

# SAFETY DATA SHEET



## BAYTRIL 100

Version	Revision Date:	SDS Number:	Date of last issue: 01/19/2017
2.3	03/27/2020	122000007167	Date of first issue: 07/02/2010

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### 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

Bayer HealthCare, LLC  
Animal Health Division  
12707 Shawnee Mission Parkway  
(West 63rd)  
Shawnee, KS 66216-1846  
UNITED STATES OF AMERICA  
(800) 633-3796

In case of emergency: (800) 422-9874  
Chemtrec: (800) 424-9300  
BAYER INFORMATION PHONE:(800) 633-3796  
INTERNATIONAL:(703) 527-3887

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### 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

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for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

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 (NO<sub>x</sub>)



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## Carbon oxides

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

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

## 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.  
 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 <sup>3</sup>	TRGS901
			0.6 ml/m <sup>3</sup>	
n-Butanol	71-36-3	TWA	20 ppm	ACGIH
		C	50 ppm 150 mg/m <sup>3</sup>	NIOSH REL
		TWA	100 ppm 300 mg/m <sup>3</sup>	OSHA Z-1
		C	50 ppm	OSHA P0

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			150 mg/m3	
Benzyl alcohol	100-51-6	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.

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/cm<sup>3</sup> (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

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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<sub>x</sub>)  
Carbon oxides

**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.



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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.  
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.



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**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**

<b>IARC</b>	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
<b>OSHA</b>	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
<b>NTP</b>	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.
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**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.

**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



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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

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### 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 : EC50 (Daphnia magna (Water flea)): 1,983 mg/l  
aquatic invertebrates Exposure time: 48 h

##### **Benzyl alcohol:**

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

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### **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.

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

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## 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.

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### 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	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 %
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### 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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate 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
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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.

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:

Health - 2	Flammability - 2	Instability - 0	Others -
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#### HMIS® IV:

Health - 2	Flammability - 2	Instability - 0	Others -
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### Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits

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OSHA P0	:	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits 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

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