Purdue Products L.P.

Material Safety Data Sheet

BETASEPT® Surgical Scrub
(4% Chlorhexidine Gluconate) **Version: 11-Jun-2013**

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: Chlorhexidone gluconate, 4% solution

Chemical Name

2,4,11,13-Tetraazatetradecanediimidamide, N,N''-bis (4-chlorophenyl)-3,12-diimino-,di-D-gluconate

Synonyms

Chlorhexidine digluconate
Chlorhexidine D-digluconate
D-Gluconic acid, compound with n,n'-bis (4- chlorophenyl)-3,12-diimino-2, 4,11,13-Tetraazatetradecanediimidamide (2:1)
1,1-hexamethylenebis [5-(4-chlorophenyl)biguanide] digluconate

Molecular Formula: $C_{22}H_{30}Cl_2N_{10} \bullet 2C_6H_{12}O_7$ **Molecular Weight**: 897.8

CAS Number: 18472-51-0

Product Use: Antiseptic/Antimicrobial. For External Use Only. Not for Retail Sale. For Professional and Hospital Use Only.

Company Identification

Responsible Party

Purdue Products L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Telephone: (888) 726-7535

EMERGENCY CONTACT

Chemtrec (800) 424-9300. For all international transportation emergencies call Chemtrec collect at (703) 527-3887.

2. HAZARDOUS COMPONENTS

Material	CAS Number	%
Chlorhexidine digluconate	18472-51-0	4
Isopropyl alcohol	67-63-0	4

May contain either or both of the following:

3. Hazards Identification

Emergency Overview

BETASEPT® Surgical Scrub 4% is an antiseptic/antimicrobial skin cleanser. Normal workplace handling should not constitute a hazard. The following information is provided for those circumstances where uncontrolled exposure may occur.

Colorless, clear liquid.
Faint alcohol-like odor.
May cause eye irritation.
May cause skin irritation and skin hypersensitization with prolonged or repeated exposure.
May cause gastrointestinal irritation if ingested.

Target organs: gastrointestinal tract, skin, eyes.

Potential Health Effects

BETASEPT® Surgical Scrub 4% is an antiseptic/antimicrobial skin cleanser. It is used for hand-scrubbing or washing by operating room personnel, for hand washing by medical personnel, for pre-operative skin preparation, and for skin wound and general skin cleansing. While BETASEPT® Surgical Scrub 4% contains as high as 4% isopropyl alcohol and 25% non-alkaline, non-ionic detergents, the contribution of these components to potential workplace hazard associated with the handling of BETASEPT® Surgical Scrub 4% is considered no greater than those posed by the chlorhexidine gluconate active component of the product as discussed below.

Eye contact with BETASEPT® Surgical Scrub 4% may cause irritation. Skin irritation may occur with prolonged or repeated application. Overexposure from repeated or prolonged skin contact may cause contact dermatitis, photosensitivity, and severe allergic responses. Anaphylaxis has been reported following administration of a chlorhexidine preparation to abraded skin wounds. Exposure of eczematous or ulcerated skin surfaces to chlorhexidine gluconate should be avoided, since these conditions may promote development of allergic reactions to chlorhexidine.

Inhalation of aerosolized BETASEPT® Surgical Scrub 4% would be expected to cause respiratory irritation (irritation of the nose and throat, coughing, difficulty breathing). Repeated inhalation of aerosolized BETASEPT® Surgical Scrub 4% may cause respiratory hypersensitization and asthma.

Ingestion of BETASEPT® Surgical Scrub 4% may cause gastrointestinal irritation (nausea, vomiting, and diarrhea) and transient to long-lasting disturbances in the sense of taste. Systemic toxicity is rare as chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. However, instances of aspiration of

ingested, regurgitated chlorhexidine gluconate solutions have resulted in hypotension and fatal Adult Respiratory Distress Syndrome (ARDS). It has been reported that isopropyl alcohol may produce gastrointestinal irritation and mild central nervous system depression in humans at doses as low as 20 mL; this would be equivalent to ingestion of 500 mL of BETASEPT® Surgical Scrub 4% and is highly unlikely to occur in a workplace setting.

Chlorhexidine gluconate and isopropyl alcohol were not teratogenic in rats. BETASEPT® Surgical Scrub 4% has not been studied in pregnant women or evaluated for reproductive effects in women; however, based on negligible transdermal absorption and long experience in the routine use of chlorhexidine scrubs by nurses and other health care professionals, BETASEPT® Surgical Scrub 4% is not expected to pose a risk to pregnant women. It is not known whether chlorhexidine gluconate passes through breast milk.

Conditions exacerbated by chlorhexidine gluconate exposure: asthma, eczema/seborrhea.

Carcinogenicity Information

Neither BETASEPT® Surgical Scrub 4% nor its components are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

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4. First Aid Measures

First Aid

INHALATION

If aerosols are inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

SKIN CONTACT

Remove contaminated clothing. Flush skin with plenty of water and wash thoroughly with soap and water. If irritation (redness, itching, swelling) develops, seek medical attention. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

INGESTION

If swallowed, do not induce vomiting. Drink two glasses of milk or water. Never give anything by mouth to an unconscious person. Get medical attention.

Notes 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

Flammable Properties

Not flammable.

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

Fire Fighting Instructions

Evacuate personnel to a safe area. Move containers from area if it can be done without risk. Wear protective clothing and positive-pressure, self-contained breathing apparatus with full protective gear.

6. Accidental Release Measures

Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up to minimize exposure to this material. Evacuate personnel from the area.

