

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

1.1. Product identifier

Product form : Mixture
 Trade name : Bactoshield[®] CHG 4% Chlorhexidine Gluconate 4% Solution Antiseptic
 Product code : 1344

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

1.2.1. Relevant identified uses

Industrial/Professional use spec. : For hospital and professional use only. Not for home use.
 Use of the substance/mixture : Antiseptic solution

1.3. Details of the supplier of the safety data sheet

STERIS Corporation
 P. O. Box 147, St. Louis, MO 63166, US
 Telephone Number for Information: 1-800-548-4873 (Customer Service - Healthcare Products)

1.4. Emergency telephone number

Emergency number : US Emergency Telephone No.1-314-535-1395 (STERIS); 1-800-424-9300 (CHEMTREC)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US Classification

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

2.2. Label elements - This product is regulated by the FDA and is exempt from GHS labeling.

FDA Product Labeling : This product is regulated by the FDA, therefore, the requirements for product labeling do not fall under the jurisdiction of the OSHA Hazard Communication Standard according to 29 CFR 1910.1200.

Hazard pictograms (GHS-US) :



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) : P202 – Do not handle until all safety precautions have been read and understood.
 P264 – Wash hands thoroughly after handling.
 P280 – Wear protective clothing, protective gloves, eye and face protection.
 P302+P352 – If on skin: wash with plenty of water.
 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 attention.
 P310 – Immediately call a Poison Center or/doctor.
 P332+P313 – If skin irritation occurs: Get medical advice/attention.
 P362 – Take off contaminated clothing and wash before reuse.
 P405 – Store locked up.

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.
 Full text of H-phrases: see Section 16.

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3.2. Mixture

Raw Material 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

Full text of R- and H-phrases: see Section 16.

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 attention 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 : 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

- Protective equipment for firefighters : 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

See Heading 8: Exposure controls and personal protection.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with eyes. Wash hands 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/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 : Wear impervious gloves to minimize skin contact.
Eye protection : Wear chemical goggles or safety glasses.
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 : Colorless
Odor : No data available
Odor 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°C
Flash point : >200°F
Self ignition temperature : No data available
Decomposition temperature : No data available
Flammability (solid, gas) : No data available
Vapor pressure : No data available
Relative vapour density at 20 °C : No data available
Relative density : 1.06 g/ml (Specific gravity)
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
Oxidizing properties : No data available
Explosive limits : No data available.

9.2. Other information

No additional information available.

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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.

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)

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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)
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12.4. Mobility in soil

No additional information available.

12.5. Other adverse effects

No additional is 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 regulated.

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 is not regulated.

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 the 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

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15.2. US State regulations

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

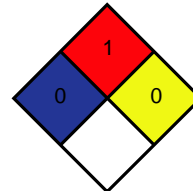
SECTION 16: Other information

Revision Date : 03/30/2015
Sources of Key data : None.
Other information : None.

Full text of H-phrases:

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 vapor
H226	Flammable liquid and vapor
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

NFPA health hazard : 0 - Exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials.
NFPA fire hazard : 1 - Materials require considerable preheating before ignition and combustion can occur.
NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and is not reactive with water.



SDS US (GHS HazCom 2012)

The information on this sheet is not a specification and does not guarantee specific properties. The information is intended to provide general knowledge as to health and safety based upon our knowledge of the handling, storage and use of the product. It is not applicable to unusual or non-standard uses of the product or where instruction or recommendations are not followed.