



SAFETY DATA SHEET

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Version 1


1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name	Betasept® (chlorhexidine gluconate, 4%) Antiseptic Surgical Scrub
Synonyms	Chlorhexidine digluconate; chlorhexidine D-digluconate
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.
Distributor Address	Purdue Products L.P. One Stamford Forum 201 Tresser Boulevard Stamford, Connecticut 06901-3431 (888) 726-7535
24 Hour Emergency Phone Number	Chemtrec (800) 424-9300 For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

2. HAZARDS IDENTIFICATION

Serious eye damage/eye irritation	Category 1
Skin sensitization	Category 1B
Specific target organ toxicity (single exposure)	Category 2

Emergency Overview

Signal Word Danger		
Hazard Statements Causes serious eye damage May cause an allergic skin reaction May cause damage to organs		
		
Appearance Clear, colorless solution	Physical state Liquid	Odor Faint alcohol-like odor

Precautionary Statements - Prevention

Do not breathe dust/fume/gas/mist/vapors/spray. Wash face, hands and any exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product.

Precautionary Statements - Response

IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

Precautionary Statements - Storage

Store locked up.

Hazards Not Otherwise Classified (HNOC)

Not Applicable.

Other Information

May be harmful if swallowed
. 0% of the mixture consists of ingredient(s) of unknown toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight %
Isopropyl alcohol	67-63-0	1-5
Chlorhexidine gluconate	18472-51-0	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 flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
Inhalation	In case of inhalation, remove 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.
Self-protection of the first aider	Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

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.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	There is no known antidote for overexposure to Betasept® Surgical Scrub 4%. The use of activated charcoal is not expected to be clinically beneficial and may obscure visualization during endoscopy. Treat symptomatically.
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5. FIRE-FIGHTING MEASURES**Suitable Extinguishing Media**

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

Unsuitable Extinguishing Media No information 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.

Other Information Not Applicable.

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.

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

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Isopropyl alcohol 67-63-0	STEL: 400 ppm TWA: 200 ppm	TWA: 400 ppm TWA: 980 mg/m ³	IDLH: 2000 ppm TWA: 400 ppm TWA: 980 mg/m ³ STEL: 500 ppm STEL: 1225 mg/m ³

Engineering Controls Handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]). Keep container tightly closed. Minimize the amount of material handled at any one time.

Individual Protection Measures (Personal Protective Equipment)

Eye/face protection In laboratory, medical or industrial settings, ANSI-approved safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting or possibility of splashing. 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

None required for medical use. 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. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be 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

Physical and Chemical Properties

Physical state	Liquid
Appearance	Clear, colorless solution
Odor	Faint alcohol-like odor
Color	Colorless
Odor threshold	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	5.5 - 7.0	
Melting point / melting range	No information available.	
Boiling point / boiling range	No information available.	
Flash point	48.9 °C / 120 °F	CC (closed cup)
Evaporation rate	No information available.	
Flammability (solid, gas)	No information available.	
Flammability limits in air		
Upper flammability limits		
Lower flammability limits		
Vapor pressure	No information available.	
Vapor density	No information available.	
Specific gravity	1.06 - 1.07	
Water solubility	Miscible in water	
Solubility in other solvents	No information available.	
Partition coefficient (n-octanol/water)	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
Formula	C ₂₂ H ₃₀ Cl ₂ N ₁₀ ·2C ₆ H ₁₂ O ₇
VOC content; (%)	No information available.
Density	No information available.
Bulk density	No information available.

10. STABILITY AND REACTIVITY

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous reactions None under normal processing.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid None known based on available information.

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

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

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation May cause irritation of respiratory tract.

Eye contact Contact with eyes may cause irritation.

Skin contact Prolonged contact may cause redness and irritation. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

Ingestion May cause irritation.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Isopropyl alcohol	4396 mg/kg (Rat) 4500 mg/kg (Mouse)	12800 mg/kg (Rabbit)	16000 ppm (Rat) 8 h 12800 ppm (Mouse) 3 h
Chlorhexidine gluconate	2000 mg/kg (Rat) 1260 mg/kg (Mouse)	-	-

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

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 produces moderate to severe eye irritation in animals.

Sensitization Chlorhexidine gluconate was a weak skin sensitizer in guinea pigs. Reports of skin sensitization studies in animals with isopropyl alcohol were not found.

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

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

Carcinogenicity No information available.

Chemical Name	ACGIH	IARC	NTP	OSHA
Isopropyl alcohol 67-63-0		Group 3		

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 No information available.

STOT-repeated exposure No information available.

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

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 hypocactivity) 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 that 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 No information available.

Acute toxicity . 0% of the mixture consists of ingredient(s) of unknown toxicity.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Isopropyl alcohol	EC50 96 h > 1000 mg/L (Desmodesmus subspicatus - static) EC50 72 h > 1000 mg/L (Desmodesmus subspicatus - static)	LC50 96 h = 11130 mg/L (Pimephales promelas - static) LC50 96 h = 9640 mg/L (Pimephales promelas - flow-through) LC50 96 h > 1400000 µg/L (Lepomis macrochirus)		EC50 48 h = 13299 mg/L (Daphnia magna - static)

Persistence and degradability No information available.

Bioaccumulation No information available.

Chemical Name	Partition coefficient
Isopropyl alcohol	0.05

Other adverse effects No information 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 Do not reuse container.

Chemical Name	California Hazardous Waste Status
Isopropyl alcohol 67-63-0	Toxic Ignitable

14. TRANSPORT INFORMATION

DOT Not regulated.

ICAO (air) Not regulated per Special Provision A197.

IATA Not regulated.

IMDG Not regulated per IMDG Code 2.10.2.7.

15. REGULATORY INFORMATION

International Inventories

TSCA Not determined.
DSL Not determined.

Legend:

TSCA - United States Toxic Substances Control Act Section 8 (b) Inventory
 DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
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

This product contains a chemical known to the State of California to cause cancer. Cocamide DEA.

US State Right-to-Know Regulations

US EPA Label Information

EPA Pesticide Registration Number Not Applicable.

16. OTHER INFORMATION

<u>NFPA</u>	Health Hazards 1	Flammability 2	Instability 0	Physical and Chemical Properties -
<u>HMIS</u>	Health Hazards 1	Flammability 2	Physical Hazards 0	Personal protection X

General Information No additional information.

Prepared By This SDS was prepared by the Occupational and Environmental Assessment Section of Purdue Pharma L.P.

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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