

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-669**

**APPROVED LABELING**

**Drug Facts (continued)**

- use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas.
- dry surgical sites (such as abdomen or arm): use one cloth to cleanse each 161 cm<sup>2</sup> area (approximately 5 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- moist surgical sites (such as inguinal fold): use one cloth to cleanse each 65 cm<sup>2</sup> area (approximately 2 x 5 inches) of skin to be prepared. Vigorously rub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- discard each cloth after a single use
- after package has been opened discard any unused cloths

**Other information**

- store product flat
- store between 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients**

aloe vera, dimethicone, fragrance, glucono-delta-lactone, glycerin, isopal, polyacrylate 20, propylene glycol, USP purified water  
cloth: polyester

**Questions or comments?**

call toll-free 800-323-2220  
(Monday to Friday 8 AM-5 PM CST)  
[www.sageproducts.com](http://www.sageproducts.com)

Reorder # 9705



**SAGE**  
PRODUCTS INC.

800-323-2220  
3909 Three Oaks Road  
Cary, IL 60013  
[www.sageproducts.com](http://www.sageproducts.com)

**SAGE**<sup>®</sup>  
PRODUCTS INC.

**2% CHLORHEXIDINE  
GLUCONATE\* CLOTH**  
**PATIENT PREOPERATIVE  
SKIN PREPARATION**

\* equivalent to 500mg chlorhexidine gluconate per cloth

**NON-STERILE**

Provides rapid bactericidal action  
against a broad spectrum of microorganisms

Significantly reduces the number  
of microorganisms on intact skin

Demonstrates continued antimicrobial  
activity for up to 6 hours after application

Alcohol free — Rinse free  
For external use only — Single use

**2 DISPOSABLE CLOTHS**  
8 in x 8 in (20.3 cm x 20.3 cm)

DO NOT MICROWAVE

**Drug Facts**

Active ingredient	Purpose
Chlorhexidine gluconate 2% solution	Antiseptic

**Uses**

- helps reduce bacteria that can potentially cause skin infection
- for preparation of skin prior to surgery

**Warnings**

For external use only

**Do not use**

- in premature or low birthweight infants, infants receiving phototherapy or children less than 2 months of age
- on patients with known allergies to chlorhexidine gluconate or any other ingredients in this product
- for lumbar punctures or in contact with the meninges
- on open skin wounds or as a general skin cleanser

**When using this product**

- keep out of eyes, ears and mouth. May cause serious or permanent injury if chlorhexidine is permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children  
If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- do not microwave
- product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products.
- To open package**
- holding top of package in one hand, lift flap on backside of package with other hand
- grasp flap at top and pull down to tear flap away and expose foam
- hold outside of package to prevent foam and cloths to prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination
- Or
- using sterile scissors, cut off end seal of package
- transfer contents onto prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination



**DO NOT FLUSH  
CLOTHS IN TOILET**

**LATEX FREE**

Patent Pending

1010

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Charles Ganley  
4/25/05 01:45:28 PM

Janice Soreth  
4/25/05 01:53:07 PM