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

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

2. HAZARDS IDENTIFICATION

Emergency Overview

Colour: clear, yellowish **Form:** liquid

GHS Classification:

Flammable liquids	:	Category 3
Eye irritation	:	Category 2
Reproductive toxicity	:	Category 1A

GHS Label element:

Hazard pictograms :

Signal word : Warning

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

H360Df May damage the unborn child. Suspected of damaging fertility.

Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P273 Avoid release to the environment.
Response:
P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.
Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Weight percent	Components	CAS-No.
10 - 30%	Propane-1,2-diol	57-55-6
40 - 70%	Propylene carbonate	108-32-7
5 - 10%	Ethanol pure	64-17-5
1.5%	Terbinafine Hydrochloride	78628-80-5
0.2%	Mometasonfuroat	83919-23-7

Other Ingredients

Weight percent	Components	CAS-No.
1.5%	Florfenicol	76639-94-6

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately.

If inhaled: Remove to fresh air. Call a physician immediately.

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

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: If swallowed, seek medical advice immediately and show this container or label.

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: Carbon monoxide (CO) Carbon dioxide (CO2)

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Use adequate ventilation.

Methods for cleaning up: Suppress (knock down) gases/vapours/mists with a water spray jet. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Place in closed containers. Label for proper disposal.

Additional advice: No special precautions required.

Further Accidental Release Notes No special precautions required.

7. HANDLING AND STORAGE

Handling:
Industrial uses: Avoid formation of aerosol. Only handle product with local exhaust ventilation. Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Propane-1,2-diol (57-55-6)

US. OARS. WEELs Workplace Environmental Exposure Level Guide
Time Weighted Average (TWA): 10 mg/m3 (Aerosol.)

Polyethyleneglycol (25322-68-3)
US. OARS. WEELs Workplace Environmental Exposure Level Guide
Time Weighted Average (TWA): 10 mg/m3 (Particulate.)

Ethanol pure (64-17-5)
US. ACGIH Threshold Limit Values
Short Term Exposure Limit (STEL): 1,000 ppm
US. NIOSH: Pocket Guide to Chemical Hazards
Recommended exposure limit (REL): 1,000 ppm, 1,900 mg/m3
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)
Permissible exposure limit: 1,000 ppm, 1,900 mg/m3

Respiratory protection:
Recommended Filter type: Organic vapor with prefilter

None required for consumer use of this product.

Hand protection:
Chemically resistant gloves.
None required for consumer use of this product.

Eye protection:
Safety glasses

None required for consumer use of this product.

Other 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	liquid
Colour:	clear, yellowish
Odour:	No applicable information is available
Odour Threshold:	No applicable information is available
Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	No applicable information is available
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:	No applicable information is available
Water solubility:	No applicable information is available
pH:	4.0 - 6.0 at (77 °F (25 °C))
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	113 °F (45 °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: No data available

Materials to avoid: Oxidizing agents

Hazardous reactions: No data available

Thermal decomposition:

No data available

Hazardous decomposition products:
Carbon monoxide (CO), Carbon dioxide (CO2)

Oxidizing properties:

No statements available.

Impact sensitivity:
No data available

11. TOXICOLOGICAL INFORMATION

Other information on toxicity:
Ethanol pure
Breathing of the fumes may lead to narcotic symptoms.

If inhaled: headaches, Vomiting, Nausea

After absorption of large quantities hypotension, coma, Unconsciousness, respiratory paralysis

Acute oral toxicity:
Propane-1,2-diol
LD50 Rat: 22,000 mg/kg
The substance or mixture has no acute oral toxicity

Propylene carbonate
LD50 Rat: 32,100 mg/kg
The substance or mixture has no acute oral toxicity

Ethanol pure
LD50 Rat: 10,470 mg/kg
The substance or mixture has no acute oral toxicity
Method: OECD 401

Terbinafine Hydrochloride
TDL0 human, female: 210 mg/kg

Florfenicol
LD50 Rat: > 2,000 mg/kg

Mometasonfuroat
LD50 Rat: > 2,000 mg/kg

Acute inhalation toxicity:
Propane-1,2-diol
LC50 Rabbit: > 317 mg/l, 2 h
The substance or mixture has no acute inhalation toxicity

Propylene carbonate
The substance or mixture has no acute inhalation toxicity
An LC50/inhalation/8h/rat could not be determined because no mortality of rats was observed at the maximum achievable concentration.

