



SAFETY DATA SHEET

A18096/08/AUS

BAYTRIL 50 ANTIBACTERIAL INJECTION

SECTION 1 – IDENTIFICATION

Bayer Australia Ltd
875 Pacific Highway
Pymble NSW 2073

Emergency Telephone Number
1800 033 111
24 hour Emergency Service Australia Wide, Toll Free

Contact Point (for non-emergency calls)
Animal Health Division
Telephone Number: (02) 9391-6000

Product Name **Baytril 50 Antibacterial Injection**

Product Use Antibacterial injection for dogs and cats.

Other Names Enrofloxacin

Schedule 4 PRESCRIPTION ANIMAL REMEDY

Creation Date 25th June 2003

Revision Date 21 March 2016

SECTION 2 – HAZARD IDENTIFICATION

Hazard Classification **HAZARDOUS SUBSTANCE**
NOT CLASSIFIED AS DANGEROUS GOODS under the Australian Dangerous Goods Code, 7th Edition.

GHS-Classification **Eye irritation, Category 2A**

Signal Word **Warning**

Hazard Statements **H319 Causes serious eye irritation**

Precautionary statements **Prevention:** P264 Wash hands thoroughly after handling. P280 Wear eye protection.
Response: P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/attention.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous
Components

n-butanol

Concentration [Weight percent] 1 - < 5

CAS-No.: 71-36-3

CAS name: 1-Butanol

GHS Classification:

Flam. Liq. 3 H226

Acute Tox. 4 H302

STOT SE 3 H335

Skin Irrit. 2 H315

Eye Dam. 1 H318

STOT SE 3 H336

Potassium hydroxide

Concentration [Weight percent] ≥ 0.5 - < 1

CAS-No.: 1310-58-3

CAS name: Potassium hydroxide

GHS Classification:

Acute Tox. 4 H302

Skin Corr. 1A H314

Met. Corr. H290

Also contains**Enrofloxacin**

Concentration [Weight percent] < 5

CAS-No.: 93106-60-6

CAS name: 3-Quinolincarboxylic acid, 1,4-dihydro-1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-4-oxo-

SECTION 4 – FIRST AID MEASURES

General	In case of accident, or if you feel unwell, seek medical advice immediately (show the label whenever possible). 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.
Inhalation	Inhalation of this product will not occur except as aspiration into the lungs after swallowing. In this event remove from exposure and perform artificial respiration if necessary.
Skin contact	Remove contaminated clothing. Wash affected area immediately with soap and water. Seek medical attention if required.
Eye contact	Irritating to eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Ingestion	If vomiting occurs keep head lower than hips to help prevent aspiration. Seek medical attention if required.
Advice to doctor	Enrofloxacin is an analogue of the human antibacterial ciprofloxacin. Ciprofloxacin is a metabolic breakdown product of enrofloxacin. Poisoning with this product is unlikely but in the event of overexposure apply basic aid and decontamination procedures. Treat symptomatically. Potassium hydroxide is included to raise formulation pH. The high pH of the formulation may produce eye irritation.

SECTION 5 – FIRE FIGHTING MEASURES

Extinguishing Media	Sprayed water jet, foam, dry powder, CO ₂ , sand.
Fire and Explosion Hazards	Non combustible material. Outer packaging may burn.
Hazardous Combustion Products	Thermal decomposition products include hydrogen cyanide, hydrogen fluoride, carbon monoxide and nitrogen oxides.
Fire Fighting	Fight fire in the early stages if safe to do so. Wear respiratory protection. In well ventilated areas wear full face mask with a combination filter. (Offers no protection from carbon monoxide) In enclosed premises: respirator with independent air supply. Contain firefighting water.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Accidental Release	<p>Use personal protective equipment. Use adequate ventilation.</p> <p>Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent spillage from spreading or entering soil, waterways and drains.</p> <p>Take up with absorbent material such as sawdust, peat or chemical binder. Fill material along with any contaminated soil etc., into sealable containers. Clean affected area with aqueous detergent and a small amount of water. Absorb this detergent/water with absorbent material. Place cleaning materials into the same container.</p> <p>Do not eat, drink or smoke during clean-up operation.</p>
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SECTION 7 – HANDLING AND STORAGE

Safe Handling	If using other than according to label, wear suitable gloves and eye/face protection.
Storage	<p>Keep out of reach of children. Store away from food, drink or animal feeding stuffs.</p> <p>To maintain product quality, store below 30°C. Protect from temperatures below 0°C and above 50°C. Keep away from heat or moisture.</p> <p>This material is a Schedule 4 drug and must be stored, handled and used in accordance with the relevant regulations.</p>

SECTION 8 – EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure Limits	<p>n-butanol: (WESAC) TWA (ppm) 50 peak limitation TWA (mg/m³) 152 peak limitation Absorption through the skin may be a significant source of exposure.</p> <p>Potassium hydroxide: (WESAC) TWA (mg/m³) 2 peak limitation</p>
Eye Protection	Irritating to eyes. Wear suitable eye/face protection.
Skin Protection	Wear suitable gloves (nitrile rubber or PVC).
Respirator	No respirator is required under normal conditions of use.

