

SAFETY DATA SHEET



Baytril® solution for injection 10%

Version 2.1

Revision Date 12/13/2017

122000001099

Print Date 06/20/2018

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product information BAYTRIL INJ 10% 250ML

Product Name: Baytril® solution for injection 10%
SDS Number: 122000001099

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

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification according to national GHS implementation:

Flammable liquids, Category 3 (H226)
Skin irritation, Category 2 (H315)
Serious eye damage, Category 1 (H318)

Label elements

Labelling according to national GHS implementation:



Danger

Hazard statements:

H226 Flammable liquid and vapour.
H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary statements:

Prevention:
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.

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P242 Use only non-sparking tools.
P243 Take action to prevent static discharges.

Hazardous components which must be listed on the label:

Components:	CAS-No.
n-Butanol	71-36-3
Potassium hydroxide	1310-58-3

Other hazards

Inhalation may cause nausea or dizziness.

Causes eye irritation.

Inhalation Skin Absorption Skin contact Eye contact

ATTENTION!

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture.

Hazardous components

n-Butanol

Concentration [Weight percent] 2.899

CAS-No.: 71-36-3

CAS name: 1-Butanol

GHS Classification:



Flam. Liq. 3 H226
Eye Dam. 1 H318
STOT SE 3 H335, H336

Potassium hydroxide

Concentration [Weight percent] 1.787

CAS-No.: 1310-58-3

CAS name: Potassium hydroxide

GHS Classification:



Met. Corr. 1 H290
Acute Tox. 4 H302
Skin Corr. 1B H314
Eye Dam. 1 H318

contains

Enrofloxacin

Concentration [Weight percent] < 10

CAS-No.: 93106-60-6

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

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For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

Description of first aid measures

General advice: Take off all contaminated clothing immediately.

If inhaled: Remove to fresh air. Call a physician immediately.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: If swallowed, seek medical advice immediately and show this container or label.

Most important acute symptoms/effects

Indication of any immediate medical attention and special treatment needed

5. FIREFIGHTING MEASURES

Extinguishing media

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

Unsuitable extinguishing media: High volume water jet

Special hazards arising from the substance or mixture

Specific hazards during firefighting: 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.

Advice for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Use with adequate ventilation.

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Environmental precautions

Methods and materials for containment and cleaning up

Methods for 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.

Reference to other sections

Additional advice: Keep away from/remove sources of ignition.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling:

Avoid formation of aerosol. Use with local exhaust ventilation. Avoid contact with skin, eyes and clothing.

Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

Conditions for safe storage, including any incompatibilities

Specific end use(s)

No statements available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
n-Butanol	71-36-3	TWA	20 ppm	ACGIH
		C	50 ppm 150 mg/m ³	NIOSH REL
		TWA	100 ppm 300 mg/m ³	OSHA Z-1
		C	50 ppm 150 mg/m ³	OSHA P0
Potassium hydroxide	1310-58-3	C	2 mg/m ³	ACGIH
		C	2 mg/m ³	NIOSH REL
		C	2 mg/m ³	OSHA P0

Personal protective equipment

Respiratory protection : Recommended Filter type:
Organic vapor with prefilter

None required for consumer use of this product.

Hand protection

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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	:	Wear suitable protective equipment. Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form:	liquid	
Colour:	yellowish	
Odour:	weak Alcohol	
Melting point/range:	No statements available.	
Boiling point/boiling range:	ca. 100 °C	
Density:	1.024 g/cm ³ at 20 °C	
Bulk density:	Not applicable	
Vapour pressure:	No statements available.	
Viscosity, dynamic:	No statements available.	
Viscosity, kinematic:	No statements available.	
Flow time:	No statements available.	
Surface tension:	No statements available.	
Water solubility:	No statements available.	
Solubility(ies):	No statements available.	
pH:	10 - 11.5 (undiluted)	
Corrosive to metal:	No statements available.	
Partition coefficient (n-octanol/water):	n-Butanol log Pow: 1	OECD 117
Flash point:	54.5 °C	
Flammability (liquid):	Does not sustain combustion.	Method: Data on a comparable substance
Explosion limits:	n-Butanol upper: 11.3 %(V) lower: 1.4 %(V)	

Other information

Miscibility with water: in all proportions

10. STABILITY AND REACTIVITY

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Reactivity

No statements available.

