SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol</td>
<td>67-63-0</td>
<td>1-5</td>
</tr>
<tr>
<td>Chlorhexidine gluconate</td>
<td>18472-51-0</td>
<td>1-5</td>
</tr>
</tbody>
</table>

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.

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.

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/PARTIAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol</td>
<td>STEL: 400 ppm</td>
<td>TWA: 400 ppm</td>
<td>IDLH: 2000 ppm</td>
</tr>
<tr>
<td>67-63-0</td>
<td>TWA: 200 ppm</td>
<td>TWA: 980 mg/m³</td>
<td>TWA: 400 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA: 980 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL: 500 ppm</td>
<td>STEL: 1225 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks • Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
<td></td>
</tr>
<tr>
<td>Appearance</td>
<td>Clear, colorless solution</td>
<td></td>
</tr>
<tr>
<td>Odor</td>
<td>Faint alcohol-like odor</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>Colorless</td>
<td></td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>5.5 - 7.0</td>
<td></td>
</tr>
<tr>
<td>Melting point / melting range</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>48.9 °C / 120 °F</td>
<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Flammability limits in air</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Upper flammability limits</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Lower flammability limits</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Specific gravity</td>
<td>1.06 - 1.07</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>Miscible in water</td>
<td></td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Kinematic viscosity</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Dynamic viscosity</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Softening point</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>897.8</td>
<td></td>
</tr>
<tr>
<td>Formula</td>
<td>C₂₂H₃₀Cl₂N₁₀·2CaH₁₂O₇</td>
<td></td>
</tr>
<tr>
<td>VOC content; (%)</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Density</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Bulk density</td>
<td>No information available.</td>
<td></td>
</tr>
</tbody>
</table>
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 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: positive
S. typhimurium TA135/pSK 1002 μm²: negative
Chromosome aberration CHO (hamster): negative
Mouse micronucleus: negative

Carcinogenicity
No information available.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol</td>
<td></td>
<td>Group 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 hypopacitivity) 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

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

Persistence and degradability: No information available.

Bioaccumulation: No information available.

Partition coefficient

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol</td>
<td>0.05</td>
</tr>
</tbody>
</table>

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.

California Hazardous Waste Status

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Hazardous Waste Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol</td>
<td>Toxic</td>
</tr>
<tr>
<td>67-63-0</td>
<td>Ignitable</td>
</tr>
</tbody>
</table>

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:
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

NFPA
Health Hazards: 1
Flammability: 2
Instability: 0
Physical and Chemical Properties:
HMIS
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.

Issue Date
14-Dec-2007
Revision Date
13-Apr-2015
Revision Note
SDS reformatted for OSHA (GHS) 2012.

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