SECTION 9 – PHYSICAL & CHEMICAL PROPERTIES

Colour	Clear, yellow-tinged to light yellow
Odour	Slight characteristic smell
Boiling Point	Approx 100°C
Solidifying Range	No statements available
Density	1.024 g/cm ³ at 20°C
Vapour Pressure	No statements available
Viscosity	No statements available
Solubility in Water	No statements available
pH	10.5 – 11.5 (undiluted)
Flash Point	Not relevant. Boils above 100°C.
Ignition Temperature	Not relevant
Explosive Limits	Not relevant

SECTION 10 – STABILITY & REACTIVITY

Chemical Stability	Product is stable. No hazardous reactions.
Conditions to Avoid	Avoid strong oxidising agents.
Incompatible Materials	Nil
Hazardous Decomposition	Thermal decomposition products include hydrogen cyanide, hydrogen fluoride, carbon monoxide and nitrogen oxides.
Hazardous Reactions	Will not polymerise.

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute Toxicity	Oral LD ₅₀ (rat) >5000 mg/kg (enrofloxacin) Oral LD ₅₀ (mouse) 4336->5000 mg/kg (enrofloxacin) Inhalation LC ₅₀ (rat) >3547 mg/m ³ (enrofloxacin)
Local Effects	Eye: Irritant to the eye. Skin: Irritant to the skin. Non-sensitising to the skin. Administration to animals over a period of several weeks at elevated dosages has produced changes in articular cartilage.
Reproductive Effects	Chronic exposure (3 months to 2 years) of laboratory species to enrofloxacin has produced testicular degeneration and associated adverse effects on spermatogenesis. None of the other ingredients of the formulation have been shown to produce reproductive or teratogenic effects.
Mutagenicity	None of the ingredients of the formulation have been shown to produce mutagenic effects.
Carcinogenic Effects	Enrofloxacin has been shown in animal tests to have no carcinogenic potential. Other ingredients are not classified as carcinogens.

SECTION 12 – ECOLOGICAL INFORMATION

Octanol/Water Partition Co-efficient	<p>$K_{ow} = 0.4$ at pH 5.0</p> <p>$K_{ow} = 3.1$ at pH 7.0</p> <p>$K_{ow} = 0.7$ at pH 9.0</p>
Ecotoxicity	<p>Following data all for enrofloxacin.</p> <p><u>Fish</u></p> <p>LC₀ 150 mg/L Golden orfe (<i>Leuciscus idus</i>)</p> <p>LC₀ (96h) >10 mg/L Rainbow trout (<i>Salmo gairdneri</i>)</p> <p>LC₀ (96h) >10 mg/L <i>Lepomis macrochirus</i></p> <p><u>Daphnia</u></p> <p>EC₀ (24h) >100 mg/L Water flea (<i>Daphnia magna</i>)</p> <p><u>Bacteria</u></p> <p>EC₀ 0.0037 mg/L <i>Pseudomonas putida</i></p> <p>Studies on the influence of enrofloxacin on glucose stimulated respiration in the soil, and on microbial mineralisation of nitrogen in the soil, have shown no adverse effects after 14 days.</p>

SECTION 13 – DISPOSAL INFORMATION

After Intended Use	Dispose of used packaging by wrapping in paper and placing in garbage.
After spill or accident	Dispose of sealed containers at an approved local waste disposal site.

SECTION 14 – TRANSPORT INFORMATION

UN No	Not classified
UN Proper Shipping Name	Not classified
Class & Subsidiary Risk	Not classified
Packaging Group	Not classified
Hazchem Code	Not classified

SECTION 15 – REGULATORY INFORMATION

Poisons Schedule	Schedule 4
APVMA Registration	The product is registered by the APVMA.
Registration Number	46028
Labelling	All necessary directions, precautions and warnings for normal use of the product are included on the product label.

SECTION 16 – OTHER INFORMATION

Summary of Changes

GHS Update.

Acronyms

ADG Code Australian Code for the Transport of Dangerous Goods by Road and Rail**APVMA** Australian Pesticides and Veterinary Medicines Authority**CAS** Chemical Abstracts Service Registry Number**GHS** Globally Harmonized System of Classification and Labelling of Chemicals**HDPE** High density polyethylene**LDPE** Low density polyethylene**OECD** Organisation for Economic Co-operation and Development**STOT** Specific Target Organ Toxicity**SUSDP** Standard for the Uniform Scheduling of Drugs and Poisons**TWA** Time Weighted Average – average airborne concentration of a particular substance when calculated over a normal eight-hour working day, for a five-day working week.**UN Number** United Nations number**WESAC** Workplace Exposure Standards for Airborne Contaminants: Safe Work Australia

Disclaimer

This Safety Data Sheet has been developed according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Third revised edition. United Nations, 2009. The data, information and recommendations herein ("information") are represented in good faith and believed to be correct as of the date hereof. The purpose of this Safety Data Sheet is to describe product in terms of their safety requirements. Bayer Australia Limited makes 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 for their purposes 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 a guaranteed analysis of any specific lot or as guaranteed specification for the product or specific lots thereof. Due care should be taken to make sure that the use or disposal of this product and / or its packaging is in compliance with relevant Federal, State and Local Government regulations.

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