

# **THE SCIENCE OF: NON-ALCOHOL HAND SANITIZER ON THE MARKET TODAY**

**X HAND SANITIZER** contains the active quaternary ammonium compound Benzalkonium Chloride (BAC). The formulation makes **X**

**HAND SANITIZER** a unique product with wide-spectrum efficiency over known pathogenic microbes. Quaternary ammonium compounds mode of action is as a cationic surfactant. This class of chemical reduces the surface tension it interfaces, and is attracted to negatively charged surfaces, including microorganisms. Quaternary ammonium compounds denature the proteins of the bacterial, viral or fungal cell, affect the metabolic reactions of the cell and allow vital substances to leak out of the cell, finally causing death.

**X HAND SANITIZER** is a ready to use hand sanitizer utilizing the active ingredient Benzalkonium Chloride (BAC) at a concentration of 0.15%. BAC is an alcohol-free, antimicrobial compound that has been widely used in the health care industry for more than 60 years in formulas for preservatives, surface cleansers, sterilizing agents, and topical antiseptic sprays.

## **X FEATURES AND BENEFITS**

Alcohol Free - Non-drying to the skin  
Non-Flammable  
Fragrance Free  
Rinse Free Formula - No soap, water, or towels needed  
Non-Irritating and Non-Toxic - Gentle to skin  
No Sticky Residue  
Antiseptic - Helps prevent infections in minor abrasions  
Hypoallergenic

## **CURRENT REGULATORY APPROVALS FOR X HAND SANITIZER**

Health Canada Approved – Drug Identification Number (DIN) xxxxxxxx  
Agriculture Canada Approved  
Canadian Food Inspection Agency Approved  
Food Safety Enhancement Program (FSEP) Compliant  
Hazard Analysis Critical Control Points (HAACP) Compliant

## **EFFICIENCY OF X**

A variety of studies and laboratory tests have been completed in order to demonstrate the efficacy of **X** and its active ingredient, Benzalkonium Chloride (BAC). The data includes independent laboratory test results, manufacturer's analysis and results, published and non-published study and test results. A compilation of data follows.

## In Vitro Test Results- Manufacturer Data

The following data was supplied by Rhone-Poulenc, manufacturer of the raw ingredient Benzalkonium Chloride.

### Biological Properties

Phenol Coefficients

Phenol Coefficients of Benzalkonium Chloride (BAC) active were determined by the official A.O.A.C procedure.

### 10- Minute Killing Dilution

Organism	Dilution of BAC Hand Sanitizer in water to get the 10 minute killing	Concentration of BAC Hand Sanitizer (ml/L) to kill in 10 minutes	Phenol	Phenol Coefficient
<i>Brucella abortus</i>	1/152.6	6.55 ml/L	1/110	1.387
<i>Escherichia coli</i>	1/101.25	9.87 ml/L	1/70	1.446
<i>Klebsiella pneumoniae</i>	1/93.75	10.66 ml/L	1/90	1.042
<i>Lactobacillus casei</i>	1/393.75	2.54 ml/L	1/100	3.937
<i>Listeria monocytogenes</i>	1/270	3.70 ml/L	1/100	2.700
<i>Mycobacterium amegmatis</i>	1/78.75	12.70 ml/L	1/65	1.211
<i>Neisseria caiarbalis</i>	1/64.89	15.41 ml/L	1/70	0.927
<i>Pasteurella multocida</i>	1/202.89	4.92 ml/L	1/110	1.844
<i>Proteus vulgaris</i>	1/45	22.22 ml/L	1/70	0.642
<i>Pseudomonas aeruginosa PRD-10</i>	1/52.25	19.14 ml/L	1/70	0.746
<i>Salmonella gallinarum</i>	1/105	9.52 ml/L	1/80	1.312
<i>Salmonella pullorum</i>	1/93.75	10.66 ml/L	1/90	1.042
<i>Salmonella typhimurium</i>	1/75	13.33 ml/L	1/70	1.071
<i>Salmonella schottumelleri</i>	1/225	4.44 ml/L	1/95	2.368
<i>Salmonella typhosa</i>	1/168.75	5.92 ml/L	1/90	1.875
<i>Shigella sonnei</i>	1/93.75	10.66 ml/L	1/80	1.172
<i>Staphylococcus aureus</i>	1/168.75	5.92 ml/L	1/60	2.812
<i>Streptococcus fecalis</i>	1/562.5	1.77 ml/L	1/70	8.028
<i>Streptococcus pyogenes C-203</i>	1/93.75	10.66 ml/L	1/80	1.172
<i>Streptococcus viridans</i>	1/262.5	3.80 ml/L	1/90	2.916
<b>FUNGI</b>				
<i>Saccharomyces cerevisiae</i>	1/187.5	5.33 ml/L	1/100	1.875
<i>Pityrosporium ovale</i>	1/131.25	7.61 ml/L	1/100	1.312