Ethanol pure
LC50 Rat: 124.7 mg/l, 4 h
ca. 65360 ppm, 4 h
The substance or mixture has no acute inhalation toxicity
Method: OECD 403

Florfenicol
LC50 Rat: > 0.28 mg/l, 4 h

Acute dermal toxicity:
Propane-1,2-diol
LD50 Rabbit: > 5,000 mg/kg
The substance or mixture has no acute dermal toxicity

Propylene carbonate
LD50 Rabbit: > 20,000 mg/kg
The substance or mixture has no acute dermal toxicity

Ethanol pure
LD50 Rabbit: 15,800 mg/kg
The substance or mixture has no acute dermal toxicity

Terbinafine Hydrochloride
LD50 Rat: > 2,000 mg/kg
The substance or mixture has no acute dermal toxicity

Acute toxicity (other routes of administration):
Terbinafine Hydrochloride
LD50 subcutaneous Rat: > 2,000 mg/kg

Skin irritation:
Propane-1,2-diol
Rabbit
Result: No skin irritation

Propylene carbonate
Rabbit
Result: No skin irritation
Method: OECD 404

Ethanol pure
Rabbit
Result: No skin irritation
Method: OECD 404

Florfenicol
Rabbit
Result: No skin irritation

Eye irritation:
Propane-1,2-diol
Rabbit
Result: No eye irritation

Propylene carbonate
Rabbit
Result: Causes eye irritation.
Method: OECD 405

Ethanol pure
Rabbit
Result: Causes eye irritation.
Method: OECD 405

Florfenicol
Rabbit
Result: Mild eye irritation

Sensitisation:
Propane-1,2-diol
Human experience
Result: Does not cause skin sensitisation.

guinea pig
Result: Does not cause skin sensitisation.

Method: OECD 406

Propylene carbonate
Result: Does not cause skin sensitisation.

Ethanol pure
Skin sensitization guinea pig
Result: Does not cause skin sensitisation.
Method: Local lymph node test (LLNA)

Florfenicol
guinea pig
Result: Does not cause skin sensitisation.

Mometasonfuroat

May cause sensitisation of susceptible persons by skin contact or by inhalation of dust.

Subacute, subchronic and prolonged toxicity:
Propane-1,2-diol
NOEL 50,000 mg/kg, Rat Oral, Exposure time 24 month

NOEL 1 mg/l, Rat Inhalation, Exposure time 3 month
Number of exposures: Once daily

Terbinafine Hydrochloride
, Lowest observed effect level 54,600 mg/kg , Monkey Oral, Exposure time 4,368 h

Genotoxicity in vitro:
Propane-1,2-diol
Ames test Bacteria
Dose: yes
Result: negative
Method: OECD 471

Mammalian cells
Result: negative
Method: OECD 476

Ethanol pure
Ames test Salmonella typhimurium
Result: negative
Method: OECD 471

Mouse lymphoma assay
Result: negative
Method: OECD 476

Florfenicol
Ames test
Result: negative

Mouse lymphoma assay
Result: negative

Micronucleus test
Result: negative

Chromosome aberration test in vitro Hamster ovary-cells
Result: negative

Genotoxicity in vivo:
Propane-1,2-diol

Result: negative
Method: OECD 478

Propylene carbonate

Result: No indication of mutagenic effects.

Ethanol pure
Chromosome aberration test in vivo, Mouse
Result: ambiguous
Method: OECD 478

Micronucleus test, Mouse
Result: negative
Method: OECD 474

Carcinogenicity:
Propane-1,2-diol
Rat:
Exposure time: 2 a
Number of exposures: Once daily
Result: negative

Ethanol pure
Result: Animal testing did not show any carcinogenic effects.

Florfenicol
Rat:
48 - 200 mg
Exposure time: 2 a
Result: negative

Reproductive toxicity:
Propane-1,2-diol
Application Route: Oral
Rat, female: Test period: 18 d
NOAEL: 1600 mg/kg
Result: Animal testing did not show any effects on fertility.

Ethanol pure
Application Route: Oral
Mouse: NOAEL: 15%
Result: Animal testing did not show any effects on fertility.
Method: OECD Test Guideline 416

Teratogenicity:
Propane-1,2-diol
Rat, male: Number of exposures: Once daily
Test period: 15 d
NOAEL: 1600 mg/l
Result: No indication of teratogenic effects.

