

0.12% Chlorhexidine Gluconate Oral Rinse

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : 0.12% Chlorhexidine Gluconate Oral Rinse

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical Agent

1.3. Details of the supplier of the safety data sheet

Xttrium Laboratories, Inc.
1200 East Business Center Drive
Mt. Prospect, IL 60056

1.4. Emergency telephone number

Emergency number : 773-268-5800

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Carc. 1A H350

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS08

Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H350 - May cause cancer

Precautionary statements (GHS-US) :

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - If exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	Trade Secret	Not classified
Ethyl alcohol	(CAS No) 64-17-5	Trade Secret	Flam. Liq. 2, H225 Carc. 1A, H350
Glycerin	(CAS No) 56-81-5	Trade Secret	Not classified
Chlorhexidine digluconate	(CAS No) 18472-51-0	Trade Secret	Acute Tox. 4 (Oral), H302
Sorbitan, isoctadecanoate, poly(oxy-1,2-ethanediyl) derivatives	(CAS No) 58205-96-2	Trade Secret	Not classified
Sodium saccharin	(CAS No) 128-44-9	Trade Secret	Not classified
C.I. Acid Blue 9, disodium salt	(CAS No) 3844-45-9	Trade Secret	Not classified

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SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: No specific first aid necessary for this route of exposure.
First-aid measures after skin contact	: Wash with soap and water. Seek medical advice if skin irritation develops or persists.
First-aid measures after eye contact	: Immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists get medical attention.
First-aid measures after ingestion	: Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: None under normal use.
Symptoms/injuries after skin contact	: None under normal use.
Symptoms/injuries after eye contact	: May produce transient eye irritation.
Symptoms/injuries after ingestion	: Ingestion of large amounts may produce signs of alcohol intoxication.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use water spray, dry chemical, alcohol foam or CO ₂
Unsuitable extinguishing media	: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
Explosion hazard	: None known.

5.3. Advice for firefighters

Protection during firefighting	: Firefighters should wear full protective gear.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
Methods for cleaning up	: Dilute with water. Keep away from ignition sources. Perform waste disposal in compliance with all applicable regulations. Flush down sewer with large quantities of water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Avoid contact with eyes. Wash thoroughly after handling.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Handling/storage area must be well ventilated, cool and dry. Materials must be isolated from potential sources of ignition. Fire fighting equipment must be available at all times.
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7.3. Specific end use(s)

Pharmaceutical Agent

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethyl alcohol (64-17-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1900 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm

Glycerin (56-81-5)		
USA OSHA	OSHA PEL (TWA) (mg/m ³)	5 mg/m ³

8.2. Exposure controls

Appropriate engineering controls	: None required under normal product handling conditions.
Hand protection	: None required under normal product handling conditions.
Eye protection	: None required under normal product handling conditions.
Skin and body protection	: Wear suitable working clothes.
Respiratory protection	: None required under normal product handling conditions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: Clear Blue
Odor	: Minty
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 200 °F
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: 721 mm Hg
Relative vapor density at 20 °C	: No data available
Specific gravity	: 1.0
Solubility	: Water:
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

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10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Protect from light, avoid acidic conditions, and avoid prolonged exposure to elevated temperatures. Maintain at or below 77°F and above 32°F.

10.5. Incompatible materials

None.

10.6. Hazardous decomposition products

Not determined.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Ethyl alcohol (64-17-5)	
LC50 inhalation rat (mg/l)	124.7 mg/l/4h
ATE US (oral)	7060.00000000 mg/kg

Glycerin (56-81-5)	
LD50 dermal rabbit	> 10 g/kg
LC50 inhalation rat (mg/l)	> 570 mg/m ³ (Exposure time: 1 h)
ATE US (oral)	12600.00000000 mg/kg

Chlorhexidine digluconate (18472-51-0)	
ATE US (oral)	500.00000000 mg/kg

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : May cause cancer.

Ethyl alcohol (64-17-5)	
IARC group	1 - Carcinogenic to humans

Sodium saccharin (128-44-9)	
IARC group	3 - Not classifiable

C.I. Acid Blue 9, disodium salt (3844-45-9)	
IARC group	3 - Not classifiable

Reproductive toxicity : Not classified
Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ethyl alcohol (64-17-5)	
LC50 fish 1	12.0 - 16.0 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 2	2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Glycerin (56-81-5)	
LC50 fish 1	51 - 57 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

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Sodium saccharin (128-44-9)

LC50 fish 1	16400 - 20400 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Ethyl alcohol (64-17-5)

Log Pow	-0.32
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Glycerin (56-81-5)

BCF fish 1	(no bioaccumulation)
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Log Pow	-1.76
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Sodium saccharin (128-44-9)

Log Pow	0.91
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12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on ozone layer : No additional information available

Effect on the global warming : No known ecological damage caused by this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

In accordance with DOT

Not a dangerous good as defined in transport regulations

SECTION 15: Regulatory information

15.1. US Federal regulations

Glycerin (56-81-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

EPA TSCA Regulatory Flag	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.
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15.2. US State regulations

Ethyl alcohol (64-17-5)

U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significance risk level (NSRL)
Yes	Yes			

Ethyl alcohol (64-17-5)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Glycerin (56-81-5)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

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Sodium saccharin (128-44-9)

U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) List

C.I. Acid Blue 9, disodium salt (3844-45-9)

U.S. - Massachusetts - Right To Know List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Carc. 1A	Carcinogenicity Category 1A
Flam. Liq. 2	Flammable liquids Category 2
H225	Highly flammable liquid and vapor
H302	Harmful if swallowed
H350	May cause cancer

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product