

## **SAFETY DATA SHEETS**

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

078041073

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078041081



## SAFETY DATA SHEET

### Baytril® Film-coated Tablets

Version 2.0

Revision Date 11/23/2016

122000007209  
Print Date 11/23/2016

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

##### Product information

**Product Name:** Baytril® Film-coated Tablets  
**SDS Number:** 122000007209

**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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#### 2. HAZARDS IDENTIFICATION

##### Classification of the substance or mixture

Not a dangerous substance / mixture according to GHS.

##### Label elements

**Labelling according to national GHS implementation:**  
Not a dangerous substance / mixture according to GHS.

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#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture.

##### Hazardous components

Substances with a workplace exposure limit

##### Cellulose

Concentration [Weight percent]  $\geq 10$  -  $< 20$   
CAS-No.: 9004-34-6  
CAS name: Cellulose  
Synonyms: cellulose, Cellulose microcrystalline

##### Enrofloxacin

Concentration [Weight percent]  $\geq 5$  -  $< 10$   
CAS-No.: 93106-60-6  
CAS name: 3-Quinolincarboxylic acid, 1,4-dihydro-1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-4-



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OXO-

Synonyms: 1-Cyclopropyl-7-(1-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinoline, Baytril active ingredient

#### Talcum

Concentration [Weight percent]  $\geq 1$  -  $< 5$

CAS-No.: 14807-96-6

CAS name: Talc ( $\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$ )

Synonyms: Talc ( $\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$ ), Talc ( $\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$ ) (Without asbestos), Talc ( $\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$ ) (Containing no asbestos and less than 1% quartz), Talc ( $\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$ ) (Grounded or powdered), Talc ( $\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$ ) (Non-fibrous), Talc ( $\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$ ) ( $< 10\%$  free silicium dioxide), Talc ( $\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$ ) (Containing no asbestos fibres), Agalite, Magnesiumsilikat

#### Magnesium distearate

Concentration [Weight percent]  $\geq 1$  -  $< 5$

CAS-No.: 557-04-0

CAS name: Octadecanoic acid, magnesium salt (2:1)

Synonyms: magnesium distearate

#### titanium dioxide

Concentration [Weight percent]  $\geq 0.1$  -  $< 1$

CAS-No.: 13463-67-7

CAS name: Titanium oxide ( $\text{TiO}_2$ )

Synonyms: titanium dioxide, titanium dioxide (Containing less than 2 % free crystalline silica and no asbestos)

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## 4. FIRST AID MEASURES

### Description of 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 irritation persists, call 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 acute symptoms/effects

### Indication of any immediate medical attention and special treatment needed

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## 5. FIREFIGHTING MEASURES

### Extinguishing media

**Suitable extinguishing media:** Any

### Special hazards arising from the substance or mixture

**Specific hazards during firefighting:** Fire may cause evolution of: Carbon monoxide (CO) Carbon



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dioxide (CO<sub>2</sub>)

**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.

### Environmental precautions

### Methods and materials for containment and cleaning up

**Methods for cleaning up:** Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

### Reference to other sections

**Additional advice:** Avoid dust formation.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

#### Handling:

Industrial uses: Avoid dust formation. Avoid contact with skin, eyes and clothing.

**No special protective measures against fire required.**

### Conditions for safe storage, including any incompatibilities

**Storage temperature:** 30 °C

### Specific end use(s)

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL



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		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
Enrofloxacin	93106-60-6	OEL (Bayer)	0.6 mg/m <sup>3</sup>	
		OEL (Bayer)	2.4 mg/m <sup>3</sup>	
Talcum	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable)	2 mg/m <sup>3</sup>	NIOSH REL
		TWA (Respirable fraction)	2 mg/m <sup>3</sup>	ACGIH
Magnesium distearate	557-04-0	TWA	10 mg/m <sup>3</sup>	ACGIH
titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	10 mg/m <sup>3</sup>	OSHA P0

**Personal protective equipment**

Respiratory protection : Recommended Filter type:  
HEPA

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.



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#### 9. PHYSICAL AND CHEMICAL PROPERTIES

##### Information on basic physical and chemical properties

Form:	tablet
Colour:	purple
Odour:	slight musty
Melting point/range:	No statements available.
Boiling point/boiling range:	No statements available.
Density:	No statements available.
Bulk density:	No statements available.
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:	No statements available.
Partition coefficient (n-octanol/water):	Magnesium distearate log Pow: 0.8
Flash point:	Not applicable
Inflammability (solid, gaseous):	No statements available.
Explosion limits:	No statements available.

