



# Equi-Soft™ Foam Antimicrobial Hand Soap

**Equi-Soft Foam** with 0.55% (w/w) benzalkonium chloride is recommended for use as a Healthcare Personnel Handwash. This recommendation is based on in vivo efficacy testing of the final formulation demonstrating that it exceeds the FDA's requirements for Healthcare Personnel Handwashes.

**Equi-Soft Foam** is formulated for use in all settings where handwashing is a critical part of infection control procedures, including acute and sub-acute care facilities, long term care facilities, clinics, dental offices, laboratories and animal health facilities

**Equi-Soft Foam** is clinically proven to deliver the efficacy of a medicated soap with the mildness of the market leading non-medicated soap.

**Equi-Soft Foam** contains glycerin, vitamin E and emollients to help moisturize and soothe skin during frequent use

**Equi-Soft Foam** is CHG (chlorhexidine gluconate) compatible

**Equi-Soft Foam** does not contain parabens, dyes, methylchloroisothiazolinone, or methylisothiazolinone

Ingredients	Function
Benzalkonium Chloride	Active Ingredient
Water	Co-solvent
Guar Gum	Skin Conditioner
Citric Acid	pH modifier
Lauryl Dimethylamine Oxide	Surfactant
Vitamin E	Anti-oxidant
Polyethylene Glycol	Emollient
Glycerides	Emollient
Hexylene Glycol	Moisturizer
Myristamide	Co-solvent
Glycerine	Moisturizer
Cocamidopropyl PG-dimonium Chloride Phosphate	Mild Surfactant / Conditioner
Methyl Gluceth-20	Emollient
PEG-12 Dimethicone	Emollient
Potassium Hydroxide	pH modifier
Phenoxyethanol	Preservative
Fragrance	Fragrance

## MICROBIAL TIME KILL

This test measures the amount of microbial kill within a given period of time. **Equi-Soft Foam** at 10% concentration was challenged with organisms at initial organism counts of  $10^6 - 10^8$  CFU/mL. The number of remaining organisms was then measured at 15, 30 and 60 second intervals. The 15 second time point is reported below.

**Laboratory Procedure: A 10% dilution of Equi-Soft Foam** was inoculated with viable cultures of each of the test organisms ( $10^6 - 10^8$  CFU/mL). An aliquot from each inoculated **Equi-Soft Foam** sample was removed at each interval and placed into subculture tubes containing neutralizers. From serial dilutions, agar plates were prepared and incubated. Plate counts were then made to determine the number of surviving organisms to calculate percent and  $\log_{10}$  reductions.

Data with a “greater than” (>) sign indicates no survivors; percent and  $\log_{10}$  reductions are based on original inoculum numbers.

### Microbial Kill Time Data

Organism	Identification Code	10% concentration after 15 sec exposure	
		Log <sub>10</sub> Reduction	Percent Reduction
<i>Acinetobacter baumannii</i>	ATCC 19606	>5.60	>99.999
<i>Acinetobacter baumannii</i> (MDR)	ATCC BAA-1605	3.89	99.987
<i>Bacteroides fragilis</i>	ATCC 43859	>5.20	>99.999
<i>Candida albicans</i>	ATCC 10231	1.18	93.400
<i>Enterobacter cloacae</i>	ATCC 13047	>5.11	>99.999
<i>Enterococcus faecalis</i>	ATCC 29212	>5.04	>99.999
<i>Enterococcus faecalis</i> (VRE)	ATCC 51299	>5.15	>99.999
<i>Enterococcus faecium</i>	ATCC 51559	>5.11	>99.999
<i>Escherichia coli</i>	ATCC 11229	>5.67	>99.999
<i>Escherichia coli</i>	ATCC 25922	4.63	99.998
<i>Escherichia coli</i> O157:H7	ATCC 43895	3.63	99.977
<i>Haemophilus influenzae</i>	ATCC 10211	>6.00	>99.999
<i>Klebsiella pneumoniae</i>	ATCC 4352	>5.69	>99.999
<i>Klebsiella pneumoniae</i>	ATCC 10031	>5.41	>99.999
<i>Klebsiella pneumoniae</i> (KPC)	ATCC BAA-1705	>5.57	>99.999
<i>Listeria monocytogenes</i>	ATCC 7644	>5.75	>99.999
<i>Micrococcus yunnanensis</i> <sup>1</sup>	ATCC 7468	>4.08	>99.992
<i>Proteus mirabilis</i>	ATCC 7002	4.26	99.995
<i>Pseudomonas aeruginosa</i>	ATCC 15442	4.76	99.998
<i>Pseudomonas aeruginosa</i>	ATCC 27853	2.46	99.657
<i>Pseudomonas stutzeri</i>	ATCC 17588	>5.41	>99.999
<i>Salmonella enterica</i>	ATCC 10708	>5.96	>99.999
<i>Salmonella enteritidis</i>	ATCC 13076	1.38	95.806
<i>Salmonella typhi</i>	ATCC 6539	>5.66	>99.999
<i>Salmonella typhimurium</i>	ATCC 13311	>5.98	>99.999

