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

Henry Schein, Inc. 135 Duryea Road

Melville, NY 11747 1-800-472-4346

1.4. Emergency telephone number

Emergency number : Chemtrec: 1-800-424-9300

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Flam. Liq. 3 H226 Skin Irrit. 2 H315 Eye Dam. 1 H318 Carc. 2 H351

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US)



GHS05





Signal word (GHS-US)

Hazard statements (GHS-US)

H226 - Flammable liquid and vapour 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 P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking

P233 - Keep container tightly closed

P240 - Ground/bond container and receiving equipment

P241 - Use explosion-proof electrical/ventilating/lighting/... equipment

P242 - Use only non-sparking tools

P243 - Take precautionary measures against static discharge

P264 - Wash ... thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302+P352 - IF ON SKIN: Wash with plenty of soap and water

P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated

clothing. Rinse skin with water/shower

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/...

P321 - Specific treatment (see ... on this label)

P332+P313 - If skin irritation occurs: Get medical advice/attention

P362 - Take off contaminated clothing

P370+P378 - In case of fire: Use ... for extinction P403+P235 - Store in a well-ventilated place. Keep cool

P405 - Store locked up

P501 - Dispose of contents/container to ...

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

No data available

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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
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 : 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 : 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 : Causes skin irritation.

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 : Flammable liquid and vapour. 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

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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.

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/m3)	980 mg/m³
USA OSHA	OSHA PEL (TWA) (ppm)	400 ppm

8.2. Exposure controls

Physical state

Appropriate engineering controls : Provide adequate general and local exhaust ventilation. Hand protection : Wear impervious gloves to minimize skin contact.

Eye protection : Chemical goggles or safety glasses.
Skin and body protection : Wear suitable working clothes.

Respiratory protection : None required under normal product handling conditions.

: Liquid

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour : colorless.

Odour : No data available
Odour threshold : No data available
pH : No data available
Relative evaporation rate (butylacetate=1) : No data available
Melting point : No data available
Freezing point : No data available

Boiling point : $97 \, ^{\circ}\text{C}$ Flash point : $125 \, ^{\circ}\text{F}$

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 : 1.06

Solubility : Water: Soluble : No data available Log Pow No data available Log Kow Viscosity, kinematic No data available Viscosity, dynamic No data available Explosive properties No data available Oxidising properties : No data available : No data available Explosive limits

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

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Chemical stability

The product is stable at normal handling- and storage conditions.

Possibility of hazardous reactions

Will not occur.

10.4. **Conditions to avoid**

Storage in excess heat (104 $^{\circ}$ 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.

SECTION 11: Toxicological information

Information on toxicological effects

: Not classified Acute toxicity

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)		
LDE0	4000 //	

isopropyi aiconoi (67-03-0)	
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 : Not classified exposure)

Aspiration hazard : Not classified

SECTION 12: Ecological information

Proprietary Component 3 (Proprietary)

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)

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

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 : D

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

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Proprietary Component 3 (Proprietary)					
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

SECTION 16: Other information

Full text of H-phrases:

ixt of Frymases.	
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Carc. 2	Carcinogenicity Category 2
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 3	Flammable liquids Category 3
Skin Corr. 1B	skin corrosion/irritation Category 1B
Skin Irrit. 2	skin corrosion/irritation Category 2
H225	Highly flammable liquid and vapour
H226	Flammable liquid and vapour
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H351	Suspected of causing 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.

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