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SAFETY DATA SHEET

122000003885

Baytril Otic

Version 2.0

Revision Date 09/02/2015

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

Product information

Product Name: Baytril Otic
SDS Number: 122000003885

Use : veterinary medicine

Company

BAYER HEALTHCARE LLC
Animal Health Division
12707 Shawnee Mission Parkway
(West 63rd)
Shawnee, KS 66216-1846
USA
(800) 633-3796

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

2. HAZARDS IDENTIFICATION

Emergency Overview

Colour: white **Form:** liquid **Odour:** slight, like fruit.

GHS Classification:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

GHS Label element:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Other hazards which do not result in classification:

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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Hazardous Ingredients:

Weight percent	Components	CAS-No.
1%	Silver sulfadiazine-I	22199-08-2
1 - 5%	Alcohol derivative	

NOT HD

Other Ingredients

Weight percent	Components	CAS-No.
0.5%	Enrofloxacin	93106-60-6

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately. Consult a physician if necessary.

If inhaled: Remove to fresh air.

Oxygen or artificial respiration if needed.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water.

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

In case of eye contact: Immediately flush eye(s) with plenty of water. If eye irritation persists, consult a specialist.

If swallowed: If the patient is conscious, rinse out mouth with water and have the patient drink a glass of water or milk to dilute the material.

Contact Number: Use the Bayer Emergency Number in Section 1

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 firefighting: Fire may cause evolution of: Sulphur oxides Nitrogen oxides (NOx) Carbon oxides

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

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

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6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for 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.

Additional advice: No special precautions required.

Further Accidental Release Notes No special precautions required.

7. HANDLING AND STORAGE**Handling:**

Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.

Storage:

Store at temperatures and conditions as indicated on the product label.

Storage temperature: 39.2 - 77 °F (4 - 25 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Respiratory protection:**

not required

Hand protection:

Chemically resistant gloves.

None required for consumer use of this product.

Eye protection:

Safety glasses

Safety glasses with side-shields

None required for consumer use of this product.

Other protective measures:

Use general room ventilation.

Please consult label for end-user requirements.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	liquid
Colour:	white
Odour:	slight, like fruit
Odour Threshold:	No applicable information is available
Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	0.985 g/cm ³ at 68 °F (20 °C) at 1,013 hPa
Bulk density:	No applicable information is available
Vapour pressure:	No applicable information is available
Viscosity, dynamic:	No applicable information is available
Viscosity, kinematic:	No applicable information is available
Flow time:	No applicable information is available
Surface tension:	No applicable information is available
Miscibility with water:	emulsifiable
Water solubility:	No applicable information is available
pH:	3.5 - 7.5
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	> 200 °F (> 93.33 °C)
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

10. STABILITY AND REACTIVITY

Conditions to avoid: Do not allow product to come in contact with:

Heat

Protect from frost.

Materials to avoid: Oxidizing agents

Hazardous reactions: No data available

Thermal decomposition:

No data available

Hazardous decomposition products:

Sulphur oxides, Nitrogen oxides (NOx), Carbon oxides

Oxidizing properties:

No statements available.

11. TOXICOLOGICAL INFORMATION

Acute oral toxicity:

Acute toxicity estimate (ATE) > 2,000 mg/kg

May be harmful if swallowed.

Method: Calculation method

Calculated for GHS Classification and Labelling.

Acute inhalation toxicity:

Acute toxicity estimate (ATE) > 20 mg/l

May be harmful if inhaled.

Method: Calculation method

Calculated for GHS Classification and Labelling.

Acute dermal toxicity:

Enrofloxacin

LD50 Rabbit: > 2,000 mg/kg

Skin irritation:

Enrofloxacin

Rabbit

Result: No skin irritation

Method: OECD 404

Eye irritation:

Enrofloxacin

Rabbit

Result: Mild eye irritation

Method: OECD 405

Sensitisation:

Enrofloxacin

Skin sensitization guinea pig

Result: Did not cause sensitisation on laboratory animals.

Method: Buehler Test

Genotoxicity in vitro:

Enrofloxacin

Ames test

Result: negative

Genotoxicity in vivo:

Enrofloxacin

Micronucleus test, Mouse

Result: No indication of clastogenic effects.

Pharmaceutic effects:

Antibiotic

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Carcinogenicity:

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

STOT - single exposure:**Components:****100-51-6 :**

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

STOT - repeated exposure:**Components:****100-51-6 :**Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

12. ECOLOGICAL INFORMATION**General advice:**

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Enrofloxacin

Acute Fish toxicity: LC0 > 10 mg/l

Test species: *Salmo gairdneri* Duration of test: 96 h

Acute Fish toxicity: LC0 > 9.6 mg/l

Test species: *Lepomis macrochirus* (Bluegill) Duration of test: 96 h**Toxicity to daphnia and other aquatic invertebrates:**

Enrofloxacin

EC0 > 10 mg/l

Test species: *Daphnia magna* (Water flea) Duration of test: 48 h**Toxicity to bacteria:**

Enrofloxacin

EC0 0.003 mg/l

tested on: *Pseudomonas putida***Toxicity on soil-dwelling organisms**

Enrofloxacin LC50 1000 ppm

Test species: *Eisenia fetida* (earthworms) Duration of test: 28 d**Photodegradation:**

Enrofloxacin

Water

half-life time (direct Photolysis): > 240 h

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13. DISPOSAL CONSIDERATIONS

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)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

14. TRANSPORT INFORMATION**Land transport (CFR)**

non-regulated

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

International IATA

IMDG

non-regulated

non-regulated

15. REGULATORY INFORMATION

Other regulations: No statements available.

US. Toxic Substances Control Act This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)

Components

None

SARA Section 311/312 Hazard

Exempt from SARA Section 311/312

Categories

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required

Components

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components

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Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
1 - 5%	Silver sulfadiazine-I	22199-08-2
1 - 5%	Alcohol derivative	

New Jersey Environmental Hazardous Substances List and/or New Jersey RTK Special Hazardous Substances Lists

Weight percent	Components	CAS-No.
1 - 5%	Silver sulfadiazine-I	22199-08-2

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Hazardous

16. OTHER INFORMATION

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.