

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Name: HIBICLENS®

Address/Phone No. : ZENECA Inc.
Wilmington
Delaware 19850-5437
Phone(24 hr.) Technical : (302) 886-3000
Chemtec : (800) 424-9300
Medical : (800) 327-8633

2. COMPOSITION/INFORMATION ON INGREDIENTS

CAS No. : None assigned for the product.
Use : Antimicrobial agent

HAZARDOUS INGREDIENT(S)	CAS No.	%(w/w)
Chlorhexidine gluconate	018472-51-0	4.0
Isopropanol (2-Propanol)	000067-63-0	4.0

3. HAZARDS IDENTIFICATION

Form : clear liquid
Color : pink
Odor : fragranced

Repeated or prolonged skin contact may cause irritation in sensitive individuals.
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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4. FIRST-AID MEASURES

Inhalation : Remove patient from exposure, keep warm and at rest.
Obtain medical attention if ill effects occur.

Skin Contact : Wash skin with water.

Eye Contact : Irrigate with eyewash solution or clean water, holding
the eyelids apart, for at least 15 minutes. Obtain
medical attention.

Ingestion : Wash out mouth with water. Obtain medical attention.

Note to Physicians

Symptomatic treatment and supportive therapy as indicated. For further
detail consult the prescribing information.

5. FIRE-FIGHTING MEASURES

Flammable Properties

Flash Point (Deg C/Deg F)	: 64.4/148
Flammable Limits (Lower) (%v/v)	: 2
Flammable Limits (Upper) (%v/v)	: 12
Flammable Limits	: (isopropanol)
Auto Ignition Temperature (Deg C/Deg F)	: No data.

Combustible.

If involved in a fire, it may emit flammable vapors.

Extinguishing Media

water spray, foam, dry chemical or CO₂.

Fire Fighting Instructions

A self contained breathing apparatus and suitable protective clothing
should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

Small spillages: Clear up spillages. Drench spillages with water and
wash to drain.

Large spillages: Do not allow to enter drains, sewers or watercourses.
Adsorb spillages onto sand, earth or any suitable adsorbent material.
Transfer to a container for disposal.

Wash the spillage area with water, and flush to a sewer serviced by a
wastewater treatment facility.

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7. HANDLING AND STORAGE

7.1 HANDLING

Avoid contact with eyes.

Follow procedures specified in the National Fire Protection Association Codes and Standards for handling combustible liquids.

7.2 STORAGE

Keep container tightly closed. Protect from light.

Storage Temperature : room temperature

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls Occupational Exposure Limits

No ACGIH TLV or OSHA PEL is assigned to this mixture.

HAZARDOUS INGREDIENT(S)	TWA		STEL/CEILING (C)		
	ppm	µg/m ³	ppm	µg/m ³	
Chlorhexidine	-	-	-	0.1	COM
This is an in-house standard for the active ingredient during manufacture.					
Isopropyl alcohol	400	983	500	1230	TLV

Personal Protective Equipment

- Respirators : If needed, use NIOSH approved respirator for organic vapors.
- Protective Clothing : Impervious gloves and apron.
- Eye Protection : Chemical tight goggles; full faceshield in addition if splashing is possible.
- Other Protective Equipment : Eyewash station and safety shower in work area.
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9. PHYSICAL AND CHEMICAL PROPERTIES

Form	: clear liquid
Color	: pink
Odor	: fragranced
pH (Value)	: 5-6.5
Boiling Point (Deg C/Deg F)	: No data.
Vapor Pressure (mm Hg)	: No data.
Solubility (Water)	: soluble
Specific Gravity	: 1.06
Vapor Density (Air= 1)	: No data.

10. STABILITY AND REACTIVITY

Stable under normal conditions.

Hazardous Reactions : Incompatible materials: strong oxidizing agents , anionic compounds
Hazardous polymerization will not occur.

Hazardous Decomposition Product(s) : carbon monoxide, carbon dioxide, nitrogen oxides, ammonia

11. TOXICOLOGICAL INFORMATION

Inhalation : The vapor has anesthetic properties and when inhaled at concentrations above the occupational exposure limit it may cause headache, fatigue, dizziness, incoordination and loss of consciousness.

Skin Contact : Repeated or prolonged skin contact may cause irritation in sensitive individuals.

Eye Contact : Liquid splashes may cause eye irritation.

Ingestion : The swallowing of small splashes is unlikely to cause any adverse effects.

Long Term Exposure : Chronic effects are unlikely.

