US - OSHA SAFETY DATA SHEET

Issue Date 26-Nov-2018 **Revision Date** 24-Jul-2019 **Version** 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Betasept® (chlorhexidine gluconate, 4%) Antiseptic Surgical Scrub

Other means of identification

Synonyms Chlorhexidine digluconate; chlorhexidine D-digluconate

Recommended use of the chemical and restrictions on use

Recommended Use This product is a topical microbicide for external use only. Not for retail sale. For professional and hospital use only.

Uses Advised Against Not for oral use.

Details of the supplier of the safety data sheet

Distributor
Avrio Health L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901-3431
(888) 827-0624.
contactavrio@avriohealth.com

Emergency telephone number

24 Hour Emergency Phone Number Chemtrec (US): 1-800-424-9300.
For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Serious Eye Damage/Eye Irritation	Category 1
Skin sensitization	Category 1B
Specific target organ toxicity (single exposure)	Category 2

Physical Hazards

Flammable Liquid	Category 3

OSHA Regulatory Status
This product is considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).

Label elements

Emergency Overview

Danger

Hazard Statements
Causes serious eye damage.
May cause an allergic skin reaction.
May cause damage to organs.
Flammable liquid and vapor.

Appearance Clear colorless liquid. **Physical State** Liquid. **Odor** Faint alcohol-like odor.

Precautionary Statements - Prevention
Do not breathe dust/fumes/gas/mist/vapors/spray. Wash face, hands and any exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product. Take precautionary measures against static discharge

Precautionary Statements - Response
If exposed or if you feel unwell: Call a POISON CENTER or doctor/physician

Precautionary Statements - Storage
Store between 20 -25 °C (68 - 77 °F) in a dry place. Avoid excessive heat above 40 °C (104°F).

Hazards not otherwise classified (HNOC)
Not applicable.

Other information
May be harmful if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Chlorhexidine digluconate; chlorhexidine D-digluconate

Chemical Name	CAS No.	Weight-%
Isopropyl Alcohol, USP/NF	67-63-0	1-5
Chlorhexidine gluconate	18472-51-0	1-5
Cocamide DEA	68603-42-9	1-5

4. FIRST AID MEASURES

First aid measures

Eye Contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact In case of contact, remove contaminated clothing. Immediately wash exposed area with soap and water. Obtain medical attention if skin reaction occurs.

Inhalation Immediately move exposed subject to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye irritation, skin irritation, respiratory irritation, including irritation of the nose and throat, coughing, and difficulty breathing, gastrointestinal irritation, nausea, vomiting, diarrhea, and transient to long-lasting disturbances in the sense of taste. Overexposure from repeated or prolonged skin contact may cause contact dermatitis, photosensitivity, and severe allergic response. Repeated inhalation may cause respiratory hypersensitization and asthma.

Indication of any immediate medical attention and special treatment needed

Note to Physicians There is no known antidote for overexposure to chlorhexidine gluconate. The use of activated charcoal is not expected to be clinically beneficial and may obscure visualization during endoscopy. Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media Not available.

Specific hazards arising from the chemical
Not flammable.

Hazardous Combustion Products Will not decompose under conditions of usual handling. Heating and alkaline pH promotes decomposition with the production of trace levels of 4-chloroaniline.

Explosion data
Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Evacuate personnel to safe areas. Use personal protection recommended in Section 8.

Environmental Precautions

Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so. Dike to collect large liquid spills.

Methods for Cleaning Up Take up with sand or other non-combustible absorbent material and place into containers for later disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling Avoid contact with skin, eyes or clothing. Wash thoroughly after handling. Wash contaminated clothing before reuse. Allow solution to dry completely prior to beginning any heat related treatments, including lasers.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store in a closed, airtight container. Store in a well-ventilated and dark place at room temperature.

Incompatible Materials Strong alkalis or reducing agents. Incompatible with soaps and other anionic materials.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, contains the following hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Isopropyl Alcohol, USP/NF 67-63-0	STEL: 400 ppm TWA: 200 ppm	TWA: 400 ppm TWA: 980 mg/m^3 (vacated) TWA: 400 ppm (vacated) TWA: 980 mg/m^3 (vacated) STEL: 500 ppm (vacated) STEL: 1225 mg/m^3	IDLH: 2000 ppm TWA: 400 ppm TWA: 980 mg/m^3 STEL: 500 ppm STEL: 1225 mg/m^3

Appropriate engineering controls

Engineering Controls In laboratories or industrial settings, handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]).

