# This SDS packet was issued with item:

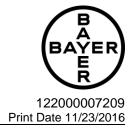
078041073

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

# **Baytril® Film-coated Tablets**

Version 2.0 Revision 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

#### 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture.

# **Hazardous components**

Substances with a workplace exposure limit

#### Cellulose

Concentration [Weight percent] >= 10 - < 20

CAS-No.: 9004-34-6 CAS name: Cellulose

Synonyms: cellulose, Cellulose microcrystalline

# **Enrofloxacin**

Concentration [Weight percent] >= 5 - < 10

CAS-No.: 93106-60-6

CAS name: 3-Quinolinecarboxylic acid, 1,4-dihydro-1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-4-

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охо-

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

ingredient

**Talcum** 

Concentration [Weight percent] >= 1 - < 5

CAS-No.: 14807-96-6

CAS name: Talc (Mg3H2(SiO3)4)

Synonyms: Talc (Mg3H2(SiO3)4), Talc (Mg3H2(SiO3)4) (Without asbestos), Talc (Mg3H2(SiO3)4) (Containing no asbestos and less than 1% quartz), Talc (Mg3H2(SiO3)4) (Grounded or powdered), Talc

(Mg3H2(SiO3)4) (Non-fibrous), Talc (Mg3H2(SiO3)4) (< 10% free silicium dioxide), Talc

(Mg3H2(SiO3)4) (Containing no asbestos fibres), Agalite, Magnesiumsilikat

Magnesium distearate

Concentration [Weight percent] >= 1 - < 5

CAS-No.: 557-04-0

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

Synonyms: magnesium distearate

titanium dioxide

Concentration [Weight percent] >= 0.1 - < 1

CAS-No.: 13463-67-7

CAS name: Titanium oxide (TiO2)

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

asbestos)

#### 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

### 5. FIREFIGHTING MEASURES

Extinguishing media

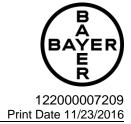
Suitable extinguishing media: Any

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 (CO2)

**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	Control	Basis
		(Form of	parameters /	
		exposure)	Permissible	
			concentration	
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA	5 mg/m3	NIOSH REL
		(Respirable)	_	
		TWA (total)	10 mg/m3	NIOSH REL



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		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	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/m3	NIOSH REL
		TWA (Respirable fraction)	2 mg/m3	ACGIH
Magnesium distearate	557-04-0	TWA	10 mg/m3	ACGIH
titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0

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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 pharmaceutials 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. No statements available. Vapour pressure: 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 Magnesium distearate OECD 107

(n-octanol/water): log Pow: 0.8 Flash point: Not applicable

Inflammability (solid, gaseous): No statements available. Explosion limits: No statements available.

Other information

Miscibility with water: Not applicable

#### 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.

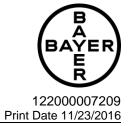
**Burning number:** 

**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 (CO2)

# **Baytril® Film-coated Tablets**





### 11. TOXICOLOGICAL INFORMATION

**Acute toxicity** 

Product:

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

Method: Calculation method

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

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.

: LC50 (Rat): > 5.05 mg/l Acute inhalation toxicity

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.

: LC50 (Rat): > 2.937 mg/l Acute inhalation toxicity

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:

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

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 : LD50 (Rat): 280 mg/kg

administration)

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: TiO2 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

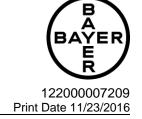
### **Enrofloxacin:**

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.

12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Components:** 

Cellulose:

: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Toxicity to fish

Exposure time: 96 h

Test Type: Acute Fish toxicity

aquatic invertebrates

Toxicity to daphnia and other : 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

aquatic invertebrates

Toxicity to daphnia and other : EC0 (Daphnia magna (Water flea)): > 10 mg/l

Exposure time: 48 h

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

Toxicity to soil dwelling

organisms

: LC50 (Eisenia fetida (earthworms)):

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** 

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

titanium dioxide:

: LC50 (Cyprinodon sp. (minnow)): 240 - 370 mg/l Toxicity to fish

Exposure time: 96 h

Test Type: Acute Fish toxicity

aquatic invertebrates

Toxicity to daphnia and other : LC50 (Mysidopsis almyra (Opposum shrimp)): 300 - 400 mg/l

Exposure time: 96 h

Persistence and degradability

**Components:** 

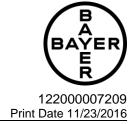
Cellulose:

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.

### 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

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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 %

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

# **Baytril® Film-coated Tablets**

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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.

### 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.