### Microbicidal-Microbiostatic Activity

The antibacterial effectiveness of Benzalkonium Chloride (BAC) hand sanitizer has been measured by an empirical broth dilution procedure in which the highest dilutions capable of inhibiting growth to 48 hours (microbiostatic) and killing all organisms in 24 hours (microbicidal) are determined.

Organism	Microbicidal	Microbiostatic
<i>Brucella abortus</i>	1/3750	1/7500
<i>Penicillium luteum</i>	1/3	1/6
<i>Penicillium notatum</i>	1/12	1/12
<i>Aerobacter aerogenes</i>	1/120	1/240
<i>Bacillus aerus, var. mycoides</i>	-	1/7500
<i>Bacillus subtilis</i>	-	1/7500
<i>Brevibacterium ammonigenes</i>	-	1/7500
<i>Klebsiella pneumoniae</i>	1/120	1/240
<i>Lactobacillus casei</i>	1/750	1/750
<i>Proteus vulgaris</i>	1/60	1/60
<i>Pseudomonas aeruginosa PRD-10</i>	1/30	1/30
<i>Salmonella gallinarum</i>	1/225	1/225
<i>Salmonella pullorum</i>	1/120	1/120
<i>Salmonella typhimurium</i>	1/120	1/240
<i>Salmonella schottumelleri</i>	1/60	1/240
<i>Salmonella typhosa</i>	1/468.75	1/937.5
<i>Salmonella choleraesuis</i>	1/225	1/225
<i>Shigella sonnei</i>	1/120	1/120
<i>Staphylococcus aureus</i>	1/937.5	1/15000
<i>Trichophyton interdigitale</i>	1/150	1/300
<i>Streptococcus pyogenes C-203</i>	1/375	1/375
<i>Streptococcus viridans</i>	1/1500	1/3000
<i>Saccharomyces cerevisiae</i>	1/750	1/1500
<i>Pityrosporum ovale</i>	1/1500	1/3000

This data shows that the BAC hand sanitizer possesses a broad spectrum of effectiveness against a variety of both gram-positive and gram-negative organisms. Data provide by Rhone-Poulenc.

### **In Vitro Test Results**

The following pathogens were killed within 15 seconds after exposure to the BAC hand sanitizer:

Candida albicans  
Candida keyfr  
Escherichia coli  
Enterococcus faecalis  
Enterococcus faecium (VRE)  
Klebsiella pneumonia  
Microcococcus luteus  
Pseudomonas aeruginosa  
Proteus mirabilis  
Salmonella typhimurium  
Serratia marcescens  
taphylococcus aureus  
Staphylococcus aureus (MRSA)  
Salmonella enteritidis  
Staphylococcus epidermidis  
Staphylococcus haemolyticus  
Staphylococcus saprophyticus  
Streptococcus pyogenes  
Herpes simplex virus Type 1  
Human Coronavirus (related to SARS)  
Trichophyton mentagrophytes  
Trichophyton rubrum  
Apergillus niger  
Hepatitis A and B

In vitro tests performed by SCI Laboratories, Inc.; revised protocol of CFR 333.470, Woodward Laboratories, Inc.; revised protocol of CFR 333.470, Viomed Laboratories, Inc.; revised protocol of ASTM E1052, and ATS Laboratories, Inc.; protocol of WLI01041603.COR

Evaluation of the Germicidal Effectiveness of a Benzalkonium Chloride (BAC) Based Hand Sanitizer completed by the Centre de recherche industrielle du Québec (CRIQ).

