



Questions and Answers about PRO~TEX™

What is PRO~TEX™ Foam Hand & Skin Sanitizer?

PRO~TEX™ Foam Hand & Skin Sanitizer, based on the active ingredient Benzalkonium chloride, is a unique, Patented formulation featuring exceptional skin feel, conditioning and moisturizing properties. The efficacy of this product has been confirmed to reduce *S. aureus* 99.999% in as little as 15 seconds. Because we do not use ethyl alcohol, our product is non-flammable and non-drying to the skin. In addition, unlike alcohol-based products, PRO~TEX™ does not require polymers or thickeners and as a result you skin does not feel sticky and your pores do not become clogged.

PRO~TEX™ Foam Hand & Skin Sanitizer is in compliance with the FDA Final Tentative Monograph for OTC Hand Sanitizer preparations (leave-on sanitizers not requiring a rinse). PRO~TEX™ Foam Hand & Skin Sanitizer is shipped from our FDA Registered Establishment. PRO~TEX™ is NSF Registered and Approved under Category E3 for Food Handlers.

Why Benzalkonium chloride-based Hand Sanitizers?

Benzalkonium chloride-based Hand Sanitizers have distinct advantages over gelled alcohol hand sanitizers. While both product forms are FDA Monograph for “leave on” products, fast acting and allow for use without water or towels, Benzalkonium chloride based products are non-flammable, less drying to skin, and will not stain clothing. Published studies report that gelled alcohol gel hand sanitizers actually make the skin more contaminated, not cleaner, due to removal of protective natural skin oils and entrapment of dead skin cells by the polymer thickeners used in the gelled alcohol products. Benzalkonium chloride is a quaternary active ingredient with a history of use in leave-on, FDA Monograph anti-bacterial skin treatment products. Leave-on Hand Sanitizers should not be used as a substitute for proper hand washing and hygiene practices.

What makes PRO~TEX™ unique?

Patented Pro~Tex™ Foam Hand & Skin Sanitizer produces a fast drying, non-sticky foam that contains unique conditioning and moisturizing ingredients, leaves the skin with a soft, silky after-feel, and does not contain polymer thickeners or silicones.



How Safe is PRO~TEX™ ?

PRO~TEX™ Foam Hand & Skin Sanitizer is very effective at reducing bacteria on the skin, yet very gentle on the skin and eyes as the Toxicity Profile below indicates:

Toxicity Profile for PRO~TEX™ Foaming Hand & Skin Sanitizer	
Acute Oral LD50	>5.0 g/kg, Category IV
Acute Dermal LD50	>2.0 g/kg, Category III
Eye Irritation	Category III
Skin Irritation	Category IV
Sensitization	Not a Skin Sensitizer

What are the affects of long-term, repeated use?

In published studies, Benzalkonium chloride based Hand Sanitizers outperform alcohol-based products for long-term effectiveness. Alcohol-based products evaporate very quickly and are no longer effective after they are dry. Benzalkonium chloride remains active on the surface of the skin, continuing to kill bacteria for hours. PRO~TEX™ actually gets better with repeated use!



What about efficacy?

PRO~TEX™ Foam Hand & Skin Sanitizer is very effective against a broad range of pathogenic bacteria in as little as 15 seconds as the **Chlorine Equivalency** and **Time Kill Data** illustrate (*see attached*).

CHLORINE EQUIVALENCY TEST - PRO~TEX™ Foaming Hand & Skin Sanitizer

The object of this test is to determine the available chlorine germicidal equivalent concentration of the product as compared to the 200, 100 and 50 ppm available chlorine in the NaOCl standard controls.

Initial suspension Population

Staphylococcus aureus ATCC #6538 7.6 X 10⁸ CFU/mL

Salmonella typhi ATCC #6539 1.2 X 10⁸ CFU/mL

TEST SUBSTANCE	CONC.	SUBCULTURE SERIES									
		1	2	3	4	5	6	7	8	9	10
TEST ORGANISM: S. aureus											
NaOCl (Control)	200 ppm	0	0	0	0	0	+	+	+	+	+
	100 ppm	0	0	+	+	+	+	+	+	+	+
	50 ppm	0	+	+	+	+	+	+	+	+	+
PRO~TEX™ Foaming Hand & Skin Sanitizer		0	0	0	0	0	0	0	0	0	0
TEST ORGANISM: S. typhi											
NaOCl (Control)	200 ppm	0	0	0	0	0	0	+	+	+	+
	100 ppm	0	0	0	+	+	+	+	+	+	+
	50 ppm	0	0	+	+	+	+	+	+	+	+
PRO~TEX™ Foaming Hand & Skin Sanitizer		0	0	0	0	0	0	0	0	0	0

+ = Growth of Organism, **0** = No Growth of Organism

The subcultures of positive broths (tubes showing Growth) demonstrated pure cultures of the test organism.

