

Sage 2% Chlorhexidine Gluconate Cloth



# Environmental data specification sheet

This document serves as a substitute for the Safety Data Sheet for US 2% CHG Cloths

2% Chlorhexidine Gluconate (CHG) is a drug product under FDA regulations<sup>1</sup>; therefore, a Safety Data Sheet is not required per OSHA. Please accept this Environmental data specifications sheet as a substitute.

### Product use:

The 2% CHG Pre-Op Prep products are topical, over-the-counter (OTC) human drug products, which are generally recognized as safe and effective, intended for use as pre-operative skin preparations. 2% CHG cloths help reduce bacteria that can potentially cause skin infections. Please follow all labeled instructions.

Please contact Sage Products, LLC for further information 3909 Three Oaks Road, Cary, Illinois 60013 800 323 2220

### **Environmental information**

Recyclability	No
Latex	N/A
Prop 65 status	This product is not subject to warning labeling under California Proposition 65.
SARA 311/312 SARA 313/302/3	Fire Hazard – No, Pressure Hazard – No, Reactivity Hazard- No, Immediate Hazard – No, Delayed Hazard – No <b>04/311/312 chemicals</b> None
REACH	N/A
Nitrosamines	nitrosamine presence is extremely unlikely in 2% Chlorohexidine Gluconate products
Use information	
Demographics	Adult patients, children and infants older than 2 months of age. Use with care in premature infants or infants under 2 months of age.
Duration of usage	Vigorously scrub skin back and forth for 3 minutes. Continued antimicrobial activity for up to 6 hours after application.



## Sage 2% Chlorhexidine Gluconate Cloth



# Environmental data specification sheet continued

### **Specifications**

**Product name** 2% Chlorhexidine Gluconate Cloth

**Description** The finished product consists of disposable polyester nonwoven cloths impregnated with a 2%

chlorhexidine gluconate (CHG) solution (approx. 500~mg CHG/ cloth) that are stacked onto a

polyethylene foam carrier and packaged in a flexible film overwrap.

Storage information Store product flat. Store between 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F)\*

**Expiration date** 14 or 18 months depending on product configuration

**Size of each**  $7.5 \text{ in } \times 7.5 \text{ in } (19.1 \text{ cm } \times 19.1 \text{ cm})$ 

Number of products in a package/case

9705-2 cloths/package,

9707 - 3 individually wrapped packages with 2 cloths each

9717-6 cloths/package

**Sterility** Non-sterile

Inactive Ingredients aloe vera, dimethicone, fragrance, glucono-delta-lactone, glycerin, Nonoxynol-9, polysorbate 20, propylene

glycol, USP purified water

**Cloth material** polyester

Country of Origin United States of America

#### **Product Information for United States**

Classification Drug (OTC)

FDA Product Code 61LBY14

Establishment Registration Number 1419181

National Drug Code (NDC): 53462-705-20, 53462-705-23, 53462-705-26

### Packaging information

**External materials used** Foam carrier - polyethylene

Flexible film overwrap - PET/Alumina-oxide coated PET/LLDPE

 $Peel- and-reseal\ label-polypropylene/adhesive/ink/polyole fin/removable\ adhesive$ 

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<sup>1.</sup> Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is exempt from OSHA's Hazardous Communication Standard requirements, including a Safety Data Sheet. (29 Code of Federal Regulations 1910.1200)

<sup>\*2%</sup> CHG cloth is approved for use in warmers at temperatures up to 125°F for up to 84 hours