

Technical Bulletin

Micro-Guard® CHG 4% safety and efficacy when used in combination with Coloplast EasiCleanse® Bath



The purpose of this technical bulletin is to share with clinical staff the efficacy and safety of Micro-Guard® CHG 4% Solution as a stand-alone product, and when added directly to a package of EasiCleanse® Bath 5- or 8-pack.

Efficacy²

Background

Antimicrobial efficacy was carried out following an In-Vitro Time-Kill Method using microorganisms based on guidance from the Proposed Rules (Federal Register/ Vol.81, No.126/ Thursday June 30, 2016) for 21 CFR Part 310: Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed amendment of the Tentative Final Monograph;

Reopening of Administrative Record (the list of microorganisms is specifically listed on page 42921). Antimicrobial efficacy was determined by comparing the time-kill results of Micro-Guard CHG 4% Solution alone, and the time-kill results of a 4 oz. bottle of MicroGuard 4% CHG combined with EasiCleanse Bath. Per the FDA definition in the proposed rule, the product will be considered bactericidal at concentration and contact time that demonstrates a 3-log₁₀ (99.9 percent) or greater reduction in bacterial viability.¹

Results

Both Micro-Guard CHG 4% Solution alone and the combination of Micro-Guard 4% CHG and EasiCleanse Bath killed all 33 listed organisms to 99.9% level at 10 minutes of exposure.

In-vitro time-kill evaluation test results for Micro-Guard CHG 4% Solution alone and in combination with EasiCleanse Bath

Microorganism species	ATCC #	% reduction for Micro-Guard CHG 4% Solution	% reduction for Micro-Guard CHG 4% Solution and EasiCleanse Bath
Actinobacter baumannii	19606	99.99%	99.99%
Burkholderia fragilis	25285	99.99%	99.99%
Burkholderia cepacia	25416	99.98%	99.98%
Campylobacter jejuni	33291	99.99%	99.99%
Campylobacter jejuni	49943	99.98%	99.99%
Candida albicans	18804	99.99%	99.99%
Enterobacter cloacae	13047	99.99%	99.99%
Enterococcus faecalis	19433	99.99%	99.99%
Enterococcus faecalis	29212	99.99%	99.99%
Enterococcus faecalis VRE	51299	99.99%	99.99%
Escherichia coli	11775	99.99%	99.99%
Escherichia coli	25922	99.99%	99.99%
Haemophilus influenzae	19418	99.99%	99.99%
Klebsiella pneumoniae	13883	99.99%	99.99%
Klebsiella pneumoniae	27736	99.99%	99.99%
Listeria monocytogenes	7644	99.99%	99.99%
Listeria monocytogenes	19115	99.99%	99.99%

(continued)

In-vitro time-kill evaluation test results for Micro-Guard CHG 4% Solution alone and in combination with EasiCleanse Bath

Microorganism species	ATCC #	% reduction for Micro-Guard CHG 4% Solution	% reduction for Micro-Guard CHG 4% Solution and EasiCleanse Bath
Pseudomonas aeruginosa	15442	99.99%	99.99%
Pseudomonas aeruginosa	27853	99.99%	99.99%
Salmonella enterica	13076	99.99%	99.99%
Salmonella enterica	14028	99.99%	99.99%
Serratia marcescens	8100	99.99%	99.99%
Serratia marcescens	14756	99.99%	99.99%
Shigella sonnei	9290	99.99%	99.99%
Shigella sonnei	25931	99.99%	99.99%
Staphylococcus aureus	6538	99.93%	99.93%
Staphylococcus aureus	29213	99.97%	99.97%
Staphylococcus aureus MRSA	33591	99.97%	99.97%
Staphylococcus aureus MRSA	33592	99.98%	99.98%
Streptococcus pneumoniae	6303	99.99%	99.99%
Streptococcus pneumoniae	49619	99.96%	99.96%
Streptococcus pyogenes	14289	99.99%	99.99%
Streptococcus pyogenes	19615	99.98%	99.98%

Safety³

Background

Safety was determined by Human Repeat Insult Patch Testing on 100 human subjects. Results were determined by comparing the irritation and sensitization results of the 4% CHG solution alone, and the irritation and sensitization results of the 4% CHG solution combined with EasiCleanse Bath.

Results

Neither the 4% CHG solution nor the combination of 4% CHG solution mixed with EasiCleanse Bath were associated with skin irritation or allergic contact dermatitis in human subjects.

¹ United States, Food and Drug Administration. "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record; Proposed Rule." 81 Fed. Reg. 42,921 (June 30, 2016).

²Antimicrobial testing, In-Vitro Time-Kill Method, Coloplast, VV-0327107.

³Safety testing, Human Repeat Insult Patch Testing, Coloplast, VV-0330143.

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Coloplast Corp. Minneapolis, MN 55411 / 1-800-533-0464

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