EFFICACY RESULTS - PRO~TEX™ Foaming Hand & Skin Sanitizer

PRO~TEX™ Foam Hand & Skin Sanitizer demonstrated an available chlorine equivalent to greater than the 200 ppm NaOCl standard control when tested against *Staphylococcus aureus* and *Salmonella typhi*.

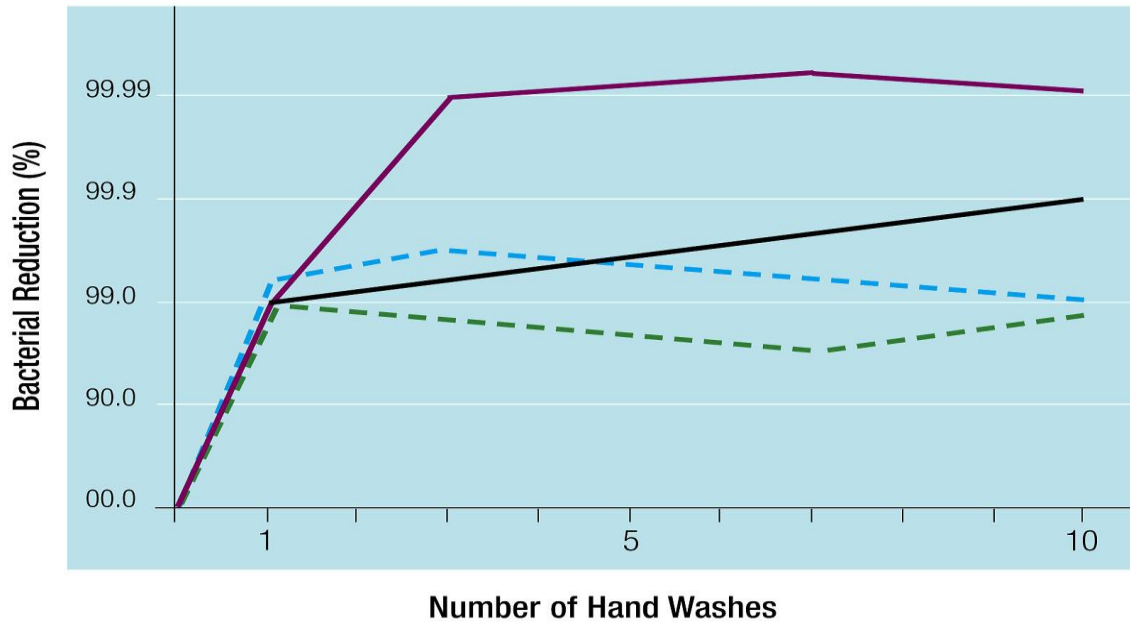
Don't hand sanitizers increase the likelihood of antibiotic resistance?

PRO~TEX™ Foam Hand & Skin Sanitizer is a broad-spectrum sanitizer with efficacy proven across a wide range of bacteria. Unlike antibiotics, topical sanitizers do not attempt to selectively eliminate only certain bacteria. This is very important because most in the medical community today believe that the recent proliferation of the "super bugs" and the anti-biotic resistant strains of bacteria are directly a result of this attempt to be selective in the elimination of some bacteria while sparing others. **PRO~TEX™** is designed to eliminate all bacteria on the skin. While some useful or harmless bacteria may be removed, this is essential in preventing mutations into "super bugs".



Active Ingredient Effectiveness*

Benzalkonium Chloride vs. Ethyl Alcohol



- FDA Minimum Standard
- Benzalkonium Chloride
- - - 62% Ethyl Alcohol
- - - 70% Ethyl Alcohol

*SOURCE: AORN Journal, August 1998

Benzalkonium Chloride, a quaternary ammonium compound used for decades as a topical anti-microbial, is proven to be effective against a wide range of bacteria, fungi and viruses such as Staph, E. Coli, Athlete’s Foot Fungus, Influenza, HIV and Hepatitis.

Any special handling considerations?

PRO-TEX™ Foam Hand & Skin Sanitizer is a stable, water-based system. Care should be taken to avoid freezing. The shelf life of the product exceeds 24 months if keep in moderate conditions.

How is it sold?

PRO-TEX™ Foam Hand & Skin Sanitizer is sold in;

- ◆ 1.7oz (50mL) bottles with foam pump (24/case)
- ◆ 7.0 oz (210mL) bottles with foam pump (12/case)
- ◆ wall-mounted foam dispensers, 1,000mL cart. (6/case)



Time Kill Study for PRO~TEX™

This study is designed to examine the rate of kill of a test substance after inoculation with a test organism. Results are expressed in percent reduction and log reduction of the test organism. Exposure time = 15 seconds.