Individual protection measures, such as personal protective equipment

Eye/Face Protection In laboratory, medical or industrial settings, safety glasses with side shields are highly recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and Body Protection In laboratory, medical or industrial settings, gloves and lab coats are recommended. Contact a health and safety professional for specific information.

Respiratory Protection Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. In the United States of America, if respirators are used, they are to be NIOSH-approved and part of a respiratory protection program instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

General Hygiene Considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid.		
Appearance	Clear colorless liquid.	**Odor**	Faint alcohol-like odor.
Color	Colorless.	**Odor Threshold**	No information available

Property	**Values**	**Remarks**
pH	5.5 - 7.0	
Melting point/freezing point	No information available	
Boiling point/boiling range	No information available	
Flash point	48.9 °C	CC (closed cup)
Evaporation rate	No information available	
Flammability (solid, gas)	No information available	
Flammability Limit in Air		
Upper flammability limit:	No information available	
Lower flammability limit:	No information available	
Vapor pressure	No information available	
Vapor density	No information available	
Specific Gravity	1.06 - 1.07	
Water solubility	Not available.	Miscible
Solubility in other solvents	No information available	
Partition coefficient	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
Explosive Properties	No information available	
Oxidizing Properties	No information available	

Other information

Softening point	No information available
Molecular weight	897.8
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY

Reactivity
Strong reaction when combined with alkaline materials.

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Hazardous Polymerization Hazardous polymerization does not occur.

Conditions to Avoid
Not available.

Incompatible Materials
Strong alkalis or reducing agents. Incompatible with soaps and other anionic materials.

Hazardous Decomposition Products

None under normal use conditions. Heating and alkaline pH will promote decomposition with the production of trace levels of 4-chloroaniline.

11. TOXICOLOGICAL INFORMATION

Product Information

Acute Toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Isopropyl Alcohol, USP/NF 67-63-0	1870 mg/kg (Rat)	4059 mg/kg (Rabbit)	72600 mg/m^3 (Rat) 4 h	-
Chlorhexidine gluconate 18472-51-0	2 g/kg (Rat)	-	-	-
Cocamide DEA 68603-42-9	12400 µL/kg (Rat) > 5000 mg/kg (Rat)	> 2 g/kg (Rabbit)	-	-

Information on toxicological effects

Symptoms May cause eye irritation, skin irritation, respiratory irritation, including irritation of the nose and throat, coughing, and difficulty breathing, gastrointestinal irritation, nausea, vomiting, diarrhea, and transient to long-lasting disturbances in the sense of taste. Overexposure from repeated or prolonged skin contact may cause contact dermatitis, photosensitivity, and severe allergic response. Repeated inhalation may cause respiratory hypersensitization and asthma.

Delayed and immediate effects as well as chronic effects from short- and long-term exposure

Skin Corrosion/Irritation Chlorhexidine gluconate: Relevant skin irritation studies in animals were not found. Isopropyl alcohol: Produces minimal to mild skin irritation in animals.

Serious Eye Damage/Eye Irritation Chlorhexidine gluconate: 20% solution produced long-lasting, severe eye irritation in animals; chlorhexidine gluconate concentrations of 0.04-0.05% produced minimal to no eye irritation. Isopropyl alcohol: Produced moderate to severe eye irritation in animals.

Sensitization Chlorhexidine gluconate: Weak skin sensitizer (guinea pigs). Isopropyl alcohol: No data found.

Germ Cell Mutagenicity Chlorhexidine gluconate: Bacterial mutagenicity: positive S. typhimurium TA135/pSK 1002 µmµ: negative Chromosome aberration CHO (hamster): negative Mouse micronucleus: negative

Carcinogenicity In a 24-month drinking water study in rats, chlorhexidine gluconate decreased water consumption, but no other toxicity or evidence of carcinogenicity was observed at the highest dosage tested (50 mg/kg/day).