OECD 107

##### Other information

Miscibility with water:	Not applicable
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#### 10. STABILITY AND REACTIVITY

##### Reactivity

No statements available.

##### Reactions with water / air:

No statements available.

##### Ignition temperature:

##### Cellulose

420 °C

##### Burning number:

##### Cellulose

at 20 °C Burning with flames or flying sparks.

##### Burning number:

##### Enrofloxacin

at 20 °C The product is flammable but not readily ignited.

##### Burning number:

##### Talcum



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at 20 °C The product is not flammable.

**Burning number:**

**Magnesium distearate**

Method: VDI 2263 The product is flammable but not readily ignited.

**Flammability (solid, gas):**

**titanium dioxide**

Product is not highly flammable.

**Chemical stability**

**Thermal decomposition:**

No data available

**Dust explosion characteristic number:**

No statements available.

**Dust explosion class:**

No data available

**Impact sensitivity:**

No data available

**Hazardous reactions:**

None known.

**Explosive properties:**

No statements available.

**Possibility of hazardous reactions**

**deflagration ability:**

No statements available.

**Smoldering combustion:**

No statements available.

**Conditions to avoid**

No data available

**Minimum ignition energy:**

No data available

**Oxidizing properties:**

No statements available.

**Incompatible materials**

**Materials to avoid:**

Oxidizing agents

**Hazardous decomposition products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)



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#### 11. TOXICOLOGICAL INFORMATION

##### 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:

###### **Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : LC50 (Rat): > 5.05 mg/l  
Exposure time: 4 h

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

###### **Enrofloxacin:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : LC50 (Rat): > 2.937 mg/l  
Exposure time: 4 h  
Assessment: The substance or mixture has no acute inhalation toxicity  
Remarks: An LC50/inhalation/4h/rat could not be determined because no mortality of rats was observed at the maximum achievable concentration.

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: May be harmful in contact with skin.

###### **Talcum:**

Acute oral toxicity : Assessment: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : Assessment: No adverse effect has been observed in acute toxicity tests.

Acute toxicity (other routes of administration) : LD50 (Rat): 280 mg/kg  
Application Route: intraperitoneal





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#### **Magnesium distearate:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

#### **titanium dioxide:**

Acute oral toxicity : LD50 (Rat): > 10,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.8 mg/l  
Exposure time: 4 h

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

#### **Skin corrosion/irritation**

##### **Components:**

##### **Cellulose:**

Species: Rabbit

Result: No skin irritation

##### **Enrofloxacin:**

Species: Rabbit

Method: OECD Test Guideline 404

Result: No skin irritation

##### **Talcum:**

Result: Mild skin irritation

#### **Magnesium distearate:**

Species: Rabbit

Method: Draize Test

Result: No skin irritation

#### **titanium dioxide:**

Result: No skin irritation

Remarks: TiO<sub>2</sub> pigments are not irritant but as with all fine powders can adsorb moisture and natural oils from the surface of the skin during prolonged exposure.

#### **Serious eye damage/eye irritation**

##### **Components:**

##### **Cellulose:**

Species: Rabbit

Result: No eye irritation

##### **Enrofloxacin:**

Species: Rabbit

Result: Mild eye irritation



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Method: OECD 405

**Talcum:**

Result: Mild eye irritation

**Magnesium distearate:**

Species: Rabbit

Result: No eye irritation

Method: Draize Test

**titanium dioxide:**

Result: No eye irritation

Remarks: Possibly mechanical irritation

### Respiratory or skin sensitisation

**Components:**

**Cellulose:**

Test Type: Skin sensitisation

Species: Guinea pig

Result: Did not cause sensitisation on laboratory animals.

Assessment: An acute toxic effect is not expected.

**Enrofloxacin:**

Test Type: Skin sensitisation

Species: Guinea pig

Method: Buehler Test

Result: Did not cause sensitisation on laboratory animals.

Assessment: May be harmful in contact with skin.

**Talcum:**

Result: Does not cause respiratory sensitisation.

Result: Does not cause skin sensitisation.

**Magnesium distearate:**

Assessment: An acute toxic effect is not expected.

### Germ cell mutagenicity

**Components:**

**Cellulose:**

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



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

#### **Enrofloxacin:**

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

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Result: No indication of clastogenic effects.

