



SAFETY DATA SHEET

A18167/05/AUS

BAYTRIL OTIC ANTIBACTERIAL DROPS

SECTION 1 – IDENTIFICATION, CONTACTS

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 Otic Antibacterial Drops
Product Use	Antibacterial/antifungal ear drops for dogs. PRESCRIPTION ANIMAL REMEDY
Other Names	Enrofloxacin, silver sulfadiazine
Creation Date	25 th June 2003
Revision Date	29 April 2013 (SDS is current for 5 years from this date)

SECTION 2 – HAZARDS IDENTIFICATION

Hazard Classification	NON-HAZARDOUS SUBSTANCE NON-DANGEROUS GOODS
Risk Phrases	None
Safety Phrases	None

SECTION 3 – COMPOSITION

Ingredients	CAS No	Proportion
Enrofloxacin*	93106-60-6	0.5%
Silver sulfadiazine**	22199-08-2	1%
Other ingredients determined not to be hazardous	-	>60%

*Enrofloxacin is a fluoroquinolone antibiotic: 1-Cyclopropyl-7-(4-ethylpiperazin-1-yl)-6-fluoro-1,4-dihydro-4-oxoquinoline-3-carboxylic acid.

**Silver sulfadiazine is a sulphonamide antibiotic: Benzenesulfonamide, 4-amino-N-2-pyrimidinyl-monosilver (+1) salt.

SECTION 4 – FIRST AID MEASURES

Label Regulated First Aid Statement	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
General	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.
Scheduled Poisons	Poisons Information Centres in each State capital city can provide additional assistance for scheduled poisons. Phone 131126.
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	Flush eye immediately with large amounts of water or normal saline, occasionally lifting eyelids, until no evidence of chemical remains. Seek medical attention if eye irritation persists.
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. Silver sulfadiazine is approved for use on human patients. Poisoning with this product is unlikely but in the event of overexposure apply basic aid and decontamination procedures. Treat symptomatically.

SECTION 5 – FIRE FIGHTING MEASURES

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

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Accidental Release	<p>Use any personal protective equipment listed in Chapter 8.</p> <p>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	No specific recommendations.
Storage	<p>Keep out of reach of children.</p> <p>Store away from food, drink or animal feeding stuffs.</p> <p>To maintain product quality, store refrigerated below 8°C.</p> <p>Protect from temperatures below 0°C and above 25°C.</p> <p>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>No exposure allocated for enrofloxacin.</p> <p>No exposure allocated for silver sulfadiazine.</p> <p>No exposure allocated for other ingredients.</p>
Ventilation	No ventilation is required under normal conditions of use.
Eye Protection	<p>No eye protection is required under normal conditions of use.</p> <p>Under other conditions of use wear safety goggles. May irritate the eyes. Avoid contact with eyes.</p>
Skin Protection	<p>No skin protection is required under normal conditions of use.</p> <p>Under other conditions of use wear rubber gloves. Wash hands after use.</p>
Respirator	No respirator is required under normal conditions of use.
Protective Material Types	Rubber, latex.
General Advice	None

SECTION 9 – PHYSICAL & CHEMICAL PROPERTIES

Physical State	Oil in water emulsion
Colour	White to off-white
Odour	Weak odour
Boiling Point	Not available
Solidifying Range	Not available
Density	1.0 kg/L at 20°C
Vapour Pressure	Not relevant
Viscosity	Slightly viscous
Solubility in Water	Miscible
pH	6.0-7.5
Flash Point	Not relevant
Ignition Temperature	Not available
Explosive Limits	Not available
Other Information	Product is packed in 15ml plastic ear dropper containers.

SECTION 10 – STABILITY & REACTIVITY

Chemical Stability	Product is stable. No hazardous reactions.
Conditions to Avoid	Avoid strong oxidising agents.
Incompatible Materials	None
Hazardous Decomposition	Thermal decomposition products include carbon monoxide and nitrogen oxides.
Hazardous Reactions	Will not polymerise.

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute Toxicity	Oral LD ₅₀ (rat) >5000 mg/kg (of formulation) Oral LD ₅₀ (mouse) >2000 mg/kg (of formulation) Inhalation LC ₅₀ (rat) >3547 mg/m ³ (enrofloxacin)
Local Effects	Eye: slightly irritant to the eye. Skin: non-irritant to the skin. Administration to the ears of animals at elevated dosages over 14 days has not produced adverse changes in the ear.
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.

SECTION 11 – TOXICOLOGICAL INFORMATION (cont.)

Mutagenicity	None of the ingredients of the formulation have been shown to produce mutagenic effects.
Carcinogenic Effects	Enrofloxacin and silver sulfadiazine have 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	Not available
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 empty container by wrapping with paper and putting 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	51924
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 from Last Edition	Update to SDS, update First Aid information.
Acronyms	<p>ADG Code Australian Code for the Transport of Dangerous Goods by Road and Rail</p> <p>APVMA Australian Pesticides and Veterinary Medicines Authority</p> <p>CAS Chemical Abstracts Service Registry Number</p> <p>HDPE High density polyethylene</p> <p>LDPE Low density polyethylene</p> <p>NOHSC National Occupational Health & Safety Commission</p> <p>SUSDP Standard for the Uniform Scheduling of Drugs and Poisons</p> <p>UN Number United Nations number</p>
Disclaimer	<p>This Safety Data Sheet has been developed according to the NOHSC National Code of Practice for the Preparation of MSDS [NOHSC:2011(2003)]. 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 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 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.</p>

END OF SDS