

Chlorhexidine Gluconate 4% Topical Solution

Safety Data Sheet

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

1.1. Product identifier

Product name. : Chlorhexidine Gluconate 4% Topical Solution

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)

Skin Irrit. 2 H315
Eye Dam. 1 H318
Carc. 2 H351

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS05

GHS08

Signal word (GHS-US) : Danger

Hazard statements (GHS-US) : H315 - Causes skin irritation
H318 - Causes serious eye damage
H351 - Suspected of causing cancer

Precautionary statements (GHS-US) : P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash thoroughly after handling
P305 + P351 + P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308 + P313 - If exposed or concerned: Get medical advice/attention
P310 - Immediately call a poison center/doctor if skin irritation occurs
P321 - Specific treatment (see label)
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
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. Substances

Not applicable

Full text of H-phrases: see section 16

3.2. Mixture

Name	Product identifier	%	GHS-US classification
Water	(CAS No) 7732-18-5	Trade Secret	Not classified
Chlorhexidine digluconate	(CAS No) 18472-51-0	Trade Secret	Acute Tox. 4 (Oral), H302
Isopropyl alcohol	(CAS No) 67-63-0	Trade Secret	Flam. Liq. 2, H225
Proprietary Component 1	(CAS No) Proprietary	Trade Secret	Not classified

Chlorhexidine Gluconate 4% Topical Solution

Safety Data Sheet

Name	Product identifier	%	GHS-US classification
Proprietary Component 2	(CAS No) Proprietary	Trade Secret	Skin Corr. 1B, H314
Proprietary Component 3	(CAS No) Proprietary	Trade Secret	Carc. 2, H351
Proprietary Component 4	(CAS No) Proprietary	Trade Secret	Not classified
Proprietary Component 5	(CAS No) Proprietary	Trade Secret	Not classified
Proprietary Component 6	(CAS No) Proprietary	Trade Secret	Not classified

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	: No specific first aid necessary for this route of exposure. If skin irritation develops or persists, seek medical attention.
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	: Do NOT induce vomiting. 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 anticipated under normal use. If skin irritation occurs, stop use of product and seek medical attention.
Symptoms/injuries after eye contact	: Causes serious eye damage.
Symptoms/injuries after ingestion	: May be harmful if swallowed.

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	: Dry chemical powder, alcohol foam, carbon dioxide, water spray, fog.
Unsuitable extinguishing media	: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable. Thermal decomposition may produce toxic fumes of ammonia, hydrogen chloride and oxides of carbon and nitrogen.
Explosion hazard	: None known.

5.3. Advice for firefighters

Protection during firefighting	: Firefighters should wear full protective gear.
--------------------------------	--

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	: Confine spill and soak up with absorbent. Place in an approved container and dispose in accordance with local, state and federal regulations.

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.
-------------------------------	--

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep away from open flames, hot surfaces and sources of ignition. Store at temperatures not exceeding 37°C.
--------------------	---

7.3. Specific end use(s)

Pharmaceutical Agent.

Chlorhexidine Gluconate 4% Topical Solution

Safety Data Sheet

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Isopropyl alcohol (67-63-0)		
USA ACGIH	ACGIH TWA (ppm)	200 ppm
USA ACGIH	ACGIH STEL (ppm)	400 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	980 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	400 ppm

8.2. Exposure controls

Appropriate engineering controls	: Provide adequate general and local exhaust ventilation.
Hand protection	: No protection required during normal use.
Eye protection	: No protection required during normal use; however, if contact with the eyes occurs, flush with plenty of water for at least 15 minutes.
Skin and body protection	: None required under normal product handling conditions.
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	: Slightly yellowish liquid.
Odor	: Odorless
Odor threshold	: No data available
pH	: 5.00 - 6.80
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: 97 °C
Flash point	: >200 °F
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Specific gravity	: 1.0000 - 1.0300
Solubility	: Water: Soluble
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
Oxidising 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.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Storage in excess heat (104 ° F) over a long period of time.

10.5. Incompatible materials

None.

Chlorhexidine Gluconate 4% Topical Solution

Safety Data Sheet

10.6. Hazardous decomposition products

Thermal decomposition may produce toxic fumes of ammonia, hydrogen chloride and oxides of carbon and nitrogen.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg

Chlorhexidine digluconate (18472-51-0)	
LD50 oral rat	2 g/kg
ATE (oral)	500.000 mg/kg

Isopropyl alcohol (67-63-0)	
LD50 oral rat	4396 mg/kg
LD50 dermal rat	12800 mg/kg
LD50 dermal rabbit	12870 mg/kg
LC50 inhalation rat (mg/l)	72.6 mg/l (Exposure time: 4 h)

Proprietary Component 6 (Proprietary)	
LD50 oral rat	7930 mg/kg
ATE (oral)	7930.000 mg/kg bodyweight

Skin corrosion/irritation : Causes skin irritation.
Serious eye damage/irritation : Causes serious eye damage.
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Suspected of causing cancer.

Isopropyl alcohol (67-63-0)	
IARC group	3

Proprietary Component 3 (Proprietary)	
IARC group	2B
National Toxicity Program (NTP) Status	1

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

Isopropyl alcohol (67-63-0)	
LC50 fishes 1	9640 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	13299 mg/l (Exposure time: 48 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	> 1000 mg/l (Exposure time: 96 h - Species: Desmodesmus subspicatus)
LC50 fish 2	11130 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 other aquatic organisms 2	> 1000 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)

Proprietary Component 3 (Proprietary)	
LC50 fishes 1	3.6 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])
EC50 Daphnia 1	4.2 mg/l (Exposure time: 24 h - Species: Daphnia magna)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Isopropyl alcohol (67-63-0)	
Log Pow	0.05 (at 25 °C)

Chlorhexidine Gluconate 4% Topical Solution

Safety Data Sheet

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

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 / ADR / RID / ADNR / IMDG / ICAO / IATA

14.1. UN number

Not applicable

14.2. UN proper shipping name

DOT Proper Shipping Name : Chlorhexidine Gluconate Aqueous Solutions of alcohol containing 24% or less alcohol by volume and no other hazardous material.

SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)

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

Chlorhexidine digluconate (18472-51-0)

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

Isopropyl alcohol (67-63-0)

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

Listed on SARA Section 313 (Specific toxic chemical listings)

EPA TSCA Regulatory Flag

T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA.

SARA Section 313 - Emission Reporting

1.0 % (only if manufactured by the strong acid process, no supplier notification)

Proprietary Component 2 (Proprietary)

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

Proprietary Component 3 (Proprietary)

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

Proprietary Component 5 (Proprietary)

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

Proprietary Component 1 (Proprietary)

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

Proprietary Component 4 (Proprietary)

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

Proprietary Component 6 (Proprietary)

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

15.2. US State regulations

Proprietary Component 3 (Proprietary)

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				

Isopropyl alcohol (67-63-0)

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

Chlorhexidine Gluconate 4% Topical Solution

Safety Data Sheet

SECTION 16: Other information

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.