Organism	Identification Code	10% concentration after 15 sec exposure	
		Log <sub>10</sub> Reduction	Percent Reduction
<i>Serratia marcescens</i>	ATCC 14756	0.70	80.000
<i>Shigella sonnei</i>	ATCC 11060	>5.20	>99.999
<i>Staphylococcus aureus</i>	ATCC 6538	3.51	99.969
<i>Staphylococcus aureus</i>	ATCC 29213	2.51	99.688
<i>Staphylococcus aureus</i> (MRSA)	ATCC 33592	2.06	99.130
<i>Staphylococcus aureus</i> (CA-MRSA)	ATCC BAA-1683	1.98	98.960
<i>Staphylococcus epidermidis</i>	ATCC 12228	2.78	99.834
<i>Staphylococcus haemolyticus</i>	ATCC 29970	>5.23	>99.999
<i>Staphylococcus hominis</i>	ATCC 27844	>4.18	>99.993
<i>Staphylococcus saprophyticus</i>	ATCC 43867	>5.32	>99.999
<i>Streptococcus pneumoniae</i>	ATCC 6303	>4.58	>99.997
<i>Streptococcus pyogenes</i>	ATCC 19615	>4.70	>99.998

<sup>†</sup> This strain was previously known as *Micrococcus luteus*

**Conclusion:** A rapid kill time (within 15 seconds) on Gram-positive and Gram-negative bacteria was demonstrated.

### MINIMUM INHIBITORY CONCENTRATION

To prove the effectiveness of **Equi-Soft Foam** against pathogenic microorganisms, tests were run to show the Minimum Inhibitory Concentration (MIC) of benzalkonium chloride needed in **Equi-Soft Foam** against Gram-positive and Gram-negative bacteria.

**Laboratory Procedure:** Within a microtiter plate, serial dilutions of **Equi-Soft Foam** were made using organism specific nutrient broth as the diluent.

Cultures of the test strains (approximately 10<sup>5</sup> CFU/mL) were inoculated into the wells of the microtiter plate with **Equi-Soft Foam** nutrient broth.

After 24 hours of incubation (as appropriate for the test organism), the microtiter plate was examined visually for turbidity as an indication of growth. The MIC was recorded as the lowest benzalkonium chloride concentration at which complete inhibition of growth was seen. The Minimum Bactericidal Concentration (MBC) was determined for wells that were turbid due to the high concentration of product. The wells were subcultured and incubated appropriately for observation of growth. MBC determinations are denoted by an asterisk (\*).

