

SAFETY DATA SHEET



Baytril Otic

Version 1.0 Revision Date: 06/24/2020 SDS Number: 122000003885 Date of last issue: -
Date of first issue: 24.06.2020

SECTION 1. IDENTIFICATION

Product information

Product Name : Baytril Otic
SDS Number : 122000003885

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)

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzyl alcohol	100-51-6	2
Alcohols, C16-18	8005-44-5	1,5
Silver sulfadiazine-I	22199-08-2	1

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.

SAFETY DATA SHEET



Baytril Otic

Version 1.0 Revision Date: 06/24/2020 SDS Number: 122000003885 Date of last issue: -
Date of first issue: 24.06.2020

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:
Sulphur oxides
Nitrogen oxides (NO_x)
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 : No special protective measures against fire required.
- Advice on safe handling : Industrial uses:
Avoid formation of aerosol.
Avoid contact with skin, eyes and clothing.
- Recommended storage temperature : 39 - 77 °F / 4 - 25 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polysorbate 60	9005-67-8	TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Respirable fraction)	3 mg/m ³	ACGIH
		TWA (Respirable fraction)	3 mg/m ³	ACGIH

SAFETY DATA SHEET



Baytril Otic

Version 1.0 Revision Date: 06/24/2020 SDS Number: 122000003885 Date of last issue: -
Date of first issue: 24.06.2020

Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
		TWA	10 ppm	US WEEL

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 : white
Odour : slight, fruity
pH : 3,5 - 7,5

Flash point : > 200 °F / > 93 °C

Density : 0,985 g/cm³ (68 °F / 20 °C, 1.013 hPa)

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:
Heat
Protect from frost.

Incompatible materials : Oxidizing agents
Hazardous decomposition products : Sulphur oxides
Nitrogen oxides (NO_x)
Carbon oxides

Baytril Otic

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/24/2020	122000003885	Date of first issue: 24.06.2020

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity**Product:**

Acute oral toxicity : Acute toxicity estimate (ATE): > 5.000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate (ATE): > 200 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Components:**Benzyl alcohol:**

Acute oral toxicity : LD50 (Rat, male): 1.620 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Alcohols, C16-18:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Skin corrosion/irritation**Components:****Benzyl alcohol:**

Species : Rabbit
Method : OECD 404
Result : No skin irritation

Alcohols, C16-18:

Species : Rabbit
Method : OECD 404
Result : non-irritant

Silver sulfadiazine-I:

Result : irritating

Serious eye damage/eye irritation**Components:****Benzyl alcohol:**

Species : Rabbit
Result : Irritation to eyes, reversing within 7 days
Method : OECD 405

Baytril Otic

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/24/2020	122000003885	Date of first issue: 24.06.2020

Alcohols, C16-18:

Species	:	Rabbit
Result	:	Mild eye irritation
Method	:	OECD 405

Silver sulfadiazine-I:

Result	:	Eye irritation
--------	---	----------------

Respiratory or skin sensitisation**Components:****Benzyl alcohol:**

Species	:	Guinea pig
Method	:	Magnusson and Kligmann maximization test
Result	:	Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity**Components:****Benzyl alcohol:**

Genotoxicity in vitro	:	Test Type: Ames test Result: negative
Genotoxicity in vivo	:	Result: No indication of mutagenic effects.

Alcohols, C16-18:

Genotoxicity in vitro	:	Test Type: Ames test 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:****Benzyl alcohol:**

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

SAFETY DATA SHEET



Baytril Otic

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/24/2020	122000003885	Date of first issue: 24.06.2020

Silver sulfadiazine-I:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Components:

Benzyl alcohol:

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

Repeated dose toxicity

Components:

Benzyl alcohol:

Species	: Rat
NOAEL	: 400 mg/kg
Exposure time	: 90-day

Further information

Product:

Pharmaceutic effects
Remarks : Antibiotic

Components:

Benzyl alcohol:

Remarks : Dermal absorption possible

Remarks : If inhaled:
irritations
Shortness of breath
Cough

Remarks : If swallowed
Vomiting
Nausea
Irritation of mucous membranes in the mouth, throat, gullet
and gastro-intestinal tract after swallowing.

Remarks : Systemic toxicity
Headache
Nausea
CNS disorders
Ataxia (uncontrolled movements)
Unconsciousness
cessation of breathing

Baytril Otic

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/24/2020	122000003885	Date of first issue: 24.06.2020

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Benzyl alcohol:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 10 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 71,4 mg/l
Exposure time: 0,5 h

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.

Alcohols, C16-18:

Toxicity to microorganisms : EC0: > 100 mg/l
Test substance: Data on a comparable substance

Ecotoxicology Assessment

Acute aquatic toxicity : slightly hazardous to water

Silver sulfadiazine-I:**Ecotoxicology Assessment**

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

Persistence and degradability**Components:****Benzyl alcohol:**

Biodegradability : Result: rapidly biodegradable
Biodegradation: 92 - 96 %
Exposure time: 28 d
Method: OECD 301 C

Alcohols, C16-18:

Biodegradability : Result: rapidly biodegradable
Biodegradation: > 60 %

Bioaccumulative potential**Components:****Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1,05

SAFETY DATA SHEET



Baytril Otic

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/24/2020	122000003885	Date of first issue: 24.06.2020

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.

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)

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

SECTION 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 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
No SARA Hazards

SAFETY DATA SHEET



Baytril Otic

Version 1.0	Revision Date: 06/24/2020	SDS Number: 122000003885	Date of last issue: - Date of first issue: 24.06.2020
----------------	------------------------------	-----------------------------	--

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Silver sulfadiazine-I	22199-08-2	1 %
-----------------------	------------	-----

US State Regulations

Massachusetts Right To Know

Benzyl alcohol	100-51-6
----------------	----------

Pennsylvania Right To Know

Benzyl alcohol	100-51-6
Silver sulfadiazine-I	22199-08-2

New York City Hazardous Substances

Silver sulfadiazine-I	22199-08-2
-----------------------	------------

California List of Hazardous Substances

Silver sulfadiazine-I	22199-08-2
-----------------------	------------

International Regulations

Montreal Protocol (Ozone Depleting Substances) : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

Stockholm Convention (Persistent Organic Pollutants) : Not applicable

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

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 - 1	Flammability - 1	Instability - 0	Others -
------------	------------------	-----------------	----------

HMIS® IV:

Health - 0	Flammability - 1	Instability - 0	Others -
------------	------------------	-----------------	----------

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
US WEEL	: USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	: 8-hour, time-weighted average
US WEEL / TWA	: 8-hr TWA

SAFETY DATA SHEET



Baytril Otic

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/24/2020	122000003885	Date of first issue: 24.06.2020

Revision Date : 06/24/2020

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.

US / EN