

BMild Antimicrobial Soap Healthcare Personnel Handwash

CLASSIFICATION

Mild Antimicrobial Soap with 0.55% benzalkonium chloride is recommended for use as an antiseptic handwash. This recommendation is based on efficacy testing of the final formulation.

Mild Antimicrobial Soap contains glycerin, vitamin E and emollients to help moisturize and soothe skin during frequent use.

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

MICROBIAL TIME KILL

This test measures the amount of microbial kill over a given period of time. **Mild Antimicrobial Soap** at 10% concentrations 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: Mild Antimicrobial Soap was inoculated with viable cultures of each of the test organisms ($10^6 - 10^8$ CFU/mL). An aliquot from each inoculated **Mild Antimicrobial Soap** 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 ₁₀ 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>Haemophilus influenzae</i> | ATCC 10211 | >6.00 | >99.999 |
| <i>Klebsiella pneumoniae</i> | ATCC 4352 | >5.69 | >99.999 |
| <i>Klebsiella pneumoniae</i> (KPC) | ATCC BAA-1705 | >5.57 | >99.999 |
| <i>Micrococcus yunnanensis</i> ¹ | 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>Serratia marcescens</i> | ATCC 14756 | 0.70 | 80.000 |
| <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 |

¹ This strain was previously known as *Micrococcus luteus*

| Organism | Identification Code | 10% concentration after 15 sec exposure | |
|-------------------------------------|---------------------|---|-------------------|
| | | Log ₁₀ Reduction | Percent Reduction |
| <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 |

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 **Mild Antimicrobial Soap** against pathogenic microorganisms, tests were run to show the Minimum Inhibitory Concentration (MIC) of benzalkonium chloride needed in **Mild Antimicrobial Soap** against Gram-positive and Gram-negative bacteria.

Laboratory Procedure: Within a microtiter plate, serial dilutions of **Mild Antimicrobial Soap** were made using organism specific nutrient broth as the diluent.

Cultures of the test strains (approximately 10⁵ CFU/mL) were inoculated into the wells of the microtiter plate with **Mild Antimicrobial Soap** 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 | Mild Antimicrobial Soap (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 |
| <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>Haemophilus influenzae</i> | ATCC 10211 | 6.54 |

| Organism | Identification Code | Mild Antimicrobial Soap (ppm benzalkonium chloride) |
|---|---------------------|--|
| <i>Klebsiella pneumoniae</i> | ATCC 4352 | 3.27 |
| <i>Klebsiella pneumoniae</i> (KPC) | ATCC BAA-1705 | 13.09 |
| <i>Micrococcus yunnanensis</i> ¹ | 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>Serratia marcescens</i> | ATCC 14756 | 1675.00 |
| <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 |

¹ This strain was previously known as *Micrococcus luteus*

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



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