



DEFEND

Instant Foaming Hand Sanitizer

Quaternary hand sanitizer formulas have distinct advantages over gelled alcohol hand sanitizers. Published studies report that quaternary based hand sanitizers demonstrated greater and sustained decontamination activity than gelled alcohol hand sanitizers that actually became less effective with repeated use and made the skin dirtier, 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 (*AORN Journal*, (68 August 1998), p. 239-251). While both product forms are FDA Monograph compliant for leave on products, fast acting and allow for use without water or towels, quaternary based products are non-flammable, less drying to skin, and will not stain clothing. Benzalkonium chloride, unlike benzethonium chloride, is the only quaternary 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.

DEFEND Instant Foaming Hand Sanitizer produces a fast drying, non-sticky foam that contains unique non-drying, conditioning and moisturizing ingredients, leaves the skin with a soft, refreshing and silky after feel, and does not contain polymer thickeners or silicones.

<u>Drug Facts</u>	
<u>Active ingredient</u>	<u>Purpose</u>
Benzalkonium Chloride	Antimicrobial
Uses	<ul style="list-style-type: none">• For hand sanitizing to decrease bacteria on the skin• Recommended for repeated use
Warning	For external use only
When using this product.	Avoid contact with eyes. In case of eye contact, flush eyes with water.
Stop use and ask a doctor.	If irritation or redness develops, or if condition persists for more than 72 hours.
Keep out of reach of children.	If swallowed, get medical attention or contact a Poison Control Center right away.
Directions	<ul style="list-style-type: none">• Pump a small amount of foam into palm of hand• Rub thoroughly over all surfaces of both hands• Rub hands together briskly until dry
Inactive ingredients	Water, dihydroxypropyl PEG-5 linoleammonium chloride, glycereth-2 cocoate, behentrimonium chloride, dihydroxyethyl cocamine oxide, Fragrance*

**Fragrance: It is not included for food handlers' formulations.*

DEFEND Fact Sheet

DEFEND Instant Foaming Hand Sanitizer, based on the active ingredient Benzalkonium chloride, is a unique formulation featuring exceptional skin feel, conditioning and moisturizing properties. The efficacy of this product has been confirmed to reduce *S. aureus* 99.9999% in as little as 15 seconds.

Why Benzalkonium chloride-based Hand Sanitizers?

History: Benzalkonium chloride 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 cleaners, sterilizing agents, and leave-on, FDA Monograph anti-bacterial skin treatment products. The chemical properties of benzalkonium chloride make it a good candidate for persistent antimicrobial activity in mammalian tissue.

EJ Singer, "Biological evaluation," in *Cationic Surfactants: Analytical and Biological Evaluation*, ed J Cross, EJ singer (New York: Marcel Dekker, 1994) 29; RS Boethling, "Environmental aspects of cationic surfactants," in *Cationic Surfactants: Analytical and Biological Evaluation*, ed J Cross, EJ Singer (New York: Marcel Dekker, 1994) 95-135; J Cross, "Introduction to cationic surfactants," in *Cationic Surfactants: Analytical and Biological Evaluation*, ed J Cross, EJ Singer (New York: Marcel Dekker, 1994) 4-28.

Effectiveness: Benzalkonium chloride-based leave-on Hand Sanitizers have demonstrated efficacy in real-world environments. When evaluated in Elementary School environments where the importance of proper hygiene practices including hand washing is taught and emphasized, the use of non-alcohol benzalkonium chloride-based leave-on instant hand sanitizers reduced illness absenteeism 30-40% in double-blind, placebo-controlled studies versus hand washing alone.

DL Dyer, AL Shinder & FS Shinder (2000). Alcohol-free instant hand sanitizer reduces illness absenteeism. *Family Medicine*, 32(9), 633-638; CG White, FS Shinder, AL Shinder & DL Dyer (2001). Reduction of Illness Absenteeism in Elementary Schools Using an Alcohol-free Instant Hand Sanitizer. *The Journal of School Nursing*, 17(5), 258-265.

Safety: **DEFEND** Instant Foaming Hand Sanitizer is non-flammable. An internet search for alcohol-based Hand Sanitizers and fire will produce multiple hits. Flash fires associated with use of alcohol-based hand hygiene products can have potentially severe consequences for health care workers and their patients. A published example reported an incidence of flash fire associated with the use of an alcohol-based hand antiseptic agent. The fire occurred when a spark of static electricity ignited the alcohol-based hand gel on the hand of a health care worker who had just removed a 100% polyester gown. The health care worker put the pre-measured amount of alcohol-based hand gel in the palm of her hand from a wall-mounted dispenser. She then removed the 100% polyester gown, placed it on a metal surface, and began rubbing the gel onto both hands. While her hands were damp, she pulled open a metal sliding door, heard an audible static spark, saw a flash of light, and experienced spontaneous flames on the palm of one hand. After the incident, the palm showed redness but no blisters. Flames singed the hair on her arm.

KA Bryant, J Pearce & B Stover (2002). Flash fire associated with the use of alcohol-based antiseptic agent. *American Journal of Infection Control*, 30 (June 2002), 256-257.