Initial Containment

Prevent material from entering sewers, waterways, or low areas. Use dikes to contain spilled material and retain for later disposal.

Spill Clean-up

Wear suitable protective clothing and equipment. Vacuum or mop up liquid and place in a container suitable for chemical waste; avoid generation of aerosols. Place collected material into a suitable container for disposal. Thoroughly wash area with detergent and water. Dispose of all solid waste and wash and rinse with water in accordance with federal, state, and local regulations.

7. Handling and Storage

Handling (Personnel)

Do not get in eyes, on skin, or on clothing. Do not taste. Wash thoroughly after handling. Wash contaminated clothing after use. Use only with adequate ventilation.

Handling (Physical Aspects)

Close container after each use.

Storage

Store in airtight container, in the dark. Keep container closed when not in use. Store at room temperature. Keep from contact with oxidizing materials.

8. Exposure Controls/Personal Protection

Engineering Controls

Handle material under adequate ventilation. Keep container tightly closed when not in use.

Personal Protective Equipment

Wear safety glasses with side shields. Wear full-face protection when judged that the possibility exists for eye and face contact.

Wear an appropriate NIOSH-approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate, to prevent skin contact. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Exposure Limits
BETASEPT® Surgical Scrub 4%: none established
Chlorhexidine gluconate: none established
Isopropyl alcohol
PEL (OSHA): 400 ppm
TLV (ACGIH): 200 ppm
TLV-STEL (ACGIH): 400 ppm

9. Physical and Chemical Properties

Physical Data

Odor:	faint alcohol-like odor
Form:	liquid
Color:	colorless
Solubility:	miscible with water
pH:	5.5 – 7.0
Specific Gravity (water=1):	1.06-1.07
Flash Point (closed cup):	>200°F

10. Stability and Reactivity

Chemical Stability

Low stability hazard expected at normal operating temperatures.

Reactivity

Not expected to be reactive.

Incompatibility with Other Materials

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

Decomposition

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

Polymerization

Material not expected to polymerize.

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11. Toxicological Information

Animal Data

BETASEPT® Surgical Scrub 4% has not undergone testing in laboratory animals. The following information is for chlorhexidine gluconate and isopropyl alcohol.

Skin/Eyes

Chlorhexidine gluconate

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. Relevant skin irritation studies in animals were not found. Chlorhexidine gluconate was a weak skin sensitizer in guinea pigs.

Isopropyl alcohol

Isopropyl alcohol produces moderate to severe eye irritation and minimal to mild skin irritation in animals. Reports of skin sensitization studies in animals with isopropyl alcohol were not found.

Acute

Chlorhexidine gluconate

Intravenous LD_{50}: rat:	24.2 mg/kg
Intravenous LD_{50}: mouse:	12.9 mg/kg
Oral LD_{50}: rat:	2000 mg/kg
Oral LD_{50}: mouse:	1260 mg/kg
Subcutaneous LD_{50}: rat:	3320 mg/kg
Subcutaneous LD_{50}: mouse:	1140 mg/kg

Isopropyl alcohol

Inhalation LC_{50}: rat: 8 hr	16000ppm
Inhalation LC_{50}: mouse: 3 hr	12800ppm
Oral LD_{50}: rat:	4700-5800 mg/kg
Oral LD_{50}: mouse:	4500 mg/kg
Subcutaneous LD_{50}: mouse:	6000 mg/kg

Subchronic

Chlorhexidine gluconate

In a 5-day study, a 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, appearance or behavior were observed.

Isopropyl Alcohol

In 3-month inhalation studies in rats and mice, narcotic effects (ataxia, hypoactivity) were observed during approximately the first two weeks during exposure to isopropanol 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 the kidneys of male rats only. No other isopropyl alcohol effects were observed among the animals in the study.

Chronic Toxicity/Carcinogenicity

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 highest dosage tested (50 mg/kg/day).

Mutagenicity/Genotoxicity:

Bacterial mutagenicity:	positive
S. typhimurium TA135/pSK1002 μmμ:	negative
Chromosome aberration CHO (hamster):	negative
Mouse micronucleus:	negative

Developmental/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.

12. Ecological Information

Ecotoxicological Information
No information available

Chemical Fate Information
No information available

13. Disposal Considerations

Disposal
This material is not listed under US RCRA. Disposal of this material must be in accordance with federal, state/provincial, and local regulations.

14. Transportation Information

Shipping Information
This material is non-hazardous under US DOT.

15. Regulatory/Statutory Information

Under California Proposition 65 ("Prop 65"), businesses are required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical. This warning can be given by a variety of means, such as by adding a statement to product labeling. On June 22, 2012, cocamide diethanolamine ("cocomide DEA"), was added to the Prop 65 list. Cocamide DEA is a diethanolamide made by reacting the mixture of fatty acids from coconut with diethanolamine. It is a viscous liquid and is used as a foaming agent in bath products like shampoos and hand soaps, and in cosmetics as an emulsifying agent.

Cocomide DEA is an inactive ingredient in Betasept® Antiseptic Surgical Scrub. As required by Prop 65, effective June 22, 2013, the Betasept® Scrub label is being modified to reflect the required warning under Prop 65. Specifically, the warnings section of the label will now also include the following: "This product contains a chemical known to the State of California to cause cancer." In addition, the front panel of the bottle now will also include: "For External Use Only. Not for Retail Sale. For Professional and Hospital Use Only."

16. Other Information

Purdue Products L.P.

The information contained in this Material 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 Material 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 Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared for Purdue Products L.P. by the Occupational and Environmental Assessment Section of Purdue Pharma L.P. and Ariel Research Corporation.