### Synopsis

The aim of the project was to determine the germicidal effectiveness of a BAC based hand sanitizer on three bacterial strains:

- ✓ Clostridium difficile (ATCC 9689)
- ✓ Methicillin-resistant Staphylococcus aureus (ATCC 33591)
- ✓ Vancomycin-resistant Streptococcus faecalis (ATCC 51299)

The germicidal effectiveness of the sanitizer was therefore evaluated separately on each of the bacterial strains at contact times of 0, 15, and 30 seconds. The hand sanitizer showed a germicidal effectiveness:

- ✓ Greater or equal to 99.9% against Clostridium difficile (ATCC 9689) in 15 seconds
- ✓ Greater or equal to 99.9% against Methicillin-resistant Staphylococcus aureus (ATCC 33591) in 15 seconds
- ✓ Greater or equal to 99.9% against Vancomycin-resistant Streptococcus faecalis (ATCC 51299) in 15 seconds

### In Vitro Test Results

Quaternary Ammonium Chloride based hand sanitizer exhibited strong germicidal activity against a variety of gram-positive and gram-negative bacteria, as well as the yeast *Candida albicans*. In most instances viable cell numbers were reduced by greater than 99.99% after a 30-second exposure period.

Test Microorganisms	Initial Inoculum (cfu/10 $\mu$ L)	Exposure Time (Minutes)			Reduction (percent)*
		0.5	1.0	2.0	
<i>Pseudomonas aeruginosa</i>	3.39 x 10 <sup>5</sup>	-	-	-	99.99
<i>Klebsiella pneumoniae</i>	2.76 x 10 <sup>5</sup>	-	-	-	99.99
<i>Escherichia coli</i>	15.8 x 10 <sup>5</sup>	-	-	-	99.99
<i>Salmonella typhimurium</i>	18.9 x 10 <sup>5</sup>	-	-	-	99.99
<i>Staphylococcus aureus</i> ATCC33591	21.2 x 10 <sup>5</sup>	(Methicillin Resistant / MRSA)			99.99
<i>Staph. epidermidis</i>	18.3 x 10 <sup>5</sup>	-	-	-	99.99
<i>Streptococcus faecalis</i> ATCC522A	9.8 x 10 <sup>5</sup>	(Vancomycin resistant enterococci/ VRE)			99.99
<i>Streptococcus agalactiae</i>	12.1 x 10 <sup>5</sup>	-	-	-	99.99
<i>Micrococcus luteus</i>	14.4 x 10 <sup>5</sup>	-	-	-	99.99
<i>Candida albicans</i>	12.6 x 10 <sup>5</sup>	-	-	-	99.99
<i>Trichophyton mentogrophytes</i> (Athlete's Foot)	9.6 x 10 <sup>5</sup>	-	-	-	99.99
<i>Salmonella choleraesuis</i>	14.1 x 10 <sup>5</sup>	-	-	-	99.99
<i>Aspergillus niger</i>	11.8 x 10 <sup>5</sup>	-	-	-	99.99
<i>Listeria monocytogenes</i>	17.9 x 10 <sup>6</sup>	0 CFU/mL			(15 seconds)
<i>Clostridium difficile</i>	1.1 x 10 <sup>4</sup>	0 CFU/mL			(15 seconds)
Human Coronavirus (resembles SARS-like virus family)		0 CFU/mL			(15 seconds)

(\*) Indicates percentage reduction in numbers of viable cells evidenced by lack of growth in Trypticase-soy Broth medium.

(-) Indicates no survival of test organisms in the recovery medium.

Evaluation of Virucidal Effect of X Hand Sanitizer for inactivation of Influenza virus in vitro performed by *Arivac* Laboratories.

