

SAFETY DATA SHEETS

This SDS packet was issued with item:

078925055

N/A

SAFETY DATA SHEET



Claro® Otic Solution

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

SECTION 1. IDENTIFICATION

Product information

Product Name : Claro® Otic Solution
SDS Number : 122000013292

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Flammable liquids : Category 3
Eye irritation : Category 2A

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H226 Flammable liquid and vapour.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces.
No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting equip-
ment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.

SAFETY DATA SHEET



Claro® Otic Solution

Version 4.0 Revision Date: 10/08/2019 SDS Number: 122000013292 Date of last issue: 11/27/2018
Date of first issue: 08/11/2015

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Propylene carbonate	108-32-7	49.9999
Ethanol	64-17-5	6
Terbinafine Hydrochloride	78628-80-5	1.5

SECTION 4. FIRST AID MEASURES

General advice : No hazards which require special first aid measures.

If inhaled : If symptoms persist, call a physician.

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.

Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing

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:
Carbon monoxide (CO)
Carbon dioxide (CO₂)

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

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

SAFETY DATA SHEET



Claro® Otic Solution

Version 4.0 Revision Date: 10/08/2019 SDS Number: 122000013292 Date of last issue: 11/27/2018
Date of first issue: 08/11/2015

for firefighters

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.
Keep away from/remove sources of ignition.

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 : Keep away from open flames, hot surfaces and sources of ignition.
Take measures to prevent the build up of electrostatic charge.

Advice on safe handling : Avoid formation of aerosol.

Conditions for safe storage : Store at temperatures and conditions as indicated on the product label.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propane-1,2-diol	57-55-6	TWA	10 mg/m ³	US WEEL
Polyethyleneglycol	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL
Ethanol	64-17-5	STEL	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m ³	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m ³	OSHA Z-1
		TWA	1,000 ppm 1,900 mg/m ³	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.

SAFETY DATA SHEET



Claro® Otic Solution

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	clear, yellowish
pH	:	4.0 - 6.0 (77 °F / 25 °C)
Flash point	:	113 °F / 45 °C
Density	:	1 g/cm ³ (68 °F / 20 °C)
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Explosive properties	:	No data 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	:	No data available
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	Carbon monoxide (CO) Carbon dioxide (CO ₂)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

**Claro® Otic Solution**

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

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

Components:**Propylene carbonate:**

Acute oral toxicity : LD50 (Rat): 32,100 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : Exposure time: 8 h
Assessment: No adverse effect has been observed in acute toxicity tests.
Remarks: An LC50/inhalation/8h/rat could not be determined because no mortality of rats was observed at the maximum achievable concentration.

Acute dermal toxicity : LD50 (Rabbit): > 20,000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Ethanol:

Acute oral toxicity : LD50 (Rat): 10,470 mg/kg
Method: OECD 401

Acute dermal toxicity : LD50 (Rabbit): 15,800 mg/kg

Terbinafine Hydrochloride:

Acute oral toxicity : TDLo (Human, female): 210 mg/kg
LD50 (Rat, male and female): > 4,000 mg/kg
Method: OECD 401
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute toxicity (other routes of administration) : LD50 (Rat): > 2,000 mg/kg
Application Route: Subcutaneous

Skin corrosion/irritation**Components:****Propylene carbonate:**

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

Ethanol:

**Claro® Otic Solution**

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

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

Terbinafine Hydrochloride:

Result : Skin irritation

Serious eye damage/eye irritation**Components:****Propylene carbonate:**

Species : Rabbit
Result : Eye irritation
Method : OECD 405

Ethanol:

Species : Rabbit
Result : Causes serious eye irritation.
Assessment : Irritating to eyes.
Method : OECD 405

Terbinafine Hydrochloride:

Result : Eye irritation

Respiratory or skin sensitisation**Components:****Propylene carbonate:**

Result : Does not cause skin sensitisation.

Ethanol:

Test Type : Skin sensitisation
Species : Guinea pig
Method : Local lymph node test (LLNA)
Result : Does not cause skin sensitisation.

Germ cell mutagenicity**Components:****Propylene carbonate:**

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

Ethanol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Method: OECD 471
Result: negative

**Claro® Otic Solution**

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

Test Type: Mouse lymphoma assay
Method: OECD 476
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vivo
Species: Mouse
Method: OECD 478
Result: ambiguous

Test Type: Micronucleus test
Species: Mouse
Method: OECD 474
Result: negative

Carcinogenicity

IARC Group 1: Carcinogenic to humans
Ethanol 64-17-5

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.

Reproductive toxicity**Components:****Ethanol:**

Effects on fertility : Species: Mouse
Application Route: Oral
General Toxicity - Parent: NOAEL: 15 %
General Toxicity F1: NOAEL: 10 %
General Toxicity F2: NOAEL: < 15 %
Method: OECD 416
Result: Animal testing did not show any effects on fertility.

STOT - single exposure**Components:****Terbinafine Hydrochloride:**

Assessment : May cause respiratory irritation.