#### **Talcum:**

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

#### **Magnesium distearate:**

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

#### **Carcinogenicity**

##### **IARC**

Group 2B: Possibly carcinogenic to humans

titanium dioxide 13463-67-7

##### **OSHA**

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

##### **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:**

##### **Talcum:**

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

#### **STOT - repeated exposure**

##### **Components:**

##### **Talcum:**

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



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#### Components:

##### **Cellulose:**

Repeated dose toxicity - Assessment : An acute toxic effect is not expected.

##### **Enrofloxacin:**

Repeated dose toxicity - Assessment : May be harmful in contact with skin.

##### **Magnesium distearate:**

Repeated dose toxicity - Assessment : An acute toxic effect is not expected.

#### **Aspiration toxicity**

#### Components:

##### **Talcum:**

No aspiration toxicity classification

#### **Further information**

#### Components:

##### **titanium dioxide:**

Remarks: As with any nuisance dust, long-term exposure to concentrations of dust above the recommended exposure level may overload lung clearance mechanism and cause adverse lung effects.

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## 12. ECOLOGICAL INFORMATION

#### **Ecotoxicity**

#### Components:

##### **Cellulose:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Test Type: Acute Fish toxicity

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h

Toxicity to algae : EC50: > 100 mg/l  
Exposure time: 96 h

NOEC: 12.5 mg/l  
Exposure time: 96 h



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#### Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

#### Enrofloxacin:

Toxicity to fish : LC0 (Salmo gairdneri): > 10 mg/l  
Exposure time: 96 h  
Test Type: Acute Fish toxicity  
  
LC0 (Lepomis macrochirus (Bluegill)): > 9.6 mg/l  
Exposure time: 96 h  
Test Type: Acute Fish toxicity

Toxicity to daphnia and other aquatic invertebrates : EC0 (Daphnia magna (Water flea)): > 10 mg/l  
Exposure time: 48 h

Toxicity to bacteria : EC0 (Pseudomonas putida): 0.003 mg/l

Toxicity to soil dwelling organisms : LC50 (Eisenia fetida (earthworms)): > 10 mg/l  
Exposure time: 28 d

#### Ecotoxicology Assessment

Acute aquatic toxicity : slightly water endangering

#### Talcum:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10 g/l  
Exposure time: 24 h

#### Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

#### Magnesium distearate:

#### Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

#### titanium dioxide:

Toxicity to fish : LC50 (Cyprinodon sp. (minnow)): 240 - 370 mg/l  
Exposure time: 96 h  
Test Type: Acute Fish toxicity  
  
Toxicity to daphnia and other aquatic invertebrates : LC50 (Mysidopsis almyra (Opposum shrimp)): 300 - 400 mg/l  
Exposure time: 96 h

#### Persistence and degradability

#### Components:

#### Cellulose:

Biodegradability : Remarks: Inherently degradable



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#### **Talcum:**

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

#### **titanium dioxide:**

Biodegradability : Remarks: Pigments are practically not biodegradable.

#### **Bioaccumulative potential**

##### **Components:**

##### **Magnesium distearate:**

Partition coefficient: n-octanol/water : log Pow: 0.8  
Method: OECD 107

##### **titanium dioxide:**

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. No data is available on the product itself.**

##### **Components:**

##### **titanium dioxide:**

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

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## 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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## 14. TRANSPORT INFORMATION



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**US Sea transport (IMDG)**  
non-regulated

**US Air transport (ICAO / IATA cargo aircraft only)**  
non-regulated

**US Air transport (ICAO / IATA passenger and cargo aircraft)**  
non-regulated

**US Land transport (CFR)**  
non-regulated

**Land transport TDG**  
non-regulated

## 15. REGULATORY INFORMATION

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

#### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

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

**SARA 311/312 Hazards** : No SARA Hazards

### US State Regulations

#### Massachusetts Right To Know

Cellulose	9004-34-6	10 - 20 %
Talcum	14807-96-6	1 - 5 %

#### Pennsylvania Right To Know

Cellulose	9004-34-6	10 - 20 %
Talcum	14807-96-6	1 - 5 %

#### New Jersey Right To Know

Cellulose	9004-34-6	10 - 20 %
Talcum	14807-96-6	1 - 5 %

#### New York City Hazardous Substances

titanium dioxide	13463-67-7	0.1 - 1 %
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#### 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

Talcum	14807-96-6
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#### California Permissible Exposure Limits for Chemical Contaminants

Talcum

14807-96-6

#### 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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## 16. OTHER INFORMATION

### 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.