packing Group	None allocated.	None allocated.	None allocated.

14.5 Environmental hazards
Not a Marine Pollutant.

14.6 Special precautions for user

Hazchem code None allocated.

15. REGULATORY INFORMATION

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

ACVM A010358 (150 MG); A010359 (50 MG)

Approval code HSR100757

Group standard Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2020

Inventory listings

AUSTRALIA: AIIC (Australian Inventory of Industrial Chemicals)
All components are listed on AIIC, or are exempt.
NEW ZEALAND: NZIoC (New Zealand Inventory of Chemicals)
All components are listed on the NZIoC inventory, or are exempt.

16. OTHER INFORMATION

Additional 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
CCID	Chemical Classification and Information Database (HSNO)
CNS	Central Nervous System
EC No.	EC No - European Community Number
EMS	Emergency Schedules (Emergency Procedures for Ships Carrying Dangerous Goods)
EPA	Environmental Protection Authority [New Zealand]
GHS	Globally Harmonized System
HSNO	Hazardous Substances and New Organisms
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)
TLV	Threshold Limit Value
TWA	Time Weighted Average

Report status

This document has been compiled by RMT on behalf of the manufacturer, importer or supplier of the product and serves as their Safety Data Sheet ('SDS').

It is based on information concerning the product which has been provided to RMT by the manufacturer, importer or supplier or obtained from third party sources and is believed to represent the current state of knowledge as to the appropriate safety and handling precautions for the product at the time of issue. Further clarification regarding any aspect of the product should be obtained directly from the manufacturer, importer or supplier.

While RMT has taken all due care to include accurate and up-to-date information in this SDS, it does not provide any warranty as to accuracy or completeness. As far as lawfully possible, RMT accepts no liability for any loss, injury or damage (including consequential loss) which may be suffered or incurred by any person as a consequence of their reliance on the information contained in this SDS.

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