

SAFETY DATA SHEET

BAYTRIL 10% INJECTABLE SOLUTION

Date of Issue: 16 March 2016



SDS NUMBER 345354/4 NZ

1. Identification of the Substance/Mixture and Supplier.

Product Name:	Baytril 10% Injectable solution
Other Product Names:	Enrofloxacin 10% Injection
Application:	Antibacterial treatment for cats and dogs. RESTRICTED VETERINARY MEDICINE
Company:	Bayer New Zealand Limited, 3 Argus Place, Hillcrest, Auckland, 0627 New Zealand.
Telephone:	0800 652 488
Facsimile:	0800 229 838
Emergency telephone:	0800 734 607 Ixom SH&E Shared services (24hr)
National Poisons Centre:	0800 POISON (0800 764766)

2. Hazards Identification.

Hazardous Status:	Classified as hazardous according to the criteria in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.
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HSNO CLASSIFICATION	GHS HAZARD STATEMENTS
6.1E (oral)	H303 May be harmful if swallowed.
6.3A	H315 Causes skin irritation.
6.9B (repeated exposure)	H373 May cause damage to organs through prolonged or repeated exposure.
8.3A	H318 Causes serious eye damage.

Signal Word:	DANGER
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PREVENTION STATEMENTS

P102	Keep out of reach of children.
P103	Read label before use.
P260	Do not breathe mist/vapours/spray.
P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

RESPONSE STATEMENTS

P101	If medical advice is needed, have product container or label at hand.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.

STORAGE STATEMENTS – N/A

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DISPOSAL STATEMENTS		
P501	Do not let this product enter the environment. Do not dispose of in waterways or sewers. Dispose of this material and its container as hazardous waste, via a licensed facility. See local council for disposal/recycling information.	
GHS DIAMONDS		
		
3. Composition/Information on Ingredients.		
Chemical Entity	CAS No	Proportion
Enrofloxacin	93106-60-6	10%
Potassium hydroxide	1310-58-3	≤ 2%
n-butanol	71-36-3	3%
4. First Aid Measures.		
General Information:	Remove victim from contaminated area. If there is a risk of unconsciousness, position and transport in a stable lateral position. Remove soiled or soaked clothing immediately. Get medical attention if you feel unwell.	
Skin Contact:	Remove contaminated clothing. Wash affected area immediately with soap and water. Seek medical attention. Take container / label or MSDS for identification.	
Eye Contact:	Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTRE or doctor/physician. Take container / label or MSDS for identification.	
Ingestion:	If vomiting occurs keep head lower than hips to help prevent aspiration. Seek medical attention immediately. Take container / label or MSDS for identification.	
Inhalation:	Under normal use inhalation is unlikely to occur. In the event remove from exposure and perform artificial respiration if necessary. Seek medical assistance if required. Take container / label or MSDS for identification.	
Further Information:	Contact the National Poisons and Hazardous Chemicals Information centre in Dunedin, PO Box 913, Dunedin. Phone 0800 764 766, 0800 POISON.	
5. Fire-Fighting Measures.		
Extinguishing media and methods:	Sprayed water jet, foam, dry chemical powder CO ₂ and sand.	
Recommended protective clothing:	Fire fighters should wear self contained breathing apparatus in enclosed areas. Contain fire fighting water. Hydrogen cyanide, hydrogen fluoride, carbon monoxide and nitrogen oxides must be anticipated	

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6. Accidental Release Measures.

Spill and leak procedure:	Take all possible steps to prevent spillage from spreading or entering soil, waterways and drains. Take up with absorbent material such as sawdust, peat or chemical binder. Place fill material along with any contaminated soil etc., into sealable containers. Clean affected area with a damp cloth. Place cleaning materials into the same container.
Protective Equipment:	Do not eat, drink or smoke during clean-up operation. Wear tightly fitting protective goggles (acid protection goggles) and protective gloves for chemicals.