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12. ECOLOGICAL INFORMATION

Environmental Fate and Distribution

The product is soluble in water.

Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Effect on Effluent Treatment

Low toxicity to sewage micro-organisms.

13. DISPOSAL CONSIDERATIONS

Disposal should be in accordance with local, state or national legislation.

Disposal Method

Discarded product is not a hazardous waste under RCRA, 40 CFR 261.

Container Disposal

Empty container retains product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

Not Classified as Dangerous for Transport.

15. REGULATORY INFORMATION

TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710:
All ingredients are on the TSCA Chemical Substances Inventory.

CERCLA and SARA Regulations (40 CFR 355, 370 and 372):
This product does not contain any chemicals subject to the reporting requirements of SARA Section 313.

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16. OTHER INFORMATION

This Material Safety Data Sheet was prepared in accordance with ANSI Standard Z400.1, 1993.

GLOSSARY

- COM : The company aims to control exposure in its workplace to this limit
This is an in-house standard for the active ingredient
handled during manufacture
- TLV : The company aims to control exposure in its workplace to the ACGIH
limit
- Sk : Can be absorbed through skin
- Sen : Capable of causing respiratory sensitization

The information herein is given in good faith but no warranty, expressed or implied, is made.

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talized depressed patients. *J Nerv Ment Dis* 1964; 132:370-375.

Rorden A, Burt CG, Holt NF: Depressive states: A pharmacotherapeutic study. Springfield study. Springfield, Ill, Charles C. Thomas, 1966.

Klerman GL, Cole JO: Clinical pharmacology of imipramine and related antidepressant compounds. *Int J Psychiatry* 1976;3:267-304

McConaghy N, Joffe AD, Kingston WR, et al: Correlation of clinical features of depressed out-patients with response to amitriptyline and protriptyline. *Br J Psychiatry* 1968; 114:103-106

McDonald DM, Perkins M, Marjerrison G, et al: A controlled comparison of amitriptyline and electroconvulsive therapy in the treatment of depression. *Am J Psychiatry* 1966;122: 1427-1431.

Slovic T, Ott J, Teitelbaum, et al: Physostigmine therapy in acute tricyclic antidepressant poisoning. *Clin Toxicol* 1971;4: 451-459.

Symposium on depression with special studies of a new antidepressant, amitriptyline. *Dis Nerv Syst*, (Sect 2) May 1961, pp 5-86.

* Registered trademark of ICI Americas Inc.

** Based on a maximum recommended amitriptyline dose of 150 mg/day or 3 mg/kg/day for a 50 kg patient.

*** Hollister LE: *JAMA* 1979;241:2380-2633.

Manufactured for
Stuart Pharmaceuticals
A business unit of ICI Americas Inc.
Wilmington, DE 19897 USA
by Merck Sharp & Dohme, Division of Merck & Co., Inc.
Rev C 05/91

Shown in Product Identification Section, page 332

Physicians' Desk Reference®

Consult 1994 Supplements for revisions

ration, and as a skin wound cleanser and general skin cleanser.

SAFETY

The extensive use of chlorhexidine gluconate for over 20 years outside the United States has produced no evidence of absorption of the compound through intact skin. The potential for producing skin reactions is extremely low. HIBICLENS can be used many times a day without causing irritation, dryness, or discomfort. Experimental studies indicate that when used for cleaning superficial wounds, HIBICLENS will neither cause additional tissue injury nor delay healing.

WARNINGS

FOR EXTERNAL USE ONLY. KEEP OUT OF EYES, EARS AND MOUTH. HIBICLENS SHOULD NOT BE USED AS A PREOPERATIVE SKIN PREPARATION OF THE FACE OR NECK. MISUSE OF HIBICLENS HAS BEEN REPORTED TO CAUSE SERIOUS AND PERMANENT EYE INJURY WHEN IT HAS BEEN PERMITTED TO ENTER AND REMAIN IN THE EYE DURING SURGICAL PROCEDURES. IF HIBICLENS SHOULD CONTACT THESE AREAS, RINSE OUT PROMPTLY AND THOROUGHLY WITH WATER. Avoid contact with meninges. HIBICLENS should not be used by persons who have a sensitivity to it or its components. Chlorhexidine gluconate has been reported to cause deafness when instilled in the middle ear through perforated ear drums. Irritation, sensitization and generalized allergic reactions have been reported with chlorhexidine-containing products, especially in the genital areas. If adverse reactions occur, discontinue use immediately and if severe, contact a physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Accidental ingestion: Chlorhexidine gluconate taken orally is poorly absorbed. Treat with gastric lavage using milk, egg white, gelatin or mild soap. Employ supportive measures as appropriate.