Reactions with water / air:

No statements available.

Ignition temperature:

n-Butanol

355 °C DIN 51794

Burning number:

No statements available.

Flammability (liquids):

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Does not sustain combustion.

Method: Data on a comparable substance

Chemical stability

Thermal decomposition:

No data available

Dust explosion characteristic number:

Not applicable

Dust explosion class:

Not applicable

Impact sensitivity:

No data available

Hazardous reactions:

No data available

Explosive properties:

No statements available.

Possibility of hazardous reactions

deflagration ability:

No statements available.

Smoldering combustion:

No statements available.

Conditions to avoid

Do not allow product to come in contact with:

Exposure to light.

Heat

Protect from frost.

Minimum ignition energy:

No data available

Oxidizing properties:

No statements available.

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Incompatible materials

Materials to avoid:

Oxidizing agents

Hazardous decomposition products

Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, Nitrogen oxides (NOx), Carbon oxides

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin Absorption
Skin contact
Eye contact

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate (ATE): > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate (ATE): > 5,000 mg/kg
Method: Calculation method

Components:

Potassium hydroxide:

Acute oral toxicity : LD50 (Rat): 333 - 388 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

Skin corrosion/irritation

Components:

n-Butanol:

Species: Rabbit
Method: OECD 404
Result: Mild skin irritation

Potassium hydroxide:

Species: Rabbit
Assessment: Causes severe skin burns and eye damage.
Result: Causes burns.

Serious eye damage/eye irritation

Components:

n-Butanol:

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



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Method: OECD 405

Potassium hydroxide:

Species: Rabbit
Result: Irreversible effects on the eye
Assessment: Causes severe skin burns and eye damage.

Respiratory or skin sensitisation

Components:

n-Butanol:

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

Potassium hydroxide:

Species: Guinea pig
Result: Does not cause skin sensitisation.

Assessment: Harmful if swallowed., Causes severe skin burns and eye damage.

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
Species: 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.

Potassium hydroxide:

- Genotoxicity in vitro : Test Type: Ames test
Result: negative
- : Test Type: Bacterial mutagenicity
Species: Escherichia coli

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Result: negative

Carcinogenicity

IARC

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.

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.

Components:

Potassium hydroxide:

Repeated dose toxicity - Assessment : Harmful if swallowed., Causes severe skin burns and eye damage.

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**
Change in righting reflex

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Liver disorders
drowsiness
Headache
Weakness

Potassium hydroxide:

Remarks: **May cause blindness.**

If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach.

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

Potassium hydroxide:

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 80 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 22 mg/l
Exposure time: 15 min

Ecotoxicology Assessment

Acute aquatic toxicity : Neutralisation will reduce ecotoxic effects.

Persistence and degradability

Components:

n-Butanol:

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

Potassium hydroxide:

Biodegradability : Remarks: The methods for determining the biological degradability are not applicable to inorganic substances.

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Bioaccumulative potential

Components:

n-Butanol:

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

Potassium hydroxide:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Mobility in soil

No data available

Other adverse effects

Product:

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

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)

14. TRANSPORT INFORMATION

US Land transport (CFR)

non-regulated

Sea transport (IMDG)

non-regulated

Air transport (IATA)

non-regulated

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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)
Potassium hydroxide	1310-58-3	1000	*

*: 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)
Skin corrosion or irritation
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 2.899 %

US State Regulations

Massachusetts Right To Know

n-Butanol 71-36-3
Potassium hydroxide 1310-58-3

Pennsylvania Right To Know

n-Butanol 71-36-3
Potassium hydroxide 1310-58-3

New York City Hazardous Substances

n-Butanol 71-36-3
Potassium hydroxide 1310-58-3

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

California List of Hazardous Substances

n-Butanol 71-36-3
Potassium hydroxide 1310-58-3

California Permissible Exposure Limits for Chemical Contaminants

n-Butanol 71-36-3
Potassium hydroxide 1310-58-3

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

TSCA : Not On TSCA Inventory

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TSCA list

No substances are subject to a Significant New Use Rule.

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

16. OTHER INFORMATION

Full text of H-Statements mentioned in chapters 2 and 3

H226	Flammable liquid and vapour.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.