

Safety Data Sheet (SDS)

Chlorhexidine Gluconate 4% Topical Solution

Issue date 05/18/2023

Reviewed on 05/18/2023

1 Identification

Product Identifier

Trade Name: CliniClean™**Product Number:** 90104, 90208, 90316, 90432, 90515, 90604**Relevant identified uses of the substance or mixture and uses advised against:** For Professional Use Only**Product Description:** Chlorhexidine Gluconate 4% Topical Solution

Details of the Supplier of the Safety Data Sheet:

HR® Pharmaceuticals, Inc.
2600 Eastern Blvd, Suite 201
York, PA 17402
Phone: (717)-252-1110
Fax: (717)685-2590
www.hrpharma.com.

Emergency telephone number:

USA, Canada, Puerto Rico and U.S. Virgin Islands: 1-800-255-3924

All other countries: +1-813-248-0585

2 Hazard(s) Identification

Classification of the substance or mixture:

Classification (GHS-US)

Skin Irrit. 2 H315

Eye Dam. 1 H318 Carc. 2

H351

Label elements:

GHS-US labeling

Hazard pictograms:



GHS05



GHS08

Signal word:

Danger

Hazard statements:

H315 - Causes skin irritation

H318 - Causes serious eye damage

H351 - Suspected of causing cancer

Precautionary statements:

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.

Other hazards:

No additional information available

Unknown acute toxicity (GHS US):

No data available

3 Composition/Information on Ingredients

Substances:

Not applicable

Full text of H-phrases: See section 16



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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. 3, H225
Proprietary Component 1	(CAS No) Proprietary	Trade Secret	Not classified
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

4 First-Aid Measures

Description of first aid measures:**General information:**

No special measures required.

After inhalation:

No specific first aid necessary for this route of exposure.

After skin contact:

No specific first aid necessary for this route of exposure. If skin irritation develops or persists, seek medical attention.

After eye contact:

Immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists get medical attention.

After ingestion:

Do NOT induce vomiting. Seek medical attention.

Most important symptoms and effects, both acute and delayed:**After inhalation:**

None under normal use

After skin contact:

None anticipated under normal use. If skin irritation occurs, stop use of product and seek medical attention

After eye contact:

Causes serious eye damage

After ingestion:

May be harmful if swallowed

Indication of any immediate medical attention and special treatment needed:

No additional information available.

5 Fire-Fighting Measures

Extinguishing media**Suitable extinguishing media:**

Dry chemical powder, alcohol foam, carbon dioxide, water spray, fog

Unsuitable extinguishing media:

None

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

Advice for firefighters**Special protective equipment for firefighters:**

Firefighters should wear full protective gear

6 Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:**For non-emergency personnel:**

No additional information available

For emergency responders:

No additional information available

Environmental precautions:

Avoid release to the environment

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

Reference to other sections: No additional information available



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7 Handling and Storage

Handling:

Precautions for safe handling: Avoid contact with eyes. Wash thoroughly after handling

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

Specific end use(s): Pharmaceutical Agent

8 Exposure Controls/Personal Protection

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

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. If contact with the eyes occurs, flush with 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

9 Physical and Chemical Properties

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

Other Information:

No additional information available



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10 Stability and Reactivity

Reactivity: No further relevant information available.

Chemical stability: Stable at normal handling and storage conditions.

Possibility of hazardous reactions: Will not occur.

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

Incompatible materials: None

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

11 Toxicological Information

Information on toxicological effects:

Acute toxicity: Not classified

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

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



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12 Ecological Information

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)

Persistence and degradability:

No further relevant information available.

Bioaccumulative potential:

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

Mobility in soil: No additional information available

Other adverse effects: No additional information available

13 Disposal Considerations

Waste treatment methods

Recommendation:

Dispose of contents/container in accordance with local/regional/national/international regulations

14 Transport Information

In accordance with DOT / ADR / RID / ADNR / IMDG / ICAO / IATA

UN-Number: Not applicable

UN proper shipping name: Chlorhexidine Gluconate Aqueous Solutions of alcohol containing 24% or less alcohol by volume and no other hazardous material

15 Regulatory Information

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	



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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

US State Regulations

Proprietary Component 3 (Proprietary)				
U.S. - California -	U.S. - California -	U.S. - California -	U.S. - California -	No significance risk level (NSRL)
Proposition 65 -	Proposition 65 -	Proposition 65 -	Proposition 65 -	
Carcinogens List	Developmental Toxicity	Reproductive Toxicity -	Reproductive Toxicity -	
		Female	Male	
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

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.