Avoid excessive heat (above 104°F).

DIRECTIONS FOR USE

Patient preoperative skin preparation
Apply HIBICLENS liberally to surgical site and scrub for at least two minutes. Dry with a sterile towel. Repeat procedure for an additional two minutes and dry with a sterile towel.
Preoperative showering and whole-body bathing
The patient should be instructed to wash the entire body, including the scalp, on two consecutive occasions immediately prior to surgery. Each procedure should consist of two consecutive thorough applications of HIBICLENS followed by thorough rinsing. If the patient's condition allows, showering is recommended for whole-body bathing. The recommended procedure is: Wet the body, including hair. Wash the hair using 25 mL of HIBICLENS and the body with another 25 mL of HIBICLENS. Rinse. Repeat. Rinse thoroughly after second application.

Skin wound and general skin cleansing

Wounds which involve more than the superficial layers of the skin should not be routinely treated with HIBICLENS. HIBICLENS should not be used for repeated general skin cleansing of large body areas except in those patients whose underlying skin condition makes it necessary to reduce the bacterial population of the skin. To use, thoroughly rinse the area to be cleansed with water. Apply the minimum amount of HIBICLENS necessary to cover the skin or wound area and wash gently. Rinse again thoroughly.

HEALTH-CARE PERSONNEL USE

SURGICAL HAND SCRUB

Directions for use of HIBICLENS Liquid: Wet hands and forearms to the elbows with warm water. (Avoid using very cold or very hot water.) Dispense about 5 mL of HIBICLENS into cupped hands. Spread over both hands. Scrub hands and forearms for 3 minutes without adding water, using a brush or sponge. (Avoid using extremely hard-bristled brushes.) While scrubbing, pay particular attention to fingernails, cuticles, and interdigital spaces. (Do not use excessive pressure to produce additional lather.) Rinse thoroughly with warm water. Dispense about 5 mL of HIBICLENS into cupped hands. Wash for an additional 3

minutes. (No need to use brush or sponge.) Then rinse thoroughly. Dry thoroughly.

HAND WASH

Wet hands with warm water. (Avoid using very cold or very hot water.) Dispense about 5 mL of HIBICLENS into cupped hands. Wash for 15 seconds. (Do not use excessive pressure to produce additional lather.) Rinse thoroughly with warm water. Dry thoroughly.

Directions for use of HIBICLENS® Sponge/Brush Open package and remove nail cleaner. Wet hands. Use nail cleaner under fingernails and to clean cuticles. Wet hands and forearms to the elbow with warm water. (Avoid using very cold or very hot water.) Wet sponge side of sponge/brush. Squeeze and pump immediately to work up adequate lather. Apply lather to hands and forearms using sponge side of the product. *Start 3 minute scrub* by using the brush side of the product to scrub only nails, cuticles, and interdigital areas. Use sponge side for scrubbing hands and forearms. (Avoid using brush on these more sensitive areas.) Rinse thoroughly with warm water. Scrub for an additional 3 minutes using sponge side only. To produce additional lather, add a small amount of water and pump the sponge. (While scrubbing, do not use excessive pressure to produce lather—a small amount of lather is all that is required to adequately cleanse skin with HIBICLENS.) Rinse and dry thoroughly. blotting hands and forearms with a soft sterile towel.

IMPORTANT LAUNDERING ADVICE FOR HOSPITAL STAFF AND OTHER USERS OF ANTISEPTIC PATIENT SKIN PREPARATIONS CONTAINING CHLORHEXIDINE GLUCONATE

Chlorhexidine gluconate is a unique agent that most closely fits the definition of an ideal antimicrobial agent, having (among others) one of the most important characteristics of persistent activity. This persistence is due to chlorhexidine gluconate binding to the protein of the skin and, thus, being available for residual activity over a relatively long period of time.

Chlorhexidine gluconate, however, binds not only to protein of the skin, but also to many fabrics, particularly cotton. Thus, special laundering procedures should be considered when such products contact these fabrics. As a result of such contact, chlorhexidine gluconate may become adsorbed onto the fabric and not be removed by washing. If sufficient available chlorine is present during the washing procedure, a fast brown stain may develop due to a chemical reaction between chlorhexidine gluconate and chlorine.