### Synopsis

#### Results and conclusion:

- ✓ **X** hand disinfectant has a cellular lysis effect until 1/10 dilution
- ✓ **X** hand disinfectant has a cellular lysis effect until 1/10 dilution after 10 seconds only of treatment.
- ✓ **X** can be used to inactivate members of virus family orthomyxo viridae including Avian Influenza A virus in 10 seconds.

The treatment of the influenza virus H1N1 at a concentration of 10<sup>3.77</sup> TCID<sub>50</sub> / (100 µl) with X hand disinfectant results in almost instantaneous lysis of cells and inactivation of the influenza virus strain used in this study.

Effectiveness of a Nonrinse, Alcohol-Free Antiseptic Hand Wash (J Am Podiatr Med Assoc 91 (6): 288-293, 2001) Anoosh Moadab, BS Kathryn F. Rupley, BS Peter Wadhams, DPM

### Synopsis

This study evaluated the efficacy of a benzalkonium chloride (BAC) hand sanitizer using the US Food and Drug Administration's (USFDA) method for testing antiseptic hand washes that podiatric physicians and other health-care personnel use. The alcohol-free product was compared with an alcohol based product. Independent researchers from the California College of Podiatric Medicine conducted the study using 40 volunteer students from the class of 2001. The results show that the BAC hand sanitizer outperformed the alcohol based hand sanitizer and met the regulatory requirements for a hand sanitizer. The alcohol based product failed as an antimicrobial hand wash and was less effective than the control soap used in the study.

Alcohol Free Hand Sanitizer to Combat Infection

AORN Journal, (68 August 1998), p. 239

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### Synopsis

Universal precautions require that perioperative health care personnel wash their hands before and after all patient contact. Time constraints, however, can make adhering to universal precautions including proper hand washing, difficult. Some perioperative health care workers, therefore, routinely use rinse-free hand sanitizers to supplement normal hand washing. This study evaluated immediate and persistent antimicrobial effectiveness of two alcohol containing hand sanitizers and a benzalkonium chloride (BAC) hand sanitizer using United State Food and Drug Administration protocol. Results indicate that all three products were equally effective after a single application. After repeated use, the alcohol containing sanitizers did not meet the federal performance standards, and the alcohol free sanitizer did. These properties and other illustrated that a nonflammable, alcohol free hand

## Alcohol Free Hand Sanitizer Reduces Elementary School Illness Absenteeism

Fam Med 2000;32(9):633-8

David L. Dyer, PhD.  
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### Synopsis

A substantial percentage of school absenteeism among children is related to transmissible infection. Rates of transmission can be reduced by hand washing with soap and water, but such washing occurs infrequently. This study tested whether an alcohol free instant hand sanitizer could reduce illness absenteeism in school age children. Compared to the hand washing only control group, students using the benzalkonium chloride based hand sanitizer were found to have 41.9% fewer illness-related absence days, representing a 28.9% and a 49.7% drop in gastrointestinal and respiratory related illness, respectively. Likewise, absence incidence decreased by 31.7%, consisting of a 44.2% and 50.2% decrease in incidence gastrointestinal and respiratory related illness, respectively. No adverse events were reported during the study.

### Reduction of Elementary School Illness Absenteeism in Elementary Schools Using an Alcohol free Instant Hand Sanitizer

The Journal of School Nursing; 17(5) October 2001, p. 258  
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### Synopsis

Hand washing is the most effective way to prevent the spread of communicable disease. The purpose of this double-blind, placebo-controlled study was to assess whether an alcohol free, instant hand sanitizer containing benzalkonium chloride could reduce illness absenteeism in a population of 769 elementary school children and serve as an effective alternative when regular soap and water hand washing was not readily available. Prior to the study, students were educated about proper hand washing technique, the importance of hand washing to prevent transmission of germs, and the relationship between germs and illnesses. Children in kindergarten through 6<sup>th</sup> grade (ages 5-12) were assigned to the active or placebo hand sanitizer product and instructed to use the product at scheduled times during the day and as needed after coughing or sneezing. Data on illness absenteeism were tracked. After 5 weeks, students using the active product were 33% less likely to have been absent because of illness when compared with the placebo group.