

ChloroPrep® patient preoperative skin preparation

Nonsterile solution label update

Prep for a label change

To improve clinician awareness and patient safety, updated ChloroPrep® patient preoperative skin preparation labels communicate that the solution is nonsterile.

Background

In 2013, the U.S. Food and Drug Administration (FDA) requested that manufacturers of over-the-counter topical antiseptics make changes to their products in an ongoing effort to improve patient safety. The modifications included a request that manufacturers use single-use packaging and revise the product labels to indicate whether the antiseptic solution and applicator contained within the product is sterile or nonsterile.

A sterile applicator with nonsterile solution

A product labeled as nonsterile does not suggest the product is contaminated with microorganisms; instead, its contents have not been sterilized individually. While all ChloroPrep applicators are sterilized at the end of the manufacturing process, the solution inside the applicators is not treated with a separate sterilization process and is, therefore, not sterile.

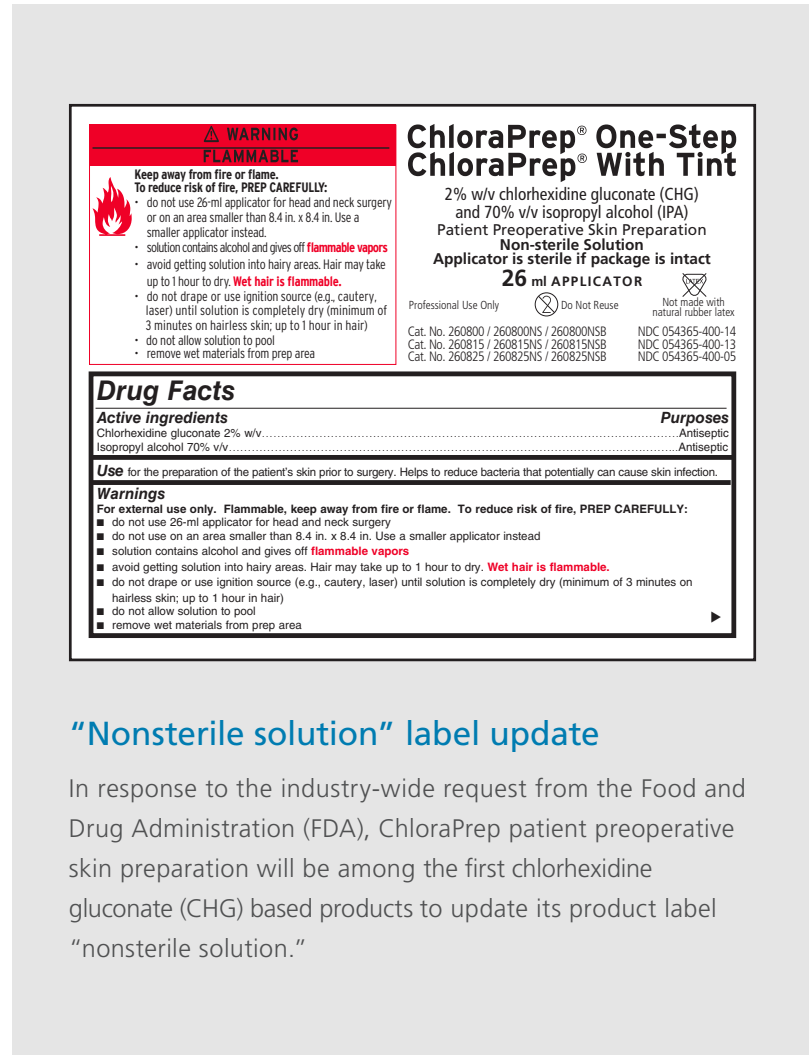
There are currently no products in the U.S. that contain a chlorhexidine gluconate (CHG)-based sterile solution—only sterile applicators.

Quality Assurance

ChloroPrep t preoperative skin preparation products have never been documented as the cause of contamination causing patient infection. The safety and consistency of ChloroPrep is guaranteed through well-designed and controlled manufacturing and testing procedures including chemical analysis, microbial analysis, applicator integrity reviews and package testing. These steps ensure that each ChloroPrep applicator will consistently perform as intended.



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“Nonsterile solution” label update

In response to the industry-wide request from the Food and Drug Administration (FDA), ChloroPrep patient preoperative skin preparation will be among the first chlorhexidine gluconate (CHG) based products to update its product label “nonsterile solution.”



CareFusion

Labels will be updated on the applicators in the ChloroPrep portfolio:

Cat. no.	Applicator
260100	Single swabstick 1.75 mL
260103	Triple swabstick 5.25 mL
260449	SEPP® applicator
260480	1 mL clear applicator
260299	FREPP® 1.5 mL clear applicator
260400	3 mL clear applicator
260415	3 mL Hi-Lite Orange® tint
260700	10.5 mL clear applicator
260715	10.5 mL Hi-Lite Orange tint
260725	10.5 mL Scrub Teal® tint
260800	26 mL clear applicator
260815	26 mL Hi-Lite Orange tint
260825	26 mL Scrub Teal tint



The same antiseptics solution

While CareFusion is updating its label, the ChloroPrep patient preoperative skin preparation formulation, patented applicator design or single-use packaging have not changed. ChloroPrep continues to be the trusted one-step, broad spectrum antiseptic that reduces microorganisms on the skin that can cause infection.

Contact your sales representative or call customer support at **800.323.9088**.

Learn more at carefusion.com/labelupdate.

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