### Minimum Inhibitory Concentration Data

Organism	Identification Code	Equi-Soft Foam (ppm benzalkonium chloride)
<i>Acinetobacter baumannii</i>	ATCC 19606	6.54
<i>Acinetobacter baumannii</i> (MDR)	ATCC BAA-1605	1.64
<i>Bacteroides fragilis</i>	ATCC 43859	1.64

Organism	Identification Code	Equi-Soft Foam (ppm benzalkonium chloride)
<i>Candida albicans</i>	ATCC 10231	3.27
<i>Enterobacter cloacae</i>	ATCC 13047	26.17
<i>Enterococcus faecalis</i>	ATCC 29212	1.64
<i>Enterococcus faecalis</i> (VRE)	ATCC 51299	6.54
<i>Enterococcus faecium</i>	ATCC 51559	3.27
<i>Escherichia coli</i>	ATCC 11229	6.54
<i>Escherichia coli</i>	ATCC 25922	6.54
<i>Escherichia coli</i> O157:H7	ATCC 43895	13.09
<i>Haemophilus influenzae</i>	ATCC 10211	6.54
<i>Klebsiella pneumoniae</i>	ATCC 4352	3.27
<i>Klebsiella pneumoniae</i>	ATCC 10031	6.54
<i>Klebsiella pneumoniae</i> (KPC)	ATCC BAA-1705	13.09
<i>Listeria monocytogenes</i>	ATCC 7644	0.82
<i>Micrococcus yunnanensis</i> <sup>1</sup>	ATCC 7468	13.09
<i>Proteus mirabilis</i>	ATCC 7002	209.38
<i>Pseudomonas aeruginosa</i>	ATCC 15442	837.50
<i>Pseudomonas aeruginosa</i>	ATCC 27853	837.50
<i>Pseudomonas stutzeri</i>	ATCC 17588	13.09
<i>Salmonella enterica</i>	ATCC 10708	104.69
<i>Salmonella enteritidis</i>	ATCC 13076	13.09
<i>Salmonella typhi</i>	ATCC 6539	6.54
<i>Salmonella typhimurium</i>	ATCC 13311	6.54
<i>Serratia marcescens</i>	ATCC 14756	1675.00
<i>Shigella sonnei</i>	ATCC 11060	6.54
<i>Staphylococcus aureus</i>	ATCC 6538	3.27
<i>Staphylococcus aureus</i>	ATCC 29213	0.41
<i>Staphylococcus aureus</i> (MRSA)	ATCC 33592	3.27
<i>Staphylococcus aureus</i> (CA-MRSA)	ATCC BAA-1683	3.27
<i>Staphylococcus epidermidis</i>	ATCC 12228	1.64
<i>Staphylococcus haemolyticus</i>	ATCC 29970	1.64
<i>Staphylococcus hominis</i>	ATCC 27844	0.82
<i>Staphylococcus saprophyticus</i>	ATCC 43867	3.27
<i>Streptococcus pneumoniae</i>	ATCC 6303	1.64
<i>Streptococcus pyogenes</i>	ATCC 19615	1.64

<sup>1</sup> This strain was previously known as *Micrococcus luteus*

**Conclusion:** This data demonstrates that **Equi-Soft Foam** with 0.55% benzalkonium chloride effectively inhibits the growth of the representative Gram-positive and Gram-negative bacteria.

### HEALTHCARE PERSONNEL HANDWASH (HCPHW)

The FDA issued a tentative final monograph (Federal Register, Vol. 59, pp. 31402 to 31452, June 17, 1994) prescribing the use of a healthcare personnel handwash method to demonstrate the antimicrobial efficacy of cleansing products containing antimicrobial ingredients for frequent use. A product labeled as a Healthcare Personnel Handwash is required to meet specific stringent guidelines by the FDA, as opposed to an antiseptic handwash, which does not require the *in vivo* testing outlined in the following test. While both the antiseptic handwash and healthcare personnel handwash are described in the monograph as “For handwashing to decrease bacteria on the skin”; a healthcare personnel handwash allows for the additional label language, “Handwash to help reduce bacteria that potentially can cause disease.” The following test was conducted by an independent laboratory following FDA Good Clinical Practices\*.