Repeated dose toxicity**Components:****Terbinafine Hydrochloride:**

Species : Monkey
LOAEL : 54,600 mg/kg
Application Route : Oral

**Claro® Otic Solution**

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

Exposure time : 4,368 h
 Target Organs : Eyes

Further information**Components:****Ethanol:**

Remarks : Breathing of the fumes may lead to narcotic symptoms.

Remarks : If inhaled:
 Headache
 Vomiting
 Nausea

Remarks : After absorption of large quantities
 hypotension
 Coma
 Unconsciousness
 respiratory paralysis

Terbinafine Hydrochloride:

Pharmaceutic effects

Remarks : Antimycotic

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Propylene carbonate:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): ca. 5,300 mg/l
 Exposure time: 96 h
 Test Type: static test
 Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l
 Exposure time: 48 h
 Test Type: static test

Toxicity to algae/aquatic plants : (Desmodesmus subspicatus (green algae)): > 500 mg/l
 Exposure time: 72 h
 Test Type: static test
 Method: DIN 38412

Toxicity to microorganisms : EC20 (Activated sludge micro-organism): > 800 mg/l
 Exposure time: 0.5 h
 Method: ISO 8192

Ecotoxicology Assessment

Acute aquatic toxicity : slightly hazardous to water

**Claro® Otic Solution**

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

Ethanol:

Toxicity to microorganisms : Toxic limit concentration (*Pseudomonas putida*): 6,500 mg/l

Terbinafine Hydrochloride:

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 0.35 mg/l
Exposure time: 48 h
Test Type: Immobilization
Method: OECD 202
GLP: yes
Remarks: Nominal concentration

Toxicity to algae/aquatic plants : EC50 (*Pseudokirchneriella subcapitata* (green algae)): 0.029 mg/l
Exposure time: 72 h
Test Type: Growth rate
Analytical monitoring: yes
Method: OECD 201
GLP: yes

M-Factor (Acute aquatic toxicity) : 10

Persistence and degradability**Components:****Propylene carbonate:**

Biodegradability : Result: rapidly biodegradable
BOD/ThOD : 86 %
Dissolved organic carbon (DOC) : 90 - 100 %
Method: ISO 7827

Ethanol:

Biodegradability : Result: rapidly biodegradable

Terbinafine Hydrochloride:

Biodegradability : aerobic
Inoculum: Activated sludge micro-organism
Concentration: 10 mg/l
Result: Not biodegradable
Biodegradation: 4 %
Exposure time: 28 d
Method: OECD 301 B
GLP: yes

SAFETY DATA SHEET



Claro® Otic Solution

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

Bioaccumulative potential

Components:

Propylene carbonate:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -0.48 (77 °F / 25 °C)

Ethanol:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: -0.320

Terbinafine Hydrochloride:

Partition coefficient: n-octanol/water : log Pow: 5.342

Mobility in soil

No data available

Other adverse effects

Product:

Components:

Propylene carbonate:

Adsorbed organic bound halogens (AOX) : Remarks: Product does not contain any organic halogens.

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

Please note that limited quantities, consumer commodity regulations or other exemptions may apply.

Land transport (CFR)

SAFETY DATA SHEET



Claro® Otic Solution

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

Proper shipping name:	ETHANOL SOLUTION
Hazard Class or Division:	3
UN/NA Number	1170
Packaging group	III
Hazard Label(s):	Flammable Liquid

Sea transport (IMDG)

UN Number	1170
Description of the goods	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Class	3
Packaging group	III
IMDG-Labels	3
EmS Number	F-E
Marine pollutant	no

Air transport (IATA)

UN Number	1170
Description of the goods	ETHANOL SOLUTION
Class	3
Packaging group	III
Dangerous goods labels	3
Environmentally hazardous	no

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 : Flammable (gases, aerosols, liquids, or solids)
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Propane-1,2-diol	57-55-6	15 %
------------------	---------	------

SAFETY DATA SHEET



Claro® Otic Solution

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

Polyethyleneglycol	25322-68-3	10 %
Ethanol	64-17-5	6 %

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

Ethanol	64-17-5
---------	---------

Pennsylvania Right To Know

Propane-1,2-diol	57-55-6
Ethanol	64-17-5

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

New York City Hazardous Substances

Ethanol	64-17-5
---------	---------

California Permissible Exposure Limits for Chemical Contaminants

Ethanol	64-17-5
---------	---------

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

TSCA : Substance(s) not listed 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 - 2	Instability - 0	Others -
------------	------------------	-----------------	----------

HMIS® IV:

Health - 2	Flammability - 2	Instability - 0	Others -
------------	------------------	-----------------	----------

Full text of other abbreviations

SAFETY DATA SHEET



Claro® Otic Solution

Version	Revision Date:	SDS Number:	Date of last issue: 11/27/2018
4.0	10/08/2019	122000013292	Date of first issue: 08/11/2015

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
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / STEL	:	Short-term exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
US WEEL / TWA	:	8-hr TWA

Revision Date : 10/08/2019

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