

SAFETY DATA SHEET



BAYTRIL 100

Version 1.0 Revision Date: 06/23/2020 SDS Number: 122000007167 Date of last issue: -
Date of first issue: 23.06.2020

SECTION 1. IDENTIFICATION

Product information

Product Name : BAYTRIL 100
Synonyms : Baytril® 100 (enrofloxacin) Injectable Solution
Baytril® 100-CA1 (enrofloxacin) Injectable Solution
SDS Number : 122000007167

Use : veterinary medicine

Company

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
USA
+1-877-Elanco1(+1-877-3526261)
elanco_sds@elanco.com

In case of emergency: CHEMTREC International: +1 703-527-3887 (24 hours)

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Flammable liquids : Category 4
Eye irritation : Category 2A

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H227 Combustible liquid.
H319 Causes serious eye irritation.

Precautionary statements :

Prevention:

P210 Keep away from heat/sparks/open flames/hot surfaces.
No smoking.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face 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.

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P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
n-Butanol	71-36-3	2,78
Benzyl alcohol	100-51-6	1,85

SECTION 4. FIRST AID MEASURES

General advice : No hazards which require special first aid measures.

If inhaled : Not an expected entry route.

In case of skin contact : If skin reactions occur, contact a physician.

In case of eye contact : Flush eyes with water as a precaution.

If swallowed : In case of accidental ingestion, contact your regional poison center or physician immediately.

Most important symptoms and effects, both acute and delayed : No information available.

Notes to physician : No information available.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire-fighting : Fire may cause evolution of:
Hydrogen cyanide (hydrocyanic acid)
Hydrogen fluoride
Nitrogen oxides (NOx)
Carbon oxides

Further information : Prevent fire extinguishing water from contaminating surface water or the ground water system.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Use with adequate ventilation.

Methods and materials for containment and cleaning up : Suppress (knock down) gases/vapours/mists with a water spray jet.

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Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Place in closed containers. Label for proper disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Industrial uses:
Avoid formation of aerosol.
Use with local exhaust ventilation.
Avoid contact with skin, eyes and clothing.
- Further information on storage conditions : Keep away from direct sunlight.
- Recommended storage temperature : < 104 °F / < 40 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Enrofloxacin	93106-60-6	Bayer OES	0,6 mg/m ³ 0,6 ml/m ³	TRGS901
n-Butanol	71-36-3	TWA	20 ppm	ACGIH
		TWA	20 ppm	ACGIH
		C	50 ppm 150 mg/m ³	NIOSH REL
		C	50 ppm 150 mg/m ³	NIOSH REL
		TWA	100 ppm 300 mg/m ³	OSHA Z-1
		TWA	100 ppm 300 mg/m ³	OSHA Z-1
		C	50 ppm 150 mg/m ³	OSHA P0
		C	50 ppm 150 mg/m ³	OSHA P0
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
		TWA	10 ppm	US WEEL

Personal protective equipment

- Respiratory protection : Recommended Filter type:
Organic vapor with prefilter
None required for consumer use of this product.
- Hand protection
Material : Chemically resistant gloves.
- Remarks : None required for consumer use of this product.

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Eye protection : Safety glasses
None required for consumer use of this product.

Protective measures : No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients.
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.
Wear suitable protective equipment.
Please consult label for end-user requirements.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solution
Colour : yellow, brownish
Odour : weak, Alcohol
pH : 8,9 - 10,9 (68 °F / 20 °C)
(undiluted)

Flash point : 145 °F / 63 °C

Density : 1,08 g/cm³ (68 °F / 20 °C)
Method: DIN 51757

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Explosive properties : No data available
Oxidizing properties : No data available

Impact sensitivity : No data available

Minimum ignition energy : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No data available
Chemical stability : No data available
Possibility of hazardous reactions : No data available

Conditions to avoid : Do not allow product to come in contact with:
Exposure to light.

Incompatible materials : Oxidizing agents
Hazardous decomposition products : Hydrogen cyanide (hydrocyanic acid)
Hydrogen fluoride
Nitrogen oxides (NO_x)
Carbon oxides

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SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

- Acute oral toxicity : Acute toxicity estimate (ATE): > 5.000 mg/kg
Method: Calculation method
- Acute inhalation toxicity : Acute toxicity estimate (ATE): > 200 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method
- Acute dermal toxicity : Acute toxicity estimate (ATE): > 5.000 mg/kg
Method: Calculation method

Components:**n-Butanol:**

- Acute oral toxicity : Assessment: The component/mixture is moderately toxic after single ingestion.

Benzyl alcohol:

- Acute oral toxicity : LD50 (Rat, male): 1.620 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.
- Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Skin corrosion/irritation**Components:****n-Butanol:**

- Species : Rabbit
Method : OECD 404
Result : Irritating to skin.

Benzyl alcohol:

- Species : Rabbit
Method : OECD 404
Result : No skin irritation

Serious eye damage/eye irritation**Components:****n-Butanol:**

- Species : Rabbit
Result : Risk of serious damage to eyes.