The procedure is designed to simulate routine hand treatment conducted for the purpose of reducing the level of hand contamination of health care personnel under conditions of frequent use. For this procedure a broth culture of *Serratia marcescens*, a species of bacteria which produces a red pigment on an agar surface, is used as an artificial contaminant bacteria on the hands. Activity is measured by comparing the number of marker bacteria removed from artificially contaminated hands, after a single use of the handwashing formulation to the baseline number, the number recovered from contaminated unwashed hands. Similar comparisons are made following the 3<sup>rd</sup>, 7<sup>th</sup> and 10<sup>th</sup> washes of a multiple (10) wash procedure. Prior to each of the ten washes, the hands are artificially contaminated with the *S. marcescens*. **Equi-Soft Foam** was tested at a 2 mL product dose with a wash time of 30 seconds.

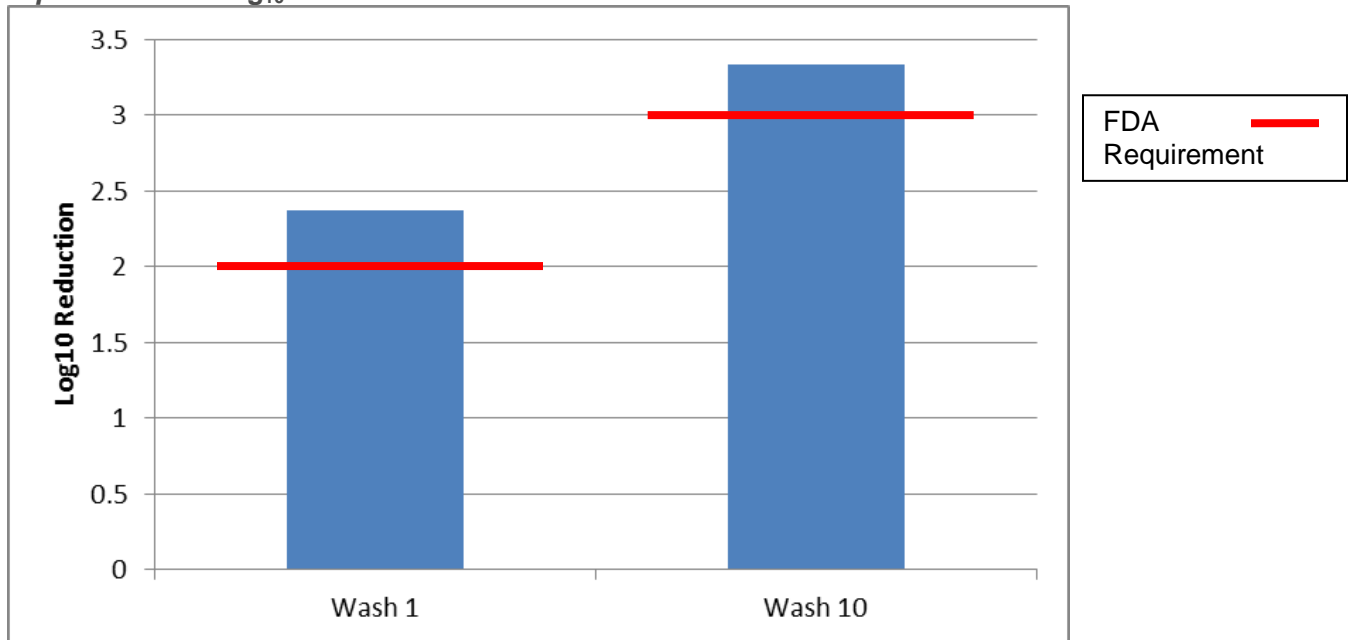
#### Healthcare Personnel Handwash Data

Treatment	Product Amount	<i>Equi-Soft Foam</i>	FDA Requirement
		Log <sub>10</sub> Reduction	Log <sub>10</sub> Reduction
Wash 1	2 mL	2.37	2
Wash 10	2 mL	3.33	3

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\* Bioscience Laboratories, Inc.

**Equi-Soft Foam log<sub>10</sub> Reduction from Baseline**



**Conclusion:** *Equi-Soft Foam* exceeded the criteria for a Healthcare Personnel handwash as defined by the June 17, 1994 FDA Proposed Monograph for Health Care Antiseptic Drug Products.



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