Chemical Name	ACGIH	IARC	NTP	OSHA
Isopropyl Alcohol, USP/NF 67-63-0		Group 3		
Cocamide DEA 68603-42-9		Group 2B		X

Legend

IARC (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

Group 3 - Not classifiable as a human carcinogen

Reproductive Toxicity Chlorhexidine gluconate: Administered by gavage to pregnant rats at dosages as high as 68.5 mg/kg/day (highest dosage tested) on days 6-15 of gestation did not induce fetal malformations.

STOT - Single Exposure Not available.

STOT - Repeated Exposure Not available.

Subchronic Toxicity Chlorhexidine gluconate: In a 5-day study, chlorhexidine gluconate aerosol was applied twice daily to rabbit nasal mucosa; the chlorhexidine gluconate concentrations were 0.20, 0.12, 0.06, or 0.03%. Histological, but not grossly observable evidence of irritation to the nasal mucosa (neutrophilic infiltrate and loss of epithelial cilia) was observed. The irritation exhibited a dose response relationship and no, no-observed effect level was observed for the microscopic changes seen in the study. It was noted, however, that at the <=0.06% level, the degree of irritation was minimal. In a one-month inhalation study, dogs were exposed to a chlorhexidine diacetate fog twice, daily. No adverse effects on hematology, clinical chemistry, body weight, temperature, or appearance and behavior were observed. Isopropyl alcohol: In 3-month inhalation studies in rats and mice, narcotic effects (ataxia hypo-activity) were observed during approximately the first two weeks during exposure to isopropyl alcohol vapors at concentrations of 1,500 - 5,000 ppm (6 hrs/day, 5 days/week). Other findings were observed only at the highest exposure level and consisted of transient changes in body weight and food consumption, increased liver weights in rats and female mice, and increased incidence of hyaline droplets in kidneys of male rats only. No other isopropyl alcohol effects were observed among the animals in the studies.

Target Organ Effects
- Gastrointestinal tract (GI).
- Skin
- Eyes.

Aspiration Hazard Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Isopropyl Alcohol, USP/NF 67-63-0	1000 mg/L: 72 h EC50 Desmodesmus subspicatus 1000 mg/L: 96 h EC50 Desmodesmus subspicatus	9640 mg/L: 96 h LC50 Pimephales promelas flow-through 11130 mg/L: 96 h LC50 Pimephales promelas Static 1400 mg/L: 96 h LC50 Lepomis macrochirus		13299 mg/L: 48 h EC50 Daphnia magna
Cocamide DEA 68603-42-9		3.6 mg/L: 96 h LC50 Brachydanio rerio semi-static		4.2 mg/L: 24 h EC50 Daphnia magna

Persistence and degradability
Not available.

Bioaccumulation
Not available.

Mobility
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Chemical Name	Partition coefficient
Isopropyl Alcohol, USP/NF 67-63-0	0.05

Other adverse effects
Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of Wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging Disposal should be in accordance with applicable regional, national and local laws and regulations. Do not reuse container.

US EPA Waste Number Not available.

California Hazardous Waste Codes Not available.

This product contains the following substances that are listed with the State of California as a hazardous waste.

Chemical Name	California Hazardous Waste Status
Isopropyl Alcohol, USP/NF 67-63-0	Toxic Ignitable

14. TRANSPORT INFORMATION

DOT Not regulated.

ICAO (air) Not regulated.

IATA Not regulated.

IMDG Not regulated.

15. REGULATORY INFORMATION

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

Chemical Name	CAS No.	Weight-%	SARA 313 - Threshold Values %
Isopropyl Alcohol, USP/NF - 67-63-0	67-63-0	1-5	1.0

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

Cocamide DEA is on California's Proposition 65 list; however, based on its percentage of the formulation, it is not considered to be hazardous.

Chemical Name	California Proposition 65
Cocamide DEA - 68603-42-9	Carcinogen

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Isopropyl Alcohol, USP/NF 67-63-0	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Prepared By IES Engineers
Issue Date 26-Nov-2018
Revision Date 24-Jul-2019
Revision Note New SDS.

Disclaimer

The information contained in this Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Safety Data Sheet relate only to the specific material designated herein and do not relate to use in combination with any other material. The data in this Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

End of Safety Data Sheet