

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

SECTION 1. IDENTIFICATION

Product information

Product Name: OtiRinse
Synonyms: ExpertCare Ear Wash
SDS Number: 122000009857

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

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	1
Nonoxynol 12	68412-54-4	0.2
Propane-1,2-diol	57-55-6	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.

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

- 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 : No special precautions are necessary for first aid responders.
- 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 for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Avoid formation of aerosol.
- 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.
- Conditions for safe storage : Store at temperatures and conditions as indicated on the product label.

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

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
Benzyl alcohol	100-51-6	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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid
- 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

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

Conditions to avoid : No data available

Incompatible materials : Oxidizing agents

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

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.

Propane-1,2-diol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : LC50 (Rabbit): > 158.5 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Skin corrosion/irritation

Components:

Benzyl alcohol:

Species : Rabbit
Method : OECD 404

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

Result : No skin irritation

Propane-1,2-diol:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Components:

Benzyl alcohol:

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

Propane-1,2-diol:

Species : Rabbit
Result : No 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.

Propane-1,2-diol:

Species : Human experience
Result : Does not cause skin sensitisation.

Species : Guinea pig
Method : OECD 406
Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Components:

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

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

Propane-1,2-diol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Bacteria
Metabolic activation: yes
Method: OECD 471

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

Result: negative

Test system: mammalian cells
Method: OECD 476
Result: negative

Genotoxicity in vivo : Method: OECD 478
Result: negative

Carcinogenicity

Components:

Propane-1,2-diol:

Species : Rat
Application Route : Oral
Exposure time : 730 days
Frequency of Treatment : once daily
Result : negative

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.

Reproductive toxicity

Components:

Propane-1,2-diol:

Effects on fertility : Species: Rat, female
Application Route: Oral
General Toxicity - Parent: NOAEL: 1,600 mg/kg
Result: Animal testing did not show any effects on fertility.

STOT - single exposure

Components:

Benzyl alcohol:

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

STOT - repeated exposure

Components:

Benzyl alcohol:

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

SAFETY DATA SHEET

OtiRinse

Version Revision Date: SDS Number: Date of last issue: 03/26/2013
2.0 03/25/2019 122000009857 Date of first issue: 03/26/2013

Repeated dose toxicity

Components:

Benzyl alcohol:

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

Propane-1,2-diol:

Species : Rat
NOAEL : 50,000 mg/kg
Application Route : Oral
Exposure time : 24 month

Species : Rat
NOAEL : 1 mg/l
Application Route : Inhalation
Exposure time : 3 month
Number of exposures : Once daily

Further information

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

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

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.

Propane-1,2-diol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 40,613 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to daphnia and other aquatic invertebrates : LC50 (Dendraster excentricus (Sand dollar)): 18,340 mg/l
Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): 20,000 mg/l
Exposure time: 18 h

Ecotoxicology Assessment

Acute aquatic toxicity : slightly hazardous to water

Persistence and degradability

Components:

Benzyl alcohol:

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

Propane-1,2-diol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 87 - 92 %
Exposure time: 28 d
Method: OECD 301 C

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

Propane-1,2-diol:

Bioaccumulation : Bioconcentration factor (BCF): 0.09

Partition coefficient: n-octanol/water : log Pow: -1.07

Mobility in soil

No data available

Other adverse effects

Product:

Components:

Propane-1,2-diol:

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

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

US Land transport (CFR)
non-regulated

Sea transport (IMDG)
non-regulated

Air transport (IATA)
non-regulated

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Hydrochloric acid	7647-01-0	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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 : No SARA Hazards

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	1 %
Benzyl alcohol	100-51-6	1 %

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Hydrochloric acid	7647-01-0	0.1249 %
Benzoic acid	65-85-0	0.1 %
Sodium hydroxide	1310-73-2	0.0249 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Hydrochloric acid	7647-01-0	0.1249 %
Benzoic acid	65-85-0	0.1 %
Sodium hydroxide	1310-73-2	0.0249 %

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

Benzyl alcohol	100-51-6
Hydrochloric acid	7647-01-0

Pennsylvania Right To Know

SAFETY DATA SHEET

OtiRinse

Version 2.0 Revision Date: 03/25/2019 SDS Number: 122000009857 Date of last issue: 03/26/2013
Date of first issue: 03/26/2013

Propane-1,2-diol	57-55-6
Benzyl alcohol	100-51-6
Hydrochloric acid	7647-01-0
Benzoic acid	65-85-0
Sodium hydroxide	1310-73-2

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

Hydrochloric acid	7647-01-0
Lactic acid	50-21-5
Benzoic acid	65-85-0
Sodium hydroxide	1310-73-2

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 - 0 Flammability - 1 Instability - 0 Others -

HMIS® IV:

Health - 0 Flammability - 1 Instability - 0 Others -

Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA : 8-hr TWA

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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.

SAFETY DATA SHEET

OtiRinse

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2013
2.0	03/25/2019	122000009857	Date of first issue: 03/26/2013

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