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Method : OECD 405

Benzyl alcohol:

Species : Rabbit
Result : Irritation to eyes, reversing within 7 days
Method : OECD 405

Respiratory or skin sensitisation

Components:

n-Butanol:

Test Type : Skin sensitisation
Species : Guinea pig
Method : OECD 406
Result : Did not cause sensitisation on laboratory animals.

Benzyl alcohol:

Species : Guinea pig
Method : Magnusson and Kligmann maximization test
Result : Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Components:

n-Butanol:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Micronucleus test
Result: negative

Test Type: In vitro gene mutation study in mammalian cells
Test system: Hamster V79-cells
Method: OECD 476
Result: No evidence of a genotoxic effect.

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Method: OECD 474
Result: No evidence of a genotoxic effect.

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Genotoxicity in vivo : Result: No indication of mutagenic effects.

Carcinogenicity

IARC No component of this product present at levels greater than or equal to 0.1% is

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identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

STOT - single exposure

Components:

n-Butanol:

Assessment : May cause respiratory irritation.

Exposure routes : Inhalation
Assessment : May cause drowsiness or dizziness.

Benzyl alcohol:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Components:

Benzyl alcohol:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

Benzyl alcohol:

Species : Rat
NOAEL : 400 mg/kg
Exposure time : 90-day

Aspiration toxicity

Components:

n-Butanol:

May be harmful if swallowed and enters airways.

Experience with human exposure

Components:

n-Butanol:

General Information : May cause skin irritation and/or dermatitis.

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Further information

Components:

n-Butanol:

Remarks : Liver and kidney injuries may occur.

Remarks : After absorption of large quantities
Dizziness
Liver disorders
drowsiness
Headache
Weakness

Benzyl alcohol:

Remarks : Dermal absorption possible

Remarks : If inhaled:
irritations
Shortness of breath
Cough

Remarks : If swallowed
Vomiting
Nausea
Irritation of mucous membranes in the mouth, throat, gullet
and gastro-intestinal tract after swallowing.

Remarks : Systemic toxicity
Headache
Nausea
CNS disorders
Ataxia (uncontrolled movements)
Unconsciousness
cessation of breathing

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

n-Butanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 1.730 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1.983 mg/l
Exposure time: 48 h

Benzyl alcohol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 10 mg/l
Exposure time: 96 h

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Test Type: Acute Fish toxicity

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 71,4 mg/l
Exposure time: 0,5 h

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.

Persistence and degradability

Components:

n-Butanol:

Biodegradability : Result: rapidly biodegradable
Biodegradation: 98 %
Exposure time: 28 d
Method: OECD 301E

Benzyl alcohol:

Biodegradability : Result: rapidly biodegradable
Biodegradation: 92 - 96 %
Exposure time: 28 d
Method: OECD 301 C

Bioaccumulative potential

Components:

n-Butanol:

Partition coefficient: n-octanol/water : log Pow: 1
Method: OECD 117

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1,05

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : Do not allow to enter surface waters or groundwater.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material

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containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
n-Butanol	71-36-3	100	100 (F003)
n-Butanol	71-36-3	100	100 (F003)
n-Butanol	71-36-3	5000	*
n-Butanol	71-36-3	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Flammable (gases, aerosols, liquids, or solids)
Serious eye damage or eye irritation

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

n-Butanol 71-36-3 2,78 %

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

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The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermedi-ate or Final VOC's (40 CFR 60.489):

n-Butanol	71-36-3	2,78 %
Benzyl alcohol	100-51-6	1,85 %

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

n-Butanol	71-36-3
Benzyl alcohol	100-51-6

Pennsylvania Right To Know

n-Butanol	71-36-3
Benzyl alcohol	100-51-6

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

New York City Hazardous Substances

n-Butanol	71-36-3
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California List of Hazardous Substances

n-Butanol	71-36-3
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California Permissible Exposure Limits for Chemical Contaminants

n-Butanol	71-36-3
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International Regulations

Montreal Protocol (Ozone Depleting Substances) : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

Stockholm Convention (Persistent Organic Pollutants) : Not applicable

The components of this product are reported in the following inventories:

TSCA : Substance(s) not listed on TSCA inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

Health - 2 Flammability - 2 Instability - 0 Others -

HMIS® IV:

Health - 2 Flammability - 2 Instability - 0 Others -

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants -
1910.1000
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-
its for Air Contaminants
TRGS901 : TRGS 901, Explanations and Basis for Exposure Limits in the
Workplace Air
US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / C : Ceiling value not be exceeded at any time.
OSHA P0 / C : Ceiling limit
OSHA Z-1 / TWA : 8-hour time weighted average
TRGS901 / Bayer OES : BOES = Bayer Occupational Exposure Standard
US WEEL / TWA : 8-hr TWA

Revision Date : 06/23/2020

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