ORGANISM	TEST POPULATION CONTROL (CFU/ml)	NUMBER OF SURVIVORS	% REDUCTION	LOG REDUCTION
Campylobacter jejuni <i>ATCC 29428</i>	1.02 X 10 ⁷	< 1.0 X 10 ²	> 99.999	> 5.00 Log ¹⁰
Candida albicans <i>ATCC 10231</i>	1.60 X 10 ⁵	6.0 X 10 ³	96.3	1.42 Log ¹⁰
Clostridium difficile (C. Diff.) <i>ATCC 9689</i>	3.40 X 10 ⁶	< 2.0	> 99.9999	> 6.20 Log ¹⁰
Enterococcus faecalis (VRE) <i>ATCC 51575 (Vancomycin Resistant)</i>	1.12 X 10 ⁶	3.2 X 10 ¹	99.99	4.54 Log ¹⁰
Escherichia coli <i>ATCC 11229</i>	3.80 X 10 ⁶	4.0	99.999	6.00 Log ¹⁰
Escherichia coli 0157:H7 <i>ATCC 35150</i>	1.26 X 10 ⁶	< 2.0	> 99.999	> 5.80 Log ¹⁰
Klebsiella pneumoniae <i>ATCC 4352</i>	1.10 X 10 ⁶	2.0	99.999	5.70 Log ¹⁰
Listeria monocytogenes <i>ATCC 19117</i>	4.70 X 10 ⁶	1.9 X 10 ³	99.9	3.39 Log ¹⁰
Pseudomonas aeruginosa <i>ATCC 15442</i>	3.50 X 10 ⁶	< 2.0	99.9999	> 6.20 Log ¹⁰
Salmonella choleraesuis serotype enteritidis <i>ATCC 4931</i>	6.80 X 10 ⁵	2.0	> 99.999	> 5.50 Log ¹⁰
Salmonella choleraesuis serotype paratyphi <i>ATCC 8759</i>	5.60 X 10 ⁵	< 2.0	> 99.999	> 5.50 Log ¹⁰
Salmonella choleraesuis serotype pullorum <i>ATCC 19945</i>	8.90 X 10 ⁵	< 2.0	> 99.999	> 5.70 Log ¹⁰
Salmonella choleraesuis serotype typhimurium <i>ATCC 23564</i>	7.70 X 10 ⁵	6.0	> 99.999	> 5.10 Log ¹⁰
Salmonella typhi <i>ATCC 6539</i>	1.27 X 10 ⁶	2.0	99.999	> 5.80 Log ¹⁰
Shigella dysenteriae <i>ATCC 13313</i>	1.30 X 10 ⁶	< 2.0	> 99.999	5.80 Log ¹⁰
Shigella flexneri <i>ATCC 12022</i>	1.39 X 10 ⁶	2.8 X 10 ¹	99.99	4.69 Log ¹⁰
Shigella sonnei <i>ATCC 25931</i>	2.43 X 10 ⁷	< 2.0 X 10 ¹	99.9999	6.09 Log ¹⁰
Staphylococcus aureus <i>ATCC 6538</i>	6.70 X 10 ⁶	< 2.0	> 99.9999	> 6.53 Log ¹⁰
Staphylococcus aureus (MRSA) <i>ATCC 33592 (Methicillin Resistant)</i>	1.23 X 10 ⁷	3.8 X 10 ³	> 99.9	3.51 Log ¹⁰
Staphylococcus aureus (CA-MRSA) <i>Community Associated Methicillin Resistant (USA 400)</i>	1.18 X 10 ⁶	5.8 X 10 ²	> 99.9	> 3.30 Log ¹⁰
Streptococcus pneumoniae <i>ATCC 6305</i>	6.40 X 10 ⁵	< 2.0	> 99.999	> 5.51 Log ¹⁰
Streptococcus pyogenes <i>ATCC 19615</i>	1.77 X 10 ⁶	< 2.0	> 99.999	> 5.90 Log ¹⁰
Vibrio cholera <i>ATCC 11623</i>	4.70 X 10 ⁵	< 2.0	> 99.999	> 5.40 Log ¹⁰
Xanthomonas axonopodis <i>ATCC 49118 (Citrus Canker)</i>	1.28 X 10 ⁶	3.6 X 10 ¹	> 99.99	4.55 Log ¹⁰
Yersinia enterocolitica <i>ATCC 23715</i>	2.23 X 10 ⁶	3.8 X 10 ¹	99.99	4.77 Log ¹⁰