7. Handling and Storage.

Handling: Storage:	Do not breathe mist/vapor/spray. Read label before use. Suitable container materials: stainless steel: V2A, V4A. Keep out of reach of children. Store away from food, drink or animal feeding stuffs. To maintain product quality, store in a dry place, protect from temperatures below -5°C and above 30°C. Keep away from light. Store so that unauthorized persons do not have access.
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8. Exposure Control/Personal Protection

Engineering measures:	Use in well ventilated area
Respiratory Protection:	No respirator is required under normal use. If the airborne concentrations exceed the TWA wear full face mask with combination filter P2 Wear protective gloves for chemicals.
Skin Protection:	Wear tightly fitting protective goggles, acid protection goggles.
Eye Protection:	Keep the place of work clean. Avoid contact with product. Keep working clothes separate. Change badly soiled or soaked clothing. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and contaminated clothing.
Hygiene measures:	
Workplace exposure limits	
n-butanol	STEL 154mg/m ³ (50ppm) (NZ WES)
potassium hydroxide	STEL 2 mg/m ³ (NZ WES)

9. Physical and Chemical Properties

Form:	Clear Liquid
Colour:	yellowish
Odour:	slight characteristic smell
pH	10, 8-11,1 (undiluted)
Boiling point	ca 10°C
Density:	1.035g/cm ³ at 20°C
Solubility in water:	Miscible
Further information	Light sensitive

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10. Stability and Reactivity

Stability:	No data
Possibility of hazardous reactions:	No data
Hazardous decomposition products:	No data
Incompatible products:	Strong oxidisers

11. Toxicological Information

Acute toxicity:	Enrofloxacin LD ₅₀ oral, rabbit 500mg/kg
Skin irritation:	Irritant
Eye irritation:	Irritant
Other information	Enrofloxacin - Retinal Toxicity in Cats It is well known that old quinolones, such as nalidixic acid, may affect the eye as a potential target organ (6). In this connection alteration of the lens or melanin-containing eye tissues (retina, iris, ciliary body) have been reported from human medicine. As a matter of precaution Baytril therefore has been evaluated in ophthalmoscopic and histopathological studies on laboratory animals, dogs, and cats. Those toxicological studies with repeated administration of high doses did not reveal any evidence of unwanted effects on the eyes of the animals examined. Sporadic reports of blindness in cats previously treated with Baytril, however, have been received mainly from the US in the last few years. In an additional safety study on cats Baytril was given over 3 weeks at different doses (5, 20, 50 mg/kg body weight) once daily. No adverse effects were observed in cats that received 5 mg Baytril per kg body weight. The administration of doses of 20 mg/kg body weight or greater caused salivation, vomiting and depression and additionally resulted in mild to severe fundic lesions on ophthalmologic examination, changes in electroretinograms (including blindness) and diffuse light microscopic alterations. It has therefore been recommended to treat cats with Baytril at daily doses not exceeding 5 mg/kg b.w., which is the officially registered dose in most countries of the world. In contrast to cats there is no evidence that visual alterations can also occur in other species, e.g. dogs. [http://www.baytril.com/index.cfm/page/13/title/Safety_and_Toxicology.htm]

12. Ecological Information

Fish toxicity	LC ₀ 150 mg/L Golden orfe (<i>Leuciscus idus</i>) LC ₀ >10mg/L (96hr) Rainbow trout (<i>Salmo gairdneri</i>) LC ₀ > 10mg/L (96hr) (<i>Lepomis macrochirus</i>)
Daphnia toxicity	EC ₀ >100 mg/L (24hr) Water flea (<i>Daphnia magna</i>)
Bacterial toxicity	EC ₀ 0.0037 mg/L <i>Pseudomonas putida</i>

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13. Disposal Considerations.

In case where larger amounts of the product have become unusable, it should be established whether material utilization is possible (if necessary consult the manufacturer/suppliers). Small amounts of product and uncleaned empty packaging should be packaged, sealed and labeled. Use only approved chemical disposal company.

14. Transportation Information.

Not regulated for transport Keep separated from foodstuffs.

15. Regulatory Information.

ACVM Number: A005581

HSNO Approval Number: HSR002146

HSNO Classification

6.1E (Oral), 6.3A, 6.9B, 8.3A

Controls for hazardous substances:

- Level 2 Emergency Management Information required when > 1 Litre is present in a workplace.
- Level 3 Emergency Management Plans required when > 10 000 Litres is present in a workplace.
- When an excess of 1000 Litres is stored, signage is required for eye corrosive substances.

Controls of hazardous substances are based upon current knowledge. Where multiple chemicals are stored, controls will take into account aggregate quantities. Contact an EPA/WorkSafe Approved Test Certifier for further information and guidance.

16. Other Information.

HSNO = Hazardous Substances and New Organisms Act.

EPA = Environmental Protection Authority

NZ WES = New Zealand Work Exposure Standard

The data given here is based on current knowledge and experience. The purpose of this Safety Data Sheet is to describe products in terms of their safety requirements. The above details do not imply any guarantee concerning composition, properties or performance of the product.