Skin Irritation: Alcohol-based hand sanitizers are effective for occasional use, but long-term, frequent use of the alcohol products can cause skin irritation. Alcohol solubilizes and strips away sebum and lipids that guard against bacterial infections of the skin. Extensive use of alcohol-based hand sanitizers actually increases the skin's susceptibility to infection by transient disease-causing bacteria. This situation can increase the chances of spreading disease-causing microorganisms among patients.

SC Harvey, "Antiseptics and disinfectants; fungicides; ectoparasiticides," in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, sixth ed, AG Gilman, LS Goodman, A Gilman eds (New York: Macmillan Publishing, 1980) 964-987; GL Grove, CR Zerweck, JM Heilman (2000). Comparison of skin condition in a 5-day healthcare personnel hand washing using a new ethanol-emollient waterless antiseptic versus Pure II or water. Atlanta, GA. Paper presented at the Centers of Disease Control 4th Decennial International Conference on Nosocomial and Healthcare-associated Infections. Abstracts P-S1-62

Virucidal Efficacy (Influenza A H1N1, Swine Flu, Mexican Flu)

The infectious agent for Swine flu (H1 N1, Mexican flu) is an Influenza A virus (HI NI). The allowed FDA OTC claim for DEFEND benzalkonium chloride-based and for Alcohol-based Hand sanitizers is "reduces bacteria on the skin." However, it is known that benzalkonium chloride is effective at inactivating Influenza A virus, based on hard surface disinfectant data, at concentrations of 0.03-0,05% benzalkonium chloride. By comparison, DEFEND contains 0.10% benzalkonium chloride: 2 to 3 times higher than what is required for disinfectant activity against Influenza virus. Typically, enveloped viruses such as Influenza A are easily inactivated by benzalkonium chloride. Note that for the same FDA claim of "reduces **bacteria** on the skin," alcohol-based products require 62% alcohol, where benzalkonium chloride requires only 0.1%. However, as mentioned above, FDA doesn't allow for virucidal claims under the Topical Antimicrobials monograph, for either benzalkonium or alcohol-based Hand Sanitizer products.

While we believe that virus claims can't be made on the product label, product literature can make reference to studies that indicate virucidal effectiveness, just as organizations such as CDC make recommendations based on literature references.

"This product is acceptable for use as a hand sanitizing product (E3) in and around food processing areas. This product may be used only after thoroughly washing hands with soap or detergent and water, followed by rinsing with potable water. A potable water rinse is not required after use of this product."

Time Kill Study

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.

<u>ORGANISM</u>	<u>% Reduction</u>	<u>Log 10 Reduction</u>
Campylobacter <i>jejuni</i> ATCC 29428	>99.999	>5.00
Candida albicans ATCC 10231	96.3	1.42

<i>Clostridium difficile</i> ATCC 9689	>99.9999	>6.20
<i>Enterococcus faecalis</i> Vancomycin Resistant (VRE) ATCC 51575	99.99	4.54
<i>Escherichia coli</i> ATCC 11229	99.999	6.00
<i>Escherichia coli</i> 0157:H7 ATCC 35150	>99.999	>5.80
<i>Klebsiella pneumoniae</i> ATCC 4352	99.999	5.70
<i>Listeria monocytogenes</i> ATCC 19117	99.9	3.39
<i>Pseudomonas aeruginosa</i> ATCC 15442	99.9999	>6.20
<i>Salmonella choleraesuis</i> serotype enteritidis ATCC 4931	>99.999	5.50
<i>Salmonella choleraesuis</i> serotype paratyphi ATCC 8759	>99.999	>5.50
<i>Salmonella choleraesuis</i> serotype pullorum ATCC 19945	>99.999	>5.70
<i>Salmonella choleraesuis</i> serotype typhimurium ATCC 23564	>99.999	>5.10
<i>Salmonella typhi</i> ATCC 6539	99.999	5.80
<i>Shigella dysenteriae</i> ATCC 13313	>99.999	>5.80
<i>Shigella flexnei</i> ATCC 12022	99.99	4.69
<i>Shigella sonnei</i> ATCC 25931	99.9999	6.09
<i>Staphylococcus aureus</i> ATCC 6538	>99.9999	>6.53
<i>Staphylococcus aureus</i> Methicillin Resistant (MRSA) ATCC 33592	>99.9	3.51
<i>Staphylococcus aureus</i> Community Associated Methicillin Resistant (MRSA) NARSA NRS 123, Genotype USA400	>99.9	>3.30
<i>Staphylococcus epidermidis</i> ATCC 12228	99.999	5,56
<i>Streptococcus pneumonia</i> ATCC 6305	>99.999	>5.51
<i>Streptococcus pyogenes</i> ATCC 19615	>99.999	>5.90
<i>Vibrio cholera</i> ATCC 11623	>99.999	>5.40
<i>Xanthomonas axonopodis</i> (Citrus Canker) ATCC 49118	>99.99	4.55
<i>Yersinia enterocolitica</i> ATCC 23715	99.99	4.77