Ethanol pure
Application Route: inhalation
Rat: NOAEL: 38 mg/l
Result: Animal studies have produced no evidence of harmful effects on development.
Method: OECD 414

Pharmaceutic effects:
Terbinafine Hydrochloride
Antimycotic

Florfenicol
Antibiotic

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

STOT - single exposure:
No data available

STOT - repeated exposure:
No data available

12. ECOLOGICAL INFORMATION

General advice:
Do not allow to enter surface waters or groundwater.

Toxicity to fish:
Propane-1,2-diol
Acute Fish toxicity: LC50 40,613 mg/l
Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

Propylene carbonate
static test: LC50 ca. 5,300 mg/l
Test species: Leuciscus idus (Golden orfe) Duration of test: 96 h
Method: DIN 38412

Ethanol pure
LC50 8,140 mg/l
Test species: Leuciscus idus (Golden orfe) Duration of test: 48 h

Florfenicol
LC50 > 830 mg/l
Test species: Lepomis macrochirus (Bluegill) Duration of test: 96 h

LC50 > 780 mg/l
Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:
Propane-1,2-diol
LC50 18,340 mg/l
Test species: Ceriodaphnia dubia (water flea) Duration of test: 48 h

Propylene carbonate
static test EC50 > 500 mg/l
Test species: Daphnia magna (Water flea) Duration of test: 48 h

Ethanol pure
EC50 9,268 - 14,221 mg/l
Test species: Daphnia magna (Water flea)

Florfenicol
EC50 > 330 mg/l
Test species: Daphnia (water flea) Duration of test: 48 h

Toxicity to algae:
Propane-1,2-diol
IC50 19,100 mg/l
tested on: Pseudokirchneriella subcapitata (green algae)

Propylene carbonate
static test > 500 mg/l
tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h
Method: DIN 38412

Ethanol pure
Toxic limit concentration 5,000 mg/l
tested on: Scenedesmus quadricauda (Green algae)

Toxicity to bacteria:
Propane-1,2-diol
NOEC 20,000 mg/l
tested on: Pseudomonas putida
Duration of test: 18 h

Propylene carbonate
EC20 > 800 mg/l
tested on: activated sludge micro-organism
Duration of test: 0.5 h
Method: ISO 8192

Ethanol pure
Toxic limit concentration 6,500 mg/l
tested on: Pseudomonas putida

Biodegradability:
Propane-1,2-diol
87 - 92 %, 28 d rapidly biodegradable
Method: OECD 301 C

Propylene carbonate
rapidly biodegradable

Ethanol pure
rapidly biodegradable

Florfenicol
Not rapidly biodegradable
inherently degradable

Bioaccumulation:
Propane-1,2-diol

Bioconcentration factor (BCF)
0.09

Propylene carbonate

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

Ethanol pure

Bioaccumulation is unlikely.

13. DISPOSAL CONSIDERATIONS

When discarded in its purchased form, this product meets the criteria of ignitability, and should be managed as hazardous waste (EPA Hazardous Waste Number D001). 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

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

Land transport (CFR)

Proper shipping name:	ETHANOL SOLUTION
Hazard Class or Division:	3
UN/NA Number:	UN1170
Packaging group	III
Hazard Label(s):	Flammable Liquid

US Sea transport (IMDG)

Proper shipping name:	ETHANOL SOLUTION
Hazard Class or Division:	3
UN number:	UN1170
Packaging group:	III
Hazard Label(s):	FLAMMABLE LIQUIDS

US Air transport (ICAO / IATA cargo aircraft only)

Proper shipping name:	ETHANOL SOLUTION
Hazard Class or Division:	3
UN/ID Number:	UN1170
Packaging group:	III
Hazard Label(s):	FLAMMABLE LIQUIDS

US Air transport (ICAO / IATA passenger and cargo aircraft)

Proper shipping name:	ETHANOL SOLUTION
Hazard Class or Division:	3
UN/ID Number:	UN1170
Packaging group:	III
Hazard Label(s):	FLAMMABLE LIQUIDS

International IATA

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

International 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

15. REGULATORY INFORMATION

Other regulations: No statements available.

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

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
None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components
None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
10 - 30%	Propane-1,2-diol	57-55-6

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.