

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078950711

N/A

# SAFETY DATA SHEET



## Baytril® 2.27% Injectable Solution

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/23/2020	122000007148	Date of first issue: 23.06.2020

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### SECTION 1. IDENTIFICATION

#### Product information

Product Name : Baytril® 2.27% Injectable Solution  
SDS Number : 122000007148

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)

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with 29 CFR 1910.1200

Serious eye damage : Category 1

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.

Precautionary statements : **Prevention:**  
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.  
P310 Immediately call a POISON CENTER/doctor.

#### Other hazards

None known.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

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Chemical name	CAS-No.	Concentration (% w/w)
n-Butanol	71-36-3	3

### 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:  
Nitrogen oxides (NO<sub>x</sub>)  
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.  
No special precautions required.
- Methods and materials for containment and cleaning up : Cover spilled product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labeled, closable containers.

### SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Industrial uses:  
Take measures to prevent the build up of electrostatic charge.  
Keep away from open flames, hot surfaces and sources of ignition.
- Advice on safe handling : Industrial uses:  
Avoid formation of aerosol.  
Avoid contact with skin, eyes and clothing.
- Recommended storage temperature : > 32 °F / > 0 °C

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Further information on storage stability : Do not freeze.

### SECTION 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
		TWA	20 ppm	ACGIH
		C	50 ppm 150 mg/m <sup>3</sup>	NIOSH REL
		C	50 ppm 150 mg/m <sup>3</sup>	NIOSH REL
		TWA	100 ppm 300 mg/m <sup>3</sup>	OSHA Z-1
		TWA	100 ppm 300 mg/m <sup>3</sup>	OSHA Z-1
		C	50 ppm 150 mg/m <sup>3</sup>	OSHA P0
		C	50 ppm 150 mg/m <sup>3</sup>	OSHA P0

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

Hygiene measures : Cleanliness Guidelines (GMP) for manufacturing of drugs  
must be observed!

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid  
Colour : yellowish  
Odour : slight, Alcohol  
pH : 11,1 - 11,5

Flash point : 127,0 °F / 52,8 °C

Flammability (liquids) : Does not sustain combustion.  
Method: Data on a comparable substance

Density : 0,95 - 1,05 g/cm<sup>3</sup>

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Solubility(ies)	
Water solubility	: soluble
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Explosive properties	: No statements 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. Heat Protect from frost.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: Nitrogen oxides (NOx) Carbon oxides

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

##### Product:

Acute oral toxicity	: Acute toxicity estimate (ATE): > 2.000 mg/kg Method: Calculation method Assessment: May be harmful if swallowed. Remarks: Calculated for GHS Classification and Labelling.
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.
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#### Skin corrosion/irritation

##### Components:

##### **n-Butanol:**

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

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

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

**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.

**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.

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**STOT - single exposure****Components:****n-Butanol:**

Assessment : May cause respiratory irritation.

Exposure routes : Inhalation

Assessment : May cause drowsiness or dizziness.

**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

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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

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**Persistence and degradability****Components:****n-Butanol:**

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

**Bioaccumulative potential****Components:****n-Butanol:**

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

**Mobility in soil**

No data available

**Other adverse effects****Product:**

Additional ecological infor- : Do not allow to enter surface waters or groundwater.  
mation No data is available on the product itself.

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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.

**National Regulations****49 CFR**

Not regulated as a dangerous good



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### 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** : Exempt from SARA Section 311/312  
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	3 %
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#### US State Regulations

##### Massachusetts Right To Know

n-Butanol	71-36-3
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##### 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 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

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

	: This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.
TSCA	: Not 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 - 0	Instability - 0	Others - 0
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#### HMIS® IV:

Health - 2	Flammability - 0	Instability -	Others -
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### 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 Limits for Air Contaminants
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

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