SUGGESTED LAUNDERING PROCEDURES TO LIMIT STAINING

1. Not Aging. Avoid allowing the product to age (set) on unwashed linens.
2. Flushing and Washing. A flush operation as the initial step in the wash process is helpful in the laundering of linen exposed to chlorhexidine gluconate. Such flushing is also important in the laundering of linen which contains organic materials such as blood or pus. For best results, warm water flushes (90°-100°F) are recommended. After a number of initial flushings followed by a washing with a low alkaline/nonchlorine detergent, most articles which come in contact with chlorhexidine gluconate should have an acceptable level of whiteness. If a rewash process using bleach is necessary to achieve a greater degree of whiteness, the bleach used should be a nonchlorine bleach.
3. Not Using Chlorine Bleach. Modern laundering methods often make the use of chlorine bleach unnecessary. It is worthwhile trying to wash without chlorine to ascertain if the resulting degree of whiteness is acceptable. Omission of chlorine from the laundering process can extend the useful life of cotton articles since oxidizing bleaches such as chlorine may cause some damage to cellulose even when used in low concentration.
4. Changing to a Peroxide-Type Bleach. Such as Sodium Percarbonate, Sodium Perborate or Hydrogen Peroxide. This should eliminate the reaction which could occur with the use of chlorine bleaches. If a chlorine bleach must be used, a concentration of less than 7 ppm available chlorine (1/10 the normal bleach level) is suggested to minimize possible staining.

A NOTE ON LAUNDERING OF PERSONAL CLOTHING

The laundering procedures set forth above using low alkaline, nonchlorinated laundry detergents are also applicable to laundering of uniforms and lab coats. Commercially available laundry detergents which do not contain chlorine include Borax, Borateam, Drest, Oxydol, and Ivory Snow. These products, however, will not remove stains previously set into the fabric.

RECLAMATION OF STAINED LINENS

For those linens which previously have been stained due to the chemical reaction between chlorhexidine gluconate and chlorine, the following laundering procedure may be helpful in reducing the visible stain:
[See table at left.]

HOW SUPPLIED

For general handwashing locations: pocket size, 16 mL foil packets; plastic disposable bottles.

HIBICLENS® Antiseptic/Antimicrobial OTC
(Hi-'bi-kleenz)
Skin Cleanser
(chlorhexidine gluconate)

DESCRIPTION

HIBICLENS is an antiseptic antimicrobial skin cleanser possessing bactericidal activity. HIBICLENS contains 4% w/v HIBITANE® (chlorhexidine gluconate), a chemically unique hexamethylenebis biguanide with inactive ingredients: fragrances, isopropyl alcohol 4%, purified water, Red 40, and other ingredients, in a mild, soothing base adjusted to pH 5.0-6.6 for optimal activity and stability as well as compatibility with the normal pH of the skin.

ACTION

HIBICLENS is bactericidal on contact. It has antiseptic activity and a persistent antimicrobial effect with rapid bactericidal activity against a wide range of microorganisms, including gram-positive bacteria, and gram-negative bacteria such as *Pseudomonas aeruginosa*. The effectiveness of HIBICLENS is not significantly reduced by the presence of organic matter, such as blood.

In a study¹ simulating surgical use, the immediate bactericidal effect of HIBICLENS after a single six-minute scrub resulted in a 99.9% reduction in resident bacterial flora, with a reduction of 99.98% after the eleventh scrub. Reductions on surgically gloved hands were maintained over the six-hour test period.

HIBICLENS displays persistent antimicrobial action. In one study², 83% of a radiolabeled formulation of HIBICLENS remained present on uncovered skin after five hours.

HIBICLENS prevents skin infection thereby reducing the risk of cross-infection.

INDICATIONS

HIBICLENS is indicated for use as a surgical scrub, as a health-care personnel handwash, for patient preoperative showering and bathing, as a patient preoperative skin prepa-

Operation	Water Level	Temperature	Time (Min)	Supplies/100 lb
Break	Low	180°F	20	1.5 lb oxalic acid
Flush	High	Cold	1	—
Emulsify	Low	160°F	5	16 oz emulsifier
Flush	High	Cold	1	—
Bleach	Low	180°F	20	2 lb alkali builder and 1 lb organic bleach
Rinse	High	Cold	1	—
Antichlor	High	Cold	2	4 oz antichlor
Rinse	High	Cold	1	—
Rinse	High	Cold	1	—
Soap	Low	Cold	4